



**Interim results for the six months ended 30 June 2016**

**16 September 2016**

**Denise Scots-Knight – CEO**

**Richard Bungay – CFO & COO**

# Disclaimer

---

This document has been prepared in good faith and with reasonable care, however the information, statements and opinions contained in it have not been verified by or on behalf of Mereo BioPharma Group plc (the Company). No representation or warranty, express or implied, is given by or on behalf the Company, its subsidiaries or any of their respective shareholders, directors, officers, advisers, agents of other persons as to the accuracy, fairness, completeness or sufficiency of the information, projections, forecasts, opinions or statements contained in the presentation. In particular, the market data in this document has been sourced from third parties and has not been verified. Any reliance the recipient places on this document is at his sole risk, and to the fullest extent permitted by law and save in the case of fraud by or on behalf of the Company, no liability is accepted for this document and any errors, omissions, misstatements or inaccuracies (negligent or otherwise) in any of the information or opinions in this document.

Certain information contained herein constitutes “forward-looking statements”, which can be identified by the use of terms such as “may”, “will”, “should”, “expect”, “anticipate”, “project”, “intend”, “continue”, “target” or “believe” (or the negatives thereof) or other variations thereon or words of similar meaning. Due to various risks, uncertainties and assumptions, actual events, results or performance of the Company may differ materially from those reflected or contemplated in such forward-looking statements. Without prejudice to the generality of the preceding paragraph, no reliance should be placed on such forward-looking statements.

# Agenda

---

- Introduction



**Dr. Denise Scots-Knight**

*CEO*

*Co-Founder*



**Richard Bungay**

*CFO & COO*

- Business Overview
- Highlights
- Strategy
- Pipeline
- Financial Overview
- Summary






## **Business Overview**

# Business overview

---

- Well financed UK-based specialty biopharmaceutical company founded in March 2015 and admitted to AIM market of LSE (MPH.L) June 2016
- Focused on the development of innovative medicines in rare and specialty disease areas
- Strategy is to selectively acquire and further develop clinical-stage product candidates with comprehensive data packages
- Business model provides flexibility to commercialise in-house or out-license
- Initial portfolio of three product candidates, each with Phase 2 clinically meaningful data, acquired from Novartis
- Strong and experienced Board comprised primarily of current and former senior leaders in the pharmaceutical and biotechnology industry
- Backed by leading healthcare focused long-term investors Invesco and Woodford – over £90m funding raised to date
- Business development activities initiated to look for additional products: opportunities from several global pharma companies currently under review

# Broad pipeline addressing high value end markets

Product candidate	Indication	Highlights	Clinical development		
			Phase 1	Phase 2	Phase 3
<b>BPS-804</b>	<ul style="list-style-type: none"> <li>Osteogenesis Imperfecta (OI)</li> </ul>	<ul style="list-style-type: none"> <li>Antibody - Sclerostin inhibitor – stimulates bone formation</li> <li>Orphan disease without approved treatments</li> </ul>			
<b>BGS-649</b>	<ul style="list-style-type: none"> <li>Hypogonadal Hypogonadism (HH) in obese men</li> </ul>	<ul style="list-style-type: none"> <li>Weekly, oral aromatase inhibitor – restores testosterone</li> <li>No disease modifying treatments yet</li> </ul>			
<b>BCT-197</b>	<ul style="list-style-type: none"> <li>Acute Exacerbations of Chronic Obstructive Pulmonary Disease (AECOPD)</li> </ul>	<ul style="list-style-type: none"> <li>Oral p38 MAP kinase inhibitor – targets acute inflammation</li> <li>No approved treatments available</li> </ul>			

## Validating relationship with Novartis:

- 19.5% shareholder; share of downstream economics
- No buy-back rights on BPS-804, BGS-649 and BCT-197
- Supply certain drug product, drug substance and placebo (long term: external CMO's)





## **Highlights**

# Operational Highlights – H1 2016

---

- **BPS-804** (antibody - sclerostin inhibitor)
  - Granted Orphan Drug Designation in US and EU
  - Following submission of Phase 2b/3 pivotal study package in H1 2016 expecting to commence trial H1 2017, pending feedback from regulator
- **BGS-649** (aromatase inhibitor)
  - Commenced Phase 2b for the treatment of hypogonadal hypogonadism in obese men
  - Study design includes a blinded review to identify any ineffective doses, planned in Q4 2016, and a six month extension study
- **BCT-197** (p38 MAP kinase inhibitor)
  - Opened US IND Q1 2016
  - Commenced Phase 2 for the treatment of acute exacerbations of COPD Q1 2016
- IP strengthened across all three programmes



# Financial Highlights – H1 2016

---

- Shares admitted to the AIM market of the London Stock Exchange on 9 June 2016
- Raised £14.8 million through private placement at time of AIM admission
  - Issue of new ordinary shares: £11.3 million
  - Novartis convertible loan: £3.5 million
  - Private placement price: £2.21 per share
- Loss after tax: £14.7 million (2015: £nil)
- Cash and cash equivalents at 30 June 2016: £70.2 million (2015: £nil)
  - Net cash inflow from financing activities: £68.5 million (2015: £nil)
  - Net cash outflow from operating activities: £10.5 million (2015: £nil)



**Strategy**

# Company strategy

1

## **Advance our initial pipeline product candidates through the clinical pathway**

- Execute Phase 2b/3 trial of BPS-804 in OI
- Execute Phase 2b dose confirmation trial of BGS-649 in HH in obese men
- Execute Phase 2 dose ranging trial of BCT-197 in AECOPD

2

## **Realise value of product portfolio through multiple avenues**

- Global commercialisation rights for all product candidates controlled
- Out-license, sell, commercialise or combine various strategies to maximise value for each of the product candidates based on clinical trial results
- Diversified portfolio aims to optimise chances of commercial success

3

## **Leverage existing business model for future scaling up of product portfolio**

- Focus on product candidates with compelling market potential, comprehensive preclinical, clinical and manufacturing data package, and a clear path to a significant value inflection point

# Product candidate selection criteria





## **Pipeline**

# Osteogenesis Imperfecta (OI)

## Disease characteristics

- A genetic and chronic disorder affecting connective tissue, thus resulting in bone fragility and reduced bone mass
- Prevalence of 20,000 to as many as 50,000 patients in the US; in Europe approx 7.5 out of 100,000
- Increased risk of bone fractures, as well as loose joints, early hearing loss, brittle teeth and respiratory problems
- c. 90% are linked to a gene mutation that produces abnormal type 1 collagen
- 8 Recognized forms of OI – Type 1 to type 8
  - Most prevalent form is type I (c. 60% of patients), also the least severe form
  - Type II is the most severe form, with few infants surviving beyond a few weeks



# BPS-804 (OI) highlights

---

## *Product highlights*

---

- Fully human monoclonal antibody inhibiting sclerostin
- 83 patients have received BPS-804 in clinical trials to date: including patients with moderate OI
- Statistically significant improvement on BMD and blood bone biomarkers
- In studies to date, BPS-804 has been safe and well tolerated in the target population
- Granted Orphan Drug Designation in US and EU

## *Phase and timing*

---

- Phase 2b/3 trial in OI types I, III and IV
- Following submission of package H1 2016 expected to start trial H1 2017, pending feedback from regulator
- Placebo controlled study including dose ranging and event driven time to first fracture (TTFF) end point:
  - Part A: dose ranging in 120 patients with biomarker interim data expected H1 2018
  - Part B: TTFF end point in approx. 300 patients following dose selection

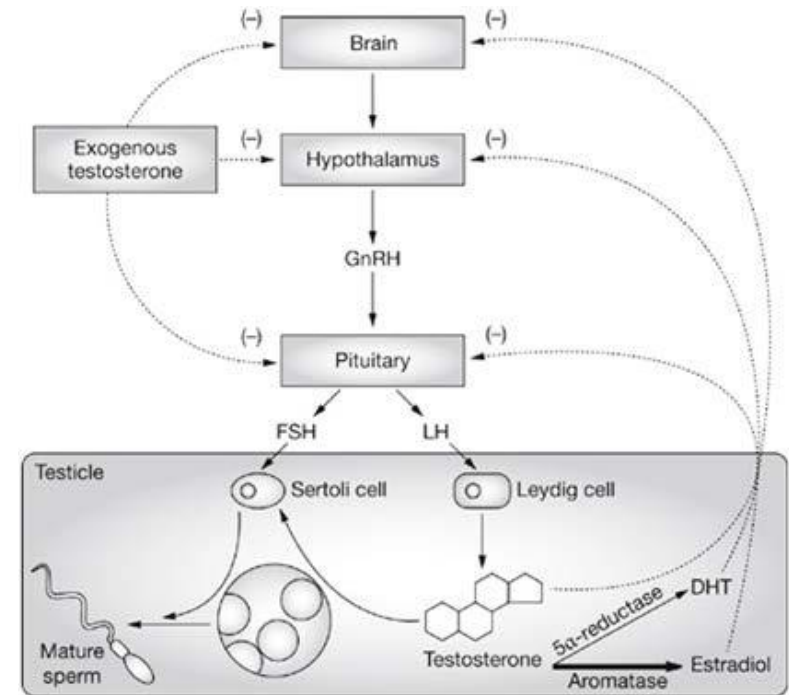
## *Differentiation*

---

- BPS-804 is expected to strengthen bone by both building bone and reducing the resorption of bone, potentially reducing fractures
- Bisphosphonates reduce the resorption of bone

# Hypogonadal Hypogonadism (HH) in obese men

- Hypogonadism in men is a clinical syndrome that results from inadequate levels of testosterone
- Current standard of care for the treatment of male hypogonadism is testosterone replacement therapy
  - No approved therapies specifically targeting obese men with HH, and current treatments having complications
  - Leading treatment AndroGel peak sales >\$1bn (2015 sales: \$694m)
- Low testosterone levels associated with increased obesity, cardiovascular disease, hypertension, insulin resistance, type 2 diabetes, depression and osteoporosis
- Prevalence of HH in symptomatic obese men in the US is c. 6m and in Europe c. 4m
- Testosterone deficiency remains significantly untreated: treatment rates estimated below 13% in the US and lower in Europe





# BGS-649 (HH) highlights

---

## *Product highlights*

---

- Weekly, oral, aromatase inhibitor to be first-line therapy for the treatment of HH in obese men
- 130 patients have received BGS-649 in clinical trials till date
- Statistically significant rise in testosterone, returning patients to normal levels, accompanied by rises in LH and FSH
- In studies to date, BGS-649 has been safe and well tolerated in the target population

## *Phase and timing*

---

- Phase 2b dose confirmation trial initiated
- Multi-center randomized double-blind study conducted in US and Europe in approx. 260 patients comparing three doses of BGS-649 and placebo
- Results expected in H2 2017 with interim analysis in Q4 2016

## *Differentiation*

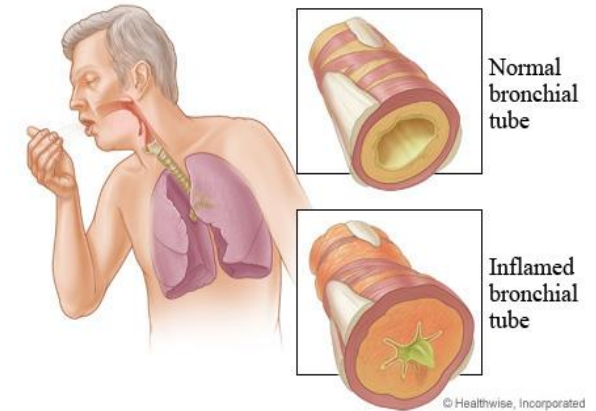
---

- BGS-649 maintains normal feedback loop in the HPT axis, maintaining or restoring gonadotropin levels
- Current data suggests that BGS-649 does not cause excessively high levels of testosterone
- Potential to improve compliance due to convenient dosing and avoids problems caused by transference

# Acute Exacerbations of COPD (AECOPD)

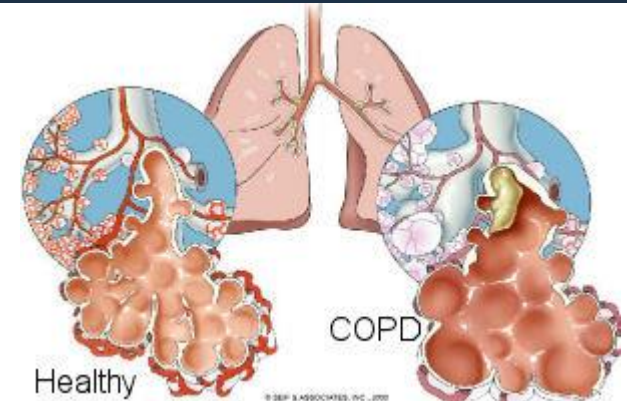
- AECOPDs occur when a patient with COPD experiences a sustained increase in cough, sputum production or dyspnea (shortness of breath), and may require hospitalisation
  - Patients on average suffer 1 – 3 exacerbations a year
  - Frequency and severity of exacerbations increases with age and disease severity
- Estimated 12mm COPD cases diagnosed in the US<sup>(1)</sup> and 13mm diagnosed in Europe<sup>(2)</sup>
- AECOPD patients account for c. 62.5% of all hospital admissions related to COPD
- Average costs in case of hospitalisation amount to c. USD7,500 in the US
- Total yearly costs of COPD in the US amount to approx. USD50bn<sup>(3)</sup> and in the EU direct costs to approx. €38.6bn

## Chronic Bronchitis



*Chronic irritation and inflammation of airways*

## Emphysema



*Breakdown of walls between alveoli / air sacs in lungs*

(1) National Heart Lung Blood Institute; (2) European COPD coalition;  
 (3) Approximately USD30bn in direct costs and USD20bn in indirect costs

# BCT-197 (AECOPD) highlights

---

## *Product highlights*

---

- Small molecule, inhibitor of the enzyme p38 MAP kinase
- Oral therapy given during an exacerbation
- 260 patients have received BCT-197 in clinical studies to date
- Clinically meaningful improvement on FEV1 and throughout the period of an exacerbation
- In studies to date, BCT-197 has been safe and well tolerated in the target population

## *Phase and timing*

---

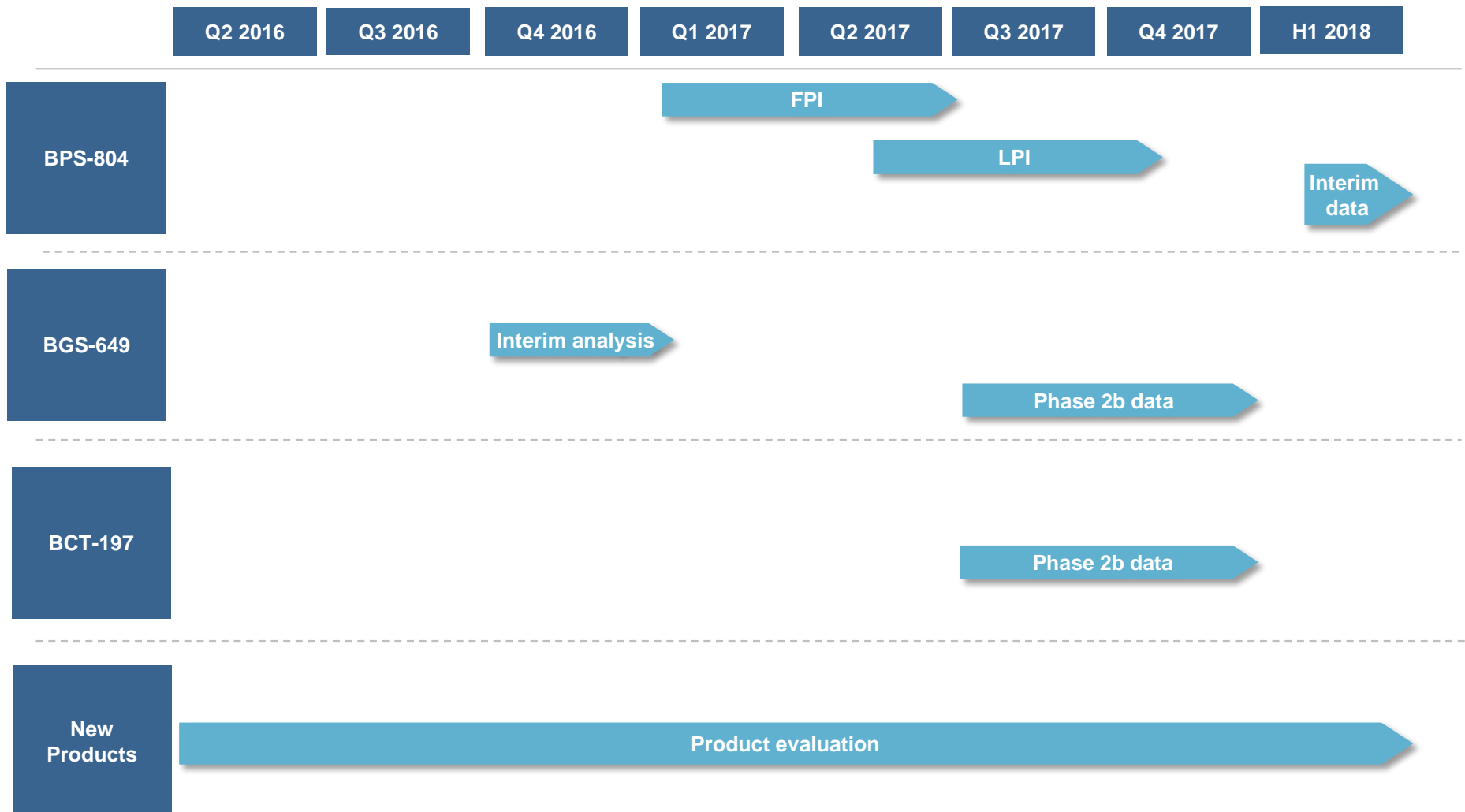
- Phase 2 dose ranging trial initiated in 2016
- Comparing two acute dosing regimens (three doses over five day period) with placebo on top of standard of care in approx. 250 patients
- Study follow up period of 26 weeks
- Results expected H2 2017

## *Differentiation*

---

- Significant unmet need as there are no approved therapies for the treatment of AECOPD
- Blocks the release of major inflammatory cytokines – treats underlying inflammation
- Potential to improve acute symptoms and reduce hospital stays, as well reducing future exacerbations and re-hospitalisations

# Projected news flow and catalysts



FPI = First Patient In

LPI = Last Patient In



## **Financial Overview**

# Fundraising overview

	£m
Private placement (Woodford, Invesco):	
• Tranche 1 (July 2015)	20.0
• Tranche 2 (June 2016)	56.5
Total private placement	76.5
Pre-admission placement (June 2016)	11.3
Novartis convertible loan	3.5
<b>TOTAL GROSS PROCEEDS</b>	<b>91.3</b>
Fees	(4.8)
<b>TOTAL NET PROCEEDS</b>	<b>86.5</b>

- Financed through three key value inflection points: BPS-804 Part A data (expected H1 2018), BGS-649 Phase 2b data (expected H2 2017) and BCT-197 Phase 2 data (expected H2 2017)

# Financial summary – H1 2016

	6 months ended 30/6/16 £m	Period ended 30/6/15 £m	Period ended 31/12/15 £m
Research & development expenses <sup>1</sup>	(11.1)	-	(5.4)
General & administrative expenses <sup>2</sup>	(5.8)	-	(7.7)
Operating loss	(16.9)	-	(13.2)
Taxation	2.2	-	1.0
Loss for the period	(14.7)	-	(12.2)
Opening cash	12.2	-	-
Operating cashflows	(10.5)	-	(6.7)
Investing cashflows	-	-	(0.2)
Financing cashflows <sup>3</sup>	68.5	-	19.1
Closing cash	70.2	-	12.4

<sup>1</sup> Includes non-cash SBP-related charge of £1.1 million

<sup>2</sup> Includes non-cash SBP-related charge of £4.2 million and currency gain of £1.2 million

<sup>3</sup> Certain fees related to fundraising which were expenses in the period ended 31/12/15



## **Summary**



# Summary

---

- Key milestones delivered for all three programmes
  - Two Phase 2 studies commenced within nine months of acquiring programmes
  - Orphan Drug Designation achieved in US and EU for BPS-804 in OI
  - Submitted package to the regulator for BPS-804 registration study
- Financial position strengthened following £14.8 million private placement
  - Total funds raised >£90 million in less than 12 months
- AIM listing facilitates potential future fundraising and product acquisition
- Business development activities ongoing with a view to expanding portfolio
  - Particular focus on rare/orphan diseases
- Well positioned to continue to deliver according to strategic objectives



**Questions?**

# Introducing the Mereo leadership team

## Strong management team



**Dr. Denise Scots-Knight**  
CEO  
Co-Founder



**Dr. Alastair MacKinnon**  
CMO  
Co-Founder



**Charles Sermon**  
General Counsel  
Co-Founder



**Richard Bungay**  
CFO & COO



**John Richard**  
Head of Corporate Development  
Co-Founder

## Experienced board of directors

### Dr. Peter Fellner (Chairman)

- Chairman Ablynx, Vernalis, Consort Medical
- Ex CEO of Celltech, Roche UK

### Dr. Anders Ekblom (Chair – Remuneration Committee)

- Two decades at AstraZeneca, including EVP, Global Drug Development, and CEO AstraZeneca Sweden

### Paul Blackburn (Chair – Audit and Risk Committee)

- Ex SVP and Financial Controller at GlaxoSmithKline

### Dr. Frank Armstrong (SID; Chair – R&D Oversight Committee)

- Ex CEO of biopharma companies including CuraGen and Fulcrum Pharma
- Chairman of Summit, Redx and Faron pharmaceuticals

### Kunal Kashyap

- Allegro Capital Advisors
- Independent director at GlaxoSmithKline Consumer Healthcare India

### Peter Bains

- CEO of Sosei and former CEO of Syngene
- Previous senior commercial roles at GlaxoSmithKline