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 March, 2023

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 March 21, 2023

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: March 21, 2023

MEREO BIOPHARMA GROUP PLC

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

Exhibit 99.1

Mereo BioPharma Provides Regulatory Updates on Alvelestat for the Treatment of Alpha-1-Antitrypsin Deficiency-Associated Lung Disease

Clear path forward with proposed single Phase 3 study evaluating alvelestat at the 240 mg dose level versus placebo at 12-18 months for potential full approval in both the U.S. and EU

No additional confirmatory study required

Company to host conference call today at 8:30am ET

London, March 21, 2023 – Mereo BioPharma Group plc (NASDAQ: MREO) (Mereo or the Company), a clinical-stage biopharmaceutical company focused on rare diseases, today announced regulatory feedback following recent end-of-Phase 2 meetings with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) related to its alvelestat program for the treatment of alpha-1-antitrypsin deficiency-associated lung disease (AATD-LD).

Based on clear recommendations from the FDA and the EMA, the Company is designing a single, global, Phase 3 study evaluating the 240 mg dose of alvelestat versus placebo in patients with AATD-LD to support applications for full marketing approvals in both the United States (U.S.) and European Union (EU). The Company's proposed Phase 3 study has two independent primary endpoints, i) a Patient- Reported Outcome (PRO), as guided by the FDA, and ii) lung density measured by CT scan, as guided by the EMA.

In line with previous guidance by the Company, Mereo is exploring potential partnerships to fund the Phase 3 study, and believes that this clear path forward will support these efforts.

Each of the proposed primary endpoints has been shown to be associated with reductions in certain disease activity biomarkers. The proposed PRO of the St. George's Respiratory Questionnaire (SGRQ) Activity domain was shown to be associated with the reduction of desmosine and Aα-Val^{360} in the Company's Phase 2 ASTRAEUS study. The association of desmosine reduction with lung density measured by CT scan was demonstrated in published clinical data in AATD [1].

Both the FDA and EMA recognize the challenges associated with development of new therapeutics for AATD-LD. Consistent with an openness to supporting the advancement of therapeutic development in this space, the EMA has indicated that for the primary endpoint of lung density measured by CT scan, it would accept a more relaxed Type 1 error (i.e., $p<0.1$) for a potential full approval that is not contingent on the outcome of a confirmatory study. Additional supportive secondary endpoints are being proposed, including biomarker-based endpoints that may provide sufficient data to validate the biomarkers for future studies.

If successful, this proposed Phase 3 study, with an expected duration of 12-18 months and an enrollment target of approximately 200 patients, is expected to support full regulatory approvals in both the U.S. and EU without an additional confirmatory trial. This could provide the Company with a path to full approval of alvelestat based on a Phase 3 trial similar in size and length to what would be required for an accelerated or conditional approval based on biomarkers. Mereo also believes that this proposed study, if successful, will support more productive initial reimbursement discussions with payors following potential regulatory approvals.

"We are very pleased with the feedback from our meetings with both the FDA and EMA, and grateful for the thorough guidance each Agency provided and the clear path forward that the Agencies have each outlined for alvelestat," said Dr. Denise Scots-Knight, Chief Executive Officer of Mereo. "We believe this is the first time a proposed registrational study in AATD-LD will use both a Patient-Reported Outcome

approach, and an objective clinical outcome measure of lung density measured by CT scan as independent primary endpoints, allowing for a clinical trial with a reasonable number of patients conducted over a manageable timeframe. We believe this represents a significant step forward in the development of new therapies for AATD-LD, and we look forward to further collaboration with both Agencies as we refine the Phase 3 study design to support alvelestat's continued efficient clinical development and its timely availability for patients."

1*: Ma et al. The Effect of Alpha-1 Proteinase Inhibitor on Biomarkers of Elastin Degradation in Alpha-1 Antitrypsin Deficiency: An Analysis of the RAPID/RAPID Extension Trials.* Chronic Obstr Pulm Dis. 2017;4(1):34-44

Conference Call and Webcast

Mereo BioPharma will hold a conference call today, March 21, at 8:30am ET. To participate by telephone, please dial (877) 418-5268 in the U.S., or (412) 902-6771 internationally, and ask for the Mereo BioPharma Group Conference Call. A live audio webcast of the call can be accessed through the Investors section of the Company's website at www.mereobiopharma.com/investors. An archived replay of the webcast will be available on the Company's website for two weeks following the live event.

About Mereo BioPharma

Mereo BioPharma is a biopharmaceutical company focused on the development of innovative therapeutics for rare diseases. The Company has developed a robust portfolio of 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 associated lung disease (AATD-LD) 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 (<5 years old) in the first half of 2023. The partnership with Ultragenyx includes potential milestone payments of up to $254 million and royalties to Mereo on commercial sales in Ultragenyx territories. Mereo has retained EU and UK commercial rights and will pay Ultragenyx royalties on commercial sales in those territories. Alvelestat has received U.S. Orphan Drug Designation for the treatment of AATD, Fast Track designation from the FDA, and positive data were recently reported from a Phase 2 proof-of-concept study in North America, Europe and the UK. In addition to the rare disease programs, Mereo has two oncology product candidates in clinical development. Etigilimab (anti-TIGIT) has completed enrollment in a Phase 1b/2 basket study evaluating its safety and efficacy 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; Navicixizumab, for the treatment of late line ovarian cancer, has completed a Phase 1 study and has been partnered with OncXerna Therapeutics, Inc. in a global licensing agreement that includes payments of up to $300 million in milestones and royalties.

About AATD

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, 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.

About Alvelestat

Alvelestat is a novel, oral small molecule designed to specifically inhibit neutrophil elastase (NE), a key enzyme involved in inflammation and the destruction of lung tissue. Alvelestat penetrates the lung

tissue and is active against both cell-bound and soluble elastase. The safety and tolerability profile of alvelestat has been established through clinical trials in over 1,000 patients with respiratory diseases, including AATD-LD, COPD, bronchiectasis, cystic fibrosis, COVID-19 and bronchiolitis obliterans syndrome following allogeneic stem cell transplant.

Forward-Looking Statements

This press release contains "forward-looking statements," including the Company's expectations regarding its proposed Phase 3 study evaluating a single dose of alvelestat versus placebo, the expectations regarding a study in pediatric patients evaluating setrusumab, and the Company's pipeline of product candidates. 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 U.S Securities Act of 1933, as amended , and Section 21E of the U.S Securities Exchange Act of 1934, as amended. 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. Such risks and uncertainties include, among others, the uncertainties inherent in the clinical development process; the Company's reliance on third parties to conduct and provide funding for its clinical trials; the Company's dependence on enrollment of patients in its clinical trials; and the Company's dependence on its key executives. 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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