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): June 11, 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.

On June 11, 2024, Ultragenyx Pharmaceutical Inc. (NASDAQ: RARE) ("Ultragenyx") and Mereo BioPharma Group plc ("Mereo" or the "Company") issued a press release announcing the interim data from the Phase 2 portion of the Phase 2/3 Orbit study. 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.

As noted in in Item 7.01 above, on June 11, 2024, Ultragenyx and the Company announced positive 14-month results from the Phase 2 portion of the ongoing Phase 2/3 Orbit study (NCT05125809) demonstrating that, as of a May 24, 2024 data cut-off date, treatment with setrusumab (UX143) continued to significantly reduce incidence of fractures in patients with OI with at least 14 months of follow-up. Treatment with setrusumab also resulted in ongoing and meaningful improvements in lumbar spine bone mineral density (BMD) at month 12 without evidence of plateau.

The large reduction in annualized radiologically confirmed fracture rate previously reported in patients treated for a minimum of 6 months was sustained in patients treated for at least 14 months with a high degree of significance. The median annualized rate of radiologically confirmed fractures across all 24 patients in the 2 years prior to treatment was 0.72. Following a mean treatment duration period of 16 months, the median annualized fracture rate was reduced 67% to 0.00 ($p=0.0014$; $n=24$). The annualized fracture rate excluded morphometric vertebral fractures and fractures of the fingers, toes, skull, and face, consistent with the Phase 3 study primary efficacy endpoint.

The reduction in annualized fracture rates was associated with continued, clinically meaningful increases in BMD. Tests conducted at the 12-month timepoint demonstrated that treatment with setrusumab resulted in a mean increase in lumbar spine BMD from baseline of 22% ($p<0.0001$, $n=19$) across all age groups (5 to < 26 years old), a further improvement from 14% observed at 6 months of treatment. This increase in BMD is reflected in the change from the mean baseline lumbar spine BMD Z-score of -1.73 to -0.49 at 12 months across all age groups, a substantial normalization in Z-score of +1.25 ($p<0.0001$, $n=18$). This is further improved from the mean 6-month Z-score change of +0.85. The improvements in BMD and Z-scores were significant and consistent across all OI sub-types studied.

As of the data cut-off, there were no treatment-related serious adverse events observed in the study. Reported adverse events were generally consistent with those observed in the Asteroid study with infusion-related events and headache determined to be the most common adverse events related to the study drug. As of the data cut-off, there were no reported hypersensitivity reactions related to setrusumab.

More detailed 14-month data will be presented at a future scientific meeting.

Forward Looking Statements

This Report contains "forward-looking statements." All statements other than statements of historical fact contained in this press release 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 BioPharma'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 BioPharma'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 BioPharma 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 June 11, 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, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: June 11, 2024

MEREO BIOPHARMA GROUP PLC

By: /s/ Charles Sermon
Name: Charles Sermon
Title: General Counsel

Exhibit 99.1

Ultragenyx and Mereo BioPharma Announce New Phase 2 Data from Phase 2/3 *Orbit* Study Demonstrating Sustained Reductions in Fracture Rates Following Treatment with Setrusumab (UX143) in Patients with Osteogenesis Imperfecta (OI)

14-month data show treatment with setrusumab resulted in a large, sustained 67% reduction in annualized fracture rate and persistent median annualized fracture rate of 0.00 (p=0.0014)

Treatment resulted in continued, substantial improvements in bone mineral density (BMD) with a mean increase from baseline of 22% (p<0.0001) and a substantial mean improvement in Z-score of +1.25 (p<0.0001)

NOVATO, Calif. and LONDON, UK — June 11, 2024 — Ultragenyx Pharmaceutical Inc. (NASDAQ: RARE) and Mereo BioPharma Group plc (NASDAQ: MREO) today announced positive 14-month results from the Phase 2 portion of the ongoing Phase 2/3 Orbit study (NCT05125809) demonstrating that, as of a May 24, 2024 data cut-off date, treatment with setrusumab (UX143) continued to significantly reduce incidence of fractures in patients with OI with at least 14 months of follow-up. Treatment with setrusumab also resulted in ongoing and meaningful improvements in lumbar spine bone mineral density (BMD) at month 12 without evidence of plateau.

The large reduction in annualized radiologically confirmed fracture rate previously reported in patients treated for a minimum of 6 months was sustained in patients treated for at least 14 months with a high degree of significance. The median annualized rate of radiologically confirmed fractures across all 24 patients in the 2 years prior to treatment was 0.72. Following a mean treatment duration period of 16 months, the median annualized fracture rate was reduced 67% to 0.00 (p=0.0014; n=24). The annualized fracture rate excluded morphometric vertebral fractures and fractures of the fingers, toes, skull, and face, consistent with the Phase 3 study primary efficacy endpoint.

“All indications are that setrusumab is having the effect we hoped for, safely reducing the incidence of fractures and improving BMD in patients with OI,” said Gary S. Gottesman, M.D., Professor of Pediatrics and Medicine, Washington University School of Medicine. “The anti-sclerostin antibody appears effective even after a year and remarkably, patients continue to make measurable gains, suggesting we will see an ongoing response over the long term.”

The reduction in annualized fracture rates was associated with continued, clinically meaningful increases in BMD. Tests conducted at the 12-month timepoint demonstrated that treatment with setrusumab resulted in a mean increase in lumbar spine BMD from baseline of 22% ($p<0.0001$, n=19) across all age groups (5 to < 26 years old), a further improvement from 14% observed at 6 months of treatment. This increase in BMD is reflected in the change from the mean baseline lumbar spine BMD Z-score of -1.73 to -0.49 at 12 months across all age groups, a substantial normalization in Z-score of +1.25 ($p<0.0001$, n=18). This is further improved from the mean 6-month Z-score change of +0.85. The improvements in BMD and Z-scores were significant and consistent across all OI sub-types studied.

“The clinically meaningful continued improvement in BMD suggests that new and stronger bone is being created that has resulted in an important reduction in fractures across age groups and types of OI,” said Eric Crombez, M.D., chief medical officer at Ultragenyx. “With our phase 3 Orbit and Cosmic studies fully enrolled we now look forward to the possibility to bring this potential new treatment to a larger number of patients living with OI.”

As of the data cut-off, there were no treatment-related serious adverse events observed in the study. Reported adverse events were generally consistent with those observed in the Asteroid study with infusion-related events and headache determined to be the most common adverse events related to the study drug. As of the data cut-off, there were no reported hypersensitivity reactions related to setrusumab.

More detailed 14-month data will be presented at a future scientific meeting.

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 trials: 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. In the Phase 2 portion, 24 patients were randomized 1:1 to receive setrusumab at one of two doses to determine the optimal dosing strategy for Phase 3. All patients from the 40 mg/kg dosing cohort have been transitioned to 20 mg/kg of setrusumab.

The pivotal Phase 3 portion of the study has enrolled an additional 158 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. All patients will transition to an extension period and receive open-label setrusumab after the Phase 3 primary analysis is complete.

The global Phase 3 *Cosmic* study is an open-label, randomized, active-controlled study in patients aged 2 to <7 years. Patients are randomized 1:1 to receive setrusumab or intravenous bisphosphonates (IV-BP) therapy to evaluate reduction in total fracture rate. The *Cosmic* study has enrolled 69 patients at 21 sites across 7 countries.

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 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.

In 2019 Mereo BioPharma completed the Phase 2b dose-finding study (*Asteroid*) for setrusumab in 112 adults with OI. The *Asteroid* study demonstrated treatment with setrusumab resulted in a clear, dose-dependent and statistically significant effect on bone formation and bone density at multiple anatomical sites among adult participants with OI.

Ultragenyx and Mereo BioPharma are collaborating on the development of setrusumab globally based on the collaboration and license agreement between the parties. The companies have developed a comprehensive late-stage program to continue development of setrusumab in pediatric and young adult patients across OI sub-types I, III and IV.

About Ultragenyx Pharmaceutical Inc.

Ultragenyx is a biopharmaceutical company committed to bringing novel products to patients for the treatment of serious rare and ultrarare genetic diseases. The company has built a diverse portfolio of approved therapies and product candidates aimed at addressing diseases with high unmet medical need and clear biology for treatment, for which there are typically no approved therapies treating the underlying disease.

The company is led by a management team experienced in the development and commercialization of rare disease therapeutics. Ultragenyx's strategy is predicated upon time- and cost-efficient drug development, with the goal of delivering safe and effective therapies to patients with the utmost urgency.

For more information on Ultragenyx, please visit the company's website at: www.ultragenyx.com.

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 pediatric study in 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 has 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 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 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 Feng Biosciences Inc. in a global licensing agreement that includes milestone payments 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.

Ultragenyx Forward-Looking Statements and Use of Digital Media

Except for the historical information contained herein, the matters set forth in this press release, including statements related to Ultragenyx's expectations and projections regarding its future operating results and financial performance, business plans and objectives for UX143, expectations regarding the tolerability and safety of UX143, and future clinical and regulatory developments for UX143 are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve substantial risks and uncertainties that could cause our clinical development programs, collaboration with third parties, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainty of clinical drug development and unpredictability and lengthy process for obtaining regulatory approvals, the ability of the company and Mereo BioPharma to successfully develop UX143, the company's ability to achieve its projected development goals in its expected timeframes, risks related to adverse side effects, risks related to reliance on third party partners to conduct certain activities on the company's behalf, the potential for any license or collaboration agreement, including the company's collaboration agreement with Mereo to be terminated, smaller than anticipated market opportunities for the company's products and product candidates, manufacturing risks, competition from other therapies or products, and other matters that could affect sufficiency of existing cash, cash equivalents and short-term investments to fund operations, the company's future operating results and financial performance, the timing of clinical trial activities and reporting results from same, and the availability or commercial potential of Ultragenyx's products and drug candidates. Ultragenyx undertakes no obligation to update or revise any forward-looking statements.

For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of Ultragenyx in general, see Ultragenyx's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 3, 2024, and its subsequent periodic reports filed with the SEC.

In addition to its SEC filings, press releases and public conference calls, Ultragenyx uses its investor relations website and social media outlets to publish important information about the company, including information that may be deemed material to investors, and to comply with its disclosure obligations under Regulation FD. Financial and other information about Ultragenyx is routinely posted and is accessible on Ultragenyx's Investor Relations website (https://ir.ultragenyx.com/) and LinkedIn website (https://www.linkedin.com/company/ultragenyx-pharmaceutical-inc-/).

Mereo BioPharma Forward-Looking Statements

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All of Mereo BioPharma'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 BioPharma'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 BioPharma's reliance on third parties to conduct and provide funding for its clinical trials; Mereo BioPharma's dependence on enrollment of patients in its clinical trials; and Mereo BioPharma's dependence on its key executives. You should carefully consider the foregoing factors and the other risks and uncertainties that affect Mereo BioPharma'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 Mereo's subsequent filings with the Securities and Exchange Commission. Mereo BioPharma wishes to caution you not to place undue reliance on any forward-looking statements, which speak only as of the date hereof. Mereo BioPharma 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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