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): October 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 October 14, 2022, Biomea Fusion, Inc. (the "Company") issued a press release titled, "BMF-219 Enters the Clinic for KRAS Solid Tumors." 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 KRAS solid tumors, 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 "BMF-219 Enters the Clinic for KRAS Solid Tumors."
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: October 18, 2022

By: /s/ Thomas Butler

Thomas Butler
Principal Executive Officer

Exhibit 99.1

BMF-219 Enters the Clinic for KRAS Solid Tumors

- Biomea Fusion announces FDA clearance of Investigational New Drug (IND) application for covalent menin inhibitor BMF-219 in KRAS solid tumors.
- Biomea Fusion will now initiate a Phase I/Ib clinical trial (COVALENT-102) of BMF-219 as a monotherapy in patients who have unresectable, locally advanced, or metastatic non-small cell lung cancer (NSCLC), colorectal cancer (CRC) or pancreatic ductal adenocarcinoma (PDAC) with a KRAS mutation.
- This Phase I/Ib clinical trial will expand BMF-219's clinical development to solid tumors; Biomea Fusion is currently underway with COVALENT-101, a Phase I clinical trial studying BMF-219 in multiple blood cancers.
- BMF-219 is the first menin inhibitor to enter clinical trials for the treatment of solid tumors.
- A targeted pan-KRAS inhibitor has the potential to treat 25-35% of NSCLC, 35-45% of CRC, and approximately 90% of PDAC patients.
- In a series of preclinical studies, BMF-219 showed strong and highly specific pan-KRAS anti-cancer activity as a single agent across KRAS G12C, G12D, G12V and G13D mutations including in NSCLC, CRC, and the most prevalent type of pancreatic cancer, PDAC.

REDWOOD CITY, Calif., October 14th, 2022 (GLOBE NEWSWIRE) — Biomea Fusion, Inc. ("Biomea") (Nasdaq: BMEA), a biopharmaceutical company focused on the discovery and development of covalent small molecules to treat patients with genetically defined cancers and metabolic diseases, today announced that the U.S. Food and Drug Administration (FDA) has cleared Biomea's IND application to begin a Phase I/Ib trial of BMF-219, a selective, covalent menin inhibitor in patients with unresectable, locally advanced, or metastatic NSCLC, CRC, and PDAC with an activating KRAS mutation.

"We are very excited to open this particular IND as we now look to validate the preclinical potential of BMF-219 in patients across several solid tumor types who have a KRAS mutation, which currently is associated with a very poor survival prognosis," said Thomas Butler, Biomea's CEO and Chairman of the Board. "In January 2022, we mapped out perhaps one of the more aggressive clinical development plans among peer companies to initiate clinical studies of BMF-219 in up to seven tumor types by the end of 2022. I am so incredibly proud of our team's extraordinary efforts to deliver on this plan, motivated by the persistent and significant unmet needs of numerous cancer patients."

Mr. Butler continued, "I would like to thank the FDA for their extraordinary effort clearing our IND on-time, and also our contract research organizations, our consultants, our investors, and of course TEAM FUSION for their commitment, guidance, and support in generating another broad and promising IND package for BMF-219."

KRAS is the most frequently mutated isoform amongst RAS oncogenes in human solid tumors, with high prevalence in NSCLC, CRC, and pancreatic cancer. With only one approved therapy targeting KRAS G12C for locally advanced or metastatic NSCLC, KRAS-driven tumors continue to represent a significant unmet medical need. A targeted pan-KRAS inhibitor has the potential to treat 25-35% of NSCLC, 35-45% of CRC, and approximately 90% of PDAC patients.

Menin is a scaffold protein and a required co-factor of oncogenic transcriptional proteins with functional interactions that are critical for the development of various cancers. As previously reported by Biomea Fusion, KRAS-mutant NSCLC, CRC, and PDAC cell lines and *ex vivo* preclinical models were highly sensitive to BMF-219. In preclinical models, high potency of BMF-219 was observed amongst various KRAS-mutant solid tumor cell lines, but not KRAS wild type, suggesting that BMF-219 broadly inhibited mutant KRAS in these tumor models. As a covalent menin inhibitor, BMF-219 has manifested advantages over the commercially KRAS-targeted inhibitor LUMIKRAS in multiple pre-clinical studies due to the independence of KRAS' phosphorylation state within G12C tumors, and more broadly the ability to target multiple activating KRAS mutations.

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.

About Non-Small Cell Lung Cancer (NSCLC)

NSCLC is the most common form of lung cancer, representing approximately 82% of all lung cancer cases or approximately 200,000 cases in the U.S. each year (Source: NCI SEER Data). Additionally, the five-year survival rate of NSCLC is approximately 25%. While lung cancer is the third most common form of cancer in the U.S. based on incidence, it contributes to the highest number of annual cancer deaths in the U.S. KRAS is the most frequently mutated oncogene in NSCLC, occurring in approximately 30% of patients. There remains a great unmet need for targeted therapies to address all KRAS driver mutations and avoid known mechanisms of resistance.

About Colorectal Cancer (CRC)

CRC is the fourth most common form of cancer and the second leading cause of cancer death in the U.S., representing approximately 150,000 cases in the U.S. each year (Source: NCI SEER Data). These cancers start in the rectum or the colon and can be diagnosed/identified early, even potentially as noncancerous polyps. The five-year survival rate of CRC is approximately 65%. Among other mutations, KRAS mutations occur in approximately 40% of patients with CRC. These mutations can not only help predict the absence of response to anti-EGFR therapy, but also result in poorer overall survival. Therefore, there's a growing unmet need for personalized therapies for patients with KRAS-mutant colorectal cancer.

About Pancreatic Cancer (PDAC)

Pancreatic cancer is a relatively rare form of cancer in the U.S., representing approximately 60,000 cases in the U.S. each year (Source: NCI SEER Data). Pancreatic cancer is an aggressive cancer with a very low five-year survival rate of approximately 11%, indicating that there is a large unmet need. 80% of patients are diagnosed at an advanced stage, contributing to the low survival rate. KRAS mutations are found in nearly all pancreatic cancer patients and are considered as a driver of the malignant process in most of those patients.

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'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

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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.

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