

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 6, 2026

MINERALYS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction  
of incorporation)

001-41614  
(Commission  
File Number)

84-1966887  
(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, include area code)

Not Applicable

(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 May 6, 2026, Mineralys Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended March 31, 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 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

<b>Exhibit No.</b>	<b>Description</b>
<a href="#">99.1</a>	Press Release Issued on May 6, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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 6, 2026

**MINERALYS THERAPEUTICS, INC.**

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



## Mineralys Therapeutics Reports First Quarter 2026 Financial Results and Provides Corporate Update

– NDA for lorundrostat in adults with hypertension accepted by FDA; assigned PDUFA target date of December 22, 2026 –

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

RADNOR, PA – May 6, 2026 – Mineralys Therapeutics, Inc. (Nasdaq: MLYS), a 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 first quarter ended March 31, 2026, and provided a corporate update.

“We continue to make strong progress advancing lorundrostat toward potential approval, moving closer towards our goal of delivering what we believe has the potential to be a best-in-class aldosterone synthase inhibitor for patients with uncontrolled or resistant hypertension,” said Jon Congleton, Chief Executive Officer of Mineralys Therapeutics. “The FDA’s acceptance of our NDA in the first quarter marks a significant milestone for Mineralys. We continue to advance pre-commercial activities to support a successful launch of lorundrostat while maintaining strategic flexibility.”

### Recent Clinical Highlights and Upcoming Milestones

- **Lorundrostat New Drug Application (NDA)** – The U.S. Food and Drug Administration (FDA) accepted the NDA for lorundrostat for the treatment of hypertension in combination with other antihypertensive drugs and assigned a Prescription Drug User Fee Act (PDUFA) target date of December 22, 2026. The NDA submission included the diverse dataset the Company has built with lorundrostat across five positive clinical trials that demonstrated clinically meaningful blood pressure (BP) reduction, 24-hour control and a favorable safety profile in adults with uncontrolled or resistant hypertension.
  - **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.
  - **Pre-Commercial Activities Underway** – The Company is executing on its pre-commercial activities in preparation for the December 22, 2026 PDUFA target date for lorundrostat. This includes engaging in market access discussions, expanded medical advocacy through communications efforts in the field to support broader education of the unmet need in uncontrolled or resistant hypertension, and sales and marketing activities preparing lorundrostat for a successful launch.
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## **First Quarter 2026 Financial Highlights**

Cash, cash equivalents and investments were \$646.1 million as of March 31, 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 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 March 31, 2026 were \$24.4 million, compared to \$37.9 million for the quarter ended March 31, 2025. The decrease in R&D expenses was primarily driven by a \$15.5 million reduction in preclinical and clinical costs following the conclusion of the lorundrostat pivotal program in the second quarter of 2025. This decrease was partially offset by \$1.1 million of increased clinical supply, manufacturing and regulatory costs and \$0.8 million of increased personnel-related expenses resulting from headcount growth and increased compensation.

General and administrative (G&A) expenses were \$21.0 million for the quarter ended March 31, 2026, compared to \$6.6 million for the quarter ended March 31, 2025. The increase in G&A expenses was primarily driven by \$7.9 million of higher professional fees, \$6.1 million of increased personnel-related expenses resulting from headcount growth and increased compensation and \$0.4 million of other general and administrative expenses.

Total other income, net was \$6.0 million for the quarter ended March 31, 2026, compared to \$2.2 million for the quarter ended March 31, 2025. The increase reflects higher interest earned on investments in money market funds and U.S. Treasuries due to higher average cash balances invested during the quarter ended March 31, 2026.

Net loss was \$39.3 million for the quarter ended March 31, 2026, compared to \$42.2 million for the quarter ended March 31, 2025. 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, May 6, 2026. 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 at [\(click here\)](#). A replay of the call will be available on the "News & Events" page in the Investors section of the Mineralys Therapeutics website [\(click here\)](#).

## **About Hypertension**

Having sustained, elevated blood pressure (BP) (or hypertension) 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.

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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 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, has 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 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 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 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 anticipated timing of the FDA's review of our accepted NDA and any subsequent regulatory approval of lorundrostat; the planned future clinical development of lorundrostat and the timing thereof; and the sufficiency of our cash, cash equivalents and investments to fund our operations. 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; any delays in the FDA's review of our accepted NDA, 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 regulatory approval of lorundrostat; later developments with the FDA may be inconsistent with the feedback from prior meetings, including whether the proposed pivotal

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program will support registration of lorundrostat following the FDA's review of our NDA submission; 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; 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; our ability to maintain uninterrupted 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 Tanabe Pharma Corporation 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](mailto:investorrelations@mineralystx.com)

**Media Relations**

Melyssa Weible

Elixir Health Public Relations

Email: [mweible@elixirhealthpr.com](mailto:mweible@elixirhealthpr.com)

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

	Three Months Ended	
	March 31,	
	2026	2025
Operating expenses:		
Research and development	\$ 24,365	\$ 37,879
General and administrative	20,975	6,568
Total operating expenses	45,340	44,447
Loss from operations	(45,340)	(44,447)
Interest income, net	5,996	2,239
Other income (expense)	5	(3)
Total other income, net	6,001	2,236
Net loss	\$ (39,339)	\$ (42,211)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.47)	\$ (0.79)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	82,834,752	53,163,551

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

	March 31, 2026	December 31, 2025
Cash, cash equivalents and investments	\$ 646,060	\$ 656,635
Total assets	\$ 652,862	\$ 661,806
Total liabilities	\$ 14,718	\$ 15,113
Total stockholders' equity	\$ 638,144	\$ 646,693