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the regenerative medicine company

Financial Results for the First Half And Second Quarter Ended 31 December 2015

February 2016

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FINANCIAL RESULTS OVERVIEW

REVIEW OF OPERATIONS

OUR FOCUS, OUR COMMITMENT

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FINANCIAL RESULTS OVERVIEW

Financial Highlights for the Six Months Ended 31 December 2015 US$m

- Cash on hand at 31 December 2015 - $120.8 million
- Q2 FY2016 Cash outflow ($19.8) reduced by >25% in comparison to Q1 FY2016 ($28.1) and Q4 FY2015 ($27.3)
- For the six months ended 31 December 2015, loss before income tax improved by 18% ($7.9) vs comparative period in FY15 principally due to:
  - R&D expenses 23% lower
  - Management & Admin costs 22% lower
- Cash managed to extend runway and achieve Tier 1 value inflexion points

Profit and Loss - Expenditure Reduced Over Prior Period US$m

	6 months ending 31 Dec 2015	6 months ending 31 Dec 2014	$ Change	%
Revenue	**11.5**	**11.3**	**0.2**	**2%**
Loss Before Income Tax	**(35.5)**	**(43.4)**	**7.9**	**18%**

Revenue increased by 2% ($0.2) vs comparative period in FY15:

- Milestone revenue of $3.5 recognized on approval of TEMCELL® Hs. Inj., compared with $2.0 in FY15
- Interest is $1.3 lower due to rate as we held more of our cash in USD deposits in line with our needs

Loss before income tax improved by 18% ($7.9) vs comparative period in FY15:

- **R&D expenses 23% lower ($7.1)** - Reduced expenditure on Tier 2 programs and labour costs
- **Management & Admin costs 22% lower ($3.2)** - Savings on labour cost, currency impacts and IP
- **Manufacturing Commercialization 25% higher ($2.9)** – Increased Phase 3 clinical supply demands

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Cash Management

US$m

	Q2 FY2016 3 months ended 31 Dec 2015	Q1 FY2016 3 months ended 30 Sep 2015	Q4 FY2015 3 months ended 30 Jun 2015
Net Cash Outflows in Operating Activities	**(19.8)**	**(28.1)**	**(27.3)**
Cash at the end of the period	**120.8**	**77.8**	**110.7**

Strengthened cash position

- US IPO completed in November 2015
- Significantly augmented existing cash reserves to $120.8 at 31 December 2015

Operating cash burn reduced

- In line with previous guidance, Q2 FY2016 Cash outflow ($19.8) reduced by >25% in comparison to Q1 FY2016 ($28.1) and Q4 FY2015 ($27.3)
- Cash being managed to extend runway and achieve Tier 1 program value inflexion points including in the P3 heart failure program, the P3 chronic back pain program and the P2 rheumatoid arthritis program, and to file with the FDA for approval of our pediatric graft versus host disease product candidate

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REVIEW OF OPERATIONS

Operational highlights for the six months ended 31 December 2015

- Recruitment of all three Tier 1 Phase 3 Clinical trials progressing well in the US, including MPC-150-IM for Chronic Heart Failure (CHF), MPC-06-ID for Chronic Low Back Pain (CLBP), and MSC-100-IV for Acute Graft Versus Host Disease (aGVHD) in children

- MPC-150-IM:
  - Phase 3 trial size significantly reduced from 1,165 to approximately 600 subjects following discussions between our commercial partner, Teva Pharmaceutical Industries Ltd, and the FDA
  - Trial is targeting patients with advanced heart failure and high rates of hospitalization or death, a significant unmet medical need
  - Updated timelines for this trial will be provided in conjunction with Teva

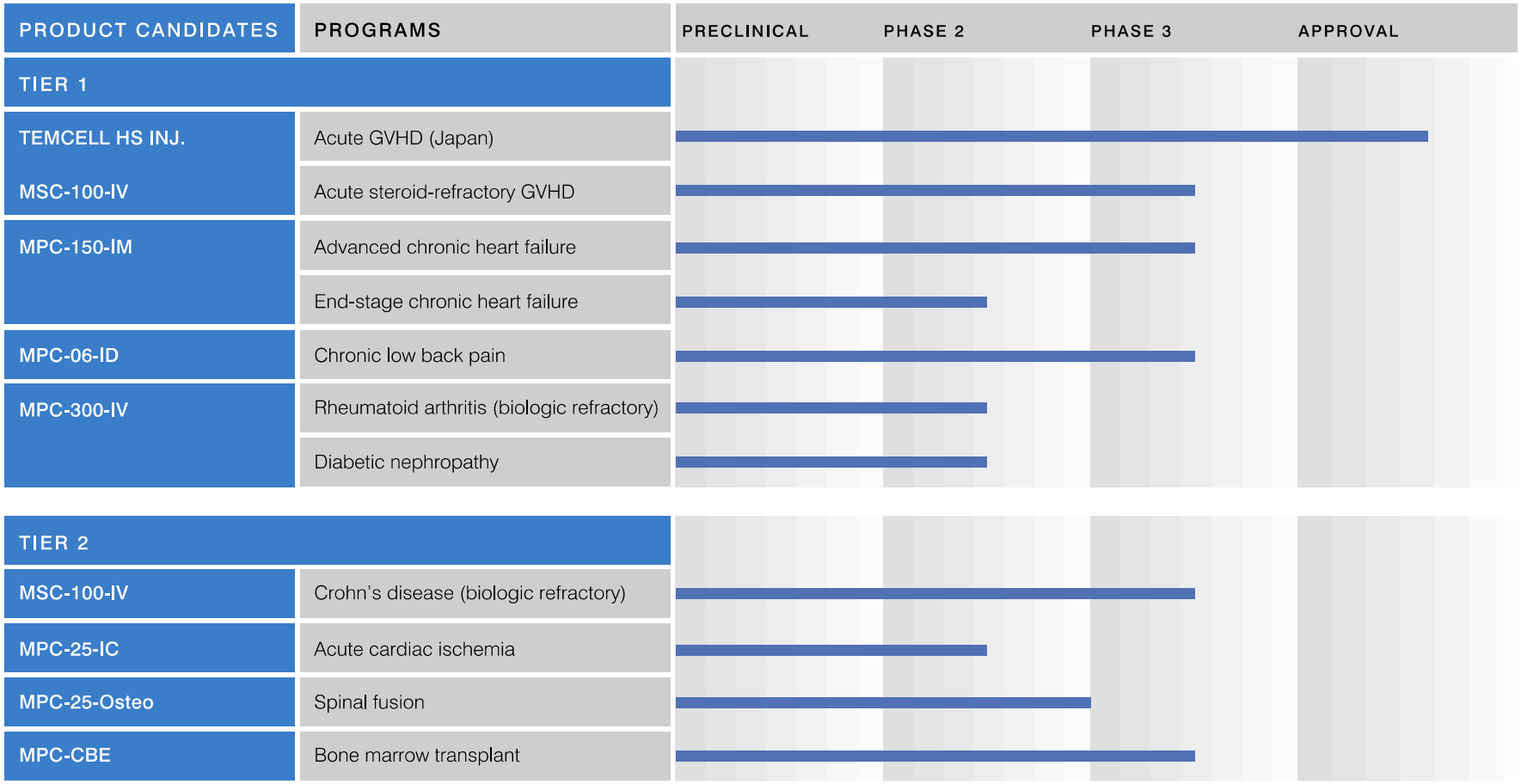
- TEMCELL® HS Inj. In Japan
  - Licensee JCR Pharmaceuticals Co. (JCR) received unconditional approval and reimbursement in Japan for adult and pediatric aGVHD
  - JCR expected to launch TEMCELL® HS Inj. in Japan for adult and pediatric aGVHD in Q1 CY 2016
  - Average reimbursement for 4 week multi-dose treatment is expected to be US$115k and will increase to US$172k if additional dosing is required
  - Mesoblast to receive royalties and other payments at pre-defined thresholds of net sales

- MPC-300-IV: Top line results from the biologic refractory rheumatoid arthritis Phase 2 trial, first dose cohort, show that a single intravenous infusion of the lower dose of MPC-300-IV was safe and resulted in early and sustained clinical responses

- Phase 2 trial results in CHF and Type 2 Diabetes published in leading peer reviewed journals, Circulation Research and Diabetes Care, respectively

Product Candidates in Major Markets with High Unmet Need

First Product on market - Three Tier 1 Product Candidates in Phase 3 Programs



This chart is figurative and does not purport to show individual trial progress within a clinical program. For product registration purposes, Phase 3 programs may require more than one trial.

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MPC-150-IM: Phase 3 Trial Recruiting Well and Targets Advanced Heart Failure where Medical Need is Greatest

- Patients with large baseline Left Ventricular End Systolic Volumes (LVESV) and advanced heart failure are at highest risk of recurrent Heart Failure - Related Major Adverse Cardiac Events (HF-MACE) including hospitalizations and death
- For these patients existing therapies are inadequate and economic burden is greatest
- Phase 2 results showed that MPC-150-IM prevented HF-MACE over 36 months in patients with advanced heart failure
- The ongoing Phase 3 trial is designed to enrich for patients with Advanced Heart Failure and high risk of HF-MACE in order to confirm therapeutic benefit of a single injection of MPC-150-IM

MPC-150-IM: Phase 3 Heart Failure Program Trial Size Reduced

Following our commercial partner's discussions with FDA, the ongoing Phase 3 program in patients with advanced heart failure, and a high risk of recurrent HF-MACE, is planned to be optimized as follows:

- Revised primary endpoint to a comparison of recurrent HF-MACE between MPC treated patients and controls
- Reduction in current Phase 3 trial size from 1,165 to 600 subjects
- Broaden enrollment centres to Europe
- Initiate a second confirmatory study, conducted in parallel in an identical patient population of up to 600 patients using the same primary endpoint

In Q2 CY 2016 Teva and Mesoblast to provide updated timelines for completion of current reduced Phase 3 Trial, regulatory submissions, and overall program completion

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MPC-300-IV: Biologic Refractory Rheumatoid Arthritis (RA) – Market Opportunity

Ongoing randomized, controlled Phase 2 Trial in 48 patients with biologic refractory rheumatoid arthritis, comparing two doses of MPC-300-IV against placebo

Market opportunity

- There are 5.3 million prevalent cases in the US, Japan, and EU5, of which there were 2.4 million in the US alone in 2014[1]
- Incidence increases with age – 8.7 per 100,000 for ages 18-34 vs. 89 per 100,000 for ages 65-74[2]
- Aging population and early diagnosis and treatment will drive expanding RA prevalence
- Targeting active RA patients who have failed a previous biologic therapy – growing target patient group

Gap in treatment options

- One third of RA patients do not respond or cannot tolerate current biologic therapies
  - Sustained remission defined by ACR 70 only occurs in 5-15% of patients on biologics[3]
  - Biologics are associated with increased incidence of opportunistic infections and malignancies
- Biologics only target single cytokine pathways even though RA involves multiple signals / pathways
- Need for disease-modifying therapies with greater safety and efficacy that induce remission in a greater percentage of patients (ACR 70) as early as possible in the disease management

Rationale for Targeting Biologic Refractory RA population

MPCs have receptors that respond to inflammatory signals, resulting in anti-inflammatory mediators

MPC-300-IV targets multiple pathways associated with treatment resistant diseases, whereas existing biologics target a single pathway

1. Decision Resources Rheumatoid Arthritis Dec 2015
2. GlobalData©: Rheumatoid Arthritis Therapeutic – Pipeline Oct 2011
3. Alivernini, S et. al. Arthritis Research & Therapy 2009, 11:R163

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MPC-300-IV: Biologic Refractory Rheumatoid Arthritis (RA) Trial Design

- Double-blind, randomized, placebo-controlled, two-dose escalating trial in the US
- Designed to evaluate safety and explore efficacy of MPC treatment in 48 patients with active RA randomized 2:1 to either placebo or a single intravenous infusion of 1 million or 2 million MPCs/kg
- Patients on stable regimen of methotrexate and have previously failed or had an adverse or inadequate clinical response to at least one biologic agent
- Lower MPC dose was evaluated in the first cohort of 24 patients, of whom 16 had failed 1-2 biologics
- Second cohort of 24 patients, evaluating higher dose of MPCs, actively recruiting
- Primary endpoint is safety, with pre-specified efficacy endpoints at 12 weeks including the American College of Rheumatology (ACR) 20%, 50% and 70% response criteria (ACR20/50/70) [1]

1: ACR20 is a key validated primary endpoint in clinical trials which is accepted by the United States Food and Drug Administration for product approval in RA

MPC-300-IV: Biologic Refractory Rheumatoid Arthritis (RA) - First Cohort Results

- Cell infusions were well tolerated with no cell-related adverse events
- The trial's 12 week, pre-specified ACR20 efficacy endpoint was achieved by 47% of all MPC-treated patients and by 60% of MPC-treated patients who failed 1-2 biologics, vs 25% and 17%, respectively, of matched placebo-treated controls
- 71% of MPC-treated patients who achieved ACR20 responses did so as early as week 1
- At week 12, 27% of MPC-treated patients, but no placebo-treated controls, achieved ACR50 or ACR70 responses
- Remission at week 12, as defined by Disease Activity Score (DAS28/CRP) <2.6, was seen in 20% of MPC-treated patients but in no controls

12-week trial results for both cohorts will be reported in Q3 CY 2016

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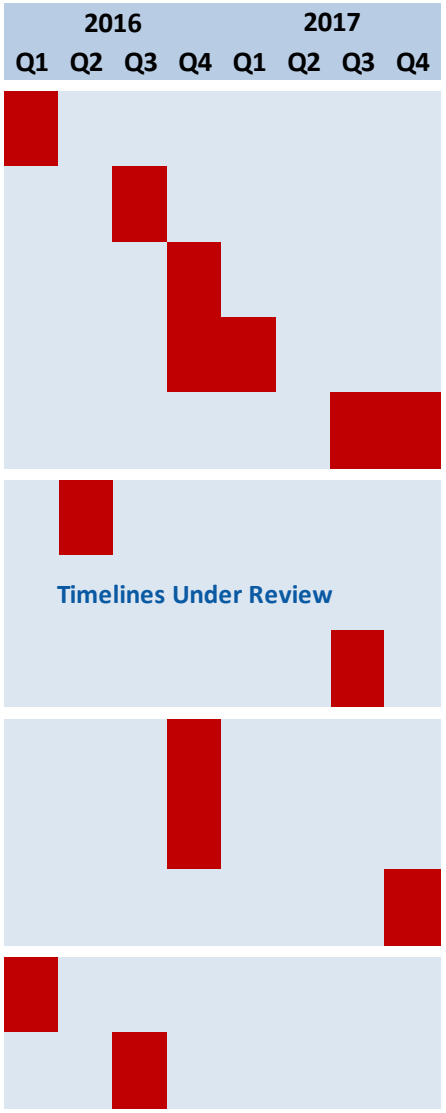
Tier 1 Product Candidate Deliverables (Calendar Year)

Product Candidate	Programs	Anticipated Milestones
MSC-100-IV / Temcell® HS Inj.	Acute Graft Versus Host Disease	Temcell® HS Inj. Launch in Japan US Pediatric Phase 3 Interim Analysis (IA) Top Line Results Phase 3 program complete, Top Line Results US Pediatric BLA Filing US Pediatric Approval
MPC-150-IM	Class II and III Heart Failure Class IV Heart Failure Requiring LVAD	Phase 3 1st IA results Phase 3 2nd IA (futility & efficacy analysis) Phase 2 trial results
MPC-06-ID	Chronic Low Back Pain Due to Degenerative Disc Disease	Phase 3 enrollment complete Trial 1 Phase 3 First IA results Trial 1 Phase 3 Second IA results Trial 1
MPC-300-IV	Rheumatoid Arthritis (Biologic Refractory)	Top line data first cohort released Full trial Results



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Corporate Deliverables

- First royalties from TEMCELL product sales in Japan expected in Q1 CY 2016
- Complete Tier 1 Phase 3 programs on schedule
- Deliver commercial manufacturing in support of product candidate launches
- Deliver on commercial partnerships
- Continued focus on cash management