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): June 6, 2024

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 June 6, 2024, Biomea Fusion, Inc. (the "Company") issued a press release titled, "Biomea Fusion Announces BMF-219 in Diabetes Placed on Clinical Hold." 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

Statements made or incorporated by reference in this Current Report on Form 8-K 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 the Company's product candidates and development programs, including BMF-219, the potential of BMF-219 as a treatment for type 2 and type 1 diabetes, the Company's research, development and regulatory plans, the progress of the Company's ongoing and planned clinical trials, including COVALENT-111 and COVALENT 112, the Company's plans to address the matters raised in the FDA's clinical hold letter, the Company's ability to resolve the clinical hold on a timely basis, or at all, the availability of data from the Company's clinical trials and the timing of such events, may be deemed to be forward-looking statements. The Company intends 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 is making this statement for purposes of complying with those safe harbor provisions.

Any forward-looking statements made or incorporated by reference in this Current Report on Form 8-K are based on the Company's current expectations, estimates and projections only as of the date of this Current Report on Form 8-K 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 the Company may encounter delays in patient enrollment and in the initiation, conduct and completion of its planned clinical trials and other research and development activities. These risks concerning the Company'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. The Company explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release titled "Biomea Fusion Announces BMF-219 in Diabetes Placed on Clinical Hold" issued by Biomea Fusion, Inc. on June 6, 2024.
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: June 7, 2024

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

Exhibit 99.1

Biomea Fusion Announces BMF-219 in Diabetes Placed on Clinical Hold

REDWOOD CITY, Calif., June 6, 2024 (GLOBE NEWSWIRE) — Biomea Fusion, Inc. ("Biomea" or the "Company") (Nasdaq: BMEA), announced that the Company has received notice from the U.S. Food and Drug Administration (FDA) that a full clinical hold has been placed on Biomea's ongoing Phase I/II clinical trials of the Company's investigational covalent menin inhibitor BMF-219 in type 2 and type 1 diabetes (COVALENT-111 and COVALENT-112), respectively. The Company will continue ongoing safety and efficacy data collection during the hold.

"We respect the FDA's decision and agree that patient safety is paramount and our top priority. We are fully collaborating and working diligently with the FDA to put a plan in place as quickly as possible to ensure patient safety and look forward to resuming the studies once we have authorization from the FDA. The results to date have supported that BMF-219 is generally well-tolerated and can restore glucose-controlled insulin production and improve glycemic control. Based on the totality of the safety and efficacy data for BMF-219 in diabetes to date, we remain committed to advancing BMF-219 with its potentially transformative profile," stated Thomas Butler, Biomea Fusion's Chief Executive Officer and Chairman of the Board.

The FDA cited deficiencies based on the level of possible drug-induced hepatotoxicity observed in the completed Dose Escalation Phase of COVALENT-111. During the Dose Escalation studies, higher doses (up to 400 mg), various food intake regimens, medical history and concomitant medications may have contributed to observed liver enzyme elevations. As previously reported, the majority of adverse events (AEs) have been mild to moderate in nature and no serious adverse reactions (SARs) have been reported to date with BMF-219 in COVALENT-111 and COVALENT-112.

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 patients were enrolled in single ascending dose cohorts to evaluate 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 standard of care medicines. Once the Escalation Phase of COVALENT-111 was completed, the study advanced into an Expansion Phase consisting of multiple cohorts dosing type 2 diabetes patients for longer dose durations. Additional information about this Phase I/II clinical trial of BMF-219 in type 2 diabetes can be found at ClinicalTrials.gov using the identifier NCT05731544.

About COVALENT-112

COVALENT-112 is a multi-site, randomized, double-blind, placebo-controlled Phase II study in adults with stage 3 type 1 diabetes. This stage describes the period following clinical diagnosis of type 1 diabetes when symptoms are present due to significant beta cell loss. COVALENT-112 will be a multi-arm trial comparing two different doses of BMF-219 to placebo (1:1:1) to evaluate the efficacy, safety, and durability of BMF-219 in adults with type 1 diabetes. Approximately 150 patients will be enrolled in the trial and will receive either BMF-219 or placebo over 12 weeks, followed by a 40-week off treatment period.

This trial also includes an open-label portion for adults with type 1 diabetes up to 15 years since diagnosis. The open-label portion (n=40) is examining the efficacy, safety, and durability of BMF-219 at two oral dose levels, 100 mg and 200 mg over 12-week treatment followed by a 40-week off treatment period.

Additional information about the Phase II clinical trial of BMF-219 in type 1 diabetes can be found at ClinicalTrials.gov using the identifier NCT06152042.

About Biomea Fusion

Biomea Fusion is a clinical stage biopharmaceutical company focused on the discovery and development of oral covalent small molecules to treat patients with metabolic diseases and genetically defined cancers. 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. We aim to have an outsized impact on the treatment of disease 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 type 2 and type 1 diabetes, our research, development and regulatory plans, the progress of our ongoing and planned clinical trials, including COVALENT-111 and COVALENT 112, our plans to address the matters raised in the FDA's clinical hold letter, our ability to resolve the clinical hold on a timely basis, or at all, the availability of data from our clinical trials 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, 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.

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