

Merrimack Reports Second Quarter 2016 Financial Results

CAMBRIDGE, Mass., Aug. 4, 2016 /PRNewswire/ -- Merrimack Pharmaceuticals, Inc. (Nasdaq: MACK) today announced its second quarter 2016 financial results. Merrimack will host a live conference call and webcast today, Thursday, August 4 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 38883620. 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 of positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency for ONIVYDE in combination with fluorouracil (5-FU) and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas who have progressed following treatment with gemcitabine-based therapy. The CHMP's positive opinion for ONIVYDE will now be reviewed by the European Commission for marketing authorization;
- Presentation of new analyses of the Phase 3 NAPOLI-1 data showing patients treated with the ONIVYDE regimen maintained similar baseline quality of life at 12 weeks despite the addition of a second chemotherapeutic agent when compared to 5-FU and leucovorin alone at the European Society for Medical Oncology (ESMO) 18th World Congress on Gastrointestinal Cancer; and
- Recognition of \$14.8 million of gross product revenues and \$12.9 million of net product revenues from U.S. commercial sales of ONIVYDE for the second quarter of 2016. This is compared to \$10.0 million of net product revenues for the first quarter of 2016, which represents an increase of \$2.9 million, or 29%, in net product revenues over the prior quarter.

Key Recent Events

Merrimack's key recent events include:

- Receipt of Fast Track designation from the U.S. Food and Drug Administration (FDA) for seribantumab (also known as MM-121) for development in patients with heregulin-positive, locally advanced or metastatic non-small cell lung cancer whose disease has progressed following immunotherapy;
- Presentation of an expanded overall survival analysis from the seribantumab Phase 2 breast cancer study indicating that seribantumab decreased risk of death by more than 50% in HER2-negative, hormone receptor positive breast cancer patients at the American Association for Cancer Research (AACR) Precision Medicine Series;
- Initiation of a Phase 1 clinical study of MM-151 in combination with ONIVYDE plus 5-FU and leucovorin in patients with RAS wild-type metastatic colorectal cancer;
- Initiation of a leading-edge biomarker-selected, multi-arm Phase 1 clinical study in metastatic colorectal, non-small cell lung, and head and neck cancers to evaluate the safety and tolerability of MM-151 in combination with seribantumab in patients with heregulin positive tumors, MM-151 in combination with MM-141 in patients with IGF-1-positive tumors, and MM-151 in combination with a MEK inhibitor (trametinib) in patients with KRAS/NRAS-mutant tumors;
- Presentation of clinical data on multiple therapeutic candidates from Merrimack's antibody engineering and antibodydirected nanotherapeutic (ADN) technology platforms at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting, including the final analysis from the Phase 1 clinical study of MM-151 showing clinical activity in multiple solid tumor types, including colorectal cancer; and

 Presentation of Merrimack's research and development strategy at its 2016 Investor Day, including updates on ONIVYDE and MM-151 development, Merrimack's ADN platform and Merrimack's systems immuno-oncology program.

Upcoming Milestones

Merrimack anticipates the following upcoming clinical milestones:

- Results in 2017 from the Phase 2 clinical study of ONIVYDE in previously untreated front-line metastatic pancreatic cancer;
- Results in 2017 from HERMIONE, the Phase 2 clinical study of MM-302 in patients with HER2-positive metastatic breast cancer that is designed to support a potential Accelerated Approval application to the FDA;
- Results in 2018 from the Phase 2 clinical study of MM-121 in patients with heregulin-positive, locally advanced or metastatic non-small cell lung cancer that is designed to support a potential Biologics License Application to the FDA; and
- Results in 2018 from the Phase 2 clinical study of MM-141 in patients with front-line metastatic pancreatic cancer who have high serum levels of free IGF-1.

Second Quarter 2016 Financial Results

The following summarizes Merrimack's financial results from the quarter ended June 30, 2016:

- Product revenues from the commercial sale of ONIVYDE, net of discounts, allowances and reserves, were \$12.9 million for the second quarter of 2016, compared to \$10.0 million for the first quarter of 2016. This represents an increase of \$2.9 million, or 29%, over the prior quarter;
- License and collaboration revenues were \$19.3 million for the second quarter of 2016, compared to \$11.3 million for the first quarter of 2016. This represents an increase of \$8.0 million from the prior quarter. This revenue includes \$10.0 million related to a substantive milestone achieved during the second quarter of 2016 as well as revenue that was recognized under the proportional performance revenue recognition model;
- Operating expenses were \$61.7 million for the second quarter of 2016 and are made up of the following:
 - \$41.0 million of research and development expenses, including a one-time \$10.0 million milestone payment made to PharmaEngine, as compared to \$32.9 million of research and development expenses incurred during the first quarter of 2016; and
 - \$20.7 million of selling, general and administrative expenses as compared to \$17.8 million of selling, general and administrative expenses incurred during the first quarter of 2016;
- Interest expense was \$21.1 million for the second quarter of 2016, compared to \$8.6 million for the first quarter of 2016. This \$12.5 million increase was primarily due to a \$14.6 million one-time, non-cash loss related to the induced 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 second quarter of 2016 was \$50.8 million, or \$0.40 per share, compared to a net loss attributable to Merrimack of \$38.5 million, or \$0.33 per share, for the first quarter of 2016.

Financial Outlook

In an effort to provide reconciliations to GAAP financial measures, Merrimack clarifies:

- Previous guidance on the achievement of \$46.5 million of net milestones in 2016 related to ONIVYDE is comprised of the anticipated achievement of \$85.0 million of milestone obligations from Shire and \$38.5 million of offsetting milestone obligations to PharmaEngine. Of the anticipated \$85.0 million of milestone obligations from Shire, \$75.0 million are expected to be classified as substantive milestones that would increase license and collaboration revenues and the remaining \$10.0 million are expected to be classified as non-substantive milestones that would be recognized through Merrimack's proportional performance revenue recognition model; and
- Previous guidance for aggregate research and development and selling, general and administrative expenses for 2016, when calculated in accordance with GAAP, was in the range of \$263.5 million to \$283.5 million, which included the anticipated achievement of \$38.5 million of milestone obligations to PharmaEngine. This corresponds to Merrimack's previously disclosed guidance that aggregate research and development and selling, general and administrative expenses, excluding anticipated milestone obligations to PharmaEngine, a non-GAAP financial measure, would be in the range of \$225.0 million to \$245.0 million for 2016.

With respect to its fiscal 2016 guidance, Merrimack:

Lowers its previously provided expense guidance range by \$20.0 million, 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 \$243.5 million to \$263.5 million. Excluding anticipated milestone obligations to PharmaEngine of \$38.5 million, this corresponds to a range of \$205.0 million to \$225.0 million for 2016,

which is a non-GAAP financial measure.

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.

Upcoming Investor Conferences

Merrimack will attend the following investor conference in the coming months:

Morgan Stanley Global Healthcare Conference, September 12th, 2016 in New York City.

A live webcast of the presentation at the Morgan Stanley Global Healthcare Conference can be accessed by visiting the Investors section of Merrimack's website at <u>investors.merrimack.com</u>. A replay of the webcast will be archived there for two weeks following the presentation.

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 www.merrimack.com or connect on Twitter at @MerrimackPharma.

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," "continue," and similar expressions. In this press release, Merrimack's forward-looking statements include, among others, statements about the timing of availability of clinical trial data, potential registration opportunities, expectations regarding potential cash inflows, revenue and expenses and Merrimack's presentations at upcoming investor conferences. 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 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. Forward-looking 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 May 2, 2016 and other reports Merrimack files with the SEC.

Merrimack Pharmaceuticals, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss (unaudited)

	Three Months Ended		
(in thousands, except per share amounts)	June 30, 2016		March 31, 2016
Revenues:			
Product revenues, net	\$ 12,851	\$	9,968
License and collaboration revenues	19,332		11,313
Other revenues	1,498	_	
Total revenues	33,681		21,281

1,872		711
40,996		32,882
20,680		17,795
63,548		51,388
(29,867)		(30,107)
(21,091)		(8,551)
(50,958)		(38,658)
(208)		(185)
\$ (50,750)	\$	(38,473)
15		(14)
\$ (50,735)	\$	(38,487)
	-	
\$ (0.40)	\$	(0.33)
126,161		116,064
\$ \$	40,996 20,680 63,548 (29,867) (21,091) (50,958) (208) \$ (50,750) \$ 50,750) \$ 50,735)	40,996 20,680 63,548 (29,867) (21,091) (50,958) (208) \$ (50,750) \$ \$ (50,735) \$ \$ (0.40) \$

Merrimack Pharmaceuticals, Inc.

Selected Balance Sheet Data (unaudited)

	As of June 30,		
(in thousands)	2016		2016
Cash, cash equivalents and marketable securities \$	82,667	\$	132,390
Working capital	28,145		63,318
Total assets	150,019		192,932
Total liabilities	351,577		410,075
Total stockholders' deficit	(201,404)		(217,197)

Merrimack Pharmaceuticals, Inc.

Selected Cash Flow Data (unautited)	Three Months Ended			
(in thousands)	June 30, 2016	-	March 31, 2016	
Net cash used in operating activities	\$ (50,903)	\$	(53,523)	
Net cash provided by (used in) investing activities	22,179		(85,491)	
Net cash provided by financing activities	1,978	_	1,645	
Net decrease in cash and cash equivalents	\$ (26,746)	\$	(137,369)	

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)

(in thousands)	of Range	of Range
Original range of anticipated aggregate research and development and selling, general and administrative expenses (GAAP measure)	\$ 263,500	\$ 283,500
Less: expenses related to one-time anticipated milestone obligations to PharmaEngine	(38,500)	(38,500)
Original range of anticipated aggregate research and development and selling, general and administrative expenses, excluding anticipated milestone obligations to PharmaEngine (non-GAAP measure)	\$ 225,000	\$ 245,000
Lowered range of anticipated aggregate research and development and selling, general and administrative expenses (GAAP measure)	\$ 243,500	\$ 263,500
Less: expenses related to one-time anticipated milestone obligations to PharmaEngine	(38,500)	(38,500)
Lowered range of anticipated aggregate research and development and selling, general and administrative expenses, excluding anticipated milestone obligations to PharmaEngine (non-GAAP measure)	\$ 205,000	\$ 225,000

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