

**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 15, 2023**

**ORCHARD THERAPEUTICS PLC**  
(Exact name of Registrant as Specified in Its Charter)

**England and Wales**  
(State or Other Jurisdiction  
of Incorporation)

**001-38722**  
(Commission  
File Number)

**Not Applicable**  
(IRS Employer  
Identification No.)

**245 Hammersmith Road  
London W6 8PW  
United Kingdom**  
(Address of Principal Executive Offices; Zip Code)

**Registrant's Telephone Number, Including Area Code: +44 (0) 203 808 8286**

**Not Applicable**  
(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:

- 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
American Depositary Shares, each representing ten ordinary shares, nominal value £0.10 per share	ORTX	The Nasdaq Capital 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 8.01 Other Events.**

On November 15, 2023, the U.S. Food and Drug Administration (“FDA”) advised Orchard Therapeutics plc (the “Company” or “Orchard”) that it does not intend to schedule an Advisory Committee meeting in connection with the FDA’s review of the Company’s Biologics License Application (“BLA”) for the commercial marketing and sale of OTL-200 in the United States for the treatment of metachromatic leukodystrophy. As previously disclosed, the FDA has set a Prescription Drug User Fee Act (PDUFA) action date for the BLA of March 18, 2024.

**Additional Information and Where to Find It**

In connection with the proposed transaction between Kyowa Kirin Co., Ltd. (“Kyowa Kirin”) and Orchard, Orchard has filed with the Securities and Exchange Commission (the “SEC”) a Proxy Statement, the definitive version of which is being mailed to Orchard security holders. Orchard may also file other documents with the SEC regarding the proposed transaction. This document is not a substitute for the Proxy Statement or any other document which Orchard may file with the SEC. INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THE PROXY STATEMENT (WHICH INCLUDES AN EXPLANATORY STATEMENT IN RESPECT OF THE SCHEME OF ARRANGEMENT OF ORCHARD, IN ACCORDANCE WITH THE REQUIREMENTS OF THE U.K. COMPANIES ACT 2006) AND ANY OTHER RELEVANT DOCUMENTS THAT ARE FILED OR WILL BE FILED WITH THE SEC, AS WELL AS ANY AMENDMENTS OR SUPPLEMENTS TO THESE DOCUMENTS, CAREFULLY AND IN THEIR ENTIRETY IF AND WHEN THEY BECOME AVAILABLE BECAUSE THEY CONTAIN OR WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION AND RELATED MATTERS. Investors and security holders may obtain a free copy of the Proxy Statement and other relevant documents containing important information about Kyowa Kirin, Orchard and the proposed transaction (if and when they become available) once such documents are filed with the SEC at the SEC’s website at [www.sec.gov](http://www.sec.gov). Copies of the documents filed with the SEC by Orchard will be available free of charge on Orchard’s website at [ir.orchard-tx.com](http://ir.orchard-tx.com) or by contacting Orchard’s Investor Relations Department at [investors@orchard-tx.com](mailto:investors@orchard-tx.com).

**Participants in the Solicitation**

Orchard and certain of its directors and executive officers may be deemed to be participants in the solicitation of proxies in respect of the proposed transaction. Information regarding Orchard’s directors and executive officers, including a description of their direct interests, by security holdings or otherwise, is contained in Orchard’s proxy statement for its 2023 annual general meeting of shareholders, which was filed with the SEC on April 27, 2023, and subsequent statements of beneficial ownership on file with the SEC. Orchard shareholders may obtain additional information regarding the direct and indirect interests of the participants in the solicitation of proxies in connection with the proposed transaction, including the interests of Orchard directors and executive officers in the transaction, which may be different than those of Orchard shareholders generally, by reading the Proxy Statement and any other relevant documents that are filed or will be filed with the SEC relating to the transaction. You may obtain free copies of these documents using the sources indicated above.

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### **Cautionary Statement Regarding Forward-Looking Statements**

This communication contains “forward-looking statements” within the meaning of the federal securities laws, including Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Exchange Act. These forward-looking statements are based on Orchard’s current expectations, estimates and projections about the expected date of closing of the proposed transaction and the potential benefits thereof, its business and industry, management’s beliefs and certain assumptions made by the Company, all of which are subject to change. All forward-looking statements by their nature address matters that involve risks and uncertainties, many of which are beyond the Company’s control, and are not guarantees of future results, such as statements about the FDA’s review of the Company’s BLA for OTL-200, the FDA’s intention not to schedule an Advisory Committee meeting and the target action date on the BLA. These and other forward-looking statements, are not guarantees of future results and are inherently subject to risks, uncertainties and assumptions that could cause actual results to differ materially from those expressed in any forward-looking statements. Accordingly, there are or will be important factors that could cause actual results to differ materially from those indicated in such statements and, therefore, you should not place undue reliance on any such statements and caution must be exercised in relying on forward-looking statements. Factors that may affect the future results of the Company are set forth in the Company’s filings with the SEC, including the Company’s most recently filed Annual Report on Form 10-K, subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the SEC, which are available on the SEC’s website at [www.sec.gov](http://www.sec.gov). The risks and uncertainties described above and in the SEC filings cited above are not exclusive and further information concerning the Company and its business, including factors that potentially could materially affect the Company’s business, financial conditions or operating results, may emerge from time to time. Moreover, other risks and uncertainties of which the Company is not currently aware may also affect the Company’s forward-looking statements and may cause actual results and the timing of events to differ materially from those anticipated. Readers are urged to consider these factors carefully in evaluating these forward-looking statements, and not to place undue reliance on any forward-looking statements, which speak only as of the date hereof. Except as required by law, the Company assumes no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

### **No Offer or Solicitation**

This communication is not intended to and shall not constitute an offer to buy or sell or the solicitation of an offer to buy or sell any securities, or a solicitation of any vote or approval, nor shall there be any offer, solicitation or sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offer of securities shall be made in the United States absent registration under the U.S. Securities Act of 1933, as amended, or pursuant to an exemption from, or in a transaction not subject to, such registration requirements.

**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.

**ORCHARD THERAPEUTICS PLC**

Date: November 21, 2023

By: /s/ Frank E. Thomas  
Frank E. Thomas  
President and Chief Operating Officer