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): September 16, 2021

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.)**

726 Main Street **Redwood City, CA**	**94063**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 980-9099

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 per share	**BMEA**	**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 September 16, 2021, Biomea Fusion, Inc. (the "Company") announced that the U.S. Food and Drug Administration has cleared the Company's Investigational New Drug application to begin a Phase 1 trial of BMF-219, a selective irreversible menin inhibitor, in adult patients with relapsed or refractory acute leukemia, including those with an MLL/KM2TA gene rearrangement or NPM1 mutation.

A copy of the press release with the foregoing announcement is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated September 16, 2021
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

BIOMEA FUSION, INC.

Date: September 17, 2021

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

Exhibit 99.1

Biomea Fusion Announces FDA Clearance of Investigational New Drug Application for Irreversible Menin Inhibitor BMF-219

- Biomea Fusion to transform to a Clinical Stage Company with First in Human (FIH) Clinical Trial
- BMF-219 advances as the first clinical stage therapeutic from the company's deep pipeline of covalent irreversible small molecules
- BMF-219 is a novel, first-in-class, irreversible menin inhibitor designed to control menin's negative impact across several indications
- FIH Study will initially enroll patients with relapsed/refractory acute leukemia, with additional indications planned
- Despite novel agents in the clinic and commercial settings, acute leukemia remains a significant unmet need due to the aggressive, heterogenous nature of the disease

REDWOOD CITY, Calif., Sept. 16, 2021 (GLOBE NEWSWIRE) — Biomea Fusion, Inc. ("Biomea") (Nasdaq: BMEA), a biopharmaceutical company focused on the discovery and development of irreversible small molecules to treat patients with genetically defined cancers, today announced that the U.S. Food and Drug Administration (FDA) has cleared the company's Investigational New Drug application to begin a Phase I trial of BMF-219, a selective irreversible menin inhibitor, in adult patients with relapsed or refractory acute leukemia including those with an MLL/KM2TA gene rearrangement or NPM1 mutation.

"First of all, I would like to take this opportunity to thank the FDA, the Contract Research Organizations, our consultants, our investors, and of course TEAM FUSION for the commitment, guidance, support, and tireless effort in getting BMF-219, an investigational new drug, in the hands of patients in need. It was a true community effort, and we are so blessed here at Biomea to be in position to provide an impactful therapy against aggressive cancers," said Thomas Butler, Biomea's CEO and Chairman of the Board. "This is just the beginning for BMF-219 as we are planning to pursue multiple indications with our novel molecule. This is also just the beginning for the company, as we continue to make significant progress with our pipeline programs. We are in a strong position to continue to bring novel small molecules into the clinic and help the many patients with life threatening and life altering diseases."

"Over the past 6 months, we have brought together a first-class team of biotech professionals to tackle our next phase of growth, which will include clinical development of BMF-219 in not only liquid but also solid tumors," said Ramses Erdtmann, Biomea's COO and President. "BMF-219 is a very special compound, with a unique effect on menin which we believe will lead to improved outcomes for patients with specific gene arrangement and mutations."

An irreversible small molecule, such as BMF-219, is a synthetic compound that forms a permanent bond to its target protein and offers a number of potential advantages over conventional reversible drugs, including greater target selectivity, lower drug exposure, and the ability to drive a deeper, more durable response.

The Phase 1, first-in-human, open-label, dose-escalation and dose-expansion clinical trial of BMF-219 will assess the safety, pharmacokinetic (PK) and pharmacodynamic (PD) profile of BMF-219 in adult patients with relapsed or refractory acute leukemia including those with an MLL/KM2TA gene rearrangement or NPM1 mutation.

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 lymph nodes, spleen, and central nervous system. 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 roughly 29%. Among patients with relapsed/refractory disease, the need is greatest, as the overall survival is approximately 3 to 9 months. It is estimated that upwards of 45% of AML patients have menin dependent genetic drivers (MML-r or NPM1).

About BMF-219

BMF-219 is an irreversibly binding inhibitor of menin, a protein that is known to play an essential role in oncogenic signaling in genetically defined leukemias. Preclinically, BMF-219 has demonstrated robust downregulation of key leukemogenic genes in addition to menin itself (via MEN1) in well-established MLLr AML cell lines. Additionally, BMF-219 has shown efficacy in multiple *in vivo* and *in vitro* models of acute leukemias. BMF-219 will be evaluated in a first-in-human trial in patients with relapsed or refractory acute leukemia with MLL/KM2TA gene rearrangement or NPM1 mutation.

About Biomea Fusion

Biomea Fusion is a biopharmaceutical company focused on the discovery, development and commercialization of irreversible small molecules to treat patients with genetically defined cancers. An irreversible small molecule is a synthetic compound that forms a permanent bond to its target protein and offers a number of potential advantages over conventional reversible 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 discovery platform to advance a pipeline of irreversible treatments against key oncogenic drivers of cancer. Biomea Fusion’s goal is to utilize its capabilities and platform to become a leader in developing irreversible small molecules in order to maximize the depth and durability of clinical benefit when treating various cancers.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding the potential safety, efficacy, and continued development of BMF-219, the timing for commencing the first in human clinical trial, the potential therapeutic indications of the Company’s products candidates, including BMF-219, the building out our proprietary irreversible platform and progress made in early-stage small pipeline molecules through their preclinical development. These statements often include words such as “believe,” “expect,” “anticipate,” “intend,” “plan,” “estimate,” “seek,” “will,” “may,” or similar expressions. Forward-looking statements are subject to a number of risks and uncertainties, many of which involve factors or circumstances that are beyond the Company’s control. Any forward-looking statements in this statement are based on management’s current expectations of future events 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. Risks that contribute to the uncertain nature of the forward-looking statements include: the success, cost, and timing of the Company’s product candidate development activities and pre-clinical studies and clinical trials, the Company’s ability to execute on its strategy, regulatory developments in the United States, the Company’s ability to fund operations, and the impact that the current COVID-19 pandemic will have on the Company’s clinical trials and pre-clinical studies, supply chain, and operations, as well as those risks and uncertainties set forth in the Company’s Quarterly Report on Form Q for the quarter ended June 30, 2021, filed with the Securities and Exchange Commission on August 11, 2021, and its other filings filed with the United States Securities and Exchange Commission filed from time. Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee that the events and circumstances reflected in the forward-looking statements will be achieved or occur, and the timing of events and circumstances and actual results could differ materially from those projected in the forward-looking statements. Accordingly, you should not place undue reliance on these forward-looking statements. All forward-looking statements contained in this press release speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Contact:

Van Sandwick
Director, Investor Relations & Corporate Development
vsandwick@biomeafusion.com
(650) 460-7759