

**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): **July 2, 2020**

**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 1.01 Entry into a Material Definitive Agreement.**

On July 2, 2020, Orchard Therapeutics (Europe) Limited (“OTL”), a wholly-owned subsidiary of Orchard Therapeutics plc (“Orchard”), entered into a manufacturing and technology development master agreement (the “Agreement”) with MolMed S.p.A. (“MolMed”), effective July 2, 2020 (the “Effective Date”), pursuant to which MolMed will develop, manufacture and supply certain viral vectors and conduct cell processing activities for certain Orchard development and commercial programs. Under the terms of the Agreement, OTL is obligated to pay MolMed a minimum product manufacturing commitment of €2.7 million per annum for the term of the Agreement, which may increase to the mid-seven figures per annum upon the achievement of certain milestones that may require additional manufacturing capacity. Additionally, OTL has committed €10.4 million per annum for dedicated manufacturing and development resources, including exclusive manufacturing suites within MolMed’s existing facilities, which OTL may increase or decrease on a rolling basis with between six and 12-months’ prior written notice to MolMed.

The Agreement has an initial term of five years, beginning on the Effective Date and ending July 2, 2025. The Agreement may be extended for an additional two years by mutual agreement of OTL and MolMed. OTL has the right to terminate the Agreement at its discretion upon 12-month’s prior written notice to MolMed, and beginning no earlier than July 2, 2022, MolMed has the right to terminate the Agreement at its discretion upon 24-month’s prior written notice to OTL. Each party may terminate the Agreement upon prior notice to the other party for an uncured material breach that the breaching party does not cure within the notice period.

The Agreement includes customary indemnification, intellectual property protection, confidentiality, remedy, representation and warranty terms and provisions, as well as certain quality requirements. MolMed is currently Orchard’s manufacturing partner for Strimvelis, OTL-200 for metachromatic leukodystrophy (MLD), OTL-103 for Wiskott Aldrich syndrome (WAS) and OTL-203 for mucopolysaccharidosis type I (MPS-I), along with other programs in its pipeline.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the Agreement, a copy of which Orchard expects to file as an exhibit to its quarterly report on Form 10-Q for the quarter ended June 30, 2020.

**Item 8.01 Other Events.**

On July 9, 2020, Orchard issued a press release announcing the extension of Orchard’s collaboration with MolMed. 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.

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Press release dated July 9, 2020</a>
104	Cover page interactive data file (embedded within the Inline XBRL document)

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**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: July 9, 2020

By: /s/ Frank E. Thomas

Frank E. Thomas

President and Chief Operating Officer



## Orchard Therapeutics and MolMed Announce Extension of Gene Therapy Manufacturing Collaboration

BOSTON and LONDON and MILAN, Italy, July 9, 2020 – Orchard Therapeutics (Nasdaq: ORTX), a global gene therapy leader, and MolMed S.p.A (MLMD.MI), one of the company's principal contract development and manufacturing partners, today announced that they have extended their collaboration – initiated in April 2018 – for a period of five years through June 2025.

With the extension of the collaboration, MolMed will continue to support activities related to the development and manufacturing of vectors and drug products for several of Orchard's investigational *ex vivo* hematopoietic stem cell (HSC) gene therapies in the upcoming years, including OTL-200 for metachromatic leukodystrophy (MLD) and OTL-103 for Wiskott Aldrich syndrome (WAS), as well as for additional pipeline programs including OTL-203 for mucopolysaccharidosis type I (MPS-I). MolMed is the first company to have obtained good manufacturing practice (GMP) authorization for the gene and cell therapy markets in Europe and is the manufacturer for Strimvelis®, Orchard's *ex vivo* HSC gene therapy for severe combined immunodeficiency due to adenosine deaminase deficiency (ADA-SCID) and the first such treatment approved by the European Medicines Agency (EMA).

"We are looking forward to continuing to build and expand upon our partnership with MolMed, who have supported the progression of many of our programs since their earliest clinical development stages," said Frank Thomas, president and chief operating officer of Orchard. "Their expertise in gene therapy manufacturing, coupled with their deep knowledge of our programs, will be invaluable as our therapies for MLD and WAS approach anticipated approval and commercialization in Europe and across the globe."

Luca Alberici, MolMed's chief business officer, added, "We are pleased to have strengthened our collaboration with Orchard to support them in their mission of bringing potentially transformative therapies to those suffering from severe rare diseases. After being Orchard's exclusive manufacturer for Strimvelis, we are looking forward to supporting their manufacturing needs for additional programs both in clinical trials and in potential commercial applications following the anticipated approval of OTL-200 for MLD in Europe later this year."

OTL-200 for MLD is currently under review by the EMA with a decision expected later this year.

### 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,

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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](http://www.orchard-tx.com), and follow us on [Twitter](#) and [LinkedIn](#).

### **About MolMed**

MolMed S.p.A. is a biotechnology company focused on research, development, manufacturing and clinical validation of novel cell and gene therapies. MolMed, established in 1996, has been listed since March 2008 on the Italian Stock Exchange managed by Borsa Italiana, and has its registered office in Milan, at the Biotechnology Department of Ospedale San Raffaele and an operating site at Bresso, at the OpenZone campus.

### **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](http://www.orchard-tx.com)), the investor relations website ([ir.orchard-tx.com](http://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. Forward-looking statements include express or implied statements relating to, among other things, Orchard's business strategy and goals, the therapeutic potential of Orchard's product candidates, including the product candidate or candidates referred to in this release, Orchard's expectations regarding the timing of regulatory submissions for or marketing approval of its product candidates, and Orchard's expectations concerning its

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partnership with MolMed. 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 severity of the impact of the COVID-19 pandemic on Orchard's business, including on clinical development and commercial programs; the risk that any one or more of Orchard's product candidates, including the product candidate or candidates referred to in this release, will not be approved, successfully developed or commercialized; 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 risk that prior results, such as signals of safety, activity or durability of effect, observed from preclinical studies or clinical trials will not be replicated or will not continue in ongoing or future studies or trials involving Orchard's product candidates; 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 risk of delays in Orchard's ability to commercialize its product candidates, if approved; and the risk that Orchard may not receive the expected benefits from its collaboration with MolMed or that Orchard or MolMed will not fully perform under the terms of their collaboration agreement. 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 March 31, 2020, as filed with the U.S. Securities and Exchange Commission (SEC) on May 7, 2020, 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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