
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): September 25, 2024

MINERALYS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation
or organization)

001-41614
(Commission File Number)

84-1966887
(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 September 25, 2024, Mineralys Therapeutics, Inc. (the Company) issued a press release announcing that it has completed target enrollment in its pivotal Advance-HTN trial of lorundrostat for the treatment of hypertension. 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 Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 hereto 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 September 25, 2024, the Company announced that it has achieved the enrollment target of 261 subjects in the pivotal Advance-HTN trial evaluating the efficacy and safety of lorundrostat for the treatment of uncontrolled hypertension or resistant hypertension, when used as an add-on therapy to a standardized background treatment of two or three antihypertensive medications. Additional subjects currently in the screening or the run-in phase for Advance-HTN may be enrolled over the next several weeks. The Company continues to expect to announce top-line data in the first quarter of 2025.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release Issued on September 25, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Forward Looking Statements

The Company 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 the Company’s current beliefs and expectations and include, but are not limited to, statements regarding: the Company’s plan to enroll additional subjects in Advance-HTN and to announce top-line data for Advance-HTN in the first quarter of 2025; 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 Advance-HTN and Launch-HTN 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 the Company’s business, including, without limitation: the Company’s 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; the Company’s 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; the Company’s ability to maintain undisrupted business operations due to any pandemic or future public health concerns; regulatory developments in the United States and foreign countries; the Company’s reliance on its exclusive license with

Mitsubishi Tanabe Pharma to provide it with intellectual property rights to develop and commercialize lorundrostat; and other risks described in the Company's filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in the Company's 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 the Company undertakes 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: September 25, 2024

MINERALYS THERAPEUTICS, INC.

By: /s/ Adam Levy
Name: Adam Levy
Title: Chief Financial Officer and Secretary



Mineralys Therapeutics Completes Target Enrollment in Pivotal Advance-HTN Trial of Lorundrostat for the Treatment of Hypertension

– On track to announce topline data in Q1 2025 –

– Virtual KOL event scheduled on October 30th to discuss the unmet need in hypertension, as well as a review of the ongoing pivotal clinical program for lorundrostat in hypertension –

RADNOR, PA – September 25, 2024 – Mineralys Therapeutics, Inc. (Nasdaq: MLYS), a clinical-stage biopharmaceutical company focused on developing medicines to target hypertension, chronic kidney disease (CKD) and other prevalent cardiovascular diseases driven by dysregulated aldosterone, today announced that it has achieved the enrollment target of 261 subjects in the pivotal Advance-HTN trial evaluating the efficacy and safety of lorundrostat for the treatment of uncontrolled hypertension (uHTN) or resistant hypertension (rHTN), when used as an add-on therapy to a standardized background treatment of two or three antihypertensive medications. Additional subjects currently in the screening or the run-in phase for Advance-HTN may be enrolled over the next several weeks. The Company continues to expect to announce topline data in the first quarter of 2025.

“We are excited to achieve target enrollment in our pivotal Advance-HTN trial. It is our goal to provide meaningful improvement in cardiovascular risk for people struggling to achieve their optimal blood pressure level,” stated David Rodman, MD, Chief Medical Officer of Mineralys Therapeutics. “We are hopeful that lorundrostat will continue to show promise for the treatment of hypertension as observed in our previous trial. We wish to thank the participating trial investigators and subjects for their enthusiasm and commitment to the development program for lorundrostat.”

The Advance-HTN trial (NCT05769608) is 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 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.

KOL Event Details

The Company will host a virtual KOL event for investors on Wednesday, October 30, 2024 at 10:00 am ET. To register for the event, click here (<https://lifescievents.com/event/mineralystx/>). This event will provide expert perspectives on the currently available treatment options for uHTN and rHTN, as well as a review of the ongoing pivotal clinical program for lorundrostat.

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. Dysregulated 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 uHTN 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 uHTN, 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

Mineralys Therapeutics is a clinical-stage biopharmaceutical company focused on developing medicines to target hypertension, CKD and other diseases driven by dysregulated 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 dysregulated 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

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