

**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): September 27, 2023

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:

<u>Title of each class</u>	<u>Trade Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 7.01 Regulation FD Disclosure

On September 27, 2023, Sagimet Biosciences Inc. (the “Company”) updated information reflected in a slide presentation, which is attached as Exhibit 99.1 hereto and incorporated herein by reference. The Company will use the updated presentation in various meetings with investors from time to time.

The information in Item 7.01 of this Current Report on Form 8-K, including the information set forth in Exhibit 99.1, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), nor shall Exhibit 99.1 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 8.01 Other Events.

On September 27, 2023, the Company issued a press release announcing that its license partner, Asclepis Bioscience Co. Ltd., has enrolled 120 patients in its Phase 3 registration clinical trial of denifanstat combined with bevacizumab for treatment of recurrent glioblastoma. A copy of this press release is attached as Exhibit 99.2 hereto and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Document
99.1	Investor Presentation of Sagimet Biosciences Inc., dated September 27, 2023
99.2	Press Release of Sagimet Biosciences Inc., dated September 27, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

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

Sagimet Biosciences Inc.

Date: September 27, 2023

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



SAGIMET

BIOSCIENCES

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

September 2023

Forward Looking Statements

- This presentation contains forward-looking statements within the meaning of, and made pursuant to the safe harbor 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 of possible or assumed future results of operations, business strategies, research and development plans, regulator market opportunity, competitive position and potential growth opportunities are forward-looking statements. They 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 in this forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “could,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “believe,” “estimate,” “predict,” “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 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, including our Phase 2b clinical trial; our relationship with Ascletis, and the success of its development efforts for denifanstat; 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 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 law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of new information, future events, changed circumstances or otherwise.

Proven Team with Development and Commercialization Experience , 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 and 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



Anthony Rimac
CFO

- Cognoa, ESCAPE Bio, Chrono Therapeutics, Aldea Pharmaceuticals, Adamas Pharmaceuticals, Aerovance
- M.B.A. – Santa Clara University; B.A. – University of California Santa Barbara



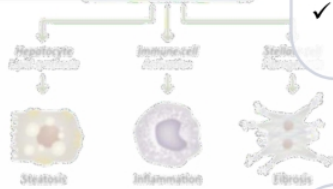
Elizabeth Rozek
General Counsel and CCO

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



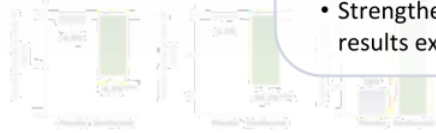
Sagimet Investment Highlights

Critical role of FASN enzyme in NASH



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

Denifanstat: FASN inhibitor with compelling clinical data



- ✓ FASCINATE-2 Phase 2b interim data
 - Statistically significant improvements in key biomarkers of NASH: liver fat, inflammation, fibrosis
 - Results consistent with Phase 2a study
 - Strengthen belief in Phase 2b liver biopsy results expected in 1Q 2024

Precision medicine is key differentiator



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

Strong rationale for FASN in acne and cancer

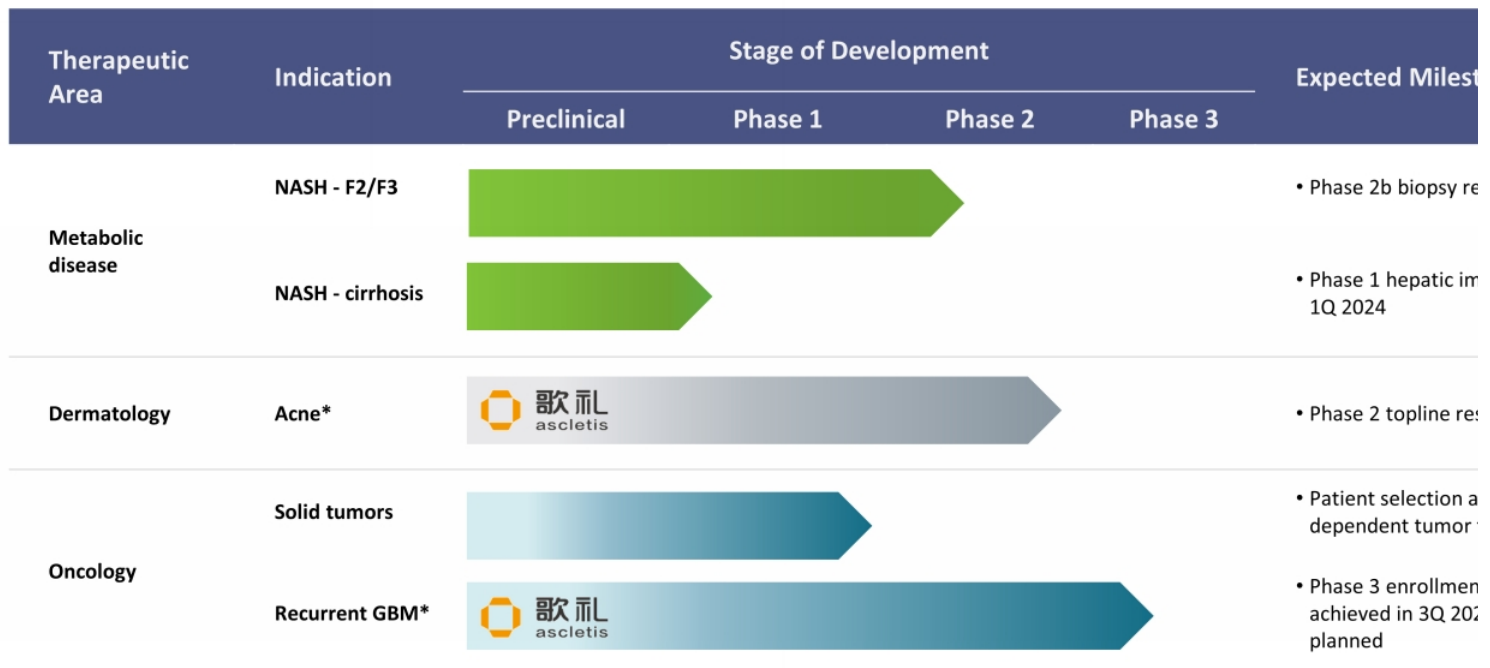


- Acne
 - ✓ Clinical proof of concept established
 - Positive Phase 2 topline results expected in May 2023 by Ascleptis
- Cancer
 - ✓ Clinical proof of concept established
 - Phase 3 rGBM trial enrollment analysis completed in September by Ascleptis

Strong financial position

- ✓ Upsized IPO completed in July 2022, resulting in \$1.1 billion of gross proceeds
- ✓ Cash and equivalents expected to support operations through into the fiscal year 2024

Denifanstat Pipeline of Multiple Indications and Clinical Milestones



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

NASH: A Burgeoning Epidemic

Patients in 2016¹
United States

85.3 million



NAFL
non-alcoholic
fatty liver

17.3 million



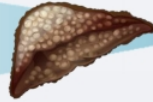
NASH
non-alcoholic
steatohepatitis

5.7 million



**NASH
mod-adv
fibrosis**
F2-F3

1.4 million
compensated and
decompensated



Cirrhosis
F4

11 thousand
annual cases among
NAFLD population



**Hepatocellular
carcinoma**

Disease challenges

- No approved drugs in U.S. or 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

Denifans

- ✓ Designed for once-daily dosing
- ✓ Rigorous and de novo lipogenesis development strategy
- ✓ Direct DNL inhibition demonstrated in preclinical models
- ✓ Improvements observed across biomarkers
- ✓ Phase 2b fully-enriched biopsy results expected
- ✓ Precision medicine approach to improve patient outcomes

DNL = de novo lipogenesis

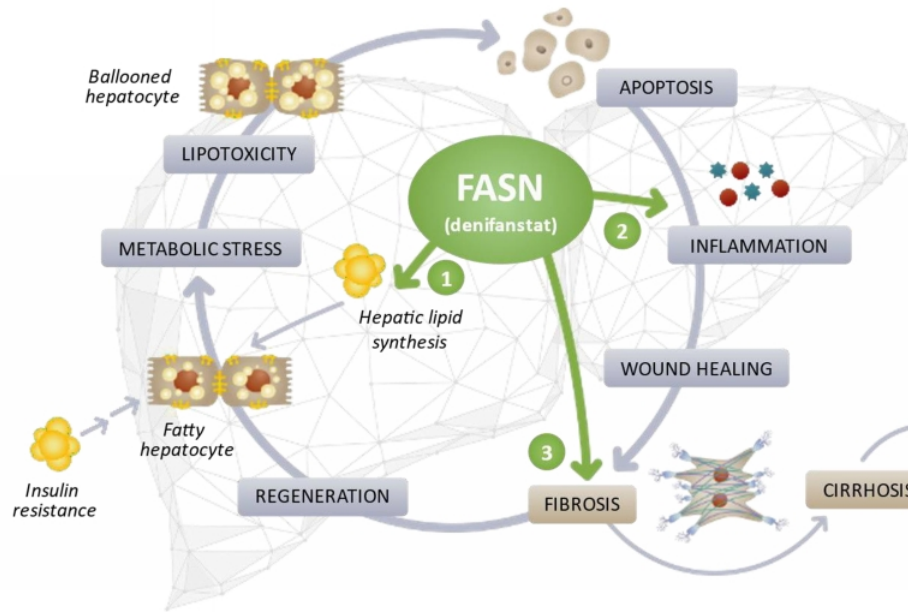
A dark blue, semi-transparent background featuring a faint, circular microscopic image of liver tissue. The image shows a central, lighter-colored lesion surrounded by a dense field of hepatocytes. The text 'Denifanstat in NASH' is overlaid in white on the central part of the image.

Denifanstat in NASH

Denifanstat: Differentiated Mechanism Believed to Target Key Driver

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

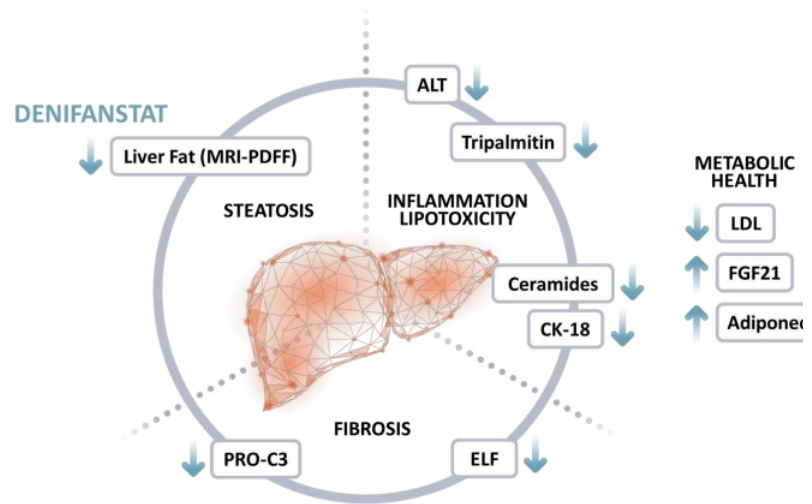
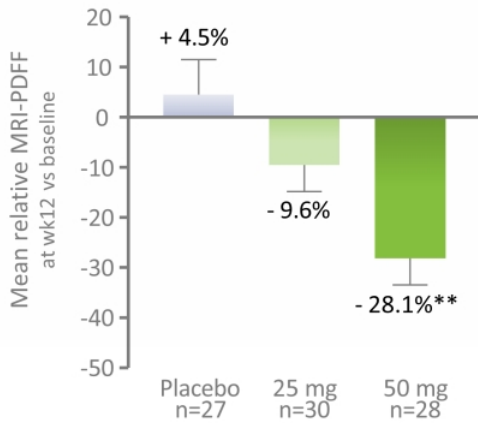


Denifanstat Showed Dose-Dependent Reduction of Liver Fat in FASCINA¹ Improved Key Drivers of NASH and Metabolic Health

FASCINATE-1 Phase 2 study¹

- Dose-finding, global, multicenter, Phase 2 trial
- Oral, once-daily, 12-week dosing
- >8% liver fat and presumed fibrosis
- U.S. and China

FASCINATE-1 Liver Fat Change



¹Loomba et al, 2021 *Gastroenterology*. doi: 10.1053/j.gastro.2021.07.025
**p<0.005, Mean ±SEM. LSM difference versus placebo for liver fat.

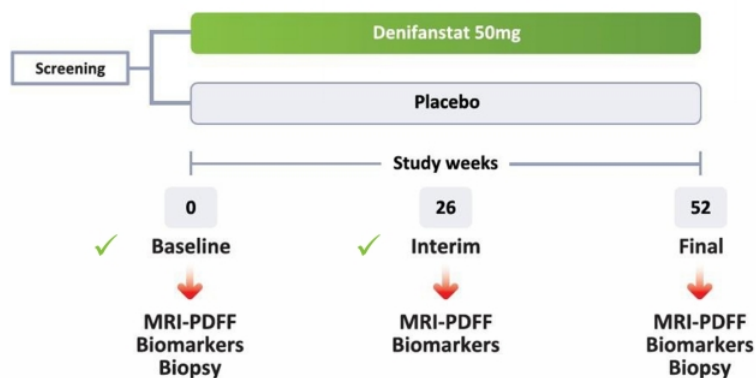
Denifanstat: Well Tolerated at 25/50mg Doses in FASCINATE-1

- 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=10
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 (30%) Gr 2: 6 (60%)
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 (10%) Gr 2: 6 (60%)

Phase 2b Biopsy Trial: Measuring Histological Improvement

FASCINATE-2 Phase 2b trial design



- Biopsy confirmed F2-F3 NASH patients
- 52 weeks, 2:1 50mg or placebo, double-blind
- Fully enrolled: 168 patients in U.S., Canada, and Europe
- Prespecified interim analysis of the first 52 patients with MRI-PDFF >8%

Primary endpoints (biopsy)

- NAS ≥ 2 points improvement w/o worsening OR resolution of NASH w/o worsening of fibrosis
 - Lead reader of liver biopsies: Pierre Bedossa MD. PhD.
- Safety

Secondary endpoints

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

Interim Analysis Cohort Represents Target Patient Population

FASCINATE-2 Phase 2b Interim Analysis Demographics			
Mean (SD)	Placebo (22)	Denifanstat (30)	Combined
Age (years)	56.8 (9.4)	56.1 (12.4)	56.4 (11.1)
Female/Male (%)	14 (63.6%) / 8 (36.4%)	17 (56.7%) / 13 (43.3%)	31 (59.6%) / 21 (40.4%)
Not Hispanic or Latino	16 (72.7%)	24 (80.0%)	40 (76.9%)
Weight (kg)	97.8 (21.9)	100.9 (21.2)	99.6 (21.4)
Diabetes (% T2DM)	13 (59.1%)	21 (70.0%)	34 (65.4%)
F2/F3 (%)	12 (54.5%) / 10 (45.5%)	12 (40.0%) / 18 (60.0%)	24 (46.2%) / 28 (53.8%)
MRI-PDFF (%)	21.78 (5.46)	17.46 (6.36)	19.29 (6.32)
Fibroscan (kPa)	10.67 (4.07)	12.29 (7.33)	11.56 (6.04)
ALT (U/L)	69.77 (42.50)	57.14 (27.55)	62.70 (35.11)
AST (U/L)	51.00 (29.87)	44.43 (22.65)	47.32 (26.00)
LDL (mg/dL)	111.37 (40.6)	96.29 (50.27)	102.86 (46.4)
ELF	9.70 (0.76)	9.73 (0.76)	9.72 (0.75)
PRO-C3 cobas® (ng/mL)	35.72 (15.71)	32.54 (11.19)	33.91 (13.28)

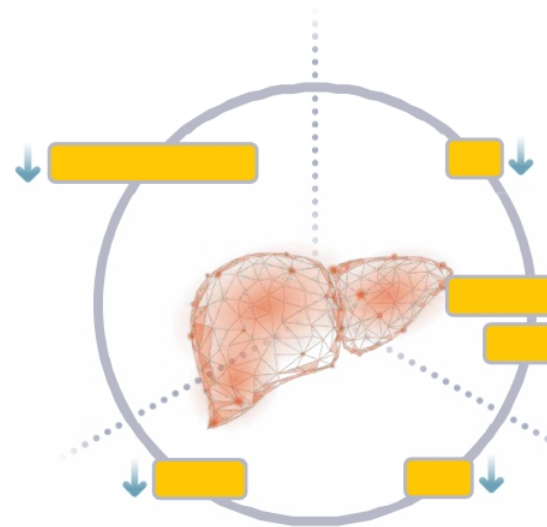
- Typical F2/F3 NAS
- Middle-aged
- High % of diabetes
- High liver fat by MRI
- Elevated liver enzymes and inflammation
- Non-invasive markers consistent with F2

FASCINATE-2 Interim Results Consistent with Comprehensive Positive Readouts from FASCINATE-1

- FASCINATE-2 interim analysis showed consistent improvements in key drivers of NASH as observed in FASCINATE-1

Mechanism	Biomarker
1 Steatosis	Liver fat (MRI-PDFF)
2 Inflammation/lipotoxicity	ALT, CK-18, ceramides
3 Fibrosis	PRO-C3, ELF

- Improvements observed in multiple biomarkers of metabolic health
 - 4 metabolic health
 - LDL-cholesterol
 - FGF-21

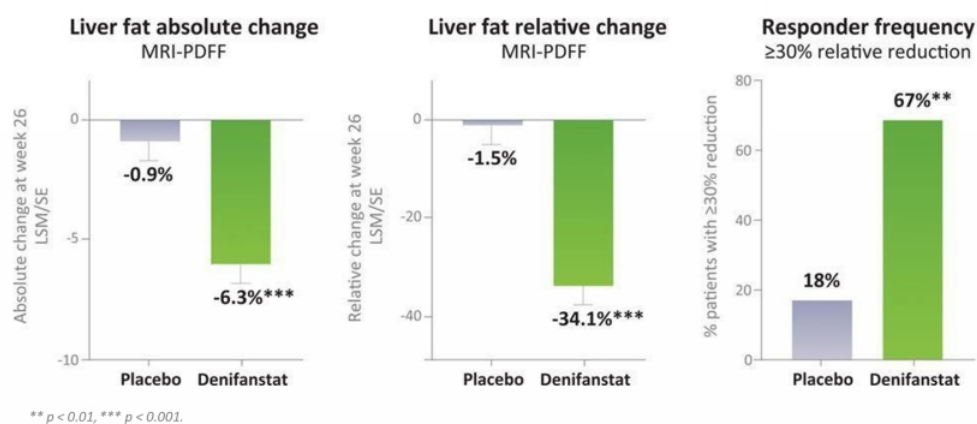


Biomarkers replicated in FASCINATE-2

Denifanstat Decreased Liver Fat

Responders Correlate with Liver Biopsy Improvement

1 Steatosis biomarker – liver fat

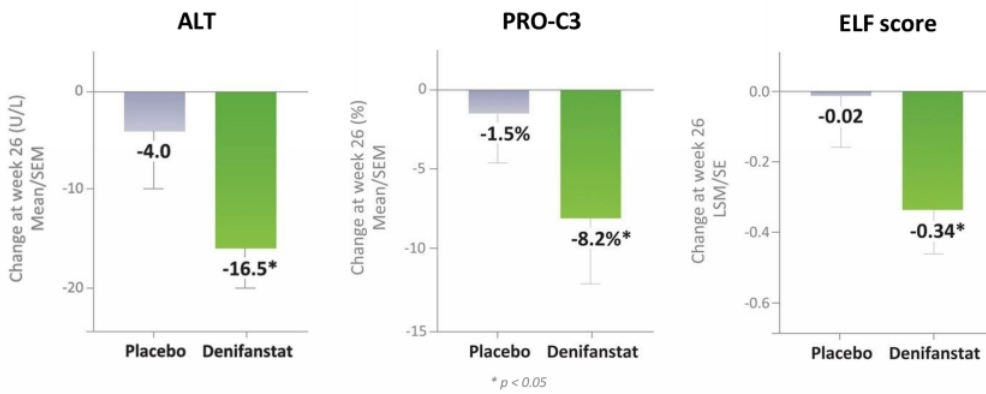


Findings to

- Denifanstat induced statistically significant reduction of liver fat
- 67% (p<0.001) M response rate
- About half of responders showed decreased liver fat
- A relative reduction ≥30% by MRI-PDFF shown to correlate with biopsy response

Denifastat Decreased PRO-C3 and ELF – Suggests Fibrosis Red

2 3 Inflammation and fibrosis biomarkers



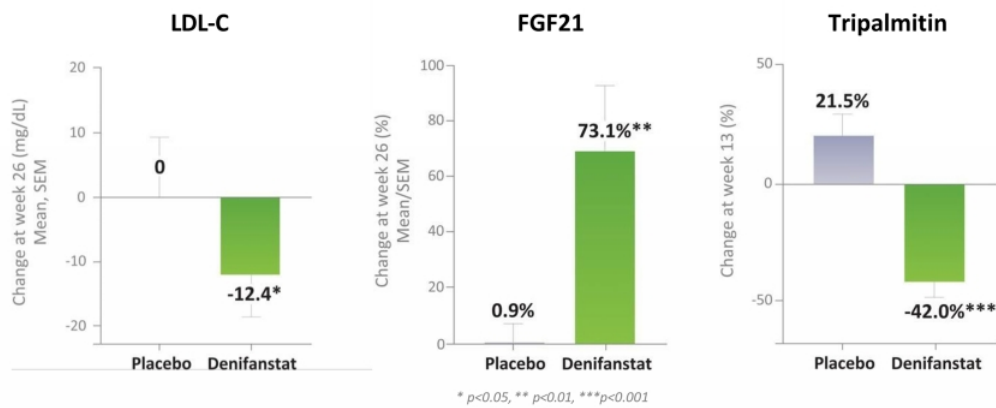
Other liver biomarkers consistent

Findings to

- ALT decrease suggests decrease in inflammation with denifanstat
- PRO-C3 decrease suggests decrease of liver fibrosis with denifanstat
- ELF score decrease suggests decrease of liver fibrosis with denifanstat. ELF score is a prognostic value

Denifanstat Improved Markers of Cardiometabolic Health

4 Metabolic health / lipid biomarkers



Findings to

- LDL-cholesterol: denifanstat may be beneficial for cardiovascular health
- FGF21 increase: may induce improved insulin sensitivity
- Tripalmitin decrease: denifanstat inhibits triglyceride synthesis and reduces palmitic acid synthesis

Denifanstat Passed Planned IDMC Safety Review in FASCINATE

Sagimet is blinded to data

- **All randomized subjects: blinded data set including active and placebo**
- Majority of AEs to date were Grade 1 or 2; no Grade ≥3 drug-related AEs
- A planned safety review of unblinded data from all 168 patients conducted by Independent Data Monitor – no concerns

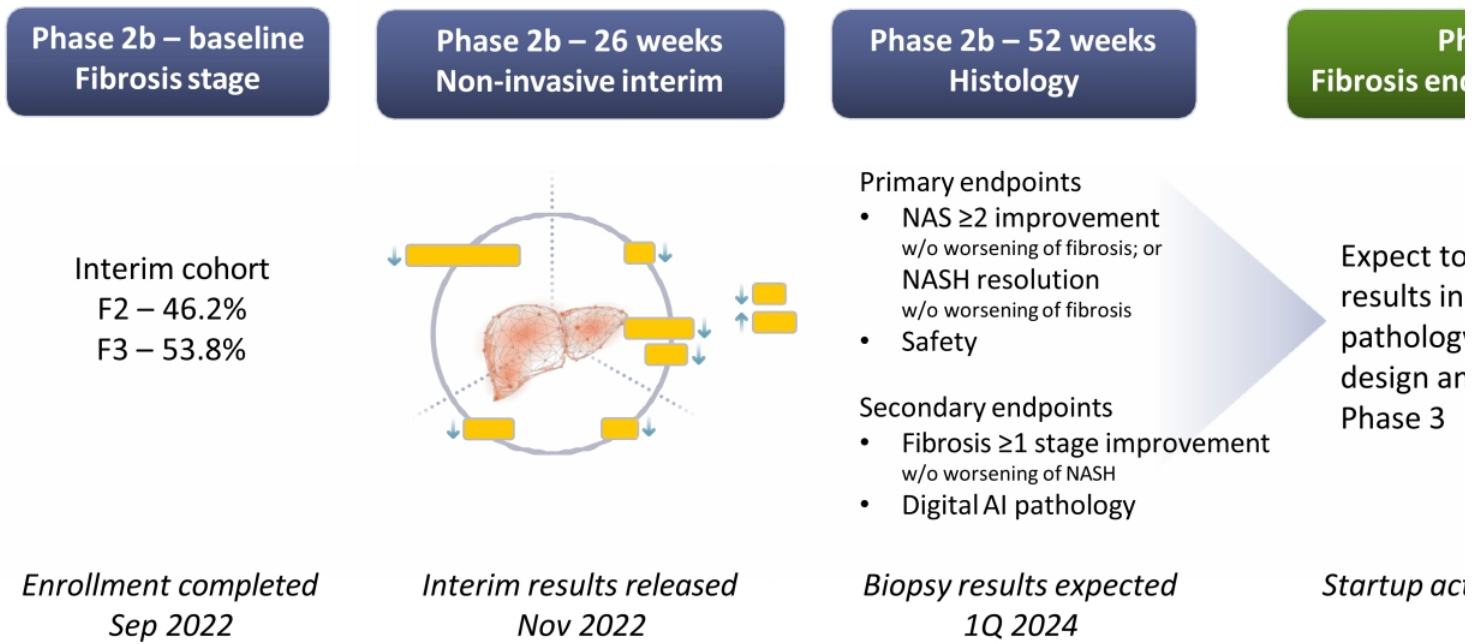
FASCINATE-2 Phase 2b - Blinded data set	
Treatment Emergent Adverse Event (TEAE) Classification	N=168 Number of Patients with Event at Stated Grade
Any TEAE	Gr 1: 115 (68.5%) Gr 2: 69 (41.1%) Gr 3: 10 (6.0%) Gr 4: 1 (0.6%)
TEAE leading to drug/placebo discontinuation	21
Treatment Emergent Serious Adverse Event (SAE)	11 (all unrelated to study treatment)
Drug/placebo-related TEAE	Gr 1: 52 (30.1%) Gr 2: 25 (14.9%)

AE data as of 3 April 2023





NASH Development Program

Progression from Phase 2b to Phase 3

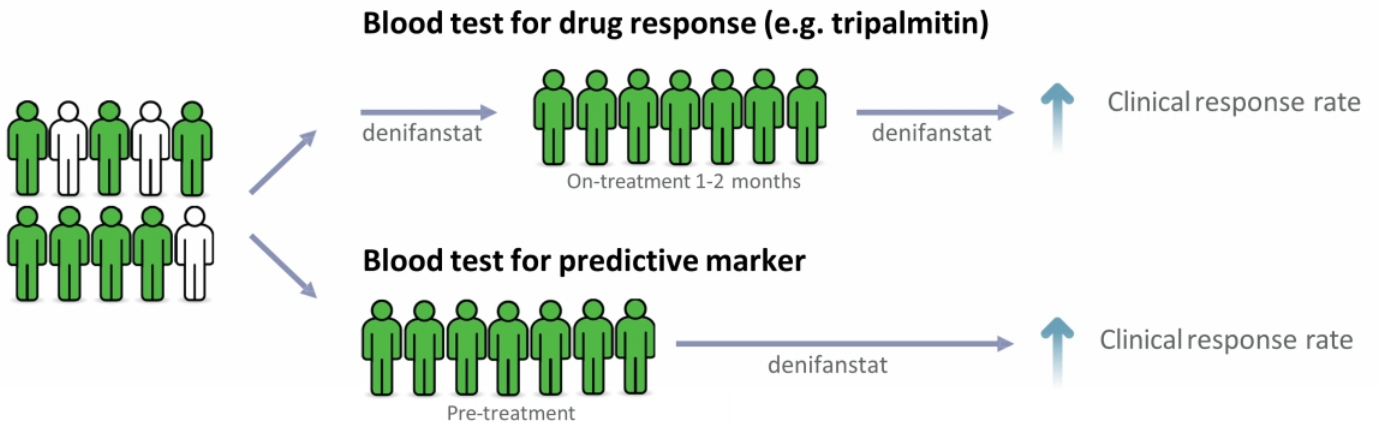


We Believe Denifanstat is Differentiated in the Evolving NASH Landscape

Mechanism	FASN inhibitors	THR β agonists	FGF-21	GLP-1 agonists	PPAR agonists	ACC inhibitors
Category	DNL pathway	Nuclear receptor	Growth factor	GLP-1	Nuclear receptor	DNL pathway
Route	Oral	Oral	Injectable 	Injectable 	Oral	Oral
Status	Phase 2 ongoing	Phase 3 complete	Phase 2 complete	Phase 2 complete	Phase 3 ongoing	Phase 2 complete
Challenges	<ul style="list-style-type: none"> Pending biopsy results 	<ul style="list-style-type: none"> Selectivity for beta isoform critical to avoid potential heart and bone safety issues 	<ul style="list-style-type: none"> Injectable Nausea and diarrhea Potential neutralizing antibodies COGS 	<ul style="list-style-type: none"> GI side effects including nausea Lack of fibrosis improvement to date 	<ul style="list-style-type: none"> Weight gain, edema, GI side effects, anemia 	<ul style="list-style-type: none"> Combinations only MOA causes triglyceride increases Lack of fibrosis improvement as monotherapy

Precision Medicine: Blood Tests May Lead to Improved Patient Outcomes

- NASH is a multi-faceted disease and patients may benefit from being matched with optimal treatment
- 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, glycooursodeoxycholic acid, D(-)-2-aminobutyric acid, PC(0-18:0/22:4). Accuracy 79%, PPV 88%, NPV 63%.

Strong Monotherapy Opportunity for Denifanstat in NASH

Expansion as backbone of combinations

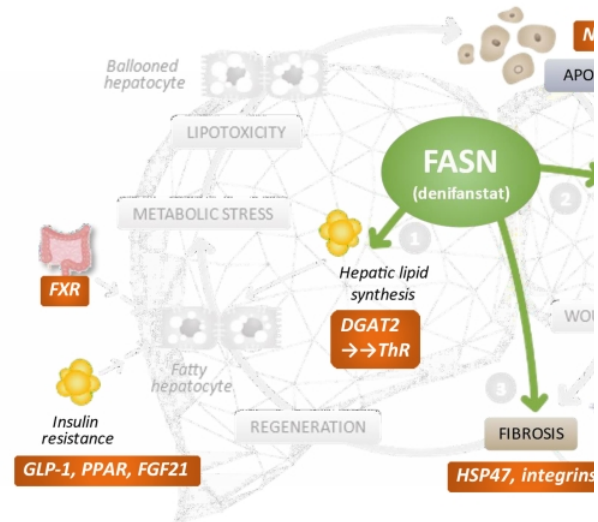
Denifanstat data support success as first line monotherapy

- ✓ 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
 - NASH agents: anti-fibrotic, other metabolic agents
 - Co-morbidities: diabetes and other cardiovascular agents

Illustrative potential combo mech



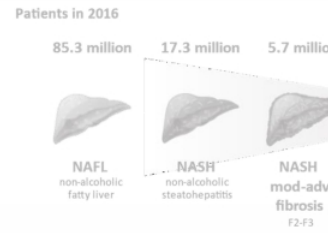
Additional Expansion Opportunities in NASH

- **Compensated cirrhotic patients (NASH 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 NASH-F4

- **Pediatric NASH**

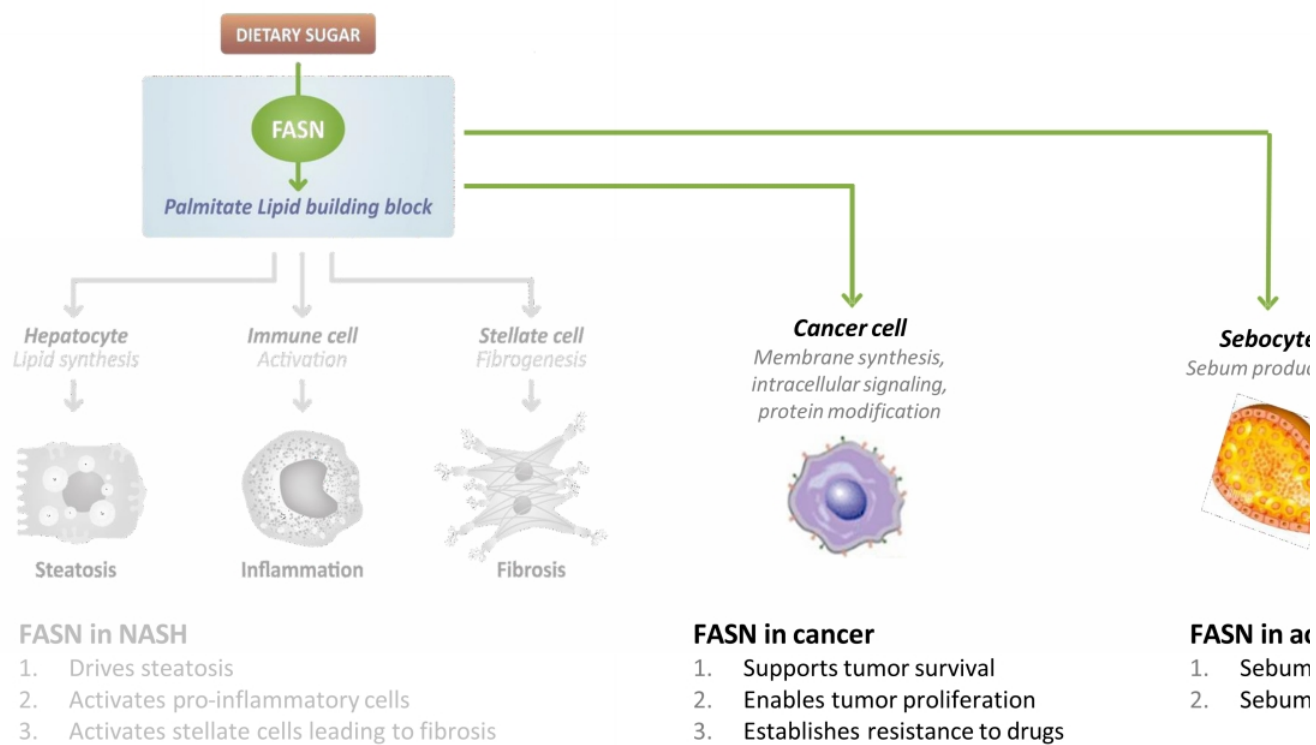
- 23% of children with NAFLD have NASH at the time of diagnosis
- Next steps
 - Compile safety data across all denifanstat studies in young adults including FASCINATE-2
 - Nonclinical toxicology study in juvenile animals – plan to initiate in 2024
 - Phase 2 trial in pediatric NASH





Other Indications

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



DNL Pathway Plays a Role in the Pathogenesis of 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
- => FASN inhibition has potential therapeutic application

Phase 1 – sebum analysis by Sagimet

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

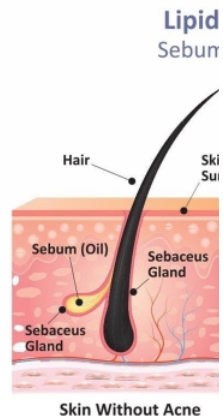
Phase 2 – acne by Asclelis in China



- 12-week trial in moderate to severe acne
- 179 pts randomized to 25/50/75 mg denifanstat and placebo
- Endpoints: % change from baseline in lesion count and/or IGA score decreased by ≥ 2

Positive topline results announced May 2023

- Met primary and secondary endpoints
- Well-tolerated
- Sagimet evaluating clinical development plans for U.S./EU and other major markets



FASN is Integral to Tumor Cell Proliferation and Survival

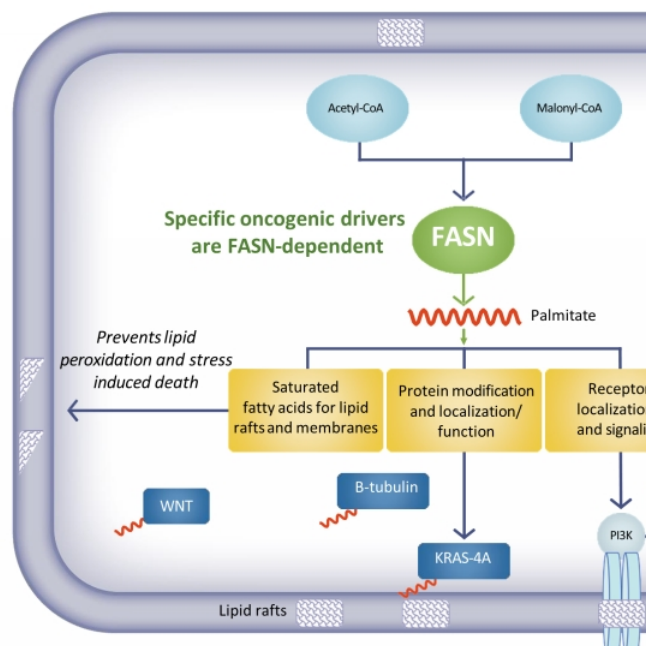
Reprogramed metabolism is one of the hallmarks of cancer

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

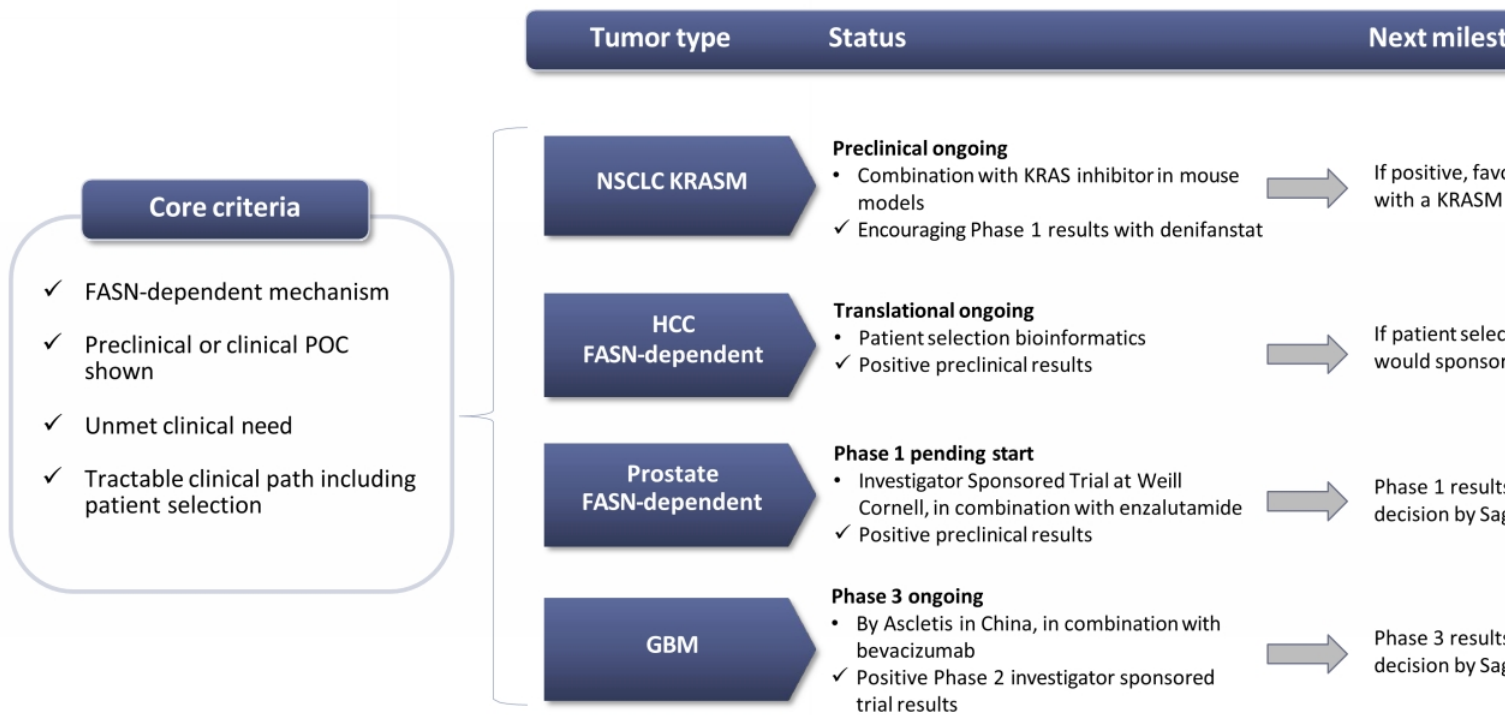
- 136 patients received denifanstat
- Heavily pretreated Phase 1 population
- Recommended Phase 2 dose defined
- Promising clinical activity consistent with proposed mechanism
 - KRAS NSCLC patients had significantly longer duration on study with denifanstat than KRASWT ($p < 0.02$), and 91% KRAS had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



Dietary fatty acids cannot compensate de novo synthesized palmitate

FASN-Dependent Tumor Types Identified that Meet Core Criteria

Program focused on 4 selected tumor types



Strong Financial Position and Intellectual Property Portfolio

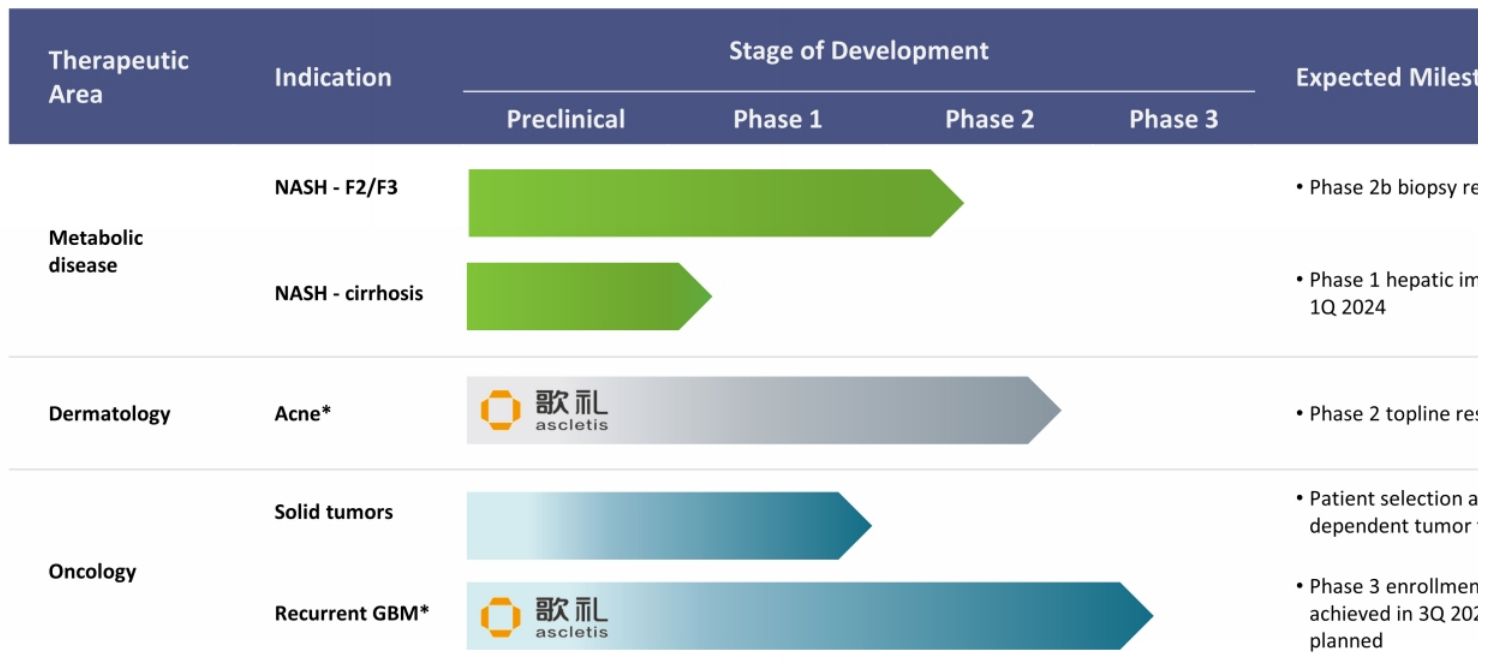
Financial highlights Nasdaq: SGMT

- ✓ Upsized IPO completed in July 2023 raised \$96.4 million of gross proceeds
- ✓ Cash and equivalents expected to fund current operations into the first quarter of 2025

Strong patent estate

- ✓ Composition of matter for denifanstat: 2032
- ✓ Issued in all key commercial territories
- ✓ Opportunities to lengthen exclusivity via Hatch-Waxman and synthesis/formulation applications

Denifanstat Pipeline of Multiple Indications and Clinical Milestones



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



Sagimet Biosciences Announces Completion of Enrollment of 120 Patients for Phase 3 Clinical Trial by Its Partner Asclepis of Denifanstat Combined with Bevacizumab for Treatment of Recurrent Glioblastoma

San Mateo, Calif., September 26, 2023 – Sagimet Biosciences Inc. (Nasdaq: SGMT), a clinical-stage biopharmaceutical company developing novel therapeutics targeting dysfunctional metabolic pathways, today announced that its license partner, Asclepis Bioscience Co. Ltd. (Asclepis), has enrolled 120 patients in its Phase 3 registration clinical trial of denifanstat combined with bevacizumab for treatment of recurrent glioblastoma (rGBM). Asclepis anticipates that this number of study subjects will provide sufficient events for its planned interim analysis of progression-free survival (PFS). Denifanstat is an oral, selective small molecule inhibitor of fatty acid synthase (FASN), a key enzyme which regulates de novo lipogenesis (DNL). Sagimet licensed the rights to develop and commercialize denifanstat in the People’s Republic of China, Hong Kong, Macau and Taiwan to Asclepis in January 2019.

Sagimet’s FASCINATE-2 Phase 2b clinical trial for denifanstat in liver biopsy-confirmed F2-F3 nonalcoholic steatohepatitis (NASH) patients is fully enrolled and biopsy results are expected in the first quarter of 2024. Sagimet also expects to report Phase 1 clinical trial results characterizing the pharmacokinetic profile of denifanstat in patients with impaired hepatic function in the first quarter of 2024.

“We congratulate Asclepis on achieving this important patient enrollment milestone in its Phase 3 clinical trial of denifanstat being conducted in China in patients with recurrent glioblastoma,” stated David Happel, Chief Executive Officer of Sagimet. “Sagimet looks forward to reporting biopsy results and other key endpoints from our Phase 2 FASCINATE-2 trial for denifanstat in patients with NASH in the first quarter of 2024, and, if the data is positive, potentially advancing the program into a registrational Phase 3 trial.”

About Sagimet Biosciences

Sagimet is a clinical-stage biopharmaceutical company developing novel therapeutics called fatty acid synthase (FASN) inhibitors that 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 nonalcoholic steatohepatitis (NASH), for which there are no treatments currently approved in the United States or Europe. Denifanstat is currently being tested in FASCINATE-2, a Phase 2b clinical trial in NASH with liver biopsy as the primary endpoint. For additional information about Sagimet, please 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 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 2b clinical trial; Sagimet's relationship with Ascleptis, and the success of its development efforts for denifanstat; the accuracy of Sagimet's estimates regarding its capital requirements; and Sagimet's ability to maintain and successfully enforce adequate intellectual property protection. These and other risks and uncertainties are described more fully in the "Risk Factors" section of Sagimet's most recent filings with the Securities and Exchange Commission and available at www.sec.gov. You should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in these forward-looking statements may not be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. Moreover, Sagimet operates in a dynamic industry and economy. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties that Sagimet may face. Except as required by applicable law, Sagimet does not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

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