Biomea Fusion Reports First Quarter 2024 Financial Results and Corporate Highlights

May 2, 2024

- Reported positive data from the escalation portion of Phase 1/2 study (COVALENT-111) in type 2 diabetes patients, displaying durable improved glycemic control while off therapy for 22 weeks, supporting the disease-modifying potential of BMF-219 to address a root cause of diabetes: a loss of healthy, insulin-producing beta cells
- Announced initial clinical data from our Phase 2 study (COVALENT-112) in type 1 diabetes from the first two type 1 diabetes patients dosed with BMF-219 and demonstrated early signs of clinical activity with improved measures of beta-cell function after initial treatment with BMF-219
- We expect a reduction in operating expenses in the second half of the year due to the near completion of enrollment of the first three arms of our type 2 diabetes study and near completion of enrollment of the open label portion of our type 1 diabetes study. Cash position of $145.3 million at the end of the first quarter of 2024

REDWOOD CITY, Calif., May 02, 2024 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. (“Biomea” or “the Company”) (Nasdaq: BMEA), a clinical-stage biopharmaceutical company dedicated to discovering and developing oral covalent small molecules to treat and improve the lives of patients with metabolic diseases and genetically defined cancers, reported first quarter 2024 financial results and corporate highlights.

“Over the last two months we have seen a significant increase in the rate of enrollment for the expansion phase cohorts of our Phase 1/2 study, COVALENT-111, investigating BMF-219 in patients with type 2 diabetes. There is currently a waitlist for the fourth cohort which we expect will open for enrollment in the second half of this year. We have also seen a significant increase in the rate of enrollment of our Phase 2 study, COVALENT-112, in patients with type 1 diabetes following the press release which provided an early look at the first two patients dosed with BMF-219. Here we highlighted the first two patients dosed with BMF-219 demonstrated an increase in C-peptide Index (Amount of C-peptide secreted per unit of glucose) during the early stages of treatment. This is truly an exciting and validating update on our progress in type 1 diabetes. Patients with type 2 diabetes have lost about 50% of their pool of beta cells while patients with type 1 diabetes have lost at least 90% of their beta-cell pool at diagnosis and are therefore not able to produce sufficient insulin to address the glucose levels in their blood. Currently approved treatments for diabetes are mostly chronic treatments helping patients to reduce the blood glucose while the mass and function of the beta cells continues to decline. We have now demonstrated in multiple preclinical experiments that BMF-219 has the potential to address diabetes at the root cause level by improving the function and mass of beta cells. The data we reported from the escalation portion of our clinical study COVALENT-111 in the first quarter of 2024 demonstrated for the first time how an agent can achieve durable glycemic control while patients are off therapy, supporting the disease-modifying potential of BMF-219 to address a root cause of diabetes,” stated Thomas Butler, Biomea Fusion’s Chief Executive Officer and Chairman of the Board. “In 2024, we expect to continue to advance our clinical programs with BMF-219 in diabetes and plan to report multiple data readouts throughout the remainder of the year, including topline Week 26 data of over 200 patients from our Phase 1/2 study, COVALENT-111, in type 2 diabetes, and topline Week 26 data from approximately 40 patients enrolled in the open label portion of our Phase 2 study, COVALENT-112, in type 1 diabetes patients. Our goal is to deliver a short-term, non-chronic treatment that will reconstitute insulin-producing beta cells, allowing the patients’ own bodies to normalize blood sugar levels.”

DIABETES

COVALENT-111 (BMF-219 for Type 2 Diabetes)

- Reported positive data from the escalation portion of Phase 2 study (COVALENT-111) in type 2 diabetes patients, supporting the disease-modifying potential of BMF-219 to address a root cause of diabetes: loss of healthy, insulin-producing beta cells.
    - After just a 4-week treatment period in type 2 diabetes patients, who had previously failed standard of care (HbA1c ≥7.0% and ≤10.5%), BMF-219 demonstrated continued glycemic control at 26 weeks, or five months, after cessation of dosing. Here, a durable glycemic response (≥1.0% HbA1C reduction) was seen in 20% and 36% of patients in once daily 100 mg and 200 mg cohorts, respectively.
    - A general dose response was observed from BMF-219 in type 2 diabetes patients supported by dose-dependent PK response. 50mg cohort had the lowest placebo adjusted mean percent change of A1c (-0.04%) while 200mg with food cohorts achieved the highest change of A1c (-1.4%).
    - BMF-219 was generally well tolerated with no serious adverse events and no adverse event-related study discontinuations, and no symptomatic or clinically significant hypoglycemia.
    - 100mg and 200mg dose levels have been selected for the first 3 Arms of the Expansion Phase, which will dose

patients up to 12 weeks (compared to 4 weeks in the Escalation Phase) and extended follow-up to Week 52.

Anticipated 2024 Milestones:

- On track to complete 400 mg cohort from the Escalation Phase of COVALENT-111.
- On track to complete enrollment of the first three expansion cohorts of COVALENT-111 (n=216) in type 2 diabetes patients with poorly controlled diabetes and provide topline 26-week follow-up data.

COVALENT-112 (BMF-219 for Type 1 Diabetes)

- Announced initial data from the first two type 1 diabetes patients dosed with BMF-219 and demonstrated early signs of clinical activity with improved measures of beta-cell function after initial treatment with BMF-219. BMF-219 was well tolerated by both patients.

Anticipated 2024 Milestones:

- On track to complete enrollment of the open label portion (n=40) of COVALENT-112 in type 1 diabetes dosed for 12 weeks with BMF-219 and provide topline 26-week follow-up data.

ONCOLOGY

COVALENT-101 (BMF-219 for Liquid Tumors)

Anticipated 2024 Milestones:

- On track to complete dose escalation portion of COVALENT-101 and establish recommended Phase 2 dose (RP2D).

COVALENT-102 (BMF-219 for Solid Tumors)

Anticipated 2024 Milestones:

- On track to complete dose escalation portion of COVALENT-102 and establish RP2D.

COVALENT-103 (BMF-500 for Acute Leukemias)

Anticipated 2024 Milestones:

- On track to complete dose escalation portion of COVALENT-103 and establish RP2D.

FUSION™ SYSTEM DISCOVERY PLATFORM

- Continued the development of the Biomea FUSION™ Platform technology.

Anticipated 2024 Milestones:

- On track to announce a third development candidate from the Biomea FUSION™ Platform technology.

FIRST QUARTER 2024 FINANCIAL RESULTS

- **Cash, Cash Equivalents, and Restricted Cash:** As of March 31, 2024, the Company had cash, cash equivalents and restricted cash of $145.3 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 $39.1 million for the three months ended March 31, 2024, which included $5.0 million of stock-based compensation, compared to a net loss of $29.1 million for the same period in 2023, which included $3.2 million of stock-based compensation.
- **Research and Development (R&D) Expenses:** R&D expenses were $33.8 million for the three months ended March 31, 2024, compared to $24.4 million for the same period in 2023. The increase of $9.4 million was primarily due to an increase in clinical and pre-clinical development cost and external consulting costs related to the Company's product candidates, BMF-219 and BMF-500, as well as an increase in personnel-related costs and facilities cost due to new lease agreements for additional office and laboratory space which commenced in 2023.
- **General and Administrative (G&A) Expenses:** G&A expenses were $7.3 million for the three months ended March 31, 2024, compared to $5.6 million for the same period in 2023. The increase of $1.6 million was primarily due to increased personnel-related expenses, including stock-based compensation.

About Biomea Fusion

Biomea Fusion is a clinical stage biopharmaceutical company focused on the discovery and development of oral covalent small molecules to treat patients with metabolic diseases and genetically defined cancers. 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, Twitter 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 BMF-219 and BMF-500, the potential of BMF-219 as a treatment for type 1 and type 2 diabetes, various types of liquid tumors and solid tumors, the potential of BMF-500 as a treatment for acute leukemia, our research, development and regulatory plans, the progress of our ongoing and planned clinical trials, including our Phase 1/2 COVALENT-111 study of BMF-219 in type 2 diabetes, our Phase 2 COVALENT-112 study of BMF-219 in type 1 diabetes, our Phase 1 COVALENT-101 study of BMF-219 in relapsed or refractory acute myeloid leukemia, our Phase 1/1b COVALENT-102 study of BMF-219 in KRAS mutant solid tumors and our Phase 1 COVALENT-103 study of BMF-500 in leukemia, the anticipated enrollment of patients and availability of data from our clinical trials and the timing of such events, and our expectations regarding the Biomea FUSION™ Platform and our plans to announce a third development candidate, 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 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 (the "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.

- See attached for financial tables -

BIOMEA FUSION, INC.
Condensed Statement of Operations and Comprehensive Loss
(Unaudited)
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2024	**2023**
Operating expenses:		
Research and development [1]	$ 33,776	$ 24,395
General and administrative [1]	7,283	5,636
Total operating expenses	41,059	30,031
Loss from operations	(41,059)	(30,031)
Interest and other income, net	1,998	980
Net loss	$ (39,061)	$ (29,051)
Other comprehensive loss:		
Unrealized gain (loss) on investments, net	—	1
Comprehensive loss	$ (39,061)	$ (29,050)
Net loss per common share, basic and diluted	$ (1.09)	$ (0.98)
Weighted-average number of common shares used to compute basic and diluted net loss per common share	35,890,370	29,586,468

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

	Three Months Ended March 31,	
	2024	**2023**
Research and development	$ 2,546	$ 1,474
General and administrative	2,476	1,759

Total stock-based compensation expense	$ 5,022	$ 3,233

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

	March 31, 2024	December 31, 2023
Cash, cash equivalents, and restricted cash	$ 145,287	$ 177,236
Working capital	122,312	156,321
Total assets	168,494	199,927
Stockholders' equity	135,314	169,237

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