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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): November 7, 2023

MINERALYS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-41614**	**84-1966887**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

150 N. Radnor Chester Road, Suite F200
Radnor, Pennsylvania 19087
(Address of principal executive offices) (Zip Code)

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

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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, par value $0.0001 per share	**MLYS**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 7, 2023, Mineralys Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2023 and provided a corporate update. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release Issued on November 7, 2023

SIGNATURES

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

Dated: November 7, 2023

MINERALYS THERAPEUTICS, INC.

By: /s/ Adam Levy

Name: Adam Levy

Title: Chief Financial Officer, Chief Business Officer and Secretary

Exhibit 99.1

Mineralys Therapeutics Reports Third Quarter 2023 Financial Results and Provides Corporate Update

– On track to initiate planned Phase 3 pivotal Launch-HTN trial of lorundrostat to treat patients with uncontrolled or resistant hypertension in 2H 2023 –

– Expect to initiate planned Phase 2 Explore-CKD trial of lorundrostat alone and in combination with SGLT2 inhibitor to treat hypertensive patients with chronic kidney disease (CKD) in 2H 2023 –

– Conference call today at 4:30 p.m. ET –

RADNOR, PA – November 7, 2023 – Mineralys Therapeutics, Inc. (Nasdaq: MLYS), a clinical-stage biopharmaceutical company focused on developing medicines to target hypertension, chronic kidney disease (CKD) and other diseases driven by abnormally elevated aldosterone, today announced financial results for the quarter ending September 30, 2023, and provided a corporate update.

"The third quarter was productive for Mineralys with ongoing progress in our clinical development of lorundrostat, the publication of our proof-of-concept study, Target-HTN, in the Journal of the American Medical Association and the addition of two new Board members. We have finalized the designs of Launch-HTN and Explore-CKD, which we believe strengthens our ability to generate data that will support patients' real-world needs. We continue to anticipate that the Phase 3 Launch-HTN and the Phase 2 Explore-CKD trials will be initiated by the end of 2023," stated Jon Congleton, Chief Executive Officer of Mineralys Therapeutics.

Recent Corporate and Clinical Highlights

- **Pivotal Advance-HTN trial** – The ongoing trial is evaluating the safety and efficacy of lorundrostat for the treatment of uncontrolled hypertension (uHTN) or resistant hypertension (rHTN), when used as an add-on therapy to standardized background treatment of two or three antihypertensive medications.

- For subjects in the Advance-HTN trial, the treatment withdrawal component of the program has been moved forward from week 48 of treatment in the open-label extension trial to week 12 of Advance-HTN. This amendment was implemented to characterize the durability of changes in blood pressure and other pharmacodynamic measures of efficacy following the double-blind treatment period. Due to this protocol amendment and the Company's current visibility into the enrollment curve, the Company's expectations for topline data have been revised from the first half of 2024 to the second half of 2024.

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

- **Late-Breaking Poster Presented at ASN's Kidney Week 2023** – The late-breaking poster presented at the American Society of Nephrology's (ASN) Kidney Week 2023 by David Rodman, Chief Medical Officer of Mineralys, highlighted lorundrostat's potential as the first precision targeted treatment for hypertension. This poster concluded that obesity, and other obesity-associated physiological changes, contribute to an enhanced response to lorundrostat. The poster is titled, "Identification of a hypertensive endotype with a median treatment effect of -32mmHg in response to the novel aldosterone synthase inhibitor lorundrostat".

- **JAMA Published Full Data from Target-HTN Trial** – In September 2023, The Journal of the American Medical Association (JAMA) published the results of Target-HTN, the first in patient trial of lorundrostat in individuals with uHTN and rHTN. This paper, authored by doctors Laffin and Nissen at the Cleveland Clinic, reported the robust blood pressure lowering potential of lorundrostat as well as a favorable tolerability profile.

- **Expanded Board of Directors** - Appointed Daphne Karydas and Glenn Sblendorio to the Company's Board of Directors, effective September 13, 2023. Ms. Karydas and Mr. Sblendorio bring executive, financial and operational leadership experience in biotechnology and biopharmaceuticals markets. Ms. Karydas was appointed chairperson of the audit committee and Mr. Sblendorio was appointed chairperson of the compensation committee.

Key Upcoming Milestones

- **Upcoming Poster Presentation at AHA Scientific Sessions 2023** – The Company has been selected to present a poster at the American Heart Association (AHA) Scientific Sessions 2023, which is being held from November 10 – 13, 2023, in Philadelphia, PA. The poster is titled, "Lorundrostat for Treatment of Obesity-Related, Aldosterone-Dependent Hypertension - An Endotype-Specific, Targeted Approach to the Treatment of Uncontrolled Hypertension".

- **Phase 3 pivotal Launch-HTN trial** – In the second half of 2023, the Company remains on track to initiate a randomized, double-blind, placebo-controlled Phase 3 trial to evaluate the safety and efficacy of lorundrostat for the treatment of uHTN or rHTN. Lorundrostat will be studied when used as an add-on therapy to prescribed background treatment of two to five antihypertensive medications in up to approximately 1,000 adult subjects. In keeping with the objective of the trial, to model real world treatment of uHTN and rHTN in the primary care setting, the trial's primary endpoint will be in-office blood pressure measurement rather than 24-hour ambulatory blood pressure measurement. Based on current projections, the topline data from this trial is now expected in the second half of 2025.

- **Explore-CKD Phase 2 trial** – The Company expects to initiate a two-part Phase 2 clinical trial for lorundrostat in hypertensive patients with stage 2-3b CKD in the second half of 2023, with topline data expected in the fourth quarter of 2024 to the first quarter of 2025. In consultation with its advisors and based on the significant unmet need, the Company has made the strategic decision to study subjects with systolic blood pressure (BP) greater than or equal to 135mmHg, as well as CKD with albuminuria.

    - The objective in Part A is to assess the effect of lorundrostat, alone or in combination with dapagliflozin in subjects with uncontrolled hypertension and stage 2-3a CKD,

on systolic BP, as well as albuminuria, a surrogate endpoint that supports long-term benefit in CKD. The Company plans to study 25mg once daily (QD) in this trial.

- The objective in Part B is to characterize the safety and tolerability of lorundrostat in subjects with uncontrolled hypertension and stage 3b CKD with albuminuria. This open-label safety study will evaluate 12.5mg QD lorundrostat with titration to 25mg QD based on pre-specified criteria. A new key exploratory objective for Part B is to assess the effect of lorundrostat on systolic BP.

Third Quarter 2023 Financial Highlights
Cash, cash equivalents and investments were $265.9 million as of September 30, 2023, compared to $110.1 million as of December 31, 2022. The Company believes that its cash, cash equivalents and investments as of September 30, 2023 will be sufficient to allow the Company to fund its planned clinical studies, as well as support corporate operations, through mid-2025.

Research and Development (R&D) expenses were $22.5 million for the quarter ended September 30, 2023, compared to $6.1 million for the quarter ended September 30, 2022. The increase in R&D expenses was primarily due to increases of $12.4 million in preclinical and clinical costs, driven by the initiation of the lorundrostat pivotal program in 2023, $2.3 million in clinical supply, manufacturing and regulatory costs and $1.7 million in higher compensation expense resulting from additions to headcount.

General and Administrative (G&A) expenses were $3.8 million for the quarter ended September 30, 2023, compared to $1.4 million for the quarter ended September 30, 2022. The increase in G&A expenses was primarily due to $1.2 million in higher professional fees associated with operating as a public company, $0.8 million in higher compensation expense resulting from additions to headcount, $0.3 million of higher insurance expense associated with new director and officer insurance policies and $0.1 million in higher other administrative expenses.

Total other income, net was $3.5 million for the quarter ended September 30, 2023, compared to $0.7 million for the quarter ended September 30, 2022, which was primarily attributable to increased interest earned on the Company's investments in money market funds and U.S. treasuries.

Net loss was $22.8 million for the quarter ended September 30, 2023, compared to $6.7 million for the quarter ended September 30, 2022. The increase was primarily attributable to the factors impacting the Company's expenses described above.

Conference Call
The Company's management team will host a conference call at 4:30 p.m. ET on Tuesday, November 7, 2023. To access the call, please dial 1-888-886-7786 in the U.S. or 1-416-764-8658 outside the U.S., followed by the conference ID: 27015887. A live webcast of the conference call may be found here https://viavid.webcasts.com/starthere.jsp?ei=1632661&tp_key=eecbf184d5. A replay of the call will be available on the "News & Events" page in the Investor Relations section of the Mineralys Therapeutics website.

About Hypertension
Having sustained, elevated blood pressure (or hypertension) increases the risk of heart disease, heart attack and stroke, which are leading causes of death in the U.S. In 2020, more than 670,000 deaths in

the U.S. included hypertension as a primary or contributing cause. Hypertension and related health issues resulted in an average annual economic burden of about $130 billion each year in the U.S., averaged over 12 years from 2003 to 2014.

Less than 50 percent of hypertension patients achieve their blood pressure goal with currently available medications. Abnormally elevated aldosterone levels are a key factor in driving hypertension in approximately 25 percent of all hypertensive patients.

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

About Lorundrostat
Lorundrostat is a proprietary, orally administered, highly selective aldosterone synthase inhibitor being developed for the treatment of uncontrolled hypertension and CKD. Lorundrostat was designed to reduce aldosterone levels by inhibiting CYP11B2, the enzyme responsible for its production. Lorundrostat has 374-fold selectivity for aldosterone-synthase inhibition versus cortisol-synthase inhibition *in vitro,* an observed half-life of 10-12 hours and demonstrated approximately a 70% reduction in plasma aldosterone concentration in hypertensive subjects.

In a Phase 2, proof-of-concept trial (Target-HTN) in uncontrolled or resistant hypertensive subjects, once-daily lorundrostat demonstrated clinically meaningful blood pressure reduction in individuals with uncontrolled hypertension, in both automated office blood pressure measurement and 24-hour ambulatory blood pressure monitoring. Adverse events observed were a modest increase in serum potassium, decrease in estimated glomerular filtration rate, urinary tract infection and hypertension with one serious adverse event possibly related to study drug being hyponatremia.

About Mineralys Therapeutics
Mineralys Therapeutics is a clinical-stage biopharmaceutical company focused on developing medicines to target hypertension, CKD and other diseases driven by abnormally elevated aldosterone. Its initial product candidate, lorundrostat, is a proprietary, orally administered, highly selective aldosterone synthase inhibitor that Mineralys Therapeutics is developing for cardiorenal conditions affected by abnormally elevated aldosterone, including hypertension and CKD. Mineralys is based in Radnor, Pennsylvania, and was founded by Catalys Pacific. For more information, please visit https://mineralystx.com. Follow Mineralys on LinkedIn and Twitter.

Forward-Looking Statements
Mineralys Therapeutics cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. The forward-looking statements are based on our current beliefs and expectations and include, but are not limited to, statements regarding: the potential therapeutic benefits of lorundrostat; the Company's expectation that aldosterone synthase inhibitors with an SGLT2 inhibitor may provide additive clinical benefits to patients; the Company's expectation that the Advance-HTN and the planned Phase 3 clinical trial of lorundrostat may serve as pivotal trials in any submission of a new drug application (NDA) to the United States Food and Drug

Administration (FDA); the Company's ability to evaluate lorundrostat as a potential treatment for CKD or uncontrolled hypertension; the planned future clinical development of lorundrostat and the timing thereof; and the expected timing of commencement and enrollment of patients in clinical trials and topline results from clinical trials. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in our business, including, without limitation: our future performance is dependent entirely on the success of lorundrostat; potential delays in the commencement, enrollment and completion of clinical trials and nonclinical studies; later developments with the FDA may be inconsistent with the feedback from the completed end of Phase 2 meeting, including whether the proposed pivotal program will support registration of lorundrostat which is a review issue with the FDA upon submission of an NDA; our dependence on third parties in connection with manufacturing, research and clinical and nonclinical testing; unexpected adverse side effects or inadequate efficacy of lorundrostat that may limit its development, regulatory approval and/or commercialization; unfavorable results from clinical trials and nonclinical studies; results of prior clinical trials and studies of lorundrostat are not necessarily predictive of future results; our ability to maintain undisrupted business operations due to any pandemic or future public health concerns; regulatory developments in the United States and foreign countries; our reliance on our exclusive license with Mitsubishi Tanabe Pharma to provide us with intellectual property rights to develop and commercialize lorundrostat; and other risks described in our filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in our annual report on Form 10-K, and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 22,499	$ 6,059	$ 46,676	$ 18,432
General and administrative	3,774	1,364	10,270	3,039
Total operating expenses	26,273	7,423	56,946	21,471
Loss from operations	(26,273)	(7,423)	(56,946)	(21,471)
Interest income, net	3,513	741	9,435	741
Other income	—	4	2	4
Total other income, net	3,513	745	9,437	745
Net loss	$ (22,760)	$ (6,678)	$ (47,509)	$ (20,726)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.57)	$ (1.29)	$ (1.36)	$ (4.02)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	39,930,748	5,181,410	34,872,287	5,152,752

Mineralys Therapeutics, Inc.
Selected Financial Information
Condensed Balance Sheet Data
(amounts in thousands)
(unaudited)

	September 30, 2023	December 31, 2022
Cash, cash equivalents and investments	$ 265,890	$ 110,110
Total assets	$ 277,555	$ 114,442
Total liabilities	$ 13,543	$ 8,067
Total stockholders' equity (deficit)	$ 264,012	$ (52,269)