

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 6-K

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16 under the Securities Exchange Act of 1934

For the month of November 2017

Commission File Number 001-37626

Mesoblast Limited

(Exact name of Registrant as specified in its charter)

Not Applicable

(Translation of Registrant's name into English)

Australia

(Jurisdiction of incorporation or organization)

Silviu Itescu

Chief Executive Officer and Executive Director

Level 38

55 Collins Street

Melbourne 3000

Australia

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover 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):

Yes No

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):

Yes No

On November 15, 2017, Mesoblast Limited filed with the Australian Securities Exchange a new release announcement and investor presentation, which are attached hereto as [Exhibit 99.1](#) and [Exhibit 99.2](#), and are incorporated herein by reference.

SIGNATURES

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 organized.

MESOBLAST LIMITED

/s/ Charlie Harrison

Charlie Harrison
Company Secretary

Dated: November 15, 2017

INDEX TO EXHIBITS

Item _____

- 99.1 Press release of Mesoblast Ltd, dated November 15, 2017.
- 99.2 Investor presentation of Mesoblast Ltd, dated November 15, 2017

**MESOBLAST OPERATIONAL HIGHLIGHTS AND FINANCIAL RESULTS
FOR THE FIRST QUARTER ENDED SEPTEMBER 30, 2017**

Melbourne, Australia; November 15, 2017; and New York, USA, November 14, 2017: Mesoblast Limited (ASX: MSB; Nasdaq: MESO) today provided the market with an update on its corporate strategy, operational highlights, and consolidated financial results for the three months ended September 30, 2017 (first quarter of FY2018).

At September 30, 2017, the Company had cash reserves of US\$62.9 million. Cash outflows from operating activities were reduced by US\$0.5m (2.3%) for the quarter as compared to the three months ended September 30, 2016 (first quarter of FY2017).

Based on cumulative clinical results to date and the serious and life-threatening nature of the diseases being targeted, the Company believes that its Phase 3 product candidates for acute graft versus host disease (aGVHD), chronic heart failure, and chronic low back pain may represent a paradigm shift in the treatment of these conditions which can lead to earlier market entry due to opportunities afforded by the United States 21st Century Cures Act.

The Company continues to have an active and ongoing strategy to partner one or more of its four Tier 1 product candidates. Fundamental to this strategy is to conclude partnership transactions with those organizations that will deliver the best short and long term outcomes for the company and maximize shareholder value.

Operational Highlights

MSC-100-IV for Acute Graft Versus Host Disease (aGVHD):

Mesoblast's proprietary allogeneic cell therapy MSC-100-IV is being evaluated in a single, open-label Phase 3 trial in up to 60 patients for product registration. This trial continues to recruit across multiple sites in North America and completion of enrollment is imminent. The goal of this trial is to obtain FDA approval in children with steroid-refractory (SR) aGVHD and then pursue label extension to adults.

The Company's GVHD strategy is based on:

- extensive clinical safety and efficacy data generated and published with MSC-100-IV in children with this life-threatening condition;
- the potential for a shortened FDA approval pathway due to the existing fast-track designation for MSC-100-IV;
- a targeted product launch strategy requiring minimal investment; and
- the ability to seek label extension to adults with high-risk steroid refractory aGVHD (liver/gut disease) and product lifecycle management to include chronic GVHD.

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

Mesoblast's proprietary allogeneic cell therapy MPC-150-IM is in late-stage clinical development in two randomized controlled trials that target, respectively, advanced and end-stage CHF. The Phase 3 trial in advanced heart failure continues to recruit across multiple sites in North America, with more than 400 of the anticipated approximately 600 NYHA Class II/III CHF patients randomized to date.

During this current quarter, the Company was pleased to report completion of enrollment in the 159-patient randomized, placebo-controlled Phase 2b trial funded by the National Institutes of Health (NIH) and the Canadian

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Institute for Health Research (CIHR) evaluating the Company's proprietary allogeneic mesenchymal precursor cell (MPC) product candidate MPC-150-IM in end-stage heart failure patients with left ventricular assist devices (LVAD).

The Company believes that:

- the LVAD market may represent an early market entry opportunity for MPC-150-IM in end-stage heart failure patients through potential to reduce LVAD morbidity, increase survival and increase LVAD use as destination therapy;
- targeted product launch strategy requires minimal investment;
- by strengthening native heart muscle, Bridge to Recovery (BTR) represents a potential high-growth market opportunity for temporary LVAD use and explantation in end-stage or Class IV heart failure patients; and
- there may be an opportunity to bridge to the larger Class III heart failure population by label extension on obtaining positive Phase 3 trial results.

MPC-06-ID for Chronic Low Back Pain (CLBP):

Mesoblast's proprietary allogeneic cell therapy MPC-06-ID is being evaluated in a 360-patient Phase 3 trial in patients with CLBP who have failed conservative measures. The trial is expected to complete enrollment in early Q1 CY18.

If the Phase 2 results, which showed durable improvement in pain and function from a single intra-discal injection, are confirmed in the Phase 3 trial, the Company believes that MPC-06-ID:

- has the potential to reduce and/or eliminate the need for opioids in the treatment of CLBP; and
- is well positioned to meet the objectives of the 21st Century Cures Act, which includes measures to combat opioid dependence and provide accelerated approval pathways for non-opioid pain reducing drugs.

Over 33,000 people in the United States died of prescription opioid related overdoses in 2016 and the opioid epidemic has been recently declared a public health emergency by the President of the United States. Given that CLBP accounts for 50% of all opioid prescriptions, a non-opioid solution to this disease is imperative.

MPC-300-IV for Systemic, Immune-mediated Diseases:

MPC-300-IV is our cellular product candidate that responds to inflammatory signals with release of counter-inflammatory factors. It has the potential to treat multiple immune-mediated diseases.

MPC-300-IV has generated positive clinical data across three randomized, placebo-controlled Phase 2 trials in disease states associated with inflammation; type 2 diabetes with inadequate glucose control, diabetic kidney disease, and biologic-refractory rheumatoid arthritis (RA).

Results from a 48-patient randomized, placebo-controlled Phase 2 trial in patients with biologic refractory RA over 52 weeks were recently presented at the 2017 American College of Rheumatology Annual Meeting in San Diego, CA. The primary objective of the study was to evaluate safety and tolerability of a single intravenous infusion in biologic refractory RA patients through a 12-week primary endpoint. Additional objectives were to evaluate clinical efficacy at the 12-week endpoint and to assess the durability of effects and safety profile over the full 52-week study.

The results showed an early and durable effect from a single infusion of MPC-300-IV in biologic-refractory RA patients. Specifically:

- Infusions were well-tolerated with no treatment-related serious adverse events reported during the 52-week period, and a safety profile over 52 weeks comparable among the placebo and two MPC treatment groups.
- A single intravenous MPC infusion in biologic refractory RA patients resulted in dose-related improvements in clinical symptoms, function, disease activity and patient-reported outcomes. Efficacy signals were observed for each of ACR 20/50/70, ACR-N, HAQ-DI, SF-36 and DAS-28 disease activity score.

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- The 2 million MPC/kg dose showed the greatest overall treatment responses. Onset of treatment responses occurred as early as 4 weeks, peaked at 12 weeks, were maintained through 39 weeks, and waned by 52 weeks.
- Greatest benefits over 52 weeks were seen in patients who had failed less than three biologics (1-2 biologic sub-group) prior to MPC treatment, identifying this as a potentially optimal target population.

The results of this Phase 2 trial identified a dose-related treatment effect, the earliest onset of the effect, and the durability from a single dose. Given the excellent safety profile, the Company intends to evaluate whether higher MPC doses can achieve even greater rates of low disease activity or remission within the first 12 weeks and beyond. The Company also plans to evaluate whether the observed durable treatment responses can be maintained for the longer term using repeat dose therapy.

Upcoming Milestones

The Company expects multiple key inflection points over the remainder of the 2018 financial year, including:

- completion of enrollment in Q4 CY2017 in the Phase 3 trial evaluating MSC-100-IV in children with aGVHD;
- the trial's 28-day primary endpoint data is expected in Q1 CY2018 and the 100-day survival result is expected in Q2 CY2018;
- completion of enrollment in early Q1 CY2018 in the Phase 3 trial evaluating MPC-06-ID in patients with chronic low back pain;
- the 6-month primary endpoint in Q1 CY2018 for the fully-enrolled Phase 3 trial evaluating MPC-150-IM in NYHA Class IV patients with advanced heart failure, with full 12-month study results expected in Q3 CY2018; and
- completion of enrollment in 2H CY2018 in the Phase 3 trial evaluating MPC-150-IM in NYHA Class III patients with advanced heart failure.

Financial Highlights

At September 30, 2017, the Company had cash reserves of US\$62.9 million, inclusive of net financing cash inflows of US\$38.4 million as a result of the entitlement offer in September 2017.

Revenues from royalties on sales of TEMCELL® HS Inj. (TEMCELL)¹ by our licensee in Japan, JCR Pharmaceuticals Co., Ltd., increased by US\$0.4 million (178%) to US\$0.6 million in the first quarter of FY2018 compared with the first quarter of FY2017. In addition, the Company recognized milestone revenue of US\$0.5 million on the cumulative sales of TEMCELL in the first quarter of FY2018.

Cash outflows from operating activities for the quarter were reduced by US\$0.5m (2.3%), compared to the first quarter of FY2017.

Mesoblast retains an equity facility for up to A\$120 million/US\$90 million, to be used at its discretion over the next two years to provide additional funds as required.

¹ TEMCELL® HS. Inj. is a registered trademark of JCR Pharmaceuticals Co., Ltd.

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Financial Results for the Three Months Ended September 30, 2017 (first quarter) (in U.S. Dollars)

The Company contained spend whilst increasing its R&D investment in Tier 1 clinical programs by constraining manufacturing production, and management and administration costs. Research and development expenses increased by US\$1.4 million (10%), this increase was offset by cost savings of US\$2.4 million (73%) for manufacturing and US\$0.4 million (8%) for management & administration for the first quarter of FY2018, compared with the first quarter of FY2017.

There was a decrease of US\$13.0 million (57%) in the loss before income tax for the first quarter of FY2018, compared with the first quarter of FY2017. This overall decrease in loss before income tax was primarily due to non-cash items that do not affect cash reserves.

The main items which impacted the loss before income tax movement were:

- **Revenues** from royalties on sales of TEMCELL increased by US\$0.4 million (178%) in the first quarter of FY2018 compared with the first quarter of FY2017 and the Company recognized milestone revenue of US\$0.5 million on the cumulative sales of TEMCELL in the first quarter of FY2018 compared with US\$Nil in the first quarter of FY2017.
- **Research and Development** expenses were US\$15.4 million for the first quarter of FY2018, compared with US\$14.0 million for the first quarter of FY2017, an increase of US\$1.4 million (10%) as the Company invested in Tier 1 clinical programs.
- **Manufacturing** expenses were US\$0.9 million for the first quarter of FY2018, compared with US\$3.3 million for the first quarter of FY2017, a decrease of US\$2.4 million (73%) due to a reduction in manufacturing activity because sufficient quantities of clinical grade product were previously manufactured for all ongoing clinical trials.
- **Management and Administration:** expenses were US\$5.0 million for the first quarter FY2018, compared with US\$5.4 million for the first quarter of FY2017, a decrease of US\$0.4 million (8%) primarily due to a decrease of US\$0.5 million in corporate overhead expenses such as rent and IT costs.

The overall decrease in loss before income tax also includes movements in other items which did not impact current cash reserves, such as: fair value remeasurement of contingent consideration, and foreign exchange movements within other operating income and expenses. The net loss attributable to ordinary shareholders was US\$7.0 million, or 1.60 cents per share, for the first quarter of FY2018, compared with US\$19.8 million, or 5.24 cents per share, for the first quarter of FY2017.

Conference Call Details

Mesoblast will be hosting a conference call beginning at 8.30am AEDT on Wednesday November 15, 2017 / 4.30pm ET on Tuesday November 14, 2017. The conference identification code is 303705.

The live webcast can be accessed via: <http://webcasting.boardroom.media/broadcast/59ff897e6afa4a0577a982bb>

To access the call, please dial:

| | |
|---------------------|-----------------|
| Australia Toll Free | 1 800 558 698 |
| Australia Alternate | 1 800 809 971 |
| United States | 1 855 881 1339 |
| United Kingdom | 0800 051 8245 |
| Japan | 0053 116 1281 |
| Singapore | 800 101 2785 |
| Hong Kong | 800 966 806 |
| International | +61 2 9007 3187 |

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Forward-Looking Statements

This press release 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. Forward-looking statements should not be read as a guarantee 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. Forward-looking statements include, but are not limited to, statements about: the initiation, timing, progress and results of Mesoblast's preclinical and clinical studies, and Mesoblast's research and development programs; Mesoblast's ability to advance product candidates into, enroll and successfully complete, clinical studies, including multi-national clinical trials; Mesoblast's ability to advance its manufacturing capabilities; the timing or likelihood of regulatory filings and approvals, manufacturing activities and product marketing activities, if any; the commercialization of Mesoblast's product candidates, if approved; regulatory or public perceptions and market acceptance surrounding the use of stem-cell based therapies; the potential for Mesoblast's product candidates, if any are approved, to be withdrawn from the market due to patient adverse events or deaths; the potential benefits of strategic collaboration agreements and Mesoblast's ability to enter into and maintain established strategic collaborations; Mesoblast's ability to establish and maintain intellectual property on its product candidates and Mesoblast's ability to successfully defend these in cases of alleged infringement; the scope of protection Mesoblast is able to establish and maintain for intellectual property rights covering its product candidates and technology; estimates of Mesoblast's expenses, future revenues, capital requirements and its needs for additional financing; Mesoblast's financial performance; developments relating to Mesoblast's competitors and industry; and the pricing and reimbursement of Mesoblast's product candidates, if approved. You should read this press release together with our 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, and 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.

For further information, please contact:

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Consolidated Income Statement

| (in U.S. dollars, in thousands, except per share amount) | Three Months Ended September 30, | |
|--|-------------------------------------|-----------------|
| | 2017 | 2016 |
| Revenue | 1,174 | 395 |
| Research & development | (15,368) | (14,004) |
| Manufacturing commercialization | (877) | (3,295) |
| Management and administration | (5,012) | (5,459) |
| Fair value remeasurement of contingent consideration | 9,495 | (1,013) |
| Other operating income and expenses | 668 | 473 |
| Loss before income tax | (9,920) | (22,903) |
| Income tax benefit/(expense) | 2,898 | 3,105 |
| Loss attributable to the owners of Mesoblast Limited | (7,022) | (19,798) |
| Losses per share from continuing operations attributable to the ordinary equity holders of the Group: | Cents | Cents |
| Basic - losses per share | (1.60) | (5.24) |
| Diluted - losses per share | (1.60) | (5.24) |

Consolidated Statement of Comprehensive Income

| (in U.S. dollars, in thousands) | Three Months Ended September 30, | |
|---|-------------------------------------|-----------------|
| | 2017 | 2016 |
| Loss for the year | (7,022) | (19,798) |
| Other comprehensive (loss)/income | | |
| <i>Items that may be reclassified to profit and loss</i> | | |
| Changes in the fair value of available-for-sale financial assets | 20 | 31 |
| Exchange differences on translation of foreign operations | (358) | 703 |
| Other comprehensive (loss)/income for the period, net of tax | (338) | 734 |
| Total comprehensive loss attributable to the owners of Mesoblast Limited | (7,360) | (19,064) |

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Consolidated Statement of Balance Sheet

| (in U.S. dollars, in thousands) | As of September 30, 2017 | As of June 30, 2017 |
|--|-----------------------------|------------------------|
| Assets | | |
| Current Assets | | |
| Cash & cash equivalents | 62,941 | 45,761 |
| Trade & other receivables | 4,590 | 3,743 |
| Prepayments | 12,796 | 14,105 |
| Total Current Assets | 80,327 | 63,609 |
| Non-Current Assets | | |
| Property, plant and equipment | 1,636 | 1,814 |
| Available-for-sale financial assets | 2,018 | 1,997 |
| Other non-current assets | 1,930 | 1,916 |
| Intangible assets | 585,987 | 586,350 |
| Total Non-Current Assets | 591,571 | 592,077 |
| Total Assets | 671,898 | 655,686 |
| Liabilities | | |
| Current Liabilities | | |
| Trade and other payables | 20,323 | 21,805 |
| Provisions | 2,447 | 14,865 |
| Total Current Liabilities | 22,770 | 36,670 |
| Non-Current Liabilities | | |
| Deferred tax liability | 46,395 | 49,293 |
| Provisions | 43,143 | 52,957 |
| Total Non-Current Liabilities | 89,538 | 102,250 |
| Total Liabilities | 112,308 | 138,920 |
| Net Assets | 559,590 | 516,766 |
| Equity | | |
| Issued Capital | 878,669 | 830,425 |
| Reserves | 32,845 | 31,243 |
| (Accumulated losses)/retained earnings | (351,924) | (344,902) |
| Total Equity | 559,590 | 516,766 |

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Consolidated Statement of Cash Flows

| (in U.S. dollars, in thousands) | Three months ended September 30, | |
|---|-------------------------------------|-----------------|
| | 2017 | 2016 |
| Cash flows from operating activities | | |
| Commercialization revenue received | 474 | 361 |
| Payments to suppliers and employees (inclusive of goods and services tax) | (20,892) | (21,369) |
| Interest received | 63 | 181 |
| Income taxes (paid)/refunded | (1) | — |
| Net cash (outflows) in operating activities | (20,356) | (20,827) |
| Cash flows from investing activities | | |
| Payments for contingent consideration | (543) | — |
| Investment in fixed assets | (83) | (290) |
| Net cash (outflows) in investing activities | (626) | (290) |
| Cash flows from financing activities | | |
| Proceeds from issue of shares | 40,449 | — |
| Payments for share issue costs | (2,001) | (55) |
| Net cash inflows/(outflows) by financing activities | 38,448 | (55) |
| Net increase/(decrease) in cash and cash equivalents | 17,466 | (21,172) |
| Cash and cash equivalents at beginning of period | 45,761 | 80,937 |
| FX (losses)/gains on the translation of foreign bank accounts | (286) | 590 |
| Cash and cash equivalents at end of period | 62,941 | 60,355 |

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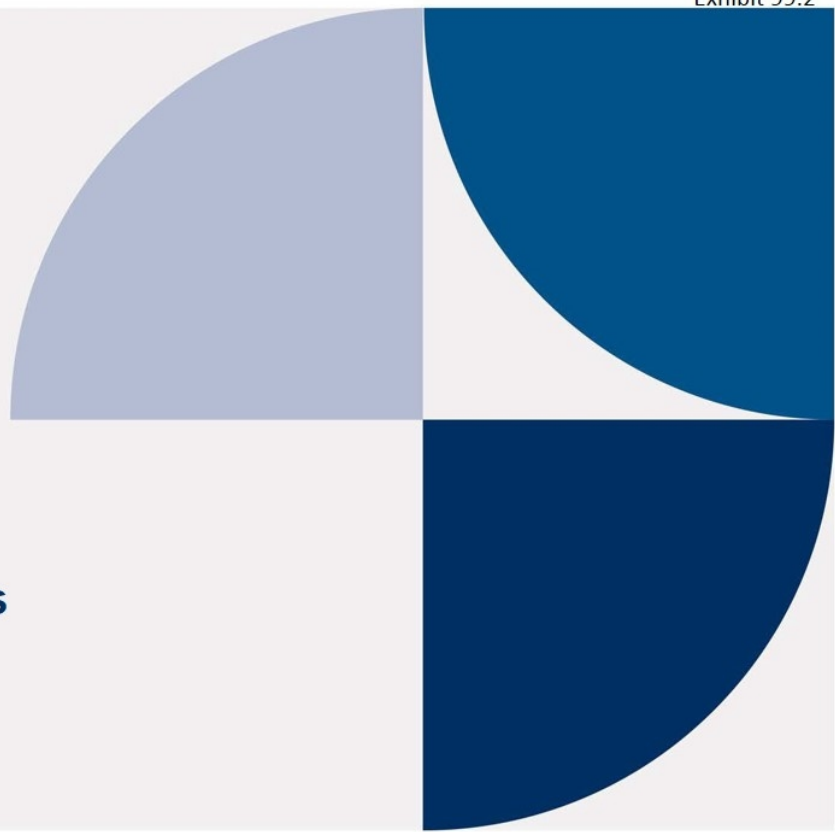


Cellular Medicines for Intractable Serious and Life-Threatening Diseases

November 2017

ASX: MSB

Nasdaq: MESO



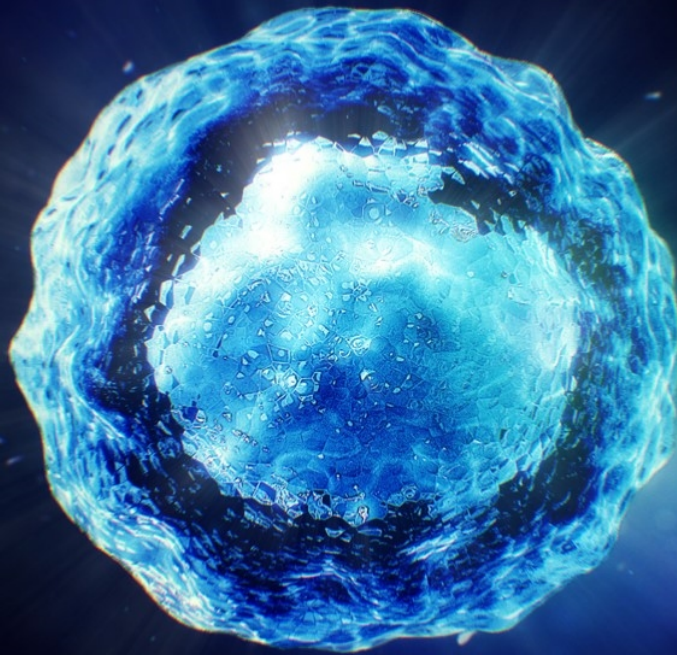


CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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 presentation 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, recent changes in regulatory laws, 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 current and potential future business partners 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 guarantee 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.

Our Mission:

Mesoblast is committed to bring to market disruptive cellular medicines to treat serious and life-threatening illnesses



Investment Proposition:

Building a Leading Franchise of Cellular Medicines



- Disruptive Cellular Technology Platform
- Commercial Translation Capabilities
- Advanced Pipeline of Cellular Medicines
- Targeting Serious or Life-Threatening Conditions with Unmet Needs

Disruptive Cellular Medicine Platform¹⁻⁴

- STRO-1⁺ Mesenchymal Precursor Cells (MPCs) are at the apex of the hierarchy of Mesenchymal Lineage cells
- STRO-1/STRO-3 immuno-selection provides a homogeneous population of MPCs with unique receptors that respond to activating inflammation and damaged-tissue signals
- In response to activating signals present in the endogenous environment, MPCs secrete a diverse variety of biomolecules responsible for immunomodulation and tissue repair
- The multi-modal mechanisms of action target multiple pathways

1. Simmons PJ and Torok-Storb, B. Identification of stromal cell precursors in bone marrow by a novel monoclonal antibody, STRO-1. *Blood*. 1991;78:55-62.
2. Gronthos S, Zannettino AC, Hay SJ, et al. Molecular and cellular characterisation of highly purified stromal stem cells derived from human bone marrow. *J Cell Sci*. 2003;116(Pt 9):1827-35.
3. See F, Seki T, Psaltis PJ, et al. Therapeutic effects of human STRO-3-selected mesenchymal precursor cells and their soluble factors in experimental myocardial ischemia. *J Cell Mol Med*. 2011;15:2117-29.
4. Psaltis PJ, Paton S, See F, et al. Enrichment for STRO-1 expression enhances the cardiovascular paracrine activity of human bone marrow-derived mesenchymal cell populations. *J Cell Physiol*. 2010;223(2):530-40.



Commercial Translation Capabilities: Technology Positioned for Scalable, Industrialized Manufacturing

- Immune privileged nature of STRO-1+ MPCs enables allogeneic “off the shelf” product candidates
- Culture expansion scalable to produce commercial quantities of potent and reproducible therapeutic doses
- In-house proprietary media formulations and commercial-grade bioreactors to deliver step-change yield improvements
- Specific formulations defined for product delineation
- Management know how in regulatory activities necessary for product approval and commercial launch
- TEMCELL® HS. Inj., first allogeneic cellular medicine received full approval in Japan and successfully launched for acute Graft vs Host Disease¹



Lonza contract manufacturing facility in Singapore

¹ TEMCELL® HS. Inj. Is the registered trademark of JCR Pharmaceuticals Co. Ltd., Mesoblast's Licensee.

Portfolio of Advanced Product Candidates:

Three Tier 1 Product Candidates in Phase 3



| | | | | | | | Commercialization | |
|--------|---|-------------------------------|--|---|---------|---------|-------------------|--|
| | Platform | Product Candidate | Therapeutic Area | Pre-Clinical/ Pre-IND | Phase 2 | Phase 3 | Approval | Partnering ¹ |
| Tier 1 | MPC | MPC-150-IM | Advanced (Class 3) HF End Stage (Class 4) HF ¹ | [Progress bars: Pre-IND to Phase 2, Phase 2 to Phase 3] | | | Japan | mesoblast <i>the regenerative medicine company</i> |
| | MPC | MPC-06-ID | Chronic Low Back Pain | [Progress bars: Pre-IND to Phase 2, Phase 2 to Phase 3] | | | | mesoblast <i>the regenerative medicine company</i> |
| | MPC | MPC-300-IV | RA DN/Type 2 Diabetes | [Progress bars: Pre-IND to Phase 2, Phase 2 to Phase 3] | | | | mesoblast <i>the regenerative medicine company</i> |
| | MSC | TEMCELL® HS Inj MSC-100-IV | Acute GVHD Acute GVHD | [Progress bars: Pre-IND to Phase 2, Phase 2 to Phase 3] | | | | mesoblast <i>the regenerative medicine company</i> JCR |
| Tier 2 | Includes MSC-100-IV (Crohn's disease – biologic refractory), MPC-25-IC (Acute Cardiac Ischemia), MPC-25-Osteo (Spinal Fusion) and MPC-75-IA (Knee Osteoarthritis) | | | | | | | |

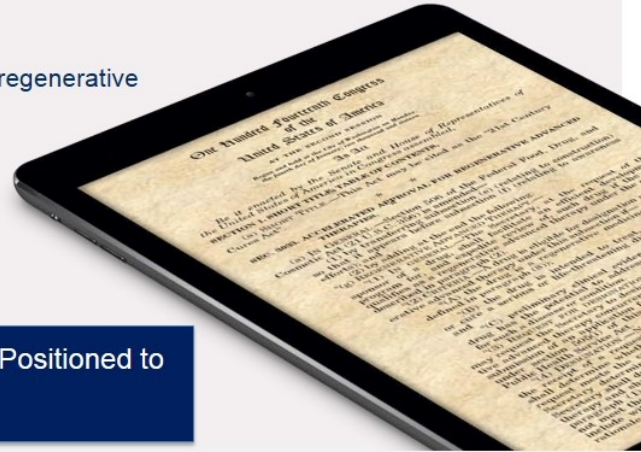
This chart is figurative and does not purport to show individual trial progress within a clinical program. For product registration purposes, Phase 3 programs may require more than one trial. Tier 1 programs represent our lead programs where we focus the majority of our time and resources. Tier 2 programs are also in development and may advance to Tier 1 depending on the merit of newly generated data, market opportunity or partnering options.

1. Clinical trial is funded by the U.S. National Institutes of Health and the Canadian Health Research Institute.

The 21st Century Cures Act (“Cures Act”):

Legislation for An Expedited Approval Path for Cellular Medicines Designated as Regenerative Medicine Advanced Therapies (RMAT)

- Cellular medicines may be designated as regenerative advanced therapies, if they are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition, and there is preliminary clinical evidence indicating the potential to address the unmet medical need
- Key benefits of the legislation for cell-based medicines, designated as regenerative advanced therapies, include:
 - Potential eligibility for priority review and accelerated approval
 - Potential to utilize surrogate endpoints for accelerated approval
 - Potential to utilize a patient registry data and other sources of “real world evidence” for post approval studies, subject to approval by the FDA



We Believe Our Portfolio of Advanced Product Candidates is Well Positioned to Achieve Accelerated Approvals Under the Cures Act

Intellectual Property:

An Extensive Portfolio Covering Composition of Matter, Manufacturing, and Therapeutic Applications of Potent Immuno-selected Mesenchymal Lineage Precursors and Progeny

~ 800 Patents and patent applications across 69 Patent Families. Protection across major markets including the U.S., Europe, Japan and China





Diverse Pipeline of Cellular Medicines





Acute Graft vs Host Disease (aGVHD)
MSC-100-IV for Steroid-Refractory aGVHD

MSC-100-IV: Market Opportunity for aGVHD

Burden of Illness

- Steroid-refractory aGVHD patients have mortality rates as high as 95%¹
- Refractory aGVHD is associated with significant extended hospital stay costs²
- aGVHD - a severe immunological reaction occurring in BMT patients
- Is a major limitation in successful allogeneic hematopoietic stem cell transplants¹

Minimal Treatment Options

- No regulatory approved treatment for SR-aGVHD outside of Japan
- No broad consensus on off-label second-line agents

Targeting Unmet Need

- Pediatrics: first-line steroid refractory
- Adults: first-line steroid refractory in high-risk (liver/gut disease) patients

Market Opportunity

- ~30,000 allogeneic BMTs performed globally (~20K US/EU5) annually, ~20% pediatric^{4,5}
- Our licensee JCR Pharmaceuticals Co., Ltd received full approval in Japan (TEMCELL® HS Inj.) for aGVHD in 2015; reimbursed up to ~\$USD195k³



1. West, J., Saliba, RM., Lima, M. (2011) Steroid-refractory acute GVHD: predictors and outcomes. *Advances in Hematology*.
2. Anthem-HealthCore/Mesoblast claims analysis (2016).
3. Based on a ¥JPY = \$USD 0.009375 spot exchange rate on as of the market close on November 11, 2016. Amounts are rounded. Source: Bloomberg.
4. 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.
5. CIBMTR, Decision resources GVHD Epi Nov 2012.



1. Target **pediatric** patients with SR-aGVHD first

- Extensive safety and efficacy data generated and published with MSC-100-IV in children with SR-aGVHD¹
- High economic burden in treatment of children with SR-aGVHD
- Fast-track designation for MSC-100-IV provides pathway for priority review and rolling review process
- Submit single, open-label Phase 3 trial via accelerated approval

2. Seek label extension for high-risk **adult** patients with SR-aGVHD (liver/gut disease)

- This adult subset has the highest mortality and greatest resistance to other treatment agents
- High economic burden in treating this population subset
- MSC-100-IV has identified efficacy signals in analyses of this subgroup in a Phase 3 randomized control trial

3. Lifecycle potential in **chronic** GVHD (cGVHD)

- Chronic GVHD represents a distinct patient population
- Proof of concept data already published for MSC in cGVHD²

1. Allogeneic Human Mesenchymal Stem Cell Therapy (Remestemcel-L, Prochymal) as a Rescue Agent for Severe Refractory Acute Graft-versus-Host Disease in Pediatric Patients - Biology of Blood and Marrow Transplantation Journal, August 2013. 2. Khandelwal P, Teusink-Cross A, Davies S (2017) Ruxolitinib as Salvage Therapy in Steroid-Refractory Acute Graft-versus-Host Disease in Pediatric Hematopoietic Stem Cell Transplant Patients. Biol Blood Marrow Transplant 23; 1122-1127

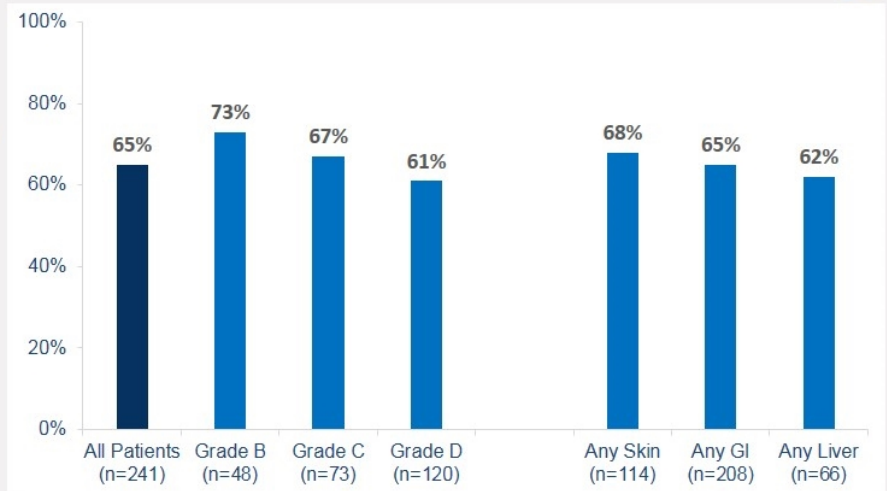
2. Weng JY, Du X, Geng SX, Peng YW, Wang Z, Lu ZS et al. Mesenchymal stem cell as salvage treatment for refractory chronic GVHD. Bone Marrow Transplant 45: 1732-1740 (2010)

MSC-100-IV: Expanded Access Program

Overall Day 28 Response in Pediatric aGVHD Patients Receiving MSC-100-IV as First-line or Salvage Therapy After Failing Steroids

Population: steroid-refractory aGVHD pediatric patients

- 241 pediatric patients undergoing HSCT were enrolled and treated at 50 sites in North America and Europe from 2007-2014
- Ages 2 months – 17 years
- Acute GvHD grades B-D (CIBMTR)
- Failed steroid treatment and multiple other agents
- aGVHD not improving after at least 3 days of methylprednisolone (at least 1 mg/kg/day or equivalent)



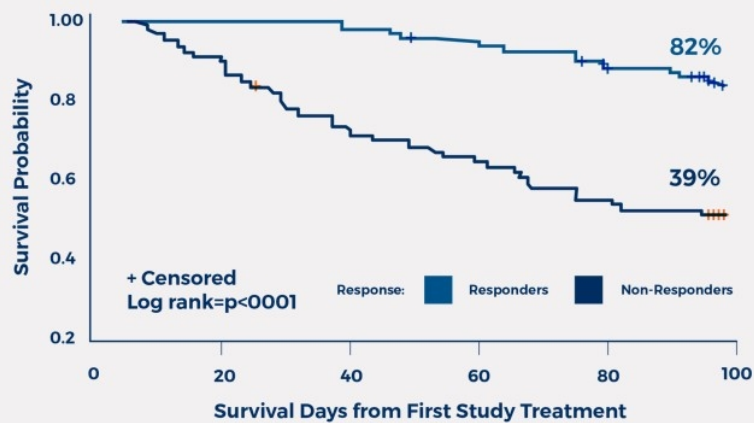
- Complete Response was 14%, Partial Response was 51%
- Responses were observed for all GVHD grades and did not differ by baseline organ involvement

Kurtzberg et al: Presentation Tandem Feb 2016

MSC-100-IV: Expanded Access Program

Correlation of Day 28 Overall Response with Day 100 Survival, Using MSC-100-IV as First-line or Salvage Therapy After Failing Steroids and/or Additional Treatments

MSC-100-IV in Children with SR-aGVHD who failed multiple other modalities
- Survival of Pediatric Patients Treated with MSC-100-IV 28-Day Responders vs Non-responders n=241



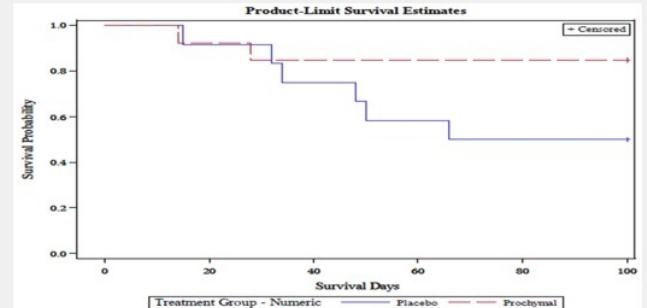
- In 241 Children under EAP, **Overall Response** (CR+PR) at Day 28 was **65%** (95% CI: 58.9%, 70.9%)
- **Day 100 survival** correlated with overall response, and was significantly improved in those who responded at Day 28 (**82% vs. 39%**, **p<0.0001**)

MSC-100-IV:

Prior Clinical Results¹ Support Ongoing Phase 3 Trial in Children with Steroid Refractory Acute GVHD (SR-aGVHD)

MSC-100-IV as first line therapy in children with SR-aGVHD

| Response at Day 28 | Randomized Placebo Controlled Trial | | Expanded Access Program |
|---|-------------------------------------|-----------------|-------------------------|
| | Placebo | MSC-100-IV | MSC-100-IV |
| Responder | 3/14 (21.4%) | 9/14 (64.3%) | 29/36 (81%) |
| Non-responder | 11/14 (78.6%) | 5/14 (35.7%) | 7/36 (19%) |
| p-value=0.0014 (combined treated vs control) | | | |



- These combined study results demonstrate that compared with placebo control patients, MSC-100-IV produced superior overall response at day 28, a clinically meaningful endpoint (p=0.0014) when used as first line therapy in these children with SR-aGVHD
- FDA agreement on ongoing Phase 3 trial design and its eligibility for accelerated approval pathway
- Enrollment criteria: MSC-100-IV being evaluated as first line therapy in children with SR-aGVHD

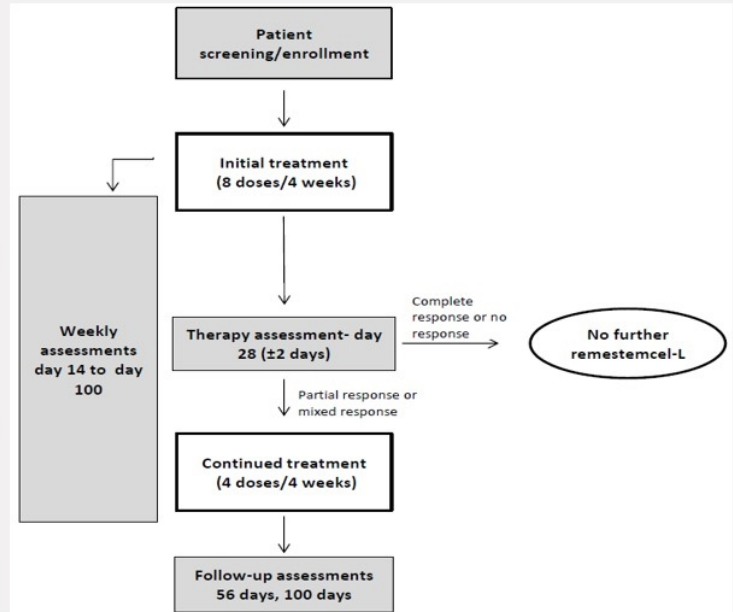
1. Protocols 275 (NCT00759018) and 280 (NCT00366145).

MSC-100-IV:

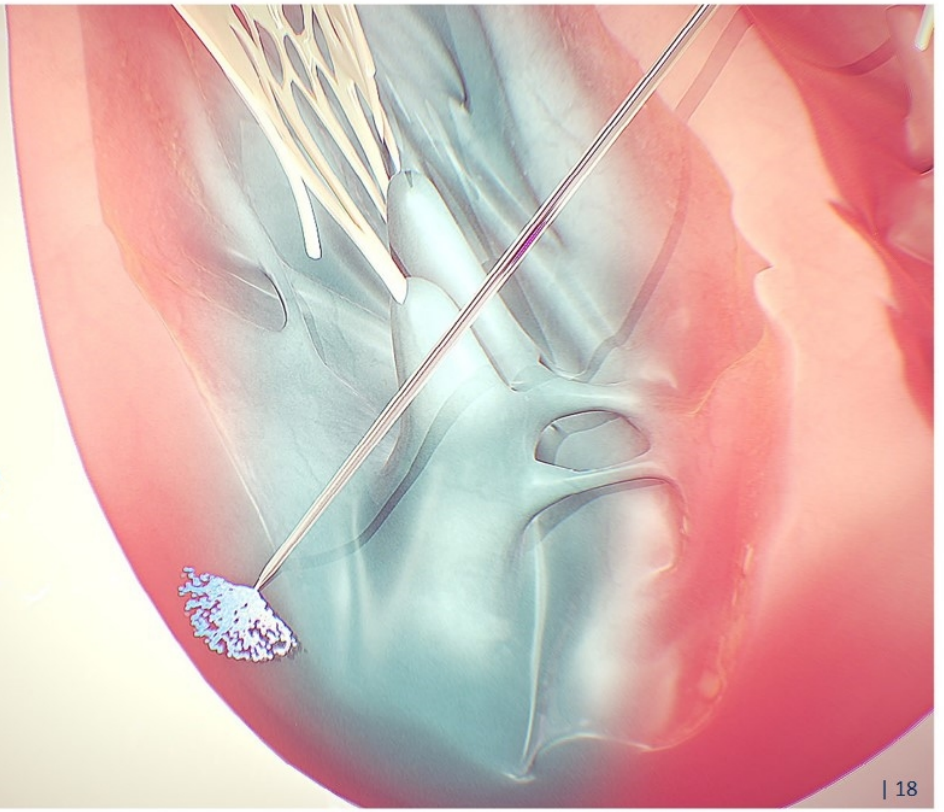
Phase 3 Pediatric Trial as First-line Therapy in aGVHD After Failing Steroids

- Multi-center, Single-Arm, Open-Label to evaluate efficacy and safety to day 100 (001) and from day 100 to day 180 (002)
- Up to 60 pediatric patients (2 months to 17 years)
- aGVHD following allogeneic HSCT failing systemic corticosteroid therapy
- Grades C and D aGVHD involving skin, liver and/or GI tract
- Grade B aGVHD involving liver and/or GI tract with or without concomitant skin disease
- Primary endpoint: **Overall response at Day 28**
- Key secondary endpoint: Survival at Day 100 in responders at Day 28
- Interim futility analysis of primary endpoint successful Nov 2016

Enrollment Complete (Q4 CY17)
Primary Endpoint Day 28 (Q1 CY18)
Day 100 survival data (Q2 CY18)

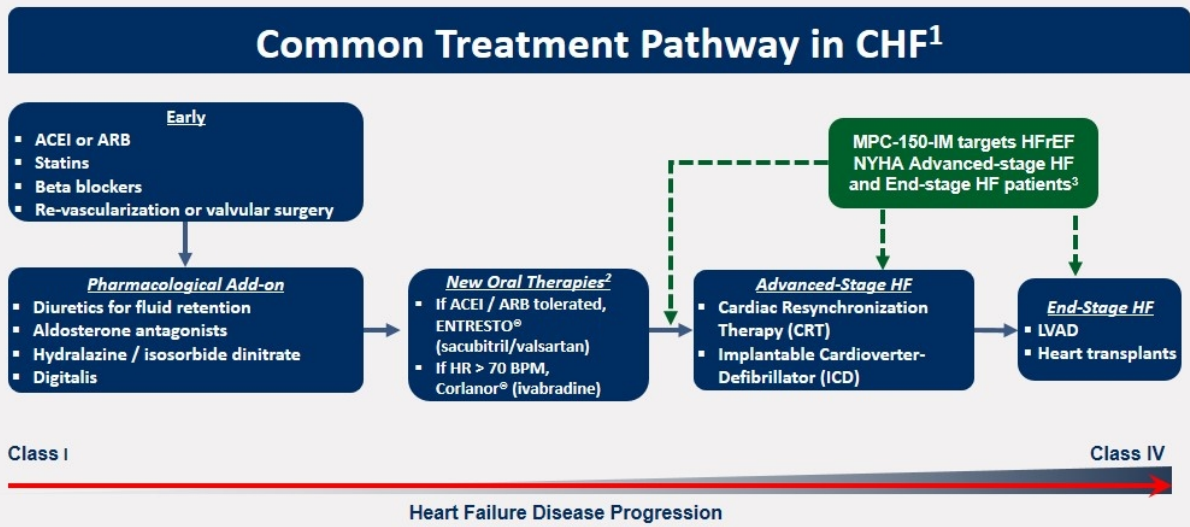


**MPC-150-IM
Chronic Heart Failure
(CHF) Program**



MPC-150-IM:

Targeting Patients with Worsening HF Despite Optimal Standard of Care



1. Source: Simon-Kucher & Partners 2017, Primary research 2017; Payers n=35, KOLs n=15, Cath lab managers n=4.

2. Corlanor® (ivabradine) approved by FDA (April 2015). ENTRESTO® (sacubitril/valsartan) approved by FDA (July 2015).

3. GlobalData-PharmaPoint Heart Failure (2016); McMurray et al., 2012; Yancy et al., 2013, 2016 ACC/AHA/HFSA Focused Update on New Pharmacological Therapy for Heart Failure: An Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure.

MPC-150-IM: Class IV Market Opportunity

Burden of Illness

- 250K – 300K patients/yr suffer from advanced systolic HF (NYHA Class IV)¹
- 50k patients/yr have end-stage heart failure
- Despite optimal medical therapy, 1-year mortality exceeds 50% in end-stage heart failure patients¹

Minimal Treatment Options

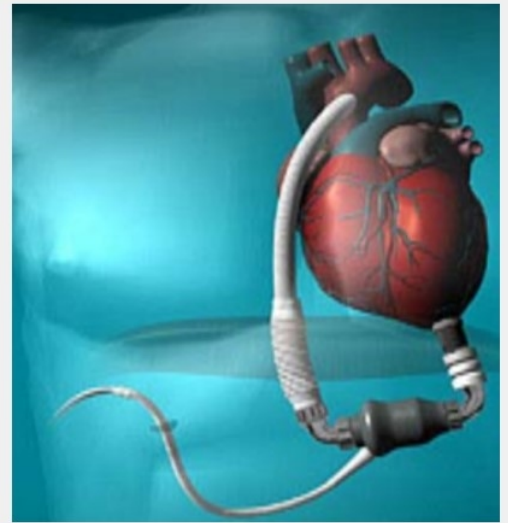
- Only ~2K heart transplants are performed in U.S. annually due to limited donors²
- LVADs have improved survival, but 1-year mortality remains at 20-30%¹
- Number of destination (permanent) LVADs implanted/yr are <5K due to associated high morbidity (e.g. GI bleeding and infection)

Unmet Need

- Strengthen native heart muscle
- Reduce re-hospitalizations
- Increase survival

Market Opportunity

- US LVAD market growing double-digit CAGR⁴
- US targeted commercial footprint (top 40 centers represent 75% of volume) provides low cost market entry³

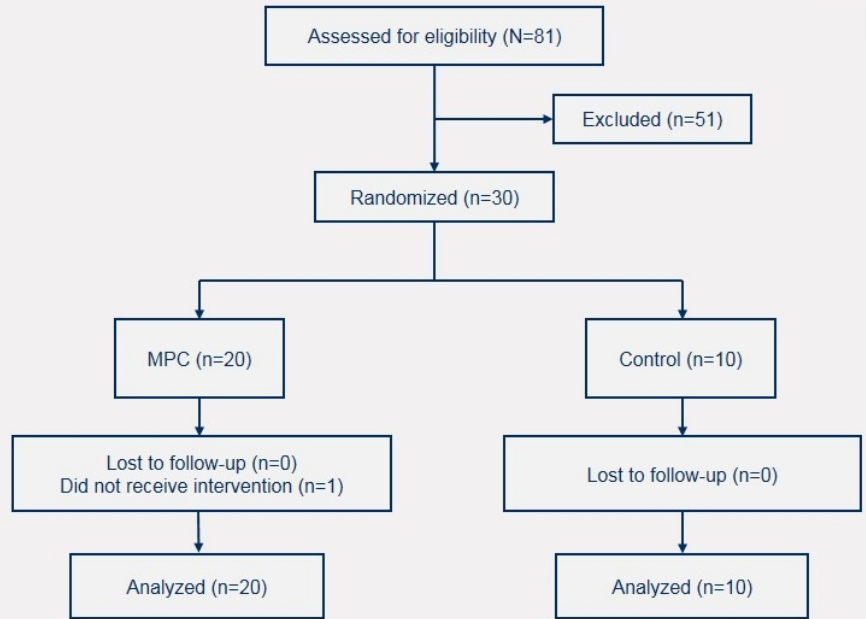


1. Gustafsson G, Rogers J. (2017) Left ventricular assist device therapy in advanced heart failure: patient selection and outcomes. *European Journal of Heart Failure* 19, 595-602.
2. Agency for Healthcare Research and Quality. HCUPnet: ICD-9 principal procedure code 27.51 2014. 3. Medicare provider charge inpatient-DRGALL-FY2014. St. Jude Medical-2016-analyst and investor day

LVAD MPC Pilot Trial Proof of Concept: Evaluating 25M MPCs as Adjunct to LVAD¹⁻²



- 57.4 yrs (± 13.6)
- 83% Male
- LVEF 18.1% (± 4.3)
- 37% Ischemic, 63% Non-ischemic
- 67% Destination, 33% Bridge to Transplant



1. Source: Ascheim DD et al. *Circulation*. 2014;129:2287-2296.

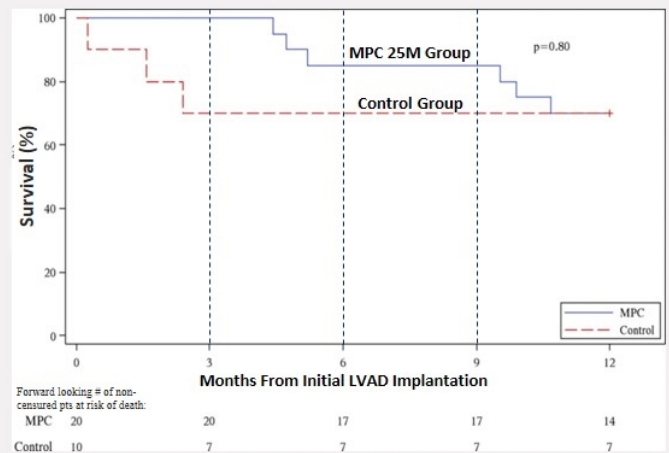
2. Study is sponsored Mt. Sinai and funded by the United States National Institutes of Health (NIH) and Canadian Institutes for Health Research, and conducted by the NIH-funded Cardiothoracic Surgical Trials Network (CTSN).

LVAD MPC Pilot Trial Outcomes:

25M MPCs Increased Ability to be Weaned off LVADs and Increased Short-Term Survival¹

- No cell-related safety events observed
- Median time to first hospitalization was 91 days in the MPC group vs 51 days in the control group
- 50% of MPC vs. 20% of control patients tolerated temporary wean at 90 days despite low dose of cells deployed
- Total number of temporary weans tolerated by MPC group was more than double that of the control group
- Using Bayesian approach, posterior probability that MPCs increased likelihood of successful wean at 90 days was 93%
- At 90 days, 30% (3/10) of controls expired compared to 0% (0/20) treated patients

LVAD MPC Pilot Trial: 12 Month Survival



1. Source: Ascheim DD et al. Circulation. 2014;129:2287-2296.

MPC-150-IM:

Phase 2b Trial Evaluating 150M MPCs in End-Stage Heart Failure Patients with LVADs



- The 159-patient, double-blind, placebo-controlled 2:1 randomized trial, is evaluating the safety and efficacy of injecting MPC-150-IM into the native myocardium of LVAD recipients
- Enrollment completed in Q3, CY2017
- Primary efficacy endpoint of the study is the number of temporary weans from LVAD tolerated over 6 months
- Secondary efficacy endpoints over 12 months include:
 - Time to re-hospitalization
 - Patient survival
 - Various quality of life measurements
- Study is sponsored by Icahn School of Medicine, funded by the United States National Institutes of Health (NIH) and Canadian Health of Research Institute, and conducted by the NIH-funded Cardiothoracic Surgical Trials Network (CTSN)

- **Phase 2B Class IV trial six-month primary endpoint reached (Q1 CY18)**
- **Phase 2B Class IV trial full data read-out (Q3 CY18)**

MPC-150-IM: Commercial Strategy



- Leverage data for potential earlier market entry opportunity for MPC-150-IM in end-stage heart failure patients (more than 5K/yr)
 - evaluate potential to reduce LVAD morbidity, increase survival and increase LVAD use as destination therapy (DT)
 - targeted product launch strategy would require minimal investment (top 40 centers represent ~75% of volume)*
 - if product strengthens native heart muscle, Bridge to Recovery (BTR) represents a future high-growth market opportunity for temporary LVAD use and explantation in end-stage, Class-IV heart failure patients (~50k/yr)

In addition to the Class IV heart failure patients, we will seek to bridge to a larger Class III heart failure population via label extension using our Phase 3 results

*Medicare provider charge inpatient-DRGALL-FY2014

MPC-150-IM: Class III Heart Failure Market Opportunity

Burden of Illness

- Globally, 17-45% of heart failure patients die within 1 year of hospital admission
- Majority die within 5 years of admission¹
- MPC-150-IM to target advanced HFrEF NYHA Class II-III with the objective of reducing major cardiovascular events (e.g. mortality and hospitalizations)

Minimal Treatment Options

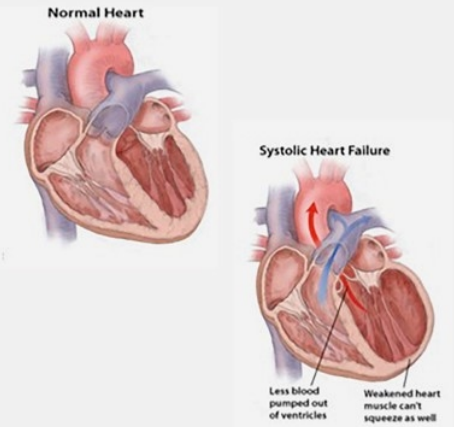
- Despite recent advancements in pharmacotherapy, limited treatment options are available for patients with advanced NYHA Class II-IV Heart Failure with Reduced Ejection Fraction (HFrEF)²

Unmet Need

- Therapy that reduces major cardiovascular events (e.g. mortality and hospitalizations) in patients with advanced HFrEF NYHA Class II – III

Market Opportunity

- NYHA Class II-IV patients with LVEF<40% in the US alone³
- Over \$60.2bn/yr in U.S. direct costs when this illness is identified as a primary diagnosis⁴
 - \$115bn as part of a disease milieu⁴; hospitalizations result in ~69% of expenditures⁵



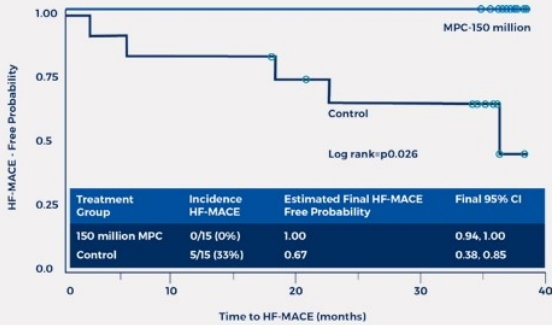
1. Heart Failure: Preventing disease and death worldwide – European Society of Cardiology 2014. 2. ACC/AHA/HFSA Focused Update on New Pharmacological Therapy for Heart Failure: An Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure. 3. Gurwitz JH, Magid DJ, Smith DH, et al. Contemporary Prevalence and Correlates of Incident Heart Failure with Preserved Ejection Fraction. The American Journal of Medicine. 2013;126(5):393-400. Derived by applying a HF-REF prevalence rate of 32.6% to the U.S. rate of 5.7m U.S. patients. 4. A Reevaluation of the Costs of Heart Failure and its Implications for Allocation of Health Resources in the United States. Voigt J. Clin. Cardiol. 37, 5, 312-321 (2014). 5. The Medical and Socioeconomic Burden of Heart Failure: A Comparative Delineation with Cancer. Dimitrios, F. International Journal of Cardiology (2015). doi: 10.1016/j.ijcard.2015.10.172.

MPC-150-IM:

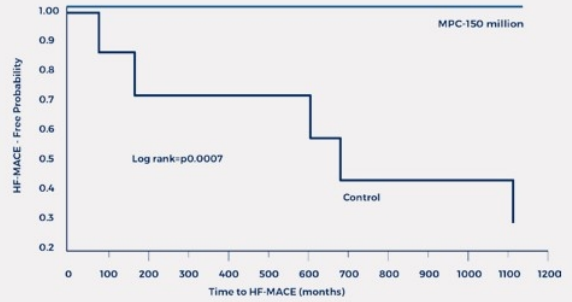
Durable (36 Months) Protection Against HF-MACE¹ in Phase 2 Trial Following Single Dose in NYHA Class II/III With Reduced Ejection Fraction



% HF-MACE Kaplan-Meier Curve over 36 months following treatment in all patients¹



HF-MACE Kaplan-Meier Curve over 36 months following treatment in patients with LVESV>100ml²



- Over 36 months, patients receiving 150M MPC had significantly greater probability of remaining free of a first HF-MACE vs. controls (0% vs. 33%, $p = 0.026$ by log-rank)
- All HF-MACE events occurred in controls with baseline Left Ventricular End Systolic Volume (LVESV)>100ml, where the treatment effect size was even greater (0% vs. 71%, $p = 0.0007$ by log rank)
- Controls with baseline LVESV>100ml had 11 total/recurrent HF-MACE events over 36 months vs. 0 in matched patients receiving 150M MPCs ($p=0.0007$)

1. HF-MACE is defined as a composite of cardiac related death or non-fatal heart failure hospitalisations. 2. Circ Res. 2015; 117:576-584. Perin E et al. A Phase II Dose-Escalation Study of Allogeneic Mesenchymal Precursor Cells in Patients With Ischemic or Non-Ischemic Heart Failure 3. Journal of Cardiac Failure 2015; Vol 21(8): S107; 19th Annual Scientific Meeting of the Heart Failure Society of America, Emerson et al.

MPC-150-IM:

Phase 3 Trial Targets Advanced Heart Failure

NYHA class II/III patients with large baseline LVESV and advanced heart failure are at highest risk of heart failure-related major adverse cardiac events (HF-MACE)

- Have increased likelihood of having recurrent HF hospitalizations
- Existing therapies are limited and economic burden is greatest

The ongoing Phase 3 trial is enriched for HF patients with high risk of HF-MACE

- Enrichment for these patients based on heart failure hospitalization in the past 9 months and/or significantly elevated baseline NT-proBNP

- Primary endpoint is a comparison of recurrent non-fatal HF-MACE between cell-treated NYHA class II/III patients and controls
- Terminal events (such as death, implantation of a mechanical heart assist device or a heart transplant) are also being analyzed as they relate to non-fatal recurrent HF-MACE

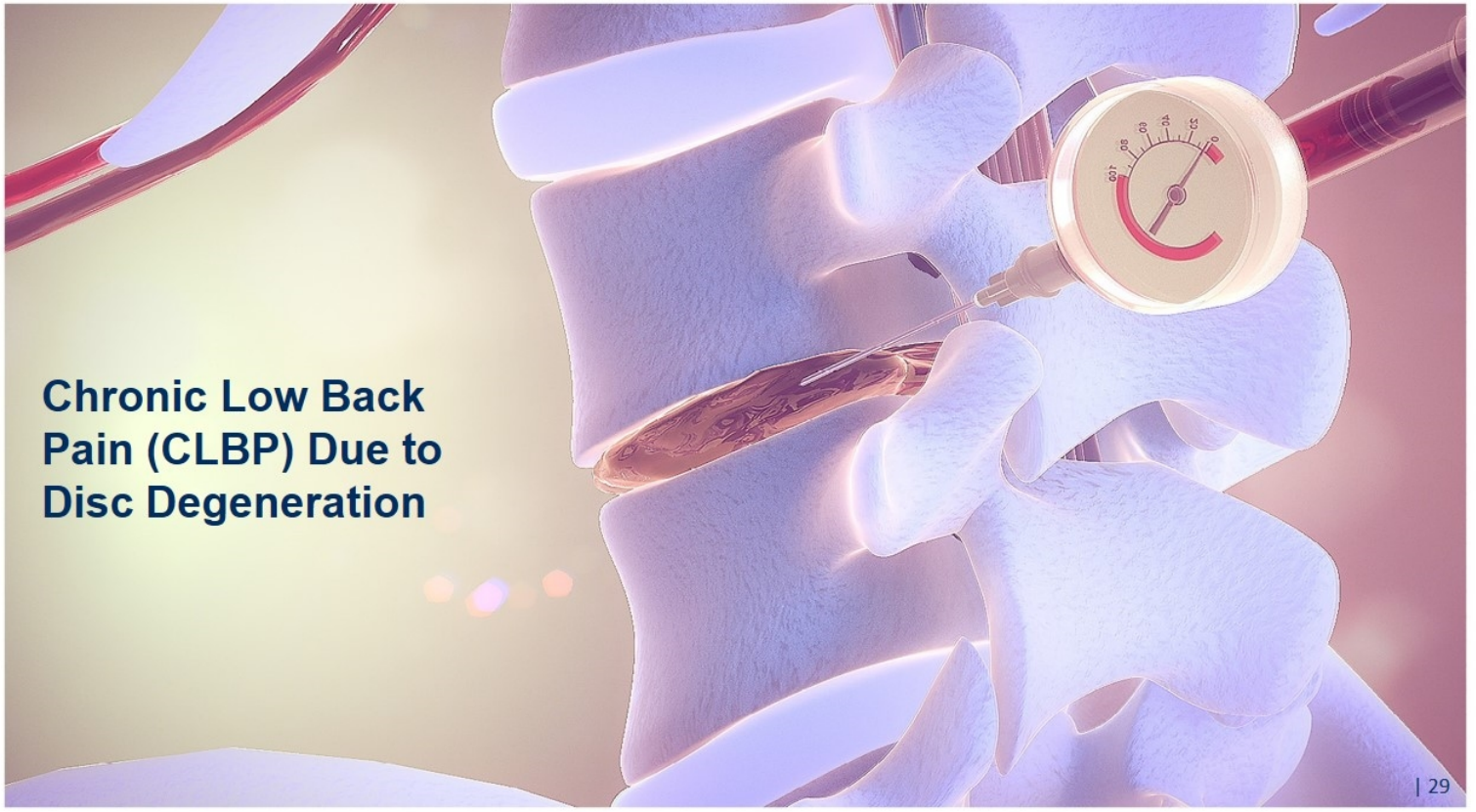
MPC-150-IM:

Operational Update for Phase 3 Trial in NYHA Class II-III Advanced CHF Patients



- Trial has enrolled more than 400 of approximately 600 patients
- In April 2017, a pre-specified interim futility analysis of the efficacy endpoint in the Phase 3 trial's first 270 patients was successfully achieved
- After completing the interim analysis, the trial's Independent Data Monitoring Committee (IDMC) formally recommended the trial be continued as planned
- Phase 3 trial targeted enrollment completion (2H CY18)

**Chronic Low Back
Pain (CLBP) Due to
Disc Degeneration**



MPC-06-ID: a non-Opioid alternative for Chronic Low Back Pain due to Degenerative Disc Disease

Burden of Illness

- Back pain causes more disability than any other condition¹
- Inflicts substantial direct and indirect costs on the healthcare system¹, including excessive use of opioids in this patient population

Minimal Treatment Options

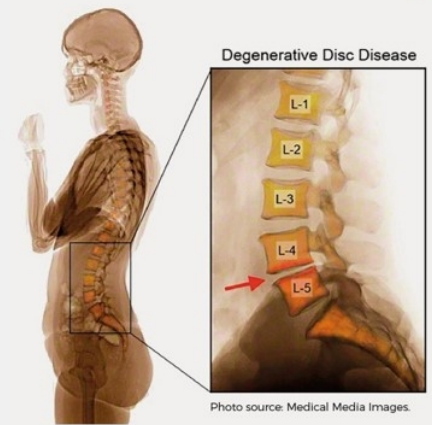
- Treatment options for patients with CLBP who fail conservative therapy include opioids and surgery
- 50% of opioid prescriptions are for chronic low back pain (CLBP)

Unmet Need

- Disease modifying therapy for durable improvement in pain and function has potential to prevent progression to opioid use or surgical intervention

Market Opportunity

- In 2016, over ~7m U.S. patients are estimated to suffer from CLBP due to degenerative disc disease (DDD)^{3,4,5}
- MPC-06-ID development program targets over ~3.2m patients



1. Williams, J., NG, Nawi, Peltzer, K. (2015) Risk factors and disability associated with low back pain in older adults in low-and middle-income countries. Results from the WHO Study on global ageing and adult health (SAGE). PloS One. 2015; 10(6): e0127880. 2. Simon, J., McAuliffe, M., Shamim, F. (2015) Discogenic Low Back Pain. Phys Med Rehabil Clin N Am 25 (2014)305-317. 3. Decision Resources: Chronic Pain December 2015. 4. LEK & NCI opinion leader interviews, and secondary analysis. 5. Navigant: Commercial Assessment for a Proprietary Cell-Based Therapy for DDD in the U.S. and the EU3 - August 2014. 6. HealthCare Utilization and Cost of Discogenic Lower Back Pain in the US - Anthem/HealthCore.

The Opioid Epidemic

- 50% of opioid prescriptions are for chronic low back pain (CLBP)
- Over 1,000 people are treated in U.S. emergency departments everyday for misusing prescription opioids
- Over 33,000 people in the U.S. died of prescription opioid related overdoses in 2016
- Opioid epidemic declared a public health emergency by U.S. President Trump in October, 2017
- A non-opioid solution for CLBP is imperative

The 21st Century Cures Act includes measures to combat opioid dependence and accelerated approval for non-opioid pain reducing drugs

Information derived from

Centers for Disease Control and Prevention, National Center for Health Statistics. Underlying Cause of Death 1999-2015 on CDC WONDER Online Database, released December, 2016. Available at: <http://wonder.cdc.gov/ucd10.html>

Substance Abuse and Mental Health Services Administration. Key Substance Use and Mental Health Indicators in the United States: Results from the 2015 National Survey on Drug Use and Health. Online Database, released September, 2016. Available at: <https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR1-2015/NSDUH-FFR1-2015/NSDUH-FFR1-2015.htm>

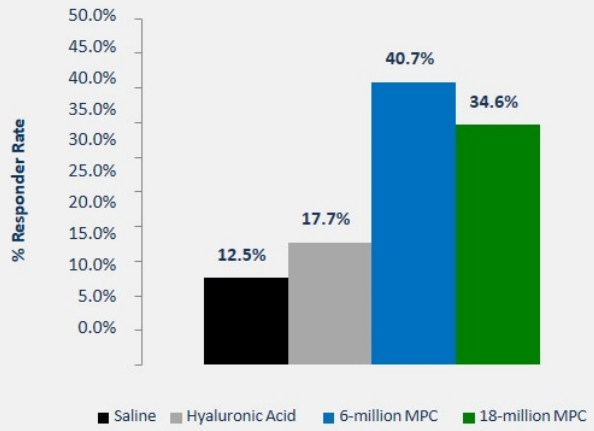
Jones CM. Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers - United States, 2002-2004 and 2008-2010. *Drug Alcohol Depend.* 2013 Sep 1;132(1-2):95-100. doi: 10.1016/j.drugalcdep.2013.01.007. Epub 2013 Feb 12.

MPC-06-ID: Phase 2 Trial Results Support Phase 3 Program



- 100 patients with >6 months of CLBP due to DDD and unresponsive to conservative therapies (incl. opioids and epidural steroids) were evaluated in a blinded, randomized, placebo controlled Phase 2 trial
- Pre-specified analyses for change in pain from baseline using VAS and change in function using ODI
- Primary endpoint composite over 24 months using pain and function thresholds ($p < 0.05$ for 6 million MPCs vs saline using Intent to Treat Analysis and $p = 0.08$ by Per Protocol Analysis)¹

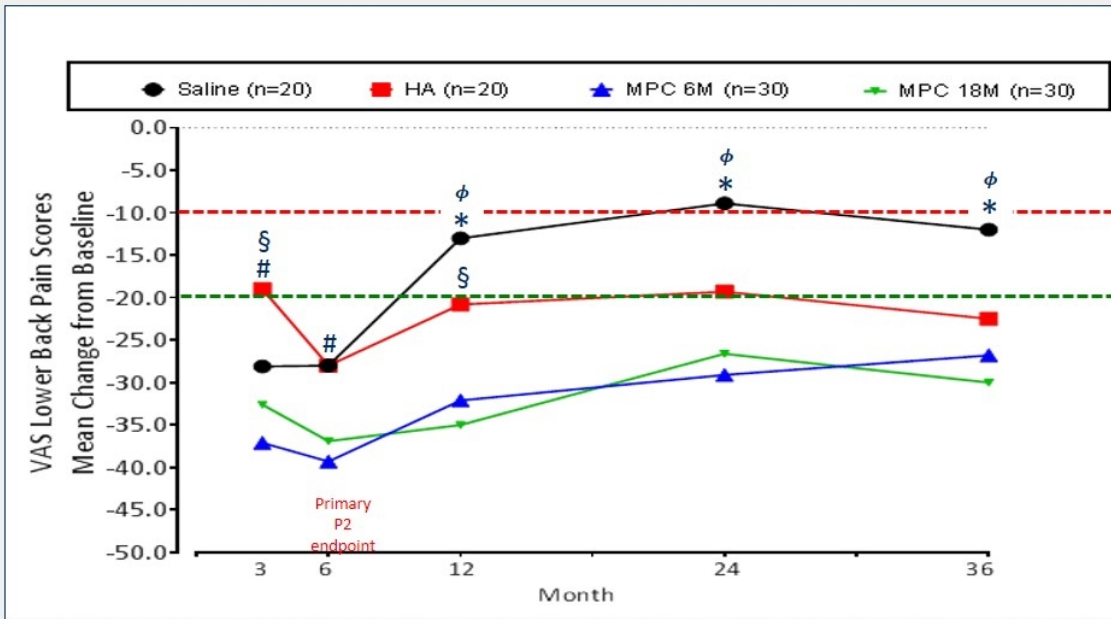
Composite Responders at both 12 & 24 Months - PP¹



1. Source Mesoblast Ltd; PP = Per Protocol population. A Composite Responder must have an optimal pain (50% reduction in VAS) AND function (15 point reduction in ODI) response AND no additional intervention.

MPC-06-ID: Phase 2 Clinical Trial Results:

Substantial Reduction in Low Back Pain Through 36 Months After Single Dose



Minimal Difference²

Substantial Clinical Improvement²

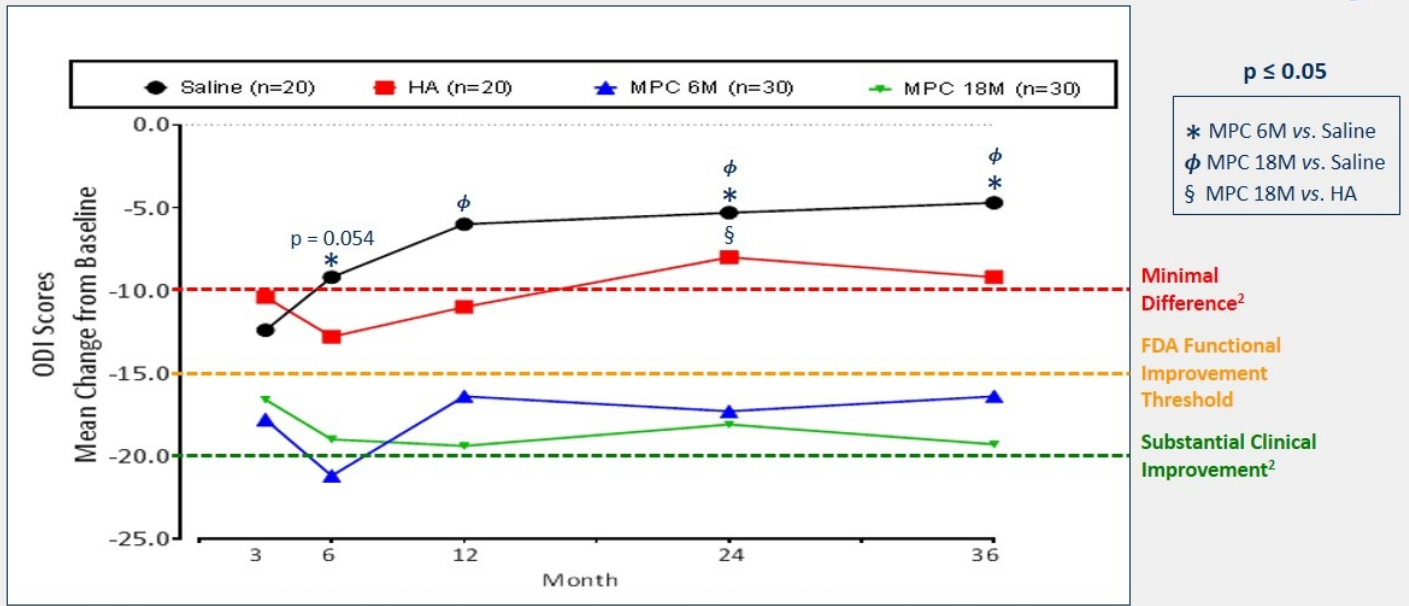
p ≤ 0.05

- * MPC 6M vs. Saline
- phi MPC 18M vs. Saline
- # MPC 6M vs. HA
- section sign MPC 18M vs. HA

1. ITT Population. Subjects failing therapy due to intervention had BOCF imputed for all visits after the intervention. Patients with missing data were considered treatment failures, so BOCF imputed for all missing values.
 2. Abdel Shaheed Christina, Maher Chris G, Williams Kylie A, Day Richard, McLachlan Andrew J. Efficacy, Tolerability, and Dose-Dependent Effects of Opioid Analgesics for Low Back Pain: A Systematic Review and Meta-analysis. JAMA Internal Medicine. American Medical Association, 2016 Jul 1;176(7):958-68.

MPC-06-ID: Phase 2 Clinical Trial Results

Reduction in Functional Disability Through 36 Months After Single Dose




1. ITT Population. Subjects failing therapy due to intervention had BOCF imputed for all visits after the intervention. Patients with missing data considered treatment failures, so BOCF imputed for all missing values.
 2. Abdel Shaheed Christina, Maher Chris G, Williams Kylie A, Day Richard, McLachlan Andrew J. Efficacy, Tolerability, and Dose-Dependent Effects of Opioid Analgesics for Low Back Pain: A Systematic Review and Meta-analysis. JAMA Internal Medicine. American Medical Association; 2016 Jul 1;176(7):958-68.



- A 360-patient Phase 3 trial across U.S. and Australian sites
- Targeted to complete recruitment early Q1 CY18
- FDA has provided written guidance:
 - Use of a composite primary endpoint at 12 and 24 months is acceptable
 - Agreed thresholds for pain (50% decrease in VAS) and function (15 point improvement in ODI)
 - No additional intervention at the treated level through 24 months

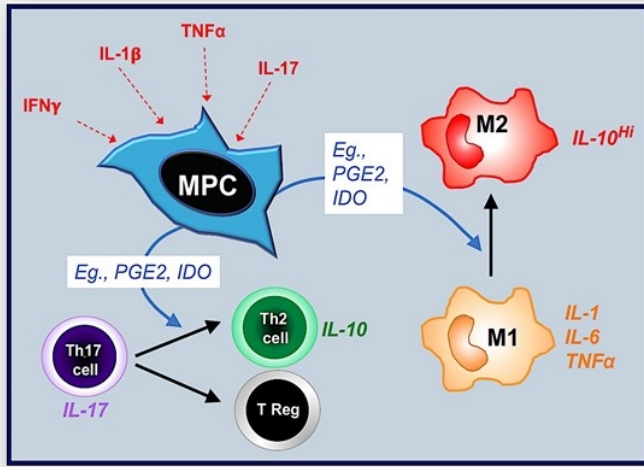
If the P3 results replicate P2 results in pain and function, leverage this product candidate as a potential non-opioid treatment option for chronic low back pain



**Our inflammatory diseases portfolio
(MPC-300-IV)**

MPC-300-IV:

Cellular product candidate that responds to multiple inflammatory signals



Phase 2 Clinical Data in Immune Mediated Diseases

- **60 patients, type 2 diabetes with inadequately controlled glucose:**
 - Randomized, placebo controlled dose-ranging study completed
 - Positive dose-dependent effects seen on reduction in HbA1c at 3 months¹
- **30 patients, diabetic kidney disease:**
 - Randomized, placebo controlled dose-ranging study completed
 - Positive effects seen on glomerular filtration rate and on inflammatory biomarkers over 6 months²
- **48 patients, biologic-refractory rheumatoid arthritis:**
 - Randomized, placebo controlled, dose-ranging study over 52 weeks

1. Allogeneic Mesenchymal Precursor Cells in Type 2 Diabetes: A Randomized, Placebo-Controlled, Dose-Escalation Safety and Tolerability Pilot Study - Diabetes Care, July 2015
2. Allogeneic Mesenchymal Precursor Cells (MPC) in Diabetic Nephropathy: A Randomized, Placebo-controlled, Dose Escalation Study - E BioMedicine, October 2016

MPC-300-IV: Biological Refractory Rheumatoid Arthritis (RA)

Market Opportunity

Burden of illness

- There are approx 6.0 million cases in the US, Japan, and EU5, with 2.9 million in the US alone in 2016^{1,2}

Treatment Options

- ~1/3 of RA patients do not respond or cannot tolerate TNF inhibitors⁴
- Low disease activity or remission is seen in low numbers of patients refractory to TNF inhibitors treated with alternative biologic agents²

Unmet Need

- Need for disease-modifying therapies that are well tolerated and induce low disease activity or remission in a greater percentage of patients as early as possible in the disease management

Market Opportunity

- In 2016, sales of RA agents, predominantly TNF inhibitors exceeded \$19 billion globally. Projections of over \$22.5 billion by 2025, due to sales of oral JAK inhibitors, TNF biosimilars³

1. GlobalData®: Rheumatoid Arthritis Global Forecast 2015-2025 0- January 2017.
2. Decision Resources Rheumatoid Arthritis Dec 2015.
3. Decision Resources Rheumatoid Arthritis April 2016.
4. Decision Resources: Unmet Need Immune and Inflammatory Disorders – Rheumatoid Arthritis April 2016.



Photo source: WebMD.



▪ Inclusion Criteria

- Inadequate response to at least 1 anti-TNF +/- other biologics
- On a stable regimen methotrexate for >4 months +/- DMARDs for >3 months

▪ Randomisation Scheme

- MPC 1 million cells/kg (N=16)
- MPC 2 x million cells/kg (N=16)
- Placebo (N=16)

▪ Objectives

- Primary: Safety and tolerability of a single intravenous MPC infusion through a 12-week primary endpoint
- Secondary: Clinical efficacy at week 4, 12, 39 and 52, primary efficacy endpoint at week 12
 - Pre-specified analyses were applied to the whole study population and the pre-specified exploratory subgroup based on whether the subjects had previously received 1-2 or >3 biologic agents and included:
 - American College of Rheumatology (ACR 20/50/70, ACR-N) composite clinical responses
 - Health assessment questionnaire-disability index (HAQ-DI)
 - Disease Activity Score (DAS28) composite measurement
 - Short-form health survey (SF-36), an assessment of health-related quality-of-life

*RF=Rheumatoid factor; anti-CCP=Cyclic citrullinated peptide antibody.

** ClinicalTrials.gov Identifier: NCT01851070.

MPC-300-IV:

Phase 2 trial in biologic refractory Rheumatoid Arthritis shows early and durable effects after single dose

- Infusions were well-tolerated and there were no treatment-related serious adverse events reported, with the safety profile comparable among the placebo and two MPC treatment groups.
- A single intravenous MPC infusion in biologic refractory RA patients resulted in dose-related improvements in clinical symptoms, function, disease activity and patient-reported outcomes. Efficacy signals were observed for each of ACR 20/50/70, ACR-N, HAQ-DI, SF-36 and DAS-28 disease activity score.
- 2 million MPC/kg dose showed greatest overall treatment responses. Onset of treatment response occurred as early as 4 weeks, peaked at 12 weeks, was sustained through 39 weeks, and waned by 52 weeks.
- Greatest benefits over 52 weeks were seen in patients who had failed less than 3 biologics (1-2 biologic sub-group) prior to MPC treatment, identifying this as a potentially optimal target population.

- **Phase 2 trial clinical responses along with the safety profile position MPC-300-IV as an early treatment option in RA patients who are resistant or intolerant to anti-TNF or other biologics**
- **Future studies will evaluate whether higher doses can induce even greater rates of low disease activity or remission within 12 weeks**



Financials & Milestones

Q1 FY18

Cash Position and Cash Flows for three months ending 30 Sep 2017 (US\$m)

| | 30 Sep 2017 | 30 Sep 2016 | \$Change |
|--|-------------|---------------|-------------|
| Operating cash outflows | (20.3) | (20.8) | 0.5 |
| Investing cash outflows | (0.6) | (0.3) | (0.3) |
| Financing cash inflows/(outflows) | 38.4 | (0.1) | 38.5 |
| Forex | (0.3) | 0.6 | (0.9) |
| Net increase (decrease) in cash | 17.2 | (20.6) | 37.8 |

- Cash outflows from Operating activities have reduced 2.3% (\$0.5 million)

| | 30 Sep 2017 | 30 Jun 2017 | \$Change |
|---------------------|-------------|-------------|-------------|
| Cash on Hand | 62.9 | 45.7 | 17.2 |

- Cash on hand increased by \$17.2 million (38%) due to net financing cash inflows of \$38.4m in the quarter as a result of the successful September 2017 entitlement offer of 36.2 million shares

Q1 FY18 - Profit and Loss for the three months ending 30 Sep 2017 (US\$m)

| For the three months ending | 30 Sep 2017 | 30 Sep 2016 | \$ Change | % |
|-----------------------------------|--------------|---------------|-------------|------------|
| Revenue | 1.2 | 0.4 | 0.8 | 197% |
| Research and Development | (15.4) | (14.0) | (1.4) | (10%) |
| Manufacturing Commercialization | (0.9) | (3.3) | 2.4 | 73% |
| Management & Administration | (5.0) | (5.5) | 0.4 | 8% |
| Contingent Consideration | 9.5 | (1.0) | 10.5 | NM |
| Other Operating Income & Expenses | 0.7 | 0.5 | 0.2 | 41% |
| Loss Before Tax | (9.9) | (22.9) | 13.0 | 57% |

Revenue increased by \$0.8 million (197%) vs comparative period in FY17

- **Commercialization revenue increased by 178% (\$0.4 million)** due to an increase in royalty income on sales of TEMCELL® Hs. Inj., versus the comparative period
- **A sales milestone of \$0.5 million was recognized** as TEMCELL® Hs. Inj., reached a cumulative sales milestone in the three months ended 30 September 2017. No milestones were recognized in the comparative quarter

Q1 FY18 - Profit and Loss for the three months ending 30 Sep 2017 (US\$m)

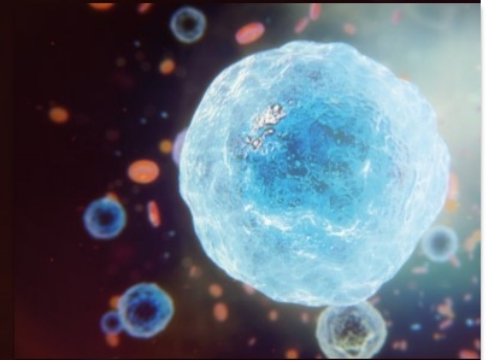
| For the three months ending | 30 Sep 2017 | 30 Sep 2016 | \$ Change | % |
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Overall management contained spend whilst increasing its R&D investment in Tier 1 clinical programs by deferring manufacturing production and constraining management and administration costs

- **R&D expenses increased by \$1.4 million (10%)** as management invested in Tier 1 clinical programs
- **Manufacturing Commercialization decreased by \$2.4 million (73%)** – sufficient clinical grade product on hand enabled the number of production runs to be reduced in the period vs the comparative quarter
- **Management & Admin costs reduced by \$0.4 million (8%)** as management contained rent and IT costs

Targeted Upcoming Milestones and Catalysts

- **MSC-100-IV for Pediatric Acute GVHD**
 - Phase 3 expected to complete enrollment (Q4 CY17)
 - Day 28 primary endpoint data read-out (Q1 CY18)
 - Day 100 survival data (Q2 CY18)
- **MPC-150-IM for Advanced and End-Stage Heart Failure**
 - Phase 2B Class IV trial six-month primary endpoint reached (Q1 CY18)¹
 - Phase 2B Class IV trial full data read-out (Q3 CY18)¹
 - Phase 3 trial for Class II/III targeted enrollment completion (H2 CY18)
- **MPC-06-ID for Chronic Low Back Pain**
 - Phase 3 trial expected to complete enrollment (early Q1 CY18)
- **Potential Corporate Partnerships**



1. Study is funded by the United States National Institutes of Health (NIH) and the Canadian Health Research Institute (CHRI), and conducted by the NIH-funded Cardiothoracic Surgical Trials Network (CTSN).

