# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

# **FORM 10-K**

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  $\mathbf{X}$ 

For the fiscal year ended December 31, 2016

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 (State or other jurisdiction of

incorporation or organization)

**One Kendall Square, Suite B7201** 

Cambridge, MA

 $\mathbf{X}$ 

(Address of principal executive offices)

02139 (Zip Code)

04-3210530 (I.R.S. Employer

Identification No.)

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

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

Title of each class

Common Stock, \$0.01 par value

Name of each exchange on which registered 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

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

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 🛛 Yes 🗆 No davs.

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).  $\boxtimes$  Yes  $\Box$  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.

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 Non-accelerated filer

 $\Box$  (Do not check if a 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

The 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, 2016, was \$657,498,088.

As of February 15, 2017, there were 130,570,161 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 2017 Annual Meeting of Stockholders. Portions of such proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

Accelerated filer 

 $\square$ Smaller reporting company

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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," "should," "continue" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

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

- the market potential and our commercialization efforts for ONIVYDE®, which we market in the United States;
- our plans to develop and commercialize our clinical stage product candidates and diagnostics;
- our ongoing and planned discovery programs, preclinical studies and clinical trials;
- the timing of the completion of our clinical trials and the availability of results from such trials;
- our collaborations with Baxalta Incorporated, Baxalta US Inc. and Baxalta GmbH, which we collectively refer to as Baxalta, and PharmaEngine, Inc., or PharmaEngine, related to ONIVYDE;
- the achievement of the various closing conditions precedent to and the consummation of our asset sale transaction with Ipsen S.A., or Ipsen, for ONIVYDE, including our U.S. commercialization rights and our licensing agreement with Baxalta, and our generic version of doxorubicin hydrochloride (HCl) liposome injection;
- our ability to establish and maintain additional collaborations;
- the timing of and our ability to obtain and maintain regulatory approvals for our products and product candidates;
- the rate and degree of market acceptance and clinical utility of our products;
- our intellectual property position;
- our commercialization, marketing and manufacturing capabilities and strategy;
- the potential advantages of our systems biology approach to drug research and development;
- the potential use of our systems biology approach in fields other than oncology; and
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this 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.

# NOTE REGARDING TRADEMARKS

ONIVYDE<sup>®</sup> is a registered trademark of Merrimack Pharmaceuticals, Inc. Any other trademarks, trade names and service marks referred to in this Annual Report on Form 10-K are the property of their respective owners.

#### Item 1. Business

# Overview

We are a biopharmaceutical company discovering, developing and commercializing innovative medicines consisting of novel therapeutics paired with 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. We view cancer as a complex engineering challenge. Through systems biology, which brings together the fields of biology, computing and engineering, we aim to decrease uncertainty in drug development and clinical validation, and move discovery efforts beyond trial and error. Our mission is to employ these insights to provide patients, physicians and the healthcare system with the medicines, tools and information to deliver integrated healthcare solutions that improve both the quality of outcomes and the efficiency of care.

We have one marketed therapeutic oncology product and multiple targeted therapeutic oncology candidates in clinical development. Our most advanced program is our therapeutic MM-398, which we market in the United States under the brand name ONIVYDE. On October 22, 2015, the U.S. Food and Drug Administration, or FDA, approved the use of ONIVYDE in combination with fluorouracil, or 5-FU, and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy. In addition, on October 18, 2016, the European Commission granted marketing authorization to our collaboration partner Baxalta for ONIVYDE in combination with 5-FU and leucovorin for the treatment of adult patients with metastatic adenocarcinoma of the pancreas who have progressed following gemcitabine-based therapy.

On January 7, 2017, we entered into an Asset Purchase and Sale Agreement, or asset sale agreement, with Ipsen pursuant to which Ipsen will acquire our right, title and interest in the non-cash assets, equipment, inventory, contracts and intellectual property primarily related to or used in our business operations and activities involving or relating to developing, manufacturing and commercializing ONIVYDE and our generic version of doxorubicin hydrochloride (HCl) liposome injection, or MM-436. The transaction described in the asset sale agreement is referred to as the asset sale. Ipsen will not acquire our rights to \$33.0 million in net milestone payments that may become payable pursuant to our license and collaboration agreement with Baxalta, or the Baxalta agreement, among other excluded assets. Pursuant to the asset sale agreement, Ipsen will pay us \$575.0 million in cash (subject to a working capital adjustment as provided in the asset sale agreement) and will assume certain related liabilities. Following the closing of the asset sale, we may be entitled to up to \$450.0 million of additional payments based on achievement by or on behalf of Ipsen of certain milestone events related to FDA approval of ONIVYDE for certain indications as described in the asset sale agreement.

The consummation of the transaction with Ipsen is subject to customary closing conditions, including, among others: (i) the receipt of the approval of our stockholders; (ii) the expiration or termination of the required waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, which waiting periods expired on February 22, 2017; (iii) the absence of a breach of our representations and warranties that would cause a material adverse effect on the commercial business; (iv) the absence of a business material adverse effect; and (v) the performance of certain covenants in all material respects. See Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations – Overview for more information regarding the asset sale.

In addition to ONIVYDE and our product candidates in clinical development, we have multiple product candidates in preclinical development. We have tailored ONIVYDE and our other product candidates to target specific disease mechanisms that our research suggests are common across many solid tumor types. We believe that ONIVYDE and our other product candidates have the potential to address major unmet medical needs.

We are also developing *in vitro* and *in vivo* diagnostics for use with each of our oncology therapeutic product candidates. Our *in vitro* diagnostic agents employ biophysical or biochemical markers of cancer, or biomarkers, which we have identified using our systems biology approach. Our *in vivo* 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 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 product to a third party, who will in turn process the drug into finished product and commercialize it globally following regulatory approval. Upon consummation of the asset sale, this agreement would be transferred to Ipsen.

# **Our Most Advanced Product Candidates**

The table and descriptions below summarize key information about ONIVYDE (MM-398) and our other clinical stage product candidates, MM-121, MM-141, MM-310, MM-302 and MM-151. Each of the product candidates described below is a targeted therapy, designed to efficiently act on selected cancer cells. These targeted therapies are either designed to deliver cytotoxic therapies to the tumor tissue, such as ONIVYDE, MM-310 and MM-302, or are monoclonal antibodies or monoclonal antibody-derived molecules that are designed to block oncogenic signaling pathways, such as MM-121, MM-141 and MM-151. Other than ONIVYDE, none of our product candidates are approved for any indication by the FDA or any other regulatory agency.

Program	Status	Commercial Rights (Territory)
ONIVYDE (MM-398) (irinotecan liposome injection)	<ul> <li>Approved by the FDA and European Commission in combination with 5- FU and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy</li> <li>Launched commercially in the United States on October 26, 2015</li> <li>Conducting a Phase 2 clinical trial in combination with 5-FU, leucovorin and oxaliplatin in patients with previously untreated, metastatic pancreatic adenocarcinoma</li> <li>Initiating a Phase 3 clinical trial as a monotherapy for the treatment of small cell lung cancer in patients that have progressed on a previous platinum- containing regimen</li> <li>Ongoing Phase 1 clinical trials in collaboration with several investigators: as a monotherapy in patients with glioma, in combination with cyclophosphamide in patients with pediatric solid tumors and in combination with veliparib in solid tumors</li> <li>Conducting a Phase 1 translational clinical trial in metastatic breast cancer designed to identify predictive biomarkers associated with MM-398</li> </ul>	Merrimack (United States) PharmaEngine (Taiwan) Baxalta (rest of world outside of United States and Taiwan)
MM-121 (seribantumab) (ErbB3 targeted monoclonal antibody)	<ul> <li>Conducting a Phase 2 clinical trial in combination with docetaxel or pemetrexed in patients with heregulin positive, advanced non-small cell lung cancer, or NSCLC</li> <li>Initiating a Phase 2 clinical trial in patients with advanced HER2 negative, estrogen receptor positive (ER+), progesterone receptor positive (PR+) and heregulin positive breast cancer.</li> </ul>	Merrimack (worldwide)
<b>MM-141</b> (istiratumab) (IGF-1R and ErbB3 targeted tetravalent bispecific antibody)	• Conducting a Phase 2 clinical trial in combination with nab-paclitaxel and gemcitabine in previously untreated metastatic pancreatic cancer patients who have high serum levels of free IGF-1	Merrimack (worldwide)
MM-310 (antibody directed nanotherapeutic; EphA2 targeted docetaxel)	• Initiating a Phase 1 clinical trial as a monotherapy in patients with solid tumors	Merrimack (worldwide)

Program	Status	Commercial Rights (Territory)
MM-302 (antibody directed nanotherapeutic; ErbB2 (HER2) targeted doxorubicin)	<ul> <li>Discontinuing a Phase 2 clinical trial in combination with trastuzumab in patients with ErbB2 (HER2) positive, locally advanced or metastatic breast cancer. In December 2016, we decided to stop this clinical trial prior to full enrollment following an opinion from the Data and Safety Monitoring Board, or DSMB, that continuing the clinical trial would be unlikely to demonstrate benefit over the comparator treatments</li> <li>We do not plan to invest in additional development of MM-302 at this time</li> </ul>	Merrimack (worldwide)
MM-151 (EGFR (ErbB1) targeted oligoclonal antibody)	<ul> <li>Completed a Phase 1 clinical trial as a monotherapy and in combination with irinotecan in patients with solid tumors</li> <li>We do not plan to invest in additional development of MM-151 at this time</li> </ul>	Merrimack (worldwide)

# ONIVYDE® (MM-398)

# **ONIVYDE** overview

ONIVYDE (irinotecan liposome injection), also known as MM-398, is a novel encapsulation of the marketed chemotherapy drug irinotecan in a liposomal formulation. ONIVYDE has been approved by the FDA, European Commission and certain other regulatory agencies in combination with 5-FU and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy. ONIVYDE is the first and only FDA-approved therapy in this setting. ONIVYDE is not indicated for use as a single agent. ONIVYDE in combination with 5-FU and leucovorin is designated as a category 1 treatment option in the 2016 National Comprehensive Cancer Network guidelines for pancreatic adenocarcinoma in the United States, as well as a category 2B status in the 2015 European Society for Medical Oncology clinical practice guidelines in the European Union.

We hold development and commercialization rights for ONIVYDE in the United States. In September 2014, we established a collaboration with Baxalta for the development and commercialization of ONIVYDE outside of the United States and Taiwan. PharmaEngine holds the development and commercialization rights to ONIVYDE in Taiwan. We believe that ONIVYDE may have potential uses in a number of other solid tumor indications beyond its currently approved indication, and additional clinical trials of ONIVYDE are ongoing or in the planning stages.

ONIVYDE has obtained orphan drug exclusivity in the United States from the FDA for the treatment of pancreatic cancer, and orphan medicinal product designation in the European Union from the European Medicines Agency, or EMA, for the treatment of pancreatic cancer. In addition, ONIVYDE is covered by multiple patents and trademarks worldwide.

On January 7, 2017, we entered into an asset sale agreement with Ipsen pursuant to which Ipsen will acquire our right, title and interest in the non-cash assets, equipment, inventory, contracts and intellectual property primarily related to or used in our business operations and activities involving or relating to developing, manufacturing and commercializing ONIVYDE, including U.S. commercialization rights and our licensing agreement with Baxalta.

#### ONIVYDE Phase 3 clinical trial for metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy

The basis of the recent FDA and European Commission approvals of ONIVYDE in combination with 5-FU and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy was our randomized, open label Phase 3 clinical trial of MM-398 in patients with metastatic adenocarcinoma of the pancreas who received prior gemcitabine-based therapy. We refer to this clinical trial as the NAPOLI-1 trial. Patients were enrolled at 76 sites in North America, South America, Europe, Asia and Oceania. The trial evaluated ONIVYDE in combination with 5-FU and leucovorin administered every two weeks and as a monotherapy administered every three weeks. Each ONIVYDE containing arm was compared to a control arm of 5-FU and leucovorin. A total of 417 patients were randomized across the three arms. The primary endpoint of the trial was overall survival. Overall survival is a measure of the time to death from treatment randomization. Primary survival analysis was based on 313 events and showed that ONIVYDE in combination with 5-FU and leucovorin significantly improved overall survival versus 5-FU and leucovorin administered every the set (0.49-0.92). The monotherapy regimen in this trial did not show improvement over the 5-FU and leucovorin arm: 4.9 months versus 4.2 months (p=0.94, HR=0.99, 95% CI: [0.77-1.28]). 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 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. The confidence interval, or CI, given after the HR reflects the amount of certainty in the estimate of the HR. An HR value that

a 95% CI is unlikely to be the true HR. ONIVYDE in combination with 5-FU and leucovorin also achieved a longer progression-free survival compared with the 5-FU and leucovorin arm (3.1 months versus 1.5 months; unstratified HR=0.56). The most common non-hematologic grade 3 and higher adverse events in the ONIVYDE 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.

In January 2016, we announced an updated overall survival analysis from our NAPOLI-1 clinical trial. The updated data analysis was based on 378 events and included data from all patients randomized across the three arms of the trial. Twelve-month survival estimates for ONIVYDE in combination with 5-FU and leucovorin were 26% (95% CI, 18-35%) compared to 16% (95% CI, 10-24%) for 5-FU and leucovorin alone. Six-month survival estimates were 53% (95% CI, 44-62%) for the ONIVYDE combination regimen versus 38% (95% CI, 29-47%) for 5-FU and leucovorin. No new safety or tolerability concerns were noted in the updated data analysis. The most common grade 3 and higher adverse events occurring at a 2% or greater incidence in the ONIVYDE containing arms were neutropenia (ONIVYDE monotherapy arm: 15%; ONIVYDE + 5-FU/LV arm: 28%), diarrhea (ONIVYDE monotherapy arm: 21%; ONIVYDE + 5-FU/LV arm: 13%), vomiting (ONIVYDE monotherapy arm: 14%; ONIVYDE + 5-FU/LV arm: 12%) and fatigue (ONIVYDE monotherapy arm: 6%; ONIVYDE + 5-FU/LV arm: 14%).

In October 2016, we updated our NAPOLI-1 analysis with the final results from our NAPOLI-1 clinical trial. The updated data analysis was based on 382 events at the final database lock in November 2015. The previously described overall survival advantage was maintained for ONIVYDE in combination with 5-FU and leucovorin versus 5-FU and leucovorin alone: 6.2 months versus 4.2 months (p=0.039, HR=0.75, 95% CI: [0.057-0.99]). Twelve-month survival estimates for ONIVYDE in combination with 5-FU and leucovorin were 26% (95% CI, 18-35%) compared to 16% (95% CI, 10-24%) for 5-FU and leucovorin alone. The overall response rate for the ONIVYDE plus 5-FU and leucovorin arm was 16% versus 1% for the 5-FU and leucovorin arm (p<0.0001). Disease control was achieved in twice as many patients treated with ONIVYDE in combination with 5-FU and leucovorin (52%) compared to 5-FU and leucovorin alone (24%). Final results suggest that patients treated with ONIVYDE in combination with 5-FU and leucovorin had no notable deterioration in quality of life at 12 weeks despite the addition of a second chemotherapeutic agent to 5-FU and leucovorin. No new safety concerns were noted and the overall safety profile was manageable with the most common grade 3 and higher adverse events of neutropenia, diarrhea, fatigue, vomiting and asthenia.

# MM-398 Phase 2 clinical trial in front-line metastatic pancreatic cancer

In October 2015, we enrolled the first patient in a Phase 2 clinical trial of MM-398 in front-line metastatic pancreatic cancer. This trial is designed to assess the safety and efficacy of the combination of MM-398 plus 5-FU and leucovorin, with or without the addition of oxaliplatin, versus nab-paclitaxel and gencitabine in patients with previously untreated, metastatic pancreatic adenocarcinoma. The trial will be conducted in two parts. In the first part of the trial, we expect to enroll approximately six to18 patients. The primary outcome for Part 1 of the trial is to evaluate the safety and tolerability of ONIVYDE in combination with 5-FU and leucovorin and oxaliplatin. In the second part of the trial, we expect an additional 150 patients (50 patients per arm) with previously untreated, metastatic pancreatic adenocarcinoma will be enrolled and randomized to receive ONIVYDE in combination with 5-FU, leucovorin and oxaliplatin, ONIVYDE in combination with 5-FU and leucovorin or nab-paclitaxel and gencitabine. In Part 2 of the trial, efficacy of the ONIVYDE containing regimens will be compared to the nab-paclitaxel and gencitabine regimen, evaluating progression free survival, or PFS, at 24 weeks, as well as overall survival, objective response rate, tumor marker CA19-9 response, safety and tolerability. 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 trial will be conducted at sites in the United States, Canada, Europe, Australia, New Zealand, Taiwan and South Korea.

# MM-398 Phase 3 clinical trial in small cell lung cancer

We are initiating a Phase 3 clinical trial studying MM-398 as a monotherapy for the treatment of small cell lung cancer in patients that have progressed on a previous platinum-containing regimen.

# MM-398 other clinical trials

We are also collaborating with several investigators to conduct additional trials of MM-398, including in a Phase 1 clinical trial utilizing a high concentration formulation of MM-398 in patients with glioma, a Phase 1 clinical trial in pediatric solid tumors and a Phase 1 clinical trial in combination with veliparib in solid tumors. In May 2016, we announced that we planned to initiate a Phase 1 clinical trial of ONIVYDE plus 5-FU and leucovorin in combination with MM-151 in patients with RAS wild-type metastatic colorectal cancer; however, based on the results of our strategic pipeline review that was completed in January 2017, we no longer plan to initiate this clinical trial.

# MM-398 diagnostic development

We believe that deposition of MM-398 in the tumor may be important to efficacy. We are exploring development of an imaging agent that may serve as a surrogate biomarker for estimating MM-398 deposition in patient tumors. Our Phase 1 translational study is designed to assess the feasibility of using an MRI-based approach with a marketed iron supplement used off-label as an imaging agent to act as a marker for MM-398 tumor response prediction. The expansion phase of this study will enroll patients who have metastatic breast cancer that is hormone receptor positive, triple negative or where active brain metastases are present. 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.

# MM-121 (seribantumab)

# MM-121 overview

MM-121 is a fully human monoclonal antibody that targets ErbB3, a cell surface receptor that is activated by its ligand heregulin. Heregulin-driven ErbB3 signaling has been implicated as a mechanism of tumor growth and resistance to targeted, cytotoxic and anti-endocrine therapies. When used in combination with cytotoxic chemotherapeutics, MM-121 is designed to block heregulin-driven ErbB3 signaling and enhance the anti-tumor effect of combination therapy partners.

Heregulin is the cognate ligand of the ErbB3 receptor and a powerful driver of cell survival signaling. 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, defining a distinct, highly drug-tolerant cancer cell phenotype potentially contributing to poor prognosis and thus identifying a potentially high unmet medical need.

#### MM-121 Phase 2 clinical trial in advanced or metastatic non-small cell lung cancer

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. In December 2015, we announced an amendment to the trial, including a change in primary endpoint from PFS to overall survival. At the time of the December 2015 amendment, the trial was expected to enroll approximately 280 heregulin positive patients to be randomized (2:1) to receive MM-121 plus the investigator's choice of docetaxel or pemetrexed alone, at sites in the United States, Canada, Asia and Europe. Based on the results of our strategic pipeline review that was completed in January 2017, we plan to modify the design of this clinical trial into a proof-of-concept study to reduce enrollment and generate data in a more homogenous patient population.

#### MM-121 Phase 2 clinical trial in breast cancer

We intend to initiate an additional Phase 2 clinical trial of MM-121 in 2017 in patients with advanced HER2 negative, estrogen receptor positive (ER+), progesterone receptor positive (PR+) and heregulin positive breast cancer.

# MM-121 previous 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 and to establish and validate clinically meaningful biomarkers that were initially identified using our systems biology approach to identify patients most likely to benefit from MM-121.

Three such previous Phase 2 clinical trials of MM-121 in NSCLC, ovarian cancer and breast cancer enrolled a total of 464 patients and evaluated whether MM-121 in combination with a standard of care therapy was more effective than the standard of care therapy alone in prolonging PFS. In the NSCLC trial, two of the three cohorts (Groups A and C) did not 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 the clinical trials of MM-121 in patients with ovarian cancer or in patients with breast cancer, although our biomarker analysis in each trial identified a potential subpopulation of patients benefiting from MM-121 in combination with either paclitaxel or exemestane, respectively. 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 trials, 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.

#### MM-121 diagnostic development

We are developing a 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 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%); and in lung cancer, heregulin-high patients had a PFS HR of 0.37 (95% CI [0.11–0.63]). 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). 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), which is an assay in which a section of tissue is stained for heregulin mRNA and scored by a certified pathologist. We have identified RNA ISH as the method to detect HRG expression on the cancer cell level with high sensitivity and specificity, and are using a qualified version of this assay in our Phase 2 NSCLC clinical trial.

# **MM-141**

# MM-141 overview

MM-141 is a fully human tetravalent bispecific antibody designed to block tumor survival signals by targeting receptor complexes containing the insulin-like growth factor 1 receptor, or IGF-1R, and ErbB3 (HER3) 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. IGF-1R and ErbB3 complexes both activate a major signaling pathway, PI3K/AKT/mTOR, that allows tumor cells to grow and develop resistance to chemotherapy. 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. In 2014, we obtained orphan drug designation in the United States for MM-141 for the treatment of pancreatic cancer.

#### MM-141 Phase 2 clinical trial in metastatic pancreatic cancer

In May 2015, we initiated a randomized, double-blinded, placebo-controlled Phase 2 clinical trial of MM-141 in combination with nab-paclitaxel and gemcitabine, versus nab-paclitaxel and gemcitabine alone in patients with newly diagnosed metastatic pancreatic cancer who have high serum levels of free IGF-1. As part of this trial, we expect that front-line metastatic pancreatic cancer patients with high serum levels of free IGF-1 will be randomized (1:1) to receive either MM-141 plus nab-paclitaxel/gemcitabine or nab-paclitaxel/gemcitabine alone. Based on the results of our strategic pipeline review that was completed in January 2017, we plan to modify the ongoing Phase 2 clinical trial of MM-141 from an original planned enrollment of approximately 140 patients down to a revised enrollment of approximately 80 patients. Eligible patients for the trial must have received no prior radiotherapy, surgery, chemotherapy or investigational therapy for the treatment of metastatic disease. The primary endpoint of the trial is PFS. Secondary endpoints include overall survival, objective response rate, safety and tolerability.

# MM-141 Phase 1 clinical trial

The design of our Phase 2 clinical trial of MM-141 was informed by our multi-arm Phase 1 clinical trial evaluating the safety and tolerability of MM-141 as a monotherapy and in combination with everolimus or with nab-paclitaxel and gencitabine in patients with advanced solid tumors. Patients in the Phase 1 trial were enrolled in one of three arms: MM-141 as a monotherapy, MM-141 in combination with everolimus and MM-141 in combination with nabpaclitaxel and gencitabine. Trial data showed common co-expression of IGF-1R and ErbB3 in solid tumors, and that the presence of this co-expression in metastatic pancreatic cancer was associated with decreased patient survival. An analysis of pre- and post-treatment biopsies confirmed that levels of IGF-1R and ErbB3 were decreased following MM-141 administration. Hyperglycemia was rare and was reported as an adverse event of Grade 3 or higher in one out of 38 patients in the trial (2.6%). The most common adverse events in the trial, of any grade, were nausea (50%), headache (47.4%) and vomiting (44.7%). MM-141 monotherapy was well tolerated with no dose limiting toxicities. The observed safety profile of MM-141 in combination with nab-paclitaxel and gencitabine was comparable to expected toxicities reported with the individual safety profiles of the chemotherapy agents.

# MM-141 diagnostic development

We are conducting research and development on an *in vitro* diagnostic for MM-141 that may 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. Our Phase 2 clinical trial of MM-141 uses a proprietary, validated test to prospectively select patients with high serum free IGF-1 levels for inclusion in the trial.

# **MM-310**

#### MM-310 overview

MM-310 is an antibody directed nanotherapeutic that encapsulates a newly engineered form of the highly potent chemotherapy docetaxel as a prodrug in an ephrin receptor A2, or EphA2, targeted liposome. In preclinical studies, MM-310 demonstrated antitumor activity in multiple models compared to free docetaxel. In the preclinical studies, EphA2 targeted liposomes entered and delivered the cytotoxic to the tumor cell while minimizing exposure to healthy tissues. MM-310 is designed to result in prolonged exposure at the tumor site and in preclinical studies had a significantly longer half-life than free docetaxel. In a sampling of approximately 200 tumors, EphA2 was found to be expressed in tumor cells, myofibroblasts and/or tumor-associated blood vessels. EphA2 overall prevalence was found to range from 50% to 100% across multiple indications. In cell models, a high level of specificity was observed in the MM-310 EphA2 targeted liposome, with a more than 100-fold increase in liposome cell association when compared to non-targeted liposomes.

#### MM-310 Phase 1 clinical trial

We expect to initiate a Phase 1 clinical trial of MM-310 in 2017 as a monotherapy to evaluate its safety and preliminary efficacy in patients with solid tumors.

#### MM-310 diagnostic development

We are evaluating certain biomarkers for further investigation as diagnostics.

#### **MM-302**

# MM-302 overview

MM-302 is an antibody directed nanotherapeutic that encapsulates doxorubicin in a HER2-targeted liposome. Doxorubicin is a marketed chemotherapy that is a member of the anthracycline class of chemotherapeutics. As a liposomal encapsulation of doxorubicin, MM-302 is designed to target and bind to cancer cells that overexpress ErbB2 (HER2) to allow for the selective uptake of drug into tumor cells while minimizing exposure to healthy tissues, such as those of the heart. Unlike other HER2 targeted agents, MM-302 is not designed to inhibit HER2 signaling pathways and relies on HER2 as a means to identify and gain access to the cancer cells.

#### MM-302 Phase 2 clinical trial in metastatic breast cancer

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. Prior to initiating the Phase 2 clinical trial of MM-302, we conducted a Phase 1 clinical trial of MM-302 in patients with advanced ErbB2 (HER2) positive breast cancer, and reported final results from this trial in April 2015.

In December 2016, we determined that we would be stopping the ongoing Phase 2 clinical trial of MM-302. The decision to stop the trial was made following an independent DSMB opinion that continuing the clinical trial would be unlikely to demonstrate benefit over the comparator treatments. Subsequent to this recommendation, a futility assessment was performed that confirmed the



DSMB's opinion. Both the treatment and control arms were found to have shorter than expected median PFS. Patients currently enrolled in the clinical trial may choose to continue on their assigned treatment based upon discussion with their study physician.

Based on the results of our strategic pipeline review that was completed in January 2017, further investment in MM-302 is being deferred at this time.

# **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. MM-151 is designed to block the signal amplification that our research suggests occurs in the EGFR (ErbB1) pathway. We have completed a Phase 1 clinical trial of MM-151 in patients with refractory solid tumors.

Based on the results of our strategic pipeline review that was completed in January 2017, further investment in MM-151 is being deferred at this time.

#### MM-151 Phase 1 clinical trial

We recently completed 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 was designed to assess the safety of MM-151 and determine the recommended Phase 2 dose. Four sites participated in this trial.

#### MM-151 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.

# **Companion Therapeutics Program**

We are evaluating combinations of our therapeutic oncology candidates, but further investment in the companion therapeutics program is being deferred at this time.

# **Preclinical Product Candidates**

We are developing preclinical product candidates for a range of solid tumor indications.

#### **Our Approach to Cancer Research**

We view cancer as a complex engineering challenge. Through systems biology, which brings together the fields of biology, computing and engineering, we aim to decrease uncertainty in drug development and clinical validation, and move discovery efforts beyond trial and error. The goal of our systems biology approach 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. Our 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. 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, and apply our insights throughout the research and development process, including for target identification, lead compound design and optimization, diagnostic discovery 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 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 systems 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 systems biology, we are incorporating the identification of biomarkers and the development of 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 systems biology can increase the productivity of biomedical research, increase the probability of approval for new drugs and produce more precisely targeted therapeutics as compared to a conventional drug development approach since systems 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 systems 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 it is possible that we may pursue some of these disease areas directly ourselves, 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 systems biology approach to the research and development of regenerative medicines to repair the heart. As of December 31, 2016, Silver Creek was a majority owned subsidiary.

# Therapeutic Design Capabilities

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 therapeutic approaches are our nanotherapeutics platform and our human antibody platform.

#### Nanotherapeutics

Our nanotherapeutics platform enables us to create both passively targeted and actively targeted liposomes, each containing different chemotherapeutic agents. Our nanotherapeutics are lipidic particles 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 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.

#### Human monoclonal antibodies

Human 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. Our human monoclonal antibody engineering platform provides us with the ability to create antibodies that are designed to inhibit specific nodes responsible for tumor growth and survival, or to address inherent drug resistance by simultaneously targeting redundant signaling pathways. We have designed antibodies for use as stand-alone 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.

# Manufacturing

We manufacture bulk drug product for commercial use and for use in our clinical trials and research and development efforts 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 nanotherapeutics, antibody-targeted nanotherapeutics and antibodies.

Our manufacturing capabilities encompass the full bulk 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 facilities and processes to provide maximum flexibility and rapid changeover for the manufacture of different product candidates. We outsource fill finish, packaging, labeling and distribution, as well as bulk manufacturing for certain antibody product candidates. As of January 31, 2017, we employed approximately 91 employees in manufacturing activities. Our manufacturing site consists of two independent facilities, one for nanoliposome manufacture and one for biologics manufacture.

Our nanoliposome facility is comprised of multiple classified suites and has been designed to comply with current FDA and EMA cGMP for the manufacture of commercial and clinical bulk drug product. The facility and processes have been designed to meet the global commercial and clinical needs of ONIVYDE, MM-436 and the other nanoliposomal products in our pipeline. In 2015, the FDA inspected and approved our nanoliposome facility for the commercial supply of bulk drug product for ONIVYDE, and in 2016, following inspection, the EMA found us to be in general compliance with the relevant European Union manufacturing directives. Following consummation of the asset sale to Ipsen, pursuant to which our nanoliposome facility would be transferred to Ipsen, Ipsen would manufacture several batches of MM-310 for us pursuant to a manufacturing services agreement that we expect to enter into.

Our biologics facility produces our antibody product candidates and is comprised of multi-suite 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 clinical trials. Although we have the capability to continue to manufacture our bulk antibody product candidates at our current facility, we have determined that utilizing contract manufacturing organizations, or CMOs, to manufacture our future needs of bulk antibody product candidates, including MM-121 and MM-141, will allow us to better meet our operational objectives.

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.



In 2013, we entered into an agreement with Watson Laboratories, Inc., or Actavis, as more fully described below, pursuant to which we utilize our nanoliposomal manufacturing capabilities to develop, manufacture and exclusively supply the bulk liposomal form of doxorubicin hydrochloride (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. Upon consummation of the asset sale, this agreement would be transferred to Ipsen.

# Sources and Availability of Raw Materials

We currently rely on single source suppliers for certain raw materials that we use for our nanoliposome manufacturing process. We purchase these materials from our suppliers on a purchase order basis and do not have long-term supply agreements in place.

#### **Commercial Activities**

In October 2015, following receipt from the FDA of marketing approval for ONIVYDE, we commenced ONIVYDE commercial activities in the United States through our focused field organization. Prior to commercial launch, we spent time and resources building our marketing, field, access and distribution teams to provide healthcare education and reimbursement support as well as our product distribution infrastructure. We believe that our commercial infrastructure provides the foundation to address the educational and supportive needs of oncologists who treat a broad array of tumor types. Outside the United States, we expect to enter into distribution and other marketing arrangements with third parties for any of our other product candidates that obtain marketing approval. Following the consummation of the asset sale, Ipsen will assume responsibility for the commercialization of ONIVYDE within the United States.

Outside of the United States and Taiwan, Baxalta has exclusive commercialization rights for all potential indications of ONIVYDE worldwide. PharmaEngine has exclusive commercialization rights in Taiwan. We believe our commercialization partners for ONIVYDE possess the relevant expertise to successfully commercialize ONIVYDE outside of the United States. For instance, Baxalta has previously demonstrated the ability to successfully launch innovative products, penetrate markets and drive the growth of multiple brands in highly competitive markets.

# 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 systems 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 trials 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 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 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 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 ONIVYDE and MM-310. 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 have developed and are developing therapeutic product candidates and diagnostics. The U.S. estimated annual incidence is based on information from the American Cancer Society, *Cancer Fact & Figures 2017*.

Tumor Type	U.S. Annual Incidence	Selected Marketed Therapies	
Breast	255,180	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	222,500	ceritinib (Zykadia®); crizotinib (Xalkori®); docetaxel (Taxotere); gemcitabine (Gemzar®); pemetrexed (Alimta®); gefitinib (Iressa®); erlotinib (Tarceva®); bevacizumab (Avastin®); paclitaxel (Taxol, Abraxane); nivolumab (Opdivo®); pembrolizumab (Keytruda®)	
Colorectal	135,430	oxaliplatin (Eloxatin®); irinotecan (Camptosar®); bevacizumab (Avastin); cetuximab (Erbitux®); panitumumab (Vectibix®); ziv- aflibercept (Zaltrap®); trifluridine/tipiracil (Lonsurf®); regorafenib (Stivarga®)	
Pancreatic	53,670	nab-paclitaxel (Abraxane); gemcitabine (Gemzar); erlotinib (Tarceva)	
Liver	40,710	sorafenib (Nexavar®)	
Brain and other nervous system cancers	23,800	temozolomide (Temodar®); carmustine (BiCNU®); polifeprosan 20 with carmustine implant (Gliadel®); bevacizumab (Avastin)	
Gastric	28,000	ramucirumab (Cyramza®); capecitabine (Xeloda); trastuzumab (Herceptin); docetaxel (Taxotere); oxaliplatin (Eloxatin); epirubicin (Ellence®)	
Ovarian	22,440	olaparib (Lynparza <sup>TM</sup> ); liposomal doxorubicin (Doxil®); bevacizumab (Avastin); paclitaxel (Taxol, Abraxane); gemcitabine (Gemzar); rucaparib (Rubraca <sup>TM</sup> )	

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.

# Pancreatic Cancer

The only indication in the United States for which we have received marketing approval from the FDA is for ONIVYDE in combination with 5-FU and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy. Pancreatic cancer is a rare and deadly disease. There are approximately 54,000 patients diagnosed with pancreatic cancer each year in the United States, the overwhelming majority of whom have adenocarcinoma. Globally there are approximately 338,000 new cases each year. Most patients receive gemcitabine-based therapy during either adjuvant/neoadjuvant treatment for locally advanced disease or during first- or second-line therapy for metastatic disease.

#### **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.

#### Baxalta

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

Under the terms of the Baxalta agreement, we received a \$100.0 million nonrefundable upfront cash payment in September 2014. In addition, we are eligible to receive from Baxalta (i) up to an aggregate of \$100.0 million upon the achievement of specified research and development milestones, of which we have received \$62.5 million from Baxalta as of December 31, 2016, (ii) up to an aggregate of \$520.0 million upon the achievement of specified regulatory milestones, of which we have received \$60.0 million from Baxalta as of December 31, 2016, (and (iii) up to an aggregate of \$250.0 million upon the achievement of specified sales milestones. Under the terms of the Baxalta agreement, we will bear up to the first \$98.8 million of costs related to the development of ONIVYDE for pancreatic cancer patients who have not previously received gemcitabine-based therapy; however, we expect most of these costs to be offset by payments received upon the achievement of clinical trial-related milestones. We will share equally with Baxalta all other clinical trial costs contemplated by the global development plan. We are also entitled to tiered, escalating royalties ranging from sub-teen double-digits to low twenties percentages of net sales of ONIVYDE in the licensed territory.

In February 2016, we entered into a commercial supply agreement with Baxalta, or the Baxalta supply agreement, pursuant to which we supply ONIVYDE to Baxalta and, at Baxalta's option, manage fill and finish activities conducted by a third-party contract manufacturer for Baxalta. Baxalta also has the option to manufacture ONIVYDE itself, in which case we will perform a technology transfer of our manufacturing process to Baxalta.

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

Under the Baxalta agreement, Baxalta has also agreed that, subject to limited exceptions, until September 23, 2017, neither Baxalta nor any of its affiliates will (1) effect or seek, offer or propose to effect, or cause or participate in or in any way advise, assist or encourage any other person to effect or seek, offer or propose to effect or cause or participate in, any acquisition of any of our securities or assets, any tender or exchange offer, merger or other business combination involving us, any recapitalization, restructuring, liquidation, dissolution or other extraordinary transaction with respect to us, or any solicitation of proxies or consents to vote any of our voting securities, (2) form, join or in any way participate in a group with respect to any of our securities, (3) otherwise act, alone or in concert with others, to seek to control or influence our management, board of directors or policies, (4) take any action

that might force us to make a public announcement regarding any of the foregoing or (5) enter into any agreements, discussions or arrangements with any third party with respect to any of the foregoing.

Upon consummation of the asset sale, both the Baxalta agreement and the Baxalta supply agreement will be assigned to Ipsen.

# **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 ONIVYDE in Europe and certain countries in Asia. Through our acquisition of Hermes in 2009, we held the rights to ONIVYDE 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 ONIVYDE 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 ONIVYDE 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 ONIVYDE, 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 in September 2014. Additionally, as a result of this amendment, a previously contingent \$5.0 million milestone payment was paid to PharmaEngine in the second quarter of 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 \$73.5 million in upfront license fees and milestone payments. This amount includes an \$11.0 million milestone payment made in July 2015 in connection with the EMA's acceptance for review of a Marketing Authorization Application for ONIVYDE, which occurred in the second quarter of 2015, a \$10.0 million milestone payment made in June 2016 in connection with the South Korean Ministry of Food and Drug Safety, or MFDS, acceptance for review of a new drug application for ONIVYDE, which occurred in the second quarter of 2016, and a \$25.5 million milestone payment made in December 2016 in connection with Baxalta's receipt of marketing authorization from the European Commission for ONIVYDE in combination with 5-FU and leucovorin for the treatment of adult patients with metastatic adenocarcinoma of the pancreas who have progressed following gemcitabine-based therapy, which occurred in the fourth quarter of 2016. In addition to these amounts, we could also be required to pay PharmaEngine up to an additional \$25.0 million in aggregate regulatory milestones, \$38.0 million in sublicense fees 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 ONIVYDE 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 ONIVYDE in such country. We are responsible for the development and commercialize ONIVYDE at its expense. Each party has agreed to use commercially reasonable efforts to develop, in accordance with a development plan, and commercialize ONIVYDE in its respective territory.

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 ONIVYDE 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 ONIVYDE or commercialization of ONIVYDE 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 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 ONIVYDE in Europe or the Asian territories, as applicable, and PharmaEngine is required to pay us single-digit royalties for net sales of ONIVYDE in such territories.

In August 2015, we also entered into a commercial supply agreement with PharmaEngine, or the PharmaEngine supply agreement, pursuant to which we supply ONIVYDE to PharmaEngine.

Upon consummation of the asset sale, both the PharmaEngine agreement and the PharmaEngine supply agreement will be assigned to Ipsen.

#### Actavis

In November 2013, we entered into a development, license and supply agreement with Actavis, or the Actavis agreement, pursuant to which we develop, manufacture and exclusively supply the bulk form of doxorubicin hydrochloride (HCl) liposome injection, or the initial product, to Actavis. We also refer to the initial product as MM-436. The Actavis agreement was subsequently amended in January 2015 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. We will manufacture and supply the initial product to Actavis in bulk form at an agreed upon unit price, and Actavis is responsible for all costs related to finished product processing and global commercialization. Pursuant to the Actavis agreement, we have also agreed to develop additional products for Actavis in the future, the identities of which will be mutually agreed upon. We are eligible to receive up to \$15.1 million in milestone and development payments, as well as additional reimbursement for specific activities performed by us at the request of Actavis. We will also receive a mid-twenties percentage of net profits on global sales of the initial product, which triggered the payment of \$1.1 million of milestones from Actavis to us. As of December 31, 2016, we had received \$4.9 million in total milestone and development payments and reimbursement for specific activities from Actavis.

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.

Upon consummation of the asset sale, the Actavis agreement will be assigned to Ipsen.

#### 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. In January 2016, Dyax was acquired by Shire 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 may 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 \$16.2 million, 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. 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.



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 value at 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

In November 2000, we entered into a separate exclusive license agreement with The Regents of the University of California, or 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**

Our success will significantly depend on our ability to obtain and maintain patent and other proprietary protection for our commercially important technology, inventions and know-how, defend and enforce our patents, preserve the confidentiality of our trade secrets, establish and protect our commercial brands and operate without infringing the valid and enforceable patents and proprietary rights of third parties. To accomplish this, we rely on a combination of intellectual property rights, including patents, trade

secrets, copyrights and trademarks, as well as regulatory exclusivity and contractual protections. 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. In some circumstances, 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.

We also rely on trademark protection of our corporate and product brands. We are the owner of multiple federal trademark registrations in the United States and outside the United States. ONIVYDE<sup>®</sup> is a registered U.S. trademark of ours. In addition, we have multiple additional pending trademark registration applications in the United States and other countries covering the MERRIMACK<sup>®</sup> and PROVYDE<sup>®</sup> word marks and related logos in trademark classes relevant to our products and services.

We seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants, scientific advisors and contractors. We require each of our employees, consultants and advisors to execute a confidentiality and inventions assignment agreement before beginning their employment, consulting or advisory relationship with us. These agreements generally provide that the individual must keep confidential and not disclose to other parties any confidential information developed or learned by the individual during the course of their relationship with us except in limited circumstances. These agreements also generally provide that we will own all inventions conceived by the individual in the course of rendering services to us. We also seek to preserve the 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.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of the use, formulation, manufacture and composition of our products and product candidates, as well as successfully asserting and/or defending these patents against third-party challenges. Our ability to protect our products and product candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities.

As of January 31, 2017, we owned or controlled a total of 33 issued U.S. patents and 171 corresponding issued foreign patents, in addition to 148 pending U.S. patent applications and 175 pending patent applications in the rest of the world, covering our most advanced product candidates. We intend to continue to protect our proprietary technology with additional filings as appropriate. We do not have patents or patent applications in every jurisdiction where there is a potential commercial market for our product candidates. We continually evaluate our patent portfolio and patent strategy and believe our owned and licensed patents and patent applications, as well as applicable periods of regulatory exclusivity available after new product approval, provide us with a competitive advantage; however, if markets where we do not have patents or patent applications become commercially important, our business may be adversely affected.

The latest patent expiration dates for issued patents covering the composition or use of each of our most advanced product candidates as of January 31, 2017 are summarized below. As described in more detail below, the expiration dates in the table below refer to the latest-expiring granted patent covering the product, product candidate, technology or use thereof in the United States, and one or more countries outside of the United States, but do not account for any patent term extension or extended exclusivity terms, such as pediatric extensions, that may be available in the United States and certain foreign jurisdictions.

Product Candidate	Latest Year of Expiration of Current Patent Protection in the United States	Latest Year of Expiration of Current Patent Protection outside the United States
ONIVYDE	2033	2025
MM-121	2031	2031
MM-141	2032	2032
MM-310	2031	2031
MM-302	2031	2019
MM-151	2032	2032

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. 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 a new drug application, or NDA, or a biologics license application, or BLA. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process, provided the total patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally calculated as one-half the time between the effective date of an investigational new drug application, or IND, and the submission date of an NDA, plus the time between the submission date of an NDA and the FDA's approval of that application. Only one patent applicable to each approved drug is eligible for the extension and the application for any patent term extension or restoration.

Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. The stated patent exclusivity dates for patent exclusivity outside of the United States may also be eligible for further extension, and/or regulatory market and/or data exclusivity in certain countries, upon product approval in individual countries for various reasons, including supplemental protection certificate(s) after product approval in eligible countries outside the United States, and/or conducting certain investigations of pediatric exclusivity or use of products covered by the applicable patent.

# ONIVYDE® (MM-398)

ONIVYDE is covered by issued U.S. patents on the product composition through at least 2028, and corresponding issued patents in other countries through at least 2025, not including additional exclusivity upon product approval from patent term extension, supplemental protection certificates and/or pediatric exclusivity.

In the United States, ONIVYDE is covered by multiple issued patents, including eight U.S. patents listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations publication, commonly known as the Orange Book, including U.S. patents covering the ONIVYDE drug product and drug substance (through at least 2028) and additional U.S. patents covering approved methods of using ONIVYDE (through at least 2033). We have applied for restoration of patent term, or patent term extension, for at least one of our U.S. patents covering the ONIVYDE drug product and drug substance listed in the Orange Book, to add patent life beyond the current expiration date. In addition, ONIVYDE may be eligible to receive an additional six months of exclusivity added to the term of individual patents and any other marketing exclusivity covering ONIVYDE under the Best Pharmaceuticals for Children Act, or BPCA, if we were to submit information which could be requested in writing by the FDA relating to the use of the active moiety of the drug in children. We also own multiple pending patent applications covering the manufacture and use of ONIVYDE in various indications, including pancreatic cancer, through at least 2033, if issued.

In Europe, the ONIVYDE liposome composition is covered by an issued European patent through at least 2025, not including additional exclusivity pursuant to supplementary protection certificates that may be obtained in the future in individual European countries in accordance with local laws.

Outside the United States and Europe, the ONIVYDE composition is covered by issued patents through 2025 in Japan and eight other countries, and pending patent applications in five countries. In addition, we own multiple pending patent applications that, if issued, provide additional patent coverage on the use of ONIVYDE for various indications through at least 2036. We may apply for extended exclusivity terms (supplemental protection certificates) for our other patents world-wide as appropriate, depending on the expected length of clinical trials and other factors involved in the submission of the relevant drug approval application.

#### MM-121 (seribantumab)

We own issued patents in the United States, Europe, Japan and eleven other countries covering the MM-121 composition through at least 2028, not including additional exclusivity available after product approval from patent term extension, supplemental protection certificates and/or pediatric exclusivity. In addition, we own granted patents in the United States, Europe and eight other countries covering treatment of patients with certain forms of breast cancer through at least 2031, and multiple pending patent applications in the United States, Europe and other countries covering various related methods of use, including the treatment of patients with heregulin positive forms of cancer (through 2034, if issued), treatment of patients with heregulin positive NSCLC (through 2036, if issued), treatment of patients with certain forms of breast cancer (through 2031 or 2032, if issued) and/or related diagnostic tests and methods (through 2029, if issued).

# MM-141 (istiratumab)

We own issued patents in the United States, Japan, and three other countries, and pending patent applications in Europe and ten other countries, covering the MM-141 composition through at least 2032, not including additional exclusivity available after product approval from patent term extension, supplemental protection certificates and/or pediatric exclusivity. In addition, we own multiple pending patent applications in the United States and Europe covering methods of treating pancreatic cancer with MM-141 (through 2035, if issued).

#### MM-310

We have an exclusive license to patent filings covering the MM-310 composition through at least 2031 from the University of California, including issued patents in the United States and four other countries, with additional patent filings in Europe and seven other countries. In addition, we own multiple pending patent filings covering the MM-310 liposome composition, companion diagnostic technology for MM-310 and therapeutic uses of MM-310 through at least 2037 (if issued).

#### MM-302

We own patent coverage on the use of the MM-302 composition in treating various forms of cancer (including breast cancer) through at least 2031 in the United States. In addition, we have an exclusive license to patents covering the MM-302 composition through at least 2019 in the United States, Europe and two other countries. Our patent coverage does not include additional exclusivity available after product approval from patent term extension, supplemental protection certificates and/or pediatric exclusivity. In addition, we own multiple pending patent applications in the United States, Europe and other countries covering various related methods of use (expiring between 2031 and 2035, if issued) and/or related diagnostic tests and methods (expiring between 2033 and 2034, if issued).

#### MM-151

We own issued patents in the United States and two other countries, and pending patent applications in Europe, Japan and eight other countries covering the MM-151 composition and related patient diagnostic technology through at least 2032, not including additional exclusivity available after product approval from patent term extension, supplemental protection certificates and/or pediatric exclusivity. In addition, we own multiple pending patent applications in the United States, Europe, Japan and additional countries covering methods of treating colorectal cancer with MM-151 (through 2035, if issued).

#### Silver Creek

In August 2010, we acquired 12,000,000 shares of Series A preferred stock of Silver Creek 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. As of December 31, 2016 and 2015, we owned approximately 50% and 56%, respectively, of the outstanding voting stock of Silver Creek, making Silver Creek a majority owned subsidiary.

Silver Creek is applying our systems 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 systems 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 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 actions, including, among other things, 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.

Generally, the process required by the FDA before a drug or biological product may be marketed in the United States 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 an abbreviated new drug application, or ANDA, for drug products or BLA for biological products, 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 ONIVYDE, will be subject to review as biological products under BLA standards. We expect that ONIVYDE will continue to be subject to review as a drug under NDA standards. MM-302 contains both drug and biological components. We believe that this combination product would be subject to review as a biological product, pursuant to a BLA.

#### 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 necessarily 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, 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. For clinical trials involving an IND, 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 clinical trials involving an IND 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 or biologic product has been associated with unexpected serious harm to patients.

#### Disclosure of clinical trial information

Sponsors of applicable 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 required before marketing of the product may begin in the United States. Under federal law, the submission of most NDAs and BLAs is subject to a substantial application user fee, currently \$2,038,100 for fiscal year 2017, and the sponsor of an approved NDA or BLA is also subject to annual product and establishment user fees, currently \$97,750 per product and \$512,200 per establishment. These fees may be increased or decreased 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, which would also be 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 biologies 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. 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, the agency 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 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 through a Risk Evaluation and Mitigation Strategy 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 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 more frequent 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 priority review guidelines, a product candidate may be eligible for 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 lifethreatening disease or condition where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more 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 from pediatric studies 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 that claims to 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 Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an 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.

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 a 30 month period, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that the patent involved is deemed invalid or not infringed.

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, except that the application may be submitted in four years if it contains a Paragraph IV certification. 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 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 U.S. 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. Our NDA for ONIVYDE was 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 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 a 30 month period, settlement of the lawsuit or a decision in the infringement case that the patent involved is deemed invalid or not infringed.

# **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 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<sup>1</sup>/<sub>2</sub> 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 and draft guidance documents related to BPCIA implementation concerning biosimilarity and interchangeability, BLA submission requirements, exclusivity, labeling and naming.

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 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<sup>1</sup>/<sub>2</sub> 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 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* diagnostics to obtain premarket approval, or 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* diagnostics, which are in the form of imaging agents, are regulated as drugs by CDER for therapeutic uses. As such, they are generally subject to the regulatory requirements applicable to other new drug candidates.

Diagnostic tests determined by the FDA to be useful, but not essential, for the safe and effective use of a corresponding therapeutic product are also subject to the same medical device pathways, but their clearance or approval would not be subject to a coordinated review of the diagnostic test and the therapeutic product.

The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risk are placed in either Class I or II, which requires the manufacturer to submit to the FDA a premarket notification requesting permission for commercial distribution.



Some low risk devices are exempt from this requirement. 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 cleared 510(k) device, are placed in Class III, requiring a PMA. 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.

# 510(k) clearance pathway

If any of the diagnostic products under development were determined by FDA not to be essential to the safe and effective prescription of a corresponding therapeutic product, it is possible that the diagnostic test could require 510(k) clearance. The FDA's 510(k) clearance pathway usually takes from three to twelve months, but it can take significantly longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, would require a new 510(k) clearance or, depending on the modification, a PMA. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) notice or a PMA, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or a PMA is obtained. If the FDA requires us to seek 510(k) clearance or a PMA for any modifications to a previously cleared product, we may be required to cease marketing or recall the modified device until we obtain this clearance or approval. Also, in these circumstances, we may be subject to significant regulatory fines or penalties.

#### PMA pathway

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. Most companion diagnostic tests have been classified as Class III devices subject to the PMA pathway.

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 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, manufacturing, 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 trials 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 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 drug experiences. 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 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, pharmaceutical companies that participate in federal healthcare programs like Medicare or Medicaid are subject to various U.S. federal and state laws that may restrict certain marketing practices. These laws include but are not limited to anti-kickback statutes and false claims statutes. The federal 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 as amended by the Health Care Education and Reconciliation Act of 2010, collectively the Health Care Reform Laws, amended the intent element of the anti-kickback statute such that liability under the statute can be proved even if a person or entity does not 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. In addition to the federal anti-kickback statute, the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic

The federal civil False Claims Act prohibits 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. Government enforcement agencies and private whistleblowers have initiated investigations or brought private lawsuits against pharmaceutical companies for a variety of allegedly improper promotional or marketing activities, such as allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product,

or for engaging in promotion for "off-label" uses. Additionally, the Health Care Reform Laws amended the federal False Claims Act such that a violation of the federal anti-kickback statute can serve as a basis for liability under the False Claims Act. In addition to the federal civil False Claims Act, the federal false statements statute prohibits, among other things, 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 majority of states also have statutes or regulations similar to the federal anti-kickback statute and/or False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. In addition, the federal transparency law under the Health Care Reform Laws, known as the Open Payments program, requires manufacturers of drugs, devices, biologics and medical supplies reimbursable under Medicaie or Medicaid to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals, as well as physician ownership and investment interests, and provides for public reporting of the data reported by manufacturers.

# Government price reporting

We are 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 jointly administered by federal and state governments for the benefit of low income and certain disabled beneficiaries. Under the Medicaid Drug Rebate Program, we are required to pay a rebate for each unit of product reimbursed by the state Medicaid programs. For most brand name drugs, including ONIVYDE, the total Medicaid rebate amount consists of the basic rebate and the additional rebate. The basic rebate is set by law as the greater of 23.1% of the drug's average manufacturer price, or AMP, or the difference between AMP and the best price for the drug available from us to any commercial customer (with limited exceptions). The additional rebate is designed to capture price increases that outpace inflation (measured by the Consumer Price Index - Urban). The rebate amount is calculated each quarter based on our report of current AMP and best price figures for each of our products to the Centers for Medicaid Services, or CMS, the federal agency that administers the Medicaid and Medicare programs. 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 Medicaid 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 Medicaid statute 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 or other conditions irrespective of age. 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 furnished by physicians under a payment methodology based on the average sales price, or ASP, of the drugs. We report ASP for ONIVYDE. 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 also paid on a methodology based on ASP, although that could change on a calendar year basis. 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. If a manufacturer is found to have made a misrepresentation in the reporting of ASP, the governing statute provides for civil monetary penalties.

Federal law requires that any company that participates in the Medicaid Drug Rebate Program also participate in the Public Health Service's, or PHS', 340B drug pricing discount program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the PHS, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the AMP and Medicaid rebate amount for the covered outpatient drug, as calculated under the Medicaid Drug Rebate Program.

In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we participate in the Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program. As part of this program, we are obligated to make our products available for procurement on an FSS contract under which we must comply with standard government terms and conditions and charge a price that is no higher than the statutory Federal Ceiling Price, or FCP, to the VA, Department of Defense, Coast Guard and the PHS. The FCP is based on the non-federal average manufacturer price, or Non-FAMP, which we calculate and report to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to penalties of \$100,000 for each item of false information. These obligations also contain extensive disclosure and certification requirements.

Under Section 703 of the National Defense Authorization Act for FY 2008, we are required to pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare retail pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP. We are required to list our covered products on a Tricare Agreement in order for these products to be eligible for Department of Defense formulary inclusion.

If we overcharge the government in connection with our FSS contract or the Tricare retail pharmacy program, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

### Data protection

We are subject to data protection laws and regulations (i.e., laws and regulations that address privacy and data security). The legislative and regulatory landscape for data protection continues to evolve, and in recent years there has been an increasing focus on privacy and data security issues. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws and federal and state consumer protection laws govern the collection, use, disclosure and protection of health-related and other personal information. Failure to comply with data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. In addition, we may obtain health information from third parties (e.g., healthcare providers who prescribe our products) that are subject to privacy and security requirements under HIPAA. We could be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information in a manner that is not authorized or permitted.

#### 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.

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 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 FDASIA, which was enacted in 2012, 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.

In addition, the Health Care Reform Laws were enacted in the United States in March 2010 and contain provisions that may reduce the profitability of drug products, including, for example, increased rebates for drugs 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.

With the new U.S. presidential administration and Congress, there will likely be additional legislative changes, including the repeal and replacement of certain provisions of the Health Care Reform Laws. To that end, on January 20, 2017, the President issued an Executive Order Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal. The Executive Order declares that, pending repeal of the Health Care Reform Laws, it is imperative for the executive branch to ensure that the law is being efficiently implemented, take all actions consistent with law to minimize the unwarranted economic and regulatory burdens of the Health Care Reform Laws, and prepare to afford the states more flexibility and control to create a more free and open healthcare market. The Executive Order directs the Secretary of Health and Human Services and the heads of all other executive departments and agencies with authorities and responsibilities under the Health Care Reform Laws to exercise their authority and discretion to waive, defer, grant exemptions from or delay the implementation of any provision or requirement of the Health Care Reform Laws that would impose a fiscal burden on any state or a cost, fee, tax, penalty or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance or makers of medical devices, products or medications.

With respect to repeal of the Health Care Reform Laws and their replacement with new legislation, it is unclear when such legislation will be enacted, what it will provide and what impact it will have on the availability of healthcare and containing or lowering the costs of healthcare.

# 21st Century Cures Act

In December 2016, Congress passed the 21st Century Cures Act, or the Cures Act, which includes a number of provisions designed to speed development of innovative therapies, provide funding authorization to the National Institutes of Health and provide funding for certain oncology-directed research. Because the Cures Act has only recently been enacted, its potential effect on our business remains unclear with the exception of a provision requiring that we post our policies on the availability of expanded access programs for individuals. In addition, the Cures Act includes provisions requiring the FDA to assess and publish guidance on the use of novel clinical trial designs, the use of real world evidence in applications, the availability of summary level review for supplemental applications for certain indications, and the qualification of drug development tools. Because these provisions allow the FDA to spend several years developing these policies, the effect on us could be delayed.

The Cures Act also authorizes \$1.8 billion in funding for the Obama Administration's "cancer moonshot" initiative to be run by the National Institutes of Health. The cancer moonshot initiative's strategic goals encourage inter-agency cooperation and fund research and innovation to catalyze new scientific breakthroughs, bring new therapies to patients, and strengthen prevention and diagnosis. The initiative aims to stimulate drug development through the creation of a public-private partnership with 20 to 30 pharmaceutical and biotechnology companies to expedite cancer researchers' access to investigational agents and approved drugs. This partnership is designed to permit researchers to obtain drugs and other technologies from a preapproved "formulary" list without having to negotiate with each company for individual research projects. We will monitor these developments but cannot currently assess how this initiative may impact our business

#### Pharmaceutical coverage, pricing and reimbursement

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. 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 ONIVYDE or any other drug products for which we obtain regulatory approval and could adversely affect our net revenue and results.

Significant uncertainty exists as to the coverage and reimbursement status of ONIVYDE or any other drug products for which we obtain regulatory approval. Sales of ONIVYDE or any of our product candidates, if approved, depend in significant part on the availability of adequate financial coverage and reimbursement from third-party payors, including government health programs such as Medicare and Medicaid, commercial health insurers and managed care organizations.

Political, economic and regulatory influences are subjecting the healthcare industry in the United States to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our products profitably. The Health Care Reform Laws expanded healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. This law substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Healthcare Reform Laws contain a number of provisions that may impact our business and operations. On February 1, 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate program under the Healthcare Reform Laws. These regulations become effective, in general, on April 1, 2016. We are evaluating the impact of these regulations on our business and operations.

The Healthcare Reform Laws also obligate the Health Resources and Services Administration, or HRSA, the agency which administers the 340B program, to create regulations and processes to improve the integrity of the 340B program and to update the agreement that manufacturers must sign to participate in the 340B program to obligate a manufacturer to offer the 340B price to covered entities if the manufacturer makes the drug available to any other purchaser at any price and to report the ceiling prices for its drugs to the government. HRSA recently issued a proposed regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, as well as proposed omnibus guidance that addresses many aspects of the 340B program, including a proposed expansion of manufacturer recordkeeping requirements and 340B ceiling price restatement and refund obligations. HRSA is currently expected to issue additional proposed regulations in 2016. Any final regulation could affect our obligations under the 340B program in ways we cannot anticipate. Further, legislation may be introduced that, if passed, could further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting.

In addition, beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologics, were reduced by 2% under the sequestration required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. Subsequent legislation extended the 2% reduction, on average, to 2025. These cuts reduce reimbursement payments related to our products, which could potentially negatively impact our revenue.

Medicare Part D provides coverage to enrolled Medicare patients for certain drugs, such as 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 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.

Third-party payors decide which drugs they will pay for and establish reimbursement and co-pay levels. The growing emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on drug pricing. 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 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. 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. Even with clinical trials, our product candidates may be considered less safe, less effective or less cost-effective than other products, and third-party payors may not provide coverage and reimbursement for our products or any of our product candidates that we commercialize, in whole or in part.

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, and 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. In addition, coverage policies, third-party reimbursement rates and drug pricing regulation may change at any time. Thus, 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. The marketability of any products for which we receive regulatory approval for commercial sale may also suffer if the government and third-party payors fail to provide adequate coverage and reimbursement.

Payors also are increasingly considering new metrics as the basis for reimbursement rates, such as ASP, AMP and actual acquisition cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. CMS surveys and publishes retail community pharmacy acquisition cost information in the form of National Average Drug Acquisition Cost, or NADAC, files to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates. It may be difficult to project the impact of these evolving reimbursement mechanics on the willingness of payors to cover our products.

For Medicare and other health insurance programs in the United States, Healthcare Common Procedure Coding System codes, or HCPCS codes, are used to ensure that claims for certain items and services (including most drugs) are submitted and adjudicated in an orderly and consistent manner. The HCPCS code set is maintained by CMS and applications for HCPCS codes are submitted to CMS. Based primarily on the existence of an HCPCS code that appropriately describes a product, a new product may be assigned to a new or existing HCPCS code and may be the only product or one of several products described by that HCPCS code. For many drug HCPCS codes, CMS sets the Medicare payment rate for the code.

Beyond the United States, 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.

#### Employees

As of January 31, 2017, we had 294 full-time employees, of whom 175 are engaged in research, development and manufacturing. None of our employees is represented by a labor union or covered by collective bargaining agreements.

On October 3, 2016, we announced a 22% reduction in headcount, or 85 employees, as part of a major corporate restructuring with the objective of prioritizing our research and development on a focused set of systems biology-derived oncology products and strengthening our financial runway. Additionally, on January 9, 2017, we announced that we will further reduce headcount in

connection with the asset sale to Ipsen and the completion of our strategic pipeline review, with approximately 121 employees who will become employees of Ipsen at the closing of the transaction, and a further approximately 94 positions that will be eliminated.

Despite these announcements, we consider our relationship with our employees to be good.

#### Segment, Geographic and Financial 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. We view our operations and manage our business in one operating segment and we operate in only one geographic region.

Financial information about (1) our net product revenues and other revenues, net loss per share available to common stockholders and our total assets is provided in our consolidated financial statements included in this Annual Report on Form 10-K and (2) our research and development expenses in each of the last three fiscal years is provided in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Information about our dependence on limited amounts of customers is provided in Note 1, "Nature of the Business and Summary of Significant Accounting Policies" – "Concentration of Credit Risk" in the accompanying notes to the consolidated financial statements.

#### **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.merrimack.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" link in the "Investors" 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.

#### Item 1A. Risk Factors

The following risk factors and other information included in this Annual Report on Form 10-K should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Please see page 2 of this Annual Report on Form 10-K for a discussion of some of the forward-looking statements that are qualified by these risk factors. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

### Risks Related to the Sale of our Commercial Business to Ipsen

#### If the asset sale is not completed, we may be unable to successfully pursue strategic alternatives for our product candidates.

If the asset sale is not completed, we may not be able to pursue strategic alternatives for our company or our product candidates because we will have limited cash reserves and limited revenues. The clinical development and potential commercialization of our product candidates requires significant capital. We had unrestricted cash and cash equivalents of \$21.5 million as of December 31, 2016. If we cannot raise additional capital, we may have difficulty servicing our debt obligations and may need to file for bankruptcy.

We may be unable to raise additional capital or may be required to incur significant costs to raise such additional capital. Our ability to raise additional capital will depend on many factors, including, but not limited to, the following:

- market conditions for debt or equity financing;
- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our product candidates or any other future product candidates;
- investors' and lenders' belief in our business plan and our ability to continue as a going concern;
- our ability to continue to comply with our obligations under our existing indebtedness;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- the outcome, timing and cost of regulatory review by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than those that we currently expect;
- the effect of competition; and
- the costs and timing of establishing manufacturing, sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval.

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

#### If the asset sale is not consummated, we may not be able to commercialize additional product candidates.

If the asset sale is not consummated, our commercialization strategy for our product candidates may depend on our ability to enter into agreements with collaborators to obtain assistance and funding for the development and potential commercialization of the relevant product candidate in the territories in which we seek to partner. Despite our efforts, we may be unable to secure additional collaborative licensing or other arrangements that are necessary for us to further develop and commercialize our product candidates.



Supporting diligence activities conducted by potential collaborators and negotiating the financial and other terms of a collaboration agreement are long, costly and complex processes with uncertain results. Due to our limited cash on hand, we may not have the financial resources to engage in discussions with third parties regarding collaborative licensing or other arrangements.

#### We cannot be sure if or when the asset sale will be completed.

The consummation of the asset sale is subject to the satisfaction or waiver of various conditions, including the approval of the asset sale by our stockholders. We cannot guarantee that the closing conditions set forth in the asset sale agreement will be satisfied. If we are unable to satisfy the closing conditions in Ipsen's favor or if other mutual closing conditions are not satisfied, Ipsen will not be obligated to complete the asset sale.

If the asset sale is not completed and the asset sale agreement is terminated because our stockholders do not approve the asset sale, we will be required to reimburse up to \$3.0 million of Ipsen's out-of-pocket expenses incurred in connection with the transaction.

If the asset sale is not completed, our board of directors, in discharging its fiduciary obligations to our stockholders, will evaluate other strategic alternatives that may be available, which alternatives may not be as favorable to our stockholders as the asset sale. We may seek another purchaser for the commercial business, but we may not be able to find a purchaser willing to offer a reasonable purchase price for the commercial business. Any future sale of the commercial business or other transactions may be subject to further stockholder approval.

### The holders of certain of our outstanding convertible securities have asserted that the asset sale constitutes a "Fundamental Change" under the indenture that governs those convertible notes.

In July 2013, we issued \$125.0 million aggregate principal amount of 4.50% convertible notes due 2020, or convertible notes, of which an aggregate principal amount of \$60.8 million remains outstanding as of December 31, 2016. On February 13, 2017, we received a letter on behalf of Wells Fargo Bank, National Association as trustee under the convertible notes, at the direction of institutions that own or manage accounts holding more than a majority of the convertible notes, or the majority holders, claiming that the asset sale is a sale of "substantially all" of our assets and, accordingly, constitutes a "Fundamental Change" under the indenture governing the convertible notes, or the convertible notes indenture. The trustee and the majority holders claim that, if the asset sale is a Fundamental Change under the convertible notes indenture, we are obligated to issue a "Fundamental Change Issuer Notice" to the holders of the convertible notes at par plus accrued and unpaid interest. We disagree with the claims in the letter, including the statement that the asset sale constitutes a sale of "substantially all" of our assets, and accordingly believe that the asset sale is not a Fundamental Change under the convertible notes pursue their claim that the asset sale is a sale of "substantially all" of our assets in litigation, such litigation could be costly to us. If we are unsuccessful in that litigation, we may be required to repay all or a portion of the convertible notes, together with interest thereon. In that event, we would be required to use a portion of the cash proceeds of the asset sale to effect such repayment, which would impact the cash available for other purposes, including the expected dividend to stockholders and the cash to be invested in our oncology pipeline.

### The announcement and pendency of the asset sale, whether or not consummated, may adversely affect our financial condition or future strategic opportunities.

The announcement and pendency of the asset sale, whether or not consummated, may adversely affect the trading price of our common stock and/or our relationships with partners and employees. In connection with the asset sale, we will be terminating a significant portion of our employees at the closing of the asset sale. In addition, our management's focus and attention may be diverted from identifying strategic alternatives during the pendency of the asset sale.

In the event that the asset sale is not completed, the announcement of the termination of the asset sale agreement may also adversely affect the trading price of our common stock and our relationships with partners and employees.

### The asset sale agreement limits our ability to sell the commercial business to a party other than Ipsen.

The asset sale agreement contains provisions that make it more difficult for us to sell the commercial business to a party other than Ipsen, including a non-solicitation provision and a provision requiring us to notify Ipsen of any solicitation or offer made by any third party in connection with the sale of the commercial business or any similar transaction. These provisions could discourage a third party that might have an interest in acquiring the commercial business from considering or proposing such a transaction, even if that party were prepared to pay consideration with a higher value than the consideration to be paid by Ipsen.



#### We may be subject to securities litigation, which is expensive and could divert our attention.

We may be subject to securities class action litigation in connection with the asset sale. Securities litigation against us could result in substantial costs and divert our management's attention from closing the asset sale, which could seriously harm our business.

### Because our business will be smaller following the sale of the commercial business, there is a possibility that our common stock may be delisted from the NASDAQ Global Market if we fail to satisfy the continued listing standards.

Even though we currently satisfy the continued listing standards for the NASDAQ Global Market, following the completion of the sale of the commercial business, our business will be smaller and, therefore, we may fail to satisfy the continued listing standards of the NASDAQ Global Market. In the event that we are unable to satisfy the continued listing standards of the NASDAQ Global Market. Any delisting of our common stock from the NASDAQ Global Market could adversely affect our ability to attract new investors, decrease the liquidity of our outstanding shares of common stock, reduce our flexibility to raise additional capital, reduce the price at which our common stock trades and increase the transaction costs inherent in trading such shares with overall negative effects for our stockholders. In addition, delisting of our common stock could deter broker-dealers from making a market in or otherwise seeking or generating interest in our common stock, and might deter certain institutions and persons from investing in our securities at all. For these reasons and others, delisting could adversely affect the price of our common stock and our business, financial condition and results of operations.

### Because the commercial business represented all of our revenues for fiscal year 2016, our business following the sale of the commercial business will be substantially different.

The commercial business represented all of our revenues for the fiscal year 2016. Following the sale of the commercial business, we will retain the pipeline business. Our results of operations and financial condition may be materially affected if we fail to grow our pipeline business, if we are unable to raise additional capital if needed to run the pipeline business, if we must incur significant costs in order to raise additional capital to run the pipeline business or if we are unable to successfully develop and commercialize our remaining product candidates.

### There can be no guarantee that Ipsen will comply with its obligation to use commercially reasonable efforts in connection with the development of ONIVYDE.

If the asset sale is completed, Ipsen has agreed to use commercially reasonable efforts to develop ONIVYDE in connection with obtaining the regulatory approval by the FDA of ONIVYDE for certain indications. Although the results of this approval process may enable Ipsen to achieve the milestones necessary for us to receive the contingent payments under the asset sale agreement, there is no guarantee that Ipsen will take the steps set forth in the asset sale agreement and that such development will lead to the successful approval of ONIVYDE for such additional indications. Therefore, there can be no guarantees that any of the milestones set forth in the asset sale agreement will be achieved and that we will receive any future contingent payments.

Whether or not the asset sale is completed, we are entitled to receive certain net milestone payments under the Baxalta agreement, up to \$33.0 million. Even though Baxalta and we have made progress towards achieving these milestones, payment of any or all of the \$33.0 million is not guaranteed.

#### We cannot predict the timing or amount of any distributions to our stockholders.

After consummation of the asset sale, we plan to issue a special cash dividend to stockholders of at least \$200.0 million. This dividend amount assumes that we will not use any of the proceeds of the asset sale to repay our outstanding convertible notes. We cannot predict the exact timing or amount of the dividend at this time, or the potential outcome of any potential litigation challenging our position that we are not obligated to repurchase the convertible notes. In addition, our board of directors will need to approve the dividend if and after the asset sale is consummated, and will only authorize a dividend if there is sufficient surplus at that time. In the event there is not sufficient surplus, we may be unable to pay the expected dividend or any dividend.

### If the asset sale disrupts our business operations and prevents us from realizing intended benefits, our business may be harmed.

The asset sale may disrupt the operation of our business and prevent us from realizing the intended benefits of the asset sale as a result of a number of obstacles, including the loss of key employees, customers or business partners, the failure to adjust or implement our business strategies, additional expenditures required to facilitate the asset sale and the diversion of management's attention from our day-to-day operations.



#### Ipsen is not assuming any of the excluded liabilities under the asset sale agreement.

Pursuant to the asset sale agreement, if the asset sale is completed, Ipsen will only assume certain specified liabilities set forth in the asset sale agreement and will not assume all of the liabilities associated with the commercial business. Certain liabilities will remain with us post-closing. While we believe that we have adequately accrued for these liabilities or are adequately insured against certain of the risks associated with such excluded liabilities, there can be no assurances that additional expenditures will not be incurred in resolving these liabilities.

#### The asset sale agreement may expose us to contingent liabilities.

We have agreed to indemnify Ipsen for certain breaches of representations, warranties or covenants made by us in the asset sale agreement and for certain specified existing litigation. We have agreed that if we cannot pay our indemnification obligations, Ipsen will have set-off rights against any future contingent payments. Significant indemnification claims by Ipsen could further materially and adversely affect our financial condition and/or significantly reduce any future contingent payments.

#### We will continue to incur the expenses of complying with public company reporting requirements following the closing of the asset sale.

After the asset sale, we will continue to be a public company. For as long as we remain a public company, we have an obligation to continue to comply with the applicable reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which include the filing with the SEC of periodic reports, proxy statements and other documents relating to our business, financial condition and other matters, even though compliance with such reporting requirements is economically burdensome.

### Risks Related to Our Financial Position and Need for Additional Capital

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

Since inception, we have incurred significant operating losses. Our net loss was \$153.5 million for the year ended December 31, 2016, \$147.8 million for the year ended December 31, 2015 and \$83.6 million for the year ended December 31, 2014. As of December 31, 2016, we had an accumulated deficit of \$954.8 million. To date, we have financed our operations primarily through private placements of our convertible preferred stock, collaborations, public offerings of our securities, secured debt financings and sales of ONIVYDE. We have devoted substantially all of our efforts to research and development, including clinical trials and recently to commercialization of our first product, ONIVYDE. We have not completed development of or commercialized any other therapeutic product candidates or diagnostics other than ONIVYDE. We expect to continue to incur significant expenses and operating losses for at least the next several years as we:

- initiate or continue clinical trials of our 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; and
- continue to provide the operational, financial and management information systems and personnel to support our product development and continued commercialization.

To become and remain profitable, we must succeed in developing and 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 or partnering those products for which we may seek and receive regulatory approval. We are only in the preliminary stages of some of these activities for most of our product candidates, and our commercial activities for ONIVYDE are still at an early stage. 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. In July 2013, we issued \$125.0 million aggregate principal amount of convertible notes, of which an aggregate principal amount of \$60.8 million remains outstanding as of December 31, 2016, and in December 2015, we issued \$175.0 million aggregate principal amount of 11.50% senior secured notes due 2022, or 2022 notes. Additionally, in November 2016, we entered into a Loan and Security Agreement, or the credit agreement, with BioPharma Credit Investments IV Sub, LP, or Pharmakon, pursuant to which a credit facility of an aggregate principal amount of at least \$15.0 million and up to \$25.0 million is available to us at any time through April 27, 2017, upon compliance with certain funding conditions. In connection with the credit agreement, we granted Pharmakon a security interest in all inventory and accounts receivable. We could in the future incur additional indebtedness beyond such amounts.

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

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

We intend to satisfy our current and future debt service obligations with our existing cash and cash equivalents and funds from external sources, and, upon consummation of the asset sale to Ipsen, we intend to prepay the 2022 notes. However, we may not have sufficient funds or may be unable to arrange for additional financing to pay any amounts due under our debt as it exists at any future point in time. 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 to continue to incur significant research and development expenses 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 supporting commercial sales of ONIVYDE through the time at which the asset sale is consummated, if ever, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution related to ONIVYDE and any other product for which we obtain regulatory approval in the future. 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.

Upon stockholder approval and the closing of the asset sale with Ipsen, we will receive a \$575.0 million upfront cash payment from Ipsen (subject to a working capital adjustment as provided in the asset sale agreement). We expect to use these proceeds to declare and pay a special cash dividend of at least \$200.0 million to stockholders and redeem the \$175.0 million outstanding aggregate principal amount of 2022 notes, which will require an additional make-whole premium payment of approximately \$20.1 million. Additionally, if the asset sale is consummated and certain milestones under the Baxalta agreement are met, we currently expect to receive up to an aggregate of \$33.0 million in net milestone payments in 2017. We believe these potential net cash inflows, along with the completion of the headcount reduction and refocused research and development efforts that were announced in January 2017, will provide financial resources sufficient to fund our operations into the second half of 2019. 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 consummation of the asset sale and the net proceeds received therefrom;
- the amount of net product revenues realized from ONIVYDE commercial sales, should the asset sale not be consummated;
- the amount of royalty and profit sharing revenue from our collaboration partners, particularly should the asset sale not be consummated;
- the progress and results of the clinical trials of our most advanced product candidates;
- the success of the Baxalta and PharmaEngine collaborations related to ONIVYDE 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 ONIVYDE that we may receive from Baxalta;
- the timing and amount of future milestone payments that we may receive from Ipsen under the asset sale agreement;
- 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 current and future product candidates;
- the costs of commercial activities, including product sales, marketing, manufacturing and distribution, particularly should the asset sale not be consummated;
- 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, particularly should the asset sale not be consummated; and
- our ability to establish and maintain additional collaborations on favorable terms, particularly marketing and distribution arrangements for oncology product candidates outside the United States and Europe.

Conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data required to obtain regulatory approval and, even if regulatory approval is obtained, achieve product sales of any of our product candidates other than ONIVYDE. In addition, ONIVYDE or any of our other



product candidates, if approved, may not achieve commercial success. We began commercializing ONIVYDE under the brand name ONIVYDE in the United States in the fourth quarter of 2015. If we fail to generate sufficient revenues from the sale of ONIVYDE or the commercialization of any of our product candidates, we will need to continue to rely on additional financing to achieve our business objectives.

If we are unable to obtain stockholder approval of the asset sale and the transaction with Ipsen is not consummated, or if we are unable to obtain other adequate financing or engage in another strategic transaction on acceptable terms and when needed, we will be required to implement further cost reduction strategies.

### Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included in this Annual Report on Form 10-K.

The report from our independent registered public accounting firm for the year ended December 31, 2016 includes an explanatory paragraph stating that our losses from operations and required additional funding to finance our operations raise substantial doubt about our ability to continue as a going concern. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. If we are unable to continue as a going concern. If we are unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited financial statements, and it is likely that investors will lose all or a part of their investment. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all.

### 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.

We do not have any committed external source of funds, other than under the asset sale agreement with Ipsen, which is subject to the achievement of certain closing conditions prior to consummation, including stockholder approval, under our collaboration with Baxalta for the development and commercialization of ONIVYDE, which is terminable by Baxalta for convenience upon 180 days' prior written notice, 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, and under our credit agreement with Pharmakon, subject to compliance with certain funding conditions. 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.

Until such time, if ever, as we can generate sufficient product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, licensing arrangements and other marketing and distribution arrangements. We also could engage in discussions with third parties regarding partnerships, joint ventures, combinations or divestitures of one or more of our businesses as we seek to further the development of our research programs, improve our cash position and maximize stockholder value. There can be no assurance as to the timing, terms or consummation of any financing, collaboration, licensing arrangement or other marketing and distribution arrangement, partnership, joint venture, combination or divestiture.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders. Additional debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and these covenants may also require us to attain certain levels of financial performance and we may not be able to do so; any such failure may result in the acceleration of such debt and the foreclosure by our creditors on the collateral we used to secure the debt. The debt issued in a debt financing would also be senior to our outstanding shares of capital stock, and may rank equally with or senior to the convertible notes and the 2022 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 financing swhen 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 successful commercialization of ONIVYDE and the success of our clinical stage product candidates. All of our product candidates other than ONIVYDE are still in preclinical and clinical development. Clinical trials of our product candidates may not be successful. If we are unable to successfully commercialize ONIVYDE or our other 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 development of ONIVYDE and our other clinical stage product candidates for the treatment of various types of cancer. All of our product candidates, including ONIVYDE in indications beyond those for which it has already received marketing approval, are still in preclinical and clinical development. Our ability to generate meaningful product revenues will depend heavily on the successful commercialization of ONIVYDE and development of our product candidates. The success of ONIVYDE and our product candidates and 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 diagnostics;
- establishing commercial manufacturing capabilities, either by building such facilities ourselves or making arrangements with third-party manufacturers;
- launching commercial sales of any approved products, whether alone or in collaboration with others;
- acceptance of any approved products by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- a continued acceptable safety profile of any products following approval; and
- qualifying for, maintaining, enforcing and defending intellectual property rights and claims.

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

For example, in connection with our strategic review of our pipeline which was completed in January 2017, we amended several of our clinical trials such as our Phase 2 clinical trial of MM-121 and our Phase 2 clinical trial of MM-141, resulting in changes to their power, design and timing, and also discontinued several trials, including our Phase 2 clinical trial of MM-302.

### Even though the ONIVYDE regimen has been approved for marketing by the FDA, European Commission and certain other regulatory agencies, we or Baxalta may never receive approval to commercialize ONIVYDE in other parts of the world.

We have out-licensed the rights for the development and commercialization of ONIVYDE outside of the United States and Taiwan. In order to market our products outside of the United States, we or our collaboration partners must comply with numerous and varying regulatory requirements of other jurisdictions regarding safety and efficacy. Approval procedures vary among jurisdictions and can involve product testing and administrative review periods different from, and greater than, those in the United States. Potential risks include that the regulatory authorities may not:

- deem our products safe and effective;
- find the data from clinical trials sufficient to support approval;
- approve of manufacturing processes and facilities; or
- approve our products for any or all indications for which approval is sought.

If ONIVYDE fails to receive marketing approval in other parts of the world, our business may be materially harmed.

### 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.

Even though ONIVYDE has been approved for marketing by the FDA, European Commission and certain other regulatory agencies in combination with 5-FU and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy, we may never receive approval to commercialize our other product candidates in the United States or other jurisdictions, or to commercialize ONIVYDE in other parts of the world or for other indications. 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, 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 December 2016, we decided to discontinue our Phase 2 clinical trial of MM-302 in combination with trastuzumab in patients with ErbB2 (HER2) positive, locally advanced or metastatic breast cancer based on an opinion from the DSMB that continuing the clinical trial would be unlikely to demonstrate benefit over the comparator treatments. We do not plan to invest in additional development of MM-302 at this time. Previously, in our Phase 2 clinical trial of MM-121 in patients with NSCLC, 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 previous Phase 2 clinical trials of MM-121 in patients with ovarian cancer or in patients with breast cancer, although our ongoing biomarker analysis in each trial identified a potential subpopulation of patients benefiting from MM-121 in combination with either paclitaxel or exemestane, respectively.

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

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

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

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 or following their approval and commercialization, we may need to modify or abandon our development or marketing of such product or product candidate.

All of our product candidates, other than ONIVYDE in combination with 5-FU and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy, 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, and it is impossible to ensure that safety or efficacy issues will not arise following regulatory approval. Currently marketed therapies for solid tumors are generally limited to some extent by their toxicity. Use of our product candidates as monotherapies in clinical trials also has resulted in adverse events consistent in nature with other marketed therapies. When used in combination with other marketed or investigational therapies, our product candidates may exacerbate adverse events associated with the other therapy. If our products or 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 or marketing. For instance, the label for ONIVYDE contains a boxed warning with respect to severe neutropenia and severe diarrhea, which must be clearly conveyed in all marketing materials. Physicians' perceptions of the risks conveyed by the ONIVYDE boxed warning could impact their willingness to prescribe ONIVYDE.

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

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

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

In general, we forecast enrollment for our clinical trials based on experience from previous clinical trials and monitor enrollment to be able to make adjustments to clinical trials when appropriate, including as a result of slower than expected enrollment that we experience from time to time in our clinical trials. For example, we experienced slower than expected enrollment in our Phase 2 clinical trial of MM-121 in combination with exemestane for hormone receptor positive breast cancer. In response, we revised the



entry criteria for the clinical trial to correspond with changes in clinical practice and also expanded the number of sites and countries participating in the clinical trial. It is possible that slow enrollment in other clinical trials in the future could require us to make similar adjustments. If these adjustments do not overcome problems with slow enrollment, we could experience significant delays or abandon the applicable clinical trial altogether.

### If we are unable to successfully develop 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* diagnostics for each of our therapeutic product candidates. There has been limited success to date industry-wide in developing diagnostics, in particular *in vitro* diagnostics. To be successful, we will need to address a number of scientific, technical, regulatory and logistical challenges.

All of our diagnostic candidates are in preclinical or clinical development. 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 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.

### Any of our product candidates that receive regulatory approval may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

Even though ONIVYDE has received marketing approval, it, or any of our other product candidates that receive marketing approval, 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 ONIVYDE and our other 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 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 effectively educate healthcare professionals or enter into agreements with third parties to sell and market our products, we may not be successful in commercializing ONIVYDE or any other product candidates for which we receive marketing approval.

ONIVYDE is the first product that we are commercializing. We have no prior experience in the sale, marketing or distribution of therapeutic products. To achieve commercial success for any approved product, we must either build a field organization or outsource this function to third parties. We have established an organization to educate healthcare professionals on ONIVYDE in the United States. We expect that Baxalta and PharmaEngine will market and sell ONIVYDE in the rest of the world in jurisdictions where ONIVYDE is approved. 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 commercial capabilities and entering into arrangements with third parties to perform these services. For example, we have a small field force of clinically trained professionals who are charged with educating healthcare professionals about ONIVYDE and Merrimack. This differs from the traditional field model in that it is neither a traditional field sales force nor a traditional medical science liaison role. While we believe that our field strategy will better meet the needs of our customers, this strategy may not be effective.

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

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

The development and commercialization of new therapeutic and diagnostic products is highly competitive. We face competition with respect to ONIVYDE and our other 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 ONIVYDE. 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 ONIVYDE or our other 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. 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.

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.

### ONIVYDE or any of our product candidates that we successfully commercialize 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, including ONIVYDE, vary widely from 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 ONIVYDE and any other approved products successfully also will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from third-party payors, including government payors such as Medicare and Medicaid, private health insurers and managed care organizations. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our products profitably. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. The federal 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 ONIVYDE and the other product candidates that we are developing and could have a material adverse effect our net revenue and results.

Third-party payors decide which drugs they will pay for and establish reimbursement and co-pay levels. The growing emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on drug pricing. 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. 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. Even with clinical trials, our product candidates may be considered less safe, less effective or less cost-effective than other products, and third-party payors may not provide coverage and reimbursement for our products or any of our product candidates that we commercialize, in whole or in part.

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 a formulary, which might not include all of the approved drugs for a particular indication, and a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved.

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, ONIVYDE and any other product for which we obtain marketing approval. 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. 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. In addition, coverage policies, third-party reimbursement rates and drug pricing regulation may change at any time. Thus, 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. The marketability of any products for which we receive regulatory approval, for commercial sale may also suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize ONIVYDE or any other product candidate that we successfully develop.

Payors also are increasingly considering new metrics as the basis for reimbursement rates, such as average sales price, average manufacturer price and actual acquisition cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. CMS surveys and publishes retail community pharmacy acquisition cost information in the NADAC files to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates. Changes in these reimbursement mechanisms may have an adverse effect on our revenue.

Moreover, there may be significant delays in obtaining reimbursement for ONIVYDE and any other 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. 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 appropriate payment rates from both government-funded and private payors for new products that we develop could therefore 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 ONIVYDE and any other 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 an even greater risk related to the commercial sale of ONIVYDE and any other products that we may develop. If we cannot successfully defend ourselves against claims that ONIVYDE or our other product candidates caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

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

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

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

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

We have based our research and development efforts on our systems biology approach to biomedical research. Notwithstanding our large investment to date and anticipated future expenditures in our proprietary approach to research and development, 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 new or additional product candidates through our systems 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 systems 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 systems 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 our systems biology approach. Silver Creek has received separate funding from investors other than us. Although we were the majority owner of Silver Creek as of December 31, 2016, 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 our systems biology approach in a way that reflects adversely on us. In addition, these companies may have difficulty raising additional funds and could encounter any of the risks in developing and commercializing product candidates to which we are subject.

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

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

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

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

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

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

### **Risks Related to Our Dependence on Third Parties**

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

In September 2014, we entered into a license and collaboration agreement with Baxalta for the development and commercialization of ONIVYDE. Prior to this collaboration, we did not have a history of working with Baxalta, nor do we have a history of working with Shire plc, which acquired Baxalta in June 2016. 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 ONIVYDE is successfully commercialized. We cannot predict the success of the collaboration.

Under our license and collaboration agreement, Baxalta has significant control over the conduct and timing of development and commercialization efforts with respect to ONIVYDE outside of the United States. We have little control over the amount, timing and quality of resources that Baxalta devotes to the development or commercialization of ONIVYDE outside of the United States. If Baxalta fails to devote sufficient financial and other resources to the future development or commercialization of ONIVYDE outside of the United States, the development and commercialization of ONIVYDE outside of the United States, the development and commercialization of ONIVYDE 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 ONIVYDE outside of the United States at all.

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

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

If Baxalta terminates our agreement at any time, whether on the basis of our uncured material breach or for any other reason, it would delay or prevent our further development of ONIVYDE 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 ONIVYDE outside of the United States on our own, seek another collaborator or licensee for such clinical development and commercialization, or abandon the future clinical development and commercialization of ONIVYDE outside of the United States.

Additionally, in June 2016, Baxalta was acquired by Shire plc. The change of control of Baxalta may adversely affect our collaborative relationship or the commercialization of ONIVYDE in the partnered territories. Such a change in control may result in a reprioritization of ONIVYDE within Baxalta's portfolio, or Baxalta failing to maintain the financial or other resources necessary to continue supporting its commercialization of ONIVYDE.

### 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 systems 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 systems biology approach.

Our likely collaborators for any distribution, marketing, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We will have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

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

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

- disputes may arise between us and the collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and
- collaborations may be terminated, such as the termination of our license and collaboration agreement with Sanofi effective December 17, 2014, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

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

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

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

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

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

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

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

We also intend to utilize diagnostics in several of our current and planned clinical trials, including current clinical trials of MM-121 and MM-141, to preselect patients who will receive specified treatment regimens. We will rely on third-party laboratories to test patient samples in connection with such 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, and any interruption in manufacturing could result in insufficient 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 commercial sales of ONIVYDE, research and development purposes and for clinical trials of our product candidates. We have limited experience in manufacturing products at a commercial scale. If we are unable to remain in compliance with regulatory requirements or retain 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 and our commercialization efforts may be materially harmed.

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. If such an event occurs, the supply of ONIVYDE and our other product candidates would be interrupted. 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 and could lose potential revenue from the sales of ONIVYDE and any other products for which we obtain regulatory approval. 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 ONIVYDE or any other products manufactured at that facility. Such an event could delay our clinical trials or reduce our product sales of ONIVYDE and any other products that are approved by the FDA.

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

Any other interruption of production at our manufacturing facility also could damage our business. For example, in 2009, we experienced a viral contamination at this facility that required that we shut the facility entirely for decontamination. Because of this contamination, the FDA placed a partial clinical hold on our 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.

## We expect to continue to contract with third parties for at least some aspects of the production of ONIVYDE and our other product candidates for commercial sale and clinical trials. This increases the risk that we will not have sufficient quantities of ONIVYDE or our other product candidates 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 ONIVYDE and our other product candidates, including the production of MM-121 and fill-finish and labeling activities for ONIVYDE and our other product candidates. In addition, while we believe that our existing manufacturing facility or additional facilities that we 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 ONIVYDE and any other products 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 in 2014, we assumed an agreement with a third-party manufacturer for the manufacture of MM-121. We do not have any other agreements with third-party manufacturers for the clinical supply to us of ONIVYDE or commercial supply to us of ONIVYDE or any other 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 or QSR or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and product candidates.

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 certain raw materials that we use for our nanoliposome 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* diagnostics. Currently, many reagents are marketed as Research Use Only products under FDA regulations.

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

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

Although we perform much of the bulk manufacturing for ONIVYDE and our other product candidates, we rely on third parties to perform the fillfinish 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 ONIVYDE and our other product candidates could be adversely impacted.

For instance, in 2010, a former fill-finish third-party contractor that we used to fill and package MM-121 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. 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-141, MM-302 and MM-151, and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that our future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate these agreements, in which event we might not be able to develop and market any product that is covered by these agreements. Termination of these licenses or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms. The occurrence of such events could materially harm our business.

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

Our success depends in large part on our and our licensors' ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology or products that we license from third parties. Therefore, we cannot be certain that these patents and applications will be prosecuted and enforced in a

manner consistent with the best interests of our business. In addition, if third parties who license patents to us fail to maintain such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated.

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

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensors' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued that protect our technology or products or that 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 or patent inventions. Assuming the other requirements for patentability are met, the first to file a patent application is entitled to the patent invention Act enacted in 2011, the United States moved to this first to file system in 2013 from the previous system under which the first to make the claimed invention was entitled to the patent rights or 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

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

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

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

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

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our products and product candidates and use our proprietary technologies without infringing the enforceable proprietary rights of third parties. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference or derivation proceedings before the U.S. Patent and Trademark Office. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on

commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business.

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

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

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

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

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

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

## We may not be able to obtain, maintain or protect proprietary rights necessary for the continued development and commercialization of our products, product candidates and research technologies, including as a result of challenges from companies who seek to sell generic versions of ONIVYDE after expiration of our orphan drug exclusivity but prior to our ONIVYDE patent expiration.

Our commercial success depends in large part on obtaining and maintaining U.S. and foreign patent protection for our products, our product candidates and our research technologies and successfully enforcing and defending these patents against third-party challenges, including with respect to generic challenges. The validity of our patents in one or more jurisdictions may be challenged by third parties, resulting in our patents being deemed invalid, unenforceable or narrowed in scope, which could compromise the scope or duration of our exclusive rights in the relevant product, product candidate or technology. For example, the validity of a U.S. patent can be challenged in the U.S. Patent and Trademark Office (e.g., through an Inter Partes Review and/or Post Grant Review Proceeding) and/or in U.S. federal district court.

In addition, our patents on ONIVYDE may also be challenged in a federal court in connection with a third party's ANDA or a Section 505(b)(2) NDA seeking FDA approval to market a generic version of ONIVYDE, resulting in a patent challenge to one or more patents listed in the Orange Book for ONIVYDE. This patent challenge can result in one or more of those Orange Book patents for ONIVYDE being deemed uninfringed, invalid, unenforceable and/or narrowed in scope, which could compromise the scope or duration of our exclusive rights in the relevant product. An ANDA or Section 505(b)(2) NDA can be filed at any time after FDA approval of ONIVYDE. Other challenges to a patent may be mounted without regard to the date of an FDA approval.

Our patents as issued or as subsequently limited by any litigation might not contain claims that are sufficiently broad to prevent others from circumventing our patent protection and utilizing our technologies. For instance, the issued patents relating to ONIVYDE and our product candidates may be limited to a particular indication and/or composition and may not cover similar compositions that have similar clinical properties. Consequently, our competitors may independently develop competing products that do not infringe our patents or other intellectual property. Also, our pending patent applications may not issue, and we may not receive any additional patents. We cannot be sure that our patents and patent applications, including our own and those that we have rights to under licenses from third parties, will adequately protect our intellectual property for a number of reasons, including, among other things, the following: (i) the patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions; (ii) the actual protection afforded by a patent can vary from country to country and may depend upon the type of patent, the scope of its coverage and the availability of legal remedies in the country; (iii) the laws of foreign countries in which we market our products may afford little or no effective protection to our intellectual property, thereby easing our competitors' ability to compete with us in such countries; (iv) intellectual property laws and regulations and legal standards relating to the validity, scope and enforcement of patents covering pharmaceutical and biotechnological inventions are continually developing and changing, both in the United States and in other important markets outside the United States; (v) third parties may challenge, infringe, circumvent or seek to invalidate existing or future patents owned by or licensed to us; and (vi) the coverage claimed in a patent application can be significantly reduced before the patent is

#### **Risks Related to Regulatory Approval of Our Product Candidates**

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

Our product candidates, including our clinical stage product candidates, and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, import, export, sampling and marketing are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing the product candidate. On October 22, 2015, we received approval from the FDA and the Taiwan Food and Drug Administration to market ONIVYDE in combination with 5-FU and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy in the United States and Taiwan, respectively, and on October 18, 2016, Baxalta received approval from the European Commission to market ONIVYDE in combination with 5-FU and leucovorin for the treatment of metastatic adenocarcinoma of the pancreas in adult patients who have progressed following gemcitabine-based therapy. ONIVYDE is our first and only product candidate to receive regulatory approval. 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. Our 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 undesirabl

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 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 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 diagnostics. We will likely rely on such third parties to also obtain any required regulatory approval for and then commercially supply such diagnostics. All of our diagnostic candidates are in preclinical or clinical development. 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* 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 diagnostic candidates are at an early stage of development, we cannot yet know what the FDA will require for any of these tests. For several of our clinical stage product candidates, namely MM-121 and MM-141, we are attempting to develop an *in vitro* 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.

Based on the FDA's past practice with companion diagnostics, if we are successful in developing a diagnostic for any of our clinical stage product candidates, we would expect that FDA approval of an *in vitro* companion diagnostic, or 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 diagnostics.

For ONIVYDE, although we are also investigating possible *in vitro* diagnostics, we are currently investigating *in vivo* diagnostics in the form of imaging agents that may help identify patients more likely to benefit from the therapy. Imaging agents for diagnostic use would most likely be regulated as drugs by the FDA's Center for Drug Evaluation and Research and, as such, would be generally subject to the regulatory requirements applicable to other new drug candidates. Alternatively, several *in vivo* imaging agents have been regulated as medical devices by FDA's Center for Devices and Radiological Health. 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.

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 diagnostics, the commercial success of any of our product candidates that require a diagnostic will be tied to and dependent on the continued ability of such third parties to make the diagnostic commercially available on reasonable terms in the relevant geographies.

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

We have obtained orphan drug exclusivity in the United States for ONIVYDE for the treatment of pancreatic cancer and orphan medicinal product designation in the European Union for ONIVYDE for the treatment of pancreatic cancer. In addition, we have obtained orphan drug designation in the United States for MM-141 for the treatment of pancreatic cancer. 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 that indication 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 Reform Laws, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on their similarity to existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until twelve years after the original branded product was approved under a BLA. The BPCIA is complex and has yet to be fully 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 twelve 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 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 ONIVYDE, 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.

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

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

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

authorities in other countries or jurisdictions or by the FDA. We or our commercialization partners may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

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

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

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

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

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

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

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



For example, in March 2010, President Obama signed into law the Health Care Reform Laws, which were intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, provide benefits for patients within a coverage gap in the Medicare Part D prescription drug program, implement rules regarding prescription drug benefits under the health insurance exchanges and changes to the Medicare Drug Rebate program, expand the PHS' 340B drug pricing program, 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. These changes impact existing government healthcare programs and are resulting in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program. Further, the Health Care Reform Laws impose 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.

Some states have elected not to expand their Medicaid programs by raising the income limit to 133% of the federal poverty level, as is permitted under the Health Care Reform Laws. For each state that does not choose to expand its Medicaid program, there may be fewer insured patients overall, which could impact our sales, business and financial condition. Where Medicaid patients receive insurance coverage under any of the new options made available through the Health Care Reform Laws, the possibility exists that manufacturers may be required to pay Medicaid rebates on drugs used under these circumstances, a decision that could impact manufacturer revenues. In addition, the federal government has also announced delays in the implementation of key provisions of the Health Care Reform Laws, including the employer mandate. The implications of these delays for our sales, business and financial condition, if any, are not yet clear.

The Health Care Reform Laws appear likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

With the new U.S. presidential administration and Congress, there will likely be additional legislative changes, including the repeal and replacement of certain provisions of the Health Care Reform Laws. To that end, on January 20, 2017, the President issued an Executive Order Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal. The Executive Order declares that, pending repeal of the Health Care Reform Laws, it is imperative for the executive branch to ensure that the law is being efficiently implemented, take all actions consistent with law to minimize the unwarranted economic and regulatory burdens of the Health Care Reform Laws, and prepare to afford the states more flexibility and control to create a more free and open healthcare market. The Executive Order directs the Secretary of Health and Human Services and the heads of all other executive departments and agencies with authorities and responsibilities under the Health Care Reform Laws to exercise their authority and discretion to waive, defer, grant exemptions from or delay the implementation of any provision or requirement of the Health Care Reform Laws that would impose a fiscal burden on any state or a cost, fee, tax, penalty or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance or makers of medical devices, products or medications.

With respect to repeal of the Health Care Reform Laws and their replacement with new legislation, it is unclear when such legislation will be enacted, what it will provide and what impact it will have on the availability of healthcare and containing or lowering the costs of healthcare.

We expect that the Health Care Reform Laws, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products or to successfully commercialize our product candidates.

## 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 for ONIVYDE and any other product approved by the FDA, various U.S. federal and state healthcare programs require that we calculate and report certain pricing information to U.S. federal and state healthcare agencies. For example, we are 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. We are also required 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 involve subjective decisions. As a result, our price reporting calculations are 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 Laws 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.

We participate in and have certain price reporting obligations to the Medicaid Drug Rebate program and other governmental pricing programs, and we have obligations to report average sales price under the Medicare program. Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by governmental or regulatory agencies and the courts. For example, the Medicaid rebate amount is computed each quarter based on our submission to the CMS of our AMP and best price for the quarter. If we become aware that our reporting for prior quarters was incorrect, or has changed as a result of recalculation of the pricing data, we will be obligated to resubmit the corrected data for a period not to exceed twelve quarters from the quarter in which the data originally were due. Such restatements and recalculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. Price recalculations also may affect the price that we will be required to charge certain safety net providers under the PHS' 340B drug pricing program.

We are liable for errors associated with our submission of pricing data and for overcharging government payers. For example, in addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted false AMP or best price information to the government, we may be liable for civil monetary penalties in the amount of \$100,000 per item of false information. Our failure to submit monthly/quarterly AMP and best price data on a timely basis could result in a civil monetary penalty of \$10,000 per day for each day the submission is late beyond the due date. In the event that CMS were to terminate our rebate agreement, no federal payments would be available under Medicaid or Medicare Part B for our products. In addition, if we overcharge the government in connection with our FSS contract or under any other government program, we will be required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges could result in allegations against us under the False Claims Act and other laws and regulations.

CMS and the Office of Inspector General of the U.S. Department of Health and Human Services have pursued manufacturers that were alleged to have failed to report these data to the government in a timely manner. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect.

If we overcharge the government in connection with our FSS contract or the Tricare retail pharmacy program, whether due to a misstated FCP or otherwise, we would be required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations.

Unexpected refunds to the federal government, and responding to a government investigation or enforcement action, would be expensive and timeconsuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

#### **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 for 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 multi-year 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 ONIVYDE and any other products for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute ONIVYDE and any other products for which we obtain marketing approval. Restrictions under applicable federal, state and foreign healthcare laws and regulations include the following:

- the federal healthcare anti-kickback statute prohibits, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward the purchasing, leasing, ordering or arranging for the purchase, order or recommendation of any item or service reimbursable under Medicare, Medicaid, or other federal healthcare programs. 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, and violations 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;
- the federal False Claims Act prohibits 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. Government enforcement agencies and private whistleblowers have initiated investigations or brought private lawsuits against pharmaceutical companies for a variety of allegedly improper promotional or marketing activities, such as allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates; allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; or engaging in promotion for "off-label" uses. Additionally, the Health Care Reform Laws amended the federal False Claims Act such that a violation of the federal anti-kickback statute can serve as a basis for liability under the False Claims Act;
- HIPAA makes it a crime to knowingly and willfully execute or attempt to execute 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, among other things, 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 Laws requires manufacturers of drugs, devices, biologics and medical supplies reimbursable under Medicare and Medicaid to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals, as well as physician ownership and investment interests, and provides for public reporting of the data reported by manufacturers;
- 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. In addition, 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. Other states require pharmaceutical manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures, or prohibit certain marketing-related activities including the provision of gifts, meals or other items to certain healthcare providers.



Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we do business 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. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could also harm our financial condition. Responding to government investigations or whistleblower lawsuits, defending any claims raised, and any resulting fines, damages, penalties, settlement payments or administrative actions, as well as any related actions brought by stockholders or other third parties, could have a material impact on our reputation, business and financial condition and divert the attention of our management from operating our business.

### 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 and will be subject to extensive regulation by federal, state and other authorities within the United States and numerous entities outside of the United States. While we have implemented 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 ONIVYDE or other 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 Data Protection and Cybersecurity**

### Our failure to comply with data protection laws and regulations could lead to government enforcement actions, private litigation and/or adverse publicity and could negatively affect our operating results and business.

We are subject to data protection laws and regulations that address privacy and data security. The legislative and regulatory landscape for data protection continues to evolve, and in recent years there has been an increasing focus on privacy and data security issues. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws and federal and state consumer protection laws govern the collection, use, disclosure and protection of health-related and other personal information. Failure to comply with data protection laws and regulations could result in government enforcement actions, which could include civil or criminal penalties, private litigation and/or adverse publicity and could negatively affect our operating results and business. In addition, we may obtain health information from third parties (e.g., healthcare providers who prescribe our products) that are subject to privacy and security requirements under HIPAA. We could be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information in a manner that is not authorized or permitted.

#### Significant disruptions of information technology systems or security breaches could adversely affect our business.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including, among other things, trade secrets or other intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party vendors who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of third-party vendors with whom we contract, and the large amounts of confidential information stored on those systems, make such systems vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third-party vendors, and/or business partners, or from cyber-attacks by malicious third parties. Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information.

Significant disruptions of our information technology systems, or those of our third-party vendors, or security breaches could adversely affect our business operations and/or result in the loss, misappropriation and/or unauthorized access, use or disclosure of, or



the prevention of access to, confidential information, including, among other things, trade secrets or other intellectual property, proprietary business information and personal information, and could result in financial, legal, business and reputational harm to us. For example, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients or employees, could harm our reputation, require us to comply with federal and/or state breach notification laws and foreign law equivalents, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. Security breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. While we have implemented security measures to protect our information technology systems and infrastructure, there can be no assurance that such measures will prevent service interruptions or security breaches that could adversely affect our business.

### **Risks Related to Employee Matters and Managing Growth**

#### Our future success depends on our ability to retain our key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the 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.

### Our corporate restructuring and the associated headcount reductions announced in October 2016 and January 2017 may not result in anticipated savings, could result in total costs and expenses and attrition that are greater than expected and could disrupt our business.

On October 3, 2016, we announced a 22% reduction in headcount as part of a major corporate restructuring with the objective of prioritizing our research and development on a focused set of systems biology-derived oncology products and strengthening our financial runway. Additionally, on January 9, 2017, we announced that we will further reduce headcount in connection with the asset sale to Ipsen and the completion of our strategic pipeline review. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition would be adversely affected. We also cannot guarantee that we will not have to undertake additional headcount reductions or restructuring activities in the future. Furthermore, our restructuring plan may be disruptive to our operations. For example, our headcount reductions could yield unanticipated consequences, such as attrition beyond planned staff reductions, or increase difficulties in our day-to-day operations. Our headcount reductions could also harm our ability to attract and retain qualified management, scientific, clinical, manufacturing and sales and marketing personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully developing and commercializing our product candidates in the future.

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

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

- the difficulty of integrating or separating the operations and personnel of the acquired companies or divested product;
- 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, acquisition or divestiture;



- the maintenance of acceptable standards, controls, procedures and policies; and
- the impairment of relationships with employees as a result of any integration or separation of management and other personnel.

If we are not successful in completing acquisitions or divestitures 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 or divestitures. 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, would significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could allow, delay or prevent an acquisition of our company on terms that other stockholders may desire.

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

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

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

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

Further, the repurchase right under the convertible 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:

- our ability to successfully commercialize ONIVYDE in combination with 5-FU and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following genetiabine-based therapy through the time at which the asset sale to Ipsen is consummated or in the event the asset sale is not consummated;
- 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;
- activism by any single large stockholder or combination of stockholders;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

### The indenture governing our 11.50% senior secured notes due 2022 imposes significant operating and financial restrictions on us and our subsidiaries that may prevent us from pursuing certain business opportunities and restrict our ability to operate our business.

On December 22, 2015, we issued \$175.0 million in aggregate principal amount of 11.50% senior secured notes due 2022. The indenture governing the 2022 notes contains covenants that restrict our and our subsidiaries' ability to take various actions, including, among other things:

- the incurrence of debt;
- the issuance of our preferred stock;
- the payment of dividends, the repurchase of shares and making certain other restricted payments;
- the prepayment, redemption or repurchase of subordinated debt;
- the sale, lease or transfer of property and assets;
- engaging in transactions with affiliates; and
- the making of investments other than those permitted by the indenture.

The indenture specifies a number of events of default, some of which are subject to applicable grace or cure periods, including, among other things, non-payment defaults, covenant defaults, cross-defaults to other material indebtedness, bankruptcy and insolvency defaults, and non-payment of material judgments.

Our ability to comply with these covenants will likely be affected by many factors, including events beyond our control, and we may not satisfy those requirements. Our failure to comply with our obligations could result in an event of default under our other indebtedness and the acceleration of our other indebtedness, in whole or in part, could result in an event of default under the indenture governing the 2022 notes.



The restrictions contained in the indenture governing the 2022 notes could also limit our ability to plan for or react to market conditions, meet capital needs or otherwise restrict our activities or business plans and adversely affect our ability to finance our operations, enter into acquisitions or to engage in other business activities that would be in our interest.

In connection with the closing of the asset sale to Ipsen, we intend to redeem all \$175.0 million aggregate principal amount of outstanding 2022 notes at the then-applicable redemption price, plus accrued and unpaid interest to the date of redemption.

### Because we do not anticipate paying regular 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. Although we plan to pay the special cash dividend following the asset sale to Ipsen, subject to approval by our board of directors, we do not currently intend to pay any regular cash dividends in the foreseeable future. In addition, the terms of our existing debt agreements limit our ability to pay dividends, and the terms of any future debt agreements may preclude us from paying dividends. As a result, with the exception of the anticipated special cash dividend, capital appreciation of our common stock, if any, 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, or upon conversion of our 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 we may issue shares of our common stock upon conversion of our outstanding convertible notes. The exercise of these options or the issuance of shares of our common stock upon conversion of our outstanding convertible notes and the subsequent sale of the underlying common stock could cause a further decline in our stock price. For instance, in April 2016, we issued an aggregate of 12,367,663 shares of our common stock to certain holders of our convertible notes who had agreed to convert an aggregate of \$64.2 million of convertible notes. 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 167,000 square feet of research, manufacturing and office space located at One Kendall Square in Cambridge, Massachusetts. The lease on our principal facilities expires in June 2019. We retain an option to renew the lease on all of our current space for an additional period of five years.

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 expires in December 2017.

#### **Item 3. Legal Proceedings**

None.

#### Item 4. Mine Safety Disclosures

Not applicable.

### 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, 2015 and 2016.

	High		Low	
Year Ended December 31, 2015				
First Quarter	\$	12.50	\$	8.37
Second Quarter	\$	13.84	\$	10.50
Third Quarter	\$	12.59	\$	7.57
Fourth Quarter	\$	10.85	\$	7.21
Year Ended December 31, 2016				
First Quarter	\$	8.91	\$	5.02
Second Quarter	\$	9.02	\$	5.28
Third Quarter	\$	6.62	\$	4.39
Fourth Quarter	\$	6.79	\$	4.03
Fourth Quarter	\$	6.79	\$	4.03

### Holders

As of January 31, 2017, there were approximately 149 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 regular cash dividends on our common stock in the foreseeable future. However, following the closing of the transaction described in the asset sale agreement with Ipsen, we expect to declare and pay a special dividend of at least \$200.0 million to our stockholders, subject to the approval of our board of directors and assuming that we do not use any of the proceeds from the asset sale to repay the convertible notes.

In addition, the terms of our existing debt agreements limit our ability to pay dividends. See Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Borrowings for more information regarding our debt agreements.

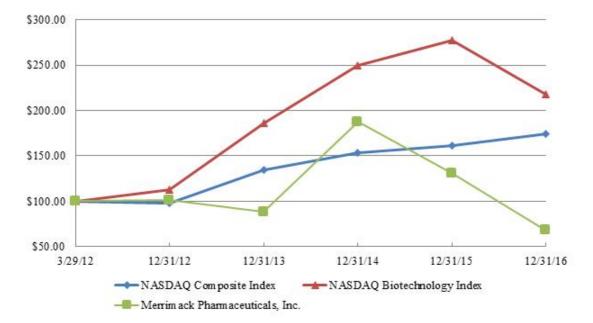
#### **Corporate Performance Graph**

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 Exchange Act, nor shall such information be incorporated by reference into any future filing under the Exchange Act or Securities Act of 1933, as amended, or the 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, 2016. 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.



## **Recent Sales of Unregistered Securities**

On December 22, 2015, we closed a private placement of \$175.0 million aggregate principal amount of 2022 notes and entered into an indenture with U.S. Bank National Association, as trustee and collateral agent, governing the 2022 notes. The 2022 notes were sold directly only to qualified institutional buyers within the meaning of Rule 144A under the Securities Act in reliance upon the exemption from the registration requirements of the Securities Act pursuant to Section 4(a)(2) thereof relative to transactions by an issuer not involving any public offering. No underwriters were involved in the sales of the 2022 notes. All purchasers of the 2022 notes represented to us in connection with their purchase that they were qualified institutional buyers and were acquiring the shares for their own account for investment purposes and not with a view to resale or distribution thereof in contravention of the Securities Act and that they were capable of evaluating the merits and risks of purchasing the 2022 notes and could bear the economic risks of investing in the 2022 notes for an indefinite period of time, including the complete loss of their investment. The purchasers received written disclosures that the 2022 notes had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration requirements. We received net proceeds from the private placement of approximately \$168.5 million, after deducting private placement and offering expenses payable by us.

## 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 operations data for the years ended December 31, 2016, 2015 and 2014 and the consolidated balance sheet data as of December 31, 2016 and 2015 from our audited consolidated financial statements included in this Annual Report on Form 10-K. We have derived the consolidated statements of operations data for the years ended December 31, 2013 and 2012 and the consolidated balance sheet data as of December 31, 2016 and 2015 from our audited consolidated financial statements included in this Annual Report on Form 10-K. We have derived the consolidated statements of operations data for the years ended December 31, 2013 and 2012 and the consolidated balance sheet data as of December 31, 2014, 2013 and 2012 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)		2016	_	2015		2014		2013		2012
<b>Consolidated Statements of Operations Data</b>										
Revenues:										
Product revenues, net	\$	53,064	\$	4,328	\$	—	\$		\$	
License and collaboration revenues		87,119		84,930		102,756		47,786		48,921
Other revenues		4,090								
Total revenues		144,273		89,258		102,756		47,786		48,921
Costs and expenses:										
Cost of revenues		6,912		46				—		
Research and development expenses		160,917		160,988		138,495		147,139		125,858
Selling, general and administrative expenses		80,729		57,795		30,517		21,187		15,805
Restructuring expenses		5,856								
Total costs and expenses		254,414		218,829		169,012		168,326		141,663
Loss from operations		(110,141)		(129,571)		(66,256)		(120,540)		(92,742)
Other income and expenses:										
Interest income		276		99		114		166		184
Interest expense (1)		(43,645)		(19,232)		(18,230)		(10,938)		(553)
Other (expense) income, net		(8)		917		813		627		1,357
Net loss		(153,518)		(147,787)		(83,559)		(130,685)		(91,754)
Net (loss) income attributable to non-controlling interest		(1,778)		170		(268)		240		(477)
Net loss attributable to Merrimack Pharmaceuticals, Inc.	\$	(151,740)	\$	(147,957)	\$	(83,291)	\$	(130,925)	\$	(91,277)
Net loss per share available to common stockholders—basic and diluted (2)	\$	(1.21)	\$	(1.33)	\$	(0.80)	\$	(1.32)	\$	(1.28)
Weighted-average common shares used in computing net loss per share available to common stockholders—basic and diluted (3)		125,334		111,356		104,410		98,919		72,831

(1) In July 2013, we issued \$125.0 million aggregate principal amount of 4.50% convertible notes due 2020 in an underwritten public offering. In November and December 2012, we borrowed an aggregate principal amount of \$40.0 million under a loan agreement with Hercules Technology Growth Capital, Inc., or Hercules. These loans with Hercules were repaid in full in December 2015. In December 2015, we issued \$175.0 million aggregate principal amount of 11.50% senior secured notes due 2022 through a private placement. On April 13, 2016, we entered into separate, privately-negotiated conversion agreements with certain holders of the convertible notes. The execution of the conversion agreements resulted in the conversion of an aggregate principal amount of \$64.2 million of convertible notes. In addition, we recognized a one-time \$14.6 million non-cash loss on extinguishment during the second quarter of 2016. This loss on extinguishment was recorded as a component of interest expense. Transaction costs incurred with third parties directly related to the conversion were allocated to the liability and equity components, resulting in additional interest expense recognized of \$0.2 million during the second quarter of 2016.

(2) The numerator in the calculation of net loss per share available to common stockholders—basic and diluted for the year ended December 31, 2012 includes unaccreted dividends on our convertible preferred stock. 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.

(3) 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 5.8 million shares of common stock. In July 2015, we entered into an agreement to sell shares of our common stock through an "at the market offering" program. We concluded sales under this program in September 2015, having sold approximately 3.8 million shares of common stock.

			Dece	ember 31,		
(in thousands)	 2016	 2015		2014	 2013	 2012 (1)
Consolidated Balance Sheet Data						
Cash and cash equivalents	\$ 21,524	\$ 185,606	\$	35,688	\$ 65,086	\$ 37,714
Marketable securities				88,340	90,116	72,238
Total assets	81,483	234,880		158,506	192,233	148,949
Loans payable (2)				39,550	39,082	39,830
Derivative liability				_		196
4.50% convertible notes (3)	46,950	88,495		80,452	72,409	
11.50% senior secured notes (4)	169,911	169,160		_		—
Deferred revenues	61,899	101,334		94,957	75,475	80,464
Total liabilities	334,142	418,569		260,577	235,361	155,369
Non-controlling interest	(1,539)	239		69	337	97
Total stockholders' deficit	(251,120)	(183,928)		(102,140)	(43,465)	(6,517)

- (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 November and December 2012, we borrowed an aggregate principal amount of \$40.0 million under a loan agreement with Hercules. These loans were repaid in full in December 2015.
- (3) In July 2013, we sold an aggregate of 5.8 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 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. On April 13, 2016, we entered into separate, privately-negotiated conversion agreements with certain holders of the convertible notes. The execution of the conversion agreements resulted in the conversion of an aggregate principal amount of \$64.2 million of convertible notes and the issuance of 12,367,663 shares of our common stock.
- (4) In December 2015, we closed a private placement of \$175.0 million aggregate principal amount of 11.50% senior secured notes due 2022 and received net proceeds of approximately \$168.5 million, after deducting private placement and offering expenses payable by us.

## 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 commercializing innovative medicines consisting of novel therapeutics paired with 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. We view cancer as a complex engineering challenge. Through systems biology, which brings together the fields of biology, computing and engineering, we aim to decrease uncertainty in drug development and clinical validation, and move discovery efforts beyond trial and error. Our mission is to employ these insights to provide patients, physicians and the healthcare system with the medicines, tools and information to deliver integrated healthcare solutions that improve both the quality of outcomes and the efficiency of care.

We have one marketed therapeutic oncology product and multiple targeted therapeutic oncology candidates in clinical development. Our most advanced program is our therapeutic ONIVYDE<sup>®</sup>, which we market in the United States. On October 22, 2015, the U.S. Food and Drug Administration, or FDA, and the Taiwan Food and Drug Administration approved the use of ONIVYDE in combination with fluorouracil, or 5-FU, and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy in the United States and Taiwan, respectively. In addition, on October 18, 2016, the European Commission granted marketing authorization to our collaboration partner Baxalta for ONIVYDE

in combination with 5-FU and leucovorin for the treatment of adult patients with metastatic adenocarcinoma of the pancreas who have progressed following gencitabine-based therapy.

In addition to ONIVYDE and our product candidates in clinical development, we have multiple product candidates in preclinical development. We have tailored ONIVYDE and our other product candidates to target specific disease mechanisms that our research suggests are common across many solid tumor types. We believe that ONIVYDE and our other product candidates have the potential to address major unmet medical needs.

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 and initiating the commercial launch of ONIVYDE and providing general and administrative support for these operations. We began to generate revenue from product sales for the first time in the fourth quarter of 2015 and, to date, have financed our operations primarily through private placements of our convertible preferred stock, collaborations, public offerings of our securities, secured debt financings and sales of ONIVYDE.

On April 13, 2016, we entered into separate, privately-negotiated conversion agreements, or the conversion agreements, with certain holders of our 4.50% convertible notes due 2020, or the convertible notes. The execution of the conversion agreements resulted in the conversion of an aggregate principal amount of \$64.2 million of convertible notes and the issuance of 12,367,663 shares of our common stock. See Note 12, "Borrowings," in the accompanying notes to the consolidated financial statements for additional information.

On October 3, 2016, we announced a 22% reduction in headcount as part of a major corporate restructuring with the objective of prioritizing our research and development on a focused set of systems biology-derived oncology products and strengthening our financial runway. On this same date, we also announced the resignation of Robert Mulroy, our former President and Chief Executive Officer, or CEO. See Note 13, "Restructuring Activities," in the accompanying notes to the consolidated financial statements for additional information. In connection with this corporate restructuring, we also initiated a strategic review of our pipeline, including a clinical and financial prioritization of our programs. This strategic review was concluded in January 2017, as described in more detail below.

On November 8, 2016, we entered into a Loan and Security Agreement, or the credit agreement, with BioPharma Credit Investments IV Sub, LP, or Pharmakon, pursuant to which a credit facility of an aggregate principal amount of at least \$15.0 million and up to \$25.0 million is available to us. The credit facility was originally available at any time through March 15, 2017 upon our request and upon compliance with certain funding conditions. On February 23, 2017, we entered into an amendment to the credit agreement whereby the availability of the credit facility was extended through April 27, 2017. In connection with any borrowings that occur under the credit agreement, we will grant Pharmakon a security interest in all inventory and accounts receivable. No amounts have yet been borrowed under the credit agreement.

On January 7, 2017, we entered into an Asset Purchase and Sale Agreement, or the asset sale agreement, with Ipsen S.A., or Ipsen, pursuant to which Ipsen will acquire our right, title and interest in the non-cash assets, equipment, inventory, contracts and intellectual property primarily related to or used in our business operations and activities involving or relating to developing, manufacturing and commercializing ONIVYDE and MM-436, or the commercial business. Ipsen will not acquire our rights to \$33.0 million in net milestone payments that may become payable pursuant to our license and collaboration agreement with Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA, which we refer to as the Baxalta agreement, among other excluded assets. Pursuant to the asset sale agreement, Ipsen will pay us \$575.0 million in cash (subject to a working capital adjustment as provided in the asset sale agreement) and will assume certain related liabilities. Following the closing of the asset sale, we may be entitled to up to \$450.0 million of additional payments based on achievement by or on behalf of Ipsen of certain milestone events related to FDA approval of ONIVYDE for certain indications as described in the asset sale agreement.

The consummation of the transaction described in the asset sale agreement is subject to customary closing conditions, including, among others: (i) the receipt of the approval of our stockholders; (ii) the expiration or termination of the required waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, which waiting periods expired on February 22, 2017; (iii) the absence of a breach of our representations and warranties that would cause a material adverse effect on the commercial business; (iv) the absence of a business material adverse effect; and (v) the performance of certain covenants in all material respects.

The asset sale agreement contains certain termination rights for us and Ipsen. Upon termination of the asset sale agreement under specified circumstances, we would be required to pay Ipsen a termination fee of \$25.0 million, including if the asset sale agreement is terminated in connection with us accepting a superior proposal or because our board of directors has changed its recommendation of the sale to our stockholders. The termination fee will also be payable if the asset sale agreement is terminated because our stockholders did not vote to adopt the asset sale agreement and, prior to such termination, a proposal to acquire at least

50% of our consolidated assets with respect to the commercial business or at least 50% of our voting securities has been publicly disclosed and we enter into a definitive agreement with respect to such proposal within 12 months after such termination, which is subsequently consummated. In addition, we would be required to reimburse Ipsen for up to \$3.0 million of its out-of-pocket expenses incurred in connection with the transaction and the asset sale agreement if the asset sale agreement is terminated because our stockholders do not vote to approve it.

In addition to the foregoing termination rights, and subject to certain limitations, we or Ipsen may terminate the asset sale agreement if the asset sale is not consummated by June 30, 2017.

Ipsen has also agreed to sublease 68,409 square feet of our manufacturing facility at the closing of the asset sale. In addition, at the closing of the asset sale, we and Ipsen will enter into an intellectual property license agreement pursuant to which Ipsen will grant us an exclusive license with respect to the portion of the transferred patents relating to certain liposomal technology and a non-exclusive license to the remainder of the transferred patents, in both cases for use outside of the field in which the commercial business will operate. In turn, we will grant Ipsen a non-exclusive license with respect to the remaining patents owned by us at the closing for use in the field in which the commercial business will operate.

On January 9, 2017, we announced that we will further reduce headcount in connection with the asset sale and the completion of our strategic pipeline review. Upon the closing of the asset sale, we will focus our development efforts on our MM-121, MM-141 and MM-310 programs. After the headcount reduction, we expect to have approximately 80 employees.

Our board of directors committed to this course of action on January 6, 2017, subject to the closing of the asset sale, which is contingent upon the closing conditions described above. The reduction in personnel is expected to be complete upon the later of the closing of the asset sale and March 10, 2017. See Note 23, "Subsequent Events," in the accompanying notes to the consolidated financial statements for additional information.

On January 16, 2017, we announced the hiring of Richard Peters, M.D., Ph.D., as our new CEO, effective as of February 6, 2017. Dr. Peters was also elected as a member of our board of directors.

We entered into an employment agreement with Dr. Peters commencing on February 6, 2017 whereby Dr. Peters will receive an annual base salary of \$700,000 and is eligible for an annual bonus of up to 65% of his base salary. Dr. Peters also received a one-time signing bonus of \$900,000. Subject to the further approval of our board of directors, we will also grant Dr. Peters an option to purchase a number of shares of our common stock equal to the lesser of (i) such number of shares that has a target grant date fair value of \$3.5 million and (ii) 2.0 million shares, with an exercise price per share equal to the fair market value of our common stock on the date of grant. The option will vest over four years at the rate of 25% on February 6, 2018 and the remainder in equal quarterly installments over the following three years.

As of December 31, 2016, we had unrestricted cash and cash equivalents of \$21.5 million. Upon stockholder approval and the closing of the asset sale with Ipsen, we will receive a \$575.0 million upfront cash payment from Ipsen (subject to a working capital adjustment as provided in the asset sale agreement). We expect to use these proceeds to declare and pay a special cash dividend of at least \$200.0 million to stockholders and redeem the \$175.0 million outstanding aggregate principal amount of 11.50% senior secured notes due 2022, or the 2022 notes, which will require an additional make-whole premium payment of approximately \$20.1 million. Additionally, if the asset sale is consummated and certain milestones under the Baxalta agreement are met, we currently expect to receive up to an aggregate of \$33.0 million in net milestone payments in 2017. We believe these potential net cash inflows, along with the completion of the headcount reduction and refocused research and development efforts that were announced in January 2017, will provide financial resources sufficient to fund our operations into the second half of 2019. If we are unable to obtain stockholder approval of the asset sale and the transaction with Ipsen is not consummated, or if we are unable to obtain other adequate financing or engage in another strategic transaction on acceptable terms and when needed, we will be required to implement further cost reduction strategies.

As the consummation of the asset sale with Ipsen is contingent upon approval by our stockholders as well as other customary closing conditions, we have concluded that there is substantial doubt as to our ability to continue as a going concern within one year after the filing date of this Annual Report on Form 10-K. See Note 22, "Going Concern," in the accompanying notes to the consolidated financial statements for additional information on our evaluation.

We have never been profitable and, as of December 31, 2016, we had an accumulated deficit of \$954.8 million. Our net loss was \$153.5 million for the year ended December 31, 2016, \$147.8 million for the year ended December 31, 2015 and \$83.6 million for the year ended December 31, 2014. We expect to continue to incur significant expenses and operating losses for at least the next several years. We expect to continue to incur significant research and development expenses 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 have entered or we expect will be entering late stage clinical development. In addition, in connection with supporting commercial sales of ONIVYDE through the time at which the asset sale is consummated, if ever, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. Until such time, if ever, as we can generate substantial license and collaboration or product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, licensing arrangements and other marketing and distribution arrangements. We also could engage in discussions with third parties regarding partnerships, joint ventures, combinations or divestitures of one or more of our businesses as we seek to further the development of our research programs, improve our cash position and maximize stockholder value. There can be no assurance as to the timing, terms or consummation of any financing, collaboration, licensing arrangement or other marketing and distribution arrangement, partnership, joint venture, combination or divestiture. We may be unable to raise capital when needed or on attractive terms, which would force us to delay, limit, reduce or terminate our research and development programs or commercialization efforts. We will need to generate significant revenues to achieve profitability, and we may never do so.

## Strategic Partnerships, Licenses and Collaborations

#### Baxalta

On September 23, 2014, we entered into the Baxalta agreement for the development and commercialization of ONIVYDE outside of the United States and Taiwan, or the licensed territory. In connection with Baxter International Inc.'s separation of the Baxalta business, the Baxalta agreement was assigned to Baxalta during the second quarter of 2015. As part of the Baxalta agreement, we granted Baxalta an exclusive, royalty-bearing right and license under our patent rights and know-how to develop and commercialize ONIVYDE in the licensed territory. Baxalta is responsible for using commercially reasonable efforts to develop, obtain regulatory approvals for and, following regulatory approval, commercialize ONIVYDE in the licensed territory. A joint steering committee comprised of an equal number of representatives from each of Baxalta and us is responsible for approving changes to the global development plan for ONIVYDE, including all budgets, and overseeing the parties' development and commercialization activities with respect to ONIVYDE. Unless otherwise agreed, we will be responsible for conducting all clinical trials contemplated by the global development plan for ONIVYDE and manufacturing all clinical material needed for such trials. Baxalta also has the option to manufacture ONIVYDE, in which case we will perform a technology transfer of our manufacturing process to Baxalta.

Under the terms of the Baxalta agreement, we received a \$100.0 million nonrefundable upfront cash payment in September 2014. In addition, we are eligible to receive from Baxalta (i) up to an aggregate of \$100.0 million upon the achievement of specified research and development milestones, of which we have received \$62.5 million from Baxalta through December 31, 2016, (ii) up to an aggregate of \$520.0 million upon the achievement of specified regulatory milestones, of which we have received \$60.0 million from Baxalta through December 31, 2016, and (iii) up to an aggregate of \$250.0 million upon the achievement of specified sales milestones. Under the terms of the Baxalta agreement, we will bear up to the first \$98.8 million of costs related to the development of ONIVYDE for pancreatic cancer patients who have not previously received gemcitabine-based therapy; however, we expect most of these costs to be offset by payments received upon the achievement of clinical trial-related milestones. We will share equally with Baxalta all other clinical trial costs contemplated by the global development plan. We are also entitled to tiered, escalating royalties ranging from sub-teen double digits to low twenties percentages of net sales of ONIVYDE in the licensed territory.

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

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

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

We have determined that the collaboration represents a services agreement and, as such, have estimated the level of effort expected to be completed as a result of providing the identified deliverables. We will recognize revenue from the nonrefundable upfront payment, forecasted non-substantive milestone payments and estimated payments related to discovery, research, development



and technology transfer services based on proportional performance as effort is completed over the expected services period, which is estimated to be substantially complete by June 30, 2022. We will periodically review and, if necessary, revise the estimated service period related to our collaboration with Baxalta. As of December 31, 2016, we have achieved \$62.5 million of the \$90.0 million of forecasted non-substantive milestones that are included in our proportional performance revenue recognition model and \$60.0 million of the \$530.0 million of substantive milestones that are included in the Baxalta agreement.

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.

From the inception of the Baxalta agreement through December 31, 2016, we have achieved the following substantive and non-substantive milestones:

- In July 2015, the European Medicines Agency, or EMA, accepted for review a Marketing Authorization Application, or MAA, filed by Baxalta
  for ONIVYDE. As a result of this acceptance, we recognized \$20.0 million of license and collaboration revenue related to a substantive
  milestone payment owed from Baxalta.
- In August 2015, we achieved a \$15.0 million milestone related to the submission of the protocol for our Phase 2 clinical trial of ONIVYDE in front-line metastatic pancreatic cancer. This milestone is a non-substantive milestone, and revenue related to the achievement of this milestone will be recognized through the proportional performance revenue recognition model.
- In October 2015, we achieved a \$47.5 million milestone related to the enrollment of the first patient in a Phase 2 clinical trial of ONIVYDE in front-line pancreatic cancer. This milestone is a non-substantive milestone, and revenue related to the achievement of this milestone will be recognized through the proportional performance revenue recognition model.
- In June 2016, the South Korean Ministry of Food and Drug Safety, or MFDS, accepted for review a new drug application filed by Baxalta for ONIVYDE. As a result of this acceptance, we recognized \$10.0 million of license and collaboration revenue related to a substantive milestone payment owed from Baxalta.
- In October 2016, the European Commission granted marketing authorization to Baxalta for ONIVYDE in combination with 5-FU and leucovorin for the treatment of adult patients with metastatic adenocarcinoma of the pancreas who have progressed following gemcitabine-based therapy. As a result of this approval and the first commercial sale of ONIVYDE made by Baxalta during the fourth quarter of 2016, we recognized \$30.0 million of license and collaboration revenue related to a substantive milestone payment owed from Baxalta.

During the years ended December 31, 2016, 2015 and 2014, we recognized license and collaboration revenues based on the following components of the Baxalta agreement:

	 Years Ended December 31,						
(in thousands)	2016		2015		2014		
Proportional performance revenue recognition model	\$ 47,119	\$	64,930	\$	10,460		
Substantive milestones	40,000		20,000				
Total	\$ 87,119	\$	84,930	\$	10,460		

During the year ended December 31, 2016, we also recognized royalty revenues of \$0.2 million related to the Baxalta agreement.

As of December 31, 2016 and 2015, we maintained the following assets and liabilities related to the Baxalta agreement:

	 December			
(in thousands)	2016		2015	
Accounts receivable, billed	\$ 860	\$	1,336	
Accounts receivable, unbilled	581		626	
Deferred revenues	56,779		97,365	

Of the \$56.8 million of deferred revenue related to the Baxalta agreement as of December 31, 2016, \$36.2 million is classified as current in the consolidated balance sheets based upon our estimate of revenue that will be recognized under the proportional performance revenue recognition model as a result of effort expected to be completed within the next twelve months.

In February 2016, we entered into a commercial supply agreement with Baxalta, or the Baxalta supply agreement, pursuant to which we supply ONIVYDE to Baxalta and, at Baxalta's option, manage fill and finish activities conducted by a third-party contract manufacturer for Baxalta.

Upon consummation of the asset sale, both the Baxalta agreement and the Baxalta supply agreement will be assigned to Ipsen.

## 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. In June 2014, we agreed with Sanofi to terminate the Sanofi agreement effective December 17, 2014. In connection with the agreement to terminate the Sanofi agreement, among other things, Sanofi transferred ownership of the investigational new drug application for MM-121 back to us in July 2014, and we waived Sanofi's obligation to reimburse us for MM-121 development costs incurred after the effective termination date. As a result of the termination of the Sanofi agreement, we are not entitled to receive any additional fees, milestone payments or reimbursements from the collaboration.

We 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 us for internal time at a designated full-time equivalent rate per year and reimbursed us for direct costs and services related to the development and manufacturing of MM-121.

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

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

As a result of the agreement to terminate the Sanofi agreement, the development period was revised to end as of December 17, 2014 and the balance of deferred revenue remaining as of April 1, 2014 was recognized prospectively on a straight-line basis over the remaining development period, ending on December 17, 2014.

We recognized no revenue under the Sanofi agreement during the years ended December 31, 2016 or 2015. During the year ended December 31, 2014, we recognized revenue based on the following components of the Sanofi agreement:

(in thousands)	Year Ended E	December 31, 2014
Upfront payment	\$	39,306
Milestone payment		16,377
Development services		18,904
Manufacturing services and other		17,709
Total	\$	92,296

We 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, we 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 receiving budget approval for these overruns.

We maintained no assets or liabilities related to the Sanofi agreement as of either December 31, 2016 or 2015.



## 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 hydrochloride (HCl) liposome injection, or the initial product, to Actavis. The Actavis agreement was subsequently amended in January 2015 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. We will manufacture and supply the initial product to Actavis in bulk form at an agreed upon unit price, and Actavis is responsible for all costs related to finished product processing and global commercialization. Pursuant to the Actavis agreement, we have also agreed to develop additional products for Actavis in the future, the identities of which will be mutually agreed upon. We are eligible to receive up to \$15.1 million in milestone and development payments, as well as additional reimbursement for specific activities performed by us at the request of Actavis. We will also receive a mid-twenties percentage of net profits on global sales of the initial product, which triggered the payment obligation of \$1.1 million of milestones from Actavis to us. As of December 31, 2016, we had received \$4.9 million in total milestone and development payments and reimbursement for specific activities from Actavis.

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

We applied revenue recognition guidance to determine whether the performance obligations under this collaboration, including the license, participation on steering committees, development services, and manufacturing and supply services, could be accounted for separately or as a single unit of accounting. We determined that these obligations represent a single unit of accounting and will recognize revenue as product is supplied to Actavis. Therefore, we have recorded \$5.1 million and \$4.0 million of total billed and billable milestones and development expenses related to the Actavis agreement as deferred revenue as of December 31, 2016 and 2015, respectively. We expect to recognize this revenue over the ten year period that begins after Actavis' first sale of applicable product under the Actavis agreement.

Upon consummation of the asset sale, the Actavis agreement will be assigned to Ipsen.

#### 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 systems biology approach to the research and development of regenerative medicines to repair the heart. On December 31, 2014, \$1.0 million of convertible notes and related accrued interest converted to shares of Silver Creek Series A preferred stock. During the year ended December 31, 2015, Silver Creek issued and sold a total of 1.6 million shares of its Series B preferred stock to investors at a price per share of \$1.35 and received net proceeds of \$2.1 million, after deducting issuance costs. During the year ended December 31, 2016, \$1.2 million of convertible notes and related accrued interest were converted to shares of Silver Creek sold 1.5 million additional shares of its Series C preferred stock. In addition, Silver Creek sold 1.5 million additional shares of its Series C preferred stock to investors at a price per share of \$1.50 and received net cash proceeds of \$2.1 million, after deducting issuance costs. In conjunction with this sale, Silver Creek also issued warrants to purchase 1.9 million shares of Silver Creek Series C preferred stock to the same new investors.

The warrants to purchase Silver Creek Series C preferred stock were classified as a current liability in accordance with Accounting Standards Codification, or ASC, 480, *Distinguishing Liabilities from Equity*, and initially measured at fair value. The fair value of the warrants was deducted from the total Silver Creek Series C preferred stock proceeds received by Silver Creek, and the remaining proceeds received were allocated to the Silver Creek Series C preferred stock, as outlined more fully in Note 6, "Fair Value of Financial Instruments," and Note 12, "Borrowings," in the accompanying notes to the consolidated financial statements. The fair value of the warrants was determined to be \$1.5 million as of December 31, 2016.

As of December 31, 2016 and 2015, we owned approximately 50% and 56%, respectively, of the outstanding voting 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 systems 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 ONIVYDE

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 ONIVYDE in Europe and certain countries in Asia. In May 2011, we entered into a new agreement with PharmaEngine, which we refer to as the PharmaEngine agreement, under which we reacquired all previously licensed rights for ONIVYDE, other than rights to commercialize ONIVYDE in Taiwan. As a result, we had the exclusive right to commercialize ONIVYDE in all territories in the world, except for Taiwan, where PharmaEngine has an exclusive commercialization right. 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 ONIVYDE, which occurred and was paid in the first quarter of 2012.

On September 22, 2014, we amended the PharmaEngine agreement to redefine sublicense revenue and reduce the portion of sublicense revenue that we are required to pay to PharmaEngine. As a result of this amendment, we made a \$7.0 million milestone payment to PharmaEngine. Additionally, as a result of this amendment, a previously contingent \$5.0 million milestone payment was paid in the second quarter of 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.

Since entering into the PharmaEngine agreement, we have paid PharmaEngine an aggregate of \$73.5 million in upfront license fees and milestone payments. This amount includes an \$11.0 million milestone payment made in July 2015 in connection with the EMA's acceptance for review of an MAA for ONIVYDE, which occurred, and was recognized as research and development expense, in the second quarter of 2015, a \$10.0 million milestone payment made in June 2016 in connection with the MFDS's acceptance for review of a new drug application for ONIVYDE, which occurred, and was recognized as research and development expense, in the second quarter of 2016 in connection with Baxalta's receipt of marketing authorization from the European Commission for ONIVYDE in combination with 5-FU and leucovorin for the treatment of adult patients with metastatic adenocarcinoma of the pancreas who have progressed following gemcitabine-based therapy, which occurred, and was recognized as recognized as research and development expense, in the fourth quarter of 2016.

In addition to these amounts, we could also be required to pay PharmaEngine up to an additional \$25.0 million in aggregate regulatory milestones, \$38.0 million in sublicense fees and \$130.0 million in aggregate sales milestones, in each case with respect to Europe and certain countries in Asia. PharmaEngine is also entitled to tiered royalties on net sales of ONIVYDE 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 ONIVYDE in these territories. Under the PharmaEngine agreement, we are responsible for all future development costs of ONIVYDE except those required specifically for regulatory approval in Taiwan.

During the years ended December 31, 2016, 2015 and 2014, we recognized research and development expenses related to the PharmaEngine agreement of \$35.6 million, \$11.4 million and \$12.6 million, respectively, which included \$35.5 million of expenses related to milestone payments in 2016, \$11.0 million of expenses related to milestone payments in 2015 and \$12.0 million of expenses related to milestone payments in 2016.

Under the PharmaEngine agreement, we are also obligated to pay PharmaEngine royalties on Baxalta's net sales of ONIVYDE in the licensed territory. We record these royalty expenses in the period that the related sales occur, and such royalty expenses are recorded as a component of "Cost of revenues" within our consolidated statements of operations and comprehensive loss. During the year ended December 31, 2016, we recorded \$0.1 million of royalty expenses related to PharmaEngine.

In August 2015, we also entered into a commercial supply agreement with PharmaEngine, or the PharmaEngine supply agreement, pursuant to which we supply ONIVYDE to PharmaEngine.

Upon consummation of the asset sale, both the PharmaEngine agreement and the PharmaEngine supply agreement will be assigned to Ipsen.

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

Our revenue to date has been derived from license fees, milestone payments and research, development, manufacturing and other payments received from collaborations, as well as from sales of ONIVYDE. 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.

Upon the FDA's approval of ONIVYDE in the fourth quarter of 2015, we began selling ONIVYDE in the United States. For the years ended December 31, 2016 and 2015, we recognized net product revenues of \$53.1 million and \$4.3 million, respectively. We estimate our net product revenues by deducting from our gross product revenues trade allowances, estimated rebates and chargeback discounts, estimated reserves for product revenues to increase in future periods as compared to the year ended December 31, 2016 as ONIVYDE continues to gain market penetration. If the asset sale with Ipsen is consummated, subsequent to the closing to the asset sale, we will no longer recognize net product revenues related to the sale of ONIVYDE.

Beginning in the second quarter of 2016, we began to recognize revenue related to the commercial supply of ONIVYDE to Baxalta and PharmaEngine. For the year ended December 31, 2016, we recognized commercial supply revenues of \$4.1 million. If the asset sale with Ipsen is not consummated, we expect that commercial supply revenues will increase in the future as we continue to provide commercial supply of ONIVYDE to Baxalta and PharmaEngine. After selling through lots that were previously expensed due to being manufactured prior to ONIVYDE receiving FDA approval, we expect commercial supply revenues to generate a gross margin in the mid-single digits. If the asset sale with Ipsen is consummated, subsequent to the closing of the asset sale and the assignment of the Baxalta and PharmaEngine supply agreements to Ipsen, we will no longer recognize revenues related to the commercial supply of ONIVYDE to Baxalta and PharmaEngine.

Beginning in the fourth quarter of 2016, we began to recognize royalty revenues on Baxalta's net sales of ONIVYDE in the licensed territory. For the year ended December 31, 2016, we recognized royalty revenues of \$0.2 million. If the asset sale with Ipsen is not consummated, we expect that royalty revenues will increase in the future as Baxalta continues to expand its sales of ONIVYDE in the licensed territory. If the asset sale with Ipsen is consummated, subsequent to the closing of the asset sale and the assignment of the Baxalta agreement to Ipsen, we will no longer recognize royalty revenues related to Baxalta's net sale of ONIVYDE in the licensed territory.

If the asset sale with Ipsen is not consummated, we expect that license and collaboration revenues recognized under the Baxalta agreement will fluctuate in future periods depending on the achievement of research and development and regulatory milestones. If the asset sale with Ipsen is consummated, subsequent to the closing of the asset sale and the assignment of the Baxalta agreement to Ipsen, we will no longer recognize license and collaboration revenues under the Baxalta agreement.

We did not recognize any revenue related to the Sanofi agreement during the years ended December 31, 2016 or 2015, nor do we anticipate recording any revenues related to the Sanofi agreement in the future, due to the termination of the Sanofi agreement effective December 17, 2014.

## Cost of revenues

Cost of revenues consists of manufacturing costs of product sold both commercially and under our commercial supply agreements with Baxalta and PharmaEngine, including shipping and handling costs, costs associated with inventory reserves or write-downs and royalties owed to PharmaEngine on Baxalta's net sales of ONIVYDE in the licensed territory. We began to capitalize costs associated with the production of ONIVYDE upon receipt of FDA approval on October 22, 2015. Costs incurred prior to receipt of marketing approval of ONIVYDE were expensed as research and development expenses.

If the asset sale with Ipsen is not consummated, we expect that our cost of revenues related to net product revenues and other revenues will fluctuate in future periods depending on our revenue mix as well as when the components of the specific ONIVYDE lots sold were produced. Certain lots of ONIVYDE were previously expensed due to being manufactured prior to ONIVYDE receiving FDA approval and therefore will not have cost of revenues associated with their sale. This benefit is expected to continue through 2017; however, the time period over which this reduced-cost inventory is consumed will depend on a number of factors, including the amount of future ONIVYDE sales, the ultimate use of this inventory in either commercial sales, clinical development or other research activities, and the ability to utilize inventory prior to its expiration date. If the asset sale with Ipsen is consummated, subsequent to the closing of the asset sale, we will no longer recognize cost of revenues related to sales of ONIVYDE.

## Research and development expenses

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

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

We expense research and development costs as incurred. Conducting a significant amount of research and development is central to our business model. Product candidates in late stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of late stage clinical trials. As a result of the further reduction in headcount and re-focusing of our development efforts announced in January 2017, we expect our research and development expenses to decrease in future periods as compared to the year ended December 31, 2016. We will still incur research and development expenses for the foreseeable future as we continue to develop our clinical stage product candidates and further advance our preclinical products and earlier stage research and development projects. Such future research and development expenses may include additional regulatory milestone payments that we are required to make under the PharmaEngine agreement.

We use our employee and infrastructure resources across multiple research and development programs. We track expenses related to our 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-based compensation expense or expenses related to preclinical programs. Costs that are not directly attributable to specific clinical programs, 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, for the years ended December 31, 2016, 2015 and 2014:

	Years Ended December 31,					
(in thousands)		2016		2015		2014
ONIVYDE	\$	53,551	\$	38,644	\$	31,792
MM-121		17,866		17,829		10,707
MM-141		13,317		12,236		14,611
MM-310		6,002		9,141		3,704
MM-302		18,810		17,595		13,982
MM-151		3,917		5,329		9,038
Companion therapeutics program		3,328		2,609		_
Preclinical, general research and discovery		37,623		49,329		47,778
Stock-based compensation		6,503		8,276		6,883
Total research and development expenses	\$	160,917	\$	160,988	\$	138,495

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

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 flows 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;
- 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.

## ONIVYDE

ONIVYDE has been approved by the FDA, European Commission and certain other regulatory agencies in combination with 5-FU and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy. In October 2015, we enrolled the first patient in a Phase 2 clinical trial of ONIVYDE in front-line metastatic pancreatic cancer. This trial is designed to assess the safety and efficacy of the combination of ONIVYDE plus 5-FU and leucovorin, with or without the addition of oxaliplatin, versus nab-paclitaxel and gemcitabine in patients with previously untreated, metastatic pancreatic adenocarcinoma. In addition, we are initiating a Phase 3 clinical trial studying ONIVYDE as a monotherapy for the treatment of small cell lung cancer in patients that have progressed on a previous platinum-containing regimen. We are also collaborating with several investigators to conduct additional trials of ONIVYDE, including in a Phase 1 clinical trial utilizing a high concentration formulation of ONIVYDE in patients with glioma, a Phase 1 clinical trial in pediatric solid tumors and a Phase 1 clinical trial in combination with veliparib in solid tumors.

In May 2016, we announced that we planned to initiate a Phase 1 clinical trial of ONIVYDE plus 5-FU and leucovorin in combination with MM-151 in patients with RAS wild-type metastatic colorectal cancer; however, based on the results of our strategic pipeline review that was completed in January 2017, we no longer plan to initiate this clinical trial.

As described above, we have paid PharmaEngine upfront license fees and milestone payments under the PharmaEngine agreement. We have recorded research and development expenses related to these upfront license fees and milestone payments to PharmaEngine of \$35.5 million, \$11.0 million and \$12.0 million during the years ended December 31, 2016, 2015 and 2014, respectively.

## MM-121 (seribantumab)

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 non-small cell lung cancer. In December 2015, we announced an amendment to the trial, including a change in primary endpoint from progression free survival to overall survival.

Based on the results of our strategic pipeline review that was completed in January 2017, we plan to modify the design of this clinical trial into a proof-of-concept study to reduce enrollment and generate data in a more homogenous patient population. We also intend to initiate an additional Phase 2 clinical trial of MM-121 in 2017 in advanced HER2 negative, estrogen receptor positive (ER+), progesterone receptor positive (PR+) and heregulin positive breast cancer.

## MM-141 (istiratumab)

In May 2015, we initiated a randomized, double-blinded, placebo-controlled Phase 2 clinical trial of MM-141 in combination with nab-paclitaxel and gemcitabine, versus nab-paclitaxel and gemcitabine alone in patients with newly diagnosed metastatic pancreatic cancer who have high serum levels of free IGF-1. We have completed a multi-arm Phase 1 clinical trial evaluating the safety and tolerability of MM-141 as a monotherapy and in combination with everolimus or with nab-paclitaxel and gemcitabine in patients with advanced solid tumors.

Based on the results of our strategic pipeline review that was completed in January 2017, we plan to modify the ongoing Phase 2 clinical trial of MM-141 from an original planned enrollment of approximately 140 patients down to a revised enrollment of approximately 80 patients.

## MM-310

We expect to initiate a Phase 1 clinical trial of MM-310 in 2017 as a monotherapy to evaluate its safety and preliminary efficacy in patients with solid tumors.

#### MM-302

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. Prior to initiating the Phase 2 clinical trial of MM-302, we conducted a Phase 1 clinical trial of MM-302 in patients with advanced ErbB2 (HER2) positive breast cancer. We reported final results from this trial in April 2015.

In December 2016, we determined that we would be stopping the ongoing Phase 2 clinical trial of MM-302. The decision to stop the trial was made following an independent Data and Safety Monitoring Board, or DSMB, opinion that continuing the clinical trial would be unlikely to demonstrate benefit over the comparator treatments. Subsequent to this recommendation, a futility assessment was performed that confirmed the DSMB's opinion. Both the treatment and control arms were found to have shorter than expected median progression free survival. While patients currently enrolled in the clinical trial may choose to continue on their assigned treatment based upon discussion with their study physician, no further development of MM-302 is being contemplated by us at this time. As a result of this determination, we recorded a non-cash impairment charge of \$2.8 million during the fourth quarter of 2016 related to an in-process research and development, or IPR&D, asset associated with MM-302. This impairment charge is a component of the \$18.8 million of total MM-302 expenses incurred during the year ended December 31, 2016.

#### MM-151

We have completed a Phase 1 clinical trial of MM-151 as a monotherapy and in combination with irinotecan in patients with solid tumors.

Based on the results of our strategic pipeline review that was completed in January 2017, further investment in MM-151 is being deferred at this time.

#### Companion therapeutics program

We are evaluating combinations of our therapeutic oncology candidates, but further investment in the companion therapeutics program is being deferred at this time.

## Selling, general and administrative expenses

Selling, general and administrative expenses consist primarily of salaries and other related costs for personnel, including stock-based compensation expenses and benefits, in our commercial, legal, intellectual property, business development, finance, information technology, corporate communications, investor relations and human resources departments. Other selling, general and administrative expenses include costs to support commercial sales, employee training and development, board of directors costs, depreciation, insurance expenses, facility-related costs not otherwise included in research and development expenses, professional fees for legal services, including patent-related expenses, and accounting and information technology services. As a result of the further reduction in headcount and re-focusing of our development efforts announced in January 2017, we expect our selling, general and administrative expenses to decrease in future periods as compared to the year ended December 31, 2016.

## **Restructuring expenses**

As a result of the October 2016 corporate restructuring activities described above, we recognized total restructuring expenses of \$5.9 million during the year ended December 31, 2016 related to stock-based compensation expense for certain terminated employees, contractual termination benefits for employees with pre-existing severance arrangements and one-time employee termination benefits. These one-time employee termination benefits were comprised of severance, benefits and related costs, all of which resulted in cash expenditures during the third and fourth quarters of 2016.

#### Interest expense

Interest expense consists primarily of cash and non-cash interest related to our convertible notes and our 2022 notes.

As a result of the conversion agreements entered into on April 13, 2016, we recognized a one-time \$14.6 million non-cash loss on extinguishment during the second quarter of 2016. This loss on extinguishment was recorded as a component of interest expense. Transaction costs incurred with third parties directly related to the conversion were allocated to the liability and equity components, resulting in additional interest expense recognized of \$0.2 million during the second quarter of 2016. We expect that interest expense will decrease in subsequent periods as compared to the year ended December 31, 2016 due to the one-time loss on extinguishment recognized in the second quarter of 2016, as well as an overall reduction in outstanding long-term debt as a result of the conversion.

## Other (expense) income, net

Other (expense) income, net consists primarily of income related to tax incentive awards, foreign currency gains and losses and other 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 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, 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, estimates of discounts and allowances related to commercial sales of ONIVYDE, estimates utilized in the valuation of inventory, useful lives with respect to long-lived assets and intangible assets, accounting for stock-based compensation, contingencies, intangible assets, goodwill, IPR&D, tax valuation reserves and accrued expenses. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 1 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.

### Inventory

We value our inventories at the lower of cost or net realizable value. We determine the cost of our inventories, which includes amounts related to materials and manufacturing overhead, on a first-in, first-out basis. We perform an assessment of the recoverability of capitalized inventory during each reporting period, and we write down any excess and obsolete inventories to their realizable value in the period in which the impairment is first identified. Such impairment charges, should they occur, are recorded as a component of "Cost of revenues."

We capitalize inventory costs associated with our products after regulatory approval when, based on our judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. Inventory acquired prior to receipt of marketing approval of a product candidate is expensed as research and development expense as incurred. Inventory that can be used in either the production of clinical or commercial product is expensed as research and development expense when selected for use in a clinical manufacturing campaign.

Shipping and handling costs for product shipments are recorded as incurred as a component of "Cost of revenues" along with amortization expense related to definite-lived intangible assets, costs associated with manufacturing the product and any inventory reserves or write-downs.

## Goodwill and intangible assets

Goodwill and indefinite-lived intangible assets, including IPR&D assets, are evaluated for impairment on an annual basis or more frequently if an indicator of impairment is present. We perform our annual goodwill and IPR&D impairment evaluations on August 31st.

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 is required; otherwise, further testing is not 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 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, we would record an impairment loss equal to the difference. We operate in one operating segment, which is considered the only reporting unit.

We commence amortization of indefinite-lived intangible assets, such as IPR&D, once the associated research and development efforts have been completed. We amortize these product-related intangible assets over their estimated useful lives, and amortization expense is recorded as a component of "Cost of revenues." We amortize other definite-lived assets, such as core technology, over their estimated useful lives as a component of "Research and development expenses." Definite-lived intangible assets are evaluated for impairment whenever events or circumstances indicate that the carrying value may not be fully recoverable.

## 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.

#### **Revenue** recognition

We recognize revenue when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the price to the customer is fixed or determinable; and collectability is reasonably assured.

## Product revenues, net

We sell ONIVYDE to a limited number of specialty pharmaceutical distributors, or distributors, in the United States. Our distributors subsequently resell the products to healthcare providers. We recognize revenue on product sales when title and risk of loss

have passed to the distributor, which is typically upon delivery. Product revenues are recorded net of applicable reserves for discounts and allowances.

In order to conclude that the price is fixed or determinable, we must be able to reasonably estimate our net product revenues upon delivery to our distributors. As such, we estimate our net product revenues by deducting from our gross product revenues trade allowances, estimated contractual discounts, estimated Medicaid rebates, estimated reserves for product returns and estimated costs of other incentives offered to patients.

These discounts and allowances are based on estimates of the amounts earned or to be claimed on the related sales. Our estimates take into consideration our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted distributor buying and payment patterns. Actual amounts may ultimately differ from our estimates. If actual results vary, we will adjust these estimates, which could have an effect on earnings in the period of adjustment.

Product revenue reserves and allowances that reduce gross revenue are categorized as follows:

*Trade allowances*: We pay fees to our distributors for providing certain data to us as well as for maintaining contractual inventory and service levels. These trade allowances are recorded as a reduction to accounts receivable on the consolidated balance sheet at the time revenue is recognized.

*Rebates and chargeback discounts*: We are subject to discount obligations under state Medicaid programs and the Public Health Service 340B Drug Pricing Program, contracts with Federal government entities purchasing via the Federal Supply Schedule and various private organizations, such as group purchasing organizations (which we collectively refer to as third-party payors). We estimate the rebates and chargeback discounts we will provide to third-party payors, based upon our expected payor mix, and deduct these estimated amounts from our gross product revenues at the time revenue is recognized. Chargeback discounts are processed when the third-party payor purchases the product at a discount from the distributor, who then in turn charges back to us the difference between the price initially paid by the distributor and the discounted price paid by the third-party payor. These chargeback discounts are recorded as a reduction to accounts receivable on the consolidated balance sheet at the time revenue is recognized. Rebates that are invoiced directly to us are recorded as accrued liabilities on the consolidated balance sheet at the time revenue is recognized.

*Product returns*: An allowance for product returns is established for returns expected to be made by distributors and is recorded at the time revenue is recognized, resulting in a reduction to product sales. In accordance with contractual terms, distributors have the right to return unopened and undamaged product that is within a permissible number of months before and after the product's expiration date, subject to contractual limitations. We have the ability to monitor inventory levels and the shelf life of product at distributors and can contractually control the amount of inventory that is sold to distributors. Based on inventory levels held by distributors and the structure of our distribution model, we have concluded that we have the ability to reasonably estimate product returns at the time revenue is recognized. Our estimated rate of return is based on historical rates of return for comparable oncology products.

*Other incentives*: We offer co-pay mitigation support to commercially insured patients. Our co-pay mitigation program is intended to reduce each participating patient's portion of the financial responsibility for a product's purchase price to a specified dollar amount. Based upon the terms of our co-pay mitigation program, we estimate average co-pay mitigation amounts in order to establish a reserve for co-pay mitigation claims and deduct these estimated amounts from our gross product revenues at the later of the date that (i) the revenues are recognized or (ii) the incentive is offered. Claims under our co-pay mitigation program are subject to expiration.

### License and collaboration revenues

We enter into biopharmaceutical product development agreements with collaborative partners for the research and development of therapeutic and diagnostic products. The terms of these agreements may include nonrefundable signing and licensing fees, funding for research, development and manufacturing, milestone payments and royalties 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.

The revenue recognition guidance related to multiple-element arrangements requires entities to separate and allocate consideration in a multipleelement 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 Baxalta agreement in September 2014, which was evaluated under the accounting guidance on revenue recognition for multipleelement 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 and the consideration expected to be received from Baxalta 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 multipleelement 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 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 product to Actavis.

Whenever we determine that an arrangement should be accounted for as a single unit of accounting, we determine the period over which the performance obligations would be performed and revenue would be recognized. If we cannot reasonably estimate the timing and the level of effort to complete our performance obligations under the arrangement, then revenue under the arrangement is recognized on a straight-line basis over the period we expect to complete our performance obligations.

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 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 our revenue model until the performance conditions are met.

#### Other revenues

We are a party to separate commercial supply agreements with Baxalta and PharmaEngine pursuant to which we supply ONIVYDE to these entities. Revenue is recognized under these commercial supply arrangements when the counterparty takes delivery of the commercial supply product and when the other general revenue recognition criteria outlined above are met.

We are also eligible to receive royalty revenues on Baxalta's net sales of ONIVYDE in the licensed territory. We recognize royalty revenues in the period that the related sales occur.

#### Stock-based compensation expense

We account for our stock-based compensation awards in accordance with ASC 718, *Compensation – Stock Compensation*. ASC 718 requires all sharebased payments to employees, including grants of employee stock options, to be recognized in the consolidated statements of operations and comprehensive loss based on their grant date fair values. For stock options granted to employees and to members of our board of directors for their service on the board of directors, we estimate the grant date fair value of each option award using the Black-Scholes option pricing model. The use of the Black-Scholes option pricing model requires us to make assumptions with respect to the expected term of the option, the expected volatility of our common stock consistent with the expected term of the option, the risk-free interest rate consistent with the expected term of the option and the expected dividend yield of our common stock. Stock-based compensation expense related to employee stock options 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. Stock-based compensation expense is then recognized on a straight-line basis over the vesting period, which is also the requisite service period.

We record stock options issued to non-employees at fair value, remeasure to reflect the current fair value at each reporting period and recognize 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.

## **Results of Operations**

#### Comparison of the years ended December 31, 2016 and 2015

	Years Ended December 31,					
(in thousands)		2016		2015		
Product revenues, net	\$	53,064	\$	4,328		
License and collaboration revenues		87,119		84,930		
Other revenues		4,090		—		
Cost of revenues		(6,912)		(46)		
Research and development expenses		(160,917)		(160,988)		
Selling, general and administrative expenses		(80,729)		(57,795)		
Restructuring expenses		(5,856)		—		
Loss from operations		(110,141)		(129,571)		
Interest income		276		99		
Interest expense		(43,645)		(19,232)		
Other (expense) income, net		(8)		917		
Net loss	\$	(153,518)	\$	(147,787)		

#### Product revenues, net

We commenced product sales of ONIVYDE in the fourth quarter of 2015 subsequent to approval by the FDA. We recognized net product revenues of \$53.1 million for the year ended December 31, 2016 as compared to \$4.3 million for the year ended December 31, 2015.

#### License and collaboration revenues

License and collaboration revenues were \$87.1 million for the year ended December 31, 2016 compared to \$84.9 million for the year ended December 31, 2015, an increase of \$2.2 million, or 3%. This increase was primarily attributable to the achievement of \$40.0 million of substantive milestones during the year ended December 31, 2016 as compared to the achievement of \$20.0 million of substantive milestones during the year ended December 31, 2016 as compared to the achievement of \$20.0 million of substantive milestones during the year ended December 31, 2015. This increase was partially offset by a decrease in revenue recognized under the Baxalta proportional performance revenue recognition model as a result of significant work performed during the year ended December 31, 2015 as we completed the Phase 3 clinical trial of ONIVYDE and prepared for regulatory approval by the FDA.

## Other revenues

We began recognizing commercial supply revenues in the second quarter of 2016 when we first supplied ONIVYDE to Baxalta and PharmaEngine. We also began recognizing royalty revenues in the fourth quarter of 2016 upon the first sales of ONIVYDE by Baxalta in the licensed territory. Other revenues were \$4.1 million in total for the year ended December 31, 2016, comprised of \$3.6 million of revenue related to ONIVYDE sold to Baxalta, \$0.3 million of revenue related to ONIVYDE sold to PharmaEngine and \$0.2 million of royalty revenues related to Baxalta's net sales of ONIVYDE in the licensed territory. No other revenues were recognized during the year ended December 31, 2015.

### Cost of revenues

We began recognizing cost of revenues in the fourth quarter of 2015 subsequent to the approval of ONIVYDE by the FDA. We recognized \$6.9 million of cost of revenues during the year ended December 31, 2016, comprised of \$3.6 million of costs related to excess and scrap inventory and excess manufacturing capacity, \$2.4 million of costs related to ONIVYDE sold to Baxalta and PharmaEngine, \$0.5 million of costs related to net product revenues, \$0.1 million of costs related to royalties owed to PharmaEngine on Baxalta's net sales of ONIVYDE in the licensed territory and \$0.3 million of other costs, including the amortization of our definite-lived ONIVYDE intangible asset. We recognized less than \$0.1 million of cost of revenues during the year ended December 31, 2015.

## Research and development expenses

Research and development expenses were \$160.9 million for the year ended December 31, 2016 compared to \$161.0 million for the year ended December 31, 2015, a decrease of \$0.1 million, or less than 1%. This decrease was primarily attributable to:

- \$3.1 million of decreased MM-310 expenses primarily due to the timing of preclinical research activities and cost conservation measures implemented during 2016;
- \$1.4 million of decreased MM-151 expenses primarily due to the completion of the Phase 1 clinical trial of MM-151 as a monotherapy and in combination with irinotecan in patients with solid tumors during 2015;
- \$11.7 million of decreased expenses related to preclinical, general research and discovery as a result of our cost management efforts and the timing of manufacturing campaigns for our preclinical programs; and
- \$1.8 million of decreased stock-based compensation expenses primarily due to a reduction in our headcount and a decrease in our stock price over the course of the year ended December 31, 2016.

These decreases were partially offset by:

- \$14.9 million of increased ONIVYDE expenses primarily due to \$35.5 million of milestone payments made to PharmaEngine in 2016, offset by decreased ONIVYDE development expenses due to manufacturing campaigns that took place during the year ended December 31, 2015 as well as the winding down of our Phase 3 clinical trial during 2015 that supported the approval of ONIVYDE by the FDA;
- \$1.0 million of increased MM-141 expenses related to increased costs associated with our ongoing Phase 2 clinical trial, which was initiated in May 2015; and
- \$1.2 million of increased MM-302 expenses primarily attributable to the non-cash impairment charge of \$2.8 million recognized during the fourth quarter of 2016 related to the MM-302 IPR&D asset, offset by decreased activity in our Phase 2 clinical trial of MM-302 in locally advanced or metastatic breast cancer.

### Selling, general and administrative expenses

Selling, general and administrative expenses were \$80.7 million for the year ended December 31, 2016 compared to \$57.8 million for the year ended December 31, 2015, an increase of \$22.9 million, or 40%. This increase was primarily attributable to \$14.5 million of increased expenses to support commercial sales of ONIVYDE, \$3.7 million of transaction costs incurred related to the asset sale and increased labor and labor-related expenses and facility-related costs.

### Restructuring expenses

We recognized restructuring expenses of \$5.9 million during the year ended December 31, 2016 related to our October 2016 corporate restructuring activities described above. No restructuring expenses were recognized during the year ended December 31, 2015.

### Interest expense

Interest expense was \$43.6 million for the year ended December 31, 2016, compared to \$19.2 million for the year ended December 31, 2015. This increase was primarily attributable to a one-time non-cash charge of \$14.6 million associated with the induced conversion of an aggregate principal amount of \$64.2 million of our convertible notes in April 2016 as well as interest expense related to our 2022 notes that were issued in December 2015, offset by a decrease in interest expense related to our previously outstanding loans payable to Hercules Technology Growth Capital, Inc., or Hercules, that were repaid in full during December 2015.

### Other (expense) income, net

Other (expense) income, net was less than \$0.1 million for the year ended December 31, 2016. Other (expense) income, net was \$0.9 million for the year ended December 31, 2015, which was primarily related to the amortization of Massachusetts Life Sciences Center, or MLSC, tax incentives.



## Comparison of the years ended December 31, 2015 and 2014

	Years Ended December 31,				
(in thousands)		2015 2014			
Product revenues, net	\$	4,328	\$		
License and collaboration revenues		84,930		102,756	
Cost of revenues		(46)		—	
Research and development expenses		(160,988)		(138,495)	
Selling, general and administrative expenses		(57,795)		(30,517)	
Loss from operations		(129,571)		(66,256)	
Interest income		99		114	
Interest expense		(19,232)		(18,230)	
Other income, net		917		813	
Net loss	\$	(147,787)	\$	(83,559)	

#### Product revenues, net

We commenced product sales of ONIVYDE in the fourth quarter of 2015 subsequent to approval by the FDA. For the year ended December 31, 2015, we recognized net product revenues of \$4.3 million. No net product revenues were recognized during the year ended December 31, 2014.

#### License and collaboration revenues

License and collaboration revenues were \$84.9 million for the year ended December 31, 2015 compared to \$102.8 million for the year ended December 31, 2014, a decrease of \$17.8 million, or 17%. The decrease was primarily attributable to the reassessment of the development period of our collaboration with Sanofi during 2014 based on the decision to terminate the arrangement effective December 17, 2014. As a result, no revenues related to our collaboration with Sanofi were recognized during 2015. We recognized \$92.3 million of license and collaboration revenues under our collaboration with Sanofi during 2014. License and collaboration revenues recognized during 2015 were exclusively related to the Baxalta agreement and were comprised of a \$20.0 million substantive milestone recognized and \$64.9 million of revenue recognized under our proportional performance revenue recognition model. We recognized \$10.5 million of license and collaboration revenues under the Baxalta agreement during the year ended December 31, 2014.

#### Cost of revenues

We began recognizing cost of revenues in the fourth quarter of 2015 subsequent to the approval of ONIVYDE by the FDA. We recognized less than \$0.1 million of cost of revenues during the year ended December 31, 2015. No cost of revenues was recognized prior to 2015.

## Research and development expenses

Research and development expenses were \$161.0 million for the year ended December 31, 2015 compared to \$138.5 million for the year ended December 31, 2014, an increase of \$22.5 million, or 16%. This increase was primarily attributable to:

- \$6.9 million of increased ONIVYDE expenses primarily due to \$3.3 million of additional manufacturing costs incurred in anticipation of ONIVYDE commercial sales and preparation for our Phase 2 clinical trial in front-line metastatic pancreatic cancer;
- \$7.1 million of increased MM-121 expenses primarily due to manufacturing costs incurred related to the initiation of our Phase 2 clinical trial in metastatic non-small cell lung cancer;

- \$5.4 million of increased MM-310 expenses primarily related to preclinical studies performed;
- \$3.6 million of increased MM-302 expenses as a result of the initiation of our Phase 2 clinical trial of MM-302 in breast cancer in August 2014;
- \$2.6 million of increased expenses related to our companion therapeutics program that was initiated in 2015;
- \$1.6 million of increased expenses related to preclinical studies, general research and discovery primarily due to an increased number of
  preclinical programs in our pipeline, increased headcount and increased size and frequency of manufacturing runs; and
- \$1.4 million of increased stock-based compensation expenses primarily due to the annual grant of stock options to employees as well as increased employee headcount.

These increases were partially offset by:

- \$2.4 million of decreased MM-141 expenses primarily due to the completion of our Phase 1 trial and timing of costs associated with our ongoing Phase 2 clinical trial, which was initiated in May 2015; and
- \$3.7 million of decreased MM-151 expenses primarily due to the timing of costs associated with our Phase 1 clinical trial, diagnostic efforts and a manufacturing campaign.

#### Selling, general and administrative expenses

Selling, general and administrative expenses were \$57.8 million for the year ended December 31, 2015 compared to \$30.5 million for the year ended December 31, 2014, an increase of \$27.3 million, or 89%. This increase was primarily attributable to \$21.3 million of increased expenses to support commercial sales of ONIVYDE as well as increased labor and labor-related expenses required to support our overall growth.

## Interest expense

Interest expense was \$19.2 million for the year ended December 31, 2015 compared to \$18.2 million for the year ended December 31, 2014. This increase was primarily attributable to interest expense related to our 2022 notes that were issued in December 2015.

## Other income, net

Other income, net was \$0.9 million and \$0.8 million for the years ended December 31, 2015 and 2014, respectively, which was primarily related to the amortization of MLSC tax incentives.

## 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, secured debt financings and sales of ONIVYDE. Through December 31, 2016, 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 a July 2013 follow-on underwritten public offering, \$38.6 million of net proceeds from our 2015 "at the market offering" program, or the ATM offering, \$39.6 million of net proceeds from the issuance of the convertible notes in our July 2013 underwritten public offering, \$168.5 million of net proceeds from the 2022 notes, \$483.4 million of upfront license fees, milestone payments, reimbursement of research and development costs and manufacturing services and other payments from our collaborations and \$45.1 million of cash receipts related to ONIVYDE sales. 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 \$4.9 million in upfront fees and reimbursements as of December 31, 2016. As of December 31, 2016, we had unrestricted cash and cash equivalents of \$21.5 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, respectively.

On November 8, 2012, we entered into a Loan and Security Agreement, or the 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. During the fourth quarter of 2015, we repaid the loans in full in conjunction with the issuance of the 2022 notes. We also paid an additional fee of \$1.2 million that was due upon full repayment of the loans, as well as interest accrued through the repayment date.

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 notes in concurrent underwritten public offerings. As a result of the concurrent common stock offering and convertible notes offering, we received aggregate net proceeds of approximately \$147.3 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

On July 13, 2015, we entered into a sales agreement with Cowen to sell, from time to time, shares of our common stock having an aggregate sales price of up to \$40.0 million through the ATM offering under which Cowen acted as sales agent. We concluded sales under the ATM offering in September 2015, having sold approximately 3.8 million shares of common stock and generating approximately \$38.6 million in net proceeds, after deducting commissions and offering expenses.

On December 22, 2015, we closed a private placement of \$175.0 million aggregate principal amount of 11.50% 2022 notes. As a result of the issuance of the 2022 notes, we received net proceeds of approximately \$168.5 million, after deducting private placement and offering expenses payable by us.

As of December 31, 2016, within our unrestricted cash and cash equivalents, \$1.9 million was cash and cash equivalents held by our majority owned subsidiary, Silver Creek, which is consolidated for financial reporting purposes. This \$1.9 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, 2016, 2015 and 2014:

	Years Ended December 31,										
(in thousands)			2016	2015		2014					
Net cash used in operating activities		\$	(170,241) \$	(105,356)	\$	(34,808)					
Net cash (used in) provided by investing activities			(3,257)	75,110		(6,011)					
Net cash provided by financing activities			9,416	180,164		11,421					
Net (decrease) increase in cash and cash equivalents		\$	(164,082) \$	149,918	\$	(29,398)					

### **Operating** activities

Cash used in operating activities of \$170.2 million during the year ended December 31, 2016 was primarily a result of our \$153.5 million net loss and a net decrease in operating assets and liabilities of \$61.7 million. The net decrease in operating assets and liabilities during the year ended December 31, 2016 was primarily driven by increases in accounts receivable and inventory related to the commercialization and sale of ONIVYDE, a decrease in accounts payable and accrued expenses and a decrease in deferred revenues related to the Baxalta agreement. These decreases were offset by \$44.9 million of non-cash items, including a \$2.8 million IPR&D impairment charge related to MM-302, a \$14.6 million non-cash loss on extinguishment related to the April 2016 conversion of a portion of our convertible notes, \$14.9 million of stock-based compensation expense and \$6.0 million of non-cash interest expense.

Cash used in operating activities of \$105.4 million during the year ended December 31, 2015 was primarily a result of our \$147.8 million net loss. This net loss was offset by a net increase in operating assets and liabilities of \$14.6 million and non-cash items of \$27.9 million, including \$15.4 million of stock-based compensation expense and \$8.2 million of non-cash interest expense. The net increase in operating assets and liabilities during the year ended December 31, 2015 was primarily driven by an increase in accounts payable and accrued expenses and an increase in deferred revenues related to the Baxalta agreement. These increases were offset by lesser increases in accounts receivable and inventory related to the commercialization and sale of ONIVYDE.

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. This net loss was offset by a net increase in operating assets and liabilities of \$23.0 million and non-cash items of \$24.9 million, including \$13.2 million of stock-based compensation expense and \$8.5 million of non-cash interest expense. The net



increase in operating assets and liabilities during the year ended December 31, 2014 was primarily driven by an increase in deferred revenues related to the Baxalta agreement and a decrease in accounts receivable related to the Sanofi agreement.

## Investing activities

Cash used in investing activities of \$3.3 million for the year ended December 31, 2016 was primarily due to purchases of marketable securities of \$84.3 million in addition to \$3.2 million of property and equipment purchases, offset by proceeds from sales and maturities of marketable securities of \$84.2 million. Cash provided by investing activities of \$75.1 million for the year ended December 31, 2015 was primarily due to proceeds from sales and maturities of marketable securities of \$87.9 million, offset by \$12.8 million of property and equipment purchases. Cash used in investing activities of \$6.0 million for the year ended December 31, 2015 was primarily due to proceed from sales and maturities of 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 \$9.4 million for the year ended December 31, 2016 was primarily due to \$6.2 million of proceeds received from the exercise of stock options and \$3.4 million of total proceeds received from the issuance of convertible promissory notes and Series C preferred stock by Silver Creek. Cash provided by financing activities of \$180.2 million for the year ended December 31, 2015 was primarily due to \$38.6 million of net proceeds from our ATM offering, \$10.1 million of proceeds from the exercise of stock options and warrants, \$169.4 million in net proceeds from the issuance of our 2022 notes, after considering the accounting treatment of \$0.9 million of issuance costs that were allocated to the associated debt modification, and \$2.1 million in net proceeds from Series B preferred stock by Silver Creek. These cash proceeds were offset by the repayment of our \$40.0 million in loans payable under the loan agreement with Hercules. Cash provided by financing activities of \$11.4 million for the year ended December 31, 2014 was primarily due to \$10.4 million of proceeds from the exercise of stock options and \$1.0 million of net proceeds from the convertible notes offered by Silver Creek.

## Funding requirements

We have incurred significant expenses and operating losses to date, and we expect to continue to incur significant expenses and operating losses for at least the next several years. We anticipate that we will continue to incur significant expenses as we:

- initiate or continue clinical trials of our 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;
- continue to support our sales, marketing and distribution infrastructure and scale up manufacturing capabilities to meet commercial demand for ONIVYDE and other products for which we may seek regulatory approval; and
- continue to provide the operational, financial and management information systems and personnel to support our product development and continued commercialization.



Upon stockholder approval and the closing of the asset sale with Ipsen, we will receive a \$575.0 million upfront cash payment from Ipsen (subject to a working capital adjustment as provided in the asset sale agreement). We expect to use these proceeds to declare and pay a special cash dividend of at least \$200.0 million to stockholders and redeem the \$175.0 million outstanding aggregate principal amount of 2022 notes, which will require an additional make-whole premium payment of approximately \$20.1 million. Additionally, if the asset sale is consummated and certain milestones under the Baxalta agreement are met, we currently expect to receive up to an aggregate of \$33.0 million in net milestone payments in 2017. We believe these potential net cash inflows, along with the completion of the headcount reduction and refocused research and development efforts that were announced in January 2017, will provide financial resources sufficient to fund our operations into the second half of 2019. 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 consummation of the asset sale and the net proceeds received therefrom;
- the amount of net product revenues realized from ONIVYDE commercial sales, should the asset sale not be consummated;
- the amount of royalty and profit sharing revenue from our collaboration partners, particularly should the asset sale not be consummated;
- the progress and results of the clinical trials of our most advanced product candidates;
- the success of the Baxalta and PharmaEngine collaborations related to ONIVYDE 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 ONIVYDE that we may receive from Baxalta;
- the timing and amount of future milestone payments that we may receive from Ipsen under the asset sale agreement;
- 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 current and future product candidates;
- the costs of commercial activities, including product sales, marketing, manufacturing and distribution, particularly should the asset sale not be consummated;
- 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, particularly should the asset sale not be consummated; 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 sufficient license and collaboration or product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, licensing arrangements and other marketing and distribution arrangements. We also could engage in discussions with third parties regarding partnerships, joint ventures, combinations or divestitures of one or more of our businesses as we seek to further the development of our research programs, improve our cash position and maximize stockholder value. There can be no assurance as to the timing, terms or consummation of any financing, collaboration, licensing arrangement or other marketing and distribution arrangement, partnership, joint venture, combination or divestiture. We do not have any committed external sources of funds, other than under the asset sale agreement with Ipsen, which is subject to the achievement of certain closing conditions prior to consummation, including stockholder approval, under our collaboration with Baxalta for the development, license and supply agreement with Actavis, which is terminable by Baxalta for convenience upon 180 days' prior written notice, under our development, license and supply agreement with Pharmakon, subject to compliance with certain funding conditions. 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.

If we are unable to obtain stockholder approval of the asset sale and the transaction with Ipsen is not consummated, or if we are unable to obtain other adequate financing or engage in another strategic transaction on acceptable terms and when needed, we will be required to implement further cost reduction strategies.

### **Borrowings**

#### 11.50% senior secured notes due 2022

On December 22, 2015, we closed a private placement of \$175.0 million aggregate principal amount of 2022 notes and entered into an indenture with U.S. Bank National Association as trustee and collateral agent. As a result of this placement, we received net proceeds of approximately \$168.5 million, after deducting private placement and offering expenses payable by us. The private placement and offering expenses included \$0.9 million of transaction costs that were expensed in accordance with the debt modification guidance per ASC 470, *Debt*. The 2022 notes bear interest at a rate of 11.50% per year, payable semi-annually on June 15 and December 15 of each year, beginning on June 15, 2016. We will pay semi-annual installments of principal on the 2022 notes of \$21,875,000 each, subject to adjustment as provided in the 2022 notes, on June 15 and December 15 of each year, beginning on June 15, and December 15, 2019. The 2022 notes will mature on December 15, 2022, unless earlier redeemed or repurchased in accordance with their terms prior to such date.

We may redeem the 2022 notes at our option, in whole or in part from time to time at a price equal to the principal amount plus accrued interest and a specified make-whole premium. If we experience certain change of control events as defined in the indenture, the holders of the 2022 notes will have the right to require us to purchase all or a portion of the 2022 notes at a purchase price in cash equal to 101% of the principal amount thereof, plus accrued and unpaid interest to the date of purchase. In addition, upon certain asset sale events as defined in the indenture, we may be required to offer to use the net proceeds thereof to purchase all or a portion of the 2022 notes at 100% of the principal amount thereof, plus accrued and unpaid interest to the date of purchase.

The 2022 notes are senior secured obligations of ours and are equal in right of payment to all existing and future pari passu indebtedness of ours (including our outstanding convertible notes), will be senior in right of payment to all existing and future subordinated indebtedness of ours, will have the benefit of a security interest in the 2022 notes collateral and will be junior in lien priority in respect of any asset-based lending collateral that secures any first priority lien obligations from time to time. The 2022 notes contain customary covenants, including covenants that limit or restrict our ability to incur liens; incur indebtedness; pay dividends, repurchase shares and make certain other restricted payments; prepay, redeem or repurchase subordinated debt; and sell, lease or transfer certain property and assets, but do not contain covenants related to future financial performance. The 2022 notes are secured by a first priority lien on substantially all of our assets.

The 2022 notes contain customary events of default. Upon certain events of default occurring, the trustee may declare 100% of the principal of and accrued and unpaid interest, if any, on all the 2022 notes to be due and payable. In the case of certain events of bankruptcy, insolvency or reorganization involving us or a restricted subsidiary, 100% of the principal of, and accrued and unpaid interest, if any, on, the 2022 notes will automatically become due and payable.

In connection with the closing of the asset sale to Ipsen, we intend to redeem all \$175.0 million aggregate principal amount of outstanding 2022 notes at the then applicable redemption price, plus accrued and unpaid interest to the date of redemption.

## 4.50% convertible notes due 2020

In July 2013, we issued \$125.0 million aggregate principal amount of convertible notes. We issued the convertible 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 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 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 notes are general unsecured senior obligations of ours and rank (i) pari

passu in seniority with respect to the 2022 notes, (ii) senior in right of payment to any of our indebtedness that is expressly subordinated in right of payment to the convertible notes, (iii) equal in right of payment to any of our unsecured indebtedness that is not so subordinated, (iv) 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 (v) structurally junior to all indebtedness and other liabilities (including trade payables) of our subsidiaries.

On April 13, 2016, we entered into separate, privately-negotiated conversion agreements with certain holders of the convertible notes. Under the conversion agreements, such holders agreed to convert an aggregate principal amount of \$64.2 million of convertible notes held by them. We initially settled each \$1,000 principal amount of convertible notes surrendered for conversion by delivering 136 shares of our common stock on April 18, 2016. In total, we issued an aggregate of 8,732,152 shares of our common stock on this initial closing date. In addition, pursuant to the conversion agreements, at the additional closings (as defined in the conversion agreements), we issued an aggregate of 3,635,511 shares of our common stock representing an aggregate of \$27.7 million as additional payments in respect of the conversion of the convertible notes. The number of additional shares was determined based on the daily VWAP (as defined in the conversion agreements) of our common stock for each of the trading days in the 10-day trading period following the date of the conversion agreements.

The outstanding convertible 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 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.

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 notes at any time, regardless of the foregoing circumstances.

Following the repayment and satisfaction in full of our obligations to Hercules under the loan agreement, which occurred in December 2015, upon any conversion of the convertible notes, the convertible 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 notes is 160 shares of our common stock per \$1,000 principal amount of convertible notes, which is equivalent to an initial conversion price of \$6.25 per share of common stock. The conversion rate will be subject to adjustment in some events, 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 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 notes may require us to repurchase all or a portion of their convertible notes for cash at a price equal to 100% of the principal amount of the convertible 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 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 notes then outstanding by written notice to us and the trustee, may, and the trustee at the request of such holders will, declare 100% of the principal of and accrued and unpaid interest on the convertible 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 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 loans in the aggregate principal amount of \$40.0 million. As permitted under the loan agreement, we 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, 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 fourth amendment to the loan agreement pursuant to which the maturity date and the period during which we make interest-only payments on our current loans in the aggregate principal amount of \$40.0 million was extended. As a result of this amendment, we were required to repay the outstanding aggregate principal balance of the loan beginning on June 1, 2016 and continuing through November 1, 2018. As a result of the FDA's approval of our new drug application, or NDA, for ONIVYDE, which occurred on October 22, 2015, we elected to extend the interest-only period by an additional six months so that we would repay the outstanding aggregate principal balance of the Ioans beginning on December 1, 2016 and continuing through November 1, 2018. In addition, as a result of the FDA's approval of our NDA for ONIVYDE, we could 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. We did not borrow against the additional term loan advance. Upon the earlier of full repayment of the loans or November 1, 2016, we were requir

In connection with the loan agreement, we granted Hercules 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. The loan agreement also contained certain representations, warranties and non-financial covenants.

During the fourth quarter of 2015, we repaid the loans in full in conjunction with the issuance of the 2022 notes. The total repayment amount included the \$40.0 million in outstanding principal, the \$1.2 million fee discussed above and interest accrued up through the repayment date.

#### Contractual obligations and commitments

The following table summarizes our contractual obligations as of December 31, 2016:

	Payments Due by Period									
(in thousands)		Total		Less than 1 year		1 to 3 years		3 to 5 years		More than 5 years
2022 notes (1)	\$	260,531	\$	20,125	\$	82,742	\$	110,141	\$	47,523
Convertible notes (1)		71,735		2,736		5,472		63,527		
Repayment of MLSC tax incentive awards		1,314		1,314		_				
Operating lease obligations		20,292		8,108		12,184				_
Antibody and technology licensing costs (2)		1,138		258		440		440		
Total contractual cash obligations	\$	355,010	\$	32,541	\$	100,838	\$	174,108	\$	47,523

(1) Payments are inclusive of interest and principal payments.

(2) Antibody and technology licensing costs include annual license maintenance fee and annual minimum royalty payments. We have not included annual license maintenance fees or annual minimum royalty payments after December 31, 2021, 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 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 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 tax credits. In exchange for these incentives, we pledged to hire an incremental 31 employees and to maintain the additional headcount through at least December 31, 2018. Due to our failure to meet this headcount target as of December 31, 2016 as a result of our October 2016 corporate restructuring activities, we will be required to repay approximately \$0.3 million of this award. As such, this repayment obligation has been included in the above table.

In March 2015, the MLSC awarded us an additional \$1.4 million of tax incentives under its Life Science Tax Incentive Program, which allows us to monetize approximately \$1.2 million of state research and development tax credits. In exchange for these incentives, we pledged to hire an incremental 75 employees and to maintain the additional headcount through at least December 31, 2019. Due to our failure to meet this headcount target as of December 31, 2016 as a result of our October 2016 corporate restructuring activities, we will be required to repay approximately \$1.0 million of this award. As such, this repayment obligation has been included in the above table.

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 Corp. related to antibody identification and evaluation, we may be 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 associated with MM-121 and MM-141. 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 may be required to make aggregate development and regulatory milestone payments of up to \$0.7 million associated with MM-302 and pay royalties in the low single digits on net sales of licensed products.
- Under an agreement with Adimab LLC, we may be 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.

## **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, 2016, we had net operating loss carryforwards for federal and state income tax purposes of \$542.7 million and \$367.4 million, respectively. Included in the federal and state net operating loss carryforwards is approximately \$39.2 million and \$25.2 million, respectively, 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 ASC 718, *Compensation – Stock Compensation*. Our existing federal and state net operating loss carryforwards will expire in years through 2036. We also have available research and development credits for federal and state income tax purposes of approximately \$27.3 million and \$16.3 million, respectively. The federal and state research and development credits will begin to expire in 2022 and 2025, respectively. As of December 31, 2016, we also have available investment tax credits for state income tax purposes of \$0.8 million, which will expire in years through 2019 if not used. In addition, we have federal orphan drug credits of \$106.4 million that begin to expire in 2031. We have 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. If the asset sale with Ipsen is consummated, we expect to utilize deferred tax assets to offset the taxable gain generated by the sale. The valuation allowance could be released during the year ended December 31, 2017 once it is determined it is more likely than not that the deferred tax assets will be realizable.

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, or 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 completed an evaluation of ownership changes through September 30, 2016 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. We believe that we may be able to utilize all of our tax attributes as a result of the analysis. 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**

See Note 1, "Nature of the Business and Summary of Significant Accounting Policies," in the accompanying notes to the consolidated financial statements for a description of recent accounting pronouncements applicable to our business.

## 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.

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

We do not currently have any auction rate or mortgage-backed securities. We do not believe our cash, cash equivalents and marketable securities 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 convertible notes bear interest at a fixed rate of 4.50% per year, payable semi-annually 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 notes.

The 2022 notes bear interest at a fixed rate of 11.50% per year, payable semi-annually in arrears on June 15 and December 15 of each year, beginning on June 15, 2016. As a result, we are not subject to interest rate risk with respect to the 2022 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-37 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, 2016. 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 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 costbenefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2016, 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.

## **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, 2016. 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, 2016, 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, 2016 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, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## Item 9B. Other Information

On February 23, 2017, we entered into an amendment to the Credit Agreement with Pharmakon whereby the availability of the credit facility was extended through April 27, 2017. The foregoing description of the amendment to the Credit Agreement does not purport to be complete and is qualified in its entirety by reference to the amendment, which is filed as an exhibit to this Annual Report on Form 10-K.

## 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 2017 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," "2016 Grants of Plan-Based Awards Table," "2016 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 2017 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 2017 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 2017 Annual Meeting of Stockholders and is incorporated herein by reference.

## Item 14. Principal Accountant 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 2017 Annual Meeting of Stockholders and is incorporated herein by reference.

## Item 15. Exhibits and Financial Statement Schedules

## (1) Financial Statements

Our consolidated financial statements are set forth on pages F-1 through F-37 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.

## Item 16. Form 10-K Summary

Not applicable.

# SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

## MERRIMACK PHARMACEUTICALS, INC.

Date: March 1, 2017

By:/s/ Richard Peters, M.D., Ph.D.

Richard Peters, M.D., Ph.D.

President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Richard Peters, M.D., Ph.D. Richard Peters, M.D., Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 1, 2017
/s/ Yasir B. Al-Wakeel, BM BCh Yasir B. Al-Wakeel, BM BCh	Chief Financial Officer and Head of Corporate Development (Principal Financial Officer)	March 1, 2017
/s/ William A. Sullivan William A. Sullivan	Principal Accounting Officer and Treasurer (Principal Accounting Officer)	March 1, 2017
/s/ Gary L. Crocker Gary L. Crocker	Chairman of the Board	March 1, 2017
/s/ John M. Dineen John M. Dineen	Director	March 1, 2017
/s/ Vivian S. Lee, M.D., Ph.D. Vivian S. Lee, M.D., Ph.D.	Director	March 1, 2017
/s/ John Mendelsohn, M.D. John Mendelsohn, M.D.	Director	March 1, 2017
/s/ Ulrik B. Nielsen, Ph.D. Ulrik B. Nielsen, Ph.D.	Director	March 1, 2017
/s/ Michael E. Porter, Ph.D. Michael E. Porter, Ph.D.	Director	March 1, 2017
/s/ James H. Quigley James H. Quigley	Director	March 1, 2017
/s/ Russell T. Ray Russell T. Ray	_ Director	March 1, 2017

# 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 operations and comprehensive loss, of noncontrolling interest and stockholders' deficit, and of cash flows present fairly, in all material respects, the financial position of Merrimack Pharmaceuticals, Inc. and its subsidiaries as of December 31, 2016 and 2015, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2016 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, 2016, 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 Management's Annual Report on Internal Control Over Financial Reporting appearing under Item 9A. 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.

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 22 to the financial statements, the Company has negative working capital and cash outflows from operating activities that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 22. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 March 1, 2017

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# **Consolidated Balance Sheets**

	December 31,							
(in thousands, except per share amounts)		2016		2015				
Assets								
Current assets:								
Cash and cash equivalents	\$	21,524	\$	185,606				
Restricted cash		102		101				
Accounts receivable, net		17,469		6,483				
Inventory		14,554		3,717				
Prepaid expenses and other current assets		3,786		5,487				
Total current assets		57,435		201,394				
Restricted cash		674		584				
Property and equipment, net		15,765		21,915				
Other assets		27		27				
Intangible assets, net		3,977		7,355				
Goodwill		3,605		3,605				
Total assets	\$	81,483	\$	234,880				
Liabilities, non-controlling interest and stockholders' deficit								
Current liabilities:								
Accounts payable, accrued expenses and other	\$	49,982	\$	52,082				
Deferred revenues		36,226		50,137				
Deferred rent		2,014		1,527				
Total current liabilities		88,222		103,746				
Deferred revenues, net of current portion		25,673		51,197				
Deferred rent, net of current portion		3,386		4,926				
Deferred tax incentives, net of current portion		_		1,045				
Long-term debt, net of current portion		216,861		257,655				
Total liabilities		334,142		418,569				
Commitments and contingencies								
Non-controlling interest		(1,539)		239				
Stockholders' deficit:								
Preferred stock, \$0.01 par value: 10,000 shares authorized at December 31, 2016								
and 2015; no shares issued or outstanding at December 31, 2016 or 2015		—		—				
Common stock, \$0.01 par value: 200,000 shares authorized at December 31, 2016 and								
2015, 130,197 and 115,871 issued and outstanding at December 31, 2016								
and 2015, respectively		1,302		1,159				
Additional paid-in capital		702,377		617,145				
Accumulated deficit		(954,799)		(802,232)				
Total stockholders' deficit		(251,120)		(183,928)				
Total liabilities, non-controlling interest and stockholders' deficit	\$	81,483	\$	234,880				

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

# **Consolidated Statements of Operations and Comprehensive Loss**

Years Ended December 31,									
2016			2015	2014					
\$	53,064	\$	4,328	\$	_				
	87,119		84,930		102,756				
	4,090				_				
	144,273		89,258		102,756				
	6,912		46		—				
	160,917		160,988		138,495				
	80,729		57,795		30,517				
	5,856				—				
	254,414		218,829		169,012				
	(110,141)		(129,571)		(66,256)				
	276		99		114				
	(43,645)		(19,232)		(18,230)				
	(8)		917		813				
	(153,518)		(147,787)		(83,559)				
	(1,778)		170		(268)				
\$	(151,740)	\$	(147,957)	\$	(83,291)				
	_		74		(50)				
	_		74		(50)				
\$	(151,740)	\$	(147,883)	\$	(83,341)				
\$	(1.21)	\$	(1.33)	\$	(0.80)				
	125,334		111,356		104,410				
		$\begin{array}{r c c c c c c c c c c c c c c c c c c c$	$\begin{array}{c c c c c c c c c c c c c c c c c c c $	$\begin{array}{c c c c c c c c c c c c c c c c c c c $	$\begin{array}{c c c c c c c c c c c c c c c c c c c $				

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

# Consolidated Statements of Non-Controlling Interest and Stockholders' Deficit

		Common Stock							
(in thousands)	Co	Non- ntrolling nterest	Shares	A	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficit
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
Conversion of Silver Creek Pharmaceuticals,									
Inc. convertible notes payable		366	—		—	678			678
Stock-based compensation		—	_		_	13,197	_		13,197
Other comprehensive loss		—	—		—		(50)	_	(50)
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)
Exercise of stock options and common stock									
warrants		_	5,360		54	10,047	—	—	10,101
Issuance of common stock in at the market									
offering, net of issuance costs			3,814		38	38,522			38,560
Issuance of Series B preferred stock by Silver									
Creek Pharmaceuticals, Inc.		895	—		—	1,188	—		1,188
Stock-based compensation		—	—		—	15,351	—		15,351
Other comprehensive income		—	—		—	—	74		74
Loss attributable to non-controlling interest		(725)	_		_			725	725
Net loss			—		—		—	(147,787)	(147,787)
Balance at December 31, 2015	\$	239	115,871	\$	1,159	\$ 617,145	\$	\$ (802,232)	\$ (183,928)
Exercise of stock options			1,958		20	6,422			6,442
Issuance of common stock due to conversion									
of convertible notes due 2020			12,368		123	100,838	_		100,961
Consideration allocated to reacquisition of									
conversion feature of convertible notes									
due 2020			—		—	(39,923)			(39,923)
Issuance of Series C preferred stock by Silver									
Creek Pharmaceuticals, Inc.		(827)	—		_	2,689			2,689
Stock-based compensation			—		—	15,206			15,206
Other comprehensive income			—		_			—	—
Loss attributable to non-controlling interest		(951)	—		—		—	951	951
Net loss		_	_		_	_		(153,518)	(153,518)
Balance at December 31, 2016	\$	(1,539)	130,197	\$	1,302	\$ 702,377	\$ —	\$ (954,799)	\$ (251,120)
				_					

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

# **Consolidated Statements of Cash Flows**

(in thousands)		2016		ded December 3 2015	2014	
Cash flows from operating activities						
Net loss	\$	(153,518)	\$	(147,787)	\$	(83,559)
Adjustments to reconcile net loss to net cash used in operating activities						
Non-cash interest expense		6,004		8,217		8,511
Non-cash loss on extinguishment of convertible notes due 2020		14,566		—		—
Loss on disposal of property and equipment		493		4		-
Gain on sale of property and equipment		(40)		—		—
Impairment of in-process research and development intangible asset		2,800		_		_
Depreciation and amortization expense		6,249		4,288		3,223
Stock-based compensation expense		14,865		15,351		13,197
Purchased premiums and interest on marketable securities				—		858
Changes in operating assets and liabilities:						
Accounts receivable		(10,986)		(3,170)		2,587
Prepaid expenses and other current assets		1,910		(850)		827
Inventory		(9,688)		(3,717)		
Accounts payable, accrued expenses and other		(3,869)		13,557		(646)
Deferred revenues		(39,435)		6,377		19,482
Deferred rent and tax incentives		408		2,374		712
Net cash used in operating activities		(170,241)		(105,356)		(34,808)
Cash flows from investing activities						
Purchase of marketable securities		(84,262)		—		(111,832)
Proceeds from sales and maturities of marketable securities		84,160		87,899		111,858
Purchase of property and equipment		(3,155)		(12,789)		(6,035)
Other investing activities, net						(2)
Net cash (used in) provided by investing activities		(3,257)		75,110		(6,011)
Cash flows from financing activities						
Proceeds from exercise of options and warrants to purchase common stock		6,224		10,087		10,384
Proceeds from issuance of convertible promissory notes by Silver Creek Pharmaceuticals, Inc.		_		_		1,044
Proceeds from at the market offering, net of issuance costs				38,560		_
Proceeds from issuance of senior secured notes due 2022, net of						
issuance costs				169,434		_
Proceeds from issuance of preferred stock by Silver Creek Pharmaceuticals, Inc.		3,361		2,083		_
Repayment of loans payable to Hercules Technology Growth Capital, Inc.		—		(40,000)		—
Other financing activities, net		(169)	_			(7)
Net cash provided by financing activities		9,416		180,164		11,421
Net (decrease) increase in cash and cash equivalents		(164,082)		149,918		(29,398)
Cash and cash equivalents, beginning of period		185,606		35,688		65,086
Cash and cash equivalents, end of period	\$	21,524	\$	185,606	\$	35,688
Non-cash investing and financing activities						
Purchases of property and equipment in accounts payable, accrued expenses and other	\$	130	\$	816	\$	704
Receivables related to stock option exercises in prepaid expenses and other current assets		232		14		
Receivables related to the sale of property and equipment in prepaid expenses and other current assets		40		_		_
Conversion of Silver Creek Pharmaceuticals, Inc. convertible notes into Silver Creek Series A preferred stock		_		_		1,044
Principal amount of convertible notes due 2020 converted into shares of common stock		64,209		_		_
Supplemental disclosure of cash flows						
Cash paid for interest	\$	23,914	\$	10,087	\$	9,510

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

#### Notes to Consolidated Financial Statements

# 1. Nature of the Business and Summary of Significant Accounting Policies

#### Nature of the Business

Merrimack Pharmaceuticals, Inc. (the "Company") is a biopharmaceutical company discovering, developing and commercializing innovative medicines consisting of novel therapeutics paired with diagnostics for the treatment of cancer. The Company has one marketed therapeutic oncology product and multiple targeted therapeutic oncology candidates in clinical development. The Company's most advanced program is its therapeutic ONIVYDE®, which it markets in the United States. In addition to ONIVYDE and its product candidates in clinical development, the Company has multiple product candidates in preclinical development. The Company has tailored ONIVYDE and its other product candidates to target specific disease mechanisms that its research suggests are common across many solid tumor types. The Company believes that ONIVYDE and its other product candidates have the potential to address major unmet medical needs. The Company also has an agreement to utilize its manufacturing expertise to develop, manufacture and exclusively supply bulk drug product to a third party, who will in turn process the drug into finished product and commercialize it globally following regulatory approval. 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, among other things, 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 expenses and operating losses to date, and it expects to continue to incur significant expenses and operating losses for at least the next several years. 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 performed an evaluation of its ability to continue as a going concern within one year after the date that the consolidated financial statements are issued, as described more fully in Note 22, "Going Concern."

The Company may seek additional funding through public or private debt or equity financings, through existing or new collaboration arrangements, or through divestitures of its assets. 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 or divest its assets. 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.

On January 7, 2017, the Company entered into an Asset Purchase and Sale Agreement (the "Asset Sale Agreement") with Ipsen S.A. ("Ipsen"). Pursuant to the Asset Sale Agreement, Ipsen will acquire the Company's right, title and interest in the non-cash assets, equipment, inventory, contracts and intellectual property primarily related to or used in the Company's business operations and activities involving or relating to developing, manufacturing and commercializing ONIVYDE and MM-436 (the "Commercial Business"). This transaction is described more fully in Note 23, "Subsequent Events."

#### Summary of Significant Accounting Policies

### **Segment 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 as one operating segment and the Company operates in only one geographic region.

#### **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 subsidiary, Merrimack Pharmaceuticals (Bermuda) Ltd., which was merged 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, estimates of discounts and allowances related to commercial sales of ONIVYDE, estimates utilized in the valuation of inventory, useful lives with respect to long-lived assets and intangible assets, accounting for stock-based compensation, contingencies, intangible assets, goodwill, in-process research and development ("IPR&D"), 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.

#### 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 December 31, 2016 and 2015, the Company recorded restricted cash of \$0.8 million and \$0.7 million, respectively, which was primarily related to the Company's facility lease.

#### **Marketable Securities**

The Company classifies marketable securities with a remaining maturity when purchased of greater than three months as available-for-sale. Availablefor-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. 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 operations and 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). Realized gains and losses are recognized in interest income. Any premium or discount arising at purchase is amortized and/or accreted to interest income.

#### Inventory

The Company values its inventories at the lower of cost or net realizable value. The Company determines the cost of its inventories, which includes amounts related to materials and manufacturing overhead, on a first-in, first-out basis. The Company performs an assessment of the recoverability of capitalized inventory during each reporting period, and it writes down any excess and obsolete inventories to their realizable value in the period in which the impairment is first identified. Such impairment charges, should they occur, are recorded as a component of "Cost of revenues."

The Company capitalizes inventory costs associated with the Company's products after regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. Inventory acquired prior to receipt of marketing approval of a product candidate is expensed as research and development expense as



incurred. Inventory that can be used in either the production of clinical or commercial product is expensed as research and development expense when selected for use in a clinical manufacturing campaign.

Shipping and handling costs for product shipments are recorded as incurred as a component of "Cost of revenues" along with amortization expense related to definite-lived intangible assets, costs associated with manufacturing the product and any inventory reserves or write-downs.

## **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.

#### **Goodwill and Intangible Assets**

Goodwill and indefinite-lived intangible assets, including IPR&D assets, are evaluated for impairment on an annual basis or more frequently if an indicator of impairment is present. The Company performs its annual goodwill and IPR&D impairment evaluations on August 31st.

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 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 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 company operates in one operating segment, which is considered the only reporting unit.

The Company commences amortization of indefinite-lived intangible assets, such as IPR&D, once the associated research and development efforts have been completed. The Company amortizes these product-related intangible assets over their estimated useful lives, and amortization expense is recorded as a component of "Cost of revenues." The Company amortizes other definite-lived assets, such as core technology, over their estimated useful lives as a component of "Research and development expenses." Definite-lived intangible assets are evaluated for impairment whenever events or circumstances indicate that the carrying value may not be fully recoverable.



## **Accrued Expenses**

As part of the process of preparing financial statements, the Company is required to estimate accrued expenses. This process involves identifying services that have been performed on the Company's behalf and estimating the level of services performed and the associated costs incurred for such services where the Company has not yet been invoiced or otherwise notified of actual cost. The Company records these estimates in its 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, the Company estimates 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, the Company adjusts the accrual accordingly. In the event that the Company does not identify costs that have been incurred or it under or overestimates the level of services performed or the costs of such services, its 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. The Company prepares its estimates based on the facts and circumstances known to it at the time and in accordance with GAAP. There have been no material changes in estimates for the periods presented.

## **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 recognizes revenue when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the price to the customer is fixed or determinable; and collectability is reasonably assured.

#### Product Revenues, Net

The Company sells ONIVYDE to a limited number of specialty pharmaceutical distributors in the United States (collectively, its "Distributors"). The Company's Distributors subsequently resell the products to healthcare providers. The Company recognizes revenue on product sales when title and risk of loss have passed to the Distributor, which is typically upon delivery. Product revenues are recorded net of applicable reserves for discounts and allowances.

In order to conclude that the price is fixed or determinable, the Company must be able to reasonably estimate its net product revenues upon delivery to its Distributors. As such, the Company estimates its net product revenues by deducting from its gross product revenues trade allowances, estimated contractual discounts, estimated Medicaid rebates, estimated reserves for product returns and estimated costs of other incentives offered to patients.

These discounts and allowances are based on estimates of the amounts earned or to be claimed on the related sales. The Company's estimates take into consideration its historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted Distributor buying and payment patterns. Actual amounts may ultimately differ from the Company's estimates. If actual results vary, the Company will adjust these estimates, which could have an effect on earnings in the period of adjustment.

Product revenue reserves and allowances that reduce gross revenue are categorized as follows:

*Trade Allowances:* The Company pays fees to its Distributors for providing certain data to the Company as well as for maintaining contractual inventory and service levels. These trade allowances are recorded as a reduction to accounts receivable on the consolidated balance sheet at the time revenue is recognized.

*Rebates and Chargeback Discounts:* The Company is subject to discount obligations under state Medicaid programs and the Public Health Service 340B Drug Pricing Program, contracts with Federal government entities purchasing via the Federal Supply Schedule and various private organizations, such as group purchasing organizations (collectively, its "Third-party Payors"). The Company estimates the rebates and chargeback discounts it will provide to Third-party Payors, based upon its estimated payor mix, and deducts these estimated amounts from its gross product revenues at the time revenue is recognized. Chargeback discounts are processed when the Third-party Payor purchases the product at a discount from the Distributor, who then in turn charges back to the Company the difference between the price initially paid by the Distributor and the discounted price paid by the Third-party Payor. These chargeback discounts are recorded as a reduction to accounts receivable on the consolidated balance sheet at the time revenue is recognized. Rebates that are invoiced directly to the Company are recorded as accrued liabilities on the consolidated balance sheet at the time revenue is recognized.

*Product Returns:* An allowance for product returns is established for returns expected to be made by Distributors and is recorded at the time revenue is recognized, resulting in a reduction to product sales. In accordance with contractual terms, Distributors have the right to return unopened and undamaged product that is within a permissible number of months before and after the product's expiration date, subject to contractual limitations. The Company has the ability to monitor inventory levels and the shelf life of product at Distributors and can contractually control the amount of inventory that is sold to Distributors. Based on inventory levels held by Distributors and the structure of the Company's distribution model, the Company has concluded that it has the ability to reasonably estimate product returns at the time revenue is recognized. The Company's estimated rate of return is based on historical rates of return for comparable oncology products.

Other Incentives: The Company offers co-pay mitigation support to commercially insured patients. The Company's co-pay mitigation program is intended to reduce each participating patient's portion of the financial responsibility for a product's purchase price to a specified dollar amount. Based upon the terms of the Company's co-pay mitigation program, the Company estimates average co-pay mitigation amounts in order to establish a reserve for co-pay mitigation claims and deducts these estimated amounts from its gross product revenues at the later of the date that (i) the revenues are recognized or (ii) the incentive is offered. Claims under the Company's co-pay mitigation program are subject to expiration.

#### License and Collaboration Revenues

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.

The revenue recognition guidance related to multiple-element arrangements requires entities to separate and allocate consideration in a multipleelement 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.

In September 2014, the Company entered into a license and collaboration agreement (the "Baxalta Agreement") with Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA (collectively, "Baxter") for the development and commercialization of ONIVYDE outside of the United States and Taiwan (the "Licensed Territory"). In connection with Baxter International Inc.'s separation of the Baxalta business, the Baxalta Agreement was assigned to Baxalta Incorporated, Baxalta US Inc. and Baxalta GmbH (collectively, "Baxalta") during the second quarter of 2015. The Baxalta Agreement 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 also 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 4, "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.

## Other Revenues

The Company is a party to separate commercial supply agreements with Baxalta and PharmaEngine, Inc. ("PharmaEngine") pursuant to which the Company supplies ONIVYDE to these entities. Revenue is recognized under these commercial supply arrangements when the counterparty takes delivery of the commercial supply product and when the other general revenue recognition criteria outlined above are met.

The Company is also eligible to receive royalty revenues on Baxalta's net sales of ONIVYDE in the Licensed Territory. The Company recognizes royalty revenues in the period that the related sales occur.

### **Research and Development Expenses**

Research and development expenses are charged to expense as incurred. Research and development expenses are comprised of 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.

#### Selling, General and Administrative Expenses

Selling, general and administrative expenses are comprised of salaries and other related costs for personnel, including stock-based compensation expenses and benefits, in the Company's commercial, legal, intellectual property, business development, finance, information technology, corporate communications, investor relations and human resources departments. Other selling, general and administrative expenses include costs to support commercial sales, employee training and development, board of directors costs, depreciation, insurance expenses, facility-related costs not otherwise included in research and development expenses, professional fees for legal services, including patent-related expenses, and accounting and information technology services.

In connection with the commercial launch of ONIVYDE on October 26, 2015, the Company began incurring advertising expenses. Advertising expenses are expensed as incurred as a component of selling, general and administrative expenses. For the years ended December 31, 2016 and 2015, advertising expenses totaled \$4.5 million and \$1.0 million, respectively.

## **Stock-Based Compensation Expense**

The Company accounts for its stock-based compensation awards in accordance with Accounting Standards Codification ("ASC") 718, *Compensation* – *Stock Compensation*. ASC 718 requires all share-based payments to employees, including grants of employee stock options, to be recognized in the consolidated statements of operations and comprehensive loss based on their grant date fair values. For stock options granted to employees and to members of the Company's Board of Directors for their service on the Board of Directors, the Company estimates the grant date fair value of each option award using the Black-Scholes option pricing model. The use of the Black-Scholes option pricing model requires the Company to make assumptions with respect to the expected term of the option, the expected volatility of the Company's common stock consistent with the expected term of the option and the expected dividend yield of the Company's common stock. Stock-based compensation expense related to employee stock options 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. Stock-based compensation expense is then recognized on a straight-line basis over the vesting period, which is also the requisite service period.

The Company records stock options issued to non-employees at fair value, 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 Loss**

Comprehensive loss consists of net loss and unrealized gains and losses on available-for-sale marketable securities.

### Other (Expense) Income, Net

The Company records income related to tax incentive awards, foreign currency gains and losses and other income or expense-related items as components of "Other (expense) income, net" within the consolidated statements of operations and comprehensive loss.

The Company has been awarded tax incentives by the Massachusetts Life Sciences Center ("MLSC"), an independent agency of the Commonwealth of Massachusetts. These tax incentives require that the Company achieve certain hiring targets. Failure to maintain the additional headcount in subsequent periods could require the Company to repay some or all of the incentives. The Company recognizes the benefit of these incentives on a straight-line basis over the five-year performance period of each award, beginning when the Company achieves the hiring goal target, with a cumulative catch-up recognized in the period that the hiring goal target is achieved. The Company received MLSC tax incentives in 2011, 2013, 2014 and 2015 totaling \$3.8 million in the aggregate, allowing the Company to monetize approximately \$3.4 million of state research and development tax credits. As a result of the October 2016 corporate restructuring described more fully in Note 13, "Restructuring Activities," the Company determined that it would be required to repay a portion of the 2014 and 2015 tax incentives received from the MLSC in the aggregate amount of \$1.3 million. Such amounts have been classified as current liabilities as of December 31, 2016.

The Company recognized \$0.1 million, \$0.7 million and \$0.4 million in income related to these MLSC tax incentives during the years ended December 31, 2016, 2015 and 2014, respectively.

### **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.

### **Concentration of Credit Risk**

Financial instruments that subject the Company to credit risk consist primarily of cash, cash equivalents and marketable securities. The Company places its cash deposits in accredited financial institutions and, therefore, the Company's management believes these funds are subject to minimal credit risk. The Company invests cash equivalents and marketable 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. The Company also is subject to credit risk from its accounts receivable related to its product sales and collaborators. The Company evaluates the creditworthiness of each of its customers and has determined that all of its customers are creditworthy. To date, the Company has not experienced significant losses with respect to the collection of its accounts receivable.

Gross revenues from each of the Company's customers who individually accounted for 10% or more of total gross revenues for the years ended December 31, 2016, 2015 and 2014 consisted of the following:

	Yea	Years Ended December 31,				
	2016	2015	2014			
Baxalta	60%	93%	10%			
Sanofi		_	90%			
AmerisourceBergen Corporation	15%	<10%				
McKesson Corporation	16%	<10%				

Gross accounts receivable related to each of the Company's customers who individually accounted for 10% or more of total gross accounts receivable as of December 31, 2016 and 2015 consisted of the following:

	Decem	oer 31,
	2016	2015
Baxalta	20%	29%
AmerisourceBergen Corporation	25%	29%
McKesson Corporation	32%	25%
Cardinal Health, Inc.	21%	16%

### **Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, "Revenue from Contracts with Customers (Topic 606)," 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 was originally effective for interim and annual periods beginning after December 15, 2016 and allows for adoption using a full retrospective method, or a modified retrospective method. Early adoption was originally not permitted. Subsequent to the issuance of ASU 2014-09, the FASB also issued the following updates related to ASC 606, *Revenue from Contracts with Customers:* 

- In August 2015, the FASB issued ASU 2015-14, "Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date," whereby the effective date for the new revenue standard was deferred by one year. As a result of ASU 2015-14, the new revenue standard is now effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2017, and early adoption is now permitted for annual periods beginning after December 15, 2016, including interim periods within that annual period.
- In March 2016, the FASB issued ASU 2016-08, "Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)," to clarify the implementation guidance on principal versus agent considerations.
- In April 2016, the FASB issued ASU 2016-10, "Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing," to clarify the principle for determining whether a good or service is "separately identifiable" from other promises in the contract and to clarify the categorization of licenses of intellectual property.
- In May 2016, the FASB issued ASU 2016-12, "Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Technical Expedients," to clarify guidance on transition, determining collectibility, non-cash consideration and the presentation of sales and other similar taxes.
- In December 2016, the FASB issued ASU 2016-20, "Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers," that allows entities not to make qualitative disclosures about remaining performance obligations in certain cases, adds disclosure requirements for entities that elect certain optional exemptions and adds twelve additional technical corrections and improvements to the new revenue standard.

The Company is currently evaluating the potential impact that the adoption of this guidance and the related transition guidance may have on the consolidated financial statements, including the adoption method to be utilized.

In August 2014, the FASB issued ASU 2014-15, "Presentation of Financial Statements – Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern," 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 is effective for annual and interim reporting periods ending after December 15, 2016, and the Company adopted this guidance for the year ended December 31, 2016, as described more fully in Note 22, "Going Concern."

In January 2016, the FASB issued ASU 2016-01, "Financial Statements – Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Liabilities," which contains a number of provisions related to the measurement, presentation and disclosure of financial instruments. This guidance will be effective for annual reporting periods beginning after December 15, 2017, including interim periods within those annual periods. Early adoption of this guidance is not permitted with the exception of certain specific presentation requirements that are not currently applicable to the Company. The Company does not anticipate a material impact to the consolidated financial statements as a result of the adoption of this guidance.

In February 2016, the FASB issued ASU 2016-02, "Leases (Topic 842)," which supersedes all existing lease accounting guidance within ASC 840, *Leases*. The new standard requires that lease assets and lease liabilities be recognized by lessees for those leases previously classified as operating leases under ASC 840, with limited exceptions. This update also creates a new definition of a lease and provides guidance as to whether a contract is or contains a lease. This guidance will be effective for annual reporting periods beginning after December 15, 2018, including interim periods within those annual reporting periods, and early adoption is permitted. The Company is currently evaluating the potential impact that the adoption of this guidance may have on the consolidated financial statements.

In March 2016, the FASB issued ASU 2016-06, "Derivatives and Hedging (Topic 815): Contingent Put and Call Options in Debt Instruments," which clarifies the requirements for assessing whether contingent call or put options that can accelerate the repayment of principal on debt instruments are clearly and closely related to their debt hosts. This guidance will be effective for annual reporting periods beginning after December 15, 2016, including interim periods within those annual reporting periods, and early adoption is permitted. The Company does not anticipate a material impact to the consolidated financial statements as a result of the adoption of this guidance.

In March 2016, the FASB issued ASU 2016-09, "Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting," which simplifies several areas of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either liabilities or equity and classification of excess tax benefits on the statement of cash flows. This guidance also permits a new entity-wide accounting policy election to either estimate the number of awards that are expected to vest or account for forfeitures when they occur. This guidance will be effective for annual reporting periods beginning after December 15, 2016, including interim periods within those annual reporting periods, and early adoption is permitted. An entity that elects early adoption must adopt all of the amendments in the same period. The Company is currently evaluating the potential impact that the adoption of this guidance may have on the consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, "Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments," which represents a new credit loss standard that will change the impairment model for most financial assets and certain other financial instruments. Specifically, this guidance will require entities to utilize a new "expected loss" model as it relates to trade and other receivables. In addition, entities will be required to recognize an allowance for estimated credit losses on available-for-sale debt securities, regardless of the length of time that a security has been in an unrealized loss position. This guidance will be effective for annual reporting periods beginning after December 15, 2019, including interim periods within those annual reporting periods, and early adoption is permitted. The Company is currently evaluating the potential impact that the adoption of this guidance may have on the consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, "Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments," which is intended to reduce diversity in practice in how entities present certain types of cash transactions in the statement of cash flows. This guidance also clarifies how the predominance principle should be applied when classifying cash receipts and cash payments that have attributes of more than one class of cash flows. This guidance will be effective for annual reporting periods beginning after December 15, 2017, including interim periods within those annual reporting periods, and early adoption is permitted. An entity that elects early adoption must adopt all of the amendments in the same period. The Company does not anticipate a material impact to the consolidated financial statements as a result of the adoption of this guidance.

In November 2016, the FASB issued ASU 2016-18, "Statement of Cash Flows (Topic 230): Restricted Cash," which will require entities to show the change in the total of cash, cash equivalents, restricted cash and restricted cash equivalents within the statement of cash flows. As a result, entities will no longer separately present transfers between unrestricted cash and restricted cash. This guidance will be effective for annual reporting periods beginning after December 15, 2017, including interim periods within those annual reporting periods, and early adoption is permitted. The Company does not anticipate a material impact to the consolidated financial statements as a result of the adoption of this guidance.

In January 2017, the FASB issued ASU 2017-04, "Intangibles – Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment," which will eliminate the requirement to calculate the implied fair value of goodwill, commonly referred to as "Step 2" in the current goodwill impairment test. An entity will still have the option to perform the qualitative assessment for a reporting unit to determine if the quantitative impairment test is necessary. This guidance will be effective for annual and interim impairment tests performed in annual reporting periods beginning after December 15, 2020, and early adoption is permitted for annual or interim impairment tests performed after January 1, 2017. The Company is currently evaluating the potential impact that the adoption of this guidance may have on the consolidated financial statements.

Other accounting standards that have been issued by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on the Company's consolidated financial statements upon adoption.

# 2. Consolidated Subsidiaries

## Silver Creek Pharmaceuticals, Inc.

On August 20, 2010, the Company acquired a controlling interest in Silver Creek. The Company has concluded that Silver Creek is a variable interest entity and that the Company is the primary beneficiary. The Company has the ability to direct the activities of Silver Creek through its ownership percentage and through the board of director seats controlled by the Company and its de facto agents. As such, Silver Creek is consolidated by the Company.

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 related accrued interest converted into 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.

During the year ended December 31, 2015, Silver Creek issued and sold a total of 1.6 million shares of Silver Creek Series B preferred stock at a price of \$1.35 per share to investors and received net cash proceeds of \$2.1 million, after deducting issuance costs. As a result of changes to the ownership composition of Silver Creek as of December 31, 2015, the non-controlling interest in Silver Creek increased by approximately \$0.9 million.

As described more fully in Note 12, "Borrowings," Silver Creek issued \$1.0 million of convertible promissory notes (the "Silver Creek Notes") in May 2016. In August 2016, Silver Creek issued \$0.2 million of additional Silver Creek Notes under the same terms as the May 2016 issuance. In December 2016, these outstanding borrowings and related accrued interest were converted into shares of Silver Creek Series C preferred stock at the Series C preferred stock value of \$1.50 per share. In addition, Silver Creek sold 1.5 million additional shares of its Series C preferred stock to new investors at a price of \$1.50 per share and received net cash proceeds of \$2.1 million, after deducting issuance costs. In conjunction with this sale, Silver Creek also issued warrants to purchase 1.9 million shares of Silver Creek Series C preferred stock to the same new investors. As a result of changes to the ownership composition of Silver Creek as of December 31, 2016, the non-controlling interest in Silver Creek decreased by approximately \$0.8 million.

As of December 31, 2016 and 2015, the Company owned approximately 50% and 56% of the outstanding voting stock of Silver Creek, respectively, and recorded a non-controlling interest of approximately \$(1.5) million and \$0.2 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, Series B and Series C preferred stock.

As of December 31, 2016, the Company consolidated Silver Creek's total assets and total liabilities of \$2.0 million and \$2.0 million, respectively. As of December 31, 2015, the Company consolidated Silver Creek's total assets and total liabilities of \$0.8 million and \$0.2 million, respectively. As of December 31, 2016 and 2015, the Company's unrestricted cash and cash equivalents balance included \$1.9 million and \$0.7 million, respectively, of cash and cash equivalents held by Silver Creek that is designated for the operations of Silver Creek.

#### 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.

## 3. Net Loss Per Common Share

Basic net loss per share is calculated by dividing the net loss available to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss available to common stockholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, convertible preferred stock, stock options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

As discussed in Note 12, "Borrowings," in July 2013, the Company issued \$125.0 million aggregate principal amount of 4.50% convertible notes due 2020 (the "Convertible Notes") in an underwritten public offering. Following the repayment and satisfaction in full of the Company's obligations to Hercules Technology Growth Capital, Inc. ("Hercules") under its Loan and Security Agreement with Hercules (the "Loan Agreement"), which occurred in December 2015, upon any conversion of the Convertible Notes, the Convertible 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. As of December 31, 2016, \$60.8 million aggregate principal amount of the Convertible Notes remain outstanding.

The stock options, warrants and conversion premium on the Convertible Notes are excluded from the calculation of diluted loss per share because the net loss for the years ended December 31, 2016, 2015 and 2014 causes such securities to be anti-dilutive. Securities excluded from the calculation of diluted loss per share are shown in the chart below:

	Year	Years Ended December 31,				
(in thousands)	2016	2015	2014			
Common stock warrants			2,381			
Outstanding options to purchase common stock	19,025	19,211	19,567			
Conversion of the Convertible Notes	12,158	25,000	25,000			

## 4. License and Collaboration Agreements

## Baxalta

On September 23, 2014, the Company and Baxter entered into the Baxalta Agreement for the development and commercialization of ONIVYDE in the Licensed Territory. In connection with Baxter's separation of the Baxalta business, the Baxalta Agreement was assigned to Baxalta during the second quarter of 2015. As part of the Baxalta Agreement, the Company granted Baxalta an exclusive, royalty-bearing right and license under the Company's patent rights and know-how to develop and commercialize ONIVYDE in the Licensed Territory. Baxalta is responsible for using commercially reasonable efforts to develop, obtain regulatory approvals for and, following regulatory approval, commercialize ONIVYDE in the Licensed Territory. A joint steering committee comprised of an equal number of representatives from each of Baxalta and the Company is responsible for approving changes to the global development plan for ONIVYDE, including all budgets, and overseeing the parties' development and commercialization activities with respect to ONIVYDE. Unless otherwise agreed, the Company will be responsible for conducting all clinical trials contemplated by the global development plan for ONIVYDE and manufacturing all clinical material needed for such trials. Baxalta also has the option to manufacture ONIVYDE, in which case the Company will perform a technology transfer of its manufacturing process to Baxalta.

Under the terms of the Baxalta Agreement, the Company received a \$100.0 million nonrefundable upfront cash payment in September 2014. In addition, the Company is eligible to receive from Baxalta (i) up to an aggregate of \$100.0 million upon the achievement of specified research and development milestones, of which the Company has received \$62.5 million from Baxalta through December 31, 2016, (ii) up to an aggregate of \$520.0 million upon the achievement of specified regulatory milestones, of which the Company has received \$60.0 million from Baxalta through December 31, 2016, and (iii) up to an aggregate of \$250.0 million upon the achievement of specified regulatory milestones, of which the Company has received \$60.0 million from Baxalta through December 31, 2016, and (iii) up to an aggregate of \$250.0 million upon the achievement of specified sales milestones. Under the terms of the Baxalta Agreement, the Company will bear up to the first \$98.8 million of costs related to the development of ONIVYDE for pancreatic cancer patients who have not previously received gemcitabine-based therapy; however, the Company expects most of these costs to be offset by payments received upon the achievement of clinical trial-related milestones. The Company and Baxalta will share equally all other clinical trial costs contemplated by the global development plan. The Company is also entitled to tiered, escalating royalties ranging from sub-teen double digits to low twenties percentages of net sales of ONIVYDE in the Licensed Territory.

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

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

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

The Company has determined that the collaboration represents a services agreement and as such has estimated the level of effort expected to be completed as a result of providing the identified deliverables. The Company will recognize revenue from the nonrefundable upfront payment, forecasted non-substantive milestone payments and estimated payments related to discovery, research, development and technology transfer services based on proportional performance as effort is completed over the expected services period, which is estimated to be substantially complete by June 30, 2022. The Company will periodically review and, if necessary, revise the estimated service period related to its collaboration with Baxalta. As of December 31, 2016, the Company has achieved \$62.5 million of the \$90.0 million of forecasted non-substantive milestones that are included in the Company's proportional performance revenue recognition model and \$60.0 million of the \$530.0 million of substantive milestones that are included in the Baxalta Agreement.

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.

From the inception of the Baxalta Agreement through December 31, 2016, the Company has achieved the following substantive and non-substantive milestones:

- In July 2015, the European Medicines Agency ("EMA") accepted for review a Marketing Authorization Application ("MAA") filed by Baxalta
  for ONIVYDE. As a result of this acceptance, the Company recognized \$20.0 million of license and collaboration revenue related to a
  substantive milestone payment owed from Baxalta.
- In August 2015, the Company achieved a \$15.0 million milestone related to the submission of the protocol for the Company's Phase 2 clinical trial of ONIVYDE in front-line metastatic pancreatic cancer. This milestone is a non-substantive milestone, and revenue related to the achievement of this milestone will be recognized through the proportional performance revenue recognition model.
- In October 2015, the Company achieved a \$47.5 million milestone related to the enrollment of the first patient in a Phase 2 clinical trial of ONIVYDE in front-line pancreatic cancer. This milestone is a non-substantive milestone, and revenue related to the achievement of this milestone will be recognized through the proportional performance revenue recognition model.
- In June 2016, the South Korean Ministry of Food and Drug Safety (the "MFDS") accepted for review a new drug application filed by Baxalta for ONIVYDE. As a result of this acceptance, the Company recognized \$10.0 million of license and collaboration revenue related to a substantive milestone payment owed from Baxalta.
- In October 2016, the European Commission granted marketing authorization to Baxalta for ONIVYDE in combination with 5-FU and leucovorin for the treatment of adult patients with metastatic adenocarcinoma of the pancreas who have progressed following gemcitabine-based therapy. As a result of this approval and the first commercial sale of ONIVYDE made by Baxalta during the fourth quarter of 2016, the Company recognized \$30.0 million of license and collaboration revenue related to a substantive milestone payment owed from Baxalta.

During the years ended December 31, 2016, 2015 and 2014, the Company recognized license and collaboration revenues based on the following components of the Baxalta Agreement:

	Years Ended December 31,						
(in thousands)		2016 2015				2014	
Proportional performance revenue recognition model	\$	47,119	\$	64,930	\$	10,460	
Substantive milestones		40,000		20,000		—	
Total	\$	87,119	\$	84,930	\$	10,460	

During the year ended December 31, 2016, the Company also recognized royalty revenues of \$0.2 million related to the Baxalta Agreement.

As of December 31, 2016 and 2015, the Company maintained the following assets and liabilities related to the Baxalta Agreement:

	December 31,							
(in thousands)	2016		2015					
Accounts receivable, billed	\$ 86	) \$	1,336					
Accounts receivable, unbilled	58	1	626					
Deferred revenues	56,77	)	97,365					

Of the \$56.8 million of deferred revenue related to the Baxalta Agreement as of December 31, 2016, \$36.2 million is classified as current in the consolidated balance sheets based upon the Company's estimate of revenue that will be recognized under the proportional performance revenue recognition model as a result of effort expected to be completed within the next twelve months.

In February 2016, the Company and Baxalta entered into a commercial supply agreement (the "Baxalta Supply Agreement") pursuant to which the Company supplies ONIVYDE to Baxalta and, at Baxalta's option, manages fill and finish activities conducted by a third-party contract manufacturer for Baxalta. The Company began supplying ONIVYDE under the Baxalta Supply Agreement during the second quarter of 2016 and recognized \$3.6 million of revenue during the year ended December 31, 2016.

## 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. Following the termination of the Sanofi Agreement, the Company is not entitled to receive any additional fees, milestone payments or reimbursements from the collaboration.

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

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

At the inception of the collaboration, the Company determined that the license, the right to future technology, back-up compounds, participation on steering committees and manufacturing services performance obligations comprising the Sanofi Agreement represented a single unit of accounting. As the Company could not reasonably estimate its level of effort over the collaboration, the Company recognized revenue from the upfront payment, milestone payments 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.

The Company recognized no revenue under the Sanofi agreement during the years ended December 31, 2016 or 2015. During the year ended December 31, 2014, the Company recognized revenue based on the following components of the Sanofi agreement:

(in thousands)	Year Ended D	ecember 31, 2014
Upfront payment	\$	39,306
Milestone payment		16,377
Development services		18,904
Manufacturing services and other		17,709
Total	\$	92,296

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.

The Company maintained no assets or liabilities related to the Sanofi Agreement as of either December 31, 2016 or 2015.

## PharmaEngine

On May 5, 2011, the Company and 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 ONIVYDE. In exchange, the Company agreed to pay PharmaEngine a nonrefundable, noncreditable upfront payment of \$10.0 million and up to an additional \$80.0 million in aggregate development and regulatory milestones and \$130.0 million in aggregate sales milestones. PharmaEngine is also entitled to tiered royalties on net sales of ONIVYDE in Europe and certain countries in Asia. PharmaEngine is not responsible for any future development costs of ONIVYDE except those required specifically for regulatory approval in Taiwan.

On September 22, 2014, the Company amended the PharmaEngine Agreement to redefine sublicense revenue and reduce the portion of sublicense revenue that the Company is required to pay to PharmaEngine. As a result of this amendment, the Company made a \$7.0 million milestone payment to PharmaEngine in September 2014. Additionally, as a result of this amendment, a previously contingent \$5.0 million milestone payment was paid to PharmaEngine in the second quarter of 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. In July 2015, the Company made an \$11.0 million milestone payment to PharmaEngine in connection with the EMA's acceptance for review of an MAA for ONIVYDE, which occurred, and was recognized as research and development expense, in the second quarter of 2015. In June 2016, the Company made a \$10.0 million milestone payment to PharmaEngine in connection with the MFDS's acceptance for review of a new drug application for ONIVYDE, which occurred, and was recognized as research and development expense, in the second quarter of 2016, the Company made a \$25.5 million milestone payment to PharmaEngine in connection with the Second quarter of 2016, the Company made a \$25.5 million milestone payment to PharmaEngine in connection with Baxalta's receipt of marketing authorization from the European Commission for ONIVYDE in combination with 5-FU and leucovorin for the treatment of adult patients with metastatic adenocarcinoma of the pancreas who have progressed following gemcitabine-based therapy, which occurred, and was recognized as research and development expense, in the fourth quarter of 2016.

During the years ended December 31, 2016, 2015 and 2014, the Company recognized research and development expenses of \$35.6 million, \$11.4 million and \$12.6 million, respectively, related to the PharmaEngine Agreement.

Under the PharmaEngine Agreement, the Company is also obligated to pay PharmaEngine royalties on Baxalta's net sales of ONIVYDE in the Licensed Territory. The Company records these royalty expenses in the period that the related sales occur, and such royalty expenses are recorded as a component of "Cost of revenues" within the consolidated statements of operations and comprehensive loss. During the year ended December 31, 2016, the Company recorded \$0.1 million of royalty expenses related to PharmaEngine.

In August 2015, the Company and PharmaEngine also entered into a commercial supply agreement (the "PharmaEngine Supply Agreement") pursuant to which the Company supplies ONIVYDE to PharmaEngine. The Company began supplying ONIVYDE

under the PharmaEngine Supply Agreement in the second quarter of 2016 and recognized \$0.3 million of revenue during the year ended December 31, 2016. No revenue related to the PharmaEngine Supply Agreement was recognized during the year ended December 31, 2015.

#### Actavis

In November 2013, the Company and Watson Laboratories, Inc. ("Actavis") entered into a development, license and supply agreement (the "Actavis Agreement") pursuant to which the Company will develop, manufacture and exclusively supply the bulk form of doxorubicin hydrochloride (HCl) liposome injection (the "Initial Product") to Actavis. The Actavis Agreement was subsequently amended in January 2015 to transfer certain responsibilities from the Company to Actavis in exchange for reducing the aggregate milestone payments that the Company is eligible to receive by \$0.4 million. The Company will manufacture and supply the Initial Product to Actavis in bulk form at an agreed upon unit price, and 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 identities of which will be mutually agreed upon. The Company is eligible to receive up to \$15.1 million in milestone and development payments, as well as additional reimbursement for specific activities performed by the Company at the request of Actavis. The Company will also receive a mid-twenties percentage of net profits on global sales of the Initial Product and any additional products. In October 2016, the U.S. Food and Drug Administration (the "FDA") accepted for review an Abbreviated New Drug Application filed by Actavis for the Initial Product, which triggered the payment obligation of \$1.1 million of milestones from Actavis to the Company. As of December 31, 2016, the Company had received \$4.9 million in total milestone and development payments and reimbursement for specific activities from Actavis.

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

The Company applied revenue recognition guidance to determine whether the performance obligations under the Actavis Agreement, including the license, participation on steering committees, development services, and manufacturing and supply services could be accounted for separately or as a single unit of accounting. The Company determined that these obligations represent a single unit of accounting and will recognize revenue as product is supplied to Actavis. Therefore, the Company has recorded \$5.1 million and \$4.0 million of billed and billable milestones and development expenses related to the Actavis Agreement as deferred revenue as of December 31, 2016 and 2015, respectively. This revenue is expected to be recognized by the Company over the ten year period that begins after Actavis' first sale of the applicable product under the Actavis Agreement.

#### 5. Product Revenue Reserves and Allowances

The following table summarizes activity in each of the product revenue reserve and allowance categories for the year ended December 31, 2016:

(in thousands)	Trade Allowan		0	Rebates and Chargeback Discounts	Product Returns	]	Other Incentives	Total
Balance at December 31, 2015	\$	138	\$	362	\$ 32	\$	8	\$ 540
Provisions related to sales in the current year	1	,900		5,928	397		5	8,230
Adjustments related to sales in the prior year		—		(213)	—		—	(213)
Credits and payments made	(1	,507)		(5,077)	(26)		(7)	(6,617)
Balance at December 31, 2016	\$	531	\$	1,000	\$ 403	\$	6	\$ 1,940

### 6. Fair Value of Financial Instruments

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



assumptions. This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value.

#### **Recurring Fair Value Measurements**

The carrying values of cash, restricted cash, prepaid expenses, accounts receivable, accounts payable and accrued expenses, and other short-term assets and liabilities approximate their respective fair values due to the short-term maturities of these assets and liabilities.

The following tables summarize assets and liabilities measured at fair value on a recurring basis as of December 31, 2016 and 2015 and the input categories associated with those assets and liabilities:

	December 31, 2016					
(in thousands)		Level 1		Level 2		Level 3
Assets:						
Money market funds	\$	12,373	\$		\$	—
Totals	\$	12,373	\$		\$	
Liabilities:						
Silver Creek warrant liability	\$		\$		\$	1,499
Totals	\$		\$		\$	1,499
			Dec	ember 31, 2015		
(in thousands)	_	Level 1		Level 2		Level 3
Assets:						
Money market funds	\$	704	\$		\$	
Totals	\$	704	\$	_	\$	_

In December 2016, Silver Creek issued warrants to purchase an aggregate of 1.9 million shares of Silver Creek Series C preferred stock (the "Silver Creek warrants"). The issuance of the Silver Creek warrants is described more fully in Note 12, "Borrowings." The Silver Creek warrants were valued at \$1.5 million as of December 31, 2016 using a Black-Scholes option pricing model, probability-weighted for different exercise scenarios. The key assumptions utilized in the Black-Scholes option pricing model as of December 31, 2016 were a risk-free interest rate of 2.3%, expected dividend yield of 0.0%, expected volatility of 61.7% and expected term of 6.9 years. Changes in the fair value of the Silver Creek warrants in subsequent periods will be recognized as a component of "Other income, net" in the consolidated statements of operations and comprehensive loss.

There were no changes in valuation techniques or transfers between the fair value measurement levels during the years ended December 31, 2016 or 2015. There were no liabilities measured at fair value on a recurring basis as of December 31, 2015.

### **Non-Recurring Fair Value Measurements**

Certain assets, including IPR&D intangible assets, may be measured at fair value on a non-recurring basis in periods subsequent to initial recognition. As described more fully in Note 9, "Goodwill and Intangible Assets, Net," the Company performed an interim impairment assessment during the fourth quarter of 2016 on the Company's IPR&D asset related to the antibody-targeted nanotherapeutic that contains a chemotherapy drug. The Company utilized a probability-weighted discounted cash flow analysis under the income approach in performing this assessment. As a result of this interim impairment assessment, the fair value of this IPR&D asset was determined to be zero as of December 31, 2016. No non-recurring fair value measurements were required during the year ended December 31, 2015.

#### **Other Fair Value Measurements**

The estimated fair value of the Convertible Notes was \$57.5 million as of December 31, 2016. The Company estimated the fair value of the Convertible Notes by using a quoted market rate in an inactive market, which is classified as a Level 2 input. The carrying value of the Convertible Notes was \$47.0 million as of December 31, 2016 due to the bifurcation of the conversion feature of the Convertible Notes as described more fully in Note 12, "Borrowings."

As discussed in Note 12, "Borrowings," in December 2015, the Company closed a private placement of \$175.0 million aggregate principal amount of 11.50% senior secured notes due 2022 (the "2022 Notes"). The Company estimated the fair value of the

2022 Notes by using publicly-available information related to one of the 2022 Notes borrower's portfolio of debt investments based on unobservable inputs, which is classified as a Level 3 input. The estimated fair value of the 2022 Notes was \$167.0 million as of December 31, 2016. The carrying value of the 2022 Notes was \$169.9 million as of December 31, 2016.

## 7. Marketable Securities

As of both December 31, 2016 and 2015, the Company maintained only cash equivalents comprised of money market funds. As of December 31, 2016, the Company did not hold any securities that were in an unrealized loss position.

There were no realized gains or losses on available-for-sale securities during the years ended December 31, 2016, 2015 or 2014.

## 8. Inventory

Inventory as of December 31, 2016 and 2015 consisted of the following:

	December 31,						
(in thousands)	2016		2015				
Raw materials	\$ 4,483	\$	900				
Work in process	8,651		2,743				
Finished goods	1,420		74				
Total inventory	\$ 14,554	\$	3,717				

Inventory acquired prior to receipt of marketing approval of ONIVYDE was expensed as research and development expense as incurred. The Company began to capitalize the costs associated with the production of ONIVYDE upon receipt of FDA approval on October 22, 2015.

During the year ended December 31, 2016, the Company incurred aggregate charges of \$3.6 million related to excess and scrap inventory and excess manufacturing capacity. These expenses were recorded as a component of "Cost of revenues."

### 9. Goodwill and Intangible Assets, Net

As part of the acquisition of Hermes BioSciences, Inc. ("Hermes") on October 6, 2009, the Company recognized goodwill of \$3.6 million and acquired IPR&D assets of \$7.0 million related to several development programs: an antibody-targeted 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 assets 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 assets.

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 recognized during the third quarter of 2013.

During the fourth quarter of 2015, upon the approval of ONIVYDE by the FDA, the Company reclassified the acquired IPR&D asset related to the nanotherapeutic that contains a chemotherapy drug to definite-lived intangible assets and commenced amortization. This definite-lived ONIVYDE intangible asset is amortized on a straight-line basis through 2028.

In December 2016, the Company determined that it would be stopping the ongoing Phase 2 clinical trial of MM-302, which utilized the antibodytargeted nanotheraputic that contains a chemotherapy drug. The decision to stop the trial was made following an independent Data and Safety Monitoring Board (the "DSMB") opinion that continuing the clinical trial would be unlikely to demonstrate benefit over the comparator treatments. Subsequent to this recommendation, a futility assessment was performed that confirmed the DSMB's opinion. Both the treatment and control arms were found to have shorter than expected median progression free survival. While patients currently enrolled in the clinical trial may choose to continue on their assigned treatment based upon discussion with their study physician, no further development of MM-302 is being contemplated by the Company at this time. As a result of this determination, the Company recorded an impairment charge of \$2.8 million during the fourth quarter of 2016. This impairment charge was recorded as a component of "Research and development expenses" within the consolidated statements of operations and comprehensive loss.



The core nano-carrier technology intangible asset is being amortized on a straight-line basis over a period of ten years, which is the Company's best estimate of the useful life of this technology.

The Company has not recorded any impairment charges related to either goodwill or definite-lived intangible assets during the years ended December 31, 2016, 2015 and 2014.

Goodwill and intangible assets as of December 31, 2016 and 2015 consisted of the following:

		December 31, 2016						
(in thousands)	Accumulated Gross Carrying Value Amortization Net Carryin							
Nano-carrier technology intangible asset	\$	3,200	\$	(2,315)	\$	885		
ONIVYDE intangible asset		3,400		(308)		3,092		
Goodwill		3,605		—		3,605		
Totals	\$	10,205	\$	(2,623)	\$	7,582		

		December 31, 2015						
(in thousands)	Gross Ca	rrying Value		Accumulated Amortization	Net	t Carrying Value		
Nano-carrier technology intangible asset	\$	3,200	\$	(1,995)	\$	1,205		
ONIVYDE intangible asset		3,400		(50)		3,350		
IPR&D		2,800				2,800		
Goodwill		3,605		_		3,605		
Totals	\$	13,005	\$	(2,045)	\$	10,960		

Amortization expense was \$0.6 million, \$0.4 million and \$0.3 million for the years ended December 31, 2016, 2015 and 2014, respectively. The weighted-average remaining amortization period for the Company's intangible assets subject to amortization is approximately 10.0 years as of December 31, 2016.

Future amortization expense for the next five-year period is expected to be as follows:

Years Ended December 31,	(in thousa	unds)
2017	\$	578
2018		578
2019		503
2020		258
2021		258

## 10. Property and Equipment, Net

Property and equipment, net as of December 31, 2016 and 2015 consisted of the following:

		December 31,			
(in thousands)		2016		2015	
Lab equipment	\$	20,752	\$	19,305	
IT equipment		8,601		7,742	
Leasehold improvements		21,153		21,026	
Furniture and fixtures		959		910	
Construction in process		515		2,243	
Total property and equipment, gross		51,980		51,226	
Less: Accumulated depreciation		(36,215)		(29,311)	
Total property and equipment, net	\$	15,765	\$	21,915	

Depreciation expense was \$7.3 million, \$5.5 million and \$4.2 million for the years ended December 31, 2016, 2015 and 2014, respectively. Capitalized interest costs were insignificant for the years ended December 31, 2016, 2015 and 2014.

During the year ended December 31, 2016, the Company recognized a \$0.5 million charge related to the disposal of property and equipment. There were no significant losses recognized related to the disposal of property and equipment during the years ended December 31, 2015 or 2014.

### 11. Accounts Payable, Accrued Expenses and Other

Accounts payable, accrued expenses and other as of December 31, 2016 and 2015 consisted of the following:

(in thousands)		2016		2015
Accounts payable	\$	3,384	\$	5,049
Accrued goods and services		15,760		14,295
Accrued clinical trial costs		11,260		12,764
Accrued drug purchase costs		910		7,460
Accrued payroll and related benefits		9,150		9,009
Accrued restructuring expenses		774		—
Accrued asset sale transaction costs		3,724		_
Accrued interest		2,100		3,041
Accrued dividends payable		19		19
Silver Creek warrant liability		1,499		
Deferred tax incentives		1,402		445
Total accounts payable, accrued expenses and other	\$	49,982	\$	52,082

## 12. Borrowings

#### 2022 Notes

On December 22, 2015, the Company closed a private placement of \$175.0 million aggregate principal amount of 11.50% 2022 Notes and entered into an indenture (the "U.S. Bank Indenture") with U.S. Bank National Association as trustee and collateral agent (the "2020 Notes Trustee"). As a result of this placement, the Company received net proceeds of approximately \$168.5 million, after deducting private placement and offering expenses payable by the Company. The private placement and offering expenses included \$0.9 million of transaction costs that were expensed in accordance with the debt modification guidance per ASC 470, *Debt*, as further discussed below. The 2022 Notes bear interest at a rate of 11.50% per year, payable semi-annually on June 15 and December 15 of each year, beginning on June 15, 2016. The Company will pay semi-annual installments of principal on the 2022 Notes of \$21,875,000 each, subject to adjustment as provided in the 2022 Notes, on June 15 and December 15 of each year, beginning on June 15, 2019. The 2022 Notes will mature on December 15, 2022, unless earlier redeemed or repurchased in accordance with their terms prior to such date.

The Company may redeem the 2022 Notes at its option, in whole or in part from time to time at a price equal to the principal amount plus accrued interest and a specified make-whole premium. If the Company experiences certain change of control events as defined in the U.S. Bank Indenture, the holders of the 2022 Notes will have the right to require the Company to purchase all or a portion of the 2022 Notes at a purchase price in cash equal to 101% of the principal amount thereof, plus accrued and unpaid interest to the date of purchase. In addition, upon certain asset sale events as defined in the U.S. Bank Indenture, the Company may be required to offer to use the net proceeds thereof to purchase all or a portion of the 2022 Notes at 100% of the principal amount thereof, plus accrued and unpaid interest to the date of purchase.

The 2022 Notes are senior secured obligations of the Company and will be equal in right of payment to all existing and future pari passu indebtedness of the Company (including the Company's outstanding Convertible Notes), will be senior in right of payment to all existing and future subordinated indebtedness of the Company, will have the benefit of a security interest in the 2022 Notes collateral and will be junior in lien priority in respect of any asset-based lending collateral that secures any first priority lien obligations from time to time. The 2022 Notes contain customary covenants, including covenants that limit or restrict the Company's ability to incur liens, incur indebtedness, and make certain restricted payments, but do not contain covenants related to future financial performance. The 2022 Notes are secured by a first priority lien on substantially all of the Company's assets.

The 2022 Notes contain customary events of default. Upon certain events of default occurring, the 2022 Notes Trustee may declare 100% of the principal of and accrued and unpaid interest, if any, on all the 2022 Notes to be due and payable. In the case of certain events of bankruptcy, insolvency or reorganization involving the Company or a restricted subsidiary, 100% of the principal of,

and accrued and unpaid interest on, the 2022 Notes will automatically become due and payable. There have been no events of default as of or during the year ended December 31, 2016.

The Company assessed the 2022 Notes pursuant to ASC 815, *Derivatives and Hedging*, to determine if any features necessitated bifurcation from the host instrument. The Company concluded that none of the embedded redemption features within the 2022 Notes require bifurcation, as these features are clearly and closely related to the host instrument.

Debt issuance costs incurred by the Company, excluding costs allocated to the debt modification as discussed below, are accounted for as a direct deduction to the carrying value of the 2022 Notes and are amortized to interest expense using the effective interest method over the life of the 2022 Notes. The effective interest rate associated with the 2022 Notes is 12.32%. For the years ended December 31, 2016 and 2015, interest expense related to the 2022 Notes was approximately \$20.9 million and \$0.5 million, respectively.

## **Convertible Notes**

In July 2013, the Company issued \$125.0 million aggregate principal amount of Convertible Notes in an underwritten public offering. The Company issued the Convertible 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 "Convertible Notes Trustee"), as supplemented by a supplemental indenture, dated as of July 17, 2013, between the Company and the Convertible Notes Trustee (together with the Base Indenture, the "Wells Fargo Indenture"). As a result of the Convertible 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 Convertible 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 Notes are general unsecured senior obligations of the Company and rank (i) pari passu in seniority with respect to the 2022 Notes, (ii) senior in right of payment to any of the Company's indebtedness that is expressly subordinated in right of payment to the Convertible Notes, (iii) equal in right of payment to any of the Company's unsecured indebtedness that is not so subordinated, (iv) effectively junior in right of payment to any of the company's usecured indebtedness and (v) structurally junior to all indebtedness and other liabilities (including trade payables) of the Company's subsidiaries.

The Company separately accounted for the liability and equity components of the Convertible Notes by bifurcating gross proceeds between the indebtedness, or liability component, and the embedded conversion option, or equity component. This bifurcation was done by estimating an effective interest rate as of the date of issuance for similar notes which do not contain an embedded conversion option. The gross proceeds received from the issuance of the Convertible 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 Convertible 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.

On April 13, 2016, the Company entered into separate, privately-negotiated conversion agreements (the "Conversion Agreements") with certain holders of the Convertible Notes. Under the Conversion Agreements, such holders agreed to convert an aggregate principal amount of \$64.2 million of Convertible Notes held by them. The Company initially settled each \$1,000 principal amount of Convertible Notes surrendered for conversion by delivering 136 shares of the Company's common stock on April 18, 2016. In total, the Company issued an aggregate of \$,732,152 shares of its common stock on this initial closing date. In addition, pursuant to the Conversion Agreements, at the additional closings (as defined in the Conversion Agreements), the Company issued an aggregate of \$,635,511 shares of the Company's common stock representing an aggregate of \$27.7 million as additional payments in respect of the conversion of the Convertible Notes. The number of additional shares was determined based on the daily VWAP (as defined in the Conversion Agreements) of the Company's common stock for each of the trading days in the 10-day trading period following the date of the Conversion Agreements. The issuance of 12,367,663 total shares of the Company's common stock pursuant to the Conversion Agreements resulted in an increase to common stock and additional paid-in capital of \$101.0 million.

As a result of the conversion, the Company recognized an overall loss on extinguishment of \$14.6 million representing the difference between the total settlement consideration transferred to the holders that was attributed to the liability component of the Convertible Notes, based on the fair value of that component at the time of conversion, and the net carrying value of the liability. The loss on extinguishment was recorded as interest expense during the second quarter of 2016. The remaining settlement consideration transferred was allocated to the reacquisition of the embedded conversion option and recognized as a \$39.8 million reduction of additional paid-in capital. Transaction costs incurred with third parties related to the conversion were allocated to the liability and

equity components and resulted in an additional \$0.2 million of interest expense and a \$0.2 million reduction of additional paid-in capital.

The outstanding Convertible 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 Convertible 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 Convertible Notes) per \$1,000 principal amount of Convertible 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 Wells Fargo Indenture.

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 Notes at any time, regardless of the foregoing circumstances.

Following the repayment and satisfaction in full of the Company's obligations to Hercules under the Loan Agreement, which occurred in December 2015, upon any conversion of the Convertible Notes, the Convertible 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 Convertible Notes is 160 shares of the Company's common stock per \$1,000 principal amount of Convertible Notes, which is equivalent to an initial conversion price of \$6.25 per share of common stock. The conversion rate will be subject to adjustment in some events, 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 Convertible Notes in connection with such a corporate event in certain circumstances.

Upon the occurrence of a fundamental change (as defined in the Wells Fargo Indenture) involving the Company, holders of the Convertible Notes may require the Company to repurchase all or a portion of their Convertible Notes for cash at a price equal to 100% of the principal amount of the Convertible Notes to be purchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

The Wells Fargo Indenture contains customary terms and covenants and events of default with respect to the Convertible Notes. If an event of default (as defined in the Wells Fargo Indenture) occurs and is continuing, the Convertible Notes Trustee by written notice to the Company, or the holders of at least 25% in aggregate principal amount of the Convertible Notes then outstanding by written notice to the Company and the Convertible Notes Trustee, may, and the Convertible Notes Trustee at the request of such holders will, declare 100% of the principal of and accrued and unpaid interest on the Convertible 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 Convertible Notes will automatically become due and payable. There have been no events of default as of or during the year ended December 31, 2016.

For the years ended December 31, 2016, 2015 and 2014, interest expense related to the Convertible Notes was \$22.7 million, \$13.7 million and \$13.7 million, respectively. As discussed above, interest expense for the year ended December 31, 2016 includes the loss on extinguishment of \$14.6 million associated with the April 2016 conversion of the Convertible Notes as well as \$0.2 million of related transaction costs.

#### Loan Agreement

In November 2012, the Company entered into the Loan Agreement with Hercules pursuant to which the Company received loans in the aggregate principal amount of \$40.0 million. The Company, as permitted under the Loan Agreement, had previously extended the interest-only payment period with the aggregate principal balance of the loans to be repaid in monthly installments starting on June 1, 2014 and continuing through November 1, 2016. On June 25, 2014, the Company entered into an amendment to the Loan Agreement, whereby the Company and Hercules agreed to extend until October 1, 2014 the period during which the Company makes interest-only payments. On November 6, 2014, the Company entered into a further amendment to the Loan Agreement, whereby the Company entered into a further amendment to the Loan Agreement, whereby the Company entered into a further amendment to the Loan Agreement, whereby the Company entered into a further amendment to the Loan Agreement, whereby the Company entered into a further amendment to the Loan Agreement, whereby the Company entered into a further amendment to the Loan Agreement, whereby the Company entered into a further amendment to the Loan Agreement, whereby the Company and Hercules agreed to extend by four additional months the period during which the Company makes interest-

only payments. On February 25, 2015, the Company entered into a fourth amendment to the Loan Agreement pursuant to which the Company and Hercules agreed to extend the maturity date and the period during which the Company makes interest-only payments on its current loans in the aggregate principal amount of \$40.0 million. As a result of this amendment, the Company was required to repay the outstanding aggregate principal balance of the loan beginning on June 1, 2016 and continuing through November 1, 2018. As a result of the FDA's approval of the Company's NDA for ONIVYDE, which occurred on October 22, 2015, the Company elected to extend the interest-only period by an additional six months such that the Company would repay the outstanding aggregate principal balance of the loans beginning on December 1, 2016 and continuing through November 1, 2018. This amendment was treated as a debt modification for accounting purposes.

Upon the earlier of full repayment of the loans or November 1, 2016, the Company was required to pay Hercules a fee of \$1.2 million, which had been recorded as a discount to the loans and as a long-term liability on the Company's consolidated balance sheets. Additionally, the Company reimbursed Hercules for costs incurred related to the loans, which was reflected as a discount to the carrying value of the loans. The Company amortized these loan discounts totaling \$1.6 million to interest expense over the term of the loans using the effective interest method.

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 contained certain representations, warranties and non-financial covenants of the Company.

During the fourth quarter of 2015, the Company repaid the loans in full in conjunction with the issuance of the 2022 Notes. The total repayment amount included the \$40.0 million in outstanding principal, the \$1.2 million fee discussed above and interest accrued up through the repayment date. The Company assessed the repayment of the Loan Agreement with Hercules in conjunction with the issuance of the 2022 Notes, of which Hercules holds a portion, in accordance with the debt extinguishment and modification guidance per ASC 470, *Debt*. Based upon this assessment, the Company concluded that this transaction represented a debt modification, and accordingly, \$0.3 million of unamortized debt issuance costs related to the Loan Agreement are being amortized as an adjustment of interest expense over the life of the 2022 Notes using the effective interest method. In addition, \$0.9 million of debt issuance costs associated with the 2022 Notes were allocated to the modified Loan Agreement and expensed as a component of "Interest expense" on the consolidated statement of operations and comprehensive loss for the year ended December 31, 2015.

For the years ended December 31, 2015 and 2014, interest expense related to the Hercules loans was \$5.4 million and \$4.7 million, respectively. No interest expense related to the Hercules loans was recognized during the year ended December 31, 2016.

### **Credit Facility**

On November 8, 2016, the Company entered into a Loan and Security Agreement (the "Credit Agreement") with BioPharma Credit Investments IV Sub, LP ("Pharmakon") pursuant to which a credit facility of an aggregate principal amount of at least \$15.0 million and up to \$25.0 million is available. The credit facility was originally available at any time through March 15, 2017 upon the Company's request and upon compliance with certain funding conditions. As described more fully in Note 23, "Subsequent Events," the availability of the credit facility was subsequently extended through April 27, 2017. If the Company borrows under the Credit Agreement, the credit facility will bear interest at an annual rate of 11.50%.

In connection with any borrowings that occur under the Credit Agreement, the Company will grant Pharmakon a security interest in all inventory and accounts receivable. The Credit Agreement also contains certain representations, warranties and non-financial covenants. In addition, the Credit Agreement grants Pharmakon an option during the two years following funding of the credit facility to participate in a future financing at an amount up to the lesser of 25% of the total amount financed or \$50.0 million. The Company had not borrowed any amounts under the Credit Agreement as of December 31, 2016.

## Silver Creek Convertible Notes

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 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 using a probability-



weighted model and was recorded as derivative liability on the consolidated balance sheets. For the year ended December 31, 2014, the derivative was remeasured upon conversion of the notes with the gain in remeasurement recognized in other income. The specific notes that were outstanding as of December 31, 2014 matured and converted, along with an immaterial amount of accrued interest into shares of Silver Creek Series A preferred stock on December 31, 2014.

In May 2016, Silver Creek issued an aggregate of \$1.0 million of Silver Creek Notes. In August 2016, Silver Creek issued \$0.2 million of additional Silver Creek Notes under the same terms as the May 2016 issuance. The Silver Creek Notes were automatically convertible into shares of Silver Creek equity under a variety of conversion scenarios. The Silver Creek Notes bore interest at 6% per annum and were set to mature and convert, along with accrued interest, into Silver Creek Series B preferred stock at a conversion price of \$1.35 per share on December 31, 2016. If, prior to maturity, Silver Creek entered into a sale or series of related sales of equity securities resulting in at least \$4.0 million of gross proceeds, the Silver Creek Notes would convert into the equity securities sold at the lesser of the price paid per share for the equity securities or \$1.60 per share. Principal and accrued interest related to the Silver Creek Notes were not permitted to be paid in cash by Silver Creek without the consent of a majority of the noteholders.

In December 2016, Silver Creek executed a Series C Preferred Stock and Warrant Purchase Agreement (the "Silver Creek Series C Agreement") whereby it agreed to sell 1.5 million shares of Silver Creek Series C preferred stock to new investors at a purchase price of \$1.50 per share. In connection with this financing, holders of the Silver Creek Notes agreed to convert all principal and accrued interest associated with the Silver Creek Notes into 0.8 million shares of Silver Creek Series C preferred stock at a conversion price of \$1.50 per share.

New purchasers of the Silver Creek Series C preferred stock also received warrants to purchase an aggregate of 1.9 million shares of Silver Creek Series C preferred stock at a future date. The exercise price of the warrants varies based upon the achievement of certain milestone events defined in the related warrant agreements. Milestone Event 1 is defined as the date that is seven business days following the acceptance by the FDA of Silver Creek's filing of an Investigational New Drug application ("IND"), or 30 business days after the IND is filed without FDA rejection of the application. Milestone Event 2 is defined as the date that is seven business days following the acte that is seven business days following the date when Silver Creek completes a Phase 1 clinical trial provided, that if Silver Creek receives proceeds of less than \$4.0 million pursuant to the sale of Series C preferred stock, Milestone Event 2 shall mean the date that is seven business days following the first dose in humans in a clinical trial.

Of the warrants to purchase 1.9 million shares of Silver Creek Series C preferred stock that were issued, warrants to purchase 1.2 million shares of Silver Creek Series C preferred stock are exercisable at an exercise price of \$1.75 per share if the warrant is exercised prior to the date that is 30 business days after the date that the holder receives notice from Silver Creek of the achievement of Milestone Event 1, or \$2.25 per share if the warrant is exercised on or after the date that is 30 business days after the holder receives notice from Silver Creek of the achievement of Milestone Event 1. The remaining warrants to purchase 0.7 million shares of Silver Creek Series C preferred stock are exercisable at an exercise price of \$2.25 per share if the warrant is exercised prior to the date that is 30 business days after the holder receives notice from Silver Creek of the achievement of Milestone Event 2, or \$2.75 per share if the warrant is exercised on or after the date that is 30 business days after the date that is 30 business days after Milestone Event 2. All warrants to purchase Silver Creek Series C preferred stock are exercisable until the earliest of (i) the consummation of a Silver Creek liquidation event, (ii) the consummation of an initial public offering of Silver Creek common stock, (iii) four months after the achievement of Milestone Event 2 or (iv) seven years from the date of issuance.

The warrants to purchase Silver Creek Series C preferred stock were classified as a current liability in accordance with ASC 480, *Distinguishing Liabilities from Equity*, and initially measured at fair value, as described more fully in Note 6, "Fair Value of Financial Instruments." The fair value of the warrants was deducted from the total Silver Creek Series C preferred stock proceeds received by Silver Creek, and the remaining proceeds received were allocated to the Silver Creek Series C preferred stock.

## **Future Minimum Payments under Outstanding Borrowings**

Future minimum payments under outstanding borrowings as of December 31, 2016 are as follows:

(in thousands)	Convertible Notes	2022 Notes
2017	\$ 2,736	\$ 20,125
2018	2,736	20,125
2019	2,736	62,617
2020	63,527	57,586
2021 and thereafter	—	100,078
Total	71,735	260,531
Less interest	(10,943)	(85,531)
Less unamortized discount	(13,842)	(5,089)
Less current portion		
Long-term debt	\$ 46,950	\$ 169,911

## 13. Restructuring Activities

On October 3, 2016, the Company announced a 22% reduction in headcount as part of a major corporate restructuring with the objective of prioritizing its research and development on a focused set of systems biology-derived oncology products and strengthening its financial runway. On this same date, the Company also announced the resignation of Robert Mulroy, the Company's former President and Chief Executive Officer ("CEO").

Under this corporate restructuring, the Company recognized total restructuring expenses of \$5.9 million during the year ended December 31, 2016 related to stock-based compensation expense for certain terminated employees, contractual termination benefits for employees with pre-existing severance arrangements and one-time employee termination benefits. These one-time employee termination benefits were comprised of severance, benefits and related costs, all of which resulted in cash expenditures during the third and fourth quarters of 2016.

The following table summarizes the charges related to the restructuring activities as of December 31, 2016:

(in thousands)	]	Expenses	Le	ess: Payments	L	ess: Non-Cash Expenses	ccrued Restructuring Expenses at December 31, 2016
Severance, benefits and related costs due							
to workforce reduction	\$	5,856	\$	(3,711)	\$	(1,371)	\$ 774
Totals	\$	5,856	\$	(3,711)	\$	(1,371)	\$ 774

## 14. Common Stock Warrants

The following is a description of the common stock warrant activity of the Company:

(in thousands, except per share amounts)	Warrants for the Purchase of Common Stock	Weighted Average Exercise Price	
Balance at December 31, 2013	2,777	\$ 3.0	)5
Exercised	(396)	\$ 3.3	8
Balance at December 31, 2014	2,381	\$ 3.0	00
Exercised	(2,355)	\$ 3.0	00
Cancelled	(26)	\$ 3.0	00
Balance at December 31, 2015		\$ -	_

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. During the year ended December 31, 2015, warrants to purchase approximately 2,295,000 shares of common stock were cashless exercised and 1,695,000 shares of common stock were issued. As of December 31, 2015, all remaining unexercised warrants for the purchase of common stock had expired and were cancelled.



## 15. Common Stock

In July 2015, the Company entered into a Sales Agreement with Cowen and Company, LLC ("Cowen") to sell shares of the Company's common stock having an aggregate sales price of up to \$40.0 million through an "at the market offering" program under which Cowen acted as the sales agent. The Company concluded sales under this program in September 2015, having sold approximately 3.8 million shares of common stock and generating approximately \$38.6 million in net proceeds, after deducting commissions and offering expenses.

As of December 31, 2016 and 2015, the Company had 200.0 million shares of \$0.01 par value common stock authorized. There were approximately 130.2 million and 115.9 million shares of common stock issued and outstanding as of December 31, 2016 and 2015, respectively.

### 16. Stock-Based Compensation

In 2008, the Company adopted the 2008 Stock Incentive Plan (as amended, the "2008 Plan") for employees, officers, directors, consultants and advisors. 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. Additional shares also become available for grant by reason of the forfeiture, cancellation, expiration or termination of existing awards. The Company registered 4.1 million, 3.7 million and 3.6 million of additional shares of common stock related to the 2011 Plan in February 2016, February 2015 and March 2014, respectively. As of December 31, 2016, there were 4.7 million shares remaining available for grant under the 2011 Plan.

During the years ended December 31, 2016, 2015 and 2014, the Company issued options to purchase 4.3 million, 3.7 million and 3.9 million shares of common stock, respectively. These options generally vest over a three-year period for employees. Options granted to directors vest immediately.

The fair value of stock options granted to employees during the years ended December 31, 2016, 2015 and 2014 was estimated at the date of grant using the following assumptions:

	Years Ended December 31,				
	2016	2015	2014		
Risk-free interest rate	1.1 - 2.0%	1.5 - 1.8%	1.6 - 2.0%		
Expected dividend yield	0%	0%	0%		
Expected term	5.0 - 5.8 years	5.0 - 5.9 years	5.0 - 5.9 years		
Expected volatility	67 - 69%	66 - 67%	64 - 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 the expected term of its stock options. Under this approach, the expected term is calculated to be the average of the ten-year contractual term of the option and the weighted-average vesting term of the option, taking into consideration multiple vesting tranches. 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 Company recognized stock-based compensation expense during the years ended December 31, 2016, 2015 and 2014 as follows:

	Years Ended December 31,					
(in thousands)		2016		2015		2014
Employee awards:						
Research and development expense	\$	6,503	\$	8,271	\$	6,864
Selling, general and administrative expense		7,331		7,022		6,065
Restructuring expense		1,371		—		_
Stock-based compensation expense for employee awards		15,205		15,293		12,929
Stock-based compensation expense for non-employee awards		1		58		268
Less: stock-based compensation expense capitalized to						
inventory		(341)		_		—
Total stock-based compensation expense	\$	14,865	\$	15,351	\$	13,197

The following table summarizes stock option activity during the year ended December 31, 2016:

Options			Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value		
19,211	\$	5.72	6.24	\$	47,963	
4,258	\$	5.57				
(1,958)	\$	3.29				
(2,487)	\$	7.04				
19,024	\$	5.77	5.97	\$	7,564	
18,794	\$	5.76	5.93	\$	7,564	
14,968	\$	5.49	5.24	\$	7,564	
	19,211 4,258 (1,958) (2,487) 19,024 18,794	Options         E5           19,211         \$           4,258         \$           (1,958)         \$           (2,487)         \$           19,024         \$           18,794         \$	19,211         \$         5.72           4,258         \$         5.57           (1,958)         \$         3.29           (2,487)         \$         7.04           19,024         \$         5.77           18,794         \$         5.76	Options         Weighted-Average Exercise Price         Remaining Contractual Term (in years)           19,211         \$ 5.72         6.24           4,258         \$ 5.57         6.24           (1,958)         \$ 3.29         6.24           (2,487)         \$ 7.04         5.77           19,024         \$ 5.77         5.97           18,794         \$ 5.76         5.93	Options         Weighted-Average Exercise Price         Remaining Contractual Term (in years)           19,211         \$ 5.72         6.24         \$           4,258         \$ 5.57         6.24         \$           (1,958)         \$ 3.29	

The weighted-average grant date fair value of stock options granted during the years ended December 31, 2016, 2015 and 2014 was \$3.32, \$5.80 and \$3.41, respectively.

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 during the years ended December 31, 2016, 2015 and 2014 was \$5.6 million, \$30.9 million and \$19.8 million, respectively.

As of December 31, 2016, there was \$12.7 million of total unrecognized stock-based compensation expense related to unvested employee stock options. The Company expects to recognize this expense over a weighted-average period of approximately 1.7 years.

# 17. Income Taxes

As a result of losses incurred, the Company did not provide for any income taxes in the years ended December 31, 2016, 2015 or 2014. A reconciliation of the Company's effective tax rate to the statutory federal income tax rate is as follows:

	Years	Years Ended December 31,					
	2016	2015	2014				
Federal income tax at statutory federal rate	35.0%	35.0%	35.0%				
State taxes	0.7	1.0	3.1				
Permanent differences	(11.6)	(6.4)	(9.1)				
Stock-based compensation	(2.2)	(1.3)	(1.7)				
Tax credits	28.0	21.3	30.5				
Foreign rate differential			(2.3)				
Change in deferred state tax rate	(0.3)	(2.3)					
Other	4.5	(0.5)	4.5				
Change in valuation allowance	(54.1)	(46.8)	(60.0)				
Total	%	%	%				

During the year ended December 31, 2014, the Company recorded a deferred tax liability related to the embedded conversion option of the Convertible Notes though equity. This deferred tax liability is reflected in the deferred tax table below, but is appropriately excluded from the effective tax rate.

Temporary differences that give rise to significant net deferred tax assets as of December 31, 2016 and 2015 are as follows:

	December 31,				
(in thousands)	 2016 201				
Deferred tax assets					
Net operating losses	\$ 194,027	\$	182,992		
Capitalized research and development expenses	15,854		21,444		
Credit carryforwards	144,823		93,113		
Depreciation	2,557		2,128		
Deferred compensation	12,463		11,664		
Accrued expenses	3,601		1,807		
Deferred revenue	21,935		10,999		
Other temporary differences	25,276		17,235		
Total gross deferred tax assets	 420,536		341,382		
Valuation allowance	(414,558)		(326,577)		
Net deferred tax assets	 5,978		14,805		
Deferred tax liabilities					
Intangible assets	(1,428)		(2,667)		
Debt discount	(4,550)		(12,138)		
Net deferred taxes	\$ _	\$			

The Company concluded that there are no significant uncertain tax positions requiring recognition in the consolidated financial statements. The Company's evaluation was performed for the tax years ended December 31, 2013 through 2016, the tax years which remain subject to examination by major tax jurisdictions as of December 31, 2016. However, to the extent the Company utilizes net operating losses from years prior to 2012, the statute remains open to the extent of the net operating losses utilized. The Company's policy is to recognize interest and penalties for uncertain tax positions as a component of income tax expense. The Company has not recognized any interest and penalties historically through December 31, 2016.

At December 31, 2016, the Company had net operating loss carryforwards for federal and state income tax purposes of \$542.7 million and \$367.4 million, respectively. Included in the federal and state net operating loss carryforwards is approximately \$39.2 million and \$25.2 million, respectively, 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 ASC 718, *Compensation – Stock Compensation*. The Company's existing federal and state net operating loss carryforwards will expire in years through 2036. The Company also has available research and development credits for federal and state income tax purposes of approximately \$27.3 million and \$16.3 million, respectively. The federal and state research and development credits will begin to expire in 2022 and 2025, respectively. As of December 31, 2016, the Company also had available investment tax credits for state income tax purposes of \$0.8 million, which will expire in years through 2019 if unused. In addition, the Company has federal orphan drug credits of \$106.4 million which begin to expire in 2031. The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are comprised principally of net operating loss carryforwards, deferred revenue and capitalized research and development excense. Under the applicable accounting standards, the Company has considered its history of losses and concluded that it is more likely than not that the Company will not recognize the benefits of federal and state deferred tax assets. Accordingly, the Company has established a full valuation allowance against the deferred tax assets to offset the taxable gain generated by the sale. The valuation allowance could be released during the year ended December 31, 2017 once it is determined it is more likely than not that the deferred tax assets will be realizable.

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. The Company completed an evaluation of ownership changes through September 30, 2016 to assess whether utilization of the Company's net operating loss or research and development credit carryforwards would be subject to an annual limitation under Section 382 of the Internal Revenue Code. The Company believes that it may be able to utilize all of its tax attributes as a result of the

analysis. To the extent an ownership change occurs in the future, the net operating loss and credit carryforwards may be subject to limitation.

The Company has not yet conducted a study of its domestic research and development credit carryforwards and orphan drug credits. This study may result in an increase or decrease to the Company's 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 Company's 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 consolidated statements of operations and comprehensive loss or consolidated statements of cash flows if an adjustment were required.

The change in the valuation allowance against the deferred tax assets in the years ended December 31, 2016, 2015 and 2014 was as follows:

(in thousands)	Balance at Beginning of Period		g		Deductions		Balance at End of Period	
December 31, 2014	\$	207,304	\$	50,185	\$	_	\$	257,489
December 31, 2015		257,489		69,088		_		326,577
December 31, 2016		326,577		87,981		_		414,558

#### 18. Commitments and Contingencies

## **Operating Leases**

The Company leases its office, laboratory and manufacturing space under non-cancelable operating leases. During August 2012, the Company entered into an Indenture of Lease (the "Amended Lease"), which amended and restated its facility lease. The Amended Lease will terminate on June 30, 2019, but the Company retains an option to renew the Amended Lease with respect to all of the leased space for an additional period of five years. In March 2013, September 2013, February 2015 and July 2015, the Company entered into further facility lease amendments for additional space that are co-terminus with the Amended Lease. In total, the Company leases approximately 167,000 square feet at its corporate headquarters in Cambridge, Massachusetts.

As part of the Amended Lease and subsequent amendments, the landlord agreed to reimburse the Company for a portion of tenant improvements made to the facility. As of December 31, 2016, the Company had received \$9.5 million of tenant improvement reimbursements. Tenant improvement reimbursements are recorded within deferred rent and are amortized over the term of the lease as reductions to rent expense.

In May 2016, the Company entered into a sublease agreement (the "Sublease") whereby a subtenant agreed to lease 8,143 square feet of office and lab space from the Company. The Sublease terminates on December 31, 2017, but may be extended through June 30, 2019 if mutually agreed upon by the Company and the subtenant. Rental income received from the subtenant has been classified by the Company as reduction of rent expense. Total future minimum rental payments to be received by the Company from the subtenant as of December 31, 2016 are \$0.6 million.

Total rent expense was \$8.6 million, \$7.4 million and \$5.9 million for the years ended December 31, 2016, 2015 and 2014, respectively.

Future minimum lease payments to be made by the Company under non-cancelable operating leases as of December 31, 2016 are as follows:

Years ended December 31,	(in thousands)
2017	\$ 8,108
2018	8,102
2019	4,082
Total future minimum lease payments	\$ 20,292

## **19. Related Party Transactions**

Related parties of the Company held approximately 7% of the outstanding shares of Silver Creek Series A and Series B preferred stock as of both December 31, 2016 and 2015. No shares of Silver Creek Series C preferred stock issued during December 2016 were held by related parties of the Company as of December 31, 2016.

## 20. Retirement Plan

On May 31, 2002, the Company established a 401(k) defined contribution savings plan (the "401(k) Plan") for its employees who meet certain service period and age requirements. Contributions are permitted up to the maximum allowed under the Internal Revenue Code of each covered employee's salary. The 401(k) Plan permits the Company to contribute at its discretion. For the years ended December 31, 2016, 2015 and 2014, the Company made contributions of \$1.3 million, \$1.1 million and \$0.8 million, respectively, to the 401(k) Plan.

## 21. Selected Quarterly Financial Data (Unaudited)

The following table contains quarterly financial information for 2016 and 2015. The Company believes that the following information reflects all normal recurring adjustments necessary for a fair statement of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

	First Quarter		econd uarter		Third Quarter		Fourth Quarter
	 -	(in th	ousands, exc	cept per share data)			
2016							
Product revenues, net	\$ 9,968	\$	12,851	\$	14,493	\$	15,752
License and collaboration revenues	11,313		19,332		12,417		44,057
Other revenues			1,498		1,161		1,431
Cost of revenues	711		1,872		1,010		3,319
Research and development expenses	32,882		40,996		32,078		54,961
Selling, general and administrative expenses	17,795		20,680		18,048		24,206
Restructuring expenses	_		_		809		5,047
Net loss	(38,658)		(50,958)		(30,275)		(33,627)
Net loss attributable to Merrimack Pharmaceuticals, Inc.	(38,473)		(50,750)		(30,068)		(32,449)
Net loss per share available to common							
stockholders—basic and diluted	(0.33)		(0.40)		(0.23)		(0.25)

	(	First Juarter	Q	econd uarter	(	Third Juarter	Fourth Quarter
			(in the	ousands, exc	ept per	share data)	
2015							
Product revenues, net	\$	—	\$	—	\$	—	\$ 4,328
License and collaboration revenues		14,842		36,558		16,440	17,090
Cost of revenues		_		_		—	46
Research and development expenses		35,679		42,806		37,763	44,740
Selling, general and administrative expenses		9,189		12,315		16,956	19,335
Net loss		(34,432)		(22,901)		(42,386)	(48,068)
Net loss attributable to Merrimack Pharmaceuticals, Inc.		(34,759)		(22,778)		(42,594)	(47,826)
Net loss per share available to common							
stockholders—basic and diluted		(0.32)		(0.21)		(0.38)	(0.41)

## 22. Going Concern

In accordance with ASC 205-40, *Going Concern*, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. The Company has suffered recurring losses from operations, has negative working capital and has cash outflows from operating activities, all of which raise substantial doubt about its ability to continue as a going concern.

As of December 31, 2016, the Company had unrestricted cash and cash equivalents of \$21.5 million. Upon stockholder approval and the closing of the asset sale with Ipsen outlined more fully in Note 23, "Subsequent Events," the Company will receive a \$575.0 million upfront cash payment from Ipsen (subject to a working capital adjustment as provided in the Asset Sale Agreement). The Company expects to use these proceeds to declare and pay a special cash dividend of at least \$200.0 million to stockholders and redeem the \$175.0 million outstanding aggregate principal amount of 2022 Notes, which will require an additional make-whole premium payment of approximately \$20.1 million. Additionally, if the asset sale is consummated and certain milestones under the Baxalta Agreement are met, the Company currently expects to receive up to an aggregate of \$33.0 million in net milestone payments in 2017. The Company believes these potential net cash inflows, along with the completion of the headcount reduction and refocused research and development efforts that were announced in January 2017, will provide financial resources sufficient to fund operations into the second half of 2019.

The consummation of the asset sale with Ipsen is contingent upon approval by the Company's stockholders as well as other customary closing conditions. If the asset sale is not consummated, the Company will not receive the \$575.0 million upfront cash payment from Ipsen, and the Company will need to obtain additional funding through public or private debt or equity financings, through existing or new collaboration arrangements, or through divestitures of its assets. The Company may not be able to obtain additional financing on acceptable terms, or at all, and the Company may not be able to enter into additional collaborative arrangements. The ability to obtain additional financing is not considered probable at this time and could result in the Company's inability to meet its obligations as they become due within one year after the date that the consolidated financial statements are issued.

Based upon the above evaluation, the Company has concluded that there is substantial doubt as to its ability to continue as a going concern within one year after the date that the consolidated financial statements are issued.

## 23. Subsequent Events

## **Asset Sale**

On January 7, 2017, the Company entered into the Asset Sale Agreement with Ipsen. Pursuant to the Asset Sale Agreement, Ipsen will acquire the Company's right, title and interest in the non-cash assets, equipment, inventory, contracts and intellectual property primarily related to or used in the Commercial Business. Ipsen will not acquire the Company's rights to \$33.0 million in net milestone payments that may become payable pursuant to the Baxalta Agreement, among other excluded assets. Pursuant to the Asset Sale Agreement, Ipsen will pay the Company \$575.0 million in cash (subject to a working capital adjustment as provided in the Asset Sale Agreement) and will assume certain related liabilities. Following the closing of the asset sale, the Company may be entitled to up to \$450.0 million of additional payments based on achievement by or on behalf of Ipsen of certain milestone events related to FDA approval of ONIVYDE for certain indications.

The consummation of the transaction is subject to customary closing conditions, including, among others: (i) the receipt of the approval of the Company's stockholders; (ii) the expiration or termination of the required waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, which waiting periods expired on February 22, 2017; (iii) the absence of a breach of the Company's representations and warranties that would cause a material adverse effect on the Commercial Business; (iv) the absence of a business material adverse effect; and (v) the performance of certain covenants in all material respects.

The Asset Sale Agreement contains certain termination rights for the Company and Ipsen. Upon termination of the Asset Sale Agreement under specified circumstances, the Company would be required to pay Ipsen a termination fee of \$25.0 million, including if the Asset Sale Agreement is terminated in connection with the Company accepting a superior proposal or because the Company's Board of Directors has changed its recommendation of the sale to its stockholders. The termination fee will also be payable if the Asset Sale Agreement is terminated because the Company's stockholders did not vote to adopt the Asset Sale Agreement and, prior to such termination, a proposal to acquire at least 50% of the consolidated assets of the Company with respect to the Commercial Business or at least 50% of the Company's voting securities has been publicly disclosed and the Company enters into a definitive agreement with respect to such proposal within 12 months after such termination, which is subsequently consummated. In addition, the Company would be required to reimburse Ipsen for up to \$3.0 million of its out-of-pocket expenses incurred in connection with the transaction and the Asset Sale Agreement if the Asset Sale Agreement is terminated because the Company stockholders do not vote to approve it.

In addition to the foregoing termination rights, and subject to certain limitations, the Company or Ipsen may terminate the Asset Sale Agreement if the asset sale is not consummated by June 30, 2017.

Ipsen has also agreed to sublease 68,409 square feet of the Company's manufacturing facility at the closing of the asset sale. In addition, at the closing of the asset sale, the Company and Ipsen will enter into an intellectual property license agreement pursuant to which Ipsen will grant the Company an exclusive license with respect to the portion of the transferred patents relating to certain

liposomal technology and a non-exclusive license to the remainder of the transferred patents, in both cases for use outside of the field in which the Commercial Business will operate. In turn, the Company will grant Ipsen a non-exclusive license with respect to the remaining patents owned by the Company at the closing for use in the field in which the Commercial Business will operate.

#### January 2017 Corporate Restructuring

On January 9, 2017, the Company announced that it will further reduce headcount in connection with the asset sale and the completion of its strategic pipeline review. Upon the closing of the asset sale, the Company will focus its development efforts on its MM-121, MM-141 and MM-310 programs. After the headcount reduction, the Company expects to have approximately 80 employees.

The Company's Board of Directors committed to this course of action on January 6, 2017, subject to the closing of the asset sale, which is contingent upon the closing conditions described above. The reduction in personnel is expected to be complete upon the later of the closing of the asset sale and March 10, 2017. The Company estimates that, if the asset sale closes, it will incur approximately \$7.5 million to \$8.5 million of restructuring expenses related to one-time employee termination benefits. These one-time employee termination benefits are comprised of severance, benefits and related costs, all of which are expected to result in cash expenditures. The specific timing of the incurrence and payment of these restructuring expenses is dependent upon the timing of the closing of the asset sale.

#### **Hiring of Chief Executive Officer**

On January 16, 2017, the Company announced the hiring of Richard Peters, M.D., Ph.D., as the Company's new CEO, effective as of February 6, 2017. Dr. Peters was also elected as a member of the Company's Board of Directors.

The Company and Dr. Peters entered into an employment agreement commencing on February 6, 2017 whereby Dr. Peters will receive an annual base salary of \$700,000 and is eligible for an annual bonus of up to 65% of his base salary. Dr. Peters also received a one-time signing bonus of \$900,000. Subject to the further approval of the Company's Board of Directors, the Company will also grant Dr. Peters an option to purchase a number of shares of the Company's common stock equal to the lesser of (i) such number of shares that has a target grant date fair value of \$3.5 million and (ii) 2.0 million shares, with an exercise price per share equal to the fair market value of the Company's common stock on the date of grant. The option will vest over four years at the rate of 25% on February 6, 2018 and the remainder in equal quarterly installments over the following three years.

#### **Extension of Credit Facility Availability**

On February 23, 2017, the Company entered into an amendment to the Credit Agreement with Pharmakon whereby the availability of the credit facility was extended through April 27, 2017. The Company had not borrowed any amounts under the Credit Agreement as of March 1, 2017.

# EXHIBIT INDEX

Exhibit Number	Description of Exhibit
2.1	Asset Purchase and Sale Agreement, dated as of January 7, 2017, by and between the Registrant and Ipsen S.A. (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed on January 9, 2017)
3.1	Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-8 filed on April 27, 2012)
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.5 to the Registrant's Registration Statement on Form S-1, as amended, filed on January 13, 2012)
4.1	Specimen certificate evidencing shares of common stock (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, as amended, filed on October 26, 2011)
4.2	Indenture, dated as of July 17, 2013, by and between the Registrant and Wells Fargo Bank, National Association, as trustee (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on July 18, 2013)
4.3	First Supplemental Indenture, dated as of July 17, 2013, by and between the Registrant and Wells Fargo Bank, National Association, as trustee (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed on July 18, 2013)
4.4	Indenture (including the Form of Note), dated as of December 22, 2015, by and among the Registrant, any Guarantor that becomes a party thereto and U.S. Bank National Association, a national banking association, as trustee and collateral agent (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on December 22, 2015)
4.5*	Loan and Security Agreement, dated as of November 8, 2016, by and between the Registrant and BioPharma Credit Investments IV Sub, LP
4.6*	First Amendment to Loan and Security Agreement, dated as of February 23, 2017, by and between the Registrant and BioPharma Credit Investments IV Sub, LP
10.1#	1999 Stock Option Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, as amended, filed on July 8, 2011)
10.2#	2008 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, as amended, filed on July 8, 2011)
10.3#	2011 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1, as amended, filed on January 13, 2012)
10.4#	Form of Incentive Stock Option Agreement under 2011 Stock Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1, as amended, filed on January 13, 2012)
10.5#	Form of Non-Qualified Stock Option Agreement under 2011 Stock Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1, as amended, filed on January 13, 2012)
10.6#*	Employment Agreement, dated as of January 17, 2017, by and between the Registrant and Richard Peters
10.7#*	Separation and Release of Claims Agreement, dated as of October 11, 2016, by and between the Registrant and Robert J. Mulroy
10.8#	Employment Agreement, dated as of August 11, 2015, by and between the Registrant and Yasir B. Al-Wakeel (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on November 9, 2015)
10.9#	Employment Agreement, dated as of February 24, 2015, by and between the Registrant and Peter N. Laivins (incorporated by reference to Exhibit 10.6 to the Registrant's Annual Report on Form 10-K filed on February 27, 2015)
10.10#	Employment Agreement, dated as of September 30, 2011, by and between the Registrant and William M. McClements (incorporated by reference to Exhibit 10.26 to the Registrant's Registration Statement on Form S-1, as amended, filed on January 13, 2012)

Exhibit Number	Description of Exhibit
10.11#	Amended and Restated Employment Agreement, dated as of August 16, 2011, by and between the Registrant and Edward J. Stewart (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1, as amended, filed on August 19, 2011)
10.12#	Amended and Restated Employment Agreement, dated as of August 16, 2011, by and between the Registrant and William A. Sullivan (incorporated by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1, as amended, filed on August 19, 2011)
10.13#	Form of Indemnification Agreement between the Registrant and each director and executive officer (incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1, as amended, filed on August 19, 2011)
10.14	Indenture of Lease, dated as of August 24, 2012, by and between the Registrant and DWF IV One Kendall, LLC (as successor-in-interest to RB Kendall Fee, LLC), as amended by the First Amendment of Lease, dated as of March 18, 2013 (incorporated by reference to Exhibit 10.14 to the Registrant's Annual Report on Form 10-K filed on March 20, 2013)
10.15	Second Amendment of Lease, dated as of September 12, 2013, by and between the Registrant and DWF IV One Kendall, LLC (as successor- in-interest to RB Kendall Fee, LLC) (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on November 8, 2013)
10.16	Third Amendment of Lease, dated as of February 23, 2015, by and between the Registrant and DWF IV One Kendall, LLC (incorporated by reference to Exhibit 10.15 to the Registrant's Annual Report on Form 10-K filed on February 27, 2015)
10.17	Fourth Amendment of Lease, dated as of July 22, 2015, by and between the Registrant and DWF IV One Kendall, LLC (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on November 9, 2015)
10.18	Sublease, dated as of August 20, 2010, by and between Silver Creek Pharmaceuticals, Inc. and FibroGen, Inc., as amended on January 20, 2011, May 4, 2011, May 26, 2011, August 1, 2011 and November 2, 2012 (incorporated by reference to Exhibit 10.15 to the Registrant's Annual Report on Form 10-K filed on March 20, 2013)
10.19	Amendment No. 6 to Sublease, dated as of December 12, 2013, by and between Silver Creek Pharmaceuticals, Inc. and FibroGen, Inc. (incorporated by reference to Exhibit 10.16 to the Registrant's Annual Report on Form 10-K filed on March 4, 2014)
10.20	Amendment No. 7 to Sublease, dated as of June 1, 2014, by and between Silver Creek Pharmaceuticals, Inc. and FibroGen, Inc. (incorporated by reference to Exhibit 10.20 to the Registrant's Annual Report on Form 10-K filed on February 26, 2016)
10.21*	Amendment No. 8 to Sublease, dated as of January 1, 2017, by and between Silver Creek Pharmaceuticals, Inc. and FibroGen, Inc.
10.22†	License and Collaboration Agreement, dated as of September 23, 2014, by and among the Registrant, Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on November 10, 2014)
10.23†	Assignment, Sublicense and Collaboration Agreement, dated as of May 5, 2011, by and between the Registrant (as successor-in-interest to Merrimack Pharmaceuticals (Bermuda) Ltd.) and PharmaEngine, Inc. (incorporated by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form S-1, as amended, filed on October 26, 2011)
10.24†	First Amendment to Assignment, Sublicense and Collaboration Agreement, dated as of September 22, 2014, by and between the Registrant and PharmaEngine, Inc. (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on November 10, 2014)
10.25†	Development, License and Supply Agreement, dated as of November 25, 2013, by and between the Registrant and Watson Laboratories, Inc. (incorporated by reference to Exhibit 10.29 to the Registrant's Annual Report on Form 10-K filed on March 4, 2014)
10.26†	First Amendment to Development, License and Supply Agreement, dated as of January 23, 2015, by and between the Registrant and Watson Laboratories, Inc. (incorporated by reference to Exhibit 10.22 to the Registrant's Annual Report on Form 10-K filed on February 27, 2015)
10.27†	Exclusive License Agreement, dated as of November 1, 2000, by and between the Registrant (as successor-in-interest to Hermes BioSciences, Inc.) and The Regents of the University of California, as amended on October 6, 2003, September 13, 2006, June 6, 2007 and September 28, 2007 (incorporated by reference to Exhibit 10.20 to the Registrant's Registration Statement on Form S-1, as amended, filed on October 26, 2011)

Exhibit Number	Description of Exhibit
10.28†	Collaboration Agreement, dated as of November 16, 2009, by and between the Registrant and Adimab LLC, as amended on April 27, 2010, June 2, 2010 and October 11, 2011 (incorporated by reference to Exhibit 10.22 to the Registrant's Registration Statement on Form S-1, as amended, filed on October 26, 2011)
10.29†	Sublicense Agreement, dated as of June 30, 2008, by and between the Registrant and Dyax Corp. (incorporated by reference to Exhibit 10.23 to the Registrant's Registration Statement on Form S-1, as amended, filed on July 8, 2011)
10.30†	Amended and Restated Collaboration Agreement, dated as of January 24, 2007, by and between the Registrant and Dyax Corp., as amended on July 31, 2008 and November 6, 2009 (incorporated by reference to Exhibit 10.24 to the Registrant's Registration Statement on Form S-1, as amended, filed on October 26, 2011)
10.31	Amendment to Amended and Restated Collaboration Agreement, dated as of January 18, 2012, by and between the Registrant and Dyax Corp. (incorporated by reference to Exhibit 10.26 to the Registrant's Annual Report on Form 10-K filed on March 20, 2013)
10.32	Collateral Agreement, dated as of December 22, 2015, by and among the Registrant, the Subsidiary Parties from time to time party thereto and U.S. Bank National Association, a national banking association, as trustee and collateral agent (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on December 22, 2015)
10.33	Form of Conversion Agreement Related to 4.50% Convertible Senior Notes due 2020 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on April 14, 2016)
21.1*	Subsidiaries of the Registrant
23.1*	Consent of PricewaterhouseCoopers LLP, an independent registered public accounting firm
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1+	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2+	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Database
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document
* Filed	herewith.
+ Furni	shed herewith.

- # Management contract or compensatory plan, contract or agreement.
- <sup>†</sup> Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

Exhibit 4.5

**Execution version** 

# LOAN AND SECURITY AGREEMENT

Dated as of November 8, 2016

between

# MERRIMACK PHARMACEUTICALS, INC. (as *Borrower*),

and

# BIOPHARMA CREDIT INVESTMENTS IV SUB, LP (as Lender)

## LOAN AND SECURITY AGREEMENT

THIS LOAN AND SECURITY AGREEMENT (this "Agreement"), dated as of November 8, 2016 (the "Effective Date") by and between MERRIMACK PHARMACEUTICALS, INC., a Delaware corporation ("Borrower"), and BIOPHARMA CREDIT INVESTMENTS IV SUB, LP, a Cayman Islands exempted limited partnership ("Lender"), provides the terms on which the Lender shall make, and Borrower shall repay, the Credit Extensions (as hereinafter defined). The parties hereto agree as follows:

## 1. <u>ACCOUNTING AND OTHER TERMS</u>

Except as otherwise expressly provided herein, all accounting terms not otherwise defined in this Agreement shall have the meanings assigned to them in conformity with GAAP. No change in the accounting principles used in the preparation of any financial statement hereafter adopted by Borrower shall be given effect for purposes of measuring compliance with any provision of <u>Section 7</u> unless Borrower and Lender agree to modify such provisions to reflect such changes in GAAP and, unless such provisions are so modified, all financial statements, Compliance Certificates and similar documents provided hereunder shall be provided together with a reconciliation between the calculations and amounts set forth therein before and after giving effect to such change in GAAP. Capitalized terms not otherwise defined in this Agreement shall have the meanings set forth in <u>Section 13</u>. All other terms contained in this Agreement, unless otherwise indicated, shall have the meaning provided by the Code to the extent such terms are defined therein.

# 2. LOANS AND TERMS OF PAYMENT

**2.1 Promise to Pay.** Borrower hereby unconditionally promises to pay Lender, the outstanding principal amount of all Term Loans advanced to Borrower by Lender and accrued and unpaid interest thereon and any other amounts due hereunder as and when due in accordance with this Agreement.

## 2.2 Term Loans.

(a) <u>Term Loan Availability</u>. Subject to the terms and conditions of this Agreement (including <u>Sections</u> 3.1 and 3.2), Lender agrees to make a term loan to Borrower on the Closing Date in a principal amount (the "**Term Loan Amount**") not less than Fifteen Million Dollars (\$15,000,000.00) and not exceeding Twenty-Five Million Dollars (\$25,000,000.00), to be evidenced by a note with an initial principal amount equal to such Term Loan Amount (the "**Term Loan**"). After repayment, the Term Loan may not be re-borrowed.

(b) <u>Repayment</u>. All unpaid principal and any accrued and unpaid interest with respect to the Term Loan is due and payable in full on the Term Loan Maturity Date. The Term Loan may be prepaid only in accordance with <u>Section 2.2(c)</u>, 2.2(d), 2.2(e), 2.2(f), 2.2(g) or 2.2(h) except as provided in <u>Section 9.1(a)</u>.

(c) <u>Mandatory Prepayment (Change of Control</u>). Upon a Change of Control, Borrower shall promptly, and in any event no later than thirty (30) days after the consummation of such Change of Control, notify Lender in writing of the occurrence of a Change of Control, which notice shall include reasonable detail as to the nature, timing and other circumstances of such Change of Control (such notice, a "**Change of Control Notice**"). Borrower shall prepay the Term Loan in full, no later than thirty (30) days after delivery to Lender of the Change of Control Notice, in an amount equal to the sum of all unpaid principal and any accrued and unpaid interest with respect to the Term Loan <u>plus</u> the Makewhole Amount payable pursuant to <u>Section 2.2(j)</u>.

(d) <u>Mandatory Prepayment (Asset Sale)</u>. (i) Upon any Asset Sale of property or assets included among the Collateral, whether or not permitted under Section 4.06 of the Indenture, Borrower shall prepay the Term Loan in full (and not in part), without any notice from or other action by Lender, within ten (10) days after the consummation of such Asset Sale, in an amount equal to the sum of all unpaid principal and any accrued and unpaid interest with respect to the Term Loan <u>plus</u> the Makewhole Amount payable pursuant to <u>Section 2.2(j)</u>. (ii) Upon any MM-398 Intellectual Property Sale, whether or not permitted under Section by Lender, within ten (10) days after the consummation of such Asset Sale, in an amount equal to the sum of all unpaid principal and any accrued and unpaid interest with respect to the Term Loan <u>plus</u> the sum of all unpaid principal and any accrued and unpaid interest with respect to the Term Loan plus the sum of all unpaid principal and any accrued and unpaid interest with respect to the Term Loan <u>plus</u> the Makewhole Amount payable pursuant to <u>Section 2.2(j)</u>. (iii) Borrower shall promptly, and in any event no later than two (2) Business Days thereafter, notify Lender in writing of the occurrence of any Asset Sale described in <u>clause (i)</u> or (ii) above, which notice shall include reasonable detail as to the nature, timing, proceeds and other circumstances of such Asset Sale (such notice, an "Asset Sale Notice").

(e) <u>Mandatory Prepayment (Senior Debt Refinancing)</u>. Without limiting (and notwithstanding) <u>Section</u> <u>2.2(g)</u>, upon the incurrence by Borrower or any of its Subsidiaries of Indebtedness that serves to refinance all or any part of the Indebtedness represented by the Securities, whether or not permitted under the Indenture or otherwise agreed to by the holders thereof, Borrower shall prepay the Term Loan in full (and not in part), without any notice from or other action by Lender, no later than ten (10) days after the occurrence of such incurrence, in an amount equal to the sum of all unpaid principal and any accrued and unpaid interest with respect to the Term Loan <u>plus</u> the Makewhole Amount payable pursuant to <u>Section 2.2(j)</u>. Borrower shall promptly, and in any event no later than two (2) Business Days thereafter, notify Lender in writing of the occurrence of any such incurrence, which notice shall include reasonable detail as to the nature, timing, amount and other circumstances of such incurrence (such notice, a "**Refinancing Notice**").

(f) <u>Mandatory Prepayment (Incurrence of Unsecured Indebtedness</u>). Upon the incurrence by Borrower or any of its Subsidiaries of unsecured Indebtedness in an aggregate amount exceeding Twenty Million Dollars (\$20,000,000.00), whether or not permitted under the Indenture or otherwise agreed to by the holders of Securities, Borrower shall prepay the Term Loan in full (and not in part), without any notice from or other action by Lender, no later than ten (10) days after the occurrence of such incurrence, in an amount equal to the sum of all unpaid principal and any accrued and unpaid interest with respect to the Term Loan <u>plus</u> the Makewhole Amount payable pursuant to <u>Section 2.2(j)</u>. Borrower shall promptly, and in any event no later

than two (2) Business Days thereafter, notify Lender in writing of the occurrence of any such incurrence, which notice shall include reasonable detail as to the nature, timing, amount and other circumstances of such incurrence (such notice, an "Unsecured Indebtedness Notice").

(g) <u>Mandatory Prepayment (Purchase of Securities</u>). Without limiting (and notwithstanding) <u>Section</u> <u>2.2(e)</u>, upon the purchase by Borrower of Securities, the aggregate principal amount of which exceeds ten percent (10%) of the aggregate principal amount of all Securities then-outstanding, whether or not permitted under the Indenture or otherwise agreed to by the holders of Securities, Borrower shall prepay the Term Loan in full (and not in part), without any notice from or other action by Lender, no later than ten (10) days after the consummation of such purchase, in an amount equal to the sum of all unpaid principal and any accrued and unpaid interest with respect to the Term Loan <u>plus</u> the Makewhole Amount payable pursuant to <u>Section 2.2(j)</u>. Borrower shall promptly, and in any event no later than two (2) Business Days thereafter, notify Lender in writing of the occurrence of any such purchase of Securities, which notice shall include reasonable detail as to the nature, timing, amount and other circumstances of such purchase (such notice, a "**Securities Purchase Notice**").

(h) <u>Permitted Prepayment of Term Loan</u>. From and after the Closing Date, Borrower shall have the option to prepay all, but not less than all, of the Term Loan advanced by Lender under this Agreement, <u>provided</u>, that (i) Borrower provides written notice to Lender of its election (which shall be irrevocable unless Lender otherwise consents in writing) to prepay the Term Loan at least ten (10) Business Days prior to such prepayment and (ii) such prepayment shall be accompanied by the Makewhole Amount payable pursuant to <u>Section 2.2(j)</u> and all other amounts payable or accrued and not yet paid hereunder and the other Loan Documents.

(i) <u>Prepayment Application</u>. All prepayments by Borrower pursuant to <u>Section 2.2(c)</u>, <u>2.2(d)</u>, <u>2.2(e)</u>, <u>2.2(f)</u>, <u>2.2(g)</u> or <u>2.2(h)</u> or as a result of acceleration of the Term Loan pursuant to <u>Section 9.1(a)</u> shall be accompanied by accrued and unpaid interest on the principal amount of the Term Loan to be prepaid to the date of payment in full. Any such prepayment (together with the accompanying Makewhole Amount that is payable pursuant to <u>Section 2.2(j)</u>), whether pursuant to <u>Section 2.2(j)</u>, whether pursuant to <u>Section 2.2(j)</u>, whether pursuant to <u>Section 9.1(a)</u>, shall be paid to Lender for application to the Obligations in the following order: (i) first, to due and unpaid Lender Expenses, (ii) second, to accrued and unpaid interest at the Default Rate, if any, (iii) third, to accrued and unpaid interest at the non-Default Rate, (iv) fourth, to the Makewhole Amount, (v) fifth, to the outstanding principal amount of the Term Loan being prepaid, and (vi) sixth, to any remaining amounts then due and payable hereunder.

(j) <u>Makewhole Amount</u>. Any prepayments of the Term Loan by Borrower (i) pursuant to <u>Section 2.2(c)</u>, 2.2(d), 2.2(e), 2.2(f), 2.2(g) or (2.2(h) or (ii) as a result of the acceleration of the Term Loan Maturity Date pursuant to <u>Section 9.1(a)</u>, shall, in any such case, be accompanied by payment of the Makewhole Amount.

# 2.3 Payment of Interest on the Credit Extensions.

(a) Interest Rate. Subject to Section 2.3(b), the principal amount outstanding under the Term Loan shall accrue interest at a fixed per annum rate (which rate shall be fixed for the duration of such Term Loan) equal to eleven and one-half percent (11.50%) per annum, which interest shall be payable quarterly in arrears commencing with the Payment Date of the first calendar quarter to occur after the Closing Date in accordance with Section 2.3(c). Interest shall accrue on the Term Loan commencing on, and including, the Closing Date, and shall accrue on the Term Loan, or any portion thereof, for the day on which the Term Loan or such portion is actually paid. Interest shall be computed on the basis of a year of 360 days and the actual number of days elapsed.

(b) <u>Default Rate</u>. Immediately upon the occurrence and during the continuance of an Event of Default (and without notice to Borrower or demand by Lender for payment thereof), the Obligations shall bear interest at a rate per annum which is three percentage points (3.00%) above the rate that is otherwise applicable thereto (the "**Default Rate**"), and such interest shall be payable entirely in cash on demand of Lender; provided, that, absent payment of such interest at the Default Rate when due, such Default Rate interest shall be capitalized on the last day of each fiscal month and such capitalized amount shall be added to the then-outstanding principal amount of the Term Loan and constitute outstanding principal for all purposes hereof. Payment, capitalization or acceptance of the increased interest rate provided in this <u>Section 2.3(b)</u> is not a permitted alternative to timely payment and shall not constitute a waiver of any Event of Default or otherwise prejudice or limit any rights or remedies of Lender.

(c) <u>Payments</u>. Except as otherwise expressly provided herein, all loan payments by Borrower hereunder shall be made to such bank account of Lender as Lender may designate by notice from time to time to Borrower on the date specified herein. Unless otherwise provided, interest is payable quarterly on the Payment Date of each calendar quarter. Payments of principal or interest received after 2:00 p.m. on such date are considered received at the opening of business on the next Business Day. When a payment is due on a day that is not a Business Day, the payment is due the next Business Day and additional fees or interest, as applicable, shall continue to accrue until paid. All payments to be made by Borrower hereunder or under any other Loan Document, including payments of principal and interest made hereunder and pursuant to any other Loan Document, and all fees, expenses, indemnities and reimbursements, shall be made without set-off, recoupment or counterclaim, in lawful money of the United States and in immediately available funds.

**2.4 Expenses.** Borrower shall pay to Lender, all Lender Expenses incurred through and after the Effective Date, upon demand.

# 2.5 Taxes; Withholding, etc.

(a) All sums payable by any Credit Party hereunder and under the other Loan Documents shall (except to the extent required by Requirements of Law) be paid free and clear of, and without any deduction or withholding on account of, any Tax imposed, levied, collected, withheld or assessed by or within the United States of America or any political subdivision in or of the United States of America or any other jurisdiction from or to which a payment is made by

or on behalf of any Credit Party or by any federation or organization of which the United States of America or any such jurisdiction is a member at the time of payment. In addition, Borrower agrees to pay, and shall indemnify and hold Lender harmless from, all present or future stamp, court or documentary, recording or filing Taxes or similar levies or Taxes which arise (i) from any payment made hereunder, (ii) from the execution, delivery, performance, enforcement or registration of any Loan Document, (iii) from the receipt or perfection of a security interest under any Loan Document, or (iv) otherwise with respect to any Loan Document, and within thirty (30) days after the date of paying such sum, Borrower shall furnish to Lender the original or a certified copy of a receipt evidencing payment thereof.

(b) If any Credit Party or any other Person is required by Requirements of Law to make any deduction or withholding on account of any Tax from any sum paid or payable by any Credit Party to Lender under any of the Loan Documents: (i) Borrower shall notify Lender of any such requirement or any change in any such requirement as soon as any Borrower becomes aware of it; (ii) Borrower shall pay any such Tax before the date on which penalties attach thereto, such payment to be made (if the liability to pay is imposed on any Credit Party) for its own account or (if that liability is imposed on Lender, as the case may be) on behalf of and in the name of Lender; and (iii) within thirty (30) days after paying any sum from which it is required by Requirements of Law to make any deduction or withholding, and within thirty (30) days after the due date of payment of any Tax which it is required by <u>clause (ii)</u> above to pay, Borrower shall deliver to Lender evidence satisfactory to Lender of such deduction, withholding or payment and of the remittance thereof to the relevant taxing or other Governmental Authority.

Lender (and any of its successors or assigns) shall deliver to Borrower on or prior to the Effective (c) Date, such properly completed and executed documentation reasonably requested by Borrower as will permit payments to be made hereunder and under any other Loan Documents without withholding or at a reduced rate of withholding. In addition, Lender (and any of its successors or assigns) shall, if reasonably requested by Borrower, deliver such other documentation prescribed by Requirements of Law or reasonably requested by Borrower as will enable Borrower to determine whether or not Lender (or its successors or assigns) is subject to backup withholding or information reporting requirements. Without limiting the generality of the foregoing, on or prior to the Effective Date, Lender shall provide to Borrower the appropriate IRS Form W-8, with any supporting information required, establishing that Lender is exempt from U.S. withholding tax on payments made hereunder and under any other Loan Documents. Lender agrees that if any form or certification it previously delivered expires or becomes obsolete or inaccurate in any respect, it shall update such form or certification or promptly notify Borrower in writing of its legal inability to do so. In furtherance of the foregoing, each Credit Party and Lender agree that, absent a change in Requirements of Law, provided that Lender provides the foregoing forms and documentation and through those forms and documentation establishes that it not subject to withholding tax under Requirements of Law, including FATCA, then any sum payable hereunder and under the other Loan Documents will not be subject to deduction by or withheld upon for U.S. Taxes by any Credit Party under this Section 2.5.

**2.6** Facility Fee. As additional consideration for Lender's agreement to advance money or extend credit for Borrower's benefit on the terms and conditions set forth in this Agreement, Borrower shall pay to Lender on the Effective Date the amount of Three Hundred and Seventy-five Thousand Dollars (\$375,000.00), which shall amount shall not be refundable, in whole or in part, for any reason (including, for the avoidance of doubt, the termination of this Agreement and any obligation of Lender to make the Term Loan hereunder pursuant to the ultimate sentence of Section 3.4).

# 2.7 Register; Term Loan Note.

(a) <u>Register</u>. Lender shall maintain at its principal office (as specified in, or as otherwise identified upon notice to the other parties hereto in accordance with, <u>Section 10</u>), a register for the recordation of the name and address of Lender, the principal of, and stated interest on, the Term Loan and the Term Loan Note held by Lender (the "**Register**"). The Register shall be available for inspection by Borrower at any reasonable time and from time to time upon reasonable prior notice. Lender shall record, or shall cause to be recorded, in the Register the principal of, and interest on, the Term Loan, and each repayment or prepayment in respect of the principal amount of the Term Loan and any such recordation shall be conclusive and binding on Borrower and Lender, absent manifest error; <u>provided</u>, that failure to make any such recordation, or any error in such recordation, shall not affect any of Borrower's Obligations in respect of the Term Loan; <u>provided further</u>, that in the event of any inconsistency between the Register and Lender's records, the recordations in the Register shall govern, absent manifest error. Borrower hereby designates Lender to serve as Borrower's agent solely for purposes of maintaining the Register as provided in this <u>Section 2.8</u>.

(b) <u>Term Loan Note</u>. Borrower shall execute and deliver to Lender or, if applicable and if so specified in such notice, to any Person who is an assignee of such Lender pursuant to <u>Section 12.1</u>, on the Closing Date a Term Loan Note to evidence the Term Loan.

# 3. <u>CONDITIONS OF LOAN</u>

3.1 Conditions Precedent to Term Loan. Lender's obligation to advance the Term Loan on the Closing Date is subject to the condition precedent that Lender shall have received such documents, in form and substance satisfactory to Lender or such other matters shall have been completed (or otherwise expressly waived in writing in Lender's sole discretion), as follows:

(a) copies of the Loan Documents originally executed and delivered by each applicable Credit Party, and each schedule to such Loan Documents (such schedules to be in form and substance reasonably satisfactory to Lender), including this Agreement, the Security Agreement and each Control Agreement required by the Lender (which such Control Agreement shall be executed by the applicable bank or financial institution);

- (b) true, correct and complete copies of the Operating Documents of each of the Credit Parties;
- (c) the Perfection Certificates for Borrower and its Subsidiaries;

(d) the organizational structure and capital structure of Borrower and each of its Subsidiaries shall be as set forth on Schedule 3.1(d);

(e) a good standing certificate for each Credit Party, certified (where applicable) by the Secretary of State of the State of incorporation of such Credit Party (or other applicable Governmental Authority) as of a date no earlier than thirty (30) days prior to the Closing Date;

(f) a director's or Secretary's Certificate with completed Borrowing Resolutions for each Credit Party;

(g) certified copies, dated as of a recent date, of lien searches, as Lender shall request, accompanied by written evidence (including any Code termination statements) that the Liens indicated in any such financing statements or other documents either constitute Permitted Liens or have been or, in connection with the Term Loan, will be terminated or released;

(h) each Credit Party shall have obtained all Governmental Approvals and all consents of other Persons, in each case that are necessary in connection with the transactions contemplated by the Loan Documents and each of the foregoing shall be in full force and effect. All applicable waiting periods shall have expired without any action being taken or threatened by any competent authority which would restrain, prevent or otherwise impose material and adverse conditions on the transactions contemplated by the Loan Documents or the financing thereof and no action, request for stay, petition for review or rehearing, reconsideration, or appeal with respect to any of the foregoing shall be pending, and the time for any applicable agency to take action to set aside its consent on its own motion shall have expired;

(i) opinions of counsel (which counsel shall be reasonably satisfactory to Lender) to the Credit Parties, in each case, in form and substance reasonably satisfactory to Lender;

(j) a summary in reasonable detail of all insurance policies required by <u>Section 6.5</u> hereof carried or maintained as of the Closing Date and evidence that such insurance policies are in full force and effect, together with appropriate evidence showing loss payable or additional insured clauses or endorsements in favor of Lender as applicable, subject to the Intercreditor Agreement;

(k) all documentation and other information required by bank regulatory authorities under applicable "know-your-customer" and anti-money laundering rules and regulations, including the U.S.A. Patriot Act (Title III of Pub. L. 107-56 (signed into law October 26, 2001)) (the "**Patriot Act**");

(1) evidence satisfactory to Lender in the form of a certificate, dated the Closing Date and signed by a Responsible Officer of Borrower, confirming that (i) on or before the Closing Date, Borrower has designated this Agreement and the Security Agreement, collectively, to be included in the definition of "Credit Agreement" under, and for all purposes of, the Indenture, and (ii) any and all requirements of Section 4.11(b) of the Indenture in connection with Lender's Lien on Collateral securing the Obligations created under the Security Agreement and the other Loan Documents, have been satisfied in full as of the Closing Date;

(m) evidence satisfactory to Lender in the form of a certificate of the Chief Financial Officer of Borrower that, as of the Closing Date, after giving effect to the incurrence of Indebtedness under the Term Loan Note, Borrower is Solvent and the Credit Parties, on a consolidated basis, are Solvent;

(n) payment of the Lender Expenses and other fees then due as specified in <u>Section 2.4</u> hereof;

(o) evidence that there shall be no litigation, public or private, or administrative proceedings, governmental investigation or other legal or regulatory developments, actual or threatened, that, singly or in the aggregate, could reasonably be expected to result in a Material Adverse Change except as set forth on <u>Schedule 5.6(b)</u>;

(p) a certificate, dated the Closing Date and signed by a Responsible Officer of Borrower, confirming satisfaction of the conditions precedent set forth in this Section 3.1 and Sections 3.2(b), (c), (d) and (e); and

(q) copy of the Intercreditor Agreement originally executed and delivered by each applicable Credit Party and the Trustee and/or Collateral Agent.

**3.2** Additional Conditions Precedent to Term Loan. The obligation of Lender to make the Term Loan on the Closing Date is subject to the satisfaction of each of the following additional conditions precedent:

(a) except as otherwise provided in <u>Section 3.4</u>, timely receipt of an executed Payment/Advance Forms in the form of <u>Exhibit A</u> hereto;

(b) each of the representations and warranties of the Credit Parties in this Agreement and the other Loan Documents which are not qualified as to materiality or Material Adverse Change shall be true, accurate, and complete in all material respects, and each of representations and warranties of the Credit Parties in this Agreement and the other Loan Documents which are qualified as to materiality or Material Adverse Change shall be true, accurate and complete in all respects, in each case, on the Closing Date, if and as applicable, as if made on such date, except to the extent that such representations and warranties specifically refer to an earlier date, in which case they shall have been true and correct in all material respects as of such earlier date;

(c) as of the Closing Date, there shall not have occurred and be continuing any "Default" or "Event of Default" (as such terms are defined in the Indenture) under the Indenture or any of the notes issued pursuant thereto or any of the guarantees thereof, or the Collateral Agreement or any of the other collateral documents relating thereto;

(d) (i) there shall not have occurred any Material Adverse Change and (ii) there shall not have occurred and be continuing any Default or Event of Default; and

(e) there shall not have occurred any Change in Law that prohibits, restricts or limits the ability of Lender to perform its obligations under any Loan Document to which it is a party.

**3.3 Covenant to Deliver.** The Credit Parties agree to deliver to Lender each item required to be delivered to Lender under this Agreement (unless otherwise waived in Lender's sole discretion) as a condition precedent to any Credit Extension. The Credit Parties expressly agree that a Credit Extension made prior to the receipt by Lender of any such item shall not constitute a waiver by Lender of the Credit Parties' obligation to deliver such item, and the making of any Credit Extension in the absence of a required item shall be in Lender's sole discretion. The request and acceptance by Borrower of the proceeds of the Term Loan shall be deemed to constitute, as of the Closing Date, a representation and warranty by Borrower that the conditions in Section 3.1 and Section 3.2 have been satisfied (unless otherwise waived in Lender's sole discretion).

3.4 **Procedures for Borrowing.** Subject to the prior satisfaction of all other applicable conditions to the making of the Term Loan set forth in this Agreement, to obtain the Term Loan, Borrower shall deliver to Lender by electronic mail or facsimile by no later than 5:00 pm on February 23, 2017 a completed Payment/Advance Form for the requested Term Loan executed by a Responsible Officer of Borrower, or his or her designee (which notice shall be irrevocable on and after the date on which such notice is given and Borrower shall be bound to make a borrowing in accordance therewith), in which case Lender shall make the Term Loan available to Borrower not later than 2:00 p.m. on the Closing Date, which such date shall occur not more than twenty (20) days after the date of delivery of such Payment/Advance Form (or, if the 20th day is not a Business Day, on the next Business Day thereafter), by wire transfer of same day funds in Dollars, to such account(s) as may be designated in writing to Lender by Borrower. Failure of Borrower to deliver such notice regarding the making of the Term Loan on or before 5:00 pm on February 23, 2017 shall be deemed to constitute Borrower's election not to request the proceeds of the Term Loan, and this Agreement shall terminate without any further obligation of Borrower hereunder other than accrued legal fees and expenses payable. Without limiting the foregoing, Borrower may terminate this Agreement, and any obligation of Lender to make the Term Loan hereunder, by written notice delivered at any time prior to the delivery of a completed Payment/Advance Form requesting a Term Loan, without any further obligation of Borrower hereunder other than for accrued and unpaid Lender Expenses pursuant to Section 2.4, which shall survive such termination.

# 4. <u>CREATION OF SECURITY INTEREST</u>

**4.1 Grant of Security Interest.** Without limiting any other security interest granted to the Secured Parties, pursuant to any Collateral Document, each of the Credit Parties hereby grants Lender to secure the payment and performance in full of all of the Obligations, a continuing security interest in, and pledges to Lender, the Collateral, wherever located, whether now owned or hereafter acquired or arising, and all proceeds and products thereof.

#### 4.2 **Priority of Security Interest.**

(a) Each Credit Party represents, warrants, and covenants that the security interest granted herein is and shall at all times continue to be a first priority perfected security interest in the Collateral (subject only to Permitted Liens that are permitted by the terms of this Agreement to have superior priority to the Lien in favor of Lender, if any).

(b) If this Agreement is terminated, Lender's Lien in the Collateral shall continue until the Obligations (other than inchoate indemnity obligations) are repaid in full in cash. Upon payment in full in cash of the Obligations (other than inchoate indemnity obligations) and at such time as Lender's obligations to make Credit Extensions has terminated, Lender shall, at the Credit Parties' sole cost and expense, release its Liens in the Collateral and all rights therein shall revert to the appropriate Credit Parties. At the request of any Credit Party following any such termination of Lender's obligations to make Credit Extensions, Lender shall deliver to such Credit Party any Collateral of such Credit Party held by Lender hereunder and execute and deliver to such Credit Party such documents as such Credit Party shall reasonably request to evidence such termination. Borrower hereby agrees to pay all reasonable costs and expenses incurred by Lender in connection with any such delivery of Collateral or the preparation, execution and delivery of any such documentation.

**4.3 Authorization to File Financing Statements.** The Credit Parties hereby authorize Lender to file financing statements, with notice to the Credit Parties, with all jurisdictions which Lender determines appropriate to perfect or protect its interest or rights hereunder, including a notice that any disposition of the Collateral, by either the Credit Parties or any other Person, shall be deemed to violate the rights of Lender under the Code, except dispositions permitted hereunder.

#### 5. <u>REPRESENTATIONS AND WARRANTIES</u>

In order to induce Lender to enter into this Agreement and to make the Credit Extensions to be made on the Closing Date, each Credit Party, jointly and severally, represents and warrants to Lender that the following statements are true and correct as of the Effective Date and as of the Closing Date (both with and without giving effect to the Term Loan), except in the case of the representations and warranties set forth in Section 5.24(c), which shall be true and correct only as of the Effective Date:

**5.1 Due Organization, Authorization; Power and Authority.** Each of the Borrower and its Subsidiaries has been duly organized, is legally existing and is in good standing (or equivalent status) under the laws of its jurisdiction of organization as identified in <u>Schedule 5.1</u>. Each of Borrower and its Subsidiaries is duly qualified as a foreign corporation (or other equivalent entity) in all jurisdictions in which the nature of its business or location of its properties require such qualifications except where the failure to be so qualified would not reasonably be expected to have a Material Adverse Change. Each of Borrower and its Subsidiaries has the requisite corporate (or other equivalent organizational) power and authority to own, lease or operate the properties and assets it purports to own, lease or operate, to carry on its business as presently conducted and to execute, deliver and perform its obligations under each Loan Document to which it is a party except where the failure to have such power and authority to own, lease or operate such properties and assets and carry on such business would not reasonably be expected to have a Material Adverse Change;

**5.2** Equity Interests and Ownership. <u>Schedule 5.2</u> sets forth a complete and accurate list of Borrower and each Subsidiary of Borrower showing, as of the Effective Date (as to each), the jurisdiction of its organization, the address of its principal place of business and its U.S. taxpayer identification number. All of the outstanding Equity Interests in Borrower and its

Subsidiaries have been duly authorized and validly issued and are fully paid and non-assessable, and, in the case of any Subsidiary of Borrower, the Equity Interests of such Subsidiary that are owned by Borrower are owned by Borrower free and clear of all Liens except Permitted Liens and those Liens created under the Security Agreement and the other Loan Documents. The organizational structure and capital structure of Borrower and each of its Subsidiaries is as set forth on <u>Schedule 3.1(d)</u>;

# 5.3 No Conflict; Government Consents.

(a) The execution and delivery by each of Borrower and its Subsidiaries of each Loan Document to which it is a party, the performance of obligations by each of Borrower and its Subsidiaries under each Loan Document to which it is a party and the consummation of the transactions contemplated hereby and thereby do not and will not, (i) contravene the terms of Borrower's or such Subsidiaries' Operating Documents, (ii) violate any Requirement of Law, determination or award applicable to Borrower or any of such Subsidiaries or their respective properties or assets, (iii) conflict with or result in the breach of, or constitute a default, result in the acceleration of any obligation or require any payment to be made under, any indenture (including the Indenture), mortgage, deed of trust, loan agreement or other agreement or instrument to which Borrower or any of its Subsidiaries is a party or by which Borrower or any of its Subsidiaries is bound or to which any of the property or assets of Borrower or any of its Subsidiaries is subject or (iv) except as contemplated by the Loan Documents, result in or require the creation or imposition of any Lien (other than any Permitted Lien) upon or with respect to any of the properties or assets of Borrower or any of its Subsidiaries, other than as set forth in <u>Schedule 5.3(a)</u> and, in the case of <u>clause (ii)</u>, <u>clause (iii)</u> and <u>clause (iv)</u>, where such violation, conflict, breach, default, acceleration, payment, creation or imposition would not reasonably be expected to have a Material Adverse Change;

(b) No exemption from, notice to, registration, filing or declaration with, or Governmental Approval or other action of any Governmental Authority, and no notice to or consent, approval, authorization or other action of any other Person, is necessary or required in connection with (i) the execution or delivery by Borrower or any of its Subsidiaries of any Loan Document to which it is a party or the performance of obligations by Borrower or any of its Subsidiaries under any Loan Document to which it is a party, (ii) the transactions contemplated by the Loan Documents, (iii) the grant by the Credit Parties of the Liens granted or purported to be granted by it pursuant to the Security Agreement and the other Loan Documents or (iv) the perfection of the Liens created under the Security Agreement and the other Loan Documents, other than (A) such exemptions, notices, registrations, filings, declarations, consents, approvals, authorizations and other actions as shall have been taken, given, made or obtained and are in full force and effect as of the Effective Date, in each case, as set forth in <u>Schedule 5.3(b)</u>, (B) such filings required to be made after the date hereof under applicable federal, state and foreign securities Requirements of Laws, if any, (C) the filing of financing statements under the Code and any other recordings (including in any applicable foreign jurisdiction) required to perfect a security interest in the Collateral and (D) such exemptions, notices, registrations, filings, declarations, consents, approvals, authorizations and other actions, filings, declarations, consents, approvals, notices, registrations, filings, declarations, consents, approvals, authorizations and other actions, filings, declarations, consents, approvals, authorizations and other actions, filings, declarations, consents, approvals, authorizations, notices, registrations, filings, declarations, consents, approvals, authorizations and other actions, the failure of which to take, give, make or obtain would not reasonably be ex

**5.4 Binding Obligation.** Each Loan Document to which Borrower or any of its Subsidiaries is a party has been duly authorized, executed and delivered by Borrower or such Subsidiary and constitutes the valid, legally binding and, assuming due authorization, execution and delivery by all other parties thereto (subject to general equitable principles, insolvency, liquidation, reorganization and other laws of general application relating to creditors' rights), enforceable obligation of Borrower or such Subsidiary, as the case may be;

**5.5 Collateral.** In connection with this Agreement, each Credit Party has delivered to Lender a completed certificate signed by such Credit Party and its Subsidiaries (each, a "Perfection Certificate", and collectively, the "Perfection Certificates"). Each Credit Party represents and warrants to Lender that:

(i) its exact legal name is that indicated on its Perfection Certificate and on the signature page (a) thereof; (ii) it is an organization of the type and is organized in the jurisdiction set forth in its Perfection Certificate; (iii) its Perfection Certificate accurately sets forth its organizational identification number or accurately states that it has none; (iv) its Perfection Certificate accurately sets forth its place of business, or, if more than one, its chief executive office as well as its mailing address (if different than its chief executive office); (v) except as set forth in the Perfection Certificates, it (and each of its predecessors) has not in the past five (5) years changed its jurisdiction of formation, organizational structure or type or any organizational number assigned to it by its jurisdiction; and (vi) all other information set forth on its Perfection Certificate pertaining to it and each of its Subsidiaries is accurate and complete (it being understood and agreed that each Credit Party may from time to time update certain information in its Perfection Certificate after the Effective Date to the extent permitted by one or more specific provisions in this Agreement). If any Credit Party is not now a Registered Organization but later becomes one, it shall promptly notify Lender of such occurrence and provide Lender with such Credit Party's organizational identification number. Lender hereby agrees that the Perfection Certificates shall be deemed to be updated to reflect information provided in any notice delivered by any Credit Party to Lender pursuant to the last full paragraph of <u>Section 7.2</u> below; provided, that any update to the Perfection Certificates by any Credit Party pursuant to the last full paragraph of Section 7.2 below shall not relieve any Credit Party of any other Obligation under this Agreement;

(b) (i) it has good title to, has rights in, and the power to transfer each item of the Collateral upon which it purports to grant a Lien hereunder or under any Collateral Document, free and clear of any and all Liens except Permitted Liens and (ii) the Collateral does not include any deposit accounts, securities accounts, commodity accounts or other investment accounts in excess of \$500,000 in the aggregate (measured by reference to the closing balance of such accounts as of each Business Day) other than the deposit accounts, securities accounts, commodity accounts or other investment accounts described in the Perfection Certificates delivered to Lender in connection herewith, or of which such Credit Party has given Lender written notice and taken such actions as are necessary (other than with respect to Excluded Accounts) to give Lender a perfected security interest therein (and upon delivery of such notice and taking such action, the Perfection Certificates will be deemed to be updated with the information contained in such notice), and (iii) Collateral consisting of Inventory is not in the possession of any third Person bailee, warehouseman or other agent or processor (including any contract manufacturing organization) with a Fair Market Value in excess of \$2,500,000 in the

aggregate (calculated based on the applicable Credit Party's estimate of the Fair Market Value of such Collateral to be possessed by such bailee, warehouseman, agent or processor (including any contract manufacturing organization) over the course of any calendar year on a weighted average basis) except as otherwise provided in the Perfection Certificates or as permitted pursuant to <u>Section</u> <u>7.2</u>. None of the Collateral shall be held at locations other than (x) as disclosed in the Perfection Certificates, (y) as permitted pursuant to <u>Section 7.2</u>, or (z) as otherwise held by field staff or employees of the Credit Parties or its patients in the ordinary course of business;

(c) With respect to Product, all Inventory of Borrower and its Subsidiaries, whether held by any of them for sale or lease, to be furnished under contract of service, or otherwise, is in all respects of good and marketable quality, free from defects, and is maintained in accordance with all applicable FDA Good Manufacturing Practices (or any foreign equivalent) using commercially reasonable efforts standard in the industry, in each case, other than such deficiencies, defects, damage, insufficiencies, neglect or shortcomings that would not reasonably be expected to have a Material Adverse Change;

(d) Each Product performs in accordance with its documented specifications and as each Credit Party or its Subsidiaries has warranted to its customers, except for such nonperformance that would not reasonably be expected to have a Material Adverse Change;

## 5.6 No Violation or Default; No Adverse Proceedings, etc.

(a) Neither Borrower nor any of its Subsidiaries is (i) in violation of its Operating Documents, (ii) in default, and no event has occurred that, with notice or lapse of time or both, would constitute such a default, in the due performance or observance of any term, covenant or condition contained in any indenture (including the Indenture), mortgage, deed of trust, loan agreement or other agreement or instrument to which Borrower or any of its Subsidiaries is a party or by which Borrower or any of its Subsidiaries is bound or to which any of the property or assets of Borrower or any of its Subsidiaries is subject, or (iii) in violation of any Requirements of Law, except, in the case of <u>clauses (ii)</u> and <u>(iii)</u> above, for any such default or violation that would not reasonably be expected to, individually or in the aggregate, have a Material Adverse Change. On the Closing Date, there exists no Event of Default or any event that, had the Term Loan Note already been issued, would constitute a Default or an Event of Default under this Agreement;

(b) Except as described on <u>Schedule 5.6(b)</u>, there are no Adverse Proceedings pending to which Borrower or any of its Subsidiaries is a party or to which any property of Borrower or any of its Subsidiaries is subject that, individually or in the aggregate, would reasonably be expected to have a Material Adverse Change. To the Knowledge of Borrower, no such Adverse Proceedings are threatened or contemplated by any Governmental Authority or threatened by other Persons. There are no current or pending legal, governmental or regulatory actions, suits or proceedings that are required under the Exchange Act to be described in the Exchange Act Documents that are not so described in the Exchange Act Documents and there are no statutes, regulations or contracts or other documents that are required under the Exchange Act to be filed as exhibits to the Exchange Act Documents or described in the Exchange Act Documents that are not so filed as exhibits to the Exchange Act Documents or described in the Exchange Act Documents;

#### 5.7 Financial Statements; Financial Condition; No Material Adverse Change.

(a) The financial statements (including the related notes thereto) of Borrower and its Subsidiaries included in the Exchange Act Documents comply in all material respects with the applicable requirements of the Securities Act and the Exchange Act, as applicable, and present fairly the financial position of Borrower and its Subsidiaries as of the dates indicated and the results of their operations and the changes in their cash flows for the periods specified. Such financial statements have been prepared in conformity with GAAP applied on a consistent basis throughout the periods covered thereby, except as otherwise disclosed therein and, in the case of unaudited, interim financial statements, subject to normal year-end audit adjustments and the exclusion of certain footnotes, and any supporting schedules included in the Exchange Act Documents present fairly the information required to be stated therein. The other financial information included in the Exchange Act Documents has been derived from the accounting records of Borrower and its Subsidiaries and presents fairly the information shown thereby;

Since December 31, 2015, (i) there has not been any material change in the capital stock (other than (b) the issuance of shares of common stock of Borrower upon exercise of stock options and warrants described as outstanding in, and the grant of options and awards under existing equity incentive plans described in, the Exchange Act Documents), short-term debt or long-term debt of Borrower or any of its Subsidiaries, or any dividend or distribution of any kind declared, set aside for payment, paid or made by Borrower on any class of capital stock, or any material adverse change, or any development that would reasonably be expected to, individually or in the aggregate, result in a material adverse change, in or affecting the business, properties, management, financial position, stockholders' equity, results of operations or prospects of Borrower and its Subsidiaries, taken as a whole, (ii) neither Borrower nor any of its Subsidiaries has entered into any transaction or agreement (whether or not in the ordinary course of business) that, individually or in the aggregate, is material to Borrower and its Subsidiaries, taken as a whole, or incurred any liability or obligation, direct or contingent, that, individually or in the aggregate, is material to Borrower and its Subsidiaries, taken as a whole, and (iii) neither Borrower nor any of its Subsidiaries has sustained any loss or interference with its business that, individually or in the aggregate, is material to Borrower and its Subsidiaries, taken as a whole, and that is either from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor disturbance or dispute or any action, order or decree of any arbitrator or Governmental Authority, except as otherwise disclosed in the Exchange Act Documents or otherwise contemplated pursuant to this Agreement;

**5.8** Solvency. The fair value of Borrower and the fair value of Borrower and its Subsidiaries on a consolidated basis exceeds the fair value of its or their liabilities (as the case may be); Borrower will not be left with unreasonably small capital after the transactions in this Agreement, and will be able to pay its debts (including trade debts) as they mature. There has been no proposal made or resolution adopted by any competent corporate body for the dissolution, winding-up or liquidation of any Credit Party, nor do any circumstances exist which may result in the dissolution, winding-up or liquidation of any Credit Party. None of the Credit Parties has (i) made a general assignment for the benefit of creditors, (ii) filed any voluntary petition in bankruptcy or suffered the filing of an involuntary petition by any creditor, (iii) suffered the attachment or judicial seizure of all or any portion of its assets, (iv) admitted in writing its inability to pay its debts as they come due, or (v) made an offer of settlement, extension or composition to its creditors generally;

**5.9 Payment of Taxes.** All U.S. federal income and all other material federal, state, foreign, provincial and other material Tax returns and reports (or extensions thereof) of each Credit Party and its Subsidiaries required to be filed by any of them have been timely filed, and all material Taxes which are due and payable by any Credit Party and its Subsidiaries and all material assessments, fees and other governmental charges upon any Credit Party and its Subsidiaries and upon their respective properties, assets, income, businesses and franchises have been timely paid except where the validity or amount thereof is being contested in good faith by appropriate proceedings; provided, that (i) the applicable Credit Party has set aside on its books adequate reserves therefor in conformity with GAAP and (ii) the failure to pay such Taxes, individually or in the aggregate, has not resulted or could not reasonably be expected to result in a Material Adverse Change. No Credit Party has knowledge of any proposed Tax deficiency or assessment against it or any of its Subsidiaries which is not being actively contested by it or such Subsidiary in good faith and by appropriate proceedings; provided, that such reserves or other appropriate provisions, if any, as shall be required in conformity with GAAP shall have been made or provided therefor. Neither any Credit Party nor any of its Subsidiaries has any obligation under any written Tax sharing agreement;

# 5.10 Environmental Matters.

(a) Borrower and its Subsidiaries (i) are, and at all prior times were, in compliance with any and all Environmental Laws, (ii) have received and are in compliance with all permits, licenses, certificates or other authorizations or approvals required of them under applicable Environmental Laws to conduct their respective businesses, (iii) have not received notice of any actual or potential liability under or relating to, or actual or potential violation of, any Environmental Laws, including for the investigation or remediation of any Release or threat of Release of Hazardous Materials, and have no Knowledge of any event or condition that could reasonably be expected to result in any such notice, (iv) are not conducting or paying for, in whole or in part, any investigation, remediation or other corrective action pursuant to any Environmental Law. There are no costs or liabilities associated with Environmental Laws of or relating to Borrower or its Subsidiaries, except in the case of each of <u>clause</u> (<u>i</u>) and <u>clause</u> (<u>ii</u>) above, for any such matter, as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Change;

(b) Except as described on <u>Schedule 5.10(b)</u>, (i) there are no proceedings that are pending, or, to the Knowledge of Borrower, contemplated, against Borrower or any of its Subsidiaries under any Environmental Laws in which a Governmental Authority is also a party, other than such proceedings regarding which it is reasonably believed no monetary sanctions of \$100,000 or more will be imposed, (ii) Borrower and its Subsidiaries are not aware of any facts or issues regarding compliance with Environmental Laws, or liabilities or other obligations under Environmental Laws, including the Release or threat of Release of Hazardous Materials, that could reasonably be expected to have a material effect on the capital expenditures, earnings or competitive position of Borrower and its Subsidiaries, and (iii) none of Borrower and its Subsidiaries material capital expenditures relating to any Environmental Laws;

(c) There has been no storage, generation, transportation, use, handling, treatment, Release or threat of Release of Hazardous Materials by, relating to or caused by Borrower or any of its Subsidiaries (or, to the Knowledge of Borrower and its Subsidiaries, any other entity (including any predecessor) for whose acts or omissions Borrower or any of its Subsidiaries is or would reasonably be expected to be liable) at, on, under or from any property or facility now or previously owned, operated or leased by Borrower or any of its Subsidiaries, or at, on, under or from any other property or facility, in violation of any Environmental Laws or in a manner or amount or to a location that would reasonably be expected to result in any liability under any Environmental Law, except for any violation or liability that would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Change;

**5.11 Material Contracts.** After giving effect to the consummation of the transactions contemplated by this Agreement, all Material Contracts are in full force and effect and constitute the valid, legally binding and (subject to general equitable principles, insolvency, liquidation, reorganization and other Requirements of Laws of general application relating to creditors' rights) enforceable obligation of Borrower or its Subsidiaries party thereto and, to the Knowledge of Borrower, all other parties thereto, except in each case as would not reasonably be expected to have a Material Adverse Change. To the Knowledge of Borrower, there are no oral waivers or modifications (or pending requests therefor) in respect of such Material Contracts, except as would not reasonably be expected to have a Material Contract, except as would not reasonably be expected to have a Material Contract binding on it except where such breaches or defaults would not reasonably be expected to have a Material Adverse Change. To the Knowledge of Borrower, no other Person party to any such Material Contract is in default thereunder except where such default would not reasonably be expected to have a Material Adverse Change. To the Knowledge of Borrower, no party to any such Material Contract has given any notice of termination or breach of any such Material Contract;

## 5.12 Regulatory Compliance.

(a) No Credit Party is an "investment company" or a company "controlled" by an "investment company" under the Investment Company Act of 1940, as amended;

(b) Each Credit Party has complied in all material respects with the Federal Fair Labor Standards Act, except where noncompliance would not reasonably be expected to have a Material Adverse Change;

(c) (i) Each Plan has been maintained in compliance with its terms and the requirements of any applicable statutes, orders, rules and regulations, including ERISA and the IRC, except for noncompliance that would not reasonably be expected to result in material liability to Borrower or its Subsidiaries, (ii) no prohibited transaction, within the meaning of Section 406 of ERISA or Section 4975 of the IRC, has occurred with respect to any Plan, excluding transactions effected pursuant to a statutory or administrative exemption that would reasonably be expected to result in a material liability to Borrower or its Subsidiaries, (iii) for each Plan that is subject to the funding rules of Section 412 of the IRC or Section 302 of ERISA, the minimum funding standard of Section 412 of the IRC or Section 302 of ERISA, as applicable, has been satisfied (without taking into account any waiver thereof or extension of any

amortization period) and is reasonably expected to be satisfied in the future (without taking into account any waiver thereof or extension of any amortization period), (iv) the fair market value of the assets of each Plan that is required to be funded equals or exceeds the present value of all benefits accrued under such Plan (determined based on those assumptions used to fund such Plan), (v) no "reportable event" (within the meaning of Section 4043(c) of ERISA) has occurred or is reasonably expected to occur that either has resulted, or would reasonably be expected to result, in a material liability to Borrower or its Subsidiaries, (vi) neither Borrower nor any member of the Controlled Group (as defined in the definition of "Plan" in <u>Section 13.1</u>) has incurred, or reasonably expects to incur, any liability under Title IV of ERISA (other than contributions to the Plan or premiums to the Pension Benefit Guaranty Corporation, in the ordinary course and without default) in respect of a Plan (including a "multiemployer plan", within the meaning of Section 4001(a)(3) of ERISA) and (vii) there is no pending audit or investigation by the IRS, the U.S. Department of Labor, the Pension Benefit Guaranty Corporation or any other Governmental Authority with respect to any Plan that would reasonably be expected to result in a material liability to Borrower or its Subsidiaries;

(d) Borrower has not failed to file with the Regulatory Agency any required filing, declaration, listing, registration, report or submission with respect to Borrower's Product candidates that are described or referred to in the Exchange Act Documents. All such filings, declarations, listings, registrations, reports or submissions were in material compliance with Requirements of Laws when filed. No deficiencies regarding compliance with Requirements of Law have been asserted by any applicable Regulatory Agency with respect to any such filings, declarations, listings, registrations, reports or submissions;

**5.13** Use of Proceeds; Margin Regulations. No part of the proceeds of the Credit Extensions will be used, directly or indirectly, for the purpose of purchasing or carrying any margin stock within the meaning of Regulation U of the Board of Governors of the Federal Reserve System (12 C.F.R. 221), or for the purpose of purchasing or carrying or trading in any securities under such circumstances as to involve Borrower in a violation of Regulation X of said Board (12 C.F.R. 224) or to involve any broker or dealer in a violation of Regulation T of said Board (12 C.F.R. 220). Borrower is not engaged in the business of extending credit for the purpose of purchasing or carrying margin stock within the meaning of Regulation U of the Board of Governors of the Federal Reserve System (12 C.F.R. 221). As used in this Section 5.13, the terms "margin stock" and "purpose of purchasing or carrying" shall have the meanings ascribed to them in said Regulation U;

5.14 **Receivable Financings.** Except as disclosed in the Exchange Act Documents, neither Borrower nor any of its Subsidiaries have entered into any Receivables Financing (as such term is defined in the Indenture);

**5.15 Labor Matters.** No labor disturbance by or dispute with employees of Borrower or any of its Subsidiaries exists or, to the Knowledge of Borrower, is contemplated or threatened, and Borrower is not aware of any existing or imminent labor disturbance by, or dispute with, the employees of any of its or its Subsidiaries' principal suppliers, contractors or customers, except as would be reasonably expected not to have a Material Adverse Change;

**5.16** Use of Proceeds. Borrower shall use the proceeds of the Credit Extensions for general corporate purposes and not for any other purposes, including personal, family, household or agricultural purposes;

**5.17 Insurance.** Except as described in the Exchange Act Documents, Borrower and its Subsidiaries have insurance covering their respective properties, operations, personnel and businesses, including business interruption insurance, which insurance is in amounts and insures against such losses and risks as Borrower reasonably believes are adequate to protect Borrower and its Subsidiaries and their respective businesses. Neither Borrower nor any of its Subsidiaries has (a) received notice from any insurer or agent of such insurer that material capital improvements or other expenditures are required or necessary to be made in order to continue such insurance or (b) any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage at reasonable cost from similar insurers as may be necessary to continue its business;

#### 5.18 FCPA; Patriot Act; OFAC.

(a) None of Borrower, its Subsidiaries and, to the Knowledge of Borrower, any director, officer, agent, employee or other person associated with or acting on behalf of Borrower or any of its Subsidiaries has (i) used any corporate funds of Borrower or any of its Subsidiaries for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity, (ii) made any direct or indirect unlawful payment to any foreign or domestic government official or employee from corporate funds of Borrower or any of its Subsidiaries, (iii) violated or is in violation of any provision of the Foreign Corrupt Practices Act of 1977, as amended, or (iv) made any bribe, rebate, payoff, influence payment, kickback or other unlawful payment;

(b) The operations of Borrower and its Subsidiaries are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the Bank Secrecy Act of 1970, as amended by Title III of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT) Act of 2001, the money laundering statutes of all applicable jurisdictions, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any Governmental Authority (collectively, the "Money Laundering Laws") and no action, suit or proceeding by or before any Governmental Authority or any arbitrator involving Borrower or any of its Subsidiaries with respect to the Money Laundering Laws is pending or, to the Knowledge of Borrower, threatened;

(c) None of Borrower, its Subsidiaries and, to the Knowledge of Borrower, any director, officer, agent, employee or Affiliate of Borrower or any of its Subsidiaries is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury ("OFAC") or imposed by the Trading with the Enemy Act, 50 U.S.C. App. 1 et seq. Borrower will not, directly or indirectly, use the proceeds of the Credit Extensions, or lend, contribute or otherwise make available such proceeds to any Subsidiary, joint venture partner or other Person, for the purpose of financing the activities of any Person currently subject to any U.S. sanctions administered by OFAC;

**5.19** Accounts Receivable. Except as described on <u>Schedule 5.19</u> or as disclosed in any Compliance Certificate, the accounts receivable for Products owing to Borrower or any of its Subsidiaries reflected in the financial statements of Borrower and its Subsidiaries included in the Exchange Act Documents and such accounts receivable arising after the date thereof and reported by Borrower under <u>Section 6.2(a)(i)</u> or (ii), (a) have arisen from bona fide transactions entered into by Borrower or its Subsidiaries involving the sale of Products in the ordinary course of business consistent with past practice, (b) constitute only valid, undisputed claims of Borrower or its Subsidiaries not subject to claims of set-off or other defenses or counterclaims other than normal cash discounts accrued in the ordinary course of business consistent with past practice, (c) have been calculated and recorded on the accounting records of Borrower and its Subsidiaries in good faith based upon reasonable assumptions and in all respects in accordance with GAAP, consistently applied, subject to normal year-end audit adjustments and the absence of disclosures normally made in footnotes, and (d) have a likelihood of collection within one hundred and twenty (120) days after billing based upon good faith estimates and reasonable assumptions;

5.20 Clinical Trials. The clinical and pre-clinical trials conducted by or, to the Knowledge of Borrower, on behalf of or sponsored by Borrower or its Subsidiaries, or in which Borrower or its Subsidiaries have participated, that are described in the Exchange Act Documents, or the results of which are referred to in the Exchange Act Documents, as applicable, were, and if still pending are, being conducted in all material respects in accordance with standard medical and scientific research standards and procedures for products or product candidates comparable to those being developed by Borrower and all Requirements of Laws of the FDA and comparable regulatory agencies outside of the United States to which they are subject (each, a "Regulatory Agency") and current Good Clinical Practices and Good Laboratory Practices. The descriptions in the Exchange Act Documents of the results of such studies and tests, when they were filed with the SEC, were accurate and complete descriptions in all material respects and fairly presented the data derived therefrom. Borrower has no Knowledge of any other trials not described in the Exchange Act Documents, the results of which are inconsistent with or call into question the results described or referred to in the Exchange Act Documents. Borrower and its Subsidiaries have operated at all times and are currently in compliance in all material respects with all Requirements of Laws of the Regulatory Agencies. Neither Borrower nor any of its Subsidiaries have received any written notices, correspondence or other communications from the Regulatory Agencies or any other Governmental Authority requiring or threatening the termination, material modification or suspension of any clinical or pre-clinical trials that are described in the Exchange Act Documents or the results of which are referred to in the Exchange Act Documents, other than ordinary course communications with respect to modifications in connection with the design and implementation of such trials, and, to Borrower's Knowledge, there are no reasonable grounds for the same;

**5.21 Regulatory Approvals.** Borrower and its Subsidiaries possess all licenses, certificates, permits and other authorizations issued by, and have made all declarations and filings with, the appropriate Governmental Authorities that are necessary for the ownership or lease of their respective properties or the conduct of their respective businesses as described in the Exchange Act Documents, except where the failure to possess or make the same would not, individually or in the aggregate, have a Material Adverse Change. Except as described in the Exchange Act Documents, neither Borrower nor any of its Subsidiaries has received notice of

any revocation or modification of any such license, certificate, permit or authorization or has any reason to believe that any such license, certificate, permit or authorization will not be renewed in the ordinary course. Except as described in the Exchange Act Documents, Borrower and its Subsidiaries (a) are, and at all times have been, in compliance with all Requirements of Laws applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, storage, import, export or disposal of any Product manufactured or distributed by Borrower or its Subsidiaries, except where such noncompliance would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Change, and (b) have not received any FDA Form 483, written notice of adverse finding, warning letter, untitled letter or other correspondence or written notice from any arbitrator or Governmental Authority alleging or asserting non-compliance with (i) any such Requirements of Laws or (ii) any licenses, exemptions, certificates, approvals, clearances, authorizations, permits and supplements or amendments thereto required by any such Requirements of Laws;

**5.22 Properties.** Each of Borrower and its Subsidiaries has good and marketable title to, or valid leasehold interests in or rights to use, all of its tangible properties and assets material to its business as presently conducted, free and clear of all Liens other than Permitted Liens. Neither Borrower nor any of its Subsidiaries owns any real property. <u>Schedule 5.22(a)</u> sets forth a complete and accurate list of all leases of real property to which Borrower or any of its Subsidiaries is party (whether as lessor, lessee or otherwise), showing as of the date hereof the street address, county and state (or other relevant jurisdiction), lessor, lessee and expiration date. To the Knowledge of Borrower, any real property held by Borrower or any of its Subsidiaries under lease constitutes the valid, legally binding and (subject to general equitable principles, insolvency, liquidation, reorganization and other Requirements of Laws of general application relating to creditors' rights) enforceable obligation of all parties thereto except as would not reasonably be expected to have a Material Adverse Change. Except as set forth on Schedule 5.22(b), no warehouse owned or operating by a third Person is used to store any Collateral, including any Product at any point in the supply chain;

#### 5.23 Intellectual Property.

(a) To the Knowledge of Borrower, Borrower owns, or possesses the right or license to use, all of the Intellectual Property that is reasonably necessary for the operation of its business as presently conducted, without conflicting with the valid and enforceable rights of any other Person, except for the failure to own or license that would not reasonably be expected to result in a Material Adverse Change. To the Knowledge of Borrower, no slogan or other advertising device, product, process, method, substance, part or other material presently employed by Borrower infringes upon any valid and enforceable rights held by any other Person except where such infringement would not reasonably be expected to have a Material Adverse Change. No claim or litigation regarding any of the foregoing is pending against Borrower or, to the Knowledge of Borrower, threatened in writing that would reasonably be expected to have a Material Adverse Change;

(b) To the Knowledge of Borrower, there is no third party infringing any Intellectual Property or proprietary right in relation to the Relevant Intellectual Property except where such infringement would not reasonably be expected to have a Material Adverse Change. To the Knowledge of Borrower, at least one claim of each of such Patents that are reasonably

necessary for the operation of the business of Borrower as presently conducted ("**Relevant Patents**") that has issued is valid and enforceable. To the Knowledge of Borrower, there are no litigation, interference or opposition proceedings pending or threatened in writing relating to the Relevant Patents that would reasonably be expected to result in a Material Adverse Change. All patent applications owned by Borrower that are reasonably necessary for the operation of the business by Borrower as currently conducted are being diligently prosecuted by Borrower, and Borrower duly maintains those Relevant Patents that have issued and are owned by it. Borrower has not been notified in writing of any actions by any Governmental Authority challenging the validity or enforceability of any of the issued Relevant Patents that would reasonably be expected to have a Material Adverse Change;

(c) Borrower is the owner or holder of each new drug application or abbreviated new drug application set forth in <u>Schedule 5.23(c)</u>. Borrower has not granted or assigned to any other Person, directly or indirectly, any rights under any such new drug application or abbreviated new drug application; <u>provided</u>, <u>however</u>, that Borrower may have assigned or granted to a Person the right to manufacture Product under such new drug application or abbreviated new drug application and/or the right to a share of profit from Borrower's sales of Product under such new drug application or abbreviated new drug application. <u>Schedule 5.23(c)</u> sets forth the Product that pertains to each such new drug application and abbreviated new drug application;

# 5.24 Additional Representations and Warranties.

(a) <u>Schedule 5.24(a)</u> sets forth a complete list of the following types of Indebtedness of Borrower and its Subsidiaries outstanding as of the Closing Date: (i) Indebtedness in respect of borrowed money; (ii) any other obligation of Borrower or any of its Subsidiaries to be liable for, or to pay, as obligor, guarantor or otherwise, on the Indebtedness for borrowed money of another Person (other than by endorsement of negotiable instruments for collection in the ordinary course of business); and (iii) to the extent not otherwise included, Indebtedness for borrowed money of another Person (whether or not such Indebtedness for borrowed money is assumed by such Person);

(b) The documents filed by Borrower with the SEC pursuant to the Exchange Act since January 1, 2016 (the "Exchange Act Documents"), when they were filed with the SEC, conformed in all material respects to the requirements of the Exchange Act, and none of such documents contained any untrue statement of a material fact or omitted to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading; and

(c) Except as disclosed in the Exchange Act Documents, to the Knowledge of Borrower, as of the Effective Date, neither Borrower nor any of its Subsidiaries has received any notice or correspondence from Shire plc or any of its Affiliates, regarding any denial, rejection or objection to the application for marketing authorization for ONIVYDE® (irinotecan liposome injection) in combination with fluorouracil (5-FU) and leucovorin for the treatment of patients with metastatic pancreatic adenocarcinoma who have progressed after gemcitabine-based therapy.

#### 6. <u>AFFIRMATIVE COVENANTS</u>

Each Credit Party covenants and agrees that, until payment in full of all Obligations (other than inchoate indemnity obligations), each Credit Party shall, and shall cause each of its Subsidiaries to:

6.1 Existence. Each Credit Party will do or cause to be done all things necessary to preserve and keep in full force and effect its respective existence, rights (charter and statutory), license and franchises; provided, however, that Borrower shall not be required to preserve any such existence, rights, license or franchises with respect to any Guarantor if the loss thereof would not, individually or in the aggregate, have a material adverse effect on the business, financial condition or results of operations of the Credit Parties taken as a whole;

## 6.2 Financial Statements, Reports, Certificates. Deliver to Lender.

#### (a) <u>Financial Statements; Compliance Certificate</u>.

Annual Financial Statements. As soon as available, but in any event within one hundred and (i) twenty (120) days (or such earlier date on which Borrower is required to file a Form 10-K under the Exchange Act, if applicable) after the end of each fiscal year of Borrower, beginning with the fiscal year ending December 31, 2015, a consolidated balance sheet of Borrower and its Subsidiaries as of the end of such fiscal year, and the related consolidated statements of income, cash flows and stockholders' equity for such fiscal year, setting forth in each case in comparative form the figures for the previous fiscal year, all prepared in accordance with GAAP, with such consolidated financial statements to be audited and accompanied by (i) a report and opinion of Borrower's independent certified public accounting firm of recognized national standing (which report and opinion shall be prepared in accordance with GAAP), stating that such financial statements fairly present, in all material respects, the consolidated financial condition, results of operations and cash flows of Borrower as of the dates and for the periods specified in accordance with GAAP, and (ii) (if and only if Borrower is required to comply with the internal control provisions pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 requiring an attestation report of such independent certified public accounting firm) an attestation report of such independent certified public accounting firm as to Borrower's internal controls pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 attesting that such internal controls meet the requirements of the Sarbanes-Oxley Act of 2002; provided, however, that Borrower shall be deemed to have made such delivery of such consolidated financial statements if such consolidated financial statements shall have been made available within the time period specified above on the SEC's EDGAR system (or any successor system adopted by the SEC). Such consolidated financial statements shall be certified by a Responsible Officer as, to his or her knowledge, fairly presenting, in all material respects, the consolidated financial condition, results of operations and cash flows of Borrower and its Subsidiaries as of the dates and for the periods specified in accordance with GAAP consistently applied;

(ii) Quarterly Financial Statements. As soon as available, but in any event within sixty (60) days (or such earlier date on which Borrower is required to file a Form 10-Q under the Exchange Act, if applicable) after the end of each of the first three (3) fiscal quarters of each fiscal year of Borrower, beginning with the fiscal quarter ending March 31, 2017, a consolidated balance sheet of Borrower and its Subsidiaries as of the end of such fiscal quarter, and the related consolidated statements of income and cash flows and for such fiscal quarter and (in respect of the second and third fiscal quarters of such fiscal year) for the then-elapsed portion of Borrower's fiscal year, setting forth in each case in comparative form the figures for the comparable period or periods in the previous fiscal year, all prepared in accordance with GAAP, subject to normal year-end audit adjustments and the absence of disclosures normally made in footnotes; provided, however, that Borrower shall be deemed to have made such delivery of such consolidated financial statements if such consolidated financial statements shall have been made available within the time period specified above on the SEC's EDGAR system (or any successor system adopted by the SEC). Such consolidated financial statements shall be certified by a Responsible Officer as, to his or her knowledge, fairly presenting, in all material respects, the consolidated financial condition, results of operations and cash flows of Borrower and its Subsidiaries as of the dates and for the periods specified in accordance with GAAP consistently applied, and on a basis consistent with the audited consolidated financial statements referred to under Section 6.2(a)(i), subject to normal year-end audit adjustments and the absence of footnotes. Notwithstanding the foregoing, if Borrower or any of its Subsidiaries have made an acquisition, the financial statements with respect to an acquired entity need not be included in the consolidated quarterly financial statements required to be delivered pursuant to this Section 6.2(a)(ii) until the first date upon which such quarterly financial statements are required to be so delivered that is at least 90 days after the date such acquisition is consummated;

(iii) <u>Quarterly Compliance Certificate</u>. As soon as available, but in no event later than sixty (60) days after the last day of each calendar quarter, commencing with the calendar quarter ending December 31, 2016, a duly completed Compliance Certificate signed by a Responsible Officer certifying that no Event of Default or Default has occurred or, if such an Event of Default or Default has occurred, specifying the nature and extent thereof and any corrective action taken or proposed to be taken with respect thereto; and

(iv) <u>Information During Event of Default</u>. As promptly as practicable (and in any event within five (5) Business Days of the request therefor), such additional information regarding the business or financial affairs of Borrower or any of its Subsidiaries, or compliance with the terms of this Agreement, as Lender may from time to time reasonably request during the existence of any Event of Default (subject to reasonable requirements of confidentiality, including requirements imposed by law or contract; <u>provided</u> that Borrower shall not be obligated to disclose any information that is reasonably subject to the assertion of attorney-client privilege);

All statements and certificates of Borrower and each of its Subsidiaries required to be delivered to Lender pursuant to this <u>Section 6.2(a)</u> will be prepared in conformity with GAAP (other than any pro forma statements and projections provided to Lender which include adjustments from GAAP, such adjusted pro forma statements and projections being in the same format as provided to the audit committee of the Board of Directors) and will fairly present in all material respects the consolidated financial condition of Borrower and its Subsidiaries and their consolidated results of operations.

(b) <u>Change of Control Notice; Asset Sale Notice; Refinancing Notice; Unsecured Indebtedness Notice;</u> <u>Securities Purchase Notice</u>. (i) A Change of Control Notice as promptly as practicable (and in any event within thirty (30) days) after the consummation of a Change of Control. (ii) An Asset Sale Notice as promptly as practicable (and in any event within two (2) Business Days) after the occurrence of any Asset Sale. (iii) A Refinancing Notice as promptly as practicable (and in any event within two (2) Business Days) after the incurrence of Indebtedness that serves to refinance all or any part of the Indebtedness represented by the Securities. (iv) An Unsecured Indebtedness Notice as promptly as practicable (and in any event within two (2) Business Days) after the incurrence of unsecured Indebtedness in an aggregate amount exceeding Twenty Million Dollars (\$20,000,000.00). (v) A Securities Purchase Notice as promptly as practicable (and in any event within two (2) Business Days) after the incurrence of Securities, the aggregate principal amount of which exceeds ten percent (10%) of the aggregate principal amount of all Securities then-outstanding.

(c) <u>Notice of Defaults, Events of Default and Material Adverse Change</u>. Notice as promptly as practicable (and in any event within two (2) Business Days) after a Responsible Officer of Borrower shall have obtained Knowledge thereof, of any Default or Event of Default or Material Adverse Change; and

(d) <u>Notice of Liens</u>. Notice as promptly as practicable (and in any event within two (2) Business Days) after a Responsible Officer of Borrower shall have obtained Knowledge thereof, of any Lien (other than a Permitted Lien) on any of the Collateral that would adversely affect the ability of Lender to exercise any of its rights or remedies hereunder or under the Security Agreement;

(e) <u>Warehouse Receipts</u>. Upon the occurrence and during the continuation of an Event of Default hereunder, deliver to Lender warehouse receipts covering any portion of the Collateral located in warehouses and for which warehouse receipts are issued;

**6.3 Inventory; Manufacturing; Returns; Maintenance of Properties.** (a) Use commercially reasonable efforts to keep all Inventory in good and marketable condition, free from material defects and otherwise use commercially reasonable efforts standard in the industry to keep all Inventory in material compliance with all applicable FDA Good Manufacturing Practices (or any foreign equivalent). (b) When any Event of Default exists hereunder, and subject to Requirements of Law, transfer Collateral constituting Inventory to warehouses or other locations designated by Lender;

6.4 Taxes; Pensions. Timely file, and require each of its Subsidiaries to timely file, all required material Tax returns and reports or extensions therefor and timely pay, and require each of its Subsidiaries to timely pay, all foreign, federal, material state and material local Taxes, assessments, deposits and contributions imposed upon it or any of its properties or assets or in respect of any of its income, businesses or franchises, and all claims (including claims for labor, services, materials and supplies) for sums that have become due and payable and that by law have or may become a Lien upon any of its properties or assets, prior to the time when any penalty or fine shall be incurred with respect thereto; provided, that no such Tax or claim need be paid if such non-payment is expressly permitted under the Indenture. No Credit Party will, nor will it permit any of its Subsidiaries to, file or consent to the filing of any consolidated income Tax return with any Person (other than Borrower or any of its Subsidiaries);

6.5 **Insurance.** Maintain or cause to be maintained, with financially sound and reputable insurers, such public liability insurance, third Person property damage insurance, business interruption insurance and casualty insurance with respect to liabilities, losses or damage in respect of the assets, properties and businesses of Borrower and its Subsidiaries as may customarily be carried or maintained under similar circumstances by Persons of established reputation engaged in similar businesses, in each case, in such amounts, with such deductibles, covering such risks and otherwise on such terms and conditions as shall be customary for such Persons acting prudently and, in all cases, as and if required under the Indenture. All property policies of the Credit Parties covering any Collateral shall have a loss payable endorsement showing Lender as loss payee as its interest may appear thereunder and waive subrogation against Lender and shall provide that the insurer must give Lender at least twenty (20) days' prior written notice before canceling, amending, or declining to renew its policy. All liability policies of the Credit Parties covering any Collateral shall show, or have endorsements showing, Lender as an additional insured as its interest may appear thereunder, and all such policies (or the loss payable and additional insured endorsements) shall provide that the insurer shall give Lender at least twenty (20) days' prior written notice before canceling, amending, or declining to renew its policy. At the request of Lender, each Credit Party shall deliver copies of such policies and evidence of all premium payments thereunder. If Borrower or any of its Subsidiaries fails to obtain insurance as required under this Section 6.5 or to pay any amount or furnish any required proof of payment to third persons and Lender, Lender may make all or part of such payment or obtain such insurance policies required in this Section 6.5, and take any action under the policies Lender deems prudent;

6.6 **Operating Accounts.** In the case of any Credit Party, not establish any new Collateral Account (other than an Excluded Account), which account results in the deposit accounts, securities accounts, commodity accounts and other investment accounts included in the Collateral to exceed \$500,000 in the aggregate, at or with any bank or financial institution unless contemporaneously with such establishment, such account is subject to a Control Agreement that is reasonably acceptable to Lender. For each Collateral Account that each Credit Party at any time maintains, such Credit Party shall cause the applicable bank or financial institution at or with which any Collateral Account is maintained to execute and deliver a Control Agreement or other appropriate instrument reasonably satisfactory to Lender with respect to such Collateral Account, which Control Agreement may not be terminated without the prior written consent of Lender. The provisions of this <u>Section 6.6</u> shall not apply to (a) any payroll accounts, payroll withholding tax accounts, pension and pension reserve accounts and employee benefit accounts

to the extent funded or maintained in accordance with prudent business practice or as required by law or (b) any other Collateral Account expressly included among Excluded Assets (collectively, the "Excluded Accounts");

6.7 Litigation Cooperation. From the date hereof and continuing through the termination of this Agreement, make available to Lender, without expense to Lender, each Credit Party and its officers, employees and agents and such Credit Party's books and records, to the extent that Lender may deem them reasonably necessary to prosecute or defend any third-Person suit or proceeding instituted by or against Lender with respect to any Collateral or relating to such Credit Party;

**6.8** Access to Collateral; Books and Records. Allow Lender, or its agents, at reasonable times during business hours, on three (3) Business Days' prior notice (provided, that no such notice is required if an Event of Default has occurred and is continuing), to inspect the Collateral and audit and copy any Credit Party's Books regarding Collateral. The foregoing inspections and audits shall be at the relevant Credit Party's expense. Such inspections or audits shall be conducted no more often than once every twelve (12) months unless an Event of Default has occurred and is continuing;

6.9 Further Assurances. At any time or from time to time upon the request of Lender, each Credit Party will, at its expense, promptly execute, acknowledge and deliver such further documents and do such other acts and things as may be reasonably necessary or proper in order to effect fully the purposes of the Loan Documents, including taking such steps as are reasonably deemed necessary or desirable by Lender to maintain, protect and enforce Lender's Lien on Collateral securing the Obligations created under the Security Agreement and the other Loan Documents;

**6.10 Post-Closing Deliverables.** Without limiting the generality of <u>Sections 6.9</u> and <u>6.11</u>, each Credit Party will use its commercially reasonable efforts to deliver to Lender (unless, on a case-by-case basis, Lender has waived in writing compliance with this <u>Section 6.10</u>) a landlord's consent or bailee waiver or subordination, as applicable, in favor of Lender for the Credit Parties' leased locations or any other location (including any warehouse or distribution center), at which the Credit Parties store or to which the Credit Parties deliver any portion of Collateral consisting of Inventory with a Fair Market Value in excess of \$2,500,000 in the aggregate (calculated based on the applicable Credit Party's estimate of the Fair Market Value of such Collateral to be possessed by any landlord, bailee, warehouseman, agent or processor (including any contract manufacturing organization) over the course of any calendar year on a weighted average basis), by the respective landlord, bailee, warehouseman, agent or processor (including any contract manufacturing organization) thereof (which consent, waiver or subordination shall include an agreement by such landlord, bailee, warehouseman, agent or processor (including any contract manufacturing organization), as the case may be, to permit reasonable access to such premises by Lender or its agents upon an Event of Default for purposes of removal of any and all such Collateral, and shall otherwise be in form and substance reasonably satisfactory to Lender), together with the duly executed original signatures thereto;

6.11 Additional Collateral; Guarantors. Without limiting the generality of <u>Sections 6.9</u> and <u>6.10</u>, and except as otherwise approved in writing by Lender, each Credit Party shall cause each of their Subject Subsidiaries, including any Subsidiary that becomes a Subject Subsidiary at any time after the Closing Date, to guarantee the Obligations and to cause each such Subject Subsidiary to grant to Lender a security interest in, all of such Subject Subsidiary's assets and property (other than Excluded Assets) constituting Collateral to secure such guaranty, except, in each case, if and to the extent such guarantee or grant is expressly prohibited under the Indenture; and

**6.12** Future Financings. If Borrower proceeds with one or more debt financing transactions at any time during the period commencing on the Closing Date and ending on (and including) the date that is the second (2nd) anniversary thereof (each, a "Future Financing"), then prior to consummating such Future Financing, Borrower shall offer to Lender the opportunity to participate in such Future Financing (whether as a lender of funds to be advanced to Borrower, a purchaser of securities to be issued by Borrower or otherwise) up to an aggregate amount equal to the lesser of (a) twenty-five percent (25.0%) of the total amount to be lent or purchased in such Future Financing and (b) Fifty Million Dollars (\$50,000,000.00) and otherwise on the same terms and subject to the same conditions as the other lenders or purchasers in such Future Financing.

# 7. <u>NEGATIVE COVENANTS</u>

Each Credit Party covenants and agrees that, until payment in full of all Obligations (other than inchoate indemnity obligations), such Credit Party shall not, and shall cause each of its Subsidiaries not to, directly or indirectly:

7.1 Dispositions. Cause or make any Asset Sale, except as expressly permitted under Section 4.06 of the Indenture; provided, however, that notwithstanding the foregoing, each Credit Party covenants and agrees that, until payment in full of all Obligations (other than inchoate indemnity obligations), such Credit Party shall not, and shall cause each of its Subsidiaries not to, directly or indirectly convey, sell, lease, transfer, assign, agree to any covenant not to sue, co-existence agreement or otherwise dispose of (including any sale-leaseback), directly or indirectly and whether in one or a series of transactions (collectively, "Transfer"), all or any part of the Collateral, except (a) Transfers of Inventory in the ordinary course of business, (b) Transfers made in connection with Permitted Liens and Permitted Investments and (c) other Transfers made in the ordinary course of business on commercially reasonable arm's length terms. For clarification, a Change of Control shall not constitute a "Transfer" for purposes of this Agreement;

7.2 Changes in Business or Business Locations. Engage in or permit any of its Subsidiaries to engage in any business other than the businesses engaged in by it and such Subsidiary, as applicable, on the Effective Date and any Similar Business. No Credit Party shall, and shall not permit any of its Subsidiaries to, without at least thirty (30) days' prior written notice to Lender: (a)(i) deliver any portion of the Collateral with a Fair Market Value in excess of \$2,500,000 in the aggregate (including any Product at any point in the supply chain but excluding any Product delivered or sold to or to be held by any patient or employee in the ordinary course of business, any sales of Inventory in the ordinary course of business, any

consignment of Collateral with a Fair Market Value in excess of \$2,500,000 in the aggregate, any Collateral located at, or in transit between, the locations set forth on <u>Schedule 5.22(a)</u> and any Collateral in Lender's possession) to a warehouse, distribution center or other location owned or operated by a third Person, or (ii) remove, in one transfer or a series of transfers, twenty percent (20%) or more of the Collateral held at any leased location to another leased location unless, in connection therewith, Borrower uses its commercially reasonable efforts to deliver to Lender (unless, on a case-by-case basis, Lender has waived in writing compliance with this <u>Section 7.2</u>) a landlord's consent or bailee waiver or subordination, as applicable, in favor of Lender for such warehouse, distribution center, leased location or other location, by the respective landlord, bailee, warehouseman, agent or processor (including any contract manufacturing organization) thereof (which consent, waiver or subordination shall include an agreement by such landlord, bailee, warehouseman, agent or processor (including any contract manufacturing organization) thereof reasonable access to such premises by Lender or its agents upon an Event of Default for purposes of removal of any and all such Collateral, and shall otherwise be in form and substance reasonably satisfactory to Lender), together with the duly executed original signatures thereto; (b) change its jurisdiction of organization; (c) change its organizational structure or type; (d) change its legal name; or (e) change any organizational number (if any) assigned by its jurisdiction of organization;

7.3 Indebtedness. Directly or indirectly, create, incur, assume or guaranty, or otherwise become or remain directly or indirectly liable with respect to, any Indebtedness, other than Permitted Indebtedness;

7.4 Encumbrances. Create, incur, allow, or suffer to exist any Lien on any of its property or assets, including all or any part of the Collateral, except as expressly permitted under Section 4.11 of the Indenture, or assign or convey any right to receive income arising from any Collateral, including the sale of any Accounts, or permit any Collateral not to be subject to the first priority security interest granted herein or otherwise pursuant to the Collateral Documents;

7.5 Maintenance of Collateral Accounts. Maintain any Collateral Account except pursuant to the terms of Section 6.6 hereof;

**7.6 Restricted Payments.** Pay or make any Restricted Payment, except as expressly permitted by Section 4.04 of the Indenture;

7.7 Other Payment Restrictions. Create or otherwise cause or suffer to exist or become effective any consensual encumbrance or restriction of any kind on the ability of any Subsidiary of Borrower to take any action described in Sections 4.05(a) through (c) of the Indenture, except as expressly permitted by Section 4.05 of the Indenture;

**7.8 Transactions with Affiliates.** Enter into or permit to exist any Affiliate Transaction, except as expressly permitted under Section 4.07 of the Indenture;

7.9 Amendments or Waivers of Organizational Documents. Agree to any amendment, restatement, supplement or other modification to, or waiver of, any of its Operating Documents in a manner that would adversely affect its ability to perform its obligations under the Loan Documents in any material respect would or adversely affect the rights, remedies and benefits available to, or conferred upon, Lender under any Loan Document;

**7.10 Compliance.** Become an "investment company" or a company controlled by an "investment company", under the Investment Company Act of 1940, as amended, or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation U of the Board of Governors of the Federal Reserve System), or use the proceeds of any Credit Extension for that purpose; no Credit Party shall cause or suffer to exist (a) the imposition of a Lien on any asset of a Credit Party or a Subsidiary of a Credit Party as a result of liabilities with respect to any Plan or (b) any other ERISA Event that, in the case of <u>clauses (a)</u> and (b) above, would, in the aggregate, result in liabilities in excess of which reasonably would be expected to result in a Material Adverse Change; fail to comply with the Federal Fair Labor Standards Act or violate any other Requirement of Law, if the violation could reasonably be expected to have a Material Adverse Change; or permit the occurrence of any other event with respect to any present pension, profit sharing or deferred compensation plan which would reasonably be expected to result in a Material Adverse Change; and

Compliance with Anti-Terrorism Laws. Lender hereby notifies each Credit Party that pursuant to the 7.11 requirements of Anti-Terrorism Laws, and Lender's policies and practices, Lender is required to obtain, verify and record certain information and documentation that identifies each Credit Party and its principals, which information includes the name and address of each Credit Party and its principals and such other information that will allow Lender to identify such party in accordance with Anti-Terrorism Laws. No Credit Party will, nor will any Credit Party permit any Subsidiary to, directly or indirectly, knowingly enter into any documents, instruments, agreements or contracts with any Person listed on the OFAC Lists, except as otherwise expressly permitted by Requirements of Law. Each Credit Party shall immediately notify Lender if any Credit Party has knowledge that any Credit Party or any Subsidiary is listed on the OFAC Lists or (a) is convicted on, (b) pleads nolo contendere to, (c) is indicted on, or (d) is arraigned and held over on charges involving money laundering or predicate crimes to money laundering. No Credit Party will, nor will any Credit Party permit any Subsidiary to, and will use commercially reasonable efforts to cause any other Affiliate not to, directly or indirectly, (i) conduct any business or engage in any transaction or dealing with any Blocked Person, including the making or receiving of any contribution of funds, goods or services to or for the benefit of any Blocked Person, except as otherwise expressly permitted by Requirements of Law, (ii) deal in, or otherwise engage in any transaction relating to, any property or interests in property blocked pursuant to Executive Order No. 13224, any similar executive order or other Anti-Terrorism Law, except as otherwise expressly permitted by Requirements of Law, or (iii) engage in or conspire to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in Executive Order No. 13224 or other Anti-Terrorism Law.

7.12 Other Negative Covenant. Except for Material Contracts in full force and effect as of the Effective Date, such other contracts or other agreements or instruments in full force and effect as of the Effective Date and described on <u>Schedule</u> 7.12 and any distributorship agreements entered into from time to time from and after the Effective Date, no Credit Party shall enter into any contractual obligation or undertaking restricting the right or ability of such Credit Party or Lender to sell, assign, convey or transfer any material amount of Collateral.

# 8. <u>EVENTS OF DEFAULT</u>

Any one of the following shall constitute an event of default (an "Event of Default") under this Agreement:

8.1 Payment Default. Any Credit Party fails to (a) make any payment of any principal of any Term Loan when and as the same shall become due and payable, whether at the due date thereof or at a date fixed for prepayment (whether voluntary or mandatory) thereof or by acceleration thereof or otherwise (including, for the avoidance of doubt, pursuant to <u>Section 2.2(c)</u>, <u>2.2(d)</u>, <u>2.2(g)</u>, <u>2.2(</u>

# 8.2 Covenant Default.

(a) The Credit Parties: (i) fail or neglect to perform any obligation in <u>Sections 6.2, 6.4, 6.5</u> or <u>6.6</u>; or (ii) violate any covenant in <u>Section 7</u>; or

(b) The Credit Parties fail or neglect to perform, keep, or observe any other term, provision, condition, covenant or agreement contained in this Agreement or any Loan Documents, and as to any default (other than those specified elsewhere in this <u>Section 8</u>) under such other term, provision, condition, covenant or agreement that can be cured, have failed to cure the default within sixty (60) days after the occurrence thereof. The cure period provided under this <u>Section 8.2(b)</u> shall not apply, among other things, to any covenants set forth in <u>clause (a)</u> above;

## 8.3 Attachment; Levy; Restraint on Business.

(a) (i) The service of process seeking to attach, by trustee or similar process, any material amount of funds of any Credit Party or of any entity under the control of any Credit Party (including a Subsidiary) on deposit or otherwise maintained with Lender or any of Lender's Affiliates, or (ii) a notice of lien or levy is filed against all or any material portion of Collateral by any Governmental Authority, and the same under <u>clauses (i)</u> and <u>(ii)</u> above are not, within ten (10) days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); or

(b) (i) Any material portion of Collateral is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents Borrower or any of its Subsidiaries from conducting any material part of its business;

**8.4 Insolvency.** (a) An involuntary proceeding shall be commenced or an involuntary petition shall be filed in a court of competent jurisdiction seeking (i) relief in respect of any Credit Party or of a substantial part of the property of any Credit Party, under Title 11 of the United States Code, as now constituted or hereafter amended, or any other federal, state or foreign bankruptcy, insolvency, receivership or similar law; (ii) the appointment of a receiver, trustee, custodian, sequestrator, conservator or similar official for any Credit Party for a substantial part of the property of any Credit Party; or (iii) the winding-up or liquidation of any Credit Party, and such proceeding or petition shall continue undismissed for sixty (60) days or an order or decree approving or ordering any of the foregoing shall be entered; or (b) any Credit Party shall (i) voluntarily commence any proceeding or file any petition seeking relief under Title 11 of the United States Code, as now constituted or hereafter amended, or any other federal, state or foreign bankruptcy, insolvency, receivership or similar law; (ii) consent to the institution of, or fail to contest in a timely and appropriate manner, any proceeding or the filing of any petition described in <u>clause (a)</u> above; (iii) apply for or consent to the appointment of a receiver, trustee, custodian, sequestrator, conservator or similar official for any Credit Party for a substantial part of the property of any Credit Party; (iv) file an answer admitting the material allegations of a petition filed against it in any such proceeding; (v) make a general assignment for the benefit of creditors; (vi) take any action for the purpose of effecting any of the foregoing; or (vii) wind up or liquidate;

**8.5 Other Agreements.** Any Credit Party fails to pay any Indebtedness (other than the Indebtedness represented by this Agreement and the other Loan Documents) within any applicable grace period after such payment is due and payable (including at final maturity) or after the acceleration of any such Indebtedness by the holders thereof because of a default, in each case, if the total amount of such Indebtedness unpaid or accelerated exceeds Twenty Million Dollars (\$20,000,000.00) or its foreign currency equivalent;

**8.6** Judgments. Any Credit Party fails to pay one or more final judgments, orders, or decrees for the payment of money in an amount in excess of Twenty Million Dollars (\$20,000,000.00) or its foreign currency equivalent when aggregated with all other final judgments, orders, or decrees for the payment of money (but excluding any final judgments, orders, or decrees for the payment of money that are covered by independent third-Person insurance as to which liability has been accepted by such insurance carrier), and the same are not, within sixty (60) consecutive days after the entry thereof, discharged, waived or stayed;

**8.7 Misrepresentations.** Any Credit Party or any Person acting for any Credit Party makes or is deemed to make any representation, warranty, or other statement now or later in this Agreement (including Section 5 hereof), any Loan Document or in any writing delivered to Lender or to induce Lender to enter this Agreement or any Loan Document, and such representation, warranty, or other statement is incorrect or false in any material respect when made or deemed to be made (or, if such representation, warranty, or other statement is qualified by materiality or Material Adverse Change, is incorrect or false in any respect when made or deemed to be made);

**8.8 Loan Documents; Collateral Documents.** (a) Any material provision of any Loan Document shall for any reason cease to be valid and binding on or enforceable against any Credit Party party thereto, or any Credit Party shall so state in writing or bring an action to limit its obligations or liabilities thereunder; (b) any Collateral Document shall for any reason (other than pursuant to the terms thereof) cease to create a valid security interest in the Collateral purported to be covered thereby or such security interest shall for any reason cease to be a perfected and first priority security interest in the Collateral subject thereto subject only to Permitted Liens; or (c) any Credit Party fails to comply for sixty (60) days after notice with its obligations contained in the Collateral Documents, except for a failure that would not be material to Lender and could not reasonably be expected to materially affect the value of the Collateral taken as a whole;

**8.9 Priority of Obligations; Security Interest.** (a) Any of the Obligations shall for any reason be subordinated or shall not have the priority contemplated by this Agreement, other than with respect to Permitted Liens; or (b) unless all of the Collateral has been released from the Liens in accordance with the provisions of the Security Agreement (including Section 8.2 thereof), any Credit Party shall assert in any pleading in any court of competent jurisdiction, that any such security interest is invalid or unenforceable;

**8.10** Guaranties. Any Guaranty (as such term is defined in the Security Agreement) ceases to be in full force and effect (except as contemplated by the terms thereof) or any Guarantor denies or disaffirms its obligations under this Agreement or the Security Agreement and such Default continues for ten (10) days; or

**8.11** Indenture. An Event of Default (as such term is defined in the Indenture) (a) without limiting the generality of <u>Section 8.4</u>, specified in Section 6.01(e) or Section 6.01(f) of the Indenture with respect to Borrower occurs; or (b) otherwise occurs and is continuing.

# 9. <u>**RIGHTS AND REMEDIES UPON AN EVENT OF DEFAULT**</u>

9.1 Rights and Remedies. While an Event of Default occurs and continues, Lender may, without notice or demand:

(a) declare all Obligations (including, for the avoidance of doubt, the Makewhole Amount) immediately due and payable (but if an Event of Default described in <u>Section 8.4</u> occurs all Obligations, including the Makewhole Amount, are automatically and immediately due and payable without any action by Lender), whereupon all Obligations for principal, interest, premium or otherwise (including, for the avoidance of doubt, the Makewhole Amount) shall become due and payable by Borrower without presentment, demand, protest or other notice of any kind, which are all expressly waived by the Credit Parties hereby;

(b) settle or adjust disputes and claims directly with Account Debtors for amounts on terms and in any order that Lender considers advisable, notify any Person owing Borrower money of Lender's security interest in such funds, and verify the amount of such account;

(c) make any payments and do any acts it considers necessary or reasonable to protect the Collateral or its security interest in the Collateral. Borrower shall assemble the Collateral if Lender requests and make it available as Lender designates. Lender may enter premises where the Collateral is located, take and maintain possession of any part of the Collateral, and pay, purchase, contest, or compromise any Lien which appears to be prior or superior to its security interest and pay all expenses incurred. Borrower hereby grants Lender a license to enter and occupy any of their premises, without charge, to exercise any of Lender's rights or remedies;

(d) apply to the Obligations (i) any balances and deposits of Borrower it holds, or (ii) any amount held by Lender owing to or for the credit or the account of Borrower;

(e) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, advertise for sale, and sell the Collateral. Subject to the Intercreditor Agreement, Lender is hereby granted a non-exclusive, royalty-free license or other right to use, without charge, Borrower's labels, Patents, copyrights, mask works, rights of use of any name, trade names, trademarks, know-how and advertising matter, or any similar property as it pertains to the Collateral, in completing production of, advertising for sale, and selling any Collateral and, in connection with Lender's exercise of its rights under this <u>Section 9.1</u>, Borrower's rights under all licenses and all franchise agreements shall inure to Lender's benefit;

(f) place a "hold" on any account maintained with Lender or deliver a notice of exclusive control, any entitlement order, or other directions or instructions pursuant to any Control Agreement or similar agreements providing control of any Collateral;

(g) demand and receive possession of Borrower's Books regarding Collateral; and

(h) subject to the Intercreditor Agreement, exercise all rights and remedies available to Lender under the Collateral Documents or any other Loan Documents or at law or equity, including all remedies provided under the Code (including disposal of the Collateral pursuant to the terms thereof).

**9.2 Power of Attorney.** Borrower hereby irrevocably appoints Lender as its lawful attorney-in-fact, exercisable upon the occurrence and during the continuance of an Event of Default, to, as applicable: (a) endorse Borrower's name on any checks or other forms of payment or security; (b) sign Borrower's name on any invoice or bill of lading for any Account or drafts against Account Debtors; (c) settle and adjust disputes and claims about the Accounts directly with Account Debtors, for amounts and on terms Lender determines reasonable; (d) make, settle, and adjust all claims under Borrower's insurance policies; (e) pay, contest or settle any Lien, charge, encumbrance, security interest, and adverse claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; and (f) transfer the Collateral into the name of Lender or a third Person as the Code permits. Borrower hereby appoints Lender as its lawful attorney-in-fact to file or record any documents necessary to perfect or continue the perfection of Lender's security interest in the Collateral regardless of whether an Event of Default has occurred until all Obligations (other than inchoate indemnity obligations) have been satisfied in full. Lender's foregoing appointment as Borrower's attorney in fact, and all of Lender's rights and powers, coupled with an interest, are irrevocable until all Obligations (other than inchoate indemnity obligations) have been fully repaid and performed.

**9.3 Protective Payments.** If Borrower fails to obtain the insurance called for by <u>Section 6.5</u> or fails to pay any premium thereon or fails to pay any other amount which Borrower is obligated to pay under this Agreement or any other Loan Document, Lender may obtain such insurance or make such payment, and all amounts so paid by Lender are Lender Expenses and immediately due and payable, bearing interest at the rate applicable to the Obligations, and secured by the Collateral. Lender will make reasonable efforts to provide Borrower with notice of Lender obtaining such insurance at the time it is obtained or within a reasonable time thereafter. No payments by Lender are deemed an agreement to make similar payments in the future or Lender's waiver of any Event of Default.

**9.4 Application of Payments and Proceeds upon Default.** If an Event of Default has occurred and is continuing, Lender shall apply any funds in its possession, whether from Borrower account balances, payments, proceeds realized as the result of any collection of Accounts or other disposition of the Collateral, or otherwise, to the Obligations in such order as Lender shall determine in its sole discretion. Any surplus shall be paid to Borrower or other Persons legally entitled thereto; Borrower shall remain liable to Lender for any deficiency. If Lender directly or indirectly enters into a deferred payment or other credit transaction with any purchaser at any sale of Collateral, Lender shall have the option, exercisable at any time, of either reducing the Obligations by the principal amount of the purchase price or deferring the reduction of the Obligations until the actual receipt by Lender of cash therefor.

9.5 Lender's Liability for Collateral. So long as Lender complies with Requirements of Law regarding the safekeeping of the Collateral in the possession or under the control of Lender, Lender shall not be liable or responsible for: (a) the safekeeping of the Collateral; (b) any loss or damage to the Collateral; or (c) any act or default of any carrier, landlord, warehouseman, bailee, agent, processor or other Person. In no event shall Lender have any liability for any diminution in the value of the Collateral for any reason. Borrower bears all risk of loss, damage or destruction of the Collateral.

9.6 No Waiver; Remedies Cumulative. Lender's failure, at any time or times, to require strict performance by Borrower of any provision of this Agreement or any other Loan Document shall not waive, affect, or diminish any right of Lender thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by the party granting the waiver and then is only effective for the specific instance and purpose for which it is given. Lender's rights and remedies under this Agreement and the other Loan Documents are cumulative. Lender has all rights and remedies provided under the Code, by law, or in equity. Lender's exercise of one right or remedy is not an election and shall not preclude Lender from exercising any other remedy under this Agreement or other remedy available at law or in equity, and Lender's waiver of any Event of Default is not a continuing waiver. Lender's delay in exercising any remedy is not a waiver, election, or acquiescence.

9.7 Demand Waiver; Makewhole Amount. Other than notices expressly required by the Loan Documents or by Requirements of Law, Borrower waives demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by Lender on which Borrower is liable. Borrower acknowledges and agrees that the Makewhole Amount shall be due and payable by Borrower upon the acceleration of the Obligations pursuant to Section 9.1(a), whether such acceleration is automatic or is effected by Lender's declaration thereof, as provided in Section 9.1(a), and Borrower waives any right to object thereto in any voluntary or involuntary bankruptcy, insolvency or similar proceeding or otherwise.

#### 10. <u>NOTICES</u>

All notices, consents, requests, approvals, demands, or other communication by any party to this Agreement or any other Loan Document must be in writing and shall be deemed to have been validly served, given, or delivered: (a) upon the earlier of actual receipt and three (3) Business Days after deposit in the U.S. mail, first class, registered or certified mail return receipt requested, with proper postage prepaid; (b) upon transmission, when sent by electronic mail or facsimile transmission; (c) one (1) Business Day after deposit with a reputable overnight courier with all charges prepaid; or (d) when delivered, if hand-delivered by messenger, all of which shall be addressed to the party to be notified and sent to the address, facsimile number, or email address (if any) indicated below. Lender or any Credit Party may change its mailing or electronic mail address or facsimile number by giving all other parties hereto written notice thereof in accordance with the terms of this <u>Section 10</u>.

If to Borrower or other Credit Party:	Merrimack Pharmaceuticals, Inc. One Kendall Square, Suite B7201 Cambridge, Massachusetts 02139 Attn: Legal Department Fax: (617) 812-8122 Email: JMunsie@merrimack.com BKickham@merrimack.com
with a copy to:	Wilmer Cutler Pickering Hale and Dorr LLP 60 State Street Boston, MA 02109 Attn: John D. Sigel, Esq. Fax: (617) 526-5000 Email: john.sigel@wilmerhale.com
If to Lender:	BioPharma Credit Investments IV Sub, LP
	c/o Pharmakon Advisors, LP 110 East 59th Street, 33rd Floor New York, NY 10022 Attn: Pedro Gonzalez de Cosio Fax: (917) 210-4048 Email: PG@pharmakonadvisors.com; JC@pharmakonadvisors.com
with copies (which shall not constitute notice) to:	
	Akin Gump Strauss Hauer & Feld LLP One Bryant Park New York, NY 10036-6745 Attn: Geoffrey E. Secol, Esq. Fax: (212) 872-1002 Email: gsecol@akingump.com

#### 11. <u>CHOICE OF LAW, VENUE, AND JURY TRIAL WAIVER</u>

New York law governs the Loan Documents without regard to principles of conflicts of law. Credit Parties and Lender each submit to the exclusive jurisdiction of the courts of the State of New York sitting in New York County, and of the United States District Court of the Southern District of New York, and any appellate court from any thereof, and agrees that all claims in respect of any such action, litigation or proceeding may be heard and determined in such New York State court or, to the fullest extent permitted by Requirements of Law, in such Federal court; <u>provided</u>, <u>however</u>, that nothing in this Agreement shall be deemed to operate to preclude Lender from bringing suit or taking other legal action in any other jurisdiction to realize on the Collateral or any other security for the Obligations, or to enforce a judgment or other court order in favor of Lender. Each Credit Party expressly submits and consents in advance to such jurisdiction in any action or suit commenced in any such court. Each Credit Party hereby waives any objection that it may have based upon lack of personal jurisdiction, improper venue, or *forum non conveniens* and hereby consents to the granting of such legal or equitable relief as is deemed appropriate by such court. Each Credit Party hereby waives personal service of the summons, complaints, and other process issued in such action or suit and agrees that service of such summons, complaints, and other process may be made by registered or certified mail addressed to such Credit Party at the address set forth in <u>Section 10</u> of this Agreement and that service so made shall be deemed completed upon the earlier to occur of such Credit Party's actual receipt thereof or three (3) days after deposit in the U.S. mails, proper postage prepaid.

TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, CREDIT PARTIES AND LENDER EACH WAIVE THEIR RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING OUT OF OR BASED UPON THIS AGREEMENT, THE LOAN DOCUMENTS OR ANY CONTEMPLATED TRANSACTION, INCLUDING CONTRACT, TORT, BREACH OF DUTY AND ALL OTHER CLAIMS. THIS WAIVER IS A MATERIAL INDUCEMENT FOR ALL PARTIES TO ENTER INTO THIS AGREEMENT. EACH PARTY HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.

#### 12. <u>GENERAL PROVISIONS</u>

**12.1** Successors and Assigns. This Agreement binds and is for the benefit of the successors and permitted assigns of each party. No Credit Party may transfer, pledge or assign this Agreement or any other Loan Document or any rights or obligations under hereunder or thereunder without Lender's prior written consent. Lender may sell, transfer, assign, pledge, negotiate, or grant participation in (any such sale, transfer, assignment, negotiation, or grant of a participation, a "Lender Transfer") all or any part of, or any interest in, Lender's obligations, rights, and benefits under this Agreement and the other Loan Documents to any Person; provided, however, that no Lender Transfer shall be made to a Person that derives more than fifty percent (50.0%) of its net revenues, on a consolidated basis, from the sale of pharmaceutical products.

#### 12.2 Indemnification; Costs and Expenses.

(a) Borrower agrees to indemnify and hold harmless Lender and each manager, partner, director, officer, employee, agent, attorney and affiliate thereof (each such person, an "**Indemnified Person**") from and against any and all Indemnified Liabilities; <u>provided</u>, that (i) no Credit Party shall have any obligation to any Indemnified Person hereunder with respect to any Indemnified Liabilities (x) to the extent such Indemnified Liabilities arise from the gross negligence, bad faith or willful misconduct of that Indemnified Person, in each case, as determined by a final, non-appealable judgment of a court of competent jurisdiction or (y) to the extent such Indemnified Liabilities resulted solely from disputes between or among Indemnified Person, and (ii) no Credit Party shall be liable for any settlement of any claim or proceeding effected by any Indemnified Person without the prior written consent of such Credit Party (which consent shall not be unreasonably withheld or delayed), but if settled with such consent or if there shall be a final judgment against an Indemnified Person, each of the Credit Parties shall indemnify and hold harmless such Indemnified Person from and against any loss or liability by reason of such settlement or judgment in the manner set forth in this Agreement.

(b) To the extent permitted by Requirements of Law, no Credit Party shall assert, and each Credit Party hereby waives, any claim against Lender and its Affiliates, directors, employees, attorneys, agents or sub-agents, on any theory of liability, for special, indirect, consequential or punitive damages (as opposed to direct or actual damages) (whether or not the claim therefor is based on contract, tort or duty imposed by any applicable legal requirement) arising out of, in connection with, arising out of, as a result of, or in any way related to, this Agreement or any Loan Document or any agreement or instrument contemplated hereby or thereby or referred to herein or therein, the transactions contemplated hereby or thereby, the Term Loan or the use of the proceeds thereof or any act or omission or event occurring in connection therewith, and each Credit Party hereby waives, releases and agrees not to sue upon any such claim or any such damages, whether or not accrued and whether or not known or suspected to exist in its favor.

(c) Any action taken by any Credit Party under or with respect to any Loan Document, even if required under any Loan Document or at the request of Lender, shall be at the expense of such Credit Party, and no Secured Party shall be required under any Loan Document to reimburse any Credit Party or any Subsidiary of any Credit Party therefor except as expressly provided therein. In addition, Borrower agrees to pay or reimburse upon demand (i) Lender for all reasonable and documented out-of-pocket costs and expenses incurred by it or any of its directors, employees, attorneys, agents or sub-agents, in connection with the investigation, development, preparation, negotiation, syndication, execution, interpretation or administration of, any modification of any term of or termination of, any Loan Document, any commitment or proposal letter therefor, any other document prepared in connection therewith or the consummation and administration of any transaction contemplated therein, (ii) Lender for all reasonable and documented out-of-pocket costs and expenses incurred by it or any of its directors, employees, attorneys, agents or sub-agents in connection with internal audit reviews and Collateral, in accordance with <u>Section 6.8</u> and (iii) Lender and its directors, employees, attorneys, agents and sub-agents, for all costs and expenses incurred in connection with (A) any refinancing or restructuring of the credit arrangements provided hereunder in the nature of a "work-out", (B) the enforcement or preservation of any right or remedy under any Loan

Document, any Obligation, with respect to the Collateral or any other related right or remedy, or (C) the commencement, defense, conduct of, intervention in, or the taking of any other action with respect to, any proceeding (including any bankruptcy or insolvency proceeding) related to any Credit Party, any Subsidiary of any Credit Party, Loan Document or Obligation (or the response to and preparation for any subpoena or request for document production relating thereto), including Lender Expenses.

**12.3** Severability of Provisions. In case any provision in or obligation hereunder or under any other Loan Document shall be invalid, illegal or unenforceable in any jurisdiction, the validity, legality and enforceability of the remaining provisions or obligations, or of such provision or obligation in any other jurisdiction, shall not in any way be affected or impaired thereby.

**12.4 Correction of Loan Documents.** Lender may correct patent errors and fill in any blanks in the Loan Documents consistent with the agreement of the parties hereto so long as Lender provides Credit Parties with written notice of such correction and allows Credit Parties at least ten (10) days to object to such correction. In the event of such objection, such correction shall not be made except by an amendment signed by Lender and Credit Parties.

#### 12.5 Amendments in Writing; Integration.

(a) Except as expressly provided in <u>Section 12.4</u>, no amendment, restatement, supplement, modification, termination or waiver of any provision of this Agreement or any other Loan Document, no approval or consent thereunder, or any consent to any departure by the Borrower therefrom, shall in any event be effective unless the same shall be in writing and signed by the Borrower and Lender.

(b) This Agreement and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Agreement and the Loan Documents merge into this Agreement and the Loan Documents.

**12.6 Counterparts.** This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Agreement.

**12.7** Survival. All covenants, representations and warranties made in this Agreement continue in full force until this Agreement has terminated pursuant to its terms (including Section 3.4) and all Obligations (other than inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) have been paid in full and satisfied. The obligation of Credit Parties in Section 12.2 to indemnify Lender shall survive until the statute of limitations with respect to such claim or cause of action shall have run.

12.8 Confidentiality. Any information regarding Credit Parties and their Subsidiaries and their businesses provided to Lender by or on behalf of any Credit Party pursuant to this Agreement shall be deemed "Confidential Information"; provided, however, that Confidential Information does not include information that is either: (a) in the public domain or in Lender's or any of its Affiliates' possession when disclosed to Lender or any of its Affiliates, or becomes part of the public domain after disclosure to Lender or any of its Affiliates other than as a result of a breach by Lender or any of its Affiliates of the obligations under this Section 12.8; or (b) disclosed to Lender or any of its Affiliates by a third Person if Lender or any of its Affiliates do not know that the third Person is prohibited from disclosing the information. Lender shall not disclose any Confidential Information to a third Person or use Confidential Information for any purpose other than the exercise of Lender's rights and the performance of Lender's obligations under the Loan Documents. The foregoing in this Section 12.8 notwithstanding, Lender may disclose Confidential Information: (i) to any of Lender's Subsidiaries or Affiliates; (ii) to prospective transferees or purchasers of any interest in the Credit Extensions; (iii) as required by law, regulation, subpoena, or other order; (iv) to the extent requested by regulators having jurisdiction over Lender or as otherwise required in connection with Lender's examination or audit; (v) as Lender considers appropriate in exercising remedies under the Loan Documents; and (vi) to third-Person service providers of Lender; provided, however, that the third Persons to which Confidential Information is disclosed pursuant to clauses (i), (ii) and (vi) are bound by obligations of confidentiality and non-use that are no less restrictive than those contained herein. Lender may use such confidential information for the development of databases, reporting purposes, and market analysis so long as such confidential information is aggregated and anonymized prior to distribution unless otherwise expressly permitted by Credit Parties.

The provisions of the immediately preceding paragraph shall survive the termination of this Agreement.

**12.9** Attorneys' Fees, Costs and Expenses. In any action or proceeding between any Credit Party and Lender arising out of or relating to the Loan Documents, the prevailing party shall be entitled to recover its reasonable attorneys' fees and other costs and expenses incurred, in addition to any other relief to which it may be entitled.

**12.10 Right of Set-Off.** In addition to any rights now or hereafter granted under Requirements of Law and not by way of limitation of any such rights, upon the occurrence of an Event of Default and at any time thereafter during the continuance of any Event of Default, Lender is hereby authorized by each Credit Party at any time or from time to time, without notice to any Credit Party or to any other Person, any such notice being hereby expressly waived, to set off and to appropriate and to apply any and all deposits (general or special, including Indebtedness evidenced by certificates of deposit, whether matured or unmatured, but not including trust accounts) and any other Indebtedness at any time held or owing by Lender to or for the credit or the account of any Credit Party against and on account of the obligations and liabilities of any Credit Party to Lender hereunder and under the other Loan Documents, including all claims of any nature or description arising out of or connected hereto or with any other Loan Document, irrespective of whether or not (a) Lender shall have made any demand hereunder or (b) the principal of or the interest on the Term Loan or any other amounts due hereunder shall have become due and payable pursuant to <u>Section 2</u> and although such obligations and liabilities, or any of them, may be contingent or unmatured.

12.11 Marshaling; Payments Set Aside. Lender shall not be under any obligation to marshal any assets in favor of any Credit Party or any other Person or against or in payment of any or all of the Obligations. To the extent that any Credit Party makes a payment or payments to Lender, or Lender enforces any Liens or exercises its rights of setoff, and such payment or payments or the proceeds of such enforcement or setoff or any part thereof are subsequently invalidated, declared to be fraudulent or preferential, set aside or required to be repaid to a trustee, receiver or any other party under any bankruptcy law, any other state or federal law, common law or any equitable cause, then, to the extent of such recovery and to the extent not expressly prohibited by Requirements of Law, the obligation or part thereof originally intended to be satisfied, and all Liens, rights and remedies therefor or related thereto, shall be revived and continued in full force and effect as if such payment or payments had not been made or such enforcement or setoff had not occurred.

**12.12** Electronic Execution of Documents. The words "execution", "signed", "signature", and words of like import in any Loan Document shall be deemed to include electronic signatures or the keeping of records in electronic form, each of which shall be of the same legal effect, validity and enforceability as a manually executed signature or the use of a paper-based recordkeeping systems, as the case may be, to the extent and as provided for in any Requirements of Law, including any state law based on the Uniform Electronic Transactions Act.

**12.13 Captions.** Section headings herein are included herein for convenience of reference only and shall not constitute a part hereof for any other purpose or be given any substantive effect.

**12.14 Construction of Agreement.** The parties hereto mutually acknowledge that they and their attorneys have participated in the preparation and negotiation of this Agreement. In cases of uncertainty this Agreement shall be construed without regard to which of the parties hereto caused the uncertainty to exist.

#### 12.15 Intercreditor Agreement Governs.

(a) The terms of this Agreement are subject to the Intercreditor Agreement. Lender (i) consents to the subordination of Liens provided for in the Intercreditor Agreement, (ii) agrees that it will be bound by and will take no actions contrary to the provisions of the Intercreditor Agreement and (iii) is authorized to enter into the Intercreditor Agreement as ABL Collateral Agent (as defined therein) and to be bound by the terms thereof. The foregoing provisions are intended as an inducement to Lender acting as a secured party under the Intercreditor Agreement to extend credit and Lender is an intended third party beneficiary of such provisions and the provisions of the Intercreditor Agreement. To the extent the provisions of this Agreement conflict or are inconsistent with the Intercreditor Agreement, Lender consents and agrees that the Intercreditor Agreement will control.

(b) Notwithstanding anything to the contrary herein, in any Noteholder Document or any ABL Document (each as defined in the Intercreditor Agreement), the Grantors shall not be required to act or refrain from acting (i) pursuant to any Noteholder Document solely with respect to any ABL First Lien Collateral (as defined in the Intercreditor Agreement) in any manner that would cause a default under any ABL Document, or (ii) pursuant to any ABL Document solely with respect to any Noteholder First Lien Collateral (as defined in the Intercreditor Agreement) in any manner that would cause a default under any ABL Document, or (ii) pursuant to any manner that would cause a default under any Noteholder Document. For the avoidance of doubt and for the purposes of this <u>Section 12.15(b)</u> only, the terms "Noteholder Document" and "ABL Document" do not include the Intercreditor Agreement.

**12.16 Third Parties.** Nothing in this Agreement, whether express or implied, is intended to: (a) confer any benefits, rights or remedies under or by reason of this Agreement on any Persons other than the express parties to it and their respective permitted successors and assigns; (b) relieve or discharge the obligation or liability of any Person not an express party to this Agreement; or (c) give any Person not an express party to this Agreement any right of subrogation or action against any party to this Agreement.

12.17 No Fiduciary Duty. Lender may have economic interests that conflict with those of the Credit Parties. Each Credit Party agrees that nothing in the Loan Documents or otherwise will be deemed to create an advisory, fiduciary or agency relationship or fiduciary or other implied duty between Lender, on the one hand, and such Credit Party, its Subsidiaries, and any of their respective stockholders or affiliates, on the other hand. Each Credit Party acknowledges and agrees that (a) the transactions contemplated by the Loan Documents are arm's-length commercial transactions between Lender, on the one hand, and such Credit Party, its Subsidiaries and their respective affiliates, on the other, (b) in connection therewith and with the process leading to such transaction, Lender is acting solely as a principal and not the agent or fiduciary of such Credit Party, its Subsidiaries or their respective affiliates, management, stockholders, creditors or any other person, (c) Lender has not assumed an advisory or fiduciary responsibility in favor of any Credit Party, its Subsidiaries or their respective affiliates with respect to the transactions contemplated hereby or the process leading thereto (irrespective of whether Lender or any of its affiliates has advised or is currently advising such Credit Party, its Subsidiaries or their respective affiliates on other matters) or any other obligation to such Credit Party, its Subsidiaries or their respective affiliates except the obligations expressly set forth in the Loan Documents, and (d) each Credit Party, its Subsidiaries and their respective affiliates have consulted their own legal and financial advisors to the extent each deemed appropriate. Each Credit Party further acknowledges and agrees that it is responsible for making its own independent judgment with respect to such transactions and the process leading thereto. Each Credit Party agrees that it will not claim that Lender has rendered advisory services of any nature or respect, or owes a fiduciary or similar duty to such Credit Party, its Subsidiaries or their respective affiliates in connection with such transaction or the process leading thereto.

#### 13. **DEFINITIONS**

**13.1 Definitions.** For the purposes of and as used in the Loan Documents: (a) references to any Person include its successors and assigns and, in the case of any Governmental Authority, any Person succeeding to its functions and capacities; (b) except as otherwise expressly provided in any Loan Document, references to any law, treaty, order, policy, rule or regulation include amendments, restatements, supplements, modifications and successors thereto; (c) the word "shall" is mandatory; (d) the word "may" is permissive; (e) the word "or" is not exclusive; (f) the words "include", "includes" and "including" are not limiting; (g) the singular includes the plural and the plural includes the singular; (h) numbers denoting amounts that are set off in parentheses are negative unless the context dictates otherwise; (i) each authorization herein shall be deemed irrevocable and coupled with an interest; (j) all accounting terms shall be interpreted, and all determinations relating thereto shall be made, in accordance with GAAP; (k) references to any time of day shall be to New York time; and (l) references to specific sections, articles, annexes, schedules and exhibits are to this Agreement. As used in this Agreement, the following capitalized terms have the following meanings:

"Account" means any "account" as defined in the Code with such additions to such term as may hereafter be made, and includes all accounts receivable, book debts, and other sums owing to Credit Parties.

"Account Debtor" means any "account debtor" as defined in the Code with such additions to such term as may hereafter be made.

"Adverse Proceeding" means any action, suit, proceeding, hearing (whether administrative, judicial or otherwise), governmental investigation or arbitration (whether or not purportedly on behalf of any Credit Party or any of its Subsidiaries) at law or in equity, or before or by any Governmental Authority, domestic or foreign (including any Environmental Claims), whether pending or, to the knowledge of any Credit Party or any of its Subsidiaries, threatened in writing against any Credit Party or any of its Subsidiaries or any property of any Credit Party or any of its Subsidiaries.

"Affiliate" of any specified Person means any other Person directly or indirectly controlling or controlled by or under common control with such specified Person. For purposes of this definition, "control" (including, with correlative meanings, the terms "controlling", "controlled by" and "under common control with"), as used with respect to any Person, means the possession, directly or indirectly, of the power to direct or cause the direction of the management or policies of such Person, whether through the ownership of voting securities, by agreement or otherwise. In no event shall Lender be deemed to be an Affiliate of Borrower or any of its Subsidiaries.

"Affiliate Transaction" has the meaning ascribed to such term in the Indenture.

"Agreement" is defined in the preamble hereof.

"Anti-Terrorism Laws" means any laws relating to terrorism or money laundering, including the Money Laundering Laws, Executive Order No. 13224 (effective September 24, 2001) and the laws administered by OFAC.

"Asset Sale" has the meaning ascribed to such term in the Indenture.

"Asset Sale Notice" is defined in Section 2.2(d).

"Bankruptcy Code" means Title 11 of the United States Code entitled "Bankruptcy" (or its foreign equivalents), as now and hereafter in effect, or any successor statute.

"Blocked Person" means (a) any Person listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (b) a Person owned or controlled by, or acting for or on behalf of, any Person that is listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (c) a Person with which Lender is prohibited from dealing or otherwise engaging in any transaction by any Anti-Terrorism Law, (d) a Person that commits, threatens or conspires to commit or supports "terrorism" as defined in Executive Order No. 13224, or (e) a Person that is named a "specially designated national" or "blocked person" on the most current list published by OFAC or other similar list.

"**Board of Directors**" means, with respect to any Person, (i) in the case of any corporation, the board of directors or similar governing body of such Person, (ii) in the case of any limited liability company, the board of managers or similar governing body of such Person, or if there is none, the board of directors (or other governing body) of the managing member of such Person, (iii) in the case of any partnership, the board of directors (or other governing body) of the general partner of such Person, and (iv) in any other case, the functional equivalent of the foregoing.

"Board of Governors" means the Board of Governors of the United States Federal Reserve System or any successor thereto.

"Books" means all books and records, including ledgers, federal and state Tax returns, records regarding a Credit Party's assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

"Borrower" is defined in the preamble hereof.

"Borrowing Resolutions" means, with respect to any Person, those resolutions adopted by such Person's Board of Directors and delivered by such Person to Lender approving the Loan Documents to which such Person is a party and the transactions contemplated thereby (including the Term Loan), together with a certificate executed by a director or its Secretary on behalf of such Person certifying that (a) such Person has the authority to execute, deliver, and perform its obligations under each of the Loan Documents to which it is a party, (b) that attached as Exhibit A to such certificate is a true, correct, and complete copy of the resolutions then in full force and effect authorizing and ratifying the execution, delivery, and performance by such Person of the Loan Documents to which it is a party and (c) the name(s) of the Person(s) authorized to execute the Loan Documents on behalf of such Person, together with a sample of the true signature(s) of such Person(s).

"Business Day" means any day that is not a Saturday or a Sunday or a day on which banks are authorized or required to be closed in New York, New York.

"CHAMPVA" means, collectively, the Civilian Health and Medical Program of the Department of Veterans Affairs, a program of medical benefits covering retirees and dependents of former members of the armed services administered by the United States Department of Veterans Affairs, and all laws, rules, regulations, manuals, orders, or requirements pertaining to such program.

"Change in Law" means the occurrence, after the date of this Agreement, of any of the following: (a) the adoption or taking into effect of any law, treaty, order, policy, rule or regulation, (b) any change in any law, treaty, order, policy, rule or regulation or in the administration, interpretation or application thereof by any Governmental Authority, or (c) the making or issuance of any request, guideline or directive (whether or not having the force of law) by any Governmental Authority; provided, that notwithstanding anything herein to the contrary, (x) the Dodd-Frank Wall Street Reform and Consumer Protection Act and all requests, rules, guidelines or directives thereunder or issued in connection therewith and (y) all requests, rules, guidelines or directives thereunder or issued in connection therewith and (y) all requests, rules, guidelines or similar authority) or the United States or foreign regulatory authorities, in each case pursuant to Basel III, shall be deemed to be a "Change in Law", regardless of the date enacted, adopted or issued.

"Change of Control" has the meaning ascribed to such term in the Indenture.

"Change of Control Notice" is defined in Section 2.2(c).

"Closing Date" means the date on which the Term Loan is advanced by Lender, which, subject to the satisfaction of the conditions precedent to the Term Loan set forth in <u>Sections 3.1</u> and <u>3.2</u>, shall be the later to occur of (a) twenty (20) days following the Effective Date and (b) March 15, 2017, or such other date as is mutually agreed in writing by the parties hereto.

"Code" means the Uniform Commercial Code, as the same may, from time to time, be enacted and in effect in the State of New York; <u>provided</u>, that to the extent that the Code is used to define any term herein or in any Loan Document and such term is defined differently in different Articles of the Code, the definition of such term contained in Article 9 shall govern; <u>provided</u> further, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection, or priority of, or remedies with respect to, Lender's Lien on any Collateral is governed by the Uniform Commercial Code in effect in a jurisdiction other than the State of New York, the term "Code" shall mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority, or remedies and for purposes of definitions relating to such provisions.

"Collateral" means, collectively, "Collateral" (as defined in the Security Agreement) and all other property of whatever kind and nature subject or purported to be subject from time to time to a Lien hereunder or under any Collateral Document, in each case, for the avoidance of doubt, not including any "Excluded Property" (as defined in the Security Agreement).

"Collateral Account" means any Deposit Account, Securities Account or Commodity Account, in each case included among the Collateral.

"Collateral Agent" has the meaning ascribed to such term in the Indenture.

"Collateral Agreement" means that certain Collateral Agreement, dated as of December 22, 2015, among Borrower, the Subject Subsidiaries and U.S. Bank National Association, as trustee and as collateral agent, as amended, extended, renewed, restated, supplemented, waived or otherwise modified from time to time.

"Collateral Documents" means the Security Agreement, the Intercreditor Agreement, the Control Agreements and all other landlord, bailee, warehouseman or other agent or processor consents, waivers, subordinations, instruments, documents and agreements delivered by any Credit Party pursuant to this Agreement or any of the other Loan Documents, in each case, in order to grant to Lender, or perfect, a Lien on any property of that Credit Party as security for the Obligations.

"Commodity Account" means any "commodity account" as defined in the Code with such additions to such term as may hereafter be made.

"Compliance Certificate" means that certain certificate in the form attached hereto as Exhibit B.

"Confidential Information" is defined in Section 12.8.

"Control Agreement" means any control agreement entered into among the depository institution at which a Credit Party maintains a Deposit Account or the securities intermediary or commodity intermediary at which a Credit Party maintains a Securities Account or a Commodity Account, such Credit Party and Lender, pursuant to which Lender obtains control (within the meaning of the Code) over such Deposit Account, Securities Account or Commodity Account.

"Credit Extensions" means the Term Loan and any other extension of credit by Lender hereunder for Borrower's benefit.

"Credit Party" means each Borrower and each Guarantor.

"Default" means an event which, with the giving of notice or the lapse of time or both, would constitute an Event of Default.

"Default Rate" is defined in Section 2.3(b).

"Deposit Account" means any "deposit account" as defined in the Code with such additions to such term as may hereafter be made.

"**Dollars**," "**dollars**" or use of the sign "**\$**" means, unless otherwise expressly noted herein, only lawful money of the United States and not any other currency, regardless of whether that currency uses the "**\$**" sign to denote its currency or may be readily converted into lawful money of the United States.

"Effective Date" is defined in the preamble hereof.

"EMA" means the European Medicines Agency.

"EMA Laws" means all applicable statutes, rules, regulations, orders and requirements administered or issued by EMA.

"Environmental Claim" means any investigation, notice, notice of violation, claim, action, suit, proceeding, demand, abatement order or other order or directive (conditional or otherwise), by any Governmental Authority or any other Person, arising (i) pursuant to or in connection with any actual or alleged violation of any Environmental Law; (ii) in connection with any Hazardous Materials or any actual or alleged Hazardous Materials Activity; or (iii) in connection with any actual or alleged damage, injury, threat or harm to health, safety, natural resources or the environment.

"Environmental Laws" means any and all current or future applicable federal, state, local and foreign laws, statutes, ordinances, Governmental Approvals, rules, regulations, requirements, decisions, judgments, decrees, orders or any other requirements of Governmental Authorities relating to, and the common law relating to, (a) environmental matters, including those relating to any Hazardous Materials Activity; (b) the generation, use, storage, transportation or disposal of Hazardous Materials; or (c) occupational safety and health, industrial hygiene, land use or the protection of human, plant or animal health or welfare, in each case, in any manner applicable to any Credit Party or any of its Subsidiaries or any Facility. pollution or the protection of the environment, natural resources or human (or occupational) health or safety, including those relating to the generation, storage, treatment, use, handling, transportation, Release or threat of Release of Hazardous Materials.

"Equity Interests" means, with respect to any Person, any and all shares, interests, participations or other equivalents (however designated) of capital stock of a corporation, any and all equivalent ownership interests in such Person (other than a corporation), including partnership interests and membership interests, and any and all warrants, rights or options to purchase or other arrangements or rights to acquire any of the foregoing (but excluding any debt security that is convertible into Equity Interests).

"ERISA" means the Employee Retirement Income Security Act of 1974, and its regulations.

"ERISA Affiliate" means, with respect to any person, any trade or business (whether or not incorporated) that, together with such person, is treated as a single employer under Section 414(b), (c), (m) or (o) of the IRC.

"ERISA Event" means (a) any "reportable event," as defined in Section 4043 of ERISA or the regulations issued thereunder, with respect to a Plan (other than an event for which the 30-day notice period is waived by regulation); (b) with respect to a Plan, the failure to satisfy the minimum funding standard of Section 412 of the IRC and Section 302 of ERISA, whether or not waived; (c) the failure to make by its due date a required installment under Section 430(j) of the IRC with respect to any Plan (including the failure to make any required contribution to a multiemployer Plan); (d) the filing pursuant to Section 412(c) of the IRC or Section 302(c) of

ERISA) of an application for a waiver of the minimum funding standard with respect to any Plan; (e) the incurrence by Borrower or any of its ERISA Affiliates of any liability under Title IV of ERISA with respect to the termination of any Plan; (f) the receipt by Borrower or its Subsidiaries or any of their respective ERISA Affiliates from the Pension Benefit Guaranty Corporation (referred to and defined in ERISA) or a plan administrator of any notice relating to the intention to terminate any Plan or Plans or to appoint a trustee to administer any Plan, or the occurrence of any event or condition which could reasonably be expected to constitute grounds under ERISA for the termination of, or the appointment of a trustee to administer, any Plan; (g) the incurrence by Borrower or its Subsidiaries or any of their respective ERISA Affiliates of any liability with respect to the withdrawal from any Plan (including a multiemployer Plan); (h) the receipt by Borrower or its Subsidiaries or any of Withdrawal Liability or a determination that a multiemployer Plan is, or is expected to be, insolvent or in reorganization, within the meaning of Title IV of ERISA; (i) the "substantial cessation of operations" within the meaning of Section 4062(e) of ERISA with respect to a Plan; (j) the imposition of any Lien security requirement as a result of any amendment to any Plan; and (k) the occurrence of a nonexempt prohibited transaction (within the meaning of Section 4975 of the IRC or Section 406 of ERISA) which could reasonably be expected to result in material liability to Borrower or its Subsidiaries.

"Event of Default" is defined in Section 8.

"Excluded Accounts" is defined in Section 6.6.

"Exchange Act" means the United States Securities Exchange Act of 1934, as amended, and the rules and regulations of the SEC promulgated thereunder.

"Exchange Act Documents" is defined in Section 5.24(b).

"Excluded Assets" shall have the meaning ascribed to such term in the Indenture.

"Facility" means any real property (including all buildings, fixtures or other improvements located thereon) now, hereafter or heretofore owned, leased, operated or used by any Credit Party or any of its Subsidiaries or any of their respective predecessors or Affiliates.

"FATCA" means Sections 1471 through 1474 of the IRC, as of the date of this Agreement (or any amended or successor version that is substantively comparable and not materially more onerous to comply with) and any current or future regulations or official interpretations thereof, and any agreements entered into pursuant to Section 1471(b)(i) of the IRC together with laws and regulations implementing such agreements.

"Fair Market Value" means, with respect to any asset or property, the price that could be negotiated in an arm's-length transaction, for cash, between a willing seller and a willing and able buyer, neither of whom is under undue pressure or compulsion to complete the transaction.

"FDA" means the United States Food and Drug Administration.

"FDA Good Manufacturing Practices" means the requirements set forth in 21 C.F.R. Part 820.

"FDA Laws" means all applicable statutes, rules, regulations, orders and requirements administered or issued by FDA.

"Federal Reserve Board" means the Board of Governors of the Federal Reserve System.

"Future Financing" is defined in Section 6.11.

"GAAP" means generally accepted accounting principles in the United States set forth in the opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board or in such other statements by such other entity as have been approved by a significant segment of the accounting profession.

"Good Clinical Practices" means the requirements set forth in 21 C.F.R. Part 11, Part 50, Part 54, Part 56, Part 312, Part 314, Part 320, Part 601, Part 812 and Part 814.

"Good Laboratory Practices" means the requirements set forth in 21 C.F.R. Part 58.

"Governmental Approval" means any consent, authorization, approval, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority.

"Governmental Authority" means any nation or government, any state or other political subdivision thereof, any agency, government department, authority, instrumentality, regulatory body, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative functions of or pertaining to government, any securities exchange and any self-regulatory organization.

"Governmental Payor Programs" means all governmental third-Person health care benefit payor programs in which any Credit Party or its Subsidiaries participates, including Medicare, Medicaid, TRICARE, CHAMPVA or any other analogous federal, state or foreign health care benefit payor programs.

"Grantor" shall have the meaning ascribed to such term in the Security Agreement.

"Guarantor" means any Subject Subsidiary, wholly-owned or controlled, in each case, directly or indirectly, by Borrower that is a present or future guarantor of the Obligations.

"Hazardous Materials" means any chemical, material or substance, exposure to which is prohibited, limited or regulated by any Governmental Authority or which may or could pose a hazard to the health and safety of the owners, occupants or any Persons in the vicinity of any Facility or to the indoor or outdoor environment.

"Hazardous Materials Activity" means any past, current, proposed or threatened activity, event or occurrence involving any Hazardous Materials, including the use, manufacture, possession, storage, holding, presence, existence, location, Release, threatened Release, discharge, placement, generation, transportation, processing, construction, treatment, abatement, removal, remediation, disposal, disposition or handling of any Hazardous Materials, and any corrective action or response action with respect to any of the foregoing.

"Health Care Laws" means, collectively, (a) any and all federal, state or local laws, rules, regulations, orders, ordinances, statutes and requirements of any Governmental Authority issued under or in connection with Medicare, Medicaid or any other Governmental Payor Program; (b) federal and state health care laws and regulations governing the confidentiality of patient information, or primarily relating to health care billing and coding advice, evaluation of patents for social benefit programs, patient health care, health care providers and health care services, including HIPAA; (c) health care accreditation standards and requirements of all applicable state laws or regulatory bodies; (d) any and all federal, state and local fraud and abuse laws of any Governmental Authority related to health care, including the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)), the civil False Claims Act (31 U.S.C. § 3729 et seq.), Sections 1320a-7 and 1320a-7a of Title 42 of the United States Code and the regulations promulgated pursuant to such statutes; (e) the Physician Payment Sunshine Act (42 U.S.C. § 1320a-7h); (e) all other applicable health care laws, rules, codes, statutes, regulations, orders, ordinances and requirements pertaining to Medicare or Medicaid, in any manner applicable to any Credit Party or any of its Subsidiaries; and (f) any and all foreign health care laws, rules, codes, statutes, requirements which, in each case, are analogous to any of the foregoing and applicable to any Credit Party or any of its Subsidiaries.

"HIPAA" means the Health Insurance Portability and Accountability Act of 1996, any and all rules or regulations promulgated from time to time thereunder, and any comparable U.S. state laws.

"Indebtedness" has the meaning ascribed to such term in the Indenture.

"Indemnified Liabilities" means, collectively, any and all liabilities, obligations, losses, damages (including natural resource damages), penalties, claims, actions, judgments, suits and related costs, expenses and disbursements of any kind or nature whatsoever (including the reasonable and documented fees and disbursements of counsel for Indemnified Persons in connection with any investigative, administrative or judicial proceeding or hearing commenced or threatened by any Person, whether or not any such Indemnified Person shall be designated as a party or a potential party thereto (it being agreed that, such counsel fees and expenses shall be limited to one primary counsel, and any additional special and local counsel in each jurisdiction deemed necessary or advisable by Lender, for the Indemnified Persons, except in the case of actual or potential conflicts of interest between or among the Indemnified Persons), and any fees or expenses incurred by Indemnified Persons in enforcing this indemnity), whether direct, indirect or consequential and whether based on any federal, state or foreign laws, statutes, rules or regulations, on common law or equitable cause or on contract or otherwise, that may be imposed on, incurred by, or asserted against any such Indemnified Person, in any manner relating to or arising out of this Agreement or the other Loan Documents or the transactions contemplated hereby or thereby (including the Lender's agreement to make Credit Extensions or the use or intended use of the proceeds thereof, or any enforcement of any of the Loan Documents (including any sale of, collection from, or other realization upon any of the Collateral or the enforcement of any guaranty of the Obligations)).

#### "Indemnified Person" is defined in <u>Section 12.2</u>.

"Indenture" means that certain Indenture, dated as of December 22, 2015, among Borrower, any Guarantor that becomes party thereto, and U.S. Bank National Association, as trustee and as collateral agent, to Borrower's 11.5% Senior Secured Notes due 2022, as amended, extended, renewed, restated, supplemented, waived or otherwise modified from time to time.

"**Insolvency Proceeding**" means, with respect to any Person, any proceeding by or against such Person under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions, extensions generally with its creditors, or proceedings seeking reorganization, arrangement, or other relief.

"Intercreditor Agreement" means the intercreditor agreement, in the form of <u>Exhibit D</u> attached hereto, among Lender, the Trustee and/or the Collateral Agent, Borrower and each Guarantor that may be party thereto from time to time, as amended, extended, renewed, restated, supplemented, waived or otherwise modified from time to time.

"Intellectual Property" means, with respect to any Person, all intellectual property and proprietary rights in any jurisdiction throughout the world, and all corresponding rights, presently or hereafter existing, including: (a) all inventions (whether or not patentable or reduced to practice), all improvements thereto, and all patents, patent applications, industrial designs, industrial design applications, and patent disclosures, together with all reissues, continuations, continuations-in-part, revisions, divisionals, extensions, and reexaminations in connection therewith; (b) all trademarks, trademark applications, tradenames, servicemarks, servicemark applications, trade dress, logos and designs, business names, company names, Internet domain names, and all other indicia of origin, all applications, registrations, and renewals in connection therewith, and all goodwill associated with any of the foregoing; (c) all copyrights and other works of authorship, mask works, database rights and moral rights, and all applications, registrations, and renewals in connection therewith; (d) all trade secrets, know-how, technologies, processes, techniques, protocols, methods, industrial models, designs, drawings, plans, specifications, research and development, and confidential information (including technical data, customer and supplier lists, pricing and cost information, and business and marketing plans and proposals); (e) all software (including source code, executable code, data, databases, and related documentation); (f) all rights of privacy and publicity, including rights to the use of names, likenesses, images, voices, signatures and biographical information of real persons; (g) licenses and commercial marketing rights; and (h) all copies and tangible embodiments or descriptions of any of the foregoing (in whatever form or medium).

"Inventory" means all "inventory" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes all merchandise, raw materials, parts, supplies, packing and shipping materials, work in process and finished products, including such inventory as is temporarily out of a Credit Party's custody or possession or in transit and including any returned goods and any documents of title representing any of the above.

"IRC" means the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder.

"Knowledge" or to the "knowledge" of a Credit Party or any of its Subsidiaries and similar qualifications or phrases means the actual knowledge of Yasir B. Al-Wakeel and Jeffrey A. Munsie.

"Lender" is defined in the preamble hereof and shall include any assignee or participant of a Loan in accordance with <u>Section 12.1</u> hereof.

"Lender Expenses" means all reasonable and documented expenses of Lender for attorneys, accountants and other professional advisors, including out-of-pocket attorneys' fees and other expenses of Lender for preparing, amending, negotiating, administering, defending and enforcing the Loan Documents (including those incurred in connection with appeals or Insolvency Proceedings) or otherwise incurred with respect to the Credit Parties in connection with the Loan Documents or the transactions contemplated therein.

"Lender Transfer" is defined in Section 12.1.

"Lien" has the meaning ascribed to such term in the Indenture.

"Loan Documents" means, collectively, this Agreement, the Term Loan Note, the Security Agreement, the Intercreditor Agreement, each Compliance Certificate, the Perfection Certificates, any Control Agreement, any other Collateral Document and any guaranties executed by a Credit Party, as such may be amended, restated or otherwise modified from time to time.

"Makewhole Amount" means, solely with respect to any prepayments of the Term Loan by Borrower pursuant to <u>Section 2.2(c)</u>, <u>2.2(d)</u>, <u>2.2(e)</u>, <u>2.2(f)</u>, <u>2.2(g)</u> or <u>2.2(h)</u> or as a result of an acceleration of the Term Loan pursuant to <u>Section 9.1(a)</u>, on any date of determination, an amount equal to any and all interest that would have accrued (but for such prepayment) on the amount of all principal prepaid by Borrower from the date of the applicable prepayment of the Term Loan through the Term Loan Maturity Date.

"Material Adverse Change" means any material adverse change in or material adverse effect on: (i) the business, financial condition, assets, liabilities (actual or contingent), operations, management, performance, prospects or properties of the Credit Parties, taken as a whole, since December 31, 2015; (ii) all or any material portion of the Collateral; (iii) the ability of any Credit Party to perform its obligations under this Agreement or any other Loan Document to which it is a party (including as a result of any Credit Party failing to remain Solvent); (iv) the ability of Lender to exercise its rights under any Loan Document or any of the rights or remedies hereunder or thereunder, including the ability of Lender to enforce this Agreement or any other Loan Document or any other Loan Document or any other Loan Document or any other Ioan Document or any of its rights or remedies hereunder or thereunder.

"Material Contract" means any contract or other agreement or instrument that has been filed by Borrower as an exhibit to any Exchange Act Document pursuant to Section 4 or Section 10 of Item 601(b) of Regulation S-K promulgated by the SEC.

"Medicaid" means, collectively, the health care assistance program established by Title XIX of the Social Security Act and any statutes succeeding thereto, and all laws, rules, regulations, orders, or requirements of any Governmental Authority pertaining to such program, including (a) all federal statutes affecting such program; (b) all state statutes and plans of Governmental Authorities for medical assistance enacted in connection with such program and federal rules and regulations promulgated in connection with such program; and (c) all applicable provisions of all rules, regulations, orders and administrative, reimbursement, and other requirements of all Government Authorities promulgated in connection with such program, in each case as the same may be amended, supplemented or otherwise modified from time to time.

"Medicare" means, collectively, the health insurance program for the aged and disabled established by Title XVIII of the Social Security Act and any statutes succeeding thereto, and all laws, rules, regulations, orders or requirements of any Governmental Authority pertaining to such program including (a) all federal statutes (whether set forth in Title XVIII of the Social Security Act or elsewhere) affecting such program; and (b) all applicable provisions of all rules, regulations, orders and administrative, reimbursement and other requirements of all Governmental Authorities promulgated in connection with such program, in each case as the same may be amended, supplemented or otherwise modified from time to time.

"MM-398 Intellectual Property Sale" has the meaning ascribed to such term in the Indenture.

"Net Proceeds" has the meaning ascribed to such term in the Indenture.

"**Obligations**" means, collectively, the Credit Parties' obligations to pay when due any and all debts, principal, interest, Lender Expenses, the Makewhole Amount and other amounts Credit Parties owe Lender now or later, under this Agreement or the other Loan Documents, including interest accruing after Insolvency Proceedings begin (whether or not allowed) and to perform Borrower's duties under the Loan Documents.

"OFAC" is defined in Section 5.18(c).

"OFAC Lists" means, collectively, the Specially Designated Nationals and Blocked Persons List maintained by OFAC pursuant to Executive Order No. 13224, 66 Fed. Reg. 49079 (September 25, 2001) or any other list of terrorists or other restricted Persons maintained pursuant to any of the rules and regulations of OFAC or pursuant to any other applicable Executive Orders.

"Operating Documents" means, collectively with respect to any Person, such Person's formation documents, as certified with the Secretary of State or other applicable Governmental Authority of such Person's jurisdiction of formation on a date that is no earlier than thirty (30) days prior to the date on which such documents are due to be delivered under this Agreement, and, (a) if such Person is a corporation, its bylaws in current form (or similar agreement), (b) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (c) if such Person is a partnership, its partnership agreement (or similar agreement), in each case, with all current amendments, restatements, supplements or modifications thereto.

"ordinary course of business" means, in respect of any transaction involving any Person, the ordinary course of such Person's business, undertaken by such Person in good faith and not for purposes of evading any covenant, prepayment obligation or restriction in any Loan Document.

"**Patent Licenses**" means (a) any agreement, whether written or oral, providing for the grant by or to a Person of any right to manufacture, use or sell any invention covered by a Patent, together with the goodwill associated therewith, all registrations and recordings thereof, and all applications in connection therewith, whether in the United States Patent and Trademark Office or in any similar office or agency of the United States, any state thereof or any other country, multinational body or any political subdivision thereof (and all related ancillary rights) and (b) all renewals thereof.

"Patents" means all patents, patent applications including any improvements, continuations, continuations-in-part, divisions, provisionals or any substitute applications, any patent issued based on or claiming priority to any of the foregoing patents or patent applications, any reissue, reexamination, renewal or patent term extension or adjustment (including any supplementary protection certificate) of any such patent or patent application, and any confirmation patent or registration patent or patent of addition based on any such patent or patent application, and all foreign counterparts of any of the foregoing.

"Patriot Act" is defined in <u>Section 3.1(l)</u>.

"Payment/Advance Form" means that certain form attached hereto as Exhibit A.

"Payment Date" means the last day of each calendar quarter.

"Perfection Certificate" is defined in Section 5.5.

"Permitted Indebtedness" means:

- (a) Credit Parties' Indebtedness to Lender under this Agreement and the other Loan Documents;
- (b) Indebtedness existing on the Closing Date and shown on <u>Schedule 5.24(a)</u> hereto;
- (c) Any other Indebtedness expressly permitted to be incurred under Section 4.03 of the Indenture; and

(d) extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness in <u>clauses (a)</u> through (c) above, <u>provided</u>, that any such extensions, refinancings, modifications, amendments or restatements are expressly permitted under the Indenture.

"Permitted Investments" shall have the meaning ascribed to such term in the Indenture.

"Permitted Liens" means:

- (a) Liens existing on the Effective Date and shown on the Perfection Certificate;
- (b) Liens arising under this Agreement and the other Loan Documents;

(c) "Permitted Liens", as such term is defined in the Indenture, including Liens expressly permitted to be created or incurred or to exist under Section 4.11 of the Indenture; and

(d) Liens incurred in the extension, renewal or refinancing of the Indebtedness secured by Liens described in <u>clauses (a)</u> through (c) above, <u>provided</u>, that any such extensions, renewals or refinancings are expressly permitted under the Indenture and not otherwise prohibited hereunder;

"**Person**" means any individual, sole proprietorship, partnership, limited liability company, joint venture, company, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

"**Plan**" means any employee benefit plan (within the meaning of Section 3(3) of ERISA) for which Borrower or any of its Subsidiaries or any member of its "Controlled Group" (defined as any organization that is a member of a controlled group of corporations within the meaning of Section 414 of the IRC) would have any liability (including any multiemployer plan within the meaning of Section 4001(a)(3) or Section 3(37) of ERISA).

"**Product**" means, (a) as of the Effective Date, (i) the product candidate referred to as MM-398 (irinotecan liposome injection) or "nal-IRI" (whether marketed under the name ONYVIDE® or any other name), and (ii) any and all product improvements, additional claims, line extensions, dosage changes and alternate delivery systems in respect thereof, and, (b) thereafter, any future product (i) commercialized by Borrower or its Subsidiaries that is owned or controlled by Borrower or its Subsidiaries, and (ii) out-licensed by Borrower or its Subsidiaries.

"Refinancing Notice" is defined in Section 2.2(e).

"Register" is defined in <u>Section 2.8(b)</u>.

"**Registered Organization**" means any "registered organization" as defined in the Code with such additions to such term as may hereafter be made.

"Regulatory Agency" is defined in Section 5.20.

"**Regulatory Approval**" means all approvals (including where applicable, pricing and reimbursement approval and schedule classifications), product or establishment licenses, registrations or authorizations of any Regulatory Agency.

"Release" means any release, spill, emission, leaking, pumping, pouring, injection, escaping, deposit, disposal, discharge, dispersal, dumping, leaching or migration of any Hazardous Material into the indoor or outdoor environment (including the abandonment or disposal of any barrels, containers or other closed receptacles containing any Hazardous Material), including the movement of any Hazardous Material through the air, soil, surface water or groundwater.

"Relevant Intellectual Property" means all registered trademarks, copyrights and Patents that are owned by or licensed to Borrower, in each case that are reasonably necessary for the operation of the business of Borrower as presently conducted.

"Relevant Patents" is defined in Section 5.24(b).

"Requirement of Law" means, as to any Person, the organizational or governing documents of such Person, and any federal, state, local or foreign law (statutory or common), treaty, rule, regulation or standard, or order, decree or determination of a court or other Governmental Authority (including FDA Laws, EMA Laws and Health Care Laws), in each case, applicable to or binding upon such Person or any of its property or to which such Person or any of its property is subject, including any regulations promulgated by applicable Regulatory Agencies.

"Responsible Officer" means, with respect to any Credit Party or its Subsidiaries, any of the Chief Executive Officer, President, Chief Financial Officer, Chairman of the Board and Director (or, in each case, the analogous foreign equivalent thereof) of such Credit Party.

"Restricted Payment" has the meaning ascribed to such term in the Indenture.

"SEC" shall mean the United States Securities and Exchange Commission.

"Secured Parties" means Lender, each other Indemnified Person and each other holder of any Obligation of a Credit Party.

"Securities" means Borrower's 11.5% Senior Secured Notes due 2022 issued pursuant to the Indenture.

"Securities Account" means any "securities account" as defined in the Code with such additions to such term as may hereafter be made.

"Securities Act" means the United States Securities Act of 1933, as amended, and the rules and regulations of the SEC promulgated thereunder.

"Security Agreement" means the Guaranty and Security Agreement, dated as of the Effective Date, by and among the Credit Parties and Lender, as such may be amended, restated or otherwise modified from time to time.

"Securities Purchase Notice" is defined in Section 2.2(h).

"Similar Business" has the meaning ascribed to such term in the Indenture.

"Social Security Act" means the Social Security Act as set forth in Title 42 of the United States Code, as amended, and any successor statute thereto, as interpreted by the rules and regulations issued thereunder, in each case as in effect from time to time. References to sections of the Social Security Act shall be construed also to refer to any successor sections.

"Solvent" means, with respect to any Person as of any date of determination, that, as of such date, (a) the value of the assets of such Person (both at fair value and present fair saleable value) is greater than the total amount of liabilities (including contingent and unliquidated liabilities) of such Person, (b) such Person is able to pay all liabilities of such Person as such liabilities mature and (c) such Person does not have unreasonably small capital. In computing the amount of contingent or unliquidated liabilities shall be computed at the amount that, in light of all the facts and circumstances existing at such time, represents the amount that can reasonably be expected to become an actual or matured liability.

"Subject Subsidiary" means each Subsidiary of Borrower that is as of the Closing Date or thereafter becomes a party to the Indenture pursuant to Section 4.10 thereof or to the Collateral Agreement as a "Subsidiary Party" (as such term is defined in the Collateral Agreement).

"Subsidiary" means, with respect to any Person, (1) any corporation, association or other business entity (other than a partnership, joint venture or limited liability company) of which more than fifty percent (50%) of the total voting power of shares of Capital Stock (as such term is defined in the Indenture) entitled (without regard to the occurrence of any contingency) to vote in the election of directors, managers or trustees thereof is at the time of determination owned or controlled, directly or indirectly, by such Person or one or more of the other Subsidiaries of that Person or a combination thereof, and (2) any partnership, joint venture or limited liability company of which (x) more than fifty percent (50%) of the capital accounts, distribution rights, total equity and voting interests or general and limited partnership interests, as applicable, are owned or controlled, directly or indirectly, by such Person or one or more of the other Subsidiaries of that Person or a combination thereof, whether in the form of membership, general, special or limited partnership interests or otherwise, and (y) such Person or any Subsidiary of such Person is a controlling general partner or otherwise controls such entity. For purposes of clarity, a Subsidiary of a Person shall not include any Person that is under common control with the first Person solely by virtue of having directors, managers or trustees in common and shall not include any Person that is solely under common control with the first Person (i.e., a sister company with a common parent).

"Tax" means any present or future tax, levy, impost, duty, assessment, charge, fee, deduction or withholding of any nature and whatever called, by whomsoever, on whomsoever and wherever imposed, levied, collected, withheld or assessed, including any tax of any kind whatsoever (whether disputed or not) imposed by any Governmental Authority).

"Term Loan" is defined in Section 2.2(a).

"Term Loan Amount" is defined in Section 2.2(a).

"Term Loan Maturity Date" means the date of the second (2nd) anniversary of the Closing Date.

"Term Loan Note" means a promissory note in substantially the form attached hereto as <u>Exhibit C</u>, as it may be amended, restated, supplemented or otherwise modified from time to time.

"Transfer" is defined in Section 7.1.

"TRICARE" means, collectively, a program of medical benefits covering former and active members of the uniformed services and certain of their dependents, financed and administered by the United States Departments of Defense, Health and Human Services and Transportation, and all laws applicable to such programs.

"Trustee" has the meaning ascribed to such term in the Indenture.

"Unsecured Indebtedness Notice" is defined in Section 2.2(f).

"Withdrawal Liability" means liability to a multiemployer Plan as a result of a complete or partial withdrawal from such multiemployer Plan, as such terms are defined in Part I of Subtitle E of Title IV of ERISA.

[signature pages follow]

**IN WITNESS WHEREOF**, the parties hereto have caused this Agreement to be executed as of the Effective Date.

### **MERRIMACK PHARMACEUTICALS, INC.,** as Borrower

By:	/s/ Yasir Al-Wakeel
Name:	Yasir Al-Wakeel
Title:	CFO

Signature Page to Loan and Security Agreement

### BIOPHARMA CREDIT INVESTMENTS IV SUB, LP, as Lender

By:	Pharmakon Advisors, LP,
	its Investment Manager

By: Pharmakon Management I, LLC, its General Partner

By:/s/ Pedro Gonzalez de CosioName:Pedro Gonzalez de CosioTitle:Managing Member

Signature Page to Loan and Security Agreement

#### EXHIBIT A – LOAN PAYMENT/ADVANCE REQUEST FORM

#### **DISBURSEMENT LETTER**

The undersigned, being the duly elected and acting \_\_\_\_\_\_\_\_ of MERRIMACK PHARMACEUTICALS, INC., a Delaware corporation ("**Borrower**") with offices located at One Kendall Square, Suite B7201, Cambridge, Massachusetts 02139, does hereby certify to BIOPHARMA CREDIT INVESTMENTS IV SUB, LP ("Lender") in connection with that certain Loan and Security Agreement dated as of November 8, 2016 by and between Borrower and Lender (the "Loan Agreement"; with other capitalized terms used below having the meanings ascribed thereto in the Loan Agreement) that:

- 1. The representations and warranties made by the Credit Parties in <u>Section 5</u> of the Loan Agreement and in the other Loan Documents, which are not qualified by materiality or Material Adverse Change, are true and correct in all material respects, and such representations and warranties which are qualified by materiality or Material Adverse Change, are true and correct in all respects, in either case, as of the date hereof.
- 2. No Default or an Event of Default has occurred and is continuing under the Loan Agreement or any other Loan Document.
- 3. The Credit Parties are in compliance with the covenants and requirements contained in <u>Sections 4</u>, <u>6</u> and <u>7</u> of the Loan Agreement.
- 4. All conditions referred to in <u>Section 3</u> of the Loan Agreement to the making of the Term Loan to be made on or about the date hereof have been satisfied or waived in writing by Lender.
- 5. No Material Adverse Change has occurred.
- 6. The undersigned is a Responsible Officer.
- The proceeds of the Term Loan shall be disbursed as set forth on Attachment A hereto on or before \_\_\_\_\_\_
   201\_\_\_.

Dated: \_\_\_\_\_, 201\_

[Signature Page Follows]

# MERRIMACK PHARMACEUTICALS, INC., as Borrower

By: Name: Title:

#### ATTACHMENT A

#### PAYMENTS TO BE DISBURSED BY OR ON BEHALF OF BORROWER ON THE CLOSING DATE AS FOLLOWS:

1. \$[Term Loan Amount], less \$[amount of Lender Expenses payable by Borrower to Lender pursuant to <u>Section 2.4</u> of the Loan Agreement]<sup>1</sup>:

Amount:	\$
Name of Bank:	
Address:	
City/ State of Bank:	
ABA Routing #:	
SWIFT:	
Name of Account:	
Account Number at Bank:	
Reference:	

Facility Fee payable on the Effective Date pursuant to Section 2.6 of the Loan Agreement and, therefore, not included here

3

#### **EXHIBIT B – COMPLIANCE CERTIFICATE**

#### TO: BIOPHARMA CREDIT INVESTMENTS IV SUB, LP

FROM: MERRIMACK PHARMACEUTICALS, INC.

The undersigned authorized officer of MERRIMACK PHARMACEUTICALS, INC., a Delaware corporation ("**Borrower**") hereby certifies that in accordance with the terms and conditions of the Loan and Security Agreement dated as of November 8, 2016 by and between Borrower and BIOPHARMA CREDIT INVESTMENTS IV SUB, LP, a Cayman Islands exempted limited partnership (the "Lender") (the "Loan Agreement"):

- (i) The Credit Parties are in complete compliance for the period ending \_\_\_\_\_\_ with all required covenants except as noted below.
- (ii) No Default or Event of Default has occurred and is continuing, except as noted below.

Attached are the financial statements required to be delivered under <u>Section 6.2</u> of the Loan Agreement. Capitalized terms used but not otherwise defined herein shall have the meanings given them in the Loan Agreement.

Date: \_\_\_\_\_

[Signature Page Follows]

# MERRIMACK PHARMACEUTICALS, INC., as Borrower

By:	
Name:	
Title:	

## Please indicate compliance status since the last Compliance Certificate by circling Yes, No, or N/A under "Complies" column.

	Reporting Covenant	Requirement	C	omplies	
1)	Annual Financial Statements	120 days after quarter end	Yes	No	N/A
2)	Quarterly Financial Statements	60 days after fiscal year end	Yes	No	N/A
3)	Information During Event of Default	Promptly (within 5 Business Days) after request	Yes	No	N/A
4)	Change of Control Notice	Promptly (within 30 days) after consummation	Yes	No	N/A
5)	Asset Sale Notice	Promptly (within 2 Business Days) after occurrence	Yes	No	N/A
6)	Refinancing Notice	Promptly (within 2 Business Days) after incurrence	Yes	No	N/A
7)	Unsecured Indebtedness Notice	Promptly (within 2 Business Days) after incurrence	Yes	No	N/A
8)	Securities Purchase Notice	Promptly (within 2 Business Days) after occurrence	Yes	No	N/A
9)	Lien Notice	Promptly (within 2 Business Days), when required	Yes	No	N/A
10)	Notice of Defaults, Events of Default & Material Adverse Change	Promptly (within 2 Business Days), when required	Yes	No	N/A

#### **Collateral Accounts**

### (Please list all accounts not previously described in the Perfection Certificate; attach separate sheet if additional space needed)

	Bank	Account Number	Contro	Control Agreement	
1) 2) 3) 4)	[Cambridge Savings]		Yes Yes Yes Yes	No No No	
5) 6)			Yes Yes	No No	
	Other Matters Have there been any prohibited Transfers since th Have there been any changes in business or busin	e last Compliance Certificate? ess locations since the last Compliance Certificate?		Yes No Yes No	
	<b>Exceptions</b> Please explain any exceptions with respect to the certification above: (If no exceptions exist, state "No exceptions." Attach separate sheet if additional space needed.)				

### LENDER USE ONLY

Compliance Status

Yes No

#### EXHIBIT C

#### **TERM LOAN NOTE**

\$

Dated: \_\_\_\_\_, 201\_

Subject to Sections 2.2(c), 2.2(d), 2.2(e), 2.2(f) and 2.2(g) or Section 9.1(a) of the Loan Agreement, Borrower shall pay the unpaid principal amount of this Term Loan Note on the Term Loan Maturity Date. Interest shall accrue on this Note commencing on, and including, the date of this Term Loan Note, and shall accrue on this Term Loan Note, or any portion thereof, including the day on which this Note or such portion is paid. Interest on this Term Loan Note shall be payable in accordance with Section 2.3 of the Loan Agreement.

Principal, interest and all other amounts due with respect to this Term Loan Note are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Term Loan Note.

The Loan Agreement, among other things, (a) provides for the making of a secured Term Loan by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Term Loan Note may not be prepaid except as set forth in Section 2.2(c), 2.2(d), 2.2(e), 2.2(f), 2.2(g) or 9.1(a) of the Loan Agreement.

This Term Loan Note and the obligation of Borrower to repay the unpaid principal amount of this Term Loan Note, interest thereon, and all other amounts due Lender under the Loan Agreement are secured pursuant to the Collateral Documents.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Term Loan Note are hereby waived.

This Note shall be governed by, and construed and interpreted in accordance with, the internal laws of the State of New York.

<u>Note Register; Ownership of Note</u>. The ownership of an interest in this Term Loan Note shall be registered on a record of ownership maintained by Lender. Notwithstanding anything else in this Term Loan Note to the contrary, the right to the principal of, and stated interest on, this Term Loan Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Term Loan Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Term Loan Note on the part of any other Person.

**IN WITNESS WHEREOF**, Borrower has caused this Term Loan Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

#### **BORROWER:**

MERRIMACK PHARMACEUTICALS, INC.

# <u>EXHIBIT D</u>

# FORM OF INTERCREDITOR AGREEMENT

# LIEN SUBORDINATION AND INTERCREDITOR AGREEMENT

dated as of

November 8, 2016

among

U.S. BANK NATIONAL ASSOCIATION, as Trustee,

# U.S. BANK NATIONAL ASSOCIATION, as Noteholder Collateral Agent,

BIOPHARMA CREDIT INVESTMENTS IV SUB, LP, as ABL Collateral Agent,

MERRIMACK PHARMACEUTICALS, INC.,

and

its Subsidiaries signatory hereto

LIEN SUBORDINATION AND INTERCREDITOR AGREEMENT (this "Agreement") dated as of November 8, 2016 among U.S. Bank National Association, as Trustee (as defined below) under the Indenture referred to herein, U.S. Bank National Association, as Noteholder Collateral Agent (as defined below) for the Noteholder Secured Parties referred to herein, Biopharma Credit Investments IV Sub, LP, as ABL Collateral Agent (as defined below) for the applicable ABL Secured Parties referred to herein, MERRIMACK PHARMACEUTICALS, INC., a Delaware corporation (the "Company"), and each subsidiary of the Company that is a signatory hereto.

Reference is made to (a) each ABL Agreement (such term and each other capitalized term used and not otherwise defined herein having the meaning assigned to it in Article I), from time to time, under which the ABL Lenders party to such ABL Agreement have extended and/or agreed to extend credit to the Company or any of its subsidiaries party to such ABL Agreement and (b) the Indenture governing the Notes. In consideration of the mutual agreements herein contained and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Trustee (for itself and on behalf of the Noteholders), the Noteholder Collateral Agent (for itself and on behalf of the Noteholder Secured Parties), the ABL Collateral Agent with respect to an ABL Agreement (for itself and on behalf of the applicable ABL Secured Parties), the Company and the subsidiaries of the Company party hereto agree as follows:

#### **ARTICLE I**

#### Definitions

SECTION 1.01 *Construction Certain Defined Terms*. (a) The definitions of terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation". The word "will" shall be construed to have the same meaning and effect as the word "shall". Unless the context requires otherwise, (i) any definition of or reference to any agreement, instrument, other document, statute or regulation herein shall be construed as referring to such agreement, instrument, other document, statute or regulation as from time to time amended, supplemented or otherwise modified, (ii) any reference herein to any Person shall be construed to include such Person's successors and assigns, but shall not be deemed to include the subsidiaries of such person unless express reference is made to such subsidiaries, (iii) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (iv) all references herein to Articles, Sections and Annexes shall be construed to refer to Articles, Sections and Annexes of this Agreement, (v) the words "asset" and "property" shall be construed to have the same meaning and effect and to refer to any and all tangible and intangible assets and properties, including cash, securities, accounts and contract rights and (vi) the term "or" is not exclusive.

(b) As used in this Agreement, the following terms have the meanings specified below:

"ABL Agreement" means any debt facility, commercial paper facility, debt securities, indenture or other form of debt financing (including convertible or exchangeable debt instruments or bank guarantees or bankers' acceptances) or other instruments or agreements evidencing Secured Bank Indebtedness (as such term is defined in the Indenture), as amended, extended, renewed, restated, supplemented, waived, replaced, restructured, repaid, refunded, refinanced or otherwise modified from time to time, with the same or different borrowers, lenders, noteholders or other creditors and agents.

"*ABL Collateral*" means, with respect to ABL Obligations under an ABL Agreement and the related ABL Security Documents, all assets and properties subject to Liens created by such ABL Security Documents to secure such ABL Obligations.

"ABL Collateral Agent" means, with respect to ABL Obligations under an ABL Agreement and the related ABL Security Documents, the applicable collateral agent (or similar agent party) in its capacity as collateral agent (or similar agent) under such ABL Documents or ABL Lender if acting as sole lender thereunder, and its successors in such capacity.

"*ABL Documents*" means, with respect to ABL Obligations under an ABL Agreement and the related ABL Security Documents, such ABL Agreement and such ABL Security Documents.

"ABL First Lien Collateral" means, with respect to ABL Obligations under an ABL Agreement and the related ABL Security Documents, any and all of the following ABL Collateral now owned or at any time hereafter acquired by the Company or any other Grantor under such ABL Security Documents (but solely to the extent that the Company or any such Grantor, as the case may be, is a party to such ABL Security Documents, and solely to the extent such party has granted an ABL Lien on such ABL Collateral pursuant to such ABL Security Documents): (a) all Inventory; (b) all Accounts arising from the sale of Inventory or provision of services; (c) to the extent evidencing, governing or securing the obligations of Account Debtors in respect of the items referred to in the preceding clauses (a) and (b), all (i) General Intangibles, (ii) Chattel Paper, (iii) Instruments, (iv) Documents, (v) Payment Intangibles (including tax refunds), other than any Payment Intangibles that represent tax refunds in respect of or otherwise relate to real property, Fixtures or Equipment, (vi) Supporting Obligations; (d) collection accounts and Deposit Accounts, including any Lockbox Account, and any cash or other assets in any such accounts constituting Proceeds of clause (a) or (b) (other than identifiable cash proceeds in respect of real estate, Fixtures or Equipment); (e) all indebtedness that arises from cash advances to enable the obligor or obligors thereon to acquire Inventory, and any Deposit Account into which such cash advances are deposited (provided no Proceeds from the sale of the Notes are deposited therein); (f) all books and records related to the foregoing; and (g) all Products and Proceeds of any and all of the foregoing in whatever form received, including proceeds of insurance policies related to Inventory or Accounts arising from the sale of Inventory of the Company or any other Grantor or provision of services by the Company or any other Grantor and business interruption insurance. All capitalized terms used in this definition and not defined elsewhere in this Agreement have the meanings assigned to them in the New York UCC.

<sup>2</sup> 

"*ABL First Lien Collateral Transition Date*" means, with respect to ABL Obligations under an ABL Agreement and the related ABL Security Documents, the earlier of (a) the date on which all such ABL Obligations shall have been paid in full (other than indemnity payments not yet accrued under such ABL Documents) and all commitments to extend credit under such ABL Agreement shall have been terminated and (b) the date on which all Senior Liens on the ABL First Lien Collateral securing such ABL Obligations shall have been released from the Liens created under such ABL Documents.

"*ABL Lenders*" means, with respect to ABL Obligations under an ABL Agreement and the related ABL Security Documents, the lenders or noteholders (or similar creditors) under such ABL Agreement.

"*ABL Liens*" means, with respect to ABL Obligations under an ABL Agreement and the related ABL Security Documents, Liens on the ABL Collateral created under such ABL Security Documents to secure such ABL Obligations.

"*ABL Obligations*" means all "Obligations" or "Secured Obligations" as such term is defined in an applicable ABL Document (or if "Obligations" or "Secured Obligations" is not defined therein, then all the liabilities and obligations under all ABL Documents purported to be secured pursuant to the related ABL Security Documents).

"*ABL Secured Parties*" means, with respect to ABL Obligations under an ABL Agreement and the related ABL Security Documents, at any time, the applicable ABL Collateral Agent, the applicable Administrative Agent, each applicable ABL Lender and each other holder of, or obligee in respect of, any such ABL Obligations outstanding at such time.

"*ABL Security Documents*" means, with respect to ABL Obligations under an ABL Agreement, such ABL Agreement (insofar as the same grants a Lien on any assets or properties of any Grantor or any of its subsidiaries to secure any such ABL Obligations), and any other documents now existing or entered into after the date hereof that grant a Lien on any assets or properties of any Grantor or any of its subsidiaries to secure any such ABL Obligations.

"Account" means "account", as defined in Article 9 of the New York UCC.

"Administrative Agent" means, with respect to ABL Obligations under an ABL Agreement and the related ABL Security Documents, the applicable administrative agent (or similar agent party) in its capacity as administrative agent (or similar agent) under such ABL Documents, and its successors in such capacity.

"Bankruptcy Code" means Title 11 of the United States Code.

"*Capital Stock*" means (a) in the case of a corporation, corporate stock or shares, (b) in the case of an association or business entity, any and all shares, interests, participations, rights or other equivalents (however designated) of corporate stock, (c) in the case of a partnership or limited liability company, partnership or membership interests (whether general or limited), and (d) any other interest or participation that confers on a Person the right to receive a share of the profits and losses of, or distributions of assets of, the issuing Person.

"Collateral" means all ABL Collateral and all Noteholder Collateral.

"Company" has the meaning set forth in the recitals hereto.

"Deposit Account" means a "deposit account" (as defined in Article 9 of the New York UCC) in which funds are held or invested for credit to or for the benefit of the Company or any other Grantor.

"*Event of Default*" means an "Event of Default" under and as defined in an ABL Agreement or the Indenture, as the context may require.

"Federal Deposit Insurance Corporation" means the Federal Deposit Insurance Corporation or any successor thereto.

"Grantor" means the Company and each subsidiary of the Company that shall have granted any Lien in favor of an ABL Collateral Agent or the Noteholder Collateral Agent on any of its assets or properties to secure any of the Obligations.

"*Indenture*" means the Indenture dated as of December 22, 2015, among the Company, the other Grantors from time to time party thereto, the Trustee and the Noteholder Collateral Agent, as amended, extended, renewed, restated, supplemented, waived, replaced, restructured, repaid, refunded, refinanced or otherwise modified from time to time, with the Trustee or a different trustee.

*"Junior Collateral"* means, with respect to each Junior Representative, the Collateral in respect of which such Junior Representative (on behalf of itself and the applicable Junior Secured Parties) holds a Junior Lien.

"*Junior Documents*" means (a) with respect to the Noteholder First Lien Collateral, the ABL Documents with respect to ABL Obligations secured by Junior Liens on such Collateral, and (b) with respect to any ABL First Lien Collateral, the Noteholder Documents.

"*Junior Liens*" means (a) with respect to any ABL First Lien Collateral, the Noteholder Liens on such Collateral, and (b) with respect to the Noteholder First Lien Collateral, the ABL Liens, if any, on such Collateral.

"Junior Representative" means (a) with respect to the Noteholder First Lien Collateral, the ABL Collateral Agent with respect to ABL Obligations secured by Junior Liens, if any, on such Collateral, and (b) with respect to any ABL First Lien Collateral, the Noteholder Collateral Agent.

"*Junior Secured Obligations*" means (a) with respect to the Noteholder Obligations, the ABL Obligations (to the extent such ABL Obligations are secured by the Noteholder First Lien Collateral), and (b) with respect to ABL Obligations secured by any ABL First Lien Collateral, the Noteholder Obligations (to the extent such Noteholder Obligations are secured by such ABL First Lien Collateral).

*"Junior Secured Parties"* means (a) with respect to the Noteholder First Lien Collateral, the applicable ABL Secured Parties, and (b) with respect to the applicable ABL First Lien Collateral, the Noteholder Secured Parties.

"*Junior Security Documents*" means (a) with respect to any ABL First Lien Collateral, the Noteholder Security Documents, and (b) with respect to the Noteholder First Lien Collateral, the ABL Security Documents with respect to ABL Obligations secured by Junior Liens on such Collateral, if any.

"*Lien*" means, with respect to any asset, any mortgage, lien, pledge, charge, security interest or encumbrance of any kind in respect of such asset, whether or not filed, recorded or otherwise perfected under applicable law (including any conditional sale or other title retention agreement, any lease in the nature thereof, any other agreement to give a security interest in and any filing of or agreement to give any financing statement under the New York UCC (or equivalent statutes of any jurisdiction).

"Lockbox Account" means any Deposit Account maintained at a depository institution whose customer deposits are insured by the Federal Deposit Insurance Corporation (to the extent required by law), into which account are paid solely the Proceeds of Inventory and Accounts that constitute ABL Collateral. All capitalized terms used in this definition and not defined elsewhere herein have the meaning assigned to them in the New York UCC.

"New York UCC" means the Uniform Commercial Code as from time to time in effect in the State of New York.

"*Noteholder Collateral*" means all assets and properties subject to Liens created by the Noteholder Security Documents to secure the Noteholder Obligations.

"Noteholder Collateral Agent" means U.S. Bank National Association, in its capacity as collateral agent under the Indenture and the Noteholder Security Documents, and its successors in such capacity.

"Noteholder Documents" means the Indenture, the Notes and the Noteholder Security Documents.

*"Noteholder First Lien Collateral"* means any and all Noteholder Collateral other than, with respect to ABL Obligations under an ABL Agreement and the related ABL Security Documents, the related ABL First Lien Collateral.

"Noteholder Liens" means Liens on the Noteholder Collateral created under the Noteholder Security Documents to secure the Noteholder Obligations.

"Noteholder Obligations" means the "Obligations" as such term is defined in the Noteholder Security Agreement.

"*Noteholder Secured Parties*" means, at any time, the Noteholder Collateral Agent, the Co-Collateral Agents (as defined in the Noteholder Security Agreement), each Noteholder, the Trustee and each other holder of, or obligee in respect of, any Noteholder Obligations outstanding at such time.

"Noteholder Security Agreement" means the Collateral Agreement dated as of December 22, 2015, among the Company, the subsidiaries of the Company from time to time party thereto, the Trustee and the Noteholder Collateral Agent for the benefit of the Noteholder Secured Parties, as amended, supplemented, restated, renewed, refunded, replaced, restructured, repaid, refinanced or otherwise modified from time to time.

*"Noteholder Security Documents"* means the Noteholder Security Agreement and any other documents (including any copyright, patent and trademark security or pledge agreements, if applicable) now existing or entered into after the date hereof that grant a Lien on any assets or properties of any Grantor or any of its subsidiaries to secure the Noteholder Obligations.

"Noteholders" means the Noteholders (or the Holders) under and as defined in the Indenture.

"Notes" means the 11.5% Senior Secured Notes due 2022 issued under the Indenture.

"Obligations" means the Noteholder Obligations and the ABL Obligations.

"*Person*" means any individual, sole proprietorship, partnership, limited liability company, joint venture, joint-stock company, trust, unincorporated organization, association, corporation, government or any agency or political subdivision thereof or any other entity.

"*Representative*" means (a) in the case of any Noteholder Obligations, the Noteholder Collateral Agent, and (b) in the case of any ABL Obligations, the ABL Collateral Agent applicable thereto.

"Secured Parties" means (a) the Noteholder Secured Parties and (b) the ABL Secured Parties.

"Security Documents" means (a) the Noteholder Security Documents and (b) the ABL Security Documents.

"Senior Collateral" means, with respect to each Senior Representative, the Collateral in respect of which such Senior Representative (on behalf of itself and the applicable Senior Secured Parties) holds a Senior Lien.

*"Senior Liens"* means (a) with respect to the Noteholder First Lien Collateral, the Noteholder Liens on such Collateral and (b) with respect to any ABL First Lien Collateral, the ABL Liens on such Collateral.

"Senior Representative" means (a) with respect to the Noteholder First Lien Collateral, the Noteholder Collateral Agent, and (b) with respect to any ABL First Lien Collateral, the ABL Collateral Agent with respect to ABL Obligations secured by Senior Liens on such Collateral.

"Senior Secured Obligations" means (a) with respect to the ABL Obligations (to the extent such Obligations are secured by the Noteholder First Lien Collateral), the Noteholder Obligations, and (b) with respect to the Noteholder Obligations (to the extent such Obligations are secured by any ABL First Lien Collateral), the ABL Obligations secured by Senior Liens on such ABL First Lien Collateral.

"Senior Secured Parties" means (a) with respect to the Noteholder First Lien Collateral, the Noteholder Secured Parties, and (b) with respect to any ABL First Lien Collateral, the ABL Secured Parties with respect to ABL Obligations secured by Senior Liens on such Collateral.

"Senior Security Documents" means (a) with respect to any ABL First Lien Collateral, the ABL Security Documents with respect to ABL Obligations secured by Senior Liens on such Collateral, and (b) with respect to the Noteholder First Lien Collateral, the Noteholder Security Documents.

"*subsidiary*" means, with respect to any Person, (a) any corporation, association or other business entity (other than a partnership, joint venture or limited liability company) of which more than 50% of the total voting power of the Capital Stock entitled (without regard to the occurrence of any contingency) to vote in the election of directors, managers or trustees thereof is at the time of determination owned or controlled, directly or indirectly, by such Person or one or more of the other subsidiaries of that Person or a combination thereof, and (b) any partnership, joint venture or limited liability company of which (x) more than 50% of the capital accounts, distribution rights, total equity and voting interests or general and limited partnership interests, as applicable, are owned or controlled, directly or indirectly, by such Person or one or more of the other subsidiaries of that Person or a combination thereof, whether in the form of membership, general, special or limited partnership interests or otherwise, and (y) such Person or any subsidiary of such person is a controlling general partner or otherwise controls such entity.

"*Trustee*" means U.S. Bank National Association, in its capacity as trustee under the Indenture, and its successors in such capacity.

## **ARTICLE II**

# Subordination of Junior Liens; Certain Agreements

SECTION 2.01 *Subordination of Junior Liens*. (a) At any time when any Senior Secured Obligations secured by Senior Collateral shall be outstanding or any commitments to extend credit that would constitute Senior Secured Obligations secured by a Senior Lien shall be in effect, all Junior Liens in respect of such Collateral are expressly subordinated and made junior in right, priority, operation and effect to any and all Senior Liens in respect of such Collateral, notwithstanding anything contained in this Agreement, the Noteholder Documents, the applicable ABL Documents or any other agreement or instrument to the contrary, and irrespective of the time, order or method of creation, attachment or perfection of such Junior Liens and such Senior Liens or any defect or deficiency or alleged defect or deficiency in any of the foregoing. For the avoidance of doubt, subject to the limitations set forth in the Indenture, the Senior Secured Obligations (secured by a Senior Lien on ABL First Lien Collateral) with respect to Noteholder Obligations may be created from time to time even if no Senior Secured Obligations exist immediately prior to such creation.

(b) It is acknowledged that, so long as Senior Secured Obligations secured by Senior Collateral shall be outstanding or any commitments to extend credit that would constitute Senior Secured Obligations secured by a Senior Lien shall be in effect, (i) all or a portion of the Senior Secured Obligations consists or may consist of Indebtedness that is revolving in nature, and the amount thereof that may be outstanding at any time or from time to time may be increased or repaid and subsequently reborrowed and (ii) the Senior Secured Obligations may, subject to the limitations set forth in the Indenture and the applicable ABL Agreement, be increased, extended, renewed, replaced, restated, supplemented, restructured, repaid, refunded, refinanced or otherwise amended or modified from time to time, all without affecting the subordination of the Junior Liens in respect of such Collateral or the provisions of this Agreement defining the relative rights of the applicable Senior Secured Parties and the applicable Junior Secured Parties. So long as Senior Secured Obligations secured by Senior Collateral shall be outstanding or any commitments to extend credit that would constitute Senior Secured Obligations secured by a Senior Lien shall be in effect, the lien priorities provided for herein shall not be altered or otherwise affected by any amendment, modification, supplement, extension, increase, replacement, renewal, restatement or refinancing of either the applicable Junior Secured Obligations or the applicable Senior Secured Obligations to the extent permitted by the Indenture, by the release of any such Collateral or of any guarantees securing any such Senior Secured Obligations or by any action that any Representative or Secured Party may take or fail to take in respect of any such Collateral or by the avoidance, invalidation or lapse of any Lien on any such Collateral.

SECTION 2.02 *No Action With Respect to Junior Collateral Subject to Senior Liens*. No Junior Representative or other Junior Secured Party shall commence or instruct any Junior Representative to commence any judicial or non-judicial foreclosure proceedings with respect to, seek to have a trustee, receiver, liquidator or similar official appointed for or over, attempt any action to take possession of, exercise any right, remedy or power with respect to, or otherwise take any action to enforce its interest in or realize upon, or take any other action available to it in respect of, any of its Junior Collateral under any Junior Security Document, applicable law or otherwise, at any time when such Junior Collateral shall be subject to any Senior Lien and any Senior Secured Obligations secured by such Senior Lien shall remain outstanding or any commitment to extend credit that would constitute Senior Secured Obligations secured by such Senior Lien shall remain in effect, it being agreed that only the Senior Representative with respect to such Collateral, acting in accordance with the applicable Senior Security Documents, shall be entitled to take any such actions or exercise any such remedies. Notwithstanding the foregoing, any Junior Representative may, subject to Section 2.05, take all such actions as it shall deem necessary to perfect or continue the perfection of its Junior Liens.

SECTION 2.03 *No Duties of Senior Representative*. (a) Each Junior Secured Party acknowledges and agrees that neither the applicable Senior Representative nor any other Senior Secured Party shall have any duties or other obligations to such Junior Secured Party with respect to any Senior Collateral, other than to transfer to the applicable Junior Representative (i) any proceeds of any such Collateral that constitutes Junior Collateral remaining in its possession following any sale, transfer or other disposition of such Collateral, the payment and satisfaction in full of the Senior Secured Obligations secured thereby and the termination of any commitment to extend credit that would constitute Senior Secured Obligations secured thereby (in each case, unless the Junior Liens on all such Junior Collateral are terminated and released prior to or

concurrently with such transaction), or, (ii) if such Senior Representative shall be in possession of all or any part of such Collateral after such payment and satisfaction in full and termination, such Collateral or any part thereof remaining, in each case without representation or warranty on the part of such Senior Representative or any Senior Secured Party. In furtherance of the foregoing, each Junior Secured Party acknowledges and agrees that until the Senior Secured Obligations secured by any Collateral in respect of which such Junior Secured Party holds a Junior Lien shall have been paid and satisfied in full and any commitment to extend credit that would constitute Senior Secured Obligations secured thereby shall have been terminated, the applicable Senior Representative shall be entitled, for the benefit of the holders of such Senior Secured Obligations, to sell, transfer or otherwise dispose of or deal with such Senior Collateral as provided herein and in compliance with the Senior Security Documents and applicable law without regard to any Junior Lien or any rights to which the holders of the applicable Junior Secured Obligations would otherwise be entitled as a result of such Junior Lien. Without limiting the foregoing, each Junior Secured Party agrees that neither the applicable Senior Representative nor any other Senior Secured Party shall have any duty or obligation first to marshal or realize upon any type of Senior Collateral (or any other collateral securing any Senior Secured Obligations on which the Senior Secured Party has a Senior Lien), or to sell, dispose of or otherwise liquidate all or any portion of such Collateral (or any other collateral securing any Senior Secured Obligations on which the Senior Secured Party has a Senior Lien), in any manner that would maximize the return to the applicable Junior Secured Parties, notwithstanding that the order and timing of any such realization, sale, disposition or liquidation may affect the amount of proceeds actually received by such Junior Secured Parties from such realization, sale, disposition or liquidation.

Each of the Junior Secured Parties waives any claim such Junior Secured Party may now or hereafter have (b) against any Senior Representative or any other Senior Secured Party (or their representatives) arising out of (i) any actions which any Senior Representative or any Senior Secured Parties take or omit to take (including, actions with respect to the creation, perfection or continuation of Liens on any of its Senior Collateral, actions with respect to the foreclosure upon, sale, release or depreciation of, or failure to realize upon, any of such Collateral and actions with respect to the collection of any claim for all or any part of any Senior Secured Obligations from any account debtor, guarantor or any other party) in accordance with the applicable Senior Security Documents, any other agreement related thereto or applicable law or to the collection of any Senior Secured Obligations or the valuation, use, protection or release of any security for any Senior Secured Obligations, (ii) any election by any Senior Representative or any Senior Secured Parties, in any proceeding instituted under the Bankruptcy Code, of the application of Section 1111(b) of the Bankruptcy Code (or under any other applicable foreign bankruptcy, insolvency, receivership or similar law) (iii) any borrowing by the Company or any of its subsidiaries, as debtor-in-possession, including any grant of a security interest, adequate protection, or administrative expense priority under Section 364 of the Bankruptcy Code to any party in connection with such borrowing, or (iv) any use of cash collateral by the Company or any of its subsidiaries, as debtor-inpossession, including any grant or award of adequate protection under Section 363 of the Bankruptcy Code to any party in connection with such use of cash collateral.

SECTION 2.04 No Interference; Payment Over; Reinstatement. (a) At any time when any Senior Secured Obligations secured by Senior Collateral shall be outstanding or any commitments to extend credit that would constitute Senior Secured Obligations secured by a Senior Lien shall be in effect, each respective Junior Secured Party agrees that (i) it will not take or cause to be taken any action the purpose or effect of which is, or could be, to make any respective Junior Lien pari passu with, or to give such Junior Secured Party any preference or priority relative to, any Senior Lien with respect to the Collateral subject to such Senior Lien and Junior Lien or any part thereof, (ii) it will not challenge or question in any proceeding the validity or enforceability of any such Senior Secured Obligations or Senior Security Document, or the validity, attachment, perfection or priority of any such Senior Lien, or the validity or enforceability of the priorities, rights or duties established by or other provisions of this Agreement, (iii) it will not take or cause to be taken any action the purpose or intent of which is, or could be, to contest, interfere, hinder or delay, in any manner, whether by judicial proceedings or otherwise, any sale, transfer or other disposition of the Collateral subject to such Junior Lien by any such Senior Secured Parties secured by Senior Liens on such Collateral or any Senior Representative acting on their behalf, (iv) it shall have no right to (A) direct any Senior Representative or any holder of Senior Secured Obligations to exercise any right, remedy or power with respect to the Collateral subject to such Junior Lien or (B) consent to the exercise by any Senior Representative or any other Senior Secured Party of any right, remedy or power with respect to the Collateral subject to such Junior Lien, (v) it will not institute any suit or assert in any suit, bankruptcy, insolvency or other proceeding any claim against any Senior Representative or other Senior Secured Party seeking damages from or other relief by way of specific performance, instructions or otherwise with respect to, and neither any Senior Representative nor any other Senior Secured Party shall be liable for, any action taken or omitted to be taken by such Senior Representative or other Senior Secured Party with respect to any Collateral securing such Senior Secured Obligations that is subject to such Junior Lien, (vi) it will not seek, and hereby waives any right, to have any Senior Collateral subject to such Junior Lien or any part thereof marshaled upon any foreclosure or other disposition of such Collateral and (vii) it will not attempt, directly or indirectly, whether by judicial proceedings or otherwise, to challenge the enforceability of any provision of this Agreement.

(b) Each Junior Representative and each other Junior Secured Party hereby agrees that if it shall obtain possession of any respective Senior Collateral or shall realize any proceeds or payment in respect of any such Collateral, pursuant to any Junior Security Document or by the exercise of any rights available to it under applicable law or in any bankruptcy, insolvency or similar proceeding or through any other exercise of remedies, at any time when any Senior Secured Obligations secured or intended to be secured by such Collateral shall remain outstanding or any commitment to extend credit that would constitute Senior Secured Obligations secured or intended to be secured by such Senior Lien shall remain in effect, then it shall hold such Collateral, proceeds or payment in trust or as agent, as the case may be, for the applicable Senior Secured Parties and transfer such Collateral, proceeds or payment, as the case may be, to the applicable Senior Representative promptly after obtaining actual knowledge or notice from the applicable Senior Secured Parties that it has possession of such Senior Collateral or proceeds or payments in respect thereof. Each Junior Secured Party agrees that if, at any time, it receives notice or obtains actual knowledge that all or part of any payment with respect to any respective Senior Secured Obligations previously made shall be rescinded for any reason whatsoever, such Junior Secured Party shall promptly pay over to the applicable Senior

Representative any payment received and then held by it in respect of any Collateral subject to any Senior Lien securing such Senior Secured Obligations and shall promptly turn any Collateral subject to any such Senior Lien then held by it over to the applicable Senior Representative, and the provisions set forth in this Agreement shall be reinstated as if such payment had not been made, until the payment and satisfaction in full of such Senior Secured Obligations.

SECTION 2.05 *Automatic Release of Junior Liens*. (a) Each Junior Representative and each other Junior Secured Party agree that in the event of a sale, transfer or other disposition of any Senior Collateral subject to any Junior Lien in favor of such Junior Secured Representative or such Junior Secured Party (regardless of whether or not an Event of Default has occurred and is continuing under the applicable Junior Documents at the time of such sale, transfer or other disposition), such Junior Lien on such Collateral shall terminate and be released automatically and without further action if the applicable Senior Liens on such Collateral are released and if such sale, transfer or other disposition either (x) is then not prohibited by such Junior Documents or (y) occurs in connection with the foreclosure (including by a Senior Representative or other Senior Secured Party) upon or other exercise of rights and remedies with respect to such Senior Collateral, *provided* that such Junior Lien shall remain in place with respect to any proceeds of a sale, transfer or other disposition under this clause (a) that remain after the satisfaction in full of such Senior Secured Obligations.

(b) Each Junior Representative agrees to execute and deliver (at the sole cost and expense of the Grantors) all such releases and other instruments as shall reasonably be requested by any applicable Senior Representative to evidence and confirm any release of Junior Collateral provided for in this Section, and upon the Junior Representative's failure to do so within the prescribed time frame set forth in New York UCC Section 9-513(b) or (c), as applicable, the appropriate Senior Representative is hereby granted a limited power of attorney to execute any necessary UCC-3 filing or similar document necessary to effect such a release.

SECTION 2.06 *Certain Agreements With Respect to Bankruptcy or Insolvency Proceedings*. (a) This Agreement shall continue in full force and effect notwithstanding the commencement of any proceeding under the Bankruptcy Code or any other Federal, state or foreign bankruptcy, insolvency, receivership or similar law by or against the Company or any of its subsidiaries.

(b) So long as any Senior Secured Obligations secured by Senior Collateral shall be outstanding or any commitments to extend credit that would constitute Senior Secured Obligations secured by a Senior Lien shall be in effect, if the Company or any of its subsidiaries shall become subject to a case under the Bankruptcy Code (or under any other applicable foreign bankruptcy, insolvency, receivership or similar law) and shall, as debtor(s)-in-possession, move for approval of financing ("*DIP Financing*") to be provided by one or more lenders (the "*DIP Lenders*") under Section 364 of the Bankruptcy Code (or under any other applicable foreign bankruptcy, insolvency, receivership or similar law) or the use of cash collateral with the consent of the DIP Lenders under Section 363 of the Bankruptcy Code (or under any other applicable foreign bankruptcy, insolvency, receivership or similar law), each Junior Secured Party agrees that it will raise no objection to (and, upon the grant or award of adequate protection acceptable to the holders of Senior Secured Obligations with comparable adequate protection granted or awarded to the ABL Collateral Agent or the Noteholder Collateral Agent and Trustee, as

applicable, junior in priority only to that of the holders of Senior Secured Obligations, shall affirmatively consent to) any such financing to the extent secured by Liens on any respective Senior Collateral securing the same ("*DIP Financing Liens*") or to any use of cash collateral that constitutes such Senior Collateral, unless the applicable Senior Secured Parties, or a representative authorized by such Senior Secured Parties, shall then oppose or object to such DIP Financing or such DIP Financing Liens or use of cash collateral (and, to the extent that such DIP Financing Liens are senior to, or rank *pari passu* with, the applicable Senior Liens, the applicable Junior Representative will, for itself and on behalf of the other applicable Junior Secured Parties, so long as each Secured Party retains Liens on all the applicable Collateral, including proceeds thereof arising after the commencement of such proceeding, with the same relative priority as existed prior to the commencement of the case under the Bankruptcy Code (or under any other applicable foreign bankruptcy, insolvency, receivership or similar law).

(c) So long as any Senior Secured Obligations secured by Senior Collateral shall be outstanding or any commitments to extend credit that would constitute Senior Secured Obligations secured by a Senior Lien shall be in effect, each Junior Secured Party agrees that it will not object to or oppose a sale or other disposition of any Senior Collateral (or any portion thereof) under Section 363 of the Bankruptcy Code or any other provision of the Bankruptcy Code (or under any other applicable foreign bankruptcy, insolvency, receivership or similar law) if the applicable Senior Secured Parties shall have consented to such sale or disposition of such Senior Collateral.

SECTION 2.07 *Reinstatement*. In the event that any of the Senior Secured Obligations shall be paid in full and such payment or any part thereof shall subsequently, for whatever reason (including an order or judgment for disgorgement of a preference under Title 11 of the Bankruptcy Code (or under any other applicable foreign bankruptcy, insolvency, receivership or similar law) or the settlement of any claim in respect thereof), be required to be returned or repaid, the terms and conditions of this Article II shall be fully applicable thereto until all such Senior Secured Obligations shall again have been paid in full in cash.

SECTION 2.08 *Entry Upon Premises by the ABL Collateral Agent and the ABL Lenders*. (a) So long as any Senior Secured Obligations secured by Senior Collateral shall be outstanding or any commitments to extend credit that would constitute Senior Secured Obligations secured by a Senior Lien shall be in effect, if any ABL Collateral Agent takes any enforcement action with respect to any ABL First Lien Collateral on which it holds ABL Liens, the Noteholder Secured Parties (i) shall cooperate with such ABL Collateral Agent (at the sole cost and expense of such ABL Collateral Agent and subject to the condition that the Noteholder Secured Parties shall have no obligation or duty to take any action or refrain from taking any action that could reasonably be expected to result in the incurrence of any liability or damage to the Noteholder Secured Parties) in its efforts to enforce its security interest in such ABL First Lien Collateral and to finish any work-in-process and assemble such ABL First Lien Collateral, (ii) shall not hinder or restrict in any respect such ABL Collateral Agent from enforcing its security interest in such ABL First Lien Collateral Agent, its employees, agents, advisers and representatives, at the sole cost and expense of the applicable ABL Secured Parties and upon reasonable advance notice, to enter upon and use the Noteholder

First Lien Collateral (including (x) equipment, processors, computers and other machinery related to the storage or processing of records, documents or files and (y) intellectual property), for a period not to exceed 90 days after the taking of such enforcement action, for purposes of (A) assembling and storing such ABL First Lien Collateral and completing the processing of and turning into finished goods of such ABL First Lien Collateral consisting of work-in-process, (B) selling any or all of the applicable ABL First Lien Collateral located on or in such Noteholder First Lien Collateral, whether in bulk, in lots or to customers in the ordinary course of business or otherwise, (C) removing any or all of the applicable ABL First Lien Collateral, or (D) taking reasonable actions to protect, secure, and otherwise enforce the rights of the applicable ABL Secured Parties in and to any applicable ABL First Lien Collateral Agent from selling, assigning or otherwise transferring any Noteholder First Lien Collateral prior to the expiration of such 90-day period if the purchaser, assignee or transferee thereof agrees to be bound by the provisions of this Section. If any stay or other order prohibiting the exercise of remedies with respect to the applicable ABL First Lien Collateral has been entered by a court of competent jurisdiction, such 90-day period shall be tolled during the pendency of any such stay or other order.

(b) In no event shall such ABL Secured Parties have any liability to the Noteholder Secured Parties pursuant to this Section as a result of any condition on or with respect to the Noteholder First Lien Collateral existing prior to the date of the exercise by such ABL Secured Parties of their rights under this Section and such ABL Secured Parties shall have no duty or liability to maintain the Noteholder First Lien Collateral in a condition or manner better than that in which it was maintained prior to the use thereof by such ABL Secured Parties, or for any diminution in the value of the Noteholder First Lien Collateral by such ABL Secured Parties in the manner and for the time periods specified under this Section 2.08. Without limiting the rights granted in this paragraph, such ABL Secured Parties shall cooperate with the Noteholder First Lien Collateral, subject to the extent such ABL Secured Parties obtain any interest in the Noteholder First Lien Collateral, subject to the condition that no ABL Secured Party shall have any obligation or duty to take any action or refrain from taking any action that could reasonably be expected to result in its incurrence of any liability or damage.

SECTION 2.09 *Insurance*. Unless and until any ABL Collateral Agent has sent written notice to the Trustee that the applicable ABL Obligations have been paid in full and all commitments to extend credit under the applicable ABL Agreement shall have been terminated, as between such ABL Collateral Agent, on the one hand, and the Trustee and the Noteholder Collateral Agent, as the case may be, on the other hand, only such ABL Collateral Agent will have the right (subject to the rights of the Grantors under the applicable ABL Documents and the Noteholder Documents) to adjust or settle any insurance policy or claim covering or constituting any of the applicable ABL First Lien Collateral in the event of any loss thereunder and to approve any award granted in any condemnation or similar proceeding solely affecting such ABL First Lien Collateral. Unless and until the Trustee has sent written notice to any ABL Collateral Agent that the Noteholder Obligations have been paid in full, as between such ABL Collateral Agent, on the one hand, and the Trustee and the Noteholder Collateral Agent, as the case may be, on the other hand, only the Noteholder Collateral Agent will have the right (subject to the rights

of the Grantors under the applicable ABL Documents and the Noteholder Documents) to adjust or settle any insurance policy covering or constituting any applicable Noteholder First Lien Collateral in the event of any loss thereunder and to approve any award granted in any condemnation or similar proceeding solely affecting any applicable Noteholder First Lien Collateral. To the extent that an insured loss covers or constitutes both ABL First Lien Collateral and Noteholder First Lien Collateral, then the applicable ABL Collateral Agent and the Noteholder Collateral Agent will work jointly and in good faith to collect, adjust or settle (subject to the rights of the Grantors under the applicable ABL Documents and the Noteholder Documents) under the relevant insurance policy.

SECTION 2.10 Refinancings. Any ABL Obligations and the Noteholder Obligations may be refinanced or replaced (either immediately or after the passage of time), in whole or in part, in each case, without notice to, or the consent (except to the extent a consent is otherwise required to permit the refinancing transaction under any ABL Document or any Noteholder Document) of any ABL Secured Party or any Noteholder Secured Party, all without affecting the Lien priorities provided for herein or the other provisions hereof, provided, however, that the holders of any such refinancing or replacement indebtedness (or an authorized agent or trustee on their behalf) bind themselves in writing to the terms of this Agreement pursuant to such documents or agreements (including amendments or supplements to this Agreement) as any applicable ABL Collateral Agent or the Noteholder Collateral Agent, as the case may be, shall reasonably request and in form and substance reasonably acceptable to each such ABL Collateral Agent or the Noteholder Collateral Agent, as the case may be. In connection with any refinancing or replacement contemplated by this Section 2.10, this Agreement shall be amended at the request and sole expense of the Company, and without the consent of any Representative, (a) to add parties (or any authorized agent or trustee therefor) providing any such refinancing or replacement indebtedness, (b) to establish that Liens on any Noteholder First Lien Collateral securing such refinancing or replacement indebtedness shall have the same priority as the Liens on any Noteholder First Lien Collateral securing the indebtedness being refinanced or replaced and (c) to establish that the Liens on any ABL First Lien Collateral securing such refinancing or replacement indebtedness shall have the same priority as the Liens on any ABL First Lien Collateral securing the indebtedness being refinanced or replaced, all on the terms provided for herein immediately prior to such refinancing or replacement.

SECTION 2.11 *Amendments to Security Documents*. (a) Without the prior written consent of any applicable Senior Representative, no Junior Security Document may be amended, supplemented or otherwise modified or entered into to the extent such amendment, supplement or modification, or the terms of any new Junior Security Document, would be prohibited by, or would require any Grantor to act or refrain from acting in a manner that would violate, any of the terms of this Agreement.

(b) In the event that any Senior Representative enters into any amendment, waiver or consent in respect of any of the Senior Security Documents for the purpose of adding to, or deleting from, or waiving or consenting to any departures from any provisions of, any such Senior Security Document that relate directly to any Senior Collateral on which a Junior Lien exists or changing in any manner the rights of such Senior Representative, the applicable Senior Secured Parties, the Company or any other Grantor thereunder (including the release of any Liens on any applicable Senior Collateral permitted by Section 2.05), then such amendment,

waiver or consent shall apply automatically to any comparable provision of the comparable Junior Security Document with respect to such Junior Lien without the consent of the applicable Junior Representative or any applicable Junior Secured Party and without any action by such Junior Representative, the Company or any other Grantor; *provided, however*, that written notice of such amendment, waiver or consent shall have been given by the Company to such Junior Representative no later than two (2) Business Days following its effectiveness; and *provided further*, that no such amendment, waiver or consent shall be effective to (i) release any Junior Liens (other than as permitted by Section 2.05), (ii) permit any Liens on the Collateral except Liens permitted under the Junior Documents or this Agreement, or (iii) impose duties on the Junior Representative without its consent. Reasonably promptly following such effectiveness, the Company shall prepare and deliver, or cause to be prepared and delivered to the applicable Junior Representative, forms of amendment documents to any applicable Junior Security Documents to evidence the amendments to such Junior Security Documents previously effected pursuant to this Section 2.11(b).

SECTION 2.12 *Legends*. Each ABL Collateral Agent acknowledges with respect to the applicable ABL Documents, and the Trustee and the Noteholder Collateral Agent acknowledge with respect to the Noteholder Documents, that each such agreement will contain the appropriate legend set forth on Annex I in substantially the same terms as set forth therein.

SECTION 2.13 *Permitted Liens*. Notwithstanding anything herein to the contrary, neither this Agreement nor any term or provision hereof shall be construed to permit any ABL Secured Party to obtain, receive or be the beneficiary of any Lien on all or any portion of any Collateral (other than the ABL Collateral, to the extent permitted under the terms of the Indenture), irrespective of the time, order or method of creation, attachment or perfection of such Lien, including any Lien arising by operation of law or in connection with any judgment.

#### **ARTICLE III**

## Gratuitous Bailment for Perfection of Certain Security Interests; Rights Under Permits and Licenses

SECTION 3.01 *General*. Each Senior Representative agrees that if it shall at any time hold a Senior Lien on any Junior Collateral that can be perfected by the possession or control of such Collateral or of any account in which such Collateral is held, and if such Collateral or any such account is in fact in the possession or under the control of such Senior Representative, such Senior Representative will serve as gratuitous bailee for the applicable Junior Representative for the sole purpose of perfecting the Junior Lien of such Junior Representative on such Collateral. It is agreed that the obligations of such Senior Representative and the rights of such Junior Representative and the other applicable Junior Secured Parties in connection with any such bailment arrangement will be in all respects subject to the provisions of Article II. Notwithstanding anything to the contrary herein, such Senior Representative will be deemed to make no representation as to the adequacy of the steps taken by it to perfect the Junior Lien on any such Collateral and shall have no responsibility, duty, obligation or liability to such Junior Representative or any other person for such perfection or failure to perfect, it being understood that the sole purpose of this Article is to enable the applicable Junior Secured Parties to obtain a perfected Junior Lien on such Collateral

to the extent, if any, that such perfection results from the possession or control of such Collateral or any such account by such Senior Representative. Subject to Section 2.07, at such time as such Senior Secured Obligations secured by the applicable Senior Lien of such Senior Representative shall have been paid and satisfied in full and any commitment to extend credit that would constitute such Senior Secured Obligations shall have been terminated, such Senior Representative shall take all such actions in its power as shall reasonably be requested by such Junior Representative (at the sole cost and expense of the Grantors) to transfer possession or control of such Collateral or any such account (in each case to the extent such Junior Representative has a Lien on such Collateral or account after giving effect to any prior or concurrent releases of Liens) to such Junior Representative.

SECTION 3.02 *Collection Accounts*. The Company and its subsidiaries, to the extent required by an applicable ABL Document, shall maintain collection accounts relating to applicable ABL First Lien Collateral (the "*Collection Accounts*", which term shall include any Lockbox Account relating to such ABL Document) in which collections from any Inventory and Accounts are deposited. The applicable ABL Collateral Agent will act as gratuitous bailee for the Trustee and the Noteholder Collateral Agent for the purpose of perfecting the Liens of the Noteholder Secured Parties in all such Collection Accounts and the cash and other assets therein as provided in Section 3.01 (but will have no duty, responsibility or obligation to the Noteholder Secured Parties except as set forth in the last sentence of this Section). Unless the Junior Liens on such ABL First Lien Collateral shall have been or concurrently are released, after the occurrence of the applicable ABL First Lien Collateral Transition Date, such ABL Collateral Agent shall at the request of the Noteholder Collateral Agent, cooperate with the Noteholder Collateral Agent (at the expense of the Grantors) in permitting "control" (as defined in Article 8 or Article 9 of the New York UCC) of any Collection Account to be transferred to the Noteholder Collateral Agent (or for other arrangements with respect to each such Collection Account satisfactory to the Noteholder Collateral Agent to be made) to the extent required by the Noteholder Security Documents.

SECTION 3.03 *Rights under Permits and Licenses*. The Trustee and the Noteholder Collateral Agent agree that if any ABL Collateral Agent shall require rights available under any permit or license controlled by the Trustee or the Noteholder Collateral Agent, as the case may be, shall take all such actions as shall be available to it (at the sole expense of the Grantors), consistent with applicable law and reasonably requested by such ABL Collateral Agent agrees that if the Trustee or the Noteholder Collateral Agent shall require rights available under any permit or license controlled by such ABL Collateral Agent, subject to the Noteholder Liens. Each ABL Collateral Agent agrees that if the Trustee or the Noteholder Collateral Agent shall require rights available under any permit or license controlled by such ABL Collateral Agent in order to realize on any Noteholder First Lien Collateral, such ABL Collateral Agent shall take all such actions as shall be available to it (at the sole expense of the Grantors), consistent with applicable law and reasonably requested by such ABL Collateral Agent shall take all such actions as shall be available to it (at the sole expense of the Grantors), consistent with applicable law and reasonably requested by the Trustee or the Noteholder Collateral Agent, as the case may be, to make such rights available to the Trustee or the Noteholder Collateral Agent, as the case may be, to make such rights available to the Trustee or the Noteholder Collateral Agent, as the case may be, to make such rights available to the Trustee or the Noteholder Collateral Agent, as the case may be, to make such rights available to the Trustee or the Noteholder Collateral Agent, as the case may be, subject to the applicable ABL Liens.

#### ARTICLE IV

#### **Existence and Amounts of Liens and Obligations**

Whenever a Representative shall be required, in connection with the exercise of its rights or the performance of its obligations hereunder, to determine the existence or amount of any Senior Secured Obligations (or the existence of any commitment to extent credit that would constitute Senior Secured Obligations) or Junior Secured Obligations (or the existence of any commitment to extent credit that would constitute Junior Secured Obligations), or the existence of any Lien securing any such obligations, or the Collateral subject to any such Lien, it may request that such information be furnished to it in writing by the other applicable Representative and shall be entitled to make such determination on the basis of the information so furnished *provided*, *however*, that if a Representative shall fail or refuse reasonably promptly to provide the requested information, the requesting Representative shall be entitled to make any such determination by such method as it may, in the exercise its good faith judgment, determine, including by reliance upon a certificate of the Company. Each Representative may rely conclusively, and shall be fully protected in so relying, on any determination made by it in accordance with the provisions of the preceding sentence (or as otherwise directed by a court of competent jurisdiction) and shall have no liability to the Company or any of its subsidiaries, any Secured Party or any other person as a result of such determination.

### ARTICLE V

#### **Consent of Grantors**

SECTION 5.01 Each Grantor hereby consents to the provisions of this Agreement and the intercreditor arrangements provided for herein and agrees that the obligations of the Grantors under the ABL Documents and the Noteholder Documents will in no way be diminished or otherwise affected by such provisions or arrangements (except as expressly provided herein).

SECTION 5.02 If a Junior Secured Party pays or distributes cash, property, or other assets to a Senior Secured Party under this Agreement, the Junior Secured Party will be subrogated to the rights of the Senior Secured Party with respect to the applicable Senior Collateral to the extent of the value of such payment or distribution; *provided* that the Junior Secured Party will not reduce the Junior Secured Obligations.

#### **ARTICLE VI**

#### **Representations and Warranties**

SECTION 6.01 *Representations and Warranties of Each Party*. Each party hereto represents and warrants to the other parties hereto as follows.

(a) Such party is duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization and has all requisite power and authority to enter into and perform its obligations under this Agreement.

(b) This Agreement has been duly executed and delivered by such party.

(c) The execution, delivery and performance by such party of this Agreement (i) do not require any consent or approval of, registration or filing with or any other action by any governmental authority of which the failure to obtain the same could reasonably be expected to have a Material Adverse Effect, (i) will not violate any applicable law or regulation or any order of any governmental authority or any indenture, agreement or other instrument binding upon such party which could reasonably be expected to have a Material Adverse Effect and (iii) will not violate the charter, by-laws or other organizational documents of such party. As used in this clause (c), "Material Adverse Effect" means, with respect to a party, a material adverse effect on (a) the business, operations, affairs, financial condition, assets or properties of such party and its subsidiaries taken as a whole, or (b) the ability of such party to perform its obligations hereunder, or (c) the validity or enforceability of this Agreement as to such party.

SECTION 6.02 *Representations and Warranties of Each Representative*. Each of the Trustee, the Noteholder Collateral Agent and the ABL Collateral Agent represents and warrants to the other parties hereto that it is authorized under the Indenture and any applicable ABL Agreement, respectively, to enter into this Agreement.

## **ARTICLE VII**

#### Miscellaneous

SECTION 7.01 *Notices*. All notices and other communications provided for herein shall be in writing and shall be delivered by hand or overnight courier service, mailed by certified or registered mail or sent by facsimile, as follows.

(a) if to the Trustee, to it at:

U.S. Bank National Association Corporate Trust Services One Federal Street, 3rd Floor Boston, Massachusetts 02110 Attention: Alison D.B. Nadeau (Merrimack 2015 Notes) Facsimile: (617) 603-6683

(b) if to the Noteholder Collateral Agent, to it at:

U.S. Bank National Association Corporate Trust Services One Federal Street, 3rd Floor Boston, Massachusetts 02110 Attention: Alison D.B. Nadeau (Merrimack 2015 Notes) Facsimile: (617) 603-6683

(c) if to the ABL Collateral Agent, to it at:

BioPharma Credit Investments IV Sub, LP c/o Pharmakon Advisors, LP 110 East 59th Street, 33rd Floor New York, NY 10022 Attn: Pedro Gonzalez de Cosio Fax: (917) 210-4048 Email: PG@pharmakonadvisors.com; JC@pharmakonadvisors.com

(d) if to the Company, to it at:

Merrimack Pharmaceuticals, Inc. One Kendall Square, Suite B7201 Cambridge, Massachusetts 02139 Attn: Legal Department Fax: (617) 812-8122

(e) if to any other Grantor, to it in care of the Company as provided in clause (d) above.

Any party hereto may change its address or facsimile number for notices and other communications hereunder by notice to the other parties hereto (and for this purpose a notice to the Company shall be deemed to be a notice to each Grantor). All notices and other communications given to any party hereto in accordance with the provisions of this Agreement shall be deemed to have been given on the date of receipt (if a Business Day) and on the next Business Day thereafter (in all other cases) if delivered by hand or overnight courier service or sent by facsimile or on the date five Business Days after dispatch by certified or registered mail if mailed, in each case delivered, sent or mailed (properly addressed) to such party as provided in this Section 7.01 or in accordance with the latest unrevoked direction from such party given in accordance with this Section 7.01. As agreed to in writing among the Company and any ABL Collateral Agent from time to time, notices and other communications may also be delivered by e-mail to the e-mail address of a representative of the applicable person provided from time to time by such person.

SECTION 7.02 *Waivers; Amendment*. (a) No failure or delay on the part of any party hereto in exercising any right or power hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such right or power, or any abandonment or discontinuance of steps to enforce such a right or power, preclude any other or further exercise thereof or the exercise of any other right or power. The rights and remedies of the parties hereto are cumulative and are not exclusive of any rights or remedies that they would otherwise have. No waiver of any provision of this Agreement or consent to any departure by any party therefrom shall in any event be effective unless the same shall be permitted by paragraph (b) of this Section, and then such waiver or consent shall be effective only in the specific instance and for the purpose for which given. No notice or demand on any party hereto in any case shall entitle such party to any other or further notice or demand in similar or other circumstances.

(b) Neither this Agreement nor any provision hereof may be terminated, waived, amended or modified except pursuant to an agreement or agreements in writing entered into by each Representative and the Company *provided*, *however*, that this Agreement may be amended from time to time (x) as provided in Section 2.10 and (y) at the sole request and expense of the Company, and without the consent of any Representative or any other party hereto, (A) to establish that the Liens on any ABL First Lien Collateral securing such ABL Obligations shall be senior to the Liens on such ABL First Lien Collateral securing any Noteholder Obligations, all on the terms provided for herein immediately prior to such amendment, (B) to establish that the Liens on such Noteholder First Lien Collateral securing any Noteholder Obligations, all on the terms provided for herein immediately prior to such amendment, and (C) to add additional Grantors. Any amendment of this Agreement that is proposed to be effected without the consent of a Representative as permitted by the proviso to the second preceding sentence shall be submitted to such Representative for its review at least five (5) Business Days prior to the proposed effectiveness of such amendment.

SECTION 7.03 *Parties in Interest*. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns, as well as the Noteholder Secured Parties and the ABL Secured Parties, all of whom are intended to be bound by, and to be third party beneficiaries of, this Agreement; *provided* that at any time and from time to time, if any Representative assigns any part of its rights or obligations under any ABL Documents or Noteholder Documents (as applicable) such that there exists more than one ABL Collateral Agent or Noteholder Collateral Agent, as applicable, (i) such Representative shall cause each such additional ABL Collateral Agent or Noteholder Collateral Agent, as applicable, to become a party hereto and (ii) the parties hereto shall execute and deliver mutually acceptable supplements or amendments hereto to set forth the rights and responsibilities of each ABL Collateral Agent or Noteholder Collateral Agent, as applicable, and designate a single primary ABL Collateral Agent or Noteholder Collateral Agent, as applicable, and designate a single primary ABL Collateral Agent or Noteholder Collateral Agent, as applicable, not designate a single primary ABL Collateral Agent or Noteholder Collateral Agent, as applicable, not designate a single primary ABL Collateral Agent or Noteholder Collateral Agent, as applicable, respectively, *provided* that such supplements or amendments maintain the respective priorities, rights and remedies with respect to the Noteholder Obligations and ABL Obligations as provided herein.

SECTION 7.04 *Survival of Agreement*. All covenants, agreements, representations and warranties made by any party in this Agreement shall be considered to have been relied upon by the other parties hereto and shall survive the execution and delivery of this Agreement.

SECTION 7.05 *Counterparts*. This Agreement may be executed in counterparts, each of which shall constitute an original but all of which when taken together shall constitute a single contract. Delivery of an executed signature page to this Agreement by facsimile transmission or by email shall be as effective as delivery of a manually signed counterpart of this Agreement.

SECTION 7.06 *Severability*. Any provision of this Agreement held to be invalid, illegal or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such invalidity, illegality or unenforceability without affecting the validity, legality and enforceability of the remaining provisions hereof, and the invalidity of a particular provision in a particular jurisdiction shall not invalidate such provision in any other jurisdiction. The parties shall endeavor in good-faith negotiations to replace the invalid, illegal or unenforceable provisions with valid provisions the economic effect of which comes as close as possible to that of the invalid, illegal or unenforceable provisions.

SECTION 7.07 *Governing Law; Jurisdiction; Consent to Service of Process*. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, without regard to principles of conflicts of law (other than Sections 5-1401 and 5-1402 of the New York General Obligations Law). EACH PARTY HERETO HEREBY SUBMITS TO THE NON-EXCLUSIVE JURISDICTION OF THE FEDERAL AND STATE COURTS OF COMPETENT JURISDICTION IN THE BOROUGH OF MANHATTAN IN THE CITY OF NEW YORK IN ANY SUIT OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY. EACH PARTY TO THIS AGREEMENT IRREVOCABLY CONSENTS TO SERVICE OF PROCESS IN THE MANNER PROVIDED FOR NOTICES IN SECTION 7.01. Nothing in this Agreement will affect the right of any party to this Agreement to serve process in any other manner permitted by law.

SECTION 7.08 *WAIVER OF JURY TRIAL*. EACH PARTY HERETO HEREBY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN ANY LEGAL PROCEEDING DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT. EACH PARTY HERETO (A) CERTIFIES THAT NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER AND (B) ACKNOWLEDGES THAT IT AND THE OTHER PARTIES HERETO HAVE BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION.

SECTION 7.09 *Waiver of Immunity.* To the extent that any Grantor may in any jurisdiction claim for itself or its assets immunity (to the extent such immunity may now or hereafter exist, whether on the grounds of sovereign immunity or otherwise) from suit, execution, attachment (whether in aid of execution, before judgment or otherwise) or other legal process (whether through service of notice or otherwise), and to the extent that in any such jurisdiction there may be attributed to itself or its assets such immunity (whether or not claimed), such Grantor irrevocably agrees with respect to any matter arising under this Agreement for the benefit of the Secured Parties not to claim, and irrevocably waives, such immunity to the full extent permitted by the Laws of such jurisdiction.

SECTION 7.10 *Headings*. Article, Section and Annex headings used herein are for convenience of reference only, are not part of this Agreement and are not to affect the construction of, or to be taken into consideration in interpreting, this Agreement.

SECTION 7.11 *Conflicts*. In the event of any conflict or inconsistency between the provisions of this Agreement and the provisions of any of the other ABL Documents and/or Noteholder Documents, the provisions of this Agreement shall control.

SECTION 7.12 *Provisions Solely to Define Relative Rights*. The provisions of this Agreement are and are intended solely for the purpose of defining the relative rights of the applicable ABL Secured Parties, on the one hand, and the Noteholder Secured Parties, on the other hand. None of the Company, any other Grantor or any other creditor thereof shall have any rights or obligations hereunder, except as expressly provided in this Agreement. Nothing in this Agreement is intended to or shall impair the obligations of the Company or any other Grantor, which are absolute and unconditional, to pay the Obligations as and when the same shall become due and payable in accordance with their terms.

SECTION 7.13 *English Language*. This Agreement and each Noteholder Document has been negotiated and executed in English. All certificates, reports, notices and other documents and communications given or delivered by any party hereto pursuant to this Agreement or any other Noteholder Document shall be in English or, if not in English, accompanied by a certified English translation thereof. The English version of any such document shall control the meaning of the matters set forth herein.

SECTION 7.14 *Concerning the Noteholder Collateral Agent*. The Noteholder Collateral Agent is entering into this Agreement solely in its capacity as Noteholder Collateral Agent under the Indenture, and not in its individual or corporate capacity. In acting hereunder, the Noteholder Collateral Agent shall be entitled to all of the rights, privileges and immunities of the Noteholder Collateral Agent set forth in the Indenture and the Noteholder Documents.

[Remainder of this page intentionally left blank]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed by their respective authorized officers as of the day and year first above written.

U.S. BANK NATIONAL ASSOCIATION	IATION,
--------------------------------	---------

as Trustee

By:		
Name:		
Title		

U.S. BANK NATIONAL ASSOCIATION,

as Noteholder Collateral Agent

By: Name: Title

Signature page to Lien Subordination and Intercreditor Agreement

# **BIOPHARMA CREDIT INVESTMENTS IV SUB, LP,** as ABL Collateral Agent

By:	Pharmakon Advisors, LP, its Investment Manager
By:	Pharmakon Management I, LLC, its General Partner
By:	
Name:	Pedro Gonzalez de Cosio

Signature page to Lien Subordination and Intercreditor Agreement

# MERRIMACK PHARMACEUTICALS, INC.

By: Name: Title:

Signature page to Lien Subordination and Intercreditor Agreement

#### Provision for each ABL Agreement and the Indenture

Reference is made to the Lien Subordination and Intercreditor Agreement dated as of November [\_\_], 2016 among U.S. Bank National Association, as Trustee, U.S. Bank National Association, as Noteholder Collateral Agent, the ABL Collateral Agent(s) for the applicable ABL Secured Parties referred to therein, Merrimack Pharmaceuticals, Inc., a Delaware corporation ("Merrimack"), and the subsidiaries of Merrimack party thereto (the "Intercreditor Agreement"; capitalized terms used in this paragraph and not defined shall have the meaning assigned to them in the Intercreditor Agreement). Each [lender/creditor/noteholder hereunder] [Noteholder, by its acceptance of a Note,] [(a) consents to the subordination of Liens provided for in the Intercreditor Agreement and [(c)] / [(b)] agrees that it will be bound by and will take no actions contrary to the provisions of the Intercreditor Agreement and [(c)] / [(b)] authorizes and instructs the [ABL Collateral Agent] [Trustee] to enter into the Intercreditor Agreement as [ABL Collateral Agent] [Trustee] and on behalf of such [Lender/Creditor] [Noteholder]. The foregoing provisions are intended as an inducement to the [lenders/creditors/noteholders] [Noteholders] are intended third party beneficiaries of such provisions of the Company] and such [lenders/creditor Agreement. In the event of any conflict or inconsistency between the provisions of this Agreement and the Intercreditor Agreement, the provisions of the Intercreditor Agreement and the Intercreditor Agreement, the provisions of the Intercreditor Agreement for the company] and such [lenders/creditor Agreement. In the event of any conflict or inconsistency between the provisions of this Agreement and the Intercreditor Agreement, the provisions of the Intercreditor Agreement shall control.

## Provision for ABL Security Documents and Noteholder Security Documents

Reference is made to the Lien Subordination and Intercreditor Agreement dated as of [\_\_\_\_\_], among U.S. Bank National Association, as Trustee, U.S. Bank National Association, as Noteholder Collateral Agent, the ABL Collateral Agent(s) for the applicable ABL Secured Parties referred to therein, Merrimack Pharmaceuticals, Inc., a Delaware corporation ("Merrimack"), and the subsidiaries of Merrimack party thereto (the "Intercreditor Agreement"; capitalized terms used in this paragraph and not defined shall have the meaning assigned to them in the Intercreditor Agreement). Notwithstanding any other provision contained herein, this Agreement, the [Liens][*insert appropriate defined term under such security document*] created hereby and the rights, remedies, duties and obligations provided for herein are subject in all respects to the provisions of the Intercreditor Agreement and, to the extent provided therein, the applicable Senior Security Documents. In the event of any conflict or inconsistency between the provisions of this Agreement and the Intercreditor Agreement, the provisions of the Intercreditor Agreement, the provisions of this Agreement and the Intercreditor Agreement, the provisions of the Intercreditor Agreement, the provisions of the Intercreditor Agreement and the Intercreditor Agreement, the provisions of the Intercreditor Agreement shall control.

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To be inserted for any Noteholder Document.

Annex I-1

# Additional Legend

Notwithstanding anything to the contrary herein, in any [Noteholder Document] [*insert appropriate description of such document*] or any [ABL Document][*insert appropriate description of such document*], the Grantors shall not be required to act or refrain from acting (a) pursuant to any [Noteholder Document] solely with respect to any [ABL First Lien Collateral][*insert appropriate defined term under such security document*] in any manner that would cause a default under any [ABL Document], or (b) pursuant to any [ABL Document] solely with respect to any [Noteholder First Lien Collateral][*insert appropriate defined term under such security document*] in any manner that would cause a default under any [ABL Document], or (b) pursuant to any [ABL Document] solely with respect to any [Noteholder First Lien Collateral][*insert appropriate defined term under such security document*] in any manner that would cause a default under any [Noteholder Document]. For avoidance of doubt, the terms [Noteholder Document] and [ABL Document] do not include the Intercreditor Agreement.

Annex I-2

# FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT

This First Amendment to Loan and Security Agreement (this "<u>First Amendment</u>") is made and entered into as of the latest dated signature on the signature page hereto by and between MERRIMACK PHARMACEUTICALS, INC., a Delaware corporation ("<u>Borrower</u>"), and BIOPHARMA CREDIT INVESTMENTS IV SUB, LP, a Cayman Islands exempted limited partnership ("<u>Lender</u>").

WHEREAS, Borrower and Lender are parties to the Loan and Security Agreement, dated as of November 8, 2016 (the "Original Agreement"); and

WHEREAS, Borrower and Lender desire to amend the Original Agreement as provided herein in order to extend the date until which Borrower may elect to draw upon the Term Loan.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. <u>Section 2.6</u>: Section 2.6 of the Original Agreement ("Facility Fee") is hereby amended by adding the following sentence at the end of such section:

"In addition, as additional consideration for Lender's agreement to advance money or extend credit for Borrower's benefit on the terms and conditions set forth in this Agreement, Borrower shall pay to Lender on the effective date of the First Amendment to this Agreement the additional amount of One Hundred and Twenty-five Thousand Dollars (\$125,000.00), which amount shall not be refundable, in whole or in part, for any reason (including, for the avoidance of doubt, the termination of this Agreement and any obligation of Lender to make the Term Loan hereunder pursuant to the ultimate sentence of <u>Section 3.4</u>)."

2. <u>Section 3.4</u>: Section 3.4 of the Original Agreement ("Procedures for Borrowing") is hereby amended by replacing each instance of the date "February 23, 2017" with "April 7, 2017".

3. <u>Definition of "Closing Date"</u>: The definition of "Closing Date" in Section 13 of the Original Agreement is hereby amended by replacing the date "March 15, 2017" with "April 27, 2017".

4. <u>Miscellaneous</u>. Except as provided herein, the Original Agreement shall remain unchanged and in full force and effect. This First Amendment may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This First Amendment shall be governed by and construed in accordance with the laws of New York without regard to its principles of conflicts of law.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties have executed this First Amendment as of the dates set forth below.

# MERRIMACK PHARMACEUTICALS, INC., as Borrower

By: <u>/s/ Jeffrey A. Munsie</u> Name: Jeffrey A. Munsie Title: General Counsel

Date: 2/16/17

# BIOPHARMA CREDIT INVESTMENTS IV SUB, LP, as Lender

By: Pharmakon Advisors, LP, its Investment Manager

By: Pharmakon Management I, LLC, its General Partner

By: <u>/s/ Pedro Gonzalez de Cosio</u> Name:Pedro Gonzalez de Cosio Title: Managing Member

Date: 2/23/17

Signature Page to First Amendment to Loan and Security Agreement

## **EMPLOYMENT AGREEMENT**

This Employment Agreement (this "<u>Agreement</u>"), dated as of January 17, 2017, is entered into by and between Merrimack Pharmaceuticals, Inc., a Delaware corporation with a place of business at One Kendall Square, Suite B7201, Cambridge, Massachusetts 02139 (the "<u>Company</u>"), and Richard Peters (the "<u>Employee</u>").

## RECITALS

WHEREAS, the Company desires to employ the Employee on the terms and conditions, and for the consideration, hereinafter set forth, and the Employee desires to be employed by the Company on such terms and conditions and for such consideration.

NOW, THEREFORE, in consideration of the foregoing and of the respective covenants and agreements of the parties herein contained, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

1. *Term of Employment*. Subject to the terms and conditions hereinafter set forth, the Company hereby employs the Employee, and the Employee hereby enters into the employment of the Company, for an employment term commencing on February 6, 2017 (the "<u>Effective Date</u>") and, unless earlier terminated in accordance with the provisions set forth in Section 7, continuing until December 31, 2017. This Agreement shall renew automatically for successive one (1) year terms, unless either party shall give the other notice of non-renewal in accordance with Section 7. The initial term of this Agreement, together with any annual renewal terms of this Agreement, shall be referred to as the "<u>Term of Employment</u>." The Employee's Base Salary (as defined below) for any renewal term shall be as agreed by the parties, provided that (i) the Base Salary shall in no event be less than the Base Salary the Employee received in the immediately preceding term, and (ii) in the absence of an agreement otherwise, the Employee's Base Salary shall be the same as the Base Salary he received in the immediately preceding term.

2. *Position*. During the Term of Employment, the Employee shall serve as the President and Chief Executive Officer of the Company and in such additional position(s) as he and the Board of Directors of the Company (the "<u>Board</u>") shall agree. As soon as practicable after the Effective Date, the Board shall elect the Employee to be a member of the Board.

3. Scope of Employment. During the Term of Employment, the Employee shall be responsible for the performance of all financial, managerial and administrative duties customarily performed by a President and Chief Executive Officer, together with such other duties as the Board and the Employee shall agree, and shall perform similar duties as requested or appropriate for affiliates (including any subsidiaries) of the Company ("<u>Affiliates</u>"). The Employee shall be accountable to the Board and shall perform and discharge, faithfully, diligently and to the best of his ability, his duties and responsibilities hereunder. The Employee shall devote his full working time and efforts to the business and affairs of the Company and its Affiliates; provided, however, that the Employee may continue to serve on the Boards of Directors and Advisory Boards of the companies on which he serves as of the date of this Agreement, so long as such service does not interfere with the performance of his duties for the Company.

4. *Compensation*. As full compensation for all services to be rendered by the Employee during the Term of Employment, the Company will provide to the Employee, and the Employee will accept, the following:

(a) *Base Salary*. During the Term of Employment, the Employee shall receive a base salary at the rate of \$26,923.08 per bi-weekly pay period (which is an annualized rate of \$700,000), less all applicable taxes and withholdings (the "<u>Base Salary</u>"), paid in installments in accordance with the Company's regularly established payroll procedure. The Employee's Base Salary shall be reviewed annually by the Board and may be adjusted from time to time in accordance with normal business practices and taking into account then-current market factors, but in no event shall the Employee's Base Salary be less than the Base Salary the Employee received from the Company in the immediately preceding year.

(b) Signing Bonus. Contingent upon the commencement of the Employee's employment and subject to the terms and conditions set forth herein, the Company agrees to pay the Employee a one-time signing bonus of \$900,000 (the "Signing Bonus"), less all applicable taxes and withholdings, which will be paid no later than the second pay period following the commencement of the Employee's employment. If prior to the one-year anniversary of the Effective Date the Employee voluntarily terminates his employment with the Company without Good Reason or the Company terminates the Employee's employment for Cause (as defined below), the Employee will be obligated to repay to the Company within sixty (60) days following his last day of employment with the Company the entire net amount of the Signing Bonus received by him.

(c) Annual Discretionary Bonus. During the Term of Employment, the Employee shall be eligible to receive a discretionary annual performance and retention bonus of up to 65% of his then-current Base Salary, at a time and under circumstances determined by the Board, in its sole discretion. In order to receive this bonus, the Employee must be an active employee of the Company on the date any bonus is determined and no discretionary annual bonus shall be considered earned before such date. Such discretionary bonus, if any, shall be paid no later than sixty (60) days following the date on which the Board approves such bonus. The Employee's bonus for 2017 shall be prorated based on the Effective Date.

(d) Stock Options; Equity Grants. Subject to approval by the Board, the Company will grant the Employee an option to purchase a number of shares of the Company's common stock equal to the lesser of (i) such number of shares that has a target grant date fair value of \$3,500,000 and (ii) 2,000,000 shares, with an exercise price equal to the fair market value per share on the date of the grant of the stock option. The stock option will vest over four years at the rate of 25% on the one-year anniversary of the Effective Date, subject to the Employee's continued employment with the Company as of that date. The remaining shares shall vest quarterly over the following three (3) years, subject to the Employee's continued employment with the Company's 2011 Stock Incentive Plan and the applicable Stock Option Agreement. The Employee shall be eligible to receive additional option grants or other equity grants at times and under circumstances determined by the Board, in its sole discretion.

(e) *Paid Time Off.* The Employee shall be eligible for paid time off in accordance with the Company's Paid Time Off Policy contained within the Company's Employee Handbook, as amended and/or superseded from time to time.

(f) *Insurance*. The Employee shall be entitled to participate in, and receive benefits under, all Company sponsored insurance and benefit programs (i.e., health, dental, life, and disability) available to senior management employees of the Company, subject to and on a basis consistent with the eligibility requirements, terms, conditions and overall administration of such programs.

(g) Other Benefits. The Employee shall be entitled to participate in, and receive benefits under, all Company employee benefit plans and arrangements (including but not limited to 401(k) and similar programs), available to senior management employees of the Company, subject to and on a basis consistent with the eligibility requirements, terms, conditions and overall administration of such plans, policies and arrangements.

5. *Expenses.* The Employee shall be entitled to reimbursement by the Company for all reasonable expenses actually incurred by him on the Company's behalf in the performance of his duties during the course of his employment by the Company, upon the prompt presentation by the Employee, from time to time and in accordance with the Company's then-current reimbursement policies, of an itemized account of such expenditures together with all supporting vouchers and receipts. All expense reimbursements shall be subject to the terms set forth in Section 5 of <u>Exhibit C</u>.

6. **Restrictive Covenants/Other Conditions to Employment**. Notwithstanding anything to the contrary contained herein, the Employee's employment hereunder is subject to and conditioned on the Employee's (i) completion of a background check and drug screen analysis satisfactory to the Company, (ii) execution and delivery to the Company of the Non-Disclosure, Developments, Non-Competition and Non-Solicitation Agreement (the "<u>Restrictive Covenants Agreement</u>") attached hereto as <u>Exhibit A</u>, and (iii) timely providing proof of his right to work in the United States. The Employee further agrees that he shall sign all consents necessary to the accomplishment of any of the foregoing, and that, should he not satisfy the conditions set forth in this Section 6, he shall not commence employment and this Agreement shall be null and void, with no obligations owed to the Employee.

# 7. Early Termination.

(a) *Death and Disability.* In the event of the Employee's death during the Term of Employment, this Agreement shall terminate immediately. If, during the Term of Employment, the Employee shall be unable for a period of more than any three (3) consecutive months or for periods aggregating more than twenty-six (26) weeks in a twelve (12) month period to perform the services provided for herein as a result of any illness or disability, the Company may terminate the Employee's employment hereunder. The Employee shall be considered unable to perform the services provided for herein if and whenever the Company reasonably determines, based upon the results of a medical examination performed by a mutually agreed-upon professional, that he is mentally or physically incapable of performing his duties hereunder with or without reasonable accommodation.

(b) *Termination for Cause.* The Employee may be terminated by the Company without notice for "Cause." The following, as determined by the Board in its reasonable judgment, shall constitute "<u>Cause</u>" for termination:

(i) *Failure to Perform Duties.* The Employee's material failure to perform (other than by reason of illness or disability) his duties to the Company, or his material negligence in the performance of his duties and/or responsibilities to the Company, provided that the Employee shall have had prior written notice and a reasonable opportunity of not less than thirty (30) days to correct any deficiency in such performance;

(ii) Breach of Employment Agreement or Restrictive Covenants Agreement. The Employee's material breach of this Agreement or the Restrictive Covenants Agreement;

(iii) *Misconduct.* The Employee's conviction for or plea of *nolo contendere* or guilty to any crime involving fraud, embezzlement or moral turpitude or any felony; or

(iv) *Harmful Conduct*. Any conduct of the Employee that is materially harmful to the business, interests or reputation of the Company, provided that the Employee shall have had prior written notice and a reasonable opportunity of not less than ten (10) days to correct any such conduct.

(c) *Termination By Company Without Cause*. The Employee may be terminated by the Company without "Cause" upon delivery of written notice to the Employee. In the event the Employee is terminated without "Cause," the Employee shall be entitled to receive the severance benefits set forth in Section 7(f) or 7(g), as applicable. The Company's decision not to renew the Term of Employment shall constitute a termination without "Cause."

(d) *Termination by the Employee for Good Reason.* This Agreement may be terminated by the Employee for "Good Reason" (as defined below), upon thirty (30) days' prior written notice to the Company specifying any and all circumstances the Employee believes to constitute the basis for Good Reason, provided that the Company shall have the opportunity to cure the asserted Good Reason within the thirty (30) day period. The Employee shall have "<u>Good Reason</u>" to terminate this Agreement in the event that the Company, without the express written consent of the Employee: (i) causes a material diminution of the Employee's authority, duties or responsibilities; (ii) materially breaches this Agreement, including, without limitation, by materially reducing the Employee's Base Salary; or (iii) relocates the Employee's place of business by more than thirty (30) miles from the Company's current Cambridge, Massachusetts office. Notwithstanding the foregoing, the Employee must give notice of his intention to resign within ninety (90) days after the occurrence of the grounds for termination for Good Reason, and resign within thirty (30) days after the expiration of the Company's 30-day cure period referenced above, or grounds for termination for Good Reason due to the circumstances specified in the notice are irrevocably waived. In the event the Employee terminates his employment for Good Reason, the Employee shall be entitled to the severance benefits set forth in Section 7(f) or 7(g), as applicable.

(e) *Effect of Early Termination*. Except for a termination by the Company without "Cause" or by the Employee for "Good Reason," in the event of any early termination of the Term of Employment, the Company's obligations under this Agreement shall immediately cease and the Employee shall be entitled to only the Employee's Base Salary and employment benefits which have accrued and to which the Employee is entitled through the date of such termination, including any bonus that may have been awarded but not yet paid. These accrued salary and benefits shall be paid on or about the date of termination. The Employee shall not be entitled to any other compensation or consideration, including any bonus not yet awarded that the Employee may have been eligible for had his Term of Employment not ceased, except as otherwise set forth in this Section 7(e). In the event of an early termination of the Term of Employment due to the Employee's death or disability, as set forth in Section 7(a), the Employee (or his estate, in the event of his death) will be eligible to receive a pro rata bonus determined in the manner set forth in the penultimate sentence of Section 7(f), which bonus shall be paid within thirty (30) days following the date of the Employee's termination.

Severance Benefits Prior to a Change in Control. If the Term of Employment is terminated by the (f) Company without "Cause" (as that term is defined in Section 7(b)) or by the Employee for "Good Reason" (as that term is defined in Section 7(d), in each case prior to a Change in Control (as that term is defined in Exhibit B), the Employee shall be entitled to receive his Base Salary and all other employment benefits accrued through the effective date of such termination, which shall be paid on or about the date of termination. In addition, provided the Employee executes and allows to become binding a severance agreement and release of claims drafted by and satisfactory to the Company (the "Release") on or before the sixtieth (60th) day after the date of termination, then beginning on the first regularly scheduled payroll date that is sixty (60) days following the date of termination (such date, the "Payment Commencement Date"), for a period of twelve (12) months (the "Severance Period"), the Company shall: (i) pay to the Employee as severance pay his Base Salary in accordance with the Company's regularly established payroll procedure and (ii) pay for coverage under any medical benefit plans provided pursuant to Section 4(f), provided the Employee is eligible for and elects to continue receiving such benefits pursuant to the federal "COBRA" law, 29 U.S.C. § 1161 et. seq., and provided further that the Employee continues to pay the applicable share of the premium for such coverage that is paid by active and similarly situated employees who receive the same type of coverage. In addition, the Company shall pay to the Employee, on the Payment Commencement Date, a pro-rata bonus equal to (A) the average of the Employee's annual bonus payments over each of the three (3) years prior to the year of termination (or, if the Employee is an executive officer, such lesser period during which the Employee served as an executive officer of the Company), or, if such termination occurs prior to the award of the Employee's first annual bonus for 2017, the Employee's target annual bonus for 2017, multiplied by (B) a fraction, the numerator of which is the number of days during the year during which the Employee remained employed by the Company and the denominator of which is 365. The distribution of all severance benefits under this Section 7(f) shall be subject to the provisions of Exhibit C.

Severance Benefits After a Change in Control. If the Term of Employment is terminated by the (g) Company without "Cause" (as that term is defined in Section 7(b)) or by the Employee for "Good Reason" (as that term is defined in Section 7(d)), in each case within the eighteen (18) month period following a Change in Control (as that term is defined in Exhibit B), the Employee shall be entitled to receive his Base Salary and all other employment benefits accrued through the effective date of such termination, which shall be paid on or about the date of termination. In addition, provided the Employee executes and allows to become binding the Release on or before the Payment Commencement Date, the Company shall: (i) pay to the Employee as severance pay on the Payment Commencement Date a lump sum amount equal to thirty-six (36) months of his Base Salary; (ii) pay to the Employee on the Payment Commencement Date a bonus equal to (A) three (3) multiplied by (B) the average of the Employee's annual bonus payments over each of the three (3) years prior to the year of termination (or, if the Employee is an executive officer, such lesser period during which the Employee served as an executive officer of the Company), or, if such termination occurs prior to the award of the Employee's first annual bonus for 2017, the Employee's target annual bonus for 2017; (iii) accelerate the vesting of all outstanding Company stock options, restricted stock or other equity awards granted to the Employee; and (iv) pay for coverage under any medical benefit plans provided pursuant to Section 4(f) for a period of eighteen (18) months following the Employee's date of termination, provided the Employee is eligible for and elects to continue receiving such benefits pursuant to the federal "COBRA" law, 29 U.S.C. § 1161 et. seq., and provided further that the Employee continues to pay the applicable share of the premium for such coverage that is paid by active and similarly situated employees who receive the same type of coverage. The distribution of all severance benefits under this Section 7(g) shall be subject to the provisions of Exhibit C.

# 8. Cutback.

Anything in this Agreement to the contrary notwithstanding and except as set forth below, in the event (a) it shall be determined that any payment, benefit, vesting or distribution to or for the benefit of the Employee (whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise) (a "Payment") would but for this Section 8 be subject to the excise tax imposed by §4999 of the Internal Revenue Code, or any comparable successor provisions (the "Excise Tax"), then the Payments shall either be (i) provided to the Employee in full, or (ii) provided to the Employee as to such lesser extent which would result in no portion of such Payments being subject to the Excise Tax, whichever of the foregoing amounts, when taking into account applicable income and employment taxes, the Excise Tax, and any other applicable taxes, results in the receipt by the Employee on an after-tax basis of the greatest amount of Payments, notwithstanding that all or some portion of such Payments may be subject to the Excise Tax. Any determination required under this Section 8 shall be made in writing in good faith by the Company's independent certified public accountants, appointed prior to any change in ownership (as defined under §280G (b)(2) of the Internal Revenue Code), and/or tax counsel selected by such accountants (the "Accounting Firm") in accordance with the principles of §280G of the Internal Revenue Code. In the event of a reduction of Payments hereunder, the Payments shall be reduced as follows: (i) first from cash payments which are included in full as parachute payments, (ii) second from equity awards which are included in full as parachute payments, (iii) third from cash payments which are partially included as parachute payments, and (iv) from equity awards that are partially included

as parachute payments, in each instance provided that §409A is complied with and the Payments to be made later in time are to be reduced before Payments to be made sooner in time. For purposes of making the calculations required by this Section 8, the Accounting Firm may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of the Internal Revenue Code, and other applicable legal authority. The Company and the Employee shall furnish to the Accounting Firm such information and documents as the Accounting Firm may reasonably request in order to make a determination under this Section 8. All fees and expenses of the Accounting Firm shall be borne solely by the Company.

(b) If, notwithstanding any reduction described in this Section 8, the Internal Revenue Service (the "<u>IRS</u>") determines that the Employee is liable for the Excise Tax as a result of the receipt of the Payments as described above, then the Employee shall be obligated to pay back to the Company, within thirty (30) days after a final IRS determination or in the event that the Employee challenges the final IRS determination, a final judicial determination, a portion of the Payments equal to the "<u>Repayment Amount</u>." The Repayment Amount with respect to the Payments shall be the smallest such amount, if any, as shall be required to be paid to the Company so that the Employee's net after-tax proceeds with respect to the Payments (after taking into account the payment of the Excise Tax and all other applicable taxes imposed on such payment) shall be maximized. The Repayment Amount with respect to the Payments shall be zero if a Repayment Amount of more than zero would not result in the Employee's net after-tax proceeds with respect to the Payments to the Excise Tax is not eliminated pursuant to this paragraph, the Employee shall pay the Excise Tax.

(c) Notwithstanding any other provision of this Section 8, if (i) there is a reduction in the Payments as described in this Section 8, (ii) the IRS later determines that the Employee is liable for the Excise Tax, the payment of which would result in the maximization of the Employee's net after-tax proceeds (calculated as if the Employee's Payments had not previously been reduced), and (iii) the Employee pays the Excise Tax, then the Company shall pay to the Employee those Payments which were reduced pursuant to this subsection as soon as administratively possible after the Employee pays the Excise Tax so that the Employee's net after-tax proceeds with respect to the Payments are maximized.

**9.** *Absence of Restrictions.* The Employee represents and warrants that he is not a party to any commitment or undertaking by which he is subject to any restriction or limitation upon his entering into this Agreement or performing the services required of him hereunder.

10. *Amendments.* Any amendment to this Agreement shall be made in writing and signed by the parties hereto.

11. *Applicable Law/Jury Trial Waiver*. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts (without reference to the conflict of laws provisions thereof). Any action, suit or other legal proceeding arising under or relating to any provision of this Agreement shall be commenced only in a court of the Commonwealth of Massachusetts (or, if appropriate, a federal court located within the Commonwealth of Massachusetts), and the Company and the Employee each consents to the jurisdiction of such a court. The Company and the Employee each hereby irrevocably waives any right to a trial by jury in any action, suit or other legal proceeding arising under or relating to any provision of this Agreement.

**12.** *Entire Agreement.* This Agreement, together with the Restrictive Covenants Agreement attached hereto as <u>Exhibit A</u> and executed as a condition of the Employee's employment, constitutes the entire agreement between the parties and supersedes all prior agreements and understandings, whether written or oral, relating to the subject matter of these agreements.

13. *Successors and Assigns*. This Agreement shall be binding upon and inure to the benefit of both parties and their respective successors and assigns, including any corporation with which or into which the Company may be merged or which may succeed to all or substantially all of its assets or business; provided, however, that the obligations of the Employee are personal and shall not be assigned by him.

14. *Acknowledgment*. The Employee states and represents that he has had an opportunity to fully discuss and review the terms of this Agreement with an attorney. The Employee further states and represents that he has carefully read this Agreement, understands the contents herein, freely and voluntarily assents to all of the terms and conditions hereof, and signs his name of his own free act.

# 15. Miscellaneous.

(a) No delay or omission by either party in exercising any right under this Agreement shall operate as a waiver of that or any other right. A waiver or consent given by either party on any one occasion shall be effective only in that instance and shall not be construed as a bar to or waiver of any right on any other occasion.

(b) The captions of the sections of this Agreement are for convenience of reference only and in no way define, limit or affect the scope or substance of any section of this Agreement.

(c) In case any provision of this Agreement shall be invalid, illegal or otherwise unenforceable, the validity, legality and enforceability of the remaining provisions shall in no way be affected or impaired thereby.

[Remainder of Page Intentionally Left Blank]

# COMPANY: MERRIMACK PHARMACEUTICALS, INC. By: /s/ Gary L. Crocker Gary L. Crocker Chairman, Board of Directors /s/ Richard Peters /s/ Richard Peters Richard Peters Richard Peters

# <u>Exhibit A</u>

# Non-Disclosure, Developments, Non-Competition and Non-Solicitation Agreement

# NON-DISCLOSURE, DEVELOPMENTS, NON-COMPETITION

# AND NON-SOLICITATION AGREEMENT

This Non-Disclosure, Developments, Non-Competition and Non-Solicitation Agreement (the "<u>Agreement</u>"), dated as of February 6, 2017, is entered into by and between Merrimack Pharmaceuticals, Inc., a Delaware corporation (the "<u>Company</u>"), and Richard Peters (the "<u>Employee</u>").

In consideration of the Employee's employment with the Company and for other valuable consideration, the receipt and sufficiency of which are hereby acknowledged by the Employee, the Employee hereby agrees as follows:

# 1. <u>Condition of Employment</u>.

The Employee acknowledges that his employment and the continuance of that employment with the Company is contingent upon his agreement to sign and adhere to the provisions of this Agreement. The Employee further acknowledges that the nature of the Company's business is such that protection of its proprietary and confidential information and goodwill with its customers and partners is critical to its survival and success.

# 2. <u>Confidential Information</u>.

The Employee agrees that all information and know-how, whether or not in writing, of a private, secret or (a) confidential nature concerning the Company and its operations and business or financial affairs (collectively, "Confidential Information") is and shall be the exclusive property of the Company. By way of illustration, but not limitation, Confidential Information may include models, systems, software and codes, or systems, software and codes in the course of development, or planned or proposed systems, software or codes, customer, prospect and supplier lists, contacts at or knowledge of customers or prospective customers, customer accounts and other customer financial information, strategic partners and/or collaborators, price lists and all other pricing, marketing and sales information, projections, results relating to the Company or any customer or supplier of the Company, databases, modules, products, programs, product improvements, product enhancements and/or developments, designs, specifications, processes, methods, techniques, operations, projects, plans, chemical compounds, chemical or biological materials, engineering data, clinical or technological data, research data, financial data, personnel information obtained pursuant to the performance of the Employee's duties for the Company, and other confidential agreements or documents (including, without limitation, clinical trial protocols and unpublished patent applications). Except as otherwise permitted by Section 5, the Employee will not disclose any Confidential Information to others outside the Company or use the same for any purpose other than the performance of his duties as an employee of the Company, either during or at any time after his employment with the Company. unless and until such Confidential Information has become public knowledge without fault by the Employee. While employed by the Company, the Employee will use the Employee's best efforts to prevent unauthorized publication or disclosure of any Confidential Information.

(b) The Employee agrees that all Company Property (as defined below), whether created by the Employee or others, that shall come into the Employee's custody or possession shall be and is the sole and exclusive property of the Company to be used only in the performance of the Employee's duties for the Company. "Company Property" means any and all written, photographic or any other record containing Confidential Information and shall include, but not be limited to, all agreements, notes, disks, files, letters, memoranda, reports, records, lists, data, drawings, sketches, notebooks, program listings, specifications, software programs, software code, computers and other electronic equipment, documentation, or other equipment or materials of any nature and in any form, containing Confidential Information. Upon the earliest of the Employee's custody or possession without retaining any copies thereof (including, without limitation, any electronic copy) and without using or allowing others to improperly use such Company Property.

(c) The Employee acknowledges that the Employee's obligations with regard to Confidential Information that are set out in Sections 2(a) and (b) extend to all information, know-how, records and tangible property of customers of the Company or suppliers to the Company or of any third party who may have disclosed or entrusted the same to the Company or to the Employee in the course of the Company's business.

# 3. <u>Developments</u>.

(a) The Employee will make full and prompt disclosure to the Company of all inventions, ideas, concepts, improvements, discoveries, methods, techniques, tools, formula, developments, enhancements, modifications, databases, processes, software and works of authorship, whether patentable or not, that are created, made, conceived or reduced to practice by the Employee or under the Employee's direction or jointly with others during the Employee's employment with the Company, whether or not during normal working hours or on the premises of the Company (all of which are collectively referred to in this Agreement as "Developments").

(b) The Employee agrees to assign and does hereby assign to the Company (or any person or entity designated by the Company) all of the Employee's right, title and interest in and to all Developments and all related intellectual property rights. Except as, and solely to the extent that, it may be necessary for the Employee to perform the Employee's duties and fulfill the Employee's obligations in the course of the Employee's employment with the Company, the Company does not grant the Employee, and the Employee agrees that he/she will not receive, any license or right to use any Development or related intellectual property right. The Employee hereby also waives all claims to moral rights in any Developments. However, this Section 3(b) shall not apply to Developments that do not relate to the present or planned business or research and development of the Company and that are made and conceived by the Employee not during normal working hours, not on the Company's premises and not using the Company's tools, devices, equipment or Confidential Information. This Section 3(b) also shall not apply to any Developments that the Employee's employee's employment with the Company, which invention(s) the Employee shall disclose on Exhibit A attached hereto. IF THERE ARE ANY SUCH DEVELOPMENTS TO BE EXCLUDED UNDER THIS AGREEMENT, THE EMPLOYEE SHALL INITIAL HERE; OTHERWISE IT WILL BE DEEMED THAT THERE ARE NO SUCH EXCLUSIONS. \_\_\_\_\_\_ The Employee understands

that, to the extent this Agreement shall be construed in accordance with the laws of any state that precludes the requirement in an employee agreement to assign certain classes of inventions made by an employee, this Section 3(b) shall be interpreted not to apply to any invention that a court rules and/or the Company agrees falls within such classes. To the extent allowed by law, the Employee hereby grants to the Company an exclusive (even unto the Employee), irrevocable, fully paid up, worldwide license to make, use and sell any and all inventions for which assignment cannot be effected.

(c) The Employee agrees to cooperate fully with the Company, both during and after the Employee's employment with the Company, with respect to the procurement, maintenance and enforcement of all copyrights, trademarks, patents and other intellectual property rights (both in the United States and foreign countries) relating to any Development. The Employee shall sign all papers, including, without limitation, copyright applications, patent applications, declarations, oaths, formal assignments, assignment of priority rights and powers of attorney, that the Company may deem necessary or desirable in order to protect and enforce its rights and interests in any Development. The Employee further agrees that if the Company is unable, after reasonable effort, to secure the signature of the Employee on any such papers, any executive officer of the Company shall be entitled to execute any such papers as the agent and the attorney-in-fact of the Employee, and the Employee hereby irrevocably designates and appoints each executive officer of the Company as the Employee's agent and attorney-in-fact for all countries worldwide to execute any such papers on the Employee's behalf, and to take any and all actions as the Company may deem necessary or desirable in order to protect its rights and interests in any Development, under the conditions described in this sentence. Should the Company engage in litigation to enforce any such intellectual property rights, the Employee agrees to appear and testify at no charge, but at the Company's expense.

# 4. <u>Non-Competition and Non-Solicitation</u>.

(a) While the Employee is employed by the Company and for a period of twelve (12) months following the Employee's termination or cessation of employment for any reason (voluntarily or involuntarily), the Employee will not, directly or indirectly:

(i) engage in any business or enterprise (whether as an owner, partner, officer, employee, director, investor, lender, consultant, independent contractor or otherwise, except as the holder of not more than 2% of the combined voting power of the outstanding stock of a publicly held company) that is competitive with the Company's business, including, without limitation, any business or enterprise that develops, designs, produces, markets or sells any product or service competitive with any product or service developed, designed, produced, marketed or sold or planned to be developed, designed, produced, marketed or sold by the Company while the Employee was employed by the Company; provided, however, that this Section 4(a)(i) shall not prohibit the Employee from serving on the Boards of Directors and Advisory Boards of, or owning a beneficial interest in, the company's business), so long as such service and/or beneficial ownership does not interfere with the performance of his duties to the Company and such companies continue to not be competitive with the Company's business.

(ii) either alone or in association with others, recruit, solicit, hire or engage as an independent contractor, or attempt to recruit, solicit, hire or engage as an independent contractor, any person who was employed by the Company or engaged as an independent contractor for the Company at any time during the period of the Employee's employment with the Company, except for an individual whose employment with or service for the Company has been terminated for a period of six (6) months or longer; and/or

(iii) either alone or in association with others, service, solicit, divert or take away, or attempt to service, solicit, divert or take away, the business or patronage of any of the clients, customers or accounts, or prospective clients, customers or accounts, of the Company that were contacted, solicited or served by the Employee while the Employee was employed by the Company or about which the Employee had access to Confidential Information in the course of his employment with the Company.

(b) The geographic scope of this Section 4 shall extend to anywhere the Company or any of its subsidiaries is doing business, has done business or has plans to do business during the Employee's employment with the Company.

(c) If any restriction set forth in this Section 4 is found by any court of competent jurisdiction to be unenforceable because it extends for too long a period of time or over too great a range of activities or in too broad a geographic area, the parties expressly agree that such court shall reform the restriction and enforce it to extend over the maximum period of time, range of activities or geographic area deemed reasonable by such court.

(d) The Employee agrees that during the non-competition and non-solicitation period, the Employee will give notice to the Company of each new job, contract assignment or other work (either as an employee, contractor or otherwise) the Employee plans to undertake at least ten (10) business days prior to beginning any such activity. The notice shall state the name and address of the individual, corporation, association or other entity or organization (the "Entity") for whom such activity is undertaken and the Employee's proposed business relationship or position with the Entity. The Employee further agrees to provide the Company with other pertinent information concerning such business activity as the Company may reasonably request in order to determine the Employee's continued compliance with his obligations under this Agreement. During the non-competition and non-solicitation period, the Employee agrees to provide a copy of this Agreement to all person and Entities with whom the Employee seeks to be hired or do business before accepting employment or engagement with any of them.

(e) If the Employee violates any of the provisions of this Section 4, the Employee shall continue to be held by the restrictions set forth in this Section 4 until a period equal to the period of restriction has expired without any violation.

# 5. <u>Scope of Disclosure Restrictions</u>.

Nothing in this Agreement prohibits the Employee from communicating with government agencies about possible violations of federal, state or local laws or otherwise providing information to government agencies or participating in government agency investigations or proceedings. The Employee is not required to notify the Company of any such communications;

provided, however, that nothing herein authorizes the disclosure of information the Employee obtained through a communication that was subject to the attorney-client privilege. Further, notwithstanding the Employee's confidentiality and nondisclosure obligations, the Employee is hereby advised as follows pursuant to the Defend Trade Secrets Act: "An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. An individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual (A) files any document containing the trade secret under seal; and (B) does not disclose the trade secret, except pursuant to court order."

# 6. <u>Other Agreements</u>.

The Employee hereby represents that, except as the Employee has disclosed in writing to the Company, the Employee is not bound by the terms of any restrictive covenant agreement with any previous employer or other party relating to the nondisclosure of trade secret or confidential or proprietary information, non-competition and/or non-solicitation of customers, clients, employees or others. The Employee further represents that the Employee's performance of all the terms of this Agreement and as an employee of the Company does not and will not breach any such restrictive covenant agreement, and the Employee will not disclose to the Company or induce the Company to use any confidential or proprietary information or material belonging to any previous employer or others.

# 7. <u>Employment At Will</u>.

The Employee acknowledges that this Agreement does not constitute a contract of employment for any period of time and does not modify the at-will nature of the Employee's employment with the Company, pursuant to which both the Company and the Employee may terminate the employment relationship at any time, for any or no reason, with or without notice.

# 8. <u>General Provisions</u>.

(a) <u>Equitable Relief</u>. The Employee acknowledges that the restrictions contained in this Agreement are necessary for the protection of the business and goodwill of the Company and are considered by the Employee to be reasonable for such purpose. The Employee agrees that any breach or threatened breach of this Agreement will cause the Company substantial and irrevocable damage that is difficult to measure. Therefore, in the event of any such breach or threatened breach, the Employee agrees that the Company, in addition to such other remedies that may be available, shall have the right to specific performance and injunctive relief without posting a bond, as well as its reasonable attorneys' fees incurred as a result of any such breach or threatened breach. The Employee hereby waives the adequacy of a remedy at law as a defense to such relief.

<sup>5</sup> 

(b) <u>Change in Terms/Conditions of Employment</u>. The Employee agrees that his obligations under this Agreement shall continue in full force and effect in the event that the Employee's job title, responsibilities, reporting structure, work location, compensation or other conditions of his employment with the Company change subsequent to the execution of this Agreement, without the need to execute a new agreement.

(c) <u>No Conflict</u>. The Employee represents that the execution and performance by the Employee of this Agreement does not and will not conflict with or breach the terms of any other agreement by which the Employee is bound.

(d) <u>Severability</u>. The invalidity or unenforceability of any provision of this Agreement shall not affect or impair the validity or enforceability of any other provision of this Agreement.

(e) <u>Waiver</u>. No delay or omission by the Company in exercising any right under this Agreement will operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion is effective only in that instance and will not be construed as a bar to or waiver of any right on any other occasion. Any waiver of any provision hereof shall be in writing and signed by the Company.

(f) <u>Successors and Assigns</u>. This Agreement shall be binding upon and inure to the benefit of both parties and their respective successors and assigns, including, without limitation, any corporation or entity with which or into which the Company may be merged or which may succeed to all or substantially all of its assets or business; provided, however, that the obligations of the Employee are personal and shall not be assigned by the Employee.

(g) <u>Governing Law, Forum and Jurisdiction/Jury Trial Waiver</u>. This Agreement shall be governed by and construed as a sealed instrument under and in accordance with the laws of the Commonwealth of Massachusetts without regard to conflict of laws provisions. Any action, suit or other legal proceeding that is commenced to resolve any matter arising under or relating to any provision of this Agreement shall be commenced only in a court of the Commonwealth of Massachusetts (or, if appropriate, a federal court located within Massachusetts), and the Company and the Employee each consents to exclusive personal jurisdiction in such a court. The Employee and the Company hereby expressly waive the right to a jury trial for any claim relating to his/its rights or obligations under this Agreement, or otherwise relating to the Employee's employment or separation from employment with the Company.

(h) <u>Captions</u>. The captions of the sections of this Agreement are for convenience of reference only and in no way define, limit or affect the scope or substance of any section of this Agreement.

(i) <u>Entire Agreement</u>. This Agreement supersedes all prior agreements, written or oral, between the Employee and the Company relating to the subject matter of this Agreement. This Agreement may not be amended, modified, changed or discharged in whole or in part (other than pursuant to Section 4(e)), except by an agreement in writing signed by the Employee and the Company.

# THE EMPLOYEE ACKNOWLEDGES THAT HE/SHE HAS CAREFULLY READ THIS AGREEMENT AND UNDERSTANDS AND AGREES TO ALL OF THE PROVISIONS IN THIS AGREEMENT.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first written above.

# COMPANY: MERRIMACK PHARMACEUTICALS, INC. By: /s/ Jeffrey A. Munsie Jeffrey A. Munsie General Counsel /s/ Richard Peters /s/ Richard Peters 8 8

# <u>Exhibit A</u>

# List of Prior Inventions and Original Works of Authorship

Title	Date	Identifying Number or Brief Description

Additional Sheets Attached Signature of Employee: Printed Name of Employee:

Date:

# Exhibit B

# **Definition of Change in Control**

A "<u>Change in Control</u>" shall occur upon any of the following events, provided, in each case, that such event constitutes a "change in control event" within the meaning of Treasury Regulation Section 1.409A-3(i)(5)(i):

(A) the acquisition by an individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) (a "Person") of beneficial ownership of any capital stock of the Company if, after such acquisition, such Person beneficially owns (within the meaning of Rule 13d-3 under the Exchange Act) 50% or more of either (x) the then-outstanding shares of common stock of the Company (the "Outstanding Company Common Stock") or (y) the combined voting power of the then-outstanding securities of the Company entitled to vote generally in the election of directors (the "Outstanding Company Voting Securities"); provided, however, that for purposes of this subsection (A), the following acquisitions shall not constitute a Change in Control: (1) any acquisition directly from the Company or (2) any acquisition by any corporation pursuant to a Business Combination (as defined below) which complies with clauses (x) and (y) of subsection (C) of this definition;

(B) a change in the composition of the Board that results in the Continuing Directors (as defined below) no longer constituting a majority of the Board (or, if applicable, the Board of Directors of a successor corporation to the Company), where the term "<u>Continuing Director</u>" means at any date a member of the Board (x) who was a member of the Board on the date of this Agreement or (y) who was nominated or elected subsequent to such date by at least a majority of the directors who were Continuing Directors at the time of such nomination or election or whose election to the Board was recommended or endorsed by at least a majority of the directors who were Continuing Directors at the time of such nomination or election or whose election to the Board was recommended, however, that there shall be excluded from this clause (y) any individual whose initial assumption of office occurred as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents, by or on behalf of a person other than the Board; or

(C) the consummation of a merger, consolidation, reorganization, recapitalization or share exchange involving the Company or a sale or other disposition of all or substantially all of the assets of the Company (a "Business Combination"), unless, immediately following such Business Combination, each of the following two conditions is satisfied: (x) all or substantially all of the individuals and entities who were the beneficial owners of the Outstanding Company Common Stock and Outstanding Company Voting Securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the then-outstanding shares of common stock and the combined voting power of the then-outstanding securities entitled to vote generally in the election of directors, respectively, of the resulting or acquiring corporation in such Business Combination (which shall include, without limitation, a corporation which as a result of such transaction owns the Company or substantially all of the Company's assets either directly or through one or more subsidiaries) (such resulting or acquiring corporation is referred to herein as the "<u>Acquiring Corporation</u>") in substantially the same

proportions as their ownership of the Outstanding Company Common Stock and Outstanding Company Voting Securities, respectively, immediately prior to such Business Combination and (y) no Person (excluding any employee benefit plan (or related trust) maintained or sponsored by the Company or by the Acquiring Corporation) beneficially owns, directly or indirectly, 50% or more of the then-outstanding shares of common stock of the Acquiring Corporation, or of the combined voting power of the then-outstanding securities of such corporation entitled to vote generally in the election of directors (except to the extent that such ownership existed prior to the Business Combination).

# Exhibit C

# Payments Subject to Section 409A

Subject to this Exhibit C, severance payments or benefits under this Agreement shall begin only on or after the date of the Employee's "separation from service" (determined as set forth below), which occurs on or after the termination of the Employee's employment. The following rules shall apply with respect to distribution of the payments and benefits, if any, to be provided to the Employee under this Agreement:

1. It is intended that each installment of the payments provided under this Agreement shall be treated as a separate "payment" for purposes of Section 409A of the Internal Revenue Code and the guidance issued thereunder ("Section 409A"). Neither the Company nor the Employee shall have the right to accelerate or defer the delivery of any such payments or benefits except to the extent specifically permitted or required by Section 409A.

2. If, as of the date of the Employee's "separation from service" from the Company, the Employee is not a "specified employee" (within the meaning of Section 409A), then each installment of the severance payments and benefits shall be made on the dates and terms set forth in this Agreement.

3. If, as of the date of the Employee's "separation from service" from the Company, the Employee is a "specified employee" (within the meaning of Section 409A), then:

(a) Each installment of the severance payments and benefits due under this Agreement that, in accordance with the dates and terms set forth herein, will in all circumstances, regardless of when the Employee's separation from service occurs, be paid within the Short-Term Deferral Period (as defined under Section 409A) shall be treated as a short-term deferral within the meaning of Treasury Regulation Section 1.409A- l(b)(4) to the maximum extent permissible under Section 409A and shall be paid at the time set forth in this Agreement; and

(b) Each installment of the severance payments and benefits due under this Agreement that is not described in this Exhibit C, Section 3(a) and that would, absent this subsection, be paid within the six (6) month period following the Employee's "separation from service" from the Company shall not be paid until the date that is six (6) months and one (1) day after such separation from service (or, if earlier, the Employee's death), with any such installments that are required to be delayed being accumulated during the six (6) month period and paid in a lump sum on the date that is six (6) months and one (1) day following the Employee's separation from service, and any subsequent installments being paid in accordance with the dates and terms set forth in this Agreement; provided, however, that the preceding provisions of this sentence shall not apply to any installment of severance payments and benefits if and to the maximum extent that such installment is deemed to be paid under a separation pay plan that does not provide for a deferral of compensation by reason of the application of Treasury Regulation 1.409A-l(b)(9)(iii) must be paid no later than the last day of the Employee's second taxable year following the taxable year in which the separation from service occurs.

4. The determination of whether and when the Employee's separation from service from the Company has occurred shall be made in a manner consistent with, and based on the presumptions set forth in, Treasury Regulation Section 1.409A-l(h). Solely for purposes of this Exhibit C, Section 4, "<u>Company</u>" shall include all persons with whom the Company would be considered a single employer under Section 414(b) and 414(c) of the Internal Revenue Code.

5. All reimbursements and in-kind benefits provided under this Agreement shall be made or provided in accordance with the requirements of Section 409A to the extent that such reimbursements or in-kind benefits are subject to Section 409A, including, where applicable, the requirement that (i) any reimbursement is for expenses incurred during the Employee's lifetime (or during a shorter period of time specified in this Agreement), (ii) the amount of expenses eligible for reimbursement during a calendar year may not affect the expenses eligible for reimbursement in any other calendar year, (iii) the reimbursement of an eligible expense will be made on or before the last day of the calendar year following the year in which the expense is incurred and (iv) the right to reimbursement is not subject to set off or liquidation or exchange for any other benefit.

6. The Company makes no representation or warranty and shall have no liability to the Employee or to any other person if any of the provisions of this Agreement (including this Exhibit C) are determined to provide for non-qualified deferred compensation subject to Section 409A but that do not satisfy an exemption from, or the conditions of, that section.

7. The Company may withhold (or cause to be withheld) from any payments made under this Agreement, all federal, state, city or other taxes as shall be required to be withheld pursuant to any law or governmental regulation or ruling.

# SEPARATION AND RELEASE OF CLAIMS AGREEMENT

This Separation and Release of Claims Agreement (the "<u>Agreement</u>") is made as of the Effective Date (as defined below) between Merrimack Pharmaceuticals, Inc. (the "<u>Company</u>") and Robert J. Mulroy ("<u>Executive</u>") (together, the "<u>Parties</u>").

WHEREAS, the Company and Executive are parties to the Amended and Restated Employment Agreement dated as of August 16, 2011 (the "<u>Employment Agreement</u>"), under which Executive currently serves as President and Chief Executive Officer of the Company;

**WHEREAS**, the Parties wish to establish terms for Executive's orderly transition and separation from the Company effective on the Separation Date (as defined below); and

**WHEREAS**, the Parties agree that the payments, benefits and rights set forth in this Agreement shall be the exclusive payments, benefits and rights due Executive;

**NOW, THEREFORE**, in consideration of the mutual covenants and agreements contained herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

# 1. <u>Separation Date; Post-Employment Consulting Arrangement</u> –

(a) Executive's effective date of separation from employment with the Company will be October 3, 2016 (the "<u>Separation Date</u>"). Executive hereby resigns, as of the Separation Date, from his employment with the Company and from his positions as a member of the Company's Board of Directors and as an officer of the Company. Executive agrees to execute and deliver any documents reasonably necessary to effectuate such resignations, provided that nothing in any such document is inconsistent with any terms set forth in this Agreement. As of the Separation Date, all salary payments from the Company will cease and any benefits Executive had as of the Separation Date under Company-provided benefit plans, programs, or practices will terminate, except as required by federal or state law or as otherwise specifically set forth in this Agreement.

(b) Upon the Separation Date, the Company and Executive shall enter into a consulting agreement in the form attached to this Agreement as Attachment A and incorporated into this Agreement (the "<u>Consulting Agreement</u>"), pursuant to which Executive shall provide assistance in connection with the Company's transition to new leadership. During the Consultation Period (as such term is defined in the Consulting Agreement), any unvested equity awards previously granted to Executive by the Company will continue to vest and be exercisable in accordance with the applicable equity plans and award agreements. It is anticipated that Executive's performance of services under the Consulting Agreement will be limited to less than one (1) day per week.

2. <u>Severance Benefits</u> – In return for Executive's timely signing and not revoking this Agreement, and subject to Executive's compliance with all terms hereof, the Company will provide Executive with the following severance benefits in full satisfaction of the Company's obligations under the Employment Agreement (the "<u>Severance Benefits</u>"):

(a) <u>Salary Continuation</u> – Commencing on the first regularly scheduled payroll date that follows the sixtieth (60<sup>th</sup>) day after the Separation Date (the "<u>Payment Commencement Date</u>"), the Company will, for a twelve (12) month period (the "<u>Severance Period</u>"), provide Executive with severance pay in the form of salary continuation payments at Executive's current annual base salary rate of \$598,689.00, less all applicable taxes and withholdings and in accordance with the Company's regular payroll practices.

(b) <u>Group Health Insurance</u> – Should Executive be eligible for and timely elect to continue receiving group health and/or dental insurance coverage under the law known as COBRA, the Company shall, until earlier of (x) the last day of the Severance Period, and (y) the date that Executive is no longer eligible for COBRA continuation coverage (the "<u>COBRA</u> <u>Contribution Period</u>"), pay on Executive's behalf the share of the premium for such coverage that it currently pays on behalf of active and similarly situated employees who receive the same type of coverage. The remaining balance of any premium costs, and all premium costs after the COBRA Contribution Period, shall be paid by Executive on a monthly basis during the elected period of health insurance coverage under COBRA for as long as, and to the extent that, he remains eligible for COBRA continuation.

(c) <u>Pro-Rata Bonus</u> – On the Payment Commencement Date, the Company shall provide Executive with a pro-rata bonus payment of \$154,271, which is equivalent to (i) the average of Executive's annual bonus payments over each of the three (3) years prior to the Separation Date, multiplied by (ii) a fraction, the numerator of which is the number of days during calendar year 2016 during which Executive remained employed by the Company and the denominator of which is 365.

(d) <u>Other Benefits Continuation</u> – During the Severance Period, the Company shall, to the extent allowed by applicable law and the applicable plan documents, continue to provide Executive with such other benefits as are described in Section 4(f) of the Employment Agreement, subject to and on a basis consistent with the terms, conditions and overall administration of such plans.

Other than the Severance Benefits, Executive will not be eligible for, nor shall he have a right to receive, any payments or benefits from the Company following the Separation Date, other than reimbursement for any outstanding business expenses in accordance with Company policy.

3. **<u>Release of Claims</u>** – In exchange for the consideration set forth in this Agreement, which Executive acknowledges he would not otherwise be entitled to receive, Executive hereby fully, forever, irrevocably and unconditionally releases, remises and discharges the Company, its affiliates, subsidiaries, parent companies, predecessors, and successors, and all of their respective past and present officers, directors, stockholders, partners, members, employees, agents, representatives, plan administrators, attorneys, insurers and

fiduciaries (each in their individual and corporate capacities) (collectively, the "Released Parties") from any and all claims, charges, complaints, demands, actions, causes of action, suits, rights, debts, sums of money, costs, accounts, reckonings, covenants, contracts, agreements, promises, doings, omissions, damages, executions, obligations, liabilities, and expenses (including attorneys' fees and costs), of every kind and nature that Executive ever had or now has against any or all of the Released Parties up to the date on which he signs this Agreement, whether known or unknown, including, but not limited to, any and all claims arising out of or relating to Executive's employment with and/or separation from the Company, including, but not limited to, all claims under Title VII of the Civil Rights Act, the Americans With Disabilities Act, the Age Discrimination in Employment Act, the Genetic Information Nondiscrimination Act, the Family and Medical Leave Act, the Worker Adjustment and Retraining Notification Act, the Rehabilitation Act, Executive Order 11246, Executive Order 11141, the Fair Credit Reporting Act, and the Employee Retirement Income Security Act, all as amended; all claims arising out of the Massachusetts Fair Employment Practices Act, Mass. Gen. Laws ch. 151B, § 1 et seq., the Massachusetts Wage Act, Mass. Gen. Laws ch. 149, § 148 et seq. (Massachusetts law regarding payment of wages and overtime), the Massachusetts Civil Rights Act, Mass. Gen. Laws ch. 12. §§ 11H and 11I, the Massachusetts Equal Rights Act, Mass. Gen. Laws. ch. 93, § 102 and Mass. Gen. Laws ch. 214, § 1C, the Massachusetts Labor and Industries Act, Mass. Gen. Laws ch. 149, § 1 et seq., Mass. Gen. Laws ch. 214, § 1B (Massachusetts right of privacy law), the Massachusetts Maternity Leave Act, Mass. Gen. Laws ch. 149, § 105D, and the Massachusetts Small Necessities Leave Act, Mass. Gen. Laws ch. 149, § 52D, all as amended; all common law claims including, but not limited to, actions in defamation, intentional infliction of emotional distress, misrepresentation, fraud, wrongful discharge, and breach of contract (including, without limitation, all claims arising out of or related to the Employment Agreement); all state and federal whistleblower claims to the maximum extent permitted by law; and any claim or damage arising out of Executive's employment with and/or separation from the Company (including a claim for retaliation) under any common law theory or any federal, state or local statute or ordinance not expressly referenced above; provided, however, that nothing in this release of claims prevents Executive from filing a charge with, cooperating with, or participating in any investigation or proceeding before, the Equal Employment Opportunity Commission or a state fair employment practices agency (except that Executive acknowledges that he may not recover any monetary benefits in connection with any such charge, investigation, or proceeding, and Executive further waives any rights or claims to any payment, benefit, attorneys' fees or other remedial relief in connection with any such charge, investigation or proceeding). This release also does not prevent Executive from reporting possible violations of federal securities laws to government enforcement agencies without notice to the Company, or from receiving any applicable award for information provided to such government enforcement agencies. Further, nothing herein shall prevent Executive from bringing claims to enforce this Agreement and/or the Consulting Agreement, or release (i) any rights Executive may have under the Company's certificate of incorporation, by-laws, insurance and/or any indemnification agreement between him and the Company (and/or otherwise under law) for indemnification and/or defense as an employee, officer or director of the Company for his service to the Company (recognizing that such

indemnification and/or defense is not guaranteed by this Agreement and shall be governed by the instrument or law, if any, providing for such indemnification and/or defense), (ii) any rights Executive may have to vested equity ownership in the Company under the applicable equity plans and agreements, (iii) any rights Executive may have to vested pension or 401(K) benefits or interests under any ERISA-Covered benefit plan (excluding severance) provided by the Company, (iv) any rights to COBRA or Workers' Compensation Benefits, or (v) any rights or claims that cannot be waived by law, including claims for unemployment benefits, which the Company agrees that it will not contest, provided that the Company will not make any false statement to any government agency.

- 4. <u>Continuing Obligations</u> Executive acknowledges and reaffirms his obligation, to the extent permitted by law and except as otherwise permitted by Section 8 below, to keep confidential and not to use or disclose any and all non-public information concerning the Company that he acquired during the course of his employment with the Company, or may acquire during his service under the Consulting Agreement, including, but not limited to, any non-public information concerning the Company's business affairs, business prospects, and financial condition. Executive further acknowledges his continuing obligations with respect to confidential information, non-competition, non-solicitation, non-disclosure and developments as set forth in Sections 6-8 of the Employment Agreement and in the Non-Competition, Non-Solicitation, Non-Disclosure and Developments Agreement dated as of August 16, 2011 (the "Restrictive Covenant Agreement") (except to the extent modified by Section 14 of the Employment Agreement), which survive his separation from employment with the Company, provided, however, the Company agrees to waive Section 4(f) of the Restrictive Covenant Agreement.
- 5. <u>Non-Disparagement</u> Executive understands and agrees that, to the extent permitted by law and except as otherwise permitted by Section 8 below, he will not, in public or private, make any false, disparaging, derogatory or defamatory statements, online (including, without limitation, on any social media, networking, or employer review site) or otherwise, to any person or entity, including, but not limited to, any media outlet, industry group, financial institution or current or former employee, board member, consultant, client or customer of the Company, regarding the Company or any of the other Released Parties, or regarding the Company's business affairs, business prospects, or financial condition. The Company will instruct its board members and executive officers, to the extent permitted by law and except as otherwise permitted by Section 8 below, not to make any false, disparaging, derogatory or defamatory statements to third parties about Executive.
- 6. <u>Return of Company Property</u> Executive confirms that he will, upon the earlier of the Company's request or the termination of his services under the Consulting Agreement, return to the Company all keys, files, records (and copies thereof), equipment (including, but not limited to, computer hardware, software and printers, wireless handheld devices, cellular phones, tablets, etc.), Company identification and any other Company-owned property in his possession or control and that he will leave intact all electronic Company documents, including but not limited to those that he developed or helped to develop

during his employment or while performing services under the Consulting Agreement. Executive further agrees that he will, upon the earlier of the Company's request or the termination of his services under the Consulting Agreement, cancel all accounts for his benefit, if any, in the Company's name, including but not limited to, credit cards, telephone charge cards, cellular phone and/or wireless data accounts and computer accounts.

- 7. <u>Confidentiality</u> Executive understands and agree that, to the extent permitted by law and except as otherwise permitted by Section 8 below, the terms and contents of this Agreement, and the contents of the negotiations and discussions resulting in this Agreement, shall be maintained as confidential by Executive and his agents and representatives and shall not be disclosed except as otherwise agreed to in writing by the Company, except as required by law, and except to his immediate family, legal, financial and tax advisors, on the condition that any individuals informed must hold the above information in strict confidence. The Company agrees that, to the extent permitted by law and except as otherwise permitted by Section 8 below, it shall keep the contents of the negotiations and discussions resulting in this Agreement confidential except as it believes in good faith to be reasonably necessary for a legitimate business purpose.
- 8. Scope of Disclosure Restrictions Nothing in this Agreement prohibits Executive or any other person from communicating with government agencies about possible violations of federal, state, or local laws or otherwise providing information to government agencies or participating in government agency investigations or proceedings. Executive is not required to notify the Company of any such communications; provided, however, that nothing herein authorizes the disclosure of information Executive obtained through a communication that was subject to the attorney-client privilege. Further, notwithstanding Executive's confidentiality and nondisclosure obligations, Executive is hereby advised as follows pursuant to the Defend Trade Secrets Act: "An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. An individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual (A) files any document containing the trade secret under seal; and (B) does not disclose the trade secret, except pursuant to court order."
- 9. <u>**Cooperation**</u> Executive agrees that, to the extent permitted by law, he shall, for one (1) year following the Separation Date, reasonably cooperate with the Company in the investigation, defense or prosecution of any claims or actions which already have been brought, are currently pending, or which may be brought in the future against the Company by a third party or by or on behalf of the Company against any third party, whether before a state or federal court, any state or federal government agency, or a mediator or arbitrator. Executive's reasonable cooperation in connection with such claims or actions shall include, but not be limited to, being available to meet with the

Company's counsel, at reasonable times and locations designated by the Company, to investigate or prepare the Company's claims or defenses, to prepare for trial or discovery or an administrative hearing, mediation, arbitration or other proceeding and to act as a witness when requested by the Company. The Company will reimburse Executive for all reasonable and documented out of pocket costs that he incurs to comply with this paragraph. Executive further agrees that, to the extent permitted by law, he will notify the Company promptly in the event that he is served with a subpoena (other than a subpoena issued by a government agency), or in the event that he is asked to provide a third party (other than a government agency) with information concerning any actual or potential complaint or claim against the Company.

- 10. **<u>Final Compensation</u>** Executive acknowledges that he has received all compensation due to him from the Company, including, but not limited to, all wages, bonuses and accrued, unused vacation time, and that, other than pursuant to the Consulting Agreement, he is not eligible or entitled to receive any additional payments or consideration from the Company beyond that provided for in Section 2 of this Agreement.
- 11. <u>Amendment and Waiver</u> This Agreement shall be binding upon the Parties and may not be modified in any manner, except by an instrument in writing of concurrent or subsequent date signed by duly authorized representatives of the Parties. This Agreement is binding upon and shall inure to the benefit of the Parties and their respective agents, assigns, heirs, executors/administrators/personal representatives, and successors. No delay or omission by the Company in exercising any right under this Agreement shall operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion shall be effective only in that instance and shall not be construed as a bar to or waiver of any right on any other occasion.
- 12. <u>Validity</u> Should any provision of this Agreement be declared or be determined by any court of competent jurisdiction to be illegal or invalid, the validity of the remaining parts, terms or provisions shall not be affected thereby and said illegal or invalid part, term or provision shall be deemed not to be a part of this Agreement.
- 13. **Nature of Agreement** Both Parties understand and agree that this Agreement is a separation agreement and does not constitute an admission of liability or wrongdoing on the part of the Company or Executive.
- 14. <u>**Time for Consideration and Revocation**</u> Executive acknowledges that he was initially presented with this Agreement on September 27, 2016. Executive understands that this Agreement shall be of no force or effect, and that he shall not be eligible for the consideration described herein, unless he signs and returns this Agreement on or before October 19, 2016, and does not revoke his acceptance in the subsequent seven (7) day period (the day immediately following expiration of such revocation period, the "Effective Date").

- 15. <u>Acknowledgments</u> Executive acknowledges that he has been given at least twenty-one (21) days to consider this Agreement, and that the Company is hereby advising him to consult with an attorney of his own choosing prior to signing this Agreement. Executive further acknowledges and agrees that any changes made to this Agreement following his initial receipt of this Agreement, whether material or immaterial, did not re-start or affect in any manner the original twenty-one (21) day consideration period. Executive understands that he may revoke this Agreement for a period of seven (7) days after he signs it by notifying the Company in writing, and this Agreement shall not be effective or enforceable until the expiration of this seven (7) day revocation period. Executive understands and agrees that by entering into this Agreement he will be waiving any and all rights or claims he might have under the Age Discrimination in Employment Act, as amended by the Older Workers Benefit Protection Act, and that he has received consideration beyond that to which he was previously entitled.
- 16. **Voluntary** Assent Executive affirms that no other promises or agreements of any kind have been made to or with Executive by any person or entity whatsoever to cause him to sign this Agreement, and that he fully understands the meaning and intent of this Agreement. Executive further states and represents that he has carefully read this Agreement, understands the contents herein, freely and voluntarily assents to all of the terms and conditions hereof, and signs his name of his own free act.
- 17. <u>Applicable Law</u> This Agreement shall be interpreted and construed by the laws of the Commonwealth of Massachusetts, without regard to conflict of laws provisions. Executive hereby irrevocably submits to and acknowledges and recognizes the jurisdiction of the courts of the Commonwealth of Massachusetts, or if appropriate, a federal court located in the Commonwealth of Massachusetts (which courts, for purposes of this Agreement, are the only courts of competent jurisdiction), over any suit, action or other proceeding arising out of, under or in connection with this Agreement or the subject matter hereof.
- 18. <u>Entire Agreement</u> This Agreement contains and constitutes the entire understanding and agreement between the Parties hereto with respect to Executive's separation from the Company, severance benefits and the settlement of claims against the Company, and cancels all previous oral and written negotiations, agreements, commitments and writings in connection therewith; provided, however, that nothing in this Section shall modify, cancel or supersede Executive's obligations set forth in Section 4 above.
- 19. <u>**Tax Acknowledgement**</u> In connection with the Severance Benefits provided to Executive pursuant to this Agreement, the Company shall withhold and remit to the tax authorities the amounts required under applicable law, and Executive shall be responsible for all applicable taxes owed by him with respect to such Severance Benefits under applicable law. Executive acknowledges that he is not relying upon the advice or representation of the Company with respect to the tax treatment of any of the Severance Benefits set forth in this Agreement.

- 20. Section 409A This Agreement, and all payments hereunder, are intended to be exempt from, or if not so exempt, to comply with the requirements of, Section 409A of the Internal Revenue Code of 1986, as amended, and the guidance issued thereunder ("Section 409A"), and this Agreement shall be interpreted and administered accordingly. Notwithstanding anything to the contrary in this Agreement, if at the time of Executive's termination of employment, he is a "specified employee" as defined under Section 409A, any and all amounts payable hereunder on account of such termination of employment that would (but for this provision) be payable within six (6) months following the date of termination, shall instead be paid on the next business day following the expiration of such six (6) month period or, if earlier, upon Executive's death; except to the extent of amounts that do not constitute a deferral of compensation within the meaning of Treasury regulation Section 1.409A 1(b) or other amounts or benefits that are exempt from or otherwise not subject to the requirements of Section 409A. For purposes of this Agreement, whether or not a termination of employment has occurred shall be determined consistently with Section 409A. In addition, each payment made pursuant to the Agreement shall be treated as a separate payment and the right to a series of installment payments hereunder is to be treated as a right to a series of separate payments.
- 21. <u>**Counterparts**</u> This Agreement may be executed in several counterparts, each of which shall be deemed to be an original, but all of which together will constitute one and the same Agreement. Facsimile and PDF signatures shall be deemed to be of equal force and effect as originals.

IN WITNESS WHEREOF, the Parties have set their hands and seals to this Agreement as of the date(s) written below.

Merrimack Pharmaceuticals, Inc.

/s/ Jeffrey A. Munsie

By: Jeffrey A. Munsie General Counsel

> I hereby agree to the terms and conditions set forth above. I have been given at least twenty-one (21) days to consider this Agreement and I have chosen to execute this on the date below. I intend that this Agreement will become a binding agreement if I do not revoke my acceptance within seven (7) days.

Date: 10/2/16

Robert J. Mulroy

/s/ Robert J. Mulroy

Date: 10/2/16

# ATTACHMENT A

# **CONSULTING AGREEMENT**

# MERRIMACK PHARMACEUTICALS, INC.

# CONSULTING AND CONFIDENTIALITY AGREEMENT

This Consulting and Confidentiality Agreement (this "<u>Agreement</u>") is entered into as of October 3, 2016 (the "<u>Effective</u> <u>Date</u>") by and between Merrimack Pharmaceuticals, Inc., a Delaware corporation (the "<u>Company</u>"), and Robert J. Mulroy (the "<u>Consultant</u>").

WHEREAS, the Consultant has certain knowledge and expertise regarding the Company as a result of having served as its President and Chief Executive Officer; and

WHEREAS, the Company desires to have the benefit of the Consultant's knowledge and experience, and the Consultant desires to provide consulting services to the Company, all as hereinafter provided in this Agreement.

NOW, THEREFORE, in consideration of the promises and mutual agreements hereinafter set forth, the sufficiency of which are hereby acknowledged, the Company and the Consultant hereby agree as follows:

### Section 1. Services.

(a) <u>Services; Performance</u>. The Consultant shall render to the Company the consulting services described in <u>Exhibit A</u> attached to this Agreement and any additional consulting services as mutually agreed to by the Consultant and the Company from time to time in writing (collectively, the "<u>Services</u>"). The Consultant shall perform such Services in a professional manner and consistent with the highest industry standards at such reasonable times as the Company may from time to time request. The Consultant shall comply with all rules, procedures and standards promulgated from time to time by the Company with respect to the Consultant's access to and use of the Company's property, information, equipment and facilities in the course of the Consultant's provision of Services hereunder.

(b) <u>Non-Exclusive</u>. The parties agree that the Consultant shall provide the Company with the Services on a nonexclusive basis, and that, at all times during the term of this Agreement, the Consultant shall be free to provide, and the Company shall be free to obtain, consulting and advisory services to/from any third party, so long as the provision of such services does not conflict with or breach the Consultant's obligations described in Sections 5 through 8.

# Section 2. Compensation and Reimbursement.

(a) <u>Compensation</u>. As consideration for the performance of Services by the Consultant hereunder, the Company shall compensate the Consultant at a rate of \$300 per hour.

(b) <u>Expense Reimbursement</u>. The Company shall reimburse the Consultant for all reasonable out-of-pocket expenses incurred by the Consultant in connection with the performance of the Services under this Agreement, so long as they are approved in writing in advance by the Company and provided such expenses are consistent with the Company's Travel and Expense Guidelines. Such expenses include, by way of example, coach-class travel, lodging, transportation and long distance telephone charges. The Company shall also reimburse the Consultant for any unusual expenses incurred at the request, and with the prior approval, of the Company.

(c) <u>Itemized Statements</u>. At the end of any month that the Consultant performs Services or incurs expenses, the Consultant shall submit to the Company an itemized statement of the Services performed, including the number of hours worked and the project to which the Services relate, and the expenses incurred, including appropriate and reasonable documentation. The Company shall pay the Consultant the amount set forth on such itemized statement within forty-five (45) days after receipt, provided that if there is any disagreement with respect to the itemized statement, the Company and the Consultant shall work together in good faith to resolve such disagreement. The Consultant shall keep full, true and accurate books of account and other records containing all particulars that may be necessary to ascertain properly and verify the fees and expenses paid pursuant to this Agreement. During the term of this Agreement, and for one (1) year thereafter, the Company or its representatives shall have the right to inspect, during regular business hours, said books of account and other records for purposes of verifying such fees and expenses.

(d) <u>No Employee Benefits</u>. The Consultant's relationship with the Company will be that of an independent contractor, and the Consultant shall not, in connection with this relationship, be entitled to any benefits, coverages or privileges, including without limitation social security, unemployment, medical or pension payments, made available to employees of the Company.

# Section 3. Term and Termination.

(a) <u>Consultation Period</u>. Subject to the terms and conditions hereinafter set forth, the term of this Agreement shall expire upon termination or expiration of the term of the Consultant's consulting arrangement with the Company hereunder (the "<u>Consultation Period</u>"), which Consultation Period shall commence on the Effective Date and shall continue until October 2, 2019 unless earlier terminated; provided, however, that the Consultation Period may be extended for an additional period(s) upon the mutual written agreement of both parties, and provided further that the Consultation Period shall automatically terminate upon the death, physical incapacitation or mental incompetence of the Consultant. The terms and conditions of this Agreement shall continue to govern any Services that continue past expiration or termination of this Agreement.

(b) <u>Termination by the Company</u>. The Company may terminate the Consultation Period for any reason, with or without Cause (as defined below), immediately upon written notice to the Consultant. The Company shall have the right to terminate the Consultation Period as set forth in this Section 3(b) without prejudice to any right or remedy it may have due to any failure of the Consultant to perform its obligations under this Agreement.

(c) <u>Termination by the Consultant</u>. The Consultant may terminate the Consultation Period for any reason, with or without cause, immediately upon written notice to the Company. The Consultant shall have such right to terminate the Consultation Period as set forth in this Section 3(c) without prejudice to any right or remedy it may have due to any failure of the Company to perform its obligations under this Agreement.

(d) Effects of Termination. In the event of any termination under this Section 3, the Consultant shall be entitled to payment for Services performed and expenses incurred in accordance with Section 2(b) prior to the effective date of such termination. In addition, but only in the event the Company terminates the Consultation Period without Cause, all unvested equity granted to the Consultant shall immediately vest and remain exercisable in accordance with the applicable equity plans and award agreements. Except as otherwise explicitly provided herein, the provisions of this Section 3(d) and Sections 6 through 10 shall survive the termination or expiration of this Agreement for any reason. For purposes hereof, "Cause" shall mean (i) a failure by the Consultant to perform the Services that results in material harm to the Company, (ii) the Consultant's material breach of this Agreement or any other written agreement with the Company, including, without limitation, the Separation and Release of Claims Agreement to which this Agreement is Attachment A, (iii) the Consultant's fraud, embezzlement or willful misconduct related to the Company, or (iv) the Consultant's conviction of, or plea of *nolo contendere* to, a misdemeanor relating to the Company, any crime involving dishonesty or moral turpitude, or any felony.

**Section 4.** <u>Independent Contractor</u>. The Consultant is not as of the Effective Date, nor shall the Consultant be deemed to be at any time during the term of this Agreement, an employee of the Company. The Consultant's status and relationship with the Company shall be that of an independent contractor and consultant. The Consultant is not authorized to assume or create any obligation or responsibility, express or implied, on behalf of, or in the name of, the Company or to bind the Company in any manner. Nothing herein shall create, expressly or by implication, a partnership, joint venture or other association between the parties. The Consultant shall be solely responsible for payment of all charges and taxes arising from its relationship to the Company as a consultant.

Section 5. <u>Certain Representations, Warranties and Covenants of the Consultant</u>. The Consultant represents, warrants and covenants to the Company that:

(a) No trade secrets or other confidential or proprietary information of any third party shall be disclosed to the Company or used by the Consultant in the performance of the Services hereunder, and, with respect to any information, know-how, knowledge or data disclosed to the Company or used by the Consultant in the performance of the Services, the Consultant has the full and unrestricted right to disclose or use the same.

(b) The Consultant is not a party to, or otherwise bound by, any employment, consulting or similar agreement, arrangement or understanding with any for-profit enterprise that is or may be a direct competitor of the Company (a "<u>Competitor</u>").

(c) If the Consultant is a faculty member of, or otherwise affiliated with, an academic institution or other not-for-profit research institution (an "<u>Academic Institution</u>"), (i) the Consultant has disclosed such fact to the Company and has provided the Company with all patent, consulting or other applicable policies and procedures of such Academic Institution, and (ii) the Consultant has obtained any and all necessary consents and satisfied any other conditions or requirements imposed by such Academic Institution to enter into this Agreement and perform Services for the Company as contemplated hereunder.

(d) Except as set forth in such policies and procedures of an Academic Institution previously provided to the Company, there are no agreements, arrangements or understandings to which the Consultant is a party, or by which the Consultant is bound, with any current or previous employer or any other party forbidding or restricting the Consultant from entering into this Agreement or performing the Services for the Company hereunder, or which otherwise conflicts with the Consultant's obligations under this Agreement, nor shall the Consultant enter into any such third party agreements, including without limitation any employment, consulting or advisory agreements, arrangements or understandings with a Competitor.

(e) The Consultant's performance of the Services or any other obligations under this Agreement does not and will not conflict with or breach any agreement, arrangement or understanding with any current or previous employer or any other party to which the Consultant is a party or by which the Consultant is bound (including without limitation any non-disclosure or non-competition agreement).

(f) The Consultant has not been debarred and, to the best of the Consultant's knowledge, is not under consideration to be debarred, by the U.S. Food and Drug Administration from working in or providing consulting or advisory services to any pharmaceutical or biotechnology company.

# Section 6. Confidentiality.

Obligations of Confidentiality. The Consultant acknowledges and agrees that the relationship between the (a) Company and the Consultant is one of high trust and confidence, and that, during the course of providing the Services, the Company may disclose to the Consultant certain confidential or proprietary information regarding the Company's products, technology, business and operations, including without limitation possible product development and marketing plans and strategies, non-public clinical and research and development information, non-public financial information (including projections), trade secrets, inventions, scientific or technical data, copies of non-publicly available agreements or documents (including patent applications), customer and supplier lists, information of third parties that the Company has an obligation to keep confidential and other confidential information as the Company may disclose to the Consultant (collectively, the "Confidential Information"). For the avoidance of doubt, Works (as defined in Section 7(a)) and the existence of a consulting relationship between the Company and the Consultant (including the terms and conditions of this Agreement) shall be deemed Confidential Information. The Consultant shall use its best efforts to maintain and protect any and all Confidential Information delivered to it and not to directly or indirectly publish, disseminate or otherwise disclose this Confidential Information to any third party. The Consultant further agrees to use the Confidential Information solely for the purposes of conducting the Services hereunder and not for the Consultant's own benefit or for the benefit of any third party. The Consultant shall not remove any Confidential Information or copies thereof from the Company's premises, except to the extent necessary to fulfill the Services.

(b) <u>Employees and Agents</u>. The Consultant shall only disclose Confidential Information to those of its employees and agents who require knowledge or access to the Confidential Information in the course of providing the Services and who are contractually bound to protect the confidentiality of such Confidential Information. The Consultant shall inform those employees and agents who have access to the Confidential Information that such information is strictly confidential. The Consultant shall use best efforts to ensure compliance by its employees and agents having access to the Confidential Information and shall be responsible for any breach of this Agreement by such employees and agents. The Consultant shall not provide Confidential Information to any of its employees or agents who do not have a need to know such Confidential Information.

(c) <u>Exceptions</u>. The Consultant's obligations as to the Confidential Information shall not apply to any portion of the Confidential Information:

(i) which is already in the Consultant's possession at the time of disclosure by the Company, other than by previous disclosure by the Company, as demonstrated by prior written records;

(ii) which is or becomes publicly available or a matter of public knowledge generally, through no act or omission by the Consultant;

(iii) which is lawfully received by the Consultant from a third party who is or was not bound in any confidential relationship to the Company at the time of such disclosure to the Consultant;

(iv) which is independently developed by the Consultant without reference to or reliance upon the Confidential Information (and such independent development can be properly demonstrated by the Consultant by documentary evidence); or

(v) which is required to be disclosed by the Consultant to comply with applicable laws or governmental regulations.

Further, notwithstanding the Consultant's confidentiality obligations hereunder, the Consultant is hereby advised as follows pursuant to the Defend Trade Secrets Act: "An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal."

(d) <u>Return of Confidential Information</u>. Any Confidential Information, including data and materials, furnished by the Company for use by the Consultant in connection with the Services shall remain the sole property of the Company. The Consultant shall promptly return all such Confidential Information to the Company upon request by the Company or upon termination or expiration of this Agreement.

(e) <u>Injunctive Relief</u>. The restrictions contained in this Agreement are necessary for the protection of the business and goodwill of the Company and are considered by the Consultant to be reasonable for such purpose. The Consultant agrees that any breach of Section 6 or 7 is likely to cause the Company substantial and irrevocable damage which is difficult to measure.

Therefore, in the event of any such breach or threatened breach, the Consultant agrees that the Company, in addition to such other remedies as may be available, shall have the right to obtain an injunction from a court restraining such a breach or threatened breach without having to prove actual damages, and the right to specific performance of the provisions of this Agreement, and the Consultant hereby waives the adequacy of a remedy at law as a defense to such relief.

# Section 7. Ownership of Work Product.

(a) <u>Works</u>. The Consultant shall promptly and fully disclose in writing to the Company all concepts, discoveries, improvements, inventions, formulae, molecules, organisms, chemical or biological materials, ideas, designs, processes, methods, products, computer programs, databases, trade secrets, know-how, technical or business innovations, writings or other works of authorship and patents or patent rights created, reduced to practice or conceived by the Consultant during the term of this Agreement and for six (6) months thereafter (whether or not patentable or copyrightable and whether made solely by the Consultant or jointly with others) which result from the Services or any information derived from the use of any facilities, equipment, supplies or Confidential Information of the Company (collectively, "<u>Works</u>"). The Consultant shall maintain adequate and current written records (in the form of notes, sketches, drawings and as may be specified by the Company) to document the conception and/or first actual reduction to practice of any Works. Such written records shall be available to and remain the sole and exclusive property of the Company at all times.

(b) <u>Ownership of Works</u>. The Works shall be and remain the sole and exclusive property of the Company or its nominees, whether or not patented or copyrighted and without regard to any termination of this Agreement. The Works are being created at the insistence of the Company and shall be deemed to be "works made for hire," except to the extent not permitted under the U.S. copyright laws. The Consultant hereby assigns to the Company all right, title and interest in and to all Works and any and all related patent rights, copyrights, trademarks, trade names and other industrial and intellectual property rights and applications, in the United States and throughout the world, and appoints any officer of the Company as its duly authorized attorney to execute, file, prosecute and protect the same before any government agency, court or authority. Upon the request of the Company and at the Company's expense, the Consultant shall execute such further assignments, documents and other instruments as may be necessary or desirable to fully and completely assign all right, title and interest in and to all Works to the Company and to assist the Company in applying for, obtaining and enforcing patents or copyrights or other rights in the United States and in any foreign country with respect to any such Works.

(c) <u>Work at Third Party Facilities</u>. The Consultant agrees not to make any use of any funds, space, personnel, facilities, equipment or other resources of a third party in performing the Services hereunder, nor take any other action, that would result in a third party owning or having rights to any Works, unless agreed upon in writing in advance by the Company. The Company and the Consultant acknowledge and agree that the Consultant's use of a third party's telephones, fax machines or computers for communication purposes does not constitute an unauthorized use of such third party's facilities under this Section 7(c).

(d) <u>Agreement with Academic Institution</u>. This Agreement is made with the understanding that the Consultant, if affiliated with an Academic Institution, may have signed an agreement concerning inventions with such Academic Institution under which the Consultant may be obligated to assign to such Academic Institution certain inventions which arise out of or otherwise relate to the Consultant's work at or for such Academic Institution or from the Consultant's use of certain of its facilities or intellectual property. In performing the Services hereunder, the Consultant agrees not to utilize Academic Institution facilities or intellectual property if the result of such use is that any Works would not be assignable solely to the Company as set forth in this Section 7.

Section 8. <u>Restriction on Solicitation</u>. During any period in which the Consultant renders Services to the Company and for a period of one (1) year thereafter, the Consultant shall not recruit or otherwise solicit, entice or induce any employee of the Company or any of its subsidiaries or affiliates to terminate his or her employment, or otherwise cease his or her relationship, with the Company or any of its subsidiaries or affiliates.

Section 9. <u>Notice</u>. Any notice required or desired to be given shall be governed solely by this paragraph. Notice shall be deemed given only upon (a) mailing of any letter or instrument by overnight delivery with a reputable carrier or by registered mail, return receipt requested, postage prepaid by the sender, or (b) personal delivery.

If to the Consultant:	If to the Company:
Robert J. Mulroy	Merrimack Pharmaceuticals, Inc.
173 Lewis Road	One Kendall Square, Suite B7201
Belmont, MA 02478	Cambridge, MA 02139
	Attn: Legal Department

From time to time, either party may, by written notice to the other in accordance with this Section 9, designate another address that shall thereupon become the effective address of such party for the purpose of this Section 9.

**Section 10.** <u>Miscellaneous</u>. This Agreement, together with all exhibits hereto, constitutes the entire understanding of the parties hereto with respect to the matters contained herein and supersedes all proposals and agreements, written or oral, and all other communications between the parties relating to the subject matter of this Agreement. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts without regard to its conflict of laws rules. The headings contained in this Agreement are for the convenience of the parties and are not to be construed as a substantive provision hereof. This Agreement may not be modified or amended except in writing signed or executed by the Consultant and the Company. In the event any provision of this Agreement is held to be unenforceable or invalid, such unenforceability or invalidity shall not affect any other provisions of this Agreement and such other provisions shall remain in full force and effect. If any provision of this Agreement is held to be excessively broad, it shall be reformed and construed by limiting and reducing it so as to be enforceable to the maximum extent permitted by law. This Agreement shall be binding upon, and inure to the benefit of, both parties hereto and their respective successors and assigns, including any corporation with or into which the Company may be merged or which may succeed to its assets or business; provided, however, that the

responsibility for actual performance of the Services is personal to the Consultant and may not be assigned or delegated by the Consultant to any other person or entity. This Agreement may be executed in counterparts and by facsimile, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed as of the date first written above.

CONSULTANT	COMPANY
/s/ Robert J. Mulroy Signature	/s/ Jeffrey A. Munsie Signature
Robert J. Mulroy       Printed Name	Jeffrey A. Munsie Printed Name
	General Counsel Title
	9

### Exhibit A

# **Description of Services**

The Consultant shall use his knowledge and expertise regarding the Company to assist Gary Crocker, the Company's Chairman of the Board and interim Chief Executive Officer, with the leadership transition of the Company. The Consultant shall only provide such assistance as is directed by Mr. Crocker. The Consultant shall not undertake any actions for or on behalf of the Company without written pre-approval from Mr. Crocker, including initiating communications with any partner, stockholder or other business contact of the Company. In addition, if any partner, stockholder or other business contact of the Consultant, the Consultant shall not substantively respond to or engage with such partner, stockholder or business contact, but rather shall promptly refer such communication to Mr. Crocker to determine the appropriate response.

### Amendment No. 8 to Sublease

THIS AMENDMENT No. 8 (the "Eighth Amendment") is effective as of January 1, 2017 (the "Eighth Amendment Effective Date") by and between SILVER CREEK PHARMACEUTICALS ("Subtenant") and FIBROGEN, INC. ("FibroGen"). This Eighth Amendment amends the Sublease entered into by and between Subtenant and FibroGen on August 6, 2010 (the "Sublease"), as previously amended (the "Prior Amendments"). Subtenant and FibroGen shall be referred to individually herein as a "Party", and collectively as, the "Parties".

WHEREAS, Subtenant is presently subletting certain office and laboratory space; and

WHEREAS, Subtenant wishes to continue to sublease certain designated office and laboratory space from FibroGen in the 409 Building; and

Now, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

- (1) Unless otherwise defined herein, all capitalized terms and phrases used in this Eighth Amendment shall have the meaning ascribed to them in the Sublease as amended by the Prior Amendments.
- (2) Section 3.2 of the Sublease is hereby deleted in its entirety and replaced with the following:

"3.2 This Sublease will expire on December 31, 2017 ("**Expiration Date**") unless offered an extension to the Sublease no later than thirty (30) days in advance of the Expiration Date."

(3) Section 4.1 of the Sublease is hereby amended with the following:

"4.1 Subtenant shall pay a monthly rent ("Rent") to FibroGen for the Subleased Premises according to the following Schedule:

Months	Rent/Sq.Ft./Mo.	Total Sq. Ft.	Amount/Mo.
September 1, 2010-January 31, 2011 (Lab/Office)	\$6.80	761.00	\$5,174.80
February 1, 2011-April 30, 2011 (Lab/Office)	\$6.80	1271.00	\$8,642.80
May 1, 2011-June 14, 2011 (Lab/Office)	\$6.80	1354.00	\$9,207.20
	\$6.50/Vivarium	348.33	\$2,264.15
June 15, 2011-July 31, 2011	\$6.80/Office/Lab	1354.00	\$9,207.20
(Lab/Office/Vivarium)		Total Sq. Ft.	Total Amt./Mo.
		1738.33	\$11,471.35
	\$6.50/Vivarium	348.33	\$511.28
August 1, 2011-August 7, 2011	\$6.80/Office/Lab	1354.00	\$2,079.00
(Lab/Office/Vivarium)		Total Sq. Ft.	Total Amt.
		1715.33	\$2,590.28
August 8, 2011-August 31, 2011* (Lab/Office/Vivarium)	\$6.50/Vivarium	348.33	\$1,752.87
	\$6.60/Office/Lab	1367.00	\$6,984.96
		Total Sq. Ft.	Total Amt.
		1715.33	\$8,737.83

	\$6.50/Vivarium	348.33	\$2,264.15
September 1, 2011-December 14, 2013	\$6.60/Office/Lab	1367.00	\$9,022.20
(Lab/Office/Vivarium)		Total Sq. Ft.	Total Amt./Mo.
		1715.33	\$11,286.35
	\$6.50/Vivarium	511.33	\$3,323.65
December 15, 2013-December 31, 2015	\$6.60/Office/Lab	1367.00	\$9,022.20
(Lab/Office/Vivarium)		Total Sq. Ft.	Total Amt./Mo.
		1878.33	\$12,345.85
January 1, 2016-December 31, 2016 (Lab/Office/Vivarium)	\$7.26	1878.33	\$13,636.68
January 1, 2017-December 31, 2017 (Lab/Office/Vivarium)	\$7.41	1878	\$13,916.00

\*Note: Pro-Rated Rent Payment"

- (4) This Eighth Amendment, together with the Sublease, as amended by the Prior Amendments, contains the entire understanding of the Parties with respect to the subject matter hereof. Except as otherwise provided herein and in the Prior Amendments, the Sublease has not been modified or amended and remains in full force and effect. All express or implied agreements and understandings that conflict with the terms of this Eighth Amendment, either oral or written, heretofore made with respect to subject matter herein are expressly superseded by this Eighth Amendment.
- (5) This Eighth Amendment may be executed in counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument. Counterparts may be signed and delivered by facsimile and/or via portable document format (pdf) (or similar format), each of which shall be binding when sent.

IN WITNESS WHEREOF, the Parties have executed this Eighth Amendment to the Sublease as of the Eighth Amendment Effective Date.

# FIBROGEN, INC.

By:	/s/ Pat Cotroneo
Name:	Pat Cotroneo
Title:	CFO
Date:	10/10/2016

# SILVER CREEK PHARMACEUTICALS

By:	/s/ John Mulroy
Name:	John Mulroy
Title:	Vice-President
Date:	10/5/2016

# SUBSIDIARIES OF THE REGISTRANT

Name Merrimack Pharmaceuticals UK Limited\* Silver Creek Pharmaceuticals, Inc. Jurisdiction of Incorporation UK Delaware

\* wholly owned

### CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Forms S-3 (No. 333-194312) and S-8 (Nos. 333-180996, 333-186370, 333-194313, 333-202346 and 333-209745) of Merrimack Pharmaceuticals, Inc. of our report dated March 1, 2017 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts March 1, 2017

#### CERTIFICATIONS

I, Richard Peters, M.D., Ph.D., certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 1, 2017

/s/ Richard Peters, M.D., Ph.D. Richard Peters, M.D., Ph.D. President and Chief Executive Officer (Principal Executive Officer)

#### CERTIFICATIONS

I, Yasir B. Al-Wakeel, BM BCh, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 1, 2017

/s/ Yasir B. Al-Wakeel, BM BCh

Yasir B. Al-Wakeel, BM BCh Chief Financial Officer and Head of Corporate Development (Principal Financial Officer)

# CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Merrimack Pharmaceuticals, Inc. (the "Company") for the period ended December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Richard Peters, M.D., Ph.D., President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

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

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

Date: March 1, 2017

/s/ Richard Peters, M.D., Ph.D.

Richard Peters, M.D., Ph.D. President and Chief Executive Officer (Principal Executive Officer)

#### CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Merrimack Pharmaceuticals, Inc. (the "Company") for the period ended December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Yasir B. Al-Wakeel, BM BCh, Chief Financial Officer and Head of Corporate Development of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

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

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

Date: March 1, 2017

/s/ Yasir B. Al-Wakeel, BM BCh

Yasir B. Al-Wakeel, BM BCh Chief Financial Officer and Head of Corporate Development (Principal Financial Officer)