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): May 2, 2024

KURA ONCOLOGY, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-37620**	**61-1547851**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

12730 High Bluff Drive, Suite 400, San Diego, CA	**92130**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (858) 500-8800

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 (see General Instructions A.2. below):

☐ 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, par value $0.0001 per share	KURA	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company 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 May 2, 2024, Kura Oncology, Inc. (the "Company") issued a press release announcing the Company's financial results for the first quarter ended March 31, 2024 and providing a corporate update. A copy of this press release is furnished herewith as Exhibit 99.1.

The information contained in this Current Report on Form 8-K under Item 2.02 and Exhibit 99.1 hereto are being furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section and will not be incorporated by reference into any registration statement filed by the Company, under the Securities Act of 1933, as amended, unless specifically identified as being incorporated therein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release dated May 2, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 thereunto duly authorized.

KURA ONCOLOGY, INC.

Date: May 2, 2024

By: /s/ Teresa Bair
Teresa Bair
Chief Legal Officer

Exhibit 99.1

Kura Oncology Reports First Quarter 2024 Financial Results

– Breakthrough Therapy Designation for ziftomenib in NPM1-mutant AML –

– Registration-directed trial of ziftomenib in NPM1-mutant AML on track to complete enrollment by mid-2024 –

– Positive preliminary combination data for ziftomenib in NPM1-mutant and KMT2A-rearranged AML –

– First patient dosed with KO-2806 and cabozantinib in renal cell carcinoma –

– $527 million in cash, cash equivalents and investments provide runway into 2027 –

– Management to host webcast and conference call today at 4:30 p.m. ET –

SAN DIEGO, May 2, 2024– Kura Oncology, Inc. (Nasdaq: KURA), a clinical-stage biopharmaceutical company committed to realizing the promise of precision medicines for the treatment of cancer, today reported first quarter 2024 financial results and provided a corporate update.

“Ziftomenib continues to demonstrate a best-in-class safety and efficacy profile as well as optimal pharmaceutical properties, which we believe will enable it to become a cornerstone of therapy in acute leukemias and beyond,” said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. “This belief is backed by increasing investigator enthusiasm, as evidenced by rapid enrollment across our ongoing ziftomenib studies, and further supported by the FDA’s decision to grant Breakthrough Therapy Designation (BTD) to ziftomenib, making it the first investigational treatment to be granted BTD for the treatment of NPM1-mutant acute myeloid leukemia (AML). In the near term, we look forward to completing enrollment in our registration-directed trial of ziftomenib in NPM1-mutant AML and working closely with FDA to bring this potentially innovative medicine to patients in urgent need of effective treatments.”

Recent Highlights

- **Breakthrough Therapy Designation for ziftomenib in NPM1-mutant AML** – Last month, the U.S. Food and Drug Administration (FDA) granted BTD to ziftomenib for the treatment of relapsed/refractory (R/R) NPM1-mutant AML. FDA granted BTD based on data from Kura’s ongoing KOMET-001 trial of ziftomenib in patients with R/R NPM1-mutant AML. BTD is awarded for a drug that treats a serious or

life-threatening condition and may demonstrate substantial improvement on one or more clinically significant endpoints over available therapies.

- **Registration-directed trial of ziftomenib in NPM1-mutant AML nearing completion** – Kura remains on track to complete enrollment of 85 patients in its KOMET-001 registration-directed trial of ziftomenib in NPM1-mutant R/R AML by mid-2024. In the Phase 1 trial, ziftomenib demonstrated a 35% CR rate and 45% overall response rate in 20 heavily pretreated patients with NPM1-mutant AML treated at the recommended Phase 2 dose. NPM1-mutant AML accounts for approximately 30% of new AML cases annually and represents a disease of significant unmet need for which no approved targeted therapy exists.

- **Positive preliminary combination data for ziftomenib in NPM1-mutant and KMT2A-rearranged AML** – In January 2024, Kura reported preliminary data from the KOMET-007 dose-escalation trial of ziftomenib in combination with venetoclax/azacitidine or cytarabine/daunorubicin (7+3) in patients with NPM1-mutant or KMT2A-rearranged AML. As of the data cutoff on January 11, 2024, all five newly diagnosed patients treated with ziftomenib and 7+3 achieved a complete remission (CR) with full count recovery, for a CR rate of 100%. The overall response rate among the 15 R/R patients treated with ziftomenib and venetoclax/azacitidine was 53%. Continuous daily dosing of ziftomenib at 200 mg was well tolerated. No differentiation syndrome events of any grade were reported, and no dose-limiting toxicities, evidence of QTc prolongation, drug-drug interactions or additive myelosuppression were observed. As of the data cutoff, 16 of the first 20 patients remained on trial, including all 11 NPM1-mutant patients.

- **Dose escalation continues in KOMET-007 combination trial of ziftomenib** – To date, the 400 mg dose of ziftomenib has been cleared in three of the four cohorts in the KOMET-007 trial: 1) in combination with venetoclax/azacitidine in R/R NPM1-mutant AML, 2) in combination with venetoclax/azacitidine in R/R KMT2A-rearranged AML and 3) in combination with 7+3 in newly diagnosed adverse risk NPM1-mutant AML. Enrollment at the 600 mg dose is ongoing in all three cohorts. Enrollment continues at the 400 mg dose in combination with 7+3 in newly diagnosed adverse risk KMT2A-rearranged AML.

- **First patients dosed in KOMET-008 combination trial of ziftomenib** – In February, Kura began dosing patients in its KOMET-008 trial of ziftomenib in combination with additional standards of care, including the FLT3 inhibitor gilteritinib, FLAG-IDA or LDAC, for the treatment of R/R NPM1-mutant or KMT2A-rearranged AML. Preclinical data for ziftomenib in combination with FLT3 inhibitors demonstrate strong synergistic effects compared to either single agent alone. Roughly half of patients with R/R NPM1-mutant AML have co-occurring FLT3 mutations, and the prognosis for these patients is poor.

- **First patients dosed with KO-2806 and cabozantinib in renal cell carcinoma** – In March, Kura announced dosing of the first patient with KO-2806, the Company’s

next-generation farnesyl transferase inhibitor (FTI), in combination with cabozantinib in clear cell renal cell carcinoma, just four months after dosing the first patients with KO-2806 as a monotherapy in the FIT-001 dose-escalation trial. The Company remains on track to dose the first patient in combination with adagrasib in KRASG12C-mutated non-small cell lung cancer by the middle of this year, as dose escalation of KO-2806 as a monotherapy continues in parallel.

Financial Results

- Research and development expenses for the first quarter of 2024 were $36.3 million, compared to $25.2 million for the first quarter of 2023.
- General and administrative expenses for the first quarter of 2024 were $18.2 million, compared to $11.4 million for the first quarter of 2023.
- Net loss for the first quarter of 2024 was $49.5 million, compared to a net loss of $34.1 million for the first quarter of 2023. This included non-cash share-based compensation expense of $8.5 million, compared to $6.8 million for the same period in 2023.
- As of March 31, 2024, Kura had cash, cash equivalents and short-term investments of $527 million, compared to $424 million as of December 31, 2023. This includes net proceeds of approximately $145.8 million from the Company's private placement in January 2024.
- Based on its operating plan, management expects that cash, cash equivalents and short-term investments will fund current operations into 2027.

Forecasted Milestones

- Complete enrollment of 85 patients in the KOMET-001 registration-directed trial of ziftomenib in NPM1-mutant R/R AML by mid-2024.
- Identify the recommended Phase 2 dose of ziftomenib in combination with venetoclax and azacitidine by mid-2024.
- Identify the recommended Phase 2 dose of ziftomenib in combination with 7+3 by mid-2024.
- Initiate Phase 1b expansion study of ziftomenib in combination with standards of care, including venetoclax/azacitidine in newly diagnosed NPM1-mutant or KMT2A-rearranged AML, in the second half of 2024.
- Submit an investigational new drug application for ziftomenib in a solid tumor indication and present preclinical data at a medical meeting in the second half of 2024.

- Dose the first patients with KO-2806 and adagrasib in KRASG12C-mutated non-small cell lung cancer by mid-2024.
- Complete enrollment of two expansion cohorts in KURRENT-HN and identify the optimal biologically active dose of tipifarnib and alpelisib by the end of 2024.
- Present data from the KURRENT-HN trial of tipifarnib in combination with alpelisib in PIK3CA-dependent head and neck squamous cell carcinoma (HNSCC) in the first half of 2025.

Conference Call and Webcast

Kura's management will host a webcast and conference call at 4:30 p.m. ET / 1:30 p.m. PT today, May 2, 2024, to discuss the financial results for the first quarter 2024 and to provide a corporate update. The live call may be accessed by dialing (888) 886-7786 for domestic callers and (416) 764-8658 for international callers and entering the conference ID: 20226736. A live webcast and archive of the call will be available online from the investor relations section of the company website at www.kuraoncology.com.

About Kura Oncology

Kura Oncology is a clinical-stage biopharmaceutical company committed to realizing the promise of precision medicines for the treatment of cancer. The Company's pipeline consists of small molecule drug candidates that target cancer signaling pathways. Ziftomenib, a once-daily, oral drug candidate targeting the menin-KMT2A protein-protein interaction, has received Breakthrough Therapy Designation for the treatment of R/R NPM1-mutant AML. Kura is currently enrolling patients in a Phase 2 registration-directed trial of ziftomenib in NPM1-mutant R/R AML (KOMET-001). The Company is also conducting a series of clinical trials to evaluate ziftomenib in combination with current standards of care in NPM1-mutant and KMT2A-rearranged newly diagnosed and R/R AML. Tipifarnib, a potent and selective FTI, is currently in a Phase 1/2 trial in combination with alpelisib for patients with PIK3CA-dependent HNSCC (KURRENT-HN). Kura is also evaluating KO-2806, a next-generation FTI, in a Phase 1 dose-escalation trial as a monotherapy and in combination with targeted therapies (FIT-001). For additional information, please visit Kura's website at www.kuraoncology.com and follow us on X and LinkedIn.

Forward-Looking Statements

This news release contains certain forward-looking statements that involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. Such forward-looking statements include statements regarding, among other things, the efficacy, safety and therapeutic potential of Kura's product candidates, ziftomenib, tipifarnib and KO-2806, progress and expected timing of Kura's drug

development programs and clinical trials and submission of regulatory filings, the presentation of data from clinical trials, plans regarding regulatory filings and future clinical trials, the regulatory approval path for tipifarnib, the strength of Kura's balance sheet and the sufficiency of cash, cash equivalents and short-term investments to fund its current operating plan to 2027. Factors that may cause actual results to differ materially include the risk that compounds that appeared promising in early research or clinical trials do not demonstrate safety and/or efficacy in later preclinical studies or clinical trials, the risk that Kura may not obtain approval to market its product candidates, uncertainties associated with performing clinical trials, regulatory filings, applications and other interactions with regulatory bodies, risks associated with reliance on third parties to successfully conduct clinical trials, the risks associated with reliance on outside financing to meet capital requirements, and other risks associated with the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such drugs. You are urged to consider statements that include the words "may," "will," "would," "could," "should," "believes," "estimates," "projects," "promise," "potential," "expects," "plans," "anticipates," "intends," "continues," "designed," "goal," or the negative of those words or other comparable words to be uncertain and forward-looking. For a further list and description of the risks and uncertainties the Company faces, please refer to the Company's periodic and other filings with the Securities and Exchange Commission, which are available at www.sec.gov. Such forward-looking statements are current only as of the date they are made, and Kura assumes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

KURA ONCOLOGY, INC.
Statements of Operations Data
(unaudited)
(in thousands, except per share data)

	Three Months Ended March 31,	
	2024	**2023**
Operating Expenses:		
Research and development	$ 36,268	$ 25,192
General and administrative	18,184	11,374
Total operating expenses	54,452	36,566
Other income, net	4,927	2,497
Net loss	$ (49,525)	$ (34,069)
Net loss per share, basic and diluted	$ (0.59)	$ (0.50)
Weighted average number of shares used in computing net loss per share, basic and diluted	83,905	68,403

KURA ONCOLOGY, INC.
Balance Sheet Data
(unaudited)
(in thousands)

	March 31, 2024	December 31, 2023
Cash, cash equivalents and short-term investments	$ 527,122	$ 423,957
Working capital	505,569	397,218
Total assets	553,908	448,935
Long-term liabilities	16,558	16,399
Accumulated deficit	(770,964)	(721,439)
Stockholders' equity	505,084	397,273

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