
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): January 4, 2024

MINERALYS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

001-41614
(Commission File Number)

84-1966887
(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On January 4, 2024, in connection with the appointment of Minji Kim, Ph.D., as Chief Business Officer, the Board of Directors of Mineralys Therapeutics, Inc. (the “Company”) approved splitting the functions of Chief Financial Officer and Chief Business Officer into two roles. As a result, effective January 4, 2024, Adam Levy no longer serves as the Company’s Chief Business Officer. Mr. Levy remains the Company’s Chief Financial Officer and Secretary.

Item 7.01. Regulation FD Disclosure.

On January 4, 2024, the Company issued a press release announcing the appointment of Minji Kim, Ph.D. as Chief Business Officer. A copy of the press release is attached 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 January 4, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: January 4, 2024

MINERALYS THERAPEUTICS, INC.

By: /s/ Adam Levy

Name: Adam Levy

Title: Chief Financial Officer and Secretary



Mineralys Therapeutics Appoints Minji Kim, Ph.D. as Chief Business Officer

RADNOR, PA – January 4, 2024 – Mineralys Therapeutics, Inc. (Nasdaq: MLYS), a clinical-stage biopharmaceutical company focused on developing medicines to target hypertension, chronic kidney disease (CKD) and other diseases driven by abnormally elevated aldosterone, today announced the appointment of Minji Kim, Ph.D. as Chief Business Officer. Adam Levy will remain in his role as Chief Financial Officer.

“With our expanding operations, we have decided to split the functions of Chief Financial Officer and Chief Business Officer into two roles, and we are excited to have Minji join our team. She brings a solid track record of generating value for multiple companies by identifying and executing strategic opportunities,” stated Jon Congleton, Chief Executive Officer of Mineralys. “We are pleased to start 2024 with our full executive team in place as we execute against our late-stage clinical development of lorundrostat for the treatment of aldosterone dependent conditions such as hypertension and chronic kidney disease.”

“With several clinical milestones for lorundrostat expected over the next 12-18 months, I am excited to join Mineralys. Given the current trajectory of the ongoing pivotal clinical development program, lorundrostat has great potential to address unmet needs in patients suffering from diseases driven by abnormally elevated aldosterone,” stated Dr. Kim.

Dr. Kim brings more than two decades of experience in business development, strategic leadership, and scientific research. During her career, she has worked with biotech companies in the U.S. and overseas across broad therapeutic and technical areas. Prior to joining Mineralys, she held the role of Chief Business Officer at Affamed Therapeutics and General Manager at Affamed Digital, and brought multiple products into their pipeline. Before Affamed, Dr. Kim was Head of Business Development and Alliance Management at Jounce Therapeutics. She led the execution of pharma partnerships and over \$200 million in non-dilutive funding for the company. Prior to Jounce, she held the role of Vice President of Corporate and Business Development at Curis, Inc. During her tenure at Curis, she led strategic transactions that had a fundamental impact on the future sustainability of the company, tripling the value of the company and pivoting its R&D direction. Previously, Dr. Kim served on the Global Oncology Business Development and Licensing group at Hoffmann-La Roche. She began her career as an instructor in neurology at Harvard Medical School. Currently, Dr. Kim is an independent board member of SK Biopharmaceuticals, a global commercial-stage life science company. She obtained her Ph.D. from Seoul National University in South Korea and her MBA from Yale School of Management.

About Lorundrostat

Lorundrostat is a proprietary, orally administered, highly selective aldosterone synthase inhibitor being developed for the treatment of uncontrolled and resistant 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.

About Mineralys Therapeutics

Mineralys Therapeutics is a clinical-stage biopharmaceutical company focused on developing medicines to target hypertension, CKD and other 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 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 or uncontrolled hypertension; 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 uninterrupted 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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