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): **October 30, 2020**

ORCHARD THERAPEUTICS PLC

(Exact name of Registrant as Specified in Its Charter)

England and Wales	**001-38722**	**Not Applicable**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

108 Cannon Street
London EC4N 6EU
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 one ordinary share, nominal value £0.10 per share	ORTX	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 8.01 Other Events.

On October 30, 2020, Orchard Therapeutics plc issued the following statement:

> Orchard Therapeutics was notified earlier this week that a patient treated under a compassionate use program in 2016 with Strimvelis®, a gammaretroviral vector-based gene therapy approved by the European Medicines Agency (EMA) for the treatment of ADA-SCID, has been diagnosed with lymphoid T-cell leukemia. Preliminary findings suggest this diagnosis may be attributable to an insertional event related to treatment with Strimvelis. The patient is undergoing treatment for the leukemia at a specialty center, and we are conducting a full investigation to determine potential causality. Our thoughts are with the patient and family during this time.
>
> Leukemia arising from the insertion of gammaretroviral vectors into the genome, a process known as insertional oncogenesis (or mutagenesis), is a known risk factor for gammaretroviral vector-based gene therapy and is described in the Strimvelis product information as a potential risk of treatment.
>
> Strimvelis is the only gammaretroviral vector-based gene therapy in Orchard's portfolio. Each of Orchard's other pipeline therapies employ a self-inactivating (SIN) lentiviral vector-based approach that has been specifically designed to avoid insertional oncogenesis after administration. No evidence of insertional oncogenesis related to lentiviral vector-based hematopoietic stem cell (HSC) gene therapy has been reported in any indication.
>
> Patient safety continues to be our highest priority, and Orchard has notified EMA and relevant local European regulatory authorities of this adverse event. Sixteen patients have been treated with Strimvelis since its approval in 2016, and no additional patients will be treated with the therapy before the investigation is complete. The company will determine the future of Strimvelis following discussions with relevant stakeholders and will provide further updates as appropriate.
>
> For more information about Strimvelis, see the EMA website.

Forward-looking statements

This Current Report on Form 8-K contains forward-looking statements, including statements related to the causation of a leukemic event experienced by a Strimvelis patient, the outcome of interactions with stakeholders, the future administration of Strimvelis to new patients and the safety profile of the company's lentiviral vector platform. 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 prior results, such as signals of safety, activity or durability of effect, observed from clinical trials will not continue or be repeated in our ongoing or planned clinical trials, will be insufficient to support regulatory submissions or marketing approval in the US and EU or that long-term adverse safety findings may be discovered. Other risks and uncertainties faced by Orchard include those identified under the heading "Risk Factors" in Orchard's quarterly report on Form 10-Q for the quarter ended June 30, 2020, as filed with the U.S. Securities and Exchange Commission (SEC), as well as subsequent filings and reports filed with the SEC. The forward-looking statements contained in this Current Report 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.

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: October 30, 2020

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