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 11, 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 7.01. Regulation FD Disclosure.

On November 11, 2023, Mineralys Therapeutics, Inc. (the "Company") issued a press release announcing its presentation of data from the Target-HTN Phase 2 trial that further defines an endotype-specific targeted approach for treating uncontrolled or resistant hypertension with lorundrostat. A copy of the press release is attached 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 8.01. Other Events.

On November 11, 2023, the Company presented data from the Target-HTN Phase 2 trial that further defines an endotype-specific targeted approach for treating uncontrolled or resistant hypertension with lorundrostat, a highly selective aldosterone synthase inhibitor. The data were presented in a poster at the American Heart Association (AHA) Scientific Sessions 2023, which is being held in Philadelphia from November 11th – 13th.

Data previously presented from Target-HTN showed that elevated body mass index (BMI) was predictive of an enhanced reduction in systolic blood pressure (BP) from lorundrostat treatment. The poster presented at the AHA Scientific Sessions 2023 included a new analysis of serum leptin levels among subjects in the trial, which showed that increased BMI was correlated with increased leptin circulation. This is consistent with emerging evidence of a leptin-driven, positive feedback loop between obesity, aldosterone and hypertension.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release Issued on November 11, 2023
104	Cover Page Interactive Date File (embedded within the Inline XBRL document)

Forward-Looking Statements

Mineralys Therapeutics cautions you that statements contained in this report 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 chronic kidney disease 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 report 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.

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 13, 2023

MINERALYS THERAPEUTICS, INC.

By: /s/ Adam Levy

Name: Adam Levy

Title: Chief Financial Officer, Chief Business Officer and Secretary

Mineralys Therapeutics Further Defines Endotype-Specific, Targeted Approach to Treatment of Uncontrolled or Resistant Hypertension with Lorundrostat Data at AHA Scientific Sessions 2023

– New analysis on serum leptin levels among patients in the Target-HTN Phase 2 trial adds to emerging evidence of positive feedback loop linking obesity, leptin and aldosterone –

– Excess aldosterone in patients with visceral obesity defines a unique hypertensive endotype with potential for an enhanced response to aldosterone-targeted therapy with lorundrostat –

– Early identification and intervention with lorundrostat may result in improved clinical outcomes for obese patients with uncontrolled or resistant hypertension –

RADNOR, PA – **November 11, 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 presented data from the Target-HTN Phase 2 trial that further defines an endotype-specific targeted approach for treating uncontrolled or resistant hypertension with lorundrostat, a highly selective aldosterone synthase inhibitor. The data were presented in a poster at the American Heart Association (AHA) Scientific Sessions 2023, which is being held in Philadelphia from November 11th –13th.

Data previously presented from Target-HTN showed that elevated body mass index (BMI) was predictive of an enhanced reduction in systolic blood pressure (BP) from lorundrostat treatment. The poster presented at the AHA Scientific Sessions 2023 included a new analysis of serum leptin levels among subjects in the trial, which showed that increased BMI was correlated with increased leptin circulation. This is consistent with emerging evidence of a leptin-driven, positive feedback loop between obesity, aldosterone and hypertension.[1]

“Through our ongoing analyses of data from the Target-HTN trial, a profile of which patients can benefit the most from lorundrostat is emerging. After examining serum leptin levels across participants, we now have evidence that this hormone, along with elevated BMI, could be a biomarker for patients who may experience a meaningful blood pressure reduction from lorundrostat treatment,” stated David Rodman, M.D., Chief Medical Officer for Mineralys. “Obesity is an epidemic and is one of the strongest risk factors for developing hypertension, which results in subsequent poor outcomes if uncontrolled. Being able to identify a hypertensive endotype, and intervene early with aldosterone-targeted therapy, would change the way clinicians currently treat the condition in practice by introducing a precision approach to care.”

A pre-specified analysis from Target-HTN showed that subjects with a BMI >30kg/m^2 experienced placebo-adjusted reductions in systolic BP of 16.7mmHg (p=0.002) and 12.3mmHg (p=0.03) with lorundrostat 50mg and 100mg once-daily (QD) doses, respectively. Findings from the new analysis showed that the same BMI range was associated with a 75% increase in mean serum leptin (21.6 ±1.9ng/mL in subjects with a BMI ≤30kg/m^2 compared to 37.8 ±2.4ng/mL in subjects with a BMI >30kg/m^2; p<0.001), indicating that increased circulating leptin may be a useful biomarker to identify lorundrostat-responsive individuals.

The Target-HTN trial demonstrated that treatment with lorundrostat at doses of 50mg and 100mg QD led to a statistically and clinically significant reduction of systolic BP in uncontrolled hypertensive individuals on at least two background antihypertensive medications. Full results from the trial were published in the *Journal of the American Medical Association (JAMA)* and simultaneously presented

during a late-breaking science session at the 2023 AHA Hypertension Scientific Sessions in September.

Target-HTN trial results support the transition to late-stage development of lorundrostat as a treatment for uncontrolled or resistant hypertension. The Company's ongoing pivotal development program for lorundrostat to treat uncontrolled or resistant hypertension is currently enrolling subjects in the pivotal Advance-HTN trial, and the second pivotal trial, Launch-HTN, trial is expected to be initiated in the second half of 2023.

The poster at AHA Scientific Sessions 2023 titled, "Lorundrostat for Treatment of Obesity-Related, Aldosterone-Dependent Hypertension - An Endotype-Specific, Targeted Approach to the Treatment of Uncontrolled Hypertension," can be accessed on the publications page of the Mineralys corporate website.

About Target-HTN
The Target-HTN (NCT05001945) Phase 2 proof-of-concept trial was a randomized, double-blind, placebo-controlled, dose-ranging, multicenter trial conducted in the U.S. The trial was designed to evaluate the safety, efficacy, tolerability and dose response of orally administered lorundrostat on BP for the treatment of uncontrolled or resistant hypertension when used as add-on therapy to stable background treatment of two or more antihypertensive agents in 200 male and female subjects 18 years of age or older. Five active doses of lorundrostat (12.5mg QD, 50mg QD, 100mg QD, 12.5mg twice daily (BID), and 25mg BID) were compared to placebo in hypertensive subjects. 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 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 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.

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.

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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.

References:

[1] Faulkner JL, et al. *Curr Opin Nephrol Hypertens*. 2081;27(2):63-69.

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