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): October 29, 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, PA 19087
(Address of principal executive offices) (Zip Code)

(888) 378-6240
(Registrant's telephone number, including 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 4, 2026, Mineralys Therapeutics, Inc. (the Company) issued a press release announcing its financial results for the quarter ended September 30, 2026 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 Item 2.02, 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On October 29, 2026, Derek DiRocco, Ph.D. informed the Board of Directors (the Board) of the Company of his decision to resign from the Board, effective as of December 31, 2026. Dr. DiRocco advised the Company that his decision was not the result of any disagreement with the Company or its management on any matter relating to the Company's operations, policies, or practices.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated November 4, 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: November 4, 2026

MINERALYS THERAPEUTICS, INC.

By: /s/ Jeffrey A. Munsie
Name: Jeffrey A. Munsie
Title: Chief Legal Officer and Secretary

Exhibit 99.1

Mineralys Therapeutics Reports Third Quarter 2026 Financial Results and Provides Corporate Update

– Commercialization plans for lorundrostat are on track ahead of PDUFA target date of December 22, 2026 –

– New analyses from the pivotal Launch-HTN trial showed 46% of participants with uncontrolled or resistant hypertension receiving lorundrostat 50 mg achieved the AHA/ACC guideline systolic blood pressure target of <130 mmHg at Week 12 –

– Transform-HTN open-label extension trial data selected for late-breaking presentation at American Heart Association Scientific Sessions 2026 –

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

RADNOR, Pa. — November 4, 2026 — Mineralys Therapeutics, Inc. (Nasdaq: MLYS), a biopharmaceutical company focused on developing medicines to target hypertension and aldosterone-related adverse outcomes in comorbid conditions 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, 2026, and provided a corporate update.

“With approximately 20 million adults in the U.S. living with uncontrolled or resistant hypertension, despite treatment, there is a significant need for new treatment options. As we approach the December 22nd PDUFA target date for lorundrostat, our focus is on completing our launch preparations so that we are ready to reach patients quickly, pending approval,” said Jon Congleton, Chief Executive Officer of Mineralys. “We also continue to highlight the data from our clinical trials in meetings with physicians and through presentations at scientific congresses, including our recent updates at AHA-HTN and ASN Kidney Week, and our upcoming presentation at the AHA Scientific Sessions. We continue to receive positive feedback from providers, payers and people living with hypertension, and we look forward to the potential to bring lorundrostat to millions of patients in need.”

Recent Highlights and Upcoming Milestones

- **Lorundrostat New Drug Application (NDA)** — The U.S. Food and Drug Administration (FDA) continues its review of the NDA for lorundrostat for the treatment of hypertension in combination with other antihypertensive drugs, with a Prescription Drug User Fee Act (PDUFA) target date of December 22, 2026.

- **New Launch-HTN and Explore-OSA Data at the American Heart Association Hypertension Scientific Sessions (AHA-HTN) and American Society of Nephrology (ASN) Kidney Week 2026**
    - A new analysis of the pivotal Phase 3 Launch-HTN trial showed that at Week 12, 46% of lorundrostat-treated participants (50 mg) achieved the AHA/ACC guideline-recommended office systolic blood pressure (SBP) target of <130 mmHg, with more than two-thirds achieving an SBP reduction of ≥10 mmHg. Participants had uncontrolled or treatment-resistant hypertension despite treatment with two to five antihypertensive therapies.
    - An additional new analysis from Launch-HTN demonstrated that lorundrostat achieved similar blood pressure reductions in participants with and without CKD, with consistent reductions across Stages 1-3 CKD. Lorundrostat also reduced albuminuria by 52% versus placebo, validating similar findings in a prior trial in participants with established CKD.
    - Final results from the Phase 2 Explore-OSA trial in overweight or obese adults with moderate-to-severe OSA and hypertension showed that lorundrostat 50 mg taken once daily in the evening reduced morning SBP by 11.1 mmHg at Week 4 ($p<0.0001$), compared with a 1.0 mmHg reduction with placebo (p=NS). No measurable change in apnea-hypopnea index was observed. Lorundrostat exhibited a favorable safety and tolerability profile, with no evidence of serious safety events, including hyperkalemia.
- **Transform-HTN Open-Label Extension Trial** — New long-term efficacy and safety data from the ongoing Transform-HTN open-label extension trial will be featured in a late-breaking presentation at the American Heart Association Scientific Sessions 2026, taking place November 6-9 in Chicago, IL.
- **Commercial Launch Readiness** — The Company is advancing its commercial launch preparations and now has an expanded medical affairs team and sales force in place. The Company continues to engage with leading hypertension experts and payers. Brand marketing preparations are well underway, and the Company is finalizing a full-service patient support program designed to ease access for physicians, their office staff and patients.

Third Quarter 2026 Financial Highlights

Cash, cash equivalents and investments were $624.7 million as of September 30, 2026, compared to $656.6 million as of December 31, 2025. The Company believes that its current cash, cash equivalents and investments will be sufficient to fund planned operations, including the commercial launch of lorundrostat, into 2028.

Research and development (R&D) expenses for the quarter ended September 30, 2026, were $22.7 million, compared to $31.5 million for the quarter ended September 30, 2025. The decrease in R&D expenses was primarily due to $8.5 million of lower preclinical and clinical costs resulting from

the conclusion of the lorundrostat pivotal program in the second quarter of 2025 and $0.3 million of decreased clinical supply, manufacturing, regulatory and other costs.

General and administrative (G&A) expenses were $37.4 million for the quarter ended September 30, 2026, compared to $9.7 million for the quarter ended September 30, 2025. The increase in G&A expenses was primarily due to investments to expand the Company's operations in preparation for commercialization, including $15.4 million in higher professional fees and $11.4 million in increased personnel-related expenses resulting from headcount growth and increased compensation, as well as $0.9 million of increased other administrative expenses.

Total other income, net was $2.8 million for the quarter ended September 30, 2026, compared to $4.2 million for the quarter ended September 30, 2025. The decrease was primarily due to $3.2 million of increased interest expense related to the senior secured term loan entered into in June 2026, partially offset by $1.8 million of increased interest earned on investments as a result of higher average cash balances during the quarter ended September 30, 2026.

Net loss was $57.3 million for the quarter ended September 30, 2026, compared to $36.9 million for the quarter ended September 30, 2025. The increase 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 4, 2026. To access the call, please dial 1-877-704-4453 in the United States or 1-201-389-0920 outside the United States, referencing conference ID 13762560. 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 Investors section of the Mineralys website here.

About Lorundrostat

Lorundrostat is an investigational, proprietary, orally administered, highly selective aldosterone synthase inhibitor being developed for the treatment of uncontrolled hypertension (uHTN) or resistant hypertension (rHTN), as well as related comorbidities, such as chronic kidney disease, obstructive sleep apnea and other diseases driven by dysregulated aldosterone. 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, has an observed half-life of 10-12 hours and demonstrated a 40-70% reduction in plasma aldosterone concentration in participants with hypertension.

Mineralys has completed six late-stage clinical trials of lorundrostat supporting its efficacy and safety profile while also validating aldosterone as an integral therapeutic target in uHTN and rHTN. The clinical program includes two pivotal, registrational trials, the Phase 3 Launch-HTN trial and Phase 2 Advance-HTN trial, which support the durable and clinically meaningful reductions in systolic blood pressure by lorundrostat. Lorundrostat was well tolerated in both trials with a favorable safety profile.

About Mineralys

Mineralys Therapeutics is a biopharmaceutical company focused on developing medicines to target hypertension and related comorbidities such as chronic kidney disease, obstructive sleep apnea and other diseases driven by dysregulated aldosterone. Its initial product candidate, lorundrostat, is an investigational, 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, X 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 Mineralys' current beliefs and expectations and include, but are not limited to, statements regarding: the anticipated timing of the FDA's review of Mineralys' accepted NDA; the potential therapeutic benefits of lorundrostat; Mineralys' expectations regarding activities to prepare for the commercial launch of lorundrostat; and the sufficiency of Mineralys' cash, cash equivalents and investments to fund its operations. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in Mineralys' business, including, without limitation: any delays in the FDA's review of Mineralys' accepted NDA, including as a result of a government shutdown or reductions in agency funding or personnel; the results of Mineralys' clinical trials, including the Launch-HTN and Advance-HTN trials, may not be deemed sufficient by the FDA to serve as the basis for regulatory approval of lorundrostat; later developments with the FDA may be inconsistent with the feedback from prior meetings, including whether the proposed pivotal program will support registration of lorundrostat following the FDA's review of Mineralys' NDA submission; the risk that future funding under the secured debt facility may not be available on the timeframe Mineralys expects, or at all, including as a result of its failure to meet the conditions required for such funding or failure to comply with the affirmative and negative covenants under the debt facility; Mineralys' future performance is dependent entirely on the success of lorundrostat; potential delays in the commencement, enrollment and completion of clinical trials and nonclinical studies; Mineralys' 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 other trade policies, and the potential for a local and/or global economic recession; Mineralys' ability to maintain undisrupted business operations due to any pandemic or future public health concerns; regulatory developments in the United States and foreign countries; and other risks described in Mineralys' filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in its 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 Mineralys 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.

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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,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 22,668	$ 31,450	$ 268,410	$ 107,607
General and administrative	37,419	9,681	83,057	24,717
Total operating expenses	60,087	41,131	351,467	132,324
Loss from operations	(60,087)	(41,131)	(351,467)	(132,324)
Other income (expense), net:				
Interest and other income	5,947	4,199	17,752	9,907
Interest expense	(3,188)	—	(4,023)	—
Total other income, net	2,759	4,199	13,729	9,907
Net loss	$ (57,328)	$ (36,932)	$ (337,738)	$ (122,417)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.64)	$ (0.52)	$ (3.95)	$ (1.94)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	88,986,795	70,594,504	85,538,811	63,133,634

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

	September 30, 2026	December 31, 2025
Cash, cash equivalents and investments	$ 624,672	$ 656,635
Total assets	$ 630,123	$ 661,806
Senior secured term loan, net	$ 98,273	$ —
Total liabilities	$ 126,348	$ 15,113
Total stockholders' equity	$ 503,775	$ 646,693