

### **Merrimack Reports Third Quarter 2016 Financial Results**

CAMBRIDGE, Mass., Nov. 9, 2016 /PRNewswire/ -- Merrimack Pharmaceuticals, Inc. (Nasdaq: MACK) today announced its third quarter 2016 financial results. Merrimack will host a live conference call and webcast today, Wednesday, November 9 at 4:30 p.m., Eastern time, to provide an update on Merrimack's progress as well as a summary of these results.

Investors and the general public are invited to listen to the call by dialing (877) 564-1301 (domestic) or (224) 357-2394 (international) five minutes prior to the start of the call and providing the passcode 89606889. A listen-only webcast of the call can be accessed in the Investors section of Merrimack's website, <u>investors.merrimack.com</u>, and a replay of the call will be archived there for six weeks following the call.

### ONIVYDE® (irinotecan liposome injection) Update

#### ONIVYDE updates include:

- Receipt by Shire plc of European Marketing Authorization for ONIVYDE for the treatment of patients with metastatic adenocarcinoma of the pancreas following gemcitabine-based therapy;
- Establishment of an initial tolerable dose for ONIVYDE in combination with 5-FU/LV and oxaliplatin in an ongoing study evaluating its use in patients with previously untreated metastatic pancreatic cancer;
- Issuance by the Centers for Medicare & Medicaid Services (CMS) of a unique, permanent J-code for ONIVYDE, which will streamline the billing and reimbursement process for healthcare providers. The new J-code, J9205 (Injection, irinotecan liposome, 1mg), will become effective for dates of service beginning January 1, 2017 and supersedes all other temporary codes;
- Shipments of ONIVYDE from specialty distributors to individual accounts and facilities, a measure of product demand, grew 18% in the third quarter of 2016 as compared to shipments in the second quarter of 2016; and
- Recognition of \$16.8 million of gross product revenues, or \$14.5 million of net product revenues, from U.S. commercial sales of ONIVYDE for the third quarter of 2016. This is compared to \$14.8 million of gross product revenues, or \$12.9 million of net product revenues for the second quarter of 2016, which represents an increase in net product revenues of 13% over the prior quarter.

#### **Key Recent Events**

Merrimack's key recent events include:

- Acceptance for review of an Abbreviated New Drug Application (ANDA) filed by Actavis LLC for generic doxorubicin hydrochloride (HCI) liposome injection (DOXIL®). This is the first product developed by Merrimack under a development, license and supply agreement with Actavis pursuant to which Merrimack is responsible for the development and commercial supply of bulk drug product. If the product is approved, Merrimack is eligible to receive a percentage share of net profits in the mid-twenties on future sales of doxorubicin HCI liposome injection in the United States.
- Announcement on October 3, 2016, of a 22% reduction in headcount as part of a major corporate restructuring with the objective of prioritizing its research and development on a focused set of systems biology-derived oncology products and strengthening its financial runway. On this same date, Merrimack also announced the resignation of Robert Mulroy, its former President and Chief Executive Officer.
- Initiation, in connection with the corporate restructuring, of a strategic review of the company's pipeline, including the clinical and financial prioritization of its programs. This review may result in amendments to Merrimack's ongoing clinical trials and other changes to its programs. The company expects to complete this review by the end of 2016. In the absence of clinical trial amendments, Merrimack believes that the data readouts of trials for its lead product

candidates, including potentially MM-302, MM-121 and ONIVYDE in front-line metastatic pancreatic cancer, will likely extend beyond its prior guidance. As part of this strategic review, the company will continue to assess these data timelines and the potential impact of any such clinical trial amendments, and will report these findings by year end.

#### Third Quarter 2016 Financial Results

The following summarizes Merrimack's financial results from the guarter ended September 30, 2016:

- Product revenues from the commercial sale of ONIVYDE, net of discounts, allowances and reserves, were \$14.5 million for the third quarter of 2016, compared to \$12.9 million for the second quarter of 2016. This represents an increase of \$1.6 million, or 13%, over the prior quarter:
- License and collaboration revenues were \$12.4 million for the third quarter of 2016, compared to \$19.3 million for the second quarter of 2016. This represents a decrease of \$6.9 million from the prior quarter. The majority of this decrease was related to a \$10.0 million substantive milestone achieved during the second quarter of 2016 offset by increased revenue that was recognized under the proportional performance revenue recognition model;
- Aggregate research and development and selling, general and administrative expenses were \$50.1 million for the third quarter of 2016, compared to \$61.7 million for the second quarter of 2016. This represents a decrease of \$11.6 million, or 19%. The majority of this decrease was related to a \$10.0 million milestone owed to PharmaEngine in the second quarter of 2016:
- Restructuring expenses were \$0.8 million for the third quarter of 2016 and were related to Merrimack implementing a 22% reduction in headcount as part of a major corporate restructuring with the objective of prioritizing its research and development on a focused set of systems biology-derived oncology products and strengthening its financing runway;
- Interest expense was \$6.9 million for the third quarter of 2016, compared to \$21.1 million for the second quarter of 2016. This \$14.2 million decrease was primarily due to a \$14.6 million one-time, non-cash loss related to the conversion of an aggregate principal amount of \$64.2 million of Merrimack's convertible notes in April 2016; and
- Net loss attributable to Merrimack for the third quarter of 2016 was \$30.1 million, or \$0.23 per share, compared to a net loss attributable to Merrimack of \$50.8 million, or \$0.40 per share, for the second quarter of 2016.

#### **Financial Outlook**

In an effort to provide further insight into the expected timing of upcoming research and development and regulatory milestones, Merrimack provides the following schedule:

Milestone Trigger		Inflows Shire plc nillions)	Cash Out PharmaEn (in mil	gine, Inc.	Expected Timing	Milestone Accounting Treatment		
Sale <sup>1</sup> of ONIVYDE in first major European country	\$	30.0	\$	25.5	Q4 2016	Substantive		
Sale <sup>1</sup> of ONIVYDE in two additional major								
European countries		30.0		3.0	First half of 2017	Substantive		
First patient dosed in small cell lung cancer trial		10.0		_	First half of 2017	Non-Substantive		
Sale <sup>1</sup> of ONIVYDE in first major non-European,								
non-Asian country		5.0		_	First half of 2017	Substantive		
Sale <sup>1</sup> of ONIVYDE in first Asian country		25.0		25.0	Second half of 2017	Substantive		
Total expected cash flows from upcoming milestones	\$	100.0	\$	53.5				

<sup>&</sup>lt;sup>1</sup> Sale means the earlier of first commercial sale or receipt of pricing/reimbursement approval.

In addition to the above milestones, future potential research and development and regulatory milestone obligations from Shire are \$427.5 million and are offset by \$35.0 million of future potential commitments to PharmaEngine related to these milestones.

With respect to its fiscal 2016 guidance, Merrimack:

Lowers and narrows its previously provided expense guidance range, such that Merrimack now anticipates aggregate research and development and selling, general and administrative expenses for 2016, when calculated in accordance with GAAP, to be in the range of \$235.5 million to \$245.5 million. Excluding anticipated milestone obligations to PharmaEngine of \$35.5 million, this corresponds to a range of \$200.0 million to \$210.0 million of anticipated aggregate research and development and selling, general and administrative expenses for 2016, which is a non-GAAP financial measure.

With respect to its fiscal 2017 guidance:

- Merrimack had previously provided guidance as to the achievement of \$46.5 million of net milestones related to ONIVYDE in 2016. Merrimack is revising this guidance to reflect that Merrimack now anticipates that only \$4.5 million of these net milestones are expected to be achieved in 2016. Merrimack now anticipates that the achievement of the remaining \$42.0 million of net milestones related to ONIVYDE will occur in the first half of 2017. This remaining amount is made up of \$32.0 million of net substantive milestones, which are expected to increase net income in 2017, and \$10.0 million of net non-substantive milestones, which are expected to increase deferred revenues on Merrimack's balance sheet, as they are included in the Shire proportional performance revenue recognition model;
- Merrimack anticipates that aggregate research and development and selling, general and administrative expenses for 2017, when calculated in accordance with GAAP, will be approximately \$193.0 million, which includes the anticipated achievement of \$28.0 million of milestone obligations to PharmaEngine. This corresponds to aggregate research and development and selling, general and administrative expenses, excluding anticipated milestone obligations to PharmaEngine, a non-GAAP financial measure, of approximately \$165.0 million for 2017; and
- Merrimack expects that at its currently forecasted spending rates, its existing financial resources, together with anticipated net product revenues and net royalty payments from sales of ONIVYDE, the net milestone payments and reimbursements it expects to receive under its Shire collaboration and access to its \$25.0 million credit facility, will be sufficient to fund its operations into 2018.

A table reconciling guidance for aggregate research and development and selling, general and administrative expenses, excluding anticipated milestone obligations to PharmaEngine, a non-GAAP financial measure, to aggregate research and development and selling, general and administrative expenses calculated in accordance with GAAP is included at the end of this press release.

#### **About Merrimack**

Merrimack is a fully integrated biopharmaceutical company that views cancer as a complex engineering challenge. Through systems biology, which brings together the fields of biology, computing and engineering, Merrimack aims to decrease uncertainty in drug development and clinical validation, and move discovery efforts beyond trial and error. Such an approach has the potential to make individualized treatment of patients a reality. Merrimack's first commercial product, ONIVYDE® (irinotecan liposome injection), was approved by the U.S. FDA in October 2015. With four additional candidates in clinical studies, several in preclinical development and multiple biomarkers designed to support patient selection, Merrimack is building one of the most robust oncology pipelines in the industry. For more information, please visit Merrimack's website at <a href="https://www.merrimack.com">www.merrimack.com</a> or connect on Twitter at <a href="https://www.merrimack.com">@MerrimackPharma</a>.

#### **Cautionary Note on Forward-Looking Statements**

To the extent that statements contained in this press release are not descriptions of historical facts, they are forwardlooking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements include any statements about Merrimack's strategy, future operations, future financial position, future revenues and future expectations and plans and prospects for Merrimack, and any other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions. In this press release, Merrimack's forward-looking statements include, among others, statements about expectations regarding the outcome and effect of its ongoing strategic review of its product candidates, expected achievement of milestones, potential cash inflows and outflows, revenue and expenses and the availability of funding sufficient to fund Merrimack's operations. Such forward-looking statements involve substantial risks and uncertainties that could cause Merrimack's clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the future sales of products, initiation of future clinical trials, availability of data from ongoing clinical trials, expectations for regulatory approvals, development progress of Merrimack's companion diagnostics, availability of funding sufficient for Merrimack's foreseeable and unforeseeable operating expenses and capital expenditure requirements, and other matters that could affect the availability or commercial potential of Merrimack's products, product candidates or companion diagnostics. Merrimack undertakes no obligation to update or revise any forward-looking statements. Forwardlooking statements should not be relied upon as representing Merrimack's views as of any date subsequent to the date hereof. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Merrimack's business in general, see the "Risk Factors" section of Merrimack's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 4, 2016 and other reports Merrimack files with the SEC.

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

	Three Months Ended					
	Sept		June 30, 2016			
(in thousands, except per share amounts)	2016					_
Revenues:						
Product revenues, net	\$	14,493		\$	12,851	
License and collaboration revenues		12,417			19,332	
Other revenues		1,161			1,498	
Total revenues		28,071			33,681	
Costs and expenses:						
Cost of revenues		1,010			1,872	
Research and development expenses		32,078			40,996	
Selling, general and administrative expenses		18,048			20,680	
Restructuring expenses		809				
Total costs and expenses		51,945			63,548	
Loss from operations		(23,874)			(29,867)	
Other income and expenses, net		(6,401)	_		(21,091)	
Net loss		(30,275)			(50,958)	
Net loss attributable to non-controlling interest		(207)	_		(208)	
Net loss attributable to Merrimack	\$	(30,068)		\$	(50,750)	
Other comprehensive (loss) income		(3)	_		15	
Comprehensive loss	\$	(30,071)	_	\$	(50,735)	
Net loss per share available to common stockholders - basic and diluted Weighted-average common shares used in computing net loss per share available to	\$	(0.23)		\$	(0.40)	
common stockholders - basic and diluted		129,212			126,161	

# Merrimack Pharmaceuticals, Inc. Selected Balance Sheet Data (unaudited)

(in thousands)		tember 30, 2016	June 30, 2016		
Cash, cash equivalents and marketable securities	\$	48,466	\$	82,667	
Working capital		1,334		28,145	
Total assets		118,409		150,019	
Total liabilities		345,552		351,577	
Total stockholders' deficit		(226,782)		(201,404)	

## Merrimack Pharmaceuticals, Inc. Selected Cash Flow Data (unaudited)

	Three Months Ended						
(in thousands)	September 30, 2016			June 30, 2016			
Net cash used in operating activities	\$	(34,918)		\$	(50,903)		
Net cash provided by investing activities		48,342			22,179		
Net cash provided by financing activities		1,548			1,978		
Net increase (decrease) in cash and cash equivalents	\$	14,972		\$	(26,746)		

This press release presents guidance regarding aggregate research and development and selling, general and administrative expenses, excluding anticipated milestone obligations to PharmaEngine, which is a financial measure not calculated in accordance with GAAP. Merrimack is providing non-GAAP information that excludes one-time anticipated milestone obligations to PharmaEngine because of the nature of these items and the impact they have on the analysis of underlying business performance and trends, including the fact that these anticipated milestone obligations to

PharmaEngine are entirely offset by anticipated milestone obligations from Shire. Management believes that providing information regarding adjusted aggregate research and development and selling, general and administrative expenses enhances investors' understanding of Merrimack's performance and of trends that facilitate comparisons between periods. This information should be considered in addition to, but not in lieu of, information prepared in accordance with GAAP. Management also uses aggregate research and development and selling, general and administrative expenses, excluding anticipated milestone obligations to PharmaEngine, to establish budgets and operational goals and to manage Merrimack's business.

The following is a reconciliation of GAAP guidance to non-GAAP guidance:

Merrimack Pharmaceuticals, Inc.
Reconciliation to Aggregate Research and Development and Selling,
General and Administrative Expenses, Excluding Anticipated Milestone
Obligations to PharmaEngine (unaudited)

	Year	Ending Dec					
	Low End of Range		High End of Range		Year Ending		
(in millions)					December 31, 2017		
Anticipated aggregate research and development and selling, general							
and administrative expenses (GAAP measure)	\$	235.0	\$	245.0	\$	193.0	
Less: expenses related to one-time anticipated milestone obligations to							
PharmaEngine		(35.0)		(35.0)		(28.0)	
Anticipated aggregate research and development and selling, general							
and administrative expenses, excluding anticipated milestone	•		•	0.4.0.0	•	405.0	
obligations to PharmaEngine (non-GAAP measure)	\$	200.0	\$	210.0	\$	165.0	

CONTACT: Geoffrey M. Grande, CFA 617-441-7602 ggrande@merrimack.com

To view the original version on PR Newswire, visit: <a href="http://www.prnewswire.com/news-releases/merrimack-reports-third-quarter-2016-financial-results-300359962.html">http://www.prnewswire.com/news-releases/merrimack-reports-third-quarter-2016-financial-results-300359962.html</a>

SOURCE Merrimack Pharmaceuticals, Inc.

News Provided by Acquire Media