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 September, 2020

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 September 24, 2020.

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: September 24, 2020

MEREO BIOPHARMA GROUP PLC

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

Exhibit 99.1

THIS ANNOUNCEMENT CONTAINS INSIDE INFORMATION AS DEFINED UNDER THE MARKET ABUSE REGULATION (EU) NO. 596/2014. UPON PUBLICATION OF THIS ANNOUNCEMENT THIS INFORMATION IS NOW CONSIDERED IN THE PUBLIC DOMAIN.

Mereo BioPharma Receives FDA Rare Pediatric Disease Designation for Setrusumab for the Treatment of Osteogenesis Imperfecta

London and Redwood City, Calif., September 24, 2020 – Mereo BioPharma Group plc (NASDAQ: MREO, AIM: MPH), "Mereo" or "the Company", a clinical-stage biopharmaceutical company focused on oncology and rare diseases, today announces that the U.S. Food and Drug Administration ("FDA") has granted Rare Pediatric Disease designation to setrusumab for the treatment of osteogenesis imperfecta ("OI"). Setrusumab is a fully humanized monoclonal antibody that inhibits sclerostin, a protein which inhibits the activity of bone-forming cells. OI is a genetic rare disorder with no approved treatments that is characterized by reduced bone mass and fragile bones that break easily. In Mereo's Phase 2b ASTEROID study, setrusumab demonstrated a dose-dependent bone building effect and a trend of reduction in fractures in addition to being safe and well tolerated in adults with OI.

The FDA grants Rare Pediatric Disease Designation for serious and life-threatening diseases that primarily affect children aged 18 years or younger and fewer than 200,000 people in the United States. If a Biologics License Application ("BLA") in the United States for setrusumab is approved, Mereo may be eligible to receive a priority review voucher from the FDA, which can be redeemed to obtain priority review for any subsequent marketing application and may be sold or transferred to other companies for their programs, as has been done by other voucher recipients.

"Receiving Rare Pediatric Disease designation from the FDA highlights the significant unmet medical need facing children with OI and underscores the potential of setrusumab to become the first approved treatment option specifically for these patients," said Dr. Denise Scots-Knight, Chief Executive Officer of Mereo. "Following the completion of our Phase 2b ASTEROID study, we are pleased that both the FDA and EMA have agreed on the principles of a design of a single Phase 3 pivotal pediatric study in OI. We believe there is a clear path forward for setrusumab in OI and are continuing discussions with potential partners prior to the initiation of a Phase 3 study consistent with our Company strategy."

About Osteogenesis Imperfecta

Osteogenesis Imperfecta (OI) is a rare genetic disorder that is characterized by fragile bones and reduced bone mass resulting in bones that break easily, loose joints and weakened teeth. In severe cases, those with OI may experience hundreds of fractures in a lifetime. In addition, people with OI often suffer muscle weakness, early hearing loss, fatigue, curved bones, scoliosis, respiratory problems and short stature, leading to significant impacts on overall health and quality of life. The majority of cases of OI (estimated at approximately 90%) are caused by a dominant mutation in a gene coding for type I collagen, a key component of healthy bone. Current treatment of OI is supportive, focusing on minimizing fractures and maximizing mobility, but to date, there are no FDA or EU approved treatments.

About Setrusumab

Setrusumab is a fully humanized monoclonal antibody that inhibits sclerostin, a protein which inhibits the activity of bone-forming cells. The mechanism of action of setrusumab could be particularly well suited for the treatment of OI and setrusumab has the potential to become the first approved treatment option that could reduce fractures and improve the quality of life for individuals with OI. Mereo has obtained orphan drug designation in OI for setrusumab in both the United States and the EU. Setrusumab was accepted into the EMA's Adaptive Pathways program in the EU and was accepted into the EMA's Priority Medicines scheme (PRIME). In the Phase 2b ASTEROID study, setrusumab demonstrated a dose-dependent bone building effect and a trend of reduction in fractures in addition to being safe and well tolerated adults with OI. Following the review of the data from the Phase 2b ASTEROID study, the FDA agreed on the principles of a design of a Phase 3 pediatric study in OI to be completed prior to the submission of a BLA in the United States, which is also in line with Mereo's proposed pivotal pediatric study design that has been agreed to in principle with the European Medicines Agency ("EMA"). Mereo intends to partner setrusumab prior to conducting a pivotal trial of setrusumab in children with severe OI.

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. Mereo's lead oncology product candidate, etigilimab (Anti-TIGIT), has completed a Phase 1a dose escalation clinical trial in patients with advanced solid tumors and has been evaluated in a Phase 1b study in combination with nivolumab in select tumor types. Mereo's rare disease product portfolio consists of setrusumab, which has completed a Phase 2b dose-ranging study in adults with OI, as well as alvelestat, which is being investigated in a Phase 2 proof-of-concept clinical trial in patients with alpha-1 antitrypsin deficiency (AATD) and in a Phase 1b/2 clinical trial in COVID-19 respiratory disease.

Additional Information

The person responsible for arranging the release of this information on behalf of the Company is Charles Sermon, General Counsel.

Forward-Looking Statements

This Announcement contains "forward-looking statements." All statements other than statements of historical fact contained in this Announcement are forward-looking statements within the meaning of Section 27A of the United States Securities Act of 1933, as amended and Section 21E of the United States Securities Exchange Act of 1934, as amended. Forward-looking statements usually relate to future events and 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. The foregoing factors and the other risks and uncertainties that affect the Company's business, including those described in its Annual Report on Form 20-F, Reports on Form 6-K and other documents filed from time to time by the Company with the United States Securities and Exchange Commission. You should not 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 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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