Sagimet Biosciences Reports Full Year 2024 Financial Results and Provides Corporate Updates

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Denifanstat Phase 3 MASH program initiated in Q4 2024; patient screening expected to start in 1H 2025

Denifanstat received Breakthrough Therapy designation from FDA for MASH

Clearance of Investigational New Drug (IND) application for FASN Inhibitor TVB-3567, to be developed for the treatment of acne

SAN MATEO, Calif., March 12, 2025 (GLOBE NEWSWIRE) -- Sagimet Biosciences Inc. (Nasdaq: SGMT), clinical-stage biopharmaceutical company developing novel therapeutics targeting dysfunctional metabolic and fibrotic pathways, today reported financial results for the full year ended December 31, 2024, and provided recent corporate updates.

“2024 was a highly productive year for Sagimet, and we’re carrying that momentum into a strong start for 2025,” said David Happel, Chief Executive Officer of Sagimet. “We are pleased to have initiated our Phase 3 denifanstat program in MASH, with site activation and patient pre-screening underway and patient screening expected to begin soon. With the successful Phase 2b FASCINATE-2 results we reported in 2024, and Breakthrough Therapy designation granted by the FDA, we are confident in denifanstat’s potential to address the significant unmet need for patients living with MASH. At the same time, we are excited to advance a second Fatty Acid Synthase inhibitor, TVB-3567, into the clinic for the potential treatment of moderate to severe acne, following IND clearance. Given the potential of FASN inhibition across multiple disease states, we look forward to progressing both denifanstat and TVB-3567 in the coming year.”

Full Year and Recent Corporate Highlights

Clinical and Regulatory Updates

- In March 2025, Sagimet announced the clearance of its IND application for a first-in-human Phase 1 clinical trial of a second FASN inhibitor, TVB-3567. The Phase 1 trial initiation is planned in 2025.
- In October 2024, Sagimet announced the successful completion of end-of-Phase 2 interactions with the FDA, supporting the advancement of denifanstat into Phase 3 development in metabolic-dysfunction associated steatohepatitis (MASH). The planned program will include two Phase 3 trials: FASCINATE-3, evaluating patients with F2/F3 (non-cirrhotic) MASH, and FASCINIT, evaluating patients with suspected or confirmed diagnosis of metabolic dysfunction-associated steatotic liver disease (MASLD)/MASH.
- In October 2024, Sagimet announced that the FDA granted Breakthrough Therapy designation to denifanstat for the treatment of non-cirrhotic MASH with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis). Breakthrough Therapy designation was supported by positive data from the Phase 2b FASCINATE-2 trial in biopsy-confirmed F2/F3 MASH patients and continuing unmet need for differentiated therapies.
- 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 and multiple secondary endpoints. Full 52-week data from the intention to treat (ITT), modified intention to treat (mITT), and F3 patient population were presented at the European Association for the Study of the Liver (EASL) Congress in June 2024.

Publications and Presentations

- 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.
- 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 the observed anti-fibrotic effect in the Phase 2b FASCINATE-2 study in F2/F3 MASH.
- In November 2024, Sagimet presented clinical denifanstat and preclinical FASN inhibitor data at the American Association for the Study of Liver Disease (AASLD) - The Liver Meeting 2024®. Phase 2b data demonstrating the anti-fibrotic activity of its FASN inhibitor denifanstat was featured in an oral presentation and poster. In addition, preclinical data demonstrating potential benefit of FASN inhibition in reversing atherosclerosis was presented in a poster.
- In October 2024, Sagimet announced the publication of results from the Phase 2b FASCINATE-2 clinical trial of denifanstat

in *The Lancet Gastroenterology & Hepatology*. The publication, titled “Denifanstat for the treatment of metabolic-dysfunction associated steatohepatitis: a multicentre, double-blind, randomised, placebo-controlled, phase 2b trial,” reported that denifanstat treatment achieved statistically significant and clinically meaningful improvements in disease activity, MASH resolution and fibrosis.

- In September 2024, Sagimet delivered an oral presentation at the 8th Annual MASH Drug Development Summit highlighting denifanstat’s direct anti-fibrotic activity in MASH.

Corporate Updates

- Throughout 2024, Sagimet announced several appointments to its board of directors, including industry leaders Tim Walbert, Paul Hoelscher, Dr. Anne Phillips and Jennifer Jarrett.
- In May 2024, Sagimet appointed Thierry Chauche as Chief Financial Officer.
- In January 2024, Sagimet completed a follow-on offering of 9,000,000 shares of its Series A common stock, resulting in $104.7 million in net proceeds.

Anticipated Upcoming Milestones

- Start-up activities for the Phase 3 program for denifanstat in MASH have begun, with sites activated and patients pre-screened in the fourth quarter of 2024. Screening of patients is expected to start in the first half of 2025. The Phase 3 program consists of two double-blind, placebo-controlled multicenter registrational trials:
  - FASCINATE-3 in patients with F2/F3 (non-cirrhotic) MASH: The trial is expected to evaluate the efficacy and safety of denifanstat in this population, with primary endpoints being liver biopsy assessments at 52 weeks, at which time Sagimet plans to seek accelerated approval in the US and Europe based on this 52-week data. The trial will continue until such point in time that the required number of clinical outcomes is reached, estimated at 3.5 years after the week 52 timepoint.
  - FASCINIT in patients with suspected or confirmed diagnosis of MASLD/MASH: The trial is expected to evaluate the safety and efficacy of denifanstat in this population, with the primary endpoint of safety and tolerability at 52 weeks. Non-invasive biomarkers will be assessed as part of the secondary endpoints, with no liver biopsy endpoint.
  - The Phase 3 program is designed to comprise a minimum of 1,800 patients exposed to denifanstat.
- A first-in-human Phase 1 trial of TVB-3567 is anticipated to initiate in 2025.
- In November 2024, the Company’s license partner for Greater 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. The Phase 3 trial was initiated following positive Phase 2 acne data reported in Q2 2023.

Financial Results for the Full Year Ended December 31, 2024

- **Cash, cash equivalents and marketable securities** as of December 31, 2024, was $158.7 million, which are expected to fund operations for at least the next 12 months from the issuance of the financial statements for the year ended December 31, 2024.
- **Research and development expense** for the three months and year ended December 31, 2024, was $14.2 million and $38.4 million, respectively, compared to $5.7 million and $19.8 million for the three months and year ended December 31, 2023, respectively.
- **General and administrative expense** for the three months and year ended December 31, 2024, was $4.0 million and $16.0 million, respectively, compared to $3.8 million and $13.0 million for the three months and year ended December 31, 2023, respectively.
- **Net loss** for the three months and year ended December 31, 2024, was $16.2 million and $45.6 million, respectively, compared to $8.2 million and $27.9 million for the three months and year ended December 31, 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 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 Phase 3 development in MASH. 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, including its Phase 3 denifanstat program and Phase 1 acne 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.

Investor Contact:
Joyce Allaire
LifeSci Advisors
JAllaire@LifeSciAdvisors.com

Media Contact:
Michael Fitzhugh
LifeSci Advisors
mfitzhugh@lifescicomms.com

SAGIMET BIOSCIENCES INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

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

	Three Months Ended December 31,		Years Ended December 31,	
	2024	2023	2024	2023
	(unaudited)			
License revenue	$ —	$ —	$ —	$ 2,000
Operating expenses:				
Research and development	14,216	5,656	38,444	19,777
General and administrative	3,979	3,810	16,010	12,963
Total operating expenses	18,195	9,466	54,454	32,740
Loss from operations	(18,195)	(9,466)	(54,454)	(30,740)
Total other income	1,994	1,315	8,887	2,864
Net loss	$ (16,201)	$ (8,151)	$ (45,567)	$ (27,876)

Net loss per share, basic and diluted	$ (0.50)	$ (0.36)	$ (1.45)	$ (2.66)
Weighted-average shares outstanding, basic and diluted	32,195,345	22,895,892	31,350,725	10,460,335
Net loss	$ (16,201)	$ (8,151)	$ (45,567)	$ (27,876)
Other comprehensive (loss) income:				
Net unrealized (loss) income on marketable securities	(211)	30	200	114
Total comprehensive loss	$ (16,412)	$ (8,121)	$ (45,367)	$ (27,762)

SAGIMET BIOSCIENCES INC.

BALANCE SHEETS

(in thousands)

	As of	
	December 31, 2024	**December 31, 2023**
Cash, cash equivalents and marketable securities	$ 158,658	$ 94,897
Total assets	$ 160,259	$ 96,719
Current liabilties	$ 4,454	$ 5,654
Stockholders' equity	$ 155,805	$ 91,065
Liabilities and stockholders' equity	$ 160,259	$ 96,719

Source: Sagimet Biosciences Inc.