

**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 15, 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 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 2.02 Results of Operations and Financial Condition

On March 15, 2023, Kronos Bio, Inc. (the "Company") issued a press release providing a corporate update and announcing its financial results for the fourth quarter and year ended December 31, 2022. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K.

The information in this Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (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 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
<u>99.1</u>	<u>Press Release, dated March 15, 2023.</u>
104	The cover page of this report has been formatted in Inline XBRL.

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: March 15, 2023

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



Kronos Bio Reports Recent Business Progress and Fourth-Quarter and Full-Year 2022 Financial Results

First patient dosed in expansion portion of KB-0742 Phase 1/2 study, with initial efficacy results expected in 2H 2023

Recommended Phase 2 dose and initial data from Phase 1b/2 study of lanraplenib in combination with gilteritinib in FLT3-mutated AML on track to report in Q4 2023 or Q1 2024

Discovery collaboration with Genentech underway

\$247.9 million in cash, cash equivalents and investments as of December 31, 2022, providing expected cash runway into the second half of 2025

San Mateo, Calif., and Cambridge, Mass., March 15, 2023 -- Kronos Bio, Inc. (Nasdaq: KRON), a company dedicated to transforming the lives of those affected by cancer, today reported recent business progress and fourth-quarter and full-year 2022 financial results.

"We have had an exciting start to 2023, with both the announcement of our discovery collaboration with Genentech and the dosing of our first patient in the expansion cohort of our Phase 1/2 study of KB-0742," said Norbert Bischofberger, Ph.D., president and chief executive officer of Kronos Bio. "We look forward to building upon this strong momentum and sharing additional data from each of our clinical programs later this year and over the course of 2024. KB-0742 has the potential to help patients with a broad variety of solid tumors, and we anticipate reporting initial efficacy data from that program in the second half of this year. For lanraplenib, our Phase 1b/2 study in combination with gilteritinib seeks to address a significant unmet need in relapsed/refractory FLT3-mutated AML, and we anticipate providing initial data and a recommended Phase 2 dose later this year or early next year. We continue to focus on strong clinical execution as we work to bring innovative therapies to patients with cancer."

Fourth Quarter and Recent Company Updates

- **KB-0742**
 - In December 2022, Kronos Bio announced that it had selected the recommended phase 2 dose in its ongoing Phase 1/2 study of KB-0742 in solid tumors, after reaching the target engagement goal with an acceptable safety profile. The analysis further showed that KB-0742 continues to demonstrate a differentiated pharmacokinetic (PK) profile, with oral bioavailability, long half-life, and dose-proportional exposure across all four dose levels, and low to moderate variability between patients. The dose escalation portion of the study is continuing with the goal of identifying the maximum tolerated dose.
 - The expansion portion of the trial is ongoing and includes Cohort A, for patients with MYC-amplified tumors, such as triple negative breast cancer, non-small cell lung cancer and ovarian cancer; and Cohort B, for patients with transcriptionally addicted cancers, including chordomas, sarcomas and small cell lung cancer. Both cohorts are enrolling, and in early 2023, the company dosed the first patient.
 - Additional results from the dose escalation portion of the Phase 1/2 study and initial efficacy data from expansion portion are expected to be presented at a medical conference in the second half of 2023.

- *Lanraplenib*
 - In December 2022, the company presented preclinical data that demonstrated anti-leukemic activity of lanraplenib in combination with multiple targeted agents in patient-derived cell isolates and cell lines at the 64th American Society of Hematology (ASH) Annual Meeting & Exposition. These data further support the biological rationale for SYK inhibition as a treatment for AML.
 - Kronos Bio anticipates sharing initial data from the Phase 1b/2 study of lanraplenib in combination with gilteritinib in patients with relapsed/refractory FLT3-mutated acute myeloid leukemia (AML), along with a recommended Phase 2 dose (RP2D), in the fourth quarter of 2023 or first quarter of 2024.

- *Discovery Collaboration with Genentech*
 - In January 2023, Kronos Bio announced that it had entered into a discovery collaboration in the field of oncology with Genentech, a member of the Roche Group, focused on discovering and developing small-molecule drugs that modulate transcription factor targets selected by Genentech. Kronos Bio will lead discovery and research activities to a defined preclinical point when Genentech will have the exclusive right to pursue further preclinical and clinical development and commercialization.
 - Under the terms of the agreement, Kronos Bio received an upfront payment of \$20 million and is eligible for additional payments, which could total up to \$554 million, based on reaching certain milestones, including discovery, preclinical, clinical and commercial milestones, as well as tiered royalties on any potential products that are commercialized as a result of the collaboration.

Fourth-Quarter and Full-Year 2022 Financial Highlights

- **Cash, Cash Equivalents and Investments:** With its ongoing and currently planned clinical programs and \$247.9 million in cash, cash equivalents and investments as of December 31, 2022, the company anticipates sufficient resources to fund its planned operations into the second half of 2025. In January 2023, the Company entered into a Collaboration and License Agreement with Genentech, Inc., to initially collaborate on two discovery research programs in oncology. Pursuant to the Agreement, the Company received an upfront payment of \$20.0 million from Genentech.
- **R&D Expenses:** Research and development expenses were \$23.2 million for the fourth quarter of 2022, which includes non-cash stock-based compensation expense of \$3.6 million. For the full year of 2022, research and development expenses were \$93.7 million, which includes non-cash stock-based compensation expense of \$15.0 million.
- **G&A Expenses:** General and administrative expenses were \$10.5 million for the fourth quarter of 2022, which includes non-cash stock-based compensation expense of \$4.1 million. For the full year of 2022, general and administrative expenses were \$43.4 million, which includes non-cash stock-based compensation expense of \$16.2 million.
- **Net Loss:** Net loss for the fourth quarter of 2022 was \$31.8 million, or \$0.56 per share, including non-cash stock-based compensation of \$7.7 million. Net loss for the full-year 2022 was \$133.2 million, or \$2.37 per share, including non-cash stock-based compensation expense of \$31.1 million.

About Kronos Bio, Inc.

Kronos Bio is a biopharmaceutical company that is advancing two investigational compounds in clinical trials for patients with cancer. The company is developing the CDK9 inhibitor KB-0742 as a treatment for *MYC*-amplified solid tumors and other transcriptionally addicted solid tumors and lanraplenib, a next-generation SYK inhibitor, for patients with FLT3-mutated acute myeloid leukemia. The company's scientific focus is on developing medicines that target the dysregulated transcription that is the hallmark of cancer and other serious diseases.

Kronos Bio is based in San Mateo, Calif., and has a research facility in Cambridge, Mass. For more information, visit www.kronosbio.com or follow the company on LinkedIn.

Forward-Looking Statements

Statements in this press release 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. The press release, in some cases, uses terms such as "anticipate," "expect," "look forward to," "potential" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements include statements regarding Kronos Bio's intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, the potential of KB-0742, the anticipated reporting of initial efficacy data for KB-0742 and the timing thereof, the anticipated providing of initial data and a recommended Phase 2 dose for lanraplenib and the timing thereof, Kronos Bio's expectations for providing data for each of its clinical programs over the course of 2024, activities and potential milestones under the discovery collaboration with Genentech, Kronos Bio's expected cash runway, 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 Kronos Bio will be able to progress its clinical trials on the timeline anticipated, including due to risks inherent in the clinical development of novel therapeutics; risks related to Kronos Bio's lack of experience as a company in conducting clinical trials; risks related to discovery and preclinical development activities, as well as risks associated with collaborations with third parties; 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 Kronos Bio's cash resources and need for additional capital. These and other risks are described in greater detail in Kronos Bio'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, 2022, filed with the SEC on November 8, 2022, and its Annual Report on Form 10-K for the year ended December 31, 2022, being filed with the SEC later today. Any forward-looking statements that are made in this press release speak only as of the date of this press release and are based on management's assumptions and estimates as of such date. Except as required by law, Kronos Bio 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 press release.

Investors:

Claudia Styslinger
Argot Partners
212-600-1902
kronosbio@argotpartners.com

Media:

Leo Vartorella/David Rosen
Argot Partners
212-600-1494
kronosbio@argotpartners.com

Kronos Bio, Inc.
Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	\$ 23,168	\$ 50,819	\$ 93,715	\$ 112,903
General and administrative	10,514	11,587	43,400	38,495
Total operating expenses	33,682	62,406	137,115	151,398
Loss from operations	(33,682)	(62,406)	(137,115)	(151,398)
Other income (expense), net:				
Interest and other income, net	1,900	72	3,911	320
Total other income (expense), net	1,900	72	3,911	320
Net loss	(31,782)	(62,334)	(133,204)	(151,078)
Other comprehensive income (loss):				
Net unrealized loss on available-for-sale securities	258	(46)	(753)	(20)
Net comprehensive loss	\$ (31,524)	\$ (62,380)	\$ (133,957)	\$ (151,098)
Net loss per share, basic and diluted	\$ (0.56)	\$ (1.13)	\$ (2.37)	\$ (2.76)
Weighted-average number of shares used to compute net loss per share, basic and diluted	56,522,785	55,358,508	56,201,398	54,753,599

Kronos Bio, Inc.
Selected Balance Sheet Data
(in thousands, except share and per share amounts)
(Unaudited)

	December 31, 2022	December 31, 2021
Cash, cash equivalents and investments	\$ 247,947	\$ 339,509
Total assets	294,938	391,476
Total liabilities	50,439	46,379
Total stockholders' equity	244,499	345,097