

**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): **June 26, 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 3.02 Unregistered Sales of Equity Securities.

The information contained in Item 7.01 of this Current Report on Form 8-K (“Current Report”) is incorporated herein by reference into this Item 3.02.

Item 7.01 Regulation FD Disclosure.

On June 26, 2023, Orchard Therapeutics plc (the “Company”) issued a press release announcing that it had completed the second closing of its previously announced private placement pursuant to the Securities Purchase Agreement, dated March 6, 2023. A copy of the press release is furnished as Exhibit 99.1 to this Current Report.

The information in this Item 7.01, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release, dated June 26, 2023
104	Cover page interactive data file (embedded within the Inline XBRL document)

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: June 26, 2023

By: /s/ Frank E. Thomas

Frank E. Thomas

President and Chief Operating Officer

**Orchard Therapeutics Announces Second Closing of Strategic Financing,
Resulting in \$34 Million of Additional Capital**

Funding from second closing extends cash runway to mid-2025 to advance the company's HSC gene therapy portfolio through several potential value-creating milestones

OTL-200 (MLD) BLA submission initiated and on track for completion in mid-2023 with potential for U.S. approval in the first half of 2024

BOSTON and LONDON, June 26, 2023 – Orchard Therapeutics (Nasdaq: ORTX), a global gene therapy leader, today announced that it has completed the second closing of its previously announced securities purchase agreement, resulting in \$34 million of new capital before placement agent and transaction fees.

In March 2023, the company completed the first closing of an innovative financing arrangement, led by RA Capital Management with participation from other leading healthcare investors that resulted in \$34 million of new capital before placement agent and transaction fees. Per the terms of the agreement, the company could bring in an aggregate of up to \$188 million (inclusive of the \$68 million raised at the first and second closings) at increasing valuations following the achievement of certain U.S. regulatory milestones for OTL-200 for MLD. The conditions of the second closing included shareholder approval and the company's intention to initiate a biologics license application (BLA) submission following receipt of minutes from a productive pre-BLA meeting with the U.S. Food and Drug Administration for OTL-200, both of which have been achieved. The second closing comprises the sale of units at a purchase price of \$8.00 per unit for aggregate proceeds of \$34 million, including the issuance of 4.25 million American Depository Shares (ADSs) as well as warrants.

“The initiation of our BLA submission marks a significant de-risking event for Orchard and our OTL-200 program ahead of a potential U.S. approval in MLD,” said Frank Thomas, president and chief operating officer of Orchard Therapeutics. “This next wave of funding from the second closing is expected to provide important capital to support preparations for our anticipated first U.S. launch and advance our next-in-line neurometabolic programs derived from our HSC gene therapy platform. We want to thank each of the participating investors for supporting this unique and innovative structure and partnering with us to develop a standout company in the field of gene therapy.”

Guggenheim Securities, LLC acted as the sole placement agent for the private placement.

Orchard intends to use the net proceeds from the offering to support its growing commercial capabilities for Libmeldy, prepare for a potential U.S. approval for OTL-200 and advance its HSC gene therapy portfolio. The company expects that its existing cash, cash equivalents and investments, inclusive of the proceeds from the second closing, will fund its anticipated operating, debt service and capital expenditure requirements into mid-2025, with the potential for additional runway extension pending the exercise of the warrants issued as part of the financing.

The securities were sold in a private placement and have not been registered under the Securities Act of 1933, as amended (Securities Act), and may not be offered or sold in the U.S. absent registration or an applicable exemption from registration requirements. The Company has agreed to file a resale registration statement with the U.S. Securities and Exchange Commission (SEC), for purposes of registering the resale of the ordinary shares issued or issuable in connection with the offering.

This press release does not constitute an offer to sell or the solicitation of an offer to buy the securities, nor shall there be any sale of the securities in any state in which such offer, solicitation or

sale would be unlawful prior to the registration or qualification under the securities laws of such state. Any offering of the securities under the resale registration statement will only be by means of a prospectus.

About Orchard Therapeutics

At Orchard Therapeutics, our vision is to end the devastation caused by genetic and other severe diseases. We aim to do this by discovering, developing and commercializing new treatments that tap into the curative potential of hematopoietic stem cell (HSC) gene therapy. In this approach, a patient's own blood stem cells are genetically modified outside of the body and then reinserted, with the goal of correcting the underlying cause of disease in a single treatment.

In 2018, the company acquired GSK's rare disease gene therapy portfolio, which originated from a pioneering collaboration between GSK and the San Raffaele Telethon Institute for Gene Therapy in Milan, Italy. Today, Orchard is advancing a pipeline spanning pre-clinical, clinical and commercial stage HSC gene therapies designed to address serious diseases where the burden is immense for patients, families and society and current treatment options are limited or do not exist.

Orchard has its global headquarters in London and U.S. headquarters in Boston. For more information, please visit www.orchard-tx.com, and follow us on Twitter and LinkedIn.

Availability of Other Information About Orchard

Investors and others should note that Orchard communicates with its investors and the public using the Company website (www.orchard-tx.com), the investor relations website (ir.orchard-tx.com), and on social media ([Twitter](#) and [LinkedIn](#)), including but not limited to investor presentations and investor fact sheets, SEC filings, press releases, public conference calls and webcasts. The information that Orchard posts on these channels and websites could be deemed to be material information. As a result, Orchard encourages investors, the media, and others interested in Orchard to review the information that is posted on these channels, including the investor relations website, on a regular basis. This list of channels may be updated from time to time on Orchard's investor relations website and may include additional social media channels. The contents of Orchard's website or these channels, or any other website that may be accessed from its website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act.

Forward-Looking Statements

This press release contains forward-looking statements, which are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All statements that are not statements of historical facts are, or may be deemed to be, forward-looking statements. Such forward-looking statements may be identified by words such as "expects," "potential," "could," or similar expressions that are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Forward-looking statements include express or implied statements relating to, among other things, Orchard's business strategy and goals, including its plans and expectations for the commercialization of Libmeldy and the advancement of its clinical and pre-clinical stage programs; statements relating to the private placement, including the expected closings, the anticipated proceeds from the private placement and the use thereof; Orchard's plans to file a resale registration statement to register the shares issued and sold in the private placement and the issuance of the shares issuable upon exercise of the warrants; Orchard's future capital needs and cash runway; the timing of Orchard's expected BLA filing with the FDA for OTL-200; and expectations related to the occurrence and timing of the U.S. approval of OTL-200. These statements are neither promises nor guarantees and are subject to a variety of risks and uncertainties, many of which are beyond Orchard's control, which could cause actual results to differ materially from those contemplated in these forward-looking statements. In particular, these risks and

uncertainties include, without limitation, the risk that the warrants issued will not become exercisable; the risk that Orchard is delayed in submitting a BLA with the FDA for OTL-200; the risk that OTL-200 is not approved by the FDA or that such approval is delayed; and the risk that investors will not exercise the warrants or that only a portion of the warrants will be exercised. Given these uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. Other risks and uncertainties faced by Orchard include those identified under the heading "Risk Factors" in Orchard's most recent annual or quarterly report filed with the SEC, as well as subsequent filings and reports filed with the SEC. The forward-looking statements contained in this press release reflect Orchard's views as of the date hereof, and Orchard does not assume and specifically disclaims any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law.

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