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): December 7, 2020

Kronos Bio, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-39592**	**82-1895605**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

1300 So. El Camino Real, Suite 300
San Mateo, California 94402
(Address of principal executive offices including 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.

On December 7, 2020, we announced U.S. Food and Drug Administration clearance of our Investigational New Drug application for KB-0742, a highly selective, orally bioavailable inhibitor of cyclin dependent kinase 9 (CDK9). We plan to begin a Phase 1/2 clinical trial of KB-0742 in patients with advanced solid tumors in the first quarter of 2021.

The open-label, Phase 1/2 clinical trial for KB-0742 will be conducted over two stages: dose escalation and expansion. The dose-escalation stage will assess the safety, pharmacokinetic (PK) and pharmacodynamic (PD) profile of KB-0742 and establish a pharmacologically active dose and schedule with an acceptable safety profile. This dose and schedule will be further studied in the subsequent expansion stage in patients with MYC-amplified solid tumors and other transcriptionally addicted rare tumors such as sarcomas and chordomas. We expect to report initial PK, PD and safety data from the dose-escalation stage of the study in 2021.

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,” “plan,” “will” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: our plan to begin a Phase 1/2 clinical trial of KB-0742 in patients with advanced solid tumors and the expected timing thereof; the design of such planned Phase 1/2 clinical trial, including to establish a pharmacologically active dose and schedule with an acceptable safety profile; our expectation to report data from such planned Phase 1/2 clinical trial and the expected timing thereof; 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: whether we will be able to initiate or complete the Phase 1/2 clinical trial of KB-0742 on the timeline expected, if at all, including due to risks associated with the COVID-19 pandemic and risks inherent in the clinical development of novel therapeutics; risks related to our lack of experience as a company in conducting clinical trials; the risk that results of preclinical studies and early clinical trials are not necessarily predictive of future results; the risk that due to the relatively small number of patients that we plan to dose in the planned Phase 1/2 clinical trial, the results from the planned Phase 1/2 clinical trial, once completed, may be less reliable than results achieved in larger clinical trials, which may hinder our efforts to further develop and obtain regulatory approval for KB-0742; and risks associated with the sufficiency of our cash resources and need for additional capital. These and other risks are described in greater detail in our filings with the Securities and Exchange Commission (SEC), including under the heading “Risk Factors” in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, filed with the SEC on November 18, 2020. 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, we assume 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.

Dated: December 7, 2020

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