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 12, 2025**

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.

On January 12, 2025, Mereo BioPharma Group plc (the "Company") issued a press release providing an update on its lead clinical programs. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in Item 7.01 of this Form 8-K (including Exhibit 99.1 attached hereto) 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, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly provided by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description of Exhibit**
99.1	Press Release, dated January 12, 2025.
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 13, 2025

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

Exhibit 99.1

Mereo BioPharma Provides Update on Lead Clinical Programs

Orbit Phase 3 study of setrusumab in osteogenesis imperfecta continuing to planned second interim analysis, expected in mid-2025

Alvelestat, for Alpha-1 Antitrypsin Deficiency-associated Lung Disease, receives positive EMA opinion on European Orphan Designation Application; European Commission expected to issue final decision in first quarter 2025

London, January 12, 2025 - 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 lead clinical programs, setrusumab, a monoclonal antibody in Phase 3 clinical development for the treatment of Osteogenesis Imperfecta (OI) through a partnership with Ultragenyx Pharmaceutical, Inc. (Ultragenyx) and alvelestat, an oral neutrophil elastase inhibitor being studied for the treatment of alpha-1 antitrypsin deficiency-associated lung disease (AATD-LD). The Company also reiterated its previous cash runway guidance that its current cash and cash equivalents are expected to fund operations into 2027, through multiple key inflection points.

"Based on the highly promising data from completed studies of setrusumab in OI, including the Phase 2 portion of the *Orbit* Study, we remain confident in the potential of setrusumab to become the standard-of-care in OI. We look forward to the second interim analysis expected mid-year as we continue our launch readiness activities in the key European markets," said Dr. Scots-Knight, Chief Executive Officer of Mereo BioPharma. "Additionally, EU Orphan Designation, which follows the granting of both Orphan Drug and Fast Track Designations from the FDA in the U.S., is another important milestone in our ongoing partnering process and our efforts to bring alvelestat to patients worldwide, including earlier stage patients who are not currently eligible for augmentation therapy in many countries. With our cash runway into 2027, we continue to be in a strong position to execute on our key milestones through 2025."

Setrusumab (UX143)

As announced by the Company's partner, Ultragenyx, the Phase 3 *Orbit* Study of setrusumab in OI is continuing to dose patients and progressing towards the planned second interim analysis expected in mid-2025, with a potential final analysis in the fourth quarter of 2025. Additionally, treatment is continuing in *Cosmic*, an open-label Phase 3 study evaluating setrusumab against intravenous bisphosphonate therapy in patients aged 2 to <7 years. Data from the *Cosmic* study will be evaluated in parallel with the *Orbit* interim and final analyses.

Alvelestat (MPH-966)

The European Medicines Agency (EMA)'s Committee for Orphan Medicinal Products (COMP) has issued a positive opinion on the Company's application for Orphan Designation for alvelestat. The COMP recommendation has been provided to the European Commission, which is expected to issue a final decision on the Orphan Designation in the first quarter of 2025. Alvelestat previously received Orphan Drug Designation and Fast Track Designation from the U.S. FDA in 2021 and 2022, respectively.

European Orphan Designation is awarded to therapeutic candidates targeting the treatment, prevention or diagnosis of life-threatening or chronically debilitating diseases with a prevalence of fewer than 5 in 10,000 people in the European Union which provide a significant benefit over available therapies, or for which no approved therapies exist. Therapeutics receiving EU Orphan Designation are eligible for ten years of marketing exclusivity upon approval, as well as fee reductions for various centralized activities including the Marketing Authorization Application, inspections and protocol assistance. Individual EU Member States also provide specific incentives to support the development, review and availability of Orphan Medicinal Products at the time of HTA evaluations and Pricing and Reimbursement negotiations.

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., has completed enrollment in the Phase 3 portion of a pivotal Phase 2/3 study in pediatrics and young adults (5 to 25 years old) for setrusumab in OI and in the Phase 3 study in pediatric patients (2 to <7 years old) in the first half of 2024. The partnership with Ultragenyx includes potential additional milestone payments of up to $245 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. Setrusumab has received orphan designation for osteogenesis imperfecta from the EMA and FDA, PRIME designation from the EMA, and Breakthrough Therapy designation and rare pediatric disease designation from the FDA. Alvelestat has received U.S. Orphan Drug Designation for the treatment of AATD and Fast Track designation from the FDA. Following results from ASTRAEUS and ATALANTa in AATD-lung disease, the Company has aligned with the FDA and the EMA on the primary endpoints for a Phase 3 pivotal study which, if successful, could enable full approval in both the U.S. and Europe. In addition to the rare disease programs, Mereo has two oncology product candidates, etigilimab, an anti-TIGIT; and navicixizumab for the potential treatment of late-line ovarian cancer. Navicixizumab has been partnered with Feng Biosciences, Inc. in a global licensing agreement that includes milestone payments and royalties. Mereo has also entered into an exclusive global license agreement with ReproNovo SA, a reproductive medicine company, for the development and commercialization of leflutrozole, a non-steroidal aromatase inhibitor.

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 Annual Report on Form 10-K, 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:

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