

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): October 5, 2023

**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 7.01 Regulation FD Disclosure.**

Kronos Bio, Inc. (the “Company”) is furnishing as Exhibit 99.1 to this report an abstract titled “A First-In-Human Study of CDK9 Inhibitor KB-0742 Demonstrates Evidence of Tolerability and Clinical Activity.” As previously announced, the Company will discuss the information in the abstract at the American Association for Cancer Research, National Cancer Institute and European Organisation for Research and Treatment of Cancer (AACR/NCI/EORTC) 2023 International Conference in Boston, MA on Friday, October 13, 2023.

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, except as expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
<a href="#">99.1</a>	<a href="#">Abstract titled “A First-In-Human Study of CDK9 Inhibitor KB-0742 Demonstrates Evidence of Tolerability and Clinical Activity.”</a>
104	The cover page of this report has been formatted in Inline XBRL.

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**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: October 5, 2023

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**Identification of Original Research:** Original Research

**Identification of Clinical Trials:** Clinical Trial, ClinicalTrials.gov Identifier: NCT04718675

**Funding Source:** Kronos Bio; Biotechnology Company.

**AACR/NCI/EORTC submission details:** Submitted on behalf of authors by Crystal Kraft, MJH Life Sciences, [ckraft@mjlifesciences.com](mailto:ckraft@mjlifesciences.com)

**AACR/NCI/EORTC Member Sponsor:**

**Presenting author:**

**Corresponding author:**

**Abstract character count:** 3099/3100 with spaces

**Topic Category:** Therapeutic agents: small molecule kinase inhibitors

**Shortened title (for internal AACR tracking):**

**Presentation preference:** Oral

**Abstract keywords (up to 3):**

**Disclosures:** required for all authors (may list up to 20, full name, academic degree(s), institution, address, email address, and disclosure of information for each author)

Title: A First-In-Human Study of CDK9 Inhibitor KB-0742 Demonstrates Evidence of Tolerability and Clinical Activity.

**Authors:** Miguel Villalona-Calero, Monica Mita, Alain Mita, Noah Federman, Drew Rasco, David Spigel, Jia Luo, Glenn J. Hanna, Gregory M. Cote, Richard E. Cutler, Pavan Kumar, Crystal J. MacKenzie, Charles Lin, Jorge F. DiMartino, Elizabeth A. Olek, Brian Van Tine

Name	Degree	Affiliation	email
Miguel Villalona-Calero	MD	City of Hope National Medical Center, California, USA	<a href="mailto:mvillalona@coh.org">mvillalona@coh.org</a>
Monica Mita	MD MDSc	Cedars-Sinai Cancer Institute, California, USA	<a href="mailto:monica.mita@cshs.org">monica.mita@cshs.org</a>
Alain Mita	MD	Cedars-Sinai Cancer Institute, California, USA	<a href="mailto:alain.mita@cshs.org">alain.mita@cshs.org</a>
Noah Federman	MD	UCLA Jonsson Comprehensive Cancer Center, California, USA	<a href="mailto:nfederman@mednet.ucla.edu">nfederman@mednet.ucla.edu</a>
Drew Rasco	MD, FASCO	START – San Antonio, Texas, USA	<a href="mailto:drasco@startsa.com">drasco@startsa.com</a>
David Spigel	MD	Sarah Cannon Research Institute at Tennessee Oncology PLLC, Tennessee, USA	<a href="mailto:david.spigel@sarahcannon.com">david.spigel@sarahcannon.com</a>

Jia Luo	MD	Dana-Farber Cancer Institute, Massachusetts USA	jia_luo@dfci.harvard.edu
Gregory M. Cote	MD PhD	Massachusetts General Hospital, Massachusetts USA	gcote@partners.org
Glenn J Hanna	MD	Dana-Farber Cancer Institute, Massachusetts USA	gjhanna@partners.org
Richard E. Cutler	PhD	Kronos Bio, California, USA	rcutler@kronosbio.com
Pavan Kumar	PhD	Kronos Bio, Massachusetts, USA	pavan.kumar@kronosbio.com
Crystal MacKenzie	BS	Kronos Bio, California USA	crystal.mackenzie@kronosbio.com
Charles Lin	PhD	Kronos Bio, California USA	charles.lin@kronosbio.com
Jorge F. DiMartino	MD PhD	Kronos Bio, California USA	jorge.dimartino@kronosbio.com
Elizabeth A Olek	DO, MPH	Kronos Bio, California USA	eolek@kronosbio.com
Brian Van Tine	MD PhD	Washington University in St. Louis, Missouri, USA	bvantine@wustl.edu

**ABSTRACT:****Background:**

Cyclin-dependent kinase 9 (CDK9) is a transcriptional regulator that mediates expression and downstream activity of oncogenic transcription factors (TFs) including MYC and chimeric TFs. Inhibiting CDK9 presents a promising approach to treat transcriptionally addicted cancers.

KB-0742 is a potent, selective, and orally bioavailable inhibitor of CDK9 that is currently being studied in a Phase 1/2 dose escalation in solid tumors and NHL and cohort expansion for patients with transcription dependent tumors (NCT04718675).

**Methods:**

KB-0742 is administered orally once daily for 3 consecutive days with 4 days off, weekly, in 28-day cycles until toxicity or disease progression.

Eligibility Criteria included age  $\geq$  18 years, relapsed or refractory solid tumors or NHL, acceptable organ function and ECOG PS  $<$  2.

Study objectives include evaluation of safety, tolerability, PK, PD, and identification of KB-0742 MTD and RP2D using a modified Continuous Reassessment Method (mCRM).

PK was measured from patient plasma and PD was assessed in peripheral blood mononuclear cells (PBMCs). PD measurements included analysis of phosphorylation of the CDK9 substrate serine 2 of the RNA Polymerase II C-terminal domain (pSER2), and of changes in gene expression of prospectively defined CDK9 responsive genes.

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**Results:**

As of 1 June 2023, 28 patients enrolled in dose escalation up to 60 mg. Patients had received a median of 4 (2-11) prior lines of therapy and remained on KB-0742 for a median of 86 days (10-311+). Twelve of 28 patients received at least 4 cycles of KB-0742. The most common tumor types enrolled were Colorectal (5), Chordoma (4), Sarcoma (4), and Breast (3).

Treatment-emergent adverse events (TEAEs) occurring in >20% of patients included nausea, vomiting, anemia, fatigue, nervous system disorders, and peripheral edema. The most common reasons for treatment discontinuation were progressive disease, TEAEs, and withdrawal of consent.

Across 4 dose levels, AUC and Cmax of KB-0742 increased linearly with a terminal half-life of 24 hours. At 60mg, evidence of target engagement was observed by pSER2 reduction and proportional changes to CKD9 responsive genes.

In the escalation phase 60 mg cohort, 3 patients, (2 colorectal and 1 PTCL) had MYC over-expressing tumors and achieved SD. Of the two patients with myxoid liposarcoma, both exhibited radiographic regression of their target lesions. One patient achieved 26% reduction in the sum of partial diameters lasting > 5 mos. The second patient achieved a RECIST 1.1 partial response and remains on treatment at > 12 mos. Consistent with the therapeutic hypothesis, both patients had TF fusions.

**Conclusions:**

KB-0742 treatment was well tolerated, with manageable toxicity, and no evidence of neutropenia. CDK9 inhibition was observed at the 60 mg dose level, and expansion cohorts in tumor types with a high prevalence of MYC amplification or overexpression and other transcriptionally addicted tumors are accruing. The MTD has not been reached and further dose escalation is continuing.

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