

**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 19, 2026**

MEREO BIOPHARMA GROUP PLC

(Exact name of registrant as specified in its charter)

England and Wales
(State or other jurisdiction of
incorporation)

001-38452
(Commission File Number)

Not Applicable
(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 19, 2026, Mereo BioPharma Group plc announced its financial results for the year ended December 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

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
99.1	Press Release, dated March 19, 2026
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 19, 2026

By: /s/ Christine Fox

Name: Christine Fox
Title: Chief Financial Officer

Mereo BioPharma Reports Full Year 2025 Financial Results and Provides Corporate Highlights

Additional data analyses from Orbit and Cosmic Phase 3 studies of setrusumab (UX143) in osteogenesis imperfecta ongoing

Cash of \$41.0 million as of December 31, 2025, expected to provide runway into to mid-2027

London, March 19, 2026 – Mereo BioPharma Group plc (NASDAQ: MREO) (“Mereo” or the “Company”), a clinical-stage biopharmaceutical company focused on rare diseases, today announced financial results for the full year ended December 31, 2025, and provided an update on recent corporate developments.

“In collaboration with our partner Ultragenyx, we have analysed a significant part of the data from the Phase 3 Orbit and Cosmic studies of setrusumab in osteogenesis imperfecta and continue to develop our understanding of the fracture data and the patient reported outcomes (PROs), especially in patients aged 2–18 years old. We believe that these data, which include pre-specified sub-groups and ad hoc analyses, may provide the basis for engagement with the regulatory agencies,” said Denise Scots-Knight, Chief Executive Officer of Mereo. “There are no FDA or EMA therapies approved specifically for OI and although bisphosphonates are used to improved bone mineral density, it remains a high unmet need. Setrusumab has demonstrated statistically significant improvements in bone mineral density as well as compelling reductions in vertebral fractures and statistically significant improvements in PROs of disease pain and daily activity in pediatric and teenage patients. We look forward to providing updates on these efforts as we progress with next steps. Alongside this, our partnering discussions around alvelestat in AATD-LD are continuing to advance on multiple fronts and our partner āshibio has indicated that it plans to initiate a Phase 2 trial of vantictumab in osteopetrosis in the second half of this year. Following our cost reductions and delays to investment in manufacturing and pre-commercial activities for setrusumab, our revised financial runway into mid-2027 enables us to potentially deliver on several key milestones during 2026.”

Setrusumab (UX143)

- As announced on December 29, 2025, the Phase 3 Orbit and Cosmic studies of setrusumab in OI did not achieve statistical significance against the primary endpoints of reduction in annualized clinical fracture rate compared to placebo or bisphosphonates, respectively.
- Both studies achieved high statistical significance against the key secondary endpoint of improvement in bone mineral density versus a placebo or versus a bisphosphonate (standard of care) comparator.
 - o The improvement in bone mineral density in the Cosmic study was associated with a decreased rate of fracture in this younger, more highly fracturing patient population, although this was not statistically significant.
- Additionally, the studies demonstrated reductions in vertebral fractures, which are a key contributor to pain and disability in this patient population and are known to drive treatment decisions, as well as improvements in patient-reported outcomes of disease severity, pain / comfort and daily activities which were statistically significant in the Orbit study in pediatrics and teens.
- The safety profile of setrusumab was consistent with that observed in prior studies.
- Further analyses of the data from both studies, including patient subgroups, are ongoing ahead of any planned interactions with the regulatory agencies.

Alvelestat (MPH-966)

- The site feasibility work for initiation of the global Phase 3 pivotal study has been completed.
 - Based on previous discussions with the FDA and EMA, Mereo anticipates a single Phase 3 trial enrolling approximately 220 early- and late-stage AATD-LD patients evaluating alvelestat over an 18-month treatment period will support regulatory submissions in both the U.S. and Europe.
 - o The primary efficacy endpoint for potential U.S. approval will be the St. George’s Respiratory Questionnaire (SGRQ) Total Score, with lung density measured by CT scan serving as the primary endpoint for potential European regulatory approval.
 - Mereo continues to be in active discussions with potential partners for the Phase 3 development and commercialization of alvelestat.
 - Additionally, the Company has designed a potential Phase 2b study of alvelestat in bronchiectasis to further support the ongoing partnering discussions.
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- o The proposed study would enroll approximately 250 patients, randomized 1:1:1 to receive one of two alvelestat doses with standard of care or placebo with standard of care, with a primary efficacy endpoint of change in exacerbation rate at six months.
- o The proposed trial design is intended to substantially de-risk potential Phase 3 development, as exacerbations are a required confirmatory endpoint in registrational trials.

Vantictumab (OMP18R5)

- The Company outlicensed vantictumab for autosomal dominant osteopetrosis Type 2 (ADO2) to āshibio, Inc. whilst retaining European rights.
 - o āshibio is responsible for funding the global program and, following regulatory discussions, plans to initiate a Phase 2 study in the second half of 2026.
- Vantictumab was previously investigated in Phase 1a/b oncology trials in around 100 patients with biomarker evidence of potential impact on osteoclast function and high bone turnover, which led to fragility fractures in some patients.
- āshibio reported promising pre-clinical data at ASBMR 2025 in an ADO2 mouse model, in which vantictumab significantly decreased areal bone mineral density and rescued the bone phenotype in this model.
- ADO2 is an inherited metabolic bone disorder characterized by impaired osteoclast function, with no currently approved therapies. This impaired osteoclast function results in the growth of dense, brittle bones leading to multiple fractures, osteomyelitis, bone pain, low blood counts and significant morbidity.

Full Year 2025 Financial Results

Total research and development (“R&D”) expenses decreased by \$3.2 million from \$20.9 million in 2024 to \$17.8 million in 2025. The decrease was primarily due to reductions in R&D expenses for alvelestat and etigilimab of \$7.7 million and \$1.0 million, respectively, partially offset by an increase of \$5.7 million in R&D expenses for setrusumab. The reductions in program expenses for alvelestat was primarily due to the completion of the activities undertaken in preparation for the potential Phase 3 study, including drug formulation and manufacturing, in the year ended December 31, 2024. The increase in program expenses for setrusumab was primarily driven by amounts due under the manufacturing and supply agreement with our partner, Ultragenyx, as well as ongoing activities we undertake related to real-world evidence programs and medical affairs activities in Europe. These are in addition to costs we incur in relation to our collaboration with Ultragenyx, who fund the global development of the program, including input into development, regulatory and manufacturing plans.

General and administrative expenses decreased by \$3.4 million from \$26.4 million in 2024 to \$23.0 million in 2025. The decrease was due to a lower accrual for annual cash bonuses of \$1.2 million, along with a reduction in professional fees.

Net loss for the full year ended December 31, 2025, was \$41.9 million, compared to \$43.3 million during 2024, primarily reflecting an operating loss of \$40.1 million and a foreign currency translation loss of \$6.3 million, partially offset by interest income of \$2.2 million and a benefit from research and development tax credit of \$1.9 million.

As of December 31, 2025, the Company had cash and cash equivalents of \$41.0 million, compared to \$69.8 million as of December 31, 2024. The Company’s expects, based on current operational plans, that its existing cash and cash equivalents balance will enable it to fund its operating expenses, and capital expenditure requirements into mid-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, 2025 were 795,658,504. Total ADS equivalents as of December 31, 2025 were 159,131,700, 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 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 and its partner for setrusumab, Ultragenyx Pharmaceutical Inc., have reported top-line results from the Phase 3 portion of a pivotal Phase 2/3 study in pediatrics and young adults (5 to 25 years old) and in the Phase 3 study in pediatric patients (2 to <7 years old) for setrusumab in OI. 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, Ashbio, Inc., is funding the global development program and 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 leflutrolole, 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

This press release contains “forward-looking statements” that involve substantial risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such 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 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 reflect our current expectations, beliefs and assumptions concerning future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Risks and uncertainties include, among other things, 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 sufficiency of existing cash to fund operations and/or the inability to raise additional funding on favorable terms or at all; the uncertainty inherent in regulatory review processes, including varying interpretations and analyses of data from clinical trials; the Company’s dependence on enrollment of patients in its clinical trials; potentially smaller than anticipated market opportunities for the Company’s product candidates; the Company’s dependence on its key executives; and the Company’s ability to maintain compliance with Nasdaq continued listing requirements.

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. Forward-looking statements are often identified by the words “believe,” “expect,” “anticipate,” “plan,” “intend,” “foresee,” “should,” “would,” “could,” “may,” “estimate,” “outlook,” “will,” “continue” 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. 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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MEREO BIOPHARMA GROUP PLC
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	\$ 40,992	\$ 69,802
Prepaid expenses and other current assets	2,531	2,175
Research and development incentives receivables	1,497	2,786
Total current assets	45,020	74,763
Property and equipment, net	137	257
Operating lease right-of-use assets, net	244	727
Intangible assets, net	516	643
Total assets	\$ 45,917	\$ 76,390
Liabilities		
Current liabilities:		
Accounts payable	\$ 1,333	\$ 2,440
Accrued expenses	2,026	4,071
Convertible loan notes – current	—	5,535
Operating lease liabilities – current	202	707
Other current liabilities	741	1,095
Total current liabilities	4,302	13,848
Warrant liabilities – non-current	38	821
Operating lease liabilities – non-current	—	187
Other non-current liabilities	661	565
Total liabilities	\$ 5,001	\$ 15,421
Shareholders' Equity		
Ordinary shares, par value £0.003 per share; 795,658,504 shares issued at December 31, 2025 (December 31, 2024: 775,728,034)	\$ 3,135	\$ 3,059
Additional paid-in capital	549,622	539,642
Accumulated deficit	(501,018)	(462,883)
Accumulated other comprehensive loss	(10,823)	(18,849)
Total shareholders' equity	40,916	60,969
Total liabilities and shareholders' equity	\$ 45,917	\$ 76,390

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

	Year Ended December 31,	
	2025	2024
Revenue	\$ 500	\$ —
Operating expenses		
Cost of revenue	(133)	—
Research and development	(17,766)	(20,930)
General and administrative	(23,008)	(26,434)
Other income	300	—
Loss from operations	(40,107)	(47,364)
Other income/(expenses)		
Interest income	2,173	3,041
Interest expense	(255)	(1,370)
Changes in the fair value of warrants	805	(419)
Foreign currency transaction (loss)/gain, net	(6,344)	1,210
Benefit from research and development tax credit	1,850	1,649
Net loss before income tax	(41,878)	(43,253)
Income tax benefit	—	—
Net loss	\$ (41,878)	\$ (43,253)
Loss per share – basic and diluted	\$ (0.05)	\$ (0.06)
Weighted average shares outstanding – basic and diluted	797,119,632	739,624,264
Net loss	\$ (41,878)	\$ (43,253)
Other comprehensive income/(loss) – Foreign currency translation adjustments, net of tax	8,026	(1,364)
Total comprehensive loss	\$ (33,852)	\$ (44,617)

