
**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 6, 2019

Mirum Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)	001-38981 (Commission File Number)	83-1281555 (I.R.S. Employer Identification No.)
950 Tower Lane, Suite 1050 Foster City, California (Address of principal executive offices)		94404 (Zip Code)
Registrant's telephone number, including area code: (650) 667-4085 (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:

- 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, par value \$0.0001 per share	MIRM	Nasdaq Global Market

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

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 2.02 Results of Operations and Financial Condition.

On November 6, 2019, Mirum Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended September 30, 2019. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section, nor shall it be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated November 6, 2019.

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 hereunto duly authorized.

Date: November 6, 2019

Mirum Pharmaceuticals, Inc.

By: /s/ Christopher Peetz
Christopher Peetz
President and Chief Executive Officer



Mirum Pharmaceuticals Reports Third Quarter Financial Results and Provides Corporate Update

Breakthrough Therapy Designation for Maralixibat for the Treatment of Pruritus Associated with Alagille Syndrome Granted

Cash, Cash Equivalents and Investments Balance of \$153.6 million

FOSTER CITY, Calif. – November 6, 2019 – Mirum Pharmaceuticals, Inc. (NASDAQ: MIRM), a biopharmaceutical company focused on the development and commercialization of novel therapies for debilitating liver diseases, today reported financial results for the quarter ended September 30, 2019 and provided an update on its clinical programs.

“The first nine months of 2019 have seen great progress towards bringing maralixibat to market for Alagille syndrome and progressive familial intrahepatic cholestasis,” said Chris Peetz, president and chief executive officer of Mirum. “The granting of breakthrough designation by the Food & Drug Administration and an oral late breaking presentation at the Liver Meeting are testimony of the tremendous potential of maralixibat for Alagille syndrome. The next 12 months are poised to be a transformational year as we prepare for commercialization and complete the MARCH-PFIC Phase 3 study.”

Key Operational Highlights

- Breakthrough Therapy Designation granted by the U.S. Food and Drug Administration (FDA) for maralixibat for the treatment of pruritus associated with Alagille syndrome (ALGS) in patients 1 year of age and older.
- Announced key data presentations at American Association for the Study of Liver Diseases AASLD, continuing to demonstrate the potential of maralixibat to durably improve clinical outcomes for children with progressive familial intrahepatic cholestasis (PFIC) Type 2 and ALGS.
- Launched Phase 3 MARCH-PFIC clinical trial. In July 2019, Mirum enrolled the first patient in the Phase 3 MARCH-PFIC clinical trial of its lead drug candidate, maralixibat, in pediatric patients with PFIC.
- In July 2019, Mirum completed its initial public offering (IPO) of 5,000,000 shares of common stock at an offering price of \$15.00 per share. Proceeds from the IPO totaled \$67.2 million, net of underwriting discounts, commissions and offering expenses.

Third Quarter 2019 Financial Results

- For the quarter ended September 30, 2019, Mirum reported a net loss of \$15.1 million.
- Total operating expenses for the quarter ended September 30, 2019 were \$15.9 million.
 - Research and development expenses for the quarter ended September 30, 2019 were \$12.2 million.
 - General and administrative expenses during the quarter ended September 30, 2019 were \$3.7 million.

As of September 30, 2019, Mirum had cash, cash equivalents and investments of \$153.6 million.

Upcoming Milestones and Expectations

- Present key data sets at the AASLD meeting in November 2019
 - Meet with the FDA in the fourth quarter of 2019 to continue discussions regarding the adequacy of Mirum’s Phase 2b data to support an NDA submission for maralixibat for pruritus associated with ALGS. Mirum anticipates providing an update in January 2020.
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- Complete enrollment of the Phase 3 MARCH-PFIC clinical trial investigating the safety and efficacy of maralixibat in patients with PFIC2 by mid-2020 and announce topline results by the end of 2020.

About Maralixibat

Maralixibat is a novel, minimally-absorbed, orally administered investigational drug being evaluated in several rare cholestatic liver diseases for pediatric populations. Maralixibat inhibits the apical sodium dependent bile acid transporter, which results in more bile acids being excreted in the feces, leading to lower levels of bile acids systemically, thereby potentially reducing bile acid mediated liver damage and related effects and complications. More than 1,500 individuals have received maralixibat, including more than 100 children who have received maralixibat as an investigational treatment for Alagille syndrome (ALGS) and progressive familial intrahepatic cholestasis (PFIC). In a Phase 2 PFIC study, a genetically defined subset of BSEP (bile salt export pump) deficient, or PFIC2, patients responded to maralixibat, which led to maralixibat receiving Breakthrough Therapy designation from the U.S. Food and Drug Administration for PFIC2. In a Phase 2b ALGS study, patients taking maralixibat had significant reductions in bile acids and pruritus compared to placebo. Maralixibat was generally well-tolerated throughout the studies. The most frequent adverse events were diarrhea, abdominal pain and vomiting.

About Mirum Pharmaceuticals

Mirum Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of a late-stage pipeline of novel therapies for debilitating liver diseases. The company's lead product candidate, maralixibat, is an investigational oral drug in development for progressive familial intrahepatic cholestasis (PFIC) and Alagille syndrome (ALGS). For more information, visit MirumPharma.com. Follow Mirum on Twitter, Facebook and LinkedIn.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include statements regarding, among other things, the results, conduct, progress and timing of Mirum's clinical trials, and the regulatory approval path for maralixibat. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "plans", "will", "believes," "anticipates," "expects," "intends," "goal," "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Mirum's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks and uncertainties associated with Mirum's business in general, and the other risks described in Mirum's filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Mirum undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

Mirum Pharmaceuticals, Inc.
Selected Consolidated Statement of Operations Data
(Unaudited)
(In thousands, except per share amounts)

	Three months Ended September 30, 2019	Three months Ended September 30, 2018	Nine months Ended September 30, 2019	Period from May 2, 2018 to September 30, 2018
Operating expenses:				
Research and development	\$ 12,159	\$ 3	\$ 28,611	\$ 3
General and administrative	3,708	62	7,474	72
Total operating expenses	15,867	65	36,085	75
Loss from operations	(15,867)	(65)	(36,085)	(75)
Interest income (expense)	785	(2)	1,485	(2)
Other income (expense), net	(5)	—	(1)	—
Net loss	\$ (15,087)	\$ (67)	\$ (34,601)	\$ (77)
Net loss per common share, basic and diluted	\$ (0.84)	\$ (0.14)	\$ (4.47)	\$ (0.26)
Weighted-average common shares outstanding, basic and diluted	17,996,065	476,905	7,745,241	290,570

Mirum Pharmaceuticals, Inc.
Selected Consolidated Balance Sheet Data
(In thousands)

	<u>September 30, 2019</u>	<u>December 31, 2018</u>
	(unaudited)	
Cash, cash equivalents and investments	\$ 153,559	\$ 51,963
Working capital	118,408	49,526
Total assets	158,273	51,975
Accumulated deficit	(51,949)	(17,348)
Total stockholders' equity (deficit)	146,203	(17,313)

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