
**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): February 24, 2022

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 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 2.02 Results of Operations and Financial Condition

On February 24, 2022, 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, 2021. 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 February 24, 2022.</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.

Dated: February 24, 2022

KRONOS BIO, INC.

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 2021 Financial Results

Phase 1/2 trial of CDK9 inhibitor KB-0742 continues to enroll patients in the dose escalation stage, with announcement of recommended Phase 2 dose and Phase 1 data expected in Q4 2022

Lanraplenib trial to start in Q1 2022; Phase 3 registrational AGILITY trial of entospletinib underway, with results anticipated in the second half of 2023

\$339.5 million in cash, cash equivalents and investments as of December 31, 2021, providing expected runway into the second half of 2024

San Mateo, Calif., and Cambridge, Mass., February 24, 2022 (GLOBE NEWSWIRE) – Kronos Bio, Inc. (Nasdaq: KRON), a company dedicated to transforming the lives of those affected by cancer and other serious diseases, today reported recent business progress and fourth-quarter and full-year 2021 financial results.

“We had a successful year, marked by the significant progress we made across our clinical pipeline, including initiating our registrational Phase 3 AGILITY study of entospletinib, and initiating our Phase 1/2 study of KB-0742 and subsequently reporting positive initial results from the KB-0742 study,” said Norbert Bischofberger, Ph.D., president and chief executive officer of Kronos Bio. “We expect to announce the initiation of our third clinical trial later this quarter. We continue to dose-escalate KB-0742 and anticipate reaching the recommended Phase 2 dose and sharing additional Phase 1 data in the fourth quarter.”

KB-0742 Update

- Kronos Bio is continuing to enroll patients in the Phase 1/2 trial of KB-0742. KB-0742 is the company’s internally discovered, highly selective, orally administered cyclin dependent kinase 9 (CDK9) inhibitor being developed to treat MYC-amplified and other transcriptionally addicted solid tumors. Kronos Bio reported positive initial data from the study last year and is continuing to dose escalate.
- The company expects to announce a recommended Phase 2 dose and announce updated Phase 1 data in Q4 2022.
- While the first stage of the study does not mandate enrollment of patients with MYC amplification or other evidence of transcriptional addiction, as the trial nears pharmacologically active dose levels, the company anticipates increased enrollment of patients who may be more likely to respond to CDK9 inhibition.

SYK Inhibitor Program Update

- Kronos Bio expects to dose the first patient in a Phase 1b/2 clinical trial of lanraplenib in the first quarter of 2022. This trial will evaluate lanraplenib in patients with relapsed or refractory FLT3-mutated acute myeloid leukemia (AML) in combination with the current standard of care, gilteritinib.
- To better focus on and prioritize the company’s resources on the areas of highest unmet need, Kronos Bio has decided not to proceed at this time with its previously planned second Phase 1b/2 clinical trial of lanraplenib in combination with venetoclax/azacitidine.

Fourth-Quarter Company Highlights

- Kronos Bio dosed the first patient 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 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. The company expects to share data from the trial in the second half of 2023.

- Kronos Bio announced positive data from the ongoing Phase 1/2 clinical trial of KB-0742. The initial analysis of the ongoing dose escalation stage of the trial demonstrated a differentiated pharmacokinetic profile and evidence of target engagement for KB-0742.
- Kronos Bio appointed Roshawn Blunt to its Board of Directors. Ms. Blunt has decades of experience in the commercialization of new therapeutics, including oncology medicines, with expertise in patient access, reimbursement and health policy. Her expertise will be highly relevant as Kronos Bio advances its lead programs.
- Kronos Bio announced its multi-year collaboration with Tempus Labs, Inc., a leader in artificial intelligence and precision medicine, during the fourth quarter. The agreement provides Kronos Bio with access to real-world patient genomic and transcriptomic data and data analytics tools, with the goal of accelerating the development of the company's current and future clinical portfolio.

Fourth-Quarter and Full-Year 2021 Financial Highlights

- **Cash, Cash Equivalents and Investments:** With its ongoing and currently planned clinical programs and \$339.5 million in cash, cash equivalents and investments as of December 31, 2021, the company anticipates sufficient resources to fund its planned operations into the second half of 2024.
- **R&D Expenses:** Research and development expenses were \$50.8 million for the fourth quarter of 2021, which includes non-cash stock-based compensation expense of \$3.4 million. For the full year of 2021, research and development expenses were \$112.9 million, which includes non-cash stock-based compensation expense of \$13.0 million.

Research and development expenses for the fourth quarter included the \$29.0 million milestone paid to Gilead Sciences upon initiation of Kronos Bio's registrational Phase 3 clinical trial of entospletinib in December 2021.

- **G&A Expenses:** General and administrative expenses were \$11.6 million for the fourth quarter of 2021, which includes non-cash stock-based compensation expense of \$4.0 million. For the full year of 2021, general and administrative expenses were \$38.5 million, which includes non-cash stock-based compensation expense of \$13.3 million.
- **Net Loss:** Net loss for the fourth quarter of 2021 was \$62.3 million, or \$1.13 per share, including non-cash stock-based compensation of \$7.4 million. Net loss for the full-year 2021 was \$151.1 million, or \$2.76 per share, including non-cash stock-based compensation expense of \$26.2 million.

About Kronos Bio, Inc.

Kronos Bio is an integrated discovery through late-stage clinical development biopharmaceutical company, focused on developing therapies that target the dysregulated transcription that causes cancer and other serious diseases. Kronos Bio's lead investigational compound is entospletinib, an orally administered, selective inhibitor targeting spleen tyrosine kinase (SYK) in clinical development for the frontline treatment of NPM1-mutated acute myeloid leukemia (AML) in combination with intensive chemotherapy. The company is also developing KB-0742, an orally administered inhibitor of cyclin dependent kinase 9 (CDK9), in Phase 1/2 clinical development for the treatment of MYC-amplified or overexpressing solid tumors.

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 "look forward," "intend," "aim," "anticipate," "goal," "future," "will," "plan," "expect," 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: Kronos Bio's plans to begin a Phase 1b/2 clinical trial of lanraplenib in the first quarter of 2022 and the design of such trial; anticipated increased enrollment of patients who may be more likely to respond to CDK9 inhibition in Kronos Bio's ongoing Phase 1/2 clinical trial of KB-0742; the anticipated timing for reaching the recommended Phase 2 dose; the anticipated timing for reporting data; the potential of the registrational Phase 3 AGILITY clinical trial of entospletinib to support accelerated approval of entospletinib as a treatment for patients newly diagnosed with NPM1-mutated AML who are fit for intensive induction chemotherapy; the potential benefits to Kronos Bio from its collaboration with Tempus; the anticipated sufficiency of the company's resources to fund its planned operations into the second half of 2024; 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 initiate or complete the current and planned clinical trials of entospletinib, lanraplenib and 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 using MRD negative complete response as the primary endpoint to support potential accelerated approval in patients newly diagnosed with NPM1-mutated AML who are fit for intensive induction chemotherapy, including the fact that so far there have not been any regulatory approvals on the basis of MRD status in AML; risks related to Kronos Bio's 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; 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, 2021, filed with the SEC on November 9, 2021, and in its Annual Report on Form 10-K for the year ended December 31, 2021, which is 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.

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,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 50,819	\$ 13,125	\$ 112,903	\$ 43,250
General and administrative	11,587	7,963	38,495	14,794
Total operating expenses	62,406	21,088	151,398	58,044
Loss from operations	(62,406)	(21,088)	(151,398)	(58,044)
Other income (expense), net:				
Change in fair value of convertible notes payable	—	(12,193)	—	(27,408)
Interest expense	—	—	—	(3,890)
Interest and other income, net	72	124	320	898
Total other income (expense), net	72	(12,069)	320	(30,400)
Net loss	(62,334)	(33,157)	(151,078)	(88,444)
Other comprehensive income (loss):				
Net unrealized loss on available-for-sale securities	(46)	(66)	(20)	(1)
Net comprehensive loss	\$ (62,380)	\$ (33,223)	\$ (151,098)	\$ (88,445)
Net loss per share, basic and diluted	\$ (1.13)	\$ (0.70)	\$ (2.76)	\$ (5.43)
Weighted-average number of shares used to compute net loss per share, basic and diluted	55,358,508	47,224,523	54,753,599	16,277,247

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

	December 31, 2021	December 31, 2020
Cash, cash equivalents and investments	\$ 339,509	\$ 462,062
Total assets	391,476	511,964
Total liabilities	46,379	46,445
Total stockholders' equity	345,097	465,519

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