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 15, 2024

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 15, 2024, Mereo BioPharma Group plc announced its financial results for the three month period ended March 31, 2024. 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

The following exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

Exhibit No.	Description of Exhibit
99.1	Press Release, dated May 15, 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: May 15, 2024

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

Exhibit 99.1

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

London, May 15, 2024 - 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, 2024, and provided an update on recent corporate highlights. The Company reported cash and cash equivalents of $48.7 million as of March 31, 2024 and continues to expect this to fund its operations into 2026.

"2024 is off to an exciting start following the completion of enrollment by our partner Ultragenyx in both the Orbit and Cosmic studies of setrusumab in Osteogenesis Imperfecta (OI) along with the continued advancement of the pre-launch activities in Mereo's European territories. These include further identification of patients who could potentially benefit from setrusumab treatment, the ongoing dialogues with the HTA's and Payors in Europe to support both rapid adoption and efficient reimbursement following a potential European approval, and SATURN," said Dr. Denise Scots-Knight, Chief Executive Officer of Mereo. "Further, in parallel with the ongoing partnering discussions for alvelestat, we have completed the initial validation work for the St. George's Respiratory Questionnaire (SGRQ) instrument in the Alpha-1 Antitrypsin Deficiency-associated Lung Disease (AATD-LD) population."

First Quarter 2024 Highlights, Recent Developments and Anticipated Milestones

Setrusumab (UX143)

- Enrollment completed in the Phase 3 Orbit and Cosmic studies of setrusumab in OI, conducted by our partner Ultragenyx.
    - The Phase 3 portion of the Orbit Phase 2/3 trial completed enrollment with 158 patients aged 5 to 25 years old. Patients were randomized 2:1 to receive setrusumab or placebo, and the study has a primary efficacy endpoint of annualized clinical fracture rate. Additional longer-term safety and efficacy data from the Phase 2 portion of the Orbit study are expected in the second half of 2024.
    - The Cosmic study was initiated in the second half of 2023 and completed full enrollment with 69 patients. Cosmic is a Phase 3 open-label, randomized study in patients aged 2 to <7 years evaluating setrusumab compared to bisphosphonates on reduction in total annualized clinical fracture rate.
- The initial results from the IMPACT Survey, a joint initiative between the Osteogenesis Imperfecta Foundation, Osteogenesis Imperfecta Federation Europe and its members, and Mereo, were recently made available. IMPACT is the largest ever burden of disease survey on the impact of OI on patients, physicians and caregivers. Additional information is available at www.impactsurveyoi.com.
- The Company continues to invest in pre-launch activities and other studies to generate further evidence that will inform coverage, pricing and reimbursement decisions in Mereo's European territory. These include SATURN (Systematic Accumulation of Treatment practices and Utilization, Real world evidence, and Natural history data for OI) which is expected to provide a coordinated data set across multiple treatment centers for OI across European countries, to support pricing and reimbursement decisions. The Company's patient identification activities are continuing, with a focus on adult patients in the key five European countries where these activities were previously initiated, and adult and pediatric patients in additional European countries.

Alvelestat (MPH-966)

- Mereo remains on-track to submit the completed initial validation work supporting the use of the SGRQ-Total Score as the primary efficacy endpoint to the FDA, alongside the detailed Phase 3 study protocol in the first half of 2024.
- The content validation of the SGRQ using semi-structured interviews with patients with AATD-LD from several sites in the United States has been completed. The analysis concluded that the current SGRQ instrument is fit for purpose with valid content measures for patients with AATD-LD and is suitable for use as a key Clinical Outcomes Assessment endpoint.
- The global Phase 3 study, which is supported by positive data from the ASTRAEUS and ATALANTa studies, is expected to enroll approximately 220 early- and late-stage patients with the severe Pi*ZZ genotype and confirmed emphysema, with a treatment period of 18 months. If the Phase 3 trial is successful, it is expected to support full approvals of alvelestat in the U.S. and Europe.
- Mereo continues to actively engage with multiple potential partners for the development and commercialization of alvelestat and aims to initiate the Phase 3 study with a partner around the end of 2024.

Etigilimab (MPH-313)

- Etigilimab in combination with nivolumab, is being studied in an ongoing investigator-led single-arm, two-stage, open-label Phase 1b/2 trial in a subtype of platinum-resistant recurrent ovarian cancer (clear cell ovarian cancer) at the MD Anderson Cancer Center, financed by the Cancer Focus Fund. Based on the results to-date, the study has been expanded from the initial 10 patients to 20 patients and an update may be provided by the investigator in the second half of 2024 or early 2025.

First Quarter 2024 Financial Results

Total research and development (R&D) expenses decreased by $1.3 million, or 25%, from $5.3 million in the first quarter of 2023 to $4.0 million in the first quarter of 2024. The decrease was primarily due to a $1.8 million reduction in R&D expenses for etigilimab, partially offset by increases of $0.3 million of R&D expenses for both setrusumab and alvelestat. The reduction in etigilimab expenses 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. Program expenses for setrusumab are in relation to increases in ongoing activities in Europe, and 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. Program expenses for alvelestat primarily include the preparatory work for the Phase 3 study, including manufacturing and drug formulation activities, SGRQ validation activities and regulatory interactions.

General and administrative expenses decreased by $0.5 million, or 8%, from $6.4 million in the first quarter of 2023 to $5.9 million in the first quarter of 2024. The decrease is primarily related to recognition of a $1.7 million reduction in expenses in the first quarter of 2024 for amounts from our depository to reimburse certain expenses incurred by us in respect of our ADR program, partially offset by an increase in employee-related expenses and professional fees. No similar reimbursements from our depository were recognized in the first quarter of 2023.

Net loss for the first quarter of 2024 was $9.0 million, compared to $12.1 million during the first quarter of 2023, primarily reflecting an operating loss of $9.9 million.

As of March 31, 2024, the Company had cash and cash equivalents of $48.7 million, compared to $57.4 million as of December 31, 2023. 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 2026. 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, 2024 were 701,349,434. Total ADS equivalents as of March 31, 2024 were 140,269,886, 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 has 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 including three rare tumors and three gynecological carcinomas – cervical, ovarian, and endometrial 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 ReproNovo SA for the development and commercialization of leflutrozole, a non-steroidal aromatase inhibitor. Under the terms of the agreement, ReproNovo, a reproductive medicine company, is responsible for all future development and commercialization of leflutrozole.

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 data)
(Unaudited)

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 48,660	$ 57,421
Prepaid expenses and other current assets	3,188	5,156
Research and development incentives receivables	1,648	1,183
Total current assets	53,496	63,760
Property and equipment, net	360	405
Operating lease right-of-use assets	1,109	1,245
Intangible assets	972	1,089
Total assets	**$ 55,937**	**$ 66,499**
Liabilities		
Current liabilities:		
Accounts payable	$ 2,455	$ 2,346
Accrued expenses	2,539	5,467
Convertible loan notes – current	4,630	—
Operating lease liabilities – current	662	652
Other current liabilities	718	1,021
Total current liabilities	11,004	9,486
Convertible loan notes – non-current	—	4,394
Warrant liabilities – non-current	855	412
Operating lease liabilities – non-current	727	906
Other non-current liabilities	513	764
Total liabilities	**13,099**	**15,962**
Commitments and contingencies (Note 15)		
Shareholders' Equity		
Ordinary shares, par value £0.003 per share; 701,349,434 shares issued at March 31, 2024 (December 31, 2023: 701,217,089).	2,775	2,775
Treasury shares	—	(1,230)
Additional paid-in capital	486,927	486,107
Accumulated deficit	(428,581)	(419,630)
Accumulated other comprehensive loss	(18,283)	(17,485)
Total shareholders' equity	42,838	50,537
Total liabilities and shareholders' equity	**$ 55,937**	**$ 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 March 31,	
	2024	2023
Revenue	$ —	$ —
Operating expenses:		
Cost of revenue	—	347
Research and development	(3,994)	(5,307)
General and administrative	(5,906)	(6,450)
Loss from operations	(9,900)	(11,410)
Other income/(expenses)		
Interest income	617	306
Interest expense	(310)	(800)
Changes in the fair value of financial instruments	(448)	542
Foreign currency transaction gain/(loss), net	613	(1,207)
Other expenses, net	—	(6)
Benefit from research and development tax credit	477	499
Net loss before income tax	(8,951)	(12,076)
Income tax benefit	—	—
Net loss	$ (8,951)	$ (12,076)
Loss per share – basic and diluted	$ (0.01)	$ (0.02)
Weighted average shares outstanding – basic and diluted	700,263,490	623,925,635
Net loss	$ (8,951)	$ (12,076)
Other comprehensive (loss)/income – Foreign currency transaction adjustments, net of tax	(798)	2,278
Total comprehensive loss	$ (9,749)	$ (9,798)