August 11, 2026

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

– PDUFA target date of December 22, 2026 for lorundrostat; commercial preparations on-track for launch upon approval –

– Appoints accomplished cardiovascular medicine executive Dr. Terry Ferguson as Chief Medical Officer to lead the Company's medical and late-stage clinical activities –

– Strengthened balance sheet and enhanced the long-term economics of lorundrostat through strategic financing initiatives and the repurchase of the Tanabe royalty obligation –

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

RADNOR, Pa., Aug. 11, 2026 (GLOBE NEWSWIRE) -- 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 second quarter ended June 30, 2026, and provided a corporate update.

"Mineralys is advancing toward an exciting next chapter as we prepare for the commercial launch of lorundrostat, pending FDA approval. The efficacy and safety profile of lorundrostat supports its potential as a compelling treatment option for patients with uncontrolled or resistant hypertension," said Jon Congleton, Chief Executive Officer of Mineralys. "We are also excited to welcome Terry Ferguson as our new Chief Medical Officer. His extensive experience in cardiovascular medicine strongly positions him to lead our medical organization. David Rodman, who guided the development of lorundrostat from proof of concept through the pivotal program, as well as our recent new drug application filing with the FDA, will continue to contribute to Mineralys in his full-time role as a Strategic Advisor."

"I am very pleased to join the team at Mineralys in advance of the December PDUFA target date," said Dr. Terry Ferguson, Chief Medical Officer of Mineralys. "Uncontrolled or resistant hypertension is a major driver of cardiovascular morbidity and mortality and a continuing issue for millions of Americans. I look forward to helping bring new treatment options, like lorundrostat, to patients with hypertension and other conditions where modulating dysregulated aldosterone may provide significant benefit."

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.

- **Appointment of New Chief Medical Officer (CMO)** — Appointed James J. "Terry" Ferguson III, M.D., as CMO, effective August 10, 2026, succeeding David Rodman, M.D., who will stay on with the Company as a full-time Strategic Advisor. Terry brings more than 35 years of experience in cardiovascular medicine and drug development, including serving as Cardiovascular Therapeutic Area Head at Amgen, nearly a decade in cardiovascular leadership roles at AstraZeneca and The Medicines Company, as well as more than two decades on the faculty of the Texas Heart Institute. Most recently, he served as Chief Medical Officer at Cadrenal Therapeutics. In his new role, Terry will lead Mineralys' medical and late-stage clinical activities.

- **Transform-HTN Open-Label Extension Trial** — The Company's ongoing Transform-HTN open-label extension trial, which supported the NDA submission, continues to enable participants to receive lorundrostat and generate additional long-term safety and efficacy data.

- **Commercial Launch Readiness** — The Company continues to advance commercial launch preparations ahead of lorundrostat's PDUFA target date of December 22, 2026 and remains on track. An experienced commercial leadership team is now in place, initial sales territories and priority geographies have been identified, and engagement continues with leading hypertension experts and payers covering a substantial majority of U.S. lives. The Company expects to have the sales organization established in advance of the anticipated PDUFA target date.

- **Strengthened Balance Sheet and Lorundrostat Economics** — During the second quarter of 2026, Mineralys strengthened its financial position and enhanced the long-term economics of lorundrostat through the following transactions**:**
    - Completed a follow-on public offering of 5,660,378 shares of common stock, generating gross proceeds of approximately $150.0 million.

    - Entered into a senior secured term loan facility for up to $500.0 million from funds managed by Pharmakon Advisors, LP, including an initial $100.0 million tranche drawn in June 2026.

    - Amended the Tanabe license agreement to eliminate the Company's royalty obligations, strengthening the Company's economic rights to lorundrostat. The Company made an upfront cash payment to Tanabe of $200.0 million and agreed to pay additional commercial milestone payments of up to $100.0 million in the aggregate (the New Milestones). As a result, the Company has remaining obligations to pay Tanabe commercial milestone payments, including the New Milestones, of up to $255.0 million in the aggregate upon first commercial sale and upon meeting certain annual sales targets, as well as up to $10.0 million related to commercialization for a potential second indication. Tanabe has also agreed to subsequently assign to Mineralys all of Tanabe's rights in the licensed intellectual property.

Second Quarter 2026 Financial Highlights

Cash, cash equivalents and investments were $661.4 million as of June 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 June 30, 2026 were $221.4 million, compared to $38.3 million for the quarter ended June 30, 2025. The increase in R&D expenses was primarily due to the $200.0 million upfront payment to Tanabe in June 2026 in connection with the license agreement amendment. The increase was also due to $0.6 million of increased personnel-related expenses resulting from headcount growth and increased compensation and $0.2 million of increased clinical supply, manufacturing, regulatory and other costs. These increases were partially offset by $17.8 million of lower preclinical and clinical costs, primarily due to the conclusion of the lorundrostat pivotal program in the second quarter of 2025.

General and administrative (G&A) expenses were $24.7 million for the quarter ended June 30, 2026, compared to $8.5 million for the quarter ended June 30, 2025. The increase in G&A expenses was primarily due to $8.0 million in higher professional fees, $8.0 million of increased personnel-related expenses resulting from headcount growth and increased compensation and $0.2 million of increased other administrative expenses.

Total other income, net was $5.0 million for the quarter ended June 30, 2026, compared to $3.5 million for the quarter ended June 30, 2025. The increase was primarily due to $2.3 million of increased interest earned on investments as a result of higher average cash balances, partially offset by $0.8 million of interest and amortization expense related to the senior secured term loan entered into in June 2026.

Net loss was $241.1 million for the quarter ended June 30, 2026, compared to $43.3 million for the quarter ended June 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, August 11, 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 13760792. 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 CKD, OSA 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 robust, 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 and any subsequent regulatory approval of lorundrostat; the potential therapeutic benefits of lorundrostat; Mineralys' expectations regarding activities to prepare for the commercial launch of lorundrostat; the capital available under Mineralys' secured debt facility, including the potential to draw down additional tranches thereunder; Mineralys' expectations with respect to finalizing an agreement with Tanabe to terminate the license agreement and to have Tanabe's rights in the licensed intellectual property transferred to Mineralys; 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 may not be able to reach agreement on the proposed termination of its license agreement with Tanabe on its expected timeframe, or at all; 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; Mineralys' reliance on its exclusive license with Tanabe to provide Mineralys with intellectual property rights to develop and commercialize lorundrostat; 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 June 30,		Six Months Ended June 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses:				
Research and development	$ 221,377	$ 38,278	$ 245,742	$ 76,157
General and administrative	24,663	8,468	45,638	15,036
Total operating expenses	246,040	46,746	291,380	91,193
Loss from operations	(246,040)	(46,746)	(291,380)	(91,193)
Interest income, net	4,956	3,474	10,952	5,713
Other income (expense)	13	(2)	18	(5)
Total other income, net	4,969	3,472	10,970	5,708
Net loss	$ (241,071)	$ (43,274)	$ (280,410)	$ (85,485)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.85)	$ (0.66)	$ (3.35)	$ (1.44)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	84,727,282	65,451,297	83,786,245	59,341,368

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

	June 30, 2026	December 31, 2025
Cash, cash equivalents and investments	$ 661,412	$ 656,635
Total assets	$ 667,853	$ 661,806
Senior secured term loan, net	$ 97,617	$ —
Total liabilities	$ 116,936	$ 15,113
Total stockholders' equity	$ 550,917	$ 646,693

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Source: Mineralys Therapeutics, Inc.