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, 2022

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 17, 2022 titled "Mereo BioPharma Receives FDA Fast Track Designation for Alvelestat for Treatment of Alpha-1 Antitrypsin Deficiency (AATD)-associated Lung Disease."

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 17, 2022

MEREO BIOPHARMA GROUP PLC

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

Mereo BioPharma Receives FDA Fast Track Designation for Alvelestat for Treatment of Alpha-1 Antitrypsin Deficiency (AATD)-associated Lung Disease

Designation Validates Alvelestat's Potential to Address a Serious Unmet Need

Company Plans R&D Update on Alvelestat in AATD-associated Lung Disease on October 31, 2022

LONDON – October 17, 2022 – Mereo BioPharma Group plc (NASDAQ: MREO), ("Mereo" or the "Company"), a clinical-stage biopharmaceutical company focused on rare diseases and oncology, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for its investigational oral neutrophil elastase inhibitor, alvelestat (MPH-966). Mereo intends to have an End-of-Phase 2 meeting with the FDA to discuss the design of a registration-enabling study for alvelestat as a treatment for AATD-associated lung disease, including the potential opportunity for an accelerated approval pathway, around the end of the year.

"AATD is a devastating inherited condition which severely affects patients' quality of life. In the ASTRAEUS study, we demonstrated alvelestat's ability to inhibit multiple specific biomarkers relevant to the disease pathway based on neutrophil elastase inhibition," said Dr. Denise Scots-Knight, Chief Executive Officer of Mereo. "We are grateful to the FDA for granting us Fast Track designation, and for their recognition of alvelestat as a potentially first-in-class oral neutrophil elastase inhibitor. We look forward to the R&D update on the alvelestat program this month, and to our future interactions with the FDA to review our plans for a pivotal trial."

AATD is a rare, genetic disease that results in a deficiency of the alpha-1 antitrypsin protein, which protects the lungs against damaging enzymes that the body releases during inflammation. 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 – permanent enlargement of parts of the lungs' airways. There are an estimated 50,000 people in North America and 60,000 in Europe with severe AATD.

In May 2022, Mereo reported positive top-line safety and efficacy data from the ASTRAEUS Phase 2 study of alvelestat in severe AATD-associated emphysema. The Company plans to provide a further update on the program on October 31, 2022.

The investigator-led ATALANTa trial, which is studying alvelestat in a broader range of AATD patient populations, including those on augmentation therapy, is expected to read out in mid-2023. In addition, alvelestat is being studied in Bronchiolitis Obliterans Syndrome (BOS), a rare condition where excessive inflammation causes thickening of the airways, severely limiting lung function.

Fast Track designation is designed to facilitate development and expedite the review of therapies with the potential to treat serious or life-threatening conditions where there is a major unmet medical need. Investigational products that receive Fast Track designation may benefit from early and frequent communication with the FDA and are eligible for rolling submission and review of the marketing application. Additionally, this designation provides potential pathways for accelerated regulatory approval.

About Mereo BioPharma

Mereo BioPharma is a biopharmaceutical company focused on the development of innovative therapeutics for rare diseases and in oncology and plans to commercialize selected rare disease programs. The Company has developed a portfolio of six clinical stage product candidates. The Company has two rare disease product candidates, setrusumab for the treatment of osteogenesis imperfecta (OI) and alvelestat for the treatment of severe Alpha-1 antitrypsin deficiency (AATD) and Bronchiolitis Obliterans Syndrome (BOS). The Company's partner, Ultragenyx Pharmaceutical, Inc., has initiated a pivotal Phase 2/3 pediatric study in young adults (5-25 years old) for setrusumab in OI and expects to initiate a study in pediatric patients (2-4 years old) in the second half of 2022. The partnership with Ultragenyx includes potential milestone payments of up to $254 million and royalties to Mereo on Ultragenyx territories. Mereo has retained EU and UK commercial rights and will pay Ultragenyx royalties on those territories. Alvelestat has received U.S. Orphan Drug Designation for the treatment of AATD, Fast Track designation from the FDA, and positive top-line data were recently reported from a Phase 2 proof-of-concept study in North America, Europe and the UK. Mereo's lead oncology product candidate, etigilimab (anti-TIGIT), is currently in 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 global licensing agreement with OncXerna includes payments of up to $300 million in milestones and royalties.

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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