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 2, 2023

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 November 2, 2023, Kura Oncology, Inc. (the "Company") issued a press release announcing the Company's financial results for the third quarter ended September 30, 2023 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 November 2, 2023
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: November 2, 2023

By: /s/ Teresa Bair

Teresa Bair
Chief Legal Officer

Kura Oncology Reports Third Quarter 2023 Financial Results

– Completion of enrollment in KOMET-001 registration-directed trial of ziftomenib in NPM1-mutant AML expected by mid-2024 –

– Preliminary data from 20 patients in KOMET-007 combination trial of ziftomenib anticipated early in first quarter of 2024 –

– First patient dosed in FIT-001 dose-escalation study of next-generation FTI, KO-2806 –

– Clinical collaboration with Mirati to evaluate KO-2806 and adagrasib in $KRAS^{G12C}$-mutated NSCLC –

– $452.6 million in cash, cash equivalents and investments provide runway to mid-2026 –

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

SAN DIEGO, Nov. 2, 2023 – 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 third quarter 2023 financial results and provided a corporate update.

“I am proud of our team’s considerable progress, as we continue to execute across all three of our wholly owned, clinical-stage programs,” said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. “We believe our lead drug candidate, ziftomenib, is well positioned for market leadership, with multibillion dollar global revenue potential in acute leukemias and beyond. Our conviction is supported by a growing body of clinical data as a monotherapy and, increasingly, in combination with standards of care. We continue to be encouraged by the rapid pace of enrollment in our KOMET-001 registration-directed trial in NPM1-mutant acute myeloid leukemia (AML), as well as in our KOMET-007 combination trial. We look forward to sharing preliminary combination data in NPM1-mutant and KMT2A-rearranged AML early next quarter.”

“Meanwhile,” continued Dr. Wilson, “we continue to unlock the substantial therapeutic and commercial value of farnesyl transferase inhibition. We believe the positive results from our AIM-HN registration-directed trial of tipifarnib and the favorable safety and tolerability profile of tipifarnib in combination with alpelisib in our ongoing KURRENT-HN trial significantly de-risk development of our next-generation farnesyl transferase inhibitor (FTI), KO-2806. We are pleased to be in the clinic with KO-2806 and look forward to evaluating it in combination with other targeted therapies, including adagrasib in $KRAS^{G12C}$-mutated non-small cell lung cancer (NSCLC) and cabozantinib in clear cell

renal cell carcinoma (ccRCC). If successful, we believe KO-2806 could become an ideal combination partner for multiple targeted therapies in large solid tumor indications."

Recent Highlights

- **Rapid pace of enrollment continues in registration-directed trial of ziftomenib in NPM1-mutant AML** – The KOMET-001 registration-directed trial of ziftomenib in NPM1-mutant relapsed or refractory AML is expected to enroll a total of 85 patients in the U.S. and Europe, with a primary endpoint of complete remission (CR) or CR with partial hematologic recovery (CRh). In the Phase 1 trial, ziftomenib demonstrated a 35% CR rate and 45% overall response rate in 20 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. Kura expects to complete enrollment of all 85 patients in the Phase 2 registration-directed trial no later than mid-2024.

- **Preliminary data from KOMET-007 combination trial of ziftomenib upcoming** – KOMET-007 is a Phase 1 dose-escalation study designed to assess safety, tolerability and preliminary activity of ziftomenib in combination with either: 1) venetoclax and azacitidine in patients with relapsed/refractory NPM1-mutant and KMT2A-rearranged AML or 2) standard induction cytarabine/daunorubicin chemotherapy (7+3) in NPM1-mutant and KMT2A-rearranged patients in the frontline setting. The Company expects to share preliminary data from 20 patients in KOMET-007, including NPM1-mutant and KMT2A-rearranged patients treated with ziftomenib in the newly diagnosed and relapsed/refractory AML settings, early in the first quarter of 2024.

- **Positive results from AIM-HN registration-directed trial of tipifarnib in HRAS mutant HNSCC** – Kura recently presented positive results from the AIM-HN registration-directed trial of tipifarnib as a monotherapy in patients with HRAS mutant head and neck squamous cell carcinoma (HNSCC). The results were featured during a late-breaking mini-oral session at the European Society for Medical Oncology Congress in Madrid. The Company continues to evaluate whether the combination of tipifarnib and alpelisib has potential to extend the clinical benefit observed in the AIM-HN trial to a broader set of HNSCC patients in its ongoing KURRENT-HN study.

- **First patient dosed in FIT-001 dose-escalation study of KO-2806** – Last month, Kura announced that the first patient was dosed in its FIT-001 Phase 1 dose-escalation trial of KO-2806. KO-2806 is a next-generation FTI designed to improve upon potency, pharmacokinetic and physicochemical properties of earlier FTI drug candidates. Concurrent with dose escalation as a monotherapy in the FIT-001 trial, the Company also plans to evaluate KO-2806 in dose-escalation combination cohorts with adagrasib in $KRAS^{G12C}$-mutated NSCLC and with cabozantinib in ccRCC.

- **Preclinical data supports clinical combinations of KO-2806 with adagrasib and cabozantinib** – Kura presented preclinical data at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics supporting its rationale to combine KO-2806 with adagrasib in $KRAS^{G12C}$-mutated NSCLC and with cabozantinib in ccRCC. The new findings illustrate the potential for FTIs to drive enhanced antitumor activity and address mechanisms of innate and adaptive resistance to targeted therapies such as KRAS inhibitors and tyrosine kinase inhibitors.

- **Clinical collaboration with Mirati to evaluate KO-2806 and adagrasib in $KRAS^{G12C}$-mutated NSCLC** – Earlier today, Kura announced a clinical collaboration and supply agreement with Mirati Therapeutics to evaluate the combination of KO-2806 and adagrasib in patients with $KRAS^{G12C}$-mutated NSCLC. Under the terms of the agreement, Kura will sponsor the Phase 1 study and Mirati will supply adagrasib for the study. The collaboration highlights the potential to address the urgent need for more durable and effective treatment options for patients with cancers driven by the $KRAS^{G12C}$-mutant oncogene.

- **Brian Powl appointed as Chief Commercial Officer** – Mr. Powl joined Kura in August 2023 with more than two decades of experience in building commercial brands in hematology and oncology, with expertise in developing and executing patient-focused strategies across sales, marketing and market access for global biotech and pharmaceutical products, including extensive global experience in hematologic malignancies.

Financial Results

- Research and development expenses for the third quarter of 2023 were $29.3 million, compared to $25.0 million for the third quarter of 2022.

- General and administrative expenses for the third quarter of 2023 were $13.1 million, compared to $11.6 million for the third quarter of 2022.

- Net loss for the third quarter of 2023 was $38.6 million, compared to a net loss of $35.5 million for the third quarter of 2022. This includes non-cash share-based compensation expense of $7.1 million, compared to $6.4 million for the same period in 2022.

- As of September 30, 2023, Kura had cash, cash equivalents and short-term investments of $452.6 million, compared to $438.0 million as of December 31, 2022.

- Based on its operating plan, management expects that cash, cash equivalents and short-term investments will fund current operations to mid-2026.

Forecasted Milestones

- Report preliminary data from 20 patients in the KOMET-007 trial of ziftomenib in combination with venetoclax and azacitidine or 7+3 early in the first quarter of 2024.
- Dose the first patients in the KOMET-008 trial of ziftomenib in combination with additional standards of care, including the FLT3 inhibitor gilteritinib, in the first quarter of 2024.
- Initiate the ziftomenib post-transplant maintenance program in the first quarter of 2024.
- Complete enrollment of 85 patients in the KOMET-001 registration-directed trial of ziftomenib in NPM1-mutant AML by mid-2024.
- Determine the optimum biologically active dose for tipifarnib in combination with alpelisib and determine next steps for the program by mid-2024.
- Dose the first patients in the FIT-001 dose-escalation trial of KO-2806 in combination with adagrasib in $KRAS^{G12C}$-mutated NSCLC by mid-2024.
- Dose the first patients in the FIT-001 dose-escalation trial of KO-2806 in combination with cabozantinib in ccRCC by mid-2024.

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, November 2, 2023, to discuss the financial results for the third quarter 2023 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: 34983466. 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 is a once-daily, oral drug candidate targeting the menin-KMT2A protein-protein interaction for the treatment of genetically defined AML patients with high unmet need. Kura is currently enrolling patients in a Phase 2 registration-directed trial of ziftomenib in NPM1-mutant relapsed or refractory AML (KOMET-001). The Company is also conducting a series of studies to evaluate ziftomenib in combination with current standards of care, beginning with venetoclax and azacitidine and 7+3 in NPM1-mutant and KMT2A-rearranged newly diagnosed and relapsed/refractory AML (KOMET-007). 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 adagrasib in $KRAS^{G12C}$-mutated NSCLC and

cabozantinib in ccRCC (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 mid-2026. 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 September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Operating Expenses:				
Research and development	$ 29,328	$ 24,973	$ 82,702	$ 70,144
General and administrative	13,145	11,621	36,340	34,565
Total operating expenses	42,473	36,594	119,042	104,709
Other income, net	3,871	1,090	9,197	1,983
Net loss	$ (38,602)	$ (35,504)	$ (109,845)	$ (102,726)
Net loss per share, basic and diluted	$ (0.50)	$ (0.53)	$ (1.53)	$ (1.54)
Weighted average number of shares used in computing net loss per share, basic and diluted	77,241	66,889	71,845	66,723

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

	September 30, 2023	**December 31, 2022**
Cash, cash equivalents and short-term investments	$ 452,593	$ 437,985
Working capital	432,392	422,369
Total assets	473,771	456,306
Long-term liabilities	16,309	11,971
Accumulated deficit	(678,653)	(568,808)
Stockholders' equity	429,937	420,278

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