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): **May 13, 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 May 13, 2025, Mereo BioPharma Group plc announced its financial results for the first quarter ended March 31, 2025 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 May 13, 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: May 13, 2025

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

Exhibit 99.1

Mereo BioPharma Reports First Quarter 2025 Financial Results and Provides Corporate Highlights

Progress continues in Phase 3 Orbit study of setrusumab in osteogenesis imperfecta (OI)

Cash of $62.5 million as of March 31, 2025, expected to fund operations into 2027

London, May 13, 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 first quarter ended March 31, 2025, and provided recent corporate highlights.

"As we close out the first quarter of 2025, we continue to anticipate this will be an important, milestone-rich year for Mereo. The Phase 3 Orbit study of setrusumab in osteogenesis imperfecta remains on track to read-out either at the second interim analysis in mid-2025 or at the final analysis in the fourth quarter. We are continuing to invest in the pre-commercial activities for setrusumab to enable a successful launch in our European territory, following potential regulatory approvals," said Dr. Denise Scots-Knight, Chief Executive Officer of Mereo. "Further, alvelestat is now Phase 3 ready and we are finalizing the trial start-up activities to support our ongoing partnering process. Along with our late-stage pipeline, we believe that continued close management of our cash balance will enable us to support our operations into 2027."

First Quarter 2025 Highlights, Recent Developments, and Anticipated Milestones

Setrusumab (UX143)

- Continued progress in the two global Phase 3 studies led by our partner Ultragenyx:
  - The randomized, placebo-controlled Phase 3 portion of the Orbit study (in patients aged 5 to 25 years) is progressing toward a second interim analysis (IA2) in mid-2025 or a final analysis in the fourth quarter of 2025. All patients have now been on therapy for at least 12 months, conduct of the study is going well and patient safety in the Phase 3 portion of the study is consistent with safety observed in the Phase 2.
  - Patients in the Cosmic study (aged 2 to <7 years) are being treated with either setrusumab or intravenous bisphosphonates (IV-BP) therapy and will be evaluated in parallel with the Orbit interim analysis. If Orbit progresses to full study completion in the fourth quarter of 2025, Cosmic will also continue to a data read-out, to align with the Orbit read-out without spending alpha at the mid-year interim assessment.
- Continued pre-commercial activities in Europe to support potential launch, including engagement with regulatory/HTA bodies and real-world data collection efforts through the SATURN program.

Alvelestat (MPH-966)

- In first quarter of 2025, the European Commission granted Orphan Designation to alvelestat for the treatment of alpha-1 antitrypsin deficiency-associated lung disease (AATD-LD). This adds to existing US FDA Orphan Drug and Fast Track designations.
- The start-up activities for the planned single, global Phase 3 pivotal study are ongoing.
- The Company remains in discussion with multiple potential development and commercialization partners.

First Quarter 2025 Financial Results

Total research and development ("R&D") expenses decreased by $0.1 million from $4.0 million in the first quarter of 2024 to $3.9 million in the first quarter of 2025. The decrease was primarily due to decreases of $1.2 million and $0.1 million in R&D expenses for alvelestat and etigilimab, offset by an increase of $1.3 million in R&D expenses for setrusumab. The decrease in program expenses for alvelestat was primarily due to undertaking reduced drug formulation and manufacturing activities in preparation for the Phase 3 study in the first quarter of 2025, compared to the first quarter of 2024. The increase in program expenses for setrusumab was primarily driven by amounts due under the manufacturing and supply agreement with our partner, Ultragenyx, ongoing activities related to real-world evidence programs and medical affairs activities in Europe and input into development, regulatory and manufacturing plans with Ultragenyx, who fund the global development of the program pursuant to our license and collaboration agreement.

General and administrative expenses increased by $1.4 million from $5.9 million in the first quarter of 2024 to $7.3 million in the first quarter of 2025. The increase was primarily due to the recognition of a $1.7 million reduction in expenses in the first quarter of 2024 for amounts received from our depository to reimburse certain expenses incurred by us in respect of our ADR program, partially offset by a net decrease in employee-related expenses and professional fees. A reimbursement in respect of our ADR program is anticipated in 2025.

Net loss for the first quarter of 2025 was $12.9 million, compared to $9.0 million during the first quarter of 2024, primarily reflecting an operating loss of $11.2 million and foreign currency translation loss.

As of March 31, 2025, the Company had cash and cash equivalents of $62.5 million, compared to $69.8 million as of December 31, 2024. 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 March 31, 2025 were 795,001,444. Total ADS equivalents as of March 31, 2025 were 159,000,288, 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
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)
(Unaudited)

	March 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 62,483	$ 69,802
Prepaid expenses and other current assets	2,519	2,175
Research and development incentives receivables	1,897	2,786
Total current assets	66,899	74,763
Property and equipment, net	247	257
Operating lease right-of-use assets, net	622	727
Intangible assets, net	554	643
Total assets	**$ 68,322**	**$ 76,390**
Liabilities		
Current liabilities:		
Accounts payable	$ 2,924	$ 2,440
Accrued expenses	2,932	4,071
Convertible loan notes – current	—	5,535
Operating lease liabilities – current	747	707
Other current liabilities	894	1,095
Total current liabilities	7,497	13,848
Warrant liabilities – non-current	419	821
Operating lease liabilities – non-current	—	187
Other non-current liabilities	325	565
Total liabilities	**$ 8,241**	**$ 15,421**
Commitments and contingencies		
Shareholders' Equity		
Ordinary shares, par value £0.003 per share; 795,001,444 shares issued at March 31, 2025 (December 31, 2024: 775,728,034).	$ 3,132	$ 3,059
Additional paid-in capital	544,266	539,642
Accumulated deficit	(472,027)	(462,883)
Accumulated other comprehensive loss	(15,290)	(18,849)
Total shareholders' equity	60,081	60,969
Total liabilities and shareholders' equity	**$ 68,322**	**$ 76,390**

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

	Three Months Ended March 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ (3,930)	$ (3,994)
General and administrative	(7,272)	(5,906)
Loss from operations	(11,202)	(9,900)
Other income/(expenses)		
Interest income	659	617
Interest expense	(180)	(310)
Changes in the fair value of warrants	416	(448)
Foreign currency transaction (loss)/gain, net	(2,765)	613
Benefit from research and development tax credit	185	477
Net loss before income tax	(12,887)	(8,951)
Income tax benefit	—	—
Net loss	$ (12,887)	$ (8,951)
Loss per share – basic and diluted	$ (0.02)	$ (0.01)
Weighted average shares outstanding – basic and diluted	784,279,387	700,263,490
Net loss	$ (12,887)	$ (8,951)
Other comprehensive income/(loss) – Foreign currency translation adjustments, net of tax	3,559	(798)
Total comprehensive loss	$ (9,328)	$ (9,749)