Sagimet Biosciences Reports Third Quarter 2023 Financial Results and Provides Corporate Updates

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On track to report topline week 52 liver biopsy results from Phase 2b FASCINATE-2 trial with denifanstat in the first quarter of 2024

Two abstracts, including late-breaker, accepted at the American Association for the Study of Liver Diseases (AASLD) – The Liver Meeting® 2023

Enrollment of 120 patients in Phase 3 registrational trial of denifanstat in recurrent glioblastoma (GBM) announced by license partner, Ascletis

Presentation of positive topline Phase 2 denifanstat monotherapy data from Ascletis' acne program

SAN MATEO, Calif., Nov. 13, 2023 (GLOBE NEWSWIRE) -- Sagimet Biosciences Inc. (Sagimet, Nasdaq: SGMT), a clinical-stage biopharmaceutical company developing novel fatty acid synthase (FASN) inhibitors that target dysfunctional metabolic pathways, today reported financial results for the third quarter ended September 30, 2023, and provided recent corporate updates.

"The data generated to date reinforce our belief that denifanstat has the potential to treat patient populations in need across important therapeutic indications including NASH, oncology, and acne. Denifanstat, as a once-daily, oral pill, offers a convenient and well-tolerated potential treatment, particularly important for NASH, for which there are currently no approved treatments in the United States or Europe," said Dave Happel, Chief Executive Officer of Sagimet. "The Sagimet team remains focused on delivering week 52 topline results, including liver biopsy, from our Phase 2b FASCINATE-2 clinical trial in NASH in the first quarter of next year, a crucial milestone in our clinical development of denifanstat."

Recent Corporate Highlights

- Two abstracts were accepted at the AASLD – The Liver Meeting® 2023, held on November 10-14, in Boston, MA.
  - An abstract detailing preclinical data from a mouse model of diet induced NASH highlighted that the combination of Sagimet's FASN inhibitor and semaglutide reduced body weight and showed further histological improvement on liver pathology, including NAFLD activity score and fibrosis compared to single agent treatment.
  - An interim analysis of FASCINATE-2, a Phase 2b randomized, placebo-controlled trial, demonstrated denifanstat's reduction of circulating saturated diacylglycerols and triacylglycerols, markers of lipotoxicity.
- In October, Sagimet's license partner for China, Ascletis Bioscience Co. Ltd. (Ascletis), presented Phase 2 topline results of denifanstat in patients with acne at the European Academy of Dermatology and Venereology (EADV) Congress 2023 in Berlin, Germany showing that denifanstat demonstrated significant efficacy in the change of total lesion and inflammatory lesion count from baseline and was well-tolerated.
- In September, Ascletis announced enrollment of 120 patients in its Phase 3 registration clinical trial of denifanstat combined with bevacizumab for treatment of recurrent GBM, which it anticipates will provide sufficient events for its planned interim analysis of progression-free survival.

Anticipated Upcoming Milestones

- The FASCINATE-2 Phase 2b clinical trial of denifanstat in liver biopsy-confirmed F2-F3 NASH patients is fully enrolled and week 52 topline results, including liver biopsy, are expected in the first quarter of 2024.
- Sagimet expects to report Phase 1 clinical trial results characterizing the pharmacokinetic and safety profile of denifanstat in patients with impaired hepatic function in the first quarter of 2024.

Financial Results for the Three Months Ended September 30, 2023

- **Cash and cash equivalents** for the third quarter ended September 30, 2023 were $101.8 million, expected to fund operations for at least the next 12 months based on management's current operating plan.
- **Revenues** for the third quarter ended September 30, 2023 were $2.0 million compared to no revenues for the third quarter of 2022. For the nine months ended September 23, 2023, Revenues were $2.0 million compared to no revenues for the same period in the prior year. The increase was due to a $2.0 million milestone payment that was recognized in July 2023.
- **Research and development (R&D) expense** for the third quarter ended September 30, 2023 was $5.0 million compared to $6.8 million for the third quarter of 2022. For the nine months ended September 30, 2023, R&D expense was $14.1 million compared to $19.1 million for the same period in the prior year. The decrease in R&D expense was primarily driven by a decrease in activities related to our FASCINATE-2 clinical trial as patients progressed through the trial.

- **General and administrative (G&A) expense** for the third quarter ended September 30, 2023 was $4.5 million compared to $0.8 million for the same period in 2022. G&A expense for the nine months ended September 30, 2023 was $9.2 million compared to $4.6 million for the same period in the prior year. The increase in G&A expense was primarily driven by expenses related to operating as a public company after completion of its IPO, including an increase in headcount and non-cash stock-based compensation.

- **Net loss** for the third quarter ended September 30, 2023 was $6.4 million compared to a net loss of $7.5 million for the third quarter of 2022. The net loss for the nine months ended September 30, 2023 totaled $19.7 million compared to $23.3 million for the same period in 2022.

About Sagimet Biosciences

Sagimet is a clinical-stage biopharmaceutical company developing novel fatty acid synthase (FASN) inhibitors that 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 NASH, for which there are no treatments currently approved in the United States or Europe. Denifanstat is currently being tested in FASCINATE-2, a Phase 2b clinical trial in NASH with liver biopsy as the primary endpoint. For additional information about Sagimet, please visit www.sagimet.com.

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 FASCINATE-2 Phase 2b clinical trial; 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,	
	2023	2022	2023	2022
Revenue:				
License revenue	$ 2,000	$ -	$ 2,000	$ -
Total revenue	2,000	-	2,000	-
Operating expenses:				

Research and development	$ 4,958	$ 6,838	$ 14,121	$ 19,072
General and administrative	4,494	848	9,153	4,595
Total operating expenses	9,452	7,686	23,274	23,667
Loss from operations	(7,452)	(7,686)	(21,274)	(23,667)
Other income, net:				
Change in fair value of redeemable convertible preferred stock warrants	-	1	(1)	3
Change in fair value of Series A common stock warrant	4	-	4	-
Interest income and other	1,095	218	1,546	360
Total other income, net	1,099	219	1,549	363
Net loss	$ (6,353)	$ (7,467)	$ (19,725)	$ (23,304)
Other comprehensive gain (loss):				
Net unrealized gain (loss) on investments in marketable securities	-	(56)	84	(162)
Total other comprehensive gain (loss)	-	(56)	84	(162)
Comprehensive loss	$ (6,353)	$ (7,523)	$ (19,641)	$ (23,466)
Net loss per share attributable to common stockholders, basic and diluted	$ -	$ (40.34)	$ -	$ (126.13)
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	-	185,084	-	184,756
Net loss per share attributable to Series A and Series B common stockholders, basic and diluted	$ (0.35)	$ -	$ (3.22)	$ -
Weighted-average shares outstanding used in computing net loss per share attributable to Series A and Series B common stockholders, basic and diluted	18,194,682	-	6,131,541	-

SAGIMET BIOSCIENCES INC.

CONDENSED BALANCE SHEETS

(Unaudited)

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

	As of September 30, 2023	As of December 31, 2022
Cash, cash equivalents and short-term investments	$ 101,842	$ 32,345
Total assets	102,925	33,031
Current liabilities	5,049	5,279
Noncurrent liabilities	1	82
Redeemable convertible preferred stock	-	214,620
Stockholders' equity (deficit)	97,875	(186,950)
Total liabilities, redeemable preferred stock and stockholders' equity (deficit)	$ 102,925	$ 33,031

SAGIMET BIOSCIENCES

Source: Sagimet Biosciences Inc.