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)