

**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): March 20, 2024

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

On March 25, 2024, Sagimet Biosciences Inc. (the “Company”) issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2023. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers

On March 20, 2024, the board of directors of the Company (the “Board”) approved the expansion of the Board from seven directors to nine directors and the appointment of each of Tim Walbert and Paul Hoelscher to serve as directors of the Board, in each case effective as of April 1, 2024 (the “Effective Date”), filling the vacancy created by such increase. Each of Mr. Walbert and Mr. Hoelscher will serve as a Class I director with a term expiring at the Company’s 2024 Annual Meeting of Stockholders (the “Annual Meeting”) or until his successor is duly elected and qualified or until his earlier resignation, death or removal. As of the Effective Date, Mr. Walbert will serve as a member of each of the Audit Committee of the Board and Compensation Committee of the Board and Mr. Hoelscher will serve as a member and chair of the Audit Committee of the Board.

Mr. Walbert, 57, has served as a senior advisor to Amgen Inc. (“Amgen”) since October 2023. Mr. Walbert was chairman, president and chief executive officer of Horizon Therapeutics plc (“Horizon”), a public biotech company, from June 2008 to October 2023, when it was acquired by Amgen for \$28 billion. Before joining Horizon, he was president, chief executive officer and director of IDM Pharma Inc. (“IDM”), a public biotechnology company, which was acquired by Takeda in June 2009. Before IDM, Mr. Walbert served as executive vice president, commercial operations at NeoPharm Inc., a public biotechnology company. From 2001 to 2005, he was divisional vice president and general manager, immunology, at Abbott Laboratories, now AbbVie Inc., leading the global development and launch of the multi-indication biologic HUMIRA, and served as divisional vice president, global cardiovascular strategy. From 1998 to 2001, Mr. Walbert served as director, CELEBREX North America, and Arthritis Team Leader, Asia Pacific, Latin America and Canada, at G.D. Searle & Company. From 1991 to 1998, he also held sales and marketing roles with increasing responsibility at G.D. Searle, Merck & Co. Inc. and Wyeth. He serves on the boards of Mirum Pharmaceuticals, Inc., a public biotech company, and Century Therapeutics, Inc., a public biotech company. He is also a member of the National Organization for Rare Disorders Advisory Board, the Wall Street Journal CEO Council, the CNBC CEO Council and serves on the Board of Trustees of Muhlenberg College. He previously served on the board of directors for Aurinia Pharmaceuticals Inc., a public pharmaceutical company, from 2020 to 2022; Excicure, Inc., a public biotechnology company, from 2019 to 2022; Asserlio Therapeutics, Inc., a public biopharma company, from 2014 to 2020; Raptor Pharmaceutical Corp., a public biotechnology company, from 2010 to 2014; XOMA Corporation, a public biotechnology company, from 2011 to 2017; and Sucampo Pharmaceuticals Inc., a public biopharmaceutical company, from 2016 to 2018. He is also a member of Economic Club of Chicago, the Commercial Club of Chicago and the Civic Committee of the Commercial Club of Chicago. Mr. Walbert was a previous board member of the Biotechnology Innovation Organization, the Pharmaceutical Research and Manufacturing Association, the Illinois Biotechnology Innovation Organization and World Business Chicago. Mr. Walbert received a Bachelor of Arts in business from Muhlenberg College in Allentown, PA.

Mr. Hoelscher, 59, served as executive vice president and chief financial officer of Horizon from 2014 until his retirement in May 2022, overseeing all aspects of Horizon’s financial operations. Prior to joining Horizon, Mr. Hoelscher held financial executive positions at OfficeMax, Inc. (“OfficeMax”), a business services company, from 2012 to 2014, including serving as senior vice president, finance – treasury and corporate development and co-leading the integration of OfficeMax and Office Depot Inc. Previously, Mr. Hoelscher held various financial leadership roles of increasing responsibility over nineteen years at Alberto Culver Company, a beauty care company, and worked in the audit practice of KPMG LLP for seven years. Mr. Hoelscher received his B.S. in accountancy from the University of Illinois at Urbana-Champaign and is a certified public accountant. Mr. Hoelscher serves on the board and is audit committee chair of Reneo Pharmaceuticals, Inc, a public pharmaceutical company, and served on the board of trustees of the Illinois Region of The Leukemia & Lymphoma Society from 2007 to 2022, including two terms as board chair.

The Board has determined that Mr. Walbert and Mr. Hoelscher are independent under the applicable Nasdaq listing rules. There are no arrangements or understandings between either Mr. Walbert or Mr. Hoelscher and any other person pursuant to which either such person was selected as a director. There are no related party transactions between the Company and either Mr. Walbert or Mr. Hoelscher (or any of their immediate family members) requiring disclosure under Item 404(a) of Regulation S-K. Neither Mr. Walbert nor Mr. Hoelscher have any family relationships with any of the Company's directors or executive officers.

In accordance with the Company's non-employee director compensation policy (the "Director Compensation Policy"), the Company will pay each of Mr. Walbert and Mr. Hoelscher respective annual retainers for their service on the Board and committees thereof. In addition, on the Effective Date, pursuant to the Director Compensation Policy, each of Mr. Walbert and Mr. Hoelscher will be granted a stock option with a grant date fair value of \$300,000 under the Company's 2023 Stock Option and Incentive Plan (collectively, the "Initial Option Grants"). The Initial Option Grants shall vest in equal monthly installments over three years following the Effective Date, subject to continued service to the Company.

Also, on March 20, 2024, Richard Rodgers and Jinzi Wu, Ph.D., current members of the Board, notified the Board that they will not stand for re-election at the Company's Annual Meeting, currently scheduled to be held on June 5, 2024. Mr. Richards and Dr. Wu will continue to serve as directors until the Annual Meeting and their decisions not to stand for re-election were not the result of any disagreement with the Company on any matters relating to the Company's operations, policies or practices. In addition, effective as of the Effective Date, Mr. Rodgers will step down from the Compensation Committee of the Board and as chair of the Audit Committee of the Board. Mr. Rodgers will continue as a member of the Audit Committee until the end of his term. The Company extends its deepest gratitude to each of Mr. Rodgers and Dr. Wu for their distinguished service to the Board and lasting contributions to the Company.

Item 7.01 Regulation FD Disclosure

On March 25, 2024, 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 Items 2.02 and 7.01 of this Current Report on Form 8-K, including the information set forth in Exhibits 99.1 and 99.2, 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"), nor shall Exhibits 99.1 and 99.2 filed herewith be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, 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

<u>Exhibit No.</u>	<u>Document</u>
99.1	Press Release of Sagimet Biosciences Inc., dated March 25, 2024
99.2	Investor Presentation of Sagimet Biosciences Inc., dated March 25, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

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

Sagimet Biosciences Inc.

Date: March 25, 2024

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



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

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

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

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

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

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

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

Full Year and Recent Highlights

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

- In January 2024, Sagimet announced positive topline results from the Phase 2b FASCINATE-2 clinical trial, evaluating denifanstat in biopsy-confirmed MASH patients with stage F2 or F3 fibrosis compared to placebo at week 52.
 - o The study met its primary efficacy endpoints:
 - MASH resolution without worsening of fibrosis with ≥ 2 -point reduction in NAS (NAFLD Activity Score) in 36% of denifanstat-treated patients vs 13% with placebo ($p=0.0022$)
 - ≥ 2 -point reduction in NAS without worsening of fibrosis in 52% of denifanstat-treated patients vs 20% with placebo ($p=0.0001$)
 - o Multiple secondary endpoints were met, achieving statistical significance, most notably fibrosis improvement by ≥ 1 stage with no worsening of MASH in 41% of denifanstat-treated patients vs 18% with placebo ($p=0.005$).
- In November 2023, Sagimet presented preclinical data evaluating denifanstat alone or in combination with semaglutide in mouse models of MASH at the 7th Obesity and NASH Drug Development Summit. The oral presentation highlighted that the FASN inhibitor, alone, was responsible for significant reduction of liver fibrosis. Additionally, the preclinical data suggested the combination of the FASN inhibitor and semaglutide has both an additive effect and provides support that distinct mechanism of actions may provide therapeutic benefit to patients with MASH.
- In October 2023, Sagimet's license partner for China, Asclestis Bioscience Co. Ltd. (Asclestis), presented Phase 2 topline results at the European Academy of Dermatology and Venereology (EADV) Congress 2023 in Berlin, Germany. The presentation demonstrated denifanstat's significant efficacy in the change of total lesion and inflammatory lesion count from baseline and was well-tolerated in patients with acne.
- In July 2023, Sagimet closed an upsized IPO of Series A common stock, at a public offering price of \$16.00 per share. Including shares issued pursuant to the exercise of the underwriters' option, the Company issued 6,026,772 shares of Series A common stock, and received net proceeds of approximately \$86.2 million.
- In January 2024, Asclestis announced the dosing of the first patient in its Phase 3 registration clinical trial of denifanstat for the treatment of moderate to severe acne.
- In January 2024, Asclestis announced the dosing of the first patient in its Phase 3 registration clinical trial of denifanstat combined with bevacizumab for treatment of recurrent glioblastoma; in September 2023, Asclestis announced enrollment of 120 patients in the trial, which it anticipates will provide sufficient events for its planned interim analysis of progression-free survival.

Anticipated Upcoming Milestones

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

Financial Results for the Year Ended December 31, 2023

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

About Sagimet Biosciences

Sagimet is a clinical-stage biopharmaceutical company developing novel fatty acid synthase (FASN) inhibitors that are designed to target dysfunctional metabolic pathways in diseases resulting from the overproduction of the fatty acid, palmitate. Sagimet's lead drug candidate, denifanstat, is an oral, once-daily pill and selective FASN inhibitor in development for the treatment of MASH. FASCINATE-2, a Phase 2b clinical trial of denifanstat in MASH with liver biopsy-based primary endpoints, was successfully completed with positive results. For additional information about Sagimet, please visit www.sagimet.com.

About MASH

MASH is a progressive and severe liver disease which is estimated to impact more than 115 million people worldwide, for which there is only one recently approved treatment in the United States and no currently approved treatments in Europe. In 2023, global liver disease medical societies and patient groups formalized the decision to rename non-alcoholic fatty liver disease (NAFLD) to metabolic dysfunction-associated steatotic liver disease (MASLD) and nonalcoholic steatohepatitis (NASH) to metabolic dysfunction-associated steatohepatitis (MASH). Additionally, an overarching term, steatotic liver disease (SLD), was established to capture multiple types of liver diseases associated with fat buildup in the liver. The goal of the name change was to establish an affirmative, non-stigmatizing name and diagnosis.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of, and made pursuant to the safe harbor provisions of, The Private Securities Litigation Reform Act of 1995. All statements contained in this press release, other than statements of historical facts or statements that relate to present facts or current conditions, including but not limited to, statements regarding: the expected timing of the presentation of data from ongoing clinical trials, Sagimet's clinical development plans and related anticipated development milestones, Sagimet's cash and financial resources and expected cash runway. These statements involve known and unknown risks, uncertainties and other important factors that may cause Sagimet's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, these statements can be identified by terms such as "may," "might," "will," "should," "expect," "plan," "aim," "seek," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "forecast," "potential" or "continue" or the negative of these terms or other similar expressions.

The forward-looking statements in this press release are only predictions. Sagimet has based these forward-looking statements largely on its current expectations and projections about future events and financial trends that Sagimet believes may affect its business, financial condition and results of operations. These forward-looking statements speak only as of the date of this press release and are subject to a number of risks, uncertainties and assumptions, some of which cannot be predicted or quantified and some of which are beyond Sagimet's control, including, among others: the clinical development and therapeutic potential of denifanstat or any other drug candidates Sagimet may develop; Sagimet's ability to advance drug candidates into and successfully complete clinical trials, including its FASCINATE-2 Phase 3 clinical trial; Sagimet's relationship with Ascletris, 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.

Contact:

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SAGIMET BIOSCIENCES INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

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

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

SAGIMET BIOSCIENCES INC.

BALANCE SHEETS

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

	As of December 31,			
	2023		2022	
Cash, cash equivalents and marketable securities	\$	94,897	\$	32,345
Total assets		96,719		33,031
Current liabilities		5,654		5,279
Noncurrent liabilities		-		82
Redeemable convertible preferred stock		-		214,620
Stockholders' equity (deficit)		91,065		(186,950)
Total liabilities, redeemable preferred stock and stockholders' equity (deficit)	\$	96,719	\$	33,031



SAGIMET

BIOSCIENCES



*Targeting Metabolic Dysfunction with
Novel Therapies to Treat MASH, Acne and Cancer*

March 2024

Forward Looking Statements

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 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 or any other drug candidates we may develop; 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; that unfavorable new clinical trial data may emerge in other clinical trials of denifanstat, including Phase 3 clinical trials; that clinical trial data are subject to differing interpretations and assessments, including by regulatory authorities; our relationship with Asclepis, 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 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.

Proven Team with Development and Commercialization Experience Across Hepatology, Metabolic Disease and Oncology



Dave Happel
President & CEO

- Cognoa: President & CEO
Chrono Therapeutics: President & CEO
Senior Executive and Commercial roles at Horizon, Raptor, Dynavax, Chiron
- M.B.A. – Indiana State University; B.A. Chemistry – Indiana University



George Kemble
Executive Chairman

- AstraZeneca (formerly MedImmune, Aviron): SVP Research for Biologics & General Manager of California operations, VP Vaccine Research & Development for Vaccines
- Ph.D. – Stanford University, Dept of Microbiology & Immunology



Eduardo Martins
CMO

- Abbvie (formerly Allergan), Eiger BioPharmaceuticals, Gilead, Genentech, Dynavax, Intermune, SciClone
- D.Phil. – University of Oxford
M.D. – Federal University of Rio de Janeiro, Brazil



Joe Oriti
Interim PFO & PAO

- Stout, Riveron, SOLIC Capital, KPMG
- B.B.A. – Kent State University




Elizabeth Rozek
General Counsel

- Cognoa, Basilea Pharmaceutica, US Department of Justice
- J.D. – University of California Berkeley
M.A. – University of California San Diego
B.A. – Brown University




Sagimet Investment Highlights

Critical role of FASN enzyme in MASH




- ✓ Key enzyme in de novo lipogenesis – responsible for excess liver fat in MASH
- ✓ FASN inhibition directly improves the 3 key drivers of MASH – liver fat, inflammation, fibrosis
- ✓ Differentiated MOA to treat growing underserved patient population

Precision medicine is key differentiator




- ✓ Blood test confirms drug response
- ✓ Predictive biomarkers identify likely responders
- ✓ Opportunity to personalize treatment and optimize outcomes

Denifanstat: FASN inhibitor with compelling clinical data



- ✓ FASCINATE-2 Phase 2b positive topline results
 - MASH resolution without worsening of fibrosis with ≥ 2 -point reduction in NAS ($p=0.002$)
 - ≥ 2 -point reduction in NAS without worsening of fibrosis ($p=0.0001$)
 - Fibrosis improvement by ≥ 1 stage with no worsening of MASH ($p=0.005$)

Strong rationale for FASN in acne and cancer



Acne

- ✓ Clinical proof of concept established in Phase 1
- ✓ Positive Phase 2 topline results announced in May 2023 by license partner Ascleptis
- ✓ Ascleptis Phase 3 in severe acne vulgaris ongoing

Cancer

- ✓ Clinical proof of concept established in Phase 1
- ✓ Phase 3 rGBM trial enrollment for interim analysis completed in September 2023 by Ascleptis

Strong financial position

- ✓ Upsized IPO completed in July 2023 raised \$86.2 million of net proceeds
- ✓ Follow-on financing completed in January 2024 raised net proceeds of \$105.8 million.
- ✓ Cash and equivalents expected to fund current operations through 2025

Development Pipeline: Indications and Clinical Milestones

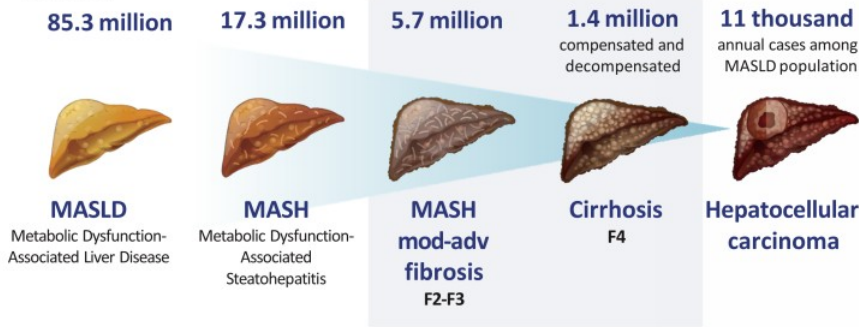
Therapeutic Area	Indication	Stage of Development				Expected Milestone / Status
		Preclinical	Phase 1	Phase 2	Phase 3	
Metabolic disease	MASH - F2/F3	TVB-2640				<ul style="list-style-type: none"> Phase 2b successfully completed; MASH Phase 3 study planned to start 2H 2024
		TVB-2640				<ul style="list-style-type: none"> Phase 1 hepatic impairment results 1Q 2024
Dermatology	Acne	TVB-3567				<ul style="list-style-type: none"> IND-enabling studies completed; evaluating timing to file IND
		TVB-2640 (ASC40)				<ul style="list-style-type: none"> Phase 3 clinical study initiated 4Q 2023*
Oncology	Solid tumors					<ul style="list-style-type: none"> Patient selection and trial design in FASN-dependent tumor types ongoing
	Recurrent glioblastoma (GBM)	TVB-2640 (ASC40)				<ul style="list-style-type: none"> Phase 3 enrollment of 120 patients achieved in 3Q 2023; interim analysis planned*

5 * Trials conducted in China by Ascletois, who has licensed development and commercialization rights to all indications in Greater China

MASH: A Burgeoning Epidemic

Patients in 2016¹

United States



Disease challenges

- Only one recently approved drug in U.S., and no approved drugs in Europe
- Complex disease, heterogeneous patient population
- Improving regulatory clarity, but liver biopsy still required

Drug development challenges

- Many molecules moved forward on weak mechanism and data
- Inappropriate biomarkers for mechanism that did not translate to clinical benefit
- Safety: triglyceride elevations, LDL elevations, liver injury

Denifanstat

- ✓ Designed for once-daily, oral dosing
- ✓ Rigorous and de-risked development strategy
- ✓ Direct DNL inhibition demonstrated in Phase 1b
- ✓ Improvements observed across biomarkers in Phase 2a
- ✓ Topline data of successfully completed Phase 2b announced in 1Q 2024
- ✓ Precision medicine approach to improve patient outcomes

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¹Estes, et al. 2018; <http://dx.doi.org/10.1016/j.jhep.2018.05.036>

Note: MASH, or metabolic dysfunction-associated steatohepatitis, was formerly known as NASH, or nonalcoholic steatohepatitis

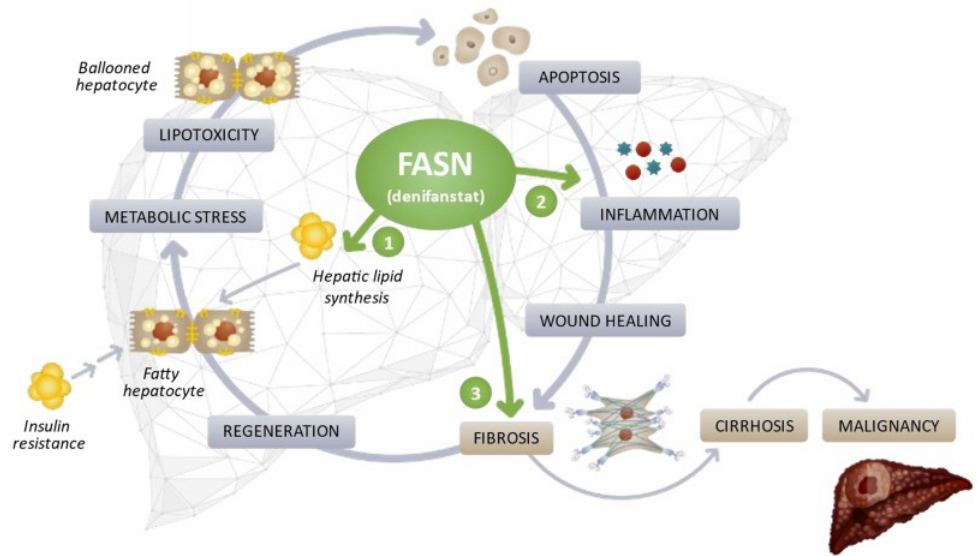
DNL = de novo lipogenesis

Denifanstat in MASH

Denifanstat: Differentiated Mechanism Believed to Target Key Drivers of MASH

Denifanstat has independent mechanisms designed to:

- 1 Block **steatosis** via inhibiting de novo lipogenesis in hepatocytes
- 2 Reduce **inflammation** via preventing immune cell activation
- 3 Blunt **fibrosis** via inhibiting stellate cell activation



Denifanstat: Well Tolerated at 25/50mg Doses in FASCINATE-1

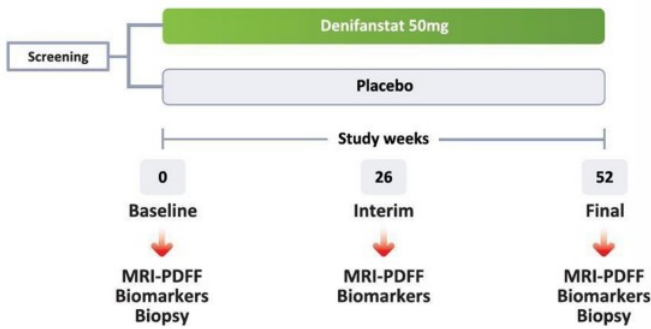
- No dose-related significant adverse events relative to placebo
- No serious AEs
- Majority of AEs were Grade 1; no Grade ≥ 3 drug-related AEs

Treatment Emergent Adverse Event (TEAE) Classification	Cohort 1			Cohort 2		Cohort 3
	US Placebo N=31	US 25mg N=33	US 50 mg N=35	China Placebo N=9	China 50 mg N=21	US 75mg N=13
Any TEAE	Gr 1: 12 (38.7%) Gr 2: 7 (22.6%)	Gr 1: 18 (54.5%) Gr 2: 7 (21.2%)	Gr 1: 12 (34.3%) Gr 2: 6 (17.1%)	Gr 1: 3 (33%) Gr 2: 2 (22%)	Gr 1: 11 (52%) Gr 2: 4 (19%) Gr 3: 2 (10%)	Gr 1: 3 (23%) Gr 2: 6 (46%)
TEAE leading to drug withdrawal	0	2 (6.1%)	0	0	0	4 (31%)
Treatment Emergent Serious Adverse Event (SAE)	0	0	0	0	0	0
Drug related TEAE	Gr 1: 3 (9.7%) Gr 2: 1 (3.2%)	Gr 1: 10 (30.3%) Gr 2: 2 (6.1%)	Gr 1: 9 (25.7%) Gr 2: 1 (2.9%)	0	Gr 1: 9 (43%) Gr 2: 4 (19%)	Gr 1: 1 (8%) Gr 2: 6 (46%)

FASCINATE-2 Phase 2b Biopsy Trial Design

Measuring Histological Improvement

FASCINATE-2 Phase 2b trial design



- Biopsy confirmed F2-F3 MASH patients
- 52 weeks, 2:1 50mg or placebo, double-blind

Primary endpoints

- NAS ≥ 2 points improvement w/o worsening of fibrosis OR
- MASH resolution + NAS ≥ 2 improvement w/o worsening of fibrosis

Other selected endpoints

- Improvement in liver fibrosis ≥ 1 stage without worsening of MASH (Bx)
- Digital AI pathology
- MRI-PDFF: absolute decrease, % change from baseline, % pts $\geq 30\%$ reduction from baseline (responders)

¹⁰ AI: Artificial Intelligence, Bx; biopsy, MRI-PDFF; magnetic resonance imaging derived proton density fat fraction, NAS; NAFLD Activity Score.

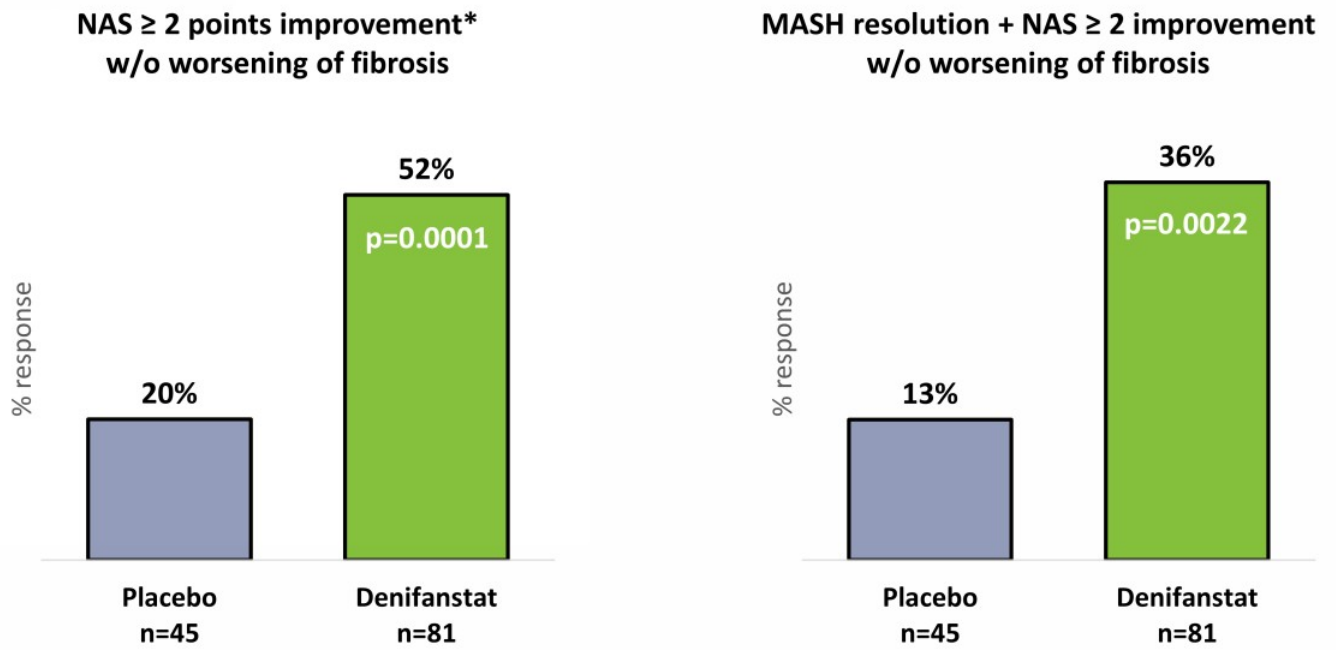
FASCINATE-2 Baseline Characteristics

Typical F2/F3 MASH Population

Parameter	Placebo, n=45	Denifanstat, n=81
Age, years	59.6 (+/- 10.9)	56.1 (+/- 10.8)
Sex, female	27 (60%)	48 (59%)
Race, White	41 (91%)	73 (90%)
Ethnicity, Hispanic or Latino	15 (33%)	27 (33%)
BMI, kg/m ²	36.5 (+/- 6.7)	34.6 (+/- 6.1)
Type 2 diabetes	27 (60%)	55 (68%)
ALT (alanine aminotransferase) U/L	67 (+/- 33)	57 (+/- 29)
AST (aspartate aminotransferase) U/L	52 (+/- 27)	48 (+/- 29)
Liver Fat Content (MRI-PDFF), %	19.0 (+/- 7.0)	16.6 (+/- 7.1)
Baseline liver biopsy NAS ≥ 5	34 (76%)	63 (78%)
Baseline liver biopsy F2/F3	22 (49%) / 23 (51%)	34 (42%) / 47 (58%)
Statin (at baseline)	21 (47%)	38 (47%)
GLP1-RA (at baseline)	4 (9%)	12 (15%)
LDL, mg/dL	103 (+/- 39)	96 (+/- 34)
Triglycerides, mg/dL	153 (+/- 67)	173 (+/- 79)
ELF (Enhanced Liver Fibrosis) Score	9.8 (+/- 0.8)	9.6 (+/- 0.8)
FAST (Fibroscan AST) Score	0.6 (0.19)	0.6 (0.20)

Primary Endpoints: Liver Biopsy

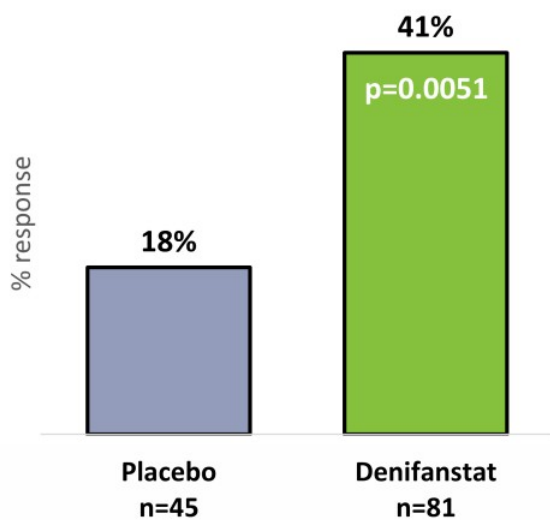
Denifanstat Achieved Statistical Significance



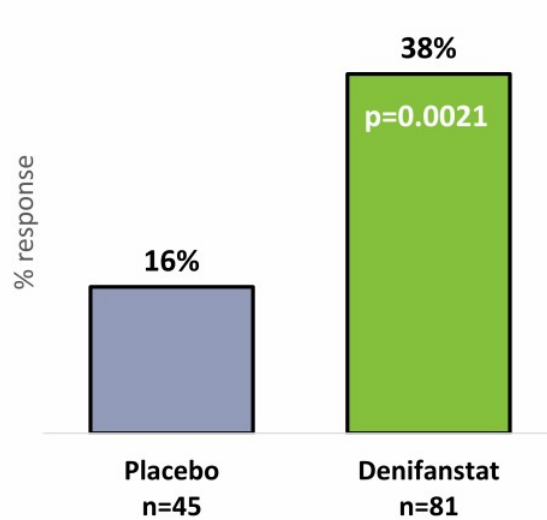
12 Cochran-Mantel-Haenszel Test – One sided at the 0.05 significance level. mITT population. * ≥1-point improvement in ballooning or inflammation.

Secondary Endpoints: Liver Biopsy *Denifanstat Achieved Statistical Significance*

**Improvement in liver fibrosis ≥ 1 stage
w/o worsening of MASH**

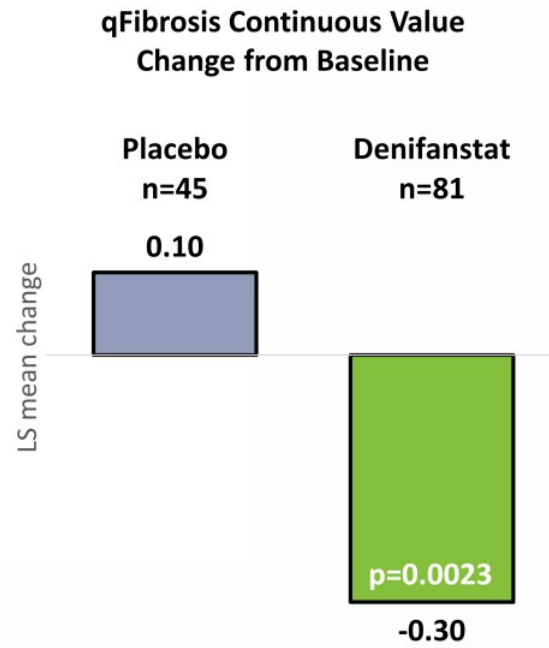


**Resolution of MASH
w/o worsening of fibrosis**



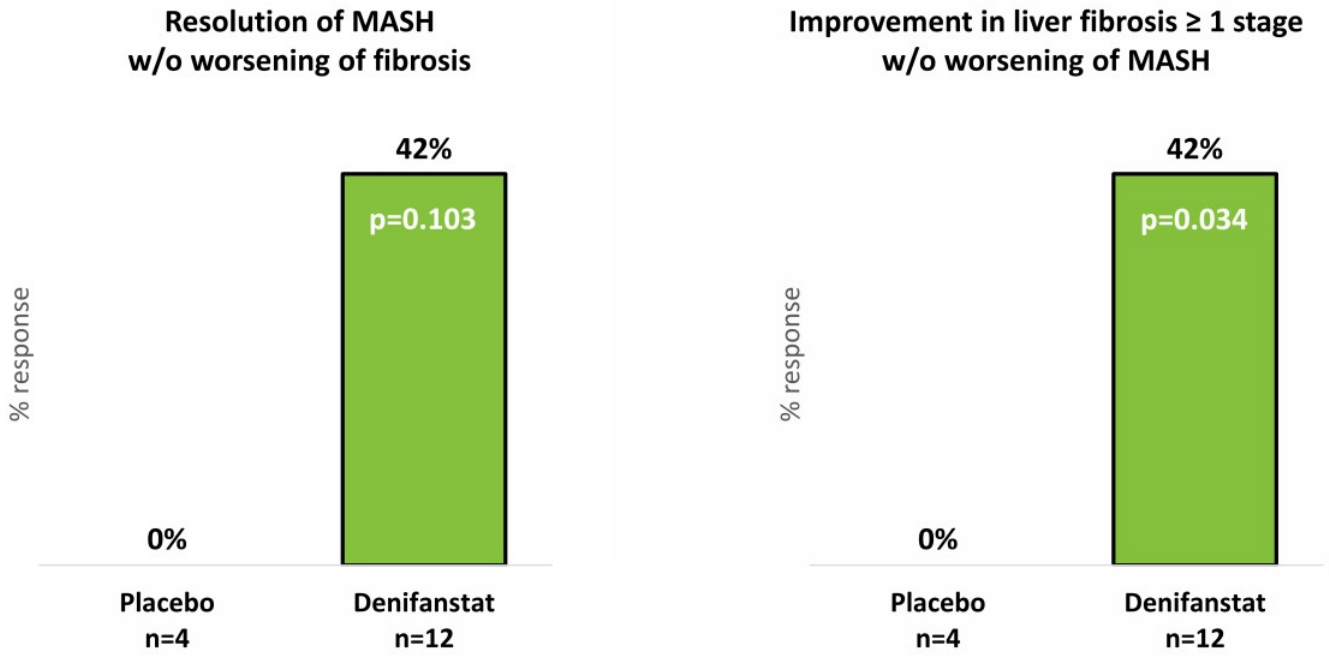
Independent Fibrosis Analysis by AI-based Digital Pathology

Supporting Evidence that Denifanstat Significantly Reduced Fibrosis



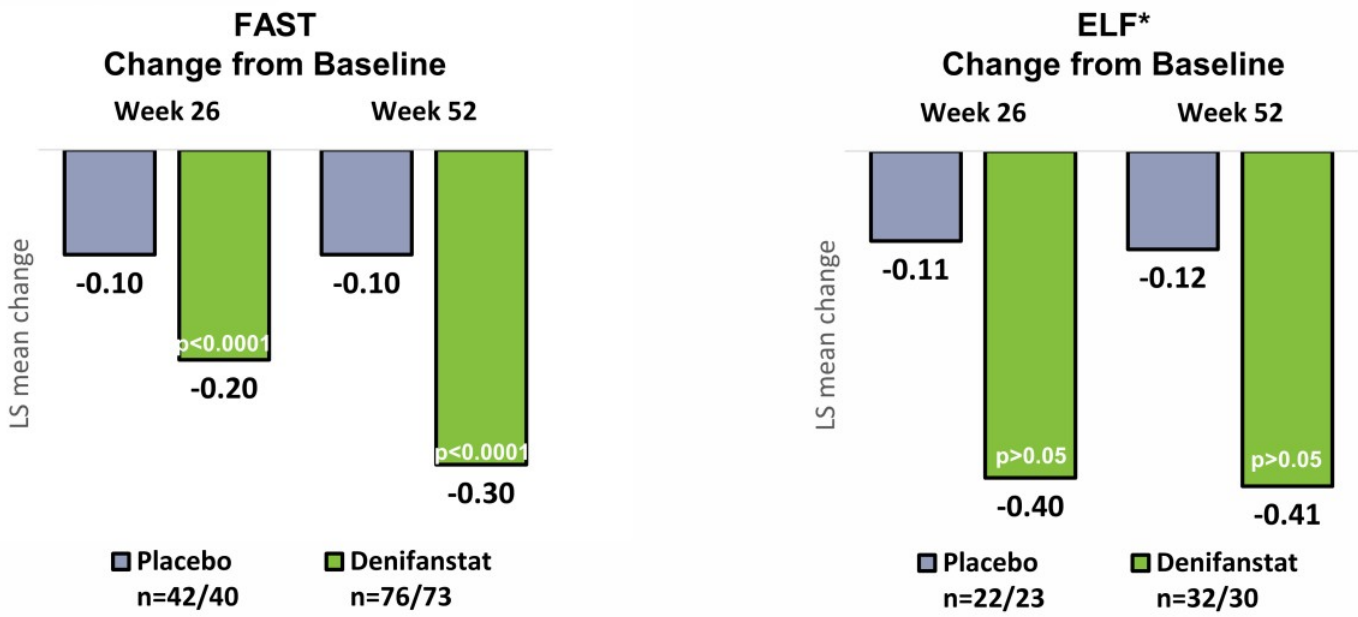
Patient Subset on Stable GLP1-RA at Baseline: Liver Biopsy

Denifanstat Improves MASH Resolution and Fibrosis



Biomarkers of Fibrosis

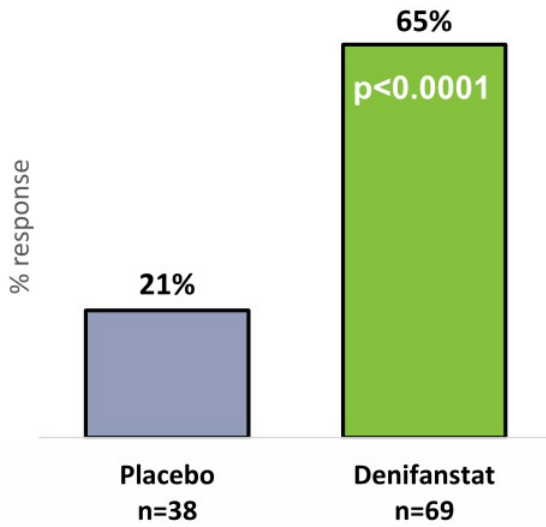
Denifanstat Decreased FAST Score and ELF



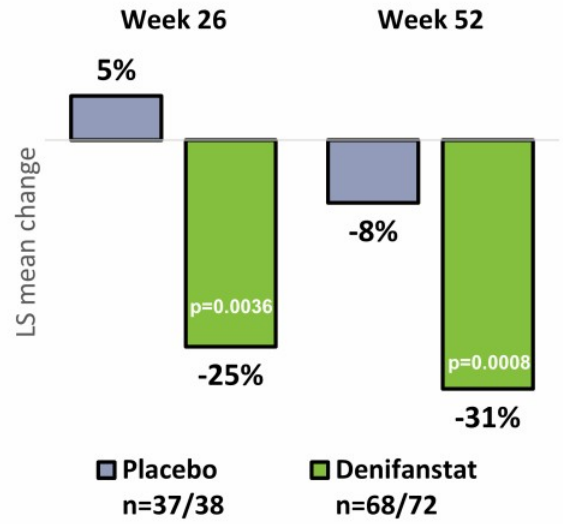
16 Mixed-effects Model for Repeated Measures – Two sided at the 0.05 significance level. mITT population. *Baseline ELF > 9.8 (mean).

Secondary Endpoint: Liver Fat by MRI-PDFF
Denifanstat Achieved Statistical Significance

**MRI-PDFF
 ≥ 30% Relative Reduction, Week 52**

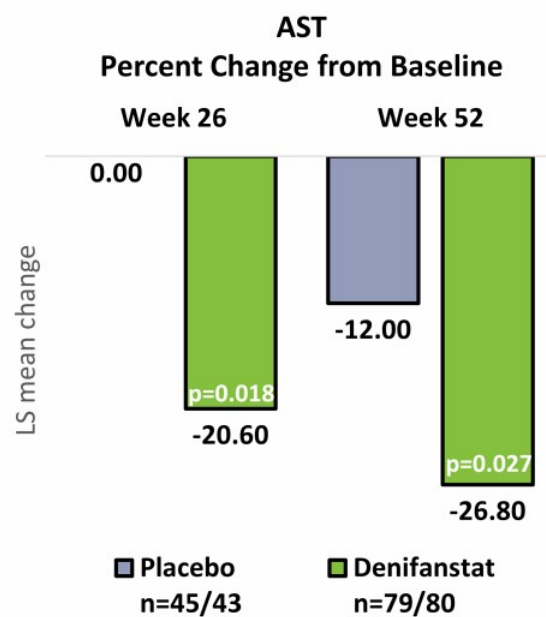
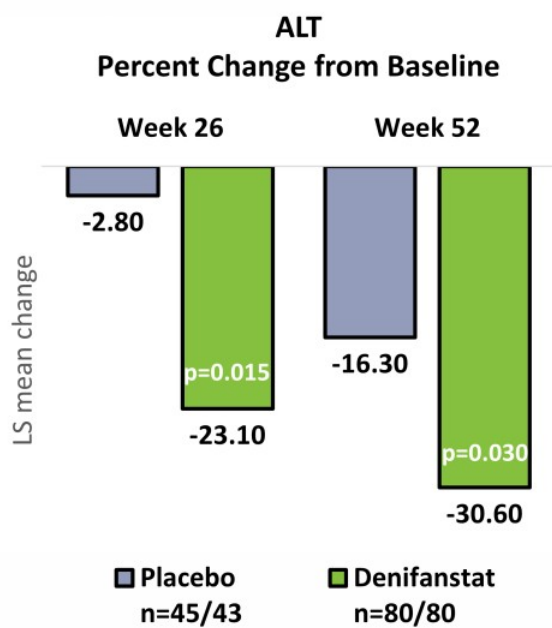


**MRI-PDFF
 Relative Change from Baseline**



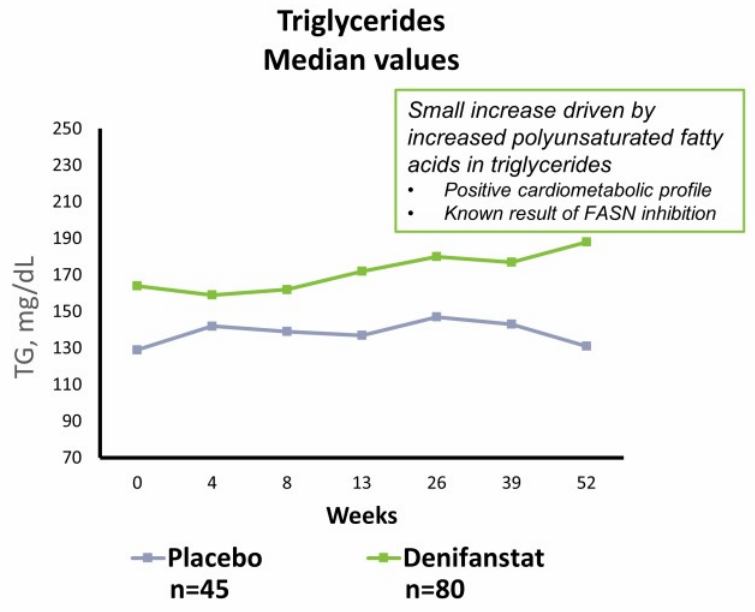
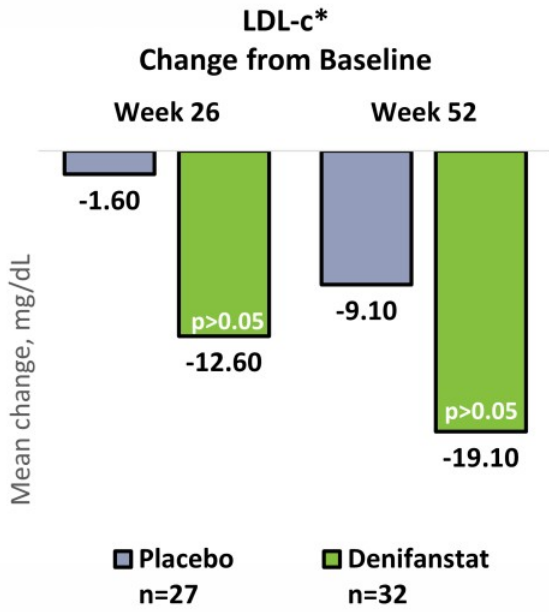
Secondary Endpoints: Liver Enzymes

Denifanstat Decreased ALT and AST Levels



Cardiometabolic health

Denifanstat Decreased LDL-c Levels



19 mITT population. *For LDL-c, baseline > 100 mg/dL. Mixed-effects Model for Repeated Measures – Two sided at the 0.05 significance level.

FASCINATE-2: Safety

Denifanstat was Generally Well Tolerated

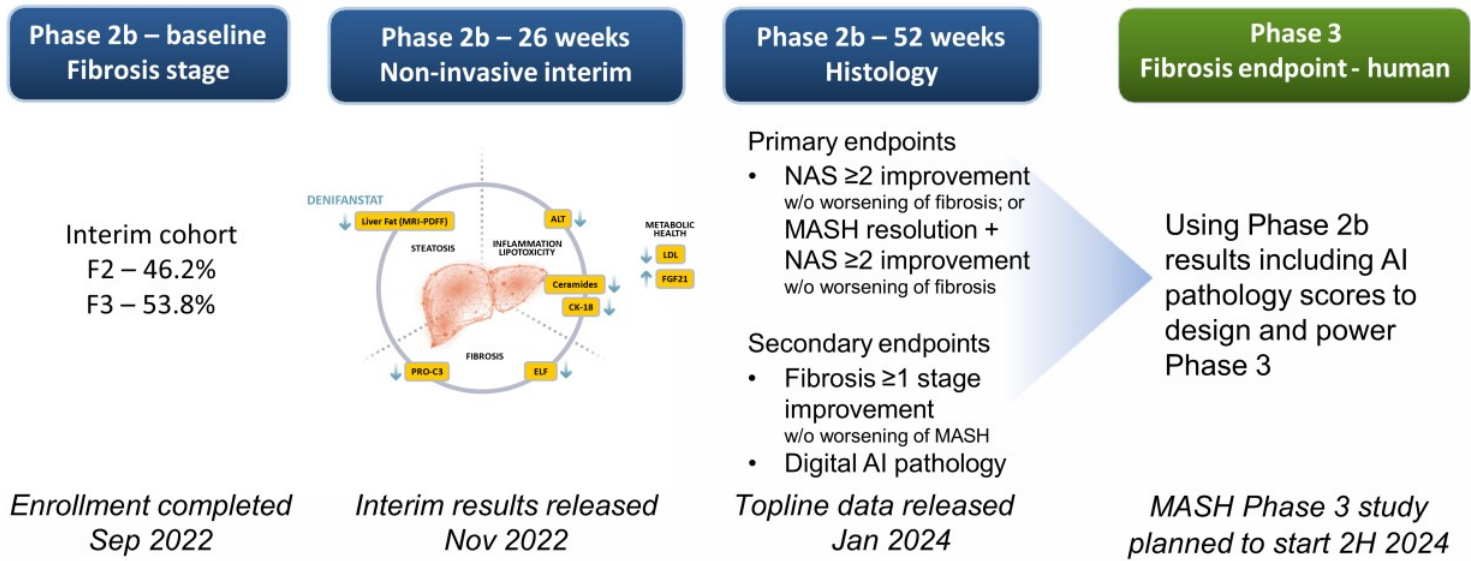


Parameter	Placebo n=56	Denifanstat N=112
Any TEAE (treatment emergent adverse event)	45 (80.4%)	96 (85.7%)
TEAE related to study drug	20 (35.7%)	51 (45.5%)
Most common TEAE related to study drug in ≥5% of patients by system organ class		
eye disorders	9 (16.1%)	17 (15.2%)
gastrointestinal disorders	5 (8.9%)	13 (11.6%)
skin and subcutaneous tissue disorders	4 (7.1%)	25 (22.3%)
TEAE leading to study drug discontinuation	3 (5.4%)	22 (19.6%)
TEAE with CTCAE Grade 3 (Severe) or higher*	3 (5.4%)	13 (11.6%)
SAE (none related to treatment)	3 (5.4%)	13 (11.6%)
Fatal TEAE	0	0



* No treatment-related AE was Grade 3 or higher

MASH Development Program

Progression from Phase 2b to Phase 3

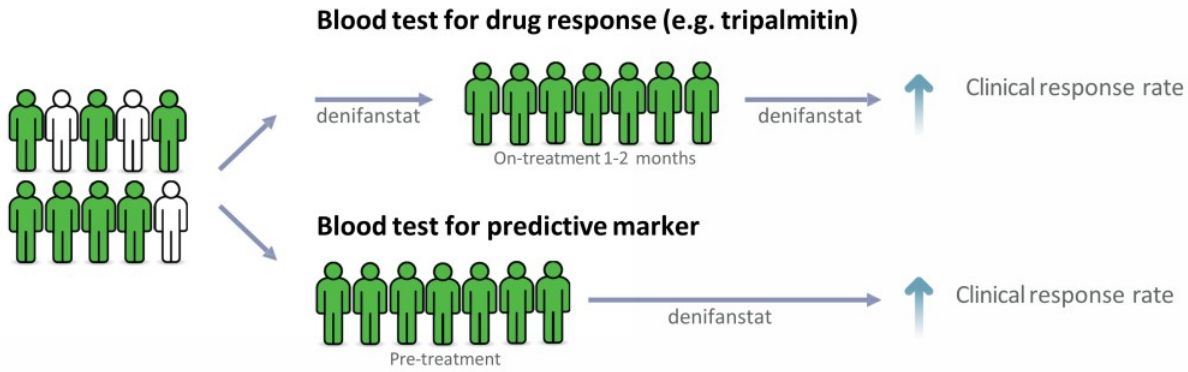


We Believe Denifanstat is Differentiated in the Evolving MASH Landscape

Mechanism	FASN inhibitors	THR β Agonists	FGF-21	GLP-1 agonists	PPAR agonists	ACC inhibitors	FXR agonists
Category	DNL pathway	Nuclear receptor	Growth factor	GLP-1	Nuclear receptor	DNL pathway	Nuclear receptor
Route	Oral	Oral			Oral	Oral	Oral
Status	Phase 2 complete Phase 3 to start 2H 2024	Approved March 2024	Phase 2 complete	Phase 2 complete	Phase 3 ongoing	Phase 2 complete	Phase 3 complete
Challenges	<ul style="list-style-type: none"> Perceived market pressure from incretin class of weight loss drugs 	<ul style="list-style-type: none"> Diarrhea Potential hormonal axis changes 	<ul style="list-style-type: none"> Bone loss Injectable Nausea and diarrhea Potential neutralizing antibodies Higher COGS 	<ul style="list-style-type: none"> GI side effects including nausea Lack of fibrosis improvement to date Muscle wasting 	<ul style="list-style-type: none"> Weight gain, edema, GI side effects, anemia Possible liver injury 	<ul style="list-style-type: none"> Combinations only MOA causes triglyceride increases Lack of fibrosis improvement as monotherapy 	<ul style="list-style-type: none"> Mixed results from several programs MOA causes pruritus and LDL-cholesterol increases

Precision Medicine: Blood Tests May Lead to Improved Patient Outcomes

- MASH is a multi-faceted disease and patients may benefit from being matched with optimal treatments
- Two approaches using blood tests are undergoing further evaluation
 - Drug response: 1-2 months after taking drug, tripalmitin identifies patients responding to drug treatment
 - Predictive marker: before taking drug, signature of 6 blood metabolites enriches for responders¹



¹Signature has 6 metabolites: ursodeoxycholic acid, DL-2-aminocaprylic acid, sarcosine, glycoursoxycholic acid, D(-)-2-aminobutyric acid, PC(0-18:0/22:4). Accuracy 79%, PPV 88%, NPV 63%.

Strong Monotherapy Opportunity for Denifanstat in MASH

Expansion as backbone of combinations

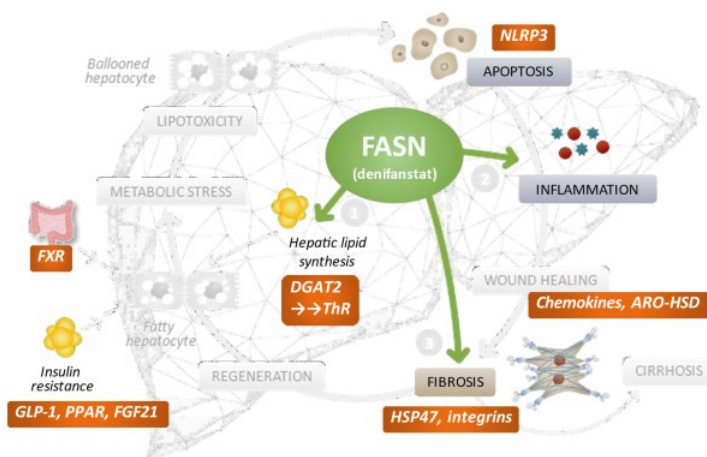
Denifanstat data support success as first line monotherapy

- ✓ Oral, once-daily tablet ideal for chronic administration
 - Tablets generally more affordable than complex biologics
- ✓ Potential to treat broad patient population
 - Including those with thyroid challenges
- ✓ Novel mechanism that acts directly upon liver
- ✓ Encouraging safety profile to date

Broaden market opportunity through combinations with denifanstat as backbone

- Denifanstat's potential
 - ✓ Complementary to other mechanisms
 - ✓ Potential for fixed dose combinations with other oral medications
- ✓ Preclinical combination studies ongoing
 - MASH agents: anti-fibrotic, other metabolic agents
 - Co-morbidities: diabetes and other cardiovascular agents

Illustrative potential combo mechanisms



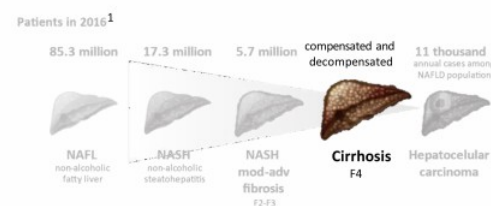
Additional Expansion Opportunities in MASH

• Compensated cirrhotic patients (MASH F4)

- Denifanstat directly targets stellate cells
- Hepatocytes continue to be functional, and patients frequently have increased liver fat
- Next steps
 - Characterize PK profile in patients with impaired hepatic function – Phase 1 results in 1Q 24
 - Positive impact on fibrosis in FASCINATE-2
 - Phase 2b/3 trial in MASH-F4

• Pediatric MASH

- 23% of children with MASLD have MASH at the time of diagnosis
- Next steps
 - Compile safety data across all denifanstat studies in young adults including FASCINATE-2
 - Nonclinical toxicology study in juvenile animals – plan to initiate in 2024
 - Phase 2 trial in pediatric MASH

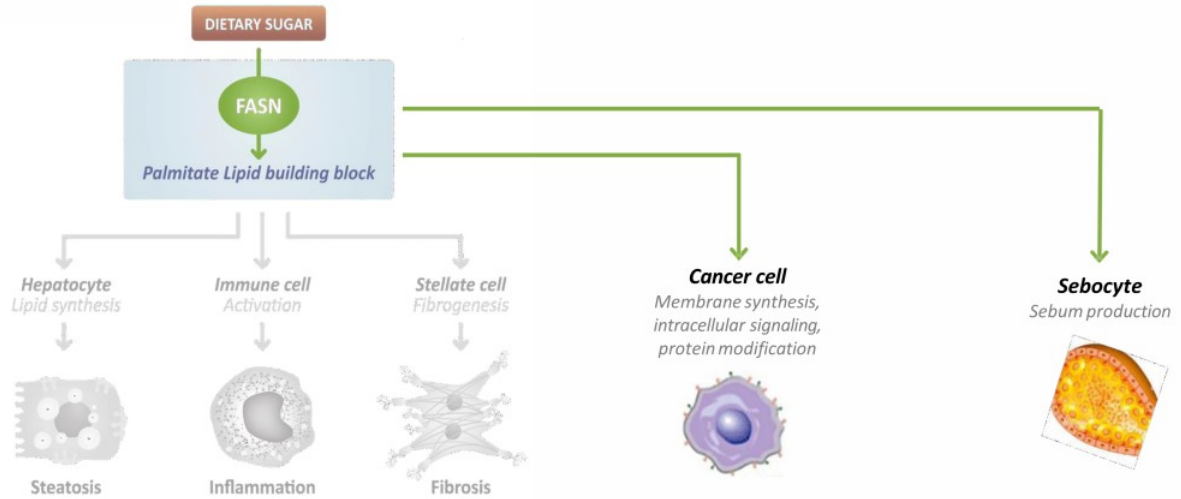


GLOBAL FATTY LIVER DAY | **GLI GLOBAL LIVER MONTH** | **JUNE 13, 2024**

10% of American children have a fatty liver. What questions should you and your pediatrician be asking?

Other Indications

FASN Hyper-Activity Plays a Key Role in Multiple Diseases Beyond MASH



FASN in MASH

1. Drives steatosis
2. Activates pro-inflammatory cells
3. Activates stellate cells leading to fibrosis

FASN in cancer

1. Supports tumor survival
2. Enables tumor proliferation
3. Establishes resistance to drugs

FASN in acne

1. Sebum production
2. Sebum composition

DNL Pathway Plays a Role in the Pathogenesis of Acne

FASN is an attractive therapeutic target for acne

- Acne is associated with excess sebum production by sebocyte cells in the skin
- Acne resolution is associated with reduced sebum production
- Sebocytes upregulate and rely on DNL/FASN to make sebum
 - >80% of key sebum lipids such as palmitate and sapienic acid produced by DNL/FASN

Phase 1 – sebum analysis by Sagimet

- Denifanstat inhibited lipogenesis in skin
- Dose-dependent
- Proof of mechanism

Phase 2 – acne by Ascleto in China



	EFFICACY RESULTS – 12 WEEKS			
	Placebo n=45	25 mg n=45	50 mg n=44	75 mg n=45
Total lesions	-34.9%	-49.5%**	-51.5%**	-48.4%**
Inflammatory lesions	-36.5%	-54.7%**	-56.7%**	-49.4%*
Non-inflammatory lesions	-35.0%	-44.4%	-46.6%	-46.5%
IGA (2-grade improvement)	15.6%	31.1%	31.8%	22.2%

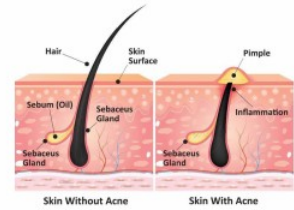
Well tolerated across dose groups

* p < 0.05 ** p < 0.01

FASN

Palmitate

Lipid synthesis
Sebum production



FASN is Integral to Tumor Cell Proliferation and Survival

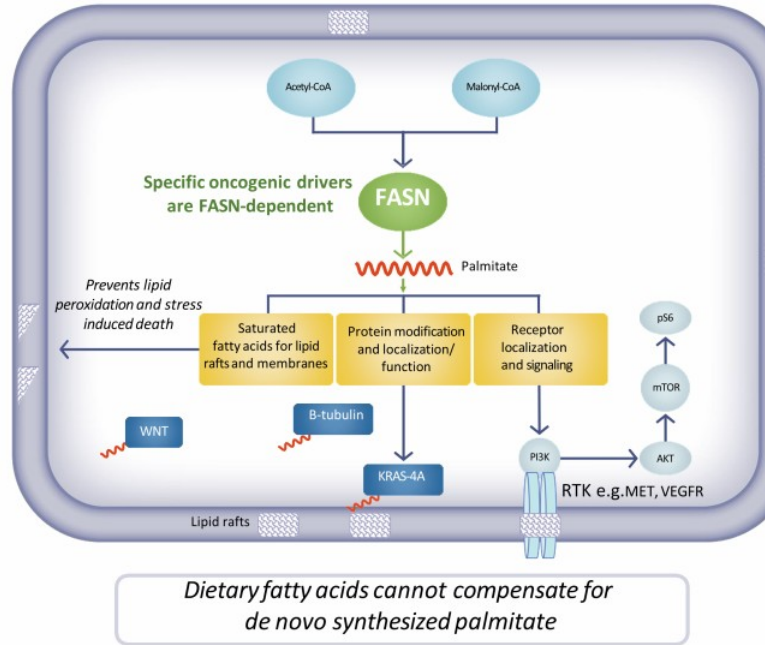
Reprogramed metabolism is one of the hallmarks of cancer

FASN-dependence

- Certain cancers are dependent on DNL/FASN for proliferation especially downstream of driver oncogenes
 - eg. KRAS in non-small cell lung cancer (NSCLC)
- Strategy → exploit this vulnerability using FASN inhibition in the combination setting to cause death

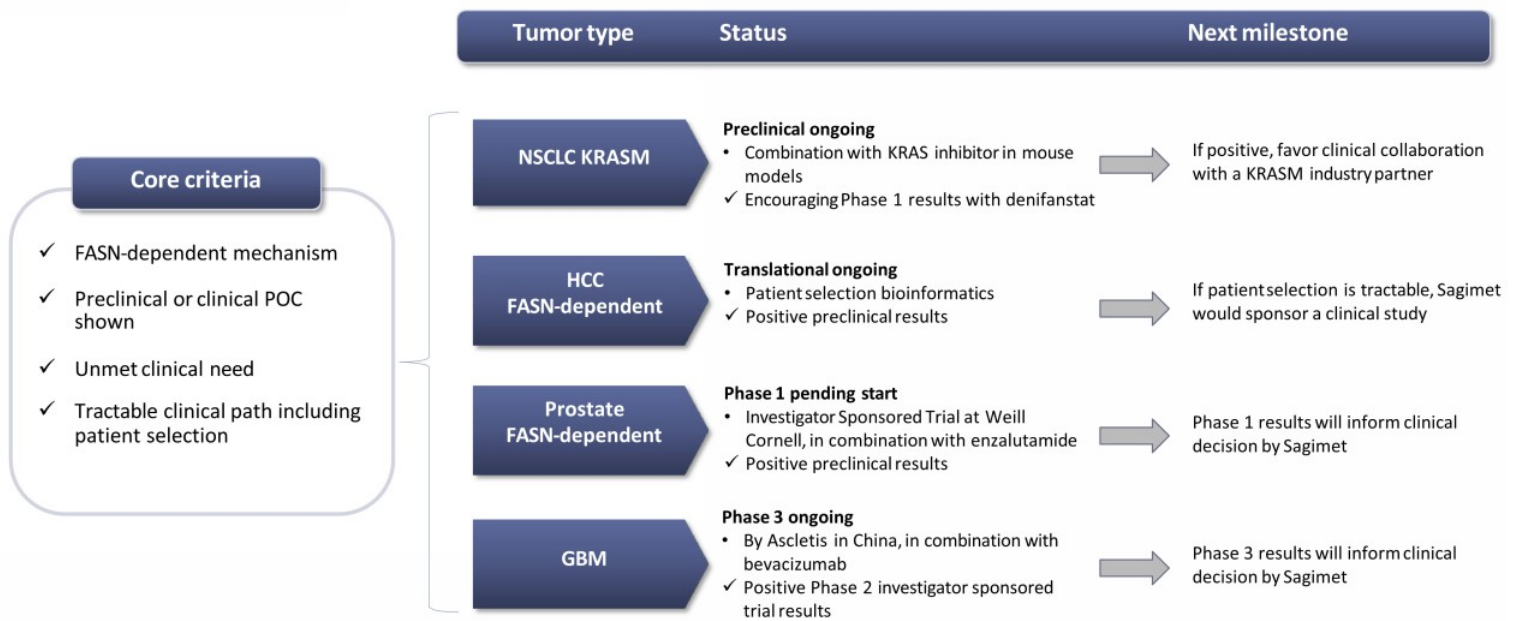
Completed Phase 1 provides foundation

- 136 patients received denifanstat
- Heavily pretreated Phase 1 population
- Recommended Phase 2 dose defined
- Promising clinical activity consistent with proposed mechanism
 - KRAS NSCLC patients had significantly longer duration on study with denifanstat than KRASWT ($p < 0.02$), and 91% KRASM had stable disease



FASN-Dependent Tumor Types Identified that Meet Core Criteria

Program focused on 4 selected tumor types



Strong Financial Position and Intellectual Property Portfolio

Financial highlights Nasdaq: SGMT

- ✓ Upsized IPO completed in July 2023 raised \$86.2 million of net proceeds
- ✓ Follow-on financing completed in January 2024 raised net proceeds of \$105.8 million.
- ✓ Cash and equivalents expected to fund current operations through 2025

Strong patent estate

- ✓ Denifanstat method of use: 2036
- ✓ Denifanstat composition of matter: 2032 (Issued in all key commercial territories)
- ✓ Opportunities exist to lengthen patent exclusivity of either composition patent or method of use patent for up to 5 years via Patent Term Extension (US) or SPC (Europe)
- ✓ Currently building out global patent portfolio to further protect commercialization of denifanstat via patent applications directed to formulations, methods of use, and synthetic methods, with potential to extend exclusivity further

Development Pipeline: Indications and Clinical Milestones

Therapeutic Area	Indication	Stage of Development				Expected Milestone / Status
		Preclinical	Phase 1	Phase 2	Phase 3	
Metabolic disease	MASH - F2/F3	TVB-2640				<ul style="list-style-type: none"> Phase 2b successfully completed; MASH Phase 3 study planned to start 2H 2024
		TVB-2640				<ul style="list-style-type: none"> Phase 1 hepatic impairment results 1Q 2024
Dermatology	Acne	TVB-3567				<ul style="list-style-type: none"> IND-enabling studies completed; evaluating timing to file IND
		TVB-2640 (ASC40)				<ul style="list-style-type: none"> Phase 3 clinical study initiated 4Q 2023*
Oncology	Solid tumors					<ul style="list-style-type: none"> Patient selection and trial design in FASN-dependent tumor types ongoing
	Recurrent glioblastoma (GBM)	TVB-2640 (ASC40)				<ul style="list-style-type: none"> Phase 3 enrollment of 120 patients achieved in 3Q 2023; interim analysis planned*

33 * Trials conducted in China by Ascletois, who has licensed development and commercialization rights to all indications in Greater China