UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 6-K

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

For the month of October, 2021

Commission File Number: 001-38452

MEREO BIOPHARMA GROUP PLC

(Translation of registrant's name into English)

4th Floor, One Cavendish Place,
London, W1G 0QF, United Kingdom
(Address of principal executive office)

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): ☐

Exhibit Index

Exhibits

99.1	Press release dated October 26, 2021 titled “Mereo BioPharma Receives U.S. Orphan Drug Designation for alvelestat in the Treatment of alpha-1 antitrypsin deficiency.”

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: October 26, 2021

MEREO BIOPHARMA GROUP PLC

By: /s/ Charles Sermon
Name: Charles Sermon
Title: General Counsel

Exhibit 99.1

Mereo BioPharma Receives U.S. Orphan Drug Designation for alvelestat in the Treatment of alpha-1 antitrypsin deficiency

London and Redwood City, Calif., October 26, 2021 - Mereo BioPharma Group plc (NASDAQ: MREO), "Mereo" or the "Company", a clinical stage biopharmaceutical company focused on oncology and rare diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to alvelestat for the treatment of alpha-1 antitrypsin deficiency (AATD).

Mereo is currently developing alvelestat for the treatment of AATD-Lung Disease (AATD-LD). AATD is a rare and life-threatening disease. "We believe that the orphan drug designation represents an important regulatory milestone, recognizing the significant and urgent unmet need for new therapies to address AATD and specifically AATD-LD," said Dr. Denise Scots-Knight, Chief Executive Officer of Mereo. "We look forward to providing an update on our program before the end of the year."

AATD is a rare, genetic disease that results in a deficiency of alpha-1 antitrypsin (AAT), a protein that is produced in the liver and normally protects the lungs against damaging enzymes that the body releases during inflammation. These damaging enzymes, specifically neutrophil elastase, lead to lung damage because of the irreversible destruction of elastin, which is critical to the structure and function of the lung. AATD can cause pulmonary emphysema, a progressive, life-threatening lung disease, which results in severe shortness of breath, wheezing, chronic cough and sputum production, as well as asthma, recurring chest infections and bronchiectasis. Lung symptoms start in early adult life and, over time, individuals with Alpha-1 lung disease may progress to needing oxygen to perform even normal daily tasks and some eventually require a lung transplant. The production of abnormal AAT in the liver can also lead to liver disease in children and adults.

The Orphan Drug Designation by the US FDA originates from the Orphan Drug Act, which was enacted in 1983 to encourage the development of innovative drugs to treat rare diseases with a target patient population of less than 200,000 in the US. Upon marketing approval, drugs with ODD qualify for seven-year market exclusivity. In addition, US FDA also rewards ODD drugs with comprehensive incentives including tax credit for clinical trial cost, waiver of marketing registration application fee, waiver or reduced annual product fee, and other benefits, such as clinical protocol assistance and qualification for expedited development programs.

About Alvelestat

Alvelestat (MPH-966) is a novel, oral small molecule designed to inhibit neutrophil elastase (NE), a neutrophil protease, a key enzyme involved in the destruction of lung tissue. Mereo is conducting a Phase 2 proof-of-concept clinical trial with alvelestat for the treatment of severe alpha-1 antitrypsin deficiency ("AATD"). By inhibiting NE, Mereo believes alvelestat has the potential to protect AATD patients from further lung damage. An investigator-initiated study with alvelestat is also underway in AATD-LD funded through an NIH National Center for Advancing Translational Sciences (NCATS) program and led by Professor Mark Dransfield (University of Alabama at Birmingham). Alvelestat is also under clinical investigation in ongoing Phase 1b/2 studies in COVID-19 and Bronchiolitis Obliterans Syndrome (BOS) following allogeneic hematopoietic stem cell transplant.

About Mereo BioPharma

Mereo BioPharma is a biopharmaceutical company focused on the development and commercialization of innovative therapeutics that aim to improve outcomes for oncology and rare diseases. The Company has developed a portfolio of six clinical stage product candidates. Mereo's lead oncology product candidate, etigilimab (anti-TIGIT), has recently advanced into an open label Phase 1b/2 basket study evaluating anti-TIGIT in combination with an anti-PD-1 in a range of tumor types including three rare tumors and three gynecological carcinomas, cervical, ovarian and endometrial

carcinomas. The Company's second oncology product, navicixizumab, for the treatment of late line ovarian cancer, has completed a Phase 1 study and has been partnered with OncXerna Therapeutics, Inc., formerly Oncologie, Inc. The Company has two rare disease product candidates: alvelestat for the treatment of severe Alpha-1 antitrypsin deficiency (AATD), which is being investigated in an ongoing Phase 2 proof-of-concept study in the U.S. and Europe, for which the Company expects to provide an update in the fourth quarter of 2021, and setrusumab for the treatment of osteogenesis imperfecta (OI). In September 2020, the FDA granted Rare Pediatric Disease designation to setrusumab for the treatment of OI. In December 2020, the Company signed a license and collaboration agreement for setrusumab in OI with Ultragenyx Pharmaceutical Inc.

Forward-Looking Statements

This press release contains "forward-looking statements." All statements other than statements of historical fact contained in this press release are forward-looking statements within the meaning of Section 27A of the United States Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the United States Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements usually relate to future events and anticipated revenues, earnings, cash flows or other aspects of our operations or operating results. Forward-looking statements are often identified by the words "believe," "expect," "anticipate," "plan," "intend," "foresee," "should," "would," "could," "may," "estimate," "outlook" and similar expressions, including the negative thereof. The absence of these words, however, does not mean that the statements are not forward-looking. These forward-looking statements are based on the Company's current expectations, beliefs and assumptions concerning future developments and business conditions and their potential effect on the Company. While management believes that these forward-looking statements are reasonable as and when made, there can be no assurance that future developments affecting the Company will be those that it anticipates.

All of the Company's forward-looking statements involve known and unknown risks and uncertainties some of which are significant or beyond its control and assumptions that could cause actual results to differ materially from the Company's historical experience and its present expectations or projections. You should carefully consider the foregoing factors and the other risks and uncertainties that affect the Company's business, including those described in the "Risk Factors" section of its latest Annual Report on Form 20-F, reports on Form 6-K and other documents furnished or filed from time to time by the Company with the Securities and Exchange Commission. The Company wishes to caution you not to place undue reliance on any forward-looking statements, which speak only as of the date hereof. The Company undertakes no obligation to publicly update or revise any of our forward-looking statements after the date they are made, whether as a result of new information, future events or otherwise, except to the extent required by law.

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