# 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): **August 12, 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 August 12, 2025, Mereo BioPharma Group plc announced its financial results for the second quarter ended June 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

| **Exhibit No.** | **Description of Exhibit** |
|---|---|
| 99.1 | Press Release, dated August 12, 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: August 12, 2025

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

**Exhibit 99.1**

**Mereo BioPharma Reports Second Quarter 2025 Financial Results and Provides Corporate Highlights**

*Data from Phase 3 Orbit and Cosmic studies of setrusumab in osteogenesis imperfecta expected around year-end 2025*

*Cash of $56.1 million as of June 30, 2025, expected to support operations into 2027*

**London, August 12, 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 second quarter ended June 30, 2025, and provided recent corporate highlights.

"We look forward to the final analysis for the two ongoing Phase 3 studies for setrusumab in osteogenesis imperfecta, the Phase 3 Orbit study in pediatric and young adult patients, and the Phase 3 Cosmic study in young pediatric patients, around the end of the year. We continue to be excited about the potential of setrusumab to reduce fractures and improve other functional parameters for individuals living with osteogenesis imperfecta," said Dr. Denise Scots-Knight, Chief Executive Officer of Mereo. "In parallel with the advancement of setrusumab, we are continuing to advance partnering discussions around alvelestat, our first-in-class oral small molecule for AATD-lung disease, and to ready the program for Phase 3 initiation. Our prudent management of our cash and resources means we are well positioned through these key milestones to support our operations into 2027."

**Second 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 their final analyses around the end of 2025. The randomized, placebo-controlled Phase 3 portion of the Orbit study was evaluated by the Data Monitoring Committee at an interim analysis in July 2025 and they informed Ultragenyx that setrusumab demonstrated an acceptable safety profile and that the study should continue to the final analysis. Data from the Cosmic study were not analyzed at the interim timepoint, consistent with the statistical analysis plan.
- Patients will continue dosing in both the Phase 3 Orbit and Cosmic studies, with the final analyses to be conducted after patients have been on therapy for at least 18-months. The threshold for the Phase 3 Orbit final analysis is $p<0.04$ and 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, working with existing OI datasets to better understand the natural history and the unmet medical need in pediatrics and adults and to generate data to support the health economic model, both important to support the assessment by Regulatory and Health Technology Assessment (HTA) bodies and payors. In addition, the activities to define the treatment landscape, including the number of treatment centers and the patient journey from childhood to adulthood, are being extended beyond the five major countries in Europe.

**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.

**Second Quarter 2025 Financial Results**

Total research and development ("R&D") expenses increased by $0.4 million from $4.9 million in the three months ended June 30, 2024, to $5.4 million in the three months ended June 30, 2025. The increase was primarily due to increases of $2.2 million in R&D expenses for setrusumab offset by decreases of $1.5 million and $0.2 million in R&D expenses for alvelestat and etigilimab, respectively. 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 decrease in program expenses for alvelestat was primarily due to the completion of the drug formulation and manufacturing activities undertaken in preparation for the Phase 3 study in the three months ended June 30, 2024.

General and administrative ("G&A") expenses decreased by $2.4 million from $7.9 million in the second quarter of 2024 to $5.5 million in the second quarter of 2025. The decrease was primarily due to the recognition of a $1.9 million reduction in expenses in the

three months ended June 30, 2025 for amounts received from our depository to reimburse certain expenses incurred by us in respect of our ADR program as well as lower professional fees.

Net loss for the second quarter ended June 30, 2025 was $14.6 million, compared to $12.3 million during the comparable period in 2024, primarily reflecting a foreign currency transaction loss of $5.4 million and increases in R&D expenses, offset by a decrease in G&A expenses and $0.5 million in revenue from a one-time milestone payment for the achievement of a clinical milestone on leflutrozole.

As of June 30, 2025, the Company had cash and cash equivalents of $56.1 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 June 30, 2025, were 795,001,444. Total ADS equivalents as of June 30, 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 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. 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 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:**


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

| | June 30, 2025 | December 31, 2024 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 56,125 | $ 69,802 |
| Prepaid expenses and other current assets | 2,545 | 2,175 |
| Research and development incentives receivables | 2,751 | 2,786 |
| Total current assets | 61,421 | 74,763 |
| Property and equipment, net | 218 | 257 |
| Operating lease right-of-use assets, net | 522 | 727 |
| Intangible assets, net | 470 | 643 |
| **Total assets** | **$ 62,631** | **$ 76,390** |
| | | |
| **Liabilities** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,138 | $ 2,440 |
| Accrued expenses | 5,041 | 4,071 |
| Convertible loan notes – current | — | 5,535 |
| Operating lease liabilities – current | 601 | 707 |
| Other current liabilities | 777 | 1,095 |
| Total current liabilities | 7,557 | 13,848 |
| Warrant liabilities – non-current | 545 | 821 |
| Operating lease liabilities – non-current | — | 187 |
| Other non-current liabilities | 352 | 565 |
| **Total liabilities** | **$ 8,454** | **$ 15,421** |
| | | |
| **Shareholders' Equity** | | |
| Ordinary shares, par value £0.003 per share; 795,001,444 shares issued at June 30, 2025 (December 31, 2024: 775,728,034) | $ 3,132 | $ 3,059 |
| Additional paid-in capital | 546,331 | 539,642 |
| Accumulated deficit | (486,643) | (462,883) |
| Accumulated other comprehensive loss | (8,643) | (18,849) |
| **Total shareholders' equity** | 54,177 | 60,969 |
| **Total liabilities and shareholders' equity** | **$ 62,631** | **$ 76,390** |

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2025** | **2024** | **2025** | **2024** |
| **Revenue** | $ 500 | $ — | $ 500 | $ — |
| **Operating expenses** | | | | |
| Cost of revenue | (132) | — | (132) | — |
| Research and development | (5,373) | (4,946) | (9,303) | (8,939) |
| General and administrative | (5,494) | (7,868) | (12,766) | (13,777) |
| **Loss from operations** | (10,499) | (12,814) | (21,701) | (22,716) |
| **Other income/(expenses)** | | | | |
| Interest income | 589 | 559 | 1,248 | 1,175 |
| Interest expense | (24) | (331) | (204) | (641) |
| Changes in the fair value of warrants | (101) | (69) | 315 | (517) |
| Foreign currency transaction (loss)/gain, net | (5,326) | 31 | (8,091) | 644 |
| Benefit from research and development tax credit | 745 | 369 | 930 | 847 |
| **Net loss before income tax** | (14,616) | (12,255) | (27,503) | (21,208) |
| Income tax benefit | — | — | — | — |
| **Net loss** | $ (14,616) | $ (12,255) | $ (27,503) | $ (21,208) |
| | | | | |
| Loss per share – basic and diluted | $ (0.02) | $ (0.02) | $ (0.03) | $ (0.03) |
| Weighted average shares outstanding – basic and diluted | 799,435,329 | 711,770,804 | 794,022,295 | 706,407,371 |
| | | | | |
| Net loss | $ (14,616) | $ (12,255) | $ (27,503) | $ (21,208) |
| Other comprehensive income/(loss) – Foreign currency translation adjustments, net of tax | 6,647 | 5 | 10,206 | (793) |
| **Total comprehensive loss** | $ (7,969) | $ (12,250) | $ (17,297) | $ (22,001) |