Kronos Bio Reports Recent Business Progress and Fourth-Quarter and Full-Year 2023 Financial Results

March 21, 2024

Phase 1/2 study of KB-0742 is on track to clear 80mg four-days-on, three-days-off schedule in the third quarter of 2024; topline data from expansion cohort at this schedule expected in the first half of 2025

IND-enabling studies for KB-9558 expected to complete in 2024 with first-in-human study anticipated to commence in the first half of 2025

$175.0 million in cash, cash equivalents and investments as of December 31, 2023, providing expected cash runway into the second half of 2026

SAN MATEO, Calif. and CAMBRIDGE, Mass., March 21, 2024 (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 fourth-quarter and full-year 2023 financial results.

"In 2023, we made great progress across our portfolio and business. We demonstrated that KB-0742 has a safety profile that is clearly differentiated from all other CDK9 inhibitors, and we believe our extended dosing schedule will show increased efficacy signals while maintaining a favorable safety profile," said Nobert Bischofberger, Ph.D., president and chief executive officer of Kronos Bio. "We also announced our second development candidate, KB-9558, which is designed to target the KAT domain of p300 and downregulate IRF4 transcription in multiple myeloma. We are looking forward to completing the IND-enabling studies in 2024 and expect to dose our first patients in the first half of 2025."

Clinical Program and Recent Company Updates

KB-0742

- At the 2023 AACR-NCI-EORTC International Conference, the Company reported target engagement, tumor regressions, and an acceptable safety profile for KB-0742 dosed at 60mg three-days-on, four-days-off in heavily pre-treated patients with transcriptionally addicted solid tumors. Out of fourteen "all-comer" patients, two patients with myxoid liposarcoma exhibited tumor regressions: one (7th line) had a partial response (per RECIST v1.1) lasting 113 days and the second achieved a 26% reduction in tumor diameters with stable disease. KB-0742 also cleared the 80mg three-days-on, four-days-off schedule in dose escalation and is currently enrolling patients in the KB-0742 60mg four-days-on, three-days-off dose escalation cohort of the Phase 1/2 trial.
- At a medical conference in mid-2024, the Company intends to share an update on the clinical data to date from patients with transcriptionally addicted tumors who were dosed with 60mg three-days-on, four-days-off, and from "all-comer" patients in the dose-escalation cohort who received 80mg three-days-on, four-days-off.
- In the third quarter of 2024, the Company expects to clear the 80mg four-days-on, three-days-off dose escalation cohort, and begin enrolling patients in an expansion cohort including one or more of the following: non-small cell lung cancer, small cell lung cancer, ovarian cancer, and triple negative breast cancer.
- The Company expects to announce topline data from the expansion cohort at the 80mg four-days-on, three-days-off dose in the first half of 2025.

KB-9558

- In December 2023, the Company announced the nomination of KB-9558, a p300 KAT inhibitor, as a development candidate.
- KB-9558 is the second development candidate to emerge from Kronos Bio's product engine, where the Company identified that inhibition of the lysine acetyltransferase (KAT) domain on p300 inhibits expression of interferon regulatory factor 4 (IRF4) and thus collapses the transcription regulatory network that is required for the survival of multiple myeloma cells.
- The Company plans to present data on KB-9558 at the American Association for Cancer Research (AACR) annual meeting, being held from April 5-10, 2024 in San Diego, California, including how targeting p300's enzymatic KAT domain can selectively downregulate IRF4.
- Pending completion of IND-enabling studies in 2024, the Company intends to initiate a first-in-human trial in relapsed or refractory multiple myeloma in the first half of 2025.

Lanraplenib

- In December 2023, after a review of data from the Phase 1b portion of its Phase 1b/2 trial of lanraplenib in combination with gilteritinib in FLT3-mutated relapsed/refractory acute myeloid leukemia (AML), the Company decided not to proceed to Phase 2.

Company Update

- Kronos Bio extended its expected cash runway by a year, into the second half of 2026, through restructurings and resource optimization.

Fourth-Quarter and Full-Year 2023 Financial Highlights

- **Cash, Cash Equivalents and Investments:** With its ongoing and currently planned clinical programs and $175.0 million in cash, cash equivalents and investments as of December 31, 2023, the Company anticipates sufficient resources to fund its planned operations into the second half of 2026.
- **R&D Expenses:** Research and development expenses were $18.7 million for the fourth quarter of 2023, which includes non-cash stock-based compensation expense of $2.5 million. For the full year of 2023, research and development expenses were $86.4 million, which includes non-cash stock-based compensation expense of $12.0 million.
- **G&A Expenses:** General and administrative expenses were $10.9 million for the fourth quarter of 2023, which includes non-cash stock-based compensation expense of $2.7 million. For the full year of 2023, general and administrative expenses were $41.7 million, which includes non-cash stock-based compensation expense of $13.0 million.
- **Net Loss:** Net loss for the fourth quarter of 2023 was $25.3 million, or $0.43 per share, including non-cash stock-based compensation expense of $5.2 million. Net loss for the full-year 2023 was $112.7 million, or $1.95 per share, including non-cash stock-based compensation expense of $25.0 million.

About Kronos Bio, Inc.

Kronos Bio is a biopharmaceutical company that is advancing an investigational CDK9 inhibitor compound, KB-0742, in a Phase 1/2 clinical trial as a treatment for MYC-amplified solid tumors and other transcriptionally addicted solid tumors as well as a preclinical development candidate, KB-9558, targeting the KAT domain of p300 for multiple myeloma. The Company's scientific focus is on developing medicines that target deregulated transcription, 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 https://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," "believe," "could," "expect," "on track," "plan," "potential," "promising," "will," 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 Phase 1/2 study of KB-0742 being on track to clear 80mg four-days-on, three-days-off schedule in Q3 2024; expected clinical results from the KB-0742 study; the expected timing for additional clinical data from the Phase 1/2 KB-0742 study; the potential completion of IND-enabling studies and the initial of a clinical trial for KB-9558 and the timing thereof; future pipeline development activities or outcomes; the potential of Kronos Bio's product candidates; 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: risks associated with changes to the assumptions underlying estimated expenses and savings; changes in the macroeconomic environment or competitive landscape that impact Kronos Bio's business; whether Kronos Bio will be able to progress its clinical trials on the timelines anticipated, including due to risks inherent in the clinical development of novel therapeutics; risks related to Kronos Bio's limited experience as a company in conducting clinical trials; the risk that results of preclinical studies and early clinical trials (including preliminary results) 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, 2023, filed with the SEC on November 13, 2023, and in its Annual Report on Form 10-K for the year ended December 31, 2023, being filed with the SEC 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 per share data)
(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Revenue	$ 2,286	$ —	$ 6,288	$ —
Operating expenses:				
Research and development	18,704	23,168	86,379	93,715
General and administrative	10,926	10,514	41,739	43,400
Total operating expenses	29,630	33,682	128,118	137,115
Loss from operations	(27,344)	(33,682)	(121,830)	(137,115)
Other income (expense), net:				

Interest and other income, net	2,024	1,900	9,157	3,911
Total other income (expense), net	2,024	1,900	9,157	3,911
Net loss	(25,320)	(31,782)	(112,673)	(133,204)
Other comprehensive income (loss):				
Net unrealized gain (loss) on available-for-sale securities	274	258	811	(753)
Net comprehensive loss	$ (25,046)	$ (31,524)	$ (111,862)	$ (133,957)
Net loss per share, basic and diluted	$ (0.43)	$ (0.56)	$ (1.95)	$ (2.37)
Weighted-average number of shares used to compute net loss per share, basic and diluted	58,268	56,523	57,744	56,201

Kronos Bio, Inc.
Selected Balance Sheet Data
(in thousands)
(Unaudited)

	December 31, 2023	December 31, 2022
Cash, cash equivalents and investments	$ 174,986	$ 247,947
Total assets	$ 213,279	$ 294,938
Total liabilities	$ 54,201	$ 50,439
Total stockholders' equity	$ 159,078	$ 244,499

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