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): May 6, 2021

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 May 6, 2021, Kura Oncology, Inc. (the "Company") issued a press release announcing the Company's financial results for the first quarter ended March 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.

Exhibit Number	Description
99.1	Press release dated May 6, 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: May 6, 2021

By: /s/ James Basta

James Basta
Chief Legal Officer and Secretary

Exhibit 99.1

Kura Oncology Reports First Quarter 2021 Financial Results

– Menin inhibitor KO-539 continues to demonstrate compelling clinical activity, favorable safety/tolerability and a wide therapeutic window –

– KOMET-001 trial amended to include Phase 1b expansion cohorts enriched with NPM1-mutant and KMT2A-rearranged relapsed/refractory AML patients –

– Data from Phase 2 trial of tipifarnib in HRAS mutant head and neck squamous cell carcinoma highlighted in *Journal of Clinical Oncology* –

– $603.9 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, May 6, 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 first quarter 2021 financial results and provided a corporate update.

“We believe KO-539 is well-positioned as a potentially best-in-class and first-in-class menin inhibitor,” said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. “This confidence is supported by a growing body of clinical data, including compelling activity, a favorable safety and tolerability profile and a wide therapeutic window. As such, we intend to conduct a comprehensive clinical development strategy for KO-539, both as a monotherapy and in combination, aimed at providing the greatest benefit to patients with acute leukemia, and we are well funded to execute on this strategy.”

“A critical component of our KO-539 development plan is the determination of an optimal Phase 2 dose,” continued Dr Wilson. “Given the wide therapeutic window of KO-539, we have amended our KOMET-001 trial to include two genetically enriched Phase 1b expansion cohorts. This should enable us to maximize the benefit-risk for KO-539 in our target patient populations and better inform an optimal dose for Phase 2 and beyond. Enrollment in these Phase 1b expansion cohorts is expected to begin mid-year, and we look forward to sharing our progress as we work to bring this important therapeutic option to patients.”

Recent Highlights

- **Enrollment in KOMET-001 Phase 1b expansion cohorts to begin shortly** – KO-539 continues to demonstrate a wide therapeutic window and compelling single-agent activity in an all-comer population of patients with relapsed or refractory acute myeloid leukemia (AML), including patients with NPM1 mutations and KMT2A rearrangements. In order to better inform an optimal Phase 2 dose, Kura has amended its KOMET-001 trial of KO-539 to include two Phase 1b expansion cohorts. Both cohorts will be enriched with NPM1-mutant and KMT2A-rearranged relapsed/refractory AML patients. The Company expects to enroll at least 12 patients in each of the Phase 1b expansion cohorts and assess those patients for safety and tolerability, pharmacokinetics/pharmacodynamics and efficacy in order to determine the recommended Phase 2 dose. In addition, the amended Phase 1b protocol gives the Company flexibility to enroll up to 18 additional patients per cohort, as appropriate. Kura believes the patients enrolled in the cohort selected as the recommended Phase 2 dose have the potential to be included in the subsequent, registration-directed portion of the KOMET-001 trial. Patient enrollment in the genetically enriched Phase 1b expansion cohorts is expected to begin at existing and new clinical sites in mid-2021.

- **Multiple expansion opportunities in acute leukemias** – Pending determination of an optimal Phase 2 dose, Kura is preparing to conduct a comprehensive clinical development plan for KO-539, both as a monotherapy and in combination, aimed at broadening the opportunity in acute leukemias. Additional opportunities include front line combination studies, additional genetic subtypes, a pediatric development strategy and other indications, such as acute lymphocytic leukemia and myelodysplastic syndrome.

- **Publication of tipifarnib Phase 2 data in *Journal of Clinical Oncology*** – Data from Kura's Phase 2 clinical trial (RUN-HN) of tipifarnib were recently published in the *Journal of Clinical Oncology*. These data formed the basis of the Breakthrough Therapy Designation granted by the U.S. Food and Drug Administration (FDA) earlier this year for the treatment of patients with recurrent or metastatic HRAS mutant head and neck squamous cell carcinoma (HNSCC). Tipifarnib is currently being evaluated in an ongoing registration-directed clinical trial (AIM-HN) in this indication of high unmet need.

- **Breakthrough Device Designation for HRAS companion diagnostic** – The FDA has granted Breakthrough Device Designation (BDD) to Illumina for a companion diagnostic to detect HRAS mutations in HNSCC in support of Kura's tipifarnib program, as the device provides for more effective treatment of a life-threatening disease. The next-generation sequencing-based companion diagnostic is being developed in collaboration with Illumina leveraging the content of TruSight Oncology 500. The BDD enables frequent interactions with the FDA and prioritized review on regulatory submissions.

Financial Results

- Research and development expenses for the first quarter of 2021 were $20.3 million, compared to $12.6 million for the first quarter of 2020.
- General and administrative expenses for the first quarter of 2021 were $10.6 million, compared to $7.6 million for the first quarter of 2020.
- Net loss for the first quarter of 2021 was $30.7 million, compared to a net loss of $19.2 million for the first quarter of 2020. This included non-cash share-based compensation expense of $5.1 million, compared to $3.2 million for the same period in 2020.
- Cash, cash equivalents and short-term investments totaled $603.9 million as of March 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.

Upcoming Milestones

- Initiation of genetically enriched Phase 1b expansion cohorts in KOMET-001 in mid-2021
- Additional Phase 1 data from KOMET-001 in the second half of 2021
- Initiation of a Phase 1/2 proof-of-concept study of tipifarnib in combination with a PI3Kα inhibitor in the second half of 2021
- Nomination of a next-generation farnesyl transferase inhibitor Development Candidate in mid-2021

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, May 6, 2021, to discuss the financial results for the first quarter 2021 and provide a corporate update. The live call may be accessed by dialing (888) 771-4371 for domestic callers and (847) 585-4405 for international callers and entering the conference code: 50156205. 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 acute myeloid leukemia, including patients with NPM1 mutations. Tipifarnib, a potent, selective and orally bioavailable farnesyl transferase inhibitor, has received Breakthrough Therapy Designation for the treatment of patients with HRAS mutant head and neck squamous cell carcinoma and is currently in a registration-directed study (AIM-HN) in patients with this devastating disease. Kura 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 and KO-539, 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 March 31,	
	2021	**2020**
Operating Expenses:		
Research and development	$ 20,324	$ 12,575
General and administrative	10,572	7,625
Total operating expenses	30,896	20,200
Other income, net	202	990
Net loss	$ (30,694)	$ (19,210)
Net loss per share, basic and diluted	$ (0.46)	$ (0.42)
Weighted average number of shares used in computing net loss per share, basic and diluted	66,218	45,411

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

	March 31, 2021	**December 31, 2020**
Cash, cash equivalents and short-term investments	$ 603,873	$ 633,320
Working capital	585,566	611,268
Total assets	620,263	647,212
Long-term liabilities	9,137	10,283
Accumulated deficit	(333,196)	(302,502)
Stockholders' equity	585,987	610,905

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