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

August 5, 2025

- *Three presentations at ADA 2025 highlighted the therapeutic potential of icovamenib across multiple aspects of metabolic health:*
  - *In patients with type 2 diabetes (T2D) not achieving glycemic targets, icovamenib demonstrated durable HbA1c reduction and improved beta-cell function subsequent to the dosing period*
  - *In a rodent model of T2D, icovamenib in combination with low-dose semaglutide, promoted enhanced glycemic control and weight loss with complete lean mass preservation*
  - *Icovamenib promoted healthy myotube morphology and reduced drug-induced atrophy in ex-vivo human myotube cultures*
- *Next-generation oral GLP-1 receptor agonist (RA) candidate, BMF-650, demonstrated robust, dose-dependent weight loss and appetite suppression in obese non-human primates; planned Investigational New Drug (IND) submission remains on track for the second half of 2025*
- *Raised approximately $42.8 million in gross proceeds through a public offering, extending projected cash runway into the second half of 2026*
- *Reduced the workforce and quarterly expenses to support the advancement of the ongoing core programs*

SAN CARLOS, Calif., Aug. 05, 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 second quarter ended June 30, 2025, and provided a business update.

“In the second quarter, we presented clinical and preclinical results with icovamenib that support its unique role as a novel, potentially first-in-class investigational agent for the treatment of type 2 diabetes as well as in obesity, while further strengthening our BMF-650 program with robust data in non-human primates,” said Mick Hitchcock, Ph.D., Interim Chief Executive Officer and Board Member of Biomea Fusion. “At ADA 2025, we showed in preclinical models that our menin inhibitor, icovamenib, in combination with low-dose semaglutide not only drove superior glycemic control but also considerably boosted weight reduction, while fully preserving lean mass and outperforming semaglutide alone. Furthermore, icovamenib promoted myotube health and reduced drug-induced atrophy in a human cell model, highlighting its potential to support muscle health. We look forward to engaging with FDA and further evaluating icovamenib in this patient setting. Our next-generation investigational GLP-1 RA, BMF-650, showed encouraging results in a 28-day study in obese cynomolgus monkeys, achieving up to 15% weight reduction and robust dose-dependent appetite suppression. These findings reinforce BMF-650’s potential as an oral GLP-1 RA. With these clinical advances and the completion of our $42.8 million equity financing, we now have the necessary resources to advance these high-priority diabetes and obesity programs.”

**Second Quarter Highlights:**

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

- Three presentations at ADA 2025 highlighted the therapeutic potential of icovamenib across multiple aspects of metabolic health:
  - In patients with T2D not achieving glycemic targets, icovamenib demonstrated durable HbA1c reduction and enhanced beta-cell function three months subsequent to the dosing period, particularly in severe insulin deficient patients enrolled in its Phase II trial; icovamenib was well tolerated across the dosing arms.
  - In a Zucker Diabetic Fatty (ZDF) rat model of T2D, treatment of icovamenib in combination with low-dose semaglutide delivered superior metabolic benefits compared to low-dose semaglutide alone:
    - 60% lower fasting blood glucose and 50% lower glucose OGTT AUC
    - Greater HbA1c decline of >1% by Day 28 and >2% by Day 39
    - Greater improvement in insulin sensitivity with a 75% lower HOMA-IR (marker of insulin resistance)
    - 2-fold increase in C-peptide to glucose ratio indicating enhanced beta cell function
    - Superior appetite suppression with a 10% greater body weight reduction than low-dose semaglutide alone
    - The observed body weight loss was primarily due to fat mass reduction with complete preservation of lean mass
  - Icovamenib also promoted healthy myotube morphology and diminished drug-induced atrophy in ex vivo human myotube cultures.

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

- In a 28-day study in obese cynomolgus monkeys, BMF-650 achieved rapid, dose-dependent reductions in food intake and significant weight loss, with average weight reductions of 15% at the higher dose of 30 mg/kg/day.
- BMF-650 was generally well tolerated across all dose levels and showed no aminotransferase elevations.
- These preclinical results compare favorably to published preclinical data from other leading oral GLP-1 RA candidates in development and support BMF-650's potential as a best-in-class oral small-molecule GLP-1 RA.

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

- Presented updated Phase I data at EHA 2025, showing sustained antileukemic responses, deep bone marrow blast reductions, and survival benefit in relapsed/refractory FLT3-mutant AML patients, all of whom had failed FLT3 inhibitor gilteritinib.
- The Company concluded its oncology efforts and is now exploring strategic partnerships for BMF-500.

**Financing & Operations**

In June 2025, Biomea closed its previously announced underwritten public offering and in July 2025 the underwriters partially exercised their over-allotment option to purchase additional shares of common stock. The aggregate gross proceeds from the offering, including the over-allotment option, were approximately $42.8 million, before deducting underwriting discounts and commissions and offering expenses payable by Biomea.

During the first half of 2025 Biomea also reduced its workforce and operational expenses and anticipates future quarterly operational expenses to be approximately 40% lower than the most recent quarter, depending on study enrollments and expansion.

**Key Anticipated 2025 Milestones:**

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

- 52-week data from the Phase II COVALENT-111 study in T2D expected in the second half of 2025.
- 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 T1D anticipated in the second half of 2025.

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

- Submission of the IND application for BMF-650 is planned for the second half of 2025.
- Phase I study initiation in obese, otherwise healthy volunteers anticipated by late 2025, pending regulatory clearance.

**Second Quarter 2025 Financial Results**

**Cash, Cash Equivalents, and Restricted Cash:** As of June 30, 2025, the Company had cash, cash equivalents and restricted cash of $56.6 million. The Company expects its cash, cash equivalents, and restricted cash to be sufficient to fund planned operating activities into the second half of 2026.

**Net Loss:** The Company reported a net loss attributable to common stockholders of $20.7 million for the three months ended June 30, 2025, which included $2.6 million of stock-based compensation, compared to a net loss of $37.3 million for the same period in 2024, which included $4.8 million of stock-based compensation. Net loss attributable to common stockholders was $50.0 million for the six months ended June 30, 2025, which included $5.7 million of stock-based compensation, compared to a net loss of $76.3 million for the same period in 2024, which included $9.9 million of stock-based compensation.

**Research and Development (R&D) Expenses:** R&D expenses were $16.6 million for the three months ended June 30, 2025, compared to $31.8 million for the same period in 2024. The decrease of approximately $15.3 million was primarily driven by a decrease of $9.1 million related to clinical activities, a decrease of $2.0 million related to preclinical and exploratory programs, a decrease of $0.1 million of manufacturing costs and a decrease of $0.2 million in other external costs related to consultants, advisors and other professional services to support our clinical studies. Personnel-related expenses decreased by $3.8 million, including stock-based compensation, due to a decrease in headcount. R&D expenses were $39.5 million for the six months ended June 30, 2025, compared to $65.6 million for the same period in 2024. The decrease of $26.1 million was primarily driven by a decrease of $16.4 million related to clinical activities, a decrease of $3.0 million related to preclinical and exploratory programs and a decrease of $1.9 million of manufacturing costs. This decrease in external costs was partially offset by an increase of $0.7 million in other external costs related to consultants, advisors and other professional services to support our clinical studies. Personnel-related expenses decreased by $5.5 million, including stock-based compensation, due to a decrease in headcount.

**General and Administrative (G&A) Expenses:** G&A expenses were $4.7 million for the three months ended June 30, 2025, compared to $7.1 million for the same period in 2024. The decrease of $2.4 million is 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 $0.4 million related to professional and legal services. G&A expenses were $11.5 million for the six months ended June 30, 2025, compared to $14.4 million for the same period in 2024. The decrease of $2.8 million is primarily driven by a decrease of $2.9 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 molecules, icovamenib and BMF-650, both being developed to significantly improve the lives of patients with diabetes, obesity, and metabolic diseases. We aim to cure.

Visit us at www.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, 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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2025 | 2024 | 2025 | 2024 |
| Operating expenses: | | | | |
| Research and development [1] | $ 16,566 | $ 31,825 | $ 39,463 | $ 65,601 |
| General and administrative [1] | 4,710 | 7,073 | 11,525 | 14,356 |
| Total operating expenses | 21,276 | 38,898 | 50,988 | 79,957 |
| Loss from operations | (21,276) | (38,898) | (50,988) | (79,957) |
| Interest and other income, net | 536 | 1,622 | 986 | 3,620 |
| Net loss and comprehensive loss | $ (20,740) | $ (37,276) | $ (50,002) | $ (76,337) |
| Net loss per common share, basic and diluted | $ (0.51) | $ (1.03) | $ (1.29) | $ (2.12) |
| Weighted-average number of shares used to compute basic and diluted net loss per common share | 40,630,403 | 36,043,561 | 38,639,834 | 35,966,965 |

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2025 | 2024 | 2025 | 2024 |
| Research and development | $ 1,568 | $ 2,448 | $ 3,488 | $ 4,994 |
| General and administrative | 1,005 | 2,392 | 2,254 | 4,868 |
| Total stock-based compensation expense | $ 2,573 | $ 4,840 | $ 5,742 | $ 9,862 |

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

| | June 30, 2025 | December 31, 2024 |
|---|---|---|
| Cash, cash equivalents, and restricted cash | $ 56,593 | $ 58,648 |
| Working capital | 47,095 | 46,659 |
| Total assets | 73,163 | 79,938 |
| Stockholders' equity | 27,510 | 51,573 |