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 June 30, 2024

OR

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

For the transition period from _____ to _____

Commission file number 001-41614

MINERALYS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**84-1966887**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

150 N. Radnor Chester Rd, Suite F200, Radnor, PA 19087
(Address, including zip code, of principal executive offices)

888-378-6240
(Registrant's telephone number, including area code)

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically 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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of August 2, 2024, there were 49,726,675 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)

	June 30, 2024	December 31, 2023
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 67,856	$ 49,304
Investments	243,259	187,263
Prepaid and other current assets	6,886	12,536
Total current assets	318,001	249,103
Investments, noncurrent	—	2,482
Property and equipment, net	42	—
Other assets	449	51
Total assets	$ 318,492	$ 251,636
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,707	$ 601
Accrued liabilities	26,690	9,881
Total current liabilities	28,397	10,482
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Common stock, $0.0001 par value; 500,000,000 shares authorized as of June 30, 2024 and December 31, 2023; 49,710,598 and 41,133,916 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	5	4
Additional paid-in capital	487,320	365,858
Accumulated deficit	(197,230)	(124,708)
Total stockholders' equity	290,095	241,154
Total liabilities and stockholders' equity	$ 318,492	$ 251,636

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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 39,273	$ 11,884	$ 70,027	$ 24,177
General and administrative	5,895	3,851	10,503	6,496
Total operating expenses	45,168	15,735	80,530	30,673
Loss from operations	(45,168)	(15,735)	(80,530)	(30,673)
Interest income, net	4,152	3,593	8,005	5,922
Other income	2	1	3	2
Total other income, net	4,154	3,594	8,008	5,924
Net loss	$ (41,014)	$ (12,141)	$ (72,522)	$ (24,749)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.83)	$ (0.31)	$ (1.54)	$ (0.77)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	49,356,287	39,754,981	47,178,288	32,301,136

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' 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
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

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

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

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

	Six Months Ended June 30,	
	2024	**2023**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (72,522)	$ (24,749)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accretion of discount on held-to-maturity securities	(5,356)	(2,837)
Stock-based compensation	5,063	2,025
Depreciation and amortization	17	—
Changes in operating assets and liabilities:		
Accrued interest receivable	303	(436)
Prepaid and other current assets	5,337	(5,304)
Accounts payable and accrued liabilities	17,873	(1,860)
Net cash used in operating activities	(49,285)	(33,161)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of marketable securities	(250,657)	(218,890)
Maturity of marketable securities	202,500	62,500
Purchases of property and equipment	(59)	—
Net cash used in investing activities	(48,216)	(156,390)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock and pre-funded warrants in a private placement offering, net of paid offering costs	116,059	—
Proceeds from stock option exercises	203	—
Proceeds from the issuance of common stock for cash under employee stock purchase plan	138	—
Offering costs paid	(347)	—
Proceeds from issuance of common stock in initial public offering, net of offering costs	—	202,990
Net cash provided by financing activities	116,053	202,990
Net increase in cash and cash equivalents	18,552	13,439
Cash, cash equivalents, and restricted cash - beginning	49,304	87,701
Cash and cash equivalents - ending[1]	$ 67,856	$ 101,140
Supplement Disclosure of Non-Cash Financing Activities:		
Offering costs included in accounts payable and accrued liabilities	$ 42	$ —
Conversion of convertible preferred stock to common stock upon closing of initial public offering	$ —	$ 159,180

(1) Cash and cash equivalents as of June 30, 2024 exclude investments of $ 243.3 million. Cash, cash equivalents, and investments amounted to $ 311.1 million as of June 30, 2024.

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

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

Note 1. Nature of Business

Mineralys Therapeutics, Inc. (the Company) is a clinical-stage biopharmaceutical company focused on developing medicines to target diseases driven by dysregulated aldosterone. The Company's clinical-stage product candidate, lorundrostat, is a proprietary, orally administered, aldosterone synthase inhibitor that the Company is initially developing for the treatment of cardiorenal conditions affected by dysregulated 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 a Phase 2 trial 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 June 30, 2024, the Company had an accumulated deficit of $197.2 million and cash, cash equivalents, and investments of $311.1 million. For the six months ended June 30, 2024, the Company had a net loss of $72.5 million and net cash used in operating activities of $49.3 million.

From inception to June 30, 2024, the Company has funded its operations by raising aggregate gross proceeds of approximately $498.8 million from the sale of the Company's common stock, convertible preferred stock, convertible notes, and pre-funded warrants. The Company has a limited operating history, and the sales and income potential of its business is unproven. The Company expects to continue to incur substantial losses in the foreseeable future as a result of the Company's research and development 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 June 30, 2024 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 (SEC) for interim reporting. As permitted under those rules and regulations, certain footnotes or other financial information normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. These condensed financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, which are necessary for a fair presentation of the Company's financial information. These unaudited condensed financial statements should be read in conjunction with the audited financial statements and related notes in the Company's Annual Report on Form 10-K for the year ended December 31, 2023.

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 equivalentsAs of June 30, 2024 and December 31, 2023, the Company did not have any restricted cash balances. The Company's cash and cash equivalents balances as of June 30, 2024 include cash balances and amounts held primarily in interest-bearing money market accounts. The following table provides a reconciliation of cash and cash equivalents as reported in the statement of cash flows to the balance sheets (in thousands):

	June 30, 2024	December 31, 2023
Cash	$ 97	$ 643
Cash equivalents	67,759	48,661
Total cash and cash equivalents	$ 67,856	$ 49,304

Concentration of Credit Risk

The Company has no significant off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts, or other hedging arrangements. Financial instruments that

potentially subject the Company to concentrations of credit risk primarily consist of cash balances in several accounts with three financial institutions 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 cash equivalents, prepaid expenses, accounts payable, and certain accrued liabilities, the recorded amount approximates estimated fair value due to their relatively short maturity period. Refer to Note 3. "*Fair Value of Financial Instruments*" for additional details of the Company's financial instruments.

Investments

The Company generally invests its excess cash in money market funds and investment-grade short- and long-term fixed-income debt securities, such as U.S. Treasury bills. Such investments are included in cash and cash equivalents, 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 six months ended June 30, 2024 and 2023, 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.

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 June 30, 2024 and December 31, 2023 were $0.4 million and $0, 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 utilizes the contractual term for options granted.

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

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

Subsequent to the closing of the Company's 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. Management evaluates its award grants and modifications and will adjust the fair value if any are determined to be spring-loaded. The Company accounts for forfeitures as they occur.

Net Loss Per Share

The Company's basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock

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

	Six Months Ended June 30,	
	2024	2023
Outstanding options	4,394,713	2,657,113
Unvested restricted stock awards	540,497	1,087,367
Total	4,935,210	3,744,480

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 June 30, 2024 and December 31, 2023 (in thousands):

	June 30, 2024	December 31, 2023
	Level 1	
Assets		
Cash equivalents		
Money market funds	$ 67,759	$ 48,661

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

U.S. Treasury Bills—As of June 30, 2024 and December 31, 2023, the Company had short- and 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 information about the Company's investments in held-to-maturity U.S. Treasury bills as of each reported date (in thousands):

		As of June 30, 2024	
Balance Sheet Location	Original Maturities	Amortized Cost	Estimated Fair Value
Investments	between 3 and 12 months	$ 243,259	$ 243,182

		As of December 31, 2023	
Balance Sheet Location	Original Maturities	Amortized Cost	Estimated Fair Value
Investments	between 3 and 12 months	$ 187,263	$ 187,293
Investments, noncurrent	greater than 1 year	2,482	2,486
Total		$ 189,745	$ 189,779

Note 4. Commitments and Contingencies

License Agreement with Mitsubishi Tanabe

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

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

Unless terminated earlier, the Mitsubishi License will continue until the expiration of all of the Company's royalty obligations to Mitsubishi Tanabe. The Company may terminate the Mitsubishi License for any or no reason upon 90 or 180 days' prior written notice to Mitsubishi Tanabe depending on whether the Lorundrostat Product has received regulatory approval. Mitsubishi Tanabe may terminate the Mitsubishi License if the Company has not initiated regulatory consultation for the first global clinical trials of lorundrostat in at least one major market country within a specified amount of time or if the Company or its affiliates or

sublicensees initiate a challenge to the patent rights licensed to the Company by Mitsubishi Tanabe. In addition, either party may terminate the Mitsubishi License in the event of an uncured material breach by or bankruptcy of the other party, subject to certain notice and cure periods, or upon the other party's bankruptcy or insolvency.

The Company incurred $0 and $4.0 million of research and development expenses pursuant to the Mitsubishi License during the six months ended June 30, 2024 and 2023, respectively, that related to the Company's initiation of its pivotal clinical program of lorundrostat. As of June 30, 2024, the Company has paid an aggregate of $9.0 million in development milestone payments and has no remaining development milestone obligations under the Mitsubishi License.

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 six months ended June 30, 2024 and 2023, 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 June 30, 2024 and December 31, 2023.

Note 5. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	June 30, 2024	December 31, 2023
Research and development expenses	$ 23,277	$ 7,122
Compensation and benefits	1,334	1,599
Professional fees and other	2,079	1,160
Total	$ 26,690	$ 9,881

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

Note 6. Capital Stock

As of June 30, 2024, the Company had reserved authorized shares of common stock for future issuance as follows:

Common stock options outstanding	4,394,713
Shares available for grant under the 2023 Plan	2,799,930
Shares available for grant under the ESPP	783,718
Pre-funded warrants issued and outstanding	549,755
Total	8,528,116

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.

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.

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.

Private Placement Offering

On February 7, 2024, the Company entered into a securities purchase agreement (the Purchase Agreement) with the purchasers named therein (the Purchasers), for the private placement (the Private Placement) of (i) 8,339,169 shares (the Shares) of the Company's common stock at a price of $13.50 per Share, and (ii) with respect to certain Purchasers, pre-funded warrants to purchase an aggregate of 549,755 shares of common stock (the Pre-Funded Warrants) in lieu of shares of common stock, at a purchase price of $13.499 per Pre-Funded Warrants (the shares of common stock issuable upon exercise of the Pre-Funded Warrants, the Warrant Shares) for aggregate net proceeds of approximately $116.1 million. The Company is using the net

proceeds from the Private Placement to fund the research and development of lorundrostat and for working capital and general corporate purposes.

Each Pre-Funded Warrant has an exercise price of $0.001 per share of common stock, is immediately exercisable on the date of issuance, and will not expire. Under the terms of the Pre-Funded Warrants, the Company may not effect the exercise of any portion of any Pre-Funded Warrant, and a holder will not have the right to exercise any portion of any Pre-Funded Warrant, which, upon giving effect to such exercise, would cause a holder (together with its affiliates) to own more than a specified beneficial ownership limitation of either 4.99%, 9.99%, or 19.99% (as selected by such holder prior to the issuance of the Pre-Funded Warrant) of the number of shares of common stock outstanding immediately after giving effect to such exercise, as such percentage ownership is determined in accordance with the terms of the Pre-Funded Warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 19.99%, provided that any increase in such percentage shall not be effective until 61 days after such notice is delivered to the Company.

The Company registered the resale of the Shares and the Warrant Shares on a shelf registration statement on Form S-3 (Registration No. 333-278122), which was declared effective by the SEC on April 11, 2024 (the Registration Statement). Pursuant to the Purchase Agreement, the Company agreed to use its reasonable best efforts to keep the Registration Statement effective until the earliest of (i) the time as all of the Shares and Warrant Shares purchased by the Purchasers pursuant to the terms of the Purchase Agreement have been sold pursuant to the Registration Statement, or (ii) such time as the Shares and Warrant Shares become eligible for resale by non-affiliates without any volume limitations or other restrictions pursuant to Rule 144 under the Securities Act of 1933, as amended, or any other rule of similar effect.

At Market Equity Offering Sales Agreement

On March 21, 2024, the Company entered into an ATM Equity Offering Sales Agreement (the ATM Agreement) with BofA Securities, Inc. and Evercore Group L.L.C. as the Company's sales agents (the Agents) and/or principals. Pursuant to the terms of the ATM Agreement, the Company may sell from time to time through the Agents shares of the Company's common stock having an aggregate offering price of up to $100,000,000 (the ATM Shares). Any ATM Shares will be issued pursuant to the Registration Statement. Sales of the ATM Shares, if any, will be made by means of ordinary brokers' transactions on the Nasdaq Global Select Market or as otherwise agreed by the Company and the Agents. Under the terms of the ATM Agreement, the Company may also sell the ATM Shares from time to time to an Agent as principal for its own account at a price to be agreed upon at the time of sale. Any sale of the ATM Shares to an Agent as principal would be pursuant to the terms of a separate terms agreement between the Company and such Agent. The Company has not yet sold any ATM Shares as of June 30, 2024.

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 awards (RSAs), dividend equivalents, restricted stock units, stock appreciation rights, and other stock or cash-based awards to its employees, consultants, and directors. The number of shares of the Company's common stock initially available for issuance under awards granted pursuant to the 2023 Plan was the sum of (i) 4,650,000 shares of the Company's common stock, plus (ii) any shares subject to outstanding awards under the 2020 Plan described 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 than100,000,000 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.

2020 Equity Incentive Plan

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

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

As of June 30, 2024, the Company had the following balances by plan:

	Options Outstanding	Unvested RSAs	Shares Available for Grant
2023 Plan	3,525,040	—	2,799,930
2020 Plan	869,673	540,497	—
Total	4,394,713	540,497	2,799,930

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. As of June 30, 2024, the Company had 783,718 shares available for issuance and27,621 cumulative shares had been issued under the ESPP.

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.

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Research and development	$ 1,281	$ 525	$ 2,246	$ 860
General and administrative	1,591	751	2,817	1,165
Total	$ 2,872	$ 1,276	$ 5,063	$ 2,025

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, 2023 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, 2023.

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, 2023, and under a similar heading in any other periodic or current report we may file with the U.S. Securities and Exchange Commission (the SEC) in the future. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances, or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

This Quarterly Report includes trademarks, tradenames, and service marks that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this Quarterly Report appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will

not assert, to the fullest extent under applicable law, our rights, or that the applicable owner will not assert its rights, to these trademarks and tradenames.

Overview

We are a clinical-stage biopharmaceutical company focused on developing medicines to target diseases driven by dysregulated aldosterone. Our clinical-stage product candidate, lorundrostat, is a proprietary, orally administered, highly selective aldosterone synthase inhibitor (ASI) that we are initially developing for the treatment of cardiorenal conditions affected by dysregulated 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. Dysregulated aldosterone levels are a key factor in driving hypertension in approximately 25% of hypertensive patients. In addition to hypertension, we intend to investigate the benefits of lorundrostat in subjects with hypertension and CKD. We believe that our product candidate holds promise to be an innovative solution for the rapidly growing unmet need in multiple cardiorenal metabolic 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 efficacy and safety of lorundrostat for the treatment of uHTN or rHTN, when used as an add-on therapy to a standardized background treatment of two or three antihypertensive medications in 261 adult subjects. Subjects who meet screening criteria will have their existing hypertension medications discontinued and start on a standard regimen of an angiotensin II receptor blocker (ARB) and a diuretic, if previously on two medications, or a standard regimen of ARB, diuretic and calcium channel blocker if previously on three to five medications. Subjects who remain hypertensive despite the standardized regimen are then randomized into three cohorts and treated for twelve weeks: lorundrostat 50 mg QD, lorundrostat 50 mg QD, and an option to titrate to 100 mg QD at week four based on defined criteria or placebo. In August 2024, we met with the U.S. Food and Drug Administration (FDA) and aligned on maintaining the primary endpoint for Advance-HTN as the change in 24-hour ambulatory systolic BP at week twelve from baseline for active cohorts versus placebo. The Advance-HTN trial is approximately 90% enrolled, and topline data from this trial are anticipated in the first quarter of 2025.

In December 2023, we initiated our second pivotal trial, Launch-HTN, a randomized, double-blind, placebo-controlled Phase 3 clinical trial to evaluate the efficacy and safety of lorundrostat for the treatment of uHTN or rHTN, when used as an add-on therapy to their existing, prescribed background treatment of two to five antihypertensive medications in up to approximately 1,000 adult subjects. Subjects are then randomized into three cohorts and treated for twelve weeks: lorundrostat 50 mg QD, lorundrostat 50 mg QD, and an option to titrate to 100 mg QD at week six based on defined criteria or placebo. Following our discussion with the FDA about the analysis plan for Launch-HTN, the primary endpoint of the trial was changed to the assessment of automated office measured systolic BP from baseline for active cohorts versus placebo at six weeks, with the results pooled for all subjects on 50 mg QD. The initial primary endpoint of the trial was change in office measured systolic BP at week twelve from baseline for active cohorts versus placebo. Enrollment is ahead of schedule, and topline data from this trial are anticipated to be available in the second half of 2025.

In mid-2023, we initiated an open-label extension trial, Transform-HTN, to allow subjects to continue to receive lorundrostat and obtain long-term efficacy and safety 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 dysregulated aldosterone biology plays a role, including CKD and cardiorenal indications.

The Explore-CKD trial is designed to evaluate lorundrostat in hypertensive subjects with Stage 2 to 3b CKD. The Phase 2 clinical trial was modified in June 2024 from its original design to enroll both naïve to and patients on SGLT2 inhibitors. This change reflects how SGLT2 inhibitors have quickly become standard of care for patients with CKD. All study participants will stay on an SGLT2 inhibitor throughout the course of the trial. We also lowered the eGFR criteria for the proof-of-concept study from 45ml/min/1.73m2 to 30ml/min/1.73m2 and eliminated the original Part B profiling portion of the study. The study periods were reduced to four weeks, which we believe will provide ample time to demonstrate clinical benefit on BP reduction and kidney benefit. The primary endpoint is placebo-adjusted change from baseline in systolic BP and an exploratory endpoint is placebo-adjusted percent change from baseline in urine albumin-to-creatinine ratio at week four. As this is an exploratory trial, interim data analyses may be conducted at one or more points in time. We are ramping up enrollment under the amended protocol, and topline data from this trial are anticipated in the first half 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 June 30, 2024, we had cash, cash equivalents, and investments of $311.1 million. From inception through the date of this Quarterly Report, we raised aggregate gross proceeds of approximately $498.8 million from the sale of common stock, convertible preferred stock, convertible notes, and pre-funded warrants. 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. In February 2024, we sold 8,339,169 shares of common stock and, to certain purchasers, 549,755 pre-funded warrants to purchase common stock for aggregate net proceeds of approximately $116.1 million, net of offering expenses, in a private placement offering (the Private Placement).

We do not have any products approved for sale, have not generated any revenue, and have incurred net losses since our inception. Our operations to date have been limited to business planning, raising capital, in-licensing and developing lorundrostat, conducting clinical trials, and other research and development activities. Our net losses for the six months ended June 30, 2024 and 2023 were $72.5 million and $24.7 million, respectively. As of June 30, 2024 and December 31, 2023, we had an accumulated deficit of $197.2 million and $124.7 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 development milestone payments of $9.0 million in the aggregate. We have remaining obligations to pay Mitsubishi Tanabe commercial milestone payments of up to $155.0 million in the aggregate upon first commercial sale and upon meeting certain annual sales targets, as well as additional commercial milestone payments of up to $10.0 million for a second indication. Additionally, we are obligated to pay Mitsubishi Tanabe tiered royalties at percentages ranging from the mid-single digits to ten percent (10%) of aggregate net sales of each Lorundrostat Product on a Lorundrostat Product-by-Lorundrostat Product and country-by-country basis, until the later of (i) the expiration of the last-to-expire valid Mitsubishi Tanabe patent claim covering a Lorundrostat Product, (ii) ten years from the first commercial sale of a Lorundrostat Product, or (iii) the expiration of regulatory exclusivity in such country. Such royalties are subject to reduction under specified conditions, including lack of patent coverage and generic competition. We incurred $0 and $4.0 million of research and development expenses pursuant to the Mitsubishi License during the six months ended June 30, 2024 and 2023, respectively, that related to the initiation of our pivotal clinical program of lorundrostat. As of June 30, 2024, we have paid an aggregate of $9.0 million in development milestone payments and have no remaining development milestone obligations under the Mitsubishi License.

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.

Private Placement Offering

On February 7, 2024, we entered into a securities purchase agreement (the Purchase Agreement) with the purchasers named therein (the Purchasers), for the Private Placement of (i) 8,339,169 shares (the Shares) of our common stock at a price of $13.50 per Share, and (ii) with respect to certain Purchasers, Pre-Funded Warrants to purchase an aggregate of 549,755 shares of common stock (the Pre-Funded Warrants) in lieu of shares of common stock, at a purchase price of $13.499 per Pre-Funded Warrant (the shares of common stock

issuable upon exercise of the Pre-Funded Warrants, the Warrant Shares) for aggregate net proceeds of approximately $116.1 million. We are using the net proceeds from the Private Placement to fund the research and development of lorundrostat and for working capital and general corporate purposes.

Each Pre-Funded Warrant has an exercise price of $0.001 per share of common stock, is immediately exercisable on the date of issuance, and will not expire. Under the terms of the Pre-Funded Warrants, we may not effect the exercise of any portion of any Pre-Funded Warrant, and a holder will not have the right to exercise any portion of any Pre-Funded Warrant, which, upon giving effect to such exercise, would cause a holder (together with its affiliates) to own more than a specified beneficial ownership limitation of either 4.99%, 9.99%, or 19.99% (as selected by such holder prior to the issuance of the Pre-Funded Warrant) of the number of shares of common stock outstanding immediately after giving effect to such exercise, as such percentage ownership is determined in accordance with the terms of the Pre-Funded Warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 19.99%, provided that any increase in such percentage shall not be effective until 61 days after such notice is delivered to us.

We registered the resale of the Shares and the Warrant Shares on a shelf registration statement on Form S-3 (Registration No. 333-278122), which was declared effective by the SEC on April 11, 2024 (the Registration Statement). Pursuant to the Purchase Agreement, we agreed to use our reasonable best efforts to keep the Registration Statement effective until the earliest of (i) the time as all of the Shares and Warrant Shares purchased by the Purchasers pursuant to the terms of the Purchase Agreement have been sold pursuant to the Registration Statement, or (ii) such time as the Shares and Warrant Shares become eligible for resale by non-affiliates without any volume limitations or other restrictions pursuant to Rule 144 under the Securities Act or any other rule of similar effect.

At Market Equity Offering Sales Agreement

On March 21, 2024, we entered into an ATM Equity Offering Sales Agreement (the ATM Agreement) with BofA Securities, Inc. and Evercore Group L.L.C. as our sales agents (the Agents) and/or principals. Pursuant to the terms of the ATM Agreement, we may sell from time to time through the Agents shares of our common stock having an aggregate offering price of up to $100,000,000 (the ATM Shares). Any ATM Shares will be issued pursuant to the Registration Statement. Sales of the ATM Shares, if any, will be made by means of ordinary brokers' transactions on the Nasdaq Global Select Market or as otherwise agreed by us and the Agents. Under the terms of the ATM Agreement, we may also sell the ATM Shares from time to time to an Agent as principal for its own account at a price to be agreed upon at the time of sale. Any sale of the ATM Shares to an Agent as principal would be pursuant to the terms of a separate terms agreement between us and such Agent. We have not yet sold any ATM Shares as of June 30, 2024.

Key Components of Results of Operations

Operating Expenses

Research and Development

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

Research and development expenses include:

- salaries, bonuses, employee benefits, and stock-based compensation charges for those individuals involved in research and development efforts;

- external research and development expenses incurred under agreements with contract research organizations (CROs) and consultants to conduct and support our clinical trials of lorundrostat, 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 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 June 30, 2024 and 2023

	Three Months Ended, June 30,		
	2024	2023	Change
	(in thousands)		
Research and development expenses	$ (39,273)	$ (11,884)	$ (27,389)
General and administrative expenses	(5,895)	(3,851)	(2,044)
Total other income, net	4,154	3,594	560
Net loss	$ (41,014)	$ (12,141)	$ (28,873)

Research and Development Expenses

Research and development expenses increased by $27.4 million for the three months ended June 30, 2024, compared to the three months ended June 30, 2023, which was primarily due to increases of $22.8 million in preclinical and clinical costs driven by the initiation of the lorundrostat pivotal program in the second quarter of 2023 and the Explore-CKD trial in the fourth quarter of 2023, $2.6 million in clinical supply, manufacturing, and regulatory costs, $1.7 million in higher compensation expense resulting from additions to headcount, increases in salaries and accrued bonuses, and increased stock-based compensation, and $0.3 million in other research and development expenses.

General and Administrative Expenses

General and administrative expenses increased by $2.0 million for the three months ended June 30, 2024, compared to the three months ended June 30, 2023. The increase was primarily due to $1.5 million in higher compensation expense resulting from additions to headcount, increases in salaries and accrued bonuses, and increased stock-based compensation, and $0.5 million in higher professional fees and other administrative expenses.

Total Other Income, Net

Total other income, net increased by $0.6 million for the three months ended June 30, 2024, compared to the three months ended June 30, 2023, which was primarily attributable to increased interest earned on our investments in money market funds and U.S. treasuries.

Comparison of the Six Months Ended June 30, 2024 and 2023

	Six Months Ended, June 30,		
	2024	2023	Change
	(in thousands)		
Research and development expenses	$ (70,027)	$ (24,177)	$ (45,850)
General and administrative expenses	(10,503)	(6,496)	(4,007)
Total other income, net	8,008	5,924	2,084
Net loss	$ (72,522)	$ (24,749)	$ (47,773)

Research and Development Expenses

Research and development expenses increased by $45.9 million for the six months ended June 30, 2024, compared to the six months ended June 30, 2023, which was primarily due to increases of $39.7 million in preclinical and clinical costs, driven by the initiation of the lorundrostat pivotal program in the second quarter of 2023 and the Explore-CKD trial in the fourth quarter of 2023, $6.4 million in clinical supply, manufacturing, and regulatory costs, $3.4 million in higher compensation expense resulting from additions to headcount, increases in salaries and accrued bonuses, and increased stock-based compensation, and $0.4 million in other research and development expenses, partially offset by a decrease of $4.0 million in license fees.

General and Administrative Expenses

General and administrative expenses increased by $4.0 million for the six months ended June 30, 2024, compared to the six months ended June 30, 2023. The increase was primarily due to $2.8 million in higher compensation expense resulting from additions to headcount, increases in salaries and accrued bonuses, and increased stock-based compensation, $0.6 million in higher professional fees, and $0.6 million in higher other administrative expenses.

Total Other Income, Net

Total other income, net increased by $2.1 million for the six months ended June 30, 2024, compared to the six months ended June 30, 2023, 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 through the date of this Quarterly Report, we raised aggregate gross proceeds of approximately $498.8 million from the sale of common stock, convertible preferred stock, convertible notes, and pre-funded warrants. As of June 30, 2024, we had cash, cash equivalents, and investments of $311.1 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. In February 2024, we sold 8,339,169 Shares and, to certain Purchasers, 549,755 Pre-Funded Warrants for aggregate net proceeds of approximately $116.1 million in a Private Placement.

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 June 30, 2024 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, manufacturing, quality, and commercial personnel;
- the timing and amount of the milestone, royalty, or other payments we must make to Mitsubishi Tanabe, from whom we have in-licensed lorundrostat, or any future licensors;
- the costs and timing of establishing or securing sales and marketing capabilities if lorundrostat or any future product candidate is approved;
- our ability to achieve sufficient market acceptance, coverage, and adequate reimbursement from third-party payors, and adequate market share and revenue for any approved products;

- patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors;
- the terms and timing of establishing and maintaining collaborations, licenses, and other similar arrangements;
- costs associated with any products or technologies that we may in-license or acquire; and
- the other risks and uncertainties described under the heading "*Risk Factor*s" in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2023 and in "*Forward-Looking Statements*" and elsewhere in this Quarterly Report.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses, and other similar arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from factors that include but are not limited to, 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 Six Months Ended June 30, 2024 and 2023

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:

	Six Months Ended June 30,		
	2024	2023	Change
	(in thousands)		
Net cash provided by (used in):			
Operating activities	$ (49,285)	$ (33,161)	$ (16,124)
Investing activities	(48,216)	(156,390)	108,174
Financing activities	116,053	202,990	(86,937)
Net	$ 18,552	$ 13,439	$ 5,113

Operating Activities

Net cash used in operating activities of $49.3 million during the six months ended June 30, 2024 increased, compared to $33.2 million during the six months ended June 30, 2023, 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 $16.1 million increase in cash used consisted of an increase in net loss, adjusted for non-cash expenses, of approximately $47.2 million, and the net effect of changes in working capital of $31.1 million.

Investing Activities

Net cash used in investing activities of $48.2 million during the six months ended June 30, 2024 decreased, compared to $156.4 million during the six months ended June 30, 2023. The decrease was primarily attributable to the timing and amount of purchases and maturities of marketable securities in each period. During the six months ended June 30, 2024 compared to the six months ended June 30, 2023, an increase in maturities of prior purchases of $140.0 million occurred, which was partially offset by an increase in purchases of $31.8 million.

Financing Activities

Net cash provided by financing activities of $116.1 million during the six months ended June 30, 2024 decreased, compared to $203.0 million during the six months ended June 30, 2023. During the six months ended June 30, 2024, we received net proceeds of $116.1 million from the sale of Shares and Pre-Funded Warrants in the Private Placement, and during the six months ended June 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.

Contractual Obligations and Commitments

Under the Mitsubishi License, we have milestone payment obligations that are contingent upon the achievement of specified levels of product sales and are required to make certain royalty payments in connection with the sale of products developed under the agreement. We are currently unable to estimate the timing or likelihood of achieving other future milestones or making future product sales. See above and Note 4. "*Commitments and Contingencies*" to our 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 six months ended June 30, 2024 to our critical accounting estimates as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2023. For information on our

significant accounting policies, please refer to Note 2. "*Summary of Significant Accounting Policies*" within our Annual Report on Form 10-K for the year ended December 31, 2023.

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 consolidated 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 June 30, 2024, 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 June 30, 2024.

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 June 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II - Other Information

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

Our business, financial condition, and operating results may be affected by a number of factors, whether currently known or unknown, including but not limited to those described in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2023 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, 2023.

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

None.

Item 3. Defaults Upon Senior Securities

Not Applicable.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

During the three months ended June 30, 2024, an affiliate of the Company, Samsara BioCapital, L.P. (Samsara), entered into a Rule 10b5-1trading plan (the Samsara 10b5-1 Plan). The Samsara 10b5-1 Plan, entered into on May 3, 2024, is intended to satisfy the affirmative defense of Rule 10b5-1(c) of the Exchange Act and provides for the sale of up to 1,691,638 shares of the Company's common stock from time to time between August 12, 2024 and April 29, 2026. The Samsara 10b5-1 Plan will expire on April 29, 2026, or earlier if all shares under the plan are sold prior to that date.Srinivas Akkaraju, M.D., Ph.D., one of our directors, is Managing General Partner of Samara and has voting and investment power over the shares held by Samsara.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation	8-K	2/14/23	3.1	
3.2	Amended and Restated Bylaws	8-K	2/14/23	3.2	
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				x

31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	x
32.1*	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	x
32.2*	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	x
101.INS	XBRL Instance Document	x
101.SCH	XBRL Taxonomy Extension Schema Document	x
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	x
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	x
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	x
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	x
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	x

* This certification is deemed not filed for 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:	August 13, 2024	By:	/s/ Jon Congleton Jon Congleton Chief Executive Officer (Principal Executive Officer)
Date:	August 13, 2024	By:	/s/ Adam Levy Adam Levy Chief Financial Officer and Secretary (Principal Financial Officer; Principal Accounting Officer)

Exhibit 31.1

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: August 13, 2024

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

Exhibit 31.2

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: August 13, 2024

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

Exhibit 32.1

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 June 30, 2024 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: August 13, 2024

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

Exhibit 32.2

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 June 30, 2024 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: August 13, 2024

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