UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

Current Report
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 8, 2024

MEREO BIOPHARMA GROUP PLC
(Exact name of registrant as specified in its charter)

England and Wales	**001-38452**	**Not Applicable**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

4th Floor, One Cavendish Place,
London, W1G 0QF
United Kingdom
(Address of principal executive offices, including zip code)

+44-333-023-7300
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
American Depositary Shares, each representing five Ordinary Shares, par value £0.003 per share	MREO	The Nasdaq Stock Market LLC
Ordinary Shares, nominal value £0.003 per share*	*	The Nasdaq Stock Market LLC

* Not for trading, but only in connection with the listing of the American Depositary Shares on The Nasdaq Stock Market LLC.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

Press Release

On January 8, 2024, Mereo BioPharma Group plc (the "Company") issued a press release providing an update on its pipeline programs as well as an update on recent corporate developments. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Domestic Issuer Status

The Company will begin to file periodic reports and registration statements on U.S. domestic issuer forms with the U.S. Securities and Exchange Commission, which are more detailed and extensive in certain respects, and which must be filed more promptly, than the forms available to a "foreign private issuer" as defined in Rule 405 under the Securities Act of 1933, as amended. Prior to January 1, 2024, the Company qualified as a foreign private issuer.

Disclosure Channels to Disseminate Information

The Company announces material information to the public about the Company, its potential product candidates and its pipeline and other matters through a variety of means, including filings with the U.S. Securities and Exchange Commission, press releases, public conference calls, the Company's website (www.mereobiopharma.com) and the investor relations section of its website (www.mereobiopharma.com/investors/overview), in order to achieve broad, non-exclusionary distribution of information to the public. The Company encourages investors and others to review the information it makes public in these locations, as such information could be deemed to be material information. This list of communication channels may be updated from time to time.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description of Exhibit
99.1	Press Release, dated January 8, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

MEREO BIOPHARMA GROUP PLC

Date: January 8, 2024

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

Exhibit 99.1

Mereo BioPharma Provides Update on Pipeline Progress and Corporate Developments

Phase 3 portion of Orbit Study and Phase 3 Cosmic Study of setrusumab for treatment of Osteogenesis Imperfecta (OI) conducted by partner Ultragenyx expected to complete enrollment around the end of 1Q 2024 and 1H 2024, respectively; Additional Phase 2 data expected in 2024

Alignment on design for single, global Phase 3 study of alvelestat in Alpha-1 Antitrypsin Deficiency-associated Lung Disease (AATD-LD) following additional interactions with U.S. FDA in 2H 2023

Signs global licensing deal for development and commercialization of leflutrozole

Reiterates previous cash runway guidance; current cash expected to fund operations into 2026

London, January 8, 2024 – Mereo BioPharma Group plc (NASDAQ: MREO) ("Mereo" or the "Company"), a clinical-stage biopharmaceutical company focused on rare diseases, today provided an update on its pipeline programs as well as an update on recent corporate developments.

"2023 was a year of tremendous progress for Mereo. Key milestones in the development of setrusumab for the treatment of OI included positive data from the Phase 2 portion of the Orbit study, and initiation of the Phase 3 portion of the Orbit study and Phase 3 Cosmic study by our partner, Ultragenyx," said Dr. Denise Scots-Knight, Chief Executive Officer of Mereo. "In addition, we significantly advanced the development of alvelestat, gaining valuable clarity on the regulatory path with both the FDA and EMA. If the proposed Phase 3 study is successful, it could support submissions for full regulatory approvals for this first-in-class therapy addressing a major unmet medical need in Alpha-1 Antitrypsin Deficiency-associated Lung Disease. These developments are expected to further support our ongoing partnering activities for alvelestat. We look forward to providing further updates on both setrusumab and alvelestat during the remainder of the year. With a cash runway into 2026 and several potential important value inflection points on the horizon in 2024, we believe that Mereo remains well positioned for long-term growth and success."

Recent Pipeline Progress

Setrusumab (UX143)

Enrollment in the Phase 3 portion of the Global Phase 2/3 Orbit study led by Mereo's partner, Ultragenyx Pharmaceutical Inc. (NASDAQ: RARE), was initiated in mid-2023 and the study is expected to be fully enrolled around the end of the first quarter of 2024. The pivotal Phase 3 portion of the Orbit study will include up to 195 patients aged 5 to <26 years randomized 2:1 to receive setrusumab or placebo, with a primary efficacy endpoint of annualized clinical fracture rate excluding fingers, toes, skull and face. Additionally, Cosmic, a Global Phase 3 open-label, randomized, active-controlled study in approximately 65 patients aged 2 to <7 years evaluating setrusumab compared to intravenous bisphosphonates on reduction in total fracture rate, including morphometric vertebral fractures, was initiated in the second half of 2023 and is anticipated to be fully enrolled in the first half of 2024.

Recent data reported in October 2023, from the 24 patients enrolled in the Phase 2 portion of the Orbit study with at least 6 months of treatment, showed that treatment with setrusumab reduced the annualized fracture rate by 67%. This reduction was associated with continuing large and meaningful improvements in bone mineral density (BMD). Setrusumab was well tolerated with no drug related serious adverse events (SAE's) reported and no reports of drug-related hypersensitivity. Additional data from the Phase 2 portion of the Orbit study are expected during 2024.

If approved by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), setrusumab would be the first FDA and EMA-approved treatment for Osteogenesis Imperfecta (OI).

The Company has received guidance from the EMA and European Health Technology Assessment (HTA) agencies on its approach to the design and delivery of a post-Marketing Authorization Evidence Generation Plan ("SATURN") and continues to interact with key decision-makers at European and national levels in Mereo's commercial territory to prepare the markets should setrusumab receive regulatory approval.

Alvelestat (MPH-966)

The Company has continued its interactions with the Division of Pulmonology, Allergy and Critical Care (DPACC) and the Division of Clinical Outcome Assessment (DCOA) of the FDA regarding the use of a Patient Reported Outcome (PRO) instrument as a potential primary endpoint in its planned Phase 3 study of alvelestat for the treatment of Alpha-1 Antitrypsin Deficiency-associated Lung Disease (AATD-LD). These interactions followed an End-of-Phase 2 meeting for the Company's ASTRAEUS study in the first quarter of 2023, at which the FDA and the Company discussed the potential use of the St George's Respiratory Questionnaire (SGRQ) Total Score and/or SGRQ Activity domain as the primary endpoint in a Phase 3 study which, if successful, could support submissions for full approval in the U.S.

In the third quarter of 2023, the Company held an additional meeting with the FDA (DPACC and the DCOA) and analyzed additional data from the investigator-led Phase 2 ATALANTa study, which was funded by the National Center for Advancing Translational Sciences (NCATS) through the National Institutes of Health (NIH)-Industry Program for discovering new therapeutic uses for existing molecules, and led by Professor Mark Dransfield from the University of Alabama at Birmingham.

Data from both the ATALANTa and ASTRAEUS studies support the use of the SGRQ Total Score as the primary endpoint in the proposed Phase 3 study based on benefits observed in patients with the severe Pi*ZZ phenotype, including those who are in the early stages of the lung disease. In some countries, these patients are currently not eligible for, or not treated with, augmentation therapy. Following additional FDA interactions in the fourth quarter of 2023, subsequent to the DCOA meeting, the Company has aligned on a Phase 3 study design using SGRQ Total Score as the primary endpoint with a functional assessment as a key secondary endpoint which, if the study is successful, is expected to support submissions for full regulatory approval in the U.S. Inclusion of patients with earlier and later stage lung disease progression in the planned registrational study could increase the addressable patient population for alvelestat.

In Europe, the Company has received guidance from the EMA on the primary endpoint for its Phase 3 clinical trial of alvelestat for the treatment of AATD-LD. The EMA has indicated that lung density by computed tomography (CT) scan with a relaxed p value ($p<0.1$) may be sufficient for full approval if the study is successful.

The Company remains engaged with multiple potential partners for the development and potential commercialization of alvelestat and expects to provide further details on these efforts in 2024.

Leflutrozole

The Company recently entered into an exclusive global license agreement with ReproNovo SA (the "License Agreement") for the development and commercialization of leflutrozole, a non-steroidal aromatase inhibitor. Under the terms of the License Agreement, ReproNovo, a reproductive medicine company, is responsible for all future development and commercialization of leflutrozole. Mereo received an upfront payment and will be eligible to receive up to $64.25 million in future clinical, regulatory and commercial milestones as well as tiered mid-single digit royalties on global annual net sales of leflutrozole.

Cash Runway Guidance and Financial Reporting Update

The Company continues to expect its existing cash and short-term deposits, excluding income from existing or potential partnerships, will enable it to fund its currently committed clinical trials, operating expenses and capital expenditure requirements into 2026.

Effective January 1, 2024, the Company began complying with and reporting under the SEC rules and Nasdaq listing requirements applicable to U.S. domestic filers.

About Mereo BioPharma

Mereo BioPharma is a biopharmaceutical company focused on the development of innovative therapeutics for rare diseases. The Company has two rare disease product candidates, setrusumab for the treatment of Osteogenesis Imperfecta (OI) and alvelestat primarily for the treatment of severe Alpha-1 Antitrypsin Deficiency-associated Lung Disease (AATD-LD). The Company's partner, Ultragenyx Pharmaceutical Inc., initiated a pivotal Phase 2/3 pediatric study in young adults (5 to <26 years old) for setrusumab in OI and a Phase 3 study in pediatric patients (2 to <7 years old) in mid-2023. The partnership with Ultragenyx includes potential milestone payments of up to $245 million (following the recent $9 million milestone) 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. Setrusumab has received orphan designation for OI from the EMA and FDA, PRIME designation from the EMA and has pediatric disease designation from the FDA. Alvelestat has received U.S. Orphan Drug Designation for the treatment of AATD, Fast Track designation from the FDA, and two Phase 2 proof-of-concept studies have been completed in North America and Europe. In addition to the rare disease programs, Mereo has two oncology product candidates in clinical development. Etigilimab (anti-TIGIT) has completed 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 and is in an ongoing Phase 1b/2 investigator led study at the MD Anderson Cancer Center in clear cell ovarian cancer; 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. Mereo has entered into an exclusive global license agreement with ReproNovo SA for the development and commercialization of leflutrozole, a non-steroidal aromatase inhibitor. Under the terms of the agreement, ReproNovo, a reproductive medicine company, is responsible for all future development and commercialization of leflutrozole.

For more information on Mereo BioPharma, please visit www.mereobiopharma.com.

Forward-Looking Statements

This press release contains "forward-looking statements" that involve substantial risks and uncertainties. All statements other than statements of historical fact contained herein 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 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, as well as discussions of potential risks, uncertainties, and other important factors in the Company's subsequent filings 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.

Mereo BioPharma Contacts:

Mereo **+44 (0)333 023 7300**

Denise Scots-Knight, Chief Executive Officer

Christine Fox, Chief Financial Officer

Burns McClellan (Investor Relations Adviser to Mereo) **+01 646 930 4406**

Lee Roth

Investors investors@mereobiopharma.com