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): August 7, 2023

MINERALYS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-41614**	**84-1966887**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

150 N. Radnor Chester Road, Suite F200
Radnor, Pennsylvania 19087
(Address of principal executive offices) (Zip Code)

(888) 378-6240
(Registrant's telephone number, include area code)

N/A
(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 August 7, 2023, Mineralys Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended June 30, 2023 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

Exhibit No.	Description
99.1	Press Release Issued on August 7, 2023

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: August 7, 2023

MINERALYS THERAPEUTICS, INC.

By: /s/ Adam Levy

Name: Adam Levy

Title: Chief Financial Officer, Chief Business Officer and Secretary

Exhibit 99.1

Mineralys Therapeutics Reports Second Quarter 2023 Financial Results and Provides Corporate Update

– Continue enrolling subjects in ongoing pivotal Advance-HTN trial of lorundrostat, for the treatment of patients with uncontrolled or resistant hypertension –

– On track to initiate planned Phase 3 pivotal Launch-HTN trial of lorundrostat for the treatment of uncontrolled or resistant hypertension in 2H 2023 –

– Announced expansion of planned Phase 2 trial of lorundrostat alone and in combination with SGLT2 inhibitor to treat patients with chronic kidney disease (CKD), expect to initiate enrollment in 2H 2023 –

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

RADNOR, PA – August 7, 2023 – Mineralys Therapeutics, Inc. (Nasdaq: MLYS), a clinical-stage biopharmaceutical company focused on developing medicines to target diseases driven by abnormally elevated aldosterone, today announced financial results for the quarter ending June 30, 2023, and provided a corporate update.

"Our team continued to make significant progress in executing our development strategy for lorundrostat during the first half of 2023. The pivotal development program for lorundrostat to treat uncontrolled hypertension (uHTN) or resistant hypertension (rHTN) is well underway, with enrollment in the Advance-HTN trial ongoing and initiation of the Phase 3 Launch-HTN trial expected in the second half of the year," stated Jon Congleton, Chief Executive Officer of Mineralys Therapeutics. "Most recently, we announced the decision to expand our planned Phase 2 trial of lorundrostat for treating patients with chronic kidney disease (CKD), which we plan on initiating during the second half of 2023. The role of aldosterone in the progression of CKD is well established. This trial will evaluate the benefit of inhibiting aldosterone production with lorundrostat as a more complete solution and promising approach to treat CKD patients."

Recent Corporate and Clinical Highlights

- **Enrollment on track for pivotal Advance-HTN trial** – Since initiating patient dosing in the ongoing Advance-HTN Phase 2 trial in April 2023, additional clinical sites have been onboarded and enrollment of subjects is on track. The Advance-HTN Phase 2 trial is evaluating the safety and efficacy of lorundrostat for the treatment of uHTN or rHTN, when used as an add-on therapy to standardized background treatment of two or three antihypertensive medications in up to approximately 300 adult subjects. The topline data from this trial is expected in the first half of 2024.

- **Open-label extension trial for long-term safety exposure** – In mid-2023, the Company initiated an open-label extension trial to obtain additional safety data. All subjects in the pivotal hypertension program, including the Advance-HTN and Launch-HTN trials, will be given the opportunity to participate in the extension trial.

- **Announced expansion of the Phase 2 trial for lorundrostat in CKD subjects** – In July 2023, the Company announced details of an expanded two-part Phase 2 clinical trial for lorundrostat as a potential therapy to treat patients with Stage 2 to 4 CKD. The trial will now include a proof-of-concept study (Part A) evaluating lorundrostat alone and in combination with an SGLT2 inhibitor in subjects with mild to moderate CKD, estimated glomerular filtration rate (eGFR) 45-90 ml/min/1.73m^2, with persistent proteinuria despite treatment with an angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB). Part A is designed to evaluate the benefit of lorundrostat on proteinuria in this CKD population. The second part of the trial is a profiling study (Part B), which will characterize the safety profile of lorundrostat in subjects with moderate to severe CKD, eGFR 25-44 ml/min/1.73m^2, with and without hypertension, despite treatment with an ACE inhibitor or ARB. The trial is expected to start enrolling patients in the second half of 2023.

Key Upcoming Milestones

- **Initiation of the Phase 2 trial of lorundrostat in CKD** – In the second half of 2023, the Company plans to initiate the two-part Phase 2 trial of lorundrostat for the treatment of subjects with CKD. Topline data from this trial are anticipated between the fourth quarter of 2024 and the first quarter of 2025. As an exploratory trial, the Company may conduct interim data analyses at one or more time points.

- **Phase 3 pivotal Launch-HTN trial** – In the second half of 2023, the Company plans to initiate a randomized, double-blind, placebo-controlled Phase 3 trial to evaluate the safety and efficacy of lorundrostat for the treatment of uHTN or rHTN, when used as an add-on therapy to prescribed background treatment of two to five antihypertensive medications in up to approximately 1,000 adult subjects. The topline data from this trial is expected in mid-2025.

Second Quarter 2023 Financial Highlights

Cash, cash equivalents and investments were $282.8 million as of June 30, 2023, compared to $110.1 million as of December 31, 2022. The Company believes that its cash, cash equivalents and investments as of June 30, 2023 will be sufficient to allow the Company to fund its planned clinical studies, as well as support corporate operations through mid-2025.

Research and Development (R&D) expenses were $11.9 million for the quarter ended June 30, 2023, compared to $5.6 million for the quarter ended June 30, 2022. The increase in R&D expenses was primarily due to increases of $4.0 million in preclinical and clinical costs, driven by the initiation of the lorundrostat pivotal program in the second quarter of 2023, $1.3 million in higher compensation expense as a result of additions to headcount and $1.0 million in clinical supply, manufacturing and regulatory costs.

General and Administrative (G&A) expenses were $3.9 million for the quarter ended June 30, 2023, compared to $0.9 million for the quarter ended June 30, 2022. The increase in G&A expenses was primarily due to $1.4 million in higher compensation expense as a result of additions to headcount, $1.1 million in higher professional fees associated with operating as a public company, $0.3 million of higher insurance expense associated with new director and officer insurance policies and $0.2 million in higher other administrative expenses.

Total other income was $3.6 million for the quarter ended June 30, 2023, compared to $0.0 for the quarter ended June 30, 2022, which was primarily attributable to interest earned during the three months ended June 30, 2023 on the Company's investments in money market funds and U.S. treasuries that began earning interest in the third quarter of 2022.
Net loss was $12.1 million for the quarter ended June 30, 2023, compared to $6.5 million for the quarter ended June 30, 2022. 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 on Monday, August 7, 2023. To access the call, please dial 1-877-704-4453 in the U.S. or 1-201-389-0920 outside the U.S., followed by the conference ID: 13739672. A live webcast of the conference call may be found here (https://viavid.webcasts.com/starthere.jsp?ei=1622853&tp_key=b8d14dbdb6). A replay of the call will be available on the "News & Events" page in the Investor Relations section of the Mineralys Therapeutics website.

About Hypertension
Having sustained, elevated blood pressure (or hypertension) increases the risk of heart disease, heart attack and stroke, which are leading causes of death in the U.S. In 2020, more than 670,000 deaths in the U.S. included hypertension as a primary or contributing cause. Hypertension and related health issues resulted in an average annual economic burden of about $130 billion each year in the U.S., averaged over 12 years from 2003 to 2014.

Less than 50 percent of hypertension patients achieve their blood pressure goal with currently available medications. Abnormally elevated aldosterone levels are a key factor in driving hypertension in approximately 25 percent of all hypertensive patients.

About Chronic Kidney Disease (CKD)
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 (15%) of U.S. adults have CKD. Diabetes and hypertension are responsible for approximately two-thirds of CKD cases. Early detection and treatment can often keep CKD from getting worse. When CKD progresses, it may eventually lead to kidney failure, which requires dialysis or a kidney transplant to maintain life.

About Lorundrostat
Lorundrostat is a proprietary, orally administered, highly selective aldosterone synthase inhibitor being developed for the treatment of uncontrolled hypertension and CKD. 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 approximately a 70% reduction in plasma aldosterone concentration in hypertensive subjects.

In a Phase 2, proof-of-concept trial (Target-HTN) in uncontrolled or resistant hypertensive subjects, once-daily lorundrostat demonstrated clinically meaningful blood pressure reduction in individuals with uncontrolled hypertension, in both automated office blood pressure measurement and 24-hour ambulatory blood pressure monitoring. Adverse events observed were a modest increase in serum

potassium, decrease in estimated glomerular filtration rate, urinary tract infection and hypertension with one serious adverse event possibly related to study drug being hyponatremia.

About Mineralys Therapeutics
Mineralys Therapeutics is a clinical-stage biopharmaceutical company focused on developing medicines to target diseases driven by abnormally elevated aldosterone. Its initial product candidate, lorundrostat, is a proprietary, orally administered, highly selective aldosterone synthase inhibitor that Mineralys Therapeutics is developing for cardiorenal conditions affected by abnormally elevated aldosterone, including hypertension and CKD. Mineralys is based in Radnor, Pennsylvania, and was founded by Catalys Pacific. For more information, please visit https://mineralystx.com. Follow Mineralys on LinkedIn and Twitter.

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 (ASIs) with an SGLT2 inhibitor may provide additive clinical benefits to patients; the Company's expectation that the Advance-HTN and the planned Phase 3 clinical trial of lorundrostat may serve as pivotal trials in any submission of a new drug application (NDA) to the United States Food and Drug Administration (FDA); the Company's ability to evaluate lorundrostat as a potential treatment for CKD; the planned future clinical development of lorundrostat and the timing thereof; and the expected timing of commencement and enrollment of patients 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: 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; 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; 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.

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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,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 11,884	$ 5,595	$ 24,177	$ 12,373
General and administrative	3,851	884	6,496	1,675
Total operating expenses	15,735	6,479	30,673	14,048
Loss from operations	(15,735)	(6,479)	(30,673)	(14,048)
Interest income, net	3,593	—	5,922	—
Other income	1	—	2	—
Total other income, net	3,594	—	5,924	—
Net loss	$ (12,141)	$ (6,479)	$ (24,749)	$ (14,048)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.31)	$ (1.26)	$ (0.77)	$ (2.73)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	39,754,981	5,152,575	32,301,136	5,138,184

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

	June 30, 2023	December 31, 2022
Cash, cash equivalents and investments	$ 282,775	$ 110,110
Total assets	$ 291,217	$ 114,442
Total liabilities	$ 6,207	$ 8,067
Total stockholders' equity (deficit)	$ 285,010	$ (52,269)