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): May 05, 2025

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 May 5, 2025, Biomea Fusion, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2025. 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 May 5, 2025, 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: May 5, 2025

By: /s/ Michael J.M. Hitchcock

Interim Chief Executive Officer, Director
(Principal Executive Officer)

Exhibit 99.1

Biomea Fusion Reports First Quarter 2025 Financial Results and Corporate Highlights

Company Announces Strategic Realignment to Focus on Core Programs and Extend Cash Runway

- *Icovamenib progressing toward the next phase of clinical development in insulin deficient type 2 diabetes patients and patients that are currently uncontrolled on a GLP-1 based therapy*
- *Biomea's next generation oral GLP-1 receptor agonist (BMF-650) filing for IND*
- *All other clinical and preclinical activities are either being partnered or closed*

REDWOOD CITY, Calif., May 5, 2025 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. ("Biomea" or "Biomea Fusion" or "the Company") (Nasdaq: BMEA), a clinical-stage diabetes and obesity company, today reported its financial results for the first quarter ended March 31, 2025, and provided a business update.

"In the first quarter of 2025, we executed a focused realignment of our operations to concentrate resources on our highest-value opportunities and extend our cash runway and position Biomea for long-term success," said Mick Hitchcock, Ph.D., Interim Chief Executive Officer and Board Member of Biomea Fusion. "With icovamenib advancing in insulin-deficient type 2 diabetes patients and BMF-650 on track for IND submission, we are strategically positioned to deliver meaningful clinical data and drive value across our metabolic pipeline. These actions reflect our commitment to capital efficiency and developing the core therapies that we believe will have the potential to transform the lives of patients with diabetes and obesity."

Strategic Realignment Highlights

- Prioritizing Core Programs: Biomea will focus development efforts and investments on icovamenib, a novel oral menin inhibitor for diabetes, and BMF-650, a next-generation oral GLP-1 receptor agonist.
- Operational Streamlining: The Company has implemented a cost-reduction initiative, including a workforce reduction of approximately 35%, to reduce the overall operating expenses and extend its cash runway into the fourth quarter of 2025. As part of this initiative, Biomea is consolidating its workforce at the current research facility known as the Biomea Innovation Lab Center located in San Carlos, CA as of May 31, eliminating the cost of maintaining two separate facilities.

Key Anticipated 2025 Milestones:

Icovamenib (Oral Small Molecule Menin Inhibitor for Type 2 and Type 1 Diabetes)

- 52-week data from the Phase II COVALENT-111 study in type 2 diabetes expected in the second half of 2025.
- Type-C meeting planned with FDA in the second half of 2025 to discuss a Phase IIb trial design and the requirements to advance icovamenib into later stage clinical development.
- Initiation of Phase II study of icovamenib in T2D patients currently uncontrolled on a GLP-1 based therapy in the second half of 2025.
- Preliminary data from the Phase II COVALENT-112 study in type 1 diabetes anticipated in the second half of 2025.

BMF-650 (Next-generation Oral Small Molecule GLP-1 Receptor Agonist for Obesity)

- Submission of the Investigational New Drug ("IND") application for BMF-650 planned for the second half of 2025.

BMF-500 (Oral Small Molecule FLT3 Inhibitor in Acute Leukemia)

- Survival data from the dose escalation study in relapsed/refractory acute leukemia expected in the second quarter of 2025.
- The Company concludes its oncology efforts with BMF-500 and is exploring strategic partnerships.

Corporate Updates

- In March 2025, the Company announced a leadership transition, appointing Board Member Mick Hitchcock, Ph.D., as Interim Chief Executive Officer, succeeding Thomas Butler.
- In January 2025, Biomea formally transitioned to a diabetes and obesity medicines company, ceasing internal development of its oncology programs.

First Quarter 2025 Financial Results

Cash, Cash Equivalents, and Restricted Cash: As of March 31, 2025, the Company had cash, cash equivalents and restricted cash of $36.2 million. We expect our cash, cash equivalents, and restricted cash to be sufficient to fund our operating plans into the fourth quarter of 2025.

Net Loss: The Company reported a net loss attributable to common stockholders of $29.3 million for the three months ended March 31, 2025, which included $3.2 million of stock-based compensation, compared to a net loss of $39.1 million for the same period in 2024, which included $5.0 million of stock-based compensation.

Research and Development ("R&D") Expenses: R&D expenses were $22.9 million for the three months ended March 31, 2025, compared to $33.8 million for the same period in 2024. This decrease of $9.2 million in external costs was primarily driven by a decrease of $7.3 million related to clinical activities, a decrease of $1.8 million related to manufacturing costs and decrease of $1.0 million related to preclinical activities and exploratory programs. This decrease in external costs was partially offset by an increase of $0.9 million in other external costs related to consultants, advisors and other professional services to support our clinical studies. Personnel-related expenses decreased by $1.7 million, including stock-based compensation.

General and Administrative ("G&A") Expenses: G&A expenses were $6.8 million for the three months ended March 31, 2025, compared to $7.3 million for the same period in 2024. The decrease is primarily due to a decrease in personnel-related expenses, including stock-based compensation of $0.9 million, resulting from a decrease in headcount. The decrease is partially offset by an increase in professional and legal services of $0.4 million.

About Biomea Fusion

Biomea Fusion is a clinical-stage diabetes and obesity medicines company focused on the development of its oral small molecules, icovamenib and BMF-650, both designed to significantly improve the lives of patients with diabetes, obesity, and metabolic diseases. 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 expected benefits resulting from the implementation of the cost saving measures and potential ability to fund key value drivers; clinical and therapeutic potential of our product candidates and development programs, including icovamenib, BMF-500, and BMF-650, the potential of icovamenib as a treatment for T1D and T2D, the potential of BMF-650 as a treatment for diabetes and obesity; our research, development and regulatory plans; the mechanism of action of our product candidates and development programs; the progress and initiation of our ongoing and upcoming clinical trials, including our Phase I/II COVALENT-111 study of icovamenib in T2D, our Phase II COVALENT-112 study of icovamenib in T1D, and our planned IND submission for the BMF-650 program; the anticipated availability of data from our clinical trials; our planned interactions with regulators, including our planned Type-C meeting with the FDA to discuss Phase II trial design and the advancement of icovamenib and the planned submission of our IND application for BMF-650, 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 preliminary or interim results of preclinical studies or clinical trials may not be predictive of future or final results in connection with future clinical trials and 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 ("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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BIOMEA FUSION, INC.
Condensed Statement of Operations and Comprehensive Loss
(Unaudited)
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2025	**2024**
Operating expenses:		
Research and development [(1)]	$ 22,897	$ 33,776
General and administrative [(1)]	6,815	7,283
Total operating expenses	29,712	41,059
Loss from operations	(29,712)	(41,059)
Interest and other income, net	450	1,998
Net loss and comprehensive loss	$ (29,262)	$ (39,061)
Net loss per common share, basic and diluted	$ (0.80)	$ (1.09)
Weighted-average number of common shares used to compute basic and diluted net loss per common share	36,627,148	35,890,370

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

	Three Months Ended March 31,	
	2025	**2024**
Research and development	$ 1,920	$ 2,546
General and administrative	1,249	2,476
Total stock-based compensation expense	$ 3,169	$ 5,022

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

	March 31, 2025	December 31, 2024
Cash, cash equivalents, and restricted cash	$ 36,233	$ 58,648
Working capital	24,868	46,659
Total assets	55,055	79,938
Stockholders' equity	28,737	51,573