Biomea Fusion Reports Fourth Quarter and Full Year 2024 Financial Results and Corporate Highlights

March 31, 2025

- **Mick Hitchcock, Ph.D., appointed Interim Chief Executive Officer**
- **Biomea preparing icovamenib for late-stage clinical development**
- **Multiple milestones anticipated in 2025 including:**
- *FDA meeting anticipated in first half 2025 to discuss icovamenib late-stage development in severe insulin deficient patients*
- *COVALENT-111 (T2D) 52-week data anticipated in second half 2025*
- *COVALENT-112 (T1D) open label data anticipated in second half 2025*
- *BMF-650 IND application submission planned in second half 2025*

REDWOOD CITY, Calif., March 31, 2025 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. (“Biomea” or “Biomea Fusion” or “the Company”) (Nasdaq: BMEA), a clinical-stage diabetes and obesity medicines company, reported fourth quarter and full year 2024 financial results and corporate highlights.

“2024 was a transformative year for Biomea, marked by the advancement of icovamenib into late-stage development and compelling clinical data that reinforced our confidence in its potential to reshape diabetes treatment, particularly for patients with severe insulin deficiency,” said Mick Hitchcock, Ph.D., Interim Chief Executive Officer and Board Member of Biomea Fusion. “As we move into this next phase, the Board made a strategic decision to align leadership with the company’s evolution, and I’m honored to step in and contribute decades of experience in late-stage development, regulatory strategy, and commercialization to help guide Biomea forward. This transition reflects the continued confidence in our menin inhibitor program and the strength of our covalent small molecule platform. We remain fully committed to advancing icovamenib and delivering on our mission to transform diabetes treatment through this disease-modifying therapy. With key data readouts and regulatory milestones ahead, 2025 is set to be a pivotal year for the company.”

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, we announced plans to position Biomea as a dedicated diabetes and obesity medicines company. Building on our most recent clinical trial results, our strategic focus for icovamenib is now exclusively centered on metabolic disorders. As a result, we are terminating all ongoing oncology trials involving icovamenib and will conclude the BMF-500 study in patients with relapsed/refractory acute leukemia with FLT3 gene mutations following the dose escalation phase. Biomea will seek strategic partnerships to advance its oncology portfolio and the capabilities of its FUSION™ System, while reallocating internal resources to accelerate our metabolic disease programs.

In October 2024, we announced the formation of our Global Scientific Advisory Board, comprised of 22 internationally recognized experts in beta cell science and diabetes therapeutics. This board will work closely with our leadership team as we continue to explore menin biology and beta cell regeneration, and advance the clinical development of icovamenib as a novel, disease-modifying treatment targeting a root cause of diabetes.

RECENT DIABETES AND OBESITY PROGRAM UPDATES

COVALENT-111 (Icovamenib for Type 2 Diabetes (“T2D”))

Study Results:

- In the dose expansion portion of the COVALENT-111 study, icovamenib demonstrated statistically significant reductions in HbA1c in the prespecified per protocol patient population, with notable effects in the severe insulin deficient patients.
- In this group, icovamenib achieved a 1.47% reduction in HbA1c at Week 26 following 12 weeks of treatment with 100 mg once a day (“QD”).
- Severe insulin deficient patients also experienced the largest mean increase in C-peptide index levels, with a 53% mean increase from baseline by Week 26, indicating enhanced endogenous insulin production.
- In a broader subset of insulin deficient patients, icovamenib treatment led to a 1.0% reduction in HbA1c at Week 26 following 12 weeks of treatment with 100 mg QD.
- The data showed that icovamenib preferentially increased insulin secretion in insulin-deficient patients, supporting its potential as a targeted therapy for individuals with severe insulin deficiency, a population with limited treatment options and the highest risk profile.
- Across all dosing groups in the severe insulin deficient subgroup, there was a strong correlation between increases in

C-peptide and reductions in HbA1c, consistent with the proposed mechanism through beta cell restoration.
- HbA1c reductions were durable at 26 weeks, 3 months post last dose, further supporting the long-lasting effect of icovamenib on glycemic control.
- Icovamenib was generally well tolerated, with no treatment discontinuations due to adverse events, no hypoglycemic episodes, and no drug-related serious adverse events reported.

Preclinical Findings:

- In preclinical experiments, including in ex vivo human islets, icovamenib was able to enhance the activity of GLP-1 RA-based therapies, potentially leading to increased insulin secretion and improved glycemic control in patients with diabetes. These effects were associated with an increase in the expression levels of the GLP-1 receptors ("GLP-1R").
- Overall results showed synergy of the combination therapy, which may allow lower doses of GLP-1-based therapies to achieve glycemic targets potentially reducing side effects and improving the tolerability of GLP-1 based therapies.

Anticipated 2025 Milestones:

- Planned U.S. Food and Drug Administration ("FDA") discussions regarding Phase II/III trial designs and the advancement of icovamenib into late-stage clinical development in the first half of 2025.
- 52-week data from the COVALENT-111 Phase II study anticipated in the second half of 2025.

COVALENT-112 (Icovamenib for Type 1 Diabetes ("T1D"))

Anticipated 2025 Milestones:

- Initial open label data from the Phase II study is expected in the second half of 2025.

BMF-650 (Oral small molecule GLP-1 RA)

Preclinical Progress:

- Preclinical studies evaluating the properties of our investigational, next-generation, oral small molecule GLP-1 RA (BMF-650) demonstrated positive early preclinical activity, including improved glucose-stimulated insulin secretion, reduction in blood glucose concentration, and appetite suppression in cynomolgus monkeys.
- In comparison to a leading oral GLP-1 RA, BMF-650 exhibited higher bioavailability and a less variable pharmacokinetic profile, which may translate to improved tolerability and enable successful dose escalation in patients.
- Human donor islet studies confirmed that BMF-650 significantly enhanced glucose-stimulated insulin secretion, aligning with findings from animal models.
- In cynomolgus monkey studies, BMF-650 demonstrated robust improvements in glucose control and insulin secretion, consistent with its effects in human donor islets.
- Appetite suppression studies revealed that daily oral dosing of BMF-650 significantly reduced food intake during peak drug concentration, with sustained effects throughout the day for a six-day study period.

Anticipated 2025 Milestones:

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

ONCOLOGY PROGRAM

COVALENT-103 Study (BMF-500):

- Preliminary Phase I data for BMF-500 in relapsed/refractory acute leukemia patients with FLT3 gene mutations having failed gilteritinib indicated clinical activity with evidence of responses, including a first complete response with incomplete hematologic recovery (CRi) and reductions in bone marrow blasts in five of six evaluable FLT3 mutated patients.
- Pharmacokinetic and pharmacodynamic analyses confirmed dose-proportional on-target FLT3 inhibition and good compartmental penetration, and BMF-500 showed a favorable safety and tolerability profile with no dose-limiting toxicities observed.

Anticipated 2025 Milestones:

- After the completion of the dose escalation of BMF-500 in relapsed/refractory acute leukemia patients with FLT3 gene mutations, we intend to conclude our oncology study with BMF-500 and explore strategic partnerships.

FOURTH QUARTER AND FULL YEAR 2024 FINANCIAL RESULTS

Cash, Cash Equivalents, and Restricted Cash: As of December 31, 2024, the Company had cash, cash equivalents and restricted cash of $58.6 million, compared to $177.2 million as of December 31, 2023.

Net Income/Loss: The Company reported a net loss attributable to common stockholders of $29.3 million for the three months ended December 31, 2024, compared to a net loss of $34.9 million for the same period in 2023. Net loss attributable to common stockholders was $138.4 million for the year ended December 31, 2024, compared to a net loss of $117.3 million for the same period in 2023.

Research and Development ("R&D") Expenses: R&D expenses were $25.2 million for the three months ended December 31, 2024, compared to $30.9 million for the same period in 2023. The decrease of $5.6 million was primarily due to the decrease in compensation and related expenses, manufacturing related expenses, and clinical related expenses. R&D expenses were $118.1 million for the year ended December 31, 2024, compared to $102.5 million for the same period in 2023. The increase of $15.5 million was primarily due to an increase in clinical development of icovamenib, consultants, advisors and other professional services to support our clinical studies, discovery research and overall research and development programs.

General and Administrative ("G&A") Expenses: G&A expenses were $4.8 million for the three months ended December 31, 2024, compared to $6.5 million for the same period in 2023. The decrease of $1.6 million was primarily due to the decrease in compensation and related expenses. G&A expenses were $26.0 million for the year ended December 31, 2024, compared to $23.6 million for the same period in 2023. The increase of $2.4 million was primarily due to increased personnel-related expenses, including stock-based compensation, due to an increase in headcount, as well as an increase in professional and consulting services to support the growth of the Company.

About Icovamenib
Icovamenib is an investigational, orally bioavailable, potent, and selective covalent inhibitor of menin. The molecule was built using Biomea Fusion's FUSION™ System and is designed to regenerate insulin-producing beta cells with the aim to cure diabetes. Icovamenib's proposed mechanism of action in diabetes is to enable the proliferation, preservation, and reactivation of a patient's own healthy, functional, insulin-producing beta cells. As the potentially first disease-modifying therapy for T1D and T2D, icovamenib could become an important addition and complement to the diabetes treatment landscape once it has successfully completed clinical studies.

About Biomea Fusion
Biomea Fusion is a clinical-stage diabetes and obesity medicines company focused on the discovery and development of oral covalent small molecules to improve the lives of patients with diabetes, obesity, and metabolic diseases. A covalent small molecule is a synthetic compound that forms a permanent bond to its target protein and offers a number of potential advantages over conventional non-covalent drugs, including greater target selectivity, lower drug exposure, and the ability to drive a deeper, more durable response.

We are utilizing our proprietary FUSION™ System to discover, design and develop a pipeline of next-generation covalent-binding small-molecule medicines designed to maximize clinical benefit for patients. We aim to have an outsized impact on the treatment of disease for the patients we serve. 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 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 T12 and T2D, the potential of BMF-650 as a treatment for diabetes and obesity, our research, development and regulatory plans, and our expectations regarding the Biomea FUSION™ System; the mechanism of action of our product candidate and development programs, and their potential relative to approved products marketed by third parties; the potential benefits to future trial design and program development of subtyping diabetes patients and their potential to be used in combination with approved products marketed by third parties; our research, development and regulatory plans, the progress 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 IND enabling studies for the BMF-650 program, the anticipated enrollment and dosing of patients and availability of data from our clinical trials, 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.

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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 December 31,		Year Ended December 31,	
	2024	2023	2024	2023
Operating expenses:				
Research and development [1]	$ 25,240	$ 30,866	$ 118,085	$ 102,546
General and administrative [1]	4,834	6,462	25,985	23,589
Total operating expenses	30,074	37,328	144,070	126,135
Loss from operations	(30,074)	(37,328)	(144,070)	(126,135)
Interest and other income, net	772	2,444	5,644	8,880
Net loss	$ (29,302)	$ (34,884)	$ (138,426)	$ (117,255)
Other comprehensive loss:				
Unrealized gain (loss) on investments, net	—	—	—	1
Comprehensive loss	$ (29,302)	$ (34,884)	$ (138,426)	$ (117,254)
Net loss per common share, basic and diluted	$ (0.81)	$ (0.98)	$ (3.83)	$ (3.44)
Weighted-average number of common shares used to compute basic and diluted net loss per common share	36,265,001	35,754,165	36,105,671	34,106,923

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

	Three Months Ended December 31,		Year Ended December 31,	
	2024	2023	2024	2023
Research and development	$ 2,344	$ 2,031	$ 9,816	$ 6,933
General and administrative	2,146	1,833	9,278	7,198
Total stock-based compensation expense	$ 4,490	$ 3,864	$ 19,094	$ 14,131

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

	December 31, 2024	December 31, 2023
Cash, cash equivalents, and restricted cash	$ 58,648	$ 177,236
Working capital	46,659	156,321
Total assets	79,938	199,927
Stockholders' equity	51,573	169,237