Sagimet Biosciences Reports Second Quarter 2024 Financial Results and Provides Corporate Updates

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Denifanstat Phase 2b FASCINATE-2 clinical trial 52-week data was presented in June at the European Association for the Study of the Liver (EASL) Congress

Preparations are ongoing to initiate a Phase 3 clinical development program for denifanstat in patients with metabolic dysfunction-associated steatohepatitis (MASH) in the second half of 2024

Two biotechnology industry leaders, Anne Phillips and Jennifer Jarrett, joined the Board of Directors effective August 1, 2024

Anticipated cash runway through 2025 with cash, cash equivalents and marketable securities totaling $188.5 million as of June 30, 2024

SAN MATEO, Calif., Aug. 14, 2024 (GLOBE NEWSWIRE) -- Sagimet Biosciences Inc. (Nasdaq: SGMT), a clinical-stage biopharmaceutical company developing novel therapeutics targeting dysfunctional metabolic pathways, today reported financial results for the second quarter ended June 30, 2024, and provided recent corporate updates.

"In June, we presented the full Phase 2b FASCINATE-2 clinical trial 52-week biopsy results at EASL showing denifanstat's statistically significant fibrosis reduction in advanced F2 and F3 patients and a statistically significant delay in progression to cirrhosis," said David Happel, Chief Executive Officer of Sagimet. "We believe these encouraging data, which demonstrate denifanstat's mechanism of action as the only fat synthesis inhibitor that directly targets the three key drivers of MASH -- fat accumulation, inflammation, and fibrosis -- differentiate denifanstat from other therapeutics in the field. We plan to initiate the Phase 3 program for denifanstat in MASH in the second half of 2024 and intend to share the Phase 3 pivotal trial design later in the year. We look forward to progressing the development of denifanstat for patients living with MASH, a condition which has grown to epidemic levels worldwide."

Recent Corporate Highlights

- On June 6, 2024, Sagimet presented the full 52-week data from the intention to treat (ITT), modified intention to treat (mITT), and F3 patient populations in the Phase 2b FASCINATE-2 clinical trial of denifanstat at EASL. Key outcomes data included:
  - A statistically significant improvement in liver fibrosis by ≥1-stage without worsening of MASH at 52-weeks in ITT population and in patients with baseline stage 3 fibrosis.
    - ITT (denifanstat 30% vs. placebo 14%, p=0.0199), and
    - F3 mITT (denifanstat 49% vs. placebo 13%, p=0.0032)
  - A statistically significant improvement in liver fibrosis by ≥2-stage without worsening of MASH at 52-weeks in mITT population and in patients with baseline stage 3 fibrosis.
    - mITT (denifanstat 20% vs. placebo 2%, p=0.0065), and
    - F3 mITT (denifanstat 34% vs. placebo 4%, p=0.0065)
  - A statistically significant difference in progression to cirrhosis (F4) in mITT population (denifanstat 5% vs. placebo 11%, p=0.0386).
  - A statistically significant difference in fibrosis improvement by ≥ 1 stage with no worsening of MASH for patients on a stable background dose of a GLP-1RA (denifanstat 42% vs. placebo 0%, p=0.034) in mITT population.
  - A statistically significant increase in beneficial polyunsaturated triglycerides at the end of 52 weeks of treatment (+42% denifanstat vs. -4% placebo, p<0.001) in the mITT population.
  - Tripalmitin, a biomarker of denifanstat activity, showed an early and sustained reduction in de novo lipogenesis at 4-weeks (-2.4ug/ml with denifanstat vs. -0.4ug/mL placebo, p=0.001) and 13-weeks (-2.2ug/mL with denifanstat vs. -0.1ug/mL placebo, p=0.005) in the ITT population.
- On June 13, the Company hosted a conference call and webcast (link here) featuring Rohit Loomba, M.D., M.H.Sc., Professor of Medicine, Chief, Division of Gastroenterology and Hepatology, and Director, MASLD Research Center, University of California San Diego, and Principal Investigator of the Phase 2b FASCINATE-2 clinical trial. In the webcast, Dr. Loomba reviewed denifanstat's strong fibrosis data as well as the preclinical data supporting the potential clinical use of denifanstat in combination with other medicines such as GLP-1s and thyroid-hormone receptor-beta (TRβ) agonists, including resmetirom, which he indicated could synergistically improve outcome of disease.
- On August 1, the Company announced the appointment to its board of directors of Dr. Anne Phillips and Jennifer Jarrett,

two biotechnology industry leaders with extensive experience in clinical development, regulatory strategy, operations, and finance.

Anticipated Upcoming Milestones

- Following the company's End-of-Phase 2 meeting with the FDA in May 2024, discussions are currently ongoing with the FDA regarding the Phase 3 development plans for denifanstat in MASH. A contract with a Contract Research Organization (CRO) for the global Phase 3 development program has been executed and study start-up operational activities are ongoing. Pending the FDA's feedback, the company plans to start the Phase 3 program in the second half of 2024.
- The Phase 3 study of denifanstat in acne, conducted by license partner Ascletis Pharmaceuticals, is recruiting in China and expected to be fully enrolled by the end of 2024. This Phase 3 study was initiated after positive Phase 2 acne data reported in Q2 2023 [link].

Financial Results for the Three and Six Months Ended June 30, 2024

- **Cash and cash equivalents and marketable securities** as of June 30, 2024 was $188.5 million, including $104.7 million net proceeds from our January 2024 follow-on offering, which are expected to fund operations through 2025 based on management's current operating plan.

- **Research and development expense** for the three and six months ended June 30, 2024 was $6.3 million and $11.6 million, respectively, compared to $4.7 million and $9.2 million for the three and six months ended June 30, 2023, respectively.

- **General and administrative expense** for the three and six months ended June 30, 2024 was $4.3 million and $7.8 million, respectively, compared to $2.4 million and $4.7 million for the three and six months ended June 30, 2023, respectively.

- **Net loss** for the three and six months ended June 30, 2024 was $8.1 million and $14.7 million, respectively, compared to $6.8 million and $13.4 million for the three and six months ended June 30, 2023, respectively.

About Sagimet Biosciences
Sagimet is a clinical-stage biopharmaceutical company developing novel fatty acid synthase (FASN) inhibitors that are designed to target dysfunctional metabolic pathways in diseases resulting from the overproduction of the fatty acid, palmitate. Sagimet's lead drug candidate, denifanstat, is an oral, once-daily pill and selective FASN inhibitor in development for the treatment of MASH. FASCINATE-2, a Phase 2b clinical trial of denifanstat in MASH with liver biopsy-based primary endpoints, was successfully completed with positive results. For additional information about Sagimet, please visit www.sagimet.com.

About MASH
MASH is a progressive and severe liver disease which is estimated to impact more than 115 million people worldwide, for which there is only one recently approved treatment in the United States and no currently approved treatments in Europe. In 2023, global liver disease medical societies and patient groups formalized the decision to rename non-alcoholic fatty liver disease (NAFLD) to metabolic dysfunction-associated steatotic liver disease (MASLD) and nonalcoholic steatohepatitis (NASH) to MASH. Additionally, an overarching term, steatotic liver disease (SLD), was established to capture multiple types of liver diseases associated with fat buildup in the liver. The goal of the name change was to establish an affirmative, non-stigmatizing name and diagnosis.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of, and made pursuant to the safe harbor provisions of, The Private Securities Litigation Reform Act of 1995. All statements contained in this press release, other than statements of historical facts or statements that relate to present facts or current conditions, including but not limited to, statements regarding: the expected timing of the presentation of data from ongoing clinical trials, Sagimet's clinical development plans and related anticipated development milestones, Sagimet's cash and financial resources and expected cash runway. These statements involve known and unknown risks, uncertainties and other important factors that may cause Sagimet's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, these statements can be identified by terms such as "may," "might," "will," "should," "expect," "plan," "aim," "seek," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "forecast," "potential" or "continue" or the negative of these terms or other similar expressions.

The forward-looking statements in this press release are only predictions. Sagimet has based these forward-looking statements largely on its current expectations and projections about future events and financial trends that Sagimet believes may affect its business, financial condition and results of operations. These forward-looking statements speak only as of the date of this press release and are subject to a number of risks, uncertainties and assumptions, some of which cannot be predicted or quantified and some of which are beyond Sagimet's control, including, among others: the clinical development and therapeutic potential of denifanstat or any other drug candidates Sagimet may develop; Sagimet's ability to advance drug candidates into and successfully complete clinical trials within anticipated timelines, including its Phase 3 denifanstat program; Sagimet's relationship with Ascletis, and the success of its development efforts for denifanstat; the accuracy of Sagimet's estimates regarding its capital requirements; and Sagimet's ability to maintain and successfully enforce adequate intellectual property protection. These and other risks and uncertainties are described more fully in the "Risk Factors" section of Sagimet's most recent filings with the Securities and Exchange Commission and available at www.sec.gov. You should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in these forward-looking statements may not be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. Moreover, Sagimet operates in a dynamic industry and economy. New risk factors and uncertainties may emerge from time to time, and it is not

possible for management to predict all risk factors and uncertainties that Sagimet may face. Except as required by applicable law, Sagimet does not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

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SAGIMET BIOSCIENCES INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

(in thousands, except for share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 6,313	$ 4,676	$ 11,575	$ 9,163
General and administrative	4,276	2,381	7,782	4,659
Total operating expenses	10,589	7,057	19,357	13,822
Loss from operations	(10,589)	(7,057)	(19,357)	(13,822)
Interest income and other	2,471	272	4,610	450
Net loss	$ (8,118)	$ (6,785)	$ (14,747)	$ (13,372)
Other comprehensive income (loss):				
Net unrealized income (loss) on marketable securities	(30)	13	(53)	84
Comprehensive loss	$ (8,148)	$ (6,772)	$ (14,800)	$ (13,288)
Net loss per share, basic and diluted	$ (0.25)	$ (35.80)	$ (0.48)	$ (71.39)
Weighted-average shares outstanding, basic and diluted	31,913,887	189,520	30,476,657	187,314

SAGIMET BIOSCIENCES INC.

CONDENSED BALANCE SHEETS

(Unaudited)

(in thousands)

	As of	
	June 30, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 188,491	$ 94,897
Total assets	$ 189,020	$ 96,719
Current liabilties	$ 5,728	$ 5,654
Stockholders' equity	$ 183,292	$ 91,065
Liabilities and stockholders' equity	$ 189,020	$ 96,719

SAGIMET BIOSCIENCES

Source: Sagimet Biosciences Inc.