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): November 10, 2025

MINERALYS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-41614**	**84-1966887**
(State or other jurisdiction of incorporation)	(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 2.02 Results of Operations and Financial Condition.

On November 10, 2025, Mineralys Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2025 and provided a corporate update. A copy of the press release is attached hereto 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 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release Issued on November 10, 2025
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: November 10, 2025

MINERALYS THERAPEUTICS, INC.

By: /s/ Adam Levy

Name: Adam Levy

Title: Chief Financial Officer and Secretary

Exhibit 99.1

Mineralys Therapeutics Reports Third Quarter 2025 Financial Results and Provides Corporate Update

– Submission of New Drug Application (NDA) for lorundrostat planned for late-2025/Q1 2026 –

– Completed enrollment in Explore-OSA trial; topline results anticipated in Q1 2026 –

– Conference call today at 4:30 p.m. ET –

RADNOR, PA – November 10, 2025 – 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 announced financial results for the third quarter ended September 30, 2025, and provided a corporate update.

"We are at an exciting point in our company's history as we prepare for our NDA submission following pre-NDA feedback from the FDA last month. Our team has developed a fulsome data package consisting of multiple clinical trials which have demonstrated a well characterized efficacy and safety profile across distinct populations with uncontrolled and resistant hypertension. These findings for lorundrostat will provide the foundation for an NDA submission which we anticipate submitting near the end of 2025 or during the first quarter of 2026," stated Jon Congleton, Chief Executive Officer of Mineralys Therapeutics.

"We continue to evaluate lorundrostat's use in prevalent comorbidities of hypertension, for which normalizing aldosterone production may result in meaningful clinical benefit. Following positive topline data from our Phase 2 Explore-CKD trial, demonstrating successful results in the OSA patient population in our Phase 2 Explore-OSA trial would continue to expand the opportunity for lorundrostat in treating hypertension patients."

Recent Clinical Highlights and Upcoming Milestones

- **Transform-HTN Open-Label Extension Trial** – The Company's open-label extension trial enables participants to continue to receive lorundrostat while allowing the Company to gather ongoing safety and efficacy data.
- **Explore-OSA Phase 2 Trial** – Enrollment is complete and topline data is anticipated in the first quarter of 2026. The trial is evaluating the safety and efficacy of lorundrostat in the treatment of overweight or obese participants with moderate-to-severe OSA and hypertension.
- **Strengthened Balance Sheet** – On September 4, 2025, the Company completed a public equity financing for gross proceeds of approximately $287.5 million, before deducting fees and expenses.

Third Quarter 2025 Financial Highlights

Cash, cash equivalents and investments were $593.6 million as of September 30, 2025, compared to $198.2 million as of December 31, 2024. The Company believes that its current cash, cash equivalents and investments will be sufficient to fund its planned clinical trials and regulatory activities, as well as support corporate operations, into 2028.

Research and Development (R&D) expenses for the quarter ended September 30, 2025 were $31.5 million, compared to $54.0 million for the quarter ended September 30, 2024. The decrease in R&D expenses was primarily due to a decrease of $26.8 million in preclinical and clinical costs primarily impacted by the conclusion of the lorundrostat pivotal program in the second quarter of 2025, partially offset by increases of $3.2 million in higher compensation expense resulting from additions to headcount, increases in salaries and accrued bonuses and increased stock-based compensation and $1.1 million in higher clinical supply, manufacturing, regulatory and other costs.

General and Administrative (G&A) expenses were $9.7 million for the quarter ended September 30, 2025, compared to $6.1 million for the quarter ended September 30, 2024. The increase in G&A expenses was primarily due to $2.2 million in higher compensation expense resulting from additions to headcount, increases in salaries and accrued bonuses and increased stock-based compensation, $1.3 million in higher professional fees and $0.1 million in other administrative expenses.

Total other income, net was $4.2 million for the quarter ended September 30, 2025, compared to $3.8 million for the quarter ended September 30, 2024. The increase was primarily attributable to increased interest earned on investments in money market funds and U.S. treasuries as a result of higher average cash balances invested during the quarter ended September 30, 2025.

Net loss was $36.9 million for the quarter ended September 30, 2025, compared to $56.3 million for the quarter ended September 30, 2024. The decrease was primarily attributable to the factors impacting the Company's expenses described above.

Conference Call

The Company's management team will host a conference call at 4:30 p.m. ET today, November 10, 2025. To access the call, please dial 1-877-704-4453 in the United States or 1-201-389-0920 outside the United States. A live webcast of the conference call may be found here. A replay of the call will be available on the "News & Events" page in the Investor Relations section of the Mineralys Therapeutics website (click here).

About Hypertension

Having sustained, elevated blood pressure (or hypertension) (BP) increases the risk of heart disease, heart attack and stroke, which are leading causes of death in the United States. In 2022, more than 685,000 deaths in the United States included hypertension as a primary or contributing cause. Hypertension and related health issues resulted in an estimated annual economic burden of about $219 billion in the United States in 2019.

Less than 50% of hypertension patients achieve their BP goal with currently available medications. Dysregulated aldosterone levels are a key factor in driving hypertension in approximately 30% of all hypertensive patients.

About Chronic Kidney Disease (CKD)

CKD, which is characterized by the gradual loss of kidney function, is estimated to affect more than 10% of the global population and is one of the leading causes of mortality worldwide. According to the U.S. Centers for Disease Control and Prevention (CDC), an estimated 1-in-7 (approximately 37 million) U.S. adults have CKD, and approximately 22 million people in the United States are living with both hypertension and CKD. The relationship between these conditions is tightly linked: sustained hypertension may contribute to impaired kidney function, and progressive decrease in kidney function may lead to worsening BP control. When CKD is present in patients with hypertension, the risk of cardiovascular disease and mortality rises significantly.

Emerging evidence points to dysregulated aldosterone as a key driver of both diseases. Excess aldosterone promotes sodium retention, vascular inflammation, and fibrosis, contributing to both uncontrolled BP and kidney injury. Despite the availability of existing therapies, a significant proportion of patients remain uncontrolled or undertreated. Early detection and targeted interventions that address underlying mechanisms, such as aldosterone dysregulation, may offer the potential to slow CKD progression, reduce cardiovascular risk, and improve long-term outcomes. Without effective management, CKD can advance to kidney failure, requiring dialysis or transplantation.

About Obstructive Sleep Apnea (OSA)

OSA is characterized by repetitive overnight hypoxic episodes and subsequent sleep fragmentation due to a complete or partial collapse of the upper airway. Moderate to severe OSA is associated with increased production of aldosterone and increased nighttime BP; standard treatment with positive airway pressure is not sufficient for BP reduction. OSA impacts almost one billion people globally, including 425 million moderate-to-severe cases. Around 80% of adults with OSA are undiagnosed. As of 2015, undiagnosed OSA is estimated to cost the United States approximately $149.6 billion annually from comorbid disease, workplace accidents, motor vehicle accidents and loss of workplace productivity.

Between 30-50% of adults with hypertension have OSA, and this number increases to between 70-80% in adults with rHTN. Additionally, untreated moderate-to-severe OSA increases the risk of rHTN. Along with hypertension, OSA is a major risk factor of cardiovascular disease, type-2 diabetes mellitus and stroke.

About Lorundrostat

Lorundrostat is a proprietary, orally administered, highly selective aldosterone synthase inhibitor being developed for the treatment of uncontrolled hypertension (uHTN) or resistant hypertension (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 a new drug application (NDA) to the U.S. Food and Drug Administration (FDA); the anticipated timing of NDA submission and the FDA's review of the same; 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 upon submission of an NDA; any delays in the FDA's review of our planned 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.

Contact:
Investor Relations
investorrelations@mineralystx.com

Media Relations
Melyssa Weible
Elixir Health Public Relations
Email: mweible@elixirhealthpr.com

Mineralys Therapeutics, Inc.
Condensed Statements of Operations
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	$ 31,450	$ 53,985	$ 107,607	$ 124,012
General and administrative	9,681	6,121	24,717	16,624
Total operating expenses	41,131	60,106	132,324	140,636
Loss from operations	(41,131)	(60,106)	(132,324)	(140,636)
Interest income, net	4,195	3,774	9,908	11,779
Other income (expense)	4	(10)	(1)	(7)
Total other income, net	4,199	3,764	9,907	11,772
Net loss	$ (36,932)	$ (56,342)	$ (122,417)	$ (128,864)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.52)	$ (1.13)	$ (1.94)	$ (2.68)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	70,594,504	49,815,186	63,133,634	48,063,638

Mineralys Therapeutics, Inc.
Selected Financial Information
Condensed Balance Sheet Data
(amounts in thousands)
(unaudited)

	September 30, 2025	December 31, 2024
Cash, cash equivalents and investments	$ 593,628	$ 198,187
Total assets	$ 599,947	$ 205,903
Total liabilities	$ 23,520	$ 14,646
Total stockholders' equity	$ 576,427	$ 191,257