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

FORM 8-K

Biomea Fusion, Inc.

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

Date of Report (Date of earliest event reported): May 27, 2021

Biomea Fusion, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40335

82-2520134
(IRS Employer
Identification No.)

726 Main Street
Redwood City, CA
(Address of Principal Executive Offices)

(Commission File Number)

94063
(Zip Code)

Registrant's Telephone Number, Including Area Code: (650) 980-9099

Not Applicable

(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.0001 par value	BMEA	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company 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 May 27, 2021, Biomea Fusion, Inc. issued a press release announcing its financial results as of and for the quarter ended March 31, 2021. The press release is being furnished as Exhibit 99.1.

The information in this Item 2.02 of this Form 8-K and the Exhibit 99.1 attached hereto 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, or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release dated May 27, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 thereunto duly authorized.

BIOMEA FUSION, INC.

Date: May 27, 2021

By: _____ /s/ Thomas Butler
Thomas Butler
Principal Executive Officer

Biomea Fusion Reports First Quarter 2021 Financial Results and Business Highlights

-- Received \$167 million in aggregate gross proceeds in April from initial public offering --

-- Advancing lead oncology program BMF-219, a small molecule irreversible menin inhibitor, toward IND filing in second half of 2021 --

-- Mick Hitchcock, Ph.D., former senior advisor to Gilead joined the Board of Directors --

May 27, 2021

REDWOOD CITY, Calif., May 27, 2021 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. ("Biomea") (Nasdaq: BMEA), a preclinical-stage biopharmaceutical company focused on the discovery and development of irreversible small molecules to treat patients with genetically defined cancers, reported financial results for the first quarter 2021.

"I could not be more proud of Team Fusion and what we have achieved scientifically and operationally during this past quarter," said Thomas Butler, Biomea's CEO and Chairman of the Board. "We continue to execute at a very high level and are on track to submit our IND application to the FDA for BMF-219 during the second half of this year. We believe that menin will become a cornerstone therapeutic target for cancer treatments, and our approach to disrupt this scaffold protein through irreversible inhibition will afford us a profound opportunity to create effective and patient-friendly therapies for some of today's most untreatable cancers. Over just a four month period, we were able to complete a Series A financing in December 2020 and our recent IPO in April, raising a combined total of \$223 million in aggregate gross proceeds. Our strong balance sheet provides us today with ample funding to fully explore the potential of BMF-219 in multiple tumor types, comprehensively build out our proprietary irreversible platform, and progress multiple early-stage small pipeline molecules into the clinic. During the same period, we also doubled the size of our team, bringing in extremely talented but also friendly and passionate people."

Business Highlights

- **Completed initial public offering ("IPO") in April.** The Company's common stock commenced trading on the Nasdaq Global Select Market under the ticker symbol "BMEA" on April 16, 2021. The IPO, at a public offering price of \$17.00 per share, raised \$167 million in aggregate gross proceeds, including shares sold to the underwriters pursuant to the exercise of their option to purchase additional shares in May 2021. As of April 30, 2021, there were 28,767,867 shares of common stock outstanding.
 - **Continue to advance lead program, BMF-219, toward the clinic.** Biomea continues to progress BMF-219, an irreversible menin inhibitor for the treatment
-

of menin-dependent cancers. Biomea anticipates filing an investigational new drug (IND) application in the second half of 2021. The company has two additional programs pursuing undisclosed targets, which are currently in the discovery phase.

- **Strengthened the Board of Directors.** In the first quarter Biomea added Mick Hitchcock, Ph.D., former senior advisor to Gilead, who brings 40 years of biotech experience in drug development and commercialization to its board of directors.

Financial Highlights

First Quarter 2021 Financial Results

- Biomea reported a net loss attributable to common stockholders of \$5.9 million for the first quarter of 2021, compared to a net loss of \$0.4 million for the same period in 2020.
- Research and development expenses were \$3.8 million for the three months ended March 31, 2021, compared to \$0.3 million for the same period in 2020. The increase in R&D expenses was primarily due to an increase in pre-clinical development activities for BMF-219 and higher personnel-related expenses.
- General and administrative expenses were \$2.1 million for the three months ended March 31, 2021, compared to \$0.1 million for the same period in 2020. The increase in G&A expenses was primarily due to higher personnel-related expenses and other corporate costs to support the Company's expanding operations.
- As of March 31, 2021, the Company had cash, cash equivalents, restricted cash, and investments of \$57.5 million.

About Biomea Fusion

Biomea Fusion is a preclinical-stage biopharmaceutical company focused on the discovery and development of irreversible small molecules to treat patients with genetically defined cancers. An irreversible small molecule drug is a synthetic compound that forms a permanent bond to its target protein and offers a number of potential advantages over conventional reversible drugs, including greater target selectivity, lower drug exposure and the ability to drive a deeper, more durable response. Leveraging its extensive expertise in irreversible binding chemistry and development, the Company built its proprietary FUSION System discovery platform to advance a pipeline of novel irreversible, small molecule therapies. The lead product candidate, BMF-219, is an orally bioavailable, potent and selective irreversible inhibitor of menin, an important transcriptional regulator known to play a direct role in oncogenic signaling in multiple cancers. In preclinical studies, administration of BMF-219 has resulted in robust anti-tumor responses across a range of liquid and solid tumor models and has been well-tolerated in animal studies. Biomea Fusion is developing BMF-219 for the treatment of liquid and solid tumors that are highly dependent on menin,

including leukemias containing the mixed lineage leukemia (“MLL”) fusion protein. The Company is currently completing investigational new drug (“IND”) enabling studies and expects to file an IND application with the U.S. Food and Drug Administration in the second half of 2021. Beyond BMF-219, the Company is utilizing its novel platform to develop irreversible treatments against other high-value oncogenic drivers of cancer and expects to nominate its second development candidate in the first half of 2022. Biomea Fusion’s goal is to utilize its capabilities and platform to become a leader in developing irreversible small molecules in order to maximize the depth and durability of clinical benefit when treating various cancers.

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. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding the potential safety, efficacy, and continued development of BMF-219, the timing for completing the IND filing or starting the clinical development, the building out our proprietary irreversible platform and progress made in early-stage small pipeline molecules through their preclinical development, including the timing for nominating development candidates in each program. These statements often include words such as “believe,” “expect,” “anticipate,” “intend,” “plan,” “estimate,” “seek,” “will,” “may,” or similar expressions. Forward-looking statements are subject to a number of risks and uncertainties, many of which involve factors or circumstances that are beyond the Company’s control. Any forward-looking statements in this statement are based on management’s current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include: the success, cost, and timing of the Company’s product candidate development activities and planned IND-enabling and clinical trials, the Company’s ability to execute on its strategy, regulatory developments in the United States, the Company’s ability to fund operations, and the impact that the current COVID-19 pandemic will have on the Company’s clinical trials and pre-clinical studies, supply chain, and operations, as well as those risks and uncertainties set forth in the Company’s Quarterly Report on Form Q for the quarter ended March 31, 2021, filed with the Securities and Exchange Commission on May 27, 2021, and its other filings filed with the United States Securities and Exchange Commission filed from time to time. Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee that the events and circumstances reflected in the forward-looking statements will be achieved or occur, and the timing of events and circumstances and actual results could differ materially from those projected in the forward-looking statements. Accordingly, you should not place undue reliance on these forward-looking statements. All forward-looking statements contained in this press release speak only as of the date on which they were made. The Company undertakes no obligation to

update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Contact:

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- See attached for financial tables -

BIOMEA FUSION, INC.
Condensed Statement of Operations
(Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2021	2020
Operating expenses:		
Research and development	\$ 3,798	\$ 334
General and administrative	2,059	64
Total operating expenses	5,857	398
Loss from operations	(5,857)	(398)
Interest and other income, net	5	0
Net loss	\$ (5,852)	\$ (398)
Other comprehensive loss:		
Changes in unrealized loss on short term investments, net	(15)	-
Comprehensive loss	\$ (5,867)	\$ (398)
Net loss per common share, basic and diluted	(0.49)	(0.05)
Weighted-average number of common shares used to compute basic and diluted net loss per common share	11,964,205	8,758,995

Includes stock-based compensation as follows:

	Three Months Ended March 31,	
	2021	2020
Research and development	\$ 313	\$ -
General and administrative	606	-
Total stock-based compensation expense	\$ 919	\$ -

BIOMEA FUSION, INC.
Condensed Balance Sheet Data
(Unaudited)
(in thousands)

	<u>March 31,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
Cash, cash equivalents, investments, and restricted cash	\$ 57,536	\$ 61,695
Working capital	43,603	60,604
Total assets	59,875	62,526
Stockholders' equity	211	5,169