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): March 27, 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 March 27, 2024, Mereo BioPharma Group plc announced its financial results for the year ended December 31, 2023. 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 March 27, 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: March 27, 2024

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

Mereo BioPharma Reports Full Year 2023 Financial Results and Provides Corporate Update

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Phase 2/3 Orbit Study and Phase 3 Cosmic Study of setrusumab in Osteogenesis Imperfecta expected to complete enrollment around the end of first quarter and in the first half of 2024, respectively

Partnering discussions for alvelestat progressing with plans to initiate Phase 3 with a partner around the end of 2024

Cash of $57.4 million as of December 31, 2023 expected to fund operations into 2026

London, March 27, 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 full year ended December 31, 2023, and provided an update on recent corporate highlights.

"We reached a number of important milestones in 2023, which have set the stage for a potentially transformative 2024," said Dr. Denise Scots-Knight, Chief Executive Officer of Mereo. "Both Orbit and Cosmic, the two Phase 3 studies of setrusumab in Osteogenesis Imperfecta (OI) being conducted by our partner Ultragenyx, are on-track to complete enrollment shortly. Our pre-launch activities are continuing to progress well. We have gained a solid understanding of the patient journey and pathways to market in the five key European markets, as well as a clear understanding of OI epidemiology in pediatrics and adults. We continue to believe that the European market for setrusumab in OI represents a significant opportunity."

Dr. Scots-Knight continued, "In addition, with the clear regulatory guidance from the FDA and the EMA for alvelestat in Alpha-1 Antitrypsin Deficiency-associated Lung Disease (AATD-LD), we are continuing our partnering discussions in parallel with all the preparatory work needed to initiate the Phase 3 global pivotal study with a partner by the end of the year. Alvelestat has the potential to become the first approved oral therapy for the treatment of AATD-LD and potentially the first to demonstrate positive clinical outcomes, especially in earlier stage patients. We maintained a strong cash position through prudent financial management and believe that Mereo remains well positioned to deliver on multiple inflection points in the year ahead."

2023 Highlights, Recent Developments and 2024 Anticipated Milestones

Setrusumab (UX143)

- Continued enrollment in two global studies, Orbit (Phase 2/3) and Cosmic (Phase 3), of setrusumab in OI patients, conducted by our partner Ultragenyx.
    - The Phase 3 portion of the Orbit Phase 2/3 trial was initiated in mid-2023 and the study is expected to be fully enrolled around the end of the first quarter of 2024. The pivotal study will include approximately 150 patients aged 5 to <26 years randomized 2:1 to receive setrusumab or placebo, with a primary efficacy endpoint of annualized clinical fracture rate.
    - Cosmic was initiated in the second half of 2023 and is anticipated to be fully enrolled in the first half of 2024. Cosmic is a Phase 3 open-label, randomized study in approximately 60 patients aged 2 to <7 years evaluating setrusumab compared to bisphosphonates on reduction in total annualized clinical fracture rate.
- In October 2023, data from the Phase 2 portion of the Phase 2/3 Orbit study showed that setrusumab treatment reduced the annualized fracture rate by 67% in patients with OI who had been treated for at least 6 months. This reduction was associated with improvements in bone mineral density (BMD). Setrusumab was well-tolerated with no serious adverse events or drug-related hypersensitivity reported. Additional data from the Phase 2 portion of the Orbit study are expected in the second half of 2024.

- 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 the EU and the UK. These include patient identification in the key European markets, interrogation of the data from IMPACT, the largest ever burden of disease survey on the impact of OI on people, their caregivers and physicians, and Project SATURN, an interrogation of existing registries in European centers of excellence, to provide a baseline of disease for OI in the current population and downstream real world evidence on the effect of treatment with setrusumab.
- The Company continues to build a compelling evidence base to support productive pricing and reimbursement discussions in the EU and the UK based on rolling interactions with the HTA and payor decision-makers.
- To-date, the Company has identified 5,000 pediatric patients and 5,000 adult patients across the five largest European markets (Germany, Italy, Spain, France and the UK) and continues to believe that the European market for setrusumab in OI represents a significant commercial opportunity based on the size of the patient population and magnitude of unmet medical need.

Alvelestat (MPH-966)

- Following extensive discussions with the Division of Pulmonology, Allergy and Critical Care (DPACC) and the Division of Clinical Outcome Assessment (DCOA) of the FDA throughout 2023, the Company has aligned on a Phase 3 study design using a patient-reported outcome (PRO) tool, the St. George's Respiratory Questionnaire (SGRQ) Total Score, as the primary efficacy endpoint, with a functional assessment as a key secondary endpoint, in the upcoming Phase 3 trial of alvelestat in AATD-lung disease.
- Mereo plans to submit the initial validation work supporting the use of SGRQ-Total Score in the AATD population, as the primary efficacy endpoint in the study alongside the detailed study protocol, to the FDA in the first half of 2024.
- In Europe, the Company will use lung density measured by CT scan as the primary endpoint for potential regulatory approval. The European Medicines Agency has indicated that a p value of <0.1 may be sufficient for full regulatory approval if the study is successful.
- The global Phase 3 study 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 US and Europe.
- The planned Phase 3 study design is supported by positive results from the ATALANTa and ASTRAEUS studies, including those with early-stage disease who may not qualify for the current standard of care nor for participation in clinical trials of other investigational therapies.
- 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.

Leflutrozole

- In December 2023, the Company 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 License Agreement, ReproNovo, a reproductive medicine company, is responsible for all future development and commercialization of leflutrozole. Mereo received an upfront payment and will be eligible to receive up to $64.25 million in future clinical, regulatory and commercial milestones as well as tiered mid-single digit royalties on global annual net sales of leflutrozole.

Navicixizumab

- In the fourth quarter of 2023, Feng Biosciences, Inc. completed a restructuring-and recapitalization and closed on a refinancing. Feng Biosciences is a clinical stage therapeutics company advancing precision medicine for people with cancer. The company will continue to utilize its Xerna™ platform to progress navicixizumab. For additional information on navicixizumab and our partner, please refer to the discussions on pages 1 and 13 of our Annual Report on Form 10-K.
- Under the global licensing agreement with Feng Biosciences, Mereo is eligible to receive up to $300 million in future clinical, regulatory and commercial milestones, and tiered sales royalties.

Full Year 2023 Financial Results

Effective January 1, 2024, the Company began complying with and reporting under the SEC rules and Nasdaq listing requirements applicable to U.S. domestic filers. Accordingly, the full year 2023 financial results are presented in accordance with accounting principles generally accepted in the United States (U.S. GAAP) and in U.S. dollars.

Revenue of $10.0 million for the year ended December 31, 2023, comprised a one-time milestone payment upon dosing of the first patient in the Phase 3 portion of the Orbit study in patients aged 5 to under 26 in accordance with the collaboration and license agreement with Ultragenyx and a $1.0 million up-front payment from the global license agreement with ReproNovo for the development and commercialization of leflutrozole.

Cost of revenue for the year ended December 31, 2023 was $2.6 million, representing amounts payable pursuant to our 2015 agreement with Novartis, under which the Company pays a percentage of proceeds resulting from milestone revenue received, subject to certain deductions.

Total research and development expenses decreased by $12.0 million, or 41%, from $29.5 million in 2022 to $17.4 million in 2023. The decrease was primarily due to a $12.4 million reduction in R&D expenses for etigilimab, partially offset by an increase of $0.7 million in expenses for setrusumab. The reduction in etigilimab expenses was primarily due to the winding down and completion 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 ongoing activities in Europe, and input into development, regulatory and manufacturing plans with our partner, Ultragenyx, as the global development of the 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 CMC and drug formulation activities, SGRQ validation activities and regulatory interactions.

General and administrative expenses decreased by $7.7 million, or 29%, from $26.1 million in 2022 to $18.4 million in 2023. The decrease is primarily related to overall reductions in staff costs, professional fees and corporate costs of $7.1 million, in addition to $3.6 million received from our depositary to reimburse certain expenses incurred by us in respect of our ADR program in the current and prior years and $2.0 million received under a claim on our Directors and Officers insurance policy to reimburse us for certain legal and professional costs incurred in prior years. General and administrative expenses included $2.7 million in 2023 (2022: $2.6 million) related to pre-commercial activities, including those to support pricing and reimbursement by HTA authorities and payor decision-makers in Europe.

Net loss for the full year ended December 31, 2023 was $29.5 million, compared to $42.2 million during the comparable period in 2022, primarily reflecting an operating loss of $28.4 million.

As of December 31, 2023, the Company had cash and cash equivalents of $57.4 million. Net cash burn during the fourth quarter of 2023 amounted to $6.7 million. 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 December 31, 2023 were 701,217,089. Total ADS equivalents as of December 31, 2023 were 140,243,417, 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 initiated the Phase 3 portion of a pivotal Phase 2/3 pediatric study in young adults (5 to <26 years old) for setrusumab in OI and a Phase 3 study in pediatric patients (2 to <7 years old) in the first half of 2023. The partnership with Ultragenyx includes potential milestone payments of up to $245 million (following the recent $9 million milestone) 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, 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 US 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:

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

	Year ended December 31, 2023	2022
Assets		
Current assets:		
Cash and cash equivalents	$ 57,421	$ 68,182
Prepaid expenses and other current assets	5,156	5,446
Research and development incentives receivables	1,183	1,569
Total current assets	63,760	75,197
Property and equipment, net	405	551
Operating lease right-of-use assets	1,245	1,665
Intangible assets	1,089	—
Total assets	**$ 66,499**	**$ 77,413**
Liabilities		
Current liabilities:		
Accounts payable	$ 2,346	$ 3,492
Accrued expenses	5,467	5,436
Convertible loan notes – current	—	13,326
Warrant liabilities – current	—	486
Operating lease liabilities – current	652	564
Other current liabilities	1,021	1,071
Total current liabilities	9,486	24,375
Convertible loan notes – non current	4,394	—
Warrant liabilities – non current	412	157
Operating lease liabilities – non current	906	1,479
Other non-current liabilities	764	—
Total liabilities	**15,962**	**26,011**
Commitments and contingencies (note 19)		
Shareholders' Equity		
Ordinary shares, par value £0.003 per share; 701,217,089 shares issued at December 31, 2023 (2022: 624,928,519).	2,775	2,478
Treasury shares	(1,230)	(1,335)
Additional paid-in capital	486,107	476,521
Accumulated deficit	(419,630)	(404,575)
Accumulated other comprehensive loss	(17,485)	(21,687)
Total shareholders' equity	50,537	51,402
Total liabilities and shareholders' equity	**$ 66,499**	**$ 77,413**

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

	Year ended December 31,	
	2023	2022
Revenue	$ 10,000	$ —
Operating expenses:		
Cost of revenue	(2,574)	1,146
Research and development	(17,418)	(29,465)
General and administrative	(18,424)	(26,107)
Loss from operations	(28,416)	(54,426)
Other income/(expenses)		
Interest income	2,131	840
Interest expense	(2,881)	(4,175)
Changes in the fair value of financial instruments	245	9,286
Foreign currency transaction (loss)/gain, net	(2,347)	2,723
Other (expenses)/income, net	(10)	1,086
Benefit from research and development tax credit	1,280	1,728
Net loss before income tax	(29,998)	(42,938)
Income tax benefit	532	718
Net loss	$ (29,466)	$ (42,220)
Loss per share – basic and diluted	$ (0.04)	$ (0.07)
Weighted average shares outstanding – basic and diluted	659,453,921	603,196,403
Net loss	$ (29,466)	$ (42,220)
Other comprehensive income/(loss) – Foreign currency transaction adjustments, net of tax	4,202	(10,660)
Total comprehensive loss	$ (25,264)	$ (52,880)