

**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): August 1, 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 August 1, 2019, Kura Oncology, Inc. (the “Company”) issued a press release announcing the Company’s financial results for the second quarter ended June 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 August 1, 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: August 1, 2019

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



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

- Registration-directed trial of tipifarnib in HRAS mutant HNSCC ongoing –
- Positive Phase 2 trial of tipifarnib in AITL and CXCL12-driven PTCL support potential paths to registration –
- Additional Phase 2 data in HRAS mutant HNSCC, other SCCs and AITL anticipated in fourth quarter of 2019 –
- Strengthened balance sheet with \$261.4 million in cash, cash equivalents and investments –
- Management to host webcast and conference call today at 4:30 p.m. ET –

SAN DIEGO, August 1, 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 second quarter 2019 financial results and provided a corporate update.

“The past quarter was highlighted by impressive data from our ongoing Phase 2 trial of tipifarnib in peripheral T-cell lymphoma (PTCL),” said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. “These data support the potential to register tipifarnib in both the angioimmunoblastic T-cell lymphoma (AITL) and PTCL not otherwise specified (PTCL-NOS) populations. In addition, we took further steps toward broadening the potential of farnesyl transferase inhibition to treat other CXCL12-driven indications of high unmet need, including diffuse large B-cell lymphoma (DLBCL), cutaneous T-cell lymphoma (CTCL), acute myeloid leukemia (AML) and pancreatic cancer. These advancements, along with the continued execution of our registration-directed study in HRAS mutant head and squamous cell carcinomas (HNSCC), are important steps toward establishing tipifarnib as a first-in-class farnesyl transferase inhibitor for patients with certain genetically defined cancers.”

“As we look toward the second half of this year and early next year, we anticipate a number of milestones across our pipeline programs,” continued Dr. Wilson, “including an update from our ongoing Phase 2 trial of tipifarnib in HRAS mutant HNSCC and other squamous cell carcinomas (SCCs), additional Phase 2 data in AITL, completion of the dose-escalation portion of the Phase 1 trial of our ERK inhibitor, KO-947, and initiation of the Phase 1 trial of our menin-MLL inhibitor, KO-539. With our successful

public offering in June, we have greater resources and flexibility to continue to create value across our pipeline.”

Recent Highlights

- **Registration-directed trial of tipifarnib in HRAS mutant HNSCC** – Kura continues to execute on its initial registration-directed trial of tipifarnib in HRAS mutant HNSCC. The clinical trial has two cohorts: A non-interventional screening and outcomes cohort (SEQ-HN) and a treatment cohort (AIM-HN). AIM-HN is designed to enroll at least 59 evaluable patients with HRAS mutant HNSCC who have received prior platinum-based therapy. AIM-HN initiated in November 2018 and is expected to take approximately two years to fully enroll.
 - **Positive Phase 2 trial of tipifarnib in AITL and CXCL12-driven PTCL** – In June 2019, Kura reported positive data from its ongoing Phase 2 trial of tipifarnib in patients with relapsed or refractory PTCL, including clinical proof-of-concept in the trial's two expansion cohorts: 1) patients with AITL, an aggressive form of T-cell lymphoma often characterized by high levels of CXCL12 expression, and 2) patients with PTCL who lack a single nucleotide variation in the 3'-untranslated region of the CXCL12 gene. The Company believes these data could support the potential registration of tipifarnib in both the AITL and PTCL-NOS patient populations and intends to seek regulatory feedback on next steps for this program. In addition, Kura plans to continue enrolling AITL patients in the trial and expects to provide additional data from this cohort at a medical meeting later this year.
 - **Expanded patent protection for tipifarnib in the U.S. and Europe** – The U.S. Patent and Trademark Office recently issued two new patents further protecting tipifarnib, including a method of treating patients with HRAS mutant HNSCC with any farnesyl transferase inhibitor and a method of treating patients with HRAS mutant non-small cell lung carcinoma with tipifarnib. In addition, the European Patent Office granted a patent directed to the use of tipifarnib as a method of treating patients with HRAS mutant HNSCC. The new patents have an expiration date of August 2036, excluding any possible patent term extension.
 - **Dose escalation in Phase 1 trial of KO-947 advancing** – Kura continues to evaluate dosing regimens for KO-947, its potent and selective small molecule inhibitor of ERK, in an ongoing Phase 1 trial, with a goal of reaching a recommended Phase 2 dose or maximum tolerated dose. The Company expects to complete the dose-escalation portion of the trial by the end of 2019.
 - **Orphan Drug Designation to KO-539 for treatment of AML** – Last week, the U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation to KO-539, Kura's menin-MLL inhibitor for the treatment of AML. The FDA cleared the investigational new drug application for KO-539 in March 2019, and the Company is in the final stages of study startup for a Phase 1 clinical trial of KO-539 in relapsed or refractory AML.
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- **Successful public offering strengthens cash position** – In June 2019, Kura completed a public offering in which the Company sold an aggregate of 6,785,000 shares of common stock at a price of \$17.00 per share. Net proceeds from the public offering, after deducting underwriting discounts, commissions and offering expenses, were approximately \$108.1 million.

Financial Results

- Research and development expenses for the second quarter of 2019 were \$11.4 million, compared to \$11.5 million for the second quarter of 2018.
- General and administrative expenses for the second quarter of 2019 were \$4.5 million, compared to \$3.8 million for the second quarter of 2018.
- Net loss for the second quarter of 2019 was \$14.9 million, or \$0.38 per share, compared to a net loss of \$14.7 million, or \$0.45 per share, for the second quarter of 2018.
- Cash, cash equivalents and short-term investments totaled \$261.4 million as of June 30, 2019, which includes net proceeds of approximately \$108.1 million from a public offering completed in June 2019, compared with \$179.0 million as of December 31, 2018.
- Management expects that current cash, cash equivalents and short-term investments will be sufficient to fund current operations into the second half of 2021.

Upcoming Milestones

- Initiation of the Phase 1 trial of KO-539 in relapsed or refractory AML in the second half of 2019
 - Additional data from the ongoing Phase 2 trial of tipifarnib in HRAS mutant HNSCC and other SCCs in the fourth quarter of 2019
 - Additional data from the AITL expansion cohort in the ongoing Phase 2 trial of tipifarnib in the fourth quarter of 2019
 - Completion of the dose-escalation portion of the Phase 1 trial of KO-947 by the end of 2019
 - 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 the first half of 2020
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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, August 1, 2019, to discuss the financial results for the second 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: 5261899. 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. Kura'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 Kura has initiated a registration-directed trial in recurrent or metastatic patients with HRAS mutant HNSCC. 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, which has been cleared to begin a Phase 1 clinical trial. 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 June 30, | | Six Months Ended June 30, | |
|---|--|--------------------|--------------------------------------|--------------------|
| | 2019 | 2018 | 2019 | 2018 |
| Operating Expenses: | | | | |
| Research and development | \$ 11,440 | \$ 11,476 | \$ 21,822 | \$ 23,042 |
| General and administrative | 4,451 | 3,800 | 9,020 | 7,225 |
| Total operating expenses | 15,891 | 15,276 | 30,842 | 30,267 |
| Other income, net | 948 | 537 | 1,959 | 924 |
| Net loss | <u>\$ (14,943)</u> | <u>\$ (14,739)</u> | <u>\$ (28,883)</u> | <u>\$ (29,343)</u> |
| Net loss per share, basic and diluted | <u>\$ (0.38)</u> | <u>\$ (0.45)</u> | <u>\$ (0.75)</u> | <u>\$ (0.91)</u> |
| Weighted average number of shares used in computing net loss per share, basic and diluted | <u>38,928</u> | <u>32,971</u> | <u>38,550</u> | <u>32,403</u> |

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

| | June 30, 2019 | December 31, 2018 |
|---|--------------------------|------------------------------|
| Cash, cash equivalents and short-term investments | \$ 261,413 | \$ 178,985 |
| Working capital | 252,672 | 167,582 |
| Total assets | 265,685 | 182,379 |
| Long-term liabilities | 7,872 | 7,779 |
| Accumulated deficit | (178,620) | (149,737) |
| Stockholders' equity | 246,581 | 160,985 |

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