
**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 11, 2026

Biomea Fusion, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-40335
(Commission File Number)

82-2520134
(IRS Employer
Identification No.)

1599 Industrial Road
San Carlos, California
(Address of principal executive offices)

94070
(Zip Code)

Registrant's telephone number, including area code: 650 980-9099

Not Applicable

(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 11, 2026, Biomea Fusion, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2026. 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 11, 2026, furnished herewith.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Biomea Fusion Reports First Quarter 2026 Financial Results and Corporate Highlights

- *Successfully completed chronic toxicology studies for icovamenib, providing the nonclinical support for advancing to chronic clinical dosing, beyond the 12-week clinical dosing that has been used to date*
- *Topline data reported from the Phase II COVALENT-112 clinical trial of icovamenib in type 1 diabetes (“T1D”), supporting proposed mechanism of action*
- *First patients dosed in the Phase II COVALENT-211 and COVALENT-212 clinical trials of icovamenib in type 2 diabetes (“T2D”); both trials are on track with topline 26-week data expected in the fourth quarter of 2026*
- *The Phase I GLP-131 (BMF-650) obesity clinical trial is on track; initial 28-day weight reduction data expected in the second quarter of 2026*
 - *Cash runway projected into the first quarter of 2027*

SAN CARLOS, Calif., May 11, 2026 (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, 2026, and provided a business update.

“Across our portfolio, we continue to execute with focus and discipline, with all of our key clinical programs progressing on track toward important upcoming milestones, while maintaining a disciplined approach to managing our cash burn,” said Mick Hitchcock, Ph.D., Interim Chief Executive Officer and Board Member of Biomea Fusion. “The recent 52-week data from the Phase II COVALENT-112 clinical trial in type 1 diabetes further support targeting menin as a novel approach across both type 1 and type 2 diabetes, which offers a paradigm shift and differs materially from existing therapeutic approaches. We are building on these findings with plans to initiate an investigator-sponsored Phase II clinical trial in collaboration with leading academic institutions specializing in T1D. We believe this collaboration, alongside the continued advancement of our type 2 diabetes and obesity programs, positions Biomea to deliver meaningful data across multiple indications in 2026.”

Recent Corporate Highlights:

Icovamenib

Potential First-in-Class Oral Small Molecule Product Candidate Targeting Menin for Diabetes

- Chronic toxicology studies in two species were successfully completed for icovamenib, providing nonclinical support for chronic clinical dosing beyond the 12-week duration used to date; findings demonstrated a favorable safety profile consistent with previously reported preclinical and clinical data.
 - With more than 400 subjects dosed to date, icovamenib was generally well tolerated and demonstrated a favorable safety profile throughout the observation periods.
 - Two Phase II clinical trials evaluating icovamenib in T2D have been initiated and enrollment is ongoing:
 - COVALENT-211, a Phase II, randomized, double-blind, placebo-controlled trial in patients with insulin-deficient T2D not achieving glycemic targets despite standard of care therapy.
 - COVALENT-212, a Phase II, randomized, double-blind, placebo-controlled trial in patients with T2D not achieving glycemic targets while on a GLP-1 RA-based therapy.
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- Both trials include a 26-week primary endpoint, with topline data anticipated in the fourth quarter of 2026.
- Topline data from the Phase II COVALENT-112 clinical trial evaluating icovamenib in T1D patients were reported from the 52-week follow-up:
 - A 52% increase from baseline in mean C-peptide AUC at Week 12, after completion of the dosing period, in patients diagnosed within 0-3 years (n=5) receiving icovamenib 200 mg, with a dose response observed vs 100 mg (n=6). Persistence observed through Week 52, with mean C-peptide AUC largely preserved in the 200 mg group (~7% decline from baseline).
 - Preservation of C-peptide also observed in patients diagnosed between 3-15 years (n=9).
 - Icovamenib was generally well tolerated across all dosing arms and demonstrated a favorable safety and tolerability profile through Week 52.
 - Comprehensive dataset to be presented at the American Diabetes Association's (ADA) Scientific Sessions (abstract is preliminary until time of presentation; full release scheduled for June 5, 2026 at 6:30 pm CDT).
 - Planning a Phase II trial in recently diagnosed T1D patients (≤ 3 years since diagnosis), in collaboration with four U.S. academic centers, to evaluate extended dosing (6–12 months) of icovamenib 200 mg and assess potential combination with an immunosuppressive agent; trial initiation expected in the second half of the year at leading centers including the Barbara Davis Center for Diabetes, Joslin Diabetes Center, University of Texas Health Science Center at San Antonio Diabetes Division, and the University of Miami Diabetes Research Institute.

BMF-650

Next-generation Oral Small Molecule GLP-1 RA Product Candidate for Obesity

- GLP-131, a Phase I randomized, double-blind, placebo-controlled clinical trial evaluating the safety, tolerability, pharmacokinetics, and pharmacodynamics of BMF-650 in otherwise healthy overweight or obese participants is ongoing.
- Initial 28-day clinical weight reduction data from the Phase I GLP-131 clinical trial is anticipated in the second quarter of 2026.

First Quarter 2026 Financial Results

- **Cash, Cash Equivalents, and Restricted Cash:** As of March 31, 2026, the Company had cash, cash equivalents and restricted cash of \$45.1 million.
 - **Net Loss:** The Company reported a net loss attributable to common stockholders of \$12.4 million for the three months ended March 31, 2026, which included \$1.6 million of stock-based compensation, compared to a net loss of \$29.3 million for the same period in 2025, which included \$3.2 million of stock-based compensation.
 - **Research and Development ("R&D") Expenses:** R&D expenses were \$9.1 million for the three months ended March 31, 2026, compared to \$22.9 million for the same period in 2025. The decrease of approximately \$13.8 million was primarily driven by a decrease of \$7.6 million in external costs primarily driven by a decrease of \$3.8 million related to clinical activities, a decrease of \$1.9 million related to preclinical and exploratory programs, and a decrease of \$1.9 million in other external costs related to consultants, advisors and other professional services to support our clinical trials. Personnel-related expenses decreased by \$4.5 million, including stock-based compensation, due to a decrease in headcount. Facilities and other allocated expenses decreased by \$1.7 million due to a decrease in rent and facilities-related costs.
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- **General and Administrative ("G&A") Expenses:** G&A expenses were \$3.7 million for the three months ended March 31, 2026, compared to \$6.8 million for the same period in 2025. The decrease of \$3.2 million was primarily driven by a decrease of \$1.9 million related to personnel-related expenses, including stock-based compensation, due to a decrease in headcount and a decrease of \$1.1 million of corporate-related expenses. Facilities and other allocated expenses decreased by \$0.2 million.
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About Biomea Fusion

Biomea Fusion is a clinical-stage diabetes and obesity medicines company focused on the development of its oral small molecule therapies, icovamenib and BMF-650, for diabetes and obesity. These programs target metabolic disorders, a global health challenge affecting nearly half of Americans and one-fifth of the world's population. Biomea's mission is to deliver transformative treatments that restore health for patients living with diabetes, obesity, and related conditions. 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 and BMF-650, the potential of icovamenib as a treatment for T1D and T2D, the potential of BMF-650 as a treatment for 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 plans to initiate a Phase II clinical trial in T1D, our Phase II COVALENT-211 clinical trial, our Phase II COVALENT-212 clinical trial and our Phase I GLP-131 clinical trial; the anticipated availability of data from our clinical trials; our planned interactions with regulators, and the timing of such events; and our expected cash runway 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,	
	2026	2025
Operating expenses:		
Research and development ⁽¹⁾	\$ 9,120	\$ 22,897
General and administrative ⁽¹⁾	3,654	6,815
Total operating expenses	12,774	29,712
Loss from operations	(12,774)	(29,712)
Change in fair value of common warrant liability	(581)	—
Gain on sale of property and equipment	510	—
Interest and other income, net	430	450
Net and comprehensive loss	\$ (12,415)	\$ (29,262)
Net loss per common share, basic and diluted	\$ (0.17)	\$ (0.80)
Weighted-average number of common shares used to compute basic and diluted net loss per common share	72,299,440	36,627,148

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

	Three Months Ended	
	March 31,	
	2026	2025
Research and development	\$ 784	\$ 1,920
General and administrative	798	1,249
Total stock-based compensation expense	\$ 1,582	\$ 3,169

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

	March 31,		December 31,
	2026		2025
Cash, cash equivalents, and restricted cash	\$ 45,062	\$	56,181
Working capital	\$ 36,655	\$	46,949
Total assets	\$ 46,385	\$	58,572
Stockholders' equity	\$ 18,719	\$	29,552
