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

11/13/2025 at 7:30 AM EST

Phase 1 clinical trial to evaluate the PK of a combination of denifanstat and resmetirom ongoing with data readout expected 1H 2026

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

Ascletis announced completion of its pre-NDA consultation with China's NMPA and plans to submit an NDA for denifanstat in China for treatment of moderate-to-severe acne vulgaris

SAN MATEO, Calif., Nov. 13, 2025 (GLOBE NEWSWIRE) -- Sagimet Biosciences Inc. (Sagimet, Nasdaq: SGMT), a clinical-stage biopharmaceutical company developing novel therapeutics targeting dysfunctional metabolic and fibrotic pathways, today reported financial results for the quarter ended September 30, 2025, and provided recent corporate updates.

"This is a dynamic period for Sagimet as we explore the therapeutic potential of FASN inhibition across different indications," said David Happel, Chief Executive Officer of Sagimet. "As part of our MASH development program targeting cirrhosis of the liver, we have initiated a Phase 1 PK trial evaluating the compatibility of a once-daily combination of denifanstat and resmetirom. We plan to use this data, if positive, to advance the combination to proof-of-concept studies in MASH patients with F4 fibrosis. Additionally, we initiated a Phase 1 clinical trial of our second FASN inhibitor, TVB-3567, for development of an acne indication. We continue to explore how FASN inhibition could benefit patients living with conditions that are currently underserved by approved therapies," he concluded.

Recent Corporate Highlights

- In September 2025, Sagimet dosed the first participants in a Phase 1 pharmacokinetic (PK) trial of a combination of its oral once-daily fatty acid synthase (FASN) inhibitor, denifanstat, and a thyroid hormone receptor beta (THR-β) agonist, resmetirom.
  - The Phase 1 PK trial of denifanstat and resmetirom is an open-label, 2-cohort study and has enrolled approximately 40 healthy adult participants. The objectives are to evaluate multiple-dose and single-dose pharmacokinetics, identify any potential drug-drug interactions (DDI), and assess the safety and tolerability of the combination.
  - Topline data from this trial are anticipated in the first half of 2026 and, if positive, may be used to advance the development of the combination for patients living with metabolic dysfunction associated steatohepatitis (MASH) into a Phase 2 clinical trial, subject to consultation with regulatory authorities.
- In October 2025, Ascletis Pharma Inc., the parent company of Sagimet's license partner for China, Ascletis Bioscience Co. Ltd. (Ascletis), announced that it completed its pre-New Drug Application (NDA) consultation with the China National Medical Products Administration (NMPA) for denifanstat for the treatment of moderate-to-severe acne vulgaris and plans to submit an NDA soon to the NMPA.
- Effective November 1, Marie O'Farrell, Ph.D., was promoted to Chief Scientific Officer and Liz Rozek, J.D., was promoted to Chief Legal & Administrative Officer.

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).
- In October 2025, Sagimet presented the data from Ascletis' Phase 3 clinical trial for the treatment of moderate to severe acne vulgaris in China at the 2025 Fall Clinical Dermatology Conference (here). As reported by Ascletis, in the clinical trial of 480 patients, once daily 50 mg denifanstat met all efficacy endpoints and was generally well-tolerated.
- In September 2025, Ascletis presented Phase 3 clinical trial data in acne at the European Academy of Dermatology and Venerology (EADV) 2025 Congress (here).

Anticipated Upcoming Milestones

- Sagimet anticipates the data read out of its Phase 1 clinical trial to evaluate the PK and tolerability of a combination of denifanstat and resmetirom in the first half of 2026.
- Subject to consultation with regulatory authorities, Sagimet anticipates starting a Phase 2 clinical trial in moderate to severe acne patients in 2026 following its ongoing Phase 1 clinical trial of TVB-3567 for development of an acne indication.

Financial Results for the Three and Nine Months Ended September 30, 2025

- **Cash, cash equivalents and marketable securities** as of September 30, 2025 were $125.5 million.
- **Research and development expense** for the three and nine months ended September 30, 2025, was $9.7 million and $32.3 million, respectively, compared to $12.7 million and $24.2 million for the three and nine months ended September 30, 2024, respectively.
- **General and administrative expense** for the three and nine months ended September 30, 2025 was $4.6 million and $13.8 million, respectively, compared to $4.2 million and $12.0 million for the three and nine months ended September 30, 2024, respectively.
- **Net loss** for the three and nine months ended September 30, 2025 was $12.9 million and $41.5 million, respectively, compared to $14.6 million and $29.4 million for the three and nine months ended September 30, 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 is currently being tested in a Phase 1 PK clinical trial and is planned to be developed for cirrhotic patients living with F4-stage MASH. 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. 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

There are 5.1 million acne patients treated by dermatologists annually in the U.S., and a total U.S. acne market of over 50 million people.[1,2] There is no cure for acne; and due to its pathology, most patients require chronic management and multiple courses of treatment for flare control annually. Additionally, adherence to topical therapies is lower than with oral agents, with an estimated 30% to 40% of patients not adhering to their topical treatments.[3]

1. Bickers DR, et al. *J Am Acad Dermatol*. 2006;55(3):490-500.
2. American Academy of Dermatology. Burden of Skin Disease. 2017. www.aad.org/BSD.
3. Purvis CG, Balogh EA, Feldman SR. Clascoterone: How the Novel Androgen Receptor Inhibitor Fits Into the Acne Treatment Paradigm. Ann Pharmacother. 2021;55(10):1297-1299. doi:10.1177/1060028021992055.

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 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.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	$ 9,730	$ 12,653	$ 32,320	$ 24,228
General and administrative	4,604	4,249	13,804	12,031
Total operating expenses	14,334	16,902	46,124	36,259
Loss from operations	(14,334)	(16,902)	(46,124)	(36,259)
Total other income	1,426	2,283	4,654	6,893
Net loss	$ (12,908)	$ (14,619)	$ (41,470)	$ (29,366)
Net loss per share, basic and diluted	$ (0.40)	$ (0.45)	$ (1.28)	$ (0.95)
Weighted-average shares outstanding, basic and diluted	32,464,893	32,143,336	32,286,188	31,036,271
Net loss	$ (12,908)	$ (14,619)	$ (41,470)	$ (29,366)
Other comprehensive income (loss):				
Net unrealized gain (loss) on marketable securities	41	464	(113)	411
Total comprehensive loss	$ (12,867)	$ (14,155)	$ (41,583)	$ (28,955)

SAGIMET BIOSCIENCES INC.

CONDENSED BALANCE SHEETS

(unaudited)

(in thousands)

	As of	
	September 30, 2025	December 31, 2024
Cash, cash equivalents and marketable securities	$ 125,499	$ 158,658
Total assets	$ 128,401	$ 160,259
Current liabilities	$ 9,146	$ 4,454
Stockholders' equity	$ 119,255	$ 155,805
Liabilities and stockholders' equity	$ 128,401	$ 160,259

Source: Sagimet Biosciences Inc.