
**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, 2018

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))

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, 2018, Kura Oncology, Inc. (the “Company”) issued a press release announcing the Company’s financial results for the third quarter ended September 30, 2018 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	Press release dated November 5, 2018

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, 2018

By: _____ /s/ Annette North
Annette North
Senior Vice President and General Counsel



Kura Oncology Reports Third Quarter 2018 Financial Results and Provides Corporate Update

- Registration-directed trial of tipifarnib in HRAS mutant HNSCC now underway –
- Encouraging preliminary clinical activity observed in HRAS mutant SCC cohort –
- Preliminary data from AITL and CXCL12+ cohorts in Phase 2 trial of tipifarnib in PTCL upcoming at ASH –
 - \$187.4 million in cash, cash equivalents and short-term investments –
 - Management to host webcast and conference call today at 4:30 p.m. ET –

SAN DIEGO, November 5, 2018 – Kura Oncology, Inc., (Nasdaq: KURA) a clinical-stage biopharmaceutical company focused on the development of precision medicines for oncology, today reported third quarter 2018 financial results and provided a corporate update.

“We are very encouraged by our growing body of data that support the potential of tipifarnib as a treatment for squamous cell carcinomas characterized by HRAS mutations,” said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. “With our registration-directed trial of tipifarnib in HRAS mutant head and neck squamous cell carcinomas (HNSCC) now underway, we are focused on generating a data package to support an application for marketing approval in that indication, as we work to broaden the potential of tipifarnib in both HRAS mutant and non-HRAS mutant cancers. In that regard, we are encouraged by preliminary signals of clinical activity observed in patients with HRAS mutant SCCs as we believe this may represent a near-term opportunity to expand the use of tipifarnib into a broader set of HRAS mutant cancers.”

“In addition,” Dr. Wilson continued, “we believe the CXCL12 pathway also holds promise for identifying patients who will respond to tipifarnib, and we look forward to showing data next month at the American Society of Hematology (ASH) Annual Meeting from our ongoing Phase 2 clinical trial in patients with peripheral T-cell lymphoma (PTCL) in which we are evaluating, on a prospective basis, the role of the CXCL12 pathway and markers of bone marrow homing as potential biomarkers of clinical activity of tipifarnib.”

Corporate Update

- **Update on positive Phase 2 trial of tipifarnib in HRAS mutant HNSCC** – In October 2018, Kura reported an update on its ongoing Phase 2 trial of tipifarnib in HRAS mutant HNSCC at the European Society for Medical Oncology (ESMO) 2018 Congress. As of the September 7, 2018 clinical data cutoff date, tumor size reductions were observed in nine of 11 evaluable patients, with five confirmed partial responses (PRs), including three patients with durable responses lasting more than 17 months. A sixth patient achieved a confirmed PR after the data cutoff. Four patients had stable disease, including two patients who experienced prolonged disease stabilization lasting more than six months. Only one patient experienced progressive disease as best response.
 - **Preliminary results from cohort of other HRAS mutant SCCs** – Preliminary results from an additional cohort of patients with other HRAS mutant squamous cell carcinomas (SCCs) were also reported at ESMO. One of the two evaluable patients in this cohort achieved a confirmed PR and the other patient achieved prolonged disease stabilization lasting more than eight months. Four patients were not evaluable as of the data cutoff date, including two patients who were pending initial efficacy assessments.
 - **Significant association observed between allele frequency and clinical benefit** – An analysis of available tumor biopsy samples from patients in Kura's ongoing Phase 2 trial in HNSCC/SCC cancers revealed a significant association between the allele frequency of HRAS mutations and clinical benefit. Of the 13 HNSCC and SCC patients with a tumor HRAS mutant allele frequency greater than 20%, six achieved PRs, one achieved an unconfirmed PR and two experienced disease stabilization greater than six months. No meaningful clinical benefit was observed in the seven patients with an allele frequency less than 20%. Based on these observations, Kura has introduced a minimum HRAS mutant allele frequency of 20% as an entry criterion in its registration-directed trial of tipifarnib in HRAS mutant HNSCC and is working to implement the same entry criterion in its ongoing Phase 2 study of tipifarnib in HRAS mutant SCCs.
 - **Initiation of registration-directed trial of tipifarnib in HRAS mutant HNSCC** – Earlier today, Kura announced that its registration-directed trial of tipifarnib in HRAS mutant HNSCC has been initiated and is open for enrollment. The global, multi-center trial has two cohorts: SEQ-HN, a non-interventional screening and outcomes cohort, and AIM-HN, a treatment cohort. AIM-HN is designed to enroll at least 59 patients with HRAS mutant HNSCC who have received prior platinum-based therapy. AIM-HN is expected to take approximately two years to fully enroll, with objective response rate as the primary endpoint. Based on feedback from the U.S. Food and Drug Administration, Kura believes that the trial, if positive, could support an application for accelerated approval.
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- **Preliminary data from expansion cohorts in Phase 2 trial of tipifarnib in PTCL at ASH** – Kura is evaluating, on a prospective basis, the role of the CXCL12 pathway and markers of bone marrow homing as potential biomarkers of clinical activity for tipifarnib in various hematologic malignancies. The Company's ongoing Phase 2 PTCL trial was the first of the three to begin and is actively enrolling patients into two cohorts: 1) patients with angioimmunoblastic T-cell lymphoma (AITL) and 2) patients with PTCL who have the absence of a single nucleotide variation in the 3' untranslated region of the CXCL12 gene. Kura expects to provide preliminary data from these cohorts at ASH in December 2018.

Financial Results

- Research and development expenses for the third quarter of 2018 were \$11.7 million, compared to \$7.1 million for the third quarter of 2017.
- General and administrative expenses for the third quarter of 2018 were \$4.3 million, compared to \$2.4 million for the third quarter of 2017.
- Net loss for the third quarter of 2018 was \$15.0 million, or \$0.40 per share, compared to \$9.3 million, or \$0.38 per share, for the third quarter of 2017.
- Cash, cash equivalents and short-term investments totaled \$187.4 million as of September 30, 2018, compared with \$93.1 million as of December 31, 2017.

Upcoming Milestones

- Preliminary data from AITL and CXCL12+ cohorts in Phase 2 trial of tipifarnib in PTCL at ASH
- Additional biomarker-enriched data from other hematologic indications in 2019
- Additional data from Phase 2 trial of tipifarnib in HRAS mutant SCC in 2019
- Data from Phase 1 dose-escalation trial of ERK inhibitor KO-947 in 2019
- Submission of an investigational new drug application for menin-MLL inhibitor KO-539 in first quarter of 2019

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 today, November 5, 2018, to discuss the financial results for the third quarter of 2018 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: 6593979. 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 will be archived there for 30 days.

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 has initiated a registration-directed trial of tipifarnib in at least 59 recurrent or metastatic patients with HRAS mutant head and neck squamous cell carcinomas. 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, currently in a Phase 1 dose-escalation trial, and KO-539, a menin-MLL inhibitor, currently in preclinical development. For additional information about Kura Oncology, 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 Oncology's product candidates, tipifarnib, KO-947 and KO-539, progress and expected timing of Kura Oncology'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 Oncology'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 Oncology 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 Oncology 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,	
	2018	2017	2018	2017
Operating Expenses:				
Research and development	\$ 11,661	\$ 7,142	\$ 34,703	\$ 18,307
General and administrative	4,321	2,357	11,546	6,775
Total operating expenses	15,982	9,499	46,249	25,082
Other income, net	975	166	1,899	396
Net loss	\$ (15,007)	\$ (9,333)	\$ (44,350)	\$ (24,686)
Net loss per share, basic and diluted	\$ (0.40)	\$ (0.38)	\$ (1.30)	\$ (1.16)
Weighted average number of shares used in computing net loss per share, basic and diluted	37,789	24,344	34,218	21,217

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

	September 30, 2018	December 31, 2017
Cash, cash equivalents and short-term investments	\$ 187,423	\$ 93,145
Working capital	177,487	84,610
Total assets	191,500	95,851
Long-term liabilities	3,988	5,955
Accumulated deficit	(133,640)	(89,290)
Stockholders' equity	174,607	79,865

Contacts

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