

**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 4, 2021

KURA ONCOLOGY, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-37620
(Commission File Number)

61-1547851
(IRS Employer
Identification No.)

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

92130
(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 4, 2021, Kura Oncology, Inc. (the “Company”) issued a press release announcing the Company’s financial results for the third quarter ended September 30, 2021 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 4, 2021
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 4, 2021

By: /s/ Teresa Bair

Teresa Bair
Chief Legal Officer



Kura Oncology Reports Third Quarter 2021 Financial Results

- Continued enrollment in Phase 1b study of menin inhibitor KO-539 in NPM1-mutant and KMT2A-rearranged relapsed/refractory AML –
- ASH presentation to highlight molecular mechanisms of activity for KO-539 and potential for synergistic activity in combination with venetoclax –
 - First clinical site activated in Phase 1/2 trial of tipifarnib plus alpelisib in HNSCC –
 - \$543.4 million in cash, cash equivalents and investments provide runway into 2024 –
 - Management to host webcast and conference call today at 4:30 p.m. ET –

SAN DIEGO, Nov. 4, 2021 – 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 2021 financial results and provided a corporate update.

“I am pleased by the progress our team has made over the past quarter, highlighted by accelerated enrollment in the Phase 1b expansion cohorts for KO-539,” said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. “We continue to be encouraged by preliminary results from the Phase 1b study, with evidence of activity at both doses and a favorable safety and tolerability profile. Pending determination of a recommended Phase 2 dose, we are designing a development strategy that builds on the potential to register KO-539 as a monotherapy, while giving us the flexibility to get to larger opportunities in combination more quickly, including in earlier lines of therapy. We look forward to providing a more comprehensive update, including results from the Phase 1a and Phase 1b studies, at a future medical meeting.”

Recent Highlights

- **Continued enrollment in Phase 1b expansion cohorts for KO-539** – Kura is currently enrolling two expansion cohorts in the Phase 1b portion of its KOMET-001 trial – a lower dose of 200 mg and a higher dose of 600 mg. Each cohort is comprised of patients with NPM1-mutant or KMT2A-rearranged relapsed or refractory acute myeloid leukemia (AML). Approximately half of an estimated 40 global sites are now actively screening patients for enrollment in the study. The Company maintains its enrollment guidance of 12 evaluable patients in each cohort by the first quarter of 2022. Once enrolled, patients in each cohort will be assessed
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for safety and tolerability, pharmacokinetics and efficacy to determine the recommended Phase 2 dose for KO-539.

- **Comprehensive clinical development strategy for KO-539** – Pending determination of a recommended Phase 2 dose, Kura intends to conduct a comprehensive clinical development plan for KO-539, both as a monotherapy and in combination. This development strategy builds on the potential to register KO-539 as a monotherapy while giving the Company the flexibility to address larger opportunities in combination more efficiently, including earlier lines of therapy.
 - **ASH presentation to highlight potential for synergistic activity of KO-539 with venetoclax** – Encouraging pre-clinical data has been generated through a research collaboration with Dr. Kapil Bhalla at the MD Anderson Cancer Center highlighting the molecular mechanisms of anti-leukemic activity for KO-539 and its potential for synergistic activity in combination with venetoclax in KMT2A-rearranged and NPM1-mutant AML models. These data have been accepted for presentation at the upcoming American Society of Hematology (ASH) Annual Meeting in December 2021. The abstract was published earlier today and is now available on the ASH website.
 - **Final results from Phase 2 study of tipifarnib in T-cell lymphoma at ASH** – Final results from a Phase 2 study of tipifarnib in patients with relapsed or refractory peripheral T-cell lymphoma (PTCL) have been accepted for oral presentation by Dr. Thomas Witzig, Hematologist at Mayo Clinic and the study's lead investigator, at the upcoming ASH Annual Meeting. The abstract is now available on the ASH website. The clinical benefit demonstrated in patients with certain subtypes of T-cell lymphoma, including an overall response rate of 56.3% (18/32) and a median overall survival of 32.8 months in patients with angioimmunoblastic T-cell lymphoma (AITL), underscores the potential to target farnesyl transferase to drive clinical benefit in patients with cancer.
 - **First clinical site activated in Phase 1/2 trial of tipifarnib plus alpelisib in HNSCC** – In July, Kura announced a clinical collaboration with Novartis to evaluate the combination of tipifarnib and the PI3K α inhibitor alpelisib in patients with head and neck squamous cell carcinoma (HNSCC). The Company believes this combination has the potential to increase the total addressable population for tipifarnib to as much as 50% of patients with HNSCC and is now beginning a Phase 1/2 clinical trial (KURRENT) of tipifarnib in combination with alpelisib in patients who have HRAS- and/or PIK3CA-dependent HNSCC. Kura has now activated the first clinical site and expects to dose the first patient in the trial by the end of 2021.
 - **Next-generation FTI program focused on delaying onset of drug resistance in large solid tumor indications** – Last quarter, Kura nominated KO-2806 as the lead development candidate in its next-generation farnesyl transferase inhibitor (FTI) program. The Company's next-generation FTI program is designed to target innovative biology and address large solid tumor indications of high unmet need
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through rational combinations, with a focus on delaying the onset of drug resistance. IND-enabling studies of KO-2806 are ongoing.

Financial Results and Guidance

- Research and development expenses for the third quarter of 2021 were \$22.4 million, compared to \$16.6 million for the third quarter of 2020.
- General and administrative expenses for the third quarter of 2021 were \$11.3 million, compared to \$7.6 million for the third quarter of 2020.
- Net loss for the third quarter of 2021 was \$33.4 million, compared to a net loss of \$23.8 million for the third quarter of 2020. This included non-cash share-based compensation expense for the third quarter of 2021 of \$6.1 million, compared to \$3.4 million for the same period in 2020.
- Cash, cash equivalents and short-term investments totaled \$543.4 million as of September 30, 2021, compared with \$633.3 million as of December 31, 2020.
- Operating expenses for the full year 2021 are expected to be in the range of \$130 million to \$140 million.
- Net cash used in operating activities for the full year 2021 is expected to be \$105 million to \$115 million.
- Management expects that current cash, cash equivalents and short-term investments will be sufficient to fund current operations into 2024.

Upcoming Milestones

- Dose first patient in the KURRENT Phase 1/2 study of tipifarnib in combination with alpelisib by the end of 2021.
- Complete enrollment of 24 evaluable patients in the KOMET-001 Phase 1b expansion cohorts by the first quarter of 2022.
- Determine the recommended Phase 2 dose of KO-539 by the first quarter of 2022.
- Submit an IND application for KO-2806 by the end of 2022.

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 4, 2021, to discuss the financial results for the third quarter 2021 and provide a corporate update. The live call may be accessed by dialing (866) 269-4260 for domestic callers and (323) 347-3277 for international callers and entering the

conference code: 9395801. 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. KO-539, a potent and selective menin inhibitor, is currently in a Phase 1/2 clinical trial (KOMET-001) and targeting patients with relapsed/refractory AML, including patients with NPM1 mutations or KMT2A rearrangements. Tipifarnib, a potent, selective and orally bioavailable farnesyl transferase inhibitor, has received Breakthrough Therapy Designation for the treatment of patients with HRAS mutant HNSCC and is currently in a registration-directed study (AIM-HN) in patients with this devastating disease. In addition, Kura is pursuing the use of tipifarnib in combination with other oncology therapeutics to address larger genetic subsets of patients, including those who have HRAS- and/or PIK3CA-dependent HNSCC. The Company is also developing a next-generation farnesyl transferase inhibitor, which is intended to target innovative biology and larger oncology indications through rational combinations. For additional information about Kura, please visit the Company'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, tipifarnib, KO-539 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, 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,	
	2021	2020	2021	2020
Operating Expenses:				
Research and development	\$ 22,367	\$ 16,601	\$ 63,765	\$ 42,873
General and administrative	11,310	7,593	34,455	22,694
Total operating expenses	33,677	24,194	98,220	65,567
Other income (expense), net	311	425	497	2,101
Net loss	\$ (33,366)	\$ (23,769)	\$ (97,723)	\$ (63,466)
Net loss per share, basic and diluted	\$ (0.50)	\$ (0.42)	\$ (1.47)	\$ (1.24)
Weighted average number of shares used in computing net loss per share, basic and diluted	66,353	56,405	66,285	51,169

KURA ONCOLOGY, INC.

Balance Sheet Data

(unaudited)

(in thousands)

	September 30, 2021	December 31, 2020
Cash, cash equivalents and short-term investments	\$ 543,445	\$ 633,320
Working capital	526,979	611,268
Total assets	561,141	647,212
Long-term liabilities	5,459	10,283
Accumulated deficit	(400,225)	(302,502)
Stockholders' equity	533,756	610,905

Contacts

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