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): December 21, 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 December 21, 2023, Mineralys Therapeutics, Inc. (the "Company") issued a press release announcing that the first subject has been dosed in the Launch-HTN pivotal trial. 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 December 21, 2023, the Company announced that the first subject has been dosed in the Launch-HTN (NCT06153693) pivotal trial to evaluate the safety and efficacy of lorundrostat for the treatment of uncontrolled hypertension or resistant hypertension, when used as an add-on therapy to prescribed background treatment.

Launch-HTN is the second of two clinical trials under the planned pivotal program to evaluate the safety and efficacy of lorundrostat when added to subjects' existing background hypertension treatment. This trial is designed to model real world treatment of uncontrolled hypertension and resistant hypertension in the primary care setting. Launch-HTN is a global, randomized, double-blinded, placebo-controlled Phase 3 trial that is designed to enroll up to approximately 1,000 eligible adult participants who are failing to achieve their blood pressure goal on two to five background antihypertensive medications. Eligible subjects will be randomized to one of three arms: placebo, lorundrostat 50 mg once daily (QD), and lorundrostat 50 mg QD and then titrated to 100 mg QD, as needed, at week six. The primary endpoint of the trial is change from baseline in systolic blood pressure versus placebo after 12 weeks of treatment, as measured by automated office blood pressure monitoring.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release Issued on December 21, 2023
104	Cover Page Interactive Date File (embedded within the Inline XBRL document)

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: December 22, 2023

MINERALYS THERAPEUTICS, INC.

By: /s/ Adam Levy

Name: Adam Levy

Title: Chief Financial Officer, Chief Business Officer and Secretary

Mineralys Therapeutics Announces First Subject Dosed in Launch-HTN, the Second Pivotal Trial of Lorundrostat for the Treatment of Hypertension

– Topline data from confirmatory Launch-HTN trial expected in 2H 2025 –

– Topline data from ongoing Advance-HTN pivotal trial expected in 2H 2024 –

RADNOR, PA – December 21, 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 that the first subject has been dosed in the Launch-HTN (NCT06153693) pivotal trial to evaluate 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 prescribed background treatment.

“Initiating this second pivotal trial demonstrates the continued progress we’re making towards introducing a targeted approach to care in hypertension by identifying and profiling potential responders to lorundrostat,” stated Jon Congleton, Chief Executive Officer of Mineralys. “In parallel with our development of lorundrostat, we have been pleased to see accumulating evidence generated by the medical community highlighting aldosterone as a key driver in cardiorenal disease.”

Launch-HTN is the second of two clinical trials under the planned pivotal program to evaluate the safety and efficacy of lorundrostat when added to subjects’ existing background hypertension treatment. This trial is designed to model real world treatment of uHTN and rHTN in the primary care setting. Launch-HTN is a global, randomized, double-blinded, placebo-controlled Phase 3 trial that is designed to enroll up to approximately 1,000 eligible adult participants who are failing to achieve their blood pressure goal on two to five background antihypertensive medications. Eligible subjects will be randomized to one of three arms: placebo, lorundrostat 50 mg once daily (QD), and lorundrostat 50 mg QD and then titrated to 100 mg QD, as needed, at week six. The primary endpoint of the trial is change from baseline in systolic blood pressure versus placebo after 12 weeks of treatment, as measured by automated office blood pressure monitoring.

Previously, in May 2023, the Company announced the first subject dosed in the first pivotal trial, Advance-HTN. The Company expects to announce topline data from the Advance-HTN trial in the second half of 2024. Subjects in both the Advance-HTN and Launch-HTN trials are provided the opportunity to participate in the open-label extension trial, Transform-HTN.

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% 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% of all hypertensive patients.

About Lorundrostat
Lorundrostat is a proprietary, orally administered, highly selective aldosterone synthase inhibitor being developed for the treatment of uncontrolled and resistant 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.

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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