

**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): **January 29, 2021**

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.)

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 January 29, 2021, Orchard Therapeutics plc issued a press release announcing the appointment of Braden Parker to the role of Chief Commercial Officer. A copy of the press release is attached as Exhibit 99.1 to this current report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release dated January 29, 2021
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: January 29, 2021

By: /s/ Frank E. Thomas

Frank E. Thomas

President and Chief Operating Officer



Orchard Therapeutics Appoints Braden Parker as Chief Commercial Officer

Commercial Launch of Libmeldy™ in Europe On-Track for 1H 2021

BOSTON and LONDON, Jan. 29, 2021 -- Orchard Therapeutics (Nasdaq: ORTX), a global gene therapy leader, today announced the appointment of Braden Parker to the role of Chief Commercial Officer (CCO). In this capacity, Mr. Parker will oversee all aspects of commercial strategy, planning and operations for the company. Mr. Parker is a seasoned commercial leader with more than 20 years of experience in the healthcare and biotech industry, including deep rare disease and gene therapy experience. Mr. Parker's previous positions include commercial leadership roles at Celgene, NPS Pharma (Shire) and PTC Therapeutics, where he led the company's first U.S. product launch in Duchenne muscular dystrophy and oversaw the strategic planning for their gene therapy business. Most recently, Mr. Parker served as Orchard's senior vice president and general manager for North America.

"Braden's appointment as chief commercial officer comes at a key inflection point for Orchard as the company evolves into a fully integrated, commercial-stage organization with the approval and upcoming launch of Libmeldy in Europe," said Frank Thomas, president and chief operating officer of Orchard. "Braden's strong track-record of successfully launching rare disease therapies, coupled with his experience in gene therapy commercialization, makes him an ideal candidate to lead our growing commercial team and infrastructure, especially as we look forward to potential additional launches in the U.S. and beyond. I am confident he will play a critical role in shaping and achieving Orchard's global growth strategy."

Mr. Parker joined Orchard from PTC Therapeutics, where he served as vice president and general manager for the U.S. organization. In this role, he oversaw commercial operations, marketing, and market access activities, and also actively engaged with the policy community on health reform and modernization efforts. Mr. Parker received his M.B.A. from New York University Stern School of Business and his B.B.A. from the University of Notre Dame.

"I am delighted to be appointed chief commercial officer at Orchard at this exciting juncture for the company, and am fortunate to have an experienced commercial leadership team already established as we embark on launching Libmeldy in Europe," said Braden Parker, chief commercial officer of Orchard. "The hematopoietic stem cell gene therapy platform approach continues to demonstrate great promise in treating diseases that have been historically difficult to address, and I look forward to the opportunity to lead Orchard's efforts to bring these potentially curative therapies to patients upon their approval."

About Libmeldy / OTL-200

Libmeldy (autologous CD34⁺ cell enriched population that contains hematopoietic stem and progenitor cells (HSPC) transduced *ex vivo* using a lentiviral vector encoding the human *arylsulfatase-A* (*ARSA*) gene), also known as OTL-200, has been approved by the European Commission for the treatment of MLD in eligible early-onset patients characterized by biallelic mutations in the *ARSA* gene leading to a reduction of the *ARSA* enzymatic activity in children with i) late infantile or early juvenile forms, without clinical manifestations of the disease, or ii) the early juvenile form, with early clinical manifestations of the disease, who still have the ability to walk independently and before the onset of cognitive decline. Libmeldy is the first therapy approved for eligible patients with early-onset MLD.

The most common adverse reaction attributed to treatment with Libmeldy was the occurrence of anti-ARSA antibodies. In addition to the risks associated with the gene therapy, treatment with Libmeldy is preceded by other medical interventions, namely bone marrow harvest or peripheral blood mobilization and apheresis, followed by myeloablative conditioning, which carry their own risks. During the clinical studies, the safety profiles of these interventions were consistent with their known safety and tolerability.

For more information about Libmeldy, please see the [Summary of Product Characteristics \(SmPC\)](#) available on the European Medicines Agency (EMA) website.

Libmeldy is not approved outside of the European Union, UK, Iceland, Liechtenstein, and Norway. OTL-200 is an investigational therapy in the U.S.

Libmeldy was developed in partnership with the San Raffaele-Telethon Institute for Gene Therapy (SR-Tiget) in Milan, Italy.

About Orchard

Orchard Therapeutics is a global gene therapy leader dedicated to transforming the lives of people affected by rare diseases through the development of innovative, potentially curative gene therapies. Our *ex vivo* autologous gene therapy approach harnesses the power of genetically modified blood stem cells and seeks to correct the underlying cause of disease in a single administration. In 2018, Orchard 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. Orchard now has one of the deepest and most advanced gene therapy product candidate pipelines in the industry spanning multiple therapeutic areas where the disease burden on children, families and caregivers is immense 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, U.S. Securities and Exchange Commission 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 of 1933.

Forward-Looking Statements

This press release contains certain forward-looking statements about Orchard's strategy, future plans and prospects, which are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements may be identified by words such as "anticipates," "believes," "expects," "plans," "intends," "projects," and "future" or similar expressions that are intended to identify forward-looking statements. 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 (OTL-200) and any other product candidates, if approved, the therapeutic potential of Libmeldy and Orchard's product

candidates and the likelihood that any such product candidates will receive regulatory approval, and Orchard's expectations regarding the size of the potential markets for Libmeldy and its product candidates. 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 of Libmeldy will not continue or be repeated in our ongoing or planned clinical trials of Libmeldy, will be insufficient to support regulatory submissions or marketing approval in the US or to maintain marketing approval in the EU, or that long-term adverse safety findings may be discovered; the risk of cessation or delay of any of Orchard's ongoing or planned clinical trials; the risk that Orchard may not successfully recruit or enroll a sufficient number of patients for its clinical trials; the delay of any of Orchard's regulatory submissions; the failure to obtain marketing approval from the applicable regulatory authorities for any of Orchard's product candidates or the receipt of restricted marketing approvals; the inability or risk of delays in Orchard's ability to commercialize its product candidates, if approved, or Libmeldy, including the risk that Orchard may not secure adequate pricing or reimbursement to support continued development or commercialization of Libmeldy; the risk that the market opportunity for Libmeldy, or any of Orchard's product candidates, may be lower than estimated; and the severity of the impact of the COVID-19 pandemic on Orchard's business, including on clinical development, its supply chain and commercial programs. 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 quarterly report on Form 10-Q for the quarter ended September 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 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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