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 25, 2020

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.)**

3033 Science Park Road, Suite 220, San Diego, CA	**92121**
(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 February 25, 2020, Kura Oncology, Inc. (the "Company") issued a press release announcing the Company's financial results for the year ended December 31, 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.

Exhibit Number	Description
99.1	Press release dated February 25, 2020

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: February 25, 2020

By: /s/ James Basta

James Basta
Chief Legal Officer and Secretary

Kura Oncology Reports Fourth Quarter and Full Year 2019 Financial Results

– Registration-directed trial of tipifarnib in HRAS mutant head and neck squamous cell carcinomas anticipated to complete enrollment in first quarter of 2021 –

– Company preparing to initiate a registration-directed trial of tipifarnib in T-cell lymphomas following positive feedback from FDA –

– Recommended Phase 2 dose defined for ERK inhibitor KO-947–

– Phase 1/2 dose-escalation continues for menin-MLL inhibitor KO-539 –

– $236.9 million in cash, cash equivalents and investments provide runway into 2022 –

– Management to host webcast and conference call today at 4:30 p.m. ET –

SAN DIEGO, Feb. 25, 2020 – 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 2019 financial results and provided a corporate update.

“We entered the new year with three wholly owned, clinical-stage drug candidates and a focus on operational execution across our pipeline,” said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. “The conduct of AIM-HN, our registrational-directed trial of tipifarnib in HRAS mutant head and neck squamous cell carcinoma (HNSCC), remains our highest priority. We have also taken a number of steps to better position the company for our next phase of growth, including an increasing investment in pre-commercial activities, expansion of our team of medical science liaisons and the appointment of a Chief Commercial Officer.

“Meanwhile, our growing body of clinical data in T-cell lymphomas, coupled with positive regulatory feedback and the high unmet need for these patients, support our efforts to expand the development of tipifarnib beyond our initial focus in HRAS mutant solid tumors,” Dr. Wilson continued. “And we continue to make progress with our emerging drug candidates, KO-947 and KO-539, each with the potential to address genetically defined populations of cancer patients. We believe we are well positioned to advance each of our programs to meaningful inflection points, and we look forward to providing updates on our progress in the year ahead.”

Recent Highlights

- **Strengthened leadership team to support pre-commercial efforts** – In January 2020, Kura appointed Kirsten Flowers to the newly created position of Chief Commercial Officer. Ms. Flowers joined from Array Biopharma, where she served as head of commercial operations until the completion of its $11.4 billion acquisition by Pfizer in July 2019. Ms. Flowers was responsible for building and leading the commercial organization that delivered the successful launch of Braftovi® + Mektovi® for patients with BRAF-mutant melanoma in the U.S. Previously, she held several leadership roles at Pfizer, including U.S. commercial lead for the launches of Ibrance® in breast cancer and Inlyta® in renal cell carcinoma.

- **Fast Track designation for tipifarnib in HRAS mutant HNSCC** – In December 2019, the U.S. Food and Drug Administration (FDA) granted Fast Track Designation to tipifarnib for the treatment of patients with HRAS mutant HNSCC after progression on platinum therapy. Fast Track Designation highlights the potential for tipifarnib to address unmet need for patients with this devastating disease. The designation offers the opportunity for frequent interactions with the FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval, as well as eligibility for rolling submission of a New Drug Application.

- **Robust activity from tipifarnib in advanced T-cell lymphomas** – Kura reported updated clinical data from its Phase 2 trial of tipifarnib as a monotherapy in relapsed or refractory nodal T-cell lymphomas, including angioimmunoblastic T-cell lymphoma (AITL). The data, presented at the American Society of Hematology Annual Meeting in December 2019, showed an objective response rate (ORR) of approximately 50% in heavily pre-treated AITL patients. Patients who carried mutations in the killer-cell immunoglobulin-like receptor (KIR), a CXCL pathway-associated biomarker, achieved an ORR of 70% and a complete response rate of 40%.

- **Positive feedback from end of Phase 2 meeting with the FDA** – Kura is now preparing to initiate a registration-directed trial of tipifarnib in advanced nodal lymphomas of T-follicular helper (TFH) origin, including AITL. This single-arm trial will target enrollment of 128 patients who are relapsed or refractory to at least one prior systemic cytotoxic therapy. The trial has two independent primary objectives, ORR in all patients enrolled and ORR in patients who carry KIR mutations. Each objective can statistically be met independently. Feedback from the Company's end-of-Phase 2 meeting with the FDA indicate that the trial, as designed, could support a New Drug Application seeking accelerated approval for tipifarnib monotherapy in lymphomas of TFH origin and/or lymphomas of TFH origin with KIR mutations.

- **New preclinical data support proof-of-concept study in pancreatic cancer** – Kura has generated new preclinical data showing tipifarnib's ability to block CXCL12 production by activated pancreatic stellate cells. In addition, the potential for synergy between tipifarnib and chemotherapy has been observed in preclinical models of pancreatic cancer. The Company believes these preclinical data, coupled with a

previously identified association between CXCL12 expression and clinical benefit, support an upcoming proof-of-concept trial of tipifarnib in combination with chemotherapy in the second-line setting for the treatment of advanced pancreatic cancer.

- **Recommended Phase 2 dose defined for ERK inhibitor KO-947** – Kura believes it has defined a recommended Phase 2 dose for KO-947 as a monotherapy. Pending agreement with the FDA, the Company plans to initiate an expansion cohort to evaluate KO-947 in HNSCC and esophageal squamous cell carcinoma (ESCC) patients with 11q13 amplifications, which are genetically defined populations identified as particularly sensitive to KO-947 as a monotherapy in preclinical models. Recently, a dose-limiting serious adverse drug reaction was observed in a single patient enrolled in the Phase 1 dose-escalation trial of KO-947. Although patients were permitted to remain on therapy, the Company voluntarily paused enrollment, and the FDA placed the trial on a partial clinical hold. Kura is working to lift the hold and resume dosing at the recommended Phase 2 dose with additional safety monitoring in place.

- **Dose-escalation continues for menin-MLL inhibitor KO-539** –KO-539 is a first-in-class, potent and selective small molecule inhibitor of the menin-MLL protein-protein interaction. Kura commenced a Phase 1/2 clinical trial of KO-539 in relapsed/refractory acute myeloid leukemia (AML) last year and the trial continues in the dose-escalation phase. The Company's goal is to reach a recommended Phase 2 dose or maximum tolerated dose with the potential to enrich in NPM1-mutant AML and MLL-rearranged genetically defined populations later this year.

Financial Results

- Research and development expenses for the fourth quarter of 2019 were $13.5 million, compared to $12.1 million for the fourth quarter of 2018. Research and development expenses for the full year 2019 were $47.8 million, compared to $46.8 million for the prior year.

- General and administrative expenses for the fourth quarter of 2019 were $5.5 million, compared to $4.6 million for the fourth quarter of 2018. General and administrative expenses for the full year 2019 were $19.7 million, compared to $16.1 million for the prior year.

- Net loss for the fourth quarter of 2019 was $17.9 million, compared to a net loss of $16.1 million for the fourth quarter of 2018. Net loss for the full year 2019 was $63.1 million, compared to a net loss of $60.4 million for the prior year. Net loss for the fourth quarter and full year of 2019 included non-cash, share-based compensation expense of $2.4 million and $9.4 million, respectively, compared to $1.7 million and $8.7 million for the same periods in 2018, respectively.

- Cash, cash equivalents and short-term investments totaled $236.9 million as of December 31, 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 its current operations into 2022.

Upcoming Milestones

- Additional data from Phase 2 trials of tipifarnib in HRAS mutant solid tumors, including HRAS mutant urothelial carcinoma, in 2020
- Initiation of a registration-directed trial of tipifarnib in AITL in the second half of 2020
- Initiation of a proof-of-concept trial of tipifarnib in pancreatic cancer in the second half of 2020
- Additional data from Phase 2 trial of tipifarnib in chronic myelomonocytic leukemia (CMML) in 2020
- Potential for full enrollment in the AIM-HN registration-directed trial of tipifarnib in HRAS mutant HNSCC in the first quarter of 2021
- Open expansion cohort of patients with HNSCC and ESCC with 11q13 amplifications in Phase 1 trial of KO-947 in 2020
- Achievement of a recommended Phase 2 dose in the Phase 1/2 dose-escalation trial of KO-539 by the end of 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 today, February 25, 2020, to discuss the financial results for the fourth quarter and full year 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: 8077975. 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 is conducting a registration-directed trial of tipifarnib 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, and KO-539, a menin-MLL inhibitor, both of which are currently in Phase 1 clinical 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 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 December 31,		Year Ended December 31,	
	2019	**2018**	**2019**	**2018**
Operating Expenses:				
Research and development	$ 13,464	$ 12,084	$ 47,826	$ 46,787
General and administrative	5,499	4,550	19,653	16,096
Total operating expenses	18,963	16,634	67,479	62,883
Other income, net	1,098	537	4,339	2,436
Net loss	$ (17,865)	$ (16,097)	$ (63,140)	$ (60,447)
Net loss per share, basic and diluted	$ (0.39)	$ (0.42)	$ (1.51)	$ (1.72)
Weighted average number of shares used in computing net loss per share, basic and diluted	45,333	38,079	41,946	35,191

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

	December 31, 2019	**December 31, 2018**
Cash, cash equivalents and short-term investments	$ 236,891	$ 178,985
Working capital	224,039	167,582
Total assets	241,972	182,379
Long-term liabilities	7,627	7,779
Accumulated deficit	(212,877)	(149,737)
Stockholders' equity	218,781	160,985

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