# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

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REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the Month of December 2018

Commission File Number: 001-38722

# ORCHARD THERAPEUTICS PLC

(Translation of registrant's name into English)

108 Cannon Street
London EC4N 6EU
United Kingdom

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ⊠ Form 40-F □

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): □

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): □

On December 13, Orchard Therapeutics plc issued a press release announcing that it had entered into a lease agreement for a manufacturing facility of approximately 150,000 square feet in Fremont, California. A copy of this press release is attached hereto as Exhibit 99.1.

**EXHIBITS** 

**Exhibit** Description

99.1 <u>Press Release dated December 13, 2018</u>

### **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, thereunto duly authorized.

Date: December 14, 2018

## ORCHARD THERAPEUTICS PLC

By: /s/ Frank E. Thomas

Frank E. Thomas Chief Financial Officer



## Orchard Therapeutics Announces the Build-out of New Gene Therapy Manufacturing Facility in California

New facility expected to create more than 100 new jobs, supporting extensive gene therapy pipeline

Enhances Orchard's capacity to develop and deliver lentiviral vector and gene-corrected hematopoetic stem cells for wide range of diseases on a global scale

**BOSTON** and **LONDON**, **Dec. 13**, **2018**—Orchard Therapeutics (NASDAQ: ORTX), a leading commercial-stage biopharmaceutical company dedicated to transforming the lives of patients with serious and life-threatening rare diseases through innovative gene therapies, today announced that it has signed a long-term lease agreement to build-out a gene therapy manufacturing facility in Fremont, California. The new 150,000-square-foot facility significantly increases Orchard's California footprint and adds to the Foster City and Menlo Park, California sites, which oversee the ongoing development and validation of the manufacture of Orchard's *ex vivo* gene therapy product candidates.

Once operational, the new site will provide significant additional CGMP manufacturing capacity for both lentiviral vector and cryopreserved cell therapy products, enhancing Orchard's ability to manufacture and deliver gene-corrected hematopoetic stem cells for a wide range of diseases on a global basis. In addition to this expanded capacity, Orchard also plans to continue its close collaborations with the Company's contract manufacturing partners.

"The expansion of our California operations to now include a manufacturing facility is a critical step in advancing Orchard's capabilities to supply products for our *ex vivo* gene therapy programs," said Stewart Craig, Ph.D., chief manufacturing officer of Orchard. "We believe that this new facility, as an early investment in our own manufacturing, will not only drive efficiencies and scalability in terms of lentiviral vector and drug product development, it will also complement the capabilities of our existing vector and drug product manufacturing partners to support the potential launch of our gene therapy clinical product candidates."

The build-out of Orchard's new manufacturing facility is expected to begin in 2019, and the Company expects to hire more than 100 full-time employees over the next few years to support in-house manufacturing efforts.

"Orchard's new California manufacturing facility will provide enhanced capacity and long-term supply in support of our extensive pipeline beyond the Company's most advanced clinical programs," said Mark Rothera, president and chief executive officer of Orchard. "We are pleased to continue our growth in the Bay Area and look forward to welcoming additional

technical and management talent to join our mission of transforming patient's lives through gene therapy."

#### **About Orchard**

Orchard Therapeutics is a fully integrated commercial-stage biopharmaceutical company dedicated to transforming the lives of patients with serious and life-threatening rare diseases through innovative gene therapies.

Orchard's portfolio of autologous *ex vivo* gene therapies includes Strimvelis, the first autologous *ex vivo* gene therapy approved by the European Medicines Agency for adenosine deaminase severe combined immunodeficiency (ADA-SCID). Additional programs for primary immune deficiencies, neurometabolic disorders and hemoglobinopathies include three advanced registrational studies for ADA-SCID, metachromatic leukodystrophy (MLD) and Wiskott-Aldrich syndrome (WAS), clinical programs for X-linked chronic granulomatous disease (X-CGD) and transfusion dependent beta-thalassemia (TDBT), as well as an extensive preclinical pipeline.

Orchard currently has offices in the U.K. and the U.S., including London, San Francisco and Boston.

#### **Forward-Looking Statements**

This press release contains certain forward-looking statements 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," "intends," "projects," "anticipates," 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 expectations regarding the build out of its manufacturing facility in Fremont, California, anticipated efficiencies and scalability of vector and drug product production, future hiring plans, future collaborations with third party manufactures and CMOs, and Orchard's ability to commercialize its product candidates, if approved, and to deliver such product candidates globally. These statements are neither promises nor guarantees, but 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, the risks and uncertainties include, without limitation: a delay in the build out of the Fremont, California manufacturing facility, the failure to obtain marketing approval from the applicable regulatory authorities for any of Orchard's product candidates, the receipt of restricted marketing approvals, or delays in Orchard's ability to commercialize its product candidates, if approved. Orchard undertakes no 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. For additional disclosure regarding these and other risks faced by Orchard, see the disclosure contained in Orchard's public filings with the Securities and Exchange Commission.

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