Sagimet Biosciences Reports First Quarter 2025 Financial Results and Provides Corporate Updates

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Phase 1 clinical trial to evaluate the pharmacokinetics (PK) of a combination of denifanstat and resmetirom expected to initiate in 2H 2025; data readout expected 1H 2026

SAN MATEO, Calif., May 08, 2025 (GLOBE NEWSWIRE) -- Sagimet Biosciences Inc. (Nasdaq: SGMT), a clinical-stage biopharmaceutical company developing novel therapeutics targeting dysfunctional metabolic and fibrotic pathways, today reported financial results for the quarter ended March 31, 2025, and provided recent corporate updates.

“Sagimet is committed to bringing innovative therapies to MASH patients, following the successful results of our Phase 2b FASCINATE-2 clinical trial of denifanstat in MASH F2-F3 patients, particularly in more advanced F3 stage patients. In a Phase 1 clinical trial in patients with and without hepatic impairment, denifanstat exhibited similar pharmacokinetic characteristics and was well tolerated among all groups. Considering these strong Phase 1 and Phase 2 data, further development of denifanstat in MASH, including as part of a combination program, could potentially offer an opportunity to serve patient groups with the strongest need of treatment including those with stage 4 fibrosis,” said David Happel, Chief Executive Officer of Sagimet. “Building on our presentation of compelling preclinical data at 2024 EASL demonstrating the synergistic effect of a FASN inhibitor combined with resmetirom on important liver disease markers, we anticipate initiating a Phase 1 clinical trial to evaluate the PK and tolerability of a combination of denifanstat and resmetirom in the second half of 2025. If the outcome of this Phase 1 trial is positive, we will explore moving into the development of a combination product -- which we envision as a single tablet -- for patients living with MASH. We remain strongly convinced of the significant therapeutic potential associated with FASN inhibition across multiple disease states.”

Recent Corporate Highlights

- Pre-clinical data presented at EASL in 2024 for two mouse models of MASH showed that the combination of a FASN inhibitor (TVB-3664, a surrogate for denifanstat) and resmetirom had a synergistic effect on important liver disease markers, including improvement of NAS (NAFLD Activity Score) by histologic analysis and more robust improvement in hepatic collagen content compared to the single agents. Synergistic activity of the combination was demonstrated in the rate of histological improvement (NAS ≥2 points). The FASN inhibitor monotherapy showed 33% improvement, resmetirom monotherapy showed 25% improvement, and the combination of the two showed an 80% improvement, a level of improvement that greatly exceeds a simple addition of the activity of the two drugs. Building on this combination data, subject to consultation with regulatory authorities, Sagimet plans to initiate a Phase 1 clinical trial to evaluate the PK of a combination of denifanstat and resmetirom in the second half of 2025, with an anticipated data readout in the first half of 2026. If the outcome of this Phase 1 clinical PK trial is positive, Sagimet anticipates exploring the development of a combination product for MASH patients.

  > 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, said, “I’m excited to see Sagimet initiate development of a combination of denifanstat and resmetirom with this Phase 1 PK trial which will potentially answer important questions about the compatibility of these two molecules in humans. Results of this Phase 1 trial, if successful, could lead to further development of a combination of Sagimet’s fat synthesis inhibitor, denifanstat, with a fat oxidizer in MASH patients, potentially including those with stage 4 fibrosis.”

- End-of-Phase 2 interactions with the FDA were successfully completed in October 2024, supporting the advancement of denifanstat into Phase 3 in MASH. While Sagimet is operationally ready to dose patients in Phase 3 trials in F2/F3 MASH patients, it does not intend to initiate these trials until such time as it has sufficient funding to do so. Sagimet is currently exploring various alternatives to fund the ongoing development of denifanstat as a monotherapy.

- Effective May 6, 2025, George Kemble, Ph.D. transitioned from his executive officer position as Executive Chairman and moved into the role of non-executive Chair of the Board. Also effective as of May 6, 2025, the Board appointed Beth Seidenberg, M.D. to serve as Lead Independent Director of the Board. Effective as of June 9, 2025, the date of Sagimet’s Annual Meeting, Merdad Parsey, M.D., Ph.D, will step off the Board. The Board thanks Dr. Parsey for his fifteen years of service to the Company as a Director.

Publications and Presentations

- In May 2025, Sagimet is presenting three poster presentations featuring additional analyses from the Phase 2b FASCINATE-2 trial of denifanstat in MASH at the European Association for the Study of Liver (EASL) Congress 2025. The posters focus on antifibrotic effects of denifanstat in difficult-to-treat patients, new bile acid biomarkers to measure denifanstat response and alternative endpoints to liver biopsy such as MRI to detect patient improvement.

- In February 2025, Sagimet delivered an oral presentation at the MASH Pathogenesis and Therapeutic Approaches Keystone Symposium. The presentation featured lipidomic data on improvements in polyunsaturated fatty acid triglycerides

and LDL cholesterol levels in advanced fibrosis patients from the Phase 2b FASCINATE-2 trial of denifanstat in MASH, and preclinical data showing reduction of LDL and chemokines in a preclinical atherosclerosis model with a FASN inhibitor (TVB-3664, a surrogate for denifanstat).

- In January 2025, Sagimet delivered an oral presentation at the 9th Annual MASH-TAG Conference highlighting the differentiated mechanism of action of the FASN inhibitor denifanstat and its observed anti-fibrotic effect in the Phase 2b FASCINATE-2 trial in F2/F3 MASH.

Anticipated Upcoming Milestones

- Phase 1 clinical trial to evaluate the PK and tolerability of a combination of denifanstat and resmetirom, planned to initiate in the second half of 2025, with an anticipated data readout in the first half of 2026.
- In November 2024, the Company's license partner for China, Ascletis BioScience Co. Ltd. (Ascletis) announced completion of enrollment of 480 patients in its Phase 3 clinical trial of denifanstat for acne in China, and that it expects to announce topline results in the second quarter of 2025.
- First-in-human Phase 1 clinical trial of TVB-3567 in acne expected to initiate in the second half of 2025, following the IND clearance in March 2025.

Financial Results for the Three Months Ended March 31, 2025

- **Cash, cash equivalents and marketable securities** as of March 31, 2025, were $144.6 million.
- **Research and development expense** for the quarter ended March 31, 2025, was $15.3 million compared to $5.3 million for the first quarter of 2024.
- **General and administrative expense** for the quarter ended March 31, 2025, was $4.5 million, compared to $3.5 million for the first quarter of 2024.
- **Net loss** for the quarter ended March 31, 2025, was $18.2 million compared to $6.6 million for the first quarter of 2024.

About Sagimet Biosciences

Sagimet is a clinical-stage biopharmaceutical company developing novel fatty acid synthase (FASN) inhibitors that are designed to target dysfunctional metabolic and fibrotic 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 metabolic dysfunction associated steatohepatitis (MASH). FASCINATE-2, a Phase 2b clinical trial of denifanstat in MASH with liver biopsy-based primary endpoints, was successfully completed with positive results. Denifanstat has been granted Breakthrough Therapy designation by the FDA for the treatment of non-cirrhotic MASH with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis), and end-of-Phase 2 interactions with the FDA have been successfully completed, supporting the advancement of denifanstat into further development. Sagimet's second FASN inhibitor, TVB-3567, a potent and selective small molecule FASN inhibitor, received IND clearance in March 2025, allowing initiation of a first-in-human Phase 1 clinical trial in acne. For additional information about Sagimet, please visit www.sagimet.com.

About MASH

Metabolic-dysfunction associated steatohepatitis (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; 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,	
	2025	2024
	(unaudited)	
Operating expenses:		
Research and development	15,342	5,262
General and administrative	4,523	3,506
Total operating expenses	19,865	8,768
Loss from operations	(19,865)	(8,768)
Total other income	1,689	2,139
Net loss	$ (18,176)	$ (6,629)
Net loss per share, basic and diluted	$ (0.56)	$ (0.23)
Weighted-average shares outstanding, basic and diluted	32,195,345	29,039,427
Net loss	$ (18,176)	$ (6,629)
Other comprehensive loss:		
Net unrealized loss on marketable securities	(109)	(23)
Total comprehensive loss	$ (18,285)	$ (6,652)

SAGIMET BIOSCIENCES INC.

CONDENSED BALANCE SHEETS

(unaudited)

(in thousands)

	As of	
	March 31, 2025	December 31, 2024
Cash, cash equivalents and marketable securities	$ 144,569	$ 158,658
Total assets	$ 146,172	$ 160,259
Current liabilties	$ 7,180	$ 4,454
Stockholders' equity	$ 138,992	$ 155,805
Liabilities and stockholders' equity	$ 146,172	$ 160,259



Source: Sagimet Biosciences Inc.