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): **December 29, 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 December 29, 2025, Mereo BioPharma Group plc ("Mereo" or the "Company") issued a press release announcing the results from the Phase 3 Orbit and Cosmic studies evaluating setrusumab (UX143) in pediatric and young adult patients with osteogenesis imperfecta (OI). A copy of the press release is attached hereto as Exhibit 99.1.

The information contained in this Item 7.01, including Exhibit 99.1 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 liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act") or the Exchange Act, except as shall be expressly set forth by reference in such a filing.

Item 8.01 Other Events.

On December 29, 2025, the Company announced the results from the Phase 3 Orbit and Cosmic studies evaluating setrusumab (UX143) in pediatric and young adult patients with osteogenesis imperfecta (OI). Neither study achieved statistical significance against the primary endpoints of reduction in annualized clinical fracture rate compared to placebo or bisphosphonates, respectively. Both studies achieved their secondary endpoints of improvements in bone mineral density (BMD) against comparators (placebo and bisphosphonates) with strong statistical significance. There was no change in the safety profile observed.

ORBIT and COSMIC bone mineral density (BMD) improvements

In the Orbit study, participants experienced statistically significant and substantial improvements in BMD compared to placebo, at levels consistent with the treatment effect observed in Phase 2 studies. These BMD changes were not accompanied by a corresponding reduction in annualized fracture rates and there was a low fracture rate in the placebo group.

In the pediatric Cosmic study, patients had a substantially higher baseline fracture rate compared to the patients enrolled in Orbit. In this younger patient population, meaningful improvements in BMD were associated with a reduction in annualized fracture rate for setrusumab treated patients over bisphosphonate treated patients, though the reduction did not meet statistical significance.

Additional analyses on the data across both studies are being conducted, including in other bone health and clinical endpoints beyond fractures.

Forward Looking Statements

This Current Report on Form 8-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, and Section 21E of the Exchange Act. Forward-looking statements usually relate to future events and anticipated revenues, earnings, cash flows or other aspects of the Company's 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 Mereo's current expectations, beliefs and assumptions concerning future developments and business conditions and their potential effect on Mereo. While management believes that these forward-looking statements are reasonable as and when made, there can be no assurance that future developments affecting Mereo will be those that it anticipates. All of Mereo'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 Mereo's historical experience and its present expectations or projections. Such risks and uncertainties include, among others, the uncertainties inherent in the clinical development process; Mereo's reliance on third parties to conduct and provide funding for its clinical trials; Mereo's dependence on enrollment of patients in its clinical trials; and Mereo's dependence on its key executives. You should carefully consider the foregoing factors and the other risks and uncertainties that affect Mereo's business, including those described in the "Risk Factors" section of its latest Annual Report on Form 10-K, as well as discussions of potential risks, uncertainties, and other important factors in Mereo's subsequent filings with the Securities and Exchange Commission. Mereo wishes to caution you not to place undue reliance on any forward-looking statements, which speak only as of the date hereof. Mereo 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.

Item 9.01 Financial Statements and Exhibits.

The following exhibit relating to Item 7.01 shall be deemed to be furnished, and not filed:

(d) Exhibits

Exhibit No.	Description of Exhibit
99.1	Press Release, dated December 29, 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: December 29, 2025

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

Exhibit 99.1

Mereo BioPharma Announces Phase 3 ORBIT and COSMIC Results for Setrusumab (UX143) in Osteogenesis Imperfecta

Neither study achieved its primary endpoint of reduction in annualized clinical fracture rate compared to placebo (ORBIT) or bisphosphonates (COSMIC)

Both studies achieved secondary endpoint of improvements in bone mineral density with strong statistical significance

London, December 29, 2025 – Mereo BioPharma Group plc (NASDAQ: MREO) ("Mereo" or the "Company"), a clinical stage biopharmaceutical company focused on rare diseases, today announced results from the Phase 3 ORBIT and COSMIC studies for setrusumab (UX143) in Osteogenesis Imperfecta (OI). Neither study achieved statistical significance against the primary endpoints of reduction in annualized clinical fracture rate compared to placebo or bisphosphonates, respectively. Both studies achieved their secondary endpoints of improvements in bone mineral density (BMD) against comparators (placebo and bisphosphonates) with strong statistical significance. There was no change in the safety profile observed.

"Whilst we are disappointed by these results, we will be conducting additional analyses on the data, to assess next steps and the best path forward for the program, especially in pediatrics given the totality of the data and lack of other treatment options for individuals with OI. In the meantime, we are carefully managing our cash resources with immediate reductions in our pre-commercial and manufacturing activities, and we are continuing to advance partnering discussions for alvelestat," said Dr. Denise Scots-Knight, Chief Executive Officer of Mereo.

ORBIT and COSMIC bone mineral density (BMD) improvements

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In the pediatric COSMIC study, patients had a substantially higher baseline fracture rate compared to the patients enrolled in ORBIT. In this younger patient population, meaningful improvements in BMD were associated with a reduction in annualized fracture rate for setrusumab treated patients over bisphosphonate treated patients, though the reduction did not meet statistical significance.

Additional analyses on the data across both studies are being conducted, including in other bone health and clinical endpoints beyond fractures.

Mereo's cash balance was $48.7 million at the end of the third quarter of 2025. The Company will tightly control costs in parallel with conducting further analysis of the setrusumab data to determine the best path forward. Meanwhile the Company will continue to seek to maximize value in its owned and partnered programs, including:

- Alvelestat for AATD-lung disease – in partnering discussions
- Vantictumab for osteopetrosis – partnered with āshibio
- Leflutrozole for male infertility – partnered with ReproNovo.

About the Setrusumab Phase 3 Program
Ultragenyx is developing setrusumab in pediatric and young adult patients across OI sub-types I, III and IV with two late-stage studies: the pivotal Phase 2/3 Orbit study and Phase 3 Cosmic study.

The global, seamless Phase 2/3 Orbit study is evaluating the effect of setrusumab on clinical fracture rate in patients aged 5 to 25 years. The pivotal Phase 3 portion of the study enrolled 159 patients at 45 sites across 11 countries, with subjects randomized 2:1 to receive setrusumab or placebo, and a primary efficacy endpoint of annualized clinical fracture rate.

The global Phase 3 Cosmic study evaluated the effect of setrusumab on reduction in annualized fracture rate in patients aged 2 to <7 years compared to bisphosphonates. The Cosmic study has enrolled 69 patients at 21 sites across 7 countries with patients randomized 1:1 to receive setrusumab or intravenous bisphosphonates (IV-BP) therapy.

About Setrusumab (UX143)
Setrusumab is a fully human monoclonal antibody that inhibits sclerostin, a negative regulator of bone formation. Blocking sclerostin is expected to increase new bone formation, bone mineral density and bone strength in OI. In mouse models of OI, the use of anti-sclerostin antibodies was shown to increase bone formation, improve bone mass to normal levels, and increase bone strength against fracture force testing to normal levels.

About Osteogenesis Imperfecta (OI)
Osteogenesis Imperfecta (OI) includes a group of genetic disorders impacting bone metabolism. Approximately 85% to 90% of OI cases are caused by genetic variants in the COL1A1 or COL1A2 genes, leading to either reduced or abnormal collagen and changes in bone metabolism. The collagen mutations in OI can result in increased bone brittleness, which contributes to a high rate of fractures. Patients with OI also exhibit inadequate production of new bone and excess bone resorption, resulting in decreased bone mineral density, bone fragility and weakness. OI can also lead to bone deformities, abnormal spine curvature, pain, decreased mobility, and short stature. No treatments are globally approved for OI, which affects approximately 60,000 people in commercially accessible geographies.

About Mereo BioPharma
Mereo BioPharma is a biopharmaceutical company focused on the development of innovative therapeutics for rare diseases. The Company has three rare disease product candidates: setrusumab for the treatment of osteogenesis imperfecta (OI); alvelestat for the treatment of alpha-1 antitrypsin deficiency-associated lung disease (AATD-LD) and vantictumab for the treatment of autosomal dominant osteopetrosis type 2 (ADO2). The Company's partner for setrusumab, Ultragenyx Pharmaceutical, Inc., has reported results from 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). 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 European Commission (“EC”) and the FDA, PRIME designation from the EMA, and has Breakthrough Therapy designation and rare pediatric disease designation from the FDA. Alvelestat has received Orphan Designation for AATD from the EC and the FDA, and Fast Track designation from the FDA for AATD-LD. 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. The Company’s partner for vantictumab, āshibio, Inc., is funding the global development program. Mereo has retained EU and UK commercial rights. 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 for the treatment of infertility in men with low testosterone. In addition, 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.

Forward-Looking Statements

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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.

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