UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 or 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of March, 2023

Commission File Number: 001-38452

MEREO BIOPHARMA GROUP PLC
(Translation of registrant's name into English)

4th Floor, One Cavendish Place,
London, W1G 0QF, United Kingdom
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

Exhibit Index

Exhibits

99.1 Press release dated March 28, 2023

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 28, 2023

MEREO BIOPHARMA GROUP PLC

By: /s/ Charles Sermon
Name: Charles Sermon
Title: General Counsel

Exhibit 99.1

Mereo BioPharma Reports Full Year 2022 Financial Results and Recent Highlights

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London, March 28, 2023 - 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 year ended December 31, 2022 and provided an update on recent corporate highlights.

"In 2022, we made important progress in the ongoing advancement of our core rare disease programs. The data from our Phase 2 ASTRAEUS study of alvelestat in severe alpha-1-antitrypsin deficiency-associated lung disease (AATD-LD) were highly encouraging, and formed the basis for productive discussions with the regulatory agencies in both the U.S. and EU, culminating in our recent announcement of the details of our potential pivotal study design," said Dr. Denise Scots-Knight, Chief Executive Officer of Mereo. "We believe our discussions with the regulatory agencies reflect the major unmet need for improved therapeutic options for these patients, and we expect that having this clear path to potential full U.S. and EU approvals based on guidance from both the FDA and EMA will support our ongoing partnering efforts. For our lead rare disease program, our partner Ultragenyx has continued to advance the development of setrusumab (UX143) for the treatment of osteogenesis imperfecta (OI), with completion of enrollment in the Phase 2 portion of the Phase 2/3 Orbit study in pediatric and adult patients and data is expected in mid-2023. Further, a study in younger pediatric patients is expected to initiate during the first half of 2023. We concluded 2022 with cash and short-term deposits of $68.2 million (£56.3 million) and maintain our expectation that we have sufficient runway to fund operations into 2026."

Highlights from 2022, Recent Developments and Anticipated Milestones

Alvelestat (MPH-966)

- Received Fast Track Designation from the U.S. Food and Drug Administration (FDA).
- Reported positive top-line biomarker data and a post-hoc analysis demonstrating an association between biomarker reductions and clinical outcomes in the Phase 2 ASTRAEUS study.
- Received clear guidance from the FDA and European Medicines Agency (EMA) that a single 12-18 month placebo-controlled Phase 3 study in approximately 200 patients would be sufficient to support full marketing approvals in both the United States (U.S) and European Union (EU).
- The independent primary endpoints of the proposed Phase 3 study are change in the St. George's Respiratory Questionnaire (SGRQ) Activity domain, as guided by the FDA and change in lung density measured by CT scan, as guided by the EMA.
- The Company is exploring potential partnerships to fund further development of alvelestat in AATD-LD.
- Two abstracts were accepted to the American Thoracic Society (ATS) 2023 annual meeting, being held May 19-24.
    - Professor Robert Stockley, Chief Investigator on the ASTRAEUS study, will deliver an oral presentation on the ASTRAEUS study data.
    - A poster will be presented on the post-hoc analysis and association between biomarker reductions and improvement in SGRQ.
- Data from the ongoing Phase 2 investigator-led study in AATD-LD (ATALANTA), including in patients who may be on augmentation therapy, is expected in Q3 2023.

Setrusumab (UX143)

- Mereo's partner Ultragenyx has completed enrollment in the Phase 2 portion of the Phase 2/3 Orbit study of setrusumab in OI patients aged five to 25. Data from the Phase 2 portion of this study is expected in mid-2023.
- A study in younger patients comparing setrusumab to bisphosphonates is expected to be initiated by Ultragenyx in 1H 2023.

Etigilimab (MPH-313)

- Enrollment in the Phase 1b/2 ACTIVATE trial has completed the Phase 1b part of the study, with a total of 76 patients enrolled. The totality of emerging data from ACTIVATE and key Phase 3 trials of other therapies targeting the TIGIT axis, particularly in NSCLC, will inform next steps for the etigilimab program, which is focused on gynecological malignancies and rare cancers. The Company expects to report additional data from the ACTIVATE study later in 2023.
- Etigilimab, in combination with nivolumab, is also being studied in an ongoing investigator-led single-arm, open-label Phase 1b/2 trial in a subtype of platinum-resistant recurrent ovarian cancer (clear cell ovarian cancer) at The University of Texas MD Anderson Cancer Center (MD Anderson), financed by the Cancer Focus Fund. MD Anderson are planning to follow per protocol procedure to expand the study from an initial 10 patients to 20 patients.

Navicixizumab (OMP305B83)

- Following regulatory interactions, Mereo's partner, OncXerna, has stated its intention to initiate a Phase 3 trial of navicixizumab in late line ovarian cancer.
- OncXerna is also dosing patients in a Phase 2 basket study evaluating navicixizumab, alone or in combination with chemotherapy, in patients with select advanced solid tumors.

Full Year 2022 Financial Results

Full year 2022 research and development expenses were £25.0 million, compared to £23.6 million, in 2021, an increase of £1.4 million, or 6%. R&D expenses relating to etigilimab increased by £2.3 million. The increase was due to the costs associated with additional patients and the duration of treatment for patients responding to therapy in 2022 compared to 2021 in the open label Phase 1b/2 basket study in combination with an anti-PD-1 in a range of tumor types. R&D expenses relating to alvelestat increased £0.1 million, or 2%, primarily reflecting the end of study related costs for the Phase 2 proof-of-concept study in AATD. Partially offsetting the increases, R&D expenses relating to setrusumab decreased by £0.2 million, or 7%. Setrusumab R&D expenditure in 2022 comprised activities associated with laying the groundwork for reimbursement discussions 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 licensing and collaboration agreement.

Administrative expenses increased by £3.6 million, or 23%, from £15.9 million in 2021 to £19.5 million in 2022. The increase was primarily driven by additional costs incurred in connection with the Schedule 13D filings and subsequent Cooperation Agreement with Rubric Capital, and increased share-based payment expenses, partially offset by a reduction in other professional fees.

Net loss attributable to equity holders for the year ended December 31, 2022 was £34.2 million, compared to a net profit of £12.7 million in 2021, primarily reflecting an operating loss of £43.6 million and a gain of £7.8 million due to changes in the fair value of financial instruments resulting from an unrealized gain on warrants.

As of December 31, 2022, the Company had cash and short-term deposits of £56.3 million ($68.2 million). Net cash burn during the fourth quarter of 2022 amounted to £11.2 million ($13.5 million). The Company expects its existing cash and short-term deposits will enable it to fund its currently committed clinical trials, operating expenses and capital expenditure requirements into 2026.

Total ordinary shares outstanding at December 31, 2022 were approximately 625 million. Total ADSs outstanding at December 31, 2022 were approximately 119 million, 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 developed a robust portfolio of clinical stage product candidates. The Company has two rare disease product candidates, setrusumab for the treatment of osteogenesis imperfecta (OI) and alvelestat for the treatment of severe alpha-1-antitrypsin deficiency-associated lung disease (AATD-LD) and Bronchiolitis Obliterans Syndrome (BOS). The Company's partner, Ultragenyx Pharmaceutical, Inc., has initiated a pivotal Phase 2/3 pediatric study in young adults (5-25 years old) for setrusumab in OI and expects to initiate a study in pediatric patients (<5 years old) in the first half of 2023. The partnership with Ultragenyx includes potential milestone payments of up to $254 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. Alvelestat has received U.S. Orphan Drug Designation for the treatment of AATD, Fast Track designation from the FDA, and positive data were reported from a Phase 2 proof-of-concept study in North America, Europe and the UK. In addition to the rare disease programs, Mereo has two oncology product candidates in clinical development. Etigilimab (anti-TIGIT) has completed enrollment in 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; Navicixizumab, for the treatment of late line ovarian cancer, has completed a Phase 1 study and has been partnered with OncXerna Therapeutics, Inc. in a global licensing agreement that includes payments of up to $300 million in milestones and royalties.

Forward-Looking Statements

This press release contains "forward-looking statements," including the Company's expectations regarding its proposed Phase 3 study evaluating a single dose of alvelestat versus placebo, the expectations regarding a study in pediatric patients evaluating setrusumab, and the Company's pipeline of product candidates. All statements other than statements of historical fact contained in this press release are forward-looking statements within the meaning of Section 27A of the U.S Securities Act of 1933, as amended, and Section 21E of the U.S 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 latest Annual Report on Form 20-F, reports on Form 6-K and other documents furnished or filed from time to time by the Company 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.

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Consolidated Statements of Comprehensive (Loss)/Income

	Year ended December 31,		
	2022	2021	2020
	£'000s	£'000s	£'000s
Revenue	—	36,464	—
Cost of revenue	936	(17,908)	—
Research and development expenses	(24,962)	(23,559)	(16,347)
Administrative expenses	(19,543)	(15,933)	(21,222)
Operating loss	**(43,569)**	**(20,936)**	**37,569**
Finance income	696	1	44
Finance costs	(3,361)	(4,022)	(6,383)
Changes in the fair value of financial instruments	7,805	40,039	(109,849)
Gain/(loss) on disposal of intangible assets	—	113	(10,872)
Net foreign exchange gain/(loss)	1,525	(954)	(1,821)
Other income and expenses	811	—	—
(Loss)/profit before tax	**(36,093)**	**14,241**	**(166,450)**
Taxation	1,897	(1,516)	2,822
(Loss)/profit for the year, attributable to equity holders of the parent	**(34,196)**	**12,725**	**(163,628)**
Items that may be reclassified subsequently to profit or loss:			
Currency translation of foreign operations	(1,828)	(191)	349
Total comprehensive (loss)/income for the year, attributable to equity holders of the parent	**(36,024)**	**12,534**	**(163,279)**
Basic (loss)/profit per share for the year (in £)	(0.06)	0.02	(0.48)
Diluted loss per share for the year (in £)	(0.06)	(0.05)	(0.48)

Consolidated Balance Sheets

	As at December 31,	
	2022	2021
	£'000s	£'000s
Assets		
Non-current assets		
Property, plant and equipment	1,831	2,530
Intangible assets	24,116	24,564
	25,947	**27,094**
Current assets		
Prepayments	3,125	2,799
R&D Tax credits	1,296	—
Other taxes receivable	614	809
Other receivables	762	1,419
Cash and short-term deposits	56,334	94,296
	62,131	**99,323**
Total assets	**88,078**	**126,417**
Equity and liabilities		
Non-current liabilities		
Provisions	—	1,320
Convertible loan notes	—	14,384
Warrant liability	129	8,336
Lease liability	1,222	1,754
Other liabilities	182	80
	1,533	**25,874**
Current liabilities		
Trade and other payables	3,078	2,499
Accruals	4,491	3,826
Current tax liabilities	—	1,522
Provisions	4,822	2,803
Convertible loan notes	11,085	—
Warrant liability	402	—
Lease liability	466	622
Other liabilities	333	1,269
	24,677	**12,541**
Total liabilities	**26,210**	**38,415**
Net Assets	**61,868**	**88,002**
Equity		
Issued capital	1,875	1,755
Share premium	254,303	247,460
Other capital reserves	132,680	129,835
Employee Benefit Trust shares	(1,058)	(1,140)
Other Reserves	7,401	7,401
Accumulated losses	(331,164)	(296,968)
Translation Reserve	(2,169)	(341)
Total equity	**61,868**	**88,002**