

**Strategic Update and Financial Results for the Three Months Ended 30 September 2015** 

December 2015



#### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This presentation includes forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Quarterly Report on Form 6-K are forward-looking statements. Words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "intend," "plan," "targets," "likely," "will," "would," "could," and similar expressions or phrases identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and future events and financial trends that we believe may affect our financial condition, results of operation, business strategy and financial needs. These statements may relate to, but are not limited to: expectations regarding the safety or efficacy of, or potential applications for, Mesoblast's adult stem cell technologies; expectations regarding the strength of Mesoblast's intellectual property, the timeline for Mesoblast's regulatory approval process, and the scalability and efficiency of manufacturing processes; expectations about Mesoblast's ability to grow its business and statements regarding its relationships with Teva Pharmaceutical Industries Ltd, JCR Pharmaceuticals Co., Ltd, and Lonza and future benefits of those relationships; statements concerning Mesoblast's share price or potential market capitalization; and statements concerning Mesoblast's capital requirements and ability to raise future capital, among others. Forward-looking statements should not be read as a quarantee of future performance or results, and actual results may differ from the results anticipated in these forward-looking statements, and the differences may be material and adverse. You should read this presentation together with our financial statements and the notes related thereto, as well as the risk factors, in our most recently filed reports with the SEC or on our website. Uncertainties and risks that may cause Mesoblast's actual results, performance or achievements to be materially different from those which may be expressed or implied by such statements, include, without limitation: risks inherent in the development and commercialization of potential products; uncertainty of clinical trial results or regulatory approvals or clearances; government regulation; the need for future capital; dependence upon collaborators; and protection of our intellectual property rights, among others. Accordingly, you should not place undue reliance on these forward-looking statements. We do not undertake any obligations to publicly update or revise any forward-looking statements, whether as a result of new information, future developments or otherwise.



# Mesoblast - a global leader in cell based medicines

Disruptive technology platform: proprietary, allogeneic, "off-the-shelf" adult stem cells with predictable therapeutic properties

Established late stage portfolio of distinct and advanced product candidates

Targeted markets with high unmet medical needs where technology shows greatest prospects

Strategic partnerships delivering clinical, manufacturing and commercial capabilities, together with financial support

Scalable, cost-efficient manufacturing capabilities

Intellectual property leadership covering compositions, uses, and manufacturing processes



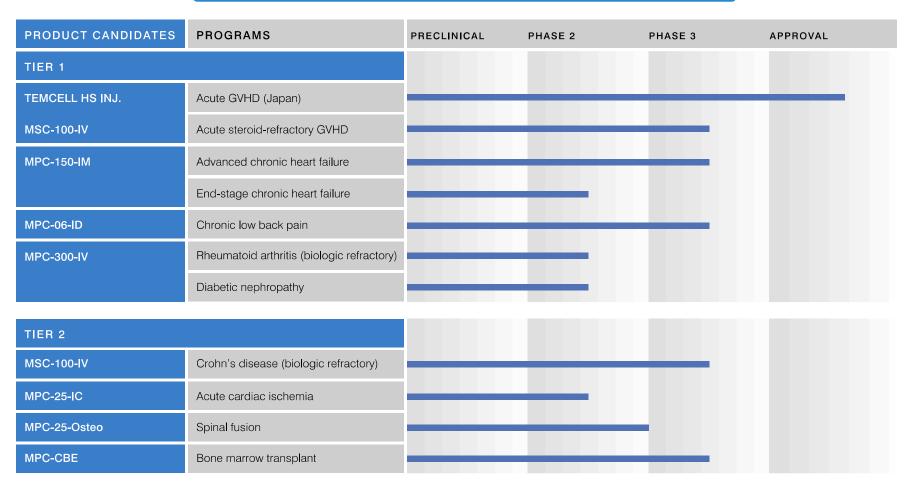
### Focused company with strong cash reserves to meet key corporate objectives

- Successfully completed US listing with access to world's largest sophisticated healthcare investor pool and analysts
- Financing raised USD \$63.5m (net proceeds) which significantly augmented existing cash reserves of USD \$77.8m at 30 September 2015
- Quarterly cash outflows expected to be reduced by approximately 20-25% in Q2-4
   FY2016 in comparison to Q1 FY2016 (USD\$28.1m) and Q4 FY2015 (USD\$27.3m)
- Cash managed to extend runway and achieve Tier 1 value inflexion points
- Major focus is FDA filing for our first US Product approval in Acute Graft Versus Host Disease (aGVHD)
- FDA Approval may be accompanied by a Rare Pediatric Disease Designation / Priority Review Voucher
- We intend to conclude additional and appropriate strategic partnerships



## Product candidates target diseases with high unmet needs

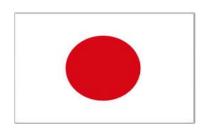
#### Three Tier 1 Product Candidates in Phase 3 Programs



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.



## MSC-100-IV / TEMCELL® HS Inj.: Product Launch Plans in aGVHD



### Japan (TEMCELL® HS Inj.): 2016 Expected Revenues

- Our licensee JCR Pharmaceuticals Co. to launch TEMCELL® HS Inj. in Japan for adult and pediatric aGVHD in Q1 2016
- Japan's National Health Insurance (NHI) set reimbursement for TEMCELL® HS
   Inj. at ¥868,680 (US\$7,200) for 72 million cells
- A four-week, multi-dose treatment course of TEMCELL for an average adult is expected to be reimbursed at ¥13,898,880 (US\$115,000), or at ¥20,848,320 (US\$172,000) if symptoms persist and additional dosing is required
- Mesoblast is entitled to receive royalties and other payments at pre-defined thresholds of cumulative net sales



### United States (MSC-100-IV): 2017 Potential FDA Approval

- Open-label Phase 3 study in 60 children actively recruiting in the US
- Interim analysis results in Q3 2016
- Recruitment complete and top-line results Q4 2016
- Complete readiness for commercial manufacturing Q4 2016
- Potential FDA filing by end 2016 based on interim analysis, Q1 2017 based on full dataset
- Potential for FDA Rare Pediatric Disease Designation / Priority Review Voucher

TEMCELL® HS Inj. is the first allogeneic stem cell product approved in Japan MSC-100-IV has the potential to be the first allogeneic stem cell product approved in US



### MSC-100-IV / TEMCELL® HS Inj.: Acute Graft vs Host Disease – Market Opportunity

# MSC-100-IV / TEMCELL® HS Inj. is targeting pediatric and adult patients with acute Graft Versus Host Disease (aGVHD) following allogeneic Bone Marrow Transplant (BMT).

# Market opportunity

- ~30,000 allogeneic BMTs performed globally each year, 25% pediatric<sup>1,2</sup>
- ~3,700 allogeneic BMTs performed in Japan each year<sup>3</sup>
- ~50% of all patients develop aGVHD (Grades II-IV)<sup>4</sup>

# No approved treatment options

- Mortality can reach 85% in patients with liver & gut complications
- No currently approved therapies for steroid refractory patients
- Off-label options have mixed efficacy with high toxicity
- Significant need for a new treatment with a favorable risk / benefit profile

# Targeted physician population

- Highly targeted physician audience & commercial footprint for pediatric launch in US
- ~ 75 centers in the US conduct pediatric allogeneic BMTs
- ~ 50% of all US pediatric transplants concentrated in 15 centers & key metropolitan areas
- 1. Gratwohl A et al Quantitative and qualitative differences in use and trends of hematopoietic stem cell transplantation: a Global Observational Study. Haematologica. 2013 Aug;98(8):1282-90.
- 2. CIBMTR, Decision resources GVHD Epi Nov 2012.
- 3. APBMT Annual Report Dec 2012; Assumes a growth rate of approximately 3% per year
- 4. Decision resources Niche Markets and Rare diseases: GVHD Nov 2012



# 2016 - 2018 Tier 1 Product Candidate Deliverables

Product Candidate	Programs	Anticipated Milestones	2016 Q1 Q2 Q3 Q4	2017 Q1 Q2 Q3 Q4	2018 H1 H2
MSC-100-IV / Temcell <sup>®</sup> 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, IA may support Regulatory 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 3 Program complete  Phase 2b trial results			
MPC-06-ID	Chronic Low Back Pain Due to Degenerative Disc Disease	Phase 3 enrollment complete Trial 1  Phase 3 IA results Trial 1  Phase 3 Program complete			
MPC-300-IV	Rheumatoid Arthritis (Biologic Refractory)	Top line data first cohort released  Full trial Results			
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	ending	3 months ending 30 Sep 2014		
Revenue	7.5	7.0	0.5	7.8
Loss Before Income Tax	13.2	15.5	2.3	15.3

### Revenue increased by 7% (\$0.5m) vs comparative period in FY14:

Milestone revenue of \$3.5m has been recognized on the full regulatory approval of TEMCELL®
 Hs. Inj

### Loss before Income Tax improved by 15% (\$2.3m) vs comparative period in FY14:

- Research & Development expenses are 14% lower (\$1.8m) with reduced expenditure in Tier 2
  programs
- Management and Admin are 20% lower (\$1.4m) as management restrained costs
- Fair value of Contingent consideration was revalued using the latest assumptions for our MSC products
- Other Operating Income and Expenses: Exchange losses were substantially eliminated with US reporting



## Increased cash reserves and reduced operating cash burn

**USDm** 

	Q1 FY2016	Q4 FY2015	
USD m	3 months ended 30 Sep 2015	3 months ended 30 June 2015	
Net Cash Outflows in Operating Activities	(28.1)	(27.3)	
Cash at the end of the period	77.8	110.7	

- Recent US listing has added \$63.5m (net proceeds) in November 2015 which significantly augmented existing cash reserves of \$77.8m at 30 September 2015
- Management's focus and prioritization will result in approximately 20-25% reduction in quarterly operating cash burn in Q2-4 FY2016 relative to last six months (Q1 FY2016 and Q4 FY2015).



### Company focused on delivery and communication of key corporate objectives

- Materially strengthened cash reserves post US listing and financing
- First royalties from TEMCELL product sales expected in Q1 2016
- Focused allocation of resources on Tier 1 product candidates
- Quarterly cash outflows expected to be reduced by approximately 20-25%
- Cash managed to extend runway and achieve Tier 1 value inflexion points
- Major focus is FDA filing for our first US Product approval in Acute Graft Versus Host Disease (aGVHD)
- We intend to conclude additional and appropriate strategic partnerships







# **Appendix** *Historical Financial Results in USD*

### Retranslation of Historical Financials to USD

# As announced the reporting currency for Mesoblast has changed from Australian dollars to US dollars, commencing with the 2015/16 financial year

- The first reported results in US dollars are these results for the three months ended
   30 September 2015
- To assist shareholders, financial information for the years ended 30 June 2012 to 30 June 2015, restated in US dollars is provided
- Information is the US dollar equivalent of financial information previously released to the market for the relevant period
- The reporting period remains for the year ended 30 June
- Previously reported Australian dollar earnings, cash flows and equity have been translated using the daily transactional exchange rate. An average of these exchange rates has been provided together with the spot exchange rates used to translate the balance sheets



# Profit and Loss – FY 2012 to FY2015

USDm

FY = Fiscal Years ended 30 June	FY12	FY13	H1 14	H2 14	FY14	Q1 15	Q2 15	Q3 15	Q4 15	FY15
Revenue	39.6	29.3	12.4	11.0	23.4	7.0	4.4	4.2	4.2	19.8
Research & Development	(37.8)	(48.5)	(23.2)	(27.7)	(50.9)	(12.9)	(17.8)	(13.4)	(18.5)	(62.6)
Manufacturing Commercialisation	(25.3)	(23.1)	(12.3)	(13.1)	(25.4)	(5.9)	(5.6)	(5.3)	(7.0)	(23.8)
Management & Administration	(24.8)	(22.9)	(11.7)	(12.7)	(24.4)	(6.9)	(7.6)	(6.8)	(8.3)	(29.6)
Fair value re-measurement of contingent consideration	-	-	-	(0.2)	(0.2)	(1.6)	(2.8)	(2.8)	0.4	(6.8)
Finance Costs	-	-	-	(4.1)	(4.1)	(1.9)	(2.7)	(2.2)	(1.7)	(8.5)
Other income and expenses	(1.0)	4.6	6.0	0.1	6.1	6.7	4.2	4.0	0.4	15.3
Pre-tax profit/(loss)	(49.3)	(60.6)	(28.8)	(46.7)	(75.5)	(15.5)	(27.9)	(22.3)	(30.5)	(96.2)
Tax	(22.8)	(1.5)	-	-	-	-	-	-	-	-
Net profit/(loss)	(72.1)	(62.1)	(28.8)	(46.7)	(75.5)	(15.5)	(27.9)	(22.3)	(30.5)	(96.2)
Earnings/(Losses) Per Share	(25.48)	(21.02)			(23.65)					(29.99)
*An average of the Exchange Rates used to translate previously reported AUD earnings	1.0131	1.0074			0.9330					0.8063



# Cash Flows – FY 2012 to FY2015

USDm

FY = Fiscal Years ended 30 June	FY12	FY13	H1 14	H2 14	FY14	Q1 15	Q2 15	Q3 15	Q4 15	FY15
Milestone payment received	-	-	-	-	-	-	2.0	-	-	2.0
R&D tax incentive received	-	-	-	8.7	8.7	-	-	-	4.5	4.5
Payments to suppliers and employees	(66.8)	(69.8)	(50.4)	(47.0)	(97.4)	(29.3)	(25.6)	(23.6)	(28.3)	(106.8)
Interest received	9.6	10.6	2.6	9.0	11.6	1.5	0.6	0.5	0.4	3.0
Other operating cash flows	(7.4)	3.4	4.0	(1.8)	2.2	-	-	0.2	(3.9)	(3.7)
Net cash inflows/(outflows) in operating activities	(64.6)	(55.8)	(43.8)	(31.1)	(74.9)	(27.8)	(22.9)	(22.9)	(27.3)	(101.0)
Payments for business combination	-	(1.6)	-	(33.4)	(33.4)	-	_	_	(2.1)	(2.1)
Investment in Fixed Assets	(2.0)	(1.3)	(0.4)	(1.3)	(1.7)	(1.3)	(0.5)	(0.1)	(0.3)	(2.2)
Other investing cash flow	(2.3)	(1.9)	(22.9)	19.8	(3.1)	(0.9)	-	(0.5)	0.6	(0.8)
Net cash inflows/(outflows) in investing activities	(4.3)	(4.8)	(23.3)	(14.9)	(38.2)	(2.2)	(0.5)	(0.6)	(1.8)	(5.1)
Net cash inflows by financing activities	5.0	174.4	1.5	0.7	2.2	0.1	0.9	0.1	44.8	45.9
Net increase/(decrease) in cash and cash equivalents	(63.9)	113.8	(65.6)	(45.3)	(110.9)	(30.0)	(22.5)	(23.4)	15.7	(60.2)
Cash and cash equivalents at beginning of year	278.9	209.5	292.4	223.9	292.4	185.0	149.2	122.4	94.7	185.0
FX gains/(losses)	(5.5)	(30.9)	(2.9)	6.4	3.5	(5.8)	(4.3)	(4.3)	0.3	(14.1)
Cash and cash equivalents at end of year	209.5	292.4	223.9	185.0	185.0	149.2	122.4	94.7	110.7	110.7
*An average of the Exchange Rates used to translate previously reported AUD earnings	1.0131	1.0074			0.9330					0.8063



FY = Fiscal Years ended 30 June	FY12	FY13	H1 14	FY14	H1 15	FY15
Cash and cash equivalents	209.5	292.5	223.9	185.0	122.4	110.7
Current receivables	10.9	11.2	15.2	5.7	7.5	4.0
Other current assets	0.3	4.1	4.0	1.2	3.9	7.8
Current assets	220.7	307.8	243.1	191.9	133.9	122.5
Property, plant and equipment	2.0	2.6	2.8	4.4	4.6	4.4
Intangible assets	506.7	508.1	648.1	648.0	650.1	650.2
Other non-current assets	4.8	1.2	1.9	2.8	2.7	4.7
Non-current assets	513.5	511.9	652.8	655.2	657.4	659.3
Total assets	734.2	819.7	895.9	847.1	791.2	781.8
Payables	11.8	19.3	27.3	19.5	21.5	28.2
Provisions	11.4	12.8	88.5	86.8	95.6	98.6
Other liabilities	223.0	203.0	209.4	202.2	194.4	187.0
Total equity	488.0	584.6	570.7	538.6	479.7	468.0
Total liabilities and equity	734.2	819.7	895.9	847.1	791.2	781.8
*Spot exchange rate used to translate previously reported AUD balance sheets	1.0191	0.9275		0.9420		0.7680

