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): November 3, 2021

Biomea Fusion, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-40335**	**82-2520134**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
650 Main Street Redwood City, CA		**94063**
(Address of Principal Executive Offices)		**(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:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
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 November 3, 2021, Biomea Fusion, Inc. issued a press release announcing its financial results for the quarter ended September 30, 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 November 3, 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: November 3, 2021

By: /s/ Thomas Butler

Thomas Butler
Principal Executive Officer

Biomea Fusion Reports Third Quarter 2021 Financial Results and Business Highlights

- Announced FDA clearance of Investigational New Drug Application (IND) for BMF-219, the company's first development candidate from the FUSION platform
- Phase I trial to enroll adult patients with relapsed or refractory acute leukemia, including those with an MLL/KMT2A gene rearrangement or NPM1 mutation
- Scientific rationale for irreversible menin inhibition in diffuse large B cell lymphoma (DLBCL) now expected in Q4 2021
- Pathway validation in diabetes anticipated in Q1 2022
- Opened Biomea Innovation Research Center, to enable the Research & Development (R&D) team to rapidly discover and develop novel irreversible covalent small molecules by leveraging the FUSION platform to build a broad portfolio of therapeutics

REDWOOD CITY, Calif., Nov. 03, 2021 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. ("Biomea") (Nasdaq: BMEA), a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel small molecules to treat and improve the lives of patients with genetically defined cancers, reported financial results for the third quarter of 2021.

"The Third Quarter was a historic one for the company as it advanced its first investigational drug into a clinical stage program. BMF-219, our internally discovered and developed small molecule, has shown broad anti-cancer activity pre-clinically and we now have the opportunity to explore this potential in patients in need." said Thomas Butler, Biomea's CEO and Chairman of the Board. "In September, we received FDA clearance of our IND for BMF-219, and we are now working diligently to initiate a Phase I study for the treatment of relapsed or refractory acute leukemia. We look forward to providing clinical development updates, as we deepen our understanding of menin's role in various cancers and the potential impact of irreversible inhibition for these patient populations. Our vision for this company has always been to develop a suite of novel covalent inhibitors that can act as single agent therapies or in combination, together, to build best-in-class medicine for patients. We have executed on this promise by hiring world-class drug hunters, and developers, and by custom designing and opening a state-of-the-art Research Center. We now have our first molecule ready for the clinic, and a number of exciting programs advancing through pre-clinical development."

Mr. Butler continued, "As we move BMF-219 into the clinic, we intend to also focus on leveraging our novel chemistry across multiple indications. To that end, we anticipate announcing our next pipeline candidate in the first half of 2022."

Business Highlights

- **FDA clearance of IND for First-in-Human Phase I Clinical Trial of BMF-219.** In September 2021, Biomea received FDA clearance of its IND for BMF-219, an irreversible menin inhibitor for the treatment of relapsed or refractory acute leukemias including those with an MLL/KM2TA gene rearrangement or NPM1 mutation.
- **Preclinical studies underway for DLBCL and multiple myeloma (MM) as potential indications for BMF-219.** Biomea is conducting preclinical studies to demonstrate the potential for BMF-219 in genetically defined patient subsets of DLBCL and MM.
- **Pathway validation studies of irreversible menin inhibition in diabetes.** Biomea is continuing preclinical studies to explore the potential of its irreversible menin inhibitor approach for the treatment of type 2 diabetes. The company plans to report findings from these studies in the fourth quarter of 2021.
- **Launch of Biomea Innovation Center; scale-up of R&D organization.** Biomea recently opened the Biomea Innovation Center with laboratory space and a dedicated R&D team focused on leveraging the company's FUSION platform to generate a broad portfolio of next generation covalent inhibitors.

"Our CEO's vision for the company is to build a fully sustainable, world-class R&D organization, which mines the deep potential of our FUSION platform and irreversible binding small molecule approach. With our recently opened Biomea Innovation Research Center and our continued scale-up of an extremely talented, forward-and creative-thinking scientific team, we will aggressively interrogate our irreversible binding approach against known and validated biological targets with the goal of rapidly advancing a broad portfolio of therapies designed to deliver enhanced efficacy and safety for patients. Thanks to our successful IPO and considering our current programs' quarterly expenses, we expect our cash balance to sustain our operations well into 2024," concluded Ramses Erdtmann, Biomea's COO and President.

Financial Highlights

Third Quarter 2021 Year to Date Financial Results

- Biomea reported a net loss attributable to common stockholders of $26.9 million for the first nine months of 2021, compared to a net loss of $1.8 million for the same period in 2020.
- Research and development expenses were $16.9 million for the first nine months of 2021, compared to $1.3 million for the same period in 2020. The increase of $15.6 million was primarily due to an increase in personnel-related expenses, as well as an increase in pre-clinical development costs, including manufacturing and external consulting, related to the IND-enabling studies for BMF-219.

- General and administrative expenses were $10.0 million for the first nine months of 2021, compared to $0.5 million for the same period in 2020. The increase of $9.5 million was primarily due to higher personnel-related expenses and other corporate costs to support the Company's public company status.
- As of September 30, 2021, the Company had cash, cash equivalents, restricted cash, and investments of $191.9 million.

About Acute Myeloid Leukemia (AML)

AML is the most common form of acute leukemia in adults and represents the largest number of annual leukemia deaths in the U.S. and Europe. AML originates within the white blood cells in the bone marrow and can rapidly move to the blood and other parts of the body, including the lymph nodes, spleen, and central nervous system. Approximately 30,000 people in the U.S. and Europe are diagnosed with AML each year, and the five-year overall survival rate in adults roughly 29%. Among patients with relapsed/refractory disease, the need is greatest, as the overall survival is approximately 3 to 9 months. It is estimated that upwards of 45% of AML patients have menin dependent genetic drivers (MML-r or NPM1).

About BMF-219

BMF-219 is an irreversibly binding inhibitor of menin, a protein that is known to play an essential role in oncogenic signaling in genetically defined leukemias. Preclinically, BMF-219 has demonstrated robust downregulation of key leukemogenic genes in addition to menin itself (via MEN1) in well-established MLLr AML cell lines. Additionally, BMF-219 has shown efficacy in multiple in vivo and in vitro models of acute leukemias. BMF-219 will be evaluated in a first-in-human trial in patients with relapsed or refractory acute leukemia with MLL/KMT2A gene rearrangement or NPM1 mutation.

About Biomea Fusion

Biomea Fusion is a biopharmaceutical company focused on the discovery and development of irreversible small molecules to treat patients with genetically defined cancers. An irreversible small molecule 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. The company is utilizing its proprietary FUSION™ System discovery platform to advance a pipeline of irreversible treatments against key oncogenic drivers of cancer. 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 initiating clinical development, the timing of pre-clinical and clinical data announcement, the timing of nominating additional product candidates, 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, and the sufficiency of our cash resources to fund our operations. 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 filings with the United States Securities and Exchange Commission. 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 7,886	$ 789	$ 16,908	$ 1,339
General and administrative	4,752	346	10,022	489
Total operating expenses	12,638	1,135	26,930	1,828
Loss from operations	(12,638)	(1,135)	(26,930)	(1,828)
Interest and other income, net	32	—	73	2
Net loss	$ (12,606)	$ (1,135)	$ (26,857)	$ (1,826)
Other comprehensive loss:				
Unrealized gain on investments, net	—	—	2	—
Comprehensive loss	$ (12,606)	$ (1,135)	$ (26,855)	$ (1,826)
Net loss per common share, basic and diluted	(0.43)	(0.10)	(1.21)	(0.18)
Weighted-average number of common shares used to compute basic and diluted net loss per common share	29,001,213	11,724,100	22,105,321	10,082,667

Includes stock-based compensation as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	$ 766	$ —	$ 1,690	$ —
General and administrative	1,155	—	2,613	—
Total stock-based compensation expense	$ 1,921	$ —	$ 4,303	$ —

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

	September 30, 2021	December 31, 2020
Cash, cash equivalents, investments, and restricted cash	$ 191,859	$ 61,695
Working capital	185,462	60,604
Total assets	199,403	62,526
Stockholders' equity	191,331	5,169