

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): December 28, 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 5.02** **Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

*Departure of Chief Financial Officer*

On December 28, 2023, Anthony Rimac provided notice of his intent to step down as the Chief Financial Officer of Sagimet Biosciences Inc. (the “Company”) effective January 31, 2024. Mr. Rimac resigned for personal reasons and not as a result of any disagreement with the Company or its independent registered public accountants on any matter relating to the Company’s financial or accounting operations, policies or practices.

The Company has retained Stout, a global advisory firm specializing in corporate finance, accounting and transaction advisory services, to provide interim support during the transition period. Gaeton Biscardi, Managing Director of Stout, will be serving as the Company’s Interim VP of Finance during this transition period, and Joe Oriti, Director of Stout, will provide his services as a consultant during the period. Contingent on the approval of the Company’s Board of Directors (the “Board”), the Company intends to appoint Mr. Oriti as Interim Principal Financial Officer of the Company following Mr. Rimac’s departure to serve in such role while the Board conducts a search of potential candidates to replace Mr. Rimac.

**Item 7.01** **Regulation FD Disclosure.**

On December 29, 2023, the Company updated information reflected in a slide presentation, which is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. Representatives of the Company will use the updated presentation in various meetings with investors from time to time.

The information contained in this Item 7.01 (including Exhibit 99.1) is being furnished and shall not be deemed “filed” for purposes of Section 18 of 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 or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

**Item 9.01** **Financial Statements and Exhibits.**

**(d) Exhibits**

Exhibit No.	Document
<a href="#">99.1</a>	<a href="#">Investor Presentation of Sagimet Biosciences Inc. , dated December 29, 2023.</a>
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: December 29, 2023

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

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# SAGIMET

BIOSCIENCES

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

December 2023

# Forward Looking Statements

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- 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, regulatory matters, 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 in our forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “might,” “could,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “believe,” “estimate,” “predict,” “potentially,” “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 drugs 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; the success 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 recent filings with the Securities and Exchange Commission and available at [www.sec.gov](http://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 & 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

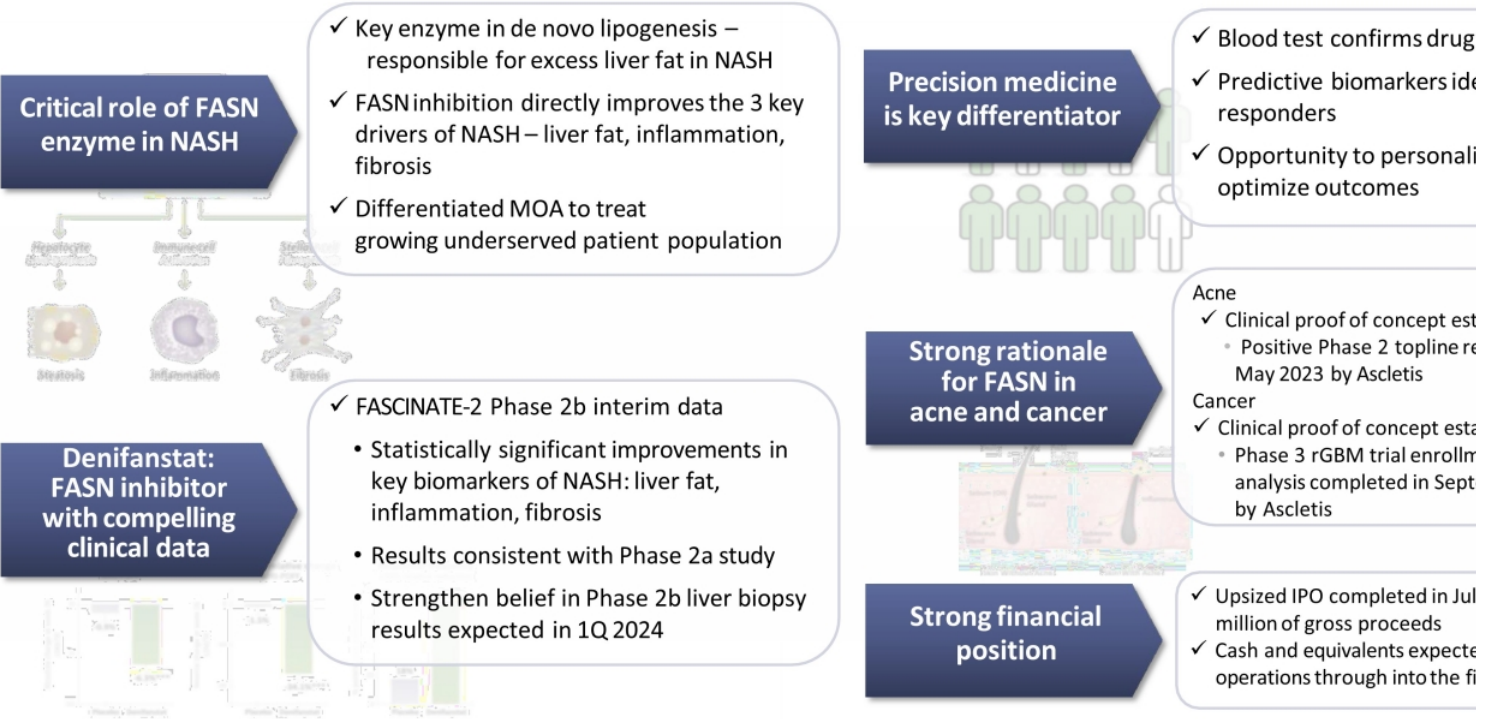


**Elizabeth Rozek**  
*General Counsel*

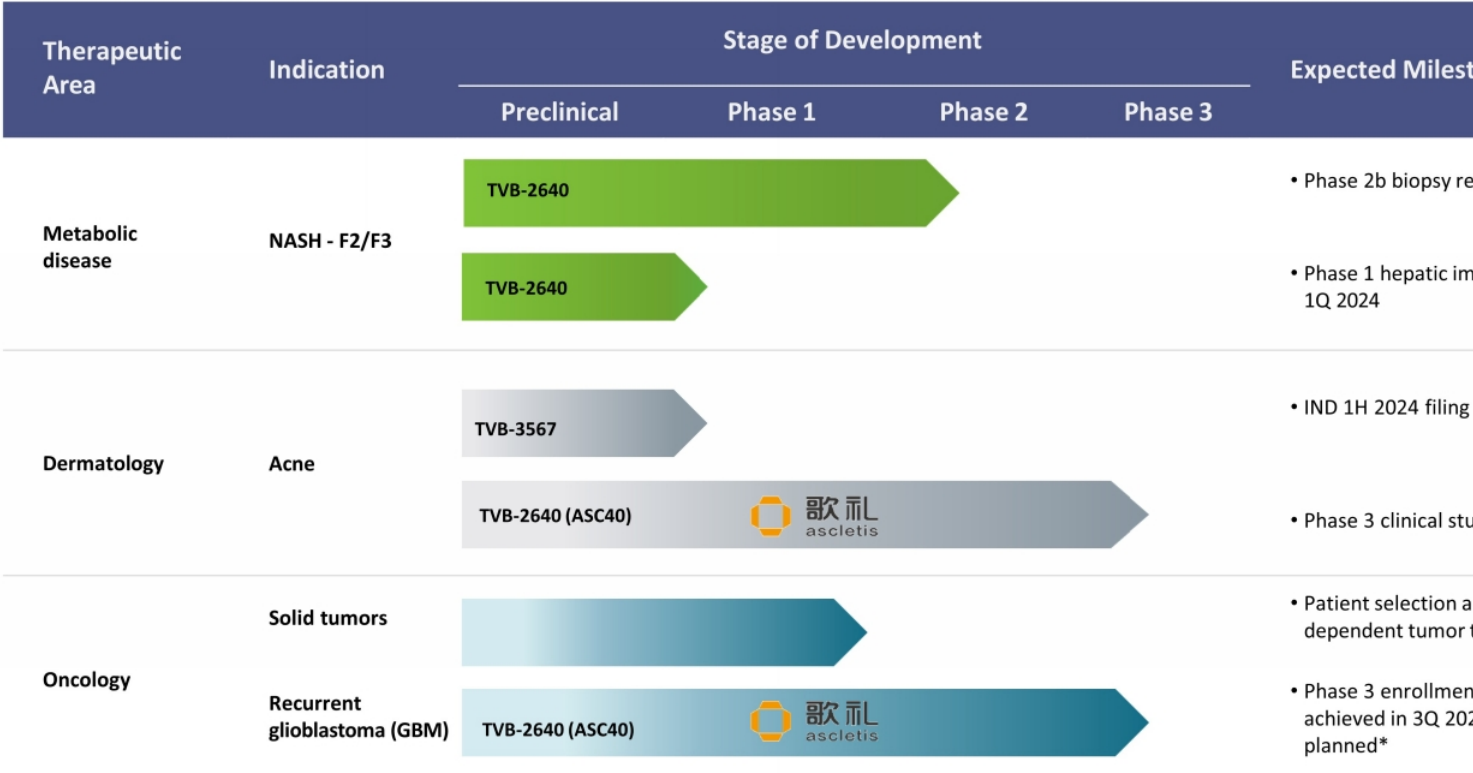
- Cognoa, Basilea Pharmaceutica, US Department of Justice
- J.D. – University of California Berkeley  
M.A. – University of California San Diego  
B.A. – Brown University



# Sagimet Investment Highlights



# Development Pipeline: Indications and Clinical Milestones



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

# NASH: A Burgeoning Epidemic

## Patients in 2016<sup>1</sup>

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

### Denifan

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

*DNL = de novo lipogenesis*



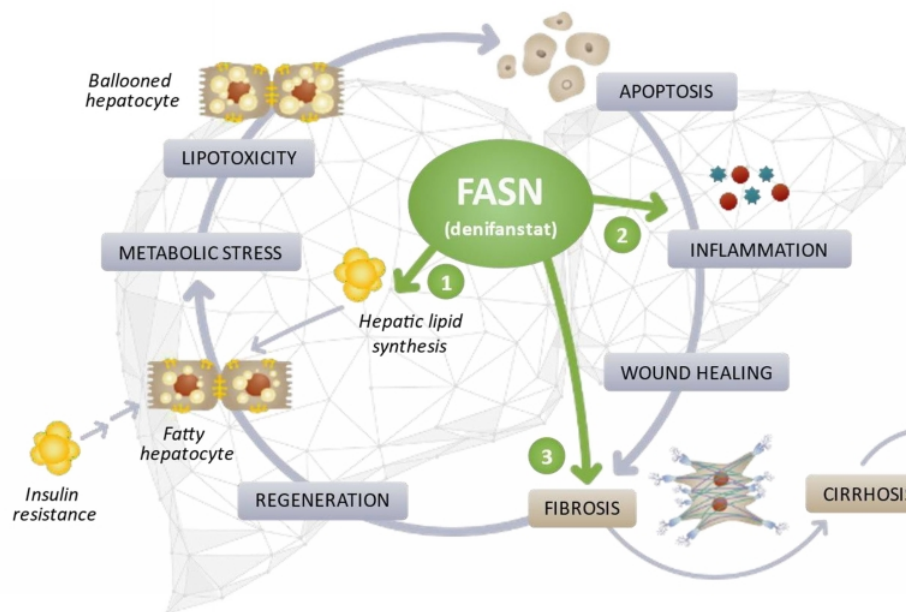
# Denifanstat in NASH

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# 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



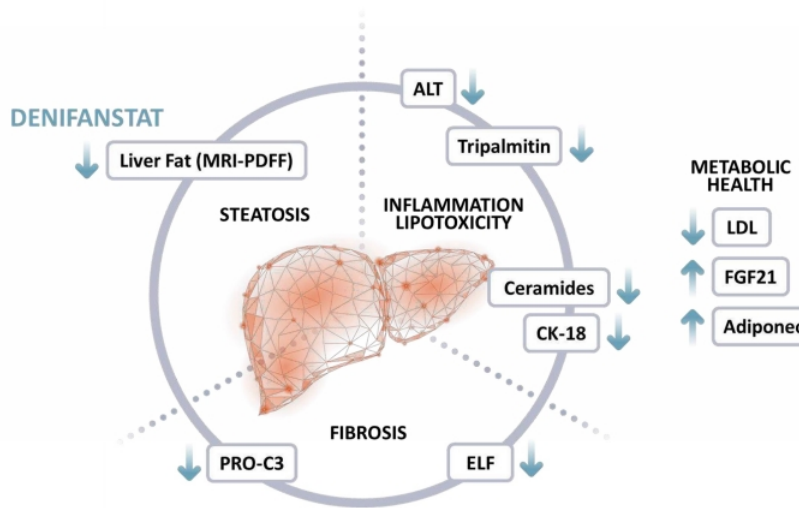
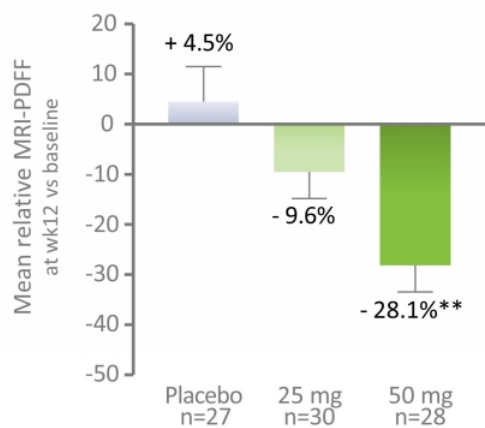
# Denifanstat Showed Dose-Dependent Reduction of Liver Fat in FASCINAT

## Improved Key Drivers of NASH and Metabolic Health

### FASCINATE-1 Phase 2 study<sup>1</sup>

- 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



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

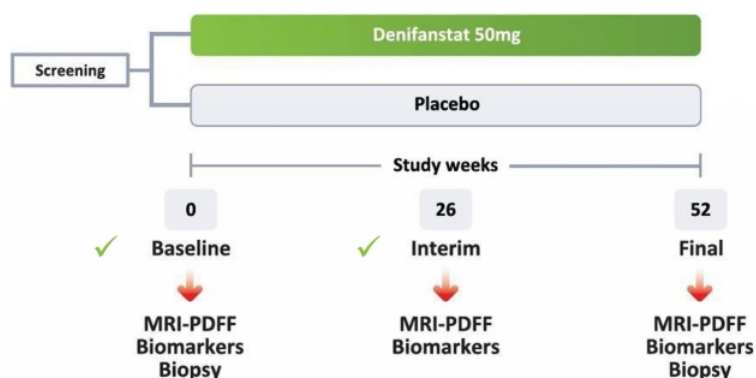
# Denifanstat: Well Tolerated at 25/50mg Doses in FASCINATE-1

- 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)

1. NAS  $\geq 2$  points improvement w/o worsening of NASH resolution + NAS  $\geq 2$  improvement w/ worsening of fibrosis
2. Safety

## Secondary endpoints

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

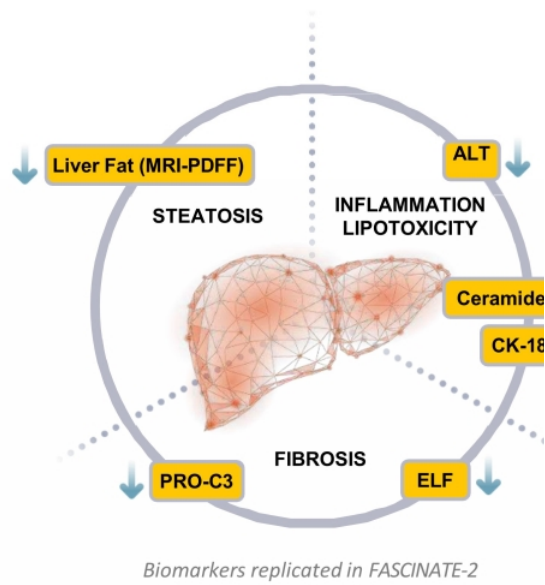
- Typical F2/F3 NASL
- Middle-aged
- High % of diabetes
- High liver fat by MRI
- Elevated liver enzymes and inflammation
- Non-invasive markers consistent with F2

# 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

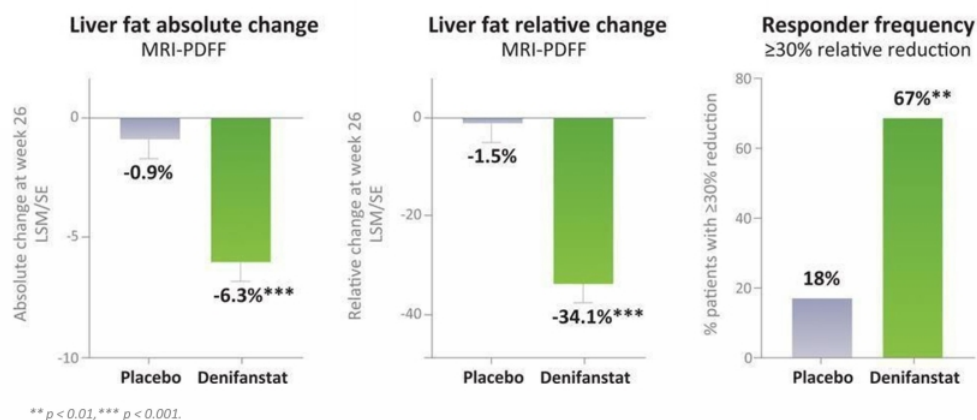
- Improvements observed in multiple biomarkers of metabolic health
  - LDL-cholesterol
  - FGF-21



# Denifanstat Decreased Liver Fat

## Responders Correlate with Liver Biopsy Improvement

### 1 Steatosis biomarker – liver fat

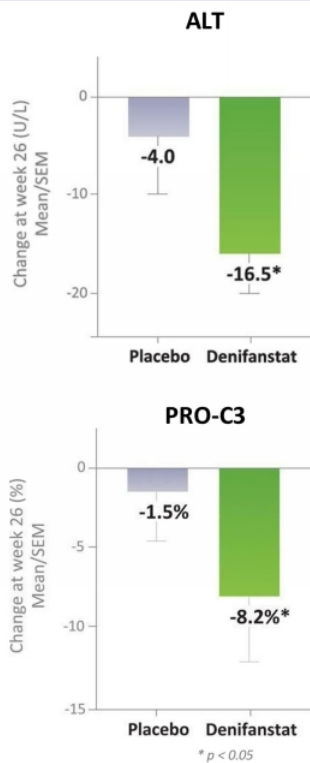


### Findings to

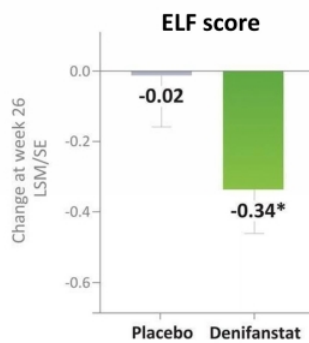
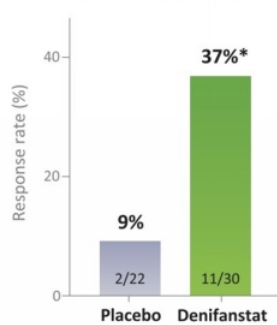
- Denifanstat induced a statistically significant reduction of liver fat
- 67% ( $p < 0.001$ ) MRI-PDFF response rate
- About half of responders had decreased liver fat on biopsy
- A relative reduction of ≥30% by MRI-PDFF was shown to correlate with biopsy response

# Denifastat Decreased PRO-C3 and ELF – Suggests Fibrosis Red

## 2 3 Inflammation and fibrosis biomarkers



### Dual liver fat & ALT responder >30% + >17U/L decrease



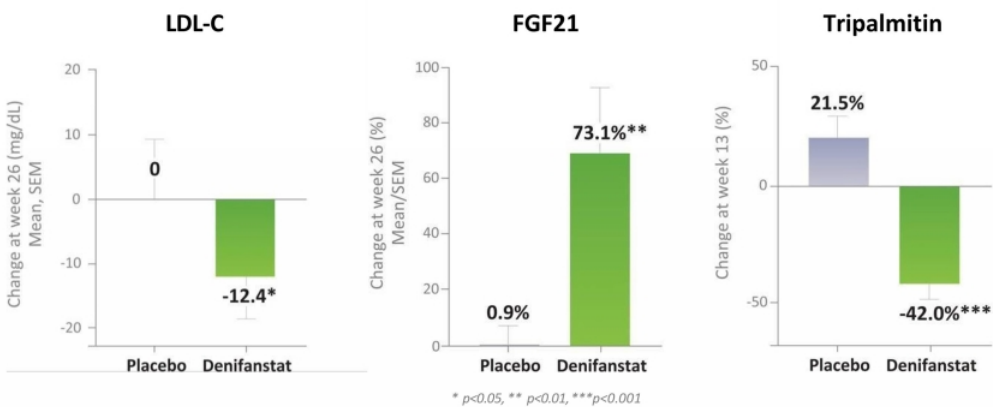
## Findings to

- ALT decrease sug decrease in inflam denifanstat
- PRO-C3 decrease decrease of liver denifanstat
- ELF score decrea decrease of liver denifanstat. ELF s prognostic value

Other liver biomarkers con

# Denifanstat Improved Markers of Cardiometabolic Health

## 4 Metabolic health / lipid biomarkers



## Findings to

- LDL-cholesterol i  
denifanstat may  
cardiovascular b
- FGF21 increase  
may induce imp  
insulin sensitivit
- Tripalmitin decre  
denifanstat inhib  
and reduced pal  
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%)

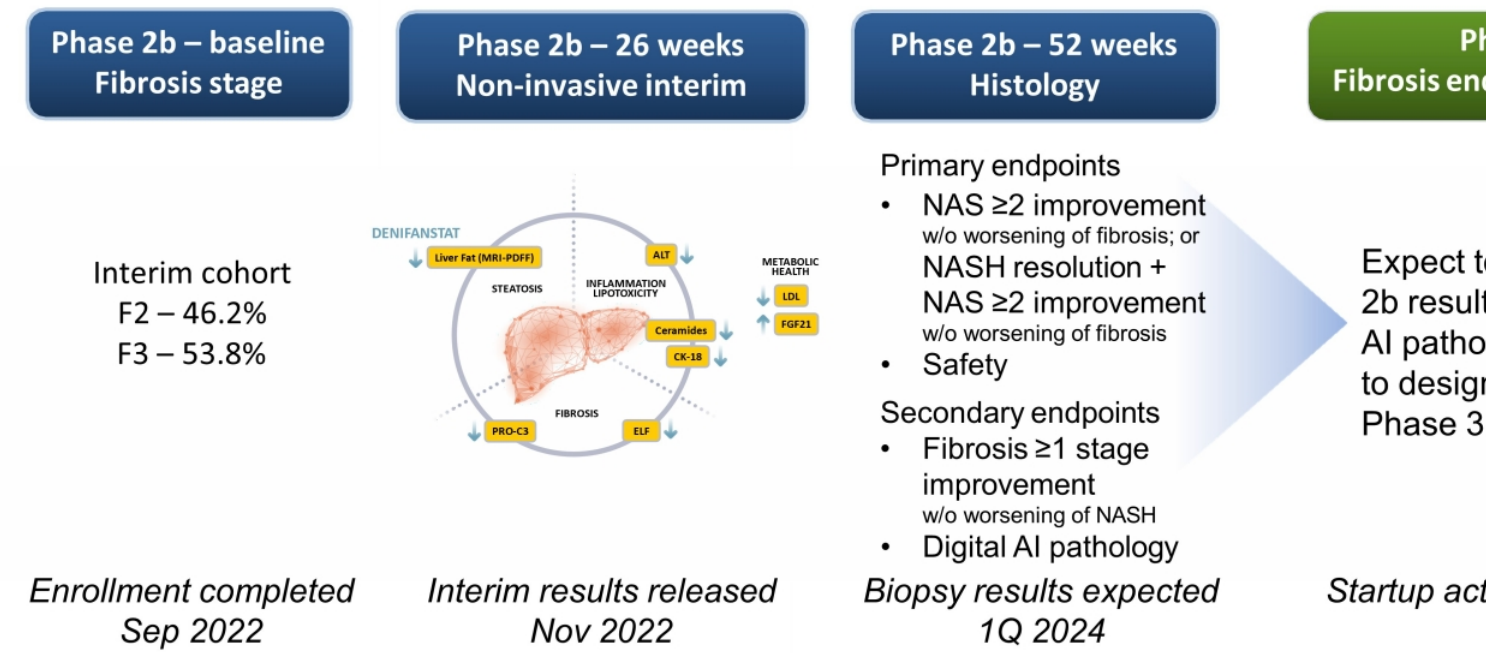
AE data as of 3 April 2023



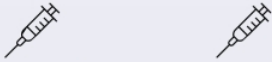
# NASH Development Program

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# Progression from Phase 2b to Phase 3

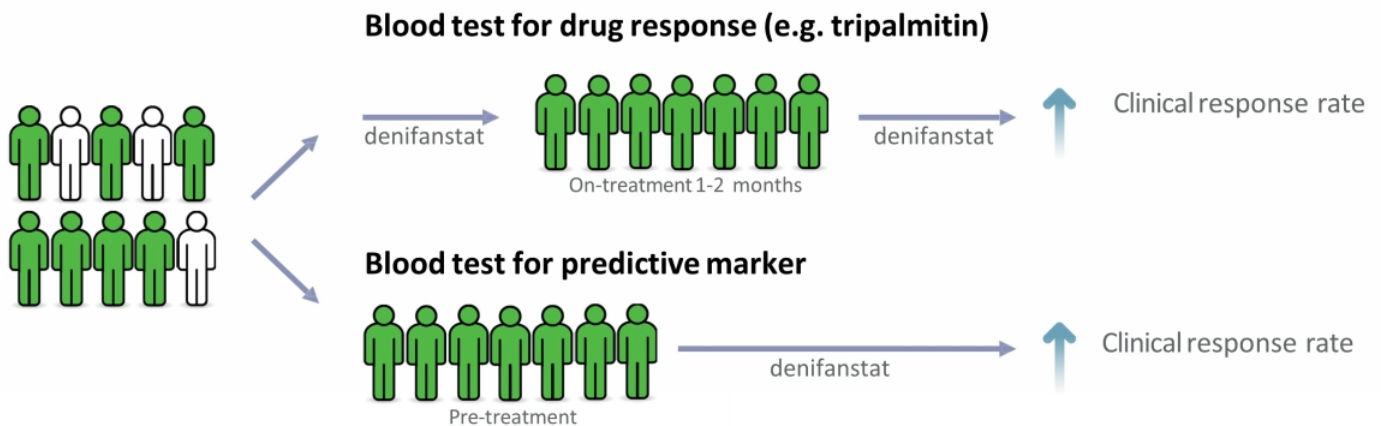


# We Believe Denifanstat is Differentiated in the Evolving NASH Landsc

Mechanism	FASN inhibitors	THR $\beta$ 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			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"><li>Pending biopsy results</li></ul>	<ul style="list-style-type: none"><li>Selectivity for beta isoform critical to avoid potential heart and bone safety issues</li></ul>	<ul style="list-style-type: none"><li>Injectable</li><li>Nausea and diarrhea</li><li>Potential neutralizing antibodies</li><li>Higher expected COGS</li></ul>	<ul style="list-style-type: none"><li>GI side effects including nausea</li><li>Lack of fibrosis improvement to date</li></ul>	<ul style="list-style-type: none"><li>Weight gain, edema, GI side effects, anemia</li></ul>	<ul style="list-style-type: none"><li>Combinations only</li><li>MOA causes triglyceride increases</li><li>Lack of fibrosis improvement as monotherapy</li></ul>

# 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 responders<sup>1</sup>



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

## Strong Monotherapy Opportunity for Denifanstat in NASH

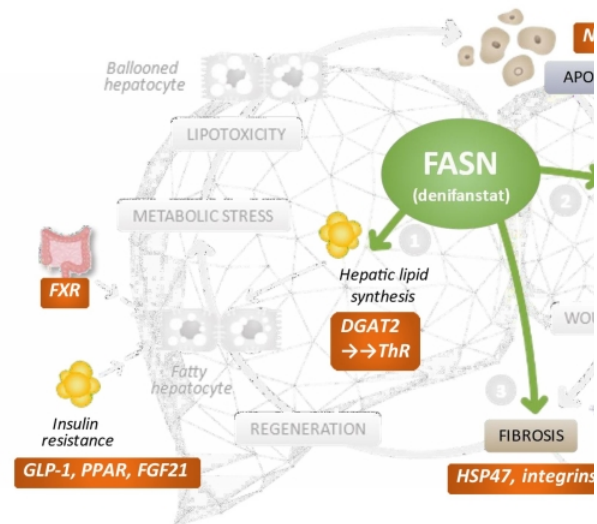
## Denifanstat data support success as first line monotherapy

- ✓ 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



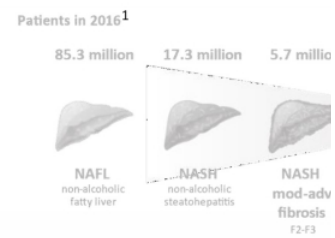
# Additional Expansion Opportunities in NASH

- **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

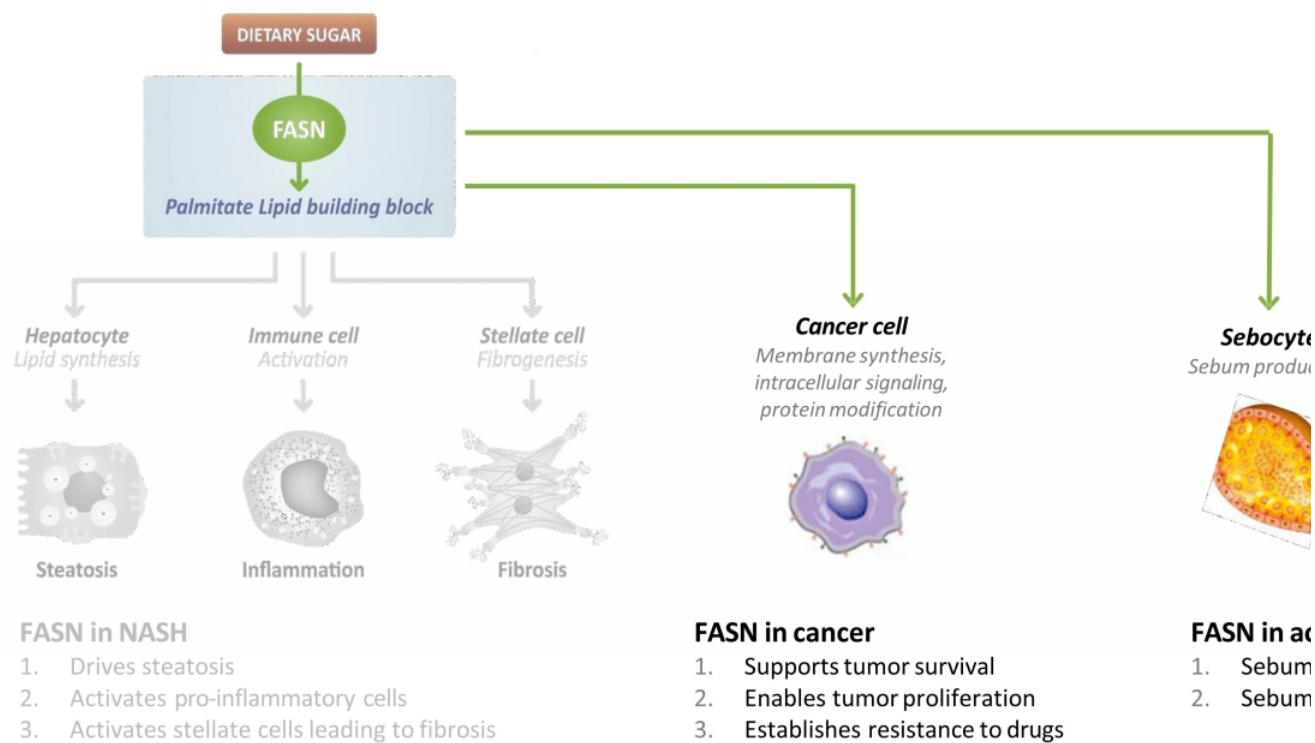




## Other Indications

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# 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

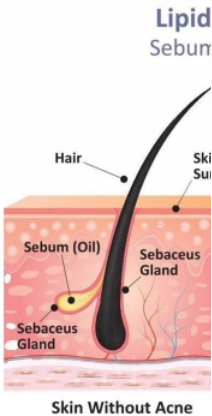
## Phase 2 – acne by Ascleitis in China



- 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  $\geq 2$

## Positive topline results announced May 2023

- Met primary and secondary endpoints
- Well-tolerated
- IND 1H 2024 filing planned



# FASN is Integral to Tumor Cell Proliferation and Survival

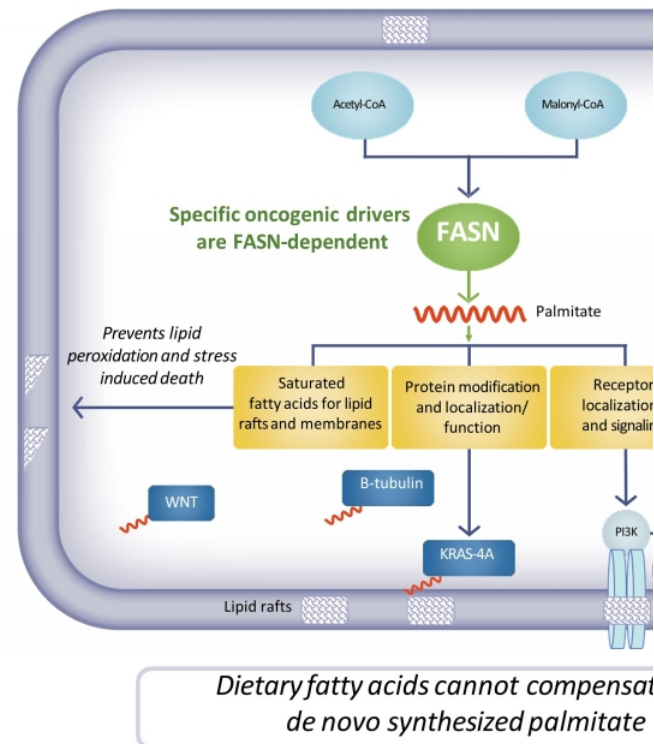
*Reprogramed metabolism is one of the hallmarks of cancer*

## 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

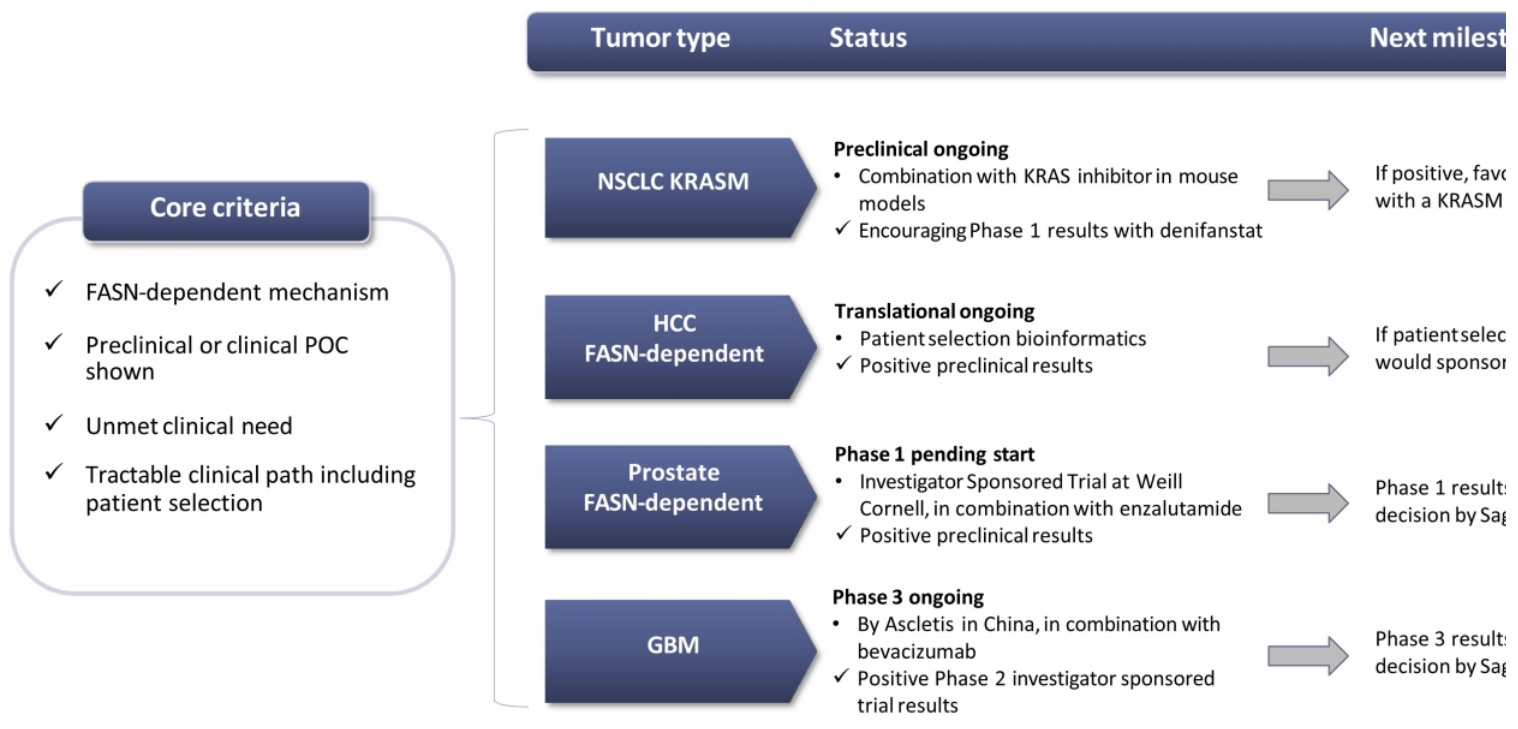
## Completed Phase 1 provides foundation

- 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



# FASN-Dependent Tumor Types Identified that Meet Core Criteria

Program focused on 4 selected tumor types



# Strong Financial Position and Intellectual Property Portfolio

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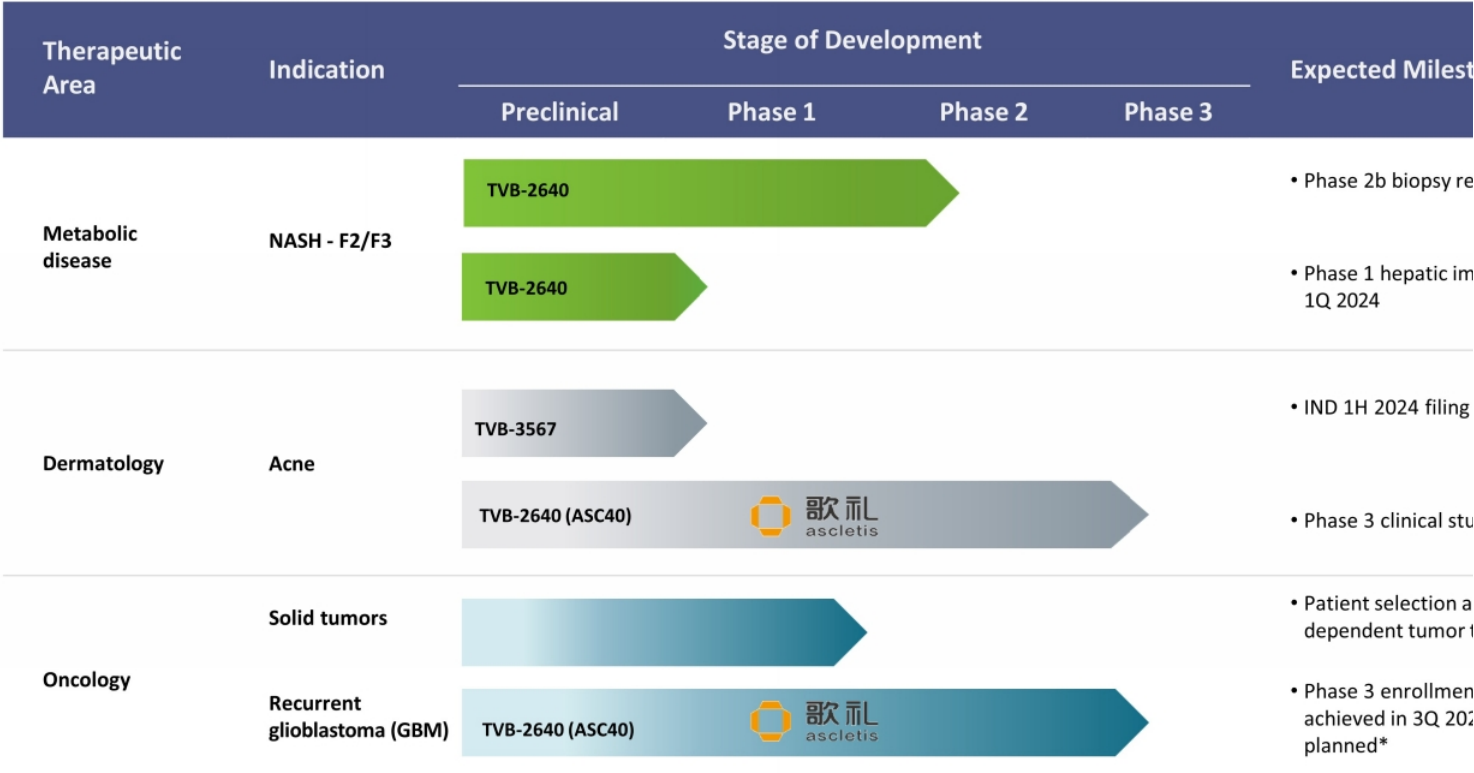
## Financial highlights Nasdaq: SGMT

- ✓ 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

# Development Pipeline: Indications and Clinical Milestones



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