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 13, 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 August 13, 2024, Mereo BioPharma Group plc announced its financial results for the second quarter ended June 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

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 August 13, 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: August 13, 2024

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

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

Phase 3 Orbit and Cosmic studies of setrusumab in OI, conducted by our partner Ultragenyx, fully enrolled

New long-term Phase 2 data from the Phase 2/3 Orbit study demonstrated continued reduction in fracture rates

Cash of $87.4 million as of June 30, 2024 expected to fund operations into 2027

London, August 13, 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 second quarter ended June 30, 2024, and provided an update on recent corporate highlights. The Company reported cash and cash equivalents of $87.4 million as of June 30, 2024, which includes the net proceeds of the Company's $50 million registered direct offering in June 2024. Mereo expects that this will provide cash runway into 2027, through multiple key inflection points.

"We continued to make significant progress this quarter highlighted by additional positive data from the Phase 2 portion of the ongoing Phase 2/3 Orbit study in patients with OI," said Dr. Denise Scots-Knight, Chief Executive Officer of Mereo. "These data showed that the statistically significant annualized fracture rate reduction of 67% was maintained following treatment with setrusumab for at least 14 months of follow-up, further demonstrating the potential of setrusumab to generate long-term, clinically meaningful benefit for people living with OI. On alvelestat, we continue to work through the detailed regulatory submissions to ensure the AATD program is Phase 3-ready by the end of the year, in parallel with our ongoing discussions with multiple potential partners. With the proceeds from our June financing, we are well positioned through our key value inflection milestones and to support the ongoing pre-commercial activities essential for a successful launch of setrusumab in Europe following its potential approval."

Second Quarter 2024 Highlights, Recent Developments and Anticipated Milestones

Setrusumab (UX143)

- The Phase 3 Orbit and Cosmic studies of setrusumab in OI, conducted by our partner Ultragenyx, were fully enrolled as of April 30, 2024.
- On June 11, 2024, Mereo and Ultragenyx, announced positive 14-month results from the Phase 2 portion of the ongoing Phase 2/3 Orbit study (NCT05125809).
    - The results from the Phase 2 portion of the *Orbit* study demonstrated that, as of the May 24, 2024 data cut-off date, treatment with setrusumab continued to significantly reduce incidence of fractures in patients with OI. Treatment with setrusumab also resulted in ongoing and meaningful improvements in lumbar spine bone mineral density (BMD) at month 12 without evidence of plateau.
- The median annualized rate of radiologically confirmed fractures across all 24 patients in the 2 years prior to treatment was 0.72. Following a mean treatment duration period of 16 months, the median annualized fracture rate was reduced by 67% to 0.00 ($p=0.0014$; $n=24$).

- The reduction in annualized fracture rates was associated with continued, clinically meaningful increases in BMD. At the 12-month time point, treatment with setrusumab resulted in a mean increase in lumbar spine BMD from baseline of 22% ($p<0.0001$, n=19) and an improvement of the lumbar spine BMD Z-score from a mean baseline of -1.73 to -0.49 at 12 months. The improvements in BMD and Z-scores were significant and consistent across all OI sub-types studied.
- As of the data cut-off date, there were no treatment-related serious adverse events observed in the study and no reported hypersensitivity reactions related to setrusumab.
- Research has been published from our osteogenesis imperfecta program: The 12-month results for the Phase 2b ASTEROID study in the Journal of Bone and Mineral Research and the first publication from 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.
- More detailed data from the Phase 2 portion of the ongoing Phase 2/3 Orbit study will be presented at an upcoming scientific meeting

Alvelestat (MPH-966)

- The Company continues to engage with multiple potential partners for the development and commercialization for alvelestat in AATD
- At the end of Q2, Mereo submitted the initial validation work for SGRQ in AATD and the detailed Phase 3 package including the study protocol to the FDA in order to maintain the potential to start the Phase 3 study around the end of 2024.

Second Quarter 2024 Financial Results

Total research and development (R&D) expenses increased by $1.2 million, or 33%, from $3.7 million in the second quarter of 2023 to $4.9 million in the second quarter of 2024. The increase was primarily due to increases of $1.9 million and $0.9 million of R&D expenses for alvelestat and setrusumab, respectively, partially offset by a $1.5 million reduction in R&D expenses for etigilimab. The increase in the program expenses for alvelestat primarily relates to preparatory work for the Phase 3 study, including manufacturing and drug formulation activities, SGRQ validation activities and regulatory filings and interactions. The increase in program expenses for setrusumab is driven by additional activities in Europe and resources for the 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. 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.

General and administrative (G&A) expenses increased by $5.2 million from $2.7 million in the second quarter of 2023 to $7.9 million in the second quarter of 2024. The increase is primarily related to: (i) a $3.4 million reduction in expenses recognized in the second quarter of 2023 for amounts from our depository to reimburse certain expenses incurred by us in respect of our ADR program, whereas in 2024, $1.7 million was received from our depository in the first quarter of 2024; and (ii) pre-commercial activities to lay the foundation for the commercial launch of setrusumab in Europe, including those to support pricing and reimbursement by HTA authorities and payor decision-makers in Europe of $0.9 million.

Net loss for the second quarter of 2024 was $12.3 million, compared to $1.8 million during the second quarter of 2023, driven primarily by a one-time milestone payment of $9.0 million received in the second quarter of 2023, and increases in R&D expenses and G&A expenses in the second quarter of 2024.

As of June 30, 2024, the Company had cash and cash equivalents of $87.4 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 June 30, 2024, were 768,821,274. Total ADS equivalents as of June 30, 2024, were 153,764,254, 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)

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 87,431	$ 57,421
Prepaid expenses and other current assets	4,489	5,156
Research and development incentives receivables	2,020	1,183
Total current assets	93,940	63,760
Property and equipment, net	338	405
Operating lease right-of-use assets, net	985	1,245
Intangible assets, net	866	1,089
Total assets	**$ 96,129**	**$ 66,499**
Liabilities		
Current liabilities:		
Accounts payable	$ 2,700	$ 2,346
Accrued expenses	3,721	5,467
Convertible loan notes – current	4,931	—
Operating lease liabilities – current	679	652
Other current liabilities	3,435	1,021
Total current liabilities	15,466	9,486
Convertible loan notes – non-current	—	4,394
Warrant liabilities – non-current	925	412
Operating lease liabilities – non-current	552	906
Other non-current liabilities	536	764
Total liabilities	**17,479**	**15,962**
Commitments and contingencies (Note 16)		
Shareholders' Equity		
Ordinary shares, par value £0.003 per share; 768,821,274 shares issued at June 30, 2024 (December 31, 2023: 701,217,089).	3,032	2,775
Treasury shares	—	(1,230)
Additional paid-in capital	534,732	486,107
Accumulated deficit	(440,836)	(419,630)
Accumulated other comprehensive loss	(18,278)	(17,485)
Total shareholders' equity	78,650	50,537
Total liabilities and shareholders' equity	**$ 96,129**	**$ 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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue	$ —	$ 9,000	$ —	$ 9,000
Operating expenses:				
Cost of revenue	—	(3,430)	—	(3,083)
Research and development	(4,946)	(3,712)	(8,939)	(9,019)
General and administrative	(7,868)	(2,669)	(13,777)	(9,119)
Loss from operations	(12,814)	(811)	(22,716)	(12,221)
Other income/(expenses)				
Interest income	559	373	1,175	679
Interest expense	(331)	(1,029)	(641)	(1,829)
Changes in the fair value of financial instruments	(69)	(102)	(517)	440
Foreign currency transaction gain/(loss), net	31	(803)	644	(2,010)
Other expenses, net	—	—	—	(6)
Benefit from research and development tax credit	369	621	847	1,120
Net loss before income tax	(12,255)	(1,751)	(21,208)	(13,827)
Income tax benefit	—	—	—	—
Net loss	$ (12,255)	$ (1,751)	$ (21,208)	$ (13,827)
Loss per share – basic and diluted	$ (0.02)	$ (0.00)	$ (0.03)	$ (0.02)
Weighted average shares outstanding – basic and diluted	711,770,804	628,421,064	706,407,371	626,185,695
Net loss	$ (12,255)	$ (1,751)	$ (21,208)	$ (13,827)
Other comprehensive (loss)/income – Foreign currency translation adjustments, net of tax	5	1,400	(793)	3,678
Total comprehensive loss	$ (12,250)	$ (351)	$ (22,001)	$ (10,149)