May 6, 2026

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 06, 2026 (GLOBE NEWSWIRE) -- 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.

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.

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 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 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 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.

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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

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Source: Mineralys Therapeutics, Inc.