August 12, 2025

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

– Presented and published the positive results from both the Launch-HTN and Advance-HTN pivotal trials at scientific meetings and in JAMA and NEJM –

– Pre-NDA meeting scheduled to take place in 4Q 2025 –

– Explore-CKD Phase 2 trial successfully achieved statistical significance in reduction of systolic BP and UACR, and demonstrated a favorable safety profile –

– Explore-OSA Phase 2 trial in OSA participants with hypertension is ongoing; topline results anticipated in 1H 2026 –

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

RADNOR, Pa., Aug. 12, 2025 (GLOBE NEWSWIRE) -- 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 second quarter ended June 30, 2025, and provided a corporate update.

“We continue to lead the way in the development of ASIs for the treatment of hypertension and related cardiorenal conditions. In the first half of 2025, we announced positive results from three clinical trials evaluating lorundrostat for the treatment of participants with uncontrolled or resistant hypertension. These data further support our belief that lorundrostat has significant potential to be a leading new therapy to control hypertension and reduce cardiovascular risk,” stated Jon Congleton, Chief Executive Officer of Mineralys Therapeutics. “The results from our clinical program have positioned us to move ahead with our NDA strategy, and we have scheduled a pre-NDA meeting with the FDA to take place in the fourth quarter of 2025.”

Recent Clinical Highlights and Upcoming Milestones

- **Pivotal Launch-HTN Phase 3 Trial** – The trial met its primary endpoint in evaluating the efficacy and safety of lorundrostat for the treatment of participants with uncontrolled hypertension (uHTN) or resistant hypertension (rHTN) as add-on therapy, who fail to achieve blood pressure (BP) control on their existing medications.
    - Published the positive results from the Launch-HTN trial in the June 30, 2025 issue of the Journal of the American Medical Association (JAMA)in a manuscript titled, “Lorundrostat in Participants with Uncontrolled and Treatment-Resistant Hypertension.”

    - Presented the positive results from the Launch-HTN trial as a late-breaking presentation at the 2025 European Society of Hypertension Meeting on Hypertension and Cardiovascular Protection in Milan, Italy.

- **Pivotal Advance-HTN Trial** –The trial met its primary endpoints in evaluating the efficacy and safety of lorundrostat for the treatment of confirmed uHTN or rHTN. These results reinforce lorundrostat's favorable benefit-risk profile in a high-risk population that would typically be treated by specialists rather than general practitioners.
    - Presented detailed results from the Advance-HTN trial in a late-breaking presentation at the American College of Cardiology's ACC.25 meeting.

    - Published the positive results from the Advance-HTN trial in the April 23, 2025 issue of the New England Journal of Medicine in a manuscript titled, "Lorundrostat Efficacy and Safety in Patients with Uncontrolled Hypertension."

- **Explore-CKD Phase 2 Trial** – Announced positive topline data from the Phase 2 Explore-CKD trial evaluating the safety and efficacy of 25 mg of lorundrostat in participants with hypertension, reduced kidney function and albuminuria. The crossover trial met its primary endpoint and demonstrated a favorable safety and tolerability profile. The trial reported that the lorundrostat 25 mg dose achieved a 9.25 mmHg reduction in systolic BP, and a 7.5 mmHg placebo-adjusted reduction (p-value = 0.0024), as assessed by automated office blood pressure (AOBP) at week four. In addition, the lorundrostat 25 mg dose achieved a reduction in spot urine albumin-to-creatinine ratio (UACR) of 30.51% from baseline, and a 25.6% placebo-adjusted reduction (p-value = 0.0015) at week four.

- **Transform-HTN Open-Label Extension Trial** – The Company's open-label extension trial that allows participants to continue to receive lorundrostat and the Company to obtain additional safety and efficacy data is ongoing.

- **Explore-OSA Phase 2 Trial** – The trial will evaluate the safety and efficacy of lorundrostat in the treatment of overweight and obese participants with moderate-to-severe OSA and uHTN or rHTN. The Company anticipates reporting topline results from Explore-OSA in 1H 2026.

Second Quarter 2025 Financial Highlights

Cash, cash equivalents and investments were $324.9 million as of June 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 2027.

Research and Development (R&D) expenses for the quarter ended June 30, 2025 were $38.3 million, compared to $39.3 million for the quarter ended June 30, 2024. The decrease in R&D expenses was primarily due to a decrease of $4.5 million in preclinical and clinical costs driven by the conclusion of the lorundrostat pivotal program in the second quarter of 2025, partially offset by increases of $2.7 million in higher compensation expense resulting from additions to headcount, increases in salaries and accrued bonuses and increased stock-based compensation and $0.8 million in higher clinical supply, manufacturing

regulatory and other costs.

General and Administrative (G&A) expenses were $8.5 million for the quarter ended June 30, 2025, compared to $5.9 million for the quarter ended June 30, 2024. The increase in G&A expenses was primarily due to $1.9 million in higher compensation expense resulting from additions to headcount, increases in salaries and accrued bonuses and increased stock-based compensation, $0.6 million in higher professional fees and $0.1 million in other administrative expenses.

Total other income, net was $3.5 million for the quarter ended June 30, 2025, compared to $4.2 million for the quarter ended June 30, 2024. The decrease was primarily attributable to decreased interest earned on investments in money market funds and U.S. treasuries as a result of lower average cash balances invested during the quarter ended June 30, 2025.

Net loss was $43.3 million for the quarter ended June 30, 2025, compared to $41.0 million for the quarter ended June 30, 2024. 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, August 12, 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 BP (or hypertension) increases the risk of heart disease, heart attack and stroke, which are leading causes of death in the United States.[1] In 2022, more than 685,000 deaths in the United States included hypertension as a primary or contributing cause.[2] Hypertension and related health issues resulted in an estimated annual economic burden of about $219 billion in the United States in 2019.[3]

Less than 50% of hypertension patients achieve their BP goal with currently available medications.[4] Dysregulated aldosterone levels are a key factor in driving hypertension in approximately 30% of all hypertensive patients.[5]

About Chronic Kidney Disease

Chronic kidney disease (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.[6] 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.[7] When CKD is present in patients with hypertension, the risk of cardiovascular disease and mortality rises significantly.[8]

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.[9,10] Despite the availability of existing therapies, a significant proportion of patients remain uncontrolled or undertreated.[4] 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.[9] Without effective management, CKD can advance to kidney failure, requiring dialysis or transplantation.[11]

About 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 OSA is defined as having between 15 and 30 breathing pauses (apnea or hypopnea events) per hour of sleep, while severe OSA indicates more than 30 breathing pauses per hour. 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 uHTN or 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 a potential pre-NDA meeting with the FDA; 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; 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.

References

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ 38,278	$ 39,273	$ 76,157	$ 70,027
General and administrative	8,468	5,895	15,036	10,503
Total operating expenses	46,746	45,168	91,193	80,530
Loss from operations	(46,746)	(45,168)	(91,193)	(80,530)
Interest income, net	3,474	4,152	5,713	8,005
Other income (expense)	(2)	2	(5)	3
Total other income, net	3,472	4,154	5,708	8,008
Net loss	$ (43,274)	$ (41,014)	$ (85,485)	$ (72,522)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.66)	$ (0.83)	$ (1.44)	$ (1.54)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	65,451,297	49,356,287	59,341,368	47,178,288

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

	June 30, 2025	December 31, 2024
Cash, cash equivalents and investments	$ 324,916	$ 198,187
Total assets	$ 335,724	$ 205,903
Total liabilities	$ 22,173	$ 14,646
Total stockholders' equity	$ 313,551	$ 191,257



Source: Mineralys Therapeutics, Inc.