

**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): February 24, 2022

**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 February 24, 2022, Kura Oncology, Inc. (the “Company”) issued a press release announcing the Company’s financial results for the fourth quarter and year ended December 31, 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.

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Press release dated February 24, 2022</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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: February 24, 2022

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

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## Kura Oncology Reports Fourth Quarter and Full Year 2021 Financial Results

- Patient enrollment continues in KOMET-001 Phase 1b study of ziftomenib (KO-539) in AML –
  - Multiple milestones and data readouts from KOMET-001 expected in 2022 –
  - First patients dosed in Phase 1/2 study of tipifarnib plus alpelisib in HNSCC –
- Abstract supporting next-generation FTI program accepted for presentation at AACR –
- \$518 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, Feb. 24, 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 fourth quarter and full year 2021 financial results and provided a corporate update.

“We have made meaningful advancements across our programs during the past year, and we begin 2022 with significant momentum, resources and enthusiasm,” said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. “By mid-2022, we expect to have three independent drug development programs with potential to create value in both solid and liquid tumor indications with high unmet need. We anticipate meaningful data catalysts for each of these programs in the next six to 24 months, beginning with top-line data from our KOMET-001 Phase 1b study. And we approach these catalysts from a position of strength, with an experienced team and more than \$500 million in cash.”

### Recent Highlights

- **Patient enrollment continues in KOMET-001 Phase 1b study of ziftomenib (KO-539)** – In January 2022, Kura received authorization from the U.S. Food and Drug Administration (FDA) to proceed with its KOMET-001 trial of ziftomenib (formerly KO-539) in patients with relapsed or refractory acute myeloid leukemia (AML), following agreement with the FDA on an enhanced mitigation strategy for differentiation syndrome. Differentiation syndrome is known to be an on-target effect associated with a number of therapeutic agents, including menin inhibitors, which may induce differentiation of leukemic blasts. Patients already enrolled in the Phase
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1b expansion cohorts were eligible to remain on study during the partial clinical hold and enrollment of new patients has resumed.

- **Multiple milestones and data readouts from KOMET-001 expected in 2022** – Kura expects to complete enrollment of 24 patients in the Phase 1b study of ziftomenib by the second quarter of 2022, after which it will assess the patients in each expansion cohort for safety and tolerability, pharmacokinetics and exposure, as well as efficacy. The Company expects to identify the recommended Phase 2 dose for ziftomenib and report top-line data from the Phase 1b study by the third quarter of 2022, with updated data from KOMET-001 reserved for a medical meeting in the fourth quarter of 2022. Meanwhile, Kura continues to add sites in the U.S. and Europe in anticipation of the subsequent Phase 2 registration-enabling portion of KOMET-001.
- **First patients dosed in Phase 1/2 trial of tipifarnib plus alpelisib in HNSCC** – Last year, Kura announced a clinical collaboration with Novartis to evaluate the combination of tipifarnib and the PI3K $\alpha$  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. In December 2021, the first patient was dosed in a Phase 1/2 clinical trial (KURRENT) of tipifarnib in combination with alpelisib. The initial cohort includes patients who have PIK3CA-dependent HNSCC. The Company expects to initiate an HRAS overexpression cohort in KURRENT by the third quarter of 2022.
- **Preclinical data supporting next-generation FTI program at AACR** – Kura's next-generation farnesyl transferase inhibitor (FTI) program is designed to target novel farnesylated targets and address large solid tumor indications of high unmet need through combination regimens, with a focus on delaying the onset of drug resistance. An abstract from one of the Company's academic collaborators, with preclinical data supporting the first opportunity in non-small cell lung cancer (NSCLC), has been accepted for presentation at the upcoming American Association for Cancer Research Annual Meeting in April 2022. Kura plans to perform initial clinical evaluation with tipifarnib in NSCLC while continuing its IND-enabling studies of KO-2806, the lead development candidate in the Company's next-generation FTI program.

## Financial Results

- Research and development expenses for the fourth quarter of 2021 were \$21.0 million, compared to \$17.5 million for the fourth quarter of 2020. Research and development expenses for the full year 2021 were \$84.7 million, compared to \$60.4 million for the prior year.
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- General and administrative expenses for the fourth quarter of 2021 were \$12.1 million, compared to \$8.8 million for the fourth quarter of 2020. General and administrative expenses for the full year 2021 were \$46.5 million, compared to \$31.5 million for the prior year.
- Net loss for the fourth quarter of 2021 was \$32.7 million, compared to a net loss of \$26.2 million for the fourth quarter of 2020. Net loss for the full year 2021 was \$130.5 million, compared to a net loss of \$89.6 million for the prior year. Net loss for the fourth quarter and full year 2021 included non-cash share-based compensation expense of \$6.4 million and \$23.6 million, respectively, \$3.7 million and \$12.8 million for the same periods in 2020.
- Cash, cash equivalents and short-term investments totaled \$518.0 million as of December 31, 2021, compared with \$633.3 million as of December 31, 2020. Management expects that current cash, cash equivalents and short-term investments will be sufficient to fund current operations into 2024.

## **2022 Milestones**

- Complete enrollment of 24 patients in the KOMET-001 Phase 1b expansion cohorts by the second quarter.
- Identify the recommended Phase 2 dose of ziftomenib (KO-539) and report top-line data from the Phase 1b expansion cohorts by the third quarter.
- Present updated data from KOMET-001 at a medical meeting in the fourth quarter.
- Initiate the HRAS overexpression cohort in the KURRENT trial of tipifarnib plus alpelisib by the third quarter.
- Report preclinical data supporting the use of a FTI to delay the onset of drug resistance in NSCLC in the second quarter.
- Submit an IND application for KO-2806 by the end of the year.

## **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, February 24, 2022, to discuss the financial results for the fourth quarter and full year 2021 and to provide a corporate update. The live call may be accessed by dialing (877) 516-3514 for domestic callers and (281) 973-6129 for international callers and entering the conference code: 8645626. 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](http://www.kuraoncology.com).

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## 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 farnesyl transferase inhibitor (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) of tipifarnib in combination with the PI3K $\alpha$  inhibitor alpelisib to address larger genetic subsets of HNSCC patients, including those whose tumors are dependent on HRAS and/or PI3K $\alpha$  pathways. The Company is also developing KO-2806, a next-generation FTI, 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](http://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

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Exchange Commission, which are available at [www.sec.gov](http://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)

	<b>Three Months Ended December 31,</b>		<b>Year Ended December 31,</b>	
	<b>2021</b>	<b>2020</b>	<b>2021</b>	<b>2020</b>
Operating Expenses:				
Research and development	\$ 20,956	\$ 17,524	\$ 84,721	\$ 60,397
General and administrative	12,082	8,808	46,537	31,502
Total operating expenses	33,038	26,332	131,258	91,899
Other income (expense), net	295	173	792	2,274
Net loss	\$ (32,743)	\$ (26,159)	\$ (130,466)	\$ (89,625)
Net loss per share, basic and diluted	\$ (0.49)	\$ (0.45)	\$ (1.97)	\$ (1.69)
Weighted average number of shares used in computing net loss per share, basic and diluted	66,550	58,760	66,352	53,077

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

	<b>December 31, 2021</b>	<b>December 31, 2020</b>
Cash, cash equivalents and short-term investments	\$ 517,960	\$ 633,320
Working capital	499,834	611,268
Total assets	534,051	647,212
Long-term liabilities	4,987	10,283
Accumulated deficit	(432,968)	(302,502)
Stockholders' equity	506,609	610,905



## Contacts

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