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): March 28, 2023

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, California	**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 March 28, 2023, Biomea Fusion, Inc. issued a press release announcing its financial results for the quarter ended and year ended December 31, 2022. 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.

99.1	Press release dated March 28, 2023, 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: March 28, 2023

By: /s/ Thomas Butler

Thomas Butler
Principal Executive Officer

Exhibit 99.1

Biomea Fusion Reports Fourth Quarter and Full Year 2022 Financial Results and Corporate Highlights

- Expanded clinical development footprint of BMF-219, the company's lead investigational, orally administered, covalent menin inhibitor, to eight liquid and solid tumor indications and type 2 diabetes across three ongoing clinical trials
  - COVALENT-101 (Phase I study) enrolling four liquid tumor cohorts, each focused on distinct patient subsets of acute lymphocytic and myeloid leukemias (ALL/AML) including patients with MLL rearrangements (MLLr) and NPM1 mutations, diffuse large B-cell lymphoma (DLBCL), multiple myeloma (MM) and most recently, chronic lymphocytic leukemia (CLL)
  - COVALENT-102 (Phase I/Ib study) enrolling patients with KRAS-mutated solid tumors, including non-small cell lung cancer (NSCLC), colorectal cancer (CRC) and pancreatic ductal adenocarcinoma (PDAC)
  - COVALENT-111 (Phase I/II study) advanced BMF-219 to the clinic for type 2 diabetes; completed the Phase I healthy volunteer portion of the study in Canada, initiated dosing of type 2 diabetic patients in the Phase II portion in the U.S. and Canada and reported initial clinical data from the first two cohorts of diabetic patients
- Continued to advance the second product candidate, BMF-500, a highly selective and potent covalent third generation FLT3 inhibitor, toward the clinic with IND filing on track for the first half of 2023
- Cash position of $113.4 million at the end of the fourth quarter of 2022

REDWOOD CITY, Calif., March 28, 2023 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. ("Biomea" or "the Company") (Nasdaq: BMEA), a clinical-stage biopharmaceutical company dedicated to discovering and developing novel covalent small molecules to treat and improve the lives of patients with genetically defined cancers and metabolic diseases, reported fourth quarter and full year 2022 financial results and business highlights.

"During 2022 we transformed Biomea from a preclinical company to a fully integrated clinical-stage company, pursuing ten indications, with two distinct molecules in three different trials. I am incredibly proud of our team's performance and dedication, which has enabled our rapid clinical progress," said Thomas Butler, CEO and Chairman of Biomea. "In 2023, we will significantly advance all three programs and plan to deliver on multiple data readouts, beginning with initial data reported this quarter from our COVALENT-111 study in patients with type 2 diabetes. Loss of mass and function of beta cells is an underlying cause of type 2 diabetes. There is biological precedent, reinforced by our preclinical data for BMF-219, that suggests inhibiting menin may enable the proliferation, preservation, and reactivation of healthy, functional beta cells capable of producing insulin, thereby leading to long-term glycemic control in patients with type 2 diabetes. None of the currently approved therapies for diabetes are effectively addressing the loss and function of beta cells. We believe the data from COVALENT-111 of our oral agent BMF-219, which we have started to report this quarter, could represent a monumental event for the treatment of patients with diabetes and a transformative milestone for our company."

2022 and Recent Clinical and Regulatory Highlights

ONCOLOGY

- **COVALENT-101 (BMF-219 for Genetically Defined Liquid Tumors)**
  - Presented robust anti-tumor activity of covalent, small molecule menin inhibitor, BMF-219, as a single agent and mechanistic evidence for novel inhibition of the menin protein in preclinical models of DLBCL, MM, and CLL. BMF-219 displayed significant single agent activity, surpassing greater than 90% cell killing at clinically relevant exposures in DLBCL, MM and CLL cell lines and patient-derived samples.

- BMF-219 is the first investigational menin inhibitor in clinical development to show potential as a therapeutic agent in hematologic malignancies outside of MLLr and NPM1 mutated AML/ALL patients, specifically in subsets of DLBCL, MM and CLL patients.
- Continued site activation and patient enrollment across four liquid tumor cohorts including patients with AML/ALL, DLBCL, MM and CLL.
- **Anticipated Milestone in 2023:**
  - On track to present initial clinical data of AML/ALL patients (including those with MLLr rearrangement and NPM1 mutations) dosed in the COVALENT-101 study in the first half of 2023.

- **COVALENT-102 (BMF-219 for KRAS-Mutant Solid Tumors)**
  - Presented strong and highly specific pan-KRAS anti-cancer activity of BMF-219 as a single agent across KRAS G12C, G12D, G12V and G13D mutant cell lines including in NSCLC, CRC and PDAC.
  - BMF-219 is the first investigational menin inhibitor in development to enter clinical trials for the treatment of solid tumors. A targeted pan-KRAS inhibitor could have the potential to treat 25-35% of NSCLC, 35-45% of CRC, and approximately 90% of PDAC patients.
  - Dosed first patient in January 2023 in COVALENT-102, a study of BMF-219 as a monotherapy in patients with unresectable, locally advanced, or metastatic NSCLC, CRC or PDAC with an activating KRAS mutation.
- **COVALENT-103 (BMF-500 for Acute Leukemias)**
  - Announced second Investigational New Drug (IND) candidate, BMF-500, a potential best-in-class oral covalent inhibitor of FLT3, designed and developed in-house, from target to IND candidate, utilizing Biomea's proprietary FUSION™ System.
  - Presented data showing multi-fold higher potency and increased cytotoxicity of Biomea's covalent FLT3 small molecule inhibitor BMF-500 compared to the commercially available reversible, non-covalent FLT3 inhibitor gilteritinib, and complete, sustained tumor regression in mouse models of FLT3-ITD AML with maintenance of effect after cessation of therapy.
  - **Anticipated Milestone in 2023**:
    - On track to file IND for BMF-500 in the first half of 2023 to initiate COVALENT-103 study in patients with acute leukemias.

DIABETES

- **COVALENT-111 (BMF-219 for Type 2 Diabetes)**
  - Presented preclinical data highlighting the ability of BMF-219 in a type 2 diabetes rat model to restore normal HOMA-B, a measure of pancreatic beta cell function, following only four weeks of treatment and to significantly lower HbA1c compared to active control, liraglutide, -3.5% vs -1.7%, respectively.
  - BMF-219 is the first investigational menin inhibitor in development to enter clinical trials for the improvement of glycemic control and insulin sensitivity in type 2 diabetes patients.
  - Completed the Phase I healthy volunteer portion of Phase I/II (COVALENT-111) study of BMF-219 in Canada. BMF-219 was well tolerated with a favorable pharmacokinetic and pharmacodynamic profile in healthy volunteers and with no safety signals detected.
  - Received FDA clearance in December 2022 to expand the Phase II portion of COVALENT-111 to sites in the U.S. and dosed the first diabetic patient in the U.S. in January 2023. Biomea continues to enroll type 2 diabetes patients in the Phase II portion of the study in the U.S. and Canada.

- In March 2023, Biomea reported initial clinical data from the first two cohorts of the Phase II portion of COVALENT-111, with initial data in its Cohort 3 (n=10 patients at 100 mg without food) showing 89% patients achieving a reduction in HbA1c, 78% of subjects achieving a ≥0.5% reduction in HbA1c and 56% achieving a ≥1.0% reduction in HbA1c (median and mean reduction over the cohort: -1.0% and -0.81%, respectively). BMF-219 demonstrated a well-tolerated safety profile with no dose discontinuations.
- **Anticipated Milestone in 2023:**
  - Further clinical updates at higher treatment doses expected including follow up on the initial dosing cohorts reported in the first quarter of 2023.

FUSION™ SYSTEM DISCOVERY PLATFORM

- Developed two covalently binding small molecules (BMF-219 and BMF-500), each within 18 months from target identification to IND candidate, leveraging the proprietary FUSION™ System Discovery Platform and showing promising preclinical profiles.
- **Anticipated Milestone in 2023:**
  - On track to announce a third development candidate from the FUSION™ platform in the first half of 2023.

FOURTH QUARTER AND FULL YEAR 2022 FINANCIAL RESULTS

- **Cash, Cash Equivalents, Restricted Cash, and Investments:** As of December 31, 2022, the Company had cash, cash equivalents, restricted cash, and investments of $113.4 million, compared to $175.7 million as of December 31, 2021.
- **Net Income/Loss:** Biomea reported a net loss attributable to common stockholders of $25.3 million for the three months ended December 31, 2022, compared to a net loss of $14.7 million for the same period in 2021. Net loss attributable to common stockholders was $81.8 million for the year ended December 31, 2022, compared to a net loss of $41.6 million for the same period in 2021.
- **Research and Development (R&D) Expenses:** R&D expenses were $20.5 million for the three months ended December 31, 2022, compared to $11.1 million for the same period in 2021. The increase of $9.5 million was primarily due to an increase in clinical and preclinical development costs as well as an increase in personnel-related expenses. R&D expenses were $62.7 million for the year ended December 31, 2022, compared to $28.0 million for the same period in 2021. The increase of $34.7 million was primarily due to an increase in personnel-related expenses, as well as an increase in clinical and preclinical development costs, including manufacturing and external consulting, related to the Company's product candidates, BMF-219 and BMF-500.
- **General and Administrative (G&A) Expenses:** G&A expenses were $5.7 million for the three months ended December 31, 2022, compared to $3.6 million for the same period in 2021. The increase of $2.1 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. G&A expenses were $20.9 million for the year ended December 31, 2022, compared to $13.7 million for the same period in 2021. The increase of $7.3 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.

About COVALENT-101

COVALENT-101 is a Phase I, open-label, multi-center, dose escalation and dose expansion study originally designed to assess the safety, tolerability, and pharmacokinetics/pharmacodynamics of oral dosing of BMF-219 in patients with R/R acute leukemias —including subpopulations where menin inhibition is expected to provide maximal therapeutic benefit (e.g., patients with MLL1/KMT2A gene rearrangements or NPM1 mutations), multiple myeloma (MM) and diffuse large B-cell lymphoma (DLBCL). The study design has now been expanded to include

a cohort for patients with R/R CLL. Additional information about the Phase I clinical trial of BMF-219 in genetically defined liquid tumors can be found at ClinicalTrials.gov using the identifier NCT05153330**.**

About COVALENT-102

COVALENT-102 is an open-label, multi-cohort, multicenter, Phase I/Ib dose finding study evaluating the safety, tolerability, and clinical activity of escalating doses of oral BMF-219 administered to patients with unresectable, locally advanced, or metastatic NSCLC, CRC, and PDAC with a KRAS mutation. Additional information about the Phase I/Ib clinical trial of BMF-219 in KRAS-mutant solid tumors can be found at ClinicalTrials.gov using the identifier NCT05631574**.**

About COVALENT-111

COVALENT-111 is a multi-site, randomized, double-blind, placebo-controlled Phase I/II study. In the completed Phase I portion of the trial, healthy subjects were enrolled in single ascending dose cohorts to ensure safety at the prospective dosing levels for type 2 diabetic patients. Phase II consists of multiple ascending dose cohorts and includes adult patients with type 2 diabetes uncontrolled by current therapies**.** Additional information about the Phase I/II clinical trial of BMF-219 in type 2 diabetes can be found at ClinicalTrials.gov using the identifier NCT05731544.

About Biomea Fusion

Biomea Fusion is a biopharmaceutical company focused on the discovery and development of covalent small molecules to treat patients with genetically defined cancers and metabolic diseases. A covalent small molecule is a synthetic compound that forms a permanent bond to its target protein and offers a number of potential advantages over conventional non-covalent 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 covalent-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 covalent 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 our cash runway, the clinical and therapeutic potential of our product candidates and development programs, including BMF-219 and BMF-500, the potential of BMF-500 as an FLT3 inhibitor, the potential of BMF-219 as a treatment for various types of cancer and diabetes, our research, development and regulatory plans, the progress of our ongoing clinical trials, including COVALENT-101, COVALENT-102 and our Phase I/II COVALENT-111 study of BMF-219 in type 2 diabetes, our plans to submit IND applications for BMF-500 in patients with FLT3 mutations, our plans to provide clinical updates on the healthy volunteer section of our Phase I/II type 2 diabetes study of BMF-219, BMF-219 in type 2 diabetes patients, and patients in the COVALENT-101 study, our plans to announce a third development candidate from the FUSION platform, and the timing of such events, 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 preclinical or clinical development, the preparation,

filing and clearance of INDs, patient enrollment and in the initiation, conduct and completion of our ongoing and planned clinical trials and other research and development activities. These risks concerning Biomea Fusion's business and operations are described in additional detail in its periodic filings with the U.S. Securities and Exchange Commission (the "SEC"), including its most recent periodic 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,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development [1]	$ 20,539	$ 11,088	$ 62,713	$ 27,996
General and administrative [1]	5,737	3,649	20,921	13,671
Total operating expenses	26,276	14,737	83,634	41,667
Loss from operations	(26,276)	(14,737)	(83,634)	(41,667)
Interest and other income, net	962	27	1,806	100
Net loss	$ (25,314)	$ (14,710)	$ (81,828)	$ (41,567)
Other comprehensive loss:				
Unrealized gain (loss) on investments, net	12	(12)	9	(10)
Comprehensive loss	$ (25,302)	$ (14,722)	$ (81,819)	$ (41,577)
Net loss per common share, basic and diluted	(0.86)	(0.51)	(2.80)	(1.74)
Weighted-average number of shares used to compute basic and diluted net loss per common share	29,441,596	29,061,076	29,271,777	23,858,552

[1] Includes stock-based compensation as follows:

	Three Months Ended December 31,		Year Ended December 31,	
	2022	**2021**	**2022**	**2021**
Research and development	$ 1,227	$ 947	$ 4,678	$ 2,637
General and administrative	1,489	984	5,658	3,597
Total stock-based compensation expense	$ 2,716	$ 1,931	$ 10,336	$ 6,234

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

	December 31, 2022	December 31, 2021
Cash, cash equivalents, investments, and restricted cash	$ 113,400	$ 175,743
Working capital	98,718	171,924
Total assets	129,307	185,705
Stockholders' equity	108,539	178,783