MERRIMACK PHARMACEUTICALS INC
Form 10-Q
August 07, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2018

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission file number: 001-35409

Merrimack Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	04-3210530
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
One Kendall Square, Suite B7201	02139

Cambridge, MA
(Address of principal executive offices) (Zip Code)

(617) 441-1000

(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer		Accelerated filer
Non-accelerated filer	(Do not check if a smaller reporting company)	Smaller reporting company
Emerging growth company		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of August 2, 2018, there were 13,342,784 shares of Common Stock, $0.01 par value per share, outstanding.

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FORWARD-LOOKING STATEMENTS

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

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

- our plans to develop and commercialize our clinical stage product candidates and 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 ability to establish and maintain collaborations for our product candidates;
- our receipt of payments related to the milestone events under the asset purchase and sale agreement with Ipsen S.A. or under the license and collaboration agreement between Baxalta Incorporated, Baxalta US Inc., Baxalta GmbH and Ipsen S.A., when expected or at all;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- the rate and degree of market acceptance and clinical utility of our product candidates;
- our intellectual property position;
- our commercialization, marketing and manufacturing capabilities and strategy;
- the potential advantages of our approach to drug research and development; and
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing.

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

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

NOTE REGARDING TRADEMARKS

ONIVYDE® is a trademark of Ipsen S.A. Any other trademarks, trade names and service marks referred to in this Quarterly Report on Form 10-Q are the property of their respective owners.

PART I

FINANCIAL INFORMATION

Item 1.Financial Statements.

Merrimack Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets

(unaudited)

(in thousands, except per share amounts)	June 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$22,460	$ 93,441
Marketable securities	37,544	—
Prepaid expenses and other current assets	1,727	1,605
Total current assets	61,731	95,046
Restricted cash	584	674
Property and equipment, net	4,143	6,467
Equity method investment	9,134	10,551
Other assets	4,634	4,588
Total assets	$80,226	$ 117,326
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable, accrued expenses and other	$15,569	$ 17,606
Deferred rent	2,325	2,171
Total current liabilities	17,894	19,777
Deferred rent, net of current portion	—	1,209
Other long-term liabilities	56	56
Total liabilities	17,950	21,042
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value: 10,000 shares authorized at June 30, 2018 and December 31, 2017; no shares issued or outstanding at June 30, 2018 or December 31, 2017	—	—
Common stock, $0.01 par value: 30,000 shares authorized at June 30, 2018 and 20,000 shares authorized at December 31, 2017; 13,343 shares issued and outstanding at June 30, 2018 and December 31, 2017	1,334	1,334
Additional paid-in capital	579,265	577,721
Accumulated deficit	(518,322)	(482,771)

Accumulated other comprehensive loss	(1)	—
Total stockholders' equity	62,276	96,284
Total liabilities and stockholders' equity	$80,226	$ 117,326

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

Merrimack Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations and Comprehensive (Loss) Income

(unaudited)

	Three Months Ended		Six Months Ended	
(in thousands, except per share amounts)	June 30, 2018	2017	June 30, 2018	2017
Operating expenses:				
Research and development expenses	$13,678	$19,751	$26,784	$41,356
General and administrative expenses	3,513	14,798	7,783	20,432
Total operating expenses	17,191	34,549	34,567	61,788
Loss from continuing operations	(17,191)	(34,549)	(34,567)	(61,788)
Other income and expenses:				
Interest income	282	382	557	396
Interest expense	—	(26,762)	—	(28,741)
Gain on sale of asset	—	1,703	—	1,703
Other income (expense), net	(860)	(659)	(1,541)	(661)
Total other income and expenses	(578)	(25,336)	(984)	(27,303)
Net loss from continuing operations before income tax benefit	(17,769)	(59,885)	(35,551)	(89,091)
Income tax benefit	—	30,239	—	30,239
Net loss from continuing operations	(17,769)	(29,646)	(35,551)	(58,852)
Discontinued operations:				
Income from discontinued operations, net of tax	—	540,485	—	539,538
Net (loss) income	(17,769)	510,839	(35,551)	480,686
Net loss attributable to non-controlling interest	—	(724)	—	(1,191)
Net (loss) income attributable to Merrimack Pharmaceuticals, Inc.	$(17,769)	$511,563	$(35,551)	$481,877
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities	11	—	(1)	—
Other comprehensive income (loss)	11	—	(1)	—
Comprehensive (loss) income	$(17,758)	$511,563	$(35,552)	$481,877
Amounts attributable to Merrimack Pharmaceuticals, Inc.:				
Net loss from continuing operations	$(17,769)	$(28,922)	$(35,551)	$(57,661)
Income from discontinued operations, net of tax	—	540,485	—	539,538
(Loss) income attributable to Merrimack Pharmaceuticals, Inc.	$(17,769)	$511,563	$(35,551)	$481,877
Basic and dilutive net (loss) income per common share				
Net loss from continuing operations	$(1.33)	$(2.18)	$(2.66)	$(4.38)
Net income from discontinued operations, net of tax	—	40.80	—	41.02
Net (loss) income per share	$(1.33)	$38.62	$(2.66)	$36.64
Weighted-average common shares used per share calculations—basic and diluted	13,343	13,246	13,343	13,153
Cash dividend paid per common share	$—	$10.55	$—	$10.55

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

Merrimack Pharmaceuticals, Inc.

Condensed Consolidated Statements of Cash Flows

(unaudited)

	Six Months Ended June 30,	
(in thousands)	2018	2017
Cash flows from operating activities		
Net (loss) income	$(35,551)	$480,686
Less:		
Gain from discontinued operations	—	539,538
Loss from continuing operations	(35,551)	(58,852)
Adjustments to reconcile net (loss) income to net cash used in operating activities		
Non-cash interest expense	—	2,374
Loss on extinguishment of debt	—	25,011
Benefit from intra-period tax allocation	—	(30,239)
Depreciation and amortization expense	2,258	2,058
Non-cash activity related to discontinued operations	—	15,025
Loss (gain) on sale of property and equipment	184	(512)
Premiums paid on marketable securities	(40)	—
Amortization and accretion on marketable securities	(223)	—
Stock-based compensation expense	1,544	9,529
Loss on equity method investment	1,417	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(79)	(3,790)
Income taxes payable	—	8,141
Accounts payable, accrued expenses and other	(2,037)	2,494
Deferred rent	(1,055)	(209)
Net cash used in continuing operations for operating activities	(33,582)	(28,970)
Net cash used in discontinuing operations for operating activities	—	(46,416)
Net cash used in operating activities	(33,582)	(75,386)
Cash flows from investing activities		
Purchase of property and equipment	(118)	(287)
Proceeds on sale of property and equipment	—	1,104
Proceeds from sale of business	—	575,000
Proceeds from maturities and sales of marketable securities	11,050	—
Purchases of marketable securities	(48,331)	—
Net cash (used in) provided by investing activities	(37,399)	575,817
Cash flows from financing activities		
Payment of debt extinguishment costs	—	(20,124)
Proceeds from exercise of options to purchase common stock	—	6,079
Proceeds from issuance of Series C preferred stock by Silver Creek Pharmaceuticals, Inc., net of issuance costs	—	2,599
Repayment of debt	—	(175,000)

Payment of dividend	—	(140,000)
Net cash used in financing activities	—	(326,446)
Net (decrease) increase in cash, cash equivalents and restricted cash	(70,981)	173,985
Cash, cash equivalents and restricted cash, beginning of period	94,217	22,300
Cash, cash equivalents and restricted cash, end of period	$23,236	$196,285
Non-cash investing and financing activities		
Purchases of property and equipment in accounts payable, accrued expenses and other	$—	$349
Receivables related to property and equipment sale in other current assets	—	155
Supplemental disclosure of cash flows		
Cash paid for interest	—	28,872

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

Merrimack Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements

(unaudited)

1. Nature of the Business

Merrimack Pharmaceuticals, Inc. (the "Company") is a clinical stage biopharmaceutical company based in Cambridge, Massachusetts that is outthinking cancer by targeting biomarker-defined cancers. The Company's vision is to ensure that cancer patients and their families live fulfilling lives. The Company's mission is to transform cancer care through the smart design and development of targeted solutions based on a deep understanding of cancer pathways and biological markers. All of the Company's development programs, including three clinical trials and six candidates in preclinical development, fit into the Company's strategy of (1) understanding the biological problems it is trying to solve, (2) designing specific solutions against the problems it is trying to solve and (3) developing those solutions for biomarker-selected patients. This three-pronged strategy seeks to ensure optimal patient outcomes.

The Company owns worldwide development and commercial rights to all of its clinical and preclinical programs. The Company's most advanced assets and a description of the status of each asset are as follows:

- MM-121 (seribantumab): MM-121 is a fully human monoclonal antibody that binds to the ErbB3 (HER3) receptor and targets heregulin positive cancers. There are two active development programs for MM-121, each in a Phase 2 clinical trial. The Company is conducting the global, open-label, biomarker-selected, Phase 2 randomized SHERLOC clinical trial evaluating MM-121 in combination with docetaxel in patients with heregulin positive non-small cell lung cancer. The Company is also conducting the global, double-blinded, placebo-controlled, biomarker-selected, Phase 2 randomized SHERBOC clinical trial evaluating MM-121 in combination with fulvestrant in patients with heregulin positive, hormone receptor positive, ErbB2 (HER2) negative, metastatic breast cancer; and
- MM-310: MM-310 is an antibody-directed nanotherapeutic that targets the ephrin receptor A2 ("EphA2") receptor and contains a novel prodrug of the highly potent chemotherapy docetaxel. The EphA2 receptor is highly expressed in most solid tumor types, such as prostate, ovarian, bladder, gastric, pancreatic and lung cancers. The Company is conducting a Phase 1 clinical trial to evaluate safety and preliminary activity of MM-310 in patients with solid tumors and to identify the maximum tolerated dose.

On June 25, 2018, the Company announced top-line results from its global, double-blinded, placebo-controlled, Phase 2 randomized CARRIE clinical trial evaluating the addition of MM-141 (istiratumab) to standard-of-care treatment in patients with previously untreated metastatic pancreatic cancer and high serum levels of the insulin-like growth factor 1 ("IGF-1"). The CARRIE clinical trial did not meet its primary or secondary efficacy endpoints in patients who received MM-141 in combination with nab-paclitaxel and gemcitabine, compared to nab-paclitaxel and gemcitabine alone. These results were consistent in all subgroups analyzed. Based on these results, the Company will not devote additional resources to and will cease all of its development activities for MM-141.

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 capital, adequate personnel, infrastructure and extensive compliance reporting capabilities.

The Company's product candidates are in development, and none are approved for any indication by the U.S. Food and Drug Administration ("FDA") or any other regulatory agency. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained or maintained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies, among others. In addition, the Company is dependent upon the services of its employees and consultants.

In accordance with Accounting Standards Codification ("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 condensed consolidated financial statements are issued. As of June 30, 2018, the Company had an accumulated deficit of $518.3 million. During the six months ended June 30, 2018, the Company incurred a net loss from continuing operations of $35.6 million and used $33.6 million of cash in continuing operations for operating activities. The Company expects to continue to generate operating losses in the foreseeable future. The Company expects that its cash, cash

equivalents and marketable securities of $60.0 million at June 30, 2018, in addition to $14.7 million in net borrowings received in July 2018 from its Loan and Security Agreement with Hercules Capital, Inc. and a $18.0 million ONIVYDE milestone payment received in August 2018 (see Note 11), will be sufficient to fund its operating expenses, debt service obligations and capital expenditure requirements into at least the first quarter of 2020. The future viability of the Company beyond that date is dependent on its ability to raise additional capital to finance its operations. The Company may receive additional milestone payments under existing agreements and will seek additional funding through public or private financings, debt financing, collaboration agreements or government grants. The inability to obtain funding, as and when needed, would have a negative impact on the Company's financial condition and ability to pursue its business strategies.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements reflect the operations of Merrimack Pharmaceuticals, Inc. and its wholly owned subsidiary. All intercompany accounts and transactions have been eliminated.

The condensed consolidated financial statements are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP").

The accounting policies followed in the preparation of the interim condensed consolidated financial statements are consistent in all material respects with those presented in Note 1 to the financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017.

Certain reclassifications have been made to the prior year's condensed consolidated balance sheet and condensed consolidated statement of cash flows to enhance comparability with the current year's condensed consolidated financial statements presentation. These reclassifications had no effect on previously reported net income within the condensed consolidated statement of operations and comprehensive (loss) income.

Consolidation

The accompanying condensed consolidated financial statements reflect Merrimack Pharmaceuticals, Inc. and its wholly owned subsidiary. For the three and six months ended June 30, 2017, the condensed consolidated financial statements also include the accounts of Silver Creek Pharmaceuticals, Inc. ("Silver Creek"). For the three and six months ended June 30, 2017, Silver Creek represented a variable interest entity that the Company consolidated as the primary beneficiary. In the third quarter of 2017, the Company deconsolidated Silver Creek from its financial statements since the Company was no longer the primary beneficiary of Silver Creek. The Company's ownership percentage decreased to less than 50% and the Company no longer controlled Silver Creek's board of directors or directed the activities that had the most significant impact on Silver Creek's economic performance. The Company accounts for its investment in Silver Creek under the equity method of accounting.

On April 3, 2017, the Company completed the sale of its right, title and interest in the non-cash assets, equipment, inventory, contracts and intellectual property primarily related to developing, manufacturing and commercializing ONIVYDE and MM-436 (the "Commercial Business"). As of March 31, 2017, the Commercial Business met all the conditions to be classified as a discontinued operation since the disposal of the Commercial Business represented a

strategic shift that had a major effect on the Company's operations and financial results. Therefore, the operating results of the Commercial Business are reported as a loss from discontinued operations, net of tax in the condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2017. During the three and six months ended June 30, 2018, there were no discontinued operations.

Unaudited Interim Financial Information

The condensed consolidated balance sheet as of December 31, 2017 was derived from audited financial statements, but does not include all disclosures required by GAAP. The condensed consolidated balance sheet as of June 30, 2018, the condensed consolidated statements of operations and comprehensive (loss) income for the three and six months ended June 30, 2018 and 2017 and the condensed consolidated statements of cash flows for the six months ended June 30, 2018 and 2017 are unaudited. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of June 30, 2018, the results of its operations for the three and six months ended June 30, 2018 and 2017, and its statements of cash flows for the six months ended June 30, 2018 and 2017. The financial data and other information disclosed in the notes related to the three and six months ended June 30, 2018 and 2017 are unaudited. The results for the three and six months ended June 30, 2018 and 2017 are not necessarily indicative of results to be expected for the year ending December 31, 2018, any other interim periods, or any future year or period.

The unaudited interim financial statements of the Company included herein have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted from this report, as is permitted by such rules and regulations. These unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements and the notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on March 12, 2018.

Condensed Consolidated Statements of Cash Flows

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the statement of financial position that sum to the total of the same such amounts shown in the statement of cash flows:

(in thousands)	June 30, 2018	June 30, 2017
Cash and cash equivalents	$22,460	$135,501
Restricted cash in prepaid expenses and other current assets	192	—
Restricted cash (short term)	—	102
Restricted cash (long term)	584	60,682
Total cash, cash equivalents and restricted cash shown in the condensed consolidated statement of cash flows	$23,236	$196,285

Restricted cash included in prepaid expenses and other current assets and restricted cash long term on the statement of financial position represent amounts pledged as collateral for operating lease obligations as contractually required. This restriction will lapse when the arrangements expire.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates, assumptions and judgments that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenue and expenses during the reporting periods. Significant estimates, assumptions and judgments reflected in these condensed consolidated financial statements include, but are not limited to, the accrual of research and development expenses and the valuation of stock-based awards. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company's estimates.

Marketable Securities

Marketable securities consist of investments with original maturities greater than ninety days. The Company has classified its investments with maturities beyond one year as short term based on their highly liquid nature and because such marketable securities represent the investment of cash that is available for current operations. The Company considers its investment portfolio of marketable debt securities as available-for-sale. Accordingly, these marketable debt securities are recorded at fair value and unrealized gains and losses are reported as a component of accumulated other comprehensive loss in stockholders' equity. Realized gains and losses and declines in value judged to be other than temporary are included as a component of other income (expense), net based on the specific identification method. When determining whether a decline in value is other than temporary, the Company considers various factors, including whether the Company has the intent to sell the security, and whether it is more likely than

not that the Company will be required to sell the security prior to recovery of its amortized cost basis.

3. 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.

The following tables show assets measured at fair value on a recurring basis as of June 30, 2018 and December 31, 2017:

	June 30, 2018		
(in thousands)	Level 1	Level 2	Level 3
Cash equivalents:			
Money market funds	$688	$—	$ —
Commercial paper	—	5,582	—
Totals	$688	$5,582	$ —
Marketable securities:			
Corporate debt securities	$—	$2,148	$ —
Commercial paper	—	25,423	—
Government securities	—	9,973	—
Totals	$—	$37,544	$ —

	December 31, 2017		
(in thousands)	Level 1	Level 2	Level 3
Cash equivalents:			
Money market funds	$89,310	$ —	$ —
Totals	$89,310	$ —	$ —

During the six months ended June 30, 2018 and the year ended December 31, 2017, there were no transfers between Level 1 and Level 2. The fair value of Level 2 instruments classified as cash equivalents and marketable debt securities were determined through third-party pricing services.

The carrying amounts reflected in the condensed consolidated balance sheets for accounts payable, accrued expenses and other liabilities approximate fair value due to their short-term maturities.

4. Marketable Securities and Cash Equivalents

The following table summarizes the Company’s marketable securities and cash equivalents as of June 30, 2018. The Company did not hold any marketable securities as of December 31, 2017.

	June 30, 2018			
(in thousands)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash equivalents:				

Money market funds	$688	$ —	$ —	$688
Commercial paper	5,582	—	—	5,582
Total cash equivalents	$6,270	$ —	$ —	$6,270
Marketable securities:				
Corporate debt securities	$2,150	$ —	$ (2)	$2,148
Commercial paper	25,423	—	—	25,423
Government securities	9,972	1	—	9,973
Total marketable securities	$37,545	$ 1	$ (2)	$37,544
Total cash equivalents and marketable securities	$43,815	$ 1	$ (2)	$43,814

5. Accounts Payable, Accrued Expenses and Other

Accounts payable, accrued expenses and other as of June 30, 2018 and December 31, 2017 consisted of the following:

(in thousands)	June 30, 2018	December 31, 2017
Accounts payable	$1,750	$ 2,887
Accrued goods and services	2,810	5,682
Accrued clinical trial costs	3,978	3,901
Accrued drug purchase costs	4,140	222
Accrued payroll and related benefits	1,489	2,884
Accrued restructuring expenses	—	628
Deferred tax incentives	1,402	1,402
Total accounts payable, accrued expenses and other	$15,569	$ 17,606

6. Stock-Based Compensation

The Company's 2011 Stock Incentive Plan (the "2011 Plan") is administered by the Company's Board of Directors and permits the Company to grant incentive and non-qualified stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards.

At June 30, 2018, there were 0.6 million shares remaining available for grant under the 2011 Plan.

During the six months ended June 30, 2018 and 2017, the Company issued options to purchase 0.6 million and 1.9 million shares of common stock, respectively. Stock options granted to employees vest over a three-year period. Stock options granted to non-employee directors prior to 2018 generally vested immediately. Stock options granted to non-employee directors in 2018 vest over a one-year period, ending on the earlier of the one-year anniversary of the grant date or the day prior to the Company's next annual meeting of stockholders after the grant date.

The fair value of stock options granted to employees during the six months ended June 30, 2018 and 2017 were estimated at the date of grant using the following assumptions:

	Six Months Ended June 30,	
	2018	2017
Risk-free interest rate	2.3 – 2.9%	1.7 – 2.1%
Expected dividend yield	0%	0%
Expected term	5.3 – 5.8 years	5.7 – 6.1 years
Expected volatility	62 – 63%	65 – 68%

The Company uses the simplified method to calculate the expected term, as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate expected term. The computation of expected volatility is based on the historical volatility of comparable companies from a representative peer group selected based on industry and market capitalization. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected life of the stock options. Management's assumptions do not include an estimated forfeiture rate.

The Company recognized stock-based compensation expense during the three and six months ended June 30, 2018 and 2017 as follows:

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
(in thousands)	2018	2017	2018	2017
Employee awards:				
Research and development expense	$280	$4,916	$614	$5,383
General and administrative expense	500	3,818	930	4,146
Total stock-based compensation expense	$780	$8,734	$1,544	$9,529

The following table summarizes stock option activity during the six months ended June 30, 2018:

(in thousands, except per share amounts)	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2017	1,616	$ 22.07	6.65	$ 60,031
Granted	625	$ 10.64		
Exercised	—	$ —		
Forfeited	(298)	$ 22.04		
Outstanding at June 30, 2018	1,943	$ 18.40	6.98	$ —
Vested and expected to vest at June 30, 2018	1,943	$ 18.40	6.98	$ —
Exercisable at June 30, 2018	1,028	$ 23.81	4.92	$ —

The weighted-average grant date fair value per share of stock options granted during the six months ended June 30, 2018 and 2017 was $6.19 and $3.80, respectively.

The aggregate intrinsic value is 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 stock options exercised during the three and six months ended June 30, 2017 was $0.9 million and $2.3 million, respectively. There were no options exercised during the three and six months ended June 30, 2018.

As of June 30, 2018, there was $6.4 million of total unrecognized stock-based compensation expense related to unvested employee stock awards. The Company expects to recognize this expense over a weighted-average period of approximately 2.31 years.

7. Net (Loss) Income Per Common Share

Basic net (loss) income per share is calculated by dividing the net (loss) income attributable to Merrimack Pharmaceuticals, Inc. by the weighted-average number of common shares outstanding during the period.

Diluted net (loss) income per share is computed by dividing the net loss attributable to Merrimack Pharmaceuticals, Inc. by the weighted-average number of dilutive common shares outstanding during the period. Dilutive shares outstanding is calculated by adding to the weighted shares outstanding any potential (unissued) shares of common stock from outstanding stock options based on the treasury stock method. In a period when a net loss is reported, all common stock equivalents are excluded from the calculation because they would have an anti-dilutive effect, meaning the loss per share would be reduced. Therefore, in periods where a loss is reported, there is no difference in basic and dilutive loss per share.

The Company follows the two-class method when computing net (loss) income per share when it has issued shares that meet the definition of participating securities. The two-class method determines net (loss) income per share for each class of common and participating securities according to dividends declared or accumulated and participating

rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based on their respective rights to receive dividends, as if all income for the period has been distributed or losses to be allocated if they are contractually required to fund losses. There were no amounts allocated to participating securities for the three and six months ended June 30, 2018 and 2017, as the Company was in a loss position and had no shares that met the definition of participating securities outstanding as of June 30, 2018 and 2017.

The stock options and conversion premium on the 4.50% convertible notes due 2020 (the “Convertible Notes”) are excluded from the calculation of diluted loss per share because the net loss for the three and six months ended June 30, 2017 causes such securities to be anti-dilutive. Outstanding securities excluded from the calculation of diluted loss per share for the three and six months ended June 30, 2018 and 2017 are shown in the chart below:

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
(in thousands)	2018	2017	2018	2017
Outstanding options to purchase common stock	1,943	1,892	1,943	1,892
Conversion of the Convertible Notes	—	1,216	—	1,216

8. Discontinued Operations

On April 3, 2017, the Company completed the sale of the Commercial Business. As of March 31, 2017, the Commercial Business met all the conditions to be classified as a discontinued operation since the disposal of the Commercial Business represented a strategic shift that had a major effect on the Company's operations and financial results.

The condensed consolidated financial statements for the three and six months ended June 30, 2017 reflect the operations of the Commercial Business as a discontinued operation. Discontinued operations for the three and six months ended June 30, 2017 includes the following:

	Three Months Ended		Six Months Ended	
(in thousands)	June 30, 2018	2017	June 30, 2018	2017
Revenues:				
Product revenues, net	$—	$—	$—	$16,135
License and collaboration revenues	—	—	—	7,797
Other revenues	—	—	—	1,973
Total revenues	—	—	—	25,905
Costs and expenses:				
Cost of revenues	—	—	—	3,890
Research and development expenses	—	—	—	3,700
Selling, general and administrative expenses	—	—	—	8,709
Restructuring expenses	—	4,216	—	9,535
Total costs and expenses	—	4,216	—	25,834
Other income and expenses:				
Interest expense	—	(1,509)	—	(6,743)
Gain on sale of commercial business	—	598,120	—	598,120
Income from discontinued operations	$—	$592,395	$—	$591,448
Income tax expense	—	(51,910)	—	(51,910)
Total income from discontinued operations	$—	$540,485	$—	$539,538

On January 8, 2017, the Company announced a reduction in headcount by approximately 30% in connection with the sale of the Commercial Business and the completion of its strategic pipeline review.

Under this corporate restructuring, for the three and six months ended June 30, 2017, the Company recognized total restructuring expenses of $4.2 million and $9.5 million, respectively, which was related to contractual termination benefits for employees with pre-existing severance arrangements. These one-time employee termination benefits are comprised of severance, benefits and related costs, all of which resulted in cash expenditures. The expense of $9.5 million was included in discontinued operations, as the costs are directly associated with the sale of the Commercial Business. For the three and six months ended June 30, 2018, there were no discontinued operations.

9. Investment in Silver Creek

On August 20, 2010, the Company acquired a controlling financial interest in Silver Creek. At such time, the Company had the ability to direct the activities of Silver Creek that most significantly impacted Silver Creek's economic performance through its ownership percentage and through the board of director seats controlled by the Company. As such, Silver Creek was consolidated by the Company.

Since the Company acquired its financial interest, Silver Creek has raised funding through the issuance of preferred stock and convertible promissory notes. The Company has not participated in any Silver Creek financings nor has it provided any funding.

During the third quarter of 2017, Silver Creek completed its Series C preferred stock financing, reducing the Company's ownership percentage in Silver Creek below 50% and resulting in the Company no longer controlling the Silver Creek board of directors. Accordingly, the Company determined that it was no longer the primary beneficiary of Silver Creek and deconsolidated Silver Creek from its financial statements on July 13, 2017. Starting on July 14, 2017, the Company accounted for its investment in Silver Creek under the equity method of accounting since the Company has the ability to exercise significant influence over Silver Creek. Under the equity method of accounting, the Company has recorded its proportionate share of Silver Creek's losses in its results of operations with a corresponding decrease in the carrying value of the investment. As of June 30, 2018, the carrying value of the

Company's investment in Silver Creek was $9.1 million. There can be no guarantee that the value of the Company's investment in Silver Creek will not realize a substantial future loss or complete loss of value. On a quarterly basis, the Company reviews the investment for impairment whenever events or changes in circumstances indicate that the carrying amount of the investment might not be recoverable. These circumstances can include, but are not limited to, negative current events or long-term outlooks impacting Silver Creek and/or its programs, planned or announced delays in the clinical development process to advance its programs, a current fair value of investment at a lower value than the Company's investment and/or investors no longer providing financial support or reducing their financial commitment to Silver Creek.

Silver Creek continues to be a related party to the Company after deconsolidation.

10. Recent Accounting Pronouncements

The Financial Accounting Standards Board ("FASB") issued the following new Accounting Standards Updates ("ASU"), which the Company adopted on January 1, 2018:

- ASU 2014-09, "Revenue from Contracts with Customers (Topic 606)" and related amendments;
- ASU 2016-01, "Financial Instruments – Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Liabilities";
- ASU 2016-15, "Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments";
- ASU 2016-18, "Statement of Cash Flows - Restricted Cash (a consensus of the FASB Emerging Issues Task Force)"; and
- ASU 2017-09, "Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting."

The adoption of these standards did not have a material impact on the Company's financial position, results of operations or statement of cash flows; however, the adoption of ASU 2016-18 resulted in the reclassification of certain prior year amounts in the Company's condensed consolidated statements of cash flows to conform to the current year presentation.

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. In July 2018, the FASB issued ASU 2018-10, "Codification Improvements to Topic 842, Leases." The amendments in ASU 2018-10 affect narrow aspects of the guidance issued in ASU 2016-02. The Company is currently evaluating the potential impact that the adoption of this guidance may have on the condensed 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 condensed consolidated financial statements.

In February 2018, the FASB issued ASU 2018-02, “Income Statement - Reporting Comprehensive Income (Topic 220).” ASU 2018-02 addresses the effect of the change in the U.S. federal corporate tax rate due to the enactment of the December 22, 2017 Tax Cuts and Jobs Act (the “Tax Act”) on items within accumulated other comprehensive loss. The guidance will be effective for the Company in the first quarter of fiscal 2020 with early adoption permitted. The Company is currently assessing the impact that adopting this new accounting standard will have on the condensed consolidated financial statements.

In July 2018, the FASB issued ASU 2018-09, “Codification Improvements.” The amendments in ASU 2018-09 affect a wide variety of topics in the FASB Accounting Standards Codification and XBRL Taxonomy. The transition and effective date guidance is based on the facts and circumstances of each amendment. Some of the amendments in ASU 2018-09 do not require transition guidance and will be effective upon issuance of the update. However, many of the amendments in ASU 2018-09 do have transition guidance with effective dates for annual periods beginning after December 15, 2018 for public business entities. The Company is currently assessing the impact that adopting this new accounting standard will have on the condensed consolidated financial statements.

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that the Company adopts as of the specified effective date. Unless otherwise discussed above, the Company does not believe that the adoption of recently issued standards has or may have a material impact on the Company's condensed consolidated financial statements or disclosures.

11. Subsequent Events

On July 2, 2018, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Hercules Capital, Inc. pursuant to which a term loan of up to an aggregate principal amount of $25.0 million is available to the Company. The Loan Agreement provides for an initial term loan advance of $15.0 million, which closed on July 2, 2018, and, at the Company's option, two additional term loan advances of $5.0 million each upon the occurrence of certain funding conditions prior to December 31, 2018 and December 31, 2019, respectively. The term loan bears interest at an annual rate equal to the greater of 9.25% and 9.25% plus the prime rate of interest minus 5.25%. The Loan Agreement provides for interest-only payments for eighteen months and repayment of the aggregate outstanding principal balance of the term loan in monthly installments starting on February 1, 2020 and continuing through August 1, 2021. In addition, the Company paid a fee of $250,000 upon closing and is required to pay a fee of 5.55% of the aggregate amount of advances under the Loan Agreement at maturity.

On April 3, 2017, the Company completed the sale of its Commercial Business to Ipsen S.A. ("Ipsen"). In connection with the sale, the Company retained the right to receive net milestone payments that may become payable related to the ex-U.S. development and commercialization of ONIVYDE for up to $33.0 million pursuant to a license and collaboration agreement (the "Baxalta Agreement") between Baxalta Incorporated, Baxalta US Inc., Baxalta GmbH and Ipsen. Shire plc is the parent entity of the Baxalta entities. The net milestones are comprised of potential payments of $18.0 million from the sale of ONIVYDE in two additional major European countries, $5.0 million related to the sale of ONIVYDE in the first major non-European, non-Asian country and $10.0 million for the first patient dosed in a pivotal clinical trial in an indication other than pancreatic cancer. In August 2018, the Company received a payment of $18.0 million for the milestone related to the sale of ONIVYDE in two additional major European countries. To date, the Company has received $18.0 million of the potential $33.0 million in milestones under the Baxalta Agreement.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and the notes to those financial statements appearing elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2017 included in our Annual Report on Form 10-K. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those set forth in Part II, Item 1A. Risk Factors of this Quarterly Report on Form 10-Q, which are incorporated herein by reference, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We are a clinical stage biopharmaceutical company based in Cambridge, Massachusetts that is outthinking cancer by targeting biomarker-defined cancers. Our vision is to ensure that cancer patients and their families live fulfilling lives. Our mission is to transform cancer care through the smart design and development of targeted solutions based on a deep understanding of cancer pathways and biological markers. All of our development programs, including three clinical trials and six candidates in preclinical development, fit into our strategy of (1) understanding the biological problems we are trying to solve, (2) designing specific solutions against the problems we are trying to solve and (3) developing those solutions for biomarker-selected patients. This three-pronged strategy seeks to ensure optimal patient outcomes.

We own worldwide development and commercial rights to all of our clinical and preclinical programs. Our most advanced assets and a description of the status of each asset are as follows:

- MM-121 (seribantumab): MM-121 is a fully human monoclonal antibody that binds to the ErbB3 (HER3) receptor and targets heregulin positive cancers. There are two active development programs for MM-121, each in a Phase 2 clinical trial. We are conducting the global, open-label, biomarker-selected, Phase 2 randomized SHERLOC clinical trial evaluating MM-121 in combination with docetaxel in patients with heregulin positive non-small cell lung cancer, or NSCLC. We are also conducting the global, double-blinded, placebo-controlled, biomarker-selected, Phase 2 randomized SHERBOC clinical trial evaluating MM-121 in combination with fulvestrant in patients with heregulin positive, hormone receptor positive, ErbB2 (HER2) negative, metastatic breast cancer; and
- MM-310: MM-310 is an antibody-directed nanotherapeutic that targets the ephrin receptor A2, or EphA2, receptor and contains a novel prodrug of the highly potent chemotherapy docetaxel. The EphA2 receptor is highly expressed in most solid tumor types, such as prostate, ovarian, bladder, gastric, pancreatic and lung cancers. We are conducting a Phase 1 clinical trial to evaluate safety and preliminary activity of MM-310 in patients with solid tumors and to identify the maximum tolerated dose.

On June 25, 2018, we announced top-line results from our global, double-blinded, placebo-controlled, Phase 2 randomized CARRIE clinical trial evaluating the addition of MM-141 (istiratumab) to standard-of-care treatment in patients with previously untreated metastatic pancreatic cancer and high serum levels of the insulin-like growth factor 1, or IGF-1. The CARRIE clinical trial did not meet its primary or secondary efficacy endpoints in patients who received MM-141 in combination with nab-paclitaxel and gemcitabine, compared to nab-paclitaxel and gemcitabine alone. These results were consistent in all subgroups analyzed. Based on these results, we will not devote additional resources to and will cease all of our development activities for MM-141.

On April 3, 2017, we completed the sale, or the asset sale, to Ipsen S.A., or Ipsen, of 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, our first commercial product, and MM-436, or the commercial business, for $580.7 million. Pursuant to the Asset Purchase

and Sale Agreement, dated as of January 7, 2017, or the asset sale agreement, between us and Ipsen, we are eligible to receive up to $450.0 million in additional regulatory approval-based milestone payments. We also retained the right to receive net milestone payments that may become payable for the ex-U.S. development and commercialization of ONIVYDE for up to $33.0 million pursuant to a license and collaboration agreement, which we refer to as the Baxalta agreement, with Baxalta Incorporated, Baxalta US Inc. and Baxalta GmbH, collectively Baxalta. Shire plc is the parent entity of Baxalta. The Baxalta agreement was assigned to Ipsen in connection with the completion of the asset sale. As of March 31, 2017, the commercial business met all the conditions to be classified as a discontinued operation since the disposal of the commercial business represented a strategic shift that had a major effect on our operations and financial results. Therefore, the operating results of the commercial business are reported in discontinued operations, net of tax in the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2017. During the three and six months ended June 30, 2018, there were no discontinued operations.

We have devoted substantially all of our resources to our drug discovery and development efforts, including conducting clinical trials for our product candidates, protecting our intellectual property and providing general and administrative support for these operations. We currently have no products approved for sale. We have financed our operations primarily through private placements of convertible preferred stock, collaborations, public offerings of our securities, secured debt financings, sales of ONIVYDE and the asset sale.

As of June 30, 2018, we had unrestricted cash and cash equivalents and marketable securities of $60.0 million. We believe that at our currently forecasted spending rates, our financial resources as of June 30, 2018, in addition to $14.7 million in net borrowings received in July 2018 pursuant to the Loan and Security Agreement, or Loan Agreement, with Hercules Capital, Inc., or Hercules, and a milestone payment of $18.0 million received in August 2018 pursuant to the Baxalta agreement (see Note 11, “Subsequent Events,” in the accompanying notes to the condensed consolidated financial statements), will be sufficient to fund our planned operations, including debt service obligations and capital expenditure requirements, into at least the first quarter of 2020.

We have never been profitable and, as of June 30, 2018, we had an accumulated deficit of $518.3 million. Our net loss from continuing operations before income tax benefit was $35.6 million and $89.1 million for the six months ended June 30, 2018 and 2017, respectively. We expect to continue to incur significant expenses and operating losses for at least the next several years as we continue the research and development of our product candidates, including multiple clinical trials for certain product candidates. 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 product candidates 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. We will need to generate significant revenues to achieve profitability, and we may never do so.

Financial Operations Overview

Revenues

In the future, we may generate revenue from a combination of research and development payments, license fees and other upfront payments, milestone payments, product sales and royalties in connection with any future collaborations and licenses. We expect that any revenue we generate will fluctuate in future periods as a result of the timing of our or a collaborator’s achievement of preclinical, clinical, regulatory and commercialization milestones, if at all, the timing and amount of any payments to us relating to such milestones and the extent to which any of our product candidates are approved and successfully commercialized by us or a collaborator. If we fail, or any future collaborator fails, to develop product candidates in a timely manner or to obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

Research and development expenses

Research and development expenses consist of the costs associated with our preclinical research activities, conduct of clinical trials, manufacturing development efforts and activities related to regulatory filings. Our research and development expenses consist of:

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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 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. We expect to maintain or increase our research and development expenses for the foreseeable future as we continue to develop our clinical stage product candidates and further advance our preclinical products and earlier stage research and development projects.

We use our employee and infrastructure resources across multiple research and development programs. We track expenses related to our 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 specific 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 three and six months ended June 30, 2018 and 2017:

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
(in thousands)	2018	2017	2018	2017
MM-121	$8,290	$3,312	$14,598	$6,907
MM-141	2,532	3,631	3,895	6,418
MM-310	66	984	1,358	2,283
Preclinical, general research and discovery	2,454	6,112	6,136	15,100
Legacy programs	56	797	183	5,265
Stock-based compensation	280	4,915	614	5,383
Total research and development expenses	$13,678	$19,751	$26,784	$41,356

The successful development of our 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 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 U.S. Food and Drug Administration, or FDA, or another regulatory authority were to require us to conduct clinical trials beyond those which we currently anticipate will be required for the completion of clinical development of a product candidate or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

MM-121 (seribantumab)

In February 2015, we initiated the global, open-label, biomarker-selected, Phase 2 randomized SHERLOC clinical trial evaluating MM-121 in combination with docetaxel, versus docetaxel alone, in patients with heregulin positive NSCLC. We expect to report top-line results from the SHERLOC clinical trial in 2018.

In February 2018, we dosed the first patient in our global, double-blinded, placebo-controlled, biomarker-selected Phase 2 randomized SHERBOC clinical trial evaluating MM-121 in combination with fulvestrant, versus fulvestrant alone, in patients with heregulin positive, hormone receptor positive, ErbB2 (HER2) negative, metastatic breast cancer.

MM-141 (istiratumab)

In May 2015, we initiated the global, double-blinded, placebo-controlled, Phase 2 randomized CARRIE clinical trial evaluating MM-141 in combination with nab-paclitaxel and gemcitabine, versus nab-paclitaxel and gemcitabine alone, in patients with previously untreated metastatic pancreatic cancer with high serum levels of free IGF-1. In June 2018, we announced top-line results from the CARRIE clinical trial, showing that the trial did not meet its primary or secondary efficacy endpoints in patients who received MM-141 in combination with nab-paclitaxel and gemcitabine, compared to nab-paclitaxel and gemcitabine alone. These results were consistent in all subgroups analyzed. Based on these results, we will not devote additional resources to and will cease all of our development activities for MM-141. As of June 30, 2018, we no longer expect to receive any future economic benefit from the CARRIE clinical trial and have accrued $1.0 million for the estimated CARRIE wind down commitments and obligations we expect to incur over the next six months. We do not believe that the results of the CARRIE clinical trial will impact the results of our other clinical and preclinical programs.

MM-310

In March 2017, we initiated a Phase 1 clinical trial of MM-310 to evaluate its safety and preliminary activity in patients with solid tumors and to identify the maximum tolerated dose. We expect to report safety data and the maximum tolerated dose from this trial in 2018.

General and administrative expenses

General and administrative expenses consist primarily of salaries and other related costs for personnel, including stock-based compensation expenses and benefits, in our legal, intellectual property, business development, finance, information technology, corporate communications, investor relations and human resources departments. Other general and administrative expenses include costs for employee training and development, board of directors costs, depreciation, insurance expenses, facility-related costs not otherwise included in research and development expenses and professional fees for legal, accounting and information technology services. We expect to maintain general and administrative expenses at similar levels in future periods as we continue to support the further research and development and commercialization of our product candidates.

Interest income

Interest income for the three and six months ended June 30, 2018 consisted primarily of interest income associated with our marketable securities. Interest income for the three and six months ended June 30, 2017 consisted primarily of interest income associated with our interest bearing cash and cash equivalent accounts.

Interest expense

Interest expense for the three and six months ended June 30, 2017 consisted primarily of cash and non-cash interest related to our 4.50% convertible notes due 2020, or convertible notes, and our 11.50% senior secured notes due 2022, or 2022 notes, both of which were extinguished in 2017.

Other income (expense), net

Other income (expense), net consists primarily of our proportionate share of losses from our equity method investment in Silver Creek Pharmaceuticals, Inc., or Silver Creek.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which we have prepared in accordance with the rules and regulations of the Securities and Exchange Commission, or the SEC, and generally accepted accounting principles in the United States, or GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. 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.

Our critical accounting policies and the methodologies and assumptions we apply under them have not materially changed since March 12, 2018, the date we filed our Annual Report on Form 10-K for the year ended December 31, 2017. For more information on our critical accounting policies, refer to our Annual Report on Form 10-K for the year ended December 31, 2017.

Results of Operations

Comparison of the three months ended June 30, 2018 and 2017

	Three Months Ended June 30,	
(in thousands)	2018	2017
Operating expenses:		
Research and development expenses	$13,678	$19,751
General and administrative expenses	3,513	14,798
Total operating expenses	17,191	34,549
Loss from continuing operations	(17,191)	(34,549)
Interest income	282	382
Interest expense	—	(26,762)
Gain on sale of assets	—	1,703
Other income (expense), net	(860)	(659)
Net loss from continuing operations	$(17,769)	$(59,885)

Research and development expenses

Research and development expenses were $13.7 million for the three months ended June 30, 2018 compared to $19.8 million for the three months ended June 30, 2017, a decrease of $6.1 million, or 31%. This decrease was primarily attributable to:

- $4.4 million decrease in expenses related to our preclinical, general research and discovery, and legacy programs related to the refocus of our early stage development spend and prioritization of our most advanced programs;
- $4.6 million decrease in stock-based compensation related to reduction in headcount; and
- $2.0 million decrease in expense related to MM-141 and MM-310 clinical trial expenses; offset by
- $5.0 million increase in expenses related to the progression of the MM-121 clinical trials and manufacturing expenses.

General and administrative expenses

General and administrative expenses were $3.5 million for the three months ended June 30, 2018 compared to $14.8 million for the three months ended June 30, 2017, a decrease of $11.3 million, or 76%. This decrease was primarily attributable to a decrease in corporate expenses related to headcount and stock-based compensation.

Interest income

Interest income was $0.3 million for the three months ended June 30, 2018 compared to $0.4 million for the three months ended June 30, 2017, primarily attributable to the interest income associated with our marketable securities.

Interest expense

Interest expense was $26.8 million for the three months ended June 30, 2017. There was no interest expense during the three months ended June 30, 2018 due to the extinguishment of debt in 2017.

Other income (expense), net

Other income (expense), net was $0.9 million of expense for the three months ended June 30, 2018, primarily attributable to our proportionate share of losses from our equity method investment in Silver Creek. Other income (expense), net was $0.7 million of expense for the three months ended June 30, 2017, primarily attributable to our losses from our variable interest entity in Silver Creek.

Comparison of the six months ended June 30, 2018 and 2017

	Six Months Ended June 30,	
(in thousands)	2018	2017
Operating expenses:		
Research and development expenses	$26,784	$41,356
General and administrative expenses	7,783	20,432
Total operating expenses	34,567	61,788
Loss from continuing operations	(34,567)	(61,788)
Interest income	557	396
Interest expense	—	(28,741)
Gain on sale of assets	—	1,703
Other income (expense), net	(1,541)	(661)
Net loss from continuing operations	$(35,551)	$(89,091)

Research and development expenses

Research and development expenses were $26.8 million for the six months ended June 30, 2018 compared to $41.4 million for the six months ended June 30, 2017, a decrease of $14.6 million, or 35%. This decrease was primarily attributable to:

- $14.0 million decrease in expenses related to our preclinical, general research and discovery, and legacy programs related to the refocus of our early stage development spend and prioritization of our most advanced programs;
- $3.5 decrease in expenses related to MM-141 and MM-310 clinical study expenses and manufacturing expenses; and
- $4.8 million decrease in stock-based compensation related to reduction in headcount; offset by
- $7.7 million increase in expenses related to the progression of MM-121 clinical trials and manufacturing expenses.

General and administrative expenses

General and administrative expenses were $7.8 million for the six months ended June 30, 2018 compared to $20.4 million for the six months ended June 30, 2017, a decrease of $12.6 million, or 62%. This decrease was primarily attributable to a decrease in corporate expenses related to headcount and stock-based compensation.

Interest income

Interest income was $0.6 million for the six months ended June 30, 2018 compared to $0.4 million for the six months ended June 30, 2017, primarily attributable to the interest income associated with our marketable securities.

Interest expense

Interest expense was $28.7 million for the six months ended June 30, 2017. There was no interest expense during the six months ended June 30, 2018 due to the extinguishment of debt in 2017.

Other income (expense), net

Other income (expense), net was $1.5 million of expense for the six months ended June 30, 2018, primarily attributable to our proportionate share of losses from our equity method investment in Silver Creek. Other income (expense), net was $0.7 million of expense for the six months ended June 30, 2017, primarily attributable to our losses from our variable interest entity in Silver Creek.

Liquidity and Capital Resources

Sources of liquidity

We have financed our operations through June 30, 2018 primarily through private placements of convertible preferred stock, collaborations, public offerings of our securities, secured debt financings, sales of ONIVYDE and the asset sale. Through June 30, 2018, we have received $580.7 million from the asset sale, $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 public offering, $38.6 million of net proceeds from our 2015 “at the market offering” program, $39.6 million of net proceeds from a secured debt financing, $120.6 million of net proceeds from the issuance of the convertible notes in our July 2013 public offering, $168.5 million of net proceeds from the issuance of the 2022 notes, $492.5 million of upfront license fees, milestone payments, reimbursement of research and development costs and manufacturing services and other payments from our collaborations and $68.9 million of cash receipts related to ONIVYDE sales. As of June 30, 2018, we had unrestricted cash and cash equivalents and marketable securities of $60.0 million. In addition, we received $14.7 million in net borrowings in July 2018 pursuant to the Loan Agreement with Hercules and a milestone payment of $18.0 million in August 2018 pursuant to the Baxalta agreement (see Note 11, “Subsequent Events,” in the accompanying notes to the condensed consolidated financial statements).

Cash flows

The following table provides information regarding our cash flows for the six months ended June 30, 2018 and 2017:

	Six Months Ended June 30,	
(in thousands)	2018	2017
Net cash used in operating activities	$(33,582)	$(75,386)
Net cash (used in) provided by investing activities	(37,399)	575,817
Net cash used in financing activities	—	(326,446)
Net (decrease) increase in cash, cash equivalents and restricted cash	$(70,981)	$173,985

Operating activities

Cash used in operating activities was $33.6 million during the six months ended June 30, 2018. The cash used in operating activities was primarily a result of our $35.6 million net loss from operations and changes in assets and liabilities of $3.2 million. The net decrease in operating assets and liabilities during the six months ended June 30, 2018 was primarily driven by decreases in accounts payable, accrued expenses and other, prepaid expenses and other current assets and deferred rent. This decrease was offset by non-cash items, including $2.3 million in depreciation and amortization, $1.5 million of stock-based compensation expense, $1.4 million in loss on equity method investment. Cash used in operating activities of $75.4 million during the six months ended June 30, 2017, of which $29.0 million was used by continuing operations and $46.4 million was used by discontinued operations. The cash used in operating activities was primarily a result of our $58.9 million net loss from continuing operations and a net increase in operating assets and liabilities of $6.6 million. The net increase in operating assets and liabilities during the six months ended June 30, 2017 was primarily driven by the increase in income taxes payable. This increase was offset by non-cash items, including $9.5 million of stock-based compensation expense, $2.4 million in non-cash interest expense, $25.0 million loss on extinguishment of debt, $30.2 million income tax benefit and $15.0 million of non-cash activity related to discontinued operations.

Investing activities

Cash used in investing activities of $37.4 million during the six months ended June 30, 2018 was primarily due to purchases of marketable securities totaling $48.3 million offset by proceeds from maturities and sales of marketable securities totaling $11.1 million. Cash provided by investing activities of $575.8 million during the six months ended June 30, 2017 was primarily due to cash received from the sale of the commercial business of $575.0 million.

Financing activities

There was no cash provided by or used in financing activities during the six months ended June 30, 2018. Cash used in financing activities of $326.4 million during the six months ended June 30, 2017 was primarily due to the $175.0 million used to settle the principle balance of the 2022 notes, $140.0 million dividend paid and $20.1 million payment of debt extinguishment costs, offset by $6.1 million in proceeds from the exercise of options to purchase common stock and $2.6 million in proceeds from the issuance of Series C preferred stock by Silver Creek, net of issuance costs.

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; and
- continue to provide the operational, financial and management information systems and personnel to support our product development.

We believe that at our currently forecasted spending rates, our financial resources as of June 30, 2018, in addition to $14.7 million in net borrowings received in July 2018 pursuant to the Loan Agreement with Hercules and a milestone payment of $18.0 million received in August 2018 pursuant to the Baxalta agreement (see Note 11, “Subsequent Events,” in the accompanying notes to the condensed consolidated financial statements), will be sufficient to fund our planned operations, including debt service obligations and capital expenditure requirements, into at least the first quarter of 2020. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, and the extent to which we utilize collaborations with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future capital requirements will depend on many factors, including:

- the progress and results of the clinical trials of our most advanced product candidates;
- our ability to establish and maintain additional collaborations on favorable terms, and the success of any such future collaborations;
- the timing and amount of potential milestone payments related to ONIVYDE that we may receive from Ipsen and Baxalta;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates;
- the costs, timing and outcome of regulatory review of our current and future product candidates;
    - the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and
- the extent to which we acquire or invest in businesses, products and technologies.

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 product candidates 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. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. For example, if we raise additional funds through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs

or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

On July 2, 2018, we entered into the Loan Agreement with Hercules pursuant to which a term loan of up to an aggregate principal amount of $25.0 million is available to us. The Loan Agreement provides for an initial term loan advance of $15.0 million, which closed on July 2, 2018, and, at our option, two additional term loan advances of $5.0 million each upon the occurrence of certain funding conditions prior to December 31, 2018 and December 31, 2019, respectively. The term loan bears interest at an annual rate equal to the greater of 9.25% and 9.25% plus the prime rate of interest minus 5.25%. The Loan Agreement provides for interest-only payments for eighteen months and repayment of the aggregate outstanding principal balance of the term loan in monthly installments starting on February 1, 2020 and continuing through August 1, 2021. In addition, we paid a fee of $250,000 upon closing and are required to pay a fee of 5.55% of the aggregate amount of advances under the Loan Agreement at maturity (see Note 11, “Subsequent Events,” in the accompanying notes to the condensed consolidated financial statements).

Other than the above, there were no material changes to our contractual obligations and commitments described under Management’s Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the SEC on March 12, 2018.

Off-Balance Sheet Arrangements

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

Recent Accounting Pronouncements

See Note 10, “Recent Accounting Pronouncements,” in the accompanying notes to the condensed consolidated financial statements for a full description of recent accounting pronouncements.

Item 3.Quantitative and Qualitative Disclosures About Market Risk.

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

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

We do not currently have any auction rate or mortgage-backed securities. We do not believe our cash, cash equivalents and 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.

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Item 4.Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2018. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2018, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended June 30, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II

OTHER INFORMATION

Item 1A.Risk Factors.

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

Risks Related to the Sale of the Commercial Business to Ipsen

Because the commercial business represented all of our revenues for fiscal year 2016 and the three months ended March 31, 2017, our business following the sale of the commercial business is substantially different than it was prior to such sale.

As a result of the completion of the asset sale with Ipsen, Ipsen acquired our right, title and interest in the commercial business. The commercial business represented all of our revenues for the fiscal year 2016 and the three months ended March 31, 2017. Following the asset sale, we retained only non-commercial assets, including our clinical and preclinical development programs, or the pipeline business. Our results of operations and financial condition may be materially affected if we fail to grow the remaining pipeline business, if we are unable to raise additional capital when needed to run the remaining pipeline business, if we must incur significant costs in order to raise additional capital to run the remaining pipeline business or if we are unable to successfully develop and commercialize our remaining product candidates.

We have been, and in the future may be, subject to securities litigation, which is expensive and could divert our attention.

We have been, and may in the future 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, which could seriously harm our business. For instance, a putative stockholder class action suit was filed by a purported stockholder of ours in the Superior Court of Massachusetts for the County of Middlesex against us and our directors. The case was captioned Robert Garfield v. Merrimack Pharmaceuticals Inc., et al., or the Garfield Action. The Garfield Action complaint alleged that our directors breached their fiduciary duties by entering into the asset sale agreement and that the definitive proxy statement relating to the asset sale contained inadequate disclosures and omissions. Although we believed that the Garfield Action was without merit, to avoid the risk of the litigation delaying or adversely affecting the asset sale and to minimize the expense of defending the litigation related to the asset sale, we agreed to make supplemental disclosures related to the asset sale and to pay the plaintiff’s counsel $375,000 in attorney’s fees in connection with the resolution of the Garfield Action. As a result, the plaintiff concluded that the claims in the Garfield Action were mooted, and the Garfield Action was dismissed with prejudice. Nonetheless, there can be no guarantee that there will not be additional securities class action litigation in connection with the asset sale.

There can be no guarantee that Ipsen will comply with its obligation to use commercially reasonable efforts in connection with the development of ONIVYDE or that the milestones set forth in the Baxalta agreement will be achieved.

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.

Additionally, although the asset sale agreement entitles us to receive certain net milestone payments of up to $33.0 million that may become payable under the Baxalta agreement, comprised of potential payments of $18.0 million from the sale of ONIVYDE in two additional major European countries, $5.0 million related to the sale of ONIVYDE in the first major non-European, non-Asian country and $10.0 million for the first patient dosed in a pivotal clinical trial in an indication other than pancreatic cancer, to date we have received payment only for the milestone related to the sale of ONIVYDE in two additional major European countries, and payment of any or all of the remaining $15.0 million under the Baxalta agreement is not guaranteed.

Ipsen did not assume any of the excluded liabilities under the asset sale agreement.

Pursuant to the asset sale agreement, Ipsen assumed only certain specified liabilities set forth in the asset sale agreement and did not assume all of the liabilities associated with the commercial business. Certain liabilities 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 any such 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.

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 from continuing operations was $35.6 million for the six months ended June 30, 2018. Our net loss from continuing operations before income tax benefit was $118.4 million for the year ended December 31, 2017, $169.5 million for the year ended December 31, 2016 and $162.8 million for the year ended December 31, 2015. As of June 30, 2018, we had an accumulated deficit of $518.3 million. To date, we have financed our operations primarily through private placements of convertible preferred stock, collaborations, public offerings of our securities, secured debt financings, sales of ONIVYDE and the asset sale. We have devoted substantially all of our efforts to research and development, including clinical trials and recently to commercialization of our first product, ONIVYDE, which was sold to Ipsen. We have not completed development of or commercialized any other product candidates or diagnostics other than ONIVYDE. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially as we:

- initiate or continue clinical trials of our 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.

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 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.

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. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or commercialization efforts.

We believe that at our currently forecasted spending rates, our financial resources as of June 30, 2018, in addition to $14.7 million in net borrowings received in July 2018 pursuant to the Loan Agreement with Hercules and a milestone payment of $18.0 million received in August 2018 pursuant to the Baxalta agreement, will be sufficient to fund our planned operations, including debt service obligations and capital expenditure requirements, into at least the first quarter of 2020. 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 may utilize collaborations with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future capital requirements will depend on many factors, including:

- the progress and results of the clinical trials of our most advanced product candidates;
- our ability to establish and maintain additional collaborations on favorable terms, and the success of any such future collaborations;
- the timing and amount of potential milestone payments related to ONIVYDE that we may receive from Ipsen and Baxalta;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our product candidates;
- the costs, timing and outcome of regulatory review of our current and future product candidates;
    - the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and
- the extent to which we acquire or invest in businesses, products and technologies.

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. In addition, any of our product candidates, even if approved, may not achieve commercial success. If we fail to generate sufficient revenues from collaborations or the commercialization of any of our product candidates, we will need to continue to rely on additional financing to achieve our business objectives.

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

We do not have any committed external source of funds other than through our $25.0 million debt facility under the Loan Agreement pursuant to which we drew an initial term loan advance of $15.0 million, which closed on July 2, 2018, and two additional term loan advances of $5.0 million each that become available to us upon the occurrence of certain funding conditions prior to December 31, 2018 and December 31, 2019, respectively. 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 product candidates 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.

On December 15, 2017, we filed a registration statement on Form S-3 with the SEC to allow the issuance of our securities from time to time in one or more offerings of up to $150,000,000 in aggregate dollar amount. This

registration statement was declared effective by the SEC on January 5, 2018. 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. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and these covenants may also require us to attain certain levels of financial performance and we may not be able to do so; any such failure may result in the acceleration of such debt and the foreclosure by our creditors on the collateral we used to secure the debt. The debt issued in a debt financing would also be senior to our outstanding shares of capital stock upon our liquidation. Significant indebtedness and the pledge of our assets as collateral in the future could limit our ability to obtain additional debt financing. If we raise additional funds through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future

revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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

On July 2, 2018, we entered into the Loan Agreement. The Loan Agreement provided for an initial term loan advance of $15.0 million, which closed on July 2, 2018, and, at our option, two additional term loan advances of $5.0 million each upon the occurrence of certain funding conditions prior to December 31, 2018 and December 31, 2019, respectively. The Loan Agreement contains certain events of default, including nonpayment, breach of covenants, representations and warranties, material adverse effect (not including clinical trial failures), insolvency and bankruptcy, judgments, cross default to other indebtedness, and suspension of trading.

In addition to the debt under the Loan Agreement, we have had in the past, and may in the future have, a significant amount of indebtedness. In July 2013, we issued $125.0 million aggregate principal amount of convertible notes. In December 2015, we issued $175.0 million aggregate principal amount of 2022 notes. Although we used a portion of the proceeds from the asset sale to fully extinguish the 2022 notes, and we have extinguished all but $56,000 of the aggregate remaining principal amount of the convertible notes, we could in the future incur additional indebtedness.

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

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

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

We intend to satisfy our current and future debt service obligations with our existing cash and cash equivalents and funds from external sources, if any. However, we may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under our existing debt. To the extent we seek funds from external sources in the future, such funds may not be available on acceptable terms, if at all. In addition, a failure to comply with the covenants under our existing debt instrument or any future 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 instrument and the pledge of our assets as collateral limit our ability to obtain additional debt financing.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for net interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such net operating losses may be carried forward indefinitely), one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation

expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain how various states will respond to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

We might not be able to utilize a significant portion of our net operating loss carryforwards and research and development tax credit carryforwards.

As of December 31, 2017, we had federal net operating loss carryforwards of $138.1 million, which begin to expire in 2034, and state net operating loss carryforwards of $223.4 million, which begin to expire in 2028. As of December 31, 2017, we also had federal research and development tax credit carryforwards of $28.8 million and state research and development tax credit carryforwards $18.7 million, which begin to expire in 2022 and 2026, respectively. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset our future income tax liabilities. Under the newly enacted federal income tax law, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain how various states will respond to the newly enacted federal tax law. If our ability to use our historical net operating loss and tax credit carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

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

We have invested and plan to continue to 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, but there can be no guarantee that our investments will not result in losses.

A decrease in the carrying value of our equity holdings in Silver Creek could adversely affect our balance sheet.

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. As these shares represented a controlling financial interest, we consolidated Silver Creek in our consolidated financial statements. In the third quarter of 2017, Silver Creek completed its Series C preferred stock financing, which reduced our ownership percentage of Silver Creek below 50% and resulted in us deconsolidating Silver Creek from our consolidated financial statements. As a result of the deconsolidation, we now account for our investment in Silver Creek under the equity method of accounting. The carrying value of our shares of Series A preferred stock of Silver Creek was $9.1 million at June 30, 2018. There can be no guarantee that the value of our investment in Silver Creek will not realize a substantial future loss or complete loss of value, which would in turn adversely affect our balance sheet. On a quarterly basis, we review the investment for impairment whenever events or changes in circumstances indicate that the carrying amount of the investment might not be recoverable. These circumstances can include, but are not limited to, negative current events or long-term outlooks impacting Silver Creek and/or its programs, planned or announced delays in the clinical development process to advance its programs, a current fair value of investment at a lower value than our investment and/or investors no longer providing

financial support or reducing their financial commitment to Silver Creek.

Risks Related to the Development and Commercialization of Our Product Candidates

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

We invest a significant portion of our efforts and financial resources in the development of our clinical stage product candidates for the treatment of various types of cancer. All of our product candidates are still in preclinical and clinical development. Our ability to generate meaningful product revenues will depend heavily on the successful development of our product candidates. The success of our product candidates, which include both our product candidates and companion diagnostic candidates, will depend on several factors, including the following:

- successful enrollment in, and completion of, preclinical studies and clinical trials;
- receipt of marketing approvals from the FDA and similar regulatory authorities outside the United States for our product candidates, including our diagnostics;

- establishing commercial manufacturing capabilities, which we anticipate doing primarily through 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 develop our product candidates, which would materially harm our business.

For example, in June 2018, we announced top-line results from the CARRIE clinical trial, showing that the trial did not meet its primary or secondary efficacy endpoints in patients who received MM-141 in combination with nab-paclitaxel and gemcitabine, compared to nab-paclitaxel and gemcitabine alone. These results were consistent in all subgroups analyzed. Based on these results, we will not devote additional resources to and will cease all of our development activities for MM-141.

In addition, in connection with our strategic review of our pipeline which was completed in January 2017, we amended our SHERLOC clinical trial, resulting in changes to its power, design and timing, and also discontinued several trials, including our Phase 2 clinical trial of MM-302.

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.

We may never receive approval to commercialize our product candidates in the United States or other jurisdictions. Before obtaining regulatory approval for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and successful interim results of a clinical trial do not necessarily predict successful final results.

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

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

- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates, companion diagnostics or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate or prohibitively expensive; 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 June 2018, we announced top-line results from the CARRIE clinical trial, showing that the trial did not meet its primary or secondary efficacy endpoints in patients who received MM-141 in combination with nab-paclitaxel and gemcitabine, compared to nab-paclitaxel and gemcitabine alone. Also, 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 Data Safety Monitoring Board that continuing the clinical trial would be unlikely to demonstrate benefit over the comparator treatments. Additionally, the previous Phase 2 clinical trials of MM-121 in unselected patient populations with NSCLC, ovarian cancer and breast cancer did not meet their primary endpoints.

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 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.

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. It is possible that slow enrollment could require us to make adjustments to our clinical trials. If these adjustments do not overcome problems with slow enrollment, we could experience significant delays or abandon the applicable clinical trial altogether.

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

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

All of our companion diagnostic candidates are in preclinical or clinical development. We have limited experience in the development of companion diagnostics and may not be successful in developing appropriate diagnostics to pair with any of our 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 to require separate regulatory approval prior to commercialization. Given our limited experience in developing diagnostics, we expect to rely in part on third parties for their design, development and manufacture. If we, or any third parties that we engage to assist us, are unable to successfully develop companion diagnostics for our product candidates, or experience delays in doing so, the development of our product candidates may be adversely affected, our product candidates may not receive marketing approval and we may not realize the full commercial potential of any product candidates 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 if any of our product candidates receive marketing approval, they may nonetheless not gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors that may be uncertain or subjective, including:

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

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

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

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

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

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

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

candidates obtain regulatory approval.

Our ability to commercialize any 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 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, any 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 any product candidate that we successfully develop.

Moreover, there may be significant delays in obtaining reimbursement for any 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 any products that we may develop.

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

- decreased demand for the 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 also may not be successful in our efforts to identify or discover new or additional product candidates beyond our current preclinical and clinical product candidates. 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.

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 biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. 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 or hazardous 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

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.

Our potential 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 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.

For instance, although it is not a collaboration agreement, Ipsen has agreed pursuant to the asset sale agreement 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.

Additionally, although the asset sale agreement entitles us to receive certain net milestone payments of up to $33.0 million that may become payable under the Baxalta agreement, comprised of potential payments of $18.0 million from the sale of ONIVYDE in two additional major European countries, $5.0 million related to the sale of ONIVYDE in the first major non-European, non-Asian country and $10.0 million for the first patient dosed in a pivotal clinical trial in an indication other than pancreatic cancer, to date we have received payment only for the milestone related to the sale of ONIVYDE in two additional major European countries, and payment of any or all of the remaining $15.0 million under the Baxalta agreement is not guaranteed.

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

Our product development programs and the potential commercialization of any 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 companion diagnostics in several of our current and planned clinical trials, including our current clinical trials of MM-121 and MM-310, to preselect patients who will receive specified treatment regimens. We will rely on third-party laboratories to test patient samples in connection with such companion diagnostics. Any failure on the part of these laboratories to properly perform such testing could jeopardize those clinical trials and delay or prevent the approval of the associated product candidate.

Risks Related to the Manufacturing of Our Product Candidates

We rely on third parties for the production of our product candidates. This increases the risk that we will not have sufficient quantities of our product candidates at an acceptable cost or on an acceptable schedule, which could delay, prevent or impair our development or commercialization efforts.

We rely on third-party manufacturers for most of the aspects of the production of our product candidates, including the production of bulk drug substance and fill finish and labeling activities. Reliance on third-party manufacturers entails risks, including:

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

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

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.

Furthermore, our products may compete with the products of other companies 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 at an appropriate scale, we may not have access to such manufacturers.

In connection with the asset sale, we entered into a transition services agreement with Ipsen, pursuant to which we and Ipsen are providing certain services to each other for a period of 24 months, including Ipsen’s agreement to manufacture MM-310 pursuant to a manufacturing services agreement. We are also party to a manufacturing agreement with Samsung Biologics Co., Ltd. for the manufacture of MM-121 and performance of associated quality related services. Although we are discussing arrangements with other third parties for our other product candidates, we do not currently have agreements for such arrangements in place and may be unable to conclude such agreements or to do so on acceptable terms.

We also rely on certain single suppliers for certain materials that we use for the manufacture of our product candidates. 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 also rely upon third-party manufacturers to provide us with necessary reagents and instruments to develop, test and manufacture our in vitro diagnostics.

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

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 and MM-310, 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 for patent protection of such inventions. Assuming the other requirements for patentability are met, the first to file a patent application is entitled to the patent. Under the America Invents Act enacted in 2011, the United States moved to this first to file system in 2013 from the previous system under which the first to make the claimed invention was entitled to the patent. We may become involved in opposition, interference or derivation proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

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

commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

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

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

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our 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. Any of these parties may breach these 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 or biosimilar versions of our products after expiration of any regulatory exclusivity but prior to the applicable 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 or biosimilar 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 may also be challenged in a federal court in connection with a third party’s abbreviated new drug application, or ANDA, a Section 505(b)(2) new drug application, or NDA, or a Biologic License Application under Section 351(k), or BLA, seeking FDA approval to market a generic version or a biosimilar version of our products, resulting in a patent challenge to one or more patents listed in the Orange Book for our product or that protect our biologic product. This patent challenge can result in one or more of those patents for our products 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, Section 505(b)(2) NDA or BLA can be filed after FDA approval of a product and the expiration of any relevant regulatory exclusivity. 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 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 issued, and, as a consequence, our and our partners' patent applications may result in patents with narrower coverage than we desire or have planned for.

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. ONIVYDE was our first and only product candidate to receive regulatory approval, and so we have only limited experience in filing and supporting the applications necessary to gain regulatory approvals. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the FDA and other regulatory agencies for each therapeutic indication to establish the product candidate’s safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA or other regulatory agencies. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use.

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

If we continue to pursue development of companion diagnostics to identify patients who are likely to benefit from our product candidates, failure to obtain approval for the companion diagnostic may prevent or delay approval of the product candidate.

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

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

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

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 would be required for approval and subsequent commercialization of each such 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.

Because we expect to rely on third parties for various aspects of the development, testing and manufacture, as well as for regulatory approval for and commercial supply, of our companion diagnostics, the commercial success of any of our product candidates that require a 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 designation for MM-121, we will have to rely on other rights and protections.

We obtained orphan drug designation in the United States for MM-121 for the treatment of heregulin positive NSCLC. 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. Additionally, maintenance of the orphan drug designation requires the company holding such designation to continue to actively pursue development in that indication.

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.

On August 3, 2017, Congress passed the FDA Reauthorization Act of 2017, or FDARA. FDARA, among other things, codified the FDA's pre-existing regulatory interpretation to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. The new legislation reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any such changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

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

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, as part of the Health Care and Education Reconciliation Act of 2010, or the Health Care Reform 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 biologics license application, or 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 could face generic competition earlier than expected. The enactment of the Generic Drug User Fee Amendments of 2012 as part of the Food and Drug Administration Safety and Innovation Act of 2012 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, is significantly decreasing 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 any product for which we obtain marketing approval, 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 any approved 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 future 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 future commercialization partners may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

Additionally, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. On March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, the referendum could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the European Union. Any delay in obtaining, or an inability to obtain, any marketing approvals as a result of Brexit or otherwise would prevent us from commercializing our product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for our product candidates, which could significantly and materially harm our business.

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

Any product for which we may 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 FDA has sweeping inspection authorities to enforce the Federal Food, Drug, and Cosmetic Act. Under the statute, 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 FDA employs a risk-based inspection schedule to ensure compliance. 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 FDA may also share inspection information with foreign governments under certain circumstances.

The FDA also has broad authority to take action 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.

Current and future legislation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of and commercialize our product candidates and affect the prices we, or they, may obtain.

In the United States and some foreign jurisdictions, there have been and continue to be a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any future collaborators, to profitably sell any products for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any future collaborators, may receive for any approved products.

In March 2010, the Health Care Reform Laws were enacted, which include measures that have significantly changed healthcare financing by both governmental and private insurers. Since enactment of the Health Care Reform Laws, there have been numerous legal challenges and legislative actions to repeal and replace provisions of the law, and we expect these to continue. For example, with enactment of the Tax Cuts and Jobs Act of 2017, which was signed by President Trump on December 22, 2017, the U.S. Congress repealed the “individual mandate.” The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, will become effective in 2019. According to the U.S. Congressional Budget Office, the repeal of the individual mandate will cause 13 million fewer Americans to be insured in 2027 and premiums in insurance markets may rise. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Health Care Reform Law-mandated fees, including the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share and the medical device excise tax on non-exempt medical devices.

The U.S. Congress may consider other legislation to replace elements of the Health Care Reform Laws during the next Congressional session. These healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price for any approved product and/or the level of reimbursement physicians receive for administering any approved product. Reductions in reimbursement levels may negatively impact the prices or the frequency with which products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Further, there have been several recent U.S. congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of products under Medicare and reform government program reimbursement methodologies for products. At the federal level, the U.S. Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control costs. At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription product and other healthcare programs. These measures could reduce the ultimate demand for our product candidates, once approved, or put

pressure on our product pricing.

Legislative and regulatory proposals have also been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us and any future collaborators to more stringent product labeling and post-marketing testing and other requirements.

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 for any product for which we receive marking approval, 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 products for which we obtain marketing approval. 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 any 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;

- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or 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 require 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 provide for public reporting of the data reported by manufacturers;
- the U.S. Foreign Corrupt Practices Act prohibits U.S. companies and their representatives from paying, offering to pay, promising or authorizing the payment of anything of value to any foreign government official, government staff member, political party or political candidate for the purpose of obtaining or retaining business or to otherwise obtain favorable treatment or influence a person working in an official capacity, and encompasses many healthcare professionals in many countries under the definition of a foreign government official;
- the Bribery Act, which applies to U.S. companies such as ourselves that conduct business in the United Kingdom, proscribes giving and receiving bribes in the public and private sectors, bribing a foreign public official and failing to have adequate procedures to prevent employees and other agents from giving bribes; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. 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 products from the market, significant fines, disqualification or debarment from participation in federally-funded healthcare programs or other sanctions or litigation, any of which events may have a significant adverse impact on our business.

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Risks Related to 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.

The collection and use of personal health data in the European Union is governed by the provisions of the General Data Protection Regulation, or GDPR, which came into effect in May 2018. This regulation imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States. Failure to comply with the requirements of the GDPR and the related national data protection laws of the European Union Member States may result in significant fines and other administrative penalties.

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. Cyber-attacks could also include phishing attempts or e-mail fraud to cause payments or information to be transmitted to an unintended recipient.

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.

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 consummated the asset sale to Ipsen in April 2017, 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 or could 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 discourage, 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.

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

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

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

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 not historically declared or paid regular cash dividends on our common stock. Although our board of directors declared a special cash dividend of $140.0 million, which was payable on May 26, 2017 to stockholders of record as of the close of business on May 17, 2017, we do not currently intend to pay any regular cash dividends in the foreseeable future. In addition, the terms of the Loan Agreement currently, and the terms of any future debt agreements may in the future, preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for holders of our common stock for the foreseeable future.

Future sales of shares of our common stock, including by us or our directors and executive officers, or shares issued upon the exercise of currently outstanding options 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. The exercise of these options 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 1,236,766 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. Any such 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.

Furthermore, on December 15, 2017, we filed a registration statement on Form S-3 with the SEC to allow the issuance of our securities from time to time in one or more offerings of up to $150,000,000 in aggregate dollar amount. This registration statement was declared effective by the SEC on January 5, 2018. Any sale of additional shares of our common stock or other securities could reduce the market price of our common stock.

Item 6.Exhibits.

Exhibit Number	Description of Exhibit
3.1*	Restated Certificate of Incorporation of the Registrant, as amended
10.1	Loan and Security Agreement, dated as of July 2, 2018, by and among the Registrant, certain subsidiaries of the Registrant from time to time party thereto, the several banks and other financial institutions or entities from time to time parties thereto and Hercules Capital, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on July 3, 2018)
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1+	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2+	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Database
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

*Filed herewith.
+Furnished herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

MERRIMACK
PHARMACEUTICALS, INC.

Date: August 7, 2018 By: /s/ Jean M. Franchi
Jean M. Franchi
Chief Financial Officer
(Principal Financial Officer)