

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 2018

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 16, 2018, 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 20, 2018

---

INDEX TO EXHIBITS

Item \_\_\_\_\_

- 99.1 Press release of Mesoblast Ltd, dated November 16, 2018.
- 99.2 Investor presentation of Mesoblast Ltd, dated November 16, 2018

**MESOBLAST REPORTS FIRST QUARTER ENDED SEPTEMBER 30, 2018 FINANCIAL RESULTS AND OPERATIONAL HIGHLIGHTS**

Melbourne, Australia, November 16, 2018 and New York, USA, November 15, 2018: Mesoblast Limited (ASX:MSB; Nasdaq:MESO) today reported strong financial results and provided operational highlights for the first quarter ended September 30, 2018.

**Key financial results for the three months ended September 30, 2018 (first quarter FY2019)**

- Significant increase in revenues to US\$11.6 million in the first quarter FY2019, compared with US\$1.2 million in the first quarter FY2018
- 66% increase in commercialization revenue from royalty income on sales of TEMCELL®<sup>1</sup> HS. Inj. for the quarter, compared with first quarter FY2018
- Reduction in operating cash outflows in first quarter FY2019 of US\$0.8 million (4%) compared with first quarter FY2018
- Loss after tax increased by \$12.5 million compared to the first quarter FY2018, \$10.1 million of which is due to non-cash remeasurement of contingent consideration in the comparative quarter
- Pro-forma cash on September 30, 2018 was US\$95.1 million including:
  - US\$55.1 million balance sheet cash, and
  - US\$40.0 million from Tasty Pharmaceutical Group (Tasty) received in October 2018 in relation to the strategic cardiovascular partnership in China announced in July 2018
- An additional US\$50.0 million may be available under existing arrangements with Hercules Capital and NovaQuest, subject to achievement of certain milestones.

**Corporate Highlights**

- Results of a 159-patient randomized placebo-controlled Phase 2 trial, sponsored and conducted by United States National Institutes of Health (NIH), evaluating MPC-150-IM in the treatment of end-stage heart failure patients implanted with a left ventricular assist device (LVAD) were presented at the 2018 American Heart Association Scientific Sessions.
  - The trial succeeded in achieving the clinically meaningful outcome of reduction in gastrointestinal (GI) bleeding and related hospitalizations
  - Results confirm the previous pilot trial, which also demonstrated significant reduction in GI bleeding and related hospitalizations in MPC-150-IM treated LVAD patients
  - Pilot trial results formed the basis for the FDA Regenerative Medicine Advanced Therapy (RMAT) designation granted in December 2017
  - The RMAT designation under the 21st Century Cures Act aims to expedite the development of regenerative medicine therapies intended for the treatment of serious diseases and life-threatening conditions
  - Company intends to meet with the FDA in 1H CY2019 to provide full study data and discuss pathway to potential Biologics License Application (BLA) filing using reduction in GI bleeding and related hospitalizations as an approvable regulatory endpoint
  - While the trial did not meet the overall primary endpoint of temporary weaning, MPC-150-IM treatment did significantly improve weaning in the 44% of patients with chronic ischemic heart failure
  - LVAD patients with ischemic heart failure closely resemble the majority of patients enrolled in the ongoing Phase 3 trial of approximately 600 patients with moderate/ advanced heart failure

**Mesoblast Limited**  
 ABN 68 109 431 870  
[www.mesoblast.com](http://www.mesoblast.com)

**Corporate Headquarters**  
 Level 38  
 55 Collins Street  
 Melbourne 3000  
 Victoria Australia  
 t +61 3 9639 6036  
 f +61 3 9639 6030

**United States Operations**  
 505 Fifth Avenue  
 Third Floor  
 New York, NY 10017  
 USA  
 t +1 212 880 2060  
 f +1 212 880 2061

**Asia**  
 20 Biopolis Way  
 #05-01 Centros  
 Biopreneur 3  
 SINGAPORE 138668  
 t +65 6570 0635  
 f +65 6570 0176

- Mesoblast's Phase 3 trial of its product candidate remestemcel-L in children with steroid-refractory acute Graft Versus Host Disease (aGVHD) demonstrated strong survival outcomes through Day 180. Mesoblast is preparing for a pre-BLA meeting to initiate filing of a marketing authorization for this product candidate in the United States.
- Mesoblast expanded its partnership with JCR Pharmaceuticals Co. Ltd. (JCR) for the treatment of wound healing in epidermolysis bullosa (EB). Having been granted Orphan Regenerative Medical Product designation for EB in October, JCR now intends to seek a label extension for TEMCELL® in Japan for EB beyond its existing approval for the treatment of aGVHD.
- Mesoblast completed its transaction with Tasy to establish a strategic cardiovascular partnership in China. In addition to US\$40 million received on closing the transaction, Mesoblast is eligible to receive up to US\$25 million on product regulatory approval in China, double-digit escalating royalties on net product sales as well as six escalating milestone payments upon the achievement of certain product sales thresholds in China.

#### Operational Highlights and Anticipated Upcoming Milestones

##### MPC-150-IM for Moderate to Advanced Heart Failure:

- The ongoing Phase 3 trial received a recommendation in October 2018 from the unblinded Independent Data Monitoring Committee to continue without modification after an evaluation of clinical safety data in the first 526 randomized patients.

##### MSC-100-IV (remestemcel-L) for pediatric steroid-refractory acute Graft Versus Host Disease (aGVHD):

- Mesoblast will seek a pre-BLA meeting to initiate filing of a marketing authorization for remestemcel-L in the United States, where there are currently no approved therapies for aGVHD.
- An existing Fast Track designation from the FDA allows eligibility for priority review and a rolling BLA review process.

##### MPC-06-ID for Chronic Low Back Pain:

- Mesoblast's Phase 3 trial in patients with chronic low back pain who have failed conservative therapy completed enrollment in March 2018, with a total of 404 patients across 48 sites being followed out for evaluation of treatment-related improvement in pain and function.

#### Financial Results for the Three Months Ended September 30, 2018 (first quarter FY2019) (in U.S. Dollars)

- **Revenues** were US\$11.6 million for the first quarter FY2019, compared with US\$1.2 million for the first quarter FY2018, an increase of US\$10.5 million. These revenues primarily consisted of:
  - o US\$1.5 million in royalties and milestones from sales of TEMCELL by our licensee in Japan, JCR Pharmaceuticals Co. Ltd. Royalties from TEMCELL increased by 66% for first quarter FY2019 compared with the first quarter FY2018
  - o US\$10.0 million milestone revenue in relation to establishing a strategic cardiovascular partnership with Tasy in China

**Mesoblast Limited**  
 ABN 68 109 431 870  
[www.mesoblast.com](http://www.mesoblast.com)

**Corporate Headquarters**  
 Level 38  
 55 Collins Street  
 Melbourne 3000  
 Victoria Australia

t +61 3 9639 6036  
 f +61 3 9639 6030

**United States Operations**  
 505 Fifth Avenue  
 Third Floor  
 New York, NY 10017  
 USA

t +1 212 880 2060  
 f +1 212 880 2061

**Asia**  
 20 Biopolis Way  
 #05-01 Centros  
 Biopreneur 3  
 SINGAPORE 138668

t +65 6570 0635  
 f +65 6570 0176

- **Research and Development** expenses were US\$18.5 million for the first quarter FY2019, compared with US\$15.4 million for the first quarter FY2018, an increase of US\$3.1 million (20%) as the Company invested in its Tier 1 clinical programs
- **Manufacturing** expenses were US\$4.3 million for the first quarter FY2019, compared with US\$0.9 million for the first quarter FY2018, an increase of US\$3.4 million due to an increase in manufacturing activities in preparation for filing the Biologics License Application (BLA) for MSC-100-IV
- **Management and Administration** expenses were US\$5.6 million for the first quarter FY2019, compared with US\$5.0 million for the first quarter FY2018, an increase of US\$0.6 million (12%) primarily due to increased legal and professional fees associated with establishing the strategic cardiovascular partnership with Tasly
- **Finance Costs** of US\$2.6 million in interest expenses were recognized in first quarter FY2019 in relation to loan and security agreements entered into with Hercules Capital in March 2018 and NovaQuest Capital in June 2018. No interest expense was recognized in the first quarter FY2018

Additional components of loss after income tax also include 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.

A non-cash income tax benefit of US\$0.7 million was recognized in the first quarter FY2019 in relation to the net change in deferred tax assets and liabilities recognized on the balance sheet during the period. On December 22, 2017, the United States signed into law the Tax Cuts and Jobs Act (the Tax Act), which changed many aspects of United States corporate income taxation, including a reduction in the corporate income tax rate from 35% to 21%. In the first quarter FY2018 deferred tax assets in the United States were recognized at 35% compared with 21% in the first quarter FY2019.

A non-cash income tax benefit of US\$2.9 million was recognized in first quarter FY2018 in relation to the net change in deferred tax assets and liabilities recognized on the balance sheet during the period.

The net loss attributable to ordinary shareholders was US\$19.5 million, or 4.07 cents loss per share, for the first quarter FY2019, compared with US\$7.0 million, or 1.58 cents loss per share, for the first quarter FY2018.

<sup>1</sup>TEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.

#### Conference Call Details

There will be a webcast today on the financial results beginning at 4.30pm on Thursday, November 15, 2018 EST; 8:30 am on Friday, November 16, 2018 AEDT.

The live webcast can be accessed via

<http://webcasting.boardroom.media/broadcast/5bcfb51cf6a4f554d0fe76af>

To access the call only, dial 1 855 881 1339 (U.S.), 1 800 558 698 (toll-free Australia) or +61 2 9007 3187 (outside of the U.S. and Australia). The conference identification code is 667811.

The archived webcast will be available on the Investor page of the Company's website: [www.mesoblast.com](http://www.mesoblast.com)

**Mesoblast Limited**  
ABN 68 109 431 870  
[www.mesoblast.com](http://www.mesoblast.com)

**Corporate Headquarters**  
Level 38  
55 Collins Street  
Melbourne 3000  
Victoria Australia  
T +61 3 9639 6036  
F +61 3 9639 6030

**United States Operations**  
505 Fifth Avenue  
Third Floor  
New York, NY 10017  
USA  
T +1 212 680 2060  
F +1 212 680 2061

**Asia**  
20 Biopolis Way  
#05-01, Centros  
Biopreneur 3  
SINGAPORE 138668  
T +65 6570 0635  
F +65 6570 0176

## About Mesoblast

Mesoblast Limited (ASX: MSB; Nasdaq: MESO) is a world leader in developing allogeneic (off-the-shelf) cellular medicines. The Company has leveraged its proprietary technology platform to establish a broad portfolio of late-stage product candidates with three product candidates in Phase 3 trials – acute graft versus host disease, chronic heart failure and chronic low back pain due to degenerative disc disease. Through a proprietary process, Mesoblast selects rare mesenchymal lineage precursor and stem cells from the bone marrow of healthy adults and creates master cell banks, which can be industrially expanded to produce thousands of doses from each donor that meet stringent release criteria, have lot to lot consistency, and can be used off-the-shelf without the need for tissue matching. Mesoblast has facilities in Melbourne, New York, Singapore and Texas and is listed on the Australian Securities Exchange (MSB) and on the Nasdaq (MESO). [www.mesoblast.com](http://www.mesoblast.com)

## Forward-Looking Statements

This announcement 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 timing, progress and results of Mesoblast's preclinical and clinical studies; Mesoblast's ability to advance product candidates into, enroll and successfully complete, clinical studies; the timing or likelihood of regulatory filings and approvals; 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:

Julie Meldrum	Schond Greenway
Corporate Communications	Investor Relations
Mesoblast	Mesoblast
T: +61 3 9639 6036	T: +1 212 880 2060
E: <a href="mailto:julie.meldrum@mesoblast.com">julie.meldrum@mesoblast.com</a>	E: <a href="mailto:schond.greenway@mesoblast.com">schond.greenway@mesoblast.com</a>

**Mesoblast Limited**  
ABN 68 109 431 870  
[www.mesoblast.com](http://www.mesoblast.com)

**Corporate Headquarters**  
Level 38  
55 Collins Street  
Melbourne 3000  
Victoria Australia

T +61 3 9639 6036  
F +61 3 9639 6030

**United States Operations**  
505 Fifth Avenue  
Third Floor  
New York, NY 10017  
USA

T +1 212 880 2060  
F +1 212 880 2061

**Asia**  
20 Biopolis Way  
#05-01 Centros  
Biopreneur 3  
SINGAPORE 138668

T +65 6570 0635  
F +65 6570 0176



## Consolidated Income Statement

(in U.S. dollars, in thousands, except per share amount)	Three Months Ended	
	2018	2017
Revenue	11,637	1,174
Research & development	(18,489)	(15,368)
Manufacturing commercialization	(4,317)	(877)
Management and administration	(5,614)	(5,012)
Fair value remeasurement of contingent consideration	(622)	9,495
Other operating income and expenses	(151)	668
Finance costs	(2,653)	—
<b>Loss before income tax</b>	<b>(20,209)</b>	<b>(9,920)</b>
Income tax benefit/(expense)	711	2,898
<b>Loss attributable to the owners of Mesoblast Limited</b>	<b>(19,498)</b>	<b>(7,022)</b>
<b>Losses per share from continuing operations attributable to the ordinary equity holders of the Group:</b>	<b>Cents</b>	<b>Cents</b>
Basic - losses per share	(4.07)	(1.58)
Diluted - losses per share	(4.07)	(1.58)

## Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	Three Months Ended	
	2018	2017
<b>Loss for the period</b>	<b>(19,498)</b>	<b>(7,022)</b>
<b>Other comprehensive (loss)/income</b>		
<i>Items that may be reclassified to profit and loss</i>		
Changes in the fair value of available-for-sale financial assets	87	20
Exchange differences on translation of foreign operations	(23)	(358)
Other comprehensive income/(loss) for the period, net of tax	64	(338)
<b>Total comprehensive losses attributable to the owners of Mesoblast Limited</b>	<b>(19,434)</b>	<b>(7,360)</b>

Mesoblast Limited  
ABN 68 109 431 870  
[www.mesoblast.com](http://www.mesoblast.com)

Corporate Headquarters  
Level 38  
55 Collins Street  
Melbourne 3000  
Victoria Australia  
T +61 3 9639 6036  
F +61 3 9639 6030

United States Operations  
505 Fifth Avenue  
Third Floor  
New York, NY 10017  
USA  
T +1 212 880 2060  
F +1 212 880 2061

Asia  
20 Biopolis Way  
#05-01 Centros  
Biopreneur 3  
SINGAPORE 138668  
T +65 6570 0635  
F +65 6570 0176

Consolidated Statement of Balance Sheet

(in U.S. dollars, in thousands)	As of September 30, 2018	As of June 30, 2018
<b>Assets</b>		
<b>Current Assets</b>		
Cash & cash equivalents	55,143	37,763
Trade & other receivables	29,539	50,366
Prepayments	13,129	12,942
<b>Total Current Assets</b>	<b>97,811</b>	<b>101,071</b>
<b>Non-Current Assets</b>		
Property, plant and equipment	1,016	1,084
Available-for-sale financial assets	2,408	2,321
Other non-current assets	3,344	3,361
Intangible assets	584,210	584,606
<b>Total Non-Current Assets</b>	<b>590,978</b>	<b>591,372</b>
<b>Total Assets</b>	<b>688,789</b>	<b>692,443</b>
<b>Liabilities</b>		
<b>Current Liabilities</b>		
Trade and other payables	19,292	18,921
Provisions	8,101	5,082
<b>Total Current Liabilities</b>	<b>27,393</b>	<b>24,003</b>
<b>Non-Current Liabilities</b>		
Deferred tax liability	19,368	20,079
Deferred consideration	10,000	—
Provisions	43,270	42,956
Borrowings	61,159	59,397
<b>Total Non-Current Liabilities</b>	<b>133,797</b>	<b>122,432</b>
<b>Total Liabilities</b>	<b>161,190</b>	<b>146,435</b>
<b>Net Assets</b>	<b>527,599</b>	<b>546,008</b>
<b>Equity</b>		
Issued Capital	889,980	889,481
Reserves	37,309	36,719
(Accumulated losses)/retained earnings	(399,690)	(380,192)
<b>Total Equity</b>	<b>527,599</b>	<b>546,008</b>

Mesoblast Limited  
 ABN 68 109 431 870  
[www.mesoblast.com](http://www.mesoblast.com)

Corporate Headquarters  
 Level 38  
 55 Collins Street  
 Melbourne 3000  
 Victoria Australia  
 t +61 3 9639 6036  
 f +61 3 9639 6030

United States Operations  
 505 Fifth Avenue  
 Third Floor  
 New York, NY 10017  
 USA  
 t +1 212 880 2060  
 f +1 212 880 2061

Asia  
 20 Biopolis Way  
 #05-01 Centros  
 Biopreneur 3  
 SINGAPORE 138668  
 t +65 6570 0635  
 f +65 6570 0176

Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	Three months ended September 30,	
	2018	2017
<b>Cash flows from operating activities</b>		
Commercialization revenue received	1,095	474
Milestone payment received	500	—
Research and development tax incentive received	1,654	—
Payments to suppliers and employees (inclusive of goods and services tax)	(22,039)	(20,892)
Interest received	136	63
Interest paid	(887)	—
Income taxes (paid)/refunded	(3)	(1)
<b>Net cash (outflows) in operating activities</b>	<b>(19,544)</b>	<b>(20,356)</b>
<b>Cash flows from investing activities</b>		
Investment in fixed assets	(39)	(83)
Payments for contingent consideration	—	(543)
<b>Net cash (outflows)/inflows in investing activities</b>	<b>(39)</b>	<b>(626)</b>
<b>Cash flows from financing activities</b>		
Proceeds from borrowings	28,950	—
Payments of transaction costs from borrowings	(1,534)	—
Proceeds from issue of shares	10,048	40,449
Payments for share issue costs	(358)	(2,001)
<b>Net cash inflows by financing activities</b>	<b>37,106</b>	<b>38,448</b>
Net decrease in cash and cash equivalents	17,523	17,466
Cash and cash equivalents at beginning of period	37,763	45,761
FX (losses)/gains on the translation of foreign bank accounts	(143)	(286)
<b>Cash and cash equivalents at end of period</b>	<b>55,143</b>	<b>62,941</b>

Mesoblast Limited  
ABN 68 109 431 870  
[www.mesoblast.com](http://www.mesoblast.com)

Corporate Headquarters  
Level 38  
55 Collins Street  
Melbourne 3000  
Victoria Australia  
T +61 3 9639 6036  
F +61 3 9639 6030

United States Operations  
505 Fifth Avenue  
Third Floor  
New York, NY 10017  
USA  
T +1 212 880 2060  
F +1 212 880 2061

Asia  
20 Biopolis Way  
#05-01 Centros  
Biopreneur 3  
SINGAPORE 138668  
T +65 6570 0635  
F +65 6570 0176



## **Operational Highlights and Financial Results for the Quarter Ended September 30, 2018**

November 2018

Nasdaq: MESO ASX: MSB

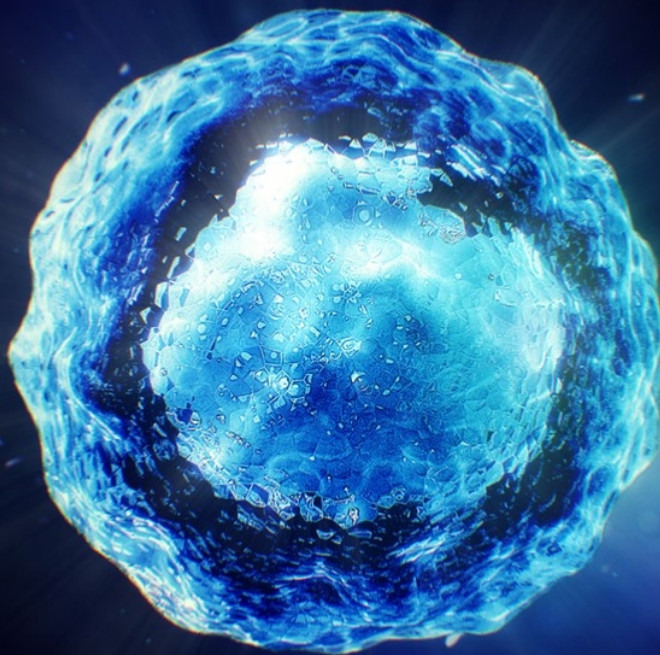


## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

*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





## Disruptive Technology Platform<sup>1</sup>

- Immuno-selected, culture expanded cellular medicines
- Well characterized mechanisms of action targeting multiple pathways
- Extensive, robust IP estate
- Targeting the most severe disease states refractory to conventional therapies

## Industrial Scale Manufacturing

- Unique cell properties enable large scale expansion and use in unrelated recipients
- Proprietary media formulations meet industrial scale needs
- 'Off the shelf' delineated products with batch to batch consistency and reproducibility

## Multiple Revenue Generating Products & Phase 3 Assets

- 2 approved products commercialized by licensees in Japan<sup>2</sup> and Europe<sup>3</sup>
- 3 product candidates in USA Phase 3 trials
- Revenue from licensees will help fund deep product pipeline

1. Mesenchymal precursor cells (MPCs) and their culture-expanded progeny mesenchymal stem cells (MSCs).

2. Licensee JCR Pharmaceuticals Co., Ltd. received the first full PMDA approval for an allogeneic cellular medicine in Japan and markets this product under its trademark, TEMCELL® Hs Inj.

3. Licensee Takeda received first central marketing authorization approval from the European Commission for an allogeneic stem cell therapy and markets this product under its trademark, Alofisel®.

# Disruptive cellular medicine technology

- STRO-1<sup>+</sup> 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 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
- Targeting multiple pathways may result in greater therapeutic benefits in complex diseases



1. Simmons PJ, et al, Blood. 1991;78:55-62  
2. Gronthos S, et al, J Cell Sci. 2003;116(Pt 9):1827-35

3. See F, et al, J Cell Mol Med. 2011;15:2117-29  
4. Psaltis PJ, et al, J Cell Physiol. 2010;223(2):530-40



# Commercial Translation Capabilities

Technology positioned for scalable, industrialized manufacturing

- Immune privileged nature of mesenchymal lineage cells enables allogeneic “off the shelf” product candidates
- Culture expansion scalable to produce anticipated commercial quantities
- Management know-how in regulatory activities necessary for product approval and commercial launch
- If successful, we believe MSC-100-IV (remestemcel-L) will likely be the first commercially produced allogeneic mesenchymal lineage cell product registered for sale in the USA



*Lonza contract manufacturing facility in Singapore*

# Global IP Estate Provides Substantial Competitive Advantage

- ~800 Patents and patent applications (69 Patent families) across all major jurisdictions
- Covers composition of matter, manufacturing, and therapeutic applications of mesenchymal lineage cells
- Enables licensing to third parties for different indications, when in alignment with our corporate strategy, e.g. TiGenix (subsequently acquired by Takeda)
- Provides strong global protection against competitors seeking to develop products in areas of core commercial focus



**Markets**  
U.S., Europe, China, and Japan

**Sources**  
Allogeneic, Autologous, (Bone Marrow, Adipose, Dental Pulp, Placenta), Pluripotent (iPS)

**Diseases**  
All Tier 1 & Tier 2 Indications, and multiple additional conditions

# Commercial Products and Clinical Pipeline Using Mesoblast's Intellectual Property and Technology Platform

PLATFORM	PRODUCT	THERAPEUTIC AREA	APPROVAL	COMMERCIAL RIGHTS	MARKETED
MSC (Bone Marrow)	TEMCELL® HS Inj <sup>1</sup>	Acute GVHD	1st allogeneic regen med approved in Japan	✓ JCR	
MSC (Adipose)	Alofisel <sup>2</sup>	Perianal Fistula	1st allogeneic regen med approved in Europe	✓ Takeda	Global

	PLATFORM	PRODUCT CANDIDATE	THERAPEUTIC AREA	PRE-CLINICAL	PHASE 2	PHASE 3	COMMERCIAL RIGHTS	IN DEVELOPMENT
	TIER 1	MSC	MSC-100-IV	Acute GVHD	[Progress bar]			
MPC		MPC-150-IM	Advanced HF (Class II/III) End-Stage HF (Class III/IV) <sup>3</sup>	[Progress bar]			mesoblast the regenerative medicine company TASLY China <sup>4</sup>	
MPC		MPC-06-ID	Chronic Low Back Pain	[Progress bar]			mesoblast the regenerative medicine company	
MPC		MPC-300-IV	Rheumatoid Arthritis Diabetic Nephropathy	[Progress bar]			mesoblast the regenerative medicine company	

**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)

- Mesoblast receives royalty income from its licensee JCR Pharmaceuticals Co Ltd on sales of JCR's TEMCELL® HS. Inj. product in Japan
- Mesoblast will receive royalty income from its licensee Takeda Pharmaceuticals on Takeda's worldwide sales of its product Alofisel® in the local treatment of perianal fistulae
- Study funded by the United States National Institutes of Health (NIH) and the Canadian Health Research Institute; conducted by the NIH-funded Cardiothoracic Surgical Trials Network
- Tasly's rights are limited to China; Tasly also has rights to develop MPC-25-IC for AMI

*This chart is figurative and does not purport to show individual trial progress within a clinical program*

## Strategic Cardiovascular Partnership in China



- Tasly Pharmaceutical Group has exclusive rights and will fund all development, manufacturing and commercialization activities in China for MPC-150-IM for the treatment or prevention of chronic heart failure and MPC-25-IC for the treatment or prevention of acute myocardial infarction
- Mesoblast received US\$40 million on closing
- Mesoblast to receive US\$25 million on product regulatory approvals in China
- Mesoblast will receive double-digit escalating royalties on net product sales and six escalating milestone payments upon product candidates reaching certain sales thresholds in China
- Partners may leverage each other's clinical trial results to support their respective regulatory submissions in the USA and China
- Our advisor on the transaction was Maxim Group LLC



## Financials

## Significant Increase in Revenue

Revenue for the quarter ending September 30, 2018 (US\$m)

For the quarter ending	September 30, 2018	September 30, 2017	\$ Change	% Change
Milestone revenue	10.5	0.5	10.0	NM
Commercialization revenue	1.0	0.6	0.4	66%
Interest revenue	0.2	0.1	0.1	93%
<b>Total revenue</b>	<b>11.6</b>	<b>1.2</b>	<b>10.5</b>	<b>NM</b>

### First quarter FY2019 revenue increased by US\$10.5 million vs 2018 revenue due to:

- Commercialization revenue from royalty income on sales of TEMCELL®<sup>1</sup> HS. Inj. increased 66% for the quarter and 116%<sup>2</sup> for the 12 months ended September 30, 2018 compared to the 12 months ended September 30, 2017
- US\$10.0 million of milestone revenue in relation to establishing a strategic cardiovascular partnership with Tasly in China

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

2. Growth reported in constant currency which eliminates the effects of fluctuations in foreign exchange rates between different reporting periods.

## Loss After Tax

Profit and Loss for the quarter ending September 30, 2018 (US\$m)

For the quarter ending	September 30, 2018	September 30, 2017	\$ Change	% Change
<b>Total revenue</b>	<b>11.6</b>	<b>1.2</b>	<b>10.5</b>	<b>NM</b>
Research and development	(18.5)	(15.4)	(3.1)	20%
Manufacturing	(4.3)	(0.9)	(3.4)	NM
Management & administration	(5.6)	(5.0)	(0.6)	12%
Contingent consideration	(0.6)	9.5	(10.1)	(107%)
Other operating income & expenses	(0.2)	0.7	(0.8)	(123%)
Finance costs	(2.6)	-	(2.6)	NM
<b>Loss before tax</b>	<b>(20.2)</b>	<b>(9.9)</b>	<b>(10.3)</b>	<b>104%</b>
Income tax benefit	0.7	2.9	(2.2)	(75%)
<b>Loss after tax</b>	<b>(19.5)</b>	<b>(7.0)</b>	<b>(12.5)</b>	<b>178%</b>

**Loss after tax increased by \$12.5 million compared to the first quarter FY2018, \$10.1 million of which is due to non-cash remeasurement of contingent consideration in the comparative quarter**

## Consistent Operating Cash Outflows

### Cash flow highlights (US\$m)

For the quarter ending	September 30, 2018	September 30, 2017	\$ Change	% Change
Operating net cash outflows	(19.5)	(20.4)	0.9	(4%)
Investing net cash (outflows)/inflows	-	(0.6)	0.6	(100%)
Financing net cash inflows	37.1	38.5	(1.4)	(4%)
Forex	(0.2)	(0.3)	0.1	(33%)
Net increase/(decrease) in cash	17.4	17.2	0.2	1%

- Operating net cash outflows reduced by 4% for the quarter ended September 30, 2018 versus the prior period due to increased revenues



## Cash Position Strengthened through Strategic Transactions

### Balance sheet cash (US\$m)

	September 30, 2018	June 30, 2018	\$Change
Reported Cash on Hand	55.1	37.8	17.3
NovaQuest financing agreement	-	39.0	(39.0)
Tasly strategic partnership	40.0	40.0	-
<b>Pro forma cash on hand</b>	<b>95.1</b>	<b>116.8</b>	<b>(21.7)</b>

- Pro forma cash on hand at September 30 includes US\$40 million received in October 2018 on closing of the strategic cardiovascular partnership with Tasly previously announced in July 2018
- An additional US\$50 million may be available under existing arrangements with Hercules Capital and NovaQuest, subject to achievement of certain milestones



## Diverse Pipeline of Cellular Medicines



**MSC-100-IV (remestemcel-L)  
for Steroid-Refractory  
Acute Graft vs Host Disease**



# Remestemcel-L: Market Opportunity for Acute Graft Versus Host Disease (aGVHD)

## Burden of Illness

- aGVHD is a life-threatening complication that occurs in ~50% of patients receiving allogeneic bone marrow transplants (BMT)<sup>1</sup>
- Steroid-refractory aGVHD is associated with **mortality rates as high as 95%<sup>1</sup> and significant extended hospital stay costs<sup>2</sup>**

## Minimal Treatment Options

- There are **no approved treatments for SR-aGVHD outside Japan**
- In Japan, Mesoblast's licensee has received the only product approval for SR-aGVHD in both children and adults

## Market Opportunity

- >30,000 allogeneic BMTs performed globally (>20K US/EU) annually, ~20% pediatric<sup>3,4</sup>
- Our licensee, JCR Pharmaceuticals Co., Ltd launched TEMCELL<sup>®</sup> HS Inj.<sup>5</sup> in Japan for SR-aGVHD in 2016; reimbursed up to ~\$USD195k<sup>6</sup>
- **SR-aGVHD represents USD > \$700m USA/EU market opportunity<sup>4,7</sup>**



1. Westin, J., Saliba, RM., Lima, M. (2011) Steroid-refractory acute GVHD: predictors and outcomes. *Advances in Hematology*. 2. Anthem-HealthCore/Mesoblast claims analysis (2016). Data on file 3. Niederwieser D, Baldomero H, Szer J. (2016) Hematopoietic stem cell transplantation activity worldwide in 2012 and a SWOT analysis of the Worldwide Network for Blood and Marrow Transplantation Group including the global survey. 4. Source: CIBMTR. Current Uses and Outcomes of Hematopoietic Cell Transplantation 2017 Summary. Passweg JR, Baldomero, H (2016) Hematopoietic stem cell transplantation in Europe 2014: more than 40,000 transplants annually. 5. TEMCELL is the registered trademark of JCR Pharmaceuticals Co. Ltd. 6. Based on a ¥/JPY = \$USD 0.009375 spot exchange rate on market close on November 11, 2016. Amounts are rounded. Source: Bloomberg. 7. Data on file

## Remestemcel-L: Phase 3 Trial Operational Update



- Phase 3 study evaluated remestemcel-L in 55 children to improve overall response rate and survival
  - 89% of children had grade C/D disease, the most severe form and historically associated with up to 95% mortality
- Study successfully met the primary endpoint of improved Day 28 Overall Response (OR)
  - 69% vs 45% protocol-defined historical control rate (p=0.0003)
- Day 100 Overall Survival 75%, with 87% survival in Day 28 responders
- Day 180 Overall Survival 69%, with 79% survival in Day 28 responders
- Remestemcel-L infusions well tolerated
- Findings consistent with previous results in 241 SR-aGVHD children under expanded access program who failed to respond to multiple biologic agents<sup>1</sup>

1. Kurtzberg J, et al. Effect of Human Mesenchymal Stem Cells (remestemcel-L) on Clinical Response and Survival Confirmed in a Large Cohort of Pediatric Patients with Severe High-Risk Steroid-Refractory Acute Graft Versus Host Disease. *BBMT*. 2016; 22.

# GVHD Pathway to Market

## Regulatory

- Preparations for Biologics License Application (BLA) filing underway
- FDA meetings and BLA filing (Q4 CY18 – Q1 CY19)
- Fast Track designation allows eligibility for priority review and rolling BLA review process

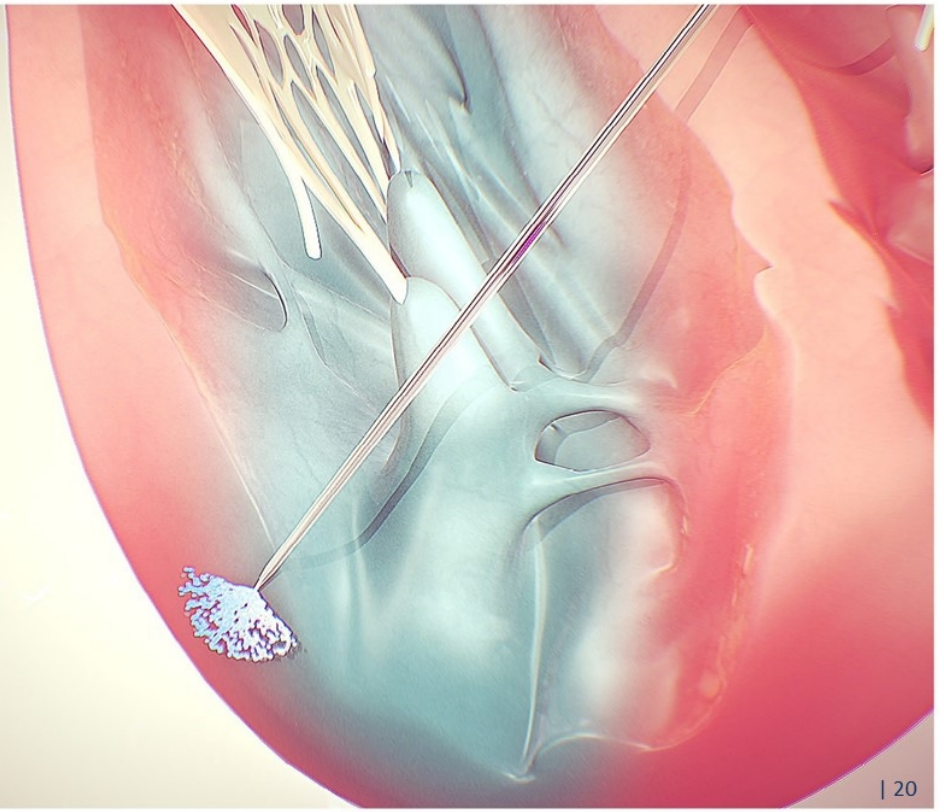
## Commercial

- Parallel track commercial planning for pricing, reimbursement approach and product launch
- Leverage TEMCELL<sup>®</sup> HS Inj. sales experience in Japan to inform commercial strategy for the USA

**Rapid adoption within two years of launch**

**Continuing growth in royalty income on TEMCELL<sup>®</sup> HS Inj. sales in Japan**

**MPC-150-IM for  
Chronic Heart Failure**

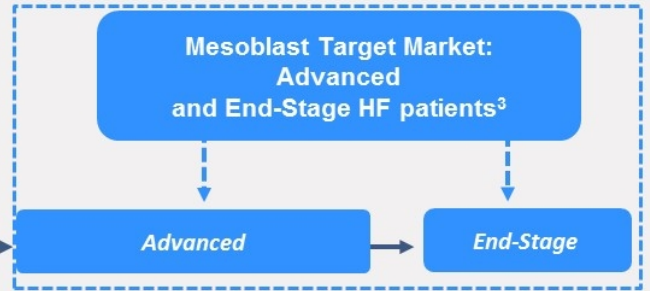


## Common Treatment Pathway in Progressive Heart Failure<sup>1</sup>

- Early**
- ACEI or ARB
  - Statins
  - Beta blockers
  - Re-vascularization or valvular surgery

- Pharmacological Add-on**
- Diuretics for fluid retention
  - Aldosterone antagonists
  - Hydralazine / isosorbide dinitrate
  - Digitalis

- New Oral Therapies for Class II-IV<sup>2</sup>**
- If ACEI / ARB tolerated, sacubitril/valsartan
  - If HR > 70 BPM, ivabradine



**Limited Therapeutic Options**

- Cardiac Resynchronization Therapy (CRT)
- Implantable Cardioverter-Defibrillator (ICD)
- LVAD
- Heart transplants

**Class I**

**Heart Failure Disease Progression**

**Class IV**

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); McIlmurray 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: Adjunctive Therapy to Improve Clinical Outcomes in LVAD Patients

## Burden of Illness

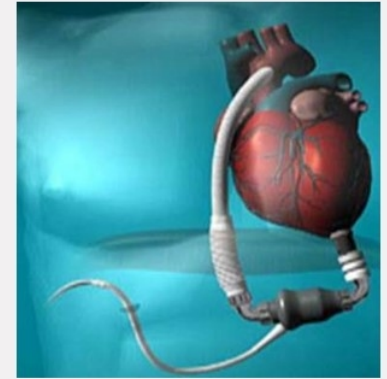
- In the USA, there are approximately 250,000–300,000 patients annually who suffer from advanced systolic heart failure (NYHA Class IIIb–IV).<sup>1</sup>
- Despite optimal medical therapy (excluding mechanical assist devices) Class IIIb have a one-year mortality >25% and exceeding 50% in class IV patients.<sup>1</sup>

## Ongoing Unmet Need

- LVADs have improved survival, but morbidity remains high with patients on average experiencing greater than two hospitalization annually.<sup>2</sup>
- Gastrointestinal (GI) bleeding is a leading cause of device attributable hospitalizations<sup>2</sup>
- **Device attributable major adverse events (DAEs) can cost on average from up to \$46.5k per hospitalization<sup>2</sup>**

## Market Opportunity

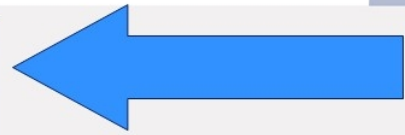
- ~4,500–5,500 assist devices are implanted annually in the United States.<sup>3, 4</sup>
- **US LVAD market is growing double-digit CAGR and represents > \$500m market opportunity<sup>3,4</sup>**
- Orphan indication with US targeted commercial footprint provides low cost market entry



<sup>1</sup>Gustafsson G, Rogers J. (2017) Left ventricular assist device therapy in advanced heart failure: patient selection and outcomes, <sup>2</sup> Mehra, MR, Salerno C, Cleveland JC (2018) Health care resources use and cost implications in the MOMENTUM 3 long-term outcome study: a randomized controlled trial of a magnetically levitated cardiac pump in advanced heart failure, <sup>3</sup>Agency for Healthcare Research and Quality – Healthcare Cost and Utilization Project – claims analysis using ICD-937.6 implantation of heart and circulatory assist systems, <sup>4</sup> Data on File

# INTERMACS\* Adverse Event Rates in LVAD Patients: Most Common Cause of Non-surgical Hospitalization is Major GI Bleeding<sup>1</sup>

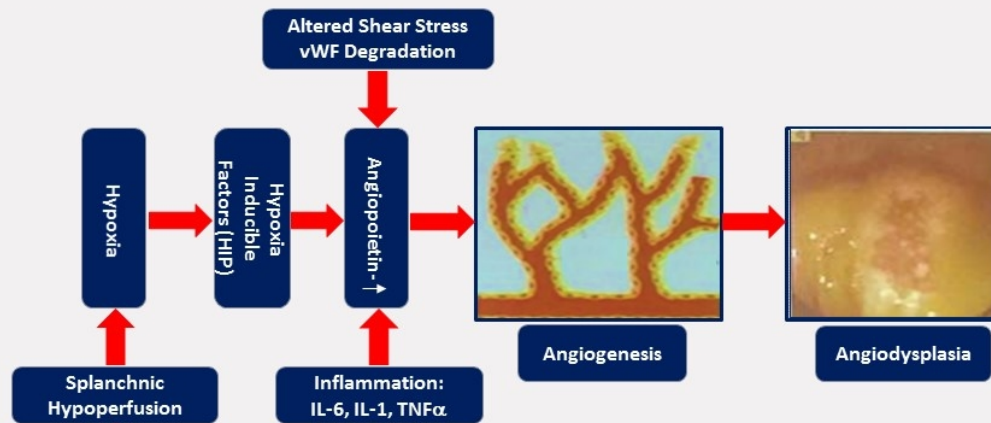
Adverse Event	Events	Rate
Bleeding	4,420	7.79
Cardiac/vascular		
Right-sided heart failure	276	0.49
Myocardial infarction	34	0.06
Cardiac arrhythmia	2,303	4.06
Pericardial drainage	305	0.54
Hypertension	115	0.20
Arterial non-CNS thrombosis	94	0.17
Venous thrombotic event	286	0.50
Hemolysis	314	0.55
Infection	4,132	7.28
Stroke	916	1.61
Renal dysfunction	876	1.54
Hepatic dysfunction	326	0.57
Respiratory failure	1,551	2.73
Wound dehiscence	96	0.17
Psychiatric episode	525	0.93
Total burden	16,569	29.20



\*Interagency Registry for Mechanically Assisted Circulation (INTERMACS): Events per 100 Patient-Months in the First 12 Months Post-Implant, based on 7,286 patients with CF-LVADs between 2012-2014.

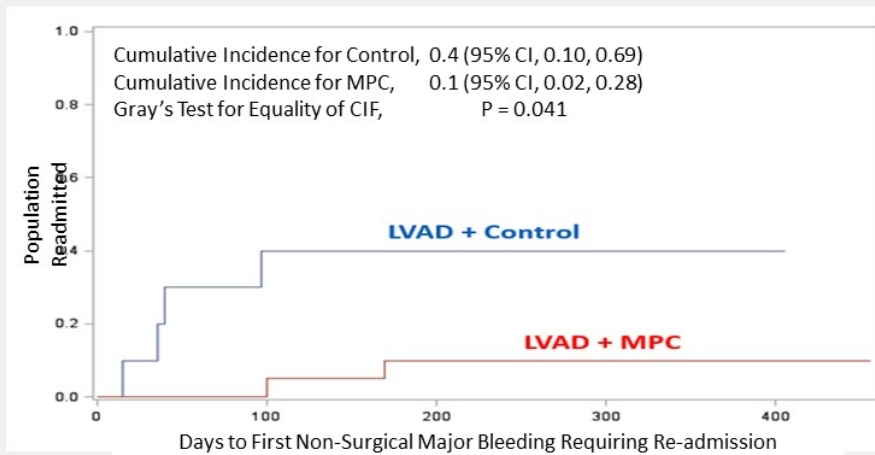
1. Left Ventricular Assist Devices for Lifelong Support Pinney SP, et al. JACC 2017;69:2845-61.

# Proposed Pathway of Angiogenesis and Non-surgical GI Bleeding During CF-LVAD



An integrating explanation relating to LVAD mediated GI bleeding events is that all of these precipitating factors are in some way related to increased systemic inflammation resulting in increased serum levels of angiopoietin-2, a well-documented agent that causes vascular disruption and destabilization.

# MPCs Reduced Major GI Bleeding in 30 Patient Pilot Trial<sup>1</sup>



- MPC group had significantly longer time to first hospitalization due to major GI bleeding ( $p < 0.05$ , Kaplan-Meier statistics)
- 71% reduction in number of patients with at least one hospitalization from GI bleeding through 6 months (16% in LVAD group vs 55% in controls,  $p = 0.03$  by chi-square test)
- 70% reduction in rate of hospitalizations due to GI bleeding per 100 patient-months of follow-up (4.2 in LVAD group vs 14.2 in controls,  $p = 0.06$  by binomial test)

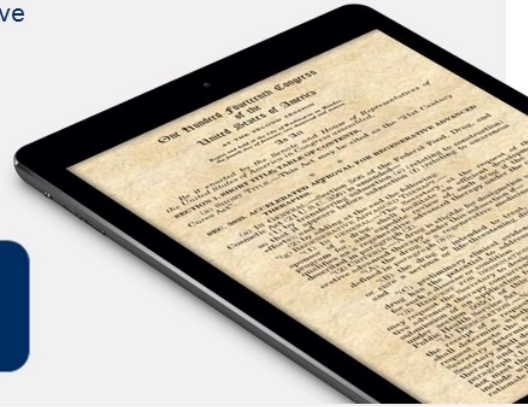
1. Source: Data on file.

# The 21<sup>st</sup> 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 patient registry data and other sources of “real world evidence” for post approval studies, subject to approval by the FDA

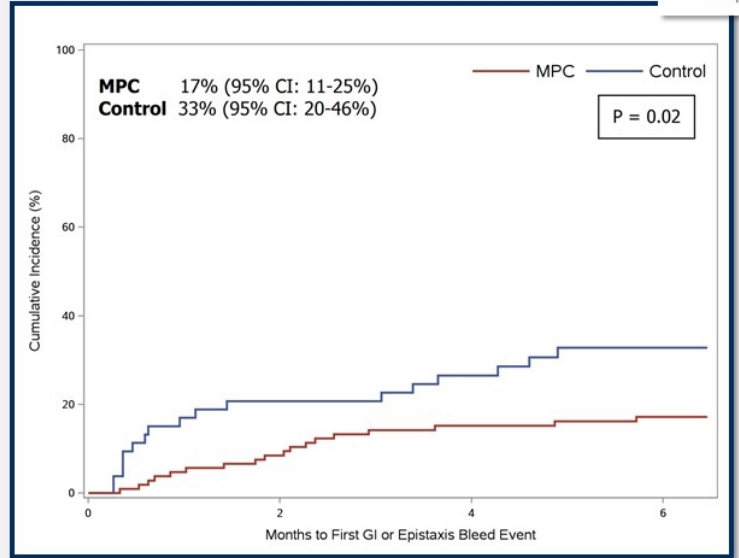
**MPC-150-IM for End-Stage Heart Failure Patients with LVADs Received RMAT Designation**



# Mucosal Bleeding at 6 Months in Phase 2 Trial

## Rate of GI/Epistaxis Bleeding

MPC (n = 106)	Control (n = 53)	P-value
Event Rate (100-Pt-Months)	Event Rate (100-Pt-Months)	
<b>3.8</b>	<b>15.9</b>	<b>&lt;0.001</b>

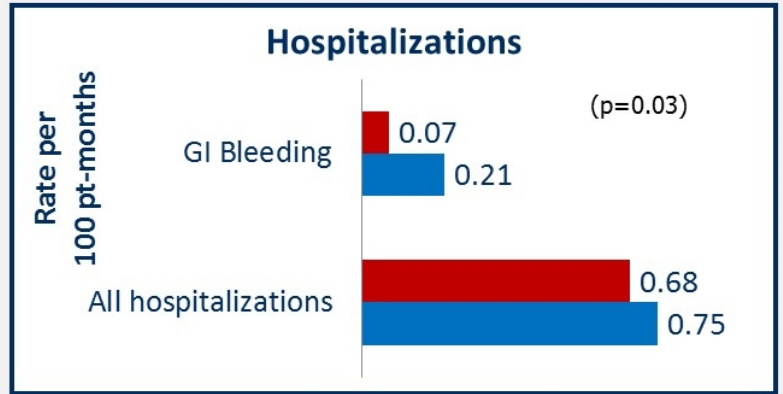
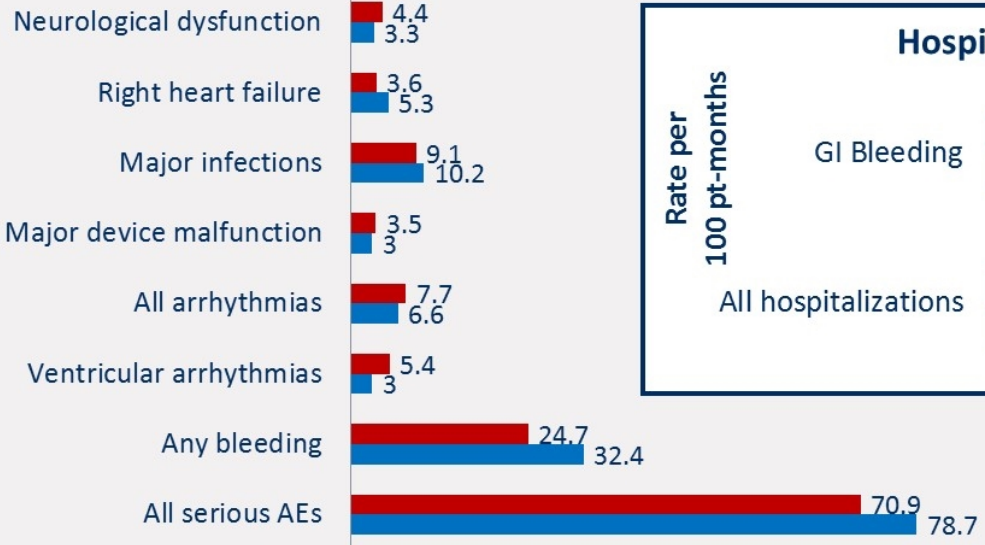


# Serious AEs & Hospitalizations at 6 Months in Phase 2 Study



■ MPC ■ Control

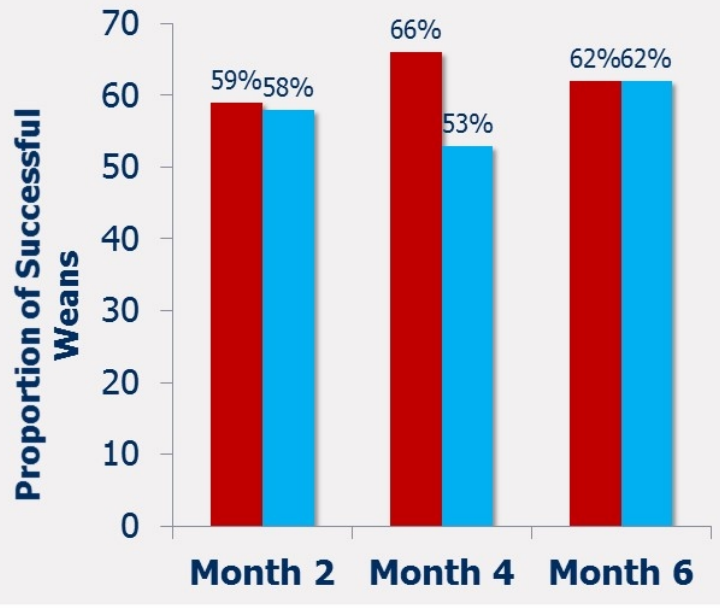
Rate per 100 pt-months



# Successful Temporary Weans from LVAD Support



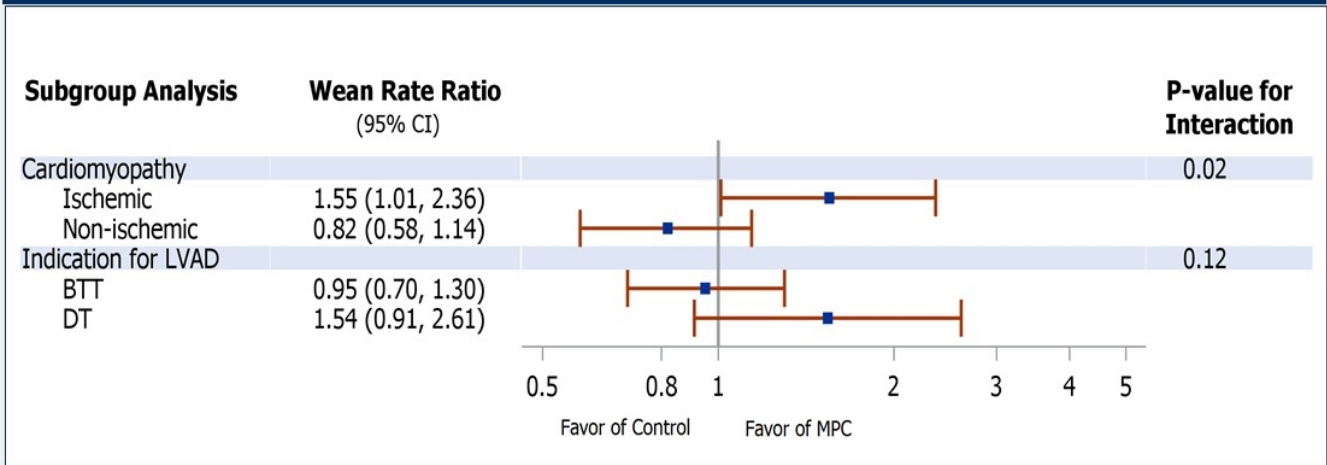
- Average proportion of successful temporary weans:
  - **61% in MPC vs. 58% in control**
  - RR=1.08 (95% CI 0.83-1.41; p=0.55)
- Posterior probability that MPC increased likelihood of successful weaning:
  - **69%** (<80% pre-defined threshold)



■ MPC  
■ Control



## Interaction of Rx and Pre-determined Subgroups on Wean Success Rate over 6 Months



## Conclusions

- The trial succeeded in achieving the clinically meaningful outcome of reduction in gastrointestinal (GI) bleeding and related hospitalizations
- Results confirm the previous pilot trial, which also demonstrated significant reduction in GI bleeding and related hospitalizations in MPC-150-IM treated LVAD patients
- Pilot trial results formed the basis for the FDA Regenerative Medicine Advanced Therapy (RMAT) designation granted in December 2017
- The RMAT designation under the 21st Century Cures Act aims to expedite the development of regenerative medicine therapies intended for the treatment of serious diseases and life-threatening conditions
- Company intends to meet with the FDA in 1H CY2019 to provide full study data and discuss pathway to potential Biologics License Application (BLA) filing using reduction in GI bleeding and related hospitalizations as an approvable regulatory endpoint
- While the trial did not meet the overall primary endpoint of temporary weaning, MPC-150-IM treatment did significantly improve weaning in the 44% of patients with chronic ischemic heart failure
- LVAD patients with ischemic heart failure closely resemble the majority of patients enrolled in the ongoing Phase 3 trial of approximately 600 patients with moderate/advanced heart failure

# MPC-150-IM: Moderate/Advanced Heart Failure Market Opportunity

## Burden of Illness/Limited Options

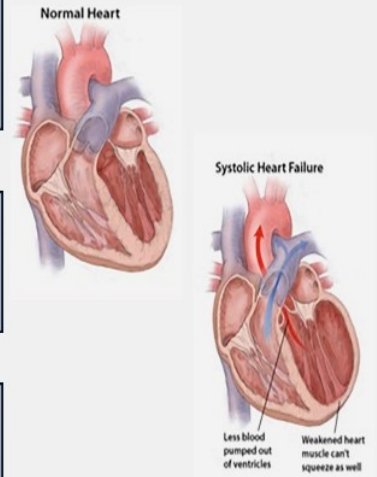
- ~ 8 million patients with chronic heart failure by 2030 in USA alone<sup>1</sup>
- 17-45% globally die within 1 year of hospital admission<sup>1</sup>
- Majority of advanced heart failure patients die within 5 years<sup>1</sup>
- Despite recent advances in newly approved drugs, limited treatment options are available for patients with advanced heart failure<sup>2</sup>

## Unmet Need

- New therapies to reduce hospitalizations and mortality in patients with advanced heart failure who have failed other therapies
- Greatest need is in NYHA class III/IV where event rate is highest

## Market Opportunity

- US healthcare costs for NYHA class II-IV patients \$115bn/year<sup>5</sup>
- Hospitalizations account for ~69% of expenditure<sup>3-5</sup>
- **Multi-billion dollar annual market opportunity in USA for a new treatment that reduces hospitalizations in advanced heart failure<sup>4,5</sup>**



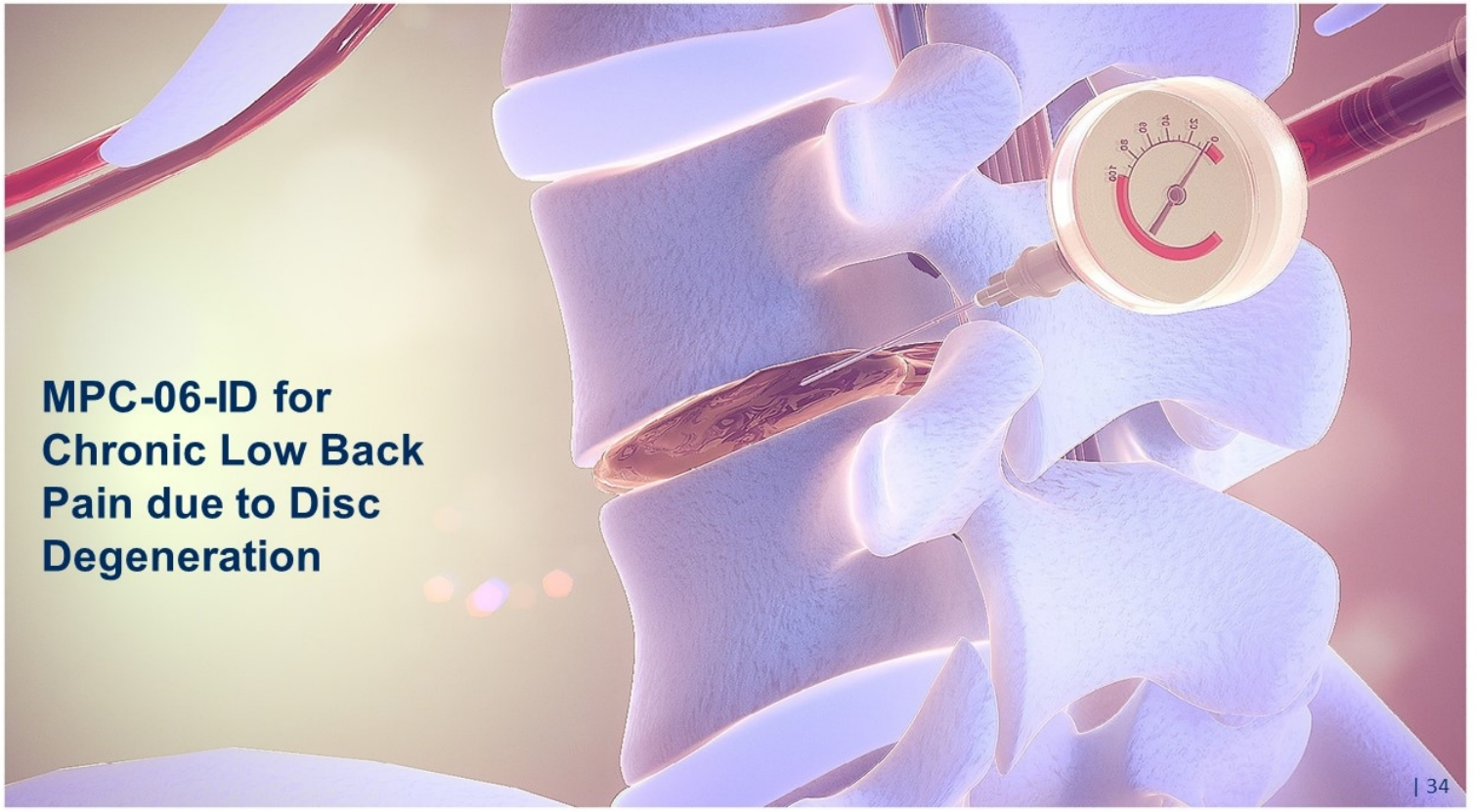
1. Heart Failure: Preventing disease and death worldwide – European Society of Cardiology. 2014. 2. ACC/AHA/HFSA Focused Update on New Pharmacological Therapy for Heart Failure: An Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure. 3. Gurwitz JH, Magid DJ, Smith DH, et al. Contemporary 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. Clinl 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: Phase 3 Program in Patients with Moderate to Advanced Heart Failure

- More than 85% of patients enrolled in events-driven USA Phase 3 trial, targeting ~600 patients
- Pre-specified interim futility analysis of the efficacy endpoint in the first 270 patients was successfully achieved in April 2017
- In October 2018, Data Monitoring Committee recommended continuation of the trial without modification after a scheduled review of available data from 526 randomized patients, including the primary and secondary endpoints of HF-MACE, terminal cardiac events, and all safety data
- Planning to initiate China Phase 3 trial in similar patient population with Tasly

**Plan to leverage USA and global Phase 3 trial results performed by strategic partners for global regulatory submissions**

**MPC-06-ID for  
Chronic Low Back  
Pain due to Disc  
Degeneration**



# MPC-06-ID: Chronic Low Back Pain due to Degenerative Disc Disease

## Burden of Illness

- Back pain causes more disability than any other condition<sup>1</sup>
- Inflicts substantial direct and indirect costs on the healthcare system,<sup>1</sup> including excessive use of opioids in this patient population<sup>2</sup>

## Minimal Treatment Options

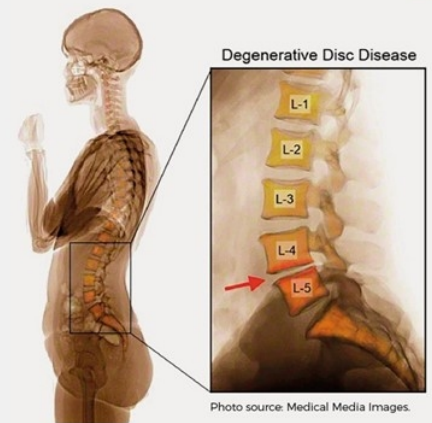
- Treatment options for patients with CLBP who fail conservative therapy include opioids and surgery
- 50% of opioid prescriptions are for chronic low back pain (CLBP)<sup>2</sup>

## Unmet Need

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

## Market Opportunity

- MPC-06-ID development focused on over ~3.2m patients with CLBP due to degenerative disc disease (DDD) in US alone<sup>3,4,5</sup>
- **USA market opportunity ~USD \$1 billion**<sup>3,4,5,6</sup>



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. Decision Resources: Pain Management Study, Chronic Pain December 2013. 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. Data on File.

## MPC-06-ID: Phase 3 Trial in Patients with Chronic Low Back Pain



- Phase 3 study completed enrollment in March 2018
- Over 400 patients were enrolled at 48 sites across USA and Australia
- Patients randomized 1:1:1 to receive saline, 6-million MPCs with hyaluronic acid and 6-million MPCs without hyaluronic acid
- Primary efficacy composite endpoint requires a patient to achieve:
  - Reduction in pain (50% decrease in VAS) and improvement in function (15 point improvement in ODI) at 12 and 24 months, and
  - No additional intervention at the treated level through 24 months



## Milestones



# CY 2018 Corporate Milestones



## **MSC-100-IV for Acute Graft versus Host Disease**

- Successfully met Day 28 primary end point pediatric Phase 3 trial (Q1 CY18) ✓
- Day 100 survival/safety data pediatric Phase 3 trial (Q2 CY18) ✓
- Day 180 survival/safety data pediatric Phase 3 trial (Q3 CY18) ✓
- FDA meetings and BLA filing (Q4 CY18 – Q1 CY19)

## **MPC-150-IM for Advanced and End-Stage Heart Failure**

- Phase 2b trial full 12 month database lock in end-stage heart failure patients with LVADs (Q3 CY18) ✓
- Phase 2b results presented as late-breaker at 2018 Scientific Session of the American Heart Association (Q4 CY18) ✓
- Phase 3 events-driven trial in moderate/advanced heart failure enrollment completion (H2 CY18)

## **MPC-06-ID for Chronic Low Back Pain**

- Phase 3 trial completed enrollment (Q1 CY18) ✓

**Completed non-dilutive transactions for commercialization of MSC-100-IV (remestemcel-L) ✓**

**Establish regional strategic and commercial partnerships (China, Japan, Europe) ✓**

**Establish global commercial partnerships**



Questions?

