

**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): April 27, 2026

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

Delaware
(State or other jurisdiction
of incorporation)

001-41742
(Commission
File Number)

20-5991472
(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
Series A Common Stock, \$0.0001 par value per share

Trade
Symbol(s)
SGMT

Name of each exchange on which registered
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.

Sagimet Biosciences, Inc. (the "Company") is furnishing with this Current Report on Form 8-K (the "Current Report") certain unaudited preliminary financial information for the Company's fiscal quarter ended March 31, 2026.

Certain Unaudited Preliminary Financial Information

The Company estimates that its cash, cash equivalents and marketable securities were approximately \$104.5 million as of March 31, 2026. This amount is unaudited and preliminary and is subject to completion of financial closing procedures, including the completion of management's reviews. As a result, this amount reflects the Company's preliminary estimate with respect to such information, based on information currently available for management, and may vary from the Company's actual financial position as of March 31, 2026. Further, this preliminary estimate is not a comprehensive statement or estimate of the Company's financial data or financial condition as of March 31, 2026. The unaudited preliminary financial data included in this Current Report on Form 8-K have been prepared by, and are the responsibility of, the Company's management team. KPMG LLP, the Company's independent registered public accounting firm, has not audited, reviewed, examined, compiled, nor applied agreed-upon procedures with respect to the unaudited preliminary financial data. Accordingly, KPMG LLP does not express an opinion or any other form of assurance with respect thereto. It is possible that the Company may identify items that require the Company to make adjustments to the financial information set forth above. This preliminary estimate should not be viewed as a substitute for financial statements prepared in accordance with generally accepted accounting principles in the United States and it is not necessarily indicative of the balance to be achieved in any future period. Additional information and disclosure would be required for a more complete understanding of the Company's financial position and results of operations as of March 31, 2026. Accordingly, no undue reliance should be placed on this preliminary estimate. The estimates should be read together with the Company's audited consolidated financial statements and related notes and the Company's other financial information reported in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2025. The Company undertake no obligation to update or revise these amounts as a result of new information or otherwise.

The information furnished pursuant to this Item 2.02 is intended to be 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, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 7.01 Regulation FD Disclosure.

On April 27, 2026, the Company updated information reflected in a slide presentation, which is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. Representatives of the Company will use the updated presentation in various meetings with investors from time to time.

The information in Item 7.01 of this Current Report on Form 8-K, including the information set forth in Exhibit 99.1, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, nor shall Exhibit 99.1 furnished herewith be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On April 27, 2026, the Company issued a press release announcing certain strategic and corporate updates. The full text of the press release is filed as Exhibit 99.2 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Document
99.1	Investor Presentation of Sagimet Biosciences Inc., dated April 27, 2026.
99.2	Press Release of Sagimet Biosciences Inc., dated April 27, 2026.
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: April 27, 2026

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



SAGIMET
BIOSCIENCES

Targeting Metabolic Dysfunction
with Novel Therapeutics

April 2026

Confidential and proprietary information of Sagimet Biosciences Inc.

Forward-Looking Statements and Disclaimer

This presentation 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. Other than statements of historical facts or statements that relate to present facts or current conditions, including but not limited to, statements regarding possible or assumed future results of operations, business strategies, research and development plans, regulatory activities, the presentation of data from clinical trials, Sagimet's clinical development plans and related timelines and anticipated clinical development milestones, market opportunity, competitive position and potential growth opportunities are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "believe," "estimate," "predict," "potential," or "continue" or the use of these terms or other similar expressions. The forward-looking statements in this presentation are only predictions. These forward-looking statements speak only as of the date of this presentation 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 our control, including, but not limited to, the following: the clinical development and therapeutic potential of denifanstat, TVB-3567 or any other drug candidates or combination therapies developed by Sagimet; our ability to advance drug candidates into and successfully complete clinical trials, the risk the topline clinical trials may not be predictive of, and may differ from final clinical data and later-stage clinical trial data; that unfavorable new clinical trial data may emerge in other clinical trials or combination therapies; that clinical trial data are subject to differing interpretations and assessments, including by regulatory authorities; our relationship with Ascleptis, and the success of our development efforts for denifanstat; the accuracy of our estimates regarding our capital requirements; risks and uncertainties related to market conditions; and our 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 our most recent filings with the Securities and Exchange Commission (SEC) and available at www.sec.gov. You should not rely on these forward-looking statements as predictions of future events. The event circumstances reflected in our forward-looking statements may not be achieved or occur, and actual results could differ materially from those projected in the forward-looking statement. Moreover, we operate 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 we may face. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of new information, future events, changed circumstances or otherwise.

Leadership Team with Proven Development and Commercialization Experience



Dave Happel *President & CEO*

>20 years of experience in executive leadership in biotech and pharma
Brought multiple innovative healthcare products to the market



Elizabeth Rozek *Chief Legal & Administrative Officer*

>20 years of legal experience including executive leadership of legal, IP and compliance functions in biopharma and



Thierry Chauche *Chief Financial Officer*

>20 years of financial and operational leadership experience in finance and healthcare companies



Marie O'Farrell *Chief Scientific Officer*

>20 years of experience in R&D and translational medicine in biopharma and biotech
Successfully guided development for multiple clinical programs



Andreas Grauer *Chief Medical Officer*

> 20 years of experience in Clinical Development and Medical Affairs across a broad range of therapeutic areas
Deep experience in regulatory interactions around the world resulting in multiple BLA and NDA approvals



Rob D'Urso *Senior Vice President, New Product Development*

>20 years of US and global leadership experience in dermatology



Sagimet at a Glance: Differentiated Dermatology Assets with Clinical Validation

Unique MOA: FASN Inhibition

- Our lead molecule, denifanstat, is a novel fatty acid synthase (FASN) inhibitor with a differentiated method of action with the potential to target multiple underserved diseases
- Strong clinical data demonstrates denifanstat's proof of concept across multiple disease states

Denifanstat in Acne

- Denifanstat met all primary and secondary endpoints in a Phase 3 clinical trial in patients with moderate to severe acne vulgaris conducted by Ascleptis, our license partner for Greater China
- Denifanstat was generally well-tolerated in Ascleptis' Phase 3 study and open-label extension study
- Ascleptis announced that denifanstat NDA for the treatment of moderate to severe acne was accepted by China NMPA in December 2025
- We plan to advance denifanstat into a Phase 3 clinical trial in moderate to severe acne patients for the 1H 2026, contingent on consultation with regulatory authorities

TVB-3567 in Acne

- Our follow-on FASN inhibitor, TVB 3567, received Investigational New Drug (IND) clearance in March 2025
- First-in-human (FIH) Phase 1 clinical trial initiated in June 2025 for development of an acne indication
- Phase 1 clinical trial results anticipated in 2026, Phase 2 proof of concept clinical trial anticipated to start in 2H 2026, subject to regulatory feedback

Strong IP, Cash Position, and Collaboration Potential

Denifanstat in Other Indications

- Successful outcome of Phase 2b clinical trial in MASH (metabolic dysfunction-associated steatohepatitis) met both primary endpoints with significant reduction in fibrosis
- Pre-clinical data demonstrated synergistic effect of combination of FASN inhibitor and resmetirom
- Phase 1 pharmacokinetics (PK) clinical trial of a combination of denifanstat and resmetirom completed December 2025
- Further MASH development to be undertaken only upon securing non-dilutive funding

IP Portfolio

- Denifanstat:
 - Composition of matter patent expected to expire in 2032; potential PTE to 2037
- TVB-3567:
 - Composition of matter patent expected to expire in 2035; potential PTE to 2038
 - Method of use application for TVB-3567 for acne filed 2025; if granted expected to expire in 2044
- Combination of denifanstat and resmetirom:
 - Application filed 2024; if granted expected to expire in 2044; potential PTE to 2048

Cash Position

- \$113.1M cash on hand as of 12/31/2025 and \$104.5M as of 3/31/2026 *

*Cash, cash equivalents and marketable securities; 3/31/2026 cash on hand unaudited, preliminary and subject to change

Development Pipeline: Multiple Indications and Clinical Milestones

Therapeutic Area	Indication	Stage of Development				Milestone / Program Updates
		Preclinical	Phase 1	Phase 2	Phase 3	
Dermatology	Acne	Denifanstat				Phase 3 clinical trial for the US expected to initiate 2H 2026
		TVB-3567				Phase 1 FIH clinical trial initiated in June 2025
		FASN inhibitor				Topical formulation in development
		 Denifanstat (ASC40)				Met all primary and secondary endpoints in Phase 3 clinical trial & NDA accepted by NMPA in December 2025*
Metabolic Disease	MASH	Denifanstat				Phase 2b clinical trial met histology primary and multiple secondary endpoints; FDA Breakthrough Therapy designation; Phase 3 ready (F2/F3 MASH)
		Denifanstat				Phase 1 clinical trial hepatic impairment results reported 1Q2024
		Denifanstat/resmetirom				Phase 1 clinical PK trial completed in December 2024
Oncology	Solid tumors	TVB-3567				Identifying FASN-dependent tumor types for potential FASN inhibitor development
		Denifanstat				

* Clinical trial conducted in China by Ascleto, who has licensed development and commercialization rights to all indications in Greater China.

FASN Inhibition Offers Differentiated MOA in Acne



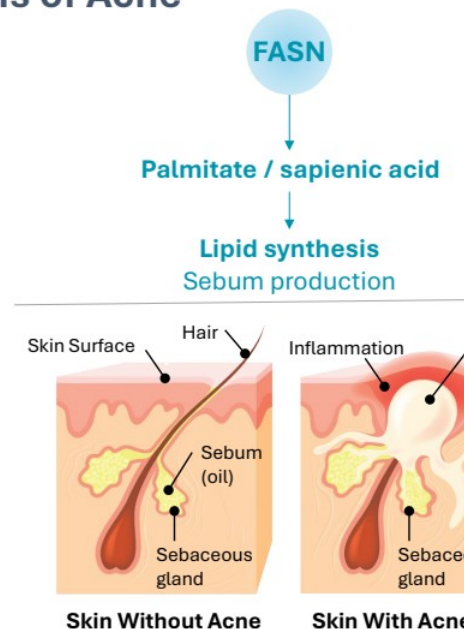
Potential Role of FASN Inhibitors in the Pathogenesis of Acne

4 key drivers of acne¹:

- Increased sebum in sebaceous glands (80% of lipids produced through DNL)²
- Abnormal or excessive follicular hyper-keratinization
- Accelerated bacterial growth (*C. acnes*)
- Localized inflammatory response

FASN inhibition MOA shows potential to treat acne:

- Denifanstat directly reduced cutaneous (skin) sebum DNL lipids in two Phase 1 clinical trials³
- FASN inhibition has potential to reduce inflammation, through decreasing cytokine secretion and Th17 activation⁴



1. Vasam M, et al., *Biochem Biophys Res.* 2023;36:101578. <https://pmc.ncbi.nlm.nih.gov/articles/PMC10709101/#abs0010>

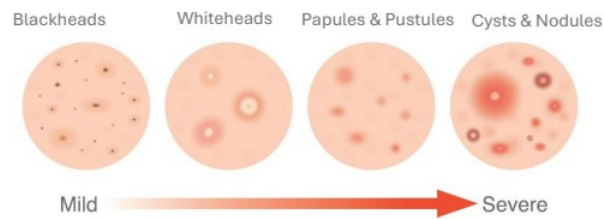
2. Esler, et al., *Sci. Transl. Med.* 2019; 11:492.

3. A) Duke G, et al., Presented at: AASLD 2016; November 11-15, 2016; Boston, MA. https://sagimet.com/wp-content/uploads/2016/11/2016_AASLD_FASN_NASH_36x
And B) Syed-Abdul MM et al., *Hepatology.* 2020;72(1):103.

4. O'Farrell M, et al. *Sci Rep.* 2022;12(1):15661.

Acne Market Overview

Global acne market is expected to reach \$20B by 2034¹



50 million people suffer with acne in the US annually²

- Acne is one of the most common skin conditions in the United States, with approximately 50 million Americans affected annually and more than 5 million seeking medical treatment for acne each year²
- Acne affects approximately 85% of persons between the ages of 12 and 24³
- 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

10 million people suffer from moderate to severe acne in the US annually

- Moderate to severe acne accounts for 20% of acne sufferers, or approximately 10 million people in the US annually⁴

1. Acne Medication Market Size to Surpass USD 19.95 Billion by 2034 Driven by Rising Acne Prevalence, Skincare Awareness, and Innovative Treatments, *Precedence Research*, Sep 2025; <https://finance.yahoo.com/news/acne-medication-market-size-surpass-114200888.html>

2. Bickers DR, et al. *J Am Acad Dermatol*. 2006;55(3):490-500. 3. Bhat K, Williams HC. Epidemiology of acne vulgaris. *Br J Dermatol*. Mar 2013;168(3):474-85. doi:10.1111/bjd.12149

4. Szepletowska M, et al., Prevalence, Intensity and Psychosocial Burden of Acne Itch: Two Different Cohorts Study. *J Clin Med*. 2023 Jun 12;12(12):3997. doi: 10.3390/jcm12123997. PMID: 37373690; PMCID: PMC10299123

Acne Treatment Algorithm

Disease management involves flare and prevention intervention

Mild Disease	Moderate to Severe Disease	Severe (Cystic) Disease	Routine Management
<p>Treatment includes topical agents used as mono or combination therapy</p> <p>Main topical therapies:</p> <ul style="list-style-type: none">• Retinoids• Benzoyl Peroxide• Antibiotics• Clascoterone• Salicylic Acid• Azelaic Acid	<p>Treatment approach adds oral products on top of topical agents</p> <p>Main oral therapies:</p> <ul style="list-style-type: none">• Antibiotics (tetracyclines, sarecycline)• Hormonal contraceptives• Spironolactone (off-label)• Intralesional corticosteroids	<p>Severe (cystic) patients are generally managed with isotretinoin (Accutane)</p> <p>Main therapy:</p> <ul style="list-style-type: none">• Isotretinoin	<p>Skin care routine address treatment related AEs</p> <p>Main approaches</p> <ul style="list-style-type: none">• OTC cleansers• Moisturizers• Sunscreens

Potential treatment positioning for FASN inhibitors

Oral FASN Inhibitor

Topical FASN Inhibitor

Source: [https://www.jaad.org/article/S0190-9622\(23\)03389-3/fulltext](https://www.jaad.org/article/S0190-9622(23)03389-3/fulltext)

Denifanstat's Clinical Data in Acne



Pharmacodynamic Data Support Mechanism of Action of Denifanstat in Acne

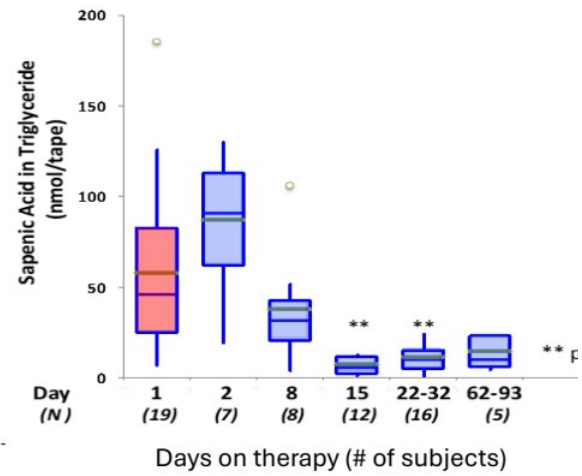
In multiple Phase 1 clinical trials, denifanstat demonstrated a decrease in DNL sebum lipids¹⁻³

- Demonstrated a >90% reduction in sebum lipids by day 15^{1,2}
- Maintained the reduced level of sebum lipids through the entire study^{1,2}
- Demonstrated a dose responsive impact on sebum lipids^{1,2}

Note: denifanstat dose in this Phase 1 clinical trial in cancer patients is several times higher than 50 mg dose tested in acne and MASH

1. Duke G, et al. Presented at: EASL 2017; April 19-23, 2017; Amsterdam, The Netherlands. https://sagimet.com/wp-content/uploads/2017/05/3VBIO_EASLposter.pdf.
2. Falchook G, et al. *EClinicalMedicine*. 2021;34:100797.
3. Duke G, et al. Presented at: AASLD 2016; November 11-15, 2016; Boston, MA. https://sagimet.com/wp-content/uploads/2016/11/2016_AASLD_FASN_NASH_36x60_v10.pdf.

Phase 1 oncology clinical trial
Sebutape® assessment of cutaneous sebum lipids



Ascletis Acne Phase 3 Clinical Trial Design

Denifanstat Phase 3 in acne

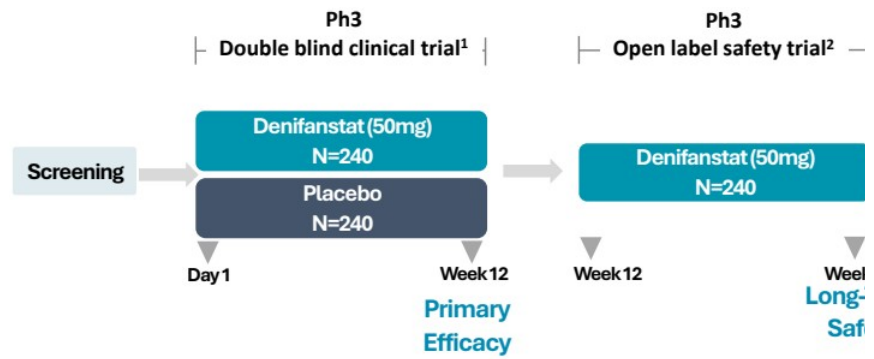
- Moderate to severe acne
- Multi-center placebo controlled
- 1:1 randomization
- Double-blind
- Once daily oral dosing
- 480 patients in China

Co-primary endpoints at week 12

- % patients who achieve IGA success (defined as at least a 2-point reduction in IGA from baseline, and an IGA of 0 or 1 at week 12)
- % change in total skin lesion counts from baseline
- % change in inflammatory skin lesion counts from baseline

Key secondary endpoint at week 12

- % change in non-inflammatory skin lesion counts from baseline



1. ClinicalTrials.gov. NCT06192264. Study ASC40-303. <https://clinicaltrials.gov/study/NCT06192264>. 2. ClinicalTrials.gov. NCT06248008. Study ASC40-304. <https://clinicaltrials.gov/study/NCT06248008>

Ascletis Acne Phase 3 Clinical Trial Met All Primary and Secondary Endpoint

Baseline Characteristics	50mg denifanstat (n=240)	Placebo (n=240)		
Total lesion count	102.2	102.1		
Inflammatory lesion count	42.1	43.1		
IGA=3 (moderate), %	85.8	85.8		
IGA=4 (severe), %	14.2	14.2		
Efficacy endpoints ¹	50mg denifanstat (n=240)	Placebo (n=240)	50mg denifanstat (placebo adjusted)	p v
% Treatment success (IGA) ² (primary endpoint)	33.2	14.6	18.6	<0.
% Change in total lesion count (primary endpoint)	-57.4	-35.4	-22.0	<0.
% Change in inflammatory lesion count (primary endpoint)	-63.5	-43.2	-20.3	<0.
% Change in non-inflammatory lesion count (key secondary endpoint)	-51.9	-28.9	-23.0	<0.
Absolute change in total lesion count (secondary endpoint)	-58.3	-36.2	-22.1	<0.
Absolute change in inflammatory lesion count (secondary endpoint)	-26.6	-18.4	-8.2	<0.

Ascletis data on file. Baseline demographics and efficacy endpoints of 50 mg denifanstat oral, once daily for 12 weeks versus Placebo (Intent-to-treat, ITT analysis change from baseline).

1. The efficacy data are LSMEANs.

2. Treatment success is defined as an Investigator's Global Assessment (IGA) score of 0 (clear) or 1 (almost clear) with at least a 2-point decrease from baseline.

Ascletis Acne Phase 3 Clinical Trial Safety Data*

Denifanstat 50mg was generally well tolerated during the 12-week study

Treatment-emergent adverse events (TEAEs):

- TEAE incidence rates were comparable between denifanstat and placebo
- Only two categories of TEAEs had an incidence rate of 5% or more:
 - Dry eye (investigator reported as “dry eye” or “xerophthalmia”) in 10.9% of denifanstat-treated subjects vs 9.2% in the placebo group*
 - Dry skin reported in 6.3% of denifanstat-treated subjects vs 2.9% in the placebo group

Adverse events (AEs):

- All denifanstat-related AEs were mild or moderate
- No denifanstat-related grade 3 or 4 AEs
- No denifanstat-related serious AEs (SAEs)
- No deaths were reported

* Ascletis data on file. The classifications of “dry eye” or “xerophthalmia” were not related to the AE grade.

Asclethis Acne Open Label Phase 3 Trial*

Denifanstat generally well-tolerated in the open label clinical trial

Treatment-emergent adverse events (TEAEs):

- Only two categories of TEAEs had an incidence rate of 5% or more with dry eye syndrome in 5.5% of denifanstat-treated subjects and dry skin reported in 5.2% of denifanstat-treated subjects

Adverse events (AEs):

- All denifanstat-related AEs were mild or moderate; no denifanstat-related Grade 3 or 4 AEs; no AE-related permanent discontinuations; Grade 1 hair thinning in the study was experienced by only 1 denifanstat-treated patient (which resolved within eight weeks while remaining in study without a change in dose); no deaths were reported

Serious adverse events (SAEs):

- No denifanstat-related SAEs; 2 non-denifanstat-related SAEs (1 breast lump, 1 contusion), both resolved

Efficacy Endpoints (secondary endpoints of the trial) :

- Efficacy endpoints (secondary endpoints of the trial) included the number of subjects with an IGA score decrease by at least 2 points, number of subjects dropping from an IGA score of 3 down to 0 or 1, the percentage reduction in total skin lesion count and the percentage reduction in inflammatory skin lesion count.
- Subjects treated with denifanstat showed improvements in all efficacy endpoints beyond those observed at 12 weeks

* Asclethis data on file. Safety and efficacy endpoints of 50 mg denifanstat oral, once daily for 52 weeks versus placebo for 12 weeks and 50mg denifanstat oral once daily for 40 weeks

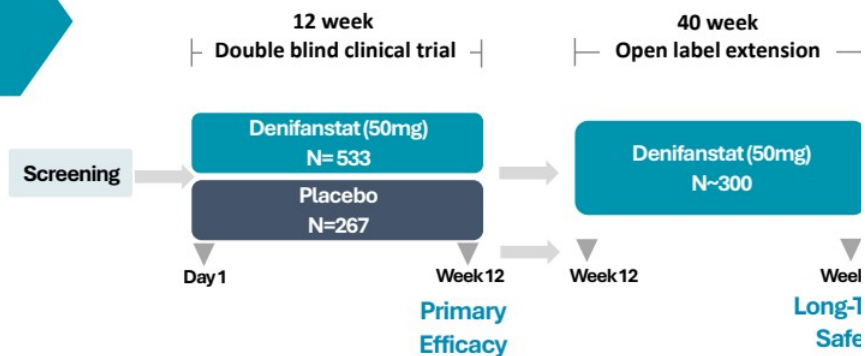
Sagimet's Upcoming Development Programs



Phase 3 Clinical Trial Design for Denifanstat in Acne

Planned Phase 3 acne clinical trial design, pending FDA agreement

- Moderate to severe acne
- Multi-center placebo controlled
- 2:1 randomization
- Double-blind
- Once daily oral dosing
- 800 patients in US



Co-primary endpoints at week 12

- % patients who achieve IGA success (defined as at least a 2-point reduction in IGA from baseline, and an IGA of 0 or 1)
- Absolute change in total skin lesion counts from baseline
- Absolute change in inflammatory skin lesion counts from baseline

FASN Inhibitor TVB-3567 FIH Ongoing Phase 1 Clinical Trial

Initiated in June 2025

A double-blind, randomized, placebo-controlled clinical trial to assess the safety, tolerability, pharmacokinetics pharmacodynamics of single and multiple ascending doses of TVB-3567 in healthy participants with or without acne.

- Includes sebum analysis as pharmacodynamic readout

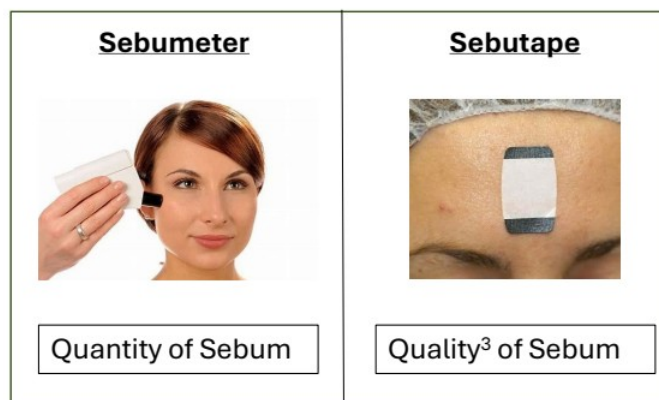
PART	DESIGN	PLANNED # of PARTICIPANTS
A	SAD ¹	~56
B	Food effect	~12
C	MAD ²	~32
D	MAD/ACNE	~28

1. SAD = Single ascending dose

2. MAD = Multiple ascending dose.

3. Lipidomic analysis with focus on FASN-derived lipids

ClinicalTrials.gov. NCT06989840. Study SB3567-CLIN-001. <https://clinicaltrials.gov/study/NCT06989840>



Potential Clinical Development Program for TVB-3567 in Acne

Phase 1 clinical trial initiated in June 2025

Goal: Initiate Phase 2 clinical trial in 2026, subject to consultation with regulatory authorities and outcome of Phase 1 clinical trial

Step 1 - Phase 1 first-in-human pharmacokinetic (PK) clinical trial of TVB-3567 in healthy volunteers

- PK and pharmacodynamics (PD) evaluation to confirm profile
- Assess safety/tolerability
- Identify potential doses for an acne Phase 2 clinical trial

Step 2 - Phase 2 clinical trial in moderate to severe acne patients

- Upon completion of Phase 1 clinical trial, plan to consult with regulatory authorities regarding Phase 2 clinical trial design, with goal of initiating Phase 2 clinical trial in 2H 2026
- Phase 2 trial design anticipated to be informed by the results of the Phase 1 clinical trial, expect a 12-week dose ranging study in moderate to severe acne patients with lesion reduction and treatment success (IGA) as endpoints

Denifanstat for Treatment of MASH

Clinical and pre-clinical data demonstrate denifanstat's potential to treat MASH (metabolic dysfunction-associated steatohepatitis)

- **MASH F2-F3:**
 - Denifanstat met both primary endpoints in Phase 2b clinical trial, with significant reduction in fibrosis and was generally well-tolerated
- **MASH F4:**
 - **Combination of denifanstat and resmetirom:**
 - Pre-clinical data demonstrated synergistic effect of combination of FASN inhibitor and resmetirom
 - Phase 1 pharmacokinetics (PK) clinical trial of a combination of denifanstat and resmetirom completed in Dec 2025
 - Global license agreement with TAPI enables access to innovative forms of resmetirom API for combination with denifanstat in a fixed dose combination (FDC) tablet

Next steps

- Plan to complete all development and regulatory activities needed for denifanstat-resmetirom combination Phase 2 readiness by end of 2026
- Further MASH development to be undertaken only upon securing non-dilutive funding

FASN Inhibition – Significant Opportunity for a Novel Treatment for Acne

FASN Inhibition in Acne

- Acne market is significant (~50m people in the US) and aligned to those patients most likely to be prescribed an oral FASN inhibitor
- Oral FASN inhibitors offer a novel mechanism of action for the potential treatment of moderate to severe acne
- Topical formulation of a FASN inhibitor in early-stage development for the potential treatment of

Potential of Denifanstat in Acne

- Denifanstat met all primary and secondary endpoints in Phase 3 clinical trial in patients with moderate to severe acne vulgaris in China, and NDA accepted by NMPA in December 2025
- Denifanstat generally well-tolerated in both Phase 3 clinical trial and in open-label Phase 3 clinic
- Sagimet plans to advance denifanstat into a Phase 3 clinical trial in moderate to severe acne patients in the US in 2H 2026, contingent on consultation with regulatory authorities

Potential of TVB-3567 in Acne

- First-in-human Phase 1 clinical trial of TVB-3567 initiated in June 2025 for development in acne
 - Upon completion of TVB-3567 Phase 1, plan to initiate TVB-3567 Phase 2 in 2026, contingent on consultation with regulatory authorities
- TVB-3567 IP:
 - Composition of matter patent expected to expire in 2035; potential PTE to 2038
 - Method of use application for TVB-3567 for acne filed 2025; if granted expected to expire in

**Sagimet Biosciences Provides Strategic and Corporate Updates**

Phase 3 clinical trial of denifanstat in moderate to severe acne patients for the U.S. planned to initiate in second half of 2026

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

Further MASH development to be undertaken only upon securing non-dilutive funding

Sagimet to host a KOL event and webcast, April 30 at 2 pm ET

San Mateo, Calif., April 27, 2026 – Sagimet Biosciences Inc. (Nasdaq: SGMT), a clinical-stage biopharmaceutical company developing novel therapeutics targeting dysfunctional metabolic and fibrotic pathways, today provided strategic and corporate updates.

“Building on the recent successful Phase 3 clinical trial in China of our lead molecule denifanstat in moderate to severe acne, we have taken the strategic decision to advance denifanstat in acne for the U.S., starting with a Phase 3 clinical trial expected to begin in the second half of 2026,” said David Happel, Chief Executive Officer of Sagimet. “We believe the large moderate to severe acne patient population is underserved by the currently approved treatments. Denifanstat, if approved, would be a convenient, once-daily oral medication and the first innovative oral treatment for acne in more than forty years.”

Fatty acid synthase (FASN) inhibition, with its ability to reduce sebum production and address local inflammation, represents a potential novel approach to treat moderate to severe acne vulgaris, a condition impacting an estimated 10 million people in the U.S. annually. The Company recently announced positive topline results in the open-label Phase 3 clinical trial conducted and reported by its license partner that evaluated the long-term safety of denifanstat tablets in patients with moderate to severe acne in China.

“We are prioritizing our dermatology franchise in our capital allocation,” said Thierry Chauche, Chief Financial Officer, “and we plan to pursue non-dilutive funding options for our MASH program.”

Recent Corporate Highlights

- Sagimet plans to initiate a Phase 3 clinical trial of denifanstat in moderate to severe acne patients for the U.S. in the second half of 2026, subject to Investigational New Drug (IND) clearance.
 - In January 2026, positive topline results were reported in the open-label Phase 3 trial (n=240) evaluating the long-term safety of 50 mg once-daily denifanstat in patients with moderate to severe acne in China by Sagimet’s license partner Ascleto Bioscience Co. Ltd. (Ascleto). Denifanstat was generally well-tolerated, and subjects treated with denifanstat showed improvements in all efficacy endpoints measured at 52 weeks (secondary endpoints of the trial).
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- First-in-human Phase 1 clinical trial of FASN inhibitor TVB-3567 is ongoing.
- The Company also plans to develop a topical formulation of a FASN inhibitor for the potential treatment of acne.
- In relation to its development program for the combination of denifanstat and resmetirom in metabolic dysfunction associated steatohepatitis (MASH), the Company reported the completion of its Phase 1 PK clinical trial in December 2025. The Company anticipates that the denifanstat and resmetirom combination program will be ready to advance into Phase 2 in the second half of 2026. The Company will undertake no further clinical development in MASH until non-dilutive financing is achieved.
- In April 2026, Sagimet announced the appointment of Andreas Grauer, MD, as Chief Medical Officer, and the retirement of its former Chief Medical Officer, Eduardo Bruno Martins, MD, DPhil. Dr. Grauer brings more than two decades of global biopharmaceutical leadership experience, with deep expertise spanning clinical development, medical affairs, and regulatory strategy across multiple therapeutic areas.

Publications and Presentations

- In April 2026, Sagimet presented analyses from the Phase 2b FASCINATE-2 trial of denifanstat in MASH of bile acid biomarkers to measure denifanstat response at the Fueling MASH: Metabolic Drivers and Inflammatory Crosstalk Keystone Symposium.

Anticipated Upcoming Milestones

- The Company plans to file an IND application for denifanstat for the treatment of moderate to severe acne in mid-2026.
- Following IND clearance, Sagimet anticipates advancing denifanstat into a registrational Phase 3 clinical trial in moderate to severe acne patients in the second half of 2026.
- Upon completion of the Phase 1 clinical trial of TVB-3567, subject to consultation with regulatory authorities, Sagimet plans to initiate a Phase 2 clinical trial with TVB-3567 in moderate to severe acne patients in the second half of 2026.

Conference Call Information

Sagimet Biosciences will host a virtual KOL event with Dr. Julie Harper to discuss its planned development of denifanstat for acne on April 30, 2026 at 2pm ET.

Live webcast available : <https://lifescievents.com/event/ha9t02g/>

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. FASN is a regulator of lipid synthesis, and a key pathway implicated in multiple diseases, such as acne, MASH and certain FASN-dependent tumor types. For additional information about Sagimet, please visit www.sagimet.com.

About Acne

Acne is one of the most common skin conditions in the U.S., with approximately 50 million Americans affected annually and more than 5 million seeking medical treatment for acne each year. Acne affects around 85% of persons between the ages of 12 and 24. Moderate to severe acne accounts for 20% of acne sufferers, or approximately 10 million people in the U.S. annually. 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.

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, 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 Asclethis, 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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