March 12, 2026

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

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

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

RADNOR, Pa., March 12, 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 fourth quarter and full year ended December 31, 2025, and provided a corporate update.

“Mineralys had a transformational year in 2025, defined by significant clinical progress and key regulatory milestones,” said Jon Congleton, Chief Executive Officer of Mineralys Therapeutics. “We successfully completed multiple clinical trials, with results published in *JAMA* and *The New England Journal of Medicine*, highlighting the potential of lorundrostat to benefit patients with inadequately controlled hypertension. We also ended the year with the submission of our first NDA for the treatment of hypertension in adults. The FDA’s acceptance of this application marked a significant milestone, and we look forward to working closely with the agency as lorundrostat advances toward potential approval and commercialization.”

Recent Clinical Highlights and Upcoming Milestones

- **Lorundrostat New Drug Application (NDA)**– Mineralys announced the U.S. Food and Drug Administration (FDA) has 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 followed a successful clinical program, which culminated in the completion of 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.

- **Explore-OSA Phase 2 Trial** – Mineralys announced topline data from the exploratory trial of lorundrostat in 48 participants with an average body mass index (BMI) of 38.2 kg/m^2, an average apnea-hypopnea index (AHI) of 48.5 events/hr and an average systolic BP of 142.3 mmHg (range 131-175 mmHg). After four weeks of treatment, lorundrostat 50 mg dosed in the evening did not demonstrate a clinically meaningful difference relative to placebo on AHI, the primary endpoint.

The trial demonstrated a clinically meaningful reduction in blood pressure at week four, with an 11.1 mmHg ($p < 0.0001$) and a 1.0 mmHg (p = NS) BP reduction with lorundrostat and placebo, respectively, in the pre-planned parallel arm analysis of the first period. There was a 6.2 mmHg placebo-adjusted reduction ($p < 0.0003$) in BP in the crossover analysis.

Lorundrostat demonstrated a favorable safety profile and was well tolerated, with no serum potassium excursions above 5.5 mmol/L. Analysis is ongoing for other endpoints in the trial and will be reported in future publications or medical meetings.

- **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.

Fourth Quarter and Full Year 2025 Financial Highlights

Cash, cash equivalents and investments were $656.6 million as of December 31, 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 year ended December 31, 2025 were $132.0 million, compared to $168.6 million for the year ended December 31, 2024. R&D expenses for the quarter ended December 31, 2025, were $24.4 million, compared to $44.6 million for the quarter ended December 31, 2024. The annual decrease in R&D expense was primarily driven by a $49.3 million reduction in preclinical and clinical costs, largely attributable to the conclusion of the lorundrostat pivotal program in the second quarter of 2025. The annual decrease was partially offset by increases of $9.9 million in compensation expense resulting from headcount growth, higher salaries and accrued bonuses and increased stock-based compensation, as well as $3.0 million in clinical supply, manufacturing and regulatory costs.

General and Administrative (G&A) expenses were $38.6 million for the year ended December 31, 2025, compared to $23.8 million for the year ended December 31, 2024. G&A expenses were $13.9 million for the quarter ended December 31, 2025, compared to $7.2 million for the quarter ended December 31, 2024. The annual increase in G&A expenses was primarily attributable to $8.9 million in higher compensation expense, driven by headcount growth, higher salaries and accrued bonuses and increased stock-based compensation. The annual increase was further attributable to $5.3 million in higher professional fees and $0.6 million in other general and administrative expenses.

Total other income, net was $16.0 million for the year ended December 31, 2025, compared to $14.6 million for the year ended December 31, 2024. Total other income, net was $6.0 million for the quarter ended December 31, 2025, compared to $2.8 million for the quarter ended December 31, 2024. The annual increase was primarily attributable to higher interest earned on investments in money market funds and U.S. treasuries, resulting from higher average cash balances invested during the year ended December 31, 2025.

Net loss was $154.7 million for the year ended December 31, 2025, compared to

$177.8 million for the year ended December 31, 2024. Net loss was $32.2 million for the quarter ended December 31, 2025, compared to $48.9 million for the quarter ended December 31, 2024. The annual 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, March 12, 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 Investor Relations section of the Mineralys Therapeutics website (click here).

About Hypertension

Having sustained, elevated 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, 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 the efficacy and safety profile while also validating aldosterone as an integral therapeutic target in uHTN and rHTN. This includes 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 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 timing and results of review of additional endpoints evaluated in the Explore-OSA clinical trial; the anticipated timing of the FDA's review of the Company's accepted NDA and any subsequent regulatory approval of lorundrostat; and the planned future clinical development of lorundrostat and the timing thereof. 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 December 31,		Year Ended December 31,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ 24,402	$ 44,569	$ 132,009	$ 168,581
General and administrative	13,878	7,198	38,595	23,822
Total operating expenses	38,280	51,767	170,604	192,403
Loss from operations	(38,280)	(51,767)	(170,604)	(192,403)
Interest income, net	6,045	2,809	15,953	14,588
Other income	1	12	—	5
Total other income, net	6,046	2,821	15,953	14,593
Net loss	$ (32,234)	$ (48,946)	$ (154,651)	$ (177,810)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.40)	$ (0.98)	$ (2.29)	$ (3.66)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	80,545,736	49,957,912	67,656,355	48,539,795

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

	December 31,	
	2025	**2024**
Cash, cash equivalents and investments	$ 656,635	$ 198,187
Total assets	$ 661,806	$ 205,903
Total liabilities	$ 15,113	$ 14,646
Total stockholders' equity	$ 646,693	$ 191,257

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Source: Mineralys Therapeutics, Inc.