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 29, 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 October 29, 2024, Biomea Fusion, Inc. issued a press release announcing its financial results for the quarter ended September 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 October 29, 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: October 29, 2024

By: /s/ Thomas Butler

Thomas Butler
Principal Executive Officer

Exhibit 99.1

Biomea Fusion Reports Third Quarter 2024 Financial Results and Corporate Highlights

- U.S. Food and Drug Administration (FDA) lifted Clinical Hold on COVALENT-111 (Type 2 Diabetes) & COVALENT-112 (Type 1 Diabetes) trials
- COVALENT-111 Phase 2b 26-week topline data of the dose expansion cohorts expected in December 2024
- COVALENT-112 Phase 2a 26-week topline data of the open label portion expected in December 2024
- On track to announce our third clinical candidate, BMF-650, for the treatment of diabetes and obesity – a next-generation, oral small-molecule GLP-1 receptor agonist (GLP-1 RA) - and preclinical data combining icovamenib (BMF-219) with a GLP-1 RA-based therapy on October 30th
- Announced formation of Biomea's Global Scientific Advisory Board with 22 world-renowned diabetes experts

REDWOOD CITY, Calif., October 29, 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 improve the lives of patients with diabetes, obesity, and genetically defined cancers, today reported third quarter 2024 financial results and corporate highlights.

"Our third quarter was a pivotal quarter for the company. Through collaborative efforts with the FDA, we efficiently resolved the clinical hold on our studies for diabetes, while keeping the expansion study readout in type 2 diabetes on track and continuing to make fundamental progress with the third development program, BMF-650. We are pleased to announce the advancement of our third clinical development candidate - a next-generation oral small molecule GLP-1 receptor agonist. Incretins have become the backbone of obesity treatment, and we believe icovamenib in combination with an incretin together can potentially become the backbone of both diabetes and obesity treatments. We have done extensive preclinical work combining icovamenib with a GLP-1 RA-based therapy and will be sharing this data together with an update on BMF-650 during our conference call on October 30th," stated Thomas Butler, Biomea Fusion's Chief Executive Officer and Chairman of the Board. "We are very excited for the planned remaining readouts this year, in particular the topline Week 26 data of Phase 2b COVALENT-111 with approximately 200 type 2 diabetes patients, which will help us define those patients that demonstrate response to icovamenib and will shape the Phase 3 patient population we should target."

DIABETES & OBESITY

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

- Announced that the FDA lifted the clinical hold on the ongoing Phase 1/2 clinical trials in type 2 and type 1 diabetes (COVALENT-111 and COVALENT-112), respectively.
- Announced the formation of our global scientific advisory board with 22 world-renowned experts in beta cell science and diabetes therapeutics.
- Announced upcoming attendance at the 1st Asian Conference on Innovative Therapies for Diabetes Management, taking place in Singapore on November 18-20, 2024, with two trial-in-progress oral presentations featuring the study designs of our ongoing diabetes studies, and one late breaker oral presentation to highlight two case studies assessing icovamenib in persons with poorly-controlled severe insulin-deficient (SIDD) type 2 diabetes.
- Announced that World Health Organization (WHO) has approved "icovamenib" as the International Nonproprietary Name (INN) for its lead product candidate BMF-219, and that the United States

Adopted Name Council has adopted “icovamenib” as the United States Adopted Name (USAN) for BMF-219.

Anticipated Milestones:

- Topline Week 26 data readout of Phase 2b of COVALENT -111 (type 2 diabetes) dose expansion cohorts with approximately 200 patients.
- Topline Week 26 data readout of Phase 2a of COVALENT-112 (type 1 diabetes) with approximately 20 patients.

BMF-650 (Oral, Small-Molecule GLP-1 RA)

Anticipated Milestones:

- Provide preclinical data on our third clinical candidate, BMF-650 – a next-generation, selective, oral small-molecule GLP-1 receptor agonist (GLP-1 RA).
- Share results of preclinical studies investigating the benefits of combining icovamenib with a GLP-1- based therapies.

ONCOLOGY

COVALENT-101 (icovamenib for Liquid Tumors)

Anticipated Milestone:

- Complete dose escalation portion of COVALENT-101 in acute myeloid leukemia.

COVALENT-102 (icovamenib for Solid Tumors)

Anticipated Milestone:

- Complete dose escalation portion of COVALENT-102.

COVALENT-103 (BMF-500 for Acute Leukemias)

Anticipated Milestone:

- Complete dose escalation portion of COVALENT-103.

FUSION™ SYSTEM DISCOVERY PLATFORM

Anticipated Milestone:

- Deliver a fourth IND candidate in 2025 based on the Biomea FUSION™ Platform technology.

THIRD QUARTER 2024 FINANCIAL RESULTS

- **Cash, Cash Equivalents, and Restricted Cash:** As of September 30, 2024, the Company had cash, cash equivalents and restricted cash of $88.3 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 $32.8 million for the three months ended September 30, 2024, which included $4.7 million of stock-based compensation, compared to a net loss of $28.4 million for the same period in 2023, which included $3.6 million of stock-based compensation. Net loss attributable to common stockholders was $109.1 million

for the nine months ended September 30, 2024, which included $14.6 million of stock-based compensation, compared to a net loss of $82.4 million for the same period in 2023, which included $10.3 million of stock-based compensation.

- **Research and Development (R&D) Expenses:** R&D expenses were $27.2 million for the three months ended September 30, 2024, compared to $25.3 million for the same period in 2023. The increase of $1.9 million was primarily due to an increase of $1.7 million in expenses related to clinical activities, $1.2 million increased in personnel-related expenses and $2.7 million related to external consultants and professional services. The increase is offset by the decrease of $1.4 million in preclinical related activities and $2.1 million decrease in manufacturing related costs. R&D expenses were $92.8 million for the nine months ended September 30, 2024, compared to $71.7 million for the same period in 2023. The increase of $21.2 million was primarily due to an increase of $13.5 million related to clinical activities related expenses, $1.2 million related to preclinical related activities, and $6.1 million in personnel-related expenses. The increase is offset by the decrease of $3.9 million in manufacturing-related costs.
- **General and Administrative (G&A) Expenses:** G&A expenses were $6.8 million for the three months ended September 30, 2024, compared to $5.8 million for the same period in 2023. The increase of $1.0 million was primarily due to increased personnel-related expenses, including stock-based compensation. G&A expenses were $21.2 million for the nine months ended September 30, 2024, compared to $17.1 million for the same period in 2023. The increase of $4.0 million was primarily due to an increase in personnel-related expenses, including stock-based compensation of $3.0 million and $1.6 million related to general external consultants and legal-related expenses. The increase is offset by the decrease in insurance and facilities related expenses of $0.5 million.

About Biomea Fusion

Biomea Fusion is a clinical-stage biopharmaceutical company focused on the discovery and development of oral covalent small molecules to improve the lives of patients with diabetes, obesity, 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, X 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, our research, development and regulatory plans, the progress of our ongoing and upcoming clinical trials, the anticipated enrollment of patients and availability of data from our clinical trials, anticipated milestones, 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:

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- 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 September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development [1]	$ 27,244	$ 25,347	$ 92,845	$ 71,680
General and administrative [1]	6,795	5,772	21,151	17,127
Total operating expenses	34,039	31,119	113,996	88,807
Loss from operations	(34,039)	(31,119)	(113,996)	(88,807)
Interest and other income, net	1,252	2,690	4,872	6,436
Net loss	$ (32,787)	$ (28,429)	$ (109,124)	$ (82,371)
Other comprehensive loss:				
Unrealized gain (loss) on investments, net	—	—	—	—
Comprehensive loss	$ (32,787)	$ (28,429)	$ (109,124)	$ (82,371)
Net loss per common share, basic and diluted	$ (0.91)	$ (0.80)	$ (3.03)	$ (2.46)
Weighted-average number of shares used to compute basic and diluted net loss per common share	36,220,736	35,653,988	36,052,173	33,551,808

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Research and development	$ 2,478	$ 1,778	$ 7,472	$ 4,902
General and administrative	2,264	1,820	7,132	5,365
Total stock-based compensation expense	$ 4,742	$ 3,598	$ 14,604	$ 10,267

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

	September 30, 2024	December 31, 2023
Cash, cash equivalents, and restricted cash	$ 88,321	$ 177,236
Working capital	66,026	156,321
Total assets	110,419	199,927
Stockholders' equity	75,972	169,237