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 3, 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 August 3, 2023, Kura Oncology, Inc. (the "Company") issued a press release announcing the Company's financial results for the second quarter ended June 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 August 3, 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: August 3, 2023

By: /s/ Teresa Bair

Teresa Bair
Chief Legal Officer

Kura Oncology Reports Second Quarter 2023 Financial Results

– Enrollment in registration-directed trial of ziftomenib in NPM1-mutant AML continues to outperform projections –

– First patients dosed in combination study of ziftomenib in NPM1-mutant and KMT2A-rearranged AML –

– Late-breaking clinical data for ziftomenib in NPM1-mutant AML presented at EHA –

– Continued evidence of clinical activity observed in trial of tipifarnib plus alpelisib in PIK3CA-dependent HNSCC –

– First-in-human study of next-generation FTI KO-2806 to begin in second half of 2023 –

– $477 million in 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, Aug. 3, 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 second quarter 2023 financial results and provided a corporate update.

“With its safety, tolerability and clinical activity profile, we believe ziftomenib has the ideal properties to become part of the backbone of acute myeloid leukemia (AML) therapy across the continuum of patient care,” said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. “Our confidence in the program is strengthened by the late-breaking clinical data presented at the European Hematology Association (EHA) Annual Congress in June, which showed one of the highest response rates reported for a targeted therapy in the setting of relapsed/refractory AML. Building on momentum generated by these data, enrollment in our Phase 2 registration-directed trial of ziftomenib in patients with relapsed/refractory NPM1-mutant AML continues to outperform our projections, an indication of both the size of this population and its significant unmet need. In addition, we are now treating NPM1-mutant and KMT2A-rearranged AML patients with ziftomenib in combination with chemotherapy- and venetoclax-based regimens, and we look forward to sharing preliminary data from this first combination study later this year or early next.”

Recent Highlights

- **Late-breaking clinical data for ziftomenib in NPM1-mutant AML** – In June, Kura reported updated data from the KOMET-001 trial of ziftomenib, including durable activity in patients with heavily pretreated and co-mutated relapsed/refractory NPM1-mutant AML. The data were featured during a late-breaking oral session at the EHA Annual Congress in Frankfurt. As of an April 12th data cutoff, seven of the 20 patients with NPM1-mutant AML treated at the recommended Phase 2 dose (RP2D) of 600 mg achieved complete remission (CR) with full count recovery, for a CR rate of 35% and an overall response rate of 45%. An eighth patient, who had a CR with partial count recovery after treatment with ziftomenib, subsequently evolved to a CR with full count recovery after stem cell transplant and remained on study as of the EHA presentation. In addition, a patient with NPM1-mutant AML treated at 200 mg remained on ziftomenib for 36 cycles as of the cutoff date. The median duration of response for all NPM1-mutant patients was 8.2 months, with a median follow-up of 8.8 months. Continuous once-daily dosing of ziftomenib was well tolerated in the Phase 1 trial and the reported adverse event profile remained consistent with features of underlying disease.

- **Enrollment in registration-directed trial of ziftomenib continues to outperform projections** – Enrollment in Kura's Phase 2 registration-directed trial of ziftomenib in NPM1-mutant relapsed or refractory AML continues to outperform the Company's projections. The trial is expected to enroll a total of 85 patients in the U.S. and Europe, with a primary endpoint of CR or CR with partial hematologic recovery (CRh). 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.

- **Multiple patients dosed in combination study of ziftomenib in NPM1-mutant and KMT2A-rearranged AML** – Kura is conducting a series of studies to evaluate ziftomenib in combination with current standards of care in earlier lines of therapy and across multiple patient populations. The Company is now dosing patients in the first of its combination studies, KOMET-007, in patients with NPM1-mutant and KMT2A-rearranged AML in the newly diagnosed and relapsed/refractory settings**.** KOMET-007 is a Phase 1 study designed to assess safety, tolerability and preliminary activity of ziftomenib in combination with venetoclax/azacitidine (ven/aza) or standard induction cytarabine/daunorubicin chemotherapy (7+3). Kura anticipates having preliminary data from the KOMET-007 study in the fourth quarter of 2023 or first quarter of 2024.

- **Continued evidence of clinical activity observed with tipifarnib plus alpelisib in PIK3CA-dependent HNSCC –** Previously, Kura reported the first demonstration of a durable clinical response with the combination of its farnesyl transferase inhibitor (FTI) tipifarnib and the PI3K alpha inhibitor alpelisib in PIK3CA-mutant head and neck squamous cell carcinoma (HNSCC). In the meantime, dose escalation in the Company's KURRENT-HN trial of tipifarnib and alpelisib has

continued, with ongoing evidence of clinical activity at multiple doses and no dose-limiting toxicities to date. Kura is now evaluating patients in the trial's highest planned dose cohort to inform selection of the optimal biologically active dose for the combination, after which the Company intends to initiate a small dose expansion of patients with PIK3CA-mutant HNSCC to validate the safety profile and activity of the combination at the RP2D. Head and neck cancer is the seventh most common cancer worldwide and remains a significant unmet need, with no approved small molecule targeted therapies.

- **First-in-human study of KO-2806 to begin in second half of 2023** – KO-2806 is a next-generation inhibitor of farnesyl transferase designed to improve upon potency, pharmacokinetic and physicochemical properties of earlier FTI drug candidates. Earlier this year, Kura received FDA clearance of its Investigational New Drug application for KO-2806. Site activation has now begun in a Phase 1 dose-escalation trial of KO-2806 (FIT-001) and the Company expects to dose the first patients in the second half of 2023. Concurrent with dose escalation as a monotherapy, Kura also plans to evaluate KO-2806 in dose escalation combination cohorts in advanced solid tumors, beginning with clear cell renal cell carcinoma (ccRCC).

Financial Results

- Research and development expenses for the second quarter of 2023 were $28.2 million, compared to $24.3 million for the second quarter of 2022.

- General and administrative expenses for the second quarter of 2023 were $11.8 million, compared to $11.1 million for the second quarter of 2022.

- Net loss for the second quarter of 2023 was $37.2 million, compared to a net loss of $34.8 million for the second quarter of 2022. This includes non-cash share-based compensation expense of $7.0 million, compared to $6.5 million for the same period in 2022.

- As of June 30, 2023, Kura had cash, cash equivalents and short-term investments of $477.0 million, compared to $438.0 million as of December 31, 2022. This includes net proceeds of approximately $93.6 million from the Company's public offering completed in June 2023.

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

Forecasted Milestones

- 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 second half of 2023.

- Preliminary data from the KOMET-007 trial of ziftomenib in combination with ven/aza or 7+3 in the fourth quarter of 2023 or first quarter of 2024.
- Dose the first patients in the ziftomenib post-transplant maintenance program in the first quarter of 2024.
- Initiate dose expansion in the KURRENT-HN trial of tipifarnib and alpelisib in mid-2024.
- Dose the first patients in the FIT-001 monotherapy dose-escalation trial of KO-2806 as a monotherapy in the second half of 2023.
- Dose the first patients in the FIT-001 dose-escalation trial of KO-2806 in combination with a targeted therapy in ccRCC in the second half of 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, August 3, 2023, to discuss the financial results for the second 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: 26884460. 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/azacitidine and standard induction cytarabine/daunorubicin chemotherapy 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 preparing to evaluate KO-2806, a next-generation FTI, in a Phase 1 dose-escalation trial as a monotherapy and in combination with other targeted therapies, beginning with ccRCC (FIT-001). For additional information, please visit Kura's website at www.kuraoncology.com and follow us on Twitter 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 into 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 June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Operating Expenses:				
Research and development	$ 28,182	$ 24,258	$ 53,374	$ 45,171
General and administrative	11,821	11,075	23,195	22,944
Total operating expenses	40,003	35,333	76,569	68,115
Other income, net	2,829	564	5,326	893
Net loss	$ (37,174)	$ (34,769)	$ (71,243)	$ (67,222)
Net loss per share, basic and diluted	$ (0.53)	$ (0.52)	$ (1.03)	$ (1.01)
Weighted average number of shares used in computing net loss per share, basic and diluted	69,795	66,672	69,103	66,639

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

	June 30, 2023	December 31, 2022
Cash, cash equivalents and short-term investments	$ 476,979	$ 437,985
Working capital	461,747	422,369
Total assets	494,737	456,306
Long-term liabilities	11,160	11,971
Accumulated deficit	(640,051)	(568,808)
Stockholders' equity	459,678	420,278

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