
**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 8, 2024**

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 1.01 Entry into a Material Definitive Agreement.

On November 8, 2024, Mereo BioPharma Group plc (the "Company") entered into an Amendment and Restatement Agreement related to an Exclusive License and Option Agreement (the "Amended AstraZeneca License Agreement") and a Deed of Amendment and Restatement related to an Amended and Restated Subscription Deed (the "Amended AstraZeneca Subscription Deed" together "the Amended AstraZeneca Agreements") with AstraZeneca AB ("AstraZeneca") that amend the terms of the original agreements signed between the parties on October 28, 2017. These agreements granted the Company an exclusive worldwide, sub-licensable license under AstraZeneca's intellectual property rights relating to certain product candidates containing a neutrophil elastase (NE) inhibitor, including the product candidate alvelestat, with an option to acquire such intellectual property rights following commencement of a pivotal trial and payment of related milestone payments, together with the acquisition of certain related assets.

The Amended AstraZeneca License Agreement modified the amount of certain existing development milestones and added new development milestones, with the Company agreeing to make potential future payments both in cash and through the issuance of a variable number of additional American Depositary Shares ("ADSs") to AstraZeneca worth up to \$114.3 million in the aggregate for products covered by the Amended AstraZeneca License Agreement.

The Amended AstraZeneca Agreements also clarify that the Subscription Price is the price per ordinary share, calculated by dividing the volume weighted average price per ADS during the thirty (30) trading day period immediately preceding the applicable milestone trigger event day by the number of ordinary shares represented by each ADS on the last trading day of such period, rounded to the nearest \$0.001.

Upon execution of the Amended AstraZeneca Agreements, the Company committed to issue 2,044,392 ordinary shares and pay \$0.5 million to AstraZeneca in connection with an agreed milestone.

The foregoing description of the Amended AstraZeneca Agreements does not purport to be complete and is qualified entirely by reference to the complete text of such documents, copies of which will be filed as exhibits to the Company's Annual Report on Form 10-K for the year ended December 31, 2024.

Item 2.02 Results of Operations and Financial Condition.

On November 12, 2024, the Company announced its financial results for the third quarter ended September 30, 2024 and provided a corporate update. 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 12, 2024.
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 12, 2024

By: /s/ Christine Fox

Name: Christine Fox

Title: Chief Financial Officer

Mereo BioPharma Reports Third Quarter 2024 Financial Results and Provides Corporate Update

Setrusumab receives Breakthrough Therapy designation from the FDA

Cash of \$80.5 million as of September 30, 2024, expected to fund operations into 2027

London, November 12, 2024 - Merco 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, 2024, and provided an update on recent corporate highlights. The Company reported cash and cash equivalents of \$80.5 million as of September 30, 2024, which the Company believes will provide runway into 2027, through multiple key inflection points.

“The Phase 3 program for setrusumab, led by our partners at Ultragenyx, continues to progress according to plan and we look forward to reporting the topline data during 2025,” said Dr. Denise Scots-Knight, Chief Executive Officer of Merco. “The recent receipt of Breakthrough Therapy designation from the U.S. FDA follows on from the PRIME designation we obtained in Europe. This reinforces the high unmet medical need for treatments for individuals affected by osteogenesis imperfecta (OI) who currently have no approved therapies, and the potential of setrusumab. Our pre-commercial efforts in our key European markets are progressing well, including the discussions with the HTAs and payors through EUNetHA and scientific advice in the individual countries. We continue to engage in discussions with multiple potential partners regarding the development and commercialization of alvelestat for AATD lung disease. We remain on track for alvelestat to be Phase 3-ready around the end of the year, further solidifying our commitment to bringing innovative treatments to individuals with rare diseases.”

Third Quarter 2024 Highlights, Recent Developments and Anticipated Milestones

Setrusumab (UX143)

- Our partner, Ultragenyx Pharmaceutical Inc., received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) for setrusumab (UX143) as a treatment to reduce the risk of fracture associated with osteogenesis imperfecta (OI) Type I, III, or IV in patients 2 years of age and older.
 - The FDA’s decision was based on preliminary clinical evidence including the positive 14-month results from the Phase 2 portion of the Orbit study, which demonstrated a rapid and clinically meaningful decrease in fracture rate in patients, and from the completed Phase 2b ASTEROID study.
- Led by Ultragenyx, the Companies are actively advancing the Phase 3 Orbit and Cosmic studies of setrusumab in OI.
- The 14-month data from the Phase 2/3 Orbit study were presented by Ultragenyx in a late-breaking oral presentation at the American Society for Bone and Mineral Research (ASBMR) 2024 Annual Meeting.
- A further paper from SATURN (Systematic Accumulation of Treatment practices and Utilization, Real world evidence, and Natural history data for OI), has been published. This is part of the Company’s pre-launch activities designed to generate additional evidence to support coverage, pricing and reimbursement decisions across Europe.

Alvelestat (MPH-966)

- Following the FDA feedback on the detailed Phase 3 package, including the study protocol and the initial validation work on SGRQ in AATD, the Company continues to expect that alvelestat will be Phase 3 ready around the end of 2024.
 - The Company remains in discussions with several potential partners regarding the development and commercialization of alvelestat for AATD.
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Third Quarter 2024 Financial Results

Total research and development (R&D) expenses decreased by \$0.4 million, or 12%, from \$3.6 million in the third quarter of 2023 to \$3.2 million in the third quarter of 2024. The decrease was primarily due to reductions in R&D expenses of \$0.6 million and \$0.4 million for etigilimab and alvelestat, respectively, partially offset by an increase of \$0.4 million for setrusumab. The reduction in program expenses for etigilimab was primarily due to the winding down and completion during 2023 of the open label Phase 1b/2 basket study in combination with an anti-PD-1 in a range of tumor types. The reduction in the program expenses for alvelestat primarily relates to lower levels of preparatory activity undertaken in respect of the Phase 3 study in the three months ended September 30, 2024 compared to 2023, particularly including manufacturing and drug formulation activities and regulatory interactions. The increase in program expenses for setrusumab was driven by additional activities in Europe and resources for input into development, regulatory and manufacturing plans with our partner, Ultragenyx, as the global development program is funded by Ultragenyx pursuant to our license and collaboration agreement.

General and administrative (G&A) expenses increased by \$0.5 million, or 9%, from \$5.7 million in the third quarter of 2023 to \$6.2 million in the third quarter of 2024. The increase primarily reflects \$0.2 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 represents increases in various corporate expenses.

Net loss for the third quarter of 2024 was \$15.0 million, compared to \$6.5 million during the third quarter of 2023. The \$9.2 million increase in net loss was driven primarily by a net foreign exchange loss of \$6.4 million for the third quarter of 2024, compared to a gain of \$2.5 million for the third quarter of 2023. This change primarily reflects a weakening of the U.S. dollar when translating U.S. dollar balances into our functional currency of pound sterling in the third quarter of 2024 and higher U.S. dollar balances.

As of September 30, 2024, the Company had cash and cash equivalents of \$80.5 million, compared to \$57.4 million as of December 31, 2023. This includes net proceeds of the \$50 million underwritten registered direct offering priced at-the-market on June 14, 2024. The Company expects, 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 including pre-commercial activities for setrusumab, 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 September 30, 2024, were 773,672,299. Total ADS equivalents as of September 30, 2024, were 154,734,459, 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 primarily 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 pediatric study in 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) in the first half of 2024. 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 EMA and FDA, PRIME designation from the EMA, and Breakthrough Therapy designation and pediatric disease designation from the FDA. Alvelestat has received U.S. Orphan Drug Designation for the treatment of AATD and Fast Track designation from the FDA. 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 in clinical development. Etigilimab (anti-TIGIT) has completed a Phase 1b/2 basket study evaluating its safety and efficacy in combination with an anti-PD-1 in a range of tumor types and is an ongoing Phase 1b/2 investigator led study at the MD Anderson Cancer Center in clear cell ovarian cancer; Navicixizumab, for the treatment of late line ovarian cancer, has completed a Phase 1 study and has been partnered

with Feng Biosciences Inc. in a global licensing agreement that includes milestone payments and royalties. Mereo has entered into an exclusive global license agreement with ReprNovo SA for the development and commercialization of leflutrozone, a non-steroidal aromatase inhibitor. Under the terms of the agreement, ReprNovo, a reproductive medicine company, is responsible for all future development and commercialization of leflutrozone.

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

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

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 80,522	\$ 57,421
Prepaid expenses and other current assets	3,830	5,156
Research and development incentives receivables	2,371	1,183
Total current assets	86,723	63,760
Property and equipment, net	315	405
Operating lease right-of-use assets, net	909	1,245
Intangible assets, net	799	1,089
Total assets	\$ 88,746	\$ 66,499
Liabilities		
Current liabilities:		
Accounts payable	\$ 1,748	\$ 2,346
Accrued expenses	3,529	5,467
Convertible loan notes – current	5,551	—
Operating lease liabilities – current	736	652
Other current liabilities	2,644	1,021
Total current liabilities	14,208	9,486
Convertible loan notes – non-current	—	4,394
Warrant liabilities – non-current	1,040	412
Operating lease liabilities – non-current	394	906
Other non-current liabilities	568	764
Total liabilities	\$ 16,210	\$ 15,962
Commitments and contingencies (Note 16)		
Shareholders' Equity		
Ordinary shares, par value £0.003 per share; 773,672,299 shares issued at September 30, 2024 (December 31, 2023: 701,217,089).		
	3,051	2,775
Treasury shares	—	(1,230)
Additional paid-in capital	536,426	486,107
Accumulated deficit	(455,837)	(419,630)
Accumulated other comprehensive loss	(11,104)	(17,485)
Total shareholders' equity	72,536	50,537
Total liabilities and shareholders' equity	\$ 88,746	\$ 66,499

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue	\$ —	\$ —	\$ —	\$ 9,000
Operating expenses:				
Cost of revenue	—	235	—	(2,847)
Research and development	(3,170)	(3,594)	(12,109)	(12,614)
General and administrative	(6,203)	(5,708)	(19,980)	(14,827)
Loss from operations	(9,373)	(9,067)	(32,089)	(21,288)
Other income/(expenses)				
Interest income	983	689	2,160	1,368
Interest expense	(353)	(700)	(995)	(2,528)
Changes in the fair value of warrants	(59)	—	(576)	440
Foreign currency transaction (loss)/gain, net	(6,425)	2,465	(5,780)	455
Other expenses, net	—	—	—	(6)
Benefit from research and development tax credit	226	82	1,073	1,202
Net loss before income tax	(15,001)	(6,531)	(36,207)	(20,357)
Income tax benefit	—	—	—	—
Net loss	<u>\$ (15,001)</u>	<u>\$ (6,531)</u>	<u>\$ (36,207)</u>	<u>\$ (20,357)</u>
Loss per share – basic and diluted	\$ (0.02)	\$ (0.01)	\$ (0.05)	\$ (0.03)
Weighted average shares outstanding – basic and diluted	<u>770,146,589</u>	<u>684,974,190</u>	<u>727,808,860</u>	<u>645,997,203</u>
Net loss	\$ (15,001)	\$ (6,531)	\$ (36,207)	\$ (20,357)
Other comprehensive income/(loss) – Foreign currency translation adjustments, net of tax	7,174	(3,579)	6,381	99
Total comprehensive loss	<u>\$ (7,827)</u>	<u>\$ (10,110)</u>	<u>\$ (29,826)</u>	<u>\$ (20,258)</u>

