Biomea Fusion Reports Third Quarter 2022 Financial Results and Business Highlights

November 7, 2022

- Continued to establish Biomea Fusion as the next-generation leader in covalent medicines
- Expanded clinical development footprint of BMF-219, the company's lead investigational, orally administered, covalent menin inhibitor, in multiple liquid and solid tumor indications, including first in class potential in KRAS-mutated solid tumors
    - COVALENT-101 (Phase I study) is now enrolling four liquid tumor cohorts, each focused on distinct patient subsets of acute lymphoblastic and myeloid leukemia (ALL/AML) including patients with MLL rearrangement and NPM1 mutation, diffuse large B-cell lymphoma (DLBCL), multiple myeloma (MM) and most recently chronic lymphocytic leukemia (CLL)
    - COVALENT-102 (Phase I/Ib study) is now enrolling patients with KRAS-mutated (pan) solid tumors, including non-small cell lung cancer (NSCLC), colorectal cancer (CRC) and pancreatic ductal adenocarcinoma (PDAC)
    - COVALENT-111 (Phase I/II study) advanced BMF-219 to the clinic for type 2 diabetes indication; cleared the Phase I healthy volunteer portion of this study in Canada and dosed first patient with type 2 diabetes
- Continued to advance company's second product candidate, BMF-500, a highly selective and potent covalent third generation FLT3 inhibitor, toward the clinic
- Continued to leverage the proprietary FUSION^{TM} System Discovery Platform to expand pipeline of covalent medicines for cancer; expect to provide an update on company's third development candidate in the first half of 2023
- Cash position of $133.8 million at the end of the third quarter of 2022

REDWOOD CITY, Calif., Nov. 07, 2022 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. (Nasdaq: BMEA), a clinical-stage biopharmaceutical company dedicated to discovering and developing novel covalent small molecules to treat and improve the lives of patients with genetically defined cancers and metabolic diseases, reported third quarter 2022 financial results and business highlights.

"We continue to solidify Biomea's position as the leader in next-generation covalent medicines, and build near- and long-term value, through our rapid progress and strong execution. With BMF-219, we have now brought the first covalent menin inhibitor to the clinic for KRAS-mutated solid tumors, adding to our already robust development strategy of BMF-219 in distinct patient subsets of multiple liquid tumors. In addition, we are very excited to announce the first type 2 diabetes patient dosed with BMF-219, which marks the first non-oncology indication for which an investigational menin inhibitor is being evaluated in the clinic," said Thomas Butler, Biomea Fusion's Chief Executive Officer and Chairman of the Board. "Over the coming quarters, we expect to gain valuable feedback and believe we will achieve clinical proof of concept for BMF-219 in multiple indications. We also continue to advance our second IND candidate, BMF-500, an investigational covalent FLT3 inhibitor with best-in-class potential, toward the clinic. BMF-500 further demonstrates the versatility enabled by our proprietary FUSION System to discover and validate novel covalent product candidates."

Third Quarter 2022 and Recent Pipeline Highlights

Oncology

- COVALENT-101
    - Continued site activation and patient enrollment across four liquid tumor cohorts including patients with AML/ALL (including those with MLL rearrangement and NPM1 mutation), DLBCL, MM and CLL
    - Cohort I (AML/ALL with MLL-r or NPM1) is enrolling patients in the escalation phase currently at Dosing Level #3. No DLTs observed, enrollment is proceeding on track for near term expansion and initial data in the first half of 2023
    - Cohort IV (CLL) achieved its first patient enrolled in October 2022
- COVALENT-102
    - Received FDA clearance in October 2022 and initiated a Phase I/Ib clinical trial of BMF-219 as a monotherapy in patients who have unresectable, locally advanced, or metastatic NSCLC, CRC or PDAC with any (pan) KRAS

mutation

- Preclinical
  - Presented abstract “Anti-tumor activity of covalent menin inhibitor, BMF-219, in High-Grade B-Cell Lymphoma and Multiple Myeloma Preclinical Models” at the 2022 International Myeloma Society (IMS) Annual Meeting in Los Angeles, CA
  - Announced abstract “BMF-500: An Orally Bioavailable Covalent Inhibitor of FLT3 with High Selectivity and Potent Antileukemic Activity in FLT3-Mutated AML” to be presented at the 2022 American Society of Hematology Annual Meeting in New Orleans, LA

Diabetes

- COVALENT-111
  - Initiated COVALENT-111 a multi-site, double-blind, randomized, placebo-controlled Phase I/II study of BMF-219 following clearance of CTA by Health Canada; alignment has been reached with the FDA on the contents of the IND filing
  - Completed the healthy volunteer portion in Phase I/II (COVALENT-111) study of BMF-219 currently ongoing in Canada. No safety signals were detected
  - Dosed first type 2 diabetes patient in Phase I/II (COVALENT-111) study of BMF-219 currently ongoing in Canada
- Preclinical
  - Presented two oral abstracts, “Oral Menin Inhibitor, BMF-219, displays a significant and durable reduction in HbA1c in a Type 2 Diabetes Rat Model” and “Oral Long-Acting Menin Inhibitor, BMF-219, Normalizes Type 2 Diabetes Mellitus in Two Rat Models” at the 2022 European Association for the Study of Diabetes (EASD) Annual Meeting in Stockholm, Sweden
  - New preclinical data from two in-vivo models at EASD demonstrated BMF-219’s ability to improve pancreatic beta cell mass and function, and BMF-219’s robust and prolonged glycemic control, insulin sensitization, and reduction of weight and lipid levels

Outlook

- Submit IND for BMF-219 in type 2 diabetes patients before the end of 2022
- Present clinical update of AML/ALL patients (including those with MLL rearrangement and NPM1 mutation), dosed in COVALENT-101 study in the first half of 2023
- Present clinical update on type 2 diabetes patients in the first half of 2023
- Submit IND for BMF-500 in patients with FLT3 mutations in the first half of 2023
- Present clinical update of the healthy volunteer section of our Phase I/II type 2 diabetes COVALENT-111 study of BMF-219 at a scientific meeting in 2023
- Expect to provide an update leveraging the proprietary FUSION^{TM} System, a discovery and design platform to expand pipeline of covalent medicines for cancer to a third development candidate in the first half of 2023

Third Quarter 2022 Financial Results

- **Cash, Cash Equivalents, Restricted Cash, and Investments:** As of September 30, 2022, the Company had cash, cash equivalents, restricted cash, and investments of $133.8 million, compared to $175.7 million as of December 31, 2021.
- **Net Income/Loss:** Biomea reported a net loss attributable to common stockholders of $22.9 million for the three months ended September 30, 2022, compared to a net loss of $12.6 million for the same period in 2021. Net loss attributable to common stockholders was $56.5 million for the nine months ended September 30, 2022, compared to a net loss of $26.9 million for the same period in 2021.
- **Research and Development (R&D) Expenses:** R&D expenses were $18.2 million for the three months ended September 30, 2022, compared to $7.9 million for the same period in 2021. The increase of $10.4 million was primarily due to an increase in preclinical and clinical development costs as well as an increase in personnel-related expenses. R&D expenses were $42.2 million for the nine months ended September 30, 2022, compared to $16.9 million for the same period in 2021. The increase of $25.3 million was primarily due to an increase in personnel-related expenses, as well as an increase in preclinical and clinical development costs, including manufacturing and external consulting, related to the Company’s

product candidates, BMF-219 and BMF-500.

- **General and Administrative (G&A) Expenses:** G&A expenses were $5.2 million for the three months ended September 30, 2022, compared to $4.8 million for the same period in 2021. The increase of $0.5 million was primarily due to higher personnel-related expenses and other corporate costs to support the Company's expanding operations as well as additional costs incurred as a public company. G&A expenses were $15.2 million for the nine months ended September 30, 2022, compared to $10.0 million for the same period in 2021. The increase of $5.2 million was primarily due to higher personnel-related expenses and other corporate costs to support the Company's expanding operations as well as additional costs incurred as a public company.

About Biomea Fusion

Biomea Fusion is a biopharmaceutical company focused on the discovery and development of covalent small molecules to treat patients with genetically defined cancers 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. The company is utilizing its proprietary FUSION™ System to advance a pipeline of covalent-binding therapeutic agents against key oncogenic drivers of cancer and metabolic diseases. Biomea Fusion's goal is to utilize its capabilities and platform to become a leader in developing covalent small molecules in order to maximize the clinical benefit when treating various cancers and metabolic diseases.

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 our cash runway, the clinical and therapeutic potential of our product candidates and development programs, including BMF-219 and BMF-500, the potential of BMF-500 as an FLT3 inhibitor, the potential of BMF-219 as a treatment for various types of cancer and diabetes, our research, development and regulatory plans, the progress of our ongoing clinical trials, including COVALENT-101, COVALENT-102 and our Phase I/II COVALENT-111 study of BMF-219 in type 2 diabetes, our plans to submit IND applications for BMF-500 in patients with FLT3 mutations and for BMF-219 in type 2 diabetes, our plans to provide clinical updates on the healthy volunteer section of our Phase I/II type 2 diabetes study of BMF-219, BMF-219 in type 2 diabetes patients, and patients in the COVALENT-101 study, 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 we may encounter delays in preclinical or clinical development, the preparation, filing and clearance of INDs, 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
(Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development [1]	$ 18,242	$ 7,886	$ 42,174	$ 16,908
General and administrative [1]	5,242	4,752	15,184	10,022
Total operating expenses	23,484	12,638	57,358	26,930
Loss from operations	(23,484)	(12,638)	(57,358)	(26,930)
Interest and other income, net	594	32	844	73
Net loss	$ (22,890)	$ (12,606)	$ (56,514)	$ (26,857)
Other comprehensive loss:				
Unrealized gain (loss) on investments, net	4	—	(3)	2
Comprehensive loss	$ (22,886)	$ (12,606)	$ (56,517)	$ (26,855)
Net loss per common share, basic and diluted	(0.78)	(0.43)	(1.93)	(1.21)

Weighted-average number of shares used to compute basic and diluted net loss per common share	29,319,042	29,001,213	29,214,549	22,105,321

(1) Includes stock-based compensation as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	$ 1,186	$ 766	$ 3,451	$ 1,690
General and administrative	1,545	1,155	4,169	2,613
Total stock-based compensation expense	$ 2,731	$ 1,921	$ 7,620	$ 4,303

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

	September 30, 2022	December 31, 2021
Cash, cash equivalents, investments, and restricted cash	$ 133,819	$ 175,743
Working capital	126,272	171,924
Total assets	145,050	185,705
Stockholders' equity	130,635	178,783

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