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): February 28, 2022

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.)**

900 Middlefield Road, 4th Floor 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 February 28, 2022, Biomea Fusion, Inc. issued a press release announcing its financial results for the year ended December 31, 2021. The full text of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

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 February 28, 2022, furnished herewith.
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: February 28, 2022

By: /s/ Thomas Butler

Thomas Butler
Principal Executive Officer

Biomea Fusion Reports Fourth Quarter and Full Year 2021 Financial Results and Corporate Highlights

- Phase I trial of BMF-219, an irreversible covalent menin inhibitor, is currently underway
- Plan to initiate trials of BMF-219 in up to seven solid and liquid tumor types and diabetes
- Plan to announce second clinical candidate in the first half of 2022
- Cash, cash equivalents, restricted cash, and investments of $175.7 million

REDWOOD CITY, Calif., February 28th, 2022 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. (“Biomea”) (Nasdaq: BMEA), a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel irreversible covalent small molecules to treat and improve the lives of patients with genetically defined cancers and metabolic diseases, reported fourth quarter and full year 2021 financial results and business highlights.

“I am proud of all that we, TEAM FUSION, accomplished in 2021 laying a firm foundation to enable our ambitious clinical development strategy for BMF-219, our irreversible covalent menin inhibitor. In January 2022, we began dosing our first patient in our initial Phase I leukemia study of BMF-219, and we are aiming to initiate human studies in up to seven different tumor types as well as diabetes over the next 12 months,” said Thomas Butler, Biomea’s CEO and Chairman of the Board. “We also have made significant progress advancing our lead preclinical programs and plan to announce our second irreversible covalent inhibitor pipeline candidate in the coming months. We anticipate that the next 12 months will be enormously productive and catalyst rich for Biomea Fusion.”

Clinical and Regulatory Highlights Last 12 months

- Enrolled first patient in first-in-human Phase I clinical trial evaluating BMF-219, Biomea’s irreversible covalent menin inhibitor, in patients with relapsed/refractory (r/r) acute leukemias, including those with MLL1/KMT2A gene rearrangements or NPM1 mutations.
- Announced 2022 clinical development plan, which includes initiating studies with BMF-219 in up to seven cancers and diabetes, subject to the submission and clearance of additional Investigational New Drug applications (INDs). These studies plan to evaluate patients with acute myeloid leukemia (AML), acute lymphocytic leukemia (ALL), multiple myeloma (MM), diffuse large B-Cell lymphoma (DLBCL), non-small cell lung cancer (NSCLC), pancreatic cancer, and colorectal cancer (CRC). Preclinical data suggests the menin complex plays a critical role in MYC-dependent oncogenic signaling, whereby menin enhances MYC-mediated transcription to promote cancer progression. Inhibition of menin is a novel approach to cancer treatment. Nonclinical studies of BMF-219 have shown sustained potent abrogation of menin-dependent cancers.
- Published preclinical abstract at ASH 2021, highlighting impact of BMF-219 on MYC activity and substantial growth inhibition compared to other menin inhibitors in DLBCL. BMF-219 was observed to elicit broad impact on the complexes surrounding menin resulting in strong modulation of MYC expression, highlighting potential in multiple cancer types.
- Expanded the Phase I study to include two additional tumor types, one with diffuse large B-cell lymphoma (DLBCL) patients and one with multiple myeloma (MM) patients.

Corporate Highlights Last 12 months

- Completed initial public offering, with net proceeds of $152.8 million.
- Opened Biomea R&D Innovation Center in Redwood City, accelerating the discovery and development of additional irreversible covalent programs via the company’s proprietary FUSION™ System.

- Grew the Biomea Fusion team to 51 employees and expanded the executive team with the hires of Chief Financial Officer, Franco Valle, and Chief Medical Officer, Steve Morris, M.D.
- Strengthened board of directors with the appointments of Michael J. M. Hitchcock, Ph.D., a tenured employee and long-time advisor to Gilead Sciences and Adjunct Professor of Microbiology at the University of Nevada Medical School; and Sumita Ray, J.D., Chief Legal and Administrative Officer at Calithera Biosciences, Inc.

Expected Milestones in 2022

- Initiate enrollment of patients with MM and DLBCL in Phase I clinical trial of BMF-219.
- Announce further preclinical data for BMF-219 in liquid and solid tumors.
- Announce preclinical validation for BMF-219 in diabetes.
- Announce second irreversible covalent inhibitor pipeline candidate in the first half of 2022.
- Submission of an IND for BMF-219 in diabetes in the second half of 2022.
- Submission of an IND for BMF-219 in KRAS-mutant solid tumors, including patients with non-small cell lung cancer (NSCLC), pancreatic cancer, and colorectal cancer (CRC) in the fourth quarter of 2022.

Fourth Quarter and Full Year 2021 Financial Results

- **Net Income/Loss:** Biomea reported a net loss attributable to common stockholders of $41.6 million for year ended December 31, 2021, compared to a net loss of $5.3 million for the same period in 2020.
- **R&D Expenses:** Research and development expenses were $28.0 million for the year ended December 31, 2021, compared to $3.7 million for the same period in 2020. The increase of $24.3 million was primarily due to an increase in personnel-related expenses, as well as an increase in preclinical and clinical development costs, including manufacturing and external consulting, related to the Company's lead product candidate, BMF-219.
- **G&A Expenses:** General and administrative expenses were $13.7 million for the year ended December 31, 2021, compared to $1.7 million for the same period in 2020. The increase of $12.0 million was primarily due to higher personnel-related expenses and other corporate costs to support the Company's expanding operations as well as additional costs incurred as a public company.
- **Cash, Cash Equivalents, Restricted Cash, and Investments:** As of December 31, 2021, the Company had cash, cash equivalents, restricted cash, and investments of $175.7 million.

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 and metabolic diseases. 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 to advance a pipeline of irreversible-binding therapeutic agents against key oncogenic drivers of cancer and metabolic diseases. 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 clinical benefit when treating various cancers and metabolic diseases.

Forward-Looking Statements

Statements we make in this press release may include statements which are not historical facts and are considered forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will," and variations of these words or similar expressions that are intended to identify forward-looking statements. Any such statements in this press release that are not statements of historical fact, including statements regarding the clinical and therapeutic potential of our product candidates and development programs, including BMF-219, the potential of BMF-219 as a treatment for various types of cancer and diabetes, our research, development and regulatory plans, including our plans to initiate clinical development of BMF-219 in up to seven distinct tumor types, as well as diabetes, and the timing of such events, including the timing of patient enrollment, data presentations, candidate selection, IND submissions and trial initiations, may be deemed to be forward-looking statements. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act and are making this statement for purposes of complying with those safe harbor provisions.

Any forward-looking statements in this press release are based on our current expectations, estimates and projections only as of the date of this release 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, including the risk that we may encounter delays in patient enrollment and in the initiation, conduct and completion of our planned clinical trials. These risks concerning Biomea Fusion's business and operations are described in additional detail in its periodic filings with the SEC, including its most recent period report filed with the SEC and subsequent filings thereafter. Biomea Fusion explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

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 December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Operating expenses:				
Research and development (1)	$ 11,088	$ 2,332	$ 27,996	$ 3,671
General and administrative (1)	3,649	1,167	13,671	1,656
Total operating expenses	14,737	3,499	41,667	5,327
Loss from operations	(14,737)	(3,499)	(41,667)	(5,327
Interest and other income, net	27	1	100	3
Net loss	$ (14,710)	$ (3,498)	$ (41,567)	$ (5,324
Other comprehensive loss:				
Unrealized gain (loss) on investments, net	(12)	—	(10)	—
Comprehensive loss	$ (14,722)	$ (3,498)	$ (41,577)	$ (5,324
Net loss per share, basic and diluted	(0.51)	(0.29)	(1.74)	(0.51
Weighted-average number of shares outstanding, basic and diluted	29,061,076	11,871,494	23,858,552	10,532,942

(1) Includes stock-based compensation as follows:

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Research and development	$ 947	$ 89	$ 2,637	$ 89
General and administrative	984	233	3,597	233
Total stock-based compensation expense	$ 1,931	$ 322	$ 6,234	$ 322

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

	December 31,	
	2021	**2020**
Cash, cash equivalents, investments, and restricted cash	$ 175,743	$ 61,695
Working capital	171,924	60,604
Total assets	185,705	62,526
Stockholders' equity	178,783	5,169