

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, 2023

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, Ste 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 and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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 Act). Yes  No

As of November 1, 2023, there were 41,105,118 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, 2023 (unaudited)	December 31, 2022
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 86,300	\$ 87,701
Investments	167,461	22,409
Prepaid and other current assets	11,614	2,701
Total current assets	265,375	112,811
Investments, noncurrent	12,129	—
Other assets	51	1,631
Total assets	\$ 277,555	\$ 114,442
<b>Liabilities, convertible preferred stock, and stockholders' equity (deficit)</b>		
Current liabilities:		
Accounts payable	\$ 5,573	\$ 1,907
Accrued liabilities	7,970	6,160
Total current liabilities	13,543	8,067
Commitments and contingencies (Note 4)		
Series A convertible preferred stock, \$0.0001 par value, 0 and 86,332,216 shares authorized and 0 and 86,332,216 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively, \$0 and \$41,180 aggregate liquidation preference as of September 30, 2023 and December 31, 2022, respectively	—	40,987
Series B convertible preferred stock, \$0.0001 par value, 0 and 136,510,868 shares authorized and 0 and 136,510,868 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively, \$0 and \$118,000 aggregate liquidation preference as of September 30, 2023 and December 31, 2022, respectively	—	117,657
Stockholders' equity (deficit):		
Common stock, \$0.0001 par value, 500,000,000 and 319,000,000 shares authorized and 41,105,118 and 6,419,238 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	4	1
Additional paid-in capital	364,327	540
Accumulated deficit	(100,319)	(52,810)
Total stockholders' equity (deficit)	264,012	(52,269)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	\$ 277,555	\$ 114,442

*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,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$ 22,499	\$ 6,059	\$ 46,676	\$ 18,432
General and administrative	3,774	1,364	10,270	3,039
Total operating expenses	26,273	7,423	56,946	21,471
Loss from operations	(26,273)	(7,423)	(56,946)	(21,471)
Interest income, net	3,513	741	9,435	741
Other income	—	4	2	4
Total other income, net	3,513	745	9,437	745
Net loss	\$ (22,760)	\$ (6,678)	\$ (47,509)	\$ (20,726)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.57)	\$ (1.29)	\$ (1.36)	\$ (4.02)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	39,930,748	5,181,410	34,872,287	5,152,752

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

**Mineralys Therapeutics, Inc.**  
**Condensed Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)**  
(in thousands, except share data)  
(unaudited)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-In- Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance as of December 31, 2021	61,180,259	\$ 28,996	—	\$ —	5,441,980	\$ 1	\$ 85	\$ (23,011)	\$ (22,925)
Issuance of Series A convertible preferred stock, net of issuance costs of \$7	25,151,957	11,991	—	—	—	—	—	—	—
Issuance of restricted stock awards	—	—	—	—	172,444	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	19	—	19
Net loss	—	—	—	—	—	—	—	(7,569)	(7,569)
Balance as of March 31, 2022	86,332,216	40,987	—	—	5,614,424	1	104	(30,580)	(30,475)
Issuance of Series B convertible preferred stock, net of issuance costs of \$343	—	—	136,510,868	117,657	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	26	—	26
Net loss	—	—	—	—	—	—	—	(6,479)	(6,479)
Balance as of June 30, 2022	86,332,216	40,987	136,510,868	117,657	5,614,424	1	130	(37,059)	(36,928)
Issuance of restricted stock awards	—	—	—	—	804,814	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	192	—	192
Net loss	—	—	—	—	—	—	—	(6,678)	(6,678)
Balance as of September 30, 2022	86,332,216	\$ 40,987	136,510,868	\$ 117,657	6,419,238	\$ 1	\$ 322	\$ (43,737)	\$ (43,414)

**Mineralys Therapeutics, Inc.**  
**Condensed Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit) (Continued)**  
(in thousands, except share data)  
(unaudited)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-In- Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance as of December 31, 2022	86,332,216	\$ 40,987	136,510,868	\$ 117,657	6,419,238	\$ 1	\$ 540	\$ (52,810)	\$ (52,269)
Conversion of preferred stock to common stock upon closing of initial public offering	(86,332,216)	(40,987)	(136,510,868)	(117,657)	20,637,415	2	158,642	—	158,644
Issuance of common stock in initial public offering, net of issuance costs of \$19,441	—	—	—	—	13,800,000	1	201,358	—	201,359
Stock-based compensation	—	—	—	—	—	—	749	—	749
Net loss	—	—	—	—	—	—	—	(12,608)	(12,608)
Balance as of March 31, 2023	—	—	—	—	40,856,653	4	361,289	(65,418)	295,875
Issuance of restricted stock awards	—	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	1,276	—	1,276
Net loss	—	—	—	—	—	—	—	(12,141)	(12,141)
Balance as of June 30, 2023	—	—	—	—	40,856,653	4	362,565	(77,559)	285,010
Issuance of common stock from stock option exercises	—	—	—	—	248,465	—	184	—	184
Stock-based compensation	—	—	—	—	—	—	1,578	—	1,578
Net loss	—	—	—	—	—	—	—	(22,760)	(22,760)
Balance as of September 30, 2023	—	\$ —	—	\$ —	41,105,118	\$ 4	\$ 364,327	\$ (100,319)	\$ 264,012

*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,	
	2023	2022
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (47,509)	\$ (20,726)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accretion of discount on held-to-maturity securities	(4,799)	(239)
Stock-based compensation	3,603	237
Changes in operating assets and liabilities:		
Accrued interest receivable	(655)	—
Prepaid and other current assets	(8,308)	(473)
Accounts payable and accrued liabilities	5,476	2,166
Net cash used in operating activities	<u>(52,192)</u>	<u>(19,035)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of marketable securities	(274,883)	(71,759)
Maturity of marketable securities	122,500	—
Net cash used in investing activities	<u>(152,383)</u>	<u>(71,759)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Issuance of common stock in initial public offering, net of offering costs	202,990	(561)
Proceeds from stock option exercises	184	—
Proceeds from the issuance of Series A convertible preferred stock, net of offering costs	—	11,991
Proceeds from the issuance of Series B convertible preferred stock, net of offering costs	—	117,657
Net cash provided by financing activities	<u>203,174</u>	<u>129,087</u>
Net increase in cash and cash equivalents	(1,401)	38,293
Cash, cash equivalents, and restricted cash - beginning	87,701	10,662
Cash and cash equivalents - ending <sup>(1)</sup>	<u>\$ 86,300</u>	<u>\$ 48,955</u>
<b>Supplement Disclosure of Non-Cash Financing Activities:</b>		
Conversion of convertible preferred stock to common stock upon closing of initial public offering	<u>\$ 159,180</u>	<u>\$ —</u>
Deferred offering costs included in accounts payable and accrued liabilities	<u>\$ —</u>	<u>\$ 421</u>

(1) Cash and cash equivalents as of September 30, 2023 exclude investments of \$179.6 million. Cash, cash equivalents, and investments amounted to \$265.9 million as of September 30, 2023.

*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 abnormally elevated aldosterone. The Company's clinical-stage product candidate, lorundrostat, is a proprietary, orally administered, aldosterone synthase inhibitor that the Company is initially developing for the treatment of cardiorenal conditions affected by abnormally elevated aldosterone, including hypertension and chronic kidney disease. The Company has initiated a pivotal clinical program of lorundrostat for the treatment of uncontrolled or resistant hypertension and has plans to initiate a Phase 2 trial in the second half of 2023 for lorundrostat in hypertensive patients with Stage 2 to 3b chronic kidney disease. 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 lorundrostat, conducting preclinical and clinical trials, and other research and development.

*Initial Public Offering*

On February 14, 2023, the Company completed an initial public offering (IPO) of 13,800,000 shares of its common stock, which included the exercise in full by the underwriters of their option to purchase 1,800,000 additional shares, at a public offering price of \$16.00 per share. The net proceeds to the Company from the IPO were \$201.4 million, net of underwriting discounts, commissions, and offering costs.

*Reverse Stock Split*

On February 1, 2023, the Company effected a one-for-10.798 reverse stock split of its issued and outstanding shares of common stock, par value \$0.0001 per share, and a proportional adjustment to the existing conversion ratio of the Company's preferred stock (the Reverse Stock Split). Accordingly, all share and per-share amounts for all periods presented in the accompanying condensed financial statements and notes thereto have been adjusted to reflect this Reverse Stock Split.

*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, 2023, the Company had an accumulated deficit of \$100.3 million and cash, cash equivalents, and investments of \$265.9 million. For the nine months ended September 30, 2023, the Company had a net loss of \$47.5 million and net cash used in operating activities of \$52.2 million.

From inception to September 30, 2023, the Company has funded its operations by raising aggregate gross proceeds of approximately \$378.8 million from the sale of the Company's common stock, convertible preferred stock, and convertible notes. 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 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, 2023 will be sufficient to allow the Company to fund operations for at least twelve months from the issuance date of these condensed financial statements.



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

**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 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, 2022.

Any reference in these notes to applicable guidance is meant to refer to the 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 and making operating decisions and, accordingly, no segment disclosures have been presented herein. 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, fair value of the Company's common stock prior to the closing of the Company's IPO, 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. As of September 30, 2023 and December 31, 2022, the Company did not have any restricted cash balances. The following table provides a reconciliation of cash, cash equivalents, and restricted cash as reported in the statement of cash flows to the balance sheets (in thousands):

	<b>September 30,</b> <b>2023</b>	<b>December 31,</b> <b>2022</b>
Cash	\$ 1,352	\$ 2,872
Cash equivalents	84,948	84,829
Total cash and cash equivalents	<u>\$ 86,300</u>	<u>\$ 87,701</u>

The Company's cash and cash equivalents balances as of September 30, 2023 include cash balances, time deposits, and amounts held primarily in interest-bearing money market accounts. As of December 31, 2021, the Company had \$50 thousand classified as restricted cash, which is reported in the 2022 opening cash, cash equivalents, and restricted cash balance reported in the condensed statements of cash flows.

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

*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 two financial institutions which, 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 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 restricted cash, 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, current investments, and investments - noncurrent 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, 2023 and 2022, 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 other income, net in the Company's condensed statements of operations and a new cost basis in the investment is established.

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

*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 statement of operations. Deferred offering costs as of September 30, 2023 and December 31, 2022 were \$0 and \$1.6 million, respectively. Such costs are classified in other assets on the condensed balance sheets.

*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 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 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 utilized 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 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. Prior to the closing of the Company's IPO, there was no public market for the Company's common stock, and the Company determined the fair value of the shares of its common stock underlying its share-based awards by considering a number of objective and subjective factors, including third-party valuations of the Company's common stock, the valuation of comparable companies, the Company's operating and financial performance, and general and industry-specific economic outlook, among other factors. 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. The Company accounts for forfeitures as they occur.

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

*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, convertible preferred stock 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 following table sets forth the potential common shares excluded from the calculation of net loss per common share because their inclusion would be anti-dilutive:

	Nine Months Ended September 30,	
	2023	2022
Outstanding options	2,568,503	1,320,932
Unvested restricted stock awards	1,047,648	1,228,075
Convertible preferred stock (as converted into common stock)	—	20,637,415
Total	<u>3,616,151</u>	<u>23,186,422</u>

*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.

**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, 2023 and December 31, 2022 (in thousands):

	September 30, 2023	December 31, 2022
	Level 1	
<b>Assets</b>		
Cash equivalents		
Money market funds	\$ 45,356	\$ 84,829
Time deposits	39,592	—
Total cash equivalents	<u>\$ 84,948</u>	<u>\$ 84,829</u>

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

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 and Time Deposits—The carrying amounts of money market funds and time deposits 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.

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

U.S. Treasury Bills—As of September 30, 2023 and December 31, 2022, the Company had short- and/or long-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 held-to-maturity U.S. Treasury bills information as of each reported date (in thousands):

Balance Sheet Location	Original Maturities	As of September 30, 2023	
		Amortized Cost	Estimated Fair Value
Investments	between 3 and 12 months	\$ 167,461	\$ 167,280
Investments, noncurrent	greater than 1 year	12,129	12,066
Total		\$ 179,590	\$ 179,346

Balance Sheet Location	Original Maturities	As of December 31, 2022	
		Amortized Cost	Estimated Fair Value
Investments	between 3 and 6 months	\$ 22,409	\$ 22,386

**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 the Company was initially obligated to pay Mitsubishi Tanabe development milestone payments of up to \$9.0 million in the aggregate and 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 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

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**(unaudited)**

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.

The Company incurred \$4.0 million and \$0 of research and development expenses related to the Mitsubishi License during the nine months ended September 30, 2023 and 2022, respectively. A development milestone was achieved in March 2023 related to the Company's planned initiation of its pivotal clinical program of lorundrostat.

*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 nine months ended September 30, 2023 and 2022, 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 liabilities related to such obligations in its condensed financial statements as of September 30, 2023 and December 31, 2022.

**Note 5. Accrued Liabilities**

Accrued liabilities consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Research and development expenses	\$ 5,853	\$ 4,846
Compensation and benefits	1,221	665
Professional fees and other	896	649
Total	\$ 7,970	\$ 6,160

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**Notes to Condensed Financial Statements**  
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**Note 6. Capital Stock**

As of September 30, 2023, the Company had reserved authorized shares of common stock for future issuance as follows:

	<b>September 30, 2023</b>
Shares available for grant under the 2023 Plan	3,198,474
Common stock options outstanding	2,568,503
Shares available for grant under the ESPP	400,000
Total	<u>6,166,977</u>

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.

Immediately prior to the closing of the IPO, 86,332,216 shares of Series A Preferred Stock and 136,510,868 shares of Series B Preferred Stock converted into 20,637,415 shares of the Company's common stock, and the carrying value of Series A Preferred Stock and Series B Preferred Stock was converted to permanent equity.

*Preferred Stock Offerings*

In February 2021, the Company entered into a Series A redeemable convertible preferred stock agreement (the Series A Purchase Agreement). From February 2021 to April 2021, the Company issued 50,311,827 shares of Series A Preferred Stock at \$0.477 per share for net proceeds of \$23.8 million. Additionally, in February 2021, the Company's convertible notes and related accrued interest converted into 10,868,432 shares of Series A Preferred Stock. The Series A Purchase Agreement provided for an additional closing for the Series A purchasers for the issuance of up to 25,151,957 shares of Series A Preferred Stock, at a purchase price of \$0.477 per share for aggregate cash proceeds of \$12.0 million, upon the achievement of the Milestone (as defined in the Series A Purchase Agreement) or a waiver of the Milestone by the requisite holders. In January 2022, the Company achieved the Milestone under the Series A Purchase Agreement and sold an aggregate of 25,151,957 shares of Series A Preferred Stock under the Series A Purchase Agreement to certain existing investors, members of the Company's board of directors and affiliates of members of its board of directors, at a purchase price of \$0.477 per share for aggregate net proceeds of approximately \$12.0 million.

In June 2022, the Company entered into a Series B convertible preferred stock agreement with certain investors, including members of the Company's board of directors and affiliates of members of its board of directors, pursuant to which the Company issued and sold to such investors an aggregate of 136,510,868 shares of Series B Preferred Stock at a purchase price of \$0.8644 per share for aggregate net proceeds of approximately \$117.7 million.

**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 (2023 Plan), under which the Company may grant stock options, restricted stock, 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

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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 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.

The number of shares initially available for issuance will be increased on January 1 of each calendar year beginning in 2024 and ending in 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.

In connection with the Company's IPO, the Company's board of directors approved the grant under the 2023 Plan of stock options to purchase an aggregate of 1,071,935 shares of its common stock to certain of the Company's employees and directors, at an exercise price equal to the IPO price of \$16.00.

*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, restricted stock awards, restricted stock unit awards, and other forms of stock awards to employees, directors, and consultants of the Company.

The board of directors or a designated committee of the board of directors is responsible for the administration of the 2020 Plan and determined the term, exercise price, and vesting terms of each award. Under the terms of existing awards, all stock option grants expire ten years from the grant date. New option grants could not have an exercise price less than 100% of the fair market value of the Company's common stock on the grant date, and generally vest over a period of four years.

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.

*2023 Employee Stock Purchase Plan*

In February 2023, the Company's board of directors and stockholders approved the 2023 Employee Stock Purchase Plan (ESPP), which became effective upon the closing of the Company's IPO. 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.

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.



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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development	\$ 759	\$ 79	\$ 1,619	\$ 109
General and administrative	819	113	1,984	128
Total	<u>\$ 1,578</u>	<u>\$ 192</u>	<u>\$ 3,603</u>	<u>\$ 237</u>

## 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, 2022 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, 2022.*

### 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 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. 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, 2022, 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.

### Overview

We are a clinical-stage biopharmaceutical company focused on developing medicines to target diseases driven by abnormally elevated aldosterone. Our clinical-stage product candidate, lorundrostat, is a proprietary, orally administered, highly selective aldosterone synthase inhibitor that we are initially developing for the

treatment of cardiorenal conditions affected by abnormally elevated aldosterone, including hypertension and chronic kidney disease (CKD). In the United States, there are over 115 million patients who have sustained elevated blood pressure (BP), or hypertension, and more than half of this population fails to achieve their BP goals, defined as BP of 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. In a Phase 2 proof-of-concept clinical trial evaluating 200 subjects with uncontrolled hypertension (uHTN) or resistant hypertension (rHTN), lorundrostat demonstrated a clinically meaningful and statistically significant reduction in BP with once-daily dosing and was well tolerated. In addition to hypertension, we intend to develop lorundrostat for the treatment of CKD and believe that our product candidate holds promise to be an innovative solution for the rapidly growing unmet need in multiple cardiorenal disorders.

## **Clinical Highlights**

### *Pivotal Hypertension Program*

In April 2023, we initiated our first pivotal trial, Advance-HTN, a randomized, double-blind, placebo-controlled Phase 2 clinical trial to evaluate the safety and efficacy of lorundrostat for the treatment of uHTN or rHTN, when used as an add-on therapy to standardized background treatment of two or three antihypertensive medications in up to approximately 300 adult subjects. Topline data from this trial is anticipated in the second half of 2024.

We also plan to initiate our second pivotal trial, Launch-HTN, a randomized, double-blind, placebo-controlled Phase 3 clinical trial in the second half of 2023 to evaluate the safety and efficacy of lorundrostat for the treatment of uHTN or rHTN, when used as an add-on therapy to prescribed background treatment of two to five antihypertensive medications in up to approximately 1,000 adult subjects. The trial is expected to have a similar design to the Target-HTN trial. Topline data from this trial is expected in the second half of 2025.

In mid-2023, we initiated an open-label extension trial to allow subjects to continue to receive lorundrostat and obtain long-term safety and efficacy data. All subjects in the pivotal hypertension program, including the Advance-HTN and Launch-HTN trials, as well as the Explore-CKD trial, will be given the opportunity to participate in the extension trial.

### *Other Indications*

Lorundrostat has been developed to normalize the production of aldosterone, and we believe this mechanism can be applied to other indications where abnormal aldosterone biology plays a role, including CKD and cardiorenal indications.

Uninhibited aldosterone is known to play a critical role in the progression of CKD. CKD is characterized by the gradual loss of kidney function, is estimated to affect more than 10% of the global population and over 23 million people in the United States, and is one of the leading causes of mortality worldwide. According to the U.S. Centers for Disease Control and Prevention (CDC), an estimated 1-in-7 (15%) of U.S. adults have CKD. Diabetes and hypertension are responsible for approximately two-thirds of CKD cases. Early detection and treatment can often keep CKD from getting worse. When CKD progresses, it may eventually lead to kidney failure, which requires dialysis or a kidney transplant to maintain life.

We plan to initiate a two-part Phase 2 trial, Explore-CKD, in the second half of 2023 for lorundrostat in hypertensive patients with Stage 2 to 3b CKD. The planned Phase 2 clinical trial includes an initial proof-of-concept portion (Part A) and a profiling portion (Part B). As this is an exploratory trial, interim data analyses may be conducted at one or more time points. Topline data from this trial is anticipated between the fourth quarter of 2024 and the first quarter of 2025.

## 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, 2023, we had cash, cash equivalents, and investments of \$265.9 million. From inception to September 30, 2023, we raised aggregate gross proceeds of approximately \$378.8 million from the sale of common stock, convertible preferred stock, and convertible notes. In February 2023, we completed our initial public offering (IPO) of 13,800,000 shares of our common stock at a price to the public of \$16.00 per share, including the exercise in full by the underwriters of their option to purchase 1,800,000 additional shares of our common stock. Including the option exercise, our aggregate net proceeds from the IPO were approximately \$201.4 million, net of underwriting discounts, commissions, and offering costs.

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 activities. Our net losses for the nine months ended September 30, 2023 and 2022 were \$47.5 million and \$20.7 million, respectively. As of September 30, 2023 and December 31, 2022, we had an accumulated deficit of \$100.3 million and \$52.8 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, potentially seek regulatory approval for lorundrostat and 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, which will not be for several years, 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 we were initially obligated to pay Mitsubishi Tanabe development milestone payments of up to \$9.0 million in the aggregate and 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 incurred \$4.0 million of research and development expenses during the nine months ended September 30, 2023 associated with an achieved development milestone in March 2023 related to the planned initiation of our pivotal clinical program of lorundrostat.

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.

## **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 and consultants to conduct and support our clinical trials of lorundrostat, and payments made under the Mitsubishi License; and
- costs related to manufacturing lorundrostat for our clinical trials.

We plan to substantially increase our research and development expenses for the foreseeable future as we continue the development of lorundrostat. 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, 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 drop-out or discontinuation rates of clinical trial patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the phase of development of the product candidate;
- the impact of any interruptions to our operations or to those of the third parties with whom we work due to the ongoing COVID-19 pandemic;
- 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, and investor and public relations costs.

#### *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, 2023 and 2022

	Three Months Ended, September 30,		Change
	2023	2022	
	(in thousands)		
Research and development expenses	\$ (22,499)	\$ (6,059)	\$ (16,440)
General and administrative expenses	(3,774)	(1,364)	(2,410)
Total other income, net	3,513	745	2,768
Net loss	\$ (22,760)	\$ (6,678)	\$ (16,082)

### Research and Development Expenses

Research and development expenses increased by \$16.4 million for the three months ended September 30, 2023, compared to the three months ended September 30, 2022, which was primarily due to increases of \$12.4 million in preclinical and clinical costs, driven by the initiation of the lorundrostat pivotal program in the second quarter of 2023, \$2.3 million in clinical supply, manufacturing, and regulatory costs, and \$1.7 million in higher compensation expense resulting from additions to headcount.

### General and Administrative Expenses

General and administrative expenses increased by \$2.4 million for the three months ended September 30, 2023, compared to the three months ended September 30, 2022. The increase was primarily due to \$1.2 million in higher professional fees associated with operating as a public company, \$0.8 million in higher compensation expense resulting from additions to headcount, \$0.3 million of higher insurance expense associated with new director and officer insurance policies, and \$0.1 million in higher other administrative expenses.

### Total Other Income, Net

Total other income, net increased by \$2.8 million for the three months ended September 30, 2023, compared to the three months ended September 30, 2022, which was primarily attributable to increased interest earned on our investments in money market funds and U.S. treasuries.

## Results of Operations

Comparison of the Nine Months Ended September 30, 2023 and 2022

	Nine Months Ended, September 30,		Change
	2023	2022	
	(in thousands)		
Research and development expenses	\$ (46,676)	\$ (18,432)	(28,244)
General and administrative expenses	(10,270)	(3,039)	(7,231)
Total other income, net	9,437	745	8,692
Net loss	\$ (47,509)	\$ (20,726)	\$ (26,783)

### Research and Development Expenses

Research and development expenses increased by \$28.2 million for the nine months ended September 30, 2023, compared to the nine months ended September 30, 2022, which was primarily due to increases of \$15.3 million in preclinical and clinical costs, driven by the initiation of the lorundrostat pivotal program in the second quarter of 2023, \$4.9 million in clinical supply, manufacturing, and regulatory costs,

\$4.0 million in license fees under the Mitsubishi License upon achieving a development milestone of lorundrostat in March 2023, \$3.9 million in higher compensation expense resulting from additions to headcount, and \$0.1 million in other research and development expenses.

#### *General and Administrative Expenses*

General and administrative expenses increased by \$7.2 million for the nine months ended September 30, 2023, compared to the nine months ended September 30, 2022. The increase was primarily due to \$3.7 million in higher professional fees associated with operating as a public company, \$2.5 million in higher compensation expense resulting from additions to headcount, \$0.8 million of higher insurance expense associated with new director and officer insurance policies, and \$0.2 million in higher other administrative expenses.

#### *Total Other Income, Net*

Total other income, net increased by \$8.7 million for the nine months ended September 30, 2023, compared to the nine months ended September 30, 2022, which was primarily attributable to increased interest earned on our investments in money market funds and U.S. treasuries.

#### **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. From inception to September 30, 2023, we raised aggregate gross proceeds of approximately \$378.8 million from the sale of common stock, convertible preferred stock, and convertible notes. As of September 30, 2023, we had cash, cash equivalents, and investments of \$265.9 million. In February 2023, we completed our IPO of 13,800,000 shares of our common stock sold at a price to the public of \$16.00 per share, including the exercise in full by the underwriters of their option to purchase 1,800,000 additional shares of our common stock, for net proceeds of approximately \$201.4 million, net of underwriting discounts, commissions, and offering costs.

Our primary uses of cash to date have been to fund our research and development 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, 2023 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, 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;
- any delays and cost increases that may result from any pandemic or other healthcare emergency;
- 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, CMC, 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; and
- the other risks and uncertainties described under the heading "Risk Factors" in [Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2022](#) and in "Special Note Regarding Forward-Looking Statements and Market Data" 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, inflation, elevated interest rates, geopolitical conflict in and around Ukraine, Israel, and other areas of the world, 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, 2023 and 2022

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:

	Nine Months Ended September 30,	
	2023	2022
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$ (52,192)	\$ (19,035)
Investing activities	(152,383)	(71,759)
Financing activities	203,174	129,087
Net	<u>\$ (1,401)</u>	<u>\$ 38,293</u>

#### Operating Activities

Net cash used in operating activities of \$52.2 million during the nine months ended September 30, 2023 increased, compared to \$19.0 million during the nine months ended September 30, 2022, which 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 \$33.2 million increase in cash used consisted of an increase in net loss, adjusted for non-cash expenses of approximately \$27.9 million and the net effect of changes in working capital of \$5.3 million.

#### Investing Activities

Net cash used in investing activities of \$152.4 million during the nine months ended September 30, 2023 increased, compared to \$71.8 million during the nine months ended September 30, 2022, which was attributable to increased purchases of marketable securities of \$203.1 million during the nine months ended September 30, 2023 subsequent to receiving cash proceeds from our IPO in February 2023, partially offset by

increased maturities of the marketable securities of \$122.5 million during the nine months ended September 30, 2023.

#### *Financing Activities*

Net cash provided by financing activities of \$203.2 million during the nine months ended September 30, 2023 increased, compared to \$129.1 million during the nine months ended September 30, 2022. During the nine months ended September 30, 2023, we received aggregate gross proceeds of \$220.8 million from the sale of our common stock in our IPO in February 2023 and paid \$17.8 million of underwriting discounts, commissions, and offering costs in the same period. During the nine months ended September 30, 2022, we received \$129.6 million in net proceeds from the issuance and sale of our Series A and Series B convertible preferred stock.

#### **Contractual Obligations and Commitments**

Under the Mitsubishi License, we have milestone payment obligations that are contingent upon the achievement of certain development milestones and specified levels of product sales and are required to make certain royalty payments in connection with the sale of products developed under the agreement. Our next anticipated development milestone of \$5.0 million will become due by us upon initiation of the Launch-HTN trial. 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 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 and stock-based compensation. 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, 2023 to our critical accounting estimates as disclosed in our 2022 Annual Report on Form 10-K. For information on our significant accounting policies, please refer to Note 2. “*Summary of Significant Accounting Policies*” within our 2022 Annual Report on Form 10-K.

#### **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 IPO, (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 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, 2023, 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 near future (especially if inflation rates further increase) 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 Rule 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, 2023.

##### *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, 2023 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 subject to any material legal proceedings. From time to time, we may be involved in legal proceedings or subject to claims incident to the ordinary course of our business. Regardless of the outcome, such proceedings or claims can have an adverse impact on us due to defense and settlement costs, diversion of resources, negative publicity, reputational harm, and other factors. There can be no assurances that favorable outcomes will be obtained.

### 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 in [Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2022](#) 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. There have been no material changes to our risk factors since our Annual Report on Form 10-K for the year ended December 31, 2022.*

### Item 2. Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities

None.

### Item 3. Defaults Upon Senior Securities

Not Applicable.

### Item 4. Mine Safety Disclosures

Not Applicable.

### Item 5. Other Information

During the three months ended September 30, 2023, 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			
		Form	Date	Number	Filed Herewith
3.1	<a href="#">Amended and Restated Certificate of Incorporation</a>	8-K	2/14/23	3.1	
3.2	<a href="#">Amended and Restated Bylaws</a>	8-K	2/14/23	3.2	
31.1	<a href="#">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</a>				X

31.2	<a href="#">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</a>	x
32.1*	<a href="#">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</a>	x
32.2*	<a href="#">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</a>	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 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 Section 13 or 15(d) 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 7, 2023

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

Date: November 7, 2023

By: /s/ Adam Levy  
Adam Levy  
Chief Financial Officer, Chief Business 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 7, 2023

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 7, 2023

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, 2023 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 7, 2023

/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, 2023 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 7, 2023

/s/ Adam Levy

Adam Levy

Chief Financial Officer

(Principal Financial Officer and Principal Accounting Officer)