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 30, 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 2.02 Results of Operations and Financial Condition.

On October 30, 2023, Biomea Fusion, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2023. The full text of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02 of this Form 8-K and the Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1	Press release dated October 30, 2023, furnished herewith.
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 30, 2023

By: /s/ Thomas Butler

Thomas Butler
Principal Executive Officer

Exhibit 99.1

Biomea Fusion Reports Third Quarter 2023 Financial Results and Corporate Highlights

- Demonstrated durable HbA1c lowering in the escalation portion of ongoing Phase II study in type 2 diabetes (COVALENT-111), with 84% of all patients showing a reduction of HbA1c after 4 weeks dosing and 74% after another 8 weeks off-treatment period
- Expansion portion of COVALENT-111 cleared and actively enrolling in the U.S. and Canada; expected to enroll approximately 200 adults with type 2 diabetes
- Investigational new drug (IND) application cleared for Phase II clinical trial of BMF-219 in type 1 diabetes (COVALENT-112); enrollment of 150 adults with type 1 diabetes anticipated to begin in Q4 2023
- Dosed first relapsed/refractory AML patient with BMF-500, Biomea's novel third generation investigational oral covalent inhibitor of FMS-like tyrosine kinase 3 (FLT3)
- Reported initial topline data of BMF-219 in ongoing Phase I clinical trial (COVALENT-101), showing 2 complete responses (CRs) out of 5 relapsed/refractory AML patients with menin-dependent mutations at Dose Level 4, with encouraging tolerability and safety data
- Announced the appointment of Juan Pablo Frías, M.D., a prominent diabetes clinical development expert as Chief Medical Officer to oversee Biomea's progressing clinical development of novel covalent menin inhibitor BMF-219 in type 2 and type 1 diabetes
- Cash position of $199.5 million at the end of the third quarter of 2023

REDWOOD CITY, Calif., Oct 30, 2023 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. ("Biomea" or "the Company") (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, reported third quarter 2023 financial results and business highlights.

"With the disease modifying potential demonstrated by BMF-219, we are excited to begin the expansion portion of COVALENT-111 in type 2 diabetes, and to initiate the evaluation of BMF-219's impact in type 1 diabetes with our COVALENT-112 study. Both studies are now open for enrollment more than a quarter ahead of schedule. With the potential to enable patients to retain and regenerate their own insulin-producing beta cells, BMF-219 may represent a promising new approach, if ultimately approved. We believe BMF-219 has the potential to halt and reverse disease progression for people with both type 1 and type 2 diabetes, enabling them to improve glycemic control while being off therapy and avoid insulin dependency," said Thomas Butler, CEO and Chairman of Biomea. "In the third quarter, we also announced the first clinical data of BMF-219 in relapsed/refractory AML patients with menin-dependent mutations, which we believe yield encouraging efficacy and safety data. Finally in this quarter, we also initiated the clinical study of our second, Biomea-discovered investigational covalent inhibitor, BMF-500, a novel FLT3 inhibitor. We look forward to reporting on our pipeline progress in both diabetes and oncology in the upcoming quarters."

THIRD QUARTER 2023 CLINICAL AND REGULATORY HIGHLIGHTS

DIABETES

- **COVALENT-111 (BMF-219 for Type 2 Diabetes)**
  - BMF-219 is an investigational diabetes therapy that in an early clinical trial has shown promising blood glucose control in adults with uncontrolled type 2 diabetes at Week 12, after 4 weeks dosing and 8 weeks off treatment.

- During the escalation phase of COVALENT-111, a total of 32 type 2 diabetes patients completed 4-weeks of dosing with BMF-219 to date (10 active patients per arm, with dose levels 100 mg with food, 100 mg, 200 mg and 200 mg with food (n=2)). Compared to baseline, 84% of all patients dosed for four weeks with BMF-219 showed a reduction in HbA1c at Week 4 and 74% at Week 12 (n=32), two months after the final dose of BMF-219. During the 4-week dosing period, BMF-219 was generally well tolerated; there were no dose reductions, dose discontinuations, or severe or serious adverse events. Also, during the off-treatment period, no severe or serious treatment emergent adverse events were noted.
- FDA and Health Canada cleared the initiation of the expansion portion of COVALENT-111, which will evaluate BMF-219 administered at 100 mg and 200 mg, with dosing durations up to 12 weeks in approximately 200 type 2 diabetes patients.
- **Anticipated Upcoming Milestones:**
  - Report topline data for the escalation portion in Q4 2023 to include multiple BMF-219 dosing cohorts (n=10 per cohort: 50 mg, 100 mg, 200 mg, 100 mg BID, 100 mg with food, and 200 mg with food (n=2)).
  - Start enrollment of expansion portion of COVALENT-111 at two dose levels including 100 mg and 200 mg, with a fourth cohort following the completion of the escalation portion.

- **COVALENT-112 (BMF-219 for Type 1 Diabetes)**
  - BMF-219 has shown the potential to specifically regenerate and retain insulin-producing beta cells in preclinical studies.
  - Announced FDA clearance of IND for Phase II study COVALENT-112 of BMF-219 in type 1 diabetes. The study is designed to enroll 150 adults with type 1 diabetes and examine the safety and efficacy of BMF-219 at two oral dose levels, 100 mg and 200 mg, for 12 weeks of treatment followed by a 40 week off-treatment period.
  - **Anticipated Upcoming Milestones:**
    - Dose the first patient in COVALENT-112.

ONCOLOGY

- **COVALENT-101 (BMF-219 for Oncology)**
  - Reported initial topline data from ongoing Phase I clinical trial (COVALENT-101) which showcased initial responses in relapsed/refractory AML patients with menin-dependent mutations.
    - New data revealed 2 CRs out of 5 pretreated patients with relapsed/refractory AML patients carrying menin-dependent mutations (MLL1r, NMP1, MLL1-PTD, and NUP98 fusion) treated at Dose Level 4.
    - 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 related QTc prolongation reported.
  - Continued site activation and patient enrollment to establish optimal dose levels across four liquid tumor cohorts including patients with AML/ALL, DLBCL, MM and CLL.
  - **Anticipated Upcoming Milestones:**
    - Report additional details of the clinical data set of AML/ALL patients dosed in the COVALENT-101 study at an upcoming medical conference.

- **COVALENT-102 (BMF-219 for KRAS-Mutant Solid Tumors)**
  - BMF-219 is the first investigational menin inhibitor in clinical development for the treatment of solid tumors; as a pan-KRAS inhibitor BMF-219 is under evaluation in subsets of NSCLC, CRC, and PDAC patients.

- Continued site activation and patient enrollment to establish optimal dose levels across all three solid tumor indications (NSCLC, CRC and PDAC with an activating KRAS mutation).

- **COVALENT-103 (BMF-500 for Acute Leukemias)**
  - Dosed first patient with BMF-500, a novel investigational third generation oral covalent inhibitor of FLT3 and the second product candidate discovered and developed by Biomea's proprietary FUSION™ System.

FUSION™ SYSTEM PLATFORM / ONGOING EFFORTS

- Continued to advance development candidates derived from Biomea's proprietary FUSION™ System platform to discover novel covalently binding small molecules. Both BMF-219 and BMF-500 were discovered via the FUSION™ System, each within 18 months from target identification to IND candidate selection.

THIRD QUARTER 2023 FINANCIAL RESULTS

- **Cash, Cash Equivalents, Restricted Cash, and Investments:** As of September 30, 2023, the Company had cash, cash equivalents, restricted cash, and investments of $199.5 million, compared to $113.4 million as of December 31, 2022.
- **Net Income/Loss:** Biomea reported a net loss attributable to common stockholders of $28.4 million for the three months ended September 30, 2023, compared to a net loss of $22.9 million for the same period in 2022. Net loss attributable to common stockholders was $82.4 million for the nine months ended September 30, 2023, compared to a net loss of $56.5 million for the same period in 2022.
- **Research and Development (R&D) Expenses:** R&D expenses were $25.3 million for the three months ended September 30, 2023, compared to $18.2 million for the same period in 2022. The increase of $7.1 million was primarily due to an increase clinical development cost and external consulting related to the Company's product candidates, BMF-219 and BMF-500, as well as increase in personnel-related costs. R&D expenses were $71.7 million for the nine months ended September 30, 2023 compared to $42.2 million for the same period in 2022. The increase of $29.5 million was primarily due to an increase personnel-related costs as well as an increase in clinical development and manufacturing costs related to the Company's product candidates, BMF-219 and BMF-500.
- **General and Administrative (G&A) Expenses:** G&A expenses were $5.8 million for the three months ended September 30, 2023, compared to $5.2 million for the same period in 2022. G&A expenses were $17.1 million for the nine months ended September 30, 2023 compared to $15.2 million for the same period in 2022. The increase in both periods was primarily due to increased personnel-related expenses, including stock-based compensation, due to an increase in headcount.

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 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 our cash runway, the clinical and therapeutic potential of our product candidates and development programs, including BMF-219 and BMF-500, the potential of BMF-500 as an FLT3 inhibitor and as a treatment for various types of cancers, the potential of BMF-219 as a treatment for various types of cancer and type 1 and type 2 diabetes, our research, development and regulatory plans, the progress of our ongoing and planned clinical trials, including COVALENT-101, COVALENT-102, COVALENT-103, our Phase I/II COVALENT-111 study of BMF-219 in type 2 diabetes and our Phase II COVALENT-112 study of BMF-219 in type 1 diabetes, our plans to provide clinical updates on additional data from the initial dosing cohorts in COVALENT-111, our plans to provide future data from the Phase II portion of COVALENT-111, complete dose escalation, identify optimal dose levels, initiate dose expansion, our plans to explore longer duration of treatment and additional dosage forms and our plans to explore the potential utility of BMF-219 in type 1 diabetes, and our plans to initiate and dose the first patient in COVALENT-112, our plans to advance and announce additional development candidates from the FUSION platform, 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, the preparation, filing and clearance of INDs, 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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- See attached for financial tables -

BIOMEA FUSION, INC.
Condensed Statement of Operations
(Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development [1]	$ 25,347	$ 18,242	$ 71,680	$ 42,174
General and administrative [1]	5,772	5,242	17,127	15,184
Total operating expenses	31,119	23,484	88,807	57,358
Loss from operations	(31,119)	(23,484)	(88,807)	(57,358)
Interest and other income, net	2,690	594	6,436	844
Net loss	$ (28,429)	$ (22,890)	$ (82,371)	$ (56,514)
Other comprehensive loss:				
Unrealized gain (loss) on investments, net	—	4	—	(3)
Comprehensive loss	$ (28,429)	$ (22,886)	$ (82,371)	$ (56,517)
Net loss per common share, basic and diluted	$ (0.80)	$ (0.78)	$ (2.46)	$ (1.93)
Weighted-average number of shares used to compute basic and diluted net loss per common share	35,653,988	29,319,042	33,551,808	29,214,549

[1] Includes stock-based compensation as follows (non-cash operating expenses):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Research and development	$ 1,778	$ 1,186	$ 4,902	$ 3,451
General and administrative	1,820	1,545	5,365	4,169
Total stock-based compensation expense	$ 3,598	$ 2,731	$ 10,267	$ 7,620

BIOMEA FUSION, INC.
Condensed Balance Sheet Data
(Unaudited)
(in thousands)

	September 30, 2023	December 31, 2022
Cash, cash equivalents, investments, and restricted cash	$ 199,459	$ 113,400
Working capital	186,294	98,718
Total assets	225,087	129,307
Stockholders' equity	199,612	108,539