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 7, 2025

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 7, 2025, Kura Oncology, Inc. (the "Company") issued a press release announcing the Company's financial results for the second quarter ended June 30, 2025 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 7, 2025
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 7, 2025

By: /s/ Teresa Bair

Teresa Bair
Chief Legal Officer

Exhibit 99.1

Kura Oncology Reports Second Quarter 2025 Financial Results

– FDA Priority Review of New Drug Application (NDA) for ziftomenib in adults with R/R NPM1-m AML with Prescription Drug User Fee Act (PDUFA) target action date set for November 30, 2025 –

– Fully engaged in commercial readiness activities in alignment with regulatory review timeline –

– KOMET-017-IC (intensive chemotherapy) and NIC (non-intensive chemotherapy) phase 3 studies in newly diagnosed AML on track to start in 2H 2025 –

– Three clinical abstracts from Kura's farnesyl transferase inhibitors (FTI) development program accepted for presentation at the 2025 ESMO Congress –

– $630.7 million in pro forma cash, together with anticipated collaboration agreement payments, expected to support ziftomenib commercialization through the frontline AML combination setting –

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

SAN DIEGO, August 7, 2025 – 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 2025 financial results and provided a corporate update.

"FDA's acceptance of our NDA for ziftomenib represents another important step toward addressing a high unmet need in patients with relapsed or refractory NPM1-mutant AML," said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. "As a menin inhibitor, ziftomenib targets a fundamental disease driver in certain genetically defined subsets of AML, and along with our partners at Kyowa Kirin, we are committed to advancing ziftomenib as a potential therapy for patients throughout the continuum of care. With preparations underway for commercialization, upcoming initiation of two registrational trials of ziftomenib in the frontline setting and a strong pipeline to support future growth, we believe Kura is well-positioned to deliver meaningful benefit to patients and long-term value to stakeholders."

Recent Highlights

- **FDA Priority Review of New Drug Application for ziftomenib with PDUFA target action date of November 30, 2025** – In June 2025, Kura and Kyowa Kirin Co., Ltd. (Kyowa Kirin) announced the U.S. Food and Drug Administration (FDA) accepted Kura's NDA seeking full approval for ziftomenib as a treatment for adult patients with relapsed or refractory (R/R) acute myeloid leukemia (AML) with a nucleophosmin 1 mutation (NPM1-m). Ziftomenib is the only menin inhibitor to receive Breakthrough Therapy Designation (BTD) for this indication. The application has been granted Priority Review and assigned a PDUFA target action date of November 30, 2025***.***

- **Commercial readiness activities advancing in line with the regulatory review timeline –** Pre-launch efforts by medical affairs, market access, patient support, and sales continue. Hiring and onboarding of U.S. field sales team are now complete. Pre-approval information exchange with key stakeholders across the AML ecosystem is ongoing.

- **Presentation of positive results from the KOMET-001 pivotal trial of ziftomenib in R/R NPM1-m AML at 2025 ASCO Annual Meeting** – The study achieved a complete remission (CR) plus CR with partial hematologic recovery (CRh) rate of 23%, an improvement over historical controls in a heavily pretreated patient population with limited survival and few treatment options. Key safety and tolerability measures, including manageable differentiation syndrome, low rates of ziftomenib-related myelosuppression and treatment discontinuation, absence of clinically significant QTc prolongation and minimal drug-drug interactions highlighted a potentially favorable benefit-risk profile for ziftomenib.

- **Presentation of clinical data from the Phase 1b expansion cohort of KOMET-007 evaluating ziftomenib in combination with intensive chemotherapy (7+3) in newly diagnosed *NPM1*-m and *KMT2A*-rearranged AML at 2025 EHA Congress –** High rates of CR and measurable residual disease (MRD) negativity with ziftomenib in combination with intensive chemotherapy in newly diagnosed NPM1-m and KMT2A-rearranged (KMT2A-r) AML were reported. Among patients achieving a composite CR, 68% of NPM1-m and 83% of KMT2A-r patients reached MRD-negative status at a median of ~4–5 weeks. At a median follow-up of 25 and 16 weeks, 96% and 88% of patients in the respective cohorts remained alive and on study. Ziftomenib was well tolerated, enabling patients to remain on treatment through consolidation and maintenance, without interruption, dose reduction, or added myelosuppression.

- **Nomination of next-generation menin inhibitor designed for the treatment of Type 1 and Type 2 diabetes and menin-dependent cardiometabolic indications** - In preclinical models of type 2 diabetes, ziftomenib has been shown to improve glucose control, enhance insulin production, reduce insulin resistance, and selectively induce beta-cell proliferation, supporting menin as a therapeutic target for beta-cell regeneration. Kura has nominated a next-generation menin inhibitor for evaluation in diabetes. Development plans and timelines will be announced in a future update.

- **Three clinical abstracts from Kura's farnesyl transferase inhibitor (FTI) program accepted for presentation at the 2025 ESMO Congress -** The presentations will include the first clinical data on Kura's lead investigational FTI therapy, KO-2806, in combination with cabozantinib in renal cell carcinoma (Poster #2604P), as well as KO-2806 monotherapy in advanced RAS-mutant solid tumors (Poster #981P). An additional abstract will highlight clinical data from the combination of the FTI tipifarnib and alpelisib in patients with PIK3CA-mutant head and neck squamous cell carcinoma (HNSCC) (Poster #1349P).

Financial Results

- Collaboration revenue from our Kyowa Kirin partnership for the second quarter of 2025 was $15.3 million, compared to no revenue for the second quarter of 2024.

- Research and development expenses for the second quarter of 2025 were $62.8 million, compared to $39.7 million for the second quarter of 2024.

- General and administrative expenses for the second quarter of 2025 were $25.2 million, compared to $16.7 million for the second quarter of 2024.

- Net loss for the second quarter of 2025 was $66.1 million, compared to a net loss of $50.8 million for the second quarter of 2024. Net loss for the second quarter included non-cash share-based compensation expense of $6.9 million, compared to $8.4 million for the same period in 2024.

- As of June 30, 2025, Kura had cash, cash equivalents and short-term investments of $630.7 million, compared to $727.4 million as of December 31, 2024.

- Based on our current plans, we believe that our cash, cash equivalents and short-term investments as of June 30, 2025 will be sufficient to enable us to fund our current operating expenses into 2027, and, combined with anticipated funding under our collaboration agreement with Kyowa Kirin, should support our ziftomenib AML program through commercialization in the frontline combination setting.

Forecasted Milestones

- Continued regulatory interactions with the FDA ahead of the November 30, 2025 PDUFA target action date for ziftomenib as a monotherapy for adult patients with relapsed or refractory NPM1-m AML.
- Initiate KOMET-017, two independent Phase 3 registration-enabling trials in frontline intensive chemotherapy and non-intensive chemotherapy AML settings, in the second half of 2025.
- Present preliminary clinical data from the KOMET-007 Phase 1b expansion cohort evaluating ziftomenib in combination with venetoclax and azacitidine in the second half of 2025.
- Initiate one or more FIT-001 expansion cohorts of KO-2806 and cabozantinib in patients with advanced renal cell carcinoma in the second half of 2025.
- Present data from the FIT-001 Phase 1 trial evaluating KO-2806 and cabozantinib in patients with renal cell carcinoma at the 2025 ESMO Congress in October 2025.
- Present data from the FIT-001 Phase 1 monotherapy dose escalation of KO-2806 in patients with RAS-mutant solid tumors at the 2025 ESMO Congress in October 2025.
- Present data from the KURRENT-HN trial evaluating tipifarnib and alpelisib in *PIK3CA*-dependent HNSCC at the 2025 ESMO Congress in October 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, August 7, 2025, to discuss the financial results for the second quarter of 2025 and to provide a corporate update. The live call may be accessed by dialing (800) 579-2543 for domestic callers and (785) 424-1789 for international callers and entering the conference ID: KURAQ2. A live webcast and archived replay of the event will be available here or online from the investor relations section of the Company's 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 designed to target cancer signaling pathways. Ziftomenib, a once-daily, oral menin inhibitor, is the first and only investigational therapy to receive Breakthrough Therapy Designation (BTD) from the U.S. Food and Drug Administration (FDA) for the treatment of relapsed or refractory (R/R) *NPM1*-mutant (*NPM1*-m) acute myeloid leukemia (AML). In November 2024, Kura

Oncology entered into a global strategic collaboration agreement with Kyowa Kirin to develop and commercialize ziftomenib for AML and other hematologic malignancies. Enrollment in KOMET-001, a Phase 2 registration-directed trial of ziftomenib in R/R *NPM1*-m AML, has been completed, and in the second quarter of 2025, the companies announced the FDA's acceptance of a New Drug Application for ziftomenib for the treatment of adult patients with R/R *NPM1*-m AML and assignment of a Prescription Drug User Fee Act target action date of November 30, 2025. Kura and Kyowa Kirin are conducting a series of clinical trials to evaluate ziftomenib in combination with current standards of care in newly diagnosed and R/R *NPM1*-m and *KMT2A*-rearranged AML. Ziftomenib is also being evaluated in a Phase 1 dose-escalation trial (KOMET-015) in combination with imatinib for treatment of patients with advanced gastrointestinal stromal tumors (GIST). KO-2806, a next-generation farnesyl transferase inhibitor (FTI), is being evaluated in a Phase 1 dose-escalation trial (FIT-001) as a monotherapy and in combination with targeted therapies for patients with various solid tumors. Tipifarnib, a potent and selective FTI, is currently in a Phase 1/2 trial (KURRENT-HN) in combination with alpelisib for patients with *PIK3CA*-dependent head and neck squamous cell carcinoma. For additional information, please visit the Kura website at https://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, KO-2806 and tipifarnib; the expected timing of clinical trials; the expected timing and presentation of results and data from clinical trials; the potential duration of FDA's review of the NDA; the potential FDA approval of product candidates; the success and impact of interactions with the FDA; 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 and, combined with anticipated collaboration funding under the Kyowa Agreement, to support Kura's ziftomenib AML program through commercialization in the 1L combination setting. 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, 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, the risk that the collaboration with Kyowa Kirin is unsuccessful, 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,	
	2025	**2024**	**2025**	**2024**
Collaboration revenue	$ 15,288	$ —	$ 29,396	$ —
Operating expenses				
Research and development	62,785	39,727	118,758	75,995
General and administrative	25,169	16,677	48,004	34,861
Total operating expenses	87,954	56,404	166,762	110,856
Other income, net	6,544	5,567	14,041	10,494
Income tax expense	—	—	(226)	—
Net loss	$ (66,122)	$ (50,837)	$ (123,551)	$ (100,362)
Net loss per share, basic and diluted	$ (0.75)	$ (0.59)	$ (1.41)	$ (1.18)
Weighted average number of shares used in computing net loss per share, basic and diluted	87,586	86,635	87,501	85,270

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

	June 30, 2025	**December 31, 2024**
Cash, cash equivalents and short-term investments	$ 630,728	$ 727,395
Working capital	552,901	666,117
Total assets	682,425	760,159
Long-term liabilities	269,765	267,807
Accumulated deficit	(1,018,973)	(895,422)
Stockholders’ equity	305,486	413,640

Contacts

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