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the regenerative medicine company

Financial Year 2015
Full Year Results
17 August 2015

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Key Achievements in FY15

Ambitious Clinical Program

Phase 3 trials on track to agreed timelines

MPC-150-IM - Chronic Heart Failure (CHF)

- ✓ Recruiting well across North American sites
- ✓ Potential for early completion of the ongoing Phase 3 trial with FDA's acceptance of demonstration of overwhelming efficacy

MPC-06-ID - Chronic Discogenic Low Back Pain (CDLBP)

- ✓ The Phase 3 program in CDLBP is recruiting well across North American sites
- ✓ Positive feedback from discussions with the European Medicines Agency expected to result in expansion to European sites

MSC-100-IV/JR-031 - Acute Graft Versus Host Disease (GVHD)

- ✓ Japanese partner JCR Pharmaceuticals Co. Ltd. filed in September 2014 for Japanese approval for acute GVHD in children and adults
- ✓ A pathway to accelerated USA approval was clarified through the FDA
- ✓ An open-label Phase 3 study of ~60 children is actively recruiting in the USA

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Key Achievements in FY15 (2)

Portfolio Targeting Inflammatory Diseases - a Major Emerging Opportunity

- ✓ Phase 2 trial in diabetic kidney disease completed enrollment with results demonstrating preservation or improvement in renal function over at least 24 weeks
- ✓ Biologic refractory Rheumatoid Arthritis (RA) - 1st cohort fully enrolled, 2nd cohort actively recruiting
- ✓ Biologic refractory Crohn's disease study continues

Significant Progress in Manufacturing

- ✓ Substantial advances in commercial scale, consistent high yield manufacturing processes
- ✓ Developed a proprietary serum-free media with potential to greatly improve yields and mitigate supply risk

Financials

- ✓ Expenses have increased by $33.2m (28% at constant currency) as we continue to invest in our late stage pipeline

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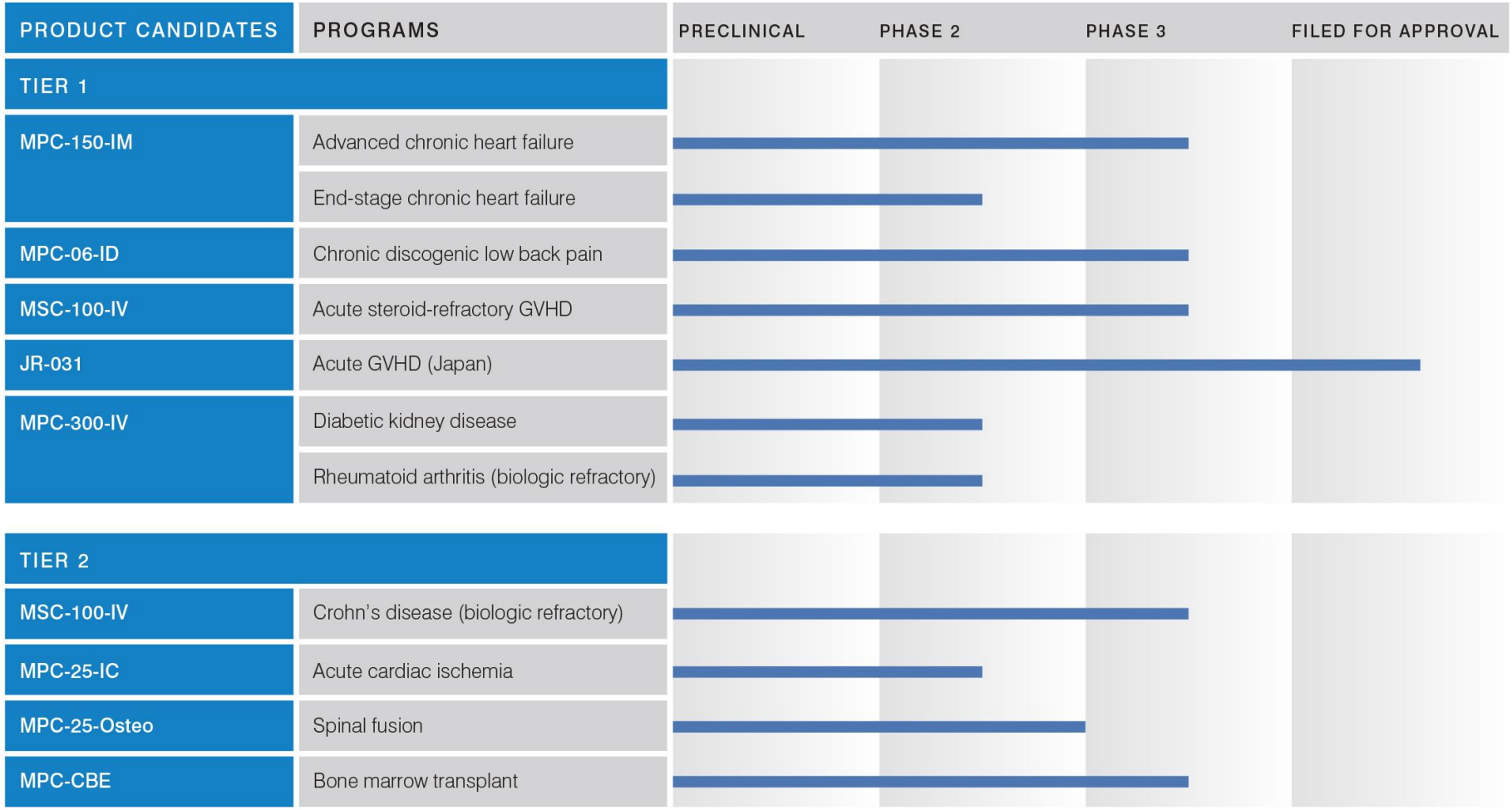
Five Product Candidates in Active Phase 3 Programs or Phase 3-ready



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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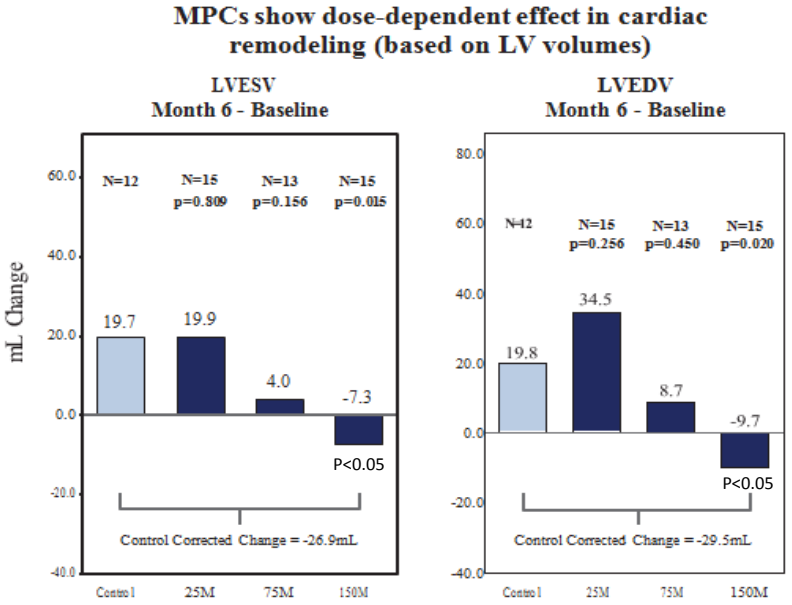
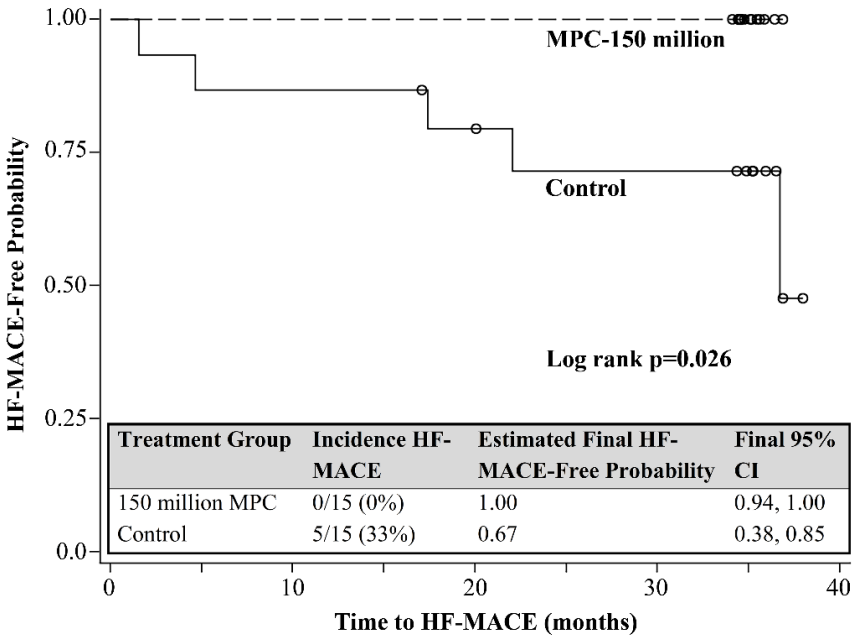
MPC-150-IM: Phase 2 Trial Results in CHF Identifies Optimal Therapeutic Dose





Treatment Group	Incidence HF-MACE	Estimated Final HF-MACE-Free Probability	Final 95% CI
150 million MPC	0/15 (0%)	1.00	0.94, 1.00
Control	5/15 (33%)	0.67	0.38, 0.85

Over 36 months:

- MPC-150-IM had significantly greater probability of remaining free of heart failure-related major adverse cardiovascular events (HF-MACE) vs. controls (0% vs. 33%, p = 0.026 by log-rank) , as recently published in the American Heart Association journal *Circulation Research*.
- The use of recurrent HF-MACE as a primary endpoint in the confirmatory study is supported by the results of the completed Phase 2 trial. Patients treated with MPC-150-IM had no HF-MACE of follow-up, compared with 11 total (recurrent) HF-MACE in the control group (p<0.001, log rank test).

Perin et al Circ Res. 2015 Jul 6 (Epub) - A Phase II Dose-Escalation Study of Allogeneic Mesenchymal Precursor Cells in Patients With Ischemic or Non-Ischemic Heart Failure

MPC-150-IM: Phase 3 Trial Design Targets Patients with High Risk of HF-MACE

- MPC-150-IM reduces incidence and recurrent episodes of HF-MACE
- Objective is to treat those patients who are most likely to respond to MPC-150-IM and who are at a high risk of recurrent HF-MACE
- Enrollment criteria for Phase 3 is designed to enrich population for high risk of recurrent HF-MACE by using the following inclusion criteria:
  - HF-related hospitalization within the past 9 months
    - Predictor of high mortality and / or rehospitalization
  - High baseline NT-proBNP levels
    - Predictor of poor clinical outcomes
  - Enrolled patients are expected to have large baseline LVESV and high rates of HF-MACE
- In light of the above, discussions were held with the US FDA to streamline the Phase 3 trial design

MPC-150-IM: Potential for Early Completion of Ongoing Phase 3 Trial with FDA's Acceptance of Demonstration of Overwhelming Efficacy

- Key conclusions regarding the ongoing Phase 3 trial were:
  - There will be a reduction in the total number of subjects to be recruited for the ongoing Phase 3 trial, using a time to first event analysis of HF-MACE as the primary endpoint, from approximately 1,730 to 1,165
  - An interim analysis will be performed in the ongoing Phase 3 trial when 50% of the HF-MACE have occurred, which will include a test for superiority allowing for the possibility of early stopping of the trial based on overwhelming efficacy
- A second, confirmatory study is planned to be conducted in parallel in an identical patient population of ~ 500 subjects using recurrent HF-MACE as the primary endpoint
- The clinical data from these two studies will be supportive to each other for product approval

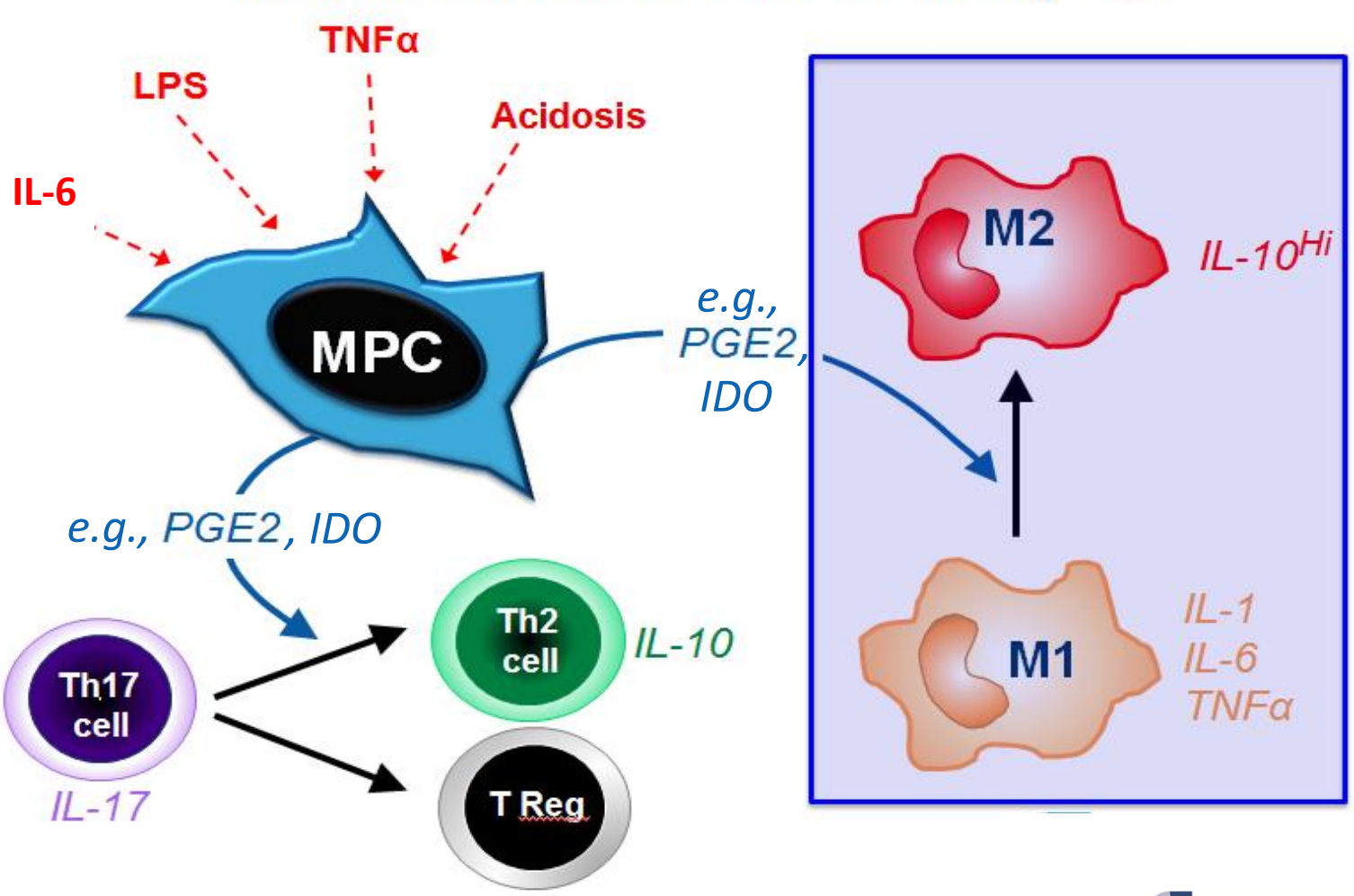
Portfolio Targeting Inflammatory Diseases - a Major Emerging Opportunity

- Mesenchymal Lineage Adult Stem Cells (MLCs*) have receptors that respond to pro-inflammatory signals, inducing release of multiple anti inflammatory mediators
- MLCs thereby target multiple immune pathways concurrently
- This should position MLC product candidates as ideal therapeutics for immune mediated diseases where multiple pathways are associated with disease activity for which there are no alternatives and/or resistance to other therapies
- MLCs have the potential for a better safety profile in terms of infectious or neoplastic complications compared with other biologic therapies for these diseases
- Mesoblast developing MLC product candidates to target
  - Diabetic Kidney Disease
  - Biologic Refractory Rheumatoid Arthritis
  - Biologic Refractory Crohn's Disease

* Comprising MPCs and MSCs

MLCs for Treatment of Chronic Inflammatory Diseases

Inflammation-dependent induction in MPC and role in regulating the function of both Th17 cells and macrophages



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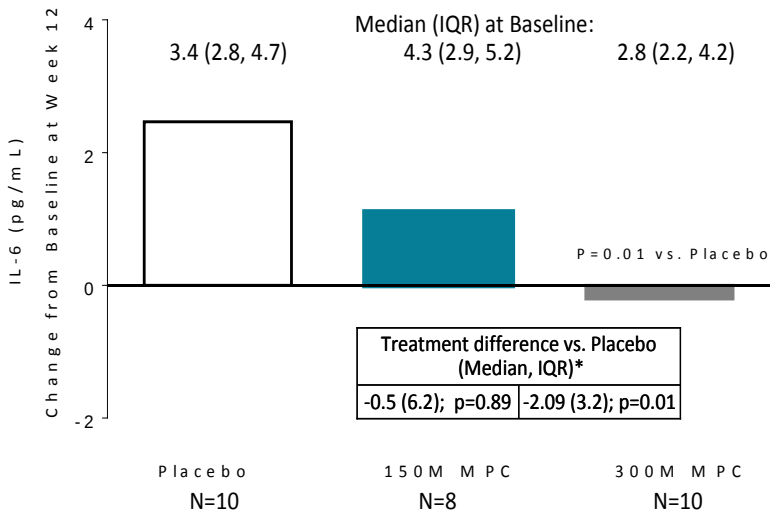
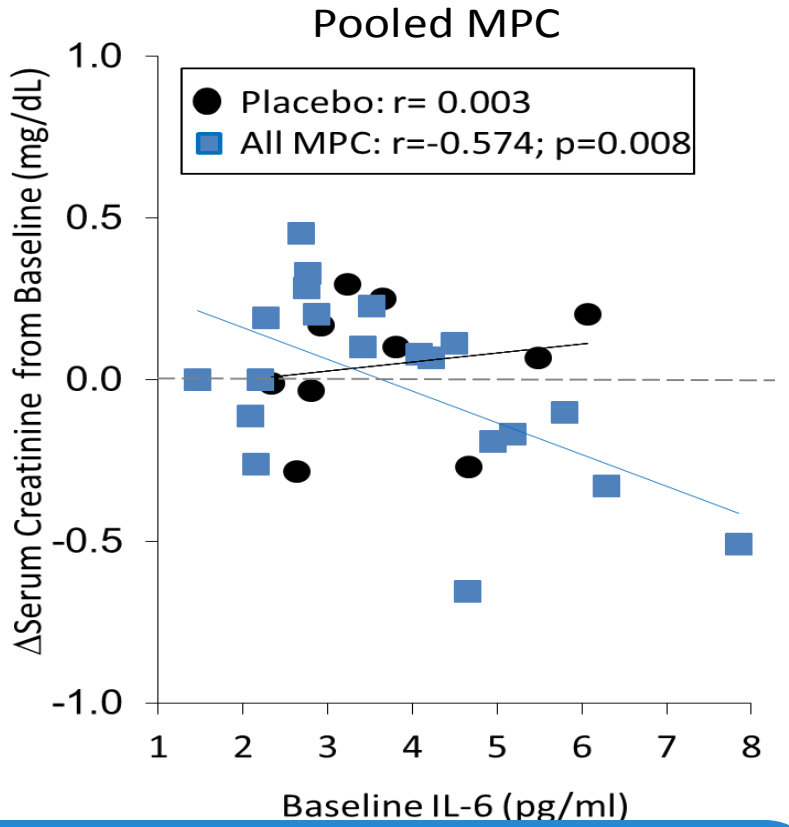
MLCs for Treatment of Chronic Inflammatory Diseases

- **MPC-300-IV - Diabetic Kidney Disease**
  - Randomized, placebo controlled, dose-escalating study in 30 patients completed
  - Demonstrated preservation or improvement in renal function over at least 24 weeks relative to controls
  - Results presented at Late Breaking Scientific Session at the 75th American Diabetes Association 2015 Annual Meeting
  - Clinical trial design planning for a Phase 2b/3 program ongoing
- **MPC-300-IV - Biologic-refractory Rheumatoid Arthritis**
  - Randomized, placebo controlled, dose-escalating Phase 2 trial in 48 patients ongoing
  - First dose / cohort 1 is fully enrolled
  - 6 month topline data for both cohorts expected in FY16
  - Results of preclinical RA study published in PLOS One journal
- **MSC-100-IV Biologic-refractory Crohn's Disease**
  - ongoing randomized, placebo-controlled, trial continues

MPC-300-IV: Diabetic Kidney Disease Phase 2 Results – Treatment Related Effects on the Inflammatory Marker IL-6 and Therapeutic Response in Patients with High Baseline IL-6 Levels



*Treatment difference estimated using Hodges-Lehmann estimator and Moses method. P-value obtained from Cochran-Mantel-Haenszel test in nonparametric ANCOVA model using treatment as a factor adjusting for eGFR randomization strata and baseline value



- Baseline eGFR>30 ml/min/1.73 m^2 and high IL-6 levels suggest two biomarkers that may predict efficacy with and response to MPC treatment in patients with pre-fibrotic renal state and aberrant pro-inflammatory milieu
- Reduction in IL-6 levels suggests that the mechanism of action of MPCs may be via reduction of pro-inflammatory monocyte cytokines in the diabetic kidney

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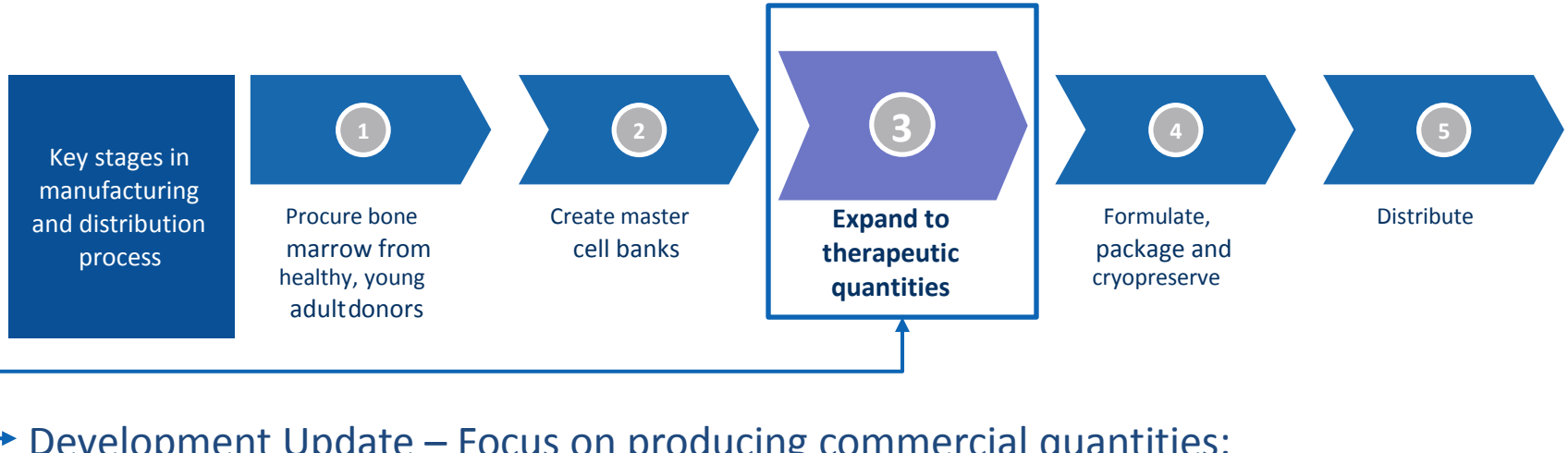
Scalable Manufacturing Capabilities: Partnership with Lonza

Manufacturing objectives

- Distinct manufacturing processes for each product
- Commercial scale processes with batch-to-batch consistency and reproducible release criteria
- Ensure commercial product supply is aligned with projected market needs

Significant Progress in Manufacturing



Development Update – Focus on producing commercial quantities:

- Substantial advances made in development of consistent high yield manufacturing processes to improve efficiency and yields in large commercial-grade bioreactors
- In-house proprietary serum-free media process has been identified, and is being developed to deliver step-change yield improvements and eliminate source capacity constraints (e.g. fetal bovine serum)
- Robust source of readily available standardized products for clinical and commercial use

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FY15 Profit and Loss AUDm

	As Reported				Constant Currency (cc)	
	30 June 2015	30 June 2014	Change	%	Change	%
Revenue from Continuing Operations	23.7	26.0	(2.3)	(9)	(4.2)	**(16)**
Other Income	18.8	11.1	7.7	69	(5.2)	**(47)**
Expenses from Continuing Operations	161.9	118.1	(43.8)	(37)	(33.2)	**(28)**
Loss After Tax	**119.4**	**81.0**	**(38.4)**	**(47)**		

Expenses have increased by $33.2m (28% cc) as we continue to invest in our late-stage pipeline

- $15.3m has been incurred on initiating two of our Tier 1 Phase 3 programs during the past year
- $11.5m of non-cash contingent consideration on milestones and royalties from sales of our MSC products as we have progressed closer to market

The depreciating exchange rate inflated the cost base by $10.6m (9%)

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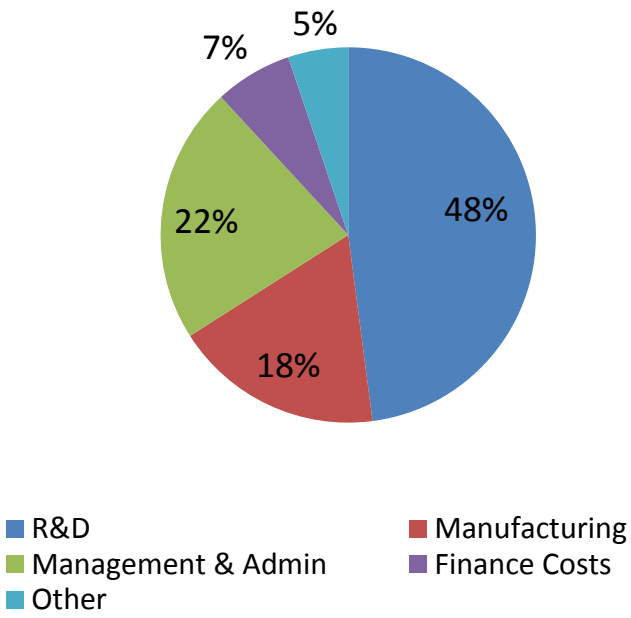
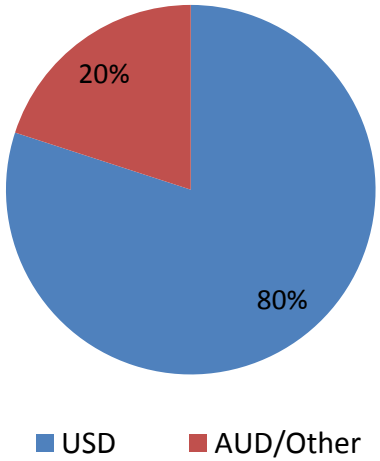
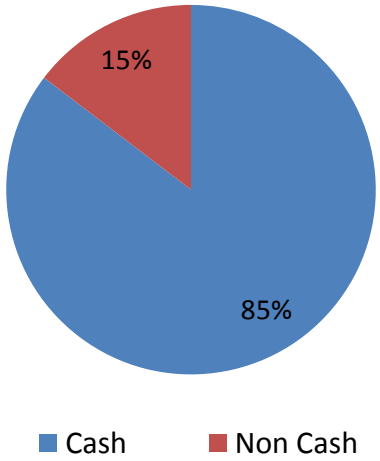
FY15 $161.9m Expenses From Continuing Operations AUDm







- R&D expenditure has increased by 40% as we continue to invest in our Phase 3 pipeline

- Underlying USD denominated content has grown from 74% to 80% and will continue to increase
- **USD will be our reporting currency from FY16**

- 15% Non cash content mainly from contingent consideration and share-based payments

FY15 Cash Flow and Cash Position AUDm

	30 June 2015	30 June 2014
Cash on hand	**144.1**	**196.4**
Operating Cash Outflows	(121.7)	(81.9)
Investing Cash Outflows	(5.6)	(40.8)
Financing Cash Inflows	59.4	2.4
Net decrease in cash prior to Exchange Effects	(67.9)	(120.2)
Exchange rate adjustments to cash	15.7	1.3
Net decrease in cash after Exchange Effects	**(52.2)**	**(118.9)**

Net Cash Consumption has halved over 2014 to $52m

- Increased Operating Cash Outflows reflects increased investment in our late-stage pipeline
- Investing Cash Outflows have been significantly reduced to $5.6m
- Financing Cash Inflows include an equity investment of $58.5m

The Company has at least 12 months cash on hand, with near term potential to extend

- A number of partnering discussions are entering late stages of negotiation
- Major capital markets always remain available

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Outlook for the Next 12 Months

MPC-150-IM CHF
- Ongoing Phase 3 clinical program continues to enroll
- Phase 3 trial interim analysis completed
- Phase 3 program broadened to include Europe and other jurisdictions

MPC-06-ID CDLBP
- Ongoing Phase 3 clinical program continues to enroll
- Expand sites to include Europe and Australia
- Anticipated partnering deal closed

MSC-100-IV/JR-031 GVHD
- Regulatory approval expected for children and adults in Japan
- Open label Phase 3 study in 60 children fully enrolled - final clinical gating for BLA submission

MLC Inflammatory Portfolio
- Diabetic kidney disease design finalized for Phase 2b/3 program
- Biologic-refractory Rheumatoid Arthritis Phase 2 topline data
- Biologic-refractory Crohn's disease top line review of interim data

Commercial Manufacturing
- Building a regulatory approval PAI readiness capability for our Tier 1 products
- Continued process development and scale up of manufacturing to optimize high yield and serum-free media conditions

Finance
- Bring in additional strategic partners to commercialize products in various jurisdictions
- Complete conversion of the business to USD as the operational currency

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Questions?