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): June 10, 2024

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 8.01. Other Events.

As previously disclosed, in April 2023, Mineralys Therapeutics, Inc. (the Company) initiated its 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 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 in 261 adult subjects. Subjects who meet screening criteria will have their existing hypertension medications discontinued and start on a standard regimen of an 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. The initial primary endpoint of the trial was change in 24-hour ambulatory systolic blood pressure (BP) at week twelve from baseline for active cohorts versus placebo. Topline data from this trial is anticipated in the fourth quarter of 2024.

In December 2023, the Company initiated its 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. The initial primary endpoint of the trial was change in office measured systolic BP at week twelve from baseline for active cohorts versus placebo. Topline data from this trial is anticipated in the second half of 2025.

During the Company's discussion with the U.S. Food and Drug Administration (FDA) about the analysis plan for Launch-HTN, the Company and the FDA agreed to make the primary endpoint of the trial 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. Based on these discussions with the FDA, the Company intends to implement a similar approach in Advance-HTN, pending alignment with the FDA, which would revise the primary endpoint of the trial to change in 24-hour ambulatory blood pressure monitoring systolic BP from baseline for active cohorts versus placebo at four weeks, with the results pooled for all subjects on 50 mg QD. All relevant efficacy measures will continue to be collected and analyzed at 12 weeks for both subjects receiving 50 mg QD and those subjects titrated to 100 mg QD. No other aspects of the trial designs for Advance-HTN and Launch-HTN are being modified at this time and no operational activities will be impacted by this change in statistical analysis.

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 revise the primary endpoint for the Advance-HTN trial; 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 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 FDA may not support the Company's proposed revision to the primary endpoint for the Advance-HTN trial; 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 us 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: June 10, 2024

MINERALYS THERAPEUTICS, INC.

By: /s/ Jon Congleton

Name: Jon Congleton

Title: Chief Executive Officer