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): March 15, 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 Global Select Market**

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 March 15, 2023, Mineralys Therapeutics, Inc. issued a press release announcing its financial results for the fourth quarter and full-year ended December 31, 2022. 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 March 15, 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: March 15, 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 Fourth Quarter and Full Year 2022 Financial Results and Provides Corporate Update

– Lorundrostat pivotal clinical program, for the treatment of patients with uncontrolled hypertension, expected to begin in the first half of 2023 –

– IPO and Nasdaq listing completed in February 2023 with total net proceeds of approximately $202.0 million, after deducting underwriting discounts, commissions and estimated offering costs –

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

RADNOR, PA – March 15, 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 fourth quarter and full year ending December 31, 2022, and provided a corporate update.

"I am extremely proud of the Mineralys Therapeutics team as we continue to make tremendous progress advancing the clinical development of lorundrostat – our proprietary highly selective aldosterone synthase inhibitor designed to reduce aldosterone levels – for the treatment of hypertension. This is a critical milestone in our Company's history, as we prepare to initiate the pivotal program to evaluate the safety and efficacy of lorundrostat for the treatment of uncontrolled and resistant hypertension in the first half of 2023," stated Jon Congleton, Chief Executive Officer of Mineralys Therapeutics. "Uncontrolled and resistant hypertension continue to impact individual patient's lives and the healthcare system at large. The closing of our IPO in February enables us to continue our efforts of developing a targeted treatment approach for hypertension with lorundrostat."

Recent Corporate and Clinical Highlights

- **Topline Data Target-HTN Phase 2 trial** – In November 2022, the Company announced positive topline data from its Target-HTN trial, a Phase 2 proof-of-concept trial for lorundrostat in the treatment of uncontrolled hypertension (uHTN) and resistant hypertension (rHTN), which support advancing the development of lorundrostat into the planned pivotal clinical program.
- **FDA End of Phase 2 Meeting** – In November 2022, the Company held an end of Phase 2 meeting with the U.S. Food and Drug Administration (FDA) to review the positive results of the Target-HTN trial, and to discuss the plans for a pivotal program for lorundrostat in hypertension. Based on the Phase 2 results and feedback from the FDA, the Company intends to initiate the pivotal program in the first half of 2023.
- **Presented Phase 2 Results at ACC.23/WCC** – In March 2023, the Company presented positive data from the Target-HTN Phase 2 study that demonstrated clinically meaningful blood pressure reduction with once-daily dosing of lorundrostat at the American College of Cardiology's 72nd Annual Scientific Session together with the World Congress of Cardiology (ACC.23/WCC), including a pre-specified analysis of hypertensive subjects with

a body mass index (BMI) ≥30 kg/m2 (obese) that showed lorundrostat demonstrated a statistically significant placebo-adjusted reduction in systolic blood pressure.

- **Presented Phase 1 Results at ACC.23/WCC** – In March 2023, the Company presented Phase 1 data from a first-in-human, safety, tolerability, pharmacokinetics, and pharmacodynamics study – conducted by Mitsubishi Tanabe Pharma – of single ascending dose and multiple ascending doses of lorundrostat that showed it was well-tolerated and had the predicted effect of suppressing aldosterone in a dose-dependent fashion without inhibiting cortisol.
- **Completed an Initial Public Offering (IPO**) – In February 2023, the Company completed an initial public offering of 13.8 million shares of common stock at a price of $16.00 per share for net proceeds of approximately $202.0 million, after deducting underwriting discounts, commissions, and estimated offering-related expenses.
- **NASDAQ Listing** – Listed the Company's common stock on the Nasdaq Global Select Market under the ticker symbol "MLYS."

Key Upcoming Milestones

- **ADVANCE-HTN Phase 2 pivotal trial** – In the first half of 2023, the Company plans to initiate the ADVANCE-HTN Phase 2 trial to evaluate the safety and efficacy of lorundrostat for the treatment of uHTN and rHTN, when used as an add-on therapy to standardized background treatment of two or more antihypertensive medications in up to approximately 300 adult subjects. The topline data from this trial is expected in the first half of 2024.
- **Phase 3 pivotal 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 and rHTN, when used as an add-on therapy to prescribed background treatment of two or more antihypertensive medications in up to approximately 1,000 adult subjects. The topline data from this trial is expected in mid-2025.
- **CKD profiling trial** – In mid-2023, the Company plans to initiate a randomized, double-blind, placebo-controlled Phase 2 trial to evaluate the safety and efficacy of lorundrostat for the treatment of uHTN and rHTN in a chronic kidney disease (CKD) population. Topline data from this trial expected in the first half of 2024.
- **Open label extension trial for long-term safety exposure** – In mid-2023, the Company plans to initiate an open label extension trial to obtain additional safety data - all subjects in the pivotal hypertension program, including the ADVANCE and Phase 3 trials will be given the opportunity to participate.

Fourth Quarter and Full-Year 2022 Financial Highlights

Research and Development (R&D) expenses were $26.3 million for the full year ended December 31, 2022, compared to $16.3 million for the full year ended December 31, 2021. R&D expenses for the three months ended December 31, 2022, were $7.8 million, compared to $6.6 million for the three months ended December 31, 2021. The increase in full-year R&D expenses was primarily due to increases of $7.4 million in preclinical and clinical costs related to the research and development of lorundrostat, $1.7 million for clinical supply, manufacturing, and regulatory costs, and $0.9 million in personnel expenses for additional employees to support research and development.

General and Administrative (G&A) expenses were $5.2 million for the full year ended December 31, 2022, compared to $2.4 million for the full year ended December 31, 2021. G&A expenses were $2.2 million for the three months ended December 31, 2022, compared to $0.5 million for the three

months ended December 31, 2021. The increase in full-year G&A expenses was primarily due to higher professional fees of $1.7 million related to accounting, legal, and other support, and personnel expenses of $1.1 million associated with additional employees.

Net loss was $29.8 million for the full year ended December 31, 2022, compared to $19.4 million for the full year ended December 31, 2021. The increase was primarily attributable to the factors described above.

Cash, cash equivalents, and marketable securities were $110.1 million as of December 31, 2022, compared to cash and cash equivalents of $10.6 million as of December 31, 2021. Subsequent to December 31, 2022, Mineralys Therapeutics completed an IPO of the Company's common stock for net proceeds of approximately $202.0 million, after deducting underwriting discounts, commissions, and estimated offering-related expenses.

Conference Call
The Company's management team will host a conference call at 4:30 p.m. ET on Wednesday, March 15, 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: 13736564. A live webcast of the conference call may be found here (https://viavid.webcasts.com/starthere.jsp?ei=1599935&tp_key=2228a12609). 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 Lorundrostat
Lorundrostat is a proprietary, orally administered, highly selective aldosterone synthase inhibitor being developed for the treatment of uncontrolled hypertension. 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* and an observed half-life of 10-12 hours. In a Phase 2, proof-of-concept study (Target-HTN) in uncontrolled and 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 initially developing for the treatment of patients with uncontrolled hypertension. Mineralys Therapeutics is based in Radnor, PA, 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 planned future clinical development of lorundrostat and the timing thereof; and expected timing of 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; 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 the COVID-19 pandemic or any other pandemic or future public health concerns; regulatory developments in the United States and foreign countries; our reliance on our exclusive license with Mitsubishi Tanabe 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.

Contact:
Investor Relations
investorrelations@mineralystx.com

Media Relations
Tom Weible
Elixir Health Public Relations
Phone: (1) 515-707-9678
Email: tweible@elixirhealthpr.com

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 7,818	$ 6,616	$ 26,250	$ 16,308
General and administrative	2,190	467	5,229	2,417
Total operating expenses	10,008	7,083	31,479	18,725
Loss from operations	(10,008)	(7,083)	(31,479)	(18,725)
Other income (expense):				
Interest income (expense), net	935	—	1,676	(27)
Change in fair value of convertible notes	—	—	—	(657)
Other income	—	—	4	1
Total other income (expense), net	935	—	1,680	(683)
Net loss	$ (9,073)	$ (7,083)	$ (29,799)	$ (19,408)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.74)	$ (1.40)	$ (5.77)	$ (3.89)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	5,210,456	5,058,938	5,167,296	4,984,286

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

	December 31,	
	2022	2021
Cash and cash equivalents	$ 87,701	$ 10,612
Marketable securities	$ 22,409	$ —
Total assets	$ 114,442	$ 11,125
Total liabilities	$ 8,067	$ 5,054
Total stockholders' deficit	$ (52,269)	$ (22,925)