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, 2024

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, 2024, Biomea Fusion, Inc. issued a press release announcing its financial results for the quarter ended June 30, 2024. 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, 2024, 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, 2024

By: /s/ Thomas Butler

Thomas Butler
Principal Executive Officer

Exhibit 99.1

Biomea Fusion Reports Second Quarter 2024 Financial Results and Corporate Highlights

- COVALENT-111 Phase 2b on track for Q4 2024 readout
- COVALENT-112 Phase 2a on track for Q4 2024 readout
- Announcement of the third program in obesity on track for Q3 2024

REDWOOD CITY, Calif., July 31, 2024 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. ("Biomea" or "the Company") (Nasdaq: BMEA), a clinical-stage biopharmaceutical company dedicated to discovering and developing oral covalent small molecules to treat and improve the lives of patients with metabolic diseases and genetically defined cancers, reported second quarter 2024 financial results and corporate highlights.

"Q2 2024 was another busy quarter for the company. The company's top priority is working with FDA to resolve the clinical hold for BMF-219 in diabetes. We have made great progress with the second program, BMF-500 and our third program will be announced following the 60th European Association for the Study of Diabetes (EASD). Topline readout from the Phase 2b of COVALENT-111 with approximately 195 patients is on track for Q4 2024, and the topline readout from the Phase 2a of COVALENT-112 with approximately 20 patients is on track for Q4 2024," stated Thomas Butler, Biomea Fusion's Chief Executive Officer and Chairman of the Board.

DIABETES

COVALENT-111 (BMF-219 for Type 2 Diabetes) & COVALENT-112 (BMF-219 for Type 1 Diabetes)

- On June 6, 2024, company announced it received notice from FDA that a full clinical hold has been placed on Biomea's ongoing Phase I/II clinical trials of the company's investigational covalent menin inhibitor BMF-219 in type 2 and type 1 diabetes (COVALENT-111 and COVALENT-112), respectively. In its communication, FDA noted deficiencies based on the level of possible drug-induced hepatotoxicity observed in the completed dose escalation phase of COVALENT-111.
- Initial data reported from the first two type 1 diabetes patients dosed with BMF-219 in COVALENT-112 demonstrated early signs of clinical activity with improved measures of beta-cell function after initial treatment with BMF-219. BMF-219 has been generally well tolerated by both patients.

Anticipated Milestones:

- Topline Week 26 data readout of Phase 2b with approximately 195 patients of COVALENT-111 expected for Q4 2024.
- Topline data readout of Phase 2a of COVALENT-112 with approximately 20 patients expected for Q4 2024**.**

OBESITY

Third Program (Oral, Small Molecule, GLP-1R Agonist)

Anticipated Milestones:

- Announce a third development candidate, a potent, selective, GLP-1 receptor agonist, expected in Q3 2024.

ONCOLOGY

COVALENT-101 (BMF-219 for Liquid Tumors)

Anticipated Milestones:

- Complete dose escalation portion of COVALENT-101 expected by year end 2024.
  (Two cohorts, CLL and DLBCL of COVALENT-101 have been discontinued due to insufficient enrollment.)

COVALENT-102 (BMF-219 for Solid Tumors)

Anticipated Milestones:

- Complete dose escalation portion of COVALENT-102 expected by year end 2024.

COVALENT-103 (BMF-500 for Acute Leukemias)

Anticipated Milestones:

- Complete dose escalation portion of COVALENT-103 expected by year end 2024.

FUSION™ SYSTEM DISCOVERY PLATFORM

- Continued the development of the Biomea FUSION™ Platform technology.

SECOND QUARTER 2024 FINANCIAL RESULTS

- **Cash, Cash Equivalents, and Restricted Cash:** As of June 30, 2024, the Company had cash, cash equivalents and restricted cash of $113.7 million, compared to $177.2 million as of December 31, 2023.
- **Net Income/Loss:** The Company reported a net loss attributable to common stockholders of $37.3 million for the three months ended June 30, 2024, which included $4.8 million of stock-based compensation, compared to a net loss of $24.9 million for the same period in 2023, which included $3.4 million of stock-based compensation. Net loss attributable to common stockholders was $76.3 million for the six months ended June 30, 2024, which included $9.9 million of stock-based compensation, compared to a net loss of $53.9 million for the same period in 2023, which included $6.7 million of stock-based compensation.
- **Research and Development (R&D) Expenses:** R&D expenses were $31.8 million for the three months ended June 30, 2024, compared to $21.9 million for the same period in 2023. The increase of $9.9 million was primarily due to an increase of $7.2 million related to clinical and $1.6 million related to pre-clinical development cost for the Company's product candidates, BMF-219 and BMF-500, as well as an increase in personnel-related costs of $1.8 million. R&D expenses were $65.6 million for the six months ended June 30, 2024, compared to $46.3 million for the same period in 2023. The increase of $19.3 million was primarily due to an increase of $11.8 million related to clinical and $2.5 million related to pre-clinical development cost for the Company's product candidates, BMF-219 and BMF-500, as well as an increase in personnel-related costs of $4.9 million.
- **General and Administrative (G&A) Expenses:** G&A expenses were $7.1 million for the three months ended June 30, 2024, compared to $5.7 million for the same period in 2023. The increase of $1.4 million was primarily due to increased personnel-related expenses, including stock-based compensation. G&A expenses were $14.4 million for the six months ended June 30, 2024, compared to $11.4 million for the same period in 2023. The increase of $3.0 million was primarily due to an increase of $2.1 million from personnel-related expenses, including stock-based compensation and $1.3 million related to general external consultants and legal related expenses.

About Biomea Fusion

Biomea Fusion is a clinical stage biopharmaceutical company focused on the discovery and development of oral covalent small molecules to treat patients with metabolic disease and genetically defined cancers. 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. 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 the clinical and therapeutic potential of our product candidates and development programs, including BMF-219 and BMF-500, the potential of BMF-219 as a treatment for type 1 and type 2 diabetes, various types of liquid tumors and leukemia, and KRAS mutant solid tumors, the potential of BMF-500 as a treatment for cancers with a FLT3 mutation, our research, development and regulatory plans, the progress of our ongoing and upcoming clinical trials, including our Phase 1/2 COVALENT-111 study of BMF-219 in type 2 diabetes, our Phase 2 COVALENT-112 study of BMF-219 in type 1 diabetes, our Phase I COVALENT-101 study of BMF-219 in relapsed or refractory acute myeloid leukemia, our Phase 1/1b COVALENT-102 study of BMF-219 in KRAS mutant solid tumors and our Phase 1 COVALENT-103 study of BMF-500 in leukemia, the anticipated enrollment of patients and availability of data from our clinical trials, our plans to address the matters raised in the FDA's clinical hold letter, our ability to resolve the clinical hold on a timely basis, or at all, our plan to announce a third program in obesity, and the timing of such events, and our expectations regarding the Biomea FUSION™ Platform and our plans to announce a third development candidate, 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, 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:

Investor Relations
Chunyi Zhao, PhD
Associate Director of Investor Relations & Corporate Development
czhao@biomeafusion.com

Media Relations
Neera Chaudhary
nchaudhary@biomeafusion.com

- See attached for financial tables -

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development [1]	$ 31,825	$ 21,938	$ 65,601	$ 46,333
General and administrative [1]	7,073	5,719	14,356	11,355
Total operating expenses	38,898	27,657	79,957	57,688
Loss from operations	(38,898)	(27,657)	(79,957)	(57,688)
Interest and other income, net	1,622	2,766	3,620	3,746
Net loss	$ (37,276)	$ (24,891)	$ (76,337)	$ (53,942)
Other comprehensive loss:				
Unrealized gain (loss) on investments, net	—	—	—	1
Comprehensive loss	$ (37,276)	$ (24,891)	$ (76,337)	$ (53,941)
Net loss per common share, basic and diluted	$ (1.03)	$ (0.70)	$ (2.12)	$ (1.66)
Weighted-average number of shares used to compute basic and diluted net loss per common share	36,043,561	35,348,293	35,966,965	32,483,297

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Research and development	$ 2,448	$ 1,650	$ 4,994	$ 3,124
General and administrative	2,392	1,786	4,868	3,545
Total stock-based compensation expense	$ 4,840	$ 3,436	$ 9,862	$ 6,669

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

	June 30, 2024	December 31, 2023
Cash, cash equivalents, and restricted cash	$ 113,655	$ 177,236
Working capital	91,125	156,321
Total assets	136,164	199,927
Stockholders' equity	103,948	169,237