

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 5, 2024

Kronos Bio, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-39592
(Commission File Number)

82-1895605
(IRS Employer Identification No.)

1300 So. El Camino Real, Suite 400
San Mateo, California
(Address of principal executive offices)

94402
(Zip Code)

Registrant's telephone number, including area code: (650) 781-5200

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, \$0.001 par value per share	KRON	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in 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 8.01 Other Events.

Kronos Bio, Inc. (the “Company”) is announcing that it has amended its protocol for its clinical trial of KB-0742, an oral CDK9 inhibitor in a phase 1/2 dose escalation and expansion trial in solid tumors.

To date, anti-tumor activity has been observed without grade 3/4 neutropenia in patients treated with KB-0742 at doses ranging from 10 mg to 80 mg using the current three-days-on, four-days-off dosing schedule. The Company has seen target engagement, tumor regressions and an acceptable safety profile at 60 mg dosed three-days-on, four-days-off, and have subsequently cleared 80 mg three-days-on, four-days-off.

Moving forward, the Company is pursuing a four-days-on, three-days-off dosing schedule to further increase patient time on KB-0742 at or above a therapeutic threshold. In a 3+3 design, the Company plans to dose escalate through doses of 60 mg, four-days-on, three-days-off, and 80 mg, four-days-on, three-days-off, before enrolling expansion cohorts at the latter dose and schedule (80 mg, four-days-on, three-days-off). KB-0742 clinical data from existing dose escalation and ongoing expansion cohorts are still expected in mid-2024. In the third quarter of 2024, the Company expects to provide an update from the new four-days-on, three-days-off dosing schedule and announce its plans for the dose expansion phase of the Phase 1/2 clinical trial of KB-0742. The Company currently contemplates the expansion cohort will include patients with either small cell or non-small cell lung cancer, ovarian cancer, or triple negative breast cancer and expects to announce topline data from the expansion phase in the first half of 2025.

Forward-Looking Statements

Statements in this report that are not statements of historical fact are forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. This report, in some cases, uses terms such as “expect,” “goal,” “plan,” “will,” “contemplate” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements include statements regarding the Company’s intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, the amended protocol for KB-0742 and the goals thereof; the expected timing for additional clinical data from the KB-0742 trial; the expected timing of the expansion cohorts of the KB-0742 trial; future dosing in the expansion cohorts of the KB-0742 trial; the potential of the Company’s product candidates, including any potential implied from early clinical data; and other statements that are not historical fact. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, including, without limitation: changes in the macroeconomic environment or competitive landscape that impact the Company’s business; whether the Company will be able to progress its ongoing and planned clinical trials on the timelines anticipated, including due to enrollment challenges and other risks inherent in the development of novel therapeutics; risks related to the Company’s limited experience as a company in conducting clinical trials; the risk that results of preclinical studies and early clinical trials (including preliminary results) are not necessarily predictive of future results; and risks associated with the sufficiency of the Company’s cash resources and need for additional capital. These and other risks are described in greater detail in the Company’s filings with the Securities and Exchange Commission (SEC), including under the heading “Risk Factors” in its Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, filed with the SEC on November 13, 2023. Any forward-looking statements that are made in this report speak only as of the date of this report and are based on management’s assumptions and estimates as of such date. Except as required by law, the Company assumes no obligation to update the forward-looking statements whether as a result of new information, future events or otherwise, after the date of this report.

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.

KRONOS BIO, INC.

By: /s/ Norbert Bischofberger
Norbert Bischofberger, Ph.D.
President and Chief Executive Officer

Dated: March 5, 2024
