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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, 2024

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	**20-5991472**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
155 Bovet Road, Suite 303 San Mateo, California	**94402**
(Address of principal executive offices)	(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	**Trading Symbol(s)**	**Name of each exchange on which registered**
Series A Common Stock, $0.0001 par value per share	SGMT	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 common stock, $0.0001 par value per share, outstanding at November 8, 2024 was 30,674,855.

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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 or any other drug candidates 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, including our planned Phase 3 clinical trials of denifanstat;
- the timing and costs involved in obtaining and maintaining regulatory approval of denifanstat or any other drug candidates 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 or any other future drug candidate;
- our estimate of the number of patients in the United States who suffer from the diseases we target, including metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), and the number of subjects that will enroll in our clinical trials;
- our relationship with Ascletis BioScience Co. Ltd. (Ascletis), 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 and any other drug candidates we may develop, and other positive results;
- our plans relating to commercializing denifanstat and any other drug candidates 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;

- our plans relating to the further development and manufacturing of denifanstat and any other drug candidates we may develop, including additional indications that we may pursue for denifanstat or other drug candidates;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our potential and ability to successfully manufacture and supply denifanstat and any other drug candidates we may develop for clinical trials and for commercial use, if approved;
- the rate and degree of market acceptance of denifanstat and any other drug candidates we may develop, as well as the pricing and reimbursement of denifanstat and any other drug candidates we may develop, if approved;
- our expectations regarding our ability to obtain, maintain, protect and enforce intellectual property protection for denifanstat and for any other future drug candidate;
- 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 Part II, Item 1A. "Risk Factors" and elsewhere in this Quarterly Report. 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.

Explanatory Note

Reflecting the change in disease nomenclature from non-alcoholic fatty liver disease (NAFLD) to metabolic dysfunction-associated steatotic liver disease (MASLD) and from nonalcoholic steatohepatitis (NASH) to metabolic dysfunction-associated steatohepatitis (MASH), we are using MASLD and MASH throughout this document other than when referring to titles of publications or other activities that utilized the term NAFLD or NASH.

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, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 77,014	$ 75,139
Short-term marketable securities	75,472	19,758
Prepaid expenses and other current assets	4,704	1,749
Total current assets	157,190	96,646
Long-term marketable securities	17,471	—
Operating lease right-of-use assets	114	73
Total assets	$ 174,775	$ 96,719
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,152	$ 186
Accrued expenses and other current liabilities (includes nil and $31 payable to related parties as of September 30, 2024 and December 31, 2023, respectively)	2,824	5,403
Operating lease liabilities	116	65
Total current liabilities	4,092	5,654
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, 2024 and December 31, 2023	—	—
Series A common stock, $0.0001 per share: 500,000,000 shares authorized; 30,674,855 and 21,375,402 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	3	2
Series B common stock, $0.0001 per share: 15,000,000 shares authorized; 1,520,490 shares issued and outstanding at September 30, 2024 and December 31, 2023	—	—
Additional paid-in capital	449,349	340,777
Accumulated deficit	(279,110)	(249,744)
Accumulated other comprehensive income	441	30
Total stockholders' equity	170,683	91,065
Total liabilities and stockholders' equity	$ 174,775	$ 96,719

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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
License revenue	$ —	$ 2,000	$ —	$ 2,000
Operating expenses:				
Research and development	12,653	4,958	24,228	14,121
General and administrative	4,249	4,494	12,031	9,153
Total operating expenses	16,902	9,452	36,259	23,274
Loss from operations	(16,902)	(7,452)	(36,259)	(21,274)
Other income (expense):				
Change in fair value of redeemable convertible preferred stock warrant liability	—	—	—	(1)
Change in fair value of Series A common stock warrant liability	—	4	—	4
Interest income and other, net	2,283	1,095	6,893	1,546
Total other income	2,283	1,099	6,893	1,549
Net loss	$ (14,619)	$ (6,353)	$ (29,366)	$ (19,725)
Net loss per share of Series A and Series B common stock outstanding, basic and diluted	$ (0.45)	$ (0.35)	$ (0.95)	$ (3.22)
Weighted-average shares of Series A and Series B common stock outstanding, basic and diluted	32,143,336	18,194,682	31,036,271	6,131,541
Net loss	$ (14,619)	$ (6,353)	$ (29,366)	$ (19,725)
Other comprehensive income:				
Net unrealized income on marketable securities	464	—	411	84
Total comprehensive loss	$ (14,155)	$ (6,353)	$ (28,955)	$ (19,641)

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

SAGIMET BIOSCIENCES INC.

CONDENSED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

(unaudited)
(in thousands, except share amounts)

	Series A Common Stock		Series B Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	Equity
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	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 investments in marketable securities	—	—	—	—	—	—	(23)	(23)
Net loss	—	—	—	—	—	(6,629)	—	(6,629)
Balance at March 31, 2024	30,393,397	$ 3	1,520,490	$ —	$ 446,381	$ (256,373)	$ 7	$ 190,018
Issuance costs related to sale of Series A common stock	—	—	—	—	(27)	—	—	(27)
Stock-based compensation expense	—	—	—	—	1,449	—	—	1,449
Unrealized loss on investments in marketable securities	—	—	—	—	—	—	(30)	(30)
Net loss	—	—	—	—	—	(8,118)	—	(8,118)
Balance at June 30, 2024	30,393,397	$ 3	1,520,490	$ —	$ 447,803	$ (264,491)	$ (23)	$ 183,292
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	30,674,855	$ 3	1,520,490	$ —	$ 449,349	$ (279,110)	$ 441	$ 170,683

	Redeemable Convertible Preferred Stock		Common Stock		Series A Common Stock		Series B Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at January 1, 2023	1,373,730,625	$ 214,620	185,084	$ 1	—	$ —	—	$ —	$ 35,001	$ (221,868)	$ (84)	$ (186,950)
Stock-based compensation expense	—	—	—	—	—	—	—	—	767	—	—	767
Unrealized gain on investments in marketable securities	—	—	—	—	—	—	—	—	—	—	71	71
Net loss	—	—	—	—	—	—	—	—	—	(6,587)	—	(6,587)
Balance at March 31, 2023	1,373,730,625	$ 214,620	185,084	$ 1	—	$ —	—	$ —	$ 35,768	$ (228,455)	$ (13)	$ (192,699)
Exercise of common stock warrants	—	—	25,231	—	—	—	—	—	—	—	—	—
Unrealized gain on investments in marketable securities	—	—	—	—	—	—	—	—	—	—	13	13
Stock-based compensation expense	—	—	—	—	—	—	—	—	1,057	—	—	1,057
Net loss	—	—	—	—	—	—	—	—	—	(6,785)	—	(6,785)
Balance at June 30, 2023	1,373,730,625	$ 214,620	210,315	$ 1	—	$ —	—	$ —	$ 36,825	$ (235,240)	$ —	$ (198,414)
Conversion of redeemable convertible preferred stock to Series A and Series B common stock	(1,373,730,625)	(214,620)	—	—	15,117,912	1	1,520,490	—	214,619	—	—	214,620
Reclass of common stock to Series A common stock	—	—	(210,315)	(1)	210,315	1	—	—	—	—	—	—
Sale of Series A common stock in public offering, net of issuance costs of $10,267	—	—	—	—	6,026,772	—	—	—	86,161	—	—	86,161
Issuance of Series A common stock upon exercise of stock options	—	—	—	—	7,614	—	—	—	6	—	—	6
Exercise of common stock warrants	—	—	—	—	12,789	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	1,855	—	—	1,855
Net loss	—	—	—	—	—	—	—	—	—	(6,353)	—	(6,353)
Balance at September 30, 2023	—	$ —	—	$ —	21,375,402	$ 2	1,520,490	$ —	$ 339,466	$ (241,593)	$ —	$ 97,875

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,	
	2024	2023
Cash flows from operating activities		
Net loss	$ (29,366)	$ (19,725)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accretion of discount on marketable securities	(1,197)	(39)
Non-cash operating lease expense	108	103
Stock-based compensation expense	3,754	3,679
Change in fair value of redeemable convertible preferred stock warrant liability	—	1
Change in fair value of Series A common stock warrant liability	—	(4)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(3,261)	(390)
Accounts payable, accrued expenses and other current liabilities	(1,351)	(200)
Operating lease liabilities	(98)	(108)
Net cash used in operating activities	(31,411)	(16,683)
Cash flows from investing activities		
Purchases of marketable securities	(94,329)	—
Sales and maturities of marketable securities	22,796	32,200
Net cash (used in) provided by investing activities	(71,533)	32,200
Cash flows from financing activities		
Proceeds from sale of Series A common stock, net of issuance costs	105,750	—
Proceeds from initial public offering, net of underwriters' commissions and discounts	—	86,161
Payment of financing costs	(1,045)	—
Proceeds from exercise of stock options	114	6
Net cash provided by financing activities	104,819	86,167
Net increase in cash and cash equivalents	1,875	101,684
Cash and cash equivalents at beginning of period	75,139	158
Cash and cash equivalents at end of period	$ 77,014	$ 101,842
Supplemental non-cash investing and financing activities:		
Deferred financing costs included in accounts payable and accrued expenses	$ 75	$ —
Right-of-use assets obtained in exchange for operating lease obligations	$ 149	$ —

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

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 for the treatment of metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH). In January 2024, the Company announced positive topline results from the Phase 2b FASCINATE-2 clinical trial evaluating denifanstat in biopsy-confirmed MASH patients with stage F2 or F3 fibrosis compared to placebo at week 52. In June 2024, the Company presented additional 52-week intention to treat (ITT) and F3 subgroup efficacy data from the Phase 2b FASCINATE-2 clinical trial.

In October 2024, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation to denifanstat for the treatment of non-cirrhotic MASH with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis). Breakthrough Therapy designation of denifanstat was supported by positive data from the Phase 2b FASCINATE-2 clinical trial in biopsy-confirmed MASH patients with stage 2 or stage 3 fibrosis.

In October 2024, the Company completed successful end-of-Phase 2 interactions with the FDA, supporting the advancement of denifanstat into Phase 3 in MASH. The planned program will include two Phase 3 trials: FASCINATE-3, evaluating patients with F2/F3 (non-cirrhotic) MASH, and FASCINIT, evaluating patients with suspected or confirmed diagnosis of metabolic dysfunction-associated steatotic liver disease (MASLD)/MASH. The Phase 3 program is expected to initiate by the end of 2024.

In addition to MASH, the Company is exploring the use of its FASN inhibitors in acne and in select forms of cancer, diseases in which dysregulation of fatty acid metabolism also plays a key role. Denifanstat is currently being tested in China by the Company's license partner, Ascletis BioScience Co. Ltd. (Ascletis), a subsidiary of Ascletis Pharma Inc. (Ascletis Pharma), in a Phase 3 clinical trial for moderate to severe acne vulgaris and a Phase 3 trial in recurrent glioblastoma multiforme (GBM) in combination with bevacizumab. In November 2024, Ascletis announced completion of enrollment of 480 patients in the acne Phase 3 clinical trial. The Company has completed Investigational New Drug (IND)-enabling studies for a second FASN inhibitor, TVB-3567.

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). Certain prior year amounts have been reclassified to conform to the current year presentation.

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 25, 2024. The accompanying interim financial statements as of September 30, 2024 and for the three and nine months ended September 30, 2024 and 2023 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, 2023 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), preferred stock and common stock valuations prior to the Company's initial public offering of Series A common stock (IPO) 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, 2024, 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, 2024, had an accumulated deficit of $279.1 million and cash, cash equivalents and marketable securities of $170.0 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 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 price of $12.50 per share and received $104.7 million in proceeds, net of issuance costs of $7.8 million.

The Company expects that its cash, cash equivalents and marketable securities as of September 30, 2024 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, if ever. 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.

In August 2024, the Company entered into a Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co. to establish an at-the-market offering (ATM Offering) through which the Company may sell, from time to time at its sole discretion up to $75.0 million of shares of its Series A common stock. There were no sales under the ATM Offering during the three and nine months ended September 30, 2024.

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, 2023, as filed with the SEC on March 25, 2024. Since the date of those audited financial statements, there have been no material changes to the Company's significant accounting policies.

Reverse stock split

A one-for-79.4784 reverse stock split of the Company's issued and outstanding common stock was effected on July 7, 2023. Stockholders entitled to fractional shares as a result of the reverse stock split received a cash payment in lieu of receiving fractional shares. Accordingly, all share and per share amounts for all periods presented in the accompanying unaudited condensed financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the effects of the reverse stock split. Shares of common stock underlying outstanding stock options and common stock warrants were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities. Shares of common stock reserved for issuance upon the conversion of the Company's preferred stock were proportionately reduced and the respective conversion prices were proportionately increased.

Net loss per share and reclassification of common stock

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.

On July 18, 2023, each share of the Company's common stock issued and outstanding became reclassified as one share of Series A common stock. Any stock certificate that immediately prior to July 18, 2023 represented shares of the Company's common stock was deemed to represent shares of Series A common stock, without the need for surrender or exchange thereof. Additionally, in connection with the IPO, the Company's outstanding redeemable convertible preferred stock automatically converted into 15,117,912 shares of Series A common stock and 1,520,490 shares of Series B common stock. The rights of the holders of Series A common stock and Series B common stock are substantially identical, except with respect to voting and conversion. Each share of Series A common stock is entitled to one vote and shares of Series B common stock are non-voting, except as may be required by law. Each share of Series B common stock may be converted at any time into one share of Series A common stock at the option of its holder, subject to certain ownership limitations. As such, basic and diluted net loss per share attributable to common stockholders is presented on a combined basis as undistributed earnings, when allocated to each series of common stock, result in the same net loss per share for all periods presented.

The following table presents the calculation of basic and diluted net loss per share for the three and nine months ended September 30, 2024 and 2023 (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Numerator:				
Net loss	$ (14,619)	$ (6,353)	$ (29,366)	$ (19,725)
Denominator:				
Weighted-average shares of Series A and Series B common stock outstanding, basic and diluted	32,143,336	18,194,682	31,036,271	6,131,541
Net loss per share of Series A and Series B common stock outstanding, basic and diluted	$ (0.45)	$ (0.35)	$ (0.95)	$ (3.22)

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,	
	2024	2023	2024	2023
Options to purchase Series A common stock	4,322,367	3,766,505	4,322,367	3,766,505
Warrants to purchase Series A common stock	1,000	1,000	1,000	1,000
Unvested restricted stock units	844,382	—	844,382	—
Total	5,167,749	3,767,505	5,167,749	3,767,505

Recently adopted accounting pronouncements

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 minimal impact on the Company's financial statements.

In August 2020, the FASB issued ASU No. 2020-06, *Debt-Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40); Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which address issues identified as a result of the complexity associated with applying GAAP for certain financial instruments with characteristics of liabilities and equity. This amendment is effective for fiscal years beginning after December 15, 2023, including interim periods within. The adoption of this standard had no impact on the Company's financial statements and related disclosures.

New accounting pronouncements not yet adopted

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280)—Improvements to Reportable Segment Disclosures*. ASU 2023-07 requires disclosure of incremental segment information on an interim and annual basis and provides new segment disclosure requirements for entities with a single reportable segment. ASU 2023-07 is effective for all public companies for fiscal years beginning after December 15, 2023, and interim periods within fiscal periods beginning after December 15, 2024, and requires retrospective application to all prior periods presented in the financial statements. The Company is assessing the impact of the adoption of this standard on its 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 assessing the impact of the adoption of this standard on its 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, 2024 and December 31, 2023, 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 $76.4 million and $74.1 million as of September 30, 2024 and December 31, 2023, 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 $92.9 million and $19.8 million as of September 30, 2024 and December 31, 2023, respectively. These available for sale securities have expected maturities ranging from 0.3 to 16.8 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, 2024, 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 $69.64 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 Series A common stock warrant liability was immaterial as of September 30, 2024 and December 31, 2023, as well as the change in fair value during the three and nine months ended September 30, 2024 and 2023. There were no transfers within the hierarchy during the periods presented.

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):

		September 30, 2024			
	Valuation Hierarchy	Amortized cost	Unrealized Gains	Unrealized Losses	Fair Value
Assets					
Cash equivalents:					
Money market funds	Level 1	$ 76,427	$ —	$ —	$ 76,427
Total cash equivalents		76,427	—	—	76,427
Short-term marketable securities:					
Commercial paper	Level 2	19,469	56	—	19,525
Corporate debt securities	Level 2	9,442	20	—	9,462
U.S. Treasury securities	Level 2	32,447	133	—	32,580
Agency securities	Level 2	11,396	22	—	11,418
Asset-backed securities	Level 2	2,480	7	—	2,487
Total short-term marketable securities		75,234	238	—	75,472
Long-term marketable securities:					
U.S. Treasury securities	Level 2	12,291	165	—	12,456
Asset-backed securities	Level 2	4,977	38	—	5,015
Total long-term marketable securities		17,268	203	—	17,471
Total cash equivalents and marketable securities		$ 168,929	$ 441	$ —	$ 169,370

	Valuation Hierarchy	December 31, 2023 Amortized cost	Unrealized Gains	Unrealized Losses	Fair Value
Assets					
Cash equivalents:					
Money market funds	Level 1	$ 69,516	$ —	$ —	$ 69,516
Corporate debt securities	Level 2	4,622	—	—	4,622
Total cash equivalents		74,138	—	—	74,138
Short-term marketable securities:					
Commercial paper	Level 2	9,879	19	—	9,898
Corporate debt securities	Level 2	2,945	4	—	2,949
U.S. Treasury securities	Level 2	6,904	7	—	6,911
Total short-term marketable securities		19,728	30	—	19,758
Total cash equivalents and marketable securities		$ 93,866	$ 30	$ —	$ 93,896

4. Prepaid Expenses and Other Current Assets

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

	As of September 30, 2024	As of December 31, 2023
Prepaid clinical costs	$ 2,933	$ —
Prepaid research and development costs	684	767
Prepaid insurance	680	585
Deferred financing costs [1]	306	323
Other	101	74
Total prepaid expenses and other current assets	$ 4,704	$ 1,749

(1) Amount as of September 30, 2024 relates to deferred financing costs related to the ATM Offering entered into during August 2024. Amount as of December 31, 2023 relates to deferred financing costs related to the Company's January 2024 follow-on offering.

5. Accrued Expenses and Other Current Liabilities

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

	As of September 30, 2024	As of December 31, 2023
Accrued payroll-related costs	$ 995	$ 1,105
Accrued clinical costs	814	2,668
Accrued research and development costs	785	632
Accrued general and administrative costs	219	442
Accrued offering costs	—	323
Other	11	233
Total accrued expenses and other current liabilities	$ 2,824	$ 5,403

6. Commitments and Contingencies

License and other agreements

Ascletis BioScience Co. Ltd

In January 2019, the Company entered into a license agreement that became effective in February 2019 with Ascletis BioScience Co. Ltd. (Ascletis), a subsidiary of Ascletis Pharma Inc. (Ascletis Pharma), a biotechnology company incorporated in the Cayman Islands and headquartered in Hangzhou, China. Ascletis 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 Ascletis refers to as ASC40. Under the terms of the license agreement, the Company granted Ascletis and its affiliates an exclusive, royalty-bearing sublicensable 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 Ascletis 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 recognized $2.0 million of revenue related to a development milestone triggered by the initial dosing of a Phase 3 trial for recurrent glioblastoma multiforme (GBM), of which $1.7 million was received from Ascletis in August 2023, net of applicable taxes, which are recorded in general and administrative expense in the statement of operations and comprehensive loss.

In July 2023, the Company entered into an Assignment and Assumption Agreement with Ascletis and Ascletis' affiliate Gannex Pharma Co., Ltd. (Gannex) under which Ascletis, 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.

Contract Research Organization

In June 2024, the Company entered into a contract with a global CRO to perform certain research and related services in connection with certain of the Company's clinical trials and research studies (CRO Services Agreement). The terms of the CRO Services Agreement require the Company to pay to the CRO certain direct fees, investigator grants and other pass-through costs, generally on an upfront prepaid basis. These payments are capitalized at the time of payment and expensed in the period in which the research and development activity is performed. The Company may terminate the CRO Services Agreement or underlying statement of work at will with 60 days' written notice.

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. The lease provides for monthly payments of approximately $12,000 with annual increases. 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.

Operating lease costs were $42,000 and $37,000 for the three months ended September 30, 2024 and 2023, respectively, and $116,000 and $111,000 for the nine months ended September 30, 2024 and 2023, respectively.

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, 2024, 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 is not party to any material legal proceedings as of September 30, 2024.

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, which automatically increased by 855,016 shares on January 1, 2024 and will increase each January 1 thereafter, by (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. As of September 30, 2024, the aggregate maximum number of shares reserved for issuance under the 2023 Plan was 3,440,984, of which 1,729,910 shares were available for future grant. 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 grants of stock-based compensation awards may be issued as inducement for new employees to accept employment offers from the Company or 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). As of September 30, 2024, 364,672 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,	
	2024	2023	2024	2023
Stock options	$ 1,316	$ 1,855	$ 2,903	$ 3,679
Restricted stock units	230	—	851	—
Total stock-based compensation expense	$ 1,546	$ 1,855	$ 3,754	$ 3,679
Included in:				
General and administrative expense	$ 1,311	$ 1,649	$ 3,005	$ 3,103
Research and development expense	235	206	749	576
Total stock-based compensation expense	$ 1,546	$ 1,855	$ 3,754	$ 3,679

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.

The following table summarizes stock option activity for the nine months ended September 30, 2024 (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
Outstanding, January 1, 2024	3,753,507	$ 7.99	7.1	$ 8
Options granted	1,375,296	4.43		
Options exercised	(17,995)	6.36		
Options forfeited/expired	(788,441)	8.50		
Outstanding, September 30, 2024 [1]	4,322,367	$ 6.77	7.5	$ —
Vested and exercisable as of September 30, 2024	2,314,801	$ 7.26	6.3	$ —

(1) Includes 492,729 performance-based options with a weighted-average exercise price of $6.42, of which 490,372 were fully vested and exercisable.

During the nine months ended September 30, 2024 and 2023, the weighted average grant-date fair value per share of stock options granted was $3.42 and $10.28, respectively. The total intrinsic value of stock options exercised during the nine months ended September 30, 2024 and 2023, was $0.1 million and $0.1 million, respectively. Additionally, during the nine months ended September 30, 2024 and 2023, cash received from the exercise of stock options was $0.1 million and approximately $6,000, respectively.

As of September 30, 2024, there was $9.5 million of unrecognized compensation expense, which is expected to be recognized over a remaining weighted-average period of 2.4 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, 2024	1,132,410	$ 2.96
Granted	49,330	5.23
Vested/released	(281,458)	2.96
Forfeited/expired	(55,900)	4.96
Outstanding, September 30, 2024	844,382	$ 2.96

As of September 30, 2024, the total unrecognized compensation expense related to unvested restricted stock units was $2.3 million, which is expected to be recognized over a remaining weighted-average period of 2.8 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,	
	2024	2023
Expected volatility	91 - 96 %	89 - 91 %
Risk-free interest rate	3.9 - 4.5 %	3.6 %
Dividend yield	—	—
Expected term (in years)	5.3 - 6.1	5.0 - 7.0

The expected term of the stock options represents the average of the contractual term of the options and the weighted-average expected vesting period. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant. The expected volatility rate was based on the historical volatilities of comparable companies in the Company's industry. The Company has never declared or paid any cash dividends and does not presently plan to pay cash dividends in the foreseeable future. Consequently, the Company used an expected dividend yield of zero.

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 will automatically increase 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. On January 1, 2024, in accordance with the ESPP, the authorized shares were increased by 213,754 shares for a total of 429,251 shares of Series A common stock available under the ESPP. No shares of Series A common stock have been issued under the ESPP to date.

8. Related Party Transactions

Jinzi J. Wu, Ph.D., a member of the Company's board of directors until June 2024, founded and serves as the chief executive officer of Ascletis, Gannex, and Ascletis Pharma.

During the nine months ended September 30, 2024 and 2023, the Company recognized $0.1 million and nil of expenses, respectively, related to its portion of expenses owed under the Ascletis license agreement, which are recorded in research and development expense in the unaudited condensed statements of operations and comprehensive loss. As of September 30, 2024 and December 31, 2023, the Company recorded nil and $31,000, respectively, of accruals related to the Ascletis license agreement. During the nine months ended September 30, 2024 and 2023, the Company paid Ascletis $0.2 million and nil, respectively, under the Ascletis manufacturing arrangement.

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our unaudited condensed financial statements and related notes included elsewhere in this Report on Form 10-Q for the quarter ended September 30, 2024 (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), formerly known as nonalcoholic steatohepatitis (NASH). Denifanstat has been studied in over 740 people to date in our clinical trials, including our Phase 2 FASCINATE-1 and Phase 2b FASINATE-2 clinical trials.

In January 2024, we announced positive topline results from 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. The Phase 2b FASCINATE-2 clinical trial achieved statistically significant results on primary and multiple secondary endpoints at week 52 in MASH patients in the modified intention to treat (mITT) population, including:

- The primary endpoints of ≥2-point reduction in NAS (NAFLD Activity Score) without worsening of fibrosis (denifanstat 52% vs. placebo 20%, p=0.0003), and MASH resolution without worsening of fibrosis with ≥2-point reduction in NAS (denifanstat 36% vs. placebo 13%, p=0.0044).

- Multiple secondary endpoints of fibrosis improvement by ≥ 1 stage with no worsening of MASH (denifanstat 41% vs. placebo 18%, p=0.0102), MASH resolution with no worsening of fibrosis (denifanstat 38% vs. placebo 16%, p=0.0043), and a greater proportion of MRI-derived proton density fat fraction (MRI-PDFF) ≥30% responders relative to placebo (denifanstat 65% vs. placebo 21%, p<0.0001). MRI-PDFF responders are patients with ≥8% liver fat content at baseline who achieve a ≥30% relative reduction of liver fat at the end of treatment.

Denifanstat showed also statistical significance in fibrosis improvement as measured by an artificial intelligence (AI) digital pathology-based qFibrosis assessment. Additionally, our precision medicine approach is core to our development strategy in MASH and includes the identification of pharmacodynamic and predictive biomarkers to confirm target engagement and clinical response in patients treated with denifanstat.

In June 2024, we presented positive data from the Phase 2b FASCINATE-2 clinical trial of denifanstat versus placebo in biopsy-confirmed MASH patients at the European Association for the Study of the Liver (EASL) Congress. Our EASL presentation included the following 52-week data from the intention to treat (ITT), mITT, and F3 mITT patient populations:

- The primary endpoint of ≥2-point reduction in NAS (NAFLD Activity Score) without worsening of fibrosis (denifanstat 38% vs. placebo 16%, p=0.0035) or MASH resolution with ≥2-point reduction in NAS without worsening of fibrosis (denifanstat 26% vs. placebo 11%, p=0.0173) in the ITT population.

- Secondary endpoints of fibrosis improvement by ≥ 1 stage with no worsening of MASH in the ITT (denifanstat 30% vs. placebo 14%, p=0.040) and F3 mITT (denifanstat 49% vs. placebo 13%, p=0.0032) populations.

- Fibrosis improvement by ≥ 2 stages with no worsening of MASH in the mITT (denifanstat 20% vs. placebo 2%, p=0.0065) and F3 mITT (denifanstat 34% vs. placebo 4%, p=0.0065) populations.

- A statistically significant difference in progression to cirrhosis (F4) in 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-1RA (denifanstat 42% vs. placebo 0%, p=0.034) in the mITT population.

- A statistically significant increase in beneficial polyunsaturated triglycerides at the end of 52 week of treatment (+42% denifanstat vs. -4% placebo, p<0.001) in the mITT population.

- A biomarker of denifanstat activity (tripalmitin) showed an early and sustained reduction in de novo lipogenesis at 4-weeks (-2.4ug/ml with denifanstat vs. -0.4ug/mL placebo, p=0.001) and 13-weeks (-2.2ug/mL with denifanstat vs. -0.1ug/mL placebo, p=0.005) in the ITT population.

In October 2024, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation to denifanstat for the treatment of non-cirrhotic MASH with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis). Treatments that receive Breakthrough Therapy designation must target a serious or life-threatening disease and preliminary clinical evidence must indicate that the drug may demonstrate a substantial improvement over existing therapies on one or more clinically significant endpoints. Breakthrough Therapy designation of denifanstat was supported by positive data from the Phase 2b FASCINATE-2 clinical trial in biopsy-confirmed MASH patients with stage 2 or stage 3 fibrosis.

In October 2024, we completed successful end-of-Phase 2 interactions with the FDA, supporting the advancement of denifanstat into Phase 3 in MASH. Based on our ongoing discussions with the FDA, the phase 3 program will consist of two double-blind, placebo-controlled multicenter registrational trials:

- FASCINATE-3 in patients with F2/F3 (non-cirrhotic) MASH: The trial is expected to evaluate the efficacy and safety of denifanstat in this population, with primary endpoints being liver biopsy assessments at 52 weeks, at which time Sagimet plans to seek accelerated approval in the U.S. and Europe. The trial will continue until such point in time that the required number of clinical outcomes is reached, which we estimate at 3.5 years.

- FASCINIT in patients with suspected or confirmed diagnosis of metabolic dysfunction-associated steatotic liver disease (MASLD)/MASH: The trial is expected to evaluate the efficacy and safety of denifanstat in this population, with primary endpoints being safety and tolerability at 52 weeks. Non-invasive biomarkers will be assessed as part of the secondary endpoints, with no liver biopsy endpoint.

The Phase 3 program is designed to comprise a minimum of 1,800 patients exposed to denifanstat and is expected to initiate by the end of 2024.

We are also evaluating the promise of FASN inhibition, beyond MASH, in additional disease areas in which dysregulation of fatty acid metabolism also plays a key role, including in acne and certain forms of cancer. Denifanstat is currently being tested in China by our license partner, Ascletis BioScience Co. Ltd. (Ascletis), a subsidiary of Ascletis Pharma Inc. (Ascletis Pharma), in a Phase 3 clinical trial for moderate to severe acne vulgaris and a Phase 3 clinical trial in recurrent glioblastoma multiforme (GBM) in combination with bevacizumab. In November 2024, Ascletis announced completion of enrollment of 480 patients in the acne Phase 3 clinical trial and that it expects to announce topline results in the second quarter of 2025. We expect these results to inform our development strategy in these indications. We have completed Investigational New Drug (IND)-enabling studies for a second FASN inhibitor, TVB-3567.

Components of results of operations

License revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from product sales for the foreseeable future. Our revenues to date have been generated solely from the license agreement with Ascletis. We expect that our revenue for the next several years will be derived primarily from this agreement and any additional collaboration into which we may enter.

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 personnel-related costs (such as salaries, employee benefits and stock-based compensation) for our personnel in research and development functions; 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.

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 substantially 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, 2024 and 2023

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

	Three Months Ended September 30,			
	2024	2023	$ Change	% Change
License revenue	$ —	$ 2,000	$ (2,000)	(100)%
Operating expenses:				
Research and development	12,653	4,958	7,695	155 %
General and administrative	4,249	4,494	(245)	(5)%
Total operating expenses	16,902	9,452	7,450	79 %
Loss from operations	(16,902)	(7,452)	(9,450)	127 %
Total other income	2,283	1,099	1,184	nm
Net loss	$ (14,619)	$ (6,353)	$ (8,266)	130 %

nm—not meaningful

License revenue – License revenue for the three months ended September 30, 2023 was $2.0 million, recognized from the license agreement with Ascletis. We did not recognize any license revenue during the three months ended September 30, 2024.

Research and development – Research and development expense increased by $7.7 million, or 155%, for the three months ended September 30, 2024, compared to the three months ended September 30, 2023. This increase was primarily due to (i) a $5.5 million net increase in clinical trial expenses related primarily to start-up costs incurred for our Phase 3 program of denifanstat in MASH, which was 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) a $1.3 million increase in manufacturing costs for clinical batches of denifanstat in preparation for the Phase 3 clinical development program, and (iii) a $0.9 million increase in other non-clinical study costs for denifanstat.

General and administrative – General and administrative expenses decreased by $0.2 million, or 5%, for the three months ended September 30, 2024, compared to the three months ended September 30, 2023 primarily due to (i) a $0.3 million decrease in stock-based compensation expense and (ii) a $0.2 million decrease in tax expense recognized in conjunction with the development milestone received from Ascletis under the Ascletis license agreement in July 2023. This decrease in general and administrative expenses was partially offset by a $0.3 million increase in professional fees largely due to public company compliance activities.

Other income – Other income increased by $1.2 million for the three months ended September 30, 2024, compared to the three months ended September 30, 2023, primarily due to an increase of interest income earned on the cash proceeds received from our initial public offering (IPO) and the January 2024 follow-on offering.

Comparison of the nine months ended September 30, 2024 and 2023

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

	Nine Months Ended September 30,			
	2024	2023	$ Change	% Change
License revenue	$ —	$ 2,000	$ (2,000)	(100)%
Operating expenses:				
Research and development	24,228	14,121	10,107	72 %
General and administrative	12,031	9,153	2,878	31 %
Total operating expenses	36,259	23,274	12,985	56 %
Loss from operations	(36,259)	(21,274)	(14,985)	70 %
Total other income	6,893	1,549	5,344	nm
Net loss	$ (29,366)	$ (19,725)	$ (9,641)	49 %

nm—not meaningful

License revenue – License revenue for the nine months ended September 30, 2023 was $2.0 million, recognized from the license agreement with Ascletis. We did not recognize any license revenue during the nine months ended September 30, 2024.

Research and development – Research and development expense increased by $10.1 million, or 72%, for the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023. This increase was primarily due to (i) a $4.5 million increase in manufacturing costs for clinical batches of denifanstat in preparation for the Phase 3 clinical development program, (ii) a $3.8 million net increase in clinical trial expenses primarily related to start-up costs incurred for our Phase 3 program of denifanstat in MASH, which was 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, and (iii) a $1.5 million increase in other non-clinical study costs for denifanstat.

General and administrative – General and administrative expenses increased by $2.9 million, or 31%, for the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023 primarily due to (i) a $1.7 million increase in professional fees, largely due to public company compliance, (ii) a $0.4 million increase in personnel related expenses, largely driven by an increase in headcount, and (iii) a $0.5 million increase in insurance expenses due to our transition to a public company in 2023.

Other income – Other income increased by $5.3 million for the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023, primarily due to an increase of interest income earned on the cash proceeds received from our IPO and the January 2024 follow-on offering.

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 Ascletis.

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 these public offerings, 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 (ATM Offering) through which we may sell, from time to time at our sole discretion up to $75.0 million of shares of our Series A common stock. There were no sales under the ATM Offering during the three and nine months ended September 30, 2024.

As of September 30, 2024, we had cash, cash equivalents and marketable securities of $170.0 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;
- 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, 2024, 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,	
	2024	2023
Net cash (used in) provided by:		
Operating activities	$ (31,411)	$ (16,683)
Investing activities	(71,533)	32,200
Financing activities	104,819	86,167
Net increase in cash and cash equivalents	$ 1,875	$ 101,684

Cash flows from operating activities. 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.

Net cash used in operating activities was $16.7 million for the nine months ended September 30, 2023 and primarily related to cash used to fund clinical development and other pre-clinical activities for denifanstat, primarily relating to the Phase 2b FASCINATE-2 trial for which topline results were announced in January 2024, as well as other costs to support our corporate infrastructure. Cash expenses were offset by the net $1.7 million development milestone received from Ascletis in connection with the Ascletis license agreement during the nine months ended September 30, 2023.

Cash flows from investing activities - 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.

Net cash provided by investing activities was $32.2 million for the nine months ended September 30, 2023, which related solely to proceeds received from sales of marketable securities.

Cash flows from financing activities - 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.

Net cash provided by financing activities was $86.2 million for the nine months ended September 30, 2023, which related primarily to the proceeds received from our IPO, net of underwriters' commissions and discounts.

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, 2024, 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, 2023.

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 Note 2. Significant Accounting Policies, 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, 2024, 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, 2024, 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, nor are we aware of any governmental proceedings involving potential monetary sanctions.

Item 1A. Risk Factors

Our business is subject to substantial risks and uncertainties. You should carefully consider the information contained in this Quarterly Report on Form 10-Q, the risks and uncertainties described below, and the risk factors and other information contained in our other public filings in evaluating our business, including our Annual Report on Form 10-K for the year ended December 31, 2023, which was filed with the SEC on March 25, 2024.

Although we have received Breakthrough Therapy designation for denifanstat, this may not lead to a faster development, regulatory review or approval process, and it does not increase the likelihood of receiving marketing approval in the United States.

In October 2024, the FDA granted Breakthrough Therapy designation to denifanstat for the treatment of non-cirrhotic MASH with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis). A Breakthrough Therapy is defined as a therapy that is intended, alone or in combination with one or more other therapies, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For therapies that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Therapies designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval.

The Breakthrough Therapy designation we have obtained for denifanstat may not result in faster development processes, reviews or approvals compared to therapies considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, the FDA may later decide that our denifanstat development program no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. In addition, the FDA may later decide that denifanstat no longer meets the conditions for qualification.

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.

Use of proceeds from initial public offering of common stock

On July 18, 2023, we completed our IPO. Our registration statement on Form S-1 (File No. 333-256648) relating to the IPO was declared effective by the SEC on July 13, 2023. We issued an aggregate of 5,312,500 shares of our Series A common stock at a price of $16.00 per share. The aggregate gross proceeds of the IPO were $96.4 million, inclusive of an additional 714,272 shares of Series A common stock sold upon the partial exercise of the underwriters' purchase option. We received approximately $86.2 million in net proceeds after deducting approximately $6.7 million in underwriting discounts and commissions and approximately $3.5 million in other offering costs. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates, or to our affiliates. Goldman Sachs & Co., Cowen and Company and Piper Sandler & Co. acted as joint book-running managers for the IPO, and JMP Securities acted as lead manager.

There has been no material change in our planned use of the net proceeds from the IPO as described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on July 17, 2023.

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

During the quarter ended September 30, 2024, none of our directors or officers (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).

Item 6. Exhibits

Exhibit Number	Description	Method of Filing
10.1	Controlled Equity Offering℠ Sales Agreement, dated as of August 15, 2024, by and between Sagimet Biosciences Inc. and Cantor Fitzgerald & Co.	Incorporated by reference to Exhibit 1.2 to the Company's Registration Statement on Form S-3 filed on August 15, 2024 (File No. 001-281582)
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
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 2022	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 14, 2024

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

Date: November 14, 2024

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

Exhibit 31.1

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, 2024 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)) 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. 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

    c. 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 14, 2024

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

Exhibit 31.2

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, 2024 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)) 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. 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

    c. 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 14, 2024

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

Exhibit 32.1

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Sagimet Biosciences Inc. (the "Company") for the quarterly period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of their knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 14, 2024

By: /s/ David Happel

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

Date: November 14, 2024

By: /s/ Thierry Chauche

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