# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 6
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REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 or 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of September, 2019

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): □

# Mereo BioPharma Announces Interim Financial Results for the Six Months Ended June 30, 2019 and Provides Corporate Update

12-Month Topline Results from Phase 2b ASTEROID Study with Setrusumab for Osteogenesis Imperfecta (OI) Expected in Q4 2019; Positive 6-Month
Data to be Featured in Late-Breaking Oral Presentation at ASBMR 2019

Conference Call Today at 8:30 a.m. EDT / 1:30 p.m. BST

**London and Redwood City, Calif., September 17, 2019** - Mereo BioPharma Group plc (NASDAQ: MREO, AIM: MPH), a clinical stage biopharmaceutical company focused on rare diseases, today announces unaudited interim financial results for the six months ended June 30, 2019 and provides a corporate update.

"The first half of 2019 has been notable for the announcement of positive six-month data for our Phase 2b ASTEROID trial which is evaluating setrusumab as a treatment for OI. We are entering another exciting period with the 12-month data from this study expected in Q4 2019 and proof-of-concept data from our Phase 2 study for alvelestat in severe alpha-1 antitrypsin deficiency expected in mid-2020," said Dr. Denise Scots-Knight, Chief Executive Officer of Mereo. "While our mission remains to provide new therapies for undertreated, chronically debilitating and life-limiting rare diseases, the proposed evaluation of alvelestat in the orphan disease bronchiolitis obliterans syndrome also strengthens our respiratory focus. We continue to advance discussions with potential partners to optimize the value of our broader product portfolio."

# **Recent Highlights and Upcoming Milestones**

# Setrusumab for Osteogenesis Imperfecta (OI)

- **12-month data from Phase 2b ASTEROID study in adult OI patients expected in Q4 2019.** In May 2019, Mereo reported positive 6-month interim data from the fully-enrolled ASTEROID study. These data were accepted for a late-breaking oral presentation at the upcoming American Society for Bone and Mineral Research (ASBMR) 2019 Annual Meeting to be held from September 20-23 in Orlando, FL, USA. The Company expects to report 12-month topline data from the blinded portion of the study in Q4 2019. There are currently no FDA or EMA- approved treatments for OI.
- **Pivotal pediatric study ready in the EU and Canada.** In addition to evaluating setrusumab in adult OI patients, Mereo's Paediatric Investigation Plan (PIP) has been approved by the EMA and a study design has been agreed for a pivotal registration trial in children. Mereo is also exploring an extension of the planned pivotal study into the U.S.

# Alvelestat for Severe Alpha-1 Antitrypsin Deficiency (AATD)

- **Enrollment continuing for the Phase 2 proof-of-concept study in severe AATD patients** with topline data expected in mid-2020. If the results are positive, Mereo intends to commence a pivotal trial in the EU and the U.S. in AATD as soon as possible therafter.
- **Investigator-sponsored clinical studies underway** in AATD and also in bronchiolitis obliterans syndrome (BOS) as a result of graft-versus-host disease (GvHD) in patients undergoing hematopoietic stem cell transplantation (HSCT). BOS is an orphan disease characterized by inflammatory obstruction of the lung's tiniest airways and is the primary cause of death in

patients who receive lung transplants. Based on the preliminary clinical data to-date, Mereo intends to investigate the use of alvelestat to treat patients with BOS patients following a lung transplant.

# Partnering Discussions Continue for Broad Portfolio of Clinical-Stage Programs

- **Leflutrozole for Hypogonadotropic Hypogonadism (HH).** Following the positive Phase 2b and six-month extension data reported in 2018, earlier this year Mereo held an advisory board to consider the future development strategy for leflutrozole, with a focus on the positive effects on semen parameters. Mereo has decided that future product development will focus on male fertility.
- Acumapimod for Acute Exacerbations of Chronic Obstructive Pulmonary Disease (AECOPD) is Phase 3-ready following a
  successful Type B End of Phase 2 meeting with the FDA and agreed outline for a pivotal Phase 3 clinical trial program. Recently, a
  positive Scientific Advice Working Party (SAWP) also took place with the EMA.
- Navicixizumab for Advanced Platinum-Resistant Ovarian Cancer. In July 2019, Mereo held a successful Type B End of Phase 1
  meeting with the FDA regarding a potential pathway for accelerated approval for navicixizumab for the treatment of patients with
  advanced ovarian cancer. Mereo and the FDA discussed, and agreed in principle, an outline for the design of a Phase 2 clinical trial
  that could potentially support the accelerated approval of navicixizumab in patients with ovarian cancer (including peritoneal or
  fallopian tube cancer) who have become resistant to prior therapies.
- **Etigilimab for Advanced Solid Tumors.** Etigilimab has completed a Phase 1a/b trial of etigilimab, administered as either a single-agent or in combination with nivolumab, in patients with advanced or metastatic solid tumors.

# Corporate

- In April 2019, Mereo completed a merger with OncoMed Pharmaceuticals, Inc ("OncoMed"), acquiring two clinical stage oncology programs - navicixizumab and etigilimab.
- Following completion of the acquisition of OncoMed, Michael Wyzga and Deepa Pakianathan, Ph.D. were appointed as Non-Executive Directors to the Mereo Board.
- In August 2019, Mereo appointed Richard Francis as Head of Pharmaceutical Development.
- In September 2019, Dr. Arun Mistry appointed as Therapeutic Area Head, Setrusumab.

### **Financial Highlights**

- Cash resources <sup>1</sup> of £36.1m as at June 30, 2019 (June 30, 2018 £36.9m)
- Loss after tax for the six-month period of £16.2m (2018: £17.0m) or 22 pence per ordinary share (2018: 24 pence per ordinary share)
- American Depositary Receipts ("ADRs") commenced trading on the NASDAQ Global Market on April 24, 2019 with the issue of 4.9m ADR's each represented by 5 ordinary shares
- 1 Cash resources is defined as the aggregate of cash and short-term deposits and short-term investments

# **Conference Call Information**

Mereo will host a live conference call and webcast today at 8:30 a.m. EDT / 1:30 p.m. BST to discuss the Company's financial results and provide a corporate update. To participate in the conference call, please dial (866) 688-2942 (U.S.) or (561) 569-9224 (U.K./International). The conference ID number is

4572478. A live and archived webcast may be accessed by visiting the Investors sections of the Company's website at <a href="https://www.mereobiopharma.com/investors/results-reports-and-presentations/">https://www.mereobiopharma.com/investors/results-reports-and-presentations/</a>. The archived webcast will remain available on the Company's website for fourteen (14) days following the live call.

#### About Mereo BioPharma

Mereo BioPharma is a biopharmaceutical company focused on the development and commercialization of innovative therapeutics that aim to improve outcomes for patients with rare diseases. Mereo's strategy is to selectively acquire product candidates for rare diseases that have already received significant investment from pharmaceutical and large biotechnology companies and that have substantial preclinical, clinical and manufacturing data packages. Mereo's lead rare disease product candidate, setrusumab, is being developed for the treatment of osteogenesis imperfecta (OI) with topline 12-month results from a Phase 2b dose ranging study expected in Q4 2019. Mereo's second lead product candidate, alvelestat, is being investigated in a Phase 2 proof-of-concept clinical trial in patients with alpha-1 antitrypsin deficiency (AATD) with topline data expected in mid-2020.

Mereo's broader pipeline consists of four additional clinical-stage product candidates; acumapimod for the treatment of acute exacerbations of chronic obstructive pulmonary disease ("AECOPD"), leflutrozole for the treatment of hypogonadotropic hypogonadism ("HH") in obese men, navicixizumab (for the treatment of platinum-resistant ovarian cancer, and etigilimab for patients with advanced or metastatic solid tumors.

# **Further Enquiries**

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#### **Forward-Looking Statements**

This document contains "forward-looking statements." All statements other than statements of historical fact contained in this presentation are forward-looking statements within the meaning of Section 27A of the United States Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the United States Securities Exchange Act of 1934, as amended (the "Exchange Act"). 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.

Factors that could cause actual results to differ materially from those in the forward-looking statements include risks relating to unanticipated costs, liabilities or delays; failure or delays in research and development programs; unanticipated changes relating to competitive factors in the Company's industry; risks relating to expectations regarding the Company's capitalization, resources and ownership structure; the availability of sufficient resources for company operations and to conduct or continue planned clinical development programs; the outcome of any legal proceedings; risks related to the ability to correctly estimate operating expenses; risks related to the ability to project future cash utilization and reserves needed for contingent future liabilities and business operations; risks related to the changes in market prices of the Company's ordinary shares; the Company's ability to hire and retain key personnel; changes in law or regulations affecting the Company; international, national or local economic, social or political conditions that could adversely affect the Company and its business; conditions in the credit markets; risks associated with assumptions the Company makes in connection with its critical accounting estimates and other judgments.

All of the Company's forward-looking statements involve 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. The foregoing factors and the other risks and uncertainties that affect the Company's business, including those described in its Annual Report on Form 20-F, Reports on Form 6-K and other documents filed from time to time by the Company with the United States Securities and Exchange Commission (the "SEC") and those described in other documents the Company may publish from time to time should be carefully considered. 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.

#### Chairman and CEO's statement

#### Introduction

The Group's strategy is to build a portfolio of rare disease products acquired from pharmaceutical companies and to develop these through regulatory approval and subsequent commercialization.

Products for use in rare (including orphan) indications represent an attractive development and commercialization opportunity for the Company, since the target patient population typically has a high unmet medical need, the compounds require more targeted clinical trials and these programmes can often utilise regulatory pathways that facilitate acceleration to the potential market. Development of rare disease therapies generally involves close co-ordination with regulators, healthcare authorities, patient organizations, key opinion leaders (KOLs) and a limited number of specialized treatment sites, which helps identification of the patient population and allows for a smaller, more targeted sales infrastructure for commercialization in key markets.

For our existing speciality and oncology programs, the Group plans to partner or sell the products at an appropriate stage in their development prior to commercialization, recognising the need for a larger sales infrastructure and greater resources to take these products successfully to market. This partnering or sale may be following dose optimisation or, in certain cases, following one or both the Phase 3 studies required for product regulatory review and approval.

We have made significant progress across our existing programs in the first half of 2019 and were pleased to announce encouraging 6-month data from an open label arm of our adult Phase 2b study for setrusumab in May 2019.

#### **Business Overview**

# Setrusumab (BPS 804)

Setrusumab is a human monoclonal antibody targeting sclerostin, which we are developing for the treatment of osteogenensis imperfecta (OI), also known as brittle bone disease, and which we acquired from Novartis in 2015. OI is a rare genetic disease which causes a collagen defects; and is characterized by fragile bones that fracture easily, as well as a variety of other physical symptoms that can severely impact patients' lives and quality of life. There are currently no FDA or EMA approved therapies for OI. An anti-sclerostin antibody is thought to be particularly well-suited to treat OI because, unlike other agents which are either anabolic or anti-resorptive, it has been demonstrated to be a strong bone-building agent that also reduces the resorption of bone, creating a dual-action anabolic effect to build overall bone density.

In May 2019 we announced encouraging 6-month data from the open-label arm of our phase 2b dose-ranging clinical study in adults with Type I, III or IV osteogenesis imperfecta (OI) treated with setrusumab (BPS-804, the "ASTEROID" Study (ClinicalTrials.gov Identifier: NCT03118570). The primary endpoint of the study is the percentage change over baseline in trabecular volumetric bone mineral density (Tr vBMD) at the radius (the wrist) at 12 months, assessed using High Resolution peripheral Quantitative Computed Tomography (HR-pQCT). The study has completed patient enrollment with 112 patients, of which 69 have Type I, 28 have Type IV and 15 have Type III OI.

In the open label arm of the study, patients received the highest of the three prospectively defined doses of setrusumab used in the blinded arms of the study, which are still ongoing. In the open label arm, the change over patients' baseline Tr vBMD was assessed at three and six months. Patients of all the three major phenotypes recruited into the full ASTEROID study were also represented in the open label arm.

At the time of the interim data cut-off, 12 patients had Tr vBMD measurements of the radius available at baseline and 3 months; and 11 had these measurements available at baseline and 6 months. Patients showed a mean increase, from baseline, of 1.4% at 3 months and 3.2% at 6 months. We believe that these increases compare very favourably to the increases in Tr vBMD at the radius in osteoporosis patients; approximately 1% at 24 months with alendronate; and of approximately 1% and 1.5% at 12 months observed with teraparitide or denosumab, respectively. Given the small sample size, the Company would not expect to see statistical significance.

Change from baseline in areal bone mineral density (BMD) at the lumbar spine, as measured by dual energy x-ray absorptiometry (DXA), is a secondary endpoint of the phase 2b study. In the open label arm, at the time of the interim data cut-off, there were 12 patients whose areal BMD at the lumbar spine DXA measurements at baseline and six months were available; and these showed a mean increase of 3.5% over baseline. This confirms the previous data generated by Novartis before Mereo acquired the product and also compares favourably with other mechanisms of action in adult OI patients were treated with PTH, where changes of 2.2% were seen at 6 months.

We expect to report the 12-month data on this same cohort of patients and for the remaining three blinded arms of the dose-ranging Phase 2b in Q4 2019. Hence, all the data on all 112 patients following 12-month treatment with setrusumab (BPS-804) will be reported before the end of 2019.

Setrusumab has been designated a PRIME (Priority Medicine) by the European Medicines Agency (EMA) and is part of the Adaptive Pathways in recognition of the high unmet medical need in OI. Following formal approval of our Paediatric Investigation Plan (PIP) by the EMA we have continued to gather regulatory input into our program through the PRIME programme and the Adaptive Pathways at the EMA. Our pivotal registration trial in children will be based on a primary endpoint of fractures over a 12-month period and will be conducted in approximately 165 children with severe disease aged 5-18 years old with OI Types I, III and IV. We also intend to validate the use of HR-pQCT as a predictive biomarker in this study. This is a key step in our plans to commercialize setrusumab in both children and adults.

During the period we have continued to have a number of interactions with the European agencies in respect of our setrusumab program. This includes submitting our "Action Plan to Marketing Authorisation" to the EMA and initiation of Scientific Advice Discussions regarding the potential regulatory qualification of HRpQCT as a biomarker. We have also engaged with the EUnetHTA groups representing European Health Technology Assessment bodies (HTAs) and held several meetings with pricing and reimbursement authorities under the Mechanism of Coordinated Access to Orphan Medicinal Products (MoCA) scheme in the EU.

In addition to evaluating setrusumab in adult OI patients, Mereo's PIP has been approved by the EMA and a study design has been agreed for a pivotal registration trial in children in the EU and Canada. Mereo is also exploring an extension of the planned pivotal study into the U.S.

We continue to develop, build and maintain close relationships with OI patient representative groups in the EU and US, systematically involving them in our interactions with authorities. We maintain close relationships with the OI Federation (OIF), representing the OI community in North America and also remain close to the KOLs and treating community in the USA, as in the EU. We recently participated in the International Conference on Children's Bone Health (ICCBH), which has an increased focus on rare bone conditions and potential future therapies.

#### Alvelestat (MPH 966)

Alvelestat is a small molecule that inhibits neutrophil elastase (NE). NE is an enzyme that attacks and progressively damages lung tissue. AATD patients either lack the protective alpha 1 anti-trypsin protein, or produce, abnormal, ineffective protein, that cannot block NE destruction. Such patients suffer progressive lung deterioration, leading to cough, wheeze, COPD-like symptoms and, ultimately, reliance on respiratory support. Some patients go on to receive lung transplants. The only approved therapy is plasma-derived intravenous protein; however, this is not reimbursed and available for use in all territories. Alvelestat may provide an oral treatment for AATD. It is believed that, by blocking the neutrophil elastase, alvelestat will protect the lungs from the progressive damage that occurs in patients with AATD lung disease. Alvelestat is not intended to target Alpha-1 liver disease, which primarily affects children. In late 2018, we commenced a Phase 2 proof-of-concept clinical trial in approximately 165 patients with severe Alpha-1 Anti Trypsin Deficiency (AATD). The primary end-point for this 12-week study is based on the biomarker desmosine, which is a breakdown product of elastin, the target of NE. If the results demonstrate a positive impact on the blockade of NE, we intend to seek regulatory advice in both the EU and the USA on the design of a pivotal trial in both territories and to commence this as soon as possible thereafter. We now expect top-line data from this study in mid-2020 rather than late 2019 as previously reported. Due to lack of broadly available therapies, AATD is often underdiagnosed, therefore, patient identification and recruitment is a key challenge. Availability of approved new therapeutic options is expected to increase awareness and diagnosis both amongst treating physicians and in the patient community alike.

We continue to develop, build and maintain close relationships with the KOLs, treating community and the AATD patient representative organisations in both the EU and North America. The Company participated in the recent International Research Conference on Alpha-1 Antitrypsin and Alpha-1 Global Patient Congress in April as part of advancing these efforts. Close collaboration continues with the treating and diagnosing community in support of the alvelestat development program.

As part of our development plans for alvelestat and looking to build out our respiratory pipeline, we are continuing to support certain investigator-led studies including the ATALANTA study into AATD led by Mark T. Dransfield and his team, supported, as previously announced, by an NCATS grant and also a study into bronchiolitis obliterans syndrome (BOS) associated with graft-versus-host disease (GvHD) in patients receiving hematopoietic stem cell transplantation (HSCT) led by Steven Z Pavletic at the NIH.

Mereo is planning to investigate the use of alvelestat to treat BOS patients as a result of lung transplant. This is an orphan disease and the primary cause of death in lung transplant patients.

#### **Financial Review**

During the period, R&D expenditure rose by £1.0 million to £11.9 million from £10.9 million in 2018. In 2019 we continued the development of our two rare disease assets setrusumab and alvelestat with R&D expenditure relating to the adult Phase 2b study and associated manufacturing costs for setrusumab and the Proof of Concept Phase 2 study in alvelestat. In the same period last year our R&D spend was focused again on the setrusumab adult Phase 2b study and also the completion of the Phase 2 studies for our specialty products acumapimod and leflutrozole, and material expenditure on the alvelestat study didn't commence until H2 2018.

Our administrative expenses reduced by £0.6 million to £6.5 million from £7.1 million in 2018 and these costs included certain IFRS non-cash adjustments and other costs of a one-off nature as set out below. On a non-GAAP basis, our underlying administrative expenses in the period were £4.9 million compared to £3.8 million in 2018. Newly acquired subsidiary OncoMed contributed £1.3 million to administrative expense over the period from date of acquisition (April 23, 2019) through end of the period.

	2019 (£ million)	2018 (£ million)
Administrative expenses (GAAP)	(6.5)	(7.1)
Share based payment charge (including NIC credit)	0.1	1.1
One-off legal and professional fees	1.5	2.2
Underlying administrative expenses (non-GAAP)	4.9	3.8

Finance charges of £1.5 million mainly relate to interest accrued and paid in respect of the bank debt of £1.6 million together with non-cash finance charges under IFRS 16 of £0.4 million together with £0.2 million in respect of the change in provision for deferred cash consideration in respect of the acquisition of a licence for alvelestat from AstraZeneca less £0.8 million in respect of IFRS credit on the change in warrant value relating to the bank debt.

Income tax benefit represents the estimate of R&D tax credit accrued during the period. Tax credits for the FY 2019 are expected to be received in 2020.

The weighted average loss per share for the six-month period was 22 pence (2018: 24 pence).

From January 1, 2019 we adopted IFRS 16 (Leases) – see Note 3. Total right-of-use assets at the period end were £13.0 million with total lease liabilities of £13.1 million.

For details of the accounting for the merger with OncoMed under IFRS 3 (Business Combinations) see Note 4. Our updated Provisional Purchase Price Allocation ("PPA") as at June 30, 2019 gives rise to negative goodwill (bargain purchase) of £3.7 million. This is because the merger consideration was calculated at the time of the merger announcement in December 2018 based on a fixed ratio of Mereo shares expected to be issued to holders of OncoMed shareholders at completion, since which time there has been a change in share price of Mereo offset somewhat by a further reduction in net assets of OncoMed due to the ongoing cash burn in OncoMed prior to completion of the acquisition.

#### Cashflow

We started the year with £25.0 million in cash and short-term deposits and £2.5 million of short-term investments, or total cash resources¹ of £27.5 million. In April 2019, we acquired \$50.8 million of cash resources¹ with the completion of the acquisition of OncoMed. After taking account of costs associated

with the merger and our operating costs in the period, net cash inflow in H1 2019 was £3.3 million with cash and short-term deposits at the period end of £28.3 million. Taking into account an increase in short-term investments of £5.3 million our total cash resources¹ increased £8.6 million to £36.1 million.

The loss before tax for the period was £18.7 million but after adjusting for non-cash items (namely the gain on bargain purchase of £3.7 million and net working capital adjustments of £7.1 million), net cash flows from operating activities were £27.6 million (2018: £15.0 million). Net cashflows from investing activities were £34.0 million in the period (2018: £0.1m) reflecting the acquisition of OncoMed. Net cashflows from financing activities were £(3.4) million (2018: £(0.8m)), relating to equity type transaction costs on the OncoMed acquisition of £0.8m, debt interest of £0.9 million, lease payments of £0.8 million and purchase of shares by the Employee Benefit Trust ("EBT") of £1.0 million.

In August 2019 OncoMed received a tax refund in respect of Alternative Minimum Tax ("AMT") of \$1.3 million from the United States Internal Revenue Service. In the UK, we expect to receive a payment of £5.2 million relating to our 2018 R&D tax claim in H2 2019.

#### Debt

In April 2019 the Group agreed an amendment to the terms of its bank loan. The interest only-period was extended to December 31, 2019 followed by a 15-month capital and interest repayment period. Based on certain milestones relating to its current clinical studies, the repayment term may be extended by an additional 12 months. Also, in June 2019, shortly after completion of the merger, the balance of the Novartis Loan Notes together with accumulated interest plus the balance of bonus shares due under the Loan Note agreement were converted into ordinary shares in Mereo. Total debt at the period end was £19.7 million (2018: £20.9 million)

#### Equity

In consideration of the acquisition of OncoMed, Mereo issued 24.8 million ordinary shares represented by 4.9 million American Depositary Shares ("ADSs"). Following completion of the amendment to its bank loan, Mereo issued 321,444 additional warrants to its lenders giving them the right to subscribe for ordinary shares at an exercise price of £2.95. In respect of the conversion of the Novartis Loan Note, Mereo issued 1,936,030 new ordinary shares to Novartis Pharma AG.

In May 2019 Mereo's EBT acquired 1,074,274 shares at a price of £0.929003 per share. Total shares held in the EBT amount to 1,237,274. These shares will be used to help meet future obligations arising under the Group's share schemes.

# Going Concern

As part of the going concern review, the Directors have considered the funding requirements of the Group through consideration of the Group's current business plan and the preparation of detailed cash flow forecasts. Under the current business plan and detailed cash flow forecasts, with ongoing R&D efforts focused on our rare disease products, setrusumab and alvelestat, we expect that our current on-hand cash resources will extend to the end of Q2 2020. Therefore, the Group requires additional external funding within the next 12 months to be able to continue as a going concern. Principally, this funding will be required to complete our current trials, fund our ongoing administrative costs and other general working capital and contractual financing requirements and to commence our pivotal paediatric study and the manufacturing scale up activities for setrusumab as we progress with our development plans for that program.

Further funding to continue to develop our rare disease products is most likely to come from a mix of additional equity funding and partnering transactions with third parties, where discussions with a wide range of partners is underway. The Directors remain confident of raising additional funding through either or both of these routes by mid-2020. In terms of further equity finance, the Company has the existing approval to issue new shares on a non-pre-emptive basis and whilst it is not possible to predict market conditions and noting that 19.6% of our issued share capital is held by the Woodford Equity Income Fund, the Directors and its advisors believe sufficient progress is being made with our development programs to be able to complete an equity raise. In addition, the upcoming newsflow from the Phase 2b top-line data in adults for setrusumab in Q4 2019 should provide an enhanced opportunity to raise further equity finance if the data is positive.

Based on the above factors the Directors believe that it remains appropriate to prepare the financial statements on a going concern basis. Because the additional finance that may result from partnering and/or further equity funding is not committed at the date of approval of these consolidated interim financial statements, our ability to complete a partnering transaction or raise further equity finance ahead of spending our current cash represents a material uncertainty as to the Group's ability to continue as a going concern.

#### Outlook

The second half of 2019 is set to be a pivotal period for Mereo. Following our announcement of the initial 6-month open label data for setrusumab in OI in May, we look forward to reporting the remaining 12-month complete dose ranging data on all 112 patients enrolled into the study in the next quarter. This is the largest interventional clinical study that has been conducted in adult OI patients in the US and EU and we anticipate will provide us with additional insights into this debilitating disease. We are keen to initiate our pivotal paediatric study in OI patients in the EU and Canada and look forward to further interactions with FDA regarding this program.

Our Phase 2 study with alvelestat in AATD is now expected to report out mid-2020 and we will provide any material updates on this program before then. We will continue to explore additional opportunities for alvelestat including BOS in lung transplant patients which fits with our focus on rare diseases with a high unmet medical need and also taps into our expertise in respiratory diseases.

We continue to focus on partnering opportunities for our non-rare disease products. In addition, with the recent activity in the rare bone disease area, we are evaluating potential partnering opportunities for setrusumab that could facilitate our "go-to-market" commercialisation strategy and will continue to evaluate fund-raising opportunities through a balanced approach.

	Notes	Six months ended June 30, 2019 Unaudited £	Six months ended June 30, 2018 Unaudited £	Year ended December 31, 2018 Audited £
Research and development expenses		(11,918,484)	(10,864,310)	(22,703,553)
Administrative expenses		(6,461,759)	(7,101,760)	(12,504,887)
Operating loss		(18,380,243)	(17,966,070)	(35,208,440)
Net income recognised on acquisition of subsidiary	4	1,035,379		
Finance income		137,014	151,467	306,831
Finance charge		(1,454,222)	(1,587,150)	(2,360,648)
Net foreign exchange gain/(loss)		(20,127)	49,305	(43,863)
Loss before tax		(18,682,199)	(19,352,448)	(37,306,120)
Taxation		2,458,567	2,364,904	5,277,380
Loss for the period, attributable to equity holders of the parent		(16,223,632)	(16,987,544)	(32,028,740)
Basic and diluted loss per share for the period		(0.22)	(0.24)	(0.45)
Other comprehensive income / (loss)				
Items that may be subsequently reclassified to the income statement				
Fair value changes on investments held at fair value through OCI		88,033		
Currency translation of foreign operations		710,830		
Total comprehensive loss for the period, attributable to equity holders of the parent		(15,424,769)	(16,987,544)	(32,028,740)

	Notes	June 30, 2019 Unaudited £	June 30, 2018 Unaudited £	December 31, 2018 Audited £
Assets				
Non-current assets				
Property, plant and equipment	5	13,100,261	151,996	148,935
Intangible assets	6	45,156,708	32,690,229	32,632,229
		58,256,969	32,842,225	32,781,164
Current assets				
Prepayments		3,068,326	1,225,744	1,066,932
R&D tax credits		7,744,634	10,516,989	5,277,380
Other receivables		1,953,886	584,821	608,893
Short-term investments		7,828,066	2,500,000	2,500,000
Cash and short-term deposits		28,289,504	34,412,363	25,041,945
		48,884,416	49,239,917	34,495,150
Total assets		107,141,385	82,082,142	67,276,314
Equity and liabilities				
Equity				
Issued capital	8	293,879	213,435	213,721
Share premium	8	121,684,154	118,369,523	118,492,073
Other capital reserves	8	58,003,847	17,746,031	18,592,618
Employee Benefit Trust shares	11	(1,304,842)	_	(306,838)
Other reserves		7,000,000	7,000,000	7,000,000
Accumulated losses		(127,356,393)	(96,179,599)	(111,220,794)
Translation reserve		710,830	_	_
Total equity		59,031,475	47,149,390	32,770,780
Non-current liabilities				
Provisions	9	1,926,916	3,993,058	2,641,353
Interest-bearing loans and borrowings	7	11,720,999	15,260,753	14,646,753
Other liabilities		34,289	_	34,289
Warrant liability	10	225,473	1,534,964	1,005,613
Lease liability		13,138,521		
		27,046,198	20,788,775	18,328,008
Current liabilities				
Trade and other payables		6,758,235	4,983,626	4,570,307
Accruals		5,960,684	3,222,982	4,437,321
Provisions	9	333,556	293,000	332,014
Interest-bearing loans and borrowings	7	8,011,237	5,644,369	6,837,884
		21,063,712	14,143,977	16,177,526
Total liabilities		48,109,910	34,932,752	34,505,534
Total equity and liabilities		107,141,385	82,082,142	67,276,314

	Notes	Six months ended June 30, 2019 Unaudited £	Six months ended June 30, 2018 Unaudited £	Year ended December 31, 2018 Audited £
Operating activities				
Loss before tax		(18,682,199)	(19,352,448)	(37,306,120)
Adjustments to reconcile loss before tax to net cash flows from operating activities:				
<ul> <li>Depreciation and impairment of property, plant and equipment</li> </ul>		724,221	20,196	37,796
<ul> <li>Share-based payment expense</li> </ul>		492,801	1,386,862	2,189,293
– Net foreign exchange (gain)/loss		20,127	(49,305)	43,863
<ul> <li>Provision for social security contributions on employee share options</li> </ul>		(722,895)	29,672	(1,446,019)
<ul> <li>Provision for deferred cash consideration</li> </ul>	9	179,000	222,000	443,000
– Interest earned		(137,014)	(151,467)	(306,831)
– Finance Charges		1,275,222	1,005,253	1,917,649
– Modification loss on bank loan		_	_	730,037
– Gain on bargain purchase	4	(3,680,053)	_	_
Working capital adjustments:				
<ul><li>(Increase) / decrease in trade and other receivables</li></ul>		(1,483,344)	720,819	804,306
<ul> <li>Increase / (decrease) in trade and other payables</li> </ul>		(5,619,217)	1,137,082	1,603,828
– Tax received		_	_	8,152,085
Net cash flows from operating activities		(27,633,350)	(15,031,336)	(23,137,113)
Investing activities				
Purchase of property, plant and equipment		_	(19,917)	(35,536)
Purchase of license		_	_	_
Disposal of property, plant and equipment		_	1,084	2,166
Proceeds from sale of short-term investments		12,463,487	_	_
Conversion of short-term investments into cash and cash equivalents		11,428,963	_	_
Acquisition of subsidiary	4	10,074,297	_	_
Interest earned		42,633	125,838	284,928
Net cash flows received / (used) in investing activities		34,009,380	107,005	251,558
Financing activities		3 1,000,000		
Proceeds from issue of ordinary shares	8	_	150,228	273,064
Transaction costs on issue of shares	Ü	(760,692)	(7,511)	(7,511)
Proceeds from issue of bank loan		(/00,052)	(7,511)	455,000
Transaction costs on bank loan		_	_	(920,859)
Proceeds from TAP agreement		_	_	78,445
Purchase of treasury shares		(998,004)	_	(306,838)
Interest paid on bank loan		(864,509)	(900,000)	(1,644,610)
Payment of lease liabilities		(776,000)	(555,555)	(1,01.1,010)
Net cash flows from financing activities		(3,399,205)	(757,283)	(2,073,309)
Net increase / (decrease) in cash and cash equivalents		2,976,825	(15,681,614)	(24,958,864)
Cash and cash equivalents at the beginning of the period		25,041,945	50,044,672	50,044,672
Effect of exchange rate changes on cash and cash equivalents		270,734	49,305	(43,863)
Cash and cash equivalents at the end of the period		28,289,504	34,412,363	25,041,945
			_ :, :1 <b>=</b> ,555	==,0 :1,0 :0

	Issued capital	Share premium	Other capital reserves	Other		Accumulated losses	Translation	Total equity
	£	£	£	reserves £	Own Shares	<u>£</u>	reserve	£.,
At January 1, 2018 – Audited	213,285	118,226,956	16,359,169	7,000,000	_	(79,315,920)	_	62,483,490
Loss for the period	_	_	_		_	(16,987,545)		(16,987,545)
IFRS 9 restatement	_	_	_	_	_	123,866	_	123,866
Share-based payments – share			1 100 010					1 120 010
options	_	_	1,136,916			_		1,136,916
Share-based payments - LTIPS	_	_	159,669	_	_	_	_	159,669
Share-based payments – deferred bonus shares			00 277					00 277
	_	_	90,277					90,277
Issue of share capital on June 1, 2018	150	150.070						150 227
(Note 8) Transaction costs on issuance of	150	150,078	_	_	_	_	_	150,227
share capital (Note 8)		(7,511)						(7,511)
	212 425		17.740.001	7 000 000		(00 170 500)		
At June 30, 2018 – Unaudited	213,435	118,369,523	17,746,031	7,000,000		(96,179,599)		47,149,390
Loss for the period	_	_	_		_	(15,041,195)		(15,041,195)
Share-based payments – share			<b>5</b> 22.020					722.020
options	_	_	733,039	_	_	_	_	733,039
Share-based payments - LTIPS	_	_	159,669			_		159,669
Share-based payments – deferred			(00.055)					(00 000)
bonus shares	_	_	(90,277)	_	_	_	_	(90,277)
Issue of share capital on August 3,								
2018 on exercise of options (Note	20	12.070						12.000
8)	30	12,870	_					12,900
Issue of share capital on October 22,								
2018 on exercise of options (Note 8)	256	109,680						109,936
Issue of warrants for TAP agreement	230	109,000	44,156		_	_		44,156
Purchase of treasury shares			44,130		(306,838)			(306,838)
-	212 721	110 402 072	10 502 610	7 000 000		(111 220 704)		
At December 31, 2018 – Audited	213,721	118,492,073	18,592,618	7,000,000	(306,838)	(111,220,794)		32,770,780
Loss for the period	_	_	_	_	_	(16,223,632)	710.020	(16,223,632)
Other comprehensive income	_	_	_			88,033	710,830	798,863
Share-based payments – share			254 120					254 120
options Share-based payments - LTIPS	_	_	354,128 138,673	_	_	_	_	354,128
Issue of share capital on April 23,	_	_	130,073			_		138,673
2019 for acquisition of OncoMed								
Pharmaceuticals Inc (Note 8)	74,350		40,818,128					40,892,478
Issue of share capital on conversion	74,330	_	40,010,120	_	<u>—</u>	_	_	40,092,470
of loan note	3,213	2,363,790					_	2,367,003
Issue of share capital for Novartis	5,215	2,303,730				<del></del>		2,307,003
bonus shares	2,595	1,588,983	(1,591,578)		_	_	_	_
Transaction costs on issuance of	2,333	1,500,505	(1,331,370)					
share capital (Note 8)	_	(760,692)		_		_		(760,692)
Equity element of convertible loan		(700,092)	(308,122)					(308,122)
Purchase of treasury shares		_	(500,122)	_	(998,004)	_		(998,004)
At June 30, 2019 – Unaudited	293,879	121,684,154	58,003,847	7,000,000	(1,304,842)	(127,356,393)	710,830	<b>59,031,475</b>
11. June 30, 2013 – Ullaudited	200,079	141,004,104	30,003,047	7,000,000	(1,004,044)	(147,000,000)	710,030	33,031,473

Notes to the interim report

#### 1. Corporate information

These financial statements are the unaudited interim consolidated financial statements of Mereo BioPharma Group plc and its subsidiaries (collectively, the "Group") for the six months ended June 30, 2019 were authorised for issue by the Directors on September 13, 2019. Mereo BioPharma Group plc (the "Company" or the "parent") is a public limited company incorporated and domiciled in the United Kingdom and whose shares are publicly traded on the AIM Market of the London Stock Exchange with a secondary listing of its American Depositary Receipts (ADR's) on the Nasdaq Global Market.

On April 23, 2019 the Group completed the acquisition of OncoMed Pharmaceuticals, Inc. ("OncoMed") a California-based and Nasdaq-listed company at which time OncoMed became a US subsidiary of Mereo. The registered office is located at Fourth Floor, 1 Cavendish Place, London W1G 0QF.

The Group is principally engaged in the research and development of novel pharmaceuticals.

#### 2. Basis of preparation

The interim condensed consolidated financial statements for the six-month period ended June 30, 2019 have been prepared in accordance with International Accounting Standards (IAS) 34 *Interim Financial Reporting*. They do not include all the information required for a complete set of IFRS financial statements. However, selected explanatory notes are included to explain events and transactions that are significant to an understanding of the changes in the Group since the most recent annual financial statements (December 31, 2018). For comparative purposes a consolidated balance sheet as at June 30, 2018 has also been presented.

The accounting policies adopted in the preparation of the interim condensed consolidated financial statements are consistent with those followed in the preparation of the Group's consolidated financial statements for the year ended December 31, 2018, except for the new accounting policies described in Note 3 (Changes in accounting policies) below. The financial information is presented in Sterling.

These condensed interim financial statements are unaudited and do not constitute statutory accounts of the Group as defined in section 434 of the Companies Act 2006.

The financial information for the year ended December 31, 2018 has been extracted from the Group's published financial statements for that year, and a copy of the statutory accounts for that financial year has been delivered to the Registrar of Companies. The auditors reported on those accounts and their report was unqualified, did not draw attention to any matters by way of emphasis and did not contain a statement under section 498(2) or (3) of the Companies Act 2006.

#### **Segmental information**

Management views the business as a single portfolio of product candidates. Only R&D expenses are monitored at a product candidate level; however, the Chief Operating Decision Maker (CODM) makes decisions over resource allocation at an overall portfolio level. The Group's financing is managed and monitored on a consolidated basis. All non-current assets held by the Group are located in the U.K. and U.S.

The Group's CODM is the executive management team (comprised of the Chief Executive Officer, Chief Financial Officer, Chief Medical Officer, General Counsel, the Head of Corporate Development and the Head of Patient Access and Commercial Planning) which manages the operating results of the business.

The operations of the Group are not prone to seasonal or cyclical variations.

# **Going Concern**

These consolidated interim financial statements have been prepared on a going concern basis, which contemplates the realisation of assets and the payment of liabilities in the ordinary course of business. The Group incurred net losses of £16.2 million and £17.0 million for the periods ended 30 June 2019 and 30 June 2018 respectively. As at 30 June 2019, the Group had total cash resources of £36.1 million and net current assets of £27.8 million.

As part of the going concern review, the Directors have considered the funding requirements of the Group through consideration of the Group's current business plan and the preparation of detailed cash flow forecasts. The going concern review prepared by the Directors extends through to December 2022 from the date of approval of these consolidated interim financial statements.

<sup>1</sup> Cash resources is defined as the aggregate of cash and short-term deposits and short-term investments

Under the current business plan and detailed cash flow forecasts, with ongoing R&D efforts focused on our rare disease products, setrusumab and alvelestat, we expect that our current on-hand cash resources will extend to the end of Q2 2020. Therefore, the Group requires additional external funding within the next 12 months to be able to continue as a going concern. Principally, this funding will be required to complete our current trials, fund our ongoing administrative costs and other general working capital and contractual financing requirements (see Note 7(b) below) and to commence our pivotal paediatric study and the manufacturing scale up activities for setrusumab as we progress with our development plans for that program.

Further funding to continue to develop our rare disease products is most likely to come from a mix of additional equity funding and partnering transactions with third parties, where discussions with a wide range of partners is already underway. The Directors remain confident of raising additional funding through either or both of these routes by mid-2020 which will provide the Group with additional funding to enable it to continue as a going concern. In terms of further equity finance, the Company has the existing approval to issue new shares on a non-pre-emptive basis and whilst it is not possible to predict market conditions and noting that 19.6% of our issued share capital is held by the Woodford Equity Income Fund, the Directors and its advisors believe sufficient progress is being made with our development programs to be able to complete an equity raise. In addition, the upcoming newsflow from the Phase 2b top-line data in adults for setrusumab in Q4 2019 should provide an enhanced opportunity to raise further equity finance if the data is positive. Because the additional finance that may result from partnering and/or further equity funding is not committed at the date of approval of these consolidated interim financial statements, these circumstances represent a material uncertainty as to the Group's ability to continue as a going concern.

These consolidated interim financial statements do not include the adjustments that would arise if the Group were unable to continue as a going concern. Should the Group be unable to obtain further finance such that the going concern basis of preparation were no longer appropriate, adjustments would be required which would include reducing the balance sheet values of assets to their recoverable amounts and to provide for further liabilities that might

### 3. Changes in accounting policies

Except as noted below, these interim consolidated financial statements have been prepared using the same accounting policies and methods of computation as compared with the most recent annual financial statements.

On January 1, 2019 the Group adopted IFRS 16 (Leases). The nature and effect of the changes from implementing IFRS 16 (Leases) most relevant to the Group's financial statements are given below.

Where relevant the Group has also implemented other amendments to existing standards and interpretations which became effective in the six-month period ended June 30, 2019. This included IFRIC 23 (Uncertainty over Income Tax Treatments). None of these amendments had a material impact on the Group's overall result and financial position.

#### 3.1 IFRS 16 Leases

# General impact of application of IFRS 16

In the current year, the Group, for the first time, has applied IFRS 16 Leases. The date of initial application of IFRS 16 for the Group is January 1, 2019.

IFRS 16 introduces new or amended requirements with respect to lease accounting. It introduces significant changes to the lessee accounting by removing the distinction between operating and finance lease, requiring the recognition of a right-of-use asset and a lease liability at commencement for all leases, except for short-term leases and leases of low value assets. In contrast to lessee accounting, the requirements for lessor accounting have remained largely unchanged.

The Group is lessee under a number of property and equipment leases, and also acts as the sublessor of two sublease agreements under one of its property leases. Details of the Group's accounting policies under IFRS 16 are set out below.

Significant judgements and estimates applied in the adoption of IFRS 16 included determining the lease term for those leases with termination or extension options, the classification of subleases as operating or finance subleases, and the incremental borrowing rate where the rate implicit in a lease could not be readily determined.

# Approach to transition

The Group has applied IFRS 16 using the modified retrospective approach, without restatement of the comparative information. In respect of those leases the Group previously treated as operating leases, the Group has elected to measure its right of use assets using the approach set out in IFRS 16.C8(b)(ii). Under IFRS 16.C8(b)(ii) right of use assets are set equal to the lease liability, adjusted for prepaid or accrued lease payments.

The Group's weighted average incremental borrowing rate applied to lease liabilities as at January 1, 2019 is 15%.

#### **Definition of a lease**

Previously, the Group determined at contract inception whether an arrangement was or contained a lease under IFRC 4 *Determining Whether an Arrangement contains a Lease*. The Group now assesses whether a contract is or contains a lease based on the new definition of a lease under IFRS 16. Under IFRS 16, a contract is or contains a lease, if the contract conveys a right to control the use of an identified asset in exchange for consideration.

On transition to IFRS 16, the Group elected to apply the practical expedient to grandfather the assessment of which transactions are leases. It applied IFRS 16 only to contracts that were previously not identified as leases. Contracts that were not identified as leases under IAS 17 and IFRIC 4 were not reassessed. In preparation for the first-time application of IFRS 16, the Group has carried out an implementation project. The new definition in IFRS 16 will not significantly change the scope of contracts that meet the definition of a lease for the Group.

At inception or on reassessment of a contract that contains a lease component, the Group allocates the consideration in the contract to each lease and non-lease component on the basis of their relative stand-alone prices.

# Practical expedients adopted on transition

Certain practical expedients permitted by IFRS 16 are used by the Group, notably:

- i) To not reassess upon transition whether an existing contract contains a lease (grandfather the previous assessment of whether a transaction was a lease under IAS 17 or IFRIC 4). The definition of a lease under IFRS 16 has been applied only to contracts entered into or changed on or after 1 January 2019;
- ii) The recognition exemptions for short-term leases (less than 12 months of lease term) and leases of low-value assets; and
- iii) Used hindsight when determining the lease term if the contract contains options to extend or terminate the lease.

#### Impact on lessee accounting

#### Former operating leases

Applying IFRS 16, for all leases, the Group:

- i) Recognises right-of-use assets and lease liabilities in the consolidated statement of financial position, initially measured at the present value of future lease payments;
- ii) Recognises depreciation of right-of-use assets and interest on lease liabilities in the consolidated statement of profit or loss; and
- iii) Separates the total amount of cash paid into a principal portion (presented within financing activities) and interest (presented within operating activities) in the consolidated statement of cash flows.

Lease incentives (e.g. rent-free periods) are recognised as part of the measurement of the right-of-use assets and lease liabilities whereas under IAS 17 they resulted in the recognition of a lease incentive liability, amortised as a reduction of rental expenses on a straight-line basis.

Under IFRS 16, right-of-use assets will be tested for impairment in accordance with IAS 36 Impairment of Assets. This replaces the previous requirement to recognise a provision for onerous lease contracts.

For short-term leases (lease term of 12 months or less) and leases of low-value assets (such as those with a value less than £5,000), the Group has opted to recognise a lease expense on a straight-line basis as permitted by IFRS 16. This expense is presented within Other operating expenses in the consolidated income statement.

As at December 31, 2018, the Group did not hold any finance leases.

# Impact on Lessor Accounting

IFRS 16 does not change substantially how a lessor accounts for leases. Under IFRS 16, a lessor continues to classify leases as either finance leases or operating leases and account for those two types of leases differently. However, IFRS 16 has changed and expanded the disclosures required, in particular regarding how a lessor manages the risks arising from its residual interest in leased assets.

Under IFRS 16, an intermediate lessor accounts for the head lease and the sublease as two separate contracts. The intermediate lessor is required to classify the sublease as a finance or operating lease by reference to the right-of-use asset arising from the head lease (and not by reference to the underlying asset as was the case under IAS 17).

As the Group continues to account for its subleases as operating leases, there has been no material impact as a result of this change.

#### Financial impact

The application of IFRS 16 to leases previously classified as operating leases under IAS 17 resulted in the recognition of right-of-use assets and lease liabilities. Prepaid rental previously recognised as assets and accrued rental previously recognised as liabilities have been derecognised and factored into the measurement of the right-of-use assets.

The Group has chosen to use the table below to set out the adjustments recognised at the date of initial application of IFRS 16.

	As previously reported at December 31, 2018 $\underline{\mathfrak{t}}$	Impact of IFRS 16 £	As restated at January 1, 2019 £
Non-current assets			
Property, plant and equipment	148,935	2,551,810	2,700,745
Prepayments and other	1,066,932	(50,253)	1,016,679
Total impact on assets		2,051,557	
Current liabilities			
Trade and other payables	4,570,307	_	4,570,307
Lease liabilities	_	606,525	606,525
Non-current liabilities			
Lease liabilities	_	1,927,122	1,927,122
Accruals	4,437,321	(32,090)	4,405,231
Total impact on liabilities		2,051,557	
Total impact on retained earnings			

Of the total right-of-use assets of £2,551,810 recognised at January 1, 2019, £1,236,613 related to leases of building and £1,315,197 to leases of equipment. On April 23, 2019, the Group acquired OncoMed Pharmaceuticals Inc. ("OncoMed") (see Note 4). On acquisition, the Group recognised a right-of-use asset of £10,755,475 relating to an acquired property lease.

The table below presents a reconciliation from operating lease commitments disclosed at December 31, 2018 to lease liabilities recognised at January 1, 2019.

	£
Operating lease commitments disclosed under IAS 17 at December 31, 2018	535,665
Effect of discounting	(944,186)
Reassessment of lease term under IFRS 16	2,942,168
Lease liabilities recognised at January 1, 2019	2,533,647

In terms of the income statement impact, the application of IFRS 16 resulted in a decrease in other operating expenses and an increase in depreciation and interest expense compared to IAS 17.

During the six months ended June 30, 2019, in relation to leases under IFRS 16 the Group recognised the following amounts in the consolidated income statement:

	Six months to June 30, 2019 £
Depreciation	552,017
Interest expense	427,943
Foreign exchange	3,222

The amounts recognised in the consolidated income statement relating to short-term leases and low-value leases, where the relevant practical expedients have been applied, is not significant.

# 4. Acquisition of subsidiary

On April 23, 2019, the Group obtained a 100% controlling interest in OncoMed Pharmaceuticals Inc. ("OncoMed"), a US company based in Redwood City, California, that had been publicly listed on NASDAQ.

OncoMed is a clinical-stage biopharmaceutical company focused on discovering and developing novel therapeutics that address the fundamental biology driving cancer's growth, resistance, recurrence and metastasis. OncoMed was acquired in order to broaden the Group's asset base, strengthen its cash position and obtain a NASDAQ listing to diversify international shareholder base of the combined group.

The acquisition has been accounted for using the acquisition method of accounting. A provisional assessment has been made of the fair value to the Group of the assets and liabilities acquired along with the contingent consideration as they are based on preliminary information received at this point and therefore subject to adjustment through December 31, 2019.

# Acquisition of subsidiary - 2019: net assets acquired

	£
Cash and short-term deposits	10,074,297
Short-term investments	29,019,206
Other receivables	154,529
Prepayments	1,696,933
Property, plant and equipment	81,985
Right-of-use assets	10,755,475
Identifiable intangible assets	12,693,479
Other liabilities	(9,214,785)
Lease liabilities	(10,688,588)
Net identifiable assets	44,572,531
Bargain purchase	(3,680,053)
Total consideration	40,892,478
Satisfied by:	
Issuance of own-equity instruments (24,783,320 ordinary shares)	40,892,478
Contingent consideration	_
Total consideration transferred	40,892,478
Net cash inflow arising on acquisition	
Cash consideration	_
Less: cash and short-term deposits acquired	(10,074,297)
	(10,074,297)

The fair value of the 24,783,320 ordinary shares issued as part of the consideration paid for OncoMed (£40,892,478) was measured on the basis of the Group's quoted share price as at the date of acquisition (i.e. April 23, 2019).

As the Group acquired OncoMed for an amount less than the fair market value of the net assets acquired on the date of acquisition, a gain on bargain purchase of £3,680,053 was realised (recognised net against the acquisition transaction costs within the consolidated statement of comprehensive loss). This was attributable to the following factors:

- (i) Subject to a working capital adjustment, the immediately pre-closing proportion of shares in Mereo due to be issued to OncoMed's shareholders as equity consideration was agreed in December 2018 based on the Group's 90-day volume-weighted average price ending on December 4, 2018 (the "reference share price"). Following a movement downward in the Group's quoted share price on the completion date (23 April 2019) in comparison with the reference share price this reduced the fair value of the consideration paid. The impact in the reduction in the total consideration paid was partly offset by; and
- (ii) In the period from announcement of the deal and the date of acquisition (April 23, 2019), a period of approximately five months, OncoMed continued to generate losses reflecting continued R&D activity together with expenditure on its overheads. This had the effect of reducing net assets acquired.

The contingent consideration arrangement requires the Group to make additional cash payments and issue new American Depositary Shares ("ADSs") if specified milestones are achieved within agreed time periods.

Additional cash consideration becomes payable, if, within eighteen months following the completion date, the Group enters into eligible partnership or investment transactions in relation to OncoMed's navicixizumab product and, within five years of the completion date, the Group receives certain eligible cash milestone payment ("NAVI Milestone"). The potential undiscounted amount of the Navi Milestone payment is subject to an aggregate cap of approximately \$80 million.

Contingent consideration in the form of new ADSs was also due in the event that Celgene Corporation ("Celgene") exercised its option in relation to OncoMed's etigilimab product. As announced in June 2019, Celgene did not exercise its option and therefore the Group will not be required to issue any ADSs under this contingent consideration arrangement.

After consideration of the significant inherent uncertainties related to the Navi milestones, the preliminary fair value of the CVRs as of the completion date was estimated to be minimal (i.e. approximates £Nil). In determining that the preliminary CVR fair value approximated nil, the following information and factors were considered:

- (i) The likelihood of Celgene exercising the exclusive option granted by OncoMed to Celgene in relation to OncoMed's etigilimab product, particularly given Bristol-Myers Squibb's proposed acquisition of Celgene;
- (ii) The uncertain outcomes of current clinical studies;
- (iii) The level of uncertainty regarding the availability of future funding partners;
- (iv) The level of uncertainty relating to the success of future development of such products; as well as
- (v) The dependency of the CVR milestones on the occurrence of events that are outside of the control of the Group.

The fair value of the financial assets includes receivables from the landlord under OncoMed's office lease arrangement in relation to tenant improvements with a fair value and a gross contractual value of £154,529. It is estimated at acquisition date that all contractual cash flows are collectable in full. Short-term investments acquired with OncoMed were treasury bills (recognised at fair value through OCI).

Acquisition-related-costs (recognised net against the gain on bargain purchase within the consolidated statement of comprehensive loss) amounted to £2,644,674.

OncoMed contributed £nil revenue and £2,283,341 to the Group's loss for the period between the date of acquisition and the balance sheet date.

If the acquisition of OncoMed had been completed on the first day of the financial year, group revenues for the period would have been £4,255,178 and the Group's loss would have been £24,340,108. This information is provided for illustrative purposes only and is not necessarily indicative of the results that the Group would have occurred had OncoMed actually been acquired at the beginning of the year, or indicative of future results of the Group.

# 5. Property, plant and equipment

On initial application of IFRS 16 the Group recognised right-of-use assets of £2,551,810. Subsequently, following the acquisition of OncoMed (Note 4), the Group recognised a right-of-use asset of £10,755,475 relating to an acquired property lease.

Further details on the initial application of IFRS 16 are presented in Note 3. The Group has decided to present right-of-use assets within property, plant and equipment.

# 6. Intangible assets

	Acquired development
At December 31, 2018 – Audited	programs £
Cost	33,005,229
Accumulated revision to estimated value	(373,000)
Net book amount	32,632,229
Six months ended June 30, 2019 – Unaudited	
At January 1, 2019	32,632,229
Acquisition of subsidiary (Note 4)	12,693,479
Revision to estimated value	(169,000)
At June 30, 2019	45,156,708
At June 30, 2019 – Unaudited	
Cost	45,698,708
Accumulated revision to estimated value	(542,000)
Net book amount	45,156,708

The present value of the provision for deferred cash consideration relating to the agreement with AstraZeneca was reviewed at June 30, 2019 (see Note 9). The decrease in present value due to changes in timelines and probability of contractual milestones being achieved was £169,000 (2018: £373,000) and is recognized as a reduction of the intangible asset in line with our accounting policies.

The intangible asset acquired with the acquisition of subsidiary of £12,693,479 (2018: £nil) is further explained within Note 4.

During the period the Group did not revise the value of any other intangible assets (2018: £nil). As the intangible assets remain under development, no amortisation charge has been recognised (2018: £nil).

# 7. Interest bearing loans and borrowings

	Six months ended June 30, 2019 Unaudited £	Six months ended June 31, 2018 Unaudited £	Year ended December 31, 2018 Audited £
Convertible loan notes (see Note 7a)		1,943,235	2,038,881
Bank loan (see Note 7b)	19,732,236	18,961,887	19,445,756
At end of year/period	19,732,236	20,905,122	21,484,637
Current	8,011,237	5,644,369	6,837,884
Non-current	11,720,999	15,260,753	14,646,753

#### 7a. Convertible loan note

On June 21, 2019 Novartis converted the remaining balance of principal and interest of £2,367,004 of loan Notes ("Novartis Notes") into 1,071,042 ordinary shares at the fixed conversion price of £2.21 per share. This has been recorded as a £2,058,882 reduction in interest bearing loans and borrowings and a reduction in other capital reserves of £308,122. Under the terms of the Notes, Novartis also received 864,988 bonus shares.

The value of the equity component of the Notes at December 31, 2018 was calculated as £308,122.

#### 7b. Bank loan

On April 23, 2019, following completion of the acquisition of OncoMed, the Group agreed an amendment to the terms of its bank loan with the lenders. The new terms extended the interest-only period to December 31, 2019 followed by a 15-month capital and interest repayment period. The Group has undertaken an assessment under IFRS 9 and believe that the change in terms should not be accounted for as a modification under IFRS 9, but instead as a change in expected cash flows. The cash flows under the bank loan were revised from May 1, 2019. The gain as a result of the changes in the estimated cash flows is recognised as a true up in the total finance cost (i.e. together with the interest expense). Management estimated the revised carrying value of the loan as of May 1, 2019 to be £19,942,551 by discounting the revised cash flows at the original discount rate of 18%. The difference between the previous and revised carrying value of the loan as at May 1, 2019 in the amount of £456,430 is recognised as a gain in profit and loss as required under IFRS 9. Following the re-estimation, the financial liability continues to be accounted for at amortised cost using the original effective interest rate.

On May 3, 2019, under the terms of the loan agreement, Mereo issued 321,444 additional warrants (see Note 10) to its lenders giving them the right to subscribe for ordinary shares at an exercise price of £2.95. The fair value of the additional warrants as of their grant date (May 3, 2019) was £131,150.

The total carrying value of the loan at June 30, 2019 was £19,732,236 (2018: £18,961,887). £8,011,237 is a current liability and £11,720,999 is a non-current liability. A total of £742,909 (2018: £186,963) of non-cash interest has been charged to the statement of comprehensive loss in the period.

# 8. Issued capital and reserves

		Six months	Year ended
	Six months to June 30,	to June 30,	December 31,
	2019	2018	2018
	Unaudited	Unaudited	Audited
	£	£	£
Ordinary share capital			
Balance at beginning of year/period	213,721	213,285	213,285
Issuances in the period	80,158	150	436
Nominal share capital at end of year/period	293,879	213,435	213,721

Ordinary shares issued and fully paid	
At January 1, 2019	71,240,272
Issued on April 23, 2019 for OncoMed acquisition	24,783,320
Issued on June 21, 2019 for conversion of loan note	1,936,030
At June 30, 2019	97,959,622
Nominal value at June 30, 2019 (£)	0.003
Issued capital at June 30, 2019 (£)	293,879
Ordinary shares issued and fully paid	
At January 1, 2018	71,094,974
Issued on June 1, 2018 for financing round	50,076
At June 30, 2018	71,145,050
Nominal value at June 30, 2018 (£)	0.003
Issued capital at June 30, 2018 (£)	213,435

Ordinary shares issued and fully paid	
At July 1, 2018	71,145,050
Issued on August 3, 2018 for exercise of share options	10,000
Issued on October 22, 2018 for exercise of share options	85,222
At December 31, 2018	71,240,272
Nominal value at December 31, 2018 (£)	0.003
Issued capital at December 31, 2018 (£)	213,721

Since January 1, 2019, the following alterations to the Company's share capital have been made:

- i) On April 23, 2019 the Company issued and allotted 24,783,320 ordinary shares of £0.003 in nominal value in the capital of the Company as consideration for the acquisition of OncoMed. The fair value of the ordinary shares was measured as £1.65; and
- ii) On June 21, 2019 Novartis converted £2,367,004 of loan notes dated June 3, 2016 into 1,071,042 ordinary shares of £0.003 in nominal value in the capital of the Company at the fixed conversion price of £2.21 per share. Under the terms of the notes, Novartis also received 864,988 bonus shares.

	£
Share premium	
At January 1, 2019 – Audited	118,492,073
Issued on June 21, 2019 for conversion of loan note	3,952,773
Transaction costs for issued share capital	(760,692)
At June 30, 2019 – Unaudited	121,684,154
	£
Share premium	
At January 1, 2018 – Audited	118,226,956
Issued on June 1, 2018 for placing for cash	150,078
Transaction costs for issued share capital	(7,511)
At June 30, 2018 – Unaudited	118,369,523
Issued on August 3, 2018 for exercise of share options	12,870
Issued on October 22, 2018 for exercise of share options	109,680
At December 31, 2018 – Audited	118,492,073

# Other capital reserves

	Shares to be issued £	Share- based payments £	Equity component of convertible loan £	Warrants issued for TAP funding £	Merger reserve £	Total £
At January 1, 2019 – Audited	1,591,578	16,648,762	308,122	44,156	_	18,592,618
Share-based payments expense during the period	_	492,801	_	_	_	492,801
Shares issued	(1,591,578)	_	_	_	_	(1,591,578)
Equity component of convertible loan instrument	_	_	(308,122)	_	_	(308,122)
Issue of share capital on April 23, 2019 for acquisition of						
OncoMed (Note 8)	_	_	_	_	40,818,128	40,818,128
At June 30, 2019 – Unaudited		17,141,563		44,156	40,818,128	58,003,847

	Shares to be issued £	Share- based payments £	Equity component of convertible loan £	Warrants issued for TAP funding £	Total £
At January 1, 2018 – Audited	1,591,578	14,459,469	308,122		16,359,169
Share-based payments expense during the period	_	1,386,862	_	_	1,386,862
At June 30, 2018 – Unaudited	1,591,578	15,846,331	308,122	_	17,746,031
Share-based payments expense during the period		915,473			915,473
Share-based payments release for exercise of options	_	(113,042)	_	_	(113,042)
Warrants issued for TAP funding				44,156	44,156
At December 31, 2018 – Audited	1,591,578	16,648,762	308,122	44,156	18,592,618

#### Shares to be issued

At January 1, 2017, £2,674,477 representing a maximum of 1,453,520 shares at £1.84 were remaining to be issued to Novartis pro rata to their percentage shareholding as and when the Company issues further ordinary shares.

Of the 1,221,361 ordinary shares issued on April 26, 2017, 588,532 shares were issued to Novartis as fully paid up bonus shares (for £nil consideration), the number of which was calculated to maintain its shareholding at 19.5%. The fair value of these shares was £1.84 per share. At December 31, 2018, £1,591,578 representing a maximum of 864,988 shares at £1.84 were remaining to be issued to Novartis pro rata to their percentage shareholding as and when the Company issues further ordinary shares

Of the 1,936,030 ordinary shares issued to Novartis on June 21, 2019, the remaining 864,988 shares were issued to Novartis as fully paid up bonus shares (for £nil consideration). The fair value of these shares was £1.84 per share.

#### **Share-based payments**

The Group has a share option scheme under which options to subscribe for the Group's shares have been granted to certain Executives, Non-Executive Directors and employees.

The share-based payment reserve is used to recognise:

- i. the value of equity-settled share-based payments provided to employees, including key management personnel, as part of their remuneration; and
- ii. deferred equity consideration.

The total charge for the six months to June 30, 2019 in respect of all share option schemes was 492,801 (June 30, 2018: £1,386,862).

On May 20, 2019, the Company granted 441,700 market value options over ADS under the Mereo 2019 Equity Incentive Plan to certain executives and other employees. The weighted average fair value of options granted was £0.61. The exercise price is \$5.40. On the same date, the Company granted 38,500 market value options over ADS under the Mereo 2019 NED Equity Incentive Plan to certain non-executives. The weighted average fair value of options granted was £0.61. The exercise price is \$5.40.

# Equity component of convertible loan instrument

The convertible loan Notes issued to Novartis are a compound instrument consisting of a liability and an equity component. The value of the equity component (cost of the conversion option) as at June 30, 2019 is £nil (June 30, 2018: £308,122). The value of the equity component (cost of the conversion option) as at December 31, 2018 was £308,122.

# Merger reserve

On April 23, 2019, the Group obtained a 100% controlling interest in OncoMed (Note 4).

The consideration paid to acquire OncoMed was 24,783,320 ordinary shares with a fair value of £40,892,478 based on the Group's quoted share price as at the date of acquisition. The nominal value of the issued capital was £74,350 with the excess, £40,818,128, classified within other capital reserves as a 'Merger reserve'.

# 9. Provisions

	Six months to June 30, 2019 Unaudited £	Six months to June 30, 2018 Unaudited £	Year ended December 31, 2018 Audited £
Social security contributions on share options	119,472	2,318,058	842,367
Provision for deferred cash consideration	2,141,000	1,968,000	2,131,000
At end of year/period	2,260,472	4,286,058	2,973,367
Current	333,556	293,000	332,014
Non-current	1,926,916	3,993,058	2,641,353
	Six months to June 30, 2019	Six months to June 30, 2018	Year ended December 31, 2018
	Unaudited	Unaudited	Audited
Social security contributions on share options	£	£	£
At beginning of year/period	842,367	£ 2,288,386	Audited £ 2,288,386
At beginning of year/period Arising during the year/period	£	£	2,288,386 —
At beginning of year/period	£	£ 2,288,386	£
At beginning of year/period Arising during the year/period	842,367 —	£ 2,288,386	2,288,386 —
At beginning of year/period Arising during the year/period Released during the year/period	842,367 — — ————————————————————————————————	2,288,386 29,672 —	2,288,386 ————————————————————————————————————

The provision for social security contributions on share options is calculated based on the number of options outstanding at the reporting date that are expected to be exercised. The provision is based on the estimated gain arising on exercise of the share options, using the best estimate of the market price at the balance sheet date. Since the Directors assume the options will be held for their full contractual life of ten years, the liability has been classified as non-current. The provision has been discounted.

Provision for deferred cash consideration	Six months to June 30, 2019 Unaudited £	Six months to June 30, 2018 Unaudited £	Year ended December 31, 2018 Audited £
At beginning of year/period	2,131,000	2,061,000	2,061,000
Arising during the year/period	_		_
Increase in provision due to the unwinding of the time value of money	179,000	222,000	443,000
Decrease in provision due to a change in estimates relating to timelines and			
probabilities of contractual milestones being achieved (see Note 6)	(169,000)	(315,000)	(373,000)
At end of year/period	2,141,000	1,968,000	2,131,000
Current	333,556	293,000	332,014
Non-current	1,807,444	1,675,000	1,798,986

The deferred cash consideration is the estimate of the quantifiable but not certain future cash payment obligations due to AstraZeneca for the acquisition of certain assets. This liability is calculated as the risk adjusted net present value of future cash payments to be made by the Group. The payments are dependent on reaching certain milestones based on the commencement and outcome of clinical trials. The likelihood of achieving such milestones is reviewed at the balance sheet date and increased or decreased as appropriate (see Note 6).

# 10. Warrant liability

	Six months to June 30, 2019 Unaudited £	Six months to June 30, 2018 Unaudited £	Year ended December 31, 2018 Audited £
At beginning of year/period	1,005,613	1,346,484	1,346,484
Arising during the year/period	131,150	_	375,343
Movement during the year/period	(911,290)	188,480	(716,214)
At end of year/period	225,473	1,534,964	1,005,613

On May 3, 2019 the Group issued 321,444 warrants to lenders of the bank loan facility (see Note 7b). These warrants will be capable of exercise until October 1, 2028 at an exercise price of £2.95.

As at June 30, 2019 a total of 1,243,908 warrants are outstanding, held by lenders of the bank loan facility, which is equivalent to 1.27% of the ordinary share capital of the Company.

The terms of the warrant instrument allow for a cashless exercise. In line with IAS 32 (Financial Instruments: Presentation), the future number of shares to be issued to the warrant-holder under a cashless exercise can only be determined at that future date. At each balance sheet date, the fair value of the warrants will be assessed using the Black-Scholes model considering appropriate amendments to inputs in respect of volatility and remaining expected life of the warrants.

The following table lists the weighted average inputs to the models used for the fair value of warrants:

	Six months to June 30, 2019 Unaudited	Six months to June 30, 2018 Unaudited	December 31, 2018 Audited
Expected volatility (%)	66	67	65
Risk-free interest rate (%)	1.26	1.38	1.56
Expected life of share options (years)	9.5	9.3	10
Market price of ordinary shares (£)	0.83	3.12	2.31
Model used	Black Scholes	Black Scholes	Black Scholes
Risk-free interest rate (%) Expected life of share options (years) Market price of ordinary shares (£)	1.26 9.5 0.83	1.38 9.3 3.12	1.5 1 2.3

The fair value of the warrants at grant was £1,292,011. At June 30, 2019 it was £225,473 (2018: £1,534,964) and at December 31, 2018 it was £1,005,613.

Since there is no historical data in relation to the expected life of the warrants the contractual life of the options was used in calculating the expense for the year.

Volatility was estimated by reference to the share price volatility of a group of comparable companies over a retrospective year equal to the expected life of the warrants.

#### 11. Related party disclosures

Transactions between the parent and its subsidiaries, which are related parties, have been eliminated on consolidation and are not disclosed in this note.

Novartis holds 15,703,871 shares in the Company at June 30, 2019 (June 30, 2018 and December 31, 2018: 13,767,841). Novartis held £2,065,011 principal value of loan Notes at June 30, 2018 and December 31, 2018.

On June 21, 2019 Novartis converted the remaining balance of principal and interest of £2,367,004 of loan Notes into 1,071,042 ordinary shares at the fixed conversion price of £2.21 per share (see Note 7a). Under the terms of the Notes, Novartis also received 864,988 bonus shares.

# Employee benefit trust

In 2016 the Company set up an Employee benefit trust for the purposes of buying and selling shares on the employees' behalf.

A total of £1,000,000of funding was paid into the Trust by the Company during the period to June 30, 2019 (2018: nil). A total of £325,000 of funding was paid into the Trust by the Company during the year ended December 31, 2018.

A total of 1,074,274 shares were purchased by the Trust during the period to June 30, 2019 (2018: nil). A total of 163,000 shares were purchased by the Trust during the year ended December 31, 2018.

As at June 30, 2019 a cash balance of £21,762 (2018: £3,600) was held by the Trust. As at December 31, 2018 a cash balance of £21,762 was held by the Trust.

# 12. Events after the reporting period

On July 23, 2019, the Company granted 215,500 market value options over ADS under the Mereo 2019 Equity Incentive Plan to certain executives and other employees at an exercise price of \$3.00 per ADS.

On July 23, 2019, the Company granted 38,500 market value options over ADS under the Mereo 2019 NED Equity Incentive Plan to certain non-executives at an exercise price of \$3.00 per ADS.

On August 1, 2019, the Company granted 50,000 market value options over ADS under the Mereo 2019 Equity Incentive Plan to certain employees at an exercise price of \$2.60 per ADS.

On August 2, 2019, the Company granted 6,000 market value options over ADS under the Mereo 2019 Equity Incentive Plan to certain employees at an exercise price of \$2.74 per ADS.

On August 6, 2019, OncoMed received a tax refund in respect of Alternative Minimum Tax ("AMT") of \$1,303,920 from the U.S. Internal Revenue Service ("IRS").

# **Exhibit Index**

No. <u>Description</u>

99.1 Press release dated September 17, 2019

# **SIGNATURE**

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: September 17, 2019

# MEREO BIOPHARMA GROUP PLC

By: /s/ Denise Scots-Knight
Name: Denise Scots-Knight
Title: Chief Executive Officer

#### Mereo BioPharma Announces Interim Financial Results for the Six Months Ended June 30, 2019 and Provides Corporate Update

12-Month Topline Results from Phase 2b ASTEROID Study with Setrusumab for Osteogenesis Imperfecta (OI) Expected in Q4 2019; Positive 6-Month Data to be Featured in Late-Breaking Oral Presentation at ASBMR 2019

Conference Call Today at 8:30 a.m. EDT / 1:30 p.m. BST

**London and Redwood City, Calif., September 17, 2019** - Mereo BioPharma Group plc (NASDAQ: MREO, AIM: MPH), a clinical stage biopharmaceutical company focused on rare diseases, today announces unaudited interim financial results for the six months ended June 30, 2019 and provides a corporate update.

"The first half of 2019 has been notable for the announcement of positive six-month data for our Phase 2b ASTEROID trial which is evaluating setrusumab as a treatment for OI. We are entering another exciting period with the 12-month data from this study expected in Q4 2019 and proof-of-concept data from our Phase 2 study for alvelestat in severe alpha-1 antitrypsin deficiency expected in mid-2020," said Dr. Denise Scots-Knight, Chief Executive Officer of Mereo. "While our mission remains to provide new therapies for undertreated, chronically debilitating and life-limiting rare diseases, the proposed evaluation of alvelestat in the orphan disease bronchiolitis obliterans syndrome also strengthens our respiratory focus. We continue to advance discussions with potential partners to optimize the value of our broader product portfolio."

#### **Recent Highlights and Upcoming Milestones**

# Setrusumab for Osteogenesis Imperfecta (OI)

- **12-month data from Phase 2b ASTEROID study in adult OI patients expected in Q4 2019.** In May 2019, Mereo reported positive 6-month interim data from the fully-enrolled ASTEROID study. These data were accepted for a late-breaking oral presentation at the upcoming American Society for Bone and Mineral Research (ASBMR) 2019 Annual Meeting to be held from September 20-23 in Orlando, FL, USA. The Company expects to report 12-month topline data from the blinded portion of the study in Q4 2019. There are currently no FDA or EMA- approved treatments for OI.
- **Pivotal pediatric study ready in the EU and Canada.** In addition to evaluating setrusumab in adult OI patients, Mereo's Paediatric Investigation Plan (PIP) has been approved by the EMA and a study design has been agreed for a pivotal registration trial in children. Mereo is also exploring an extension of the planned pivotal study into the U.S.

#### Alvelestat for Severe Alpha-1 Antitrypsin Deficiency (AATD)

- **Enrollment continuing for the Phase 2 proof-of-concept study in severe AATD patients** with topline data expected in mid-2020. If the results are positive, Mereo intends to commence a pivotal trial in the EU and the U.S. in AATD as soon as possible therafter.
- **Investigator-sponsored clinical studies underway** in AATD and also in bronchiolitis obliterans syndrome (BOS) as a result of graft-versus-host disease (GvHD) in patients undergoing hematopoietic stem cell transplantation (HSCT). BOS is an orphan disease characterized by inflammatory obstruction of the lung's tiniest airways and is the primary cause of death in

patients who receive lung transplants. Based on the preliminary clinical data to-date, Mereo intends to investigate the use of alvelestat to treat patients with BOS patients following a lung transplant.

# Partnering Discussions Continue for Broad Portfolio of Clinical-Stage Programs

- **Leflutrozole for Hypogonadotropic Hypogonadism (HH).** Following the positive Phase 2b and six-month extension data reported in 2018, earlier this year Mereo held an advisory board to consider the future development strategy for leflutrozole, with a focus on the positive effects on semen parameters. Mereo has decided that future product development will focus on male fertility.
- Acumapimod for Acute Exacerbations of Chronic Obstructive Pulmonary Disease (AECOPD) is Phase 3-ready following a
  successful Type B End of Phase 2 meeting with the FDA and agreed outline for a pivotal Phase 3 clinical trial program. Recently, a
  positive Scientific Advice Working Party (SAWP) also took place with the EMA.
- Navicixizumab for Advanced Platinum-Resistant Ovarian Cancer. In July 2019, Mereo held a successful Type B End of Phase 1
  meeting with the FDA regarding a potential pathway for accelerated approval for navicixizumab for the treatment of patients with
  advanced ovarian cancer. Mereo and the FDA discussed, and agreed in principle, an outline for the design of a Phase 2 clinical trial
  that could potentially support the accelerated approval of navicixizumab in patients with ovarian cancer (including peritoneal or
  fallopian tube cancer) who have become resistant to prior therapies.
- **Etigilimab for Advanced Solid Tumors.** Etigilimab has completed a Phase 1a/b trial of etigilimab, administered as either a single-agent or in combination with nivolumab, in patients with advanced or metastatic solid tumors.

# Corporate

- In April 2019, Mereo completed a merger with OncoMed Pharmaceuticals, Inc ("OncoMed"), acquiring two clinical stage oncology programs - navicixizumab and etigilimab.
- Following completion of the acquisition of OncoMed, Michael Wyzga and Deepa Pakianathan, Ph.D. were appointed as Non-Executive Directors to the Mereo Board.
- In August 2019, Mereo appointed Richard Francis as Head of Pharmaceutical Development.
- In September 2019, Dr. Arun Mistry appointed as Therapeutic Area Head, Setrusumab.

### **Financial Highlights**

- Cash resources 1 of £36.1m as at June 30, 2019 (June 30, 2018 £36.9m)
- Loss after tax for the six-month period of £16.2m (2018: £17.0m) or 22 pence per ordinary share (2018: 24 pence per ordinary share)
- American Depositary Receipts ("ADRs") commenced trading on the NASDAQ Global Market on April 24, 2019 with the issue of 4.9m ADR's each represented by 5 ordinary shares
- Cash resources is defined as the aggregate of cash and short-term deposits and short-term investments

# **Conference Call Information**

Mereo will host a live conference call and webcast today at 8:30 a.m. EDT / 1:30 p.m. BST to discuss the Company's financial results and provide a corporate update. To participate in the conference call, please dial (866) 688-2942 (U.S.) or (561) 569-9224 (U.K./International). The conference ID number is

4572478. A live and archived webcast may be accessed by visiting the Investors sections of the Company's website at <a href="https://www.mereobiopharma.com/investors/results-reports-and-presentations/">https://www.mereobiopharma.com/investors/results-reports-and-presentations/</a>. The archived webcast will remain available on the Company's website for fourteen (14) days following the live call.

#### About Mereo BioPharma

Mereo BioPharma is a biopharmaceutical company focused on the development and commercialization of innovative therapeutics that aim to improve outcomes for patients with rare diseases. Mereo's strategy is to selectively acquire product candidates for rare diseases that have already received significant investment from pharmaceutical and large biotechnology companies and that have substantial preclinical, clinical and manufacturing data packages. Mereo's lead rare disease product candidate, setrusumab, is being developed for the treatment of osteogenesis imperfecta (OI) with topline 12-month results from a Phase 2b dose ranging study expected in Q4 2019. Mereo's second lead product candidate, alvelestat, is being investigated in a Phase 2 proof-of-concept clinical trial in patients with alpha-1 antitrypsin deficiency (AATD) with topline data expected in mid-2020.

Mereo's broader pipeline consists of four additional clinical-stage product candidates; acumapimod for the treatment of acute exacerbations of chronic obstructive pulmonary disease ("AECOPD"), leflutrozole for the treatment of hypogonadotropic hypogonadism ("HH") in obese men, navicixizumab (for the treatment of platinum-resistant ovarian cancer, and etigilimab for patients with advanced or metastatic solid tumors.

# **Further Enquiries**

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#### **Forward-Looking Statements**

This document contains "forward-looking statements." All statements other than statements of historical fact contained in this presentation are forward-looking statements within the meaning of Section 27A of the United States Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the United States Securities Exchange Act of 1934, as amended (the "Exchange Act"). 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.

Factors that could cause actual results to differ materially from those in the forward-looking statements include risks relating to unanticipated costs, liabilities or delays; failure or delays in research and development programs; unanticipated changes relating to competitive factors in the Company's industry; risks relating to expectations regarding the Company's capitalization, resources and ownership structure; the availability of sufficient resources for company operations and to conduct or continue planned clinical development programs; the outcome of any legal proceedings; risks related to the ability to correctly estimate operating expenses; risks related to the ability to project future cash utilization and reserves needed for contingent future liabilities and business operations; risks related to the changes in market prices of the Company's ordinary shares; the Company's ability to hire and retain key personnel; changes in law or regulations affecting the Company; international, national or local economic, social or political conditions that could adversely affect the Company and its business; conditions in the credit markets; risks associated with assumptions the Company makes in connection with its critical accounting estimates and other judgments.

All of the Company's forward-looking statements involve 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. The foregoing factors and the other risks and uncertainties that affect the Company's business, including those described in its Annual Report on Form 20-F, Reports on Form 6-K and other documents filed from time to time by the Company with the United States Securities and Exchange Commission (the "SEC") and those described in other documents the Company may publish from time to time should be carefully considered. 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.

	Notes	Six months ended June 30, 2019 Unaudited £	Six months ended June 30, 2018 Unaudited £	Year ended December 31, 2018 Audited £
Research and development expenses		(11,918,484)	(10,864,310)	(22,703,553)
Administrative expenses		(6,461,759)	(7,101,760)	(12,504,887)
Operating loss		(18,380,243)	(17,966,070)	(35,208,440)
Net income recognised on acquisition of subsidiary	4	1,035,379	_	_
Finance income		137,014	151,467	306,831
Finance charge		(1,454,222)	(1,587,150)	(2,360,648)
Net foreign exchange gain/(loss)		(20,127)	49,305	(43,863)
Loss before tax		(18,682,199)	(19,352,448)	(37,306,120)
Taxation		2,458,567	2,364,904	5,277,380
Loss for the period, attributable to equity holders of the parent		(16,223,632)	(16,987,544)	(32,028,740)
Basic and diluted loss per share for the period		(0.22)	(0.24)	(0.45)
Other comprehensive income / (loss)				
Items that may be subsequently reclassified to the income statement				
Fair value changes on investments held at fair value through OCI		88,033		
Currency translation of foreign operations		710,830		
Total comprehensive loss for the period, attributable to equity holders of the parent		(15,424,769)	(16,987,544)	(32,028,740)

	Notes	June 30, 2019 Unaudited £	June 30, 2018 Unaudited £	December 31, 2018 Audited £
Assets				
Non-current assets				
Property, plant and equipment	5	13,100,261	151,996	148,935
Intangible assets	6	45,156,708	32,690,229	32,632,229
		58,256,969	32,842,225	32,781,164
Current assets				
Prepayments		3,068,326	1,225,744	1,066,932
R&D tax credits		7,744,634	10,516,989	5,277,380
Other receivables		1,953,886	584,821	608,893
Short-term investments		7,828,066	2,500,000	2,500,000
Cash and short-term deposits		28,289,504	34,412,363	25,041,945
		48,884,416	49,239,917	34,495,150
Total assets		107,141,385	82,082,142	67,276,314
Equity and liabilities				
Equity				
Issued capital	8	293,879	213,435	213,721
Share premium	8	121,684,154	118,369,523	118,492,073
Other capital reserves	8	58,003,847	17,746,031	18,592,618
Employee Benefit Trust shares	11	(1,304,842)	_	(306,838)
Other reserves		7,000,000	7,000,000	7,000,000
Accumulated losses		(127,356,393)	(96,179,599)	(111,220,794)
Translation reserve		710,830		
Total equity		59,031,475	47,149,390	32,770,780
Non-current liabilities				
Provisions	9	1,926,916	3,993,058	2,641,353
Interest-bearing loans and borrowings	7	11,720,999	15,260,753	14,646,753
Other liabilities		34,289	_	34,289
Warrant liability	10	225,473	1,534,964	1,005,613
Lease liability		13,138,521		
		27,046,198	20,788,775	18,328,008
Current liabilities				
Trade and other payables		6,758,235	4,983,626	4,570,307
Accruals		5,960,684	3,222,982	4,437,321
Provisions	9	333,556	293,000	332,014
Interest-bearing loans and borrowings	7	8,011,237	5,644,369	6,837,884
		21,063,712	14,143,977	16,177,526
Total liabilities		48,109,910	34,932,752	34,505,534
Total equity and liabilities		107,141,385	82,082,142	67,276,314