
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2025

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 001-41742

Sagimet Biosciences Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

155 Bovet Road, Suite 303
San Mateo, California
(Address of principal executive offices)

20-5991472
(I.R.S. Employer
Identification No.)

94402
(Zip Code)

(650) 561-8600

(Registrant's telephone number, including area code)

N/A

(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class
Series A Common Stock,
\$0.0001 par value per share

Trading Symbol(s)
SGMT

Name of each exchange on which registered
Nasdaq Global Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The number of shares of the registrant's Series A and B common stock, \$0.0001 par value per share, outstanding at November 6, 2025 was 31,001,109 and 1,520,490, respectively.

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (this Quarterly Report) contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our future results of operations and financial position, business strategy, drug candidates, planned preclinical studies and clinical trials, results of preclinical studies, clinical trials, research and development costs, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that are in some cases beyond our control and 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. Forward-looking statements contained in this Quarterly Report include, but are not limited to, statements about:

- our financial performance;
- our ability to obtain additional cash and the sufficiency of our existing cash, cash equivalents and marketable securities to fund our future operating expenses and capital expenditure requirements;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements, and needs for additional financing;
- the scope, progress, results and costs of developing denifanstat, TVB-3567 or any other drug candidates or combination therapies we may develop, and conducting preclinical studies and clinical trials;
- our ability to advance drug candidates into, and successfully complete, clinical trials within anticipated timelines;
- the timing and costs involved in obtaining and maintaining regulatory approval of denifanstat, TVB-3567 or any other drug candidates or combination therapies we may develop, and the timing or likelihood of regulatory filings and approvals, including our expectation to seek special designations or accelerated approvals for our drug candidates for various indications;
- current and future agreements with third parties in connection with the development and commercialization of denifanstat, TVB-3567 or any other future drug candidate or combination therapy;
- our estimate of the number of patients in the United States who suffer from the diseases we target and the number of subjects that will enroll in our clinical trials;
- our relationship with Ascleto BioScience Co. Ltd. (Ascleto), and its affiliate Gannex Pharma Co., Ltd. (Gannex), and the success of their development efforts for denifanstat;
- the ability of our clinical trials to demonstrate the safety and efficacy of denifanstat, TVB-3567 and any other drug candidates or combination therapies we may develop;
- our plans relating to commercializing denifanstat, TVB-3567 and any other drug candidates or combination therapies we may develop, if approved, including the geographic areas of focus and our ability to grow a sales team;
- the success of competing therapies that are or may become available;
- developments relating to our competitors and our industry, including competing drug candidates and therapies;

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- our plans relating to the further development and manufacturing of denifanstat, TVB-3567 and any other drug candidates or combination therapies we may develop, including additional indications that we may pursue for denifanstat, TVB-3567 or other drug candidates or combination therapies;
- our ability to obtain sufficient funding or enter into a strategic collaboration to initiate Phase 3 clinical trials for denifanstat in metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH);
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our potential and ability to successfully manufacture and supply denifanstat, TVB-3567 and any other drug candidates or combination therapies we may develop for clinical trials and for commercial use, if approved;
- the rate and degree of market acceptance of denifanstat, TVB-3567 and any other drug candidates or combination therapies we may develop, as well as the pricing and reimbursement of denifanstat, TVB-3567 and any other drug candidates or combination therapies we may develop, if approved;
- our expectations regarding our ability to obtain, maintain, protect and enforce intellectual property protection for denifanstat, TVB-3567 and for any other future drug candidate or combination therapy;
- our ability to realize the anticipated benefits of any strategic transactions;
- our ability to attract and retain the continued service of our key personnel and to identify, hire, and then retain additional qualified personnel and our ability to attract additional collaborators with development, regulatory and commercialization expertise;
- the impact of macroeconomic conditions and geopolitical turmoil on our business and operations;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act; and
- our anticipated use of our existing cash, cash equivalents and marketable securities.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Quarterly Report and are subject to a number of risks, uncertainties and assumptions described in the section titled “Risk Factors” set forth in Part II, Item 1A “Risk Factors” in this Quarterly Report, the section titled “Risk Factors” set forth in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2024 and the section titled “Risk Factors” set forth in Part II, Item 1A of our subsequent Quarterly Reports on Form 10-Q. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, 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. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein until after we distribute this Quarterly Report, whether as a result of any new information, future events or otherwise.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

PART I. FINANCIAL INFORMATION

Item 1. Condensed Financial Statements

**SAGIMET BIOSCIENCES INC.
CONDENSED BALANCE SHEETS**

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

	As of	
	September 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	\$ 32,496	\$ 75,840
Short-term marketable securities	84,197	75,410
Prepaid expenses and other current assets	2,787	1,524
Total current assets	119,480	152,774
Long-term marketable securities	8,806	7,408
Operating lease right-of-use assets	115	77
Total assets	<u>\$ 128,401</u>	<u>\$ 160,259</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 4,243	\$ 1,425
Accrued expenses and other current liabilities	4,788	2,951
Operating lease liabilities	115	78
Total current liabilities	9,146	4,454
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Undesignated preferred stock, \$0.0001 per share: 10,000,000 shares authorized; no shares issued and outstanding at September 30, 2025 and December 31, 2024	—	—
Series A common stock, \$0.0001 per share: 500,000,000 shares authorized; 31,001,109 shares issued and outstanding at September 30, 2025; 30,674,855 shares issued and outstanding at December 31, 2024	3	3
Series B common stock, \$0.0001 per share: 15,000,000 shares authorized; 1,520,490 shares issued and outstanding at September 30, 2025 and December 31, 2024	—	—
Additional paid-in capital	455,916	450,883
Accumulated deficit	(336,781)	(295,311)
Accumulated other comprehensive income	117	230
Total stockholders' equity	119,255	155,805
Total liabilities and stockholders' equity	<u>\$ 128,401</u>	<u>\$ 160,259</u>

The accompanying notes are an integral part of these unaudited condensed financial statements.

SAGIMET BIOSCIENCES INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	2025	2024	2025	2024
Operating expenses:				
Research and development	\$ 9,730	12,653	\$ 32,320	\$ 24,228
General and administrative	4,604	4,249	13,804	12,031
Total operating expenses	<u>14,334</u>	<u>16,902</u>	<u>46,124</u>	<u>36,259</u>
Loss from operations	<u>(14,334)</u>	<u>(16,902)</u>	<u>(46,124)</u>	<u>(36,259)</u>
Other income:				
Interest income and other, net	1,426	2,283	4,654	6,893
Total other income	<u>1,426</u>	<u>2,283</u>	<u>4,654</u>	<u>6,893</u>
Net loss	<u>\$ (12,908)</u>	<u>\$ (14,619)</u>	<u>\$ (41,470)</u>	<u>\$ (29,366)</u>
Net loss per share of Series A and Series B common stock				
outstanding, basic and diluted	<u>\$ (0.40)</u>	<u>\$ (0.45)</u>	<u>\$ (1.28)</u>	<u>\$ (0.95)</u>
Weighted-average shares of Series A and Series B common stock				
outstanding, basic and diluted	<u>32,464,893</u>	<u>32,143,336</u>	<u>32,286,188</u>	<u>31,036,271</u>
Net loss	\$ (12,908)	\$ (14,619)	\$ (41,470)	\$ (29,366)
Other comprehensive income (loss):				
Net unrealized gain (loss) on marketable securities	41	464	(113)	411
Total comprehensive loss	<u>\$ (12,867)</u>	<u>\$ (14,155)</u>	<u>\$ (41,583)</u>	<u>\$ (28,955)</u>

The accompanying notes are an integral part of these unaudited condensed financial statements.

SAGIMET BIOSCIENCES INC.
CONDENSED STATEMENTS OF
STOCKHOLDERS' EQUITY

(unaudited)
(in thousands, except share amounts)

	Series A Common Stock		Series B Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at January 1, 2025	30,674,855	\$ 3	1,520,490	\$ —	\$ 450,883	\$ (295,311)	\$ 230	\$ 155,805
Stock-based compensation expense	—	—	—	—	1,472	—	—	1,472
Unrealized loss on marketable securities	—	—	—	—	—	—	(109)	(109)
Net loss	—	—	—	—	—	(18,176)	—	(18,176)
Balance at March 31, 2025	<u>30,674,855</u>	<u>\$ 3</u>	<u>1,520,490</u>	<u>\$ —</u>	<u>\$ 452,355</u>	<u>\$ (313,487)</u>	<u>\$ 121</u>	<u>\$ 138,992</u>
Issuance of Series A common stock upon exercise of stock options	99	—	—	—	1	—	—	1
Stock-based compensation expense	—	—	—	—	1,598	—	—	1,598
Unrealized loss on marketable securities	—	—	—	—	—	—	(45)	(45)
Net loss	—	—	—	—	—	(10,386)	—	(10,386)
Balance at June 30, 2025	<u>30,674,954</u>	<u>\$ 3</u>	<u>1,520,490</u>	<u>\$ —</u>	<u>\$ 453,954</u>	<u>\$ (323,873)</u>	<u>\$ 76</u>	<u>\$ 130,160</u>
Issuance of Series A common stock for vesting of restricted stock units	281,462	—	—	—	—	—	—	—
Issuance of Series A common stock upon exercise of stock options	44,693	—	—	—	274	—	—	274
Stock-based compensation expense	—	—	—	—	1,688	—	—	1,688
Unrealized gain on marketable securities	—	—	—	—	—	—	41	41
Net loss	—	—	—	—	—	(12,908)	—	(12,908)
Balance at September 30, 2025	<u>31,001,109</u>	<u>\$ 3</u>	<u>1,520,490</u>	<u>\$ —</u>	<u>\$ 455,916</u>	<u>\$ (336,781)</u>	<u>\$ 117</u>	<u>\$ 119,255</u>

	Series A Common Stock		Series B Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at January 1, 2024	21,375,402	\$ 2	1,520,490	\$ —	\$ 340,777	\$ (249,744)	\$ 30	\$ 91,065
Sale of Series A common stock, net of issuance costs of \$7,796	9,000,000	1	—	—	104,731	—	—	104,732
Issuance of Series A common stock upon exercise of stock options	17,995	—	—	—	114	—	—	114
Stock-based compensation expense	—	—	—	—	759	—	—	759
Unrealized loss on marketable securities	—	—	—	—	—	—	(23)	(23)
Net loss	—	—	—	—	—	(6,629)	—	(6,629)
Balance at March 31, 2024	<u>30,393,397</u>	<u>\$ 3</u>	<u>1,520,490</u>	<u>\$ —</u>	<u>\$ 446,381</u>	<u>\$ (256,373)</u>	<u>\$ 7</u>	<u>\$ 190,018</u>
Issuance costs related to sale of Series A common stock	—	—	—	—	(27)	—	—	(27)
Stock-based compensation expense	—	—	—	—	1,449	—	—	1,449
Unrealized loss on marketable securities	—	—	—	—	—	—	(30)	(30)
Net loss	—	—	—	—	—	(8,118)	—	(8,118)
Balance at June 30, 2024	<u>30,393,397</u>	<u>\$ 3</u>	<u>1,520,490</u>	<u>\$ —</u>	<u>\$ 447,803</u>	<u>\$ (264,491)</u>	<u>\$ (23)</u>	<u>\$ 183,292</u>
Issuance of Series A common stock for vesting of restricted stock units	281,458	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	1,546	—	—	1,546
Unrealized gain on investments in marketable securities	—	—	—	—	—	—	464	464
Net loss	—	—	—	—	—	(14,619)	—	(14,619)
Balance at September 30, 2024	<u>30,674,855</u>	<u>\$ 3</u>	<u>1,520,490</u>	<u>\$ —</u>	<u>\$ 449,349</u>	<u>\$ (279,110)</u>	<u>\$ 441</u>	<u>\$ 170,683</u>

The accompanying notes are an integral part of these unaudited condensed financial statements

SAGIMET BIOSCIENCES INC.
CONDENSED STATEMENTS OF CASH FLOWS
(unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2025	2024
Cash flows from operating activities		
Net loss	\$ (41,470)	\$ (29,366)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accretion of discount on marketable securities, net	(689)	(1,197)
Non-cash operating lease expense	114	108
Stock-based compensation expense	4,758	3,754
Write-off of deferred financing costs	230	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,547)	(3,261)
Accounts payable, accrued expenses and other current liabilities	4,902	(1,351)
Operating lease liabilities	(115)	(98)
Net cash used in operating activities	<u>(33,817)</u>	<u>(31,411)</u>
Cash flows from investing activities		
Purchases of marketable securities	(89,788)	(94,329)
Sales and maturities of marketable securities	79,986	22,796
Net cash used in investing activities	<u>(9,802)</u>	<u>(71,533)</u>
Cash flows from financing activities		
Proceeds from sale of Series A common stock, net of issuance costs	—	105,750
Payment of financing costs	—	(1,045)
Proceeds from exercise of stock options	275	114
Net cash provided by financing activities	<u>275</u>	<u>104,819</u>
Net (decrease) increase in cash and cash equivalents	<u>(43,344)</u>	<u>1,875</u>
Cash and cash equivalents at beginning of period	75,840	75,139
Cash and cash equivalents at end of period	<u>\$ 32,496</u>	<u>\$ 77,014</u>
Supplemental non-cash investing and financing activities:		
Deferred financing costs within accounts payable and accrued expenses	<u>\$ 75</u>	<u>\$ 75</u>
Right-of-use assets obtained in exchange for operating lease obligations	<u>\$ 152</u>	<u>\$ 149</u>

The accompanying notes are an integral part of these unaudited condensed financial statements.

SAGIMET BIOSCIENCES INC.

NOTES TO THE CONDENSED FINANCIAL STATEMENTS (unaudited)

1. Description of Business and Basis of Presentation

Description of business

Sagimet Biosciences Inc. (the Company), a Delaware corporation headquartered in San Mateo, California, is a clinical-stage biopharmaceutical company developing novel therapeutics called fatty acid synthase (FASN) inhibitors that target dysfunctional metabolic and fibrotic pathways in diseases resulting from the overproduction of the fatty acid, palmitate. The Company's lead drug candidate, denifanstat, is an oral, once-daily pill and selective FASN inhibitor in development for metabolic dysfunction-associated steatohepatitis (MASH), acne, and select forms of cancer.

In MASH, denifanstat met all primary and multiple secondary endpoints in FASCINATE-2, a Phase 2b clinical trial, was granted Breakthrough Therapy designation by the U.S. Food and Drug Administration (FDA) and has completed end-of-Phase 2 interactions with the FDA. In September 2025, the Company initiated a Phase 1 pharmacokinetic (PK) clinical trial of a combination of denifanstat and a thyroid hormone receptor beta (THR- β) agonist, resmetirom, for development in MASH.

In acne, denifanstat met all primary and secondary endpoints in a Phase 3 trial in moderate to severe acne vulgaris conducted by the Company's license partner, Ascletris BioScience Co. Ltd. (Ascletris), in China. In June 2025, the Company initiated a first-in-human Phase 1 clinical trial of Sagimet's second FASN inhibitor, TVB-3567, a potent and selective small molecule FASN inhibitor, for development of an acne indication.

Basis of presentation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted (GAAP) in the United States. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Updates (ASU) promulgated by the Financial Accounting Standards Board (FASB).

These unaudited interim financial statements and accompanying notes should be read in conjunction with the Company's annual financial statements and the notes thereto included in the Company's Form 10-K, as filed with the Securities and Exchange Commission (SEC) on March 12, 2025. The accompanying interim financial statements as of September 30, 2025 and for the three and nine months ended September 30, 2025 and 2024 are unaudited but include all adjustments that management believes to be necessary for a fair presentation of the periods presented. Interim results are not necessarily indicative of results for a full year. Balance sheet amounts as of December 31, 2024 have been derived from the audited financial statements as of that date.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities as of the date of the financial statements and reported amounts of revenues and expenses during the reporting period. Such estimates include accruals of research and development expenses, accrued costs for services rendered under agreements with third-party contract research organizations (CROs) and stock option valuations and stock-based compensation. On an ongoing basis, the Company evaluates its estimates and judgments, which are based on historical and anticipated results and trends and on various other assumptions that management believes to be reasonable under the circumstances. Actual results could differ from those estimates.

Emerging growth company status

The Company is an emerging growth company (EGC) as defined in the Jumpstart Our Business Startups Acts of 2012, as amended (the JOBS Act), and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not EGCs. The Company may take advantage of these exemptions until it is no longer an EGC under Section 107 of the JOBS Act and has elected to use the extended transition period for complying with new or revised accounting standards. As a result of this election, the Company's financial statements may not be comparable to those issued by companies that comply with the effective dates pursuant to public company FASB standards.

Liquidity

The accompanying unaudited financial statements have been prepared assuming the Company will continue as a going concern, which contemplates continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The Company will require substantial additional capital to fund its research and development and ongoing operating expenses. As of September 30, 2025, the Company has relied on public and private equity and debt financings and proceeds from licensing arrangements to fund its operations. The Company has incurred recurring losses and negative cash flows from operations since inception, and, as of September 30, 2025, had an accumulated deficit of \$336.8 million and cash, cash equivalents and marketable securities of \$125.5 million. The Company expects to incur additional losses and negative cash flows from operations for the foreseeable future.

In July and August 2023, the Company completed its initial public offering (IPO) and, inclusive of the partial exercise of the underwriters' overallotment option, the Company sold an aggregate of 6,026,772 shares of Series A common stock at a public offering price of \$16.00 per share and received \$86.2 million in net proceeds. In January 2024, the Company completed a follow-on offering whereby it sold 9,000,000 shares of its Series A common stock at a price of \$12.50 per share and received \$104.7 million in proceeds, net of issuance costs of \$7.8 million.

In August 2024, the Company entered into a Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co. to establish an at-the-market offering (2024 ATM Offering) through which the Company may sell, from time to time at its sole discretion, up to \$75.0 million shares of its Series A common stock. In connection with the establishment of the 2025 ATM Offering (as defined below), the Company terminated the 2024 ATM Offering. No shares of Series A common stock were sold under the 2024 ATM Offering prior to such termination.

In August 2025, the Company entered into a Sales Agreement with Leerink Partners LLC to establish an at-the-market offering (2025 ATM Offering) through which the Company may sell, from time to time at its sole discretion, up to \$75.0 million shares of its Series A common stock. There were no sales under the 2025 ATM Offering during the three months ended September 30, 2025.

The Company expects that its cash, cash equivalents and marketable securities as of September 30, 2025 will be sufficient to fund the Company's operating expenses for at least the next 12 months from the issuance of these financial statements. In the future, the Company will need to raise additional funds until it is able to generate sufficient revenues to fund its development activities. The Company's future operating activities, coupled with its plans to raise capital or issue debt financing, may provide additional liquidity in the future, however these actions are not solely within the control of the Company, and the Company is unable to predict the outcome of these actions to generate the liquidity ultimately required.

2. Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited financial statements and the notes thereto, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2024, as filed with the SEC on March 12, 2025. Since the date of those audited financial statements, there have been no material changes to the Company's significant accounting policies.

Net loss per share attributable to common stockholders

Basic and diluted net loss per share is computed using the two-class method required for multiple classes of common stock and participating securities. The Company's participating securities do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders for all periods presented. Basic net loss per common share attributable to common stockholders is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss by the weighted-average number of common shares and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share attributable to common stockholders' calculation, common stock options, restricted stock units and common stock warrants are considered to be potentially dilutive securities. As the Company has reported a net loss for the periods presented, basic and diluted net loss per share attributable to common stockholders is the same as all potentially dilutive securities would have an anti-dilutive impact.

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The following table presents the calculation of basic and diluted net loss per share for the three and nine months ended September 30, 2025 and 2024 (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Numerator:				
Net loss	\$ (12,908)	\$ (14,619)	\$ (41,470)	\$ (29,366)
Denominator:				
Weighted-average shares of Series A and Series B common stock outstanding, basic and diluted	32,464,893	32,143,336	32,286,188	31,036,271
Net loss per share of Series A and Series B common stock outstanding, basic and diluted	\$ (0.40)	\$ (0.45)	\$ (1.28)	\$ (0.95)

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares of Series A and Series B common stock outstanding, as their effect would have been anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Options to purchase Series A common stock	5,694,175	4,322,367	5,694,175	4,322,367
Warrants to purchase Series A common stock	1,000	1,000	1,000	1,000
Restricted stock units	816,937	844,382	816,937	844,382
Total	6,512,112	5,167,749	6,512,112	5,167,749

New accounting pronouncements not yet adopted

The Company considers the applicability and impact of all ASUs. ASUs not discussed below were assessed and either determined to be not applicable or expected to have a minimal impact on the Company's financial statements.

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, which requires public business entities to disclose, for interim and annual reporting periods, additional information about certain income statement expense categories. ASU 2024-03 is effective for annual periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted and is effective on either a prospective basis or retrospective basis. The Company is currently evaluating the impact of the adoption of this standard on its financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740) - Improvements to Income Tax Disclosures*, a final standard on improvements to income tax disclosures. The standard requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. The standard is intended to benefit investors by providing more detailed income tax disclosures that would be useful in making capital allocation decisions and applies to all entities subject to income taxes. The new standard is effective for annual periods beginning after December 15, 2024. The Company is currently evaluating the impact of the adoption of this standard on its disclosures and will adopt the ASU for its Annual Report on Form 10-K for the year ended December 31, 2025.

One Big Beautiful Bill Act

On July 4, 2025, the One Big Beautiful Bill Act (OBBBA) was enacted in the United States. The OBBBA includes significant provisions, such as the permanent extension of certain expiring provisions of the Tax Cuts and Jobs Act and modifications to capitalization of research and development expenses, among others. The legislation has multiple effective dates, with certain provisions effective in 2025 and others implemented through 2027. The Company is currently in the process of assessing the potential impact of this legislation on its deferred tax assets, financial statements and related disclosures.

3. Fair Value Measurements and Fair Value of Financial Instruments

The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1 - Quoted prices in active markets for identical assets or liabilities.

Level 2 - Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

As of September 30, 2025 and December 31, 2024, financial assets measured at fair value on a recurring basis consisted of cash equivalents and marketable securities. Cash equivalents consist primarily of money market funds and other investments that are readily convertible into cash and have maturities of three months or less at the time of acquisition. The fair value of cash equivalents was \$32.1 million and \$75.3 million as of September 30, 2025 and December 31, 2024, respectively. The Company considers marketable securities with maturities greater than three months at the time of acquisition to be available-for-sale securities. The fair value of available-for-sale securities was \$93.0 million and \$82.8 million as of September 30, 2025 and December 31, 2024, respectively. These available-for-sale securities have expected maturities ranging from 0.1 to 15.2 months, and securities with an expected maturity greater than 12 months as of the balance sheet date, are classified in long-term. The fair value of marketable securities, which are Level 2 financial instruments, is based upon market prices quoted on the last day of the fiscal period or other observable market inputs. The Company obtains pricing information from its investment manager and generally determines the fair value of investment securities using standard observable inputs, including reported trades, broker-dealer quotes, bids and/or offers.

The Company evaluates securities with unrealized losses, if any, to determine whether the decline in fair value has resulted from credit loss or other factors, including various qualitative factors. As of September 30, 2025, the Company has not recognized any impairment or credit losses on the Company's available-for-sale securities. While the Company classifies these securities as available-for-sale, the Company does not intend to sell its investments and based on its current plans, the Company currently believes it has the ability to hold these investments until maturity.

The carrying values of the Company's accounts payable and accrued expenses and other current liabilities approximate their fair values due to the short-term nature of these liabilities.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

The Company's Level 3 liabilities that are measured at fair value on a recurring basis consist of the Series A common stock warrant liability related to the warrant to purchase 1,000 shares of Series A common stock with an exercise price of \$69.94 per share and an expiration date of July 18, 2026, the third anniversary date of the closing of the Company's IPO. The fair value of the Series A common stock warrant liability was immaterial as of September 30, 2025 and December 31, 2024, as well as the change in fair value during the three and nine months ended September 30, 2025 and 2024. There were no transfers within the hierarchy during the periods presented.

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The following tables set forth the Company's financial assets that were measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	Valuation Hierarchy	September 30, 2025			Fair Value
		Amortized Cost	Unrealized Gains	Unrealized Losses	
Assets					
Cash equivalents:					
Money market funds	Level 1	\$ 32,083	\$ —	\$ —	\$ 32,083
Total cash equivalents		32,083	—	—	32,083
Short-term marketable securities:					
Commercial paper	Level 2	19,845	13	—	19,858
Corporate debt securities	Level 2	1,485	2	—	1,487
U.S. Treasury securities	Level 2	52,227	66	(1)	52,292
Agency securities	Level 2	4,491	2	—	4,493
Asset-backed securities	Level 2	6,054	13	—	6,067
Total short-term marketable securities		84,102	96	(1)	84,197
Long-term marketable securities:					
Commercial paper	Level 2	2,757	—	(1)	2,756
U.S. Treasury securities	Level 2	6,027	23	—	6,050
Total long-term marketable securities		8,784	23	(1)	8,806
Total cash equivalents and marketable securities		\$ 124,969	\$ 119	\$ (2)	\$ 125,086

	Valuation Hierarchy	December 31, 2024			Fair Value
		Amortized Cost	Unrealized Gains	Unrealized Losses	
Assets					
Cash equivalents:					
Money market funds	Level 1	\$ 72,800	\$ —	\$ —	\$ 72,800
U.S. Treasury securities	Level 2	2,477	—	—	2,477
Total cash equivalents		75,277	—	—	75,277
Short-term marketable securities:					
Commercial paper	Level 2	14,447	25	(1)	14,471
Corporate debt securities	Level 2	6,909	7	—	6,916
U.S. Treasury securities	Level 2	27,493	123	—	27,616
Agency securities	Level 2	21,345	12	(2)	21,355
Asset-backed securities	Level 2	5,030	22	—	5,052
Total short-term marketable securities		75,224	189	(3)	75,410
Long-term marketable securities:					
U.S. Treasury securities	Level 2	4,884	36	—	4,920
Asset-backed securities	Level 2	2,480	8	—	2,488
Total long-term marketable securities		7,364	44	—	7,408
Total cash equivalents and marketable securities		\$ 157,865	\$ 233	\$ (3)	\$ 158,095

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	As of	
	September 30, 2025	December 31, 2024
Prepaid clinical costs	\$ 570	\$ 436
Prepaid research and development costs	1,089	48
Prepaid insurance	628	577
Deferred financing costs	247	306
Other	253	157
Total prepaid expenses and other current assets	<u>\$ 2,787</u>	<u>\$ 1,524</u>

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	As of	
	September 30, 2025	December 31, 2024
Accrued license fee	\$ 2,500	\$ —
Accrued payroll-related costs	1,292	1,358
Accrued clinical costs	109	528
Accrued research and development costs	588	516
Accrued general and administrative costs	291	544
Other	8	5
Total accrued expenses and other current liabilities	<u>\$ 4,788</u>	<u>\$ 2,951</u>

6. Commitments and Contingencies

License and other agreements

Ascleto BioScience Co. Ltd

In January 2019, the Company entered into a license agreement that became effective in February 2019 with Ascleto BioScience Co. Ltd. (Ascleto), a subsidiary of Ascleto Pharma Inc. (Ascleto Pharma), a biotechnology company incorporated in the Cayman Islands and headquartered in Hangzhou, China. Ascleto Pharma, through a subsidiary, was the lead investor in the Company's Series E redeemable convertible preferred stock financing in February 2019. The parties entered into this agreement with the intention to develop, manufacture, and commercialize the Company's proprietary FASN inhibitor, denifanstat, which Ascleto refers to as ASC40. Under the terms of the license agreement, the Company granted Ascleto and its affiliates an exclusive, royalty-bearing sublicenseable right and license under the Company's intellectual property to develop, manufacture, commercialize and otherwise exploit denifanstat and other products containing denifanstat-related compounds in Greater China, consisting of the People's Republic of China, Hong Kong, Macau and Taiwan.

The Company is eligible to receive development and commercial milestone payments from Ascleto in aggregate of up to \$122.0 million as well as tiered royalties ranging from percentages in the high single digits to mid-teens on future net sales of denifanstat in Greater China. The license and the research and development services components of this license agreement are representative of a relationship with a customer, and therefore, the Company evaluated the license agreement under the provisions of ASC 606, *Revenue from Contracts with Customers*. The developmental and commercial event-based milestone payments represent variable consideration, and the Company used the most likely amount method to estimate this variable consideration because the potential milestone payment is a binary event, as the Company will either receive the milestone payment or it will not. Given the high degree of uncertainty around

achievement of these milestones, the Company determined the milestone amounts to be fully constrained and will not recognize revenue until the uncertainty associated with these payments is resolved. Any consideration related to royalties will be recognized if and when the related sales occur. The Company re-assesses the transaction price in each reporting period and when events whose outcomes are resolved or other changes in circumstances occur.

In July 2023, the Company entered into an Assignment and Assumption Agreement with Ascletois and Ascletois' affiliate Gannex Pharma Co., Ltd. (Gannex) under which Ascletois, while remaining responsible for performance under the license agreement, assigned all of its rights and obligations under the license agreement to Gannex and Gannex assumed such rights and obligations, effective as of October 2019.

Facility Lease Agreement

On March 12, 2019, the Company executed a 38-month non-cancelable operating lease agreement for 3,030 square feet of office space for its headquarters facility in San Mateo, California, which commenced April 1, 2019. In December, 2021, the lease agreement was amended to extend the term of the lease through June 2024; in April 2024, the Company amended the lease agreement to (i) extend the lease through June 30, 2025 and (ii) increase the monthly lease payment to approximately \$13,000 beginning on July 1, 2024, which resulted in an increase in the Company's operating lease right-of-use asset and corresponding operating lease liability of \$0.1 million on the amendment date. In May 2025, the Company amended the lease agreement to extend the term of the lease through June 2026, which resulted in an increase in the Company's operating lease right-of-use asset and corresponding operating lease liability of \$0.2 million on the amendment date.

Operating lease costs were \$39,000 and \$42,000 for the three months ended September 30, 2025, and 2024, respectively and \$119,000 and \$116,000 for the nine months ended September 30, 2025 and 2024, respectively.

Other Agreements

In September 2025, the Company entered into a term sheet with a contract manufacturing organization (CMO) which included the binding grant of a global, exclusive license to certain innovative intellectual property rights in connection with the manufacturing of active pharmaceutical ingredients (API) (the CMO Term Sheet). Upon execution of the CMO Term Sheet, a non-refundable up-front payment of \$2.5 million was due, which was recognized in research and development expense during the three months ended September 30, 2025 and is reflected in accrued expenses and other current liabilities on the condensed balance sheet as of September 30, 2025.

Guarantees and indemnifications

In the normal course of business, the Company enters into agreements that contain a variety of representations and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. In addition, the Company has entered into indemnification agreements with members of its board of directors and its executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. As of September 30, 2025, the Company does not have any material indemnification claims that were probable or reasonably possible and consequently has not recorded related liabilities.

Legal Proceedings

From time to time, the Company may become involved in various legal proceedings that arise in the ordinary course of its business. The Company records a liability for such matters when it is probable that future losses will be incurred and that such losses can be reasonably estimated. Significant judgment by the Company is required to determine both probability and the estimated amount. The Company is not party to any material legal proceedings as of September 30, 2025.

7. Stock-Based Compensation

The 2023 Stock Option and Incentive Plan (2023 Plan) was adopted by the board of directors, approved by the Company's stockholders on July 4, 2023, and became effective on July 13, 2023, replacing the 2017 Equity Incentive Plan. The number of shares initially reserved for issuance under the 2023 Plan was 2,585,968. The number of shares will automatically increase each January 1, by

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(i) 4% of the outstanding number of shares of the Company's Series A common stock on the immediately preceding December 31 or (ii) a lesser number of shares as determined by the compensation committee of the board of directors. In accordance with the 2023 Plan, the shares reserved for issuance automatically increased by 855,016 shares on January 1, 2024, and by 1,226,994 shares on January 1, 2025. As of September 30, 2025, the aggregate maximum number of shares reserved for issuance under the 2023 Plan was 4,667,978, of which 1,426,290 shares were available for future grants. Option grants issued under the 2023 Plan are exercisable for up to 10 years from the date of issuance.

In March 2024, the Company established a pool of 1,000,000 shares of Series A common stock (Inducement Pool) from which equity grants in the form of options and restricted stock units may be issued as inducement for new employees to accept employment offers from the Company or for individuals returning to employment after a bona fide period of non-employment with the Company. Inducement Pool grants are granted outside of the 2023 Plan and do not require approval from the Company's stockholders pursuant to the Nasdaq inducement grant exception in accordance with Nasdaq Listing Rule 5635(c)(4). In February 2025, the Company increased the number of shares available for issuance by 300,000 shares, increasing the total number of shares available for issuance under the Inducement Pool to 1,300,000 shares. As of September 30, 2025, 404,017 shares were available for future grants from the Inducement Pool.

Total stock-based compensation recorded in the condensed statements of operations and comprehensive loss related to stock options and restricted stock units for employees and non-employees was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Stock options	\$ 1,402	\$ 1,316	\$ 3,941	\$ 2,903
Restricted stock units	286	230	817	851
Total stock-based compensation expense	<u>\$ 1,688</u>	<u>\$ 1,546</u>	<u>\$ 4,758</u>	<u>\$ 3,754</u>
Included in:				
General and administrative expense	\$ 1,454	\$ 1,311	\$ 4,068	\$ 3,005
Research and development expense	234	235	690	749
Total stock-based compensation expense	<u>\$ 1,688</u>	<u>\$ 1,546</u>	<u>\$ 4,758</u>	<u>\$ 3,754</u>

Stock options

The Company grants stock options which consist of (i) time-based options, which vest and become exercisable, subject to the participant's continued employment or service through the applicable vesting date and (ii) performance-based options, which vest based on performance measures against predetermined objectives that include successful completion of qualified equity offerings or announced topline results for clinical trials and positive clinical results over a specified performance period. The Company's time-based options have various vesting schedules that range from vesting immediately to vesting over a four-year period.

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The following table summarizes stock option activity for the nine months ended September 30, 2025 (in thousands, except share and per share data):

	Number of Shares Underlying Outstanding Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value ⁽¹⁾
Outstanding, January 1, 2025	4,462,517	\$ 6.58	7.4	\$ 619
Granted	1,276,597	4.83		
Exercised	(44,792)	6.14		
Forfeited/expired	(147)	23.05		
Outstanding, September 30, 2025 ⁽²⁾	<u>5,694,175</u>	\$ 6.19	7.3	\$ 7,048
Vested and expected to vest, September 30, 2025	<u>5,694,175</u>	\$ 6.19	7.3	\$ 7,048
Exercisable at September 30, 2025	<u>3,422,341</u>	\$ 6.74	6.3	\$ 2,668

- (1) Aggregate intrinsic value represents the difference between the fair value of the Company's Series A common stock on the last day of the fiscal period and the exercise price, multiplied by the number of options outstanding.
- (2) Includes 477,467 performance-based options with a weighted-average exercise price of \$6.44, all of which were fully vested and exercisable.

During the nine months ended September 30, 2025 and 2024, the weighted average grant-date fair value per share of stock options granted was \$3.77 and \$3.42, respectively. The total intrinsic value of stock options exercised during the nine months ended September 30, 2025 and 2024, was \$0.2 and \$0.1 million, respectively. Additionally, during the nine months ended September 30, 2025 and 2024, cash received from the exercise of stock options was approximately \$0.3 and \$0.1 million, respectively.

As of September 30, 2025, there was \$9.4 million of unrecognized compensation expense, which is expected to be recognized over a remaining weighted-average period of 2.2 years.

Restricted stock units

The Company's restricted stock units generally vest over a four-year period in equal amounts on an annual basis, provided the employee remains continuously employed with the Company. The fair value of the restricted stock units is equal to the closing price of the Company's Series A common stock on the grant date.

The following table summarizes restricted stock unit activity:

	Restricted Stock Units	Weighted-Average Grant Date Fair Value
Outstanding, January 1, 2025	844,382	\$ 2.96
Granted	254,017	4.71
Vested/released	(281,462)	2.96
Outstanding, September 30, 2025	<u>816,937</u>	<u>\$ 3.50</u>

As of September 30, 2025, the total unrecognized compensation expense related to unvested restricted stock units was \$2.5 million, which is expected to be recognized over a remaining weighted-average period of 2.4 years.

Valuation assumptions

The fair value of each stock option granted was estimated on the date of grant using the Black-Scholes option pricing model using the following assumptions:

	Nine Months Ended September 30,	
	2025	2024
Expected volatility	95 - 96 %	91 - 96 %
Risk-free interest rate	4.1 - 4.3 %	3.9 - 4.5 %
Dividend yield	—	—
Expected term (in years)	5.3 - 6.0	5.3 - 6.1

The expected term is determined using the simplified method, which represents the average of the contractual term of the options and the weighted-average expected vesting period. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the option. The expected stock volatility rate is based on the volatility rates of comparable publicly held companies over a period equal to the expected term of the option. The Company utilizes a dividend yield of zero based on the fact that the Company has never paid cash dividends to stockholders and has no current intentions to pay cash dividends.

Employee stock purchase plan

The 2023 Employee Stock Purchase Plan (the ESPP) was adopted by the board of directors in July 2023 with an initial total of 215,497 shares of Series A common stock reserved for issuance. Under the ESPP plan, the amount of shares reserved automatically increases each January 1 through January 1, 2033, by the least of (i) 215,497 shares of Series A common stock, (ii) 1% of the outstanding number of shares of the Company's Series A common stock on the immediately preceding December 31 or (iii) such lesser number of shares of Series A common stock as determined by the administrator of the ESPP. In accordance with the ESPP, the shares reserved for issuance automatically increased by 213,754 shares on January 1, 2024, and by 215,497 shares on January 1, 2025. As of September 30, 2025, the aggregate maximum number of shares reserved for issuance under the ESPP was 644,748. No shares of Series A common stock have been issued under the ESPP to date.

8. Segment Reporting

Operating segments are defined as components of an entity about which discrete financial information is evaluated regularly by the chief operating decision maker (CODM) in deciding how to allocate resources and assess performance. The Company operates and manages its business as one business segment, which is development and commercialization of therapeutics for the treatment of MASH, acne and other diseases where FASN plays a pathogenic role. Accordingly, the Company has one reportable segment. The Company has a single management team that reports to the Chief Executive Officer, the Company's CODM, who comprehensively manages the entire Company. The accounting policies of the segment are the same as those described in the summary of significant accounting policies.

When evaluating the Company's financial performance, the CODM is regularly provided with more detailed expense information than what is included in the Company's statements of operations and comprehensive loss. The CODM uses net loss, as reported in the statements of operations and comprehensive loss, in evaluating the performance of the segment. Decisions regarding resource allocation are made primarily during the annual budget planning process and reallocated as needed throughout the year. The measure of segment assets is reported on the balance sheets as total assets.

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The following table shows a reconciliation of the Company's net loss, including the significant expense categories regularly provided to and reviewed by the CODM, as computed under U.S. GAAP, to the Company's total net loss in the statements of operations and comprehensive loss, for the three and nine months ended September 30, 2025, and 2024 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Denifanstat external research and development expenses	5,784	11,888	23,878	21,167
TVB-3567 external research and development expenses	2,735	208	4,955	223
External general and administrative expenses	2,315	1,971	6,946	6,313
Personnel costs	1,733	1,707	5,459	4,701
Stock-based compensation	1,688	1,546	4,758	3,754
Other segment items ⁽¹⁾	(1,347)	(2,701)	(4,526)	(6,792)
Segment net loss	<u>\$ 12,908</u>	<u>\$ 14,619</u>	<u>\$ 41,470</u>	<u>\$ 29,366</u>

(1) Other segment items consist of (i) interest and other income, net and (ii) other internal operating research and development expenses.

ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read together with our unaudited condensed financial statements and related notes included elsewhere in this report on Form 10-Q for the quarter ended September 30, 2025 (Quarterly Report). This discussion and analysis and other parts of this Quarterly Report contain forward-looking statements based upon our current plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and beliefs. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors" and elsewhere in this Quarterly Report. You should carefully read the "Risk Factors" section of this Quarterly Report to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements.

Overview

We are a clinical-stage biopharmaceutical company developing novel therapeutics called fatty acid synthase (FASN) inhibitors that target dysfunctional metabolic and fibrotic pathways in diseases resulting from the overproduction of the fatty acid, palmitate. Our lead drug candidate, denifanstat, is an oral, once-daily pill and selective FASN inhibitor in development for the treatment of metabolic dysfunction-associated steatohepatitis (MASH), acne, and select forms of cancer.

MASH

Phase 2b FASCINATE-2 clinical trial of denifanstat in MASH

Denifanstat met all primary and multiple secondary endpoints in the Phase 2b FASCINATE-2 clinical trial evaluating denifanstat in 168 biopsy-confirmed MASH patients with stage F2 or F3 fibrosis compared to placebo at week 52. We announced topline results in January 2024 and published the trial results in *The Lancet Gastroenterology & Hepatology* in October 2024. Denifanstat also demonstrated anti-fibrotic activity, including in patients with advanced fibrosis, as seen in the F3 modified intention to treat (mITT) population and qF4 patients (qF4 patients are AI-defined F4, based on the second harmonic generation (SGH) HistoIndex platform, which may encompass late stage F3 as well as F4 patients):

- Fibrosis improvement by ≥ 1 stage with no worsening of MASH (F3 mITT population: denifanstat 49% vs. placebo 13%, $p=0.0032$).
- Fibrosis improvement by ≥ 2 stages with no worsening of MASH (mITT population: denifanstat 20% vs. placebo 2%, $p=0.0065$; F3 mITT population: denifanstat 34% vs. placebo 4%, $p=0.0065$).
- A statistically significant difference in progression to cirrhosis (F4) (mITT population: denifanstat 5% vs. placebo 11%, $p=0.0386$).
- A statistically significant difference in fibrosis improvement by ≥ 1 stage with no worsening of MASH for patients on a stable background dose of a GLP-1 Receptor Agonist (mITT population: denifanstat 42% vs. placebo 0%, $p=0.034$).
- 85% of qF4 patients decreased by 1 or 2 qFibrosis stages measured by AI-based pathology (SGH, HistoIndex).
- Statistically significant liver fibrosis regression in the portal and peri-portal regions (observed with AI-based digital pathology). Select fibrosis parameters in the peri-portal and portal regions are part of AI-based composite score that have been recently linked to major adverse liver outcomes (MALO) and mortality.

As in prior studies, denifanstat was generally well tolerated. No treatment-related serious adverse events (SAEs) were observed, and the majority of adverse events (AEs) were mild to moderate in nature (Grades 1 and 2). There were no Grade ≥ 3 treatment-related AEs and no drug-induced liver injury (DILI) signal in the study. The most common treatment-related AEs by system organ class (observed in $\geq 5\%$ of patients in the study) were eye disorders, gastrointestinal disorders, and skin and subcutaneous tissue disorders. The incidence of treatment emergent adverse events (TEAEs) leading to treatment discontinuation was 19.6% in the denifanstat group compared to 5.4% in placebo.

Phase 1 pharmacokinetic (PK) clinical trial of a combination of denifanstat and resmetirom

In September 2025, we initiated a Phase 1 clinical trial to evaluate the PK and tolerability of a combination of denifanstat and a thyroid hormone receptor beta (THR- β) agonist, resmetirom (Rezdiffra™). The Phase 1 PK trial of denifanstat and resmetirom is an open-label, 2-cohort study enrolling approximately 40 healthy adult participants; trial objectives are to evaluate multiple-dose and single-dose pharmacokinetics, identify any potential drug-drug interactions (DDI), and assess the safety and tolerability of the combination.

Our combination program builds upon preclinical data we presented at the European Association for the Study of the Liver (EASL) Congress in 2024 for two mouse models of MASH, showing that the combination of a FASN inhibitor (TVB-3664, a surrogate for denifanstat) and resmetirom, had a synergistic effect on important liver disease markers, including improvement of NAS by histologic analysis and more robust improvement in hepatic collagen content compared to the single agents. Synergistic activity of the combination was demonstrated in the rate of histological improvement (NAS ≥ 2 points), which was 33% for FASN inhibitor monotherapy, 25% for resmetirom monotherapy, and 80% for the combination of the two, a level of improvement that greatly exceeds a simple addition of the activity of the two drugs.

We anticipate topline data from this Phase 1 PK trial to be available in the first half of 2026 and plan to use it to inform the optimal dose levels of denifanstat and resmetirom to evaluate in a Phase 2 combination proof-of-concept efficacy trial in F4 MASH patients, subject to consultation with regulatory authorities.

Acne

In addition to MASH, we are exploring our FASN inhibitors in acne, in which dysregulation of fatty acid metabolism also plays a key role.

Phase 3 clinical trial of denifanstat in acne

In June 2025, our license partner for China, Ascletis BioScience Co. Ltd. (Ascletis), a subsidiary of Ascletis Pharma Inc. (Ascletis Pharma) announced that denifanstat met all primary and secondary endpoints in its Phase 3 trial in moderate to severe acne vulgaris in China. The Phase 3 clinical trial was a randomized, double-blind, placebo-controlled, multicenter clinical trial of 480 enrolled patients randomized 1:1 to receive denifanstat 50mg or placebo, once daily for 12 weeks.

Ascletis reported the following efficacy data from the Phase 3 trial:

- All primary endpoints were met, including:
 - the percentage of treatment success (defined as an Investigator's Global Assessment (IGA) score of 0 (clear) or 1 (almost clear) with at least a 2-point decrease from baseline) (denifanstat 33.2% vs. placebo 14.6%, $p < 0.0001$).
 - the percentage change in total lesion count (denifanstat -57.4% vs. placebo -35.4%, $p < 0.0001$).
 - the percentage change in inflammatory lesion count (denifanstat -63.5% vs. placebo -43.2%, $p < 0.0001$).
- The secondary endpoint of change in non-inflammatory lesion count was also met (denifanstat -51.9% vs. placebo -28.9%, $p < 0.0001$).

Ascletris reported that denifanstat was generally well-tolerated. Following 12 weeks of once-daily oral administration at 50 mg, the incidence rates of TEAEs were comparable between denifanstat and placebo.

In October 2025, Ascletris announced that it had completed its pre-New Drug Application (NDA) consultation with the China National Medical Products Administration (NMPA) for denifanstat for the treatment of moderate to severe acne vulgaris and plans to submit an NDA soon to the NMPA.

Phase 1 clinical trial of TVB-3567

In June 2025, we initiated a first-in-human Phase 1 clinical trial of our potent and selective small molecule FASN inhibitor, TVB-3567, for development of an acne indication. The Phase 1 clinical trial is a randomized double-blind placebo-controlled trial designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of TVB-3567 in healthy participants with or without acne. The trial is comprised of several parts, including single ascending dose cohorts and multiple ascending dose cohorts in participants without acne, followed by testing in participants with acne including evaluation of pharmacodynamic biomarkers. Subject to consultation with regulatory authorities, and contingent on the results of the Phase 1 trial, we anticipate initiating the Phase 2 trial of TVB-3567 in 2026.

Components of results of operations

Research and development expenses

Research and development expenses represent costs incurred in performing research, development and manufacturing activities in support of our own product development efforts and include internal personnel-related costs (such as salaries, employee benefits and stock-based compensation) for our personnel in research and development functions; as well as external costs, including costs related to acquiring, developing and manufacturing supplies for preclinical studies, clinical trials and other studies, including fees paid to contract manufacturing organizations (CMOs); costs and expenses related to agreements with contract research organizations (CROs), investigative sites and consultants to conduct non-clinical and preclinical studies and clinical trials; professional and consulting services costs; and facility and other allocated costs. Research and development expenses also include the costs of acquired product licenses and related technology rights where there is no alternative future use.

All research and development expenses are charged to operations as incurred in accordance with Accounting Standards Codification 730, *Research and Development*. We account for non-refundable advance payments for goods and services that will be used in future research and development activities as expenses when the service has been performed or when the goods have been received, rather than when the payment is made.

We expect our research and development expenses to increase substantially for the foreseeable future as we advance our drug candidates into and through preclinical studies and clinical trials, pursue regulatory approval and expand our pipeline.

General and administrative expenses

Our general and administrative expenses consist primarily of costs and expenses related to: personnel (including salaries, employee benefits and stock-based compensation) in our executive, finance and accounting and other administrative functions; legal services, including relating to intellectual property and corporate matters; accounting, auditing, consulting and tax services; insurance; information technology; and facility and other allocated costs not otherwise included in research and development expenses.

We expect our general and administrative expenses to increase for the foreseeable future as we increase our headcount and continue to grow our corporate infrastructure. We also anticipate that we will incur increased expenses as a result of operating as a public company, including expenses related to audit, legal and tax-related services associated with maintaining compliance with Securities and Exchange Commission (SEC) rules and regulations and those of any national securities exchange on which our securities are traded, additional insurance expenses, investor relations activities and other administrative and professional services.

Other income

Other income consists primarily of interest income earned on our cash, cash equivalents and marketable securities offset by accretion of discounts to maturity on our marketable securities.

Results of operations

Comparison of the three months ended September 30, 2025 and 2024

The following table summarizes our results of operations for the periods indicated (in thousands):

	Three Months Ended September 30,		\$ Change	% Change
	2025	2024		
Operating expenses:				
Research and development	\$ 9,730	\$ 12,653	\$ (2,923)	(23)%
General and administrative	4,604	4,249	355	8 %
Total operating expenses	14,334	16,902	(2,568)	(15)%
Loss from operations	(14,334)	(16,902)	2,568	(15)%
Total other income	1,426	2,283	(857)	(38)%
Net loss	\$ (12,908)	\$ (14,619)	\$ 1,711	(12)%

Research and development – Research and development expenses for the three months ended September 30, 2025 and 2024 were comprised of the following (in thousands):

	Three Months Ended September 30,		\$ Change	% Change
	2025	2024		
External expenses				
Clinical development and research	\$ 3,305	\$ 8,694	\$ (5,389)	(62)%
Manufacturing and non-clinical	4,842	2,675	2,167	81 %
External consulting and other	372	727	(355)	(49)%
Subtotal - external expenses	\$ 8,519	\$ 12,096	\$ (3,577)	(30)%
Internal expenses				
Personnel costs	\$ 898	\$ 740	\$ 158	21 %
Stock-based compensation	234	235	(1)	(0)%
Other internal operating expenses	79	(418)	497	(119)%
Subtotal - internal expenses	\$ 1,211	\$ 557	\$ 654	117 %
Total research and development expenses	\$ 9,730	\$ 12,653	\$ (2,923)	(23)%

Research and development expenses decreased by \$2.9 million, or 23%, for the three months ended September 30, 2025, compared to the three months ended September 30, 2024. This decrease was primarily due to a \$5.4 million decrease in clinical development and research expenses related primarily to lower clinical trial costs incurred for our Phase 3 program of denifanstat in MASH, which was partially offset by higher costs for the Phase 1 clinical trial of TVB-3567, which was initiated in June 2025, and the Phase 1 PK clinical trial for the combination of denifanstat and resmetrom, which was initiated in September 2025. This decrease was further partially offset by an increase in manufacturing and non-clinical expenses of \$2.2 million relating primarily to the \$2.5 million up-front license fee recognized in connection with entering into a term sheet with a CMO (the CMO Term Sheet) in September 2025.

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External research and development expenses for the three months ended September 30, 2025 and 2024 were comprised of the following (in thousands):

	Three Months Ended September 30,		\$ Change	% Change
	2025	2024		
Denifanstat external research and development expenses	\$ 5,784	\$ 11,888	\$ (6,104)	(51)%
TVB-3567 external research and development expenses	2,735	208	2,527	1,215 %
Total external research and development expenses	\$ 8,519	\$ 12,096	\$ (3,577)	(30)%

General and administrative – General and administrative expenses increased by \$0.4 million, or 8%, for the three months ended September 30, 2025, compared to the three months ended September 30, 2024 primarily due to a \$0.4 million increase in consulting and professional fees, driven by legal fees and the write-off of deferred financing costs.

Other income – Other income decreased by \$0.9 million for the three months ended September 30, 2025, compared to the three months ended September 30, 2024, due to a decrease in interest income earned driven by a lower cash, cash equivalents and marketable securities balance as well as lower yields during the three months ended September 30, 2025.

Comparison of the nine months ended September 30, 2025 and 2024

The following table summarizes our results of operations for the periods indicated (in thousands):

	Nine Months Ended September 30,		\$ Change	% Change
	2025	2024		
Operating expenses:				
Research and development	\$ 32,320	\$ 24,228	\$ 8,092	33 %
General and administrative	13,804	12,031	1,773	15 %
Total operating expenses	46,124	36,259	9,865	27 %
Loss from operations	(46,124)	(36,259)	(9,865)	27 %
Total other income	4,654	6,893	(2,239)	(32)%
Net loss	\$ (41,470)	\$ (29,366)	\$ (12,104)	41 %

Research and development – Research and development expenses for the nine months ended September 30, 2025 and 2024 were comprised of the following (in thousands):

	Nine Months Ended September 30,		\$ Change	% Change
	2025	2024		
External expenses				
Clinical development and research	\$ 18,595	\$ 13,311	\$ 5,284	40 %
Manufacturing and non-clinical	8,782	6,592	2,190	33 %
External consulting and other	1,456	1,487	(31)	(2)%
Subtotal - external expenses	\$ 28,833	\$ 21,390	\$ 7,443	35 %
Internal expenses				
Personnel costs	\$ 2,669	\$ 1,988	\$ 681	34 %
Stock-based compensation	690	749	(59)	(8)%
Other internal operating expenses	128	101	27	27 %
Subtotal - internal expenses	\$ 3,487	\$ 2,838	\$ 649	23 %
Total research and development expenses	\$ 32,320	\$ 24,228	\$ 8,092	33 %

Research and development expenses increased by \$8.1 million, or 33%, for the nine months ended September 30, 2025, compared to the nine months ended September 30, 2024. This increase was primarily due to (i) a \$5.3 million increase in clinical development and research expenses related primarily to clinical trial costs incurred for our Phase 3 program of denifanstat in MASH, as well as costs incurred for the Phase 1 clinical trial of TVB-3567, which was initiated in June 2025, and the Phase 1 PK clinical trial for the combination

of denifanstat and resmetirom, which was initiated in September 2025, partially offset by lower clinical trial expenses for the Phase 2b FASCINATE-2 trial as the trial was substantially complete in the first quarter of 2024 and topline results for the trial were announced in January 2024, (ii) an increase in manufacturing and non-clinical expenses of \$2.2 million relating primarily to the \$2.5 million up-front license fee recognized in connection with entering into the CMO Term Sheet in September 2025, and (iii) a \$0.7 million increase in personnel costs due to an increase in headcount.

External research and development expenses for the nine months ended September 30, 2025 and 2024 were comprised of the following (in thousands):

	Nine Months Ended September 30,		\$ Change	% Change
	2025	2024		
Denifanstat external research and development expenses	\$ 23,878	\$ 21,167	\$ 2,711	13 %
TVB-3567 external research and development expenses	4,955	223	4,732	2,122 %
Total external research and development expenses	\$ 28,833	\$ 21,390	\$ 7,443	35 %

General and administrative – General and administrative expenses increased by \$1.8 million, or 15%, for the nine months ended September 30, 2025, compared to the nine months ended September 30, 2024 primarily due to (i) a \$1.1 million increase in stock-based compensation driven by an increase in headcount, and (ii) a \$0.8 million increase in consulting and professional fees, driven by legal fees and the write-off of deferred financing costs.

Other income – Other income decreased by \$2.2 million for the nine months ended September 30, 2025, compared to the nine months ended September 30, 2024, due to a decrease in interest income earned driven by a lower cash, cash equivalents and marketable securities balance as well as lower yields during the nine months ended September 30, 2025.

Liquidity and capital resources

Sources and uses of cash

Since our inception, we have devoted substantially all of our resources to researching, discovering and developing our pipeline of proprietary FASN inhibitors and other drug targets, organizing and staffing our company, performing business planning, establishing our intellectual property portfolio, raising capital and general and administration activities to support and expand such activities. We do not have any products approved for sale and have not generated any revenue from product sales. Our revenues to date have been generated solely from the license agreement with Asclelis.

To date, we have financed our operations primarily through public and private equity and debt financings, including our IPO of Series A common stock in July 2023 and our follow-on offering in January 2024, from which we received aggregate net proceeds of \$190.9 million. Prior to becoming a public company, we raised \$233.3 million in gross proceeds from the sale of our redeemable convertible preferred stock and convertible notes.

In August 2024, we entered into a Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co. to establish an at-the-market offering (2024 ATM Offering) through which we may offer and sell, from time to time at our sole discretion, up to \$75.0 million of shares of our Series A common stock. In connection with the establishment of the 2025 ATM Offering (as defined below), we terminated the 2024 ATM Offering. No shares of Series A common stock were sold under the 2024 ATM Offering prior to such termination.

In August 2025, we entered into a Sales Agreement with Leerink Partners LLC to establish an at-the-market offering (2025 ATM Offering) through which we may sell, from time to time at our sole discretion, up to \$75.0 million shares of our Series A common stock. There were no sales under the 2025 ATM Offering during the three months ended September 30, 2025.

As of September 30, 2025, we had cash, cash equivalents and marketable securities of \$125.5 million. We do not expect to generate any revenue from commercial product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our drug candidates, which we expect will take a number of years, if ever. We anticipate that we will continue to incur significant expenses for the foreseeable future as we continue to advance our drug candidates through preclinical and clinical trials;

manufacture supplies for our preclinical studies and clinical trials; expand our corporate infrastructure, including the costs associated with being a public company; pursue regulatory approval of our drug candidates; hire additional personnel; acquire, discover, validate and develop additional drug candidates; and obtain, maintain, expand and protect our intellectual property portfolio.

Until we can generate a sufficient amount of revenue from the commercialization of our drug candidates or additional revenue from collaboration agreements with third parties, if ever, we expect to finance our future cash needs through public or private equity or debt financings, third-party funding and marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. The sale of equity or convertible debt securities may result in dilution to our stockholders and, in the case of preferred equity securities or convertible debt, those securities could provide for rights, preferences or privileges senior to those of our common stock. Debt financings may subject us to covenant limitations or restrictions on our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Our ability to raise additional funds may be adversely impacted by macroeconomic conditions, disruptions to and volatility in the credit and financial markets and geopolitical turmoil. There can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable or acceptable to us. If we are unable to obtain adequate financing when needed or on terms favorable or acceptable to us, we may be forced to delay, reduce the scope of or eliminate one or more of our research and development programs.

Our future capital requirements will depend on many factors, including:

- difficulties obtaining regulatory approval to commence a clinical trial or complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial;
- conditions imposed on us by the FDA or other regulatory authorities regarding the scope or design of our clinical trials;
- delays in reaching or failing to reach agreement on acceptable terms with prospective CROs, CMOs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly;
- insufficient supply of our drug candidates or other materials necessary to conduct and complete our clinical trials;
- difficulties obtaining institutional review board (IRB) or ethics committee approval to conduct a clinical trial at a prospective site;
- slow enrollment and retention rate of subjects in our clinical trials;
- the FDA or other regulatory authority requiring alterations to any of our study designs, our preclinical strategy or our manufacturing plans;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines; serious and unexpected drug-related side effects related to the drug candidate being tested;
- lack of adequate funding to continue clinical trials;
- subjects experiencing severe or unexpected drug-related adverse effects;
- occurrence of severe adverse effects in clinical trials of the same class of agents conducted by other companies;
- any changes to our manufacturing process, suppliers or formulation that may be necessary or desired;
- third-party vendors not performing manufacturing and distribution services in a timely manner or to sufficient quality standards;

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- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practice (GCP), or other regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications; and
- failure of our third-party contractors, such as CROs and CMOs, or our investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner.

A change in the outcome of any of these or other variables could significantly change our costs and timing associated with the development of our drug candidates. Furthermore, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such change.

We rely and will continue to rely on third parties in the conduct of our preclinical studies and clinical trials and for manufacturing and supply of our drug candidates. We have no internal manufacturing capabilities, and we will continue to rely on third parties for our preclinical study and clinical trial materials. Given our stage of development, we do not yet have a marketing or sales organization or commercial infrastructure. Accordingly, if we obtain regulatory approval for any of our drug candidates, we also expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution.

We enter into contracts in the normal course of business for products and services, including contract research and contract manufacturing services, which include provisions allowing for termination under certain conditions and timelines. These contracts generally do not include payments for early termination and are considered cancellable contracts.

Based on our current business plans, we believe that our existing cash, cash equivalents, and marketable securities as of September 30, 2025, will be sufficient for us to fund our operating expenses for at least the next 12 months from the issuance of this Quarterly Report.

Cash flows

The following table shows a summary of our cash flows for each of the periods presented below (in thousands):

	Nine Months Ended September 30,	
	2025	2024
Net cash (used in) provided by:		
Operating activities	\$ (33,817)	\$ (31,411)
Investing activities	(9,802)	(71,533)
Financing activities	275	104,819
Net (decrease) increase in cash and cash equivalents	\$ (43,344)	\$ 1,875

Cash flows from operating activities. Net cash used in operating activities was \$33.8 million for the nine months ended September 30, 2025, and primarily related to cash used to fund clinical development, manufacturing and other non-clinical activities for denifanstat, inclusive of trial costs for our Phase 3 program of denifanstat in MASH as well as the Phase 1 PK clinical trial for the combination of denifanstat and resmetirom, clinical development and manufacturing costs for TVB-3567, as well as costs associated with operating as a public company.

Net cash used in operating activities was \$31.4 million for the nine months ended September 30, 2024, and primarily related to cash used to fund clinical development, manufacturing and other non-clinical activities for denifanstat, inclusive of clinical-batch manufacturing and other trial start-up costs for our Phase 3 program of denifanstat in MASH, as well as costs to build out our corporate infrastructure and costs associated with being a public company.

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Cash flows from investing activities - Net cash used in investing activities was \$9.8 million for the nine months ended September 30, 2025 and related to purchases of marketable securities of \$89.8 million, partially offset by proceeds received from the sale and maturity of marketable securities of \$80.0 million.

Net cash used in investing activities was \$71.5 million for the nine months ended September 30, 2024 and related to purchases of marketable securities of \$94.3 million, partially offset by proceeds received from the sale and maturity of marketable securities of \$22.8 million.

Cash flows from financing activities – Net cash provided by financing activities was approximately \$0.3 million for the nine months ended September 30, 2025, relating to proceeds from stock option exercises during the period.

Net cash provided by financing activities was \$104.8 million for the nine months ended September 30, 2024, which primarily related to net cash proceeds of \$105.7 million received from the sale of Series A common stock in our January 2024 follow-on offering and \$0.1 million in proceeds from stock option exercises during the period, offset by the payment of financing costs related to the January 2024 follow-on offering of \$1.0 million.

Critical accounting policies and estimates

We prepare our financial statements in accordance with accounting principles generally accepted in the United States of America. The preparation of financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, costs and expenses and related disclosures. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ significantly from the estimates made and changes in estimates may occur.

During the nine months ended September 30, 2025, there were no material changes to our critical accounting estimates or in the methodology used for estimates from those described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report on Form 10-K for the year ended December 31, 2024.

Emerging growth company and smaller reporting status

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act (the JOBS Act). Under the JOBS Act, emerging growth companies can delay the adoption of new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for emerging growth companies include an exemption from the requirement to provide an auditor’s report on internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, as amended, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation and less extensive disclosure about our executive compensation arrangements. We have elected to use the extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that (i) we are no longer an emerging growth company or (ii) we affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earliest of (i) the last day of our first fiscal year in which we have total annual gross revenues of \$1.235 billion or more, (ii) December 31, 2028, (iii) the date on which we are deemed to be a large accelerated filer, under the rules of the SEC, which means the market value of equity securities that is held by non-affiliates exceeds \$700.0 million as of the prior June 30th and (iv) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

We are also a “smaller reporting company,” meaning that the market value of our stock held by non-affiliates is less than \$700 million and our annual revenue was less than \$100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than \$250 million or (ii) our annual revenue is less than \$100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Recently adopted accounting pronouncements

See “Notes to the Financial Statements—Note 2” included in our unaudited interim financial statements in Item 1 of this Quarterly Report for more information.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this item.

Item 4. Controls and Procedures

Disclosure controls and procedures

We maintain “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, (Exchange Act), that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Quarterly Report. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of September 30, 2025, our disclosure controls and procedures were effective to provide reasonable assurance that the information required to be disclosed by us in this Quarterly Report was (a) reported within the time periods specified by the SEC rules and regulations, and (b) communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding any required disclosure.

Changes in internal control over financial reporting

During the quarter ended September 30, 2025, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which would have a material adverse effect on our results of operations, financial condition or cash flows.

Item 1A. Risk Factors

There have been no material changes in our risk factors from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2024.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Recent sales of unregistered equity securities

There were no unregistered sales of equity securities during the period covered by this quarterly report on Form 10-Q.

Issuer purchases of equity securities

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Rule 10b5-1 trading plans

Except as set forth below, no director or officer (as defined in Rule 16a-1 under the Exchange Act) adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement" (as those terms are defined in Item 408 of Regulation S-K) during the quarter ended September 30, 2025.

- On August 21, 2025, George Kemble, our Chairman of the Board, adopted a Rule 10b5-1 trading plan providing for the sale of up to 371,193 shares of Series A common stock vested under outstanding stock options and 75,376 shares of Series A common stock vested under restricted stock units. Mr. Kemble's Rule 10b5-1 trading plan will remain in effect until the earlier of (i) July 23, 2027; or (ii) the date on which the aggregate 446,569 shares of Series A common stock have been sold under the 10b5-1 trading plan. This trading plan was entered into during an open trading window in accordance with the Company's policies on insider trading and was intended to satisfy Rule 10b5-1(c).

Item 6. Exhibits

Exhibit Number	Description	Method of Filing
10.1	Sales Agreement Dated as of August 14, 2025 between Leerink Partners LLC and Sagimet Biosciences Inc.	Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-41742) filed on August 14, 2025
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith

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31.2	Certification of Principal Financial and Accounting Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
32.1	Certification of Principal Executive Officer and Principal Financial and Accounting Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document	Filed herewith
101.SCH	Inline XBRL Taxonomy Extension Schema Document	Filed herewith
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	Filed herewith
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	Filed herewith
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	Filed herewith
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)	Filed herewith

SIGNATURES

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

SAGIMET BIOSCIENCES, INC.

Date: November 13, 2025

By: /s/ David Happel
David Happel
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 13, 2025

By: /s/ Thierry Chauche
Thierry Chauche
Chief Financial Officer
(Principal Financial and Accounting Officer)

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) OR 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, David Happel, certify that:

1. I have reviewed this Form 10-Q for the Quarterly Period Ended September 30, 2025 of Sagimet Biosciences Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2025

By: /s/ David Happel

David Happel
President and Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) OR 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Thierry Chauche, certify that:

1. I have reviewed this Form 10-Q for the Quarterly Period Ended September 30, 2025 of Sagimet Biosciences Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2025

By: /s/ Thierry Chauche

Thierry Chauche
Chief Financial Officer
(Principal Financial and Accounting Officer)
