

**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 5, 2019

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.)

3033 Science Park Road, Suite 220, San Diego, CA
(Address of Principal Executive Offices)

92121
(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 5, 2019, Kura Oncology, Inc. (the “Company”) issued a press release announcing the Company’s financial results for the third quarter ended September 30, 2019 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.

<u>Exhibit Number</u>	<u>Description</u>
99.1	<u>Press release dated November 5, 2019</u>

SIGNATURE

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 5, 2019

By: _____ /s/ Marc Grasso, M.D.
Marc Grasso, M.D.
Chief Financial Officer and Chief Business Officer



Kura Oncology Reports Third Quarter 2019 Financial Results and Provides Corporate Update

- Updated data from Phase 2 trial of tipifarnib in HRAS mutant HNSCC support enrichment strategy in ongoing registration-directed trial –
 - Data from Phase 2 trial of tipifarnib in AITL accepted for oral presentation at ASH 2019 –
- Initiation of first-in-class menin-MLL inhibitor KO-539 gives Company three wholly owned, clinical-stage oncology assets –
 - \$250 million in cash, cash equivalents and investments provide runway into second half of 2021 –
 - Management to host webcast and conference call today at 4:30 p.m. ET –

SAN DIEGO, Nov. 5, 2019 – 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 2019 financial results and provided a corporate update.

“We continue to be very encouraged by our growing body of data that support the potential of tipifarnib, highlighted recently by impressive results from our ongoing Phase 2 trial in HRAS mutant head and neck squamous cell carcinomas (HNSCC),” said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. “These data underscore the activity of tipifarnib in this difficult-to-treat patient population, and we believe they increase the probability of success of our registrational strategy in HRAS mutant HNSCC. We continue to execute on our AIM-HN registration-directed trial, which, if positive, will establish tipifarnib as a first-in-class farnesyl transferase inhibitor for patients with cancer. In addition, we look forward to additional data later this year from our ongoing Phase 2 trial in angioimmunoblastic T-cell lymphoma (AITL), an indication for which we are seeking regulatory feedback regarding next steps.”

“Meanwhile, we continue to make steady and encouraging progress with our emerging pipeline programs,” Dr. Wilson continued, “including continued dose escalation of our ERK inhibitor, KO-947, and the initiation of a Phase 1 trial of our first-in-class menin-MLL inhibitor, KO-539, in patients with relapsed or refractory acute myeloid leukemia (AML). We believe both of our early-stage drug candidates represent differentiated approaches that could potentially address large indications with high unmet need, and we look forward to sharing updates on all of our progress in the months ahead.”

Recent Highlights

- **Durable anti-tumor activity in Phase 2 trial of tipifarnib in HRAS mutant HNSCC** – Last week, Kura reported updated data from its RUN-HN Phase 2 trial of tipifarnib in HNSCC patients with high HRAS mutant variant allele frequency at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics in Boston. The preliminary results showed that 10 of the 18 efficacy-evaluable patients achieved a confirmed partial response (PR), for an objective response rate of 56%. In addition, eight patients experienced disease stabilization, including two who achieved an unconfirmed PR, one of whom was awaiting a confirmatory response assessment as of the data cutoff date. The median progression-free survival (PFS) of the 18 evaluable patients treated with tipifarnib was 6.1 months, compared to 2.8 months on their last prior therapy, including 8.3 months among patients who achieved a PR on tipifarnib and 4.5 months for those with stable disease. Patients had a median of two prior lines of therapy (range 0-6), with no responses observed on their last prior therapy.
 - **Updated Phase 2 data support enrichment strategy in ongoing registration-directed trial** – Of the eight efficacy-evaluable patients in the RUN-HN Phase 2 trial who were prospectively enrolled with high HRAS mutant variant allele frequency, three achieved a confirmed PR and five had stable disease, including two who achieved an unconfirmed PR, one of whom is awaiting a confirmatory response assessment. Kura's registration-directed trial, AIM-HN, is designed to enroll at least 59 evaluable HNSCC patients with high HRAS mutant variant allele frequency who have received prior platinum-based therapy. AIM-HN was initiated in November 2018 and is now open in more than 75 clinical sites worldwide. The trial is expected to require approximately two years for full enrollment. Based upon the statistical assumptions, AIM-HN could be positive as soon as 15 responses are confirmed.
 - **Positive Phase 2 trial of tipifarnib in HRAS mutant urothelial carcinoma** – In September 2019, Kura reported that an investigator-sponsored Phase 2 trial of tipifarnib in HRAS mutant urothelial carcinomas met its primary efficacy endpoint prior to completion of enrollment. The trial is being conducted at the Samsung Medical Center in Seoul, South Korea. Five of the 13 evaluable patients experienced confirmed objective responses, with four patients having experienced PFS of greater than 6 months. Further analyses of the trial are ongoing, and data are expected to be presented at a medical meeting next year.
 - **Data from Phase 2 trial of tipifarnib in AITL accepted for oral presentation at ASH.** In June 2019, Kura announced that the primary endpoint was achieved in both expansion cohorts in its Phase 2 trial of tipifarnib in patients with relapsed or refractory peripheral T-cell lymphoma (PTCL). Additional data, including new patients from the AITL expansion cohort, have been accepted for oral presentation at the upcoming American Society of Hematology (ASH) Annual Meeting in December 2019.
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- **Expanded patent exclusivity for tipifarnib** – In September 2019, the U.S. Patent and Trademark Office issued a new patent further extending Kura's exclusivity to the use of any farnesyl transferase inhibitor (FTi) for the treatment of CXCL12-expressing PTCL and AML. This adds to the Company's growing portfolio of patents involving CXCL12 pathway biomarkers and follows the issuance of another patent earlier this year that covers the use of any FTi for the treatment of HRAS mutant HNSCC. These new patents expire in 2037 and 2036, respectively, excluding any possible patent term extension. The Company continues to aggressively pursue additional intellectual property protection, both in the U.S. and abroad.
- **Initiated Phase 1 trial of KO-539 in relapsed or refractory AML** – In September 2019, the first patient was dosed in a Phase 1 trial of KO-539, Kura's first-in-class, potent and selective small molecule inhibitor of the menin-mixed lineage leukemia (menin-MLL) interaction. The Phase 1, open-label, dose-escalation trial is designed to determine the recommended Phase 2 dose or maximum tolerated dose of KO-539 in patients with relapsed or refractory AML. Upon completion of the dose-escalation portion of the trial, expansion cohorts are planned to further assess the safety and activity of KO-539 in specific genetic subgroups, such as patients with MLL fusions or partial tandem duplications and patients with mutations in the NPM1 oncogene.
- **Strengthened senior leadership team and board of directors** – Kura recently added Kathleen Ford as Chief Operating Officer, James Basta as Chief Legal Officer and Diane Parks as a member of the board of directors. Previously, Ms. Ford was Senior Vice President, Head of Global Clinical Operations at Merck Serono, a division of Merck KGaA, Mr. Basta was Senior Vice President, Chief Corporation Counsel at Biogen, and Ms. Parks was most recently Senior Vice President, Head of U.S. Commercial at Kite Pharma. All three are valuable additions to Kura, as the Company continues to advance its three clinical-stage oncology assets and begins to focus on commercial readiness.

Financial Results

- Research and development expenses for the third quarter of 2019 were \$12.5 million, compared to \$11.7 million for the third quarter of 2018.
 - General and administrative expenses for the third quarter of 2019 were \$5.1 million, compared to \$4.3 million for the third quarter of 2018.
 - Net loss for the third quarter of 2019 was \$16.4 million, or \$0.36 per share, compared to \$15.0 million, or \$0.40 per share, for the third quarter of 2018.
 - Cash, cash equivalents and short-term investments totaled \$250.1 million as of September 30, 2019, compared with \$179.0 million as of December 31, 2018.
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- Management continues to expect that current cash, cash equivalents and short-term investments will be sufficient to fund current operations into the second half of 2021.

Upcoming Milestones

- Additional data from the AITL expansion cohort in the ongoing Phase 2 trial of tipifarnib in PTCL at ASH in December 2019
- Regulatory feedback from the Phase 2 trial of tipifarnib in AITL in the first half of 2020
- Additional data from the ongoing Phase 2 trial of tipifarnib in chronic myelomonocytic leukemia (CMML) in the first half of 2020
- Initiation of a proof-of-concept study of tipifarnib in pancreatic cancer in 2020
- Data from the Phase 2 investigator-sponsored trial of tipifarnib in urothelial carcinoma in 2020
- Potential for full enrollment in the AIM-HN registration-directed trial of tipifarnib in HRAS mutant HNSCC by the end of 2020
- Completion of the dose-escalation portion of the Phase 1 trial of KO-947 by the end of 2019 or early 2020
- Initiation of tumor-specific extension cohort(s) in the Phase 1 trial of KO-947 in 2020
- Achievement of a recommended Phase 2 dose in the Phase 1 dose-escalation trial of KO-539 in 2020

Conference Call and Webcast

Kura's management will host a webcast and conference call today at 4:30 p.m. ET / 1:30 p.m. PT, November 5, 2019, to discuss the financial results for the third quarter 2019 and 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: 5159117. A live webcast of the call will be available from the Investors and Media section of the Company's website at www.kuraoncology.com, and a replay will be available shortly after the live event.

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 where there is a strong scientific and clinical rationale to improve outcomes by identifying

those patients most likely to benefit from treatment. Kura's lead drug candidate is tipifarnib, a farnesyl transferase inhibitor, for which the Company is conducting a registration-directed trial in recurrent or metastatic patients with HRAS mutant head and neck squamous cell carcinoma. In addition, tipifarnib is being evaluated in multiple other Phase 2 clinical trials in solid tumor and hematologic indications. Kura's pipeline also includes KO-947, an ERK inhibitor, and KO-539, a menin-MLL inhibitor, both of which are currently in Phase 1 dose-escalation trials. 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-947 and KO-539, progress and expected timing of Kura's drug development programs and clinical trials and submission of regulatory filings, the potential expansion of tipifarnib to additional indications, 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 and applications, 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,	
	2019	2018	2019	2018
Operating Expenses:				
Research and development	\$ 12,540	\$ 11,661	\$ 34,362	\$ 34,703
General and administrative	5,134	4,321	14,154	11,546
Total operating expenses	17,674	15,982	48,516	46,249
Other income, net	1,282	975	3,241	1,899
Net loss	<u>\$ (16,392)</u>	<u>\$ (15,007)</u>	<u>\$ (45,275)</u>	<u>\$ (44,350)</u>
Net loss per share, basic and diluted	<u>\$ (0.36)</u>	<u>\$ (0.40)</u>	<u>\$ (1.11)</u>	<u>\$ (1.30)</u>
Weighted average number of shares used in computing net loss per share, basic and diluted	<u>45,241</u>	<u>37,789</u>	<u>40,805</u>	<u>34,218</u>

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

	September 30, 2019	December 31, 2018
Cash, cash equivalents and short-term investments	\$ 250,126	\$ 178,985
Working capital	239,836	167,582
Total assets	254,602	182,379
Long-term liabilities	7,906	7,779
Accumulated deficit	(195,012)	(149,737)
Stockholders' equity	233,584	160,985

Contacts

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