
**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): **November 10, 2025**

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 November 10, 2025, Mereo BioPharma Group plc announced its financial results for the third quarter ended September 30, 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 November 10, 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: November 10, 2025

By: /s/ Christine Fox

Name: Christine Fox
Title: Chief Financial Officer

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

Data from Phase 3 Orbit and Cosmic studies of setrusumab in osteogenesis imperfecta on-track for around the end of 2025

Cash of \$48.7 million as of September 30, 2025, expected to support operations into 2027

London, November 10, 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 third quarter ended September 30, 2025, and provided recent corporate highlights.

“We are rapidly approaching a major transition period in our corporate evolution, with the Phase 3 Orbit and Cosmic studies of setrusumab in osteogenesis imperfecta on track to read out around the end of the year. Based on the data from prior studies, we remain confident in the potential of setrusumab to reduce fractures and improve quality of life for people with OI. We continue to invest in commercial readiness activities to ensure Mereo is well positioned for a potential launch in our European territories,” said Dr. Denise Scots-Knight, Chief Executive Officer of Mereo. “Alongside the progress of the setrusumab program, we are continuing to advance partnering discussions for alvelestat. In addition, we are excited to have retained European commercial rights in our recent partnership deal with āshibio for vantiactumab, which is being investigated in autosomal dominant osteopetrosis type 2, another rare bone disease for which promising preclinical data were presented at this year’s ASBMR Annual Meeting. With \$48.7 million of cash at the end of the third quarter, we remain well-capitalized to continue executing through these important milestones.”

Third Quarter 2025 Highlights, Recent Developments, and Anticipated Milestones

Setrusumab (UX143) for osteogenesis imperfecta (OI)

- The Phase 3 Orbit and Cosmic studies, led by our partner Ultragenyx, evaluating setrusumab in pediatric and young adult patients and young pediatric patients with OI, are progressing towards final analyses at which time patients will have been on therapy for at least 18 months.
- The data from both Orbit and Cosmic are expected around the end of 2025. The threshold for the Phase 3 Orbit final analysis is $p < 0.039$ and the threshold for the Phase 3 Cosmic final analysis is $p < 0.05$.
- Pre-commercial efforts continue in Europe where Mereo holds commercial rights. These include continuation of the SATURN program and an expansion of the activities to determine the potential addressable market and identify treatment centers beyond the five major countries in Europe to the Nordic and Benelux regions.

Alvelestat (MPH-966) for alpha-1-anti-trypsin deficiency lung disease (AATD-LD)

- Activities to support initiation of the planned single, global Phase 3 pivotal study are ongoing.
- The Company continues to be actively engaged with multiple potential partners regarding development and commercialization of alvelestat.

Vantiactumab for autosomal dominant osteopetrosis type 2 (ADO2)

- Vantiactumab is a fully-human monoclonal antibody that binds to certain frizzled receptors and inhibits Wnt signaling pathways, which was previously being developed in oncology settings.
- Mereo granted āshibio, Inc. an exclusive license to develop vantiactumab in ADO2. Under the agreement, announced in August 2025, Mereo has retained European commercial rights, and has granted āshibio the right to commercialize in the U.S. and rest of the world.

Third Quarter 2025 Financial Results

Total research and development (“R&D”) expenses increased by \$1.1 million, from \$3.2 million in the third quarter of 2024 to \$4.3 million in the three months ended September 30, 2025. The increase was primarily due to increases of \$0.9 million in R&D expenses for setrusumab and \$0.5 million for alvelestat, partially offset by a reduction of \$0.2 million in R&D expenses for etigilimab. 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 related to real-world evidence programs and medical affairs activities in Europe. This is 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. The increase in program expenses for alvelestat was

primarily due to activities undertaken in preparation for the Phase 3 study, including drug product and packaging, in the three months ended September 30, 2025.

General and administrative (“G&A”) expenses decreased by \$0.2 million, from \$6.2 million in the third quarter of 2024 to \$6.0 million in the third quarter of 2025. The decrease was primarily due to lower professional fees.

Net loss for the third quarter of 2025 was \$7.0 million compared to \$15.0 million for the third quarter of 2024, primarily reflecting an operating loss of \$10.0 million and a foreign currency transaction gain of \$1.9 million.

As of September 30, 2025, the Company had cash and cash equivalents of \$48.7 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 payments associated with a potential partnership for alvelestat or business development activity around any of the Company’s non-core programs.

Total ordinary shares issued as of September 30, 2025, were 795,484,404. Total ADS equivalents as of September 30, 2025, were 159,096,880, 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 vantiactumab for the treatment of autosomal dominant osteopetrosis type 2 (ADO2). The Company’s partner for setrusumab, 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. The Company’s partner for vantiactumab, 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 leflutroazole, 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. 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:

Mereo +44 (0)333 023 7300
Denise Scots-Knight, Chief Executive Officer
Christine Fox, Chief Financial Officer

Burns McClellan (Investor Relations Adviser to Mereo) +01 646 930 4406
Lee Roth

Investors investors@mereobiopharma.com

MEREO BIOPHARMA GROUP PLC
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)
(Unaudited)

	<u>September 30,</u> <u>2025</u>	<u>December 31,</u> <u>2024</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 48,698	\$ 69,802
Prepaid expenses and other current assets	2,694	2,175
Research and development incentives receivables	1,015	2,786
Total current assets	<u>52,407</u>	<u>74,763</u>
Property and equipment, net	174	257
Operating lease right-of-use assets, net	378	727
Intangible assets, net	643	643
Total assets	<u>\$ 53,602</u>	<u>\$ 76,390</u>
Liabilities		
Current liabilities:		
Accounts payable	\$ 879	\$ 2,440
Accrued expenses	4,118	4,071
Convertible loan notes – current	—	5,535
Operating lease liabilities – current	397	707
Other current liabilities	622	1,095
Total current liabilities	<u>6,016</u>	<u>13,848</u>
Warrant liabilities – non-current	336	821
Operating lease liabilities – non-current	—	187
Other non-current liabilities	652	565
Total liabilities	<u>\$ 7,004</u>	<u>\$ 15,421</u>
Shareholders' Equity		
Ordinary shares, par value £0.003 per share; 795,484,404 shares issued at September 30, 2025 (December 31, 2024: 775,728,034)	\$ 3,134	\$ 3,059
Additional paid-in capital	548,041	539,642
Accumulated deficit	(493,667)	(462,883)
Accumulated other comprehensive loss	(10,910)	(18,849)
Total shareholders' equity	<u>46,598</u>	<u>60,969</u>
Total liabilities and shareholders' equity	<u>\$ 53,602</u>	<u>\$ 76,390</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenue	\$ —	\$ —	\$ 500	\$ —
Operating expenses				
Cost of revenue	—	—	(133)	—
Research and development	(4,270)	(3,170)	(13,573)	(12,109)
General and administrative	(6,045)	(6,203)	(18,811)	(19,980)
Other income	300	—	300	—
Loss from operations	(10,015)	(9,373)	(31,717)	(32,089)
Other income/(expenses)				
Interest income	504	983	1,752	2,160
Interest expense	(28)	(353)	(232)	(995)
Changes in the fair value of warrants	196	(59)	511	(576)
Foreign currency transaction gain/(loss), net	1,873	(6,425)	(6,218)	(5,780)
Benefit from research and development tax credit	446	226	1,377	1,073
Net loss before income tax	(7,024)	(15,001)	(34,527)	(36,207)
Income tax benefit	—	—	—	—
Net loss	<u>\$ (7,024)</u>	<u>\$ (15,001)</u>	<u>\$ (34,527)</u>	<u>\$ (36,207)</u>
Loss per share – basic and diluted	\$ (0.01)	\$ (0.02)	\$ (0.04)	\$ (0.05)
Weighted average shares outstanding – basic and diluted	799,947,013	770,146,589	796,018,903	727,808,860
Net loss	\$ (7,024)	\$ (15,001)	\$ (34,527)	\$ (36,207)
Other comprehensive (loss)/income – Foreign currency translation adjustments, net of tax	(2,267)	7,174	7,939	6,381
Total comprehensive loss	<u>\$ (9,291)</u>	<u>\$ (7,827)</u>	<u>\$ (26,588)</u>	<u>\$ (29,826)</u>

