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): July 24, 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 8.01 Other Events.

On July 24, 2023, Biomea Fusion, Inc. (the "Company") issued a press release titled, "BMF-219 Induces Complete Responses in Target Acute Myeloid Leukemia (AML) Patient Population." A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

Forward Looking Statements

This Current Report on Form 8-K and certain of the materials filed or furnished herewith contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding the Offering, and expectations regarding the Company's cash runway, use of capital, expenses and other future financial results. The words "may," "might," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "expect," "estimate," "seek," "predict," "future," "project," "potential," "continue," "target" and similar words or expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements, such as those related to the clinical and therapeutic potential of the Company's product candidates, and development programs, including BMF-219, the potential of BMF-219 as a treatment for various types of cancer and diabetes, the Company's research, development and regulatory plans, including its pursuit of BMF-219 in metabolic diseases, the Company's plans to continue the evaluation of BMF-219 in various types of cancer in the Company's COVALENT-101 study, the progress of the Company's ongoing COVALENT-101 clinical trial, the availability of future data from the study, and the timing of such events are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this Current Report on Form 8-K or the materials furnished or filed herewith, including, without limitation, uncertainties related to the risks that initial results may not be indicative of final results in later clinical trials, the Company may encounter delays or unforeseen results in preclinical development, IND-filing and acceptance, patient enrollment and in the initiation, conduct and completion of its ongoing and planned clinical trials and other research, development and regulatory activities. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in the Company's most recent Annual Report on Form 10-K or Quarterly Report on Form 10-Q, as well as any subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent the Company's views only as of today and should not be relied upon as representing its views as of any subsequent date. The Company explicitly disclaims any obligation to update any forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release titled "BMF-219 Induces Complete Responses in Target Acute Myeloid Leukemia (AML) Patient Population" issued by Biomea Fusion, Inc. on July 24, 2023.
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: July 25, 2023

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

Exhibit 99.1

BMF-219 Induces Complete Responses in Target Acute Myeloid Leukemia (AML) Patient Population

- Initial topline data from COVALENT-101 trial revealed 2 complete responses (CRs) out of 5 relapsed/refractory AML patients carrying menin-dependent mutations treated at Dose Level 4
- Dose Level 4 exposure correlates with initial activity seen in BMF-219's pre-clinical studies
- Safety profile of BMF-219 supports further dose escalation; enrollment for Dose Level 5 has commenced to explore the optimal biological dose
- BMF-219, the first and only investigational covalent small-molecule menin inhibitor in clinical development, was generally well tolerated with no dose-limiting toxicities observed, and no QTc prolongation reported
- Company to submit additional details of this clinical data set at an upcoming medical conference

REDWOOD CITY, Calif., July 24, 2023 (GLOBE NEWSWIRE) – Biomea Fusion, Inc. ("Biomea") (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, today announced preliminary topline data from its ongoing Phase I clinical trial, COVALENT-101, showcasing initial responses in relapsed/refractory AML patients with menin-dependent mutations.

In the COVALENT-101 study, BMF-219 is orally administered on a daily schedule in continuous 28-day cycles. The preliminary analysis as of July 13, 2023 of Dose Level 4 [500 mg once daily (non-CYP3A4 inhibitor arm) and 125 mg once daily (CYP3A4 inhibitor arm), both producing comparable exposures] showed CRs in 2 of 5 AML patients with known menin-dependent mutations (KMT2Ar/MLL1r, 1 patient; NPM1, 2-patients; MLL-PTD, 1-patient; and NUP98 fusion, 1-patient). These relapsed/refractory patients had a range of prior therapies (1 to 8) and two complete responses (1 CR, 1 CRi) were observed within the first two 28-day treatment cycles with BMF-219. Patients were previously treated with standard-of-care and investigational therapies including allogeneic bone marrow transplant. Both patients who achieved CRs continue on BMF-219 treatment. Dose Level 4 is the first dose level which focused primarily on enrolling patients with known menin-dependent mutations.

BMF-219 has been generally well tolerated with no QTc prolongation reported. At the time of this analysis, a total of 20 AML patients have received BMF-219 during the dose escalation portion of the COVALENT-101 study. Initially, patients were enrolled agnostic to mutational status; subsequently, the study protocol was amended to enrich for patients with AML harboring menin-dependent mutations.

Dose Level 4 was cleared with no dose-limiting toxicities observed, allowing for the continuation of dose escalation. Enrollment for Dose Level 5 has commenced to further optimize and explore the potential to improve upon these preliminary results. Completion of the dose escalation for the acute leukemia cohort is anticipated later this year. Biomea is planning to present additional clinical data from the COVALENT-101 study at an upcoming scientific conference, including comprehensive results from the acute leukemia patients dosed during the escalation phase.

“We are very excited to share these early findings confirming that our targeted, covalently binding menin inhibitor, BMF-219, can elicit profound and rapid responses in patients with menin inhibitor-sensitive acute leukemia even at this dose level, which we believe we can further build on,” said Steve Morris, MD, Biomea’s Chief Medical Officer. “Notably these complete remissions were achieved within the first two cycles of BMF-219 therapy in relapsed/refractory AML patients who had limited therapeutic options and an overall poor prognosis. We are continuing to dose escalate and are looking forward to identifying the recommended Phase 2 dose within the next several months.”

About BMF-219

BMF-219 is a covalently binding inhibitor of menin, a protein known to play an essential role in oncogenic signaling in genetically defined leukemias as well as in diabetes. Preclinically, BMF-219 has demonstrated in well-established acute leukemia cell lines robust downregulation of key leukemogenic genes in addition to menin itself. Additionally, BMF-219 has shown anticancer efficacy in multiple in vitro, in vivo, and ex vivo models of acute leukemia, multiple myeloma, diffuse large B-cell lymphoma and chronic lymphocytic leukemia. BMF-219 is currently being evaluated in first-in-human clinical trials enrolling patients with specific menin-dependent mutations in liquid and solid tumors as well as patients with diabetes.

About COVALENT-101

COVALENT-101 is a Phase I, open-label, multi-center, dose-escalation and dose-expansion study designed to assess the safety, tolerability, and pharmacokinetics/pharmacodynamics of oral dosing of BMF-219 in patients with relapsed/refractory (R/R) acute leukemias —including subpopulations where menin inhibition is expected to provide therapeutic benefit (e.g., patients with MLL1/KMT2A gene rearrangements or NPM1 mutations). The study is designed to enroll subsets of acute leukemia patients who are receiving a CYP3A4 inhibitor and also those not receiving a CYP3A4 inhibitor. COVALENT-101 is also investigating the dosing of BMF-219 in other patient populations where preclinical studies have shown high menin

dependence, such as multiple myeloma, diffuse large B-cell lymphoma, and chronic lymphocytic leukemia. Additional information about this Phase I clinical trial of BMF-219 can be found at ClinicalTrials.gov using the identifier NCT05153330.

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 spleen, central nervous system, and other organs. 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 is roughly 29%. Among patients with relapsed/refractory disease, the need is greatest, as the overall survival is only approximately 3 to 9 months. It is estimated that upwards of 45% of AML patients have menin-dependent genetic drivers (MLL1-r, NPM1 mutant, and certain additional less common but recurrent gene mutations).

About Biomea Fusion

Biomea Fusion is a clinical stage 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.

We are utilizing our proprietary FUSION™ System to discover, design and develop a pipeline of next-generation covalent-binding small molecule medicines designed to maximize clinical benefit for patients with various cancers and metabolic diseases, including diabetes. We aim to have an outsized impact on the treatment of those diseases for the patients we serve. We aim to cure.

Visit us at biomeafusion.com and follow us on LinkedIn, Twitter and Facebook.

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 pursuit of BMF-219 in metabolic diseases, our plans to continue the evaluation of BMF-219 in various types of cancer in our COVALENT-101 study, the progress of our ongoing COVALENT-101 clinical trial, the availability of future data from the study, 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.

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