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 May, 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): ☐

Mereo BioPharma Group plc Announces Positive Top-Line Efficacy and Safety Data from "ASTRAEUS" Phase 2 Trial of Alvelestat in Alpha-1 Antitrypsin Deficiency-associated Emphysema

On May 9, 2022, Mereo BioPharma Group plc (the "Company") announced positive top-line efficacy and safety results from "ASTRAEUS" a Phase 2 study of the investigational oral neutrophil elastase (NE) inhibitor, alvelestat (MPH-966), in patients with severe alpha-1 antitrypsin deficiency-related emphysema, or AATD. The double-blind placebo-controlled study evaluated two different doses of alvelestat (high or low dose) or placebo, over a 12-week period (at weeks four, eight and 12) and the effect on three primary biomarker endpoints associated with AATD-related lung disease (AATD-LD), blood neutrophil elastase activity, Aa-val^{360} and the elastin breakdown product, desmosine. A total of 99 patients were enrolled and 98 patients were dosed in the study. At the high dose, alvelestat demonstrated statistically significant changes versus placebo in all three primary biomarker endpoints.

ASTRAEUS Study Design Overview

ASTRAEUS (ClinicalTrials.gov Identifier: NCT03636347) was a randomized double-blind placebo-controlled study in patients naïve to augmentation therapy or following a six-month wash-out period. The study enrolled 99 adults with severe AATD related emphysema across 26 sites in North America, Europe and the U.K. of which 98 were dosed. To support the use of a biomarker development strategy interrogating the pathogenic pathway, an amendment elevated two secondary biomarkers (neutrophil elastase (NE) activity and Aa-val^{360}) to primary endpoints in addition to desmosine resulting in three primary biomarker primary endpoints. Patients were randomized to one of three different arms, high dose, low dose or placebo, following Independent Safety Data Monitoring Committee (IDMC) review of the initial cohorts. The protocol allowed prioritization of enrollment to the high dose arm in the case of recruitment challenges and this change was implemented during the COVID-19 pandemic. The Company made the decision to close the study when it was determined an adequate number of subjects had been recruited to the high dose arm to assess the primary endpoints.

Patients underwent a twelve-week dosing period followed by a four-week follow-up. The primary endpoints included within individual percentage change from baseline up to end of treatment within a treatment arm and in comparison to placebo at weeks, four, eight and 12 in blood NE activity, blood Aa-Val^{360} levels and plasma desmosine levels. The secondary endpoints were the proportion of subjects with NE below the limit of quantitation and Pharmacokinetic (PK), safety and tolerability. Exploratory endpoints included rate of acute exacerbations of COPD, pulmonary function tests, St. Georges Respiratory questionnaire, inflammatory and lung damage biomarkers.

The study was originally designed to enroll 165 patients, however, the Company took the decision to close the study when it was determined an adequate number of subjects were recruited to the high dose arm to assess the primary endpoints, with a total of 99 patients enrolled.

Enrollment Overview

At the close of the study the number of patients enrolled and completed in the arms were, 41 in the high dose arm, 22 in the low dose arm and 36 in the placebo arm. All patients were of the severe alpha 1-antitrypsin ("AAT") deficiency (PiZZ) genotype representing the more severe patient population which occurs in Z allele homozygotes and is associated with early-onset emphysema. All patients had low AAT levels and only 11% of the patients had received prior augmentation therapy. The wash-out period was greater than two years for those patients who had received prior augmentation therapy.

ASTRAEUS Efficacy

The study enrolled 99 patients with 98 patients being dosed. The full analysis set (FAS) includes subjects with at least one measurement of a primary endpoint post baseline, a total of 94 patients. Due to the known effect of acute respiratory exacerbations increasing Aa-val^{360} and desmosine in AATD patients, a per protocol set (PPS) was defined in the Statistical Analysis Plan and identified prior to unblinding excluding these subjects who had moderate/severe acute exacerbations. The per protocol set includes 84 patients. Data from the three primary endpoints are presented below.

Neutrophil Elastase Activity

Statistically significant inhibition of NE was observed from first assessment at week four, and this was maintained over the course of the study. The effect was greater in the high dose compared to the low dose. No significant changes from baseline were observed in the placebo arm.

Week	Within Group % Change from Baseline LSM			
	Low Dose (n=20)	*P value*	*High dose (n=39)*	*P value*
4	-89.9%	0.001**	-88.9%	<0.001***
8	-83.5%	0.006**	-93.9%	<0.001***
12	-81.7%	0.026*	-87.8%	<0.001***

Changes versus placebo *< 0.02, ** < 0.01, ***<0.001 (LSM – least squared means).

Aa-val^{360}

At the high dose of alvelestat, Aa-val^{360} decreased below baseline at week four with progressive decreases resulting in statistical significance verses placebo at weeks eight and 12. The placebo showed an increase at all time points.

Week	% Change Alvelestat vs Placebo LSM	
	High Dose	*P value*
4	-8.1%	0.146
8	-27.1%	0.006
12	-27.6%	0.002

Smaller effects were observed in the low dose arm, and these generally did not reach statistical significance (LSM - least squared means).

Desmosine

At the high dose of alvelestat desmosine levels decreased with time whereas placebo increased over time.

Week	Within Group % Change from Baseline LSM			
	High Dose	*P value*	*Placebo*	*P value*
4	-9.4%	0.097	10.1%	NS >0.9
8	-13.7%	0.035*	17.9%	NS >0.9
12	-10.6%	0.061#	18.1%	NS >0.9

*p = 0.032 alvelestat versus placebo, #p =0.181 alvelestat versus placebo (LSM – least squared means).

No changes in the level of desmosine in the low dose could be detected at any time point. However, the number of patients in the low dose arm were small due to the preferential enrollment to the high dose group, reducing the power to detect effects in this arm.

The percentage changes in desmosine and Aa-val^{360} at the high dose were comparable to those reported with placebo-controlled augmentation studies following three and six months of treatment. Desmosine and Aa-val^{360} have been demonstrated to correlate with lung function and lung density in patients with AATD and respond to AAT replacement during weekly intravenous augmentation therapy.

The Company plans to complete additional analyses on the other secondary and exploratory endpoints in the second half of 2022.

Safety and Tolerability

Consistent with the known safety profile of alvelestat, no safety signals were observed in adverse event (AE) monitoring. Most AEs were mild to moderate, including within Adverse Events of Special Interest (AESI) which were observed in 23 subjects. AESIs of infection were recorded in 21 subjects and these were of similar frequency and severity in the alvelestat and placebo arms and were events expected in the disease population. A single AESI of liver enzyme (Alanine Transaminase) elevation $\geq$5 x Upper Limit of Normal (ULN), associated with raised Aspartate Transaminase (AST) $\geq$2 x ULN, without raised bilirubin occurred at week 8 in the high dose arm. The event met study drug stopping criteria and the raised transaminase levels dropped over the course of the next 10 days. One case of prolonged QTcF occurred in a subject who was on medication known to prolong QTcF at entry to the study. This event occurred at the high dose during the week 4 study visit and the study drug was discontinued. There were no incidences of Hy's law nor deaths on study.

Treatment emergent adverse events, including SAEs, were more frequent in the alvelestat groups predominantly due to headache. Dose-escalation for the high dose arm was instigated to manage the headaches.

Updated Cash Balance Update and Guidance

As of March 31, 2022, the Company had cash and short-term deposits of £84.9 million ($111.4 million). The Company expects its existing cash and short-term deposits will enable it to fund its currently committed clinical trials, operating expenses and capital expenditure requirements into 2024.

Next Steps

The Company plans to analyze the additional data on the secondary and exploratory endpoints in the second half of 2022 and to then engage with the regulators in the US and Europe for an End of Phase 2 meeting to determine the design of a pivotal registrational trial for alvelestat for the treatment of AATD-LD.

The investigator led ATALANta trial studying alvelestat in a broader range of patient populations, including other genotypes and those on augmentation therapy, is expected to read out in the first half of 2023.

The contents of this Report on Form 6-K (excluding Exhibit 99.1 hereto) are incorporated by reference in the Company's registration statement on Form F-3 (File No. 333-258495).

About AATD-LD

Alpha-1 antitrypsin deficiency is a genetic condition that results in progressive alveolar destruction leading to emphysema. People with alpha-1 antitrypsin deficiency have significantly reduced levels of AAT, a protective protein that inhibits the protease, neutrophil elastase. Unopposed neutrophil elastase is believed to the key enzyme in the causal pathologic pathway of AATD-LD. AATD-LD presents at age 20 to 50 with symptoms including, shortness of breath, cough, and reduced exercise tolerance. People with AATD may progress to chronic oxygen therapy, lung surgery, transplant, and death.

About Alvelestat

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About Mereo BioPharma Group plc

Mereo BioPharma Group plc is a biopharmaceutical company focused on the development of innovative therapeutics that aim to improve outcomes for oncology and rare diseases and plans to commercialize selected rare disease programs. The Company has developed a portfolio of six clinical stage product candidates. Mereo's lead oncology product candidate, etigilimab (anti-TIGIT), has 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) and Bronchiolitis Obliterans Syndrome (BOS), and setrusumab for the treatment of osteogenesis imperfecta (OI). Alvelestat has recently received U.S. Orphan Drug Designation for the treatment of AATD and positive top-line data were recently reported from a Phase 2 proof-of-concept study in North America, Europe and the UK. 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 (2-5 years old) in the second half of 2022.

Forward-Looking Statements

This Report on Form 6-K contains "forward-looking statements." All statements other than statements of historical fact contained herein are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the 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.

Exhibit Index

Exhibits

99.1	Press release dated May 9, 2022 titled "Mereo BioPharma Announces Positive Top-Line Efficacy and Safety Data from "ASTRAEUS" Phase 2 Trial of Alvelestat in Alpha-1 Antitrypsin Deficiency-associated Emphysema."

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: May 9, 2022

MEREO BIOPHARMA GROUP PLC

By: /s/ Christine Fox
Name: Christine Fox
Title: Chief Financial Officer

Exhibit 99.1

Mereo BioPharma announces Positive Top-Line Efficacy and Safety Data from "ASTRAEUS" Phase 2 Trial of Alvelestat in Alpha-1 Antitrypsin Deficiency-associated Emphysema

Statistically significant inhibition of blood neutrophil elastase activity of up to 90% in patients in both high and low dose alvelestat groups throughout the 12-week dosing period

*Statistically significant reductions in the biomarkers A*a-*val360 and desmosine at the high dose demonstrating clear impact of alvelestat on the pathogenic pathway of AATD-lung disease*

No safety signals were associated with alvelestat

Conference Call Today at 10:30 a.m. ET

London and Redwood City, Calif., May 9, 2022 – Mereo BioPharma Group plc (NASDAQ: MREO), ("Mereo" or "the Company"), a clinical-stage biopharmaceutical company focused on oncology and rare diseases, today announced positive top-line efficacy and safety results from "ASTRAEUS" a Phase 2 study of the investigational oral neutrophil elastase (NE) inhibitor, alvelestat (MPH-966), in patients with severe alpha-1 antitrypsin deficiency-associated emphysema.

The double-blind placebo-controlled study evaluated two different doses of alvelestat (high or low dose) or placebo, over a 12-week period (at weeks four, eight and 12) and the effect on three primary biomarker endpoints associated with AATD-related lung disease (AATD-LD), blood neutrophil elastase activity, Aa-val^{360} and the elastin breakdown product, desmosine. A total of 99 patients were enrolled and 98 patients were dosed in the study. At the high dose, alvelestat demonstrated statistically significant changes versus placebo in all three primary biomarker endpoints.

"These positive top-line results demonstrate the clear impact of alvelestat on key known biomarkers along the pathogenic pathway of AATD-LD," said Dr. Denise Scots-Knight, Chief Executive Officer of Mereo. "Alvelestat has the potential to be the first-in-class oral neutrophil elastase inhibitor for the treatment of AATD-LD. We look forward to analyzing the additional data on the secondary and exploratory endpoints and to engaging with the regulators on the design of a pivotal study."

Mereo is grateful for the commitment of individuals with AATD who volunteered to take part in the study, to the investigators and their teams, especially as the study was conducted during height of the COVID-19 pandemic. The Company also thanks the Alpha-1 Foundation for their funding in support of the study.

"We are exceptionally pleased with these results, for the first time demonstrating the specific inhibition of neutrophil elastase on biomarkers relevant to the disease pathway in patients with severe AATD-related emphysema. As an oral therapy, alvelestat has the potential to significantly improve the management of AATD, and we look forward to further development to increase the therapeutic options for patients," stated Prof. Robert Stockley, Lung Investigation Unit, University of Birmingham (United Kingdom) and Chief Investigator of the ASTRAEUS trial.

Prof. Mark Dransfield, of the University of Alabama at Birmingham (United States) and principal investigator of the ATALANTa study (a companion trial to ASTRAEUS), stated “We are delighted to see these positive results from ASTRAEUS and will be building on the data with our ATALANTa study investigating alvelestat in a broader group of patients, including those already on AAT augmentation. We look forward to the additional data readout adding to the learnings from ASTRAEUS presented today.”

Conference Call and Webcast

Mereo BioPharma will hold a conference call today, May 9, at 10:30am EDT. To participate by telephone, please dial US (toll free): (866) 374-5140 or international: (404) 400-0571. The conference ID number is 50222760. To view the slideshow please use the live webcast at https://wsw.com/webcast/cc/mph.l3/1480428 or 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 presentation.

ASTRAEUS Study Design Overview

ASTRAEUS (ClinicalTrials.gov Identifier: NCT03636347) was a randomized double-blind placebo-controlled study in patients naïve to augmentation or following a 6-month wash-out period. The study enrolled 99 adults with severe AATD related emphysema across 26 sites in North America, EU and U.K. of which 98 were dosed. To support the use of a biomarker development strategy interrogating the pathogenic pathway, as previously announced, an amendment elevated two secondary biomarkers (NE activity and Aa-val^{360}) to primary endpoints in addition to desmosine resulting in three biomarker primary endpoints. Patients were randomized to one of three different arms, high dose, low dose or placebo, following Independent Safety Data Monitoring Committee (IDMC) review of the safety from the initial cohorts. As previously announced, the protocol allowed prioritization of enrollment to the high dose arm in the case of recruitment challenges and this change was implemented during the COVID-19 pandemic. As previously announced, the Company took the decision to close the study when it was determined an adequate number of patients had been recruited to the high dose arm to assess the primary endpoints.

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ASTRAEUS Efficacy

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Aa-val360

At the high dose of alvelestat, Aa-val360 decreased below baseline at week four with progressive decreases resulting in statistical significance versus placebo at weeks 8 and 12. The placebo showed an increase at all time points.

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The Company plans to complete additional analyses on the other secondary and exploratory endpoints in 2H 2022.

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