Sagimet Biosciences Reports Full Year 2023 Financial Results and Provides Corporate Updates

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Reported positive topline data from the Phase 2b FASCINATE-2 trial; at week 52 denifanstat met both primary efficacy endpoints and demonstrated statistically significant reduction in fibrosis

Presented late-breaking poster at the American Association for the Study of Liver Diseases (AASLD) - The Liver Meeting® 2023 showcasing the beneficial shift in lipid profile in denifanstat-treated patients

End-of-Phase 2 meeting with U.S. Food and Drug Administration (FDA) expected in first half of 2024; preparing to initiate pivotal Phase 3 trial evaluating denifanstat in patients with metabolic dysfunction-associated steatohepatitis (MASH) in the second half of 2024

Extended anticipated cash runway through 2025 by completing follow-on offering in January 2024 for $104.7 million in net proceeds; cash, cash equivalents and marketable securities totaled $94.9 million as of December 31, 2023

SAN MATEO, Calif., March 25, 2024 (GLOBE NEWSWIRE) -- Sagimet Biosciences Inc. (Sagimet, Nasdaq: SGMT), a clinical-stage biopharmaceutical company developing novel fatty acid synthase (FASN) inhibitors designed to target dysfunctional metabolic and fibrotic pathways, today reported financial results for the full year ended December 31, 2023, and provided corporate updates.

"2023 was an outstanding year for Sagimet, as we successfully transitioned to a public company and made significant progress in further clinically validating the therapeutic potential of denifanstat in patients living with MASH," said David Happel, Chief Executive Officer of Sagimet. "Denifanstat's novel mechanism of action targets the three key drivers of MASH, and we are pleased that the topline results from our Phase 2b FASCINATE-2 clinical trial met both primary efficacy endpoints and demonstrated a statistically significant reduction in fibrosis. We look forward to presenting the full data set at upcoming medical conferences later this year and expect to initiate a pivotal Phase 3 trial for denifanstat in MASH in the second half of 2024."

Full Year and Recent Highlights

- In January 2024, Sagimet sold 9,000,000 shares of its Series A common stock in an underwritten public offering and received $104.7 million in net proceeds. Proceeds from the offering, together with its existing cash, cash equivalents and marketable securities will be used (i) to advance the development of denifanstat and begin startup activities related to the pivotal Phase 3 program in MASH, formerly known as nonalcoholic steatohepatitis (NASH), including manufacturing of additional drug supply, (ii) to advance the development of TVB-3567 and submit an investigational new drug application for a Phase 1 clinical trial for the treatment of acne and (iii) for other general corporate purposes, including additional clinical development, working capital and operating expenses.

- 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:
        - MASH resolution without worsening of fibrosis with ≥2-point reduction in NAS (NAFLD Activity Score) in 36% of denifanstat-treated patients vs 13% with placebo (p=0.0022)
        - ≥2-point reduction in NAS without worsening of fibrosis in 52% of denifanstat-treated patients vs 20% with placebo (p=0.0001)
    - Multiple secondary endpoints were met, achieving statistical significance, most notably fibrosis improvement by ≥ 1 stage with no worsening of MASH in 41% of denifanstat-treated patients vs 18% with placebo (p=0.005).

- In November 2023, Sagimet presented preclinical data evaluating denifanstat alone or in combination with semaglutide in mouse models of MASH at the 7th Obesity and NASH Drug Development Summit. The oral presentation highlighted that the FASN inhibitor, alone, was responsible for significant reduction of liver fibrosis. Additionally, the preclinical data suggested the combination of the FASN inhibitor and semaglutide has both an additive effect and provides support that distinct mechanism of actions may provide therapeutic benefit to patients with MASH.

- In October 2023, Sagimet's license partner for China, Ascletis Bioscience Co. Ltd. (Ascletis), presented Phase 2 topline results at the European Academy of Dermatology and Venereology (EADV) Congress 2023 in Berlin, Germany. The presentation demonstrated denifanstat's significant efficacy in the change of total lesion and inflammatory lesion count from baseline and was well-tolerated in patients with acne.

- In July 2023, Sagimet closed an upsized IPO of Series A common stock, at a public offering price of $16.00 per share. Including shares issued pursuant to the exercise of the underwriters' option, the Company issued 6,026,772 shares of

Series A common stock, and received net proceeds of approximately $86.2 million.

- In January 2024, Ascletis announced the dosing of the first patient in its Phase 3 registration clinical trial of denifanstat for the treatment of moderate to severe acne.
- In January 2024, Ascletis announced the dosing of the first patient in its Phase 3 registration clinical trial of denifanstat combined with bevacizumab for treatment of recurrent glioblastoma; in September 2023, Ascletis announced enrollment of 120 patients in the trial, which it anticipates will provide sufficient events for its planned interim analysis of progression-free survival.

Anticipated Upcoming Milestones

- The Phase 1 clinical trial results characterizing the pharmacokinetic and tolerability profile of denifanstat in patients with impaired hepatic function are anticipated in the first quarter of 2024.
- Sagimet expects to hold an End-of-Phase 2 meeting with the FDA in the first half of 2024, and plans to initiate the pivotal Phase 3 clinical trial of denifanstat in the second half of 2024.
- Sagimet has completed IND-enabling studies for TVB-3567, a FASN inhibitor, and are evaluating the timing to file an investigational new drug (IND) application for a Phase 1 clinical trial evaluating TVB-3567 in acne.

Financial Results for the Year Ended December 31, 2023

- **Cash, cash equivalents and marketable securities** for the year ended December 31, 2023 were $94.9 million, and together with the $104.7 million in net proceeds from the January 2024 public offering, are expected to fund operations for at least the next 12 months based on management's current operating plan.
- **Revenues** for the year ended December 31, 2023 were $2.0 million compared to no revenues for fiscal 2022. 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 year ended December 31, 2023 was $19.8 million compared to $24.9 million for the same period in 2022. The decrease in R&D expense was primarily driven by a decrease in activities related to our FASCINATE-2 clinical trial as we completed the trial in 2023 and reported positive top-line data in January 2024.
- **General and administrative (G&A) expense** for the year ended December 31, 2023 was $13.0 million compared to $6.1 million for the same period in 2022. The increase in G&A expense was primarily driven by expenses related to operating as a public company after completion of our IPO, including an increase in headcount and non-cash stock-based compensation.
- **Net loss** for the year ended December 31, 2023 was $27.9 million compared to a net loss of $30.5 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 are designed to 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 MASH. FASCINATE-2, a Phase 2b clinical trial of denifanstat in MASH with liver biopsy-based primary endpoints, was successfully completed with positive results. 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 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 metabolic dysfunction-associated steatohepatitis (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, including its FASCINATE-2 Phase 3 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.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

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

	Year Ended December 31,	
	2023	**2022**
Revenue:		
License revenue	$ 2,000	$ —
Total revenue	2,000	—
Operating expenses:		
Research and development	19,777	24,919
General and administrative	12,963	6,136
Total operating expenses	32,740	31,055
Loss from operations	(30,740)	(31,055)
Other income, net:		
Change in fair value of stock warrant liability	4	3
Interest income and other	2,860	553
Total other income, net	2,864	556
Net loss	$ (27,876)	$ (30,499)
Other comprehensive gain (loss):		
Net unrealized gain (loss) on marketable securities	114	(84)
Total other comprehensive gain (loss)	114	(84)
Comprehensive loss	$ (27,762)	$ (30,583)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.66)	$ (165.20)
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	10,460,335	184,619

SAGIMET BIOSCIENCES INC.
BALANCE SHEETS
(in thousands, except for share and per share amounts)

(unaudited)

	As of December 31,	
	2023	**2022**

Cash, cash equivalents and marketable securities	$	94,897	$	32,345
Total assets		96,719		33,031
Current liabilities		5,654		5,279
Noncurrent liabilities		-		82
Redeemable convertible preferred stock		-		214,620
Stockholders' equity (deficit)		91,065		(186,950)
Total liabilities, redeemable preferred stock and stockholders' equity (deficit)	$	96,719	$	33,031

Source: Sagimet Biosciences Inc.