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): December 14, 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** **(Address of Principal Executive Offices)**	**94063** **(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 December 14, 2022, Biomea Fusion, Inc. (the "Company") issued a press release titled, "Biomea Fusion Announces FDA Clearance of Investigational New Drug (IND) Application for Covalent Menin Inhibitor BMF-219 in Type 2 Diabetes." A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and 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 Company's cash runway, 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 the Company's pursuit of BMF-219 in metabolic diseases, the Company's plans to continue the evaluation of BMF-219 for type 2 diabetes in its COVALENT-111 study, the availability of data from the Phase II portion of the study 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 or unforeseen results in preclinical development, IND-filing and acceptance, patient enrollment and in the initiation, conduct and completion of its planned clinical trials and other research, development and regulatory 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 FDA Clearance of Investigational New Drug (IND) Application for Covalent Menin Inhibitor BMF-219 in Type 2 Diabetes."
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: December 16, 2022

By: /s/ Thomas Butler

Thomas Butler
Principal Executive Officer

Exhibit 99.1

Biomea Fusion Announces FDA Clearance of Investigational New Drug (IND) Application for Covalent Menin Inhibitor BMF-219 in Type 2 Diabetes

- COVALENT-111, a Phase I/II clinical trial in patients with type 2 diabetes, already underway in Canada, will now activate sites in the US
- As previously reported, the Phase I portion of COVALENT-111 has been completed, with BMF-219 demonstrating a favorable safety, pharmacokinetics (PK) and pharmacodynamics (PD) profile
- Ongoing Phase II portion is evaluating BMF-219's long-term glycemic control by restoring the pool and health of beta cells in type 2 diabetes patients
- Initial data from the Phase II portion of the study is expected in the first half of 2023
- Company to host conference call on Thursday, December 15 at 4 PM EST featuring the BMF-219 clinical program in type 2 diabetes

REDWOOD CITY, Calif., December 14, 2022 (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 the U.S. Food and Drug Administration (FDA) has cleared Biomea's IND application for BMF-219 in type 2 diabetes to support the expansion of the COVALENT-111 study to sites in the U.S.

Biomea management will host a conference call on Thursday, December 15 at 4PM EST to provide an overview of the COVALENT-111 study, as well as further details on the role of menin in diabetes and BMF-219's potentially disease-modifying impact on beta cell health.

"We are excited to now clinically evaluate the impact that we have observed with BMF-219 in preclinical studies on the health of beta cells, which is critical to enabling patients with diabetes to naturally produce insulin. In animal models, BMF-219 has shown a very unique profile in preserving, reactivating and regenerating beta cells," said Dr. Steve Morris, Chief Medical Officer. "During my 40 years in medicine, I have not seen a more direct and elegant approach to addressing this root cause of diabetes."

“With this IND clearance for BMF-219, we have reached another critical milestone in our pursuit of providing an important new medicine to diabetes patients that addresses the underlying disease physiology. COVALENT-111 is a historic study, representing the first clinical evaluation of an orally administered, covalent small molecule directly targeting menin, a well-known regulator of beta cell homeostasis,” stated Thomas Butler, Biomea Fusion’s Chief Executive Officer and Chairman of the Board. “I would like to thank all involved for their considerable guidance and collaboration throughout the preparation and submission of this application. I would also like to especially thank, TEAM FUSION for their commitment and support in generating the first non-oncology IND package for BMF-219 in the US.”

Beta cell loss is a critical component of the etiology and pathogenesis of type 1 and type 2 diabetes; menin is thought to function as the brakes on beta cell recovery in the pancreas. BMF-219 was designed to specifically inhibit menin. Preclinical studies have shown the potential of BMF-219 to restore the health of functional beta cells.

Upcoming Webcast

A live webcast of Biomea’s virtual investor R&D event on Thursday, December 15th at 4:00 pm ET featuring the BMF-219 program in diabetes will be available to registered attendees under the Investors and Media section of the company’s website at https://investors.biomeafusion.com/news-events/events. A replay of the presentation will be archived on Biomea’s site for 14 days following the event.

Callers are encouraged to utilize the free webcast at https://investors.biomeafusion.com/news-events/events. Those who plan on participating in the Q&A or do not have internet available may access the call by dialing (844) 543-0451 (U.S. domestic) or +1 (213) 320-2545 (international).

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. BMF-219 was well tolerated and showed a favorable PK and PD profile. The ongoing Phase II portion consists of multiple ascending dose cohorts and includes adult patients with type 2 diabetes uncontrolled by current therapies. It is designed to examine the capacity of BMF-219 to provide long-term glycemic control by restoring the patient’s pool of beta cells.

About Menin in Diabetes

Loss of functional beta cell mass is a core component of the natural history in both types of diabetes — type 1 diabetes (mediated by autoimmune dysfunction) and type 2 diabetes (mediated by metabolic dysfunction). Beta cells are found in the pancreas and are responsible for the synthesis and secretion of insulin. Insulin is a hormone that helps

the body use glucose for energy and helps control blood glucose levels. In patients with diabetes, beta cell mass and function are diminished, leading to insufficient insulin secretion and hyperglycemia. Menin is thought to act as a brake on beta-cell turnover and growth, supporting the notion that inhibition of menin could lead to the regeneration of normal, healthy beta cells. Based on these and other scientific findings, Biomea is exploring the potential for BMF-219-mediated menin inhibition as a viable therapeutic approach to permanently halt or reverse progression of type 2 diabetes.

About Type 2 Diabetes

Diabetes is considered a chronic health condition that affects how the body turns food into energy and results in too much sugar in the bloodstream. Over time, this can cause serious health problems and damage vital organs. Most people with diabetes have a shorter life expectancy than people without this disease. The CDC estimates 1 in 3 Americans will develop diabetes at some point in their life. More than 37 million people of all ages (about 11% of the US population) have diabetes today. 96 million adults (more than 1 in 3) have pre-diabetes, blood sugars that are higher than normal but not high enough to be classified as diabetes. Diabetes is also one of the largest economic burdens on the United States' health care system with $1 out of every $4 in US health care costs being spent on caring for people with diabetes. Despite the availability of current medication, there is a significant need in the treatment and care of patients with diabetes.

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. 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 is a leader in advancing next-generation covalent small molecule medicines designed to maximize clinical benefit to treat 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, 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 for type 2 diabetes in our COVALENT-111 study, the availability of data from the Phase II portion of 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.

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 or unforeseen results in preclinical development, IND-filing and acceptance, patient enrollment and in the initiation, conduct and completion of our planned clinical trials and other research, development and regulatory 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:

Sasha Blaug
SVP Corporate Development
sb@biomeafusion.com
(650) 460-7759