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): July 31, 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 July 31, 2023, Biomea Fusion, Inc. issued a press release announcing its financial results for the quarter ended June 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 July 31, 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: July 31, 2023

By: /s/ Thomas Butler

Thomas Butler
Principal Executive Officer

Exhibit 99.1

Biomea Fusion Reports Second Quarter 2023 Financial Results and Corporate Highlights

- Reported additional positive clinical data at ADA 83rd Scientific Sessions from the first two cohorts of patients with type 2 diabetes from ongoing Phase I/II study (COVALENT-111) evaluating BMF-219 as a novel, potentially disease-modifying treatment candidate for patients with type 2 diabetes
    - New data highlighted specific patients treated with BMF-219 for 4 weeks maintained or experienced a further decrease in HbA1c levels 8 weeks after treatment was completed, up to a 2.4% reduction from baseline
    - BMF-219's mechanism of action is to enable the proliferation, preservation, and reactivation of a patient's own healthy, functional, insulin-producing beta cells
    - As the potentially first disease-modifying therapy for type 2 diabetes, BMF-219 could be an important addition and complement to the treatment landscape, if approved
- Reported initial topline data from ongoing Phase I clinical trial (COVALENT-101) showcasing initial responses in relapsed/refractory Acute Myeloid Leukemia (AML)
    - New data revealed 2 complete responses (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 enrolling four liquid tumor cohorts in ongoing Phase I study of BMF-219 (COVALENT-101), and three KRAS-mutated solid tumors in ongoing Phase I study of BMF-219 (COVALENT-102)
- Continued advancing second product candidate, BMF-500, a novel third generation covalent inhibitor of fms-like tyrosine kinase 3 (FLT3), toward the clinic; initiated a Phase I study of BMF-500 (COVALENT-103)
- Cash position of $223.3 million at the end of the second quarter of 2023

REDWOOD CITY, Calif., July 31, 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 second quarter 2023 financial results and business highlights.

"At the American Diabetes Association Annual Meeting in June, data presented from the COVALENT-111 study demonstrated for the first time how our investigational agent, BMF-219, may control blood glucose for diabetes patients 8 weeks after treatment had been completed," said Thomas Butler, CEO and Chairman of Biomea. "The loss of mass and function of beta cells is an underlying cause of type 2 diabetes. We have now demonstrated from our clinical data to date, that inhibiting menin with BMF-219, may represent a new and important mechanism of action with lasting benefits for patients with type 2 diabetes. Our goal at Biomea is to develop a treatment that can halt or reverse disease progression in patients with type 1 and type 2 diabetes. A restored pool of healthy beta cells may allow patients to increase insulin production and achieve glycemic control while being off therapy. Our aspiration with BMF-219 is to help millions of type 2 diabetes patients break free from the current treatment paradigm in which, regardless of which currently approved treatments they take, their disease generally continues to progress."

Mr. Butler further explained, "An orally delivered drug that, if approved, could restore healthy, functional, insulin-producing beta cells in type 2 diabetes patients would become a critical complement to nearly any currently

approved therapies and, over time, could become an important standalone treatment. We look forward to continuing to evaluate BMF-219's proposed mechanism of action and its potential therapeutic impact as this study progresses. Momentum for our diabetes program continues to build rapidly as the team executes at a high level. Our oncology programs are also gaining momentum as we approach target exposure in COVALENT-101 and COVALENT-102, our blood cancer and solid tumor studies."

Second Quarter 2023 Clinical and Regulatory Highlights

DIABETES

- **COVALENT-111 (BMF-219 for Diabetes)**
  - BMF-219 is an investigational diabetes therapy that is aimed at reversing disease progression in patients with Type 1 or Type 2 Diabetes.
  - Reported new clinical data from the first two cohorts of the ongoing Phase II study (COVALENT-111) at the American Diabetes Association (ADA) 83rd Scientific Sessions. Patients received BMF-219 in each cohort for four weeks with or without food and were then followed for 22 weeks after treatment (n=12 per cohort with 10 patients receiving 100 mg BMF-219 once daily and 2 patients receiving placebo). As reported, eight weeks after completing treatment with BMF-219, patients with type 2 diabetes showed an increase of C-peptide and an improvement of HOMA-B, measured during oral glucose tolerance testing (OGTT), supporting improved beta cell function for these patients.
    - For Cohort 3 (100 mg BMF-219 QD without food for 4 weeks)
      - 50% of patients (n=5/10) saw a continued improvement in HbA1c with a mean reduction in HbA1c of 1.49% at Week 12, compared to the mean reduction of 0.9% at the end of the dosing period at Week 4 (an additional 62% HbA1c reduction)
      - 60% (n=6/10) of patients achieved an HbA1c of 7% or below at the end of Week 12, compared to 30% (n=3/10) at the end of dosing period (Week 4) and 10% (n=1/10) at the end of Week 1
      - The average C-peptide expression for patients in Cohort 3 increased through Week 8. A similar increase in HOMA-B was observed, stabilizing at Week 8
      - As measured by continuous glucose monitoring (CGM), 7 of 10 (70%) of patients maintained or improved time in range while off treatment (between Week 4 and Week 12)
    - BMF-219 demonstrated encouraging tolerability data with no dose reductions, or discontinuations. No patients showed symptomatic hypoglycemia, significant changes in hemoglobin levels. During the off-treatment period (Week 4 to Week 12), no severe or serious TEAEs were noted. As reported in March 2023, during the 4-week dosing period, in Cohorts 2 and 3 (100 mg QD, n=20; Placebo, n=4), 2 of 20 patients treated with BMF-219 showed mild (Grade 1) related treatment emergent adverse events (TEAEs) compared to no related TEAEs in 4 patients treated with placebo.
    - BMF-219 is an investigational diabetes therapy which showed initial improvements in glycemic control during and after cessation of treatment.
  - **Anticipated Upcoming Milestones:**
    - Complete dose escalation in COVALENT-111 (YE 2023)
    - Initiate dose expansion portion of COVALENT-111 (Q1 2024)
    - Initiate a clinical trial in Type 1 Diabetes patients (Q1 2024)

ONCOLOGY

- **COVALENT-101 (BMF-219 for Oncology)**
  - Reported initial topline data from ongoing Phase I clinical trial (COVALENT-101) showcasing initial responses in relapsed/refractory AML patients with menin-dependent mutations.
    - New data revealed 2 CRs out of 5 relapsed/refractory AML patients carrying menin-dependent mutations 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 QTc prolongation reported
    - Dose Level 4 exposure correlates with initial activity seen in BMF-219's pre-clinical studies
    - Safety profile of BMF-219 supports further dose escalation; enrollment for Dose Level 5 has commenced to explore the optimal biological dose
  - BMF-219 is the first investigational menin inhibitor in clinical development to be evaluated as a potential therapeutic agent in hematologic malignancies outside of MLL1r and NPM1 mutated AML/acute lymphoblastic leukemia (ALL) patients, specifically in subsets of diffuse large B-cell lymphoma (DLBCL), multiple myeloma (MM) and chronic lymphocytic leukemia (CLL).
  - 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 this 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. A targeted pan-KRAS inhibitor could have the potential to treat 25-35% of NSCLC, 35-45% of CRC, and approximately 90% of 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)**
  - BMF-500 is an investigational oral covalent inhibitor of FLT3, designed and developed in-house, and the second investigational compound discovered by Biomea's FUSION™ System.
  - Continued advancing toward the clinic, with investigational new drug (IND) application cleared and initiated a Phase I study of BMF-500 (COVALENT-103)

FUSION™ SYSTEM DISCOVERY PLATFORM

- Continued to advance third development candidate 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.

SECOND QUARTER 2023 FINANCIAL RESULTS

- **Cash, Cash Equivalents, Restricted Cash, and Investments:** As of June 30, 2023, the Company had cash, cash equivalents, restricted cash, and investments of $223.3 million, compared to $113.4 million as of December 31, 2022.
- **Net Income/Loss:** Biomea reported a net loss attributable to common stockholders of $24.9 million for the three months ended June 30, 2023, compared to a net loss of $17.3 million for the same period in 2022. Net loss attributable to common stockholders was $53.9 million for the six months ended June 30, 2023, compared to a net loss of $33.6 million for the same period in 2022.

- **Research and Development (R&D) Expenses:** R&D expenses were $21.9 million for the three months ended June 30, 2023, compared to $12.6 million for the same period in 2022. The increase of $9.4 million was primarily due to an increase personnel-related costs as well as an increase in clinical development costs, including manufacturing and external consulting, related to the Company's product candidates, BMF-219 and BMF-500. R&D expenses were $46.3 million for the six months ended June 30, 2023 compared to $23.9 million for the same period in 2022. The increase of $22.4 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 $5.7 million for the three months ended June 30, 2023, compared to $4.9 million for the same period in 2022. G&A expenses were $11.4 million for the six months ended June 30, 2023 compared to $9.9 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 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 diabetes, our research, development and regulatory plans, the progress of our ongoing and planned clinical trials, including COVALENT-101, COVALENT-102, COVALENT-103 and our Phase I/II COVALENT-111 study of BMF-219 in type 2 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, our plans to announce a third development candidate 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.

Contact:
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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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development [1]	$ 21,938	$ 12,582	$ 46,333	$ 23,932
General and administrative [1]	5,719	4,892	11,355	9,942
Total operating expenses	27,657	17,474	57,688	33,874
Loss from operations	(27,657)	(17,474)	(57,688)	(33,874)
Interest and other income, net	2,766	216	3,746	250
Net loss	$ (24,891)	$ (17,258)	$ (53,942)	$ (33,624)
Other comprehensive loss:				
Unrealized gain (loss) on investments, net	—	6	1	(7)
Comprehensive loss	$ (24,891)	$ (17,252)	$ (53,941)	$ (33,631)
Net loss per common share, basic and diluted	$ (0.70)	$ (0.59)	$ (1.66)	$ (1.15)
Weighted-average number of shares used to compute basic and diluted net loss per common share	35,348,293	29,196,398	32,483,297	29,161,437

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Research and development	$ 1,650	$ 1,253	$ 3,124	$ 2,265
General and administrative	1,786	1,306	3,545	2,624
Total stock-based compensation expense	$ 3,436	$ 2,559	$ 6,669	$ 4,889

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

	June 30, 2023	December 31, 2022
Cash, cash equivalents, investments, and restricted cash	$ 223,259	$ 113,400
Working capital	211,579	98,718
Total assets	248,674	129,307
Stockholders' equity	224,305	108,539