

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2025

OR

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

For the transition period from _____ to _____

Commission file number 001-41614

MINERALYS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

84-1966887

(I.R.S. Employer Identification No.)

150 N. Radnor Chester Rd, Suite F200, Radnor, PA 19087

(Address, including zip code, of principal executive offices)

888-378-6240

(Registrant's telephone number, including area code)

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, \$0.0001 par value per share	MLYS	The Nasdaq Stock Market LLC

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 ☒

As of November 3, 2025, there were 79,139,956 shares of the registrant's common stock outstanding.

Mineralys Therapeutics, Inc.
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Part I - Financial Information
Item 1. Financial Statements

Mineralys Therapeutics, Inc.
Condensed Balance Sheets
(in thousands, except share and per share amounts)

	September 30, 2025 (unaudited)	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	\$ 217,597	\$ 114,091
Investments	376,031	84,096
Prepaid and other current assets	6,168	7,164
Total current assets	599,796	205,351
Property and equipment, net	7	53
Other assets	144	499
Total assets	<u>\$ 599,947</u>	<u>\$ 205,903</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,121	\$ 479
Accrued liabilities	22,399	14,167
Total current liabilities	23,520	14,646
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Common stock, \$0.0001 par value; 500,000,000 shares authorized as of September 30, 2025 and December 31, 2024; 78,969,459 and 49,821,915 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	8	5
Additional paid-in capital	1,001,354	493,770
Accumulated deficit	(424,935)	(302,518)
Total stockholders' equity	576,427	191,257
Total liabilities and stockholders' equity	<u>\$ 599,947</u>	<u>\$ 205,903</u>

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

Mineralys Therapeutics, Inc.
Condensed Statements of Operations
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	\$ 31,450	\$ 53,985	\$ 107,607	\$ 124,012
General and administrative	9,681	6,121	24,717	16,624
Total operating expenses	41,131	60,106	132,324	140,636
Loss from operations	(41,131)	(60,106)	(132,324)	(140,636)
Interest income, net	4,195	3,774	9,908	11,779
Other income (expense)	4	(10)	(1)	(7)
Total other income, net	4,199	3,764	9,907	11,772
Net loss	\$ (36,932)	\$ (56,342)	\$ (122,417)	\$ (128,864)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.52)	\$ (1.13)	\$ (1.94)	\$ (2.68)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	70,594,504	49,815,186	63,133,634	48,063,638

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

Mineralys Therapeutics, Inc.
Condensed Statements of Stockholders' Equity
(in thousands, except share data)
(unaudited)

	Common Stock		Additional Paid-In-Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance as of December 31, 2023	41,133,916	\$ 4	\$ 365,858	\$ (124,708)	\$ 241,154
Issuance of common stock and pre-funded warrants in private placement offering, net of offering costs of \$3,941	8,339,169	1	116,058	—	116,059
Issuance of common stock from stock option exercises	159,904	—	149	—	149
Stock-based compensation	—	—	2,191	—	2,191
Net loss	—	—	—	(31,508)	(31,508)
Balance as of March 31, 2024	49,632,989	5	484,256	(156,216)	328,045
Issuance of common stock from stock option exercises	58,717	—	54	—	54
Issuance of common stock for cash under employee stock purchase plan	18,892	—	138	—	138
Stock-based compensation	—	—	2,872	—	2,872
Net loss	—	—	—	(41,014)	(41,014)
Balance as of June 30, 2024	49,710,598	5	487,320	(197,230)	290,095
Issuance of common stock from stock option exercises	45,348	—	40	—	40
Stock-based compensation	—	—	3,139	—	3,139
Net loss	—	—	—	(56,342)	(56,342)
Balance as of September 30, 2024	49,755,946	\$ 5	\$ 490,499	\$ (253,572)	\$ 236,932

Mineralys Therapeutics, Inc.
Condensed Statements of Stockholders' Equity (Continued)
(in thousands, except share data)
(unaudited)

	Common Stock		Additional Paid-In-Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance as of December 31, 2024	49,821,915	\$ 5	\$ 493,770	\$ (302,518)	\$ 191,257
Issuance of common stock in public offering, net of offering costs of \$12,509	14,907,406	1	188,740	—	188,741
Issuance of common stock from stock option exercises	146,907	—	123	—	123
Stock-based compensation	—	—	3,645	—	3,645
Net loss	—	—	—	(42,211)	(42,211)
Balance as of March 31, 2025	64,876,228	6	686,278	(344,729)	341,555
Issuance of common stock pursuant to ATM Agreement, net of issuance costs of \$46	674,518	—	9,496	—	9,496
Issuance of common stock from stock option exercises	161,059	—	1,079	—	1,079
Issuance of common stock for cash under employee stock purchase plan	13,604	—	142	—	142
Stock-based compensation	—	—	4,553	—	4,553
Net loss	—	—	—	(43,274)	(43,274)
Balance as of June 30, 2025	65,725,409	6	701,548	(388,003)	313,551
Issuance of common stock in public offering, net of offering costs of \$17,932	11,274,509	2	269,566	—	269,568
Issuance of common stock pursuant to ATM Agreement, net of issuance costs of \$88	1,239,522	—	17,775	—	17,775
Issuance of common stock from stock option exercises	730,019	—	6,624	—	6,624
Stock-based compensation	—	—	5,841	—	5,841
Net loss	—	—	—	(36,932)	(36,932)
Balance as of September 30, 2025	78,969,459	\$ 8	\$ 1,001,354	\$ (424,935)	\$ 576,427

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

Mineralys Therapeutics, Inc.
Condensed Statements of Cash Flows
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2025	2024
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (122,417)	\$ (128,864)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accretion of discount on held-to-maturity securities	(5,671)	(8,068)
Stock-based compensation	14,039	8,202
Depreciation and amortization	46	28
Changes in operating assets and liabilities:		
Accrued interest receivable	15	326
Prepaid, other current assets, and other assets	902	8,068
Accounts payable and accrued liabilities	8,558	20,837
Net cash used in operating activities	(104,528)	(99,471)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of marketable securities	(546,264)	(309,515)
Maturities of marketable securities	260,000	341,000
Purchases of property and equipment	—	(96)
Net cash used in investing activities	(286,264)	31,389
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock in September 2025 public offering, net of offering costs	270,200	—
Proceeds from issuance of common stock in March 2025 public offering, net of offering costs	188,880	—
Proceeds from issuance of common stock pursuant to ATM Agreement, net of issuance costs	27,336	—
Proceeds from stock option exercises	7,826	243
Proceeds from issuance of common stock for cash under employee stock purchase plan	142	138
Payment of shelf offering costs	(86)	(388)
Proceeds from issuance of common stock and pre-funded warrants in a private placement offering, net of offering costs	—	116,059
Net cash provided by financing activities	494,298	116,052
Net increase in cash and cash equivalents	103,506	47,970
Cash and cash equivalents - beginning	114,091	49,304
Cash and cash equivalents - ending ⁽¹⁾	\$ 217,597	\$ 97,274
Supplement Disclosure of Non-Cash Financing Activities:		
Offering costs included in accounts payable and accrued liabilities	\$ 317	\$ —

(1) Cash and cash equivalents as of September 30, 2025 exclude investments of \$ 376.0 million. Cash, cash equivalents, and investments amounted to \$ 593.6 million as of September 30, 2025.

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

Mineralys Therapeutics, Inc.
Notes to Condensed Financial Statements
(unaudited)

Note 1. Nature of Business

Mineralys Therapeutics, Inc. (the Company) is a clinical-stage biopharmaceutical company focused on developing medicines to target diseases driven by dysregulated aldosterone. The Company's clinical-stage product candidate, lorundrostat, is a proprietary, orally administered, aldosterone synthase inhibitor that the Company is developing for the treatment of cardiorenal conditions affected by dysregulated aldosterone, including hypertension and related comorbidities, such as chronic kidney disease and obstructive sleep apnea. This year, the Company completed two pivotal clinical trials of lorundrostat for the treatment of uncontrolled or resistant hypertension and a Phase 2 trial of lorundrostat in hypertensive participants with Stage 2 to 3b chronic kidney disease. The Company is also conducting a Phase 2 trial of lorundrostat in hypertensive participants with obstructive sleep apnea. The Company was incorporated as a Delaware corporation in May 2019, and it is headquartered in Radnor, Pennsylvania. The Company's operations to date have been limited to business planning, raising capital, in-licensing, conducting preclinical and clinical trials, and other research and development.

Liquidity and Capital Resources

Since its inception, the Company has not generated any revenue from product sales or other sources and has incurred significant operating losses and negative cash flows from operations. The Company's primary uses of cash to date have been to fund research and development activities, business planning, establishing and maintaining the Company's intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations. As of September 30, 2025, the Company had an accumulated deficit of \$424.9 million and cash, cash equivalents, and investments of \$593.6 million. For the nine months ended September 30, 2025, the Company had a net loss of \$122.4 million and net cash used in operating activities of \$104.5 million.

Since inception, the Company has funded its operations by raising aggregate gross proceeds of approximately \$1.0 billion from the sale of the Company's common stock, convertible preferred stock, convertible notes, and pre-funded warrants. The Company has a limited operating history, and the sales and income potential of its business is unproven. The Company expects to continue to incur substantial losses in the foreseeable future as a result of the Company's research and development and other activities. Additional funding will be required in the future to continue with the Company's planned research and development and other activities. The Company expects to finance its operations through equity offerings, debt financings, and other capital sources, including potential strategic collaborations, licensing, and other similar arrangements. The Company believes that its cash, cash equivalents, and investments as of September 30, 2025 will be sufficient to allow the Company to fund operations for at least twelve months from the issuance date of these condensed financial statements.

Note 2. Summary of Significant Accounting Policies*Basis of Presentation*

The unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) and applicable rules and regulations of the U.S. Securities and Exchange Commission (SEC) for interim reporting. As permitted under those rules and regulations, certain footnotes or other financial information normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. These condensed financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, which are necessary for a fair presentation of the Company's financial information. These unaudited condensed financial statements should be read in conjunction with the audited financial statements and related notes in the Company's Annual Report on Form 10-K for the year ended December 31, 2024.

Mineralys Therapeutics, Inc.
Notes to Condensed Financial Statements
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Any reference in these notes to applicable guidance is meant to refer to authoritative U.S. GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Updates of the Financial Accounting Standards Board (FASB).

Segment Information

The Company operates in one operating segment for the purposes of assessing performance, making operating decisions, and allocating Company resources. The Company's chief operating decision maker (CODM) is its chief executive officer, who considers net loss to evaluate overall expenses associated with conducting research and development activities, which includes evaluating the progress of ongoing clinical trials and the planning and execution of current and future research and development and other activities. Further, the CODM reviews and utilizes functional expenses (research and development and general and administrative) as reported in the statements of operations to manage the Company's operations. Other segment items included in net loss are interest income, net and other income (expense). These measures of performance, significant expenses, and other items are each reflected in the statements of operations. The accounting policies of the segment are the same as those described below. The measure of segment assets is reported on the balance sheets as total assets. All assets are held in the United States.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of income and expenses during the reporting period. Actual results could differ from those estimates. Estimates have been used in the following areas, among others: research and development accruals and income taxes.

Cash and Cash Equivalents

All highly liquid investments that have maturities of 90 days or less at the date of purchase are classified as cash equivalents. The Company's cash and cash equivalents balances as of September 30, 2025 and December 31, 2024 include cash balances and amounts held primarily in interest-bearing money market accounts and U.S. Treasury bills. As of September 30, 2025 and December 31, 2024, the Company did not have any restricted cash balances. The following table provides a reconciliation of cash and cash equivalents as reported in the condensed statements of cash flows to the condensed balance sheets (in thousands):

	September 30, 2025	December 31, 2024
Cash	\$ 1,213	\$ 664
Cash equivalents	216,384	113,427
Total cash and cash equivalents	<u>\$ 217,597</u>	<u>\$ 114,091</u>

Concentration of Credit Risk

The Company has no significant off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts, or other hedging arrangements. Financial instruments that potentially subject the Company to concentrations of credit risk primarily consist of cash balances in several accounts with three financial institutions that, from time to time, are in excess of federally insured limits.

Fair Value Measurements

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. ASC Topic 820, Fair Value Measurement, establishes a hierarchy of inputs used in measuring fair value that maximizes the use of

Mineralys Therapeutics, Inc.
Notes to Condensed Financial Statements
(unaudited)

observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available.

Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value and is not a measure of the investment credit quality. The three levels of the fair value hierarchy are described below:

- Level 1 – quoted prices in active markets for identical assets and liabilities
- Level 2 – other significant observable inputs (including quoted prices for similar assets and liabilities, interest rates, credit risk, etc.)
- Level 3 – significant unobservable inputs (including the Company's own assumptions in determining the fair value of assets and liabilities)

For certain financial instruments, including cash and cash equivalents, prepaid expenses, accounts payable, and certain accrued liabilities, the recorded amount approximates estimated fair value due to their relatively short maturity period. Refer to Note 3, "*Fair Value of Financial Instruments*" for additional details of the Company's financial instruments.

Investments

The Company generally invests its excess cash in money market funds and investment-grade short- and long-term fixed-income debt securities, such as U.S. Treasury bills. Such investments are included in cash and cash equivalents and investments in the condensed balance sheets.

The Company determines the appropriate classification of short-term and long-term securities at the time of purchase and re-evaluates such designation as of each balance sheet date. Securities are classified as held-to-maturity when the Company has the positive intent and ability to hold the securities to maturity. Held-to-maturity securities are carried at amortized cost, adjusted for the accretion of discounts using the interest method.

The Company invested in marketable securities during the nine months ended September 30, 2025 and 2024, and no impairment charges were recorded. For held-to-maturity investments, the Company periodically reviews each individual security position that has an unrealized loss, or impairment, to determine if that impairment is other-than-temporary. If the Company believes an impairment of a security position is other than temporary, based on available quantitative and qualitative information as of the report date, the loss will be recognized within total other income, net in the Company's condensed statements of operations, and a new cost basis in the investment will be established.

Deferred Offering Costs

The Company capitalizes certain legal, professional, accounting, and other third-party fees that are directly associated with in-process equity issuances as deferred offering costs until such equity issuances are consummated. After consummation of the equity issuance, these costs are recorded as a reduction in the capitalized amount associated with the equity issuance. Should the equity issuance be abandoned, the deferred offering costs are expensed immediately as a charge to operating expenses in the condensed statements of operations. Deferred offering costs as of September 30, 2025 and December 31, 2024 were \$0 and \$0.4 million, respectively. Such costs are classified in other assets on the condensed balance sheets.

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Notes to Condensed Financial Statements
(unaudited)

Stock-Based Compensation

The Company accounts for its stock-based compensation awards in accordance with ASC Topic 718, Compensation – Stock Compensation (ASC 718). ASC 718 requires all stock-based payments to employees, including grants of employee stock options, to be recognized in the condensed statements of operations based on their fair values. The Company's stock-based awards are subject only to service-based vesting conditions. The Company measures restricted common stock awards using the difference, if any, between the purchase price per share of the award and the fair value of the Company's common stock at the date of the grant or modification. The Company estimates the fair value of its stock option awards using the Black-Scholes option pricing model, which requires the input of assumptions, including (i) the expected stock price volatility, (ii) the calculation of the expected term of the award, (iii) the risk-free interest rate, and (iv) expected dividends.

Volatility — Due to the Company's limited operating history and a lack of company-specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar publicly-traded companies. The Company believes that the companies in the group were most representative of the Company and had characteristics similar to its own, including stage of product development, a focus on the life sciences industry, and other economic and industry characteristics.

Expected Term — The Company uses the simplified method to calculate the expected term, as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term for options granted, and utilizes the contractual term for options granted.

Risk-Free Interest Rate — The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected life of the stock options.

Expected Dividends — To date, the Company has not issued any dividends and does not expect to issue dividends over the life of the options and therefore has estimated the dividend yield to be zero.

Subsequent to the closing of the Company's initial public offering of its common stock in February 2023 (IPO), the Company determines the fair market value of its common stock using the closing price of its common stock as reported on the Nasdaq Global Select Market. The assumptions underlying these valuations represented management's best estimate, with the assistance of a third-party valuation specialist, which involved inherent uncertainties and the application of management's judgment. As a result, if the Company had used different assumptions or estimates, the fair value of the Company's common stock and its stock-based compensation expense could have been materially different.

Compensation expense related to awards is recognized on a straight-line basis by recognizing the grant date fair value over the associated service period of the award, which is generally the vesting term. Management evaluates its award grants and modifications and will adjust the fair value if any are determined to be spring-loaded. The Company accounts for forfeitures as they occur.

Net Loss Per Share

The Company's basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period. The diluted net loss per share attributable to common stockholders is computed by giving effect to all potential common stock equivalents outstanding for the period determined using the treasury stock method. For purposes of this calculation, unvested restricted stock awards and stock options to purchase common stock are considered to be common stock equivalents but have been excluded from the calculation of diluted net loss per share attributable to common stockholders as their effect is anti-dilutive. The weighted-average number of common shares used in the basic and diluted net loss per share attributable to common stockholders calculations includes the weighted-average pre-funded warrants outstanding during the period, as they are exercisable at any time for nominal cash consideration. The following table sets forth the potential

Mineralys Therapeutics, Inc.
Notes to Condensed Financial Statements
(unaudited)

common shares excluded from the calculation of net loss per share attributable to common stockholders because their inclusion would be anti-dilutive:

	Nine Months Ended September 30,	
	2025	2024
Outstanding options	6,612,340	4,677,742
Unvested restricted stock awards	186,872	450,478
Total	6,799,212	5,128,220

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which expands annual and interim disclosure requirements for reportable segments, including public entities with a single reportable segment, primarily through enhanced disclosures about significant segment expenses. The Company adopted this standard for the Company's fiscal year 2024 annual reporting period, and it is applicable to interim periods thereafter.

In November 2024, the FASB issued ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses (ASU 2024-03), and in January 2025, the FASB issued ASU 2025-01, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Clarifying the Effective Date, which clarified the effective date of ASU 2024-03. ASU 2024-03 will require the Company to disclose additional information about specific expense categories in the notes to the financial statements on an annual and interim basis. ASU 2024-03 is effective for the Company's fiscal year 2027 and may be adopted on a prospective or retrospective basis. Early adoption is permitted. The Company is evaluating the impact of ASU 2024-03 on its financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740) - Improvements to Income Tax Disclosures. The new standard requires a company to expand its existing income tax disclosures, specifically related to the rate reconciliation and income taxes paid. The standard is effective for the Company beginning in fiscal year 2025. The Company does not expect to early adopt this new accounting standard. The new standard is expected to be applied prospectively, but retrospective application is permitted. The Company is currently evaluating the impact of ASU 2023-09 on its financial statements and related disclosures.

Note 3. Fair Value of Financial Instruments

The following table presents financial instruments measured at fair value on a recurring basis based on the fair value hierarchy as of September 30, 2025 and December 31, 2024 (in thousands):

	September 30, 2025	December 31, 2024
	Level 1	
Assets		
Cash equivalents		
Money market funds	\$ 111,936	\$ 83,602

There were no transfers within the fair value hierarchy during the periods presented.

Mineralys Therapeutics, Inc.
Notes to Condensed Financial Statements
(unaudited)

The following methods and assumptions were used by the Company in estimating the fair values of each class of financial instrument disclosed herein:

Money Market Funds—The carrying amounts of money market funds reported as cash and cash equivalents in the condensed balance sheets approximate their fair values due to their short-term nature. The fair values of money market funds are determined by Level 1 inputs utilizing quoted prices (unadjusted) in active markets for identical assets.

U.S. Treasury Bills—As of September 30, 2025 and December 31, 2024, the Company had short-term U.S. Treasury bills. Fair values of these securities are determined by Level 2 inputs utilizing quoted prices (unadjusted) in active markets for similar assets. The following table presents information about the Company's investments in held-to-maturity U.S. Treasury bills as of each reported date (in thousands):

Balance Sheet Location	Original Maturities	As of September 30, 2025	
		Amortized Cost	Estimated Fair Value
Cash and cash equivalents	less than 3 months	\$ 104,448	\$ 104,445
Investments	between 3 and 12 months	376,031	376,063
Total		<u>\$ 480,479</u>	<u>\$ 480,508</u>

Balance Sheet Location	Original Maturities	As of December 31, 2024	
		Amortized Cost	Estimated Fair Value
Cash and cash equivalents	less than 3 months	\$ 29,825	\$ 29,829
Investments	between 3 and 12 months	84,096	84,123
Total		<u>\$ 113,921</u>	<u>\$ 113,952</u>

Note 4. Commitments and Contingencies

License Agreement with Mitsubishi Tanabe

In July 2020, the Company entered into a license agreement (the Mitsubishi License) with Mitsubishi Tanabe Pharmaceutical Company (Mitsubishi Tanabe), pursuant to which Mitsubishi Tanabe granted the Company an exclusive, worldwide, royalty-bearing, sublicensable license under Mitsubishi Tanabe's patent and other intellectual property rights to exploit products incorporating lorundrostat (formerly MT-4129) (Lorundrostat Products) for the prevention, treatment, diagnosis, detection, monitoring, or predisposition testing with respect to indications, diseases, and conditions in humans. Pursuant to the Mitsubishi License, the Company paid Mitsubishi Tanabe a \$1.0 million upfront fee and development milestone payments of \$9.0 million in the aggregate. The Company has remaining obligations to pay Mitsubishi Tanabe commercial milestone payments of up to \$155.0 million in the aggregate upon first commercial sale and upon meeting certain annual sales targets, as well as additional commercial milestone payments of up to \$10.0 million for a second indication. Additionally, the Company is obligated to pay Mitsubishi Tanabe tiered royalties at percentages ranging from the mid-single-digits to ten percent (10%) of aggregate net sales of each Lorundrostat Product on a Lorundrostat Product-by-Lorundrostat Product and country-by-country basis, until the later of (i) the expiration of the last-to-expire valid Mitsubishi Tanabe patent claim covering a Lorundrostat Product, (ii) ten years from the first commercial sale of a Lorundrostat Product, or (iii) the expiration of regulatory exclusivity in such country. Such royalties are subject to reduction under specified conditions, including lack of patent coverage and generic competition.

The Company has no remaining development milestone obligations under the Mitsubishi License and did not incur any development or commercial expenses pursuant to the Mitsubishi License during the three or nine months ended September 30, 2025 and 2024.

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The Company is obligated to use commercially reasonable efforts to conduct and complete the development activities and to file for regulatory approval for at least one Lorundrostat Product in a major market country and consider in good faith developing at least one Lorundrostat Product in a non-major market country. If the Company elects to sublicense its rights under the Mitsubishi License to a third party with respect to exploitation of lorundrostat or any Lorundrostat Product in certain countries in Asia, the Company has agreed to negotiate such a sublicense first, for a specified period of time, with Mitsubishi Tanabe, if Mitsubishi Tanabe notifies the Company that it would like to obtain such a sublicense. The Company also agreed not to commercialize any competing product prior to three years following the first commercial sale of the first Lorundrostat Product in any country without Mitsubishi Tanabe's prior consent.

Unless terminated earlier, the Mitsubishi License will continue until the expiration of all of the Company's royalty obligations to Mitsubishi Tanabe. The Company may terminate the Mitsubishi License for any or no reason upon 90 or 180 days' prior written notice to Mitsubishi Tanabe depending on whether the Lorundrostat Product has received regulatory approval. Mitsubishi Tanabe may terminate the Mitsubishi License if the Company has not initiated regulatory consultation for the first global clinical trials of lorundrostat in at least one major market country within a specified amount of time or if the Company or its affiliates or sublicensees initiate a challenge to the patent rights licensed to the Company by Mitsubishi Tanabe. In addition, either party may terminate the Mitsubishi License in the event of an uncured material breach by or bankruptcy of the other party, subject to certain notice and cure periods, or upon the other party's bankruptcy or insolvency.

Litigation

Liabilities for loss contingencies arising from claims, assessments, litigation, fines, penalties, and other sources are recorded when it is probable that a liability has been incurred and the amount can be reasonably estimated. From time to time, the Company may become involved in legal proceedings arising in the ordinary course of business. The Company was not subject to any material legal proceedings during the three or nine months ended September 30, 2025 and 2024, and no material legal proceedings are currently pending or threatened.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising from breach of such agreements or intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with officers of the Company and members of its board of directors 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. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements, and it has not accrued any material liabilities related to such obligations in its condensed financial statements as of September 30, 2025 and December 31, 2024.

Note 5. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2025	December 31, 2024
Research and development expenses	\$ 14,638	\$ 8,614
Compensation and benefits	3,880	3,582
Professional fees and other	3,881	1,971
Total	<u>\$ 22,399</u>	<u>\$ 14,167</u>

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Note 6. Capital Stock

As of September 30, 2025, the Company had reserved authorized shares of common stock for future issuance as follows:

Common stock options outstanding	6,612,340
Shares available for grant under the 2023 Plan	1,412,873
Shares available for grant under the ESPP	1,260,337
Shares available for grant under the 2025 Inducement Plan	1,000,000
Pre-funded warrants issued and outstanding	549,755
Total	10,835,305

In connection with the closing of the IPO in February 2023, the Company's board of directors approved an amendment to the Company's amended and restated certificate of incorporation (the Restated Certificate). The Restated Certificate amended and restated the Company's amended and restated certificate of incorporation, in its entirety to, among other things, increase the authorized number of shares of common stock to 500,000,000 shares and authorize 50,000,000 shares of undesignated preferred stock that may be issued from time to time by the Company's board of directors in one or more series.

Public Offerings

On September 2, 2025, the Company entered into an underwriting agreement (the September 2025 Underwriting Agreement) with BofA Securities, Inc., Evercore Group L.L.C. and Goldman Sachs & Co. LLC as representatives of the several underwriters named therein (collectively, the Underwriters), relating to the issuance and sale of 11,274,509 shares of the Company's common stock at a price of \$25.50 per share for net proceeds of approximately \$269.6 million after deducting an underwriting discount of 6% and other offering expenses. The offering was made pursuant to the Company's registration statements on Form S-3 and Form S-3MEF (Registration Statement Nos. 333-278122 and 333-289998, respectively) previously filed with and declared effective by the SEC, and a prospectus supplement and accompanying prospectus filed with the SEC. The Company is using the net proceeds from this offering to fund clinical development of lorundrostat, including research and development and manufacturing, and pre-commercialization activities, as well as for working capital and general corporate purposes.

On March 11, 2025, the Company entered into an underwriting agreement (the March 2025 Underwriting Agreement) with the Underwriters, relating to the issuance and sale of 14,907,406 shares of the Company's common stock at a price of \$13.50 per share for net proceeds of approximately \$188.7 million after deducting an underwriting discount of 6% and other offering expenses. The offering was made pursuant to the Company's shelf registration statement on Form S-3 (Registration Statement No. 333-278122) previously filed with and declared effective by the SEC (the Registration Statement), and a prospectus supplement and accompanying prospectus filed with the SEC. The Company is using the net proceeds from this offering to fund the clinical development of lorundrostat, including research and development, manufacturing, and pre-commercialization activities, as well as for working capital and general corporate purposes.

At Market Equity Offering Sales Agreement

On March 21, 2024, the Company entered into an ATM Equity Offering Sales Agreement (the ATM Agreement) with BofA Securities, Inc. and Evercore Group L.L.C. as the Company's sales agents (the Agents) and/or principals. Pursuant to the terms of the ATM Agreement, the Company was permitted to sell from time to time through the Agents shares of the Company's common stock having an aggregate offering price of up to \$100.0 million (the ATM Shares). However, on September 2, 2025, the Company delivered written notice to the Agents that it was suspending its use of and terminating the prospectus supplement, dated April 11, 2024, related to the ATM Shares previously issuable pursuant to the terms of the ATM Agreement (the ATM

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Prospectus Supplement). On November 6, 2025, the Company delivered a written notice to the Agents to exercise its right to terminate the ATM Agreement, effective November 9, 2025.

Prior to the termination of the ATM Agreement and the ATM Prospectus Supplement, the ATM Shares were issuable pursuant to the Registration Statement. Sales of the ATM Shares were made by means of ordinary brokers' transactions on the Nasdaq Global Select Market or as otherwise agreed by the Company and the Agents. Under the terms of the ATM Agreement, the Company was permitted to sell the ATM Shares from time to time to an Agent as principal for its own account at a price to be agreed upon at the time of sale. Any sale of the ATM Shares to an Agent as principal would have been pursuant to the terms of a separate terms agreement between the Company and such Agent. Beginning in April 2025 and through September 30, 2025, the Company sold an aggregate of 1,914,040 ATM Shares at a weighted-average price of \$14.32 per share for aggregate net proceeds of approximately \$27.3 million after deducting commissions to the Agents and other offering expenses. During the three months ended September 30, 2025, the Company sold an aggregate of 1,239,522 ATM Shares at a weighted-average price of \$14.41 per share for aggregate net proceeds of approximately \$17.8 million after deducting commissions to the Agents and other offering expenses.

As of September 30, 2025, the Company had approximately \$72.6 million of ATM Shares remaining available for sale pursuant to the ATM Agreement. However, following the termination of the ATM Prospectus Supplement and the ATM Agreement, the Company may not make any sales of ATM Shares pursuant to the ATM Agreement.

Private Placement Offering

On February 7, 2024, the Company entered into a securities purchase agreement (the Purchase Agreement) with the purchasers named therein (the Purchasers), for the private placement (the Private Placement) of (i) 8,339,169 shares (the Shares) of the Company's common stock at a price of \$13.50 per Share, and (ii) with respect to certain Purchasers, pre-funded warrants to purchase an aggregate of 549,755 shares of common stock (the Pre-Funded Warrants) in lieu of shares of common stock, at a purchase price of \$13.499 per Pre-Funded Warrant (the shares of common stock issuable upon exercise of the Pre-Funded Warrants, the Warrant Shares) for aggregate net proceeds of approximately \$116.1 million. Each Pre-Funded Warrant has an exercise price of \$0.001 per share of common stock, is immediately exercisable on the date of issuance, and will not expire. The Company is using the net proceeds from the Private Placement to fund the research and development of lorundrostat and for working capital and general corporate purposes.

The Company registered the resale of the Shares and the Warrant Shares on the Registration Statement. Pursuant to the Purchase Agreement, the Company agreed to use its reasonable best efforts to keep the Registration Statement effective until the earliest of (i) the time as all of the Shares and Warrant Shares purchased by the Purchasers pursuant to the terms of the Purchase Agreement have been sold pursuant to the Registration Statement, or (ii) such time as the Shares and Warrant Shares become eligible for resale by non-affiliates without any volume limitations or other restrictions pursuant to Rule 144 under the Securities Act of 1933, as amended, or any other rule of similar effect.

Note 7. Stock-Based Compensation

2023 Incentive Award Plan

In February 2023, the Company's board of directors adopted and stockholders approved the 2023 Incentive Award Plan that became effective upon the closing of the IPO (the 2023 Plan), under which the Company may grant stock options, restricted stock awards (RSAs), dividend equivalents, restricted stock units, stock appreciation rights, and other stock or cash-based awards to its employees, consultants, and directors. The number of shares of the Company's common stock initially available for issuance under awards granted pursuant to the 2023 Plan was the sum of (i) 4,650,000 shares of the Company's common stock, plus (ii) any shares subject to outstanding awards under the 2020 Plan described and defined below as of the effective date of the 2023 Plan that become available for issuance under the 2023 Plan thereafter in accordance with its terms.

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The number of shares initially available for issuance will be increased on January 1 of each calendar year beginning in 2024 and ending in and including 2033, by an amount equal to the lesser of (i) 4% of the shares of the Company's common stock outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares as determined by the Company's board of directors. No more than 100,000,000 shares of the Company's common stock may be issued upon the exercise of incentive stock options under the 2023 Plan. Shares issued under the 2023 Plan may be authorized but unissued shares, shares purchased on the open market, or treasury shares.

2025 Employment Inducement Incentive Award Plan

On February 10, 2025, the Company's board of directors adopted and approved the 2025 Employment Inducement Incentive Award Plan (the 2025 Inducement Plan), which became effective on February 10, 2025. In accordance with Rule 5635(c)(4) of the Nasdaq Stock Market listing rules, equity awards under the 2025 Inducement Plan may only be made to an employee if he or she is granted such awards in connection with the commencement of his or her employment with the Company and such grant is a material inducement to his or her entering into employment with the Company. The Company has reserved 1,000,000 shares of common stock for issuance pursuant to non-qualified stock options and restricted stock units under the 2025 Inducement Plan. As of November 10, 2025, no shares had been issued under the 2025 Inducement Plan.

2020 Equity Incentive Plan

On July 7, 2020, the board of directors adopted, and the Company's stockholders approved, the 2020 Equity Incentive Plan. The 2020 Equity Incentive Plan, as amended and restated (the 2020 Plan), provided for the grant of incentive stock options to employees of the Company, and for the grant of non-statutory stock options, RSAs, restricted stock unit awards, and other forms of stock awards to employees, directors, and consultants of the Company.

Subsequent to the closing of the IPO, no additional awards will be granted under the 2020 Plan. However, the 2020 Plan will continue to govern the terms and conditions of the outstanding awards granted under it. Shares of the Company's common stock subject to awards granted under the 2020 Plan that expire, lapse, or are terminated, exchanged for cash, surrendered, repurchased, or forfeited following the effective date of the 2020 Plan will be available for issuance under the 2023 Plan in accordance with its terms.

As of September 30, 2025, the Company had the following balances by plan:

	Options Outstanding	Unvested RSAs	Shares Available for Grant
2023 Plan	6,264,374	—	1,412,873
2020 Plan	347,966	186,872	—
2025 Inducement Plan	—	—	1,000,000
Total	6,612,340	186,872	2,412,873

2023 Employee Stock Purchase Plan

In February 2023, the Company's board of directors and stockholders approved the 2023 Employee Stock Purchase Plan (the ESPP), which became effective in February 2023. The ESPP permits eligible employees who elect to participate in an offering under the ESPP to have up to a specified percentage of their eligible compensation withheld, subject to certain limitations, to purchase shares of common stock pursuant to the ESPP. A total of 400,000 shares of the Company's common stock was initially reserved for issuance under the ESPP. The first ESPP offering period commenced on July 1, 2023, with each new six-month offering period beginning each January 1 and July 1. ESPP purchases of common stock occur at a price equal to 85% of the lower of (i) the closing price on the first trading day of the offering period or (ii) the closing price on the last trading day of the offering period. As of September 30, 2025, the Company had 1,260,337 shares available for issuance, and 49,221 cumulative shares had been issued under the ESPP.

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In addition, the number of shares available for issuance under the ESPP will be annually increased on January 1 of each calendar year beginning in 2024 and ending in and including 2033, by an amount equal to the lesser of (i) 1% of the shares outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares as is determined by the Company's board of directors, provided that no more than 15,000,000 shares of the Company's common stock may be issued under the ESPP.

Total stock-based compensation expense reported in the condensed statements of operations was allocated as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Research and development	\$ 3,154	\$ 1,392	\$ 6,725	\$ 3,638
General and administrative	2,687	1,747	7,314	4,564
Total	<u>\$ 5,841</u>	<u>\$ 3,139</u>	<u>\$ 14,039</u>	<u>\$ 8,202</u>

Note 8. Income Taxes

The Company is subject to taxation in the United States and various states. The Company computes its quarterly income tax provision by using a forecasted annual effective tax rate and adjusts for any discrete items arising during the quarter. The primary difference between the effective tax rate and the federal statutory rate is due to federal and state income tax expense offset by valuation allowance on the Company's deferred tax assets.

The Company recorded no income tax expense for the nine months ended September 30, 2025 and 2024. No tax benefit was provided for losses incurred in the United States because those losses are offset by a full valuation allowance.

On July 4, 2025, the One Big Beautiful Bill Act (OBBBA) was signed into law, which enacts significant changes to U.S. tax and related laws. Some of the provisions of the new tax law affecting corporations include but are not limited to current deduction of domestic research expenses, increasing the limit of the deduction of interest expense deduction to thirty percent of EBITDA, and one hundred percent bonus depreciation on eligible property acquired after January 19, 2025. The Company has evaluated the impact of the new tax law on its financial condition and results of operations. OBBBA will have no impact on the Company's effective income tax rate, its net deferred federal income tax liability, or current taxes payable. The impact of the tax law changes from the OBBBA is included in the Company's financial statements beginning in the three months ended September 30, 2025.

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

The following discussion and analysis and the unaudited interim financial statements included in this Quarterly Report on Form 10-Q (Quarterly Report) should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2024 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in the Annual Report on Form 10-K for the year ended December 31, 2024.

Special Note Regarding Forward-Looking Statements

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, research and development plans, the anticipated timing, costs, design, and conduct of our ongoing and planned preclinical studies and planned clinical trials for lorundrostat and any future product candidates, the timing and likelihood of regulatory filings and approvals for lorundrostat (including the anticipated timing of the new drug application (NDA) submission for lorundrostat) and any future product candidates, our ability to commercialize our product candidates, if approved, the potential to develop future product candidates, the potential benefits of strategic collaborations and our intent to enter into any strategic arrangements, the timing and likelihood of success, and plans and objectives of management for future operations and future results of anticipated product development efforts, are forward-looking statements. These statements involve known and unknown risks, uncertainties, and other important factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements, including the timing, volume and nature of feedback or requests from the U.S. Food and Drug Administration (FDA) in connection with our planned NDA submission, macroeconomic trends and uncertainty with regard to high interest rates, elevated inflation, tariffs and other trade policies, and the potential for a local and/or global economic recession. This Quarterly Report also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions, and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

In some cases, you can identify forward-looking statements by terms such as “anticipate,” “believe,” “continue” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will” or “would” or the negative of these terms or other similar expressions. The forward-looking statements in this Quarterly Report are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition, and results of operations. 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, including, without limitation, the risk factors described in Part II, Item 1A, “[Risk Factors](#),” in Part I, Item 1A, “[Risk Factors](#)” in our Annual Report on Form 10-K for the year ended December 31, 2024, and under a similar heading in any other periodic or current report we may file with the U.S. Securities and Exchange Commission (the SEC) in the future. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances, or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

This Quarterly Report includes trademarks, tradenames, and service marks that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this Quarterly Report appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or that the applicable owner will not assert its rights, to these trademarks and tradenames.

Overview

We are a clinical-stage biopharmaceutical company focused on developing medicines to target diseases driven by dysregulated aldosterone. Our clinical-stage product candidate, lorundrostat, is a proprietary, orally administered, highly selective aldosterone synthase inhibitor (ASI) that we are developing for the treatment of cardiorenal conditions affected by dysregulated aldosterone, including hypertension and related comorbidities such as chronic kidney disease (CKD) and obstructive sleep apnea (OSA). In the United States, there are approximately 120 million patients with sustained elevated blood pressure (BP), or hypertension, and more than half of this population fails to achieve their BP goals, defined as BP below 130/80 mmHg, with currently available medications. There are over 30 million treated patients who do not achieve their BP goal, of whom approximately 20 million have systolic BP levels greater than 140 mmHg. Patients with hypertension that persists despite taking two or more medications have 1.8 and 2.5 times greater mortality risk due to either cardiovascular disease or stroke, respectively. Dysregulated aldosterone levels are a key factor in driving hypertension in approximately 30% of hypertensive patients.

Our research and development has been committed to clinical trials researching the benefits of lorundrostat for the treatment of uncontrolled hypertension (uHTN) or resistant hypertension (rHTN) and hypertensive patients with CKD and OSA. In the first half of 2025, we announced the positive results of our pivotal program for lorundrostat (Advance-HTN and Launch-HTN) and our Phase 2 Explore-CKD trial, which are described further below. Research to date has demonstrated the opportunities for lorundrostat as a solution for patients in the treatment of hypertension, including hypertensive patients with CKD and OSA. Based on the positive results from our pivotal program, we plan to submit an NDA in late 2025 or during the first quarter of 2026. We also believe, based on available clinical data, that our product candidate holds promise to be an innovative solution for the rapidly growing unmet need in multiple cardiorenal metabolic disorders.

Clinical Program Highlights

In March 2025, we announced that our pivotal trials, Launch-HTN and Advance-HTN, both of which evaluated the efficacy and safety of lorundrostat for the treatment of uHTN or rHTN, successfully achieved statistical significance and were clinically meaningful in their primary efficacy endpoints and demonstrated a favorable safety and tolerability profile. Based on the outcome of Launch-HTN and Advance-HTN, we plan to submit an NDA in late 2025 or during the first quarter of 2026. We also believe the Launch-HTN and Advance-HTN results demonstrate the opportunity for lorundrostat in third-line or later treatment of patients with hypertension. Our ongoing Transform-HTN open-label extension trial allows participants to continue to receive lorundrostat and generate additional safety and efficacy data. The Launch-HTN trial results were presented in a late-breaking presentation at the 2025 European Society of Hypertension Meeting on Hypertension and Cardiovascular Protection in May 2025 and published in the June 30, 2025 issue of the Journal of the American Medical Association (JAMA, DOI:10.1001/jama.9413). The Advance-HTN trial results were presented in a late-breaking presentation at the American College of Cardiology's Annual Scientific Session & Expo (ACC.25) held in March 2025 and published in the April 23, 2025 issue of the New England Journal of Medicine (NEJM, DOI: 10.1056/NEJMoa2501440).

In June 2025, we announced positive topline data from our Phase 2 Explore-CKD trial evaluating the safety and efficacy of 25 mg of lorundrostat in addition to a sodium-glucose cotransporter 2 (SGLT2) inhibitor for the treatment of hypertension in participants with hypertension and comorbid CKD. The trial was highly statistically significant and was clinically meaningful in both endpoints and demonstrated a favorable safety and tolerability profile. Greater detail of the results of these trials is described below.

Transform-HTN is an open-label extension trial allowing participants to continue to receive lorundrostat and to obtain ongoing long-term efficacy and safety data. All participants in the pivotal hypertension program, including the Advance-HTN and Launch-HTN trials, as well as the Explore-CKD trial, were given the opportunity to participate in the extension trial.

Lorundrostat has been developed to address dysregulated aldosterone, and we believe this mechanism may be applicable to other indications where dysregulated aldosterone biology plays a role. Most recently, we have begun to explore lorundrostat for patients with OSA and hypertension.

In January 2025, we announced that the FDA cleared our investigational new drug application for Explore-OSA to evaluate the effect of lorundrostat in the treatment of overweight and obese participants with moderate-to-severe OSA and hypertension. Explore-OSA is a placebo-controlled, crossover trial that will evaluate the safety and efficacy of lorundrostat 50 mg once daily (QD) in the evening in approximately 40 participants with hypertension and moderate-to-severe OSA. Participants will be at least 18 years old, with a systolic BP ≥ 130 mmHg and ≤ 180 mmHg, with a body mass index (BMI) ≥ 27 kg/m², and the trial will be conducted across approximately 35 sites. The key objective of this trial is to evaluate the hypothesis that lorundrostat both alleviates the severity of upper airway obstruction and reduces nocturnal hypertension. The primary outcome measure is absolute change in the frequency of apnea-hypopnea episodes compared to placebo. The key secondary objective is to quantify BP throughout the night using continuous BP monitoring during the performance of a standard sleep study without the use of CPAP. Standard patient-reported outcomes specific to OSA will also be assessed. We initiated Explore-OSA in the first quarter of 2025, and enrollment was completed in the third quarter of 2025. We anticipate reporting topline results from Explore-OSA in the first quarter of 2026.

Pivotal Program Clinical Trial Results

Efficacy Results

Launch-HTN was a large, global, randomized, double-blinded, placebo-controlled Phase 3 clinical trial, which enrolled eligible adult participants who failed to achieve their BP goal despite being on two to five antihypertensive medications. Launch-HTN reflects the real-world setting for clinicians by utilizing automated office blood pressure measurement and allowing participants to stay on their existing medications. Participants were randomized into three cohorts for twelve weeks receiving one of the following treatments: lorundrostat 50 mg QD, lorundrostat 50 mg QD and an option to titrate to 100 mg QD at week six based on defined criteria or placebo. The primary endpoint of the trial was the assessment of automated office measured systolic BP from baseline for active cohorts versus placebo at six weeks, with the results pooled for all participants on 50 mg QD. The trial met its endpoints, demonstrating clinically meaningful, statistically significant mean reduction from baseline in placebo-adjusted systolic BP at week six, and the benefit was sustained with potential further reduction through week 12.

Launch-HTN Phase 3 Trial (automated office systolic BP measure, n=1,083 randomized)				
	Week 6 (50 mg pooled)		Week 12	
	Absolute Reduction	Placebo-Adjusted Reduction	Absolute Reduction	Placebo-Adjusted Reduction
50 mg	-16.9 mmHg	-9.1 mmHg (p<0.0001)*	-19.0 mmHg	-11.6 mmHg (p<0.0001)
50 to100 mg			-15.7 mmHg	-8.4 mmHg (p=0.0016)
* Primary endpoint				

Key characteristics of participants enrolled in the Launch-HTN trial include: approximately 63% had a BMI greater than or equal to 30kg/m², approximately 47% were women, and approximately 29% were Black or African American.

The Advance-HTN trial was a randomized, double-blind, placebo-controlled Phase 2 pivotal trial that evaluated the efficacy and safety of lorundrostat for the treatment of confirmed uHTN or rHTN, when used as add-on therapy to a standardized background treatment of two or three antihypertensive medications in adult participants. Participants who met screening criteria discontinued their existing hypertension medications and started on a standard regimen of an angiotensin II receptor blocker (ARB) and a diuretic, if previously on two medications, or a standard regimen of ARB, diuretic and calcium channel blocker if previously on three to five medications. Participants who remained hypertensive despite the standardized regimen were then randomized into three cohorts for twelve weeks receiving one of the following treatments: lorundrostat 50 mg QD, lorundrostat 50 mg QD and an option to titrate to 100 mg QD at week four based on defined criteria or placebo. The primary endpoint of Advance-HTN was change in 24-hour ambulatory systolic BP at week twelve from baseline for each active cohort versus placebo.

The trial was designed to evaluate lorundrostat in a uHTN or rHTN population at the highest risk, and which would normally be treated by a specialist, given severity of their condition. The trial met its primary endpoint as well as additional prespecified outcome measures, including measures of efficacy in the dose-escalation cohort, safety, and tolerability, and were consistent with those observed in the Launch-HTN trial.

Advance-HTN Phase 2 Trial (24-hour ambulatory systolic BP, n=285 randomized)				
	Week 4 (50 mg pooled)		Week 12	
	Absolute Reduction	Placebo-Adjusted Reduction	Absolute Reduction	Placebo-Adjusted Reduction*
50 mg	-11.5 mmHg	-5.3 mmHg (p=0.0006)	-15.4 mmHg	-7.9 mmHg (p=0.001)
50 to 100 mg			-13.9 mmHg	-6.5 mmHg (p=0.006)
<i>* Primary endpoint</i>				

Key characteristics of participants enrolled in the Advance-HTN trial include: approximately 66% had a BMI greater than or equal to 30kg/m², approximately 40% were women, and approximately 53% were Black or African American.

Safety and Tolerability Results

We believe clinical safety findings in the two pivotal trials, including adrenocorticotrophic hormone-stimulated and serum cortisol, change in serum potassium, serum sodium, and estimated glomerular filtration rate (eGFR), as well as incidence of hypotension, support a favorable benefit-risk profile.

In the two active treatment arms of the Launch-HTN trial, 50 mg and 50 mg with optional dose escalation to 100 mg, the incidence of treatment-emergent serious adverse events (SAEs) was twelve participants (2.2%) and two participants (0.7%), respectively, compared with eight participants (3.0%) in the placebo arm. There was only one participant (0.1%) in the trial with a treatment-related SAE that occurred in the 50 mg arm. The incidence of hyperkalemia (serum potassium >6.0 mmol/L) at the scheduled study visit was 1.1% and 1.5% in the 50 mg and 50 to 100 mg arms, respectively. The per-protocol procedure for validation of suspected factitious hyperkalemia (most often due to phlebotomy-related hemolysis and release of potassium from red blood cells) specified a repeat potassium measurement within 72 hours while still taking study medication to confirm validity and provide an accurate determination of the true incidence of hyperkalemia. After exclusion of the spurious results, the incidence of confirmed hyperkalemia was 0.6% and 1.1% in the 50 mg and 50 to 100 mg arms, respectively.

In the Advance-HTN trial, there were six participants (6.4%) and eight participants (8.4%) with treatment-emergent SAEs in the lorundrostat 50 mg and lorundrostat 50 to 100 mg arms, respectively, compared to two participants (2.1%) in the placebo arm. Treatment-related SAEs occurred in 2%, 1%, and 0% of participants in the lorundrostat 50 mg, lorundrostat 50 to 100 mg, and placebo arms, respectively. The incidence of hyperkalemia (serum potassium >6.0 mmol/L) at the scheduled study visit was 5.3% and 7.4% in the 50 mg and 50 to 100 mg arms, respectively. The per-protocol procedure for validation of suspected factitious hyperkalemia (most often due to phlebotomy-related hemolysis and release of potassium from red blood cells) specified a repeat potassium measurement within 72 hours while still taking study medication to confirm validity and provide an accurate determination of the true incidence of hyperkalemia. After exclusion of the spurious results, the incidence of confirmed hyperkalemia was 2.1% and 3.2% in the 50 mg and 50 to 100 mg arms, respectively.

Explore-CKD Clinical Trial Results

Efficacy, Safety, and Tolerability Results

The Explore-CKD trial was a randomized, double-blind, placebo controlled, two-period, two-sequence (2x2) crossover trial. This phase 2 trial was designed to evaluate efficacy in terms of systolic BP and urine albumin-to-creatinine ratio (UACR) reduction, and safety of four-week 25 mg QD lorundrostat added to a background treatment that included an SGLT2 inhibitor and an angiotensin-converting enzyme inhibitor (ACEi) or an ARB in CKD participants with an eGFR ≥ 30 mL/min/1.73m² and albuminuria (UACR of 200-5,000 mg/g). The primary endpoint was placebo-adjusted change from baseline in systolic BP at week four, and an exploratory endpoint was placebo-adjusted percent change from baseline in UACR at week four. The trial was highly statistically significant and was clinically meaningful in both of these endpoints and demonstrated a favorable safety and tolerability profile.

Explore-CKD Phase 2 Trial (N=59)

	Placebo	Lorundrostat 25 mg	Placebo-Adjusted
Change in systolic BP (mmHg)*	-1.76	-9.25	-7.5 (p=0.0024)
Change in spot UACR (mg/g)	-6.60%	-30.51%	-25.60% (p=0.0015)
Change in eGFR** (mL/min/1.73m ²)	-2.20%	-6.78%	-4.58% (p=0.0362)
Treatment Emergent Adverse Events (TEAEs) leading to discontinuation of study drug	1/57 (2%)	2/58 (3%)	
Confirmed hyperkalemia*** (K + >6.0 mmol/L)	0/57 (0%)	3/58 (5%)	

BP, blood pressure; UACR, Urine albumin-to-creatinine ratio; TEAE, Treatment-emergent adverse event

* Primary endpoint.

** Cystatin-C formula, a surrogate biomarker of renal function not subject to MATE1 transport and elimination in the glomeruli of the kidney.

*** Per protocol Systolic BP, UACR, and eGFR estimates and p values from Mixed Effects Model for a crossover trial with multiple baselines.

SAEs were reported in two participants (3%) during the lorundrostat treatment period and none during the placebo treatment period. TEAEs leading to discontinuation occurred in one participant (2%) during the placebo treatment period and in two participants (3%) during the lorundrostat treatment period.

During lorundrostat treatment, one participant discontinued treatment due to elevation of potassium associated with reduced eGFR, and one participant discontinued treatment due to reduction in eGFR alone. During the lorundrostat treatment period, an anticipated, modest decrease in mean eGFR was observed (-6.8% lorundrostat, -4.6% mL/min/1.73m² placebo-adjusted). Reduction in eGFR is also seen with other renin-angiotensin-aldosterone pathway inhibitors, including ACE inhibitors, ARBs and mineralocorticoid receptor

antagonists. This is the result of a reduction in the deleterious over-perfusion of glomeruli due, in part, to reduced BP.

These findings add to a growing body of evidence supporting the efficacy and safety of aldosterone synthase inhibitors in addressing the underlying mechanisms of hypertension, including in individuals with reduced kidney function and albuminuria. The reduction in UACR observed in this trial is consistent with the potential of lorundrostat to have renal protective effects.

Four successful clinical trials have been completed supporting the efficacy and safety profile of lorundrostat while also validating aldosterone as an integral therapeutic target in uHTN and rHTN. This includes three trials of lorundrostat for the treatment of participants with uHTN and rHTN: the pivotal Phase 3 Launch-HTN and Phase 2 Advance-HTN trials, and the Phase 2, dose-ranging, Target-HTN trial, which demonstrated clinically meaningful reductions in systolic BP and a favorable safety and tolerability profile. The fourth trial, Explore-CKD, provides data that augments the antihypertensive profile of lorundrostat by evaluating the efficacy and safety of lorundrostat in participants with compromised renal function. We continue to study lorundrostat in the ongoing, open-label Transform-HTN extension trial, which is evaluating long-term efficacy, safety, and tolerability. Additionally, the Explore-OSA trial was initiated in the first quarter of 2025, and enrollment was completed in the third quarter of 2025. We anticipate reporting topline results from Explore-OSA in the first quarter of 2026.

Financial Overview

We commenced our operations in May 2019 and have devoted substantially all of our resources to date to organizing and staffing our company, business planning, raising capital, in-licensing our product candidate, lorundrostat, establishing our intellectual property portfolio, conducting research, preclinical studies, and clinical trials, and providing other general and administrative support for our operations. As of September 30, 2025, we had cash, cash equivalents, and investments of \$593.6 million. Since inception, we have raised aggregate gross proceeds of approximately \$1.0 billion from the sale of common stock, convertible preferred stock, convertible notes, and pre-funded warrants. In September 2025, we sold 11,274,509 shares of common stock for net proceeds of approximately \$269.6 million after deducting an underwriting discount of 6% and other offering expenses. In March 2025, we sold 14,907,406 shares of common stock for net proceeds of approximately \$188.7 million after deducting an underwriting discount of 6% and other offering expenses. Beginning in April 2025 and through November 10, 2025, we have sold an aggregate of 1,914,040 ATM Shares (as defined below) for aggregate net proceeds of approximately \$27.3 million after deducting commission to the Agents and other offering expenses. In February 2024, we sold 8,339,169 shares of common stock and, to certain purchasers, 549,755 pre-funded warrants to purchase common stock for aggregate net proceeds of approximately \$116.1 million, net of offering expenses, in a private placement offering (the Private Placement).

We do not have any products approved for sale, have not generated any revenue, and have incurred net losses since our inception. Our operations to date have been limited to business planning, raising capital, in-licensing and developing lorundrostat, conducting clinical trials, and other research and development and other activities. Our net losses for the nine months ended September 30, 2025 and 2024 were \$122.4 million and \$128.9 million, respectively. As of September 30, 2025 and December 31, 2024, we had an accumulated deficit of \$424.9 million and \$302.5 million, respectively. Our net losses may fluctuate significantly from quarter to quarter and year to year, depending on the timing of our clinical development activities and other research and development activities. We expect our expenses and operating losses will increase substantially as we conduct our ongoing and planned clinical trials for lorundrostat, seek regulatory approval for lorundrostat and potentially any future product candidates we may develop, expand our clinical, regulatory, quality, manufacturing, and commercialization capabilities, obtain, maintain, protect and enforce our intellectual property, expand our general and administrative support functions, including hiring additional personnel, and incur additional costs associated with operating as a public company.

Based on our current operating plan, we believe that our cash, cash equivalents, and investments will be sufficient to allow us to fund our operations for at least twelve months. We have never generated any

revenue and do not expect to generate any revenue from product sales unless and until we successfully complete the development of, and obtain regulatory approval for, lorundrostat, if ever. Accordingly, until such time as we can generate significant revenue from sales of lorundrostat, if ever, we expect to finance our cash needs through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses, and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. For more information, see [“Liquidity and Capital Resources.”](#)

License Agreement with Mitsubishi Tanabe

In July 2020, we entered into a license agreement (the Mitsubishi License) with Mitsubishi Tanabe Pharmaceutical Company (Mitsubishi Tanabe), pursuant to which Mitsubishi Tanabe granted us an exclusive, worldwide, royalty-bearing, sublicensable license under Mitsubishi Tanabe’s patent and other intellectual property rights to exploit products incorporating lorundrostat (formerly MT-4129) (Lorundrostat Products) for the prevention, treatment, diagnosis, detection, monitoring, or predisposition testing with respect to indications, diseases, and conditions in humans. Pursuant to the Mitsubishi License, we paid Mitsubishi Tanabe a \$1.0 million upfront fee and development milestone payments of \$9.0 million in the aggregate. We have remaining obligations to pay Mitsubishi Tanabe commercial milestone payments of up to \$155.0 million in the aggregate upon first commercial sale and upon meeting certain annual sales targets, as well as additional commercial milestone payments of up to \$10.0 million for a second indication. Additionally, we are obligated to pay Mitsubishi Tanabe tiered royalties at percentages ranging from the mid-single digits to ten percent (10%) of aggregate net sales of each Lorundrostat Product on a Lorundrostat Product-by-Lorundrostat Product and country-by-country basis, until the later of (i) the expiration of the last-to-expire valid Mitsubishi Tanabe patent claim covering a Lorundrostat Product, (ii) ten years from the first commercial sale of a Lorundrostat Product, or (iii) the expiration of regulatory exclusivity in such country. Such royalties are subject to reduction under specified conditions, including lack of patent coverage and generic competition. We have no remaining development milestone obligations under the Mitsubishi License and did not incur any development or commercial expenses pursuant to the Mitsubishi License during the nine months ended September 30, 2025 and 2024.

We are obligated to use commercially reasonable efforts to conduct and complete the development activities and to file for regulatory approval for at least one Lorundrostat Product in a major market country and consider in good faith developing at least one Lorundrostat Product in a non-major market country. If we elect to sublicense our rights under the Mitsubishi License to a third party with respect to exploitation of lorundrostat or any Lorundrostat Product in certain countries in Asia, we have agreed to negotiate such a sublicense first, for a specified period of time, with Mitsubishi Tanabe, if Mitsubishi Tanabe notifies us that it would like to obtain such a sublicense. We also agreed not to commercialize any competing product prior to three years following the first commercial sale of the first Lorundrostat Product in any country without Mitsubishi Tanabe’s prior consent.

Public Offerings

On September 2, 2025, we entered into an underwriting agreement (the September 2025 Underwriting Agreement) with BofA Securities, Inc., Evercore Group L.L.C. and Goldman Sachs & Co. LLC as representatives of the several underwriters named therein (collectively, the Underwriters), relating to the issuance and sale of 11,274,509 shares of our common stock at a price of \$25.50 per share for net proceeds of approximately \$269.6 million after deducting an underwriting discount of 6% and other offering expenses. The offering was made pursuant to our registration statements on Form S-3 and Form S-3MEF (Registration Statement Nos. 333-278122 and 333-289998, respectively) previously filed with and declared effective by the SEC, and a prospectus supplement and accompanying prospectus filed with the SEC. We are using the net

proceeds from this offering to fund clinical development of lorundrostat, including research and development and manufacturing, and pre-commercialization activities, as well as for working capital and general corporate purposes.

In March 2025, we entered into an underwriting agreement (the March 2025 Underwriting Agreement) with the Underwriters, relating to the issuance and sale of 14,907,406 shares of the Company's common stock at a price of \$13.50 per share for net proceeds of approximately \$188.7 million after deducting an underwriting discount of 6% and other offering expenses. The offering was made pursuant to our shelf registration statement on Form S-3 (Registration Statement No. 333-278122) previously filed with and declared effective by the SEC (the Registration Statement), and a prospectus supplement and accompanying prospectus filed with the SEC. We are using the net proceeds from this offering to fund the clinical development of lorundrostat, including research and development, manufacturing, and pre-commercialization activities, as well as for working capital and general corporate purposes.

At Market Equity Offering Sales Agreement

On March 21, 2024, we entered into an ATM Equity Offering Sales Agreement (the ATM Agreement) with BofA Securities, Inc. and Evercore Group L.L.C. as our sales agents (the Agents) and/or principals. Pursuant to the terms of the ATM Agreement, we were permitted to sell from time to time through the Agents shares of our common stock having an aggregate offering price of up to \$100.0 million (the ATM Shares). However, on September 2, 2025, the Company delivered written notice to the Agents that it was suspending its use of and terminating the prospectus supplement, dated April 11, 2024, related to the ATM Shares previously issuable pursuant to the terms of the ATM Agreement (the ATM Prospectus Supplement). On November 6, 2025, we delivered a written notice to the Agents to exercise our right to terminate the ATM Agreement, effective November 9, 2025.

Prior to the termination of the ATM Agreement and the ATM Prospectus Supplement, the ATM Shares were issuable pursuant to the Registration Statement. Sales of the ATM Shares were made by means of ordinary brokers' transactions on the Nasdaq Global Select Market or as otherwise agreed by us and the Agents. Under the terms of the ATM Agreement, we were permitted to sell the ATM Shares from time to time to an Agent as principal for its own account at a price to be agreed upon at the time of sale. Any sale of the ATM Shares to an Agent as principal would have been pursuant to the terms of a separate terms agreement between us and such Agent. Beginning in April 2025 and through September 30, 2025, we sold an aggregate of 1,914,040 ATM Shares at a weighted-average price of \$14.32 per share for aggregate net proceeds of approximately \$27.3 million after deducting commissions to the Agents and other offering expenses. During the three months ended September 30, 2025, we sold an aggregate of 1,239,522 ATM Shares at a weighted-average price of \$14.41 per share for aggregate net proceeds of approximately \$17.8 million after deducting commissions to the Agents and other offering expenses.

Private Placement Offering

On February 7, 2024, we entered into a securities purchase agreement (the Purchase Agreement) with the purchasers named therein (the Purchasers), for the Private Placement of (i) 8,339,169 shares (the Shares) of our common stock at a price of \$13.50 per Share, and (ii) with respect to certain Purchasers, pre-funded warrants to purchase an aggregate of 549,755 shares of common stock (the Pre-Funded Warrants) in lieu of shares of common stock, at a purchase price of \$13.499 per Pre-Funded Warrant (the shares of common stock issuable upon exercise of the Pre-Funded Warrants, the Warrant Shares) for aggregate net proceeds of approximately \$116.1 million. Each Pre-Funded Warrant has an exercise price of \$0.001 per share of common stock, is immediately exercisable on the date of issuance, and will not expire. We are using the net proceeds from the Private Placement to fund the research and development of lorundrostat and for working capital and general corporate purposes.

We registered the resale of the Shares and the Warrant Shares on the Registration Statement. Pursuant to the Purchase Agreement, we agreed to use our reasonable best efforts to keep the Registration Statement

effective until the earliest of (i) the time as all of the Shares and Warrant Shares purchased by the Purchasers pursuant to the terms of the Purchase Agreement have been sold pursuant to the Registration Statement, or (ii) such time as the Shares and Warrant Shares become eligible for resale by non-affiliates without any volume limitations or other restrictions pursuant to Rule 144 under the Securities Act or any other rule of similar effect.

Key Components of Results of Operations

Operating Expenses

Research and Development

Research and development expenses consist primarily of external and internal costs related to the development of lorundrostat. Research and development expenses are recognized as incurred, and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods are received or when the services are performed.

Research and development expenses include:

- salaries, bonuses, employee benefits, and stock-based compensation charges for those individuals involved in research and development efforts;
- external research and development expenses incurred under agreements with contract research organizations (CROs) and consultants to conduct and support our clinical trials of lorundrostat;
- costs related to manufacturing lorundrostat for our clinical trials; and
- costs related to advancing our commercial readiness activities in preparation for a potential launch of lorundrostat for patients with hypertension, if approved by the FDA.

Our research and development expenses are primarily driven by the timing and phase of our clinical trials, including the initiation and completion of studies, the number of trials in progress, and the size and complexity of each trial. We expect certain research and development expenses related to our clinical trial activities to decline in upcoming periods as certain trials have been completed relative to prior periods. We cannot determine with certainty the timing of initiation, the duration, or the completion costs of current or future clinical trials and preclinical studies of lorundrostat or any future product candidates due to the inherently unpredictable nature of clinical and preclinical development. Clinical and preclinical development timelines, the probability of success, and development costs can differ materially from expectations. In addition, we cannot forecast whether lorundrostat or any future product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Our future development costs may vary significantly based on factors such as:

- the initiation, type, number, scope, progress, expansions, results, costs, and timing of clinical trials and preclinical studies of lorundrostat and any future product candidates we may choose to pursue, including any modifications to clinical development plans based on feedback that we may receive from regulatory authorities;
- our ability and strategic decision to develop future product candidates other than lorundrostat, and the timing of such development, if any;
- our ability to receive timely regulatory approvals for lorundrostat, any future product candidates, and additional indications of lorundrostat and any future product candidates, in the jurisdictions in which we or any future partners apply for such approvals;

- the costs and timing of manufacturing lorundrostat or any future product candidates for use in our trials, including as a result of inflation, changes in international trade policies and tariffs, any supply chain issues, or component shortages;
- any additional jurisdictions in which we may seek approval for lorundrostat and any future product candidates and the timing of seeking approval in such jurisdictions;
- the drop-out or discontinuation rates of clinical trial participants;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of participant participation in the trials and follow-up;
- the phase of development of the product candidate;
- the efficacy and safety profile of the relevant product candidate; and
- the extent to which we establish strategic collaborations or other arrangements.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related expenses, including employee salaries, bonuses, benefits, and stock-based compensation charges, for personnel in executive and administrative functions. Other significant general and administrative expenses include legal fees relating to intellectual property and corporate matters, professional fees for accounting, tax and consulting services, and insurance costs. We expect our general and administrative expenses will increase for the foreseeable future to support our increased research and development activities, manufacturing activities, and the increased costs associated with operating as a public company. These increased costs will likely include increased expenses related to the hiring of additional personnel, audit, legal, regulatory, and tax-related services associated with maintaining compliance with the exchange listing and the SEC requirements and requirements of the Sarbanes-Oxley Act of 2002, director and officer insurance costs, investor and public relations costs, business development, commercial expenses, and medical affairs.

Other Income, Net

Interest Income, Net

Interest income reported in each period is associated with our investments in money market funds and U.S. treasuries, net of fees, or other related expenses.

Results of Operations

Comparison of the Three Months Ended September 30, 2025 and 2024

	Three Months Ended, September 30,		Change
	2025	2024	
	(in thousands)		
Research and development expenses	\$ (31,450)	\$ (53,985)	\$ 22,535
General and administrative expenses	(9,681)	(6,121)	(3,560)
Total other income, net	4,199	3,764	435
Net loss	<u>\$ (36,932)</u>	<u>\$ (56,342)</u>	<u>\$ 19,410</u>

Research and Development Expenses

Research and development expenses decreased by \$22.5 million for the three months ended September 30, 2025, compared to the three months ended September 30, 2024, which was primarily due to a decrease of \$26.8 million in preclinical and clinical costs, primarily impacted by the conclusion of the lorundrostat pivotal program in the second quarter of 2025, partially offset by increases of \$3.2 million in higher compensation expense resulting from additions to headcount, increases in salaries and accrued bonuses and increased stock-based compensation, and \$1.1 million in higher clinical supply, manufacturing, regulatory, and other costs.

General and Administrative Expenses

General and administrative expenses increased by \$3.6 million for the three months ended September 30, 2025, compared to the three months ended September 30, 2024. The increase was primarily due to \$2.2 million in higher compensation expense resulting from additions to headcount, increases in salaries and accrued bonuses, and increased stock-based compensation, \$1.3 million in higher professional fees, and \$0.1 million in other administrative expenses.

Total Other Income, Net

Total other income, net increased by \$0.4 million for the three months ended September 30, 2025, compared to the three months ended September 30, 2024, which was primarily attributable to increased interest earned on our investments in money market funds and U.S. treasuries as a result of higher average cash balances invested during the three months ended September 30, 2025.

Comparison of the Nine Months Ended September 30, 2025 and 2024

	Nine Months Ended, September 30,		Change
	2025	2024	
	(in thousands)		
Research and development expenses	\$ (107,607)	\$ (124,012)	\$ 16,405
General and administrative expenses	(24,717)	(16,624)	(8,093)
Total other income, net	9,907	11,772	(1,865)
Net loss	\$ (122,417)	\$ (128,864)	\$ 6,447

Research and Development Expenses

Research and development expenses decreased by \$16.4 million for the nine months ended September 30, 2025, compared to the nine months ended September 30, 2024, which was primarily due to a decrease of \$26.5 million in preclinical and clinical costs primarily impacted by the conclusion of the lorundrostat pivotal program in the second quarter of 2025, partially offset by increases of \$8.7 million in compensation expense resulting from additions to headcount, increases in salaries and accrued bonuses, and increased stock-based compensation and \$1.3 million in clinical supply, manufacturing, and regulatory costs.

General and Administrative Expenses

General and administrative expenses increased by \$8.1 million for the nine months ended September 30, 2025, compared to the nine months ended September 30, 2024. The increase was primarily due to increases of \$5.3 million in compensation expense resulting from additions to headcount, increases in salaries and accrued bonuses, and increased stock-based compensation, \$2.6 million for professional fees, and \$0.2 million for other administrative expenses.

Total Other Income, Net

Total other income, net decreased by \$1.9 million for the nine months ended September 30, 2025, compared to the nine months ended September 30, 2024, which was primarily attributable to decreased interest earned on our investments in money market funds and U.S. treasuries as a result of lower average cash balances invested during the nine months ended September 30, 2025.

Liquidity and Capital Resources

We have incurred net losses and negative cash flows from operations since our inception and anticipate we will continue to incur net losses and have negative cash flows from operations for the foreseeable future as we continue the development of, seek regulatory approval for, and potentially commercialize lorundrostat, seek to identify, assess, acquire, and in-license intellectual property related to or develop additional product candidates and operate as a public company. Since inception, we have raised aggregate gross proceeds of approximately \$1.0 billion from the sale of common stock, convertible preferred stock, convertible notes, and pre-funded warrants. As of September 30, 2025, we had cash, cash equivalents, and investments of \$593.6 million. In September 2025, we sold 11,274,509 shares of common stock for net proceeds of approximately \$269.6 million after deducting an underwriting discount of 6% and other offering expenses. In March 2025, we sold 14,907,406 shares of common stock for net proceeds of approximately \$188.7 million after deducting an underwriting discount of 6% and other offering expenses. Beginning in April 2025 and through November 10, 2025, we sold an aggregate of 1,914,040 ATM Shares for aggregate net proceeds of approximately \$27.3 million after deducting commission to the Agents and other offering expenses. In February 2024, we sold 8,339,169 Shares and, to certain Purchasers, 549,755 Pre-Funded Warrants for aggregate net proceeds of approximately \$116.1 million in the Private Placement.

Our primary uses of cash to date have been to fund our research and development and other activities, including with respect to lorundrostat, business planning, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations.

Funding Requirements

Based on our current operating plan, we believe that our cash, cash equivalents, and investments as of September 30, 2025 will be sufficient to allow us to fund our operations for at least twelve months. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Additionally, the process of testing product candidates in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain.

Our future capital requirements will depend on many factors, including, but not limited to:

- the initiation, type, number, scope, progress, expansions, results, costs, and timing of clinical trials and preclinical studies of lorundrostat and any future product candidates we may choose to pursue, including any modifications to clinical development plans based on feedback that we may receive from regulatory authorities;
- our ability and strategic decision to develop future product candidates other than lorundrostat, and the timing of such development, if any;
- our ability to receive timely regulatory approvals for lorundrostat, any future product candidates, and additional indications of lorundrostat and any future product candidates, in the jurisdictions in which we or any future partners apply for such approvals;

- the costs and timing of manufacturing for lorundrostat, or any future product candidate, including commercial manufacture at sufficient scale, if any product candidate is approved, including as a result of inflation, changes in international trade policies and tariffs, any supply chain issues, or component shortages;
- any additional jurisdictions in which we may seek approval for lorundrostat and any future product candidates and timing of seeking approval in such jurisdictions;
- the costs, timing, and outcome of regulatory meetings and reviews of lorundrostat or any future product candidates;
- the costs of obtaining, maintaining, enforcing, and protecting our patents and other intellectual property and proprietary rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal control over financial reporting;
- the costs associated with hiring additional personnel and consultants as our business grows, including additional executive officers and clinical development, regulatory, manufacturing, quality, and commercial personnel;
- the timing and amount of the milestone, royalty, or other payments we must make to Mitsubishi Tanabe, from whom we have in-licensed lorundrostat, or any future licensors;
- the costs and timing of establishing or securing sales and marketing capabilities if lorundrostat or any future product candidate is approved;
- our ability to achieve sufficient market acceptance, coverage, and adequate reimbursement from third-party payors, and adequate market share and revenue for any approved products;
- patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors;
- the terms and timing of establishing and maintaining collaborations, licenses, and other similar arrangements;
- costs associated with any products or technologies that we may in-license or acquire;
- any delays and cost increases that may result from any pandemic or other healthcare emergency; and
- the other risks and uncertainties described under the heading "[Risk Factors](#)," "[Special Note Regarding Forward-Looking Statements](#)," and elsewhere in this Quarterly Report.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses, and other similar arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting 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 potential worsening global economic conditions and the disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from factors that include but are not limited to, geopolitical conflict in and around Ukraine, Israel, Iran and other areas of the world, inflation, changes in international trade policies and tariffs, diminished liquidity and credit availability,

declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. If we raise additional funds through future collaborations, licenses, or other similar arrangements with third parties, we may have to relinquish valuable rights to our future revenue streams, product candidates, research programs, intellectual property or proprietary technology, or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed or on terms acceptable to us, we may be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves, or on less favorable terms than we would otherwise choose.

Cash Flows

Comparison of the Nine Months Ended September 30, 2025 and 2024

Since our inception, we have primarily used our available cash to fund expenditures related to the in-license and development of lorundrostat. The following table sets forth a summary of cash flows for the periods presented (in thousands):

	Nine Months Ended September 30,		Change
	2025	2024	
Net cash provided by (used in):			
Operating activities	\$ (104,528)	\$ (99,471)	\$ (5,057)
Investing activities	(286,264)	31,389	(317,653)
Financing activities	494,298	116,052	378,246
Net	<u>\$ 103,506</u>	<u>\$ 47,970</u>	<u>\$ 55,536</u>

Operating Activities

Net cash used in operating activities was \$104.5 million during the nine months ended September 30, 2025, compared to \$99.5 million during the nine months ended September 30, 2024, resulting in an increase that was primarily attributable to an increase in cash used to support our operating activities, including but not limited to, the development of lorundrostat and related clinical trial expenses, personnel and compensation expense, legal and professional fees to support our operations, and general working capital requirements. The \$5.1 million increase in cash used consisted of the net effect of changes in working capital of \$19.8 million and a decrease in net loss, adjusted for non-cash expenses, of approximately \$14.7 million.

Investing Activities

Net cash used in investing activities was \$286.3 million for the nine months ended September 30, 2025, compared to net cash provided by investing activities of \$31.4 million for the nine months ended September 30, 2024. Net cash (used in) provided by investing activities during the nine months ended September 30, 2025 and 2024 was primarily driven by the timing and volume of purchases and maturities of marketable securities in each period. During the nine months ended September 30, 2025, there was a \$236.7 million increase in purchases of marketable securities, partially offset by an \$81.0 million decrease in maturities of previously purchased marketable securities, compared to the nine months ended September 30, 2024.

Financing Activities

Net cash provided by financing activities of \$494.3 million during the nine months ended September 30, 2025, increased compared to \$116.1 million during the nine months ended September 30, 2024. During the nine months ended September 30, 2025, we received net proceeds of \$270.2 million from the sale of common stock in our September 2025 public offering, \$188.9 million from the sale of common stock in our March 2025 public offering, and \$27.3 million from the sale of ATM Shares, and during the nine months ended September 30, 2024, we received net proceeds of \$116.1 million from the sale of Shares and Pre-Funded Warrants in the Private Placement. Additionally, during the nine months ended September 30, 2025, we received increased proceeds of \$7.6 million from stock option exercises as compared to the nine months ended September 30, 2024.

Contractual Obligations and Commitments

Under the Mitsubishi License, we have milestone payment obligations that are contingent upon the achievement of specified levels of product sales and are required to make certain royalty payments in connection with the sale of products developed under the agreement. We are currently unable to estimate the timing or likelihood of achieving other future milestones or making future product sales. See above and Note 4. “*Commitments and Contingencies*” to our condensed financial statements included elsewhere in this Quarterly Report for additional information regarding the Mitsubishi License.

We enter into contracts in the normal course of business for contract research services, contract manufacturing services, professional services, and other services and products for operating purposes. These contracts generally provide for termination after a notice period, and, therefore, are cancelable contracts.

Critical Accounting Estimates

We have prepared the condensed financial statements in accordance with accounting principles generally accepted in the United States of America. The preparation of these condensed financial statements requires us to make estimates, assumptions, and judgments that affect the reported amounts of assets, liabilities, expenses, and related disclosures at the date of the condensed financial statements, and the reported amounts of expenses during the reporting period. On an ongoing basis, management evaluates its critical estimates, including those related to prepaid and accrued research and development expenses. We base our estimates on our historical experience and on assumptions that we believe are reasonable; however, actual results may differ materially from these estimates under different assumptions or conditions.

There were no changes during the nine months ended September 30, 2025 to our critical accounting estimates as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2024. For information on our significant accounting policies, please refer to Note 2. “*Summary of Significant Accounting Policies*” within our Annual Report on Form 10-K for the year ended December 31, 2024.

JOBS Act and Smaller Reporting Company Status

As an emerging growth company under the Jumpstart Our Business Startups Act of 2012, as amended (the JOBS Act), we can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for complying with new or revised accounting standards, and as a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates. We intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002.

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of the consummation of our initial public offering in February 2023, (ii) the last

day of the fiscal year in which we have total annual gross revenue of at least \$1.235 billion, (iii) the last day of the fiscal year in which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if, among other factors, the market value of our common stock held by non-affiliates exceeded \$700.0 million as of the last business day of the second fiscal quarter of such year (subject to certain conditions), or (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 as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than \$250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than \$100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than \$700.0 million measured on the last business day of our second fiscal quarter.

Recently Issued Accounting Pronouncements

We have reviewed all recently issued accounting pronouncements and have determined that, other than as disclosed elsewhere in this Quarterly Report, such standards do not have a material impact on our condensed financial statements or do not otherwise apply to our operations.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

We are exposed to market risk related to changes in interest rates of our investment portfolio of cash equivalents and investments. As of September 30, 2025, our cash equivalents and investments consisted of money market funds and U.S. treasury securities. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. The fair value of our short-term cash equivalents and investments is subject to change as a result of potential changes in market interest rates. Due to the nature of our cash equivalents and investments, we believe an immediate hypothetical 10% change in interest rates would not have had a material effect on our results of operations during the periods presented.

Foreign Currency Exchange Risk

We are exposed to market risk related to changes in foreign currency exchange rates. We contract with vendors that are located outside the United States and certain invoices are denominated in foreign currencies. We are subject to fluctuations in foreign currency rates in connection with these arrangements. To date, these fluctuations have not been significant, and we have not had a formal hedging program with respect to foreign currency. We believe an immediate hypothetical 10% change in exchange rates would not have had a material effect on our results of operations during the periods presented.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and research and development contract costs. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, we may experience some effect in the future due to an impact on the costs to conduct clinical trials, labor costs we incur to attract and retain qualified personnel, and other operational costs. Inflationary costs could adversely affect our business, financial condition, and results of operations.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the design and operation of our disclosure controls and procedures, as such term is defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Exchange Act, as of the end of the period covered by this Quarterly Report. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective and were operating at a reasonable assurance level as of September 30, 2025.

Changes in Internal Control over Financial Reporting

Management has determined that there were no changes in our internal control over financial reporting that occurred during the three months ended September 30, 2025 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

We are not currently a party to any material proceeding. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm, and other factors.

Item 1A. Risk Factors

Our business, financial condition, and operating results may be affected by a number of factors, whether currently known or unknown, including but not limited to those described below and in [Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2024](#) under the heading “Risk Factors.” Any one or more of such factors could directly or indirectly cause our actual results of operations and financial condition to vary materially from past or anticipated future results of operations and financial condition. Any of these factors, in whole or in part, alone or combined with any of the other factors, could materially and adversely affect our business, financial condition, results of operations, and stock price. Except as set forth below, there have been no material changes to our risk factors since our Annual Report on Form 10-K for the year ended December 31, 2024.

The risk factor titled “Inflation could adversely affect our business and results of operations.” from our Annual Report on Form 10-K for the year ended December 31, 2024 is amended and restated as follows:

Changes in trade policy and inflation could adversely affect our business and results of operations.

The U.S. government has adopted new approaches to trade policy, and in some cases may renegotiate, or potentially terminate, certain existing bilateral or multilateral trade agreements. The U.S. government has also imposed tariffs on most foreign goods and has raised the possibility of imposing significant tariff increases or expanding the tariffs to capture other countries and types of goods. In particular, tariffs are likely to make procuring materials for producing active pharmaceutical ingredients more difficult or costly or require us to incur significant costs to transition to alternative suppliers. Future tariff increases, expanding the tariffs to cover other countries, or other changes in U.S. trade policy could exacerbate these challenges. In response to these tariffs, other countries have threatened, announced, or implemented retaliatory tariffs on U.S. goods, and such retaliatory actions are likely to continue for at least as long as U.S. tariffs remain elevated.

While inflation in the United States has been relatively low in recent years, the economy in the United States has encountered a material level of inflation since 2021. Although inflation has eased somewhat in 2024 and 2025, it has raised our costs for commodities, labor, materials, services, and other costs required to grow and operate our business, and failure to secure these on reasonable terms may adversely impact our financial condition.

Elevated inflation, along with public health concerns, domestic and international elections and other political developments, and global supply chain disruptions, have caused, and may in the future cause, domestic and global economic uncertainty and uncertainty about the interest rate environment, which may make it more difficult, costly, or dilutive for us to secure additional financing. In addition, political tensions and uncertainty as a result of trade policies could reduce trade volume, investment, technological exchange, and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. A failure to adequately respond to these risks could have a material adverse impact on our financial position.

The risk factor titled “Changes in tax law may materially adversely affect our financial condition, results of operations, and cash flows, or adversely impact the value of an investment in our common stock.” from our Annual Report on Form 10-K for the year ended December 31, 2024 is amended and restated as follows:

Changes in tax laws or in their implementation or interpretation may materially adversely affect our financial condition, results of operations, and cash flows, or adversely impact the value of an investment in our common stock.

New income, sales, use, or other tax laws, statutes, rules, regulations, or ordinances could be enacted or amended at any time, or interpreted, changed, modified, or applied adversely to us, any of which could adversely affect our business operations and financial performance. For example, the Inflation Reduction Act (IRA) was signed into law in August 2022, and the One Big Beautiful Bill Act (OBBBA) was signed into law in July 2025. The OBBBA contains numerous tax provisions that we are currently in the process of evaluating, and which may affect our business or financial condition. Regulatory guidance under the IRA, the OBBBA, and other tax-related legislation is and continues to be forthcoming, and such guidance could ultimately increase or lessen the impact of these laws on our business and financial condition. In addition, it is uncertain if and to what extent various states will conform to changes to federal tax legislation. We urge our investors to consult with their legal and tax advisors with respect to any changes in tax law and the potential tax consequences of investing in our common stock.

The risk factor titled “Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain, or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved, or commercialized in a timely manner or at all, which could negatively impact our business.” from our Annual Report on Form 10-K for the year ended December 31, 2024 is amended and restated as follows:

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain, or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved, or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and other government agencies to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, a government agency’s ability to hire and retain key personnel and accept the payment of user fees, government shutdowns and other events that may otherwise affect the government agency’s ability to perform routine functions. Average review times at the FDA and other government agencies have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs or modifications to approved drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times, including the ongoing shutdown that began on October 1, 2025, and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. While the COVID-19 pandemic is no longer having a significant disruptive impact on the FDA’s standard inspection operations of domestic and foreign manufacturing facilities, it is possible that another global pandemic could result in similar issues faced during the COVID-19 pandemic. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in the future. If the current government shutdown continues or a new government shutdown occurs, or if future global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the

ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, including our planned NDA for lorundrostat, which could have a material adverse effect on our business.

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

None.

Item 3. Defaults Upon Senior Securities

Not Applicable.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

During the three months ended September 30, 2025, none of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) adopted or terminated any contract, instruction, or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) of the Exchange Act or any non-Rule 10b5-1 trading arrangement (as defined in the SEC's rules).

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation	8-K	2/14/23	3.1	
3.2	Amended and Restated Bylaws	8-K	2/14/23	3.2	
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				x
31.2	Certification of Principal Financial 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				x
32.1*	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				x
32.2*	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				x
101.INS	XBRL Instance Document				x
101.SCH	XBRL Taxonomy Extension Schema Document				x
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				x
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				x
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				x

101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	x
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	x

* This certification is deemed not filed for the purpose of Section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

SIGNATURES

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

MINERALYS THERAPEUTICS, INC.

Date: November 10, 2025

By: /s/ Jon Congleton
Jon Congleton
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 10, 2025

By: /s/ Adam Levy
Adam Levy
Chief Financial Officer and Secretary
(Principal Financial Officer; Principal Accounting Officer)

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

I, Jon Congleton, certify that:

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

Date: November 10, 2025

By: /s/ Jon Congleton
Jon Congleton
Chief Executive Officer
(Principal Executive Officer)

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

I, Adam Levy, certify that:

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

Date: November 10, 2025

By: /s/ Adam Levy
Adam Levy
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

**CERTIFICATION 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 of Mineralys Therapeutics, Inc., a Delaware corporation (the “Company”) on Form 10-Q for the period ending September 30, 2025 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I certify, pursuant to 18 U.S.C. § 1350 as, adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 10, 2025

/s/ Jon Congleton

Jon Congleton

Chief Executive Officer

(Principal Executive Officer)

**CERTIFICATION 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 of Mineralys Therapeutics, Inc., a Delaware corporation (the “Company”) on Form 10-Q for the period ending September 30, 2025 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I certify, pursuant to 18 U.S.C. § 1350 as, adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 10, 2025

/s/ Adam Levy

Adam Levy

Chief Financial Officer

(Principal Financial Officer and Principal Accounting Officer)