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

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Denifanstat Phase 2b FASCINATE-2 clinical data to be presented as an oral presentation at the EASL International Liver Congress 2024 taking place in Milan, Italy from June 5-8, 2024

End-of-Phase 2 meeting with U.S. Food and Drug Administration (FDA) expected in the second quarter of 2024

Preparations are underway to start a pivotal Phase 3 trial evaluating denifanstat in patients with metabolic dysfunction-associated steatohepatitis (MASH) in the second half of 2024

Anticipated cash runway through 2025 with cash, cash equivalents and marketable securities totaling $193.7 million as of March 31, 2024

SAN MATEO, Calif., May 15, 2024 (GLOBE NEWSWIRE) -- Sagimet Biosciences Inc. (Sagimet, Nasdaq: SGMT), a clinical-stage biopharmaceutical company developing novel fatty acid synthase (FASN) inhibitors designed to target dysfunctional metabolic and fibrotic pathways, today reported financial results for the quarter ended March 31, 2024, and provided recent corporate updates.

“Sagimet continues to focus on advancing the clinical development of denifanstat in MASH,” said David Happel, Chief Executive Officer of Sagimet. “In the first quarter of 2024, we announced the Phase 2b FASCINATE-2 clinical trial met both primary efficacy endpoints and demonstrated statistically significant reduction in fibrosis, and our successful completion of a follow-on offering netting $104.7 million in proceeds. We look forward to presenting the full FASCINATE-2 Phase 2b 52-week biopsy results at EASL in June 2024. We plan to start a Phase 3 clinical trial of denifanstat in MASH in the second half of 2024 following the End-of-Phase 2 meeting with the FDA expected in the second quarter of 2024.”

Recent Corporate Highlights

- In January 2024, Sagimet announced positive topline results from the Phase 2b FASCINATE-2 clinical trial, evaluating denifanstat in biopsy-confirmed MASH patients with stage F2 or F3 fibrosis compared to placebo at week 52.
  - The study met its primary efficacy endpoints:
    - MASH resolution without worsening of fibrosis with ≥2-point reduction in NAS (NAFLD Activity Score) in 36% of denifanstat-treated patients vs 13% with placebo (p=0.0022)
    - ≥2-point reduction in NAS without worsening of fibrosis in 52% of denifanstat-treated patients vs 20% with placebo (p=0.0001)
  - Multiple secondary endpoints were met, achieving statistical significance, most notably fibrosis improvement by ≥ 1 stage with no worsening of MASH in 41% of denifanstat-treated patients vs 18% with placebo (p=0.005).
- In January 2024, Sagimet sold 9,000,000 shares of its Series A common stock in an underwritten public offering and received $104.7 million in net proceeds. Proceeds from the offering, together with its existing cash, cash equivalents and marketable securities will be used to continue advancement of the Sagimet pipeline, and other general corporate purposes including working capital and operating expenses.
- In March 2024, the company announced completion of the Phase 1 hepatic impairment trial. This trial, designed to assess the safety and pharmacokinetics of denifanstat in subjects with hepatic impairment, is a typical requirement of development programs in MASH. Denifanstat was well-tolerated and no safety signals were reported. The pharmacokinetic results from this trial support the planned Phase 3 clinical trial for denifanstat in MASH.
- In March 2024, the company announced the appointment of two biotechnology industry leaders, Tim Walbert and Paul Hoelscher, to the board of directors of the company, effective April 1, 2024.

Anticipated Upcoming Milestones

- The FDA End-of-Phase 2 meeting for denifanstat in MASH is expected in the second quarter of 2024. Pending the outcome of that meeting, the company expects to start a denifanstat pivotal Phase 3 clinical trial in MASH during the second half of 2024.

Financial Results for the Three Months Ended March 31, 2024

- **Cash, cash equivalents and marketable securities** as of March 31, 2024 were $193.7 million, including $104.7 million net proceeds from our January 2024 follow-on offering, which are expected to fund operations for at least the next 12 months based on management’s current operating plan.

- **Research and development expense** for the quarter ended March 31, 2024 was $5.3 million compared to $4.5 million for the first quarter of 2023.

- **General and administrative expense** for the quarter ended March 31, 2024 was $3.5 million compared to $2.3 million for the first quarter of 2023.

- **Net loss** for the first quarter ended March 31, 2024 was $6.6 million compared to a net loss of $6.6 million for the first quarter of 2023.

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 metabolic dysfunction-associated steatohepatitis (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, 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 March 31,	
	2024	**2023**
Operating expenses:		
Research and development	$ 5,262	$ 4,487
General and administrative	3,506	2,278
Total operating expenses	8,768	6,765
Loss from operations	(8,768)	(6,765)
Other income, net:		
Change in fair value of stock warrant liability	-	(2)
Interest income and other	2,139	180

Net loss	$ (6,629)	$ (6,587)
Other comprehensive gain (loss):		
Net unrealized gain (loss) on marketable securities	(23)	71
Total other comprehensive gain (loss)	(23)	71
Comprehensive loss	$ (6,652)	$ (6,516)
Net loss per share, basic and diluted	$ (0.23)	$ (35.58)
Weighted-average shares outstanding, basic and diluted	29,039,427	185,137

SAGIMET BIOSCIENCES INC.
CONDENSED BALANCE SHEETS
(Unaudited)
(in thousands)

	As of	
	March 31, 2024	**December 31, 2023**
Cash, cash equivalents and marketable securities	$ 193,705	$ 94,897
Total assets	$ 194,528	$ 96,719
Current liabilties	$ 4,510	$ 5,654
Stockholders' equity	$ 190,018	$ 91,065
Liabilities and stockholders' equity	$ 194,528	$ 96,719

Source: Sagimet Biosciences Inc.