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, 2022

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, 2022, Kura Oncology, Inc. (the "Company") issued a press release announcing the Company's financial results for the second quarter ended June 30, 2022 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, 2022
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, 2022

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

Kura Oncology Reports Second Quarter 2022 Financial Results

– Recommended Phase 2 dose for ziftomenib identified, pending FDA review –

– Additional 18 patients enrolled in KOMET-001 trial of ziftomenib in NPM1-mutant and KMT2A-rearranged AML –

– Preliminary activity observed in KURRENT-HN trial of tipifarnib plus alpelisib in PIK3CA-dependent HNSCC, first patient dosed in HRAS overexpression cohort –

– $450 million in cash, cash equivalents and investments provide runway through 2024 –

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

SAN DIEGO, August 3, 2022 – 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 2022 financial results and provided a corporate update.

“We continue to advance our programs toward a series of important milestones later this year,” said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. “For our menin inhibitor program, we have nearly completed our assessment of patients in the Phase 1b expansion cohorts of our KOMET-001 trial required to identify a recommended Phase 2 dose and remain enthusiastic about the potential for ziftomenib in the treatment of acute leukemias. We look forward to sharing the recommended Phase 2 dose later this year, pending FDA review, along with topline data from the Phase 1b study, followed by a more complete dataset at a medical meeting in the fourth quarter.”

“For our farnesyl transferase inhibitor (FTI) program,” Dr. Wilson continued, “we are encouraged by the preliminary safety and tolerability of tipifarnib in combination with the PI3Kα inhibitor, alpelisib, as well as early evidence of clinical activity observed in our KURRENT-HN trial. Meanwhile, we remain on track to initiate our KURRENT-LUNG trial of tipifarnib in combination with the EGFR inhibitor, osimertinib, later this quarter and submit an investigational new drug (IND) application for our next-generation FTI, KO-2806, by year end. And we approach these milestones from a position of financial strength, with $450 million in cash and investments that provide runway through 2024.”

Recent Highlights

- **Recommended Phase 2 dose for ziftomenib identified, pending FDA review** – In May 2022, Kura announced that it completed enrollment of the 24 patients in the Phase 1b expansion cohorts of the KOMET-001 trial required to identify a recommended Phase 2 dose for ziftomenib. The two Phase 1b expansion cohorts – 200 mg and 600 mg – are each comprised of patients with NPM1-mutant or KMT2A-rearranged relapsed/refractory acute myeloid leukemia (AML). The Company has nearly completed its assessment of the patients for efficacy, safety and tolerability as well as pharmacokinetics and exposure, and believes it has identified a recommended Phase 2 dose for ziftomenib, pending FDA review.

- **Additional 18 patients enrolled in KOMET-001 trial** – Since May 2022, Kura has enrolled an additional 18 patients with NPM1-mutant or KMT2A-rearranged relapsed/refractory AML in the Phase 1b expansion cohorts as the Company prepares to transition into the Phase 2 registration-directed portion of the KOMET-001 trial and initiate a series of combination studies in the relapsed and frontline settings, pending determination of the recommended Phase 2 dose in consultation with the FDA. Kura believes data from all patients treated at the recommended Phase 2 dose will have the potential to contribute to the registrational patient population.

- **Preliminary activity observed in KURRENT-HN trial of tipifarnib plus alpelisib** –Enrollment continues in the Phase 1/2 KURRENT-HN trial of tipifarnib in combination with the PI3Kα inhibitor, alpelisib, in patients with head and neck squamous cell carcinoma (HNSCC). The initial cohort includes patients who have PIK3CA-dependent HNSCC. In addition, the first patient has been dosed in a second cohort of patients with HRAS overexpression. Kura is encouraged by the preliminary safety and tolerability of the combination thus far, as well as early evidence of clinical activity. The Company believes the combination with alpelisib has the potential to increase the total addressable population for tipifarnib to as much as 50% of patients with HNSCC.

- **KURRENT-LUNG trial of tipifarnib plus osimertinib to initiate this quarter** – Kura is preparing to initiate a Phase 1 KURRENT-LUNG trial of tipifarnib in combination with osimertinib in EGFR-mutated non-small cell lung cancer (NSCLC) later this quarter. Preclinical data, generated through a collaboration with INSERM (the French National Institute of Health and Medical Research), support the potential of tipifarnib to prevent emergence of resistance to osimertinib in EGFR-mutant NSCLC. The Company intends to perform initial clinical evaluation with tipifarnib while advancing its next-generation FTI, KO-2806, through IND-enabling studies.

Financial Results

- Research and development expenses for the second quarter of 2022 were $24.3 million, compared to $21.1 million for the second quarter of 2021. The increase in R&D expenses was primarily due to increases in clinical trial costs related to the ziftomenib program and personnel costs.
- General and administrative expenses for the second quarter of 2022 were $11.1 million, compared to $12.6 million for the second quarter of 2021. The decrease in G&A expenses was primarily due to decreases in personnel costs and professional fees.
- Net loss for the second quarter of 2022 was $34.8 million, compared to a net loss of $33.7 million for the second quarter of 2021.This included non-cash share-based compensation expense of $6.5 million, compared to $6.0 million for the same period in 2021.
- Cash, cash equivalents and short-term investments totaled $450.3 million as of June 30, 2022, compared with $518.0 million as of December 31, 2021. Based on its operating plan, management expects that cash, cash equivalents and short-term investments will fund current operations through 2024.

2022 Milestones

- Determine the recommended Phase 2 dose for ziftomenib in consultation with the FDA and report topline data from the Phase 1b study later this year.
- Present updated data from KOMET-001 at a medical meeting in the fourth quarter.
- Initiate the KURRENT-LUNG trial of tipifarnib and osimertinib in the third quarter.
- Submit an IND application for KO-2806 in the fourth quarter.

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, 2022, to discuss the financial results for the second quarter 2022 and to provide a corporate update. The live call may be accessed by dialing (888) 882-4478 for domestic callers and (323) 794-2590 for international callers and entering the conference ID: 8696904. 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 (KO-539), a potent and selective menin inhibitor, is currently in a Phase 1b clinical trial (KOMET-001) for patients with relapsed/refractory AML, including patients with NPM1 mutations or KMT2A rearrangements. Tipifarnib, a potent, selective and orally bioavailable FTI, has received Breakthrough Therapy Designation for the treatment of patients with HRAS mutant HNSCC and is currently in a registration-directed trial (AIM-HN) in patients with this devastating disease. In addition, Kura is conducting a Phase 1/2 trial (KURRENT-HN) of tipifarnib in combination with the PI3Kα inhibitor alpelisib to address larger genetic subsets of HNSCC patients, including those whose tumors are dependent on HRAS and/or PI3Kα pathways. The Company is also preparing to initiate a Phase 1 trial (KURRENT-LUNG) of tipifarnib in combination with osimertinib in treatment-naïve locally advanced/metastatic EGFR mutated NSCLC. Kura intends to perform initial clinical evaluation with tipifarnib while in parallel advancing KO-2806, the Company's next-generation FTI, through IND-enabling studies. For additional information, please visit Kura's website at www.kuraoncology.com.

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 adequacy of cash on hand. 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, including the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2022, 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,	
	2022	**2021**	**2022**	**2021**
Operating Expenses:				
Research and development	$ 24,258	$ 21,074	$ 45,171	$ 41,398
General and administrative	11,075	12,573	22,944	23,145
Total operating expenses	35,333	33,647	68,115	64,543
Other income (expense), net	564	(16)	893	186
Net loss	$ (34,769)	$ (33,663)	$ (67,222)	$ (64,357)
Net loss per share, basic and diluted	$ (0.52)	$ (0.51)	$ (1.01)	$ (0.97)
Weighted average number of shares used in computing net loss per share, basic and diluted	66,672	66,282	66,639	66,250

KURA ONCOLOGY, INC.

Balance Sheet Data

(unaudited)

(in thousands)

	June 30, 2022	**December 31, 2021**
Cash, cash equivalents and short-term investments	$ 450,258	$ 517,960
Working capital	441,913	499,834
Total assets	471,425	534,051
Long-term liabilities	4,061	4,987
Accumulated deficit	(500,190)	(432,968)
Stockholders' equity	449,491	506,609

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