# 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 12, 2026**

# 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.**
**950 Tower Lane, Suite 1500,**
**Foster City, CA 94404**
**(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 12, 2026, Sagimet Biosciences Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2026. 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 7.01 Regulation FD Disclosure.**

On November 12, 2026, the Company updated information reflected in a slide presentation, which is attached as Exhibit 99.2 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 99.2, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, nor shall Exhibit 99.2 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 9.01 Financial Statements and Exhibits.**

**(d) Exhibits**

| Exhibit No. | Document |
|---|---|
| 99.1 | Press Release of Sagimet Biosciences Inc., dated November 12, 2026. |
| 99.2 | Investor Presentation of Sagimet Biosciences Inc., dated November 12, 2026. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document). |

**SIGNATURES**

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 12, 2026

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

**Sagimet Biosciences Reports Third Quarter 2026 Financial Results and Provides Corporate Updates**

- *Registrational U.S. AURORA Phase 3 clinical trial underway for denifanstat in moderate to severe acne, with topline data anticipated in the second half of 2027*
- *Positive denifanstat Phase 3 clinical trial results in China from license partner Ascletis, and continued improvement and sustained efficacy across all efficacy endpoints through 52 weeks in the open-label extension clinical trial, presented at EADV 2026 and Fall Clinical Dermatology 2026*
- *Completed underwritten offering of Series A Common Stock and pre-funded warrants in October, with gross proceeds of $115 million*
- *Pro forma cash and investments balance of approximately $356 million as of September 30, expected to fund current operations through mid-2029 including through readout of data from the denifanstat AURORA Phase 3 clinical trial in moderate to severe acne and potential NDA submission*

**FOSTER CITY, Calif., November 12, 2026 (GLOBE NEWSWIRE) —** Sagimet Biosciences Inc. (Nasdaq: SGMT), a clinical-stage biopharmaceutical company developing inhibitors of fatty acid synthase (FASN), a key lipid synthesis regulator, for acne, today reported financial results for the quarter ended September 30, 2026, and provided corporate updates.

"Building on the positive Phase 3 results from our license partner Ascletis, we have initiated our pivotal U.S. AURORA Phase 3 clinical trial," said David Happel, Chief Executive Officer of Sagimet. "With our October equity financing, we are well positioned to fund our programs through mid-2029, including the anticipated Phase 3 denifanstat data readout and the potential submission of an NDA. If approved, denifanstat would be the first oral acne treatment with a novel mechanism of action approved by the FDA in more than 40 years, offering a new treatment option for approximately 10 million Americans living with moderate to severe acne."

**Recent Corporate Highlights**

- **AURORA Phase 3 clinical trial:** In October 2026, Sagimet announced that the first patient had been dosed in its AURORA registrational U.S. Phase 3 clinical trial of once-daily denifanstat in adults and adolescents aged 12 years and older with moderate to severe acne. The Company plans to enroll approximately 800 patients in AURORA, including approximately 450 adolescents aged 12 to 17 years. The trial is intended to support a potential U.S. New Drug Application (NDA), with topline data expected in the second half of 2027.

- **Equity financing:** In October 2026, Sagimet completed an underwritten offering of Series A common stock and pre-funded warrants, resulting in approximately $115.0 million in gross proceeds, before deducting underwriting discounts and commissions and other offering expenses.
- **TVB-3567:** The single- and multiple-ascending dose and food effect parts of the first-in-human Phase 1 clinical trial of FASN inhibitor TVB-3567 completed dosing and TVB-3567 was generally well tolerated. Part D of the trial evaluating pharmacodynamic biomarkers in acne patients is ongoing. Phase 2 doses have been identified, and the Company anticipates initiating the Phase 2 clinical trial of TVB-3567 in moderate to severe acne patients before the end of 2026.
- **KOL event:** On September 30, 2026, Sagimet hosted a virtual key opinion leader (KOL) event featuring Julie Harper, MD, Founding Director and past President of the American Acne and Rosacea Society. During this event, the Company and Dr. Harper reviewed the 52-week data from license partner Ascletis' Phase 3 open-label extension clinical trial of denifanstat in moderate to severe acne vulgaris in China and provided an update on Sagimet's U.S. AURORA Phase 3 clinical trial of denifanstat for the treatment of moderate to severe acne (here).

**Publications and Presentations**

- **EADV 2026:** In September 2026, Sagimet announced positive full 52-week results from Ascletis' Phase 3 open-label extension clinical trial of denifanstat in moderate to severe acne, which were presented by Ascletis at the European Academy of Dermatology and Venereology (EADV) Congress. Denifanstat showed progressive and sustained improvements across all efficacy endpoints in the open-label extension, including Investigator's Global Assessment (IGA) success with a response rate of 57%, 72% reduction in total lesions, and 77% reduction in inflammatory lesions, and was generally well-tolerated, with no adverse event-related permanent discontinuations (here).
- **Fall Clinical Dermatology 2026:** In October 2026, Sagimet presented the positive 52-week results from Ascletis' Phase 3 open-label extension trial, previously presented by Ascletis at EADV 2026, together with mechanistic data supporting denifanstat's differentiated approach to targeting key aspects of acne pathogenesis: sebum production and inflammation (here).

**Anticipated Upcoming Milestones**

- **Denifanstat:** Continue enrollment in the U.S. AURORA Phase 3 clinical trial in moderate to severe acne, with topline data expected in the second half of 2027.
- **TVB-3567:** Initiate a Phase 2 trial in moderate to severe acne by year-end 2026.
- **Topical FASN inhibitor:** Continue development of a topical formulation of a FASN inhibitor for the potential treatment of acne.

**Financial Results for the Three and Nine Months Ended September 30, 2026**

- **Cash, cash equivalents and marketable securities** as of September 30, 2026, were $275.8 million, which included $27.5 million of investor funds received prior to the closing of the October 2026 underwritten offering of Series A common stock and pre-funded warrants. Pro forma cash, cash equivalents and marketable securities as of September 30 of $355.8 million, includes $80.0 million in additional net proceeds received on October 1 from the October 2026 underwritten offering.

- **Research and development expense** for the three and nine months ended September 30, 2026, was $16.3 million and $34.9 million, respectively, compared to $9.7 million and $32.3 million for the three and nine months ended September 30, 2025, respectively.
- **General and administrative expense** for the three and nine months ended September 30, 2026, was $5.2 million and $14.2 million, respectively, compared to $4.6 million and $13.8 million for the three and nine months ended September 30, 2025, respectively.
- **Net loss** for the three and nine months ended September 30, 2026, was $19.1 million and $43.8 million, respectively, compared to $12.9 million and $41.5 million for the three and nine months ended September 30, 2025, respectively.

**About the AURORA Phase 3 Clinical Trial**

AURORA (NCT07863193) is a multi-center, randomized, double-blind, placebo-controlled Phase 3 clinical trial of denifanstat in moderate to severe acne. AURORA is anticipated to enroll approximately 800 U.S. patients aged 12 years and older, of which 450 are expected to be adolescents aged 12 to 17 years. Patients will be randomized 2:1 to receive denifanstat 50 mg or placebo once daily for 12 weeks. The trial will have three co-primary endpoints that will be assessed at week 12: the proportion of patients achieving treatment success in a global assessment score, defined as at least a 2-point reduction from baseline with a score of 0 (clear) or 1 (almost clear); absolute change in inflammatory skin lesion counts from baseline; and absolute change in non-inflammatory skin lesion counts from baseline. A subset of approximately 530 patients completing the double-blind period will be eligible to enter a 40-week open-label extension evaluating the long-term safety of denifanstat.

**About Denifanstat**

Denifanstat is an oral, once-daily FASN inhibitor in development for the treatment of moderate to severe acne. In trials conducted by Sagimet's license partner, Ascletis BioScience Co. Ltd. (Ascletis) in China, denifanstat met all primary and secondary endpoints in a 12-week randomized, double-blind Phase 3 clinical trial in moderate to severe acne vulgaris and was generally well-tolerated and showed improvements in all efficacy endpoints measured at 52 weeks (secondary endpoints of the trial) in an open-label extension clinical trial evaluating denifanstat's long-term safety. Denifanstat is being developed by Ascletis as ASC40 for acne in China and by Sagimet in the rest of world.

**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 6.8 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.

**About Sagimet Biosciences**

Sagimet is a clinical-stage biopharmaceutical company advancing a portfolio of novel fatty acid synthase (FASN) inhibitors. FASN is a key regulator of the *de novo* lipogenesis pathway, which is overactive in acne and can cause elevated sebum and inflammation. FASN is also implicated in other diseases, including MASH and certain FASN-dependent tumor types. Denifanstat, Sagimet's lead drug candidate, is an oral, once-daily FASN inhibitor currently being evaluated in a U.S. Phase 3 registrational clinical trial for moderate to severe acne. For more information, 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 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 Ascletis, and the success of its development and registration 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, | |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 | 2025 |
| Operating expenses: | | | | |
| Research and development | $ 16,340 | $ 9,730 | $ 34,870 | $ 32,320 |
| General and administrative | 5,227 | 4,604 | 14,228 | 13,804 |
| Total operating expenses | 21,567 | 14,334 | 49,098 | 46,124 |
| Loss from operations | (21,567) | (14,334) | (49,098) | (46,124) |
| Total other income | 2,418 | 1,426 | 5,346 | 4,654 |
| Net loss | $ (19,149) | $ (12,908) | $ (43,752) | $ (41,470) |
| Net loss per share, basic and diluted | $ (0.31) | $ (0.40) | $ (0.88) | $ (1.28) |
| Weighted-average shares outstanding, basic and diluted | 62,339,331 | 32,464,893 | 49,446,941 | 32,286,188 |
| Net loss | $ (19,149) | $ (12,908) | $ (43,752) | $ (41,470) |
| Other comprehensive (loss) income: | | | | |
| Net unrealized (loss) gain on marketable securities | (483) | 41 | (680) | (113) |
| Total comprehensive loss | $ (19,632) | $ (12,867) | $ (44,432) | $ (41,583) |

**SAGIMET BIOSCIENCES INC.**

**CONDENSED BALANCE SHEETS**

**(unaudited)**

**(in thousands)**

| | As of | |
|---|---|---|
| | September 30, 2026 | December 31, 2025 |
| Cash, cash equivalents and marketable securities | $ 275,822 | $ 113,124 |
| Total assets | $ 282,093 | $ 116,482 |
| Current liabilities | $ 37,985 | $ 5,101 |
| Noncurrent liabilities | $ 1,927 | $ — |
| Stockholders' equity | $ 242,181 | $ 111,381 |
| Liabilities and stockholders' equity | $ 282,093 | $ 116,482 |

Exhibit 99.2

SAGIMET BIOSCIENCES



# Targeting Metabolic Dysfunction with Novel Therapeutics

November 2026

# 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. All statements contained in this document, 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 to be 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 negative 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, among others: 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 trials; our ability to advance drug candidates into and successfully complete clinical trials within anticipated timelines; that unfavorable new clinical trial data may emerge in other clinical trials of our product candidates; that clinical trial data are subject to differing interpretations and assessments, including by regulatory authorities; our relationship with Ascletis, and the success of its development efforts for denifanstat; the accuracy of our estimates regarding our capital requirements; 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 events and 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 statements.

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 any 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 biotech



**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 Products*

>20 years of US and global leadership experience in dermatology

Pfizer raptor MedImmune AMGEN DYNAVAX ALEXION Intercept U.S. Department of JUSTICE ISDIN

HORIZON AstraZeneca abbvie Genentech proventionbio NOVARTIS P&G Health basilea PHARMACEUTICA Dr.Reddy's

# 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

**Denifanstat in Acne**

- Denifanstat met all primary and secondary endpoints in a Phase 3 clinical trial (ASC40-303) in patients with moderate to severe acne vulgaris conducted by Ascletis, our license partner for Greater China
- Denifanstat was generally well-tolerated in the Phase 3 acne clinical trial and open-label extension (OLE) clinical trial conducted by license partner Ascletis in China
- During the OLE (ASC40-304), patients showed further improvement in IGA success and lesion count reductions compared to ASC40-303 baseline
- Ascletis announced that the denifanstat NDA for the treatment of moderate to severe acne was accepted for review by the China NMPA in December 2025
- First patient dosed in AURORA Phase 3 clinical trial in the US for patients with moderate to severe acne in Oct 2026; topline results expected in 2H 2027

**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. Dosing for SAD/MAD and food effect parts complete, TVB-3567 was generally well-tolerated; Phase 2 doses have been identified
- Phase 2 proof of concept clinical trial anticipated to begin before the end of 2026

# 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 in December 2025
- Further MASH development to be undertaken only upon securing non-dilutive funding

**IP Portfolio**

- Denifanstat:
  - Composition of matter patent – expiration date 2032; potential PTE to 2037
- TVB-3567:
  - Composition of matter patent – expiration date 2035; potential PTE to 2038
  - Exploring pathway to extend protection into 2040's
- Combination of denifanstat and resmetirom:
  - Patent granted in Q3 2026 – expiration date 2044

**Cash Position**

- ~$356M pro forma cash on hand as of 9/30/2026*, which includes proceeds from the $115M financing completed in October, expected to fund current operations through mid-2029 including through readout of data from the denifanstat AURORA Phase 3 clinical trial in moderate to severe acne and potential NDA submission

*Cash, cash equivalents and marketable securities, unaudited

# Development Pipeline: Multiple Indications and Clinical Milestones

| Therapeutic Area | Indication | Stage of Development | Milestone / Program Updates |
|---|---|---|---|
| Dermatology | Acne | Denifanstat | First patient dosed in AURORA Phase 3 clinical trial in Oct 2026 |
| | | TVB-3567 | Phase 1 FIH clinical trial initiated in June 2025; dosing for SAD/MAD and food effect parts complete; Phase 2 expected to initiate by end of 2026 |
| | | FASN inhibitor | Topical formulation in development |
| | | 歌礼 ascletis Denifanstat (ASC40) | Met all primary and secondary endpoints in Phase 3 clinical trial & NDA accepted by NMPA for review 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 PK clinical trial completed in December 2025 |
| Oncology | Solid tumors | TVB-3567 | Identifying FASN-dependent tumor types for potential FASN inhibitor development |
| | | Denifanstat | |

Preclinical | Phase 1 | Phase 2 | Phase 3

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

SAGIMET BIOSCIENCES



# Significant U.S. Acne Market Potential for Denifanstat

# Significant U.S. Acne Market Opportunity for Denifanstat

## Novel MOA Supports Significant Market Potential

### Large U.S. Acne Market

- **50 million** people suffer from acne in the US annually, of which **10 million** have moderate to severe acne[1,2]
- Acne affects **~85%** of 12-24-years-old[3]
- **6.8 million** patients seeking treatment in 2025
- **33.7 million** acne prescriptions in 2025
- **12.6 million** oral acne prescriptions in 2025 (37% of the market)

### Unmet Need with Current Treatments

- Current topical treatments have various limitations including: photosensitivity, application site burning/stinging, and/or compliance limitations for treatment of large body areas
- Current oral treatments have various limitations including: contributing to antibiotic resistance, slow onset of action and/or hormonal-related adverse events

### Denifanstat Has Potential to Capture Significant Market Share

- **Novel**, **once-daily** oral fatty acid synthase (FASN) inhibitor
- Statistically significant effect on skin lesions **starting week 4** and **continued clinical improvement** demonstrated in positive Ascletis Phase 3 studies
- **Generally well-tolerated** in clinical studies

Source: IQVIA data on file; Ascletis clinical studies

1. Reynolds R, et al., Guidelines of care for the management of acne vulgaris, JAAD, 2024; 90, 1006.e1-1006.e30.
2. Szepietowska 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. 3. Bhate K, Williams HC. Epidemiology of acne vulgaris. Br J Dermatol. Mar 2013;168(3):474-85. doi:10.1111/bjd.12149

# Acne Treatment Algorithm

## Per the Current AAD Acne Guidelines, Disease Management Involves Flare and Prevention Intervention



**Mild Acne (~38M*)**

**Treatment includes topical agents used as mono or combination therapy**

Primary topical therapies:

- Retinoids
- Benzoyl Peroxide
- Antibiotics
- Clascoterone
- Salicylic and Azelaic Acid



**Moderate to Severe Acne (~10M*)**

**Treatment approach adds oral products on top of topical agents**

Primary oral therapies:

- Antibiotics (tetracyclines, sarecycline)
- Hormonal contraceptives
- Spironolactone (off-label)

Can also be treated with physical procedures (lasers, peels, corticosteroid injections)



**Cystic Acne (~2M*)**

**Cystic patients are generally managed with isotretinoin (Accutane)**

Primary therapy:

- Isotretinoin

**Routine Management**

**Skin care routines to address treatment-related adverse events**

Primary approaches are OTC cleansers, moisturizers, and sunscreens

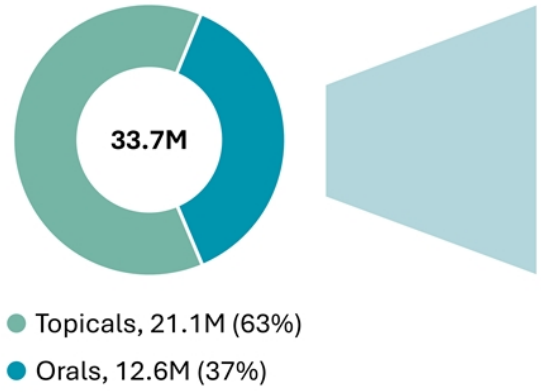
Source for Acne Treatment Algorithm: https://www.jaad.org/article/S0190-9622(23)03389-3/fulltext

* 38M, 10M and 2M represent the annual number of acne sufferers in the US with mild, moderate to severe and cystic acne, respectively. Sources: 1. Reynolds R, et al., Guidelines of care for the management of acne vulgaris, JAAD, 2024; 90, 1006.e1-1006.e30. 2. Szepietowska 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. 3. https://www.jaad.org/article/0190-9622(92)70135-3/abstract

# U.S. Acne Market Landscape

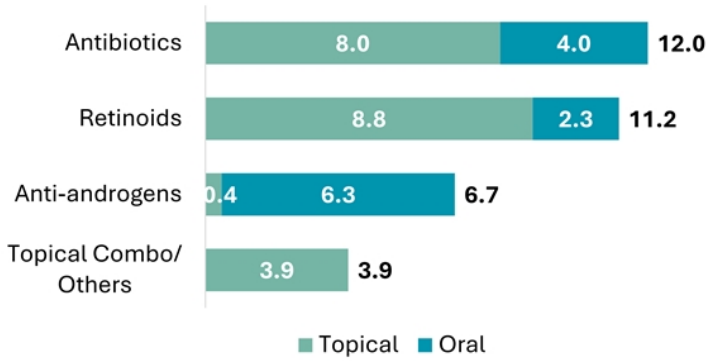
## 33.7M Annual Prescriptions for Acne in 2025, Including 12.6M for Oral Treatments

### Acne Prescriptions by delivery, 2025 (in M)




- Topicals, 21.1M (63%)
- Orals, 12.6M (37%)

### Prescriptions by category, 2025 (in M)




## Denifanstat's novel mechanism of action supports its significant market potential

Source: IQVIA data on file

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# FASN Inhibition Offers Differentiated MOA in Acne

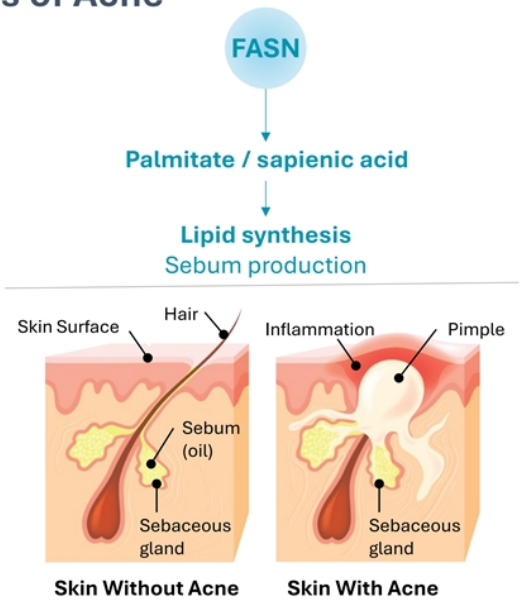
# Potential Role of FASN Inhibitors in the Pathogenesis of Acne

## 4 key drivers of acne[1]:

- 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 trials[3]
- In nonclinical studies, FASN inhibitors reduced sebum-related lipids in human sebocytes[4]
- FASN inhibition has potential to reduce inflammation, through decreasing cytokine secretion and Th17 activation[5]





1. Vasam M, et al., *Biochem Biophys Rep*. 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_36x60_v10.pdf. And B) Syed-Abdul MM et al., *Hepatology*. 2020;72(1):103.
4. Tsai et al, 2026, SID 2026 (Poster LB1208).-5. O'Farrell M, et al. *Sci Rep*. 2022;12(1):15661.

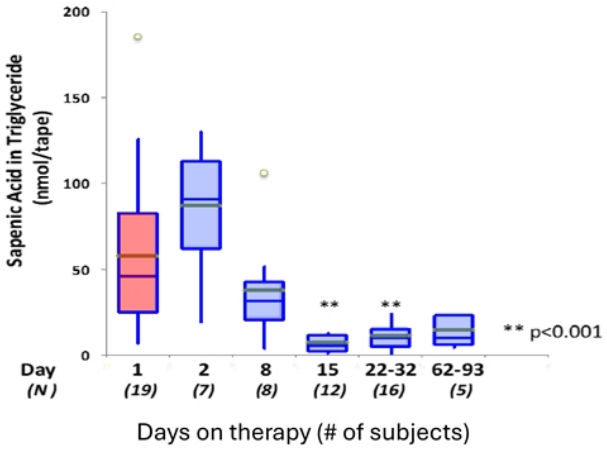
# Pharmacodynamic Data Support Mechanism of Action of Denifanstat in Acne

## In multiple Phase 1 clinical trials, denifanstat demonstrated a decrease in DNL sebum lipids[1-3]

- Demonstrated a >90% reduction in sebum lipids by day 15[1,2]
- Maintained the reduced level of sebum lipids through the entire trial[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

**Phase 1 oncology clinical trial**
**Sebutape® assessment of cutaneous sebum lipids[1,2]**





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.

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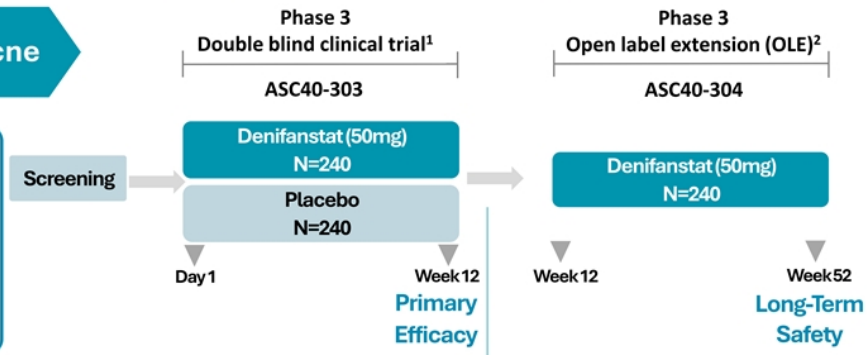
# Denifanstat's Clinical Data in Acne

# Design of Acne Phase 3 Clinical Trials (ASC40-303 and ASC40-304)

## Clinical Trials Conducted in China by Sagimet's License Partner, Ascletis

**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

**Primary endpoint of OLE**

- Long term safety of Denifanstat 50mg

**Secondary/Efficacy endpoints of OLE**

- Subjects with ≥2 point reduction in IGA from baseline
- Subjects with IGA score ≥3 reaching IGA of 0 or 1
- % reduction in total lesion count from baseline
- % reduction in inflammatory lesion count 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; this trial referred to herein as "OLE".

# ASC40-303 Baseline Characteristics

| Baseline Characteristics | 50mg Denifanstat (n=240) | Placebo (n=240) | Total (n=480) |
|---|---|---|---|
| Age, years, mean (SD) | 22.7 (4.0) | 22.5 (3.5) | 22.6 (3.8) |
| Male, n (%) | 79 (32.9) | 71 (29.6) | 150 (31.3) |
| Female, n (%) | 161 (67.1) | 169 (70.4) | 330 (68.8) |
| IGA=3 (moderate), n (%) | 206 (85.8) | 206 (85.8) | 412 (85.8) |
| IGA=4 (severe), n (%) | 34 (14.2) | 34 (14.2) | 68 (14.2) |
| Total lesion count, mean (SD) | 102.2 (24.6) | 102.1 (25.1) | 102.1 (24.8) |
| Inflammatory lesion count, mean (SD) | 42.1 (11.7) | 43.1 (12.2) | 42.6 (11.9) |
| Non-Inflammatory lesion count, mean (SD) | 60.0 (19.8) | 59.0 (20.0) | 59.5 (19.9) |

Ascletis data on file. SD = standard deviation.

# Denifanstat Met All Primary and Secondary Endpoints in Acne Phase 3 Clinical Trial (ASC40-303)

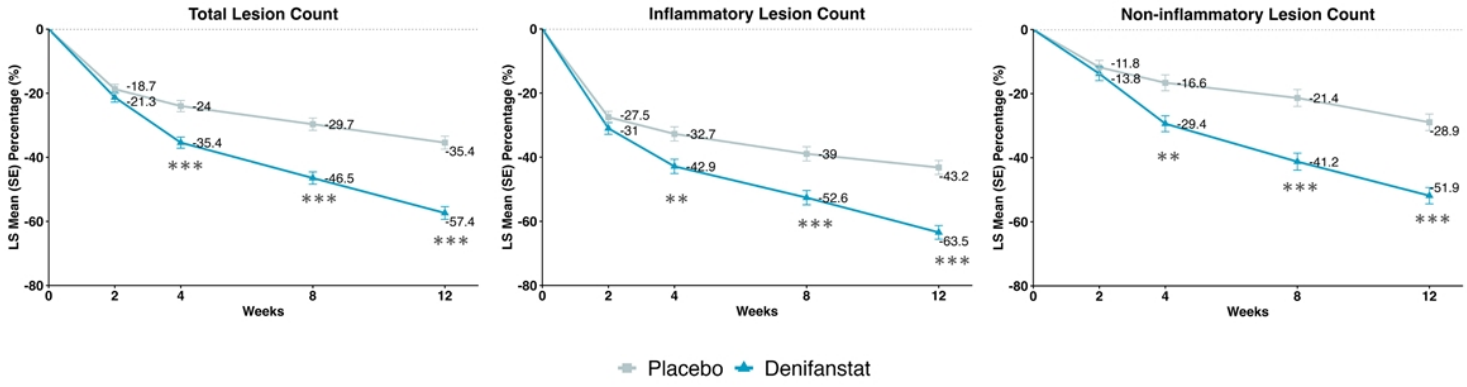
| Efficacy endpoints [1] | 50mg Denifanstat (n=240) | Placebo (n=240) | 50mg Denifanstat (placebo adjusted) | p value |
|---|---|---|---|---|
| % Treatment success (IGA) [2] (primary endpoint) | 33.2 | 14.6 | 18.6 | <0.0001 |
| % Change in total lesion count (primary endpoint) | -57.4 | -35.4 | -22.0 | <0.0001 |
| % Change in inflammatory lesion count (primary endpoint) | -63.5 | -43.2 | -20.3 | <0.0001 |
| % Change in non-inflammatory lesion count (key secondary endpoint) | -51.9 | -28.9 | -23.0 | <0.0001 |
| Absolute change in total lesion count (secondary endpoint) | -58.3 | -36.2 | -22.1 | <0.0001 |
| Absolute change in inflammatory lesion count (secondary endpoint) | -26.6 | -18.4 | -8.2 | <0.0001 |
| Absolute change in non-inflammatory lesion count (exploratory endpoint) | -31.7 | -17.9 | -13.8 | <0.0001 |

Ascletis data on file. 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.

# In ASC40-303, Denifanstat Showed Statistically Significant Effect on Skin Lesions Starting Week 4

## Percent Change in Total, Inflammatory and Non-inflammatory Lesion Count Over Time




Ascletis data on file. Note: * p<0.01, ** p<0.01, *** p<0.001

# ASC40-303 Safety Data

## Denifanstat 50mg Was Generally Well-Tolerated During the 12-Week Clinical Trial

### Adverse events (AEs):

- AE incidence rates were comparable between denifanstat and placebo
- Only two categories of treatment related AEs 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 8.0% in the placebo group*
  - Dry skin reported in 6.3% of denifanstat-treated subjects vs 2.9% in the placebo group
- 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. In the placebo group, dry eye Treatment Emergent AEs were 9.2%.

# Baseline Characteristics of ASC40-304 Extension Cohorts at ASC40-303 Baseline

## Baseline Characteristics of OLE Cohorts Consistent With Overall Study Population

| Baseline Characteristics | Denifanstat/Denifanstat (n=116) | Placebo/Denifanstat (n=124) | ASC40-303 Total Baseline (n=480) |
|---|---|---|---|
| Age, years, mean (SD) | 22.5 (4.1) | 22.3 (3.3) | 22.6 (3.8) |
| Male, n (%) | 31 (26.7) | 47 (37.9) | 150 (31.3) |
| Female, n (%) | 85 (73.3) | 77 (62.1) | 330 (68.8) |
| IGA=3 (moderate), n (%) | 101 (87.1) | 106 (85.5) | 412 (85.8) |
| IGA=4 (severe), n (%) | 15 (12.9) | 18 (14.5) | 68 (14.2) |
| Total lesion count, mean (SD) | 102.8 (25.3) | 103.2 (24.4) | 102.1 (24.8) |
| Inflammatory lesion count, mean (SD) | 42.0 (12.2) | 43.5 (11.8) | 42.6 (11.9) |
| Non-Inflammatory lesion count, mean (SD) | 60.8 (19.3) | 59.7 (20.9) | 59.5 (19.9) |

Ascletis data on file. SD = standard deviation.

# ASC40-304 Safety Data

## Denifanstat Generally Well-Tolerated in the OLE Clinical Trial

### Adverse events (AEs):

- All denifanstat-related AEs were mild or moderate; no denifanstat-related Grade 3 or 4 AEs
- Only two categories of treatment related AEs had an incidence of 5% or more in denifanstat-treated patients in 52 weeks
  - dry eye syndrome in 5.9%
  - dry skin reported in 7.1 %
- In the 40-week open label extension alone, the incidence of treatment related AEs of dry skin was 2.5% and 2.1% for dry eye
- No AE-related permanent discontinuations
- Grade 1 hair thinning in the clinical trial was experienced by only 1 denifanstat-treated patient; resolved within eight weeks while remaining in trial without a change in dose
  - Grade 1 hair thinning was experienced by 1 placebo-treated patient in the 12-week randomized phase of the phase 3 trial

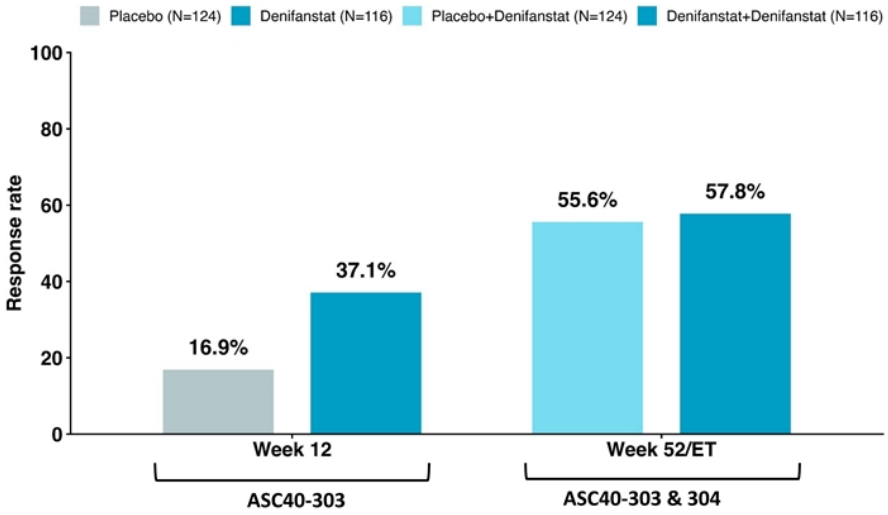
### Serious adverse events (SAEs):

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

* Ascletis 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.

# During the OLE (ASC40-304), Patients Showed Further Improvement in IGA Success Compared to ASC40-303 Baseline

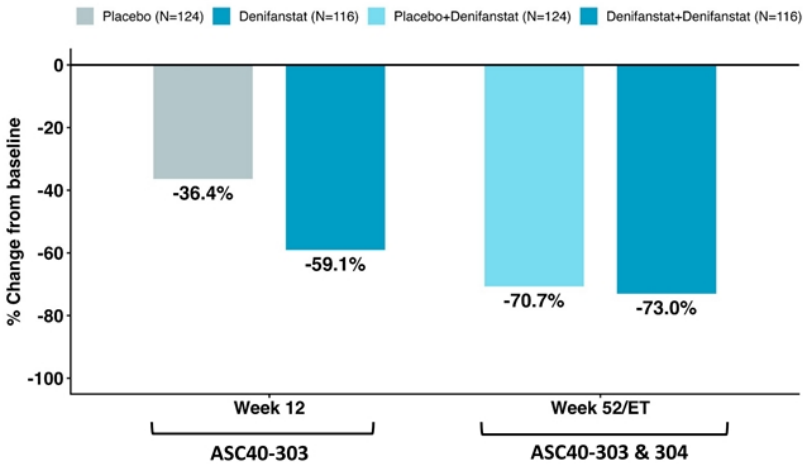
## % Patients with IGA ≥ 3 at ASC40-303 Baseline Reaching IGA of 0 or 1 during OLE




Ascletis data on file. Week 52/ET ("Early Termination") = patients who completed the clinical trial plus all patients who terminated the clinical trial early with the last observation carried forward.

# During the OLE (ASC40-304), Patients Showed Further Reduction in Total Lesion Counts (TLC) Compared to ASC40-303 Baseline

## TLC Mean % Change in TLC From ASC40-303 Baseline in OLE Patients

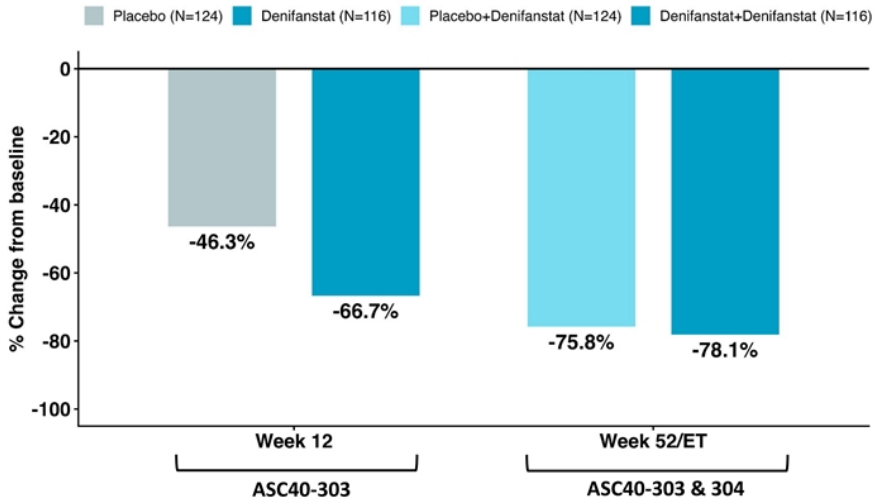



Total skin lesion counts reduced by approximately 75% compared to ASC40-303 baseline for patients who completed the OLE trial.

Ascletis data on file. Week 52/ET ("Early Termination") = patients who completed the clinical trial plus all patients who terminated the trial early with the last observation carried forward.

# During the OLE (ASC40-304), Patients Showed Further Reduction in Inflammatory Lesion Counts (ILC) Compared to ASC40-303 Baseline

## ILC Mean % Change From ASC40-303 Baseline in OLE Patients

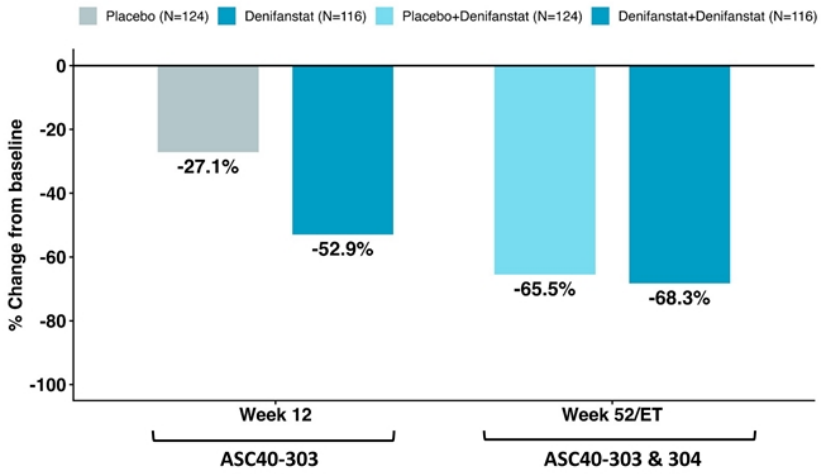



Inflammatory skin lesion counts reduced by approximately 80% compared to ASC40-303 baseline for patients who completed the OLE trial.

Ascletis data on file. Week 52/ET ("Early Termination") = patients who completed the clinical trial plus all patients who terminated the trial early with the last observation carried forward.

# During the OLE (ASC40-304), Patients Showed Further Reduction in Non-Inflammatory Lesion Counts (NILC) Compared to ASC40-303 Baseline

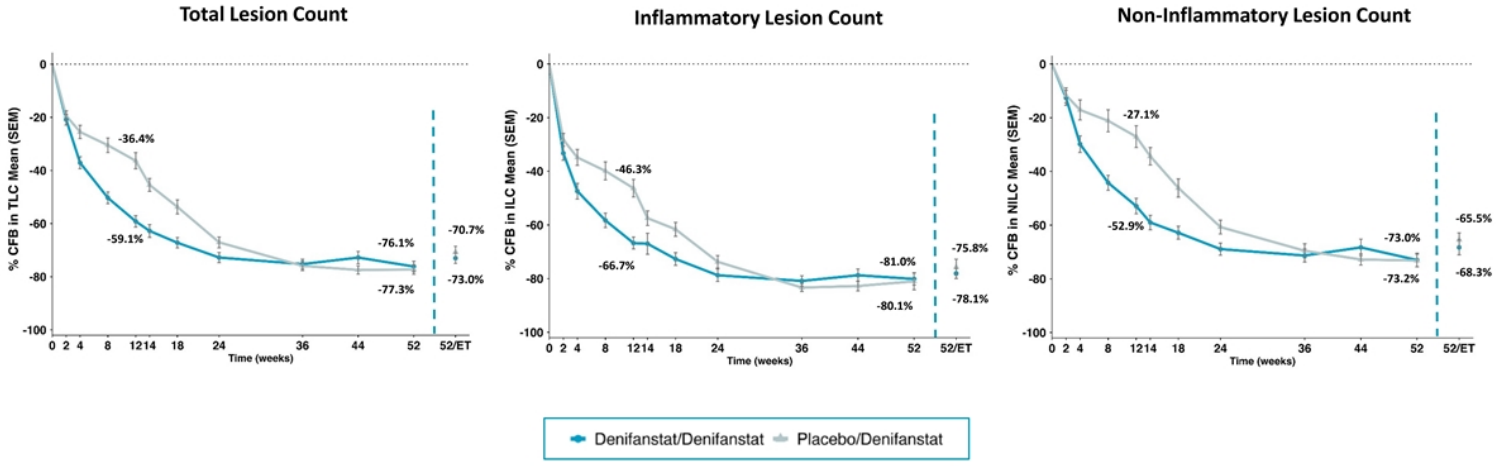
## NILC Mean % Change From ASC-303 Baseline in OLE Patients




Ascletis data on file. Week 52/ET ("Early Termination") = patients who completed the clinical trial plus all patients who terminated the trial early with the last observation carried forward.

# During the OLE (ASC40-304), Patients Showed Improved Efficacy Through Week 24-36, Which Was Sustained Through Week 52

## Percent Change in Total, Inflammatory and Non-inflammatory Lesion Count Over Time




CFB: Change from ASC-303 Baseline, SEM: Standard Error of the Mean, TLC: Total Lesion Count, ILC: Inflammatory Lesion Count, NILC: Non-Inflammatory Lesion Count.
Ascletis data on file. Week 52/ET ("Early Termination") = patients who completed the clinical trial plus all patients who terminated the trial early with the last observation carried forward.

# Acne Phase 3 Clinical Trials (ASC40-303 and ASC40-304)

## Summary

- In ASC40-303, patients dosed with denifanstat 50mg over 12 weeks demonstrated statistically significant improvement in:
  - Investigator Global Assessment (IGA)-scores
  - Inflammatory, non-inflammatory, and total lesion counts
- In ASC40-303, denifanstat showed statistically significant effect on skin lesions starting week 4
- During the OLE (ASC40-304), patients showed further improvement in IGA success and lesion count reductions compared to ASC40-303 baseline
- In both clinical trials, denifanstat was generally well-tolerated
  - All denifanstat-related AEs were mild or moderate, with no denifanstat-related SAEs reported

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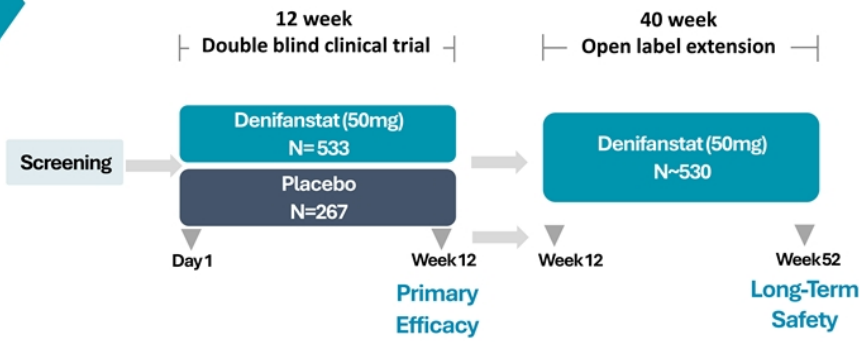


# Sagimet's Development Programs

# AURORA Phase 3 Clinical Trial for Denifanstat in Acne

## AURORA Phase 3 acne clinical trial design

- Moderate to severe acne
- Multi-center placebo controlled
- 2:1 randomization
- Double-blind
- Once daily oral dosing
- 800 patients in US, including 450 12–17-year-old patients




**Co-primary endpoints at week 12**

- % patients who achieve treatment success (defined as at least a 2-point reduction in global assessment from baseline, and a score of 0 or 1)
- Absolute change in inflammatory skin lesion counts from baseline
- Absolute change in non-inflammatory skin lesion counts from baseline

**Key Timepoints**

- IND clearance and FDA "Study May Proceed" letter received in July 2026
- First patient dosed in AURORA Phase 3 clinical trial in the US for patients with moderate to severe acne in Oct 2026

# 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 and 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 |

| **Sebumeter** | **Sebutape** |
|---|---|
|  |  |
| Quantity of Sebum | Quality[3] of Sebum |

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

- **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
  - Dosing for SAD/MAD and food effect parts complete, TVB-3567 was generally well tolerated
  - Phase 2 doses have been identified
  - Part D (PD in Acne patients) on-going

- **Phase 2 clinical trial in moderate to severe acne patients**
  - Plan to initiate Phase 2 clinical trial before the end of 2026
  - Phase 2 clinical trial design informed by the results of the Phase 1 clinical trial
    - 12-week dose ranging clinical trial in moderate to severe acne patients
    - Endpoints anticipated to include total and inflammatory lesion count reduction; improvement in the acne global assessment score will be explored

# 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 consult with the FDA regarding a denifanstat-resmetirom combination Phase 2 study design in 1Q 2027, after which we anticipate that the program will be Phase 2 ready
- 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 acne

**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 clinical trial
- During the OLE (ASC40-304), patients showed further improvement in IGA success and lesion count reductions compared to ASC40-303 baseline
- First patient dosed in AURORA Phase 3 clinical trial in the US for patients with moderate to severe acne in Oct 2026; topline results expected in 2H 2027

**Potential of TVB-3567 in Acne**

- First-in-human Phase 1 clinical trial of TVB-3567 initiated in June 2025 for development in acne
  - Dosing for SAD/MAD and food effect parts complete, TVB-3567 was generally well tolerated; Phase 2 doses have been identified
  - Plan to initiate TVB-3567 Phase 2 before the end of 2026
- TVB-3567 IP:
  - Composition of matter patent – expiration date 2035; potential PTE to 2038
  - Exploring pathway to extend protection into 2040's