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): January 6, 2026

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 January 6, 2026, Mineralys Therapeutics, Inc. (the Company) issued a press release providing a corporate update and announcing its participation in the upcoming LifeSci Partners Corporate Access event on January 12-14, 2026. 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, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933 or the Securities Exchange Act of 1934, except as shall be expressly set forth by specific reference in that filing.

Item 8.01. Other Events.

On January 6, 2026, the Company issued a press release disclosing that it (i) filed a new drug application for lorundrostat to the U.S. Food and Drug Administration in late 2025 and (ii) remains on track to report topline results from its Phase 2 Explore-OSA trial, which is evaluating the safety and efficacy of lorundrostat in participants with moderate to severe obstructive sleep apnea and hypertension, in the first quarter of 2026.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release Issued on January 6, 2026
104	Cover Page Interactive Data 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: January 6, 2026

MINERALYS THERAPEUTICS, INC.

By: /s/ Adam Levy

Name: Adam Levy

Title: Chief Financial Officer and Secretary

Mineralys Therapeutics Provides Corporate Update and Announces Participation in Upcoming LifeSci Partners Corporate Access Event in January 2026

RADNOR, PA – January 6, 2026 – Mineralys Therapeutics, Inc. (Nasdaq: MLYS), a clinical-stage biopharmaceutical company focused on developing medicines to target hypertension and related comorbidities such as chronic kidney disease (CKD), obstructive sleep apnea (OSA) and other diseases driven by dysregulated aldosterone, today issued a corporate update highlighting several recent and upcoming clinical and regulatory milestones. In addition, the Company announced that its management team will participate in the 15th LifeSci Partners Corporate Access event taking place January 12-14, 2026, in San Francisco, California.

"As we reflect on the data generated with lorundrostat to date, we are more confident than ever of the drug candidate's best-in-class profile, based on the clinically meaningful blood pressure reduction, the demonstrated 24-hour control, its benefit across the spectrum of difficult-to-treat patients, and its safety and tolerability profile," said Jon Congleton, Chief Executive Officer of Mineralys Therapeutics. "We look forward to reporting the Explore-OSA data in the first quarter of 2026, which we expect will further support our strategy to extend lorundrostat's profile in treating patients with hypertension and comorbid conditions."

Recent Clinical Highlights and Upcoming Milestones:

- **Explore-OSA Phase 2 Trial** – The Company remains on track to report topline results from the Phase 2 Explore-OSA trial in the first quarter of 2026. Enrollment was completed in the third quarter of 2025, and the trial is evaluating the benefits of lorundrostat on symptoms of OSA and blood pressure in participants with hypertension and moderate to severe OSA.

- **Lorundrostat New Drug Application (NDA)** – Mineralys filed an NDA for lorundrostat to the U.S. Food and Drug Administration (FDA) in late 2025. The submission followed a successful clinical program, which culminated in the completion of three positive clinical trials of lorundrostat in 2025. In these trials, lorundrostat demonstrated best-in-class safety and 24-hour blood pressure control across a spectrum of distinct and diverse patient populations.

- **Transform-HTN Open-Label Extension Trial** – The Company's ongoing open-label extension trial, which supported the NDA submission, enables participants to continue to receive lorundrostat and allows the Company to gather additional long-term safety and efficacy data.

- **Explore-CKD Phase 2 Trial** – Mineralys announced positive data from the Phase 2 Explore-CKD trial evaluating the safety and efficacy of 25 mg of lorundrostat in participants with hypertension, reduced kidney function and albuminuria. The crossover trial met its primary endpoint on systolic blood pressure reduction and demonstrated meaningful reduction in proteinuria.

- **Pivotal Launch-HTN Phase 3 Trial** – The global trial met its primary endpoint in evaluating the efficacy and safety of lorundrostat for the treatment of participants with uncontrolled hypertension (uHTN) or resistant hypertension (rHTN) as add-on therapy, who fail to achieve blood pressure (BP) control on their existing medications.

- **Pivotal Advance-HTN Trial** – The trial met its primary endpoints in evaluating the efficacy and safety of lorundrostat for the treatment of confirmed uHTN or rHTN on top of optimized, standardized AHA guideline background medications. These results reinforce lorundrostat's favorable benefit-risk profile in a high-risk population that would typically be treated by specialists rather than general practitioners.

About Lorundrostat

Lorundrostat is a proprietary, orally administered, highly selective aldosterone synthase inhibitor being developed for the treatment of uHTN or rHTN, as well as CKD and OSA. 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 a 40-70% reduction in plasma aldosterone concentration in hypertensive participants.

The Company has now completed four successful clinical trials of lorundrostat supporting the efficacy and safety profile while also validating aldosterone as an integral therapeutic target in uHTN and rHTN. The Company has completed two pivotal, registrational trials, including the Phase 3 Launch-HTN trial and Phase 2 Advance-HTN trial, which support the robust, durable and clinically meaningful reductions in systolic BP by lorundrostat. Lorundrostat was well tolerated in both trials with a favorable safety profile.

About Mineralys

Mineralys Therapeutics is a clinical-stage biopharmaceutical company focused on developing medicines to target hypertension and related comorbidities such as CKD, OSA and other diseases driven by dysregulated aldosterone. Its initial product candidate, lorundrostat, is a proprietary, orally administered, highly selective aldosterone synthase inhibitor. Mineralys is based in Radnor, Pennsylvania, and was founded by Catalys Pacific. For more information, please visit https://mineralystx.com. Follow Mineralys on LinkedIn, Twitter and Bluesky.

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 Advance-HTN and Launch-HTN may serve as pivotal trials in submission of an NDA to the FDA; the anticipated timing of the FDA's review of our NDA submission; the Company's ability to evaluate lorundrostat as a potential treatment for CKD, OSA, uHTN or rHTN; the planned future clinical development of lorundrostat and the timing thereof; and the expected timing of commencement and enrollment of participants 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: topline results that we report are based on a preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trial and such topline data may not accurately reflect the complete results of a clinical trial; 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 following submission of an NDA; any delays in the FDA's review of our NDA submission, including as a result of a government shutdown or reductions in agency funding or personnel, the results of our clinical trials, including the Advance-HTN and Launch-HTN trials, may not be deemed sufficient by the FDA to serve as the basis for an NDA submission or regulatory approval of lorundrostat; 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; macroeconomic trends and uncertainty with regard to high interest rates, elevated inflation, tariffs, and the potential for a local and/or

global economic recession; 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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