Sagimet Biosciences Reports Fourth Quarter and Full Year 2025 Financial Results and Provides Corporate Updates

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Completed Phase 1 pharmacokinetic (PK) clinical trial of denifanstat and resmetirom combination

Phase 2 trial of denifanstat/resmetirom combination in F4 MASH patients planned to initiate in 2H 2026

Secured global, exclusive license to TAPI's innovative forms of resmetirom active pharmaceutical ingredients (API)

First-in-human Phase 1 clinical trial of FASN inhibitor TVB-3567 ongoing

Positive topline results in open-label Phase 3 trial evaluating the long-term safety of denifanstat in patients with moderate to severe acne in China reported by Ascletis

China's National Medical Products Administration (NMPA) accepted Ascletis' New Drug Application (NDA) for denifanstat for the treatment of moderate to severe acne

SAN MATEO, Calif., March 11, 2026 (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 fourth quarter and full year ended December 31, 2025, and provided recent corporate updates.

"2025 saw important advances in both our MASH and acne programs," said David Happel, Chief Executive Officer of Sagimet. "We completed our Phase 1 PK clinical trial of denifanstat and resmetirom combination and anticipate advancing the combination into a proof-of-concept Phase 2 clinical trial in F4 MASH, for which there are currently no approved treatments, in the second half of the year. In acne, positive 52-week data from our license partner Ascletis' Phase 3 open-label acne trial with denifanstat will support Ascletis' NDA that was accepted by the Chinese NMPA. We anticipate further exploring the potential role of FASN inhibition in acne in clinical development in 2026."

Recent Corporate Highlights

Clinical and Regulatory Updates

- In December 2025, Sagimet announced the completion of its open-label Phase 1 pharmacokinetic (PK) clinical trial of its oral once-daily fatty acid synthase (FASN) inhibitor, denifanstat, and a thyroid hormone receptor beta (THR-β) agonist, resmetirom, to evaluate pharmacokinetics and potential drug-drug interactions (DDI), and to assess the safety and tolerability of the combination. The combination of denifanstat and resmetirom was generally well-tolerated over the duration of the study, with no safety signals. No serious adverse events occurred, and there were no clinically significant laboratory results, and no treatment discontinuations. Sagimet plans to use these data to advance the development of the combination into a Phase 2 proof-of-concept trial for patients living with MASH with F4 fibrosis.
- In June 2025, the Company initiated a first-in-human Phase 1 clinical trial of TVB-3567, a FASN inhibitor that is being developed for an acne indication. The Phase 1 clinical trial is a randomized, double-blind, placebo-controlled trial designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of TVB-3567 in healthy participants with or without acne.

Publications and Presentations

- In November 2025, Sagimet presented two posters at the American Association for the Study of Liver Disease (AASLD) - The Liver Meeting® 2025:
  - In a secondary analysis of the denifanstat Phase 2b FASCINATE-2 clinical trial, denifanstat elicited a significant ≥2-stage improvement in fibrosis in F3 MASH patients, and improved liver fibrosis and several noninvasive biomarkers in a subpopulation of qFibrosis stage 4 MASH patients identified by AI-based digital pathology (here).
  - An analysis utilizing spatial computational histology relying on baseline fibrosis features was used to predict response to denifanstat (here).

Corporate Updates

- In January 2026, Sagimet's license partner Ascletis Bioscience Co. Ltd. (Ascletis) reported positive topline results in the open-label Phase 3 trial evaluating the long-term safety of ASC40 (denifanstat) tablets in patients with moderate to severe acne in China. This open-label Phase 3 trial enrolled 240 subjects who received oral denifanstat 50 mg once daily for up to 40 weeks. Subjects who were originally randomized to denifanstat in the 12-week ASC40-303 trial had a total of 52 weeks

of denifanstat exposure at the end of the long-term safety study. Primary endpoints evaluated safety, and secondary endpoints evaluated certain efficacy measures for up to 52 weeks of denifanstat treatment. Denifanstat was generally well tolerated. Furthermore, subjects treated with denifanstat showed improvements in all of the efficacy endpoints (secondary endpoints of the trial), beyond those observed at 12 weeks.

- In December 2025, Sagimet announced its entry into a license agreement with Assia Chemical Industries Ltd. (Assia), doing business as TAPI Technology & API Services (TAPI), a subsidiary of Teva Pharmaceutical Industries Ltd. Under the agreement, TAPI granted Sagimet a global, exclusive license to certain intellectual property rights covering innovative forms of TAPI's resmetirom active pharmaceutical ingredient (API) for Sagimet's technical evaluation and manufacture, and, if elected by Sagimet, further development of a fixed-dose combination (FDC) product containing denifanstat and resmetirom. Pending patent applications filed by Sagimet and TAPI cover the FDC and the innovative resmetirom forms, respectively.
- In December 2025, China's National Medical Products Administration (NMPA) accepted Ascletis' New Drug Application (NDA) for denifanstat for the treatment of moderate to severe acne.

Anticipated Upcoming Milestones

- Following the completion of the Phase 1 PK clinical trial of the combination of denifanstat and resmetirom, Sagimet plans to advance the development of the combination into a Phase 2 proof-of-concept trial for patients living with MASH with F4 fibrosis, expected to initiate in the second half of 2026, subject to consultation with regulatory authorities.
- Upon completion of the Phase 1 clinical trial of TVB-3567, and subject to consultation with regulatory authorities, Sagimet anticipates starting a Phase 2 clinical trial with TVB-3567 in moderate to severe acne patients in 2026.

Financial Results for the Full Year Ended December 31, 2025

- **Cash, cash equivalents and marketable securities** as of December 31, 2025 were $113.1 million.
- **Research and development expense** for the three months and year ended December 31, 2025, was $6.7 million and $39.1 million, respectively, compared to $14.2 million and $38.4 million for the three months and year ended December 31, 2024, respectively.
- **General and administrative expense** for the three months and year ended December 31, 2025, was $4.0 million and $17.8 million, respectively, compared to $4.0 million and $16.0 million for the three months and year ended December 31, 2024, respectively.
- **Net loss** for the three months and year ended December 31, 2025, was $9.6 million and $51.0 million, respectively, compared to $16.2 million and $45.6 million for the three months and year ended December 31, 2024, respectively.

About Sagimet Biosciences

Sagimet is a clinical-stage biopharmaceutical company developing novel FASN inhibitors designed to target dysfunctional metabolic and fibrotic pathways in conditions resulting from the overproduction of the fatty acid, palmitate. Denifanstat, an oral, once-daily pill, met all primary endpoints in its Phase 2b FASCINATE-2 clinical trial in MASH, as well as all primary and secondary endpoints in Sagimet's license partner for China's Phase 3 clinical trial in moderate-to-severe acne. A combination of denifanstat and resmetirom was tested in a Phase 1 PK clinical trial and is planned to be developed for patients with MASH cirrhosis (F4). TVB-3567, a second oral FASN inhibitor which is planned to be developed for acne, is currently being tested in a Phase 1 first-in-human clinical trial. 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 265 million people worldwide[1]. MASH is characterized by the build-up of fat in the liver and various degrees of inflammation and fibrosis along with systemic metabolic changes including dyslipidemia (increased fat levels in blood) and insulin resistance. Patients with moderate to severe disease who have advanced fibrosis (F3) or cirrhosis (F4) have the highest risk of liver-related outcomes such as decompensation, hepatocellular carcinoma, and liver transplantation. There are few approved treatments for non-cirrhotic MASH (stages F1, F2 and F3 fibrosis) and no approved treatments for MASH cirrhosis (F4).

About Acne

Over 50 million people suffer from acne in the U.S., with 5.1 million acne patients treated by dermatologists annually, making it one of the most prevalent skin diseases addressed by physicians.[2,3] There is no cure for acne; and due to its pathology, most patients require chronic management and multiple annual courses of treatment for flare control. Adherence to topical therapies is lower than with oral agents, with an estimated 30% to 40% of patients not adhering to their topical treatments.[4]

Patients with acne vulgaris have increased sebum production compared to non-acne populations which contributes to the pathogenesis of the disease. Increased sebum production is due to increased de novo lipogenesis (DNL) locally in the sebocytes. FASN is the last committed step in the DNL pathway which produces the majority (>80%) of key sebum lipids such as palmitate and sapienic acid in acne, and FASN also contributes to inflammatory pathways, making the inhibition of FASN a potentially impactful approach to address acne.

1. Younossi ZM, et al. *Hepatology*. 2023;77(4): 1335-1347.

2. Bickers DR, et al. *J Am Acad Dermatol*. 2006;55(3):490-500.
3. American Academy of Dermatology. Burden of Skin Disease. 2017. www.aad.org/BSD.
4. Purvis CG, et al. *Ann Pharmacother*. 2021;55(10):1297-1299.

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 timelines and anticipated development milestones, Sagimet's cash and financial resources and expected cash runway are forward-looking statements. 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, TVB-3567 or any other drug candidates or combination therapies developed by Sagimet; 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.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

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

	Three Months Ended December 31,		Years Ended December 31,	
	2025	2024	2025	2024
Operating expenses:	(unaudited)			
Research and development	$ 6,734	$ 14,216	$ 39,054	$ 38,444
General and administrative	4,031	3,979	17,835	16,010
Total operating expenses	10,765	18,195	56,889	54,454
Loss from operations	(10,765)	(18,195)	(56,889)	(54,454)
Total other income	1,197	1,994	5,851	8,887
Net loss	$ (9,568)	$ (16,201)	$ (51,038)	$ (45,567)
Net loss per share, basic and diluted	$ (0.29)	$ (0.50)	$ (1.58)	$ (1.45)
Weighted-average shares outstanding, basic and diluted	32,521,599	32,195,345	32,345,525	31,350,725
Net loss	$ (9,568)	$ (16,201)	$ (51,038)	$ (45,567)
Other comprehensive income (loss):				
Net unrealized gain (loss) on marketable securities	3	(211)	(110)	200
Total comprehensive loss	$ (9,565)	$ (16,412)	$ (51,148)	$ (45,367)

SAGIMET BIOSCIENCES INC.

BALANCE SHEETS

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

	As of	
	December 31, 2025	**December 31, 2024**
Cash, cash equivalents and marketable securities	$ 113,124	$ 158,658
Total assets	$ 116,482	$ 160,259
Current liabilties	$ 5,101	$ 4,454
Stockholders' equity	$ 111,381	$ 155,805
Liabilities and stockholders' equity	$ 116,482	$ 160,259

Source: Sagimet Biosciences Inc.