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 July, 2019

Commission File Number: 001-38452

MEREO BIOPHARMA GROUP PLC
(Translation of registrant's name into English)

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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 ☐

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MEREO BIOPHARMA GROUP PLC

MEREO BIOPHARMA ANNOUNCES SUCCESSFUL TYPE B MEETING WITH U.S. FDA AND OUTLINES ACCELERATED APPROVAL PATHWAY FOR NAVICIXIZUMAB IN ADVANCED OVARIAN CANCER

London and Redwood City, Calif., July 15, 2019 - Mereo BioPharma Group plc (NASDAQ: MREO, AIM: MPH), a clinical stage biopharmaceutical company focused on rare diseases, today announces that it has held a successful Type B meeting with the U.S. Food and Drug Administration (FDA) regarding a potential pathway for accelerated approval for navicixizumab for the treatment of patients with advanced ovarian cancer. Navicixizumab is an anti-DLL4/VEGF bispecific antibody and one of two product candidates Mereo acquired through its April 2019 merger with OncoMed Pharmaceuticals, Inc. Navicixizumab has completed a Phase 1a monotherapy study in patients with various types of refractory solid tumors and is currently being evaluated in an ongoing Phase 1b study in combination with paclitaxel in patients with advanced platinum-resistant ovarian cancer.

In the Type B meeting, Mereo and the FDA discussed, and agreed in principle, an outline for the design of a Phase 2 clinical trial that could potentially support the accelerated approval of navicixizumab in patients with ovarian cancer (including peritoneal or fallopian tube cancer) who have become resistant to their prior therapies. The primary endpoint of the study will be confirmed overall response rate (ORR). Secondary endpoints will include duration of response (DOR), safety, CA-125 response rate, progression free survival and overall survival. Patients who receive navicixizumab will be treated Q2W on days 0, 7, and 14 of every 28-day cycle.

Jill Henrich, Senior Vice President of Regulatory Affairs, Mereo BioPharma commented, “There are limited treatment options for patients with platinum-resistant ovarian cancer who have also failed multiple other therapies. We believe the 41% (18/44) unconfirmed ORR seen in the Phase 1b study as of the last interim data cut at the end of Q1 2019 is encouraging and we are pleased that the FDA has recognized both the unmet medical need in this difficult-to-treat patient population as well as the potential of navicixizumab to provide a meaningful treatment option for these patients. In line with our corporate strategy to focus on the development of our rare disease product portfolio, we have commenced partnering discussions for navicixizumab and look forward to continued progress on this front.”

About Navicixizumab

Navicixizumab is an anti-DLL4/VEGF bispecific antibody designed to inhibit both DLL4 in the Notch cancer stem cell pathway as well as vascular endothelial growth factor (VEGF) and thereby induce potent anti-tumor responses while mitigating certain angiogenic-related toxicities. In preclinical studies, navicixizumab demonstrated robust in vivo anti-tumor efficacy across a range of solid tumor xenografts, including colon, ovarian, lung and pancreatic cancers, among others. In a Phase 1a study with single-agent navicixizumab, 19 of 66 patients with various types of refractory solid tumors had tumor shrinkage following treatment with navicixizumab. Notably, 3 of the 12 (25%) ovarian cancer patients treated in the trial achieved an unconfirmed partial response with single-agent navicixizumab therapy.

A Phase 1b dose escalation and expansion study of navicixizumab plus paclitaxel has completed enrolment of 44 platinum resistant ovarian cancer patients who had failed >2 prior therapies and/or received prior bevacizumab. As of the last interim data analysis at the end of Q1 2019, the median number of prior therapies was 4, 100% of patients had previously received both paclitaxel and a platinum agent, 68% had previously received bevacizumab and 41% had received a PARP inhibitor. The unconfirmed response rate was 41%. The unconfirmed ORR for bevacizumab-naïve patients was 64% and 30% for bevacizumab pre-treated patients. The median PFS for all patients was 7.3 months. The most common related adverse events of any grade were hypertension (68%), fatigue (46%), headache (25%), neutropenia (21%), diarrhea18%), pulmonary hypertension (14%), dyspnea (14%) and peripheral edema (14%). There were no cases of Grade 3 pulmonary hypertension. Other related adverse events of special interest were one Grade 1 related heart failure, one Grade 3 and one Grade 4 related thrombocytopenia, and one Grade 4 related gastrointestinal perforation. Navicixizumab resulted in treatment-induced ADA formation in 5 out of 29 (17%) subjects. Accelerated clearance and decreased exposure of navicixizumab was evident in 3 of the 5 ADA positive subjects. Two of these 3 subjects had an infusion reaction.

About Mereo

Mereo is a biopharmaceutical company focused on the development and commercialization of innovative therapeutics that aim to improve outcomes for patients with rare diseases. Mereo's strategy is to selectively acquire product candidates for rare diseases that have already received significant investment from pharmaceutical and large biotechnology companies and that have substantial preclinical, clinical and manufacturing data packages. Mereo's existing portfolio consists of six clinical stage product candidates.

- Setrusumab for osteogenesis imperfecta (OI). In October 2018, the Company announced completion of enrollment of 112 adult patients in a Phase 2b dose ranging study with initial positive 6-month open label data announced in May 2019 and top-line 12-month blinded dose ranging data expected in Q4 2019. A pediatric Phase 3 study design has also been approved by the EMA. Setrusumab has orphan designation in the U.S. and the EU and has been accepted into the PRIME and Adaptive Pathways in EU;
- Alvelestat for alpha-1 antitrypsin deficiency (AATD). The Company has initiated a Phase 2 proof-of-concept clinical trial in patients with severe AATD in the United States and the EU and expects to report top-line data from this trial around the end of 2019;
- Acumapimod for severe exacerbations of COPD. The Company announced positive Phase 2 data in May 2018 and recently announced the outline of the pivotal Phase 3 study including the primary and key secondary endpoints following the successful end of Phase 2 Type B meeting with the FDA;
- Leflutrozole for hypogonadotropic hypogonadism (HH). The Company announced positive top-line Phase 2b data in March 2018 and positive results from the Phase 2b safety extension study in December 2018;
- Navicixizumab has completed a Phase 1a single-agent clinical trial in patients with advanced solid tumors and is currently in a Phase 1b trial in combination with a standard paclitaxel regimen in patients with platinum-resistant ovarian cancer. This study recently completed enrollment; and
- Etigilimab has completed a single-agent Phase 1a trial in patients with advanced or metastatic solid tumors and the Phase 1b combination study with nivolumab has fully enrolled and is currently in the safety monitoring phase.

Further Enquiries

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SIGNATURE

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: July 15, 2019

MEREO BIOPHARMA GROUP PLC

By: /s/ Denise Scots-Knight
Name: Denise Scots-Knight
Title: Chief Executive Officer