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 6, 2021

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 400
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 6, 2021, Kronos Bio, Inc. (the “Company”) announced that the first patient has been dosed in the registrational Phase 3 AGILITY clinical trial of entospletinib, a selective inhibitor targeting spleen tyrosine kinase (“SYK”), in combination with standard of care anthracycline and cytarabine (7+3) chemotherapy. This trial is the first in acute myeloid leukemia (“AML”) to use measurable residual disease (“MRD”) as the primary endpoint and has the potential to support accelerated approval of entospletinib by the U.S. Food and Drug Administration as a treatment for patients newly diagnosed with NPM1-mutated AML who are fit for intensive induction.

Entospletinib is the Company’s lead product candidate and the Company expects to share data from the trial in the second half of 2023. The randomized, double-blind, placebo-controlled trial is designed to assess the efficacy and safety of entospletinib in combination with intensive induction and consolidation chemotherapy in approximately 180 adults who have been newly diagnosed with NPM1-mutated AML. This trial will test the hypothesis, based on robust preclinical and Phase 2 clinical data, that NPM1 mutation leads to dependency on SYK signaling. The NPM1 mutation is present in about 30% of all adult patients with AML.

The primary endpoint of the trial is MRD negative complete response (“CR”), as measured by molecular detection of mutant NPM1 alleles in bone marrow, which affords a high degree of sensitivity to detect MRD. Numerous clinical studies have shown that patients with NPM1 mutations who achieve MRD negative CR after induction chemotherapy survive longer than patients who achieve CR but have detectable MRD. If successful, this would be the first time MRD is used as the basis for seeking accelerated approval in AML.

The decision to proceed with this trial design was made after an End-of-Phase 2 discussion with the U.S. Food and Drug Administration. In the trial, patients will be randomized 1:1 to receive either entospletinib or placebo in combination with standard induction and consolidation chemotherapy. Remission and MRD status will be assessed after the first two cycles of chemotherapy and patients may receive up to a total of five cycles. Event-free survival (“EFS”) is a key secondary endpoint, and mature EFS data will potentially be used to support full approval.

The Company acquired entospletinib and another SYK inhibitor, lanraplenib, from Gilead Sciences in July 2020. As previously reported, under the agreement with Gilead, the initiation of the Phase 3 trial triggers a $29 million milestone payment from the Company to Gilead. The payment will be recorded in the fourth quarter.

Lanraplenib is being developed for the treatment of patients with relapsed/refractory FLT3-mutated AML and patients newly diagnosed with NPM1-mutated and/or FLT3-mutated AML who are older than 75 years old or are not eligible for intensive induction chemotherapy.

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 “potential,” “expects,” "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, the timing for expected data from the Phase 3 clinical trial of entospletinib, potential approval and potential accelerated approval of entospletinib, the design of the Phase 3 clinical trial, 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 complete the Phase 3 clinical trial of entospletinib on the timeframe expected, or at all, including due to risks associated with the COVID-19 pandemic and risks inherent in the clinical development of novel therapeutics; to date

there have not been any regulatory approvals on the basis of MRD status in AML; risks related to our limited 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; and risks associated with the sufficiency of our cash resources and need for additional capital. These and other risks and uncertainties are described in greater detail in the Company's 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, 2021, filed with the SEC on November 9, 2021. 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.

Dated: December 6, 2021

By: /s/ Norbert Bischofberger

Norbert Bischofberger, Ph.D.

President and Chief Executive Officer