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): **March 26, 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 2.02 Results of Operations and Financial Condition.

On March 26, 2025, Mereo BioPharma Group plc announced its financial results for the year ended December 31, 2024 and provided recent corporate highlights. 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 2.02 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 March 26, 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: March 26, 2025

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

Exhibit 99.1

Mereo BioPharma Reports Full Year 2024 Financial Results and Provides Corporate Highlights

Orbit Phase 3 study of setrusumab in osteogenesis imperfecta progressing toward second interim analysis, expected mid-2025

Alvelestat granted Orphan Designation by the European Commission for treatment of Alpha-1 Antitrypsin Deficiency-associated Lung Disease (AATD-LD)

Cash of $69.8 million as of December 31, 2024, expected to fund operations into 2027

London, March 26, 2025 – Mereo BioPharma Group plc (NASDAQ: MREO) ("Mereo" or the "Company"), a clinical-stage biopharmaceutical company focused on rare diseases, today announced its financial results for the full year ended December 31, 2024, and provided recent corporate highlights.

"2024 was a year of focused execution and strategic advancement at Mereo, driving our lead programs closer to key milestones," said Dr. Denise Scots-Knight, Chief Executive Officer of Mereo. "The Phase 3 Orbit study of setrusumab in osteogenesis imperfecta (OI) is set to read out at the upcoming second interim analysis mid-year or at the final analysis during the fourth quarter of 2025. This could set the stage for us, alongside our partner Ultragenyx, to file for regulatory approvals in the U.S. and EU. Our European pre-commercial activities are ongoing, where we are focused on laying the foundation for a successful and efficient commercial launch, following potential regulatory approval. On alvelestat, the recent receipt of European Orphan Designation and the Phase 3 readiness activities have been highly supportive for our ongoing partnering process. With a strong financial position, we look forward to a transformative 2025, focused on bringing life-changing therapies to patients with rare diseases."

2024 Highlights, Recent Developments, and 2025 Anticipated Milestones

Setrusumab (UX143)

- Continued progress in two global studies, the Phase 3 portion of Orbit (Phase 2/3) and Cosmic (Phase 3), of setrusumab in OI patients, led by our partner Ultragenyx.
  - The Phase 3 portion of the Orbit Study is continuing to dose pediatric and young adult patients, with the second interim analysis expected mid-2025 and potential final analysis in the fourth quarter of 2025.
  - Treatment is ongoing in the open-label Phase 3 Cosmic study evaluating setrusumab against intravenous bisphosphonate therapy in patients aged 2 to <7 years. Data from this study will be evaluated in parallel with the interim or final analysis from the Orbit study.
- Pre-commercial activities to lay the foundation for launch ongoing.
  - Scientific advice obtained from GBA in Germany and NICE in the U.K.
  - Progress on project SATURN with existing registries that are appropriate sources of data on the natural history of OI and longitudinal data with the standard-of-care.

Alvelestat (MPH-966)

- In the first quarter of 2025, the European Commission granted Orphan Designation to alvelestat for the treatment of AATD-LD. This designation followed a positive recommendation from the EMA Committee for Orphan Medicinal Products in January 2025.
  - Alvelestat previously received Orphan Drug Designation and Fast Track Designation from the U.S. FDA in 2021 and 2022, respectively.
- The Company remains in discussion with multiple potential partners for the development and commercialization of alvelestat.

Full Year 2024 Financial Results

Total research and development ("R&D") expenses increased by $3.5 million from $17.4 million in 2023 to $20.9 million in 2024. The increase was primarily due to increases of $6.2 million and $2.6 million in R&D expenses for alvelestat and setrusumab, respectively, partially offset by a $5.5 million decrease in R&D expenses for etigilimab. The increase in program expenses for alvelestat is due to the preparatory work for the Phase 3 study. This principally comprised drug formulation and manufacturing activities, SGRQ validation activities and regulatory interactions. The increase in program expenses for setrusumab was primarily due to higher levels of ongoing activities in Europe, including real-world evidence programs and medical affairs activities, and amounts under the manufacturing and supply agreement with our partner, Ultragenyx, along with input into development, regulatory and manufacturing plans with Ultragenyx, who fund the global development of the program pursuant to our license and collaboration agreement. The reduction in program expenses for etigilimab was primarily due to the winding down and completion of the open label Phase 1b/2 basket study in combination with an anti-PD-1 in a range of tumor types.

General and administrative expenses increased by $8.0 million from $18.4 million in 2023 to $26.4 million in 2024. The increase primarily reflects $2.7 million higher pre-commercial activities to lay the foundation for the commercial launch of setrusumab in Europe, including activities to support pricing and reimbursement by HTA authorities and payor decision-makers in Europe. The remaining increase is driven by additional corporate expenses, including employee-related costs and legal and professional fees in respect of compliance with the U.S. domestic reporting regime, and reductions in reimbursements of certain expenses from our depository in respect of our ADR program and settlement of a claim under our D&O insurance policy in the prior year.

Net loss for the full year ended December 31, 2024 was $43.3 million, compared to $29.5 million during the comparable period in 2023, primarily reflecting an operating loss of $47.4 million, partially offset by interest income and the benefit from R&D tax credits.

As of December 31, 2024, the Company had cash and cash equivalents of $69.8 million, compared to $57.4 million as of December 31, 2023. The Company's guidance remains unchanged, and it continues to expect, based on current operational plans, that its existing cash and cash equivalents balance will enable it to fund its currently committed clinical trials, operating expenses, and capital expenditure requirements into 2027. This guidance does not include any potential upfront payments associated with a partnership for alvelestat or business development activity around any of the Company's non-core programs.

Total ordinary shares issued as of December 31, 2024 were 775,728,034. Total ADS equivalents as of December 31, 2024 were 155,145,606, with each ADS representing five ordinary shares of the Company.

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 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). 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. 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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MEREO BIOPHARMA GROUP PLC
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 69,802	$ 57,421
Prepaid expenses and other current assets	2,175	5,156
Research and development incentives receivables	2,786	1,183
Total current assets	74,763	63,760
Property and equipment, net	257	405
Operating lease right-of-use assets, net	727	1,245
Intangible assets, net	643	1,089
Total assets	**$ 76,390**	**$ 66,499**
Liabilities		
Current liabilities:		
Accounts payable	$ 2,440	$ 2,346
Accrued expenses	4,071	5,467
Convertible loan notes – current	5,535	—
Operating lease liabilities – current	707	652
Other current liabilities	1,095	1,021
Total current liabilities	13,848	9,486
Convertible loan notes – non-current	—	4,394
Warrant liabilities – non-current	821	412
Operating lease liabilities – non-current	187	906
Other non-current liabilities	565	764
Total liabilities	**$ 15,421**	**$ 15,962**
Commitments and contingencies (Note 17)		
Shareholders' Equity		
Ordinary shares, par value £0.003 per share; 775,728,034 shares issued at December 31, 2024 (December 31, 2023: 701,217,089).	3,059	2,775
Treasury shares	—	(1,230)
Additional paid-in capital	539,642	486,107
Accumulated deficit	(462,883)	(419,630)
Accumulated other comprehensive loss	(18,849)	(17,485)
Total shareholders' equity	60,969	50,537
Total liabilities and shareholders' equity	**$ 76,390**	**$ 66,499**

MEREO BIOPHARMA GROUP PLC
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except per share amounts)

	Year Ended December 31,	
	2024	**2023**
Revenue	$ —	$ 10,000
Operating expenses:		
Cost of revenue	—	(2,574)
Research and development	(20,930)	(17,418)
General and administrative	(26,434)	(18,424)
Loss from operations	(47,364)	(28,416)
Other income/(expenses)		
Interest income	3,041	2,131
Interest expense	(1,370)	(2,881)
Changes in the fair value of warrants	(419)	245
Foreign currency transaction gain/(loss), net	1,210	(2,347)
Other expenses, net	—	(10)
Benefit from research and development tax credit	1,649	1,280
Net loss before income tax	(43,253)	(29,998)
Income tax benefit	—	532
Net loss	$ (43,253)	$ (29,466)
Loss per share – basic and diluted	$ (0.06)	$ (0.04)
Weighted average shares outstanding – basic and diluted	739,624,264	659,453,921
Net loss	$ (43,253)	$ (29,466)
Other comprehensive (loss)/income – Foreign currency translation adjustments, net of tax	(1,364)	4,202
Total comprehensive loss	$ (44,617)	$ (25,264)