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): May 2, 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 Global Select Market**

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.

On May 2, 2023, Mineralys Therapeutics, Inc. (the "Company"), announced the first patient dosed in the ADVANCE-HTN pivotal trial to evaluate the safety and efficacy of lorundrostat for the treatment of uncontrolled hypertension (uHTN) and resistant hypertension (rHTN) when used as an add-on therapy to standardized background treatment of two or three antihypertensive medications. The topline data from this trial are expected in the first half of 2024.

The randomized, double-blind, placebo-controlled ADVANCE-HTN trial will enroll up to approximately 300 eligible adult participants who will be randomized to 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 four. The primary endpoint of the trial is change in systolic blood pressure versus placebo after 12 weeks of treatment, as measured by 24-hour ambulatory blood pressure monitoring.

This is the first of two clinical trials under the planned pivotal program to evaluate the safety and efficacy of lorundrostat for the treatment of uHTN and rHTN. The second pivotal trial, a Phase 3 trial in a larger population of uHTN and rHTN subjects, is expected to begin enrolling in the second half of 2023, with data anticipated in mid-2025. Patients from both studies will be offered the opportunity to participate in an open label extension trial after completion of these trials. In addition, the Company plans to initiate a randomized, double-blind, placebo-controlled Phase 2 trial to evaluate the safety and efficacy of lorundrostat for the treatment of uHTN and rHTN in a chronic kidney disease (CKD) population in mid-2023. Topline data from the CKD trial is expected in the first half of 2024.

Uncontrolled and resistant hypertension represent a significant unmet need within the approximately 115 million patients in the U.S. who have high blood pressure. More than half of hypertensive patients fail to achieve their blood pressure goals despite treatment, and approximately 20 million treated patients have systolic blood pressure greater than 140 mmHg.

In November 2022, the Company presented results of its Target-HTN Phase 2 trial demonstrating that lorundrostat lowered the systolic blood pressure of patients with uHTN and rHTN at a clinically meaningful and statistically significant level, with a mean placebo-adjusted reduction in systolic blood pressure of 9.6 mmHg and 7.8 mmHg with a 50 mg or 100 mg QD dose, respectively. Additionally, treatment with lorundrostat demonstrated a robust effect in obese patients, who, studies show, tend to have abnormal aldosterone biology. The Company believes the approach of reducing aldosterone production can provide an effective, targeted approach for the control of hypertension, especially in the rapidly growing subset of hypertensive individuals with obesity.

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 our current beliefs and expectations and include, but are not limited to, statements regarding: the potential therapeutic benefits of lorundrostat; the planned future clinical development of lorundrostat and the timing thereof; and expected timing of 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; 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; regulatory developments in the United States and foreign countries; our reliance on our exclusive license with Mitsubishi Tanabe 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: May 2, 2023

MINERALYS THERAPEUTICS, INC.

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