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

# FORM 8-K

**CURRENT REPORT**
**Pursuant to Section 13 or 15(d)**
**of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): November 9, 2022 (November 9, 2022)**

# Merrimack Pharmaceuticals, Inc.
**(Exact Name of Registrant as Specified in its Charter)**

| **Delaware** | **001-35409** | **04-3210530** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

**One Broadway, 14th Floor**
**Cambridge, MA 02142**
**(Address of Principal Executive Offices)**

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

**(Former Name or Former Address, if Changed Since Last Report)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| **Common stock, $0.01 par value** | **MACK** | **Nasdaq Global Market** |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR 230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR 240.12b-2).

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. ☐

**Item 7.01 Regulation FD Disclosure.**

On November 9, 2022, Merrimack Pharmaceuticals, Inc. ("Merrimack" or the "Company") announced that Ipsen, SA ("Ipsen") issued a press release stating that Onivyde® regimen demonstrated statistically significant improvement in overall survival in previously untreated metastatic pancreatic ductal adenocarcinoma. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

*The information in this Item 7.01 and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.*

**Item 8.01 Other Events.**

On November 9, 2022, Merrimack announced that Ipsen issued a press release stating that Onivyde® regimen demonstrated statistically significant improvement in overall survival in previously untreated metastatic pancreatic ductal adenocarcinoma.

The Ipsen press release stated that the trial "met its primary endpoint demonstrating clinically meaningful and statistically significant improvement in overall survival compared to nabpaclitaxel plus gemcitabine in 770 previously untreated patients with metastatic pancreatic ductal adenocarcinoma (mPDAC) and key secondary efficacy outcome of progression-free survival (PFS) also showed significant improvement over the comparator arm. The safety profile of Onivyde in the NAPOLI 3 trial was consistent with those observed in the previous phase I/II mPDAC study."

Ipsen indicated in its press release that it intends to file a supplemental New Drug Application with the U.S. Food and Drug Administration for Onivyde in combination with oxaliplatin plus 5- fluorouracil/leucovorin for the treatment of patients with previously untreated mPDAC following the Fast Track Designation granted in 2020.

**Forward Looking Statements**

To the extent that statements contained in the Merrimack August 3, 2022 press release are not descriptions of historical facts, they are forward-looking 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, Merrimack's rights to receive payments related to certain milestone events or whether such milestones will be achieved, if at all, the sufficiency of Merrimack's cash resources and Merrimack's strategic plan, including any potential distribution of additional cash. Such forward-looking statements involve substantial risks and uncertainties that could cause Merrimack's 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: Positive information about pre-clinical and early stage clinical trial results does not ensure that later stage or larger scale clinical trials will be successful. For example, Onivyde® may not demonstrate promising therapeutic effect or appropriate safety profiles in current or later stage or larger scale clinical trials as a result of known or as yet unanticipated side effects. The results achieved in later stage trials may not be sufficient to meet applicable regulatory standards or to justify further development. Problems or delays may arise prior to the initiation of planned clinical trials, during clinical trials or in the course of developing, testing or manufacturing that could lead Ipsen and Elevation Oncology and their partners and collaborators to fail to initiate or to discontinue development. Even if later stage clinical trials are successful, unexpected concerns may arise from subsequent analysis of data or from additional data. Obstacles may arise or issues may be identified in connection with review of clinical data with regulatory authorities. Regulatory authorities may disagree with Ipsen and Elevation Oncology's view of the data or require additional data or information or additional studies. In addition, the planned timing of initiation and completion of clinical trials based upon Onivyde and the anti-HER Program are subject to the ability of each of Ipsen and Elevation Oncology, respectively, to enroll patients, enter into agreements with clinical trial sites and investigators, and overcome technical hurdles and other issues related to the conduct of the trials for which each of them is responsible. Additionally, each of Ipsen and Elevation Oncology are subject to the risk that they may not successfully commercialize these development programs. Merrimack is also subject to the risk that it may not have funding sufficient for its foreseeable and unforeseeable operating expenses and capital expenditure requirements. In addition, press releases and other public statements by Ipsen and Elevation Oncology may contain forward-looking statements. 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 Annual Report on Form 10-K filed with the SEC on March 9, 2022, any subsequent quarterly report on Form 10-Q filed by Merrimack and the other reports Merrimack files with the Securities and Exchange Commission.

**Item 9.01 Financial Statements And Exhibits**

(d) Exhibits. The Exhibit Index set forth below is incorporated herein by reference.

**EXHIBIT INDEX**

| Exhibit Number | Exhibit Title |
|---|---|
| 99.1 | Press release dated November 9, 2022 entitled "Merrimack provides Ipsen report that Onivyde® regimen demonstrated statistically significant improvement in overall survival in previously untreated metastatic pancreatic ductal adenocarcinoma" |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

**SIGNATURE**

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 hereunto duly authorized.

MERRIMACK PHARMACEUTICALS, INC.

Date: November 9, 2022

By: /s/ Gary L. Crocker
Gary L. Crocker
President

**Merrimack provides Ipsen report that Onivyde® regimen demonstrated statistically significant improvement in overall survival in previously untreated metastatic pancreatic ductal adenocarcinoma**

**Cambridge, MA, November 9, 2022 /Business Wire/** – Merrimack Pharmaceuticals, Inc. (Nasdaq: MACK) [("Merrimack" or the "Company")] announced that Ipsen, SA ("Ipsen") issued a press release today reporting its primary analysis of the results of its Phase III NAPOLI 3 trial of Onivyde® (irinotecan liposome injection) plus 5 fluorouracil/leucovorin and oxaliplatin (NALIRIFOX regimen) as a treatment of first line metastatic pancreatic ductal adenocarcinoma (mPDAC).

The Ipsen press release indicates that the trial "met its primary endpoint demonstrating clinically meaningful and statistically significant improvement in overall survival compared to nab-paclitaxel plus gemcitabine in 770 previously untreated patients with metastatic pancreatic ductal adenocarcinoma (mPDAC) and key secondary efficacy outcome of progression-free survival (PFS) also showed significant improvement over the comparator arm. The safety profile of Onivyde in the NAPOLI 3 trial was consistent with those observed in the previous phase I/II mPDAC study."

Ipsen also indicated in its update that it intends to file a supplemental New Drug Application with the U.S. Food and Drug Administration for Onivyde in combination with oxaliplatin plus 5- fluorouracil/leucovorin for the treatment of patients with previously untreated mPDAC following the Fast Track Designation granted in 2020.

"We are encouraged by these results which indicate progress toward a potential future milestone payment from Ipsen," said Gary Crocker, Chairman and CEO of Merrimack Pharmaceuticals. "We congratulate the Ipsen team and look forward to continuing to await further public announcements from Ipsen regarding progress with this important program."

**About Merrimack**

Merrimack Pharmaceuticals, Inc. is a biopharmaceutical company based in Cambridge, Massachusetts that is entitled to receive up to $450.0 million in contingent milestone payments related to its sale of Onivyde to Ipsen S.A. in April 2017. These milestone payments would be payable by Ipsen upon approval by the U.S. Food and Drug Administration ("FDA") of Onivyde for certain additional clinical indications. Onivyde is already approved by the FDA in combination with fluorouracil (5-FU) and leucovorin (LV) for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-

based therapy. This existing approval is unrelated to any future potential milestone payments. Merrimack's agreement with Ipsen does not require Ipsen to provide Merrimack with any information on the progress of Onivyde clinical trials that is not publicly available. Merrimack is also entitled to potentially receive up to $54.5 million in contingent milestone payments related to its sale of anti-HER3 programs to Elevation Oncology (formerly 14ner Oncology, Inc.) in July 2019.

**Forward Looking Statements**

To the extent that statements contained in this press release are not descriptions of historical facts, they are forward-looking 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, Merrimack's rights to receive payments related to certain milestone events or whether such milestones will be achieved, if at all, the sufficiency of Merrimack's cash resources and Merrimack's strategic plan, including any potential distribution of additional cash. Such forward-looking statements involve substantial risks and uncertainties that could cause Merrimack's 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: Positive information about pre-clinical and early stage clinical trial results does not ensure that later stage or larger scale clinical trials will be successful. For example, Onivyde® may not demonstrate promising therapeutic effect or appropriate safety profiles in current or later stage or larger scale clinical trials as a result of known or as yet unanticipated side effects. The results achieved in later stage trials may not be sufficient to meet applicable regulatory standards or to justify further development. Problems or delays may arise prior to the initiation of planned clinical trials, during clinical trials or in the course of developing, testing or manufacturing that could lead Ipsen and Elevation Oncology and their partners and collaborators to fail to initiate or to discontinue development. Even if later stage clinical trials are successful, unexpected concerns may arise from subsequent analysis of data or from additional data. Obstacles may arise or issues may be identified in connection with review of clinical data with regulatory authorities. Regulatory authorities may disagree with Ipsen and Elevation Oncology's view of the data or require additional data or information or additional studies. In addition, the planned timing of initiation and completion of clinical trials based upon Onivyde and the anti-HER Program are subject to the ability of each of Ipsen and Elevation Oncology, respectively, to enroll patients, enter into agreements with clinical trial sites and investigators, and overcome technical hurdles and other issues related to the conduct of the trials for which each of them is responsible. Additionally, each of Ipsen and Elevation Oncology are subject to the risk that they may not successfully commercialize these development programs. Merrimack is also subject to the risk that it may not have funding sufficient for its foreseeable and unforeseeable operating expenses and capital expenditure requirements. In addition, press releases and other public statements by Ipsen and Elevation Oncology may contain forward-looking statements. 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 Annual Report on Form 10-K filed with the SEC on March 9, 2022, any subsequent quarterly report on Form 10-Q filed by Merrimack and the other reports Merrimack files with the Securities and Exchange Commission.

**Contact**

Tim Surgenor

ir@merrimack.com