

**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 20, 2024

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.)

12730 High Bluff Drive, Suite 400
San Diego, CA
(Address of principal executive offices)

92130
(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 Instruction 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 1.01 Entry into a Material Definitive Agreement.

On November 20, 2024, Kura Oncology, Inc. (the “**Company**”) and Kyowa Kirin Co., Ltd. and Kyowa Kirin, Inc. (together, “**Kyowa Kirin**”) entered into a collaboration and license agreement (the “**Agreement**”) to develop and commercialize globally the Company’s product candidate, ziftomenib, a potent, selective oral menin inhibitor, for the treatment of patients with acute myeloid leukemia (“**AML**”) and other hematologic malignancies. In addition, Kyowa Kirin has an option to expand the parties’ collaboration on the development and commercialization of ziftomenib under the Agreement to include gastrointestinal stromal tumors (“**GIST**”) and other solid tumor indications (the “**Field Expansion Option**”), which option can be exercised within a specified time period after receipt of clinical data from the ongoing proof-of-concept study evaluating ziftomenib and imatinib in patients with advanced GIST who are not successfully treated with imatinib.

United States Development and Commercialization. The Company will lead all development, manufacture, and regulatory activities and commercial strategy development for ziftomenib in the United States. Under the terms of the Agreement, the parties will conduct research and development activities designed to support regulatory approval of ziftomenib in the United States under a mutually-agreed development plan and budget and under the oversight of a joint steering committee. The parties plan to conduct multiple phase 2 and phase 3 clinical trials of ziftomenib, as a monotherapy and in combination with other active ingredients, in AML and other hematologic malignancies over the next several years. Each party will conduct the activities allocated to it under the development plan. The Company will fund the specified development activities set forth in the initial development plan that are planned to be conducted prior to the end of 2028 (regardless of when such activities are actually conducted), and the parties will share equally (50/50) all development costs for all other development activities in the United States that are agreed by the parties to be included in the development plan, including clinical trials and post-marketing commitments that are reasonably necessary for obtaining or maintaining regulatory approval of ziftomenib in the United States. In addition, the Company will conduct certain specified development and manufacturing activities outside the scope of the mutually-agreed development plan at its sole cost and expense. Following regulatory approval, the Company will commercialize and book sales of ziftomenib in the United States and Kyowa Kirin will have the right and responsibility to co-promote ziftomenib for up to a certain percentage of the details in the United States. The parties will perform commercialization activities in accordance with a co-created United States territory commercialization plan and budget. The parties will share equally all costs and expenses for, and profits or losses from, the commercialization of ziftomenib in the United States.

Ex-United States Development and Commercialization. Kyowa Kirin will lead development, regulatory activities and commercial strategy development for ziftomenib outside of the United States, and will be solely responsible for the conduct and funding of such activities that are specific to the exploitation of ziftomenib outside of the United States. Following regulatory approval, Kyowa Kirin will be solely responsible for the conduct and funding of commercialization of ziftomenib outside of the United States (including booking sales). Kyowa Kirin is required to use commercially reasonable efforts to conduct the development of ziftomenib outside the United States in accordance with an ex-United States territory development plan, to achieve the development milestone events outside the United States that entitle the Company to receive corresponding development milestone payments, and to commercialize ziftomenib in each country outside of the United States where it has received regulatory approval. Development and commercialization activities outside of the United States will also be under the oversight of the joint steering committee and applicable subcommittees.

Licenses. The Company grants Kyowa Kirin a co-exclusive license to develop and commercialize ziftomenib in the United States for the treatment, diagnosis and prevention of hematologic malignancies and, if Kyowa Kirin exercises the Field Expansion Option, the treatment, diagnosis and prevention of all cancers (the “**Field**”). The Company also grants Kyowa Kirin a co-exclusive license to develop, manufacture and use ziftomenib outside the United States in the Field, and an exclusive license to commercialize ziftomenib outside the United States in the Field.

Retained Rights. The Company’s ongoing efforts to advance multiple, next-generation menin inhibitor drug candidates targeting certain oncology indications, as well as diabetes and other metabolic diseases, are expressly excluded from the collaboration, subject to certain specified restrictions for certain oncology indications and the Company’s exclusivity obligations described below.

Exclusivity. The Company may not, itself or with a third party, commercialize any molecule that inhibits, degrades or modulates menin or the interaction of menin and another protein in the Field other than ziftomenib in accordance with the Agreement. Kyowa Kirin may not, itself or with a third party, commercialize any molecule that inhibits, degrades or modulates menin or the interaction of menin and another protein other than ziftomenib in accordance with the Agreement. During the term of the Agreement, Kyowa Kirin may not, and may not grant a license or enable a third party, directly or indirectly, to, promote, sell or otherwise commercialize ziftomenib outside of the Field. In addition, during the term, the Company may not, and may not grant a license or enable a third party, directly or indirectly, to, clinically develop or commercialize ziftomenib outside of the Field in a manner that would reasonably be expected to result in off-label use in the Field, except that the foregoing restriction on Company will not apply to solid tumor indications if Kyowa Kirin does not exercise the Field Expansion Option.

Supply. The Company will be responsible for the manufacture and supply of ziftomenib for development and commercialization globally, pursuant to the terms of a supply agreement to be negotiated by the parties. Kyowa Kirin has the right to request the Company to conduct a manufacturing technology transfer and to take over the responsibility of commercial supply of ziftomenib outside the United States.

Financial Terms. The Company will receive an upfront payment of \$330 million and is eligible to receive up to \$420 million in near-term milestone payments, including a payment upon the launch of ziftomenib in the monotherapy relapsed/refractory (R/R) setting. In addition, the Company is eligible to receive additional development, regulatory and commercial milestone payments of \$513 million for the existing Field (i.e., hematologic malignancies), and if Kyowa Kirin exercises the Field Expansion Option, the Company is eligible for upfront and milestone payments totaling \$228 million for the expanded Field, totaling up to \$1.491 billion in upfront and milestone payments in the aggregate. The Company is also eligible to receive tiered double-digit royalties on sales of ziftomenib outside of the United States on a country-by-country basis until the latest of expiration of the last-to-expire valid claim of the Company's patent rights licensed to Kyowa Kirin in such country, expiration of the last-to-expire regulatory exclusivity in such country and ten years after first commercial sale in such country.

Termination. The Agreement will remain in effect in the United States until the latest of expiration of all valid claims of the Company's patent rights licensed to Kyowa Kirin, expiration of the last-to-expire regulatory exclusivity or ten years after first commercial sale. The Agreement will remain in effect outside the United States until the expiration of the last-to-expire royalty term. Either party may terminate the Agreement for uncured material breach by or insolvency of the other party. Kyowa Kirin may terminate the Agreement for convenience upon twelve months' prior written notice. In addition, Kyowa Kirin has the right to terminate the Agreement with a shorter specified notice period upon the occurrence of a material adverse regulatory event or certain other specified events. The Company may terminate the Agreement if Kyowa Kirin or any of its affiliates or sublicensees challenges the validity or enforceability of any of the patent rights licensed to Kyowa Kirin by the Company.

The foregoing description of the material terms of the Agreement is qualified in its entirety by reference to the full text of the Agreement, a copy of which will be filed as an exhibit to the Company's annual report on Form 10-K for the year ending December 31, 2024 with the Securities and Exchange Commission (the "SEC").

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, including without limitation statements regarding the Company's receipt of an upfront payment and potential receipt of an additional upfront payment, milestone payments and tiered double-digit royalties under the Agreement, Kyowa Kirin's option under the Agreement and potential exercise thereof, the development plan under the Agreement and potential regulatory approval of ziftomenib in the United States. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "target," "should," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various important factors, including risks relating to the success of the collaboration and development of ziftomenib under the collaboration, Kyowa Kirin's willingness to exercise its option, risks and uncertainties associated with the Company's business and finances in general, and risks described under the caption "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2024, which is on file with the SEC; and risks described in other filings that the Company makes with the SEC in the future. Any forward-looking statements contained in this Current Report on Form 8-K speak only as of the date hereof, and the Company expressly disclaims any obligation to update any forward-looking statements, whether because of new information, future events or otherwise.

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 hereunto duly authorized.

Date: November 20, 2024

KURA ONCOLOGY, INC.

By: /s/ Teresa Bair

Teresa Bair
Chief Legal Officer