# Biomea Fusion Reports Third Quarter 2025 Financial Results and Corporate Highlights

November 4, 2025

- *Advances diabetes and obesity programs with icovamenib demonstrating durable 52-Week Phase II data and with BMF-650, Biomea's next-generation, oral small molecule glucagon-like peptide-1 ("GLP-1") receptor agonist ("RA"), dosing its first patient in a Phase I clinical trial*
- *Presented preclinical activity of icovamenib in combination with semaglutide in type 2 diabetes ("T2D") animal model at EASD Annual Meeting, demonstrating enhanced glycemic control and body weight reduction with preservation of lean mass*
- *Raised approximately $68 million in gross proceeds through two public offerings, extending projected cash runway into the first quarter of 2027*

SAN CARLOS, Calif., Nov. 04, 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 third quarter ended September 30, 2025, and provided a business update.

"Since I joined the company we have reduced our expenses and focused the team on our core assets, advancing them to the next clinical milestones. During the third quarter we streamlined the operations, bringing the workforce down to approximately 40 employees. In addition, we released promising Phase II icovamenib data, which then provided the necessary tailwind to gain funding into 2027," said Mick Hitchcock, Ph.D., Interim Chief Executive Officer and Board Member of Biomea Fusion. "Icovamenib demonstrated continued reduction in HbA1c, nine months-post dosing in both of our identified target populations while maintaining a safety profile similar to placebo. These findings support our thesis that menin inhibition can potentially address the underlying cause of diabetes. Icovamenib is now moving rapidly into two Phase II studies enrolling each of these patient subtypes. With BMF-650, we also made great progress and have now dosed our first patient in a Phase I study."

**Third Quarter Highlights:**

**Icovamenib (Oral Small Molecule Menin Inhibitor for T2D and Type 1 Diabetes ("T1D"))**

- Reported positive 52-week follow-up results from the Company's Phase II COVALENT-111 study of icovamenib in T2D. The study demonstrated durable and clinically meaningful HbA1c reductions nine months after completion of dosing.
  - In patients with severe insulin-deficient diabetes receiving one or more antihyperglycemic agents at baseline, icovamenib achieved a sustained 1.5% mean reduction in HbA1c at Week 52, following only 12 weeks of dosing (Arm B, p = 0.01).
  - The 52-week analysis also showed clinically meaningful benefit in study participants who were receiving GLP-1-based therapy but had not achieved glycemic targets at study entry (all arms, n=11). In this subgroup, 8 or 12 weeks of icovamenib resulted in a 1.3% reduction in HbA1c.
  - Icovamenib was generally well tolerated across all dosing arms, with no treatment-related serious adverse events or discontinuations due to adverse events observed during the 52-week observation period.
- Presentation at the 61st European Association for the Study of Diabetes (EASD) Annual Meeting:
  - Presented preclinical data demonstrating enhanced activity of icovamenib in combination with semaglutide in a T2D animal model. The combination therapy achieved superior glycemic control, improved beta-cell function, and greater body-weight reduction while preserving lean mass, compared to semaglutide alone. These findings further support the potential of icovamenib to complement GLP-1 RAs and enhance long-term metabolic outcomes.

**BMF-650 (Next-generation Oral Small Molecule GLP-1 RA for Obesity)**

- The Investigational New Drug application was accepted, and the first patient has been dosed in a Phase I study. The study will assess in several single ascending and multiple ascending dose cohorts the 28-day weight loss potential of BMF-650 in obese, otherwise healthy volunteers.
- Presented new preclinical findings from a 28-day weight loss study in obese nonhuman primates evaluating BMF-650, which led to marked reductions in food intake and progressive body weight reductions. These data compared favorably to

published preclinical data of another leading oral GLP-1 RA candidate in development.

**Financing & Operations**

In October 2025, Biomea completed its previously announced underwritten public offering. The gross proceeds from the offering were approximately $25.0 million, before deducting underwriting discounts and commissions and offering expenses payable by Biomea.

During the third quarter, Biomea continued to reduce its expenses, achieving a year-over-year decrease of more than 50% in operating expenses.

**Key Anticipated Milestones:**

**Icovamenib (Oral Small Molecule Menin Inhibitor for T2D and T1D)**

- Food Effect Study (COVALENT-121) is ongoing, to optimize the dosing criteria for icovamenib, and expected to be completed by December 2025.
- Initiation of Phase IIb trial (COVALENT-211) in severe insulin-deficient T2D patients is expected in the fourth quarter of 2025, with First Patient In ("FPI") expected in the first quarter of 2026.
- Initiation of Phase II trial (COVALENT-212) in T2D patients currently not achieving glycemic targets on a GLP-1 based therapy is expected in the fourth quarter of 2025, with FPI expected in the first quarter of 2026.

**BMF-650 (Next-generation Oral Small Molecule GLP-1 RA for Obesity)**

- Phase I trial (GLP-131) Biomea's oral GLP-1 RA (BMF-650) in obese, otherwise healthy volunteers is ongoing and anticipated to deliver 28-day weight reduction data in the first half of 2026.

**Third Quarter 2025 Financial Results**

- **Cash, Cash Equivalents, and Restricted Cash:** As of September 30, 2025, the Company had cash, cash equivalents and restricted cash of $47.0 million.
- **Net Loss:** The Company reported a net loss attributable to common stockholders of $16.4 million for the three months ended September 30, 2025, which included $1.9 million of stock-based compensation, compared to a net loss of $32.8 million for the same period in 2024, which included $4.7 million of stock-based compensation. Net loss attributable to common stockholders was $66.4 million for the nine months ended September 30, 2025, which included $7.7 million of stock-based compensation, compared to a net loss of $109.1 million for the same period in 2024, which included $14.6 million of stock-based compensation.
- **Research and Development ("R&D") Expenses:** R&D expenses were $14.4 million for the three months ended September 30, 2025, compared to $27.2 million for the same period in 2024. The decrease of approximately $12.8 million was primarily driven by a decrease of $4.7 million related to clinical activities, a decrease of $2.6 million in other external costs related to consultants, advisors and other professional services to support our clinical studies and a decrease of $0.5 million related to preclinical and exploratory programs, partially offset by an increase of $0.5 million in manufacturing costs. Personnel-related expenses decreased by $4.8 million, including stock-based compensation, due to a decrease in headcount. Facilities and other allocated expenses decreased by $0.7 million due to a decrease in rent and facilities-related costs. R&D expenses were $53.8 million for the nine months ended September 30, 2025, compared to $92.8 million for the same period in 2024. The decrease of $39.0 million was primarily driven by a decrease of $21.1 million related to clinical activities, a decrease of $3.6 million related to preclinical and exploratory programs, a decrease of $2.0 million in other external costs related to consultants, advisors and other professional services to support our clinical studies, a decrease of $1.3 million of manufacturing costs. Personnel-related expenses decreased by $10.2 million, including stock-based compensation, due to a decrease in headcount. Facilities and other allocated expenses decreased by $0.7 million due to a decrease in rent and facilities-related costs.
- **General and Administrative ("G&A") Expenses:** G&A expenses were $4.2 million for the three months ended September 30, 2025, compared to $6.8 million for the same period in 2024. The decrease of $2.6 million was primarily driven by a decrease of $2.5 million related to personnel-related expenses, including stock-based compensation, due to a decrease in headcount and a decrease of $0.1 million related to facilities-related costs. G&A expenses were $15.7 million for the nine months ended September 30, 2025, compared to $21.2 million for the same period in 2024. The decrease of $5.4 million was primarily driven by a decrease of $5.4 million related to personnel-related expenses, including stock-based compensation, due to a decrease in headcount.

**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 Phase I/II COVALENT-111 study of icovamenib in T2D, our Phase II COVALENT-112 study of icovamenib in T1D, and our Phase I trial for BMF-650; 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.

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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, | |
|---|---|---|---|---|
| | 2025 | 2024 | 2025 | 2024 |
| Operating expenses: | | | | |
| Research and development[1] | $ 14,401 | $ 27,244 | $ 53,864 | $ 92,845 |
| General and administrative[1] | 4,199 | 6,795 | 15,724 | 21,151 |
| Impairment of long-lived assets | 2,205 | — | 2,205 | — |
| Total operating expenses | 20,805 | 34,039 | 71,793 | 113,996 |
| Loss from operations | (20,805) | (34,039) | (71,793) | (113,996) |
| Interest and other income, net | 4,398 | 1,252 | 5,384 | 4,872 |
| Net loss and comprehensive loss | $ (16,407) | $ (32,787) | $ (66,409) | $ (109,124) |
| Net loss per common share, basic and diluted | $ (0.27) | $ (0.91) | $ (1.45) | $ (3.03) |
| Weighted-average number of shares used to compute basic and diluted net loss per common share | 59,848,325 | 36,220,736 | 45,787,018 | 36,052,173 |

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2025 | 2024 | 2025 | 2024 |
| Research and development | $ 1,075 | $ 2,478 | $ 4,563 | $ 7,472 |
| General and administrative | 865 | 2,264 | 3,119 | 7,132 |
| Total stock-based compensation expense | $ 1,940 | $ 4,742 | $ 7,682 | $ 14,604 |

**Condensed Balance Sheet Data**
**(Unaudited)**
**(in thousands)**

| | September 30, 2025 | December 31, 2024 |
|---|---|---|
| Cash, cash equivalents, and restricted cash | $ 47,011 | $ 58,648 |
| Working capital | $ 33,875 | $ 46,659 |
| Total assets | $ 55,187 | $ 79,938 |
| Stockholders' equity | $ 15,619 | $ 51,573 |