UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 14, 2024

SAGIMET BIOSCIENCES INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-41742**	**20-5991472**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

Sagimet Biosciences Inc.
155 Bovet Road, Suite 303,
San Mateo, California 94402
(Address of principal executive offices, including zip code)

(650) 561-8600
(Registrant's telephone number, including area code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trade Symbol(s)	Name of each exchange on which registered
Series A Common Stock, $0.0001 par value per share	SGMT	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition

On November 14, 2024, Sagimet Biosciences Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2024. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in this Item 2.02 (including Exhibit 99.1) is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section and shall not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Document
99.1	Press Release of Sagimet Biosciences Inc., dated November 14, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Sagimet Biosciences Inc.

Date: November 14, 2024

By: /s/ David Happel
David Happel
Chief Executive Officer

Exhibit 99.1

Sagimet Biosciences Reports Third Quarter 2024 Financial Results and Provides Corporate Updates

Denifanstat received Breakthrough Therapy designation from FDA for MASH

Results from Phase 2b FASCINATE-2 study of denifanstat published in The Lancet Gastroenterology & Hepatology

Successful completion of end-of-Phase 2 interactions with FDA on the development of denifanstat for MASH; Phase 3 program initiation expected by end of 2024

Anticipated cash runway through 2025, with cash, cash equivalents and marketable securities totaling $170.0 million as of September 30, 2024

San Mateo, Calif., November 14, 2024 – 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 third quarter ended September 30, 2024, and provided recent corporate updates.

"As we approach the end of 2024, the Sagimet team remains focused on advancing denifanstat towards a pivotal Phase 3 program in MASH," said David Happel, Chief Executive Officer of Sagimet. "The publication of our Phase 2b FASCINATE-2 study results in a highly regarded *Lancet* journal highlighted denifanstat's strong efficacy and tolerability data and its highly differentiated mechanism of action which enables denifanstat to improve the key drivers of MASH: fat accumulation, inflammation, and fibrosis. In addition, we are proud to have recently received Breakthrough Therapy designation for denifanstat in MASH from the FDA, demonstrating denifanstat's potential to address the significant unmet need for new therapies for this serious disease, and, with the successful completion of end-of-Phase 2 interactions with FDA, we look forward to initiating our planned Phase 3 program for denifanstat by the end of 2024."

Recent Corporate Highlights

- On October 29, Sagimet announced the successful completion of end-of-Phase 2 interactions with the U.S. Food and Drug Administration (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.

- On October 11, the Company 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, ph2b trial," reported that denifanstat treatment achieved statistically significant and clinically meaningful improvements in disease activity, MASH resolution and fibrosis.

- On October 1, 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.

- On September 26, the Company delivered an oral presentation at the 8th Annual MASH Drug Development Summit highlighting denifanstat's direct anti-fibrotic activity in MASH.

- On August 1, the Company announced the appointment to its board of directors of Dr. Anne Phillips and Jennifer Jarrett, two biotechnology industry leaders with extensive experience in clinical development, regulatory strategy, operations, and finance.

Anticipated Upcoming Milestones

- The Phase 3 program for denifanstat in MASH is expected to initiate by the end of 2024. Based on ongoing discussions with the FDA, the planned Phase 3 program will consist 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. The trial will continue until such point in time that the required number of clinical outcomes is reached, estimated at 3.5 years.

    - FASCINIT in patients with suspected or confirmed diagnosis of MASLD/MASH: The trial is expected to evaluate the efficacy and safety of denifanstat in this population, with primary endpoints being 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.

- 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 Three Months Ended September 30, 2024

- **Cash, cash equivalents and marketable securities** as of September 30, 2024 was $170.0 million, including $104.7 million net proceeds from our January 2024 follow-on offering, which are expected to fund operations through 2025 based on management's current operating plan.

- **Research and development expense** for the three and nine months ended September 30, 2024 was $12.7 million and $24.2 million, respectively, compared to $5.0 million and $14.1 million for the three and nine months ended September 30, 2023, respectively.

- **General and administrative expense** for the three and nine months ended September 30, 2024 was $4.2 million and $12.0 million, respectively, compared to $4.5 million and $9.2 million for the three and nine months ended September 30, 2023, respectively.

- **Net loss for** the three and nine months ended September 30, 2024 was $14.6 million and $29.4 million, respectively, compared to $6.4 million and $19.7 million for the three and nine months ended September 30, 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 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

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; 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,	
	2024	2023	2024	2023
License revenue	$ —	$ 2,000	$ —	$ 2,000
Operating expenses:				
Research and development	12,653	4,958	24,228	14,121
General and administrative	4,249	4,494	12,031	9,153
Total operating expenses	16,902	9,452	36,259	23,274
Loss from operations	(16,902)	(7,452)	(36,259)	(21,274)
Total other income	2,283	1,099	6,893	1,549
Net loss	$ (14,619)	$ (6,353)	$ (29,366)	$ (19,725)
Net loss per share, basic and diluted	$ (0.45)	$ (0.35)	$ (0.95)	$ (3.22)
Weighted-average shares outstanding, basic and diluted	32,143,336	18,194,682	31,036,271	6,131,541
Net loss	$ (14,619)	$ (6,353)	$ (29,366)	$ (19,725)
Other comprehensive income:				
Net unrealized income on marketable securities	464	—	411	84
Total comprehensive loss	$ (14,155)	$ (6,353)	$ (28,955)	$ (19,641)

SAGIMET BIOSCIENCES INC.

CONDENSED BALANCE SHEETS

(unaudited)

(in thousands)

	As of	
	September 30, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 169,957	$ 94,897
Total assets	$ 174,775	$ 96,719
Current liabilties	$ 4,092	$ 5,654
Stockholders' equity	$ 170,683	$ 91,065
Liabilities and stockholders' equity	$ 174,775	$ 96,719