# **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): November 9, 2021

# 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						
(Former nar	N/A me or former address, if changed since las	st report.)				
Check the appropriate box below if the Form 8-K filing is intended to	o simultaneously satisfy the filing obligation o	f the registrant under any of the following provisions:				
☐ Written communications pursuant to Rule 425 under the Secu	urities Act (17 CFR 230.425)					
Soliciting material pursuant to Rule 14a-12 under the Exchan	,					
Pre-commencement communications pursuant to Rule 14d-2(	• • •	<i>"</i>				
Pre-commencement communications pursuant to Rule 13e-4(	(c) under the Exchange Act (17 CFR 240.13e	e-4(c))				
Securities	s registered pursuant to Section 12(b) of t	he 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 growt Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of t		105 of the Securities Act of 1933 (§230.405 of this chapter) or				
Emerging growth company $oxtimes$						
If an emerging growth company, indicate by check mark if the regist accounting standards provided pursuant to Section 13(a) of the Exc		nsition period for complying with any new or revised financial				

#### Item 2.02 Results of Operations and Financial Condition.

On November 9, 2021, Kronos Bio, Inc. issued a press release providing a corporate update and announcing its financial results for the quarter ended September 30, 2021. A copy of the press release is being furnished as Exhibit 99.1 to this report.

The information in this report 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, 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 filing.

#### Item 9.01 Financial Statements and Exhibits.

#### (d) Exhibits.

Exhibit No.	Description
<u>99.1</u>	Press Release, dated November 9, 2021.
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: November 9, 2021

By: /s/ Norbert Bischofberger

Norbert Bischofberger, Ph.D.

President and Chief Executive Officer



#### Kronos Bio Reports Recent Business Progress and Third-Quarter Financial Results

Company today announces progression of two discovery programs within its pipeline

Highlights from the quarter include presentation of preclinical data on the company's CDK9 inhibitor KB-0742 at AACR-NCI-EORTC meeting in October; Kronos Bio remains on track to report interim data from ongoing Phase 1/2 trial of KB-0742 by year end

\$398.4 million in cash, cash equivalents and investments as of September 30, 2021

San Mateo, Calif., and Cambridge, Mass., November 9, 2021 (GLOBE NEWSWIRE) – Kronos Bio, Inc. (Nasdaq: KRON), a company dedicated to transforming the lives of those affected by cancer, today reported recent business progress and third-quarter financial results.

"As we approach the end of the year, we look forward to reporting interim data from the ongoing Phase 1/2 study of our internally discovered CDK9 inhibitor, KB-0742, capping off a year of significant progress," said Norbert Bischofberger, Ph.D., president and chief executive officer of Kronos Bio. "In addition to continued execution across our clinical stage programs, I am also pleased with the progress we are making with our pipeline – particularly the addition of two new discovery programs, which underscore the capabilities of our product engine."

#### **Pipeline Progress**

Kronos Bio today announced it has initiated two new discovery programs, each focused on a distinct target or node identified through the company's research and mapping of the MYC and AR transcriptional regulatory networks (TRNs).

- Target 1: MYC TRN. Dysregulation of the MYC TRN is a hallmark of cancer and occurs in a large percentage of cancers. The
  company's existing development candidate, KB-0742, targets CDK9 and is being evaluated in a Phase 1/2 clinical study. KB-0742 is
  intended to target MYC dysregulation in the context of MYC genomic amplification, which occurs in 30% of all solid tumors. The new
  Target 1 program is aimed at modulating a protein-protein interaction in the MYC TRN with the objective of treating additional MYCdysregulated cancers beyond those targeted by KB-0742.
- Target 2: AR TRN. Dysregulation of the AR (androgen receptor) TRN is a primary driver of prostate cancer. Although therapies that directly inhibit the androgen receptor already exist, many patients with prostate cancer ultimately develop resistance to these therapies and patients with castration-resistant prostate cancer (CRPC) have a particularly poor prognosis. This new program aims to overcome resistance to current therapies by targeting an AR cofactor that selectively modulates the AR TRN in the context of CRPC.
- The company anticipates identifying a lead candidate and submitting an Investigational New Drug (IND) application out of one of its discovery programs in 2023.

Additionally, Kronos Bio yesterday announced a multi-year collaboration with Tempus, a leader in artificial intelligence and precision medicine. The agreement will provide 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.

#### **Third-Quarter Company Highlights**

- Kronos Bio presented preclinical data characterizing the pharmacokinetic (PK) and pharmacodynamic (PD) profile of KB-0742 in a
  poster at the AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics in October 2021.
  These data build on results first shared at the American Association for Cancer Research meeting earlier this year. The new data
  demonstrated a favorable preclinical PK profile and human PK projection that support the intermittent dosing schedule for patients in
  the Phase 1/2 study.
- The U.S. Food and Drug Administration cleared the company's IND for lanraplenib, a next-generation spleen tyrosine kinase (SYK) inhibitor. This allows Kronos Bio to proceed with its planned Phase 1b/2 clinical trial of the compound in patients with relapsed or refractory FLT3-mutated acute myeloid leukemia (AML) in combination with gilteritinib.

#### **Upcoming Milestones**

- The company plans to report interim safety, PK and PD data in Q4 2021 from the ongoing dose escalation phase of its Phase 1/2 clinical trial of KB-0742, which is being developed to treat MYC-amplified or over-expressing solid tumors.
- Kronos Bio remains on track to dose the first patient in its planned Phase 3 clinical trial of entospletinib before the end of the year, with data readout expected in the second half of 2023. This trial will assess measurable residual disease (MRD) negative complete response as the primary endpoint to support potential accelerated approval in patients newly diagnosed with NPM1-mutated AML and eligible for intensive induction chemotherapy.
- The company expects to dose the first patient in the first of two planned Phase 1b/2 clinical trials of lanraplenib in the first quarter of 2022. This first trial will evaluate lanraplenib in patients with relapsed or refractory FLT3-mutated AML.
- Kronos Bio plans to initiate a second Phase 1b/2 clinical trial of lanraplenib, in combination with venetoclax/azacitidine in patients newly diagnosed with NPM1-mutated and/or FLT3-mutated AML who are older than age 75 or not eligible for intensive induction chemotherapy in the first half of 2022.

#### Third Quarter Financial Highlights

- Cash, Cash Equivalents and Investments: As of September 30, 2021, cash, cash equivalents and investments totaled \$398.4 million.
- **R&D Expenses**: Research and development expenses were \$24.7 million for the third quarter of 2021, which includes non-cash stock-based compensation expense of \$3.5 million.
- **G&A Expenses**: General and administrative expenses were \$9.0 million for the third quarter of 2021, which includes non-cash stockbased compensation expense of \$3.6 million.
- **Net Loss**: Net loss for the third quarter of 2021 was \$33.6 million, or \$0.61 per share, including non-cash stock-based compensation expense of \$7.1 million.

#### About Kronos Bio, Inc.

Kronos Bio is a clinical-stage biopharmaceutical company dedicated to discovering and developing therapies that seek to transform the lives of those affected by cancer. The company focuses on targeting dysregulated transcription factors and the regulatory networks within cells that drive cancerous growth. Kronos Bio's lead investigational therapy is entospletinib, a selective inhibitor targeting spleen tyrosine kinase (SYK) in development for the frontline treatment of NPM1-mutated acute myeloid leukemia (AML). The company is also developing KB-0742, an oral inhibitor of cyclin dependent kinase 9 (CDK9), 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 <u>www.kronosbio.com</u> 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: the potential of KB-0742 to target MYC dysregulation in the context of MYC genomic amplification; the potential of the Target 1 program to treat MYC-dysregulated cancers; the potential of the Target 2 program to treat patients with CRPC; Kronos Bio's plans to submit an IND application out of one of its discovery programs in 2023; the potential benefits to Kronos Bio from its collaboration agreement with Tempus, including the acceleration of Kronos Bio's current and future clinical portfolio; Kronos Bio's plans to initiate a registrational Phase 3 trial of entospletinib later this year and the ability of the trial to support potential accelerated approval of entospletinib in patients newly diagnosed with NPM1-mutated AML and eligible for intensive induction chemotherapy; Kronos Bio's plans to begin a Phase 1b/2 clinical trial of lanraplenib in the first quarter of 2022 and another Phase 1b/2 clinical trial of lanraplenib in the first half of 2022; the design of such planned Phase 1b/2 clinical trials of lanraplenib; the expected timing for reporting data; anticipated inflection points in the coming months; 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 and eligible 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 June 30, 2021, filed with the SEC on August 12, 2021. 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 September 30,		Nine months ended September 30,				
	2021		2020		2021		2020
Operating expenses:							
Research and development	\$ 24,688	\$	16,755	\$	62,084	\$	30,125
General and administrative	8,985		4,054		26,908		6,831
Total operating expenses	 33,673		20,809		88,992		36,956
Loss from operations	(33,673)		(20,809)		(88,992)		(36,956)
Other income (expense), net:							
Change in fair value of convertible notes payable	_		(15,215)		_		(15,215)
Interest expense	_		(3,889)		_		(3,890)
Interest and other income, net	70		200		248		774
Total other income (expense), net	70		(18,904)		248		(18,331)
Net loss	 (33,603)		(39,713)		(88,744)		(55,287)
Other comprehensive income (loss):			<del></del>				
Net unrealized gain (loss) on available-for-sale securities	1		(117)		26		65
Net comprehensive loss	\$ (33,602)	\$	(39,830)	\$	(88,718)	\$	(55,222)
Net loss per share, basic and diluted	\$ (0.61)	\$	(6.48)	\$	(1.63)	\$	(9.39)
Weighted-average shares of common stock, basic and diluted	54,977,085		6,127,146		54,549,747		5,886,191

#### Kronos Bio, Inc. **Selected Balance Sheet Data**

(in thousands, except share and per share amounts) (Unaudited)

	Septe	ember 30, 2021	December 31, 2020
Cash, cash equivalents and investments	\$	398,382	\$ 462,062
Total assets		447,529	511,964
Total liabilities		48,506	46,445
Total stockholders' equity		399,023	465,519

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