# 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): August 12, 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**

**1300 So. El Camino Real, Suite 300**
**San Mateo, California 94402**
**(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 August 12, 2021, Kronos Bio, Inc. issued a press release providing a corporate update and announcing its financial results for the quarter ended June 30, 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 |
|---|---|
| 99.1 | Press Release, dated August 12, 2021. |

**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: August 12, 2021

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

**Kronos Bio Reports Recent Business Progress and Second Quarter Financial Results**

*Announced FDA clearance of Investigational New Drug application (IND) for lanraplenib (LANRA) for treatment of patients with acute myeloid leukemia (AML)*

*Unveiled SYK portfolio strategy and highlighted momentum of CDK9 inhibitor and discovery programs at virtual R&D Day*

*$419.3 million in cash, cash equivalents and investments as of June 30, 2021*

**San Mateo, Calif., and Cambridge, Mass., August 12, 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 second quarter financial results.

“At our virtual R&D Day in May, we outlined our vision for expanding and driving progress in our pipeline of clinical programs that target dysregulated transcription factors and the regulatory networks within cancerous cells. This included unveiling the development strategy for our SYK inhibitor portfolio, which comprises entospletinib (ENTO) and LANRA. These differentiated clinical-stage investigational development candidates have the potential to address the mutations that are present in more than two-thirds of patients with AML,” said Norbert Bischofberger, Ph.D., president and CEO. “We are poised to initiate our registrational Phase 3 trial later this year to support potential accelerated approval of ENTO in patients newly diagnosed with NPM1-mutated AML. With the recent FDA clearance of our IND for LANRA in relapsed or refractory FLT-3 mutant AML, we plan to launch our second SYK inhibitor clinical trial in the fourth quarter of 2021, when we also expect to report initial Phase 1 data from our trial of KB-0742, our potent oral, highly selective cyclin dependent kinase 9 inhibitor. I am proud of our Company’s momentum and anticipate multiple important inflection points in the coming months.”

**Recent Company Highlights**

- Received clearance from U.S. Food and Drug Administration (FDA) for the IND application of LANRA, a next-generation spleen tyrosine kinase (SYK) inhibitor. The first of two planned Phase 1/2 clinical trials is expected to initiate in Q4 2021 in patients with relapsed or refractor FLT3-mutated AML and will include a dose-escalation and an expansion cohort study design. The first stage will evaluate initial safety, pharmacokinetic (PK) and anti-leukemic activity of escalating once-daily doses of LANRA in combination with gilteritinib. Initial data from this first stage of the trial are anticipated to be available in the second half of 2022.
- On track to initiate the Phase 3 trial of ENTO in the second half of 2021 with a pivotal data readout expected in the second half of 2023.
- This trial will assess measurable residual disease (MRD) negative complete response (CR) as the primary endpoint to support potential accelerated approval in patients newly diagnosed with NPM1-mutated AML.
- Anticipates reporting initial safety, PK and pharmacodynamic (PD) data from Phase 1 trial of KB-0742, a highly selective, orally bioavailable cyclin dependent kinase 9 (CDK9) inhibitor being developed to treat MYC-amplified solid tumors, in the fourth quarter of 2021. The company presented preclinical data for KB-0742 at the American Association for Cancer Research (AACR) Annual Meeting in April 2021, which showed CDK9 inhibition on an intermittent dosing schedule with KB-0742 resulted in sustained inhibition of tumor growth in multiple types of solid tumors. The findings suggest that genomic amplification of MYC, a well-characterized transcription factor and a long-recognized driver of cancer, is a key factor of sensitivity to CDK9 inhibition.

- Hosted a virtual R&D Day in May 2021 to discuss the company's development strategy for the SYK inhibitors ENTO and LANRA, expectations for the upcoming Phase 1 data readout for KB-0742 and potential populations for expansion cohorts of a Phase 1/2 trial, along with an overview of the company's differentiated drug discovery platform and future pipeline programs.

**Second Quarter Financial Highlights**

**Cash, Cash Equivalents and Investments**: As of June 30, 2021, cash, cash equivalents and investments totaled $419.3 million.

**R&D Expenses**: Research and development expenses were $19.8 million for the second quarter of 2021, which includes non-cash stock-based compensation expense of $3.4 million.

**G&A Expenses**: General and administrative expenses were $9.3 million for the second quarter of 2021, which includes non-cash stock-based compensation expense of $3.0 million.

**Net Loss**: Net loss for the second quarter of 2021 was $29.1 million, or $0.53 per share, including non-cash stock-based compensation expense of $6.4 million.

**About Kronos Bio, Inc.**
Kronos Bio is a clinical-stage biopharmaceutical company dedicated to discovering, developing and commercializing 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 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 "expects," "planned," "prepare," "begin," "initiate," "commence," "look forward," "guide," "intends," "will," "should," "seek" 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 ENTO and LANRA to address the mutations that are present in more than two-thirds of patients with acute myeloid leukemia; Kronos Bio's plans to initiate a registrational Phase 3 trial of ENTO later this year and the ability of the trial to support potential accelerated approval of ENTO in patients newly diagnosed with NPM1-mutated AML; Kronos Bio's plans to begin a Phase 1/2 clinical trial of LANRA in the fourth quarter of 2021 and the design of such planned Phase 1/2 clinical trial; 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 complete the current and planned clinical trials of ENTO, LANRA 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 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 March 31, 2021, filed with the SEC on May 11, 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 June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Operating expenses: | | | | |
| Research and development | $ 19,802 | $ 7,175 | $ 37,396 | $ 13,370 |
| General and administrative | 9,339 | 1,623 | 17,923 | 2,777 |
| Total operating expenses | 29,141 | 8,798 | 55,319 | 16,147 |
| Loss from operations | (29,141) | (8,798) | (55,319) | (16,147) |
| Other income (expense), net: | | | | |
| Interest expense | — | — | — | (1) |
| Interest and other income, net | 86 | 219 | 178 | 574 |
| Total other income (expense), net | 86 | 219 | 178 | 573 |
| Net loss | (29,055) | (8,579) | (55,141) | (15,574) |
| Other comprehensive income (loss): | | | | |
| Net unrealized gain (loss) on available-for-sale securities | 29 | 24 | 25 | 182 |
| Net comprehensive loss | $ (29,026) | $ (8,555) | $ (55,116) | $ (15,392) |
| Net loss per share, basic and diluted | $ (0.53) | $ (1.47) | $ (1.01) | $ (2.70) |
| Weighted-average shares of common stock, basic and diluted | 54,506,195 | 5,833,946 | 54,330,402 | 5,764,389 |

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

| | June 30, 2021 | December 31, 2020 |
|---|---|---|
| Cash, cash equivalents and investments | $ 419,254 | $ 462,062 |
| Total assets | 471,742 | 511,964 |
| Total liabilities | 47,635 | 46,445 |
| Total stockholders' equity | 424,107 | 465,519 |

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

**Media:**
Sheryl Seapy
Real Chemistry
949-903-4750
sseapy@realchemistry.com