Biomea Fusion Reports Third Quarter 2026 Financial Results and Corporate Highlights

November 10, 2026

- *Completed enrollment in the Phase II COVALENT-211 clinical trial evaluating icovamenib in patients with insulin-deficient type 2 diabetes ("T2D"); topline data expected in the first quarter of 2027*
- *Enrollment ongoing in the Phase II COVALENT-212 clinical trial evaluating icovamenib in patients with T2D not achieving glycemic targets on GLP-1 receptor agonist ("GLP-1 RA")-based therapy; topline data expected in the second quarter of 2027*
- *Announced Phase I results for BMF-650, an investigational next-generation oral GLP-1 RA, that, demonstrated weight reduction over 28 days and a generally favorable tolerability profile*
- *First patient dosed in the Open Label Adaptive Platform ("OPAL") trial evaluating icovamenib in combination with semaglutide, in collaboration with the University of Leicester*
- *Cash runway projected into the second quarter of 2027*

SAN CARLOS, Calif., Nov. 10, 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 third quarter ended September 30, 2026, and provided a business update.

"The third quarter was marked by meaningful execution across both of our clinical programs. We completed enrollment in our first diabetes Phase II clinical trial, COVALENT-211, and continue to advance enrollment in our Phase II COVALENT-212 clinical trial, bringing us closer to important Phase II data readouts for icovamenib in two distinct diabetes populations that we estimate represent over 30% of treated patients with diabetes in the U.S.," - said Mick Hitchcock, Ph.D., Interim Chief Executive Officer of Biomea Fusion. "We also reported first-in-human results for BMF-650, providing initial clinical support for our design hypothesis, in that BMF-650 achieved meaningful weight reduction while limited GI side effects were observed, all of which were Grade 1 AEs at the highest dose level. Encouragingly, BMF-650 demonstrated weight reduction and a generally favorable tolerability profile with only one-step titration. We also made important progress with the OPAL trial, overseen by the Leicester Diabetes Centre, dosing the first patient evaluating icovamenib in combination with semaglutide. Together, we believe these accomplishments reinforce our confidence in our pipeline and position us for several important Phase II readouts in 2027."

Recent Corporate Highlights:

Icovamenib

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

- Three Phase II clinical trials evaluating icovamenib in T2D and obesity are ongoing:
  - COVALENT-211: Completed enrollment in the Phase II, randomized, double-blind, placebo-controlled clinical trial evaluating icovamenib in patients with insulin-deficient T2D not achieving glycemic targets despite standard-of-care therapy. Primary endpoint data evaluating HbA1c reduction at Week 26 are expected in the first quarter of 2027.
  - COVALENT-212: Enrollment is ongoing in the Phase II, randomized, double-blind, placebo-controlled clinical trial evaluating icovamenib in patients with T2D not achieving glycemic targets on GLP-1 receptor agonist ("GLP-1 RA") based therapy. Primary endpoint data evaluating HbA1c reduction at Week 26 are expected in the second quarter of 2027.
  - First patient has been dosed in the ongoing OPAL study in collaboration with the University of Leicester to evaluate icovamenib in a Phase II clinical trial in combination with semaglutide in obesity through a newly activated experimental arm of the Open Label Adaptive Platform Trial. The randomized, double-blind study will assess physical function, body weight, body composition, muscle health and metabolic outcomes, with the primary endpoint assessed at Week 24. Topline data is anticipated at the end of 2027.

BMF-650

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

- Announced Phase I GLP-131 clinical trial results for BMF-650, its investigational oral small molecule GLP-1 RA, that demonstrated consistent weight reduction across five multiple ascending dose ("MAD") cohorts over four weeks and an encouraging tolerability profile, including rapid one-step titration to the 400 mg once-daily target dose.
- Across Cohorts 1-4, mean weight reduction ranged from 1.5% to 3.2% at Day 29, compared with 0.1% for pooled placebo. At doses of 200 mg or higher once daily, mean weekly weight reduction was approximately 0.97 kg.
- In Cohort 5, conducted under confinement to ensure dosing compliance and better characterize safety and tolerability, mean weight reduction was 6.1% (6.2 kg) at Day 29, averaging approximately 1.55 kg per week without observed attenuation during treatment. As confinement appeared to affect eating behavior, these results should be interpreted separately from outpatient Cohorts 1-4.
- BMF-650 was generally well tolerated across all five active-dose MAD cohorts (n=40) to date, with all reported treatment-emergent adverse events ("TEAEs") being mild or moderate. There were no severe or serious TEAEs, TEAE-related dose modifications, or TEAE-related study discontinuations.
- In Cohort 5, rapid one-step titration from 200 mg to 400 mg once daily after one week demonstrated similar gastrointestinal tolerability to slower titration regimens. All reported TEAEs were mild, with nausea and vomiting each reported in 12.5% of Cohort 5 participants, supporting further evaluation of a potential "no titration" dosing regimen.
- Following completion of Phase I data collection, additional clinical development of BMF-650 will require longer-term toxicology studies. Biomea intends to continue this work while positioning the program for a potential strategic partnership, including licensing opportunities for late-stage development and commercialization.

Third Quarter 2026 Financial Results

- **Cash, Cash Equivalents, and Restricted Cash:** As of September 30, 2026, the Company had cash, cash equivalents and restricted cash of $26.8 million.
- **Net Loss:** The Company reported a net loss attributable to common stockholders of $6.2 million for the three months ended September 30, 2026, which included $1.6 million of stock-based compensation, compared to a net loss of $16.4 million for the same period in 2025, which included $1.9 million of stock-based compensation. The Company reported a net loss attributable to common stockholders of $26.9 million for the nine months ended September 30, 2026, which included $4.8 million of stock-based compensation, compared to a net loss of $66.4 million for the same period in 2025, which included $7.7 million of stock-based compensation.
- **Research and Development ("R&D") Expenses:** R&D expenses were $8.5 million for the three months ended September 30, 2026, compared to $14.4 million for the same period in 2025. The decrease of $5.9 million was primarily driven by a decrease of $1.2 million related to nonclinical and exploratory programs, a decrease of $1.0 million of manufacturing costs, a decrease of $1.0 million in other external costs related to consultants, advisors and other professional services to support our clinical studies, and a decrease of $0.9 million related to clinical activities. Personnel-related expenses decreased by $1.0 million, including stock-based compensation, due to a decrease in headcount. Facilities and other allocated expenses decreased by $0.9 million due to a decrease in rent and facilities-related costs. R&D expenses were $26.8 million for the nine months ended September 30, 2026, compared to $53.9 million for the same period in 2025. The decrease of $14.8 million in external costs was primarily driven by a decrease of $4.6 million related to nonclinical and exploratory programs, a decrease of $4.2 million in other external costs related to consultants, advisors and other professional services to support our clinical studies, a decrease of $4.0 million related to clinical activities and a decrease of $2.0 million of manufacturing costs. Personnel-related expenses decreased by $8.0 million, including stock-based compensation, due to a decrease in headcount. Facilities and other allocated expenses decreased by $4.3 million due to a decrease in rent and facilities-related costs.
- **General and Administrative ("G&A") Expenses:** G&A expenses were $4.4 million for the three months ended September 30, 2026, compared to $4.2 million for the same period in 2025. The increase of $0.2 million was primarily driven by an increase of $0.6 million of corporate-related expenses, offset by a decrease of $0.4 million related to personnel-related expenses, including stock-based compensation, due to a decrease in headcount. Facilities and other allocated expenses decreased by less than $0.1 million. G&A expenses were $11.7 million for the nine months ended September 30, 2026, compared to $15.7 million for the same period in 2025. The decrease of $4.0 million was primarily driven by a decrease of $3.1 million related to personnel-related expenses, including stock-based compensation, due to a decrease in headcount and a decrease of $0.7 million of corporate-related expenses. Facilities and other allocated expenses decreased by $0.2 million.

About Biomea Fusion

Biomea Fusion is a clinical-stage diabetes and obesity medicines company focused on the development of its oral small molecule therapeutic candidates, 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, our Phase I GLP-131 clinical trial and additional toxicology studies for BMF-650; the anticipated availability of data from our clinical trials; our planned interactions with regulators, our plans to pursue a strategic partnership for BMF-650, 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 nonclinical 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 nonclinical 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.

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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 September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development [1]	$ 8,531	$ 14,401	$ 26,793	$ 53,864
General and administrative [1]	4,432	4,199	11,710	15,724
Impairment of long-lived assets	—	2,205	—	2,205
Total operating expenses	12,963	20,805	38,503	71,793
Loss from operations	(12,963)	(20,805)	(38,503)	(71,793)
Change in fair value of common warrant liability	6,513	3,872	10,051	4,099
Gain on sale of property and equipment	—	—	510	—
Interest and other income, net	267	526	1,016	1,285
Net and comprehensive loss	$ (6,183)	$ (16,407)	$ (26,926)	$ (66,409)
Net loss per common share, basic and diluted	$ (0.09)	$ (0.27)	$ (0.37)	$ (1.45)
Weighted-average number of common shares used to compute basic and diluted net loss per common share	72,591,786	59,848,325	72,418,224	45,787,018

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

	Three Months Ended	Nine Months Ended

	September 30,		September 30,	
	2026	2025	2026	2025
Research and development	$ 775	$ 1,075	$ 2,338	$ 4,563
General and administrative	845	865	2,451	3,119
Total stock-based compensation expense	$ 1,620	$ 1,940	$ 4,789	$ 7,682

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

	September 30, 2026	December 31, 2025
Cash, cash equivalents, and restricted cash	$ 26,772	$ 56,181
Working capital	$ 14,522	$ 46,949
Total assets	$ 28,097	$ 58,572
Stockholders' equity	$ 7,586	$ 29,552