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 August 2019

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 ☑

INFORMATION CONTAINED ON THIS REPORT ON FORM 6-K

On August 30, 2019, 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: September 5, 2019

INDEX TO EXHIBITS

Item	
99.1	Press release of Mesoblast Ltd, dated August 30, 2019.
99.2	Investor presentation of Mesoblast Ltd, dated August 30, 2019

asx announcement

mesoblast
the regenerative medicine company

MESOBLAST REPORTS 2019 FULL YEAR RESULTS

Strong Operational Progress and Continued Growth in Revenues from Royalties

Melbourne, Australia; August 30, 2019; and New York, USA, August 29, 2019: Mesoblast Limited (ASX: MSB; Nasdaq: MESO) today reported strong operational progress and financial highlights for the fourth quarter and full-year ended June 30, 2019 (FY2019).
Mesoblast Chief Executive Dr Silviu Itescu stated: "The Company is well positioned to deliver substantial shareholder value in the coming year. Our expenditure over the 2019 financial year has been specifically targeted at advancing our lead cell therapy candidates towards commercialization. We are excited about the planned readouts of our major Phase 3 trials in chronic heart failure and low back pain, and are also especially pleased with the growth in revenues on graft versus host disease (GVHD) product sales in Japan as we progress the United States Food and Drug Administration (FDA) filing process to seek approval of our GVHD product in the United States market."

Continued Growth in Revenues from Japan Royalties

The Company is pleased to report continued growth in revenues from royalties on sales of TEMCELL® HS. Inj.[1] in Japan for steroid-refractory acute graft versus host disease (aGVHD) by Mesoblast licensee JCR Pharmaceuticals Co. Ltd. Revenues from royalties on TEMCELL sales increased by 37% to US$5.0 million for the fiscal year. In the most recent quarter, revenues from royalties increased by 54% to US$1.7 million. Total revenue was stable at US$16.7 million in FY2019 compared with US$17.3 million in FY2018.

Capital Strategy

Cash on hand was US$50.4 million (A$71.9 million) at June 30, 2019.

In addition, Mesoblast may have access to additional sources of capital, as follows:

- Under its agreements with Hercules Capital, Inc. and NovaQuest Capital Management, LLC., the Company has up to US$35.0 million available subject to achievement of certain milestones.
- Mesoblast has entered into a Subscription Commitment Letter with its largest institutional shareholder, M&G Investment Management, for US$15.0 million in Mesoblast ordinary shares, exercisable by the Company on or before 31 December 2019, subject to customary diligence and with pricing to be agreed at the time Mesoblast gives notice
- The Company will receive further milestone and royalty payments from its existing strategic partners JCR, Takeda Pharmaceuticals Company Ltd. and Tasly Pharmaceutical Group.
- Mesoblast remains in advanced negotiations with a number of additional potential commercial partners regarding transactions and access to non-dilutive capital[2].
- Mesoblast has extended its fully discretionary equity facility with Kentgrove Capital of up to A$120.0 million (approximately US$82.0 million) for the next 24 months.

Graft Versus Host Disease

There are more than 30,000 allogeneic bone marrow transplants performed annually worldwide[3], primarily in patients being treated for blood cancers. The most severe forms of the disease, Grades C/D or III/IV, are frequently refractory to steroid therapy and associated with mortality rates as high as 90%[4,5].

There are no approved therapies for aGVHD in the United States for children under 12.

Mesoblast Limited
ABN 68 109 431 870

www.mesoblast.com

Corporate Headquarters
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55 Collins Street
Melbourne 3000
Victoria Australia

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

United States Operations
505 Fifth Avenue
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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

In Mesoblast's Phase 3 trial of 55 children with aGVHD - 89% of whom had Grade C/D disease - treatment with remestemcel-L resulted in a six-month survival of 69%. In addition, achievement of an Overall Response at Day 28, which occurred in 69% of patients, predicted highest survival at Day 100 and Day 180, which was 85% and 79%, respectively. The trial successfully met its primary endpoint of increased Day 28 Overall Response compared with a protocol-defined historical control rate of 45% (p=0.0003). These data are consistent with prior results from an Expanded Access Program in 241 children where remestemcel-L was used as salvage therapy after failure of steroids and other agents.

Remestemcel-L is administered to patients in a series of intravenous infusions. Remestemcel-L has demonstrated immunomodulatory properties to counteract the inflammatory processes that are implicated in aGVHD by down-regulating the production of pro-inflammatory cytokines, increasing production of anti-inflammatory cytokines, and enabling recruitment of naturally occurring anti-inflammatory cells to involved tissues.

Potential United States Market for Remestemcel-L

The product adoption and reimbursement seen in the Japan GVHD market for TEMCELL informs Mesoblast's United States commercial strategy for remestemcel-L in aGVHD. The Company believes that the United States addressable market opportunity for remestemcel-L in aGVHD in children and adults is approximately eight times larger than Japan given differences in population size, incidence of aGVHD, and relative pharmacoeconomics[6,,7,8,9].

Mesoblast is preparing for potential product launch in the United States of remestemcel-L for aGVHD in children. Health economics and outcomes research data presented by Mesoblast at the 24th European Hematology Association Congress indicated that pediatric aGVHD may result in significant deterioration in quality of life and additional direct healthcare costs of an average of up to US$500,000 per patient. This represents a significant commercial opportunity for Mesoblast's first potential product launch in the United States.

Filing for FDA approval

The rolling Biologics License Application (BLA) submission to the FDA is underway and we expect to complete the filing in CY2019. Remestemcel-L has received Fast Track designation for aGVHD and under this designation Mesoblast can request a priority review once its BLA filing is accepted by the FDA.

Commercial Activities for Potential Launch in United States

In line with our expected timelines for potential United States launch of remestemcel-L, Mesoblast has increased expenditure on commercial manufacturing activities and commercial team ramp up in parallel with its FDA filing activities.

Life Cycle Strategy for Remestemcel-L

Mesoblast intends to expand its clinical program into the adult aGVHD segment. In addition, an investigator-initiated study evaluating remestemcel-L in children is planned in the United States for chronic GVHD.

Mesoblast has the right to use all safety and efficacy data generated by JCR in Japan for TEMCELL to support its life cycle strategy for remestemcel-L in the United States and other major healthcare markets. JCR has filed to extend marketing approval for TEMCELL in wound healing in patients with Epidermolysis Bullosa, and is evaluating the use of TEMCELL for the treatment of newborns who lack sufficient blood supply and oxygen to the brain, a condition termed hypoxic ischemic encephalopathy.

Chronic Heart Failure

Advanced Heart Failure

In the United States alone, of more than 6.5 million patients with chronic heart failure, there are more than 1.3 million patients with advanced stage of the disease who have high rates of morbidity and mortality despite maximal existing therapies[10]. This well-defined major treatment gap in these needy patients is a potential multi-billion dollar market opportunity for Mesoblast. The objective of treatment with Mesoblast's allogeneic cell therapy Revascor is to prevent or delay further progression of heart failure or death.

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Corporate Headquarters
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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

The American Heart Association journal *Circulation Research*[11] recently published a Special Article highlighting the important potential clinical benefits of Revascor as an immunotherapy in patients with advanced chronic heart failure, stating that there is a biologic rationale for the use of Revascor in targeting cardiac inflammation in order to improve heart failure outcomes.

In a post-hoc analysis of an earlier Phase 2 trial published in *Circulation Research*[12], it was found that control patients with very enlarged hearts (left ventricular end systolic volume >100ml) deteriorated most rapidly, while similar patients receiving Revascor were protected against disease progression. These Phase 2 findings identified the patient population most likely to benefit from Revascor and guided the clinical trial design for the subsequent Phase 3 study.

In Mesoblast's randomized, placebo-controlled Phase 3 trial, enrollment of 566 patients has been completed across 55 centers in North America. The trial's primary endpoint is reduction in heart failure-related hospital admissions, and the key secondary endpoint is reduction in terminal cardiac events.

Revascor was successful in April 2017 in a pre-specified futility analysis of the Phase 3 trial's primary efficacy endpoint in the first 270 patients enrolled in the trial.

Currently, approximately 90% of events in this Phase 3 trial have been accrued and validated. Mesoblast expects the trial to accrue all the requisite primary events by the end of CY2019 with readouts planned during the first half of CY2020.

End-stage Heart Failure

In the United States, over 60,000 patients annually suffer from end-stage heart failure[13], and despite optimal medical therapy these patients have a one-year mortality exceeding 50%[14]. The only options to increase survival in these patients are the use of heart transplants or left ventricular assist devices (LVADs). The use of LVADs is gaining momentum, with approximately 5,500 LVADs implanted annually in the United States[15,16,17].

In patients implanted with an LVAD, endothelial dysfunction and reduced blood flow caused by severe inflammation result in a compensatory abnormal network of blood vessels in the gastrointestinal tract, with potentially life-threatening bleeding in up to 40% of patients[17,18]. Mesoblast believes that Revascor may address the severe inflammation that leads to these major bleeding complications.

In November 2018, United States National Institutes of Health investigators presented results of a 159-patient randomized placebo-controlled Phase 2 clinical trial at the American Heart Association Scientific Sessions. In the Phase 2 trial, a single intra-myocardial injection of Revascor at the time of LVAD implantation resulted in a 76% reduction in major GI bleeding events and 65% reduction in related hospitalizations in the overall patient population studied. In a post-hoc analysis in patients with an ischemic cause of their heart failure, these effects of Revascor were even greater, as well as an observed significant increase in the ability to wean off device support, suggesting strengthening of the native heart muscle.

The FDA recently provided guidance on the pathway for marketing authorization of Revascor in this indication.

Key outcomes were:

- FDA reiterated that a reduction in major gastrointestinal bleeding events and/or epistaxis, collectively termed major mucosal bleeding events, is an important clinical outcome in patients implanted with an LVAD.
- FDA confirmed that data from the recently completed 159-patient placebo-controlled trial showing that Revascor reduced major mucosal bleeding events can support product marketing authorization through a BLA, with confirmatory clinical trial data.
- FDA agreed on a confirmatory Phase 3 trial of Revascor in LVAD patients, with a primary endpoint of reduction in major mucosal bleeding events, and key secondary endpoints demonstrating improvement in various parameters of cardiovascular function.

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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

Revascor is being developed for these patients under existing FDA Regenerative Medicine Advanced Therapy (RMAT) and Orphan Drug designations.

The confirmatory trial is planned to be conducted with the International Center for Health Outcomes Innovation Research (InCHOIR) at the Icahn School of Medicine at Mount Sinai in New York, in line with an existing Memorandum of Understanding. It is expected to be initiated before the end of CY2019.

Chronic Low Back Pain

Approximately 3.2 million patients in the United States alone suffer from chronic low back pain due to moderate degenerative disc disease[19]. After failure of conservative measures (medication, injections, epidural steroid, physical therapy etc.), there is a need for treatments that both reduce pain and improve function over a sustained period of time.

In post-hoc results from an earlier randomized, placebo-controlled Phase 2 trial in 100 patients, data showed that a single intra-discal injection of MPC-06-ID resulted in over a three-fold increase relative to saline controls in successfully achieving a composite endpoint consisting of 50% improvement in low back pain and 15 point improvement in function at both 12 and 24 months with no treatment or surgical interventions at the treated level through 24 months. In this study, 37% of patients treated with MPC-06-ID compared with 10% in the control group achieved this composite endpoint over two years.

This composite endpoint is the primary endpoint in the Phase 3 clinical trial for chronic low back pain which completed enrollment in March 2018 with 404 patients randomized 2:1 to receive either MPC-06-ID or saline control. Follow-up of patients in the Phase 3 trial of MPC-06-ID is continuing to a 24-month assessment of safety and efficacy. All patients will have completed 24 months of follow-up by the first quarter of CY 2020, with readouts planned mid-CY2020.

Board and Senior Executive Appointments in Line with Commercialization Plans

As Mesoblast transitions to a commercial stage company, there have been two key additions to its Board of Directors and the appointment of a new Chief Medical Officer.

Joseph R. Swedish has been appointed as Mesoblast's non-executive Chairman and Shawn Tomasello as a non-executive Director.

Mr Swedish most recently served as Chairman, President and CEO of Anthem Inc., a Fortune 29 company and the leading health benefits provider in the U.S. He also serves on the boards of IBM Corporation, CDW Corporation, Proteus Digital Health, and Centrexion Therapeutics. Ms Tomasello was Chief Commercial Officer at leading immuno-oncology cell therapy company Kite Pharma, where she played a pivotal role in its acquisition in 2017 by Gilead Sciences. Prior to this she served as Chief Commercial Officer at Pharmacyclics, Inc., which was acquired in 2015 by AbbVie, Inc. Ms Tomasello previously was President of the Americas, Hematology and Oncology at Celgene Corporation. Ms Tomasello currently serves on the Board of Directors of Centrexion Therapeutics, Oxford BioTherapeutics and Diplomat Rx.

Mesoblast's new Chief Medical Officer, Dr Fred Grossman, brings a wealth of commercial experience gained from numerous leadership roles at global pharmaceutical companies. He has over 20 years of industry experience, and has held key leadership positions at major global pharmaceutical companies, including Eli Lilly, Johnson & Johnson (J&J), Bristol Myers Squibb (BMS), Sunovion, and Glenmark. During his career, he has managed global clinical development, pharmacovigilance, medical affairs and clinical operations for innovative product development, as well as FDA approvals and post-market support for numerous blockbuster, specialty and generic products. Dr Grossman has led and built teams in the United States, Europe and Japan with responsibility for global medical affairs, global clinical development, health economics and outcomes research and global drug safety.

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Manufacturing

Mesoblast is developing patent-protected product candidates for a range of inflammatory and immune-mediated conditions using a scalable, allogeneic (off-the-shelf) cellular medicine platform technology.

The Company's manufacturing activities meet stringent criteria set by international regulatory agencies, including the FDA and EMA. Mesoblast's product candidates contain well-characterized cell populations, and our robust quality assurance processes ensures final product with batch-to-batch consistency and reproducibility as measured by well-established product release assays.

Mesoblast has proprietary technology that facilitates the increase in yields necessary for the long-term commercial supply of our product candidates, and next generation manufacturing processes using three-dimensional bioreactors to reduce labour and drive down cost of goods.

Intellectual Property

Mesoblast continues to protect and expand its extensive estate of patent rights and intellectual property with approximately 995 patents and patent applications across 68 patent families. These patents relate principally to compositions of matter, methods of manufacture, and uses/indications of mesenchymal lineage cells.

More specifically, the Company's patent estate includes issued patent and patent applications in major markets, including, but not limited to, the United States, Europe, Japan and China. The patents that Mesoblast has obtained, and continue to apply for, cover mesenchymal lineage cell technologies and product candidates derived from these technologies, irrespective of the tissue source, including bone marrow, adipose, placenta, umbilical cord and dental pulp.

Among the indication-specific issued or pending patents covering product candidates derived from the Company's mesenchymal lineage cells are those which are directed to its lead product candidates for aGVHD, advanced heart failure, chronic low back pain, as well as chronic auto-immune conditions such as rheumatoid arthritis. Mesoblast also has issued and pending patents covering other pipeline indications, including diabetic kidney disease, inflammatory bowel disease (e.g. Crohn's disease), neurologic diseases, eye diseases and additional orthopedic diseases. In addition, the Company has in-licensed patents covering complementary technologies, such as other types of mesenchymal lineage cells, cell surface modification technologies, pay-loading technology and protein and gene technologies, as part of its strategy to expand its targeted disease applications and manage the life cycle of its current lead programs.

Licensing agreements with JCR, Tasly and Takeda highlight the strength of Mesoblast's extensive intellectual property portfolio covering mesenchymal lineage cells. Mesoblast will continue to use its patents to prosecute its commercial rights as they relate to its core strategic product portfolio. When consistent with the Company's strategic objectives, it may consider providing third parties with commercial access to its patent portfolio.

Detailed Financial Results for the Year Ended June 30, 2019

- **Revenues** were US$16.7 million for FY2019, compared to US$17.3 million for FY2018. Revenues comprised:
  - US$10.0 million revenue recognized in FY2019 in relation to establishing a partnership with Tasly in China, compared with US$11.8 million revenue recognized in FY2018 in relation to the patent license agreement with Takeda Pharmaceutical Company Limited.
  - US$6.0 million royalties and milestone revenues recognized in FY2019 from sales of TEMCELL by JCR compared with US$5.1 million in FY2018, an increase of US$0.9 million. Royalty revenue on sales of TEMCELL increased by 37% for FY2019 compared to FY2018.
- **Research and Development** expenses were US$59.8 million for FY2019, compared to US$65.9 million for FY2018. This US$6.1 million decrease was due to a reduction in third party costs in our Phase 3 clinical trials.

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F +65 6570 0176

- **Manufacturing** expenses were US$15.4 million for FY2019, compared to US$5.5 million for FY2018, an increase of US$9.9 million for commercial manufacturing investment primarily to support the potential launch of remestemcel-L.
- **Management and Administration** expenses were US$21.6 million for FY2019, compared to US$21.9 million for FY2018, a decrease of US$0.3 million.
- **Finance Costs** of US$11.3 million in interest expenses were recognized for FY2019, of which US$4.6 million was paid in cash, compared with US$1.8 million for FY2018, in relation to financial agreements with Hercules and NovaQuest.

Additional components of loss after income tax also include movements in other items which did not impact current cash reserves, such as income tax benefits, fair value remeasurement of contingent consideration, remeasurement of borrowing arrangements and foreign exchange movements within other operating income and expenses.

In FY2019, the net loss attributable to ordinary shareholders was 18.16 cents per share for FY2019, compared with a loss per share of 7.58 cents for FY2018. There was an after tax loss of US$89.8 million in FY2019, compared to US$35.3 million for FY2018. The increase in the loss is primarily due to commercial manufacturing investment of US$9.9 million to support potential launch of remestemcel-L, and an increase of US$9.5 million in finance costs. Additionally, in the FY2018 comparative period, the Company recognized a one-off non-cash income tax benefit of US$23.0 million primarily due to a revaluation of tax liabilities given changes in tax rates and a non-cash US$10.5 million gain on remeasurement of contingent consideration for reduction of future payments to third parties.

Conference Call Details

There will be a webcast today on the financial results beginning at 8am AEST (Friday August 30, 2019); 6pm EDT (Thursday August 29, 2019). It can be accessed via https://s1.c-conf.com/diamondpass/mesoblast-10001891-invite.html

To access the call only, dial 1800 558 698 (toll-free Australia), 1 855 881 1339 (toll-free U.S.), or +61 2 9007 3187 (outside of the U.S. and Australia). The conference identification code is 10001891.

The archived webcast will be available on the Investor page of the Company's website: www.mesoblast.com

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

References

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2. Mesoblast does not make any representation or give any assurance that such a partnering transaction will be concluded.
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14. United Network for Organ Sharing.
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18. 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.
19. Decision Resources: Chronic Pain December 2015.

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 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, and ability to access, 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:

Julie Meldrum
Corporate Communications
Mesoblast
T: +61 3 9639 6036
E: julie.meldrum@mesoblast.com

Schond Greenway
Investor Relations
Mesoblast
T: +1 212 880 2060
E: schond.greenway@mesoblast.com

Consolidated Income Statement

(in U.S. dollars, in thousands, except per share amount)	(unaudited) Three Months Ended June 30, 2019	2018	(audited) Year Ended June 30, 2019	2018
Revenue	1,967	1,700	16,722	17,341
Research & development	(11,435)	(17,539)	(59,815)	(65,927)
Manufacturing commercialization	(2,448)	(2,121)	(15,358)	(5,508)
Management and administration	(5,627)	(5,219)	(21,625)	(21,907)
Fair value remeasurement of contingent consideration	(2,912)	2,661	(6,264)	10,541
Other operating income and expenses	(26)	69	(1,086)	1,312
Finance costs	(3,422)	(1,406)	(11,328)	(1,829)
Loss before income tax	**(23,903)**	**(21,855)**	**(98,754)**	**(65,977)**
Income tax benefit	3,177	1,021	8,955	30,687
Loss attributable to the owners of Mesoblast Limited	**(20,726)**	**(20,834)**	**(89,799)**	**(35,290)**
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:	**Cents**	**Cents**	**Cents**	**Cents**
Basic - losses per share	(4.15)	(4.39)	(18.16)	(7.58)
Diluted - losses per share	(4.15)	(4.39)	(18.16)	(7.58)

Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	(unaudited) Three Months Ended June 30, 2019	2018	(audited) Year Ended June 30, 2019	2018
Loss for the period	**(20,726)**	**(20,834)**	**(89,799)**	**(35,290)**
Other comprehensive (loss)/income				
Items that may be reclassified to profit and loss				
Changes in the fair value of financial assets	(284)	183	(4)	324
Exchange differences on translation of foreign operations	(33)	(334)	(137)	(903)
Other comprehensive (loss)/income for the period, net of tax	**(317)**	**(151)**	**(141)**	**(579)**
Total comprehensive losses attributable to the owners of Mesoblast Limited	**(21,043)**	**(20,985)**	**(89,940)**	**(35,869)**

Mesoblast Limited
ABN 68 109 431 870

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 Balance Sheet

(in U.S. dollars, in thousands)	(audited) As of June 30, 2019	2018
Assets		
Current Assets		
Cash & cash equivalents	50,426	37,763
Trade & other receivables	4,060	50,366
Prepayments	8,036	12,942
Total Current Assets	**62,522**	**101,071**
Non-Current Assets		
Property, plant and equipment	826	1,084
Financial assets at fair value through other comprehensive income	2,317	2,321
Other non-current assets	3,324	3,361
Intangible assets	583,126	584,606
Total Non-Current Assets	**589,593**	**591,372**
Total Assets	**652,115**	**692,443**
Liabilities		
Current Liabilities		
Trade and other payables	13,060	18,921
Provisions	7,264	5,082
Borrowings	14,007	—
Deferred consideration	10,000	—
Total Current Liabilities	**44,331**	**24,003**
Non-Current Liabilities		
Deferred tax liability	11,124	20,079
Provisions	48,329	42,956
Borrowings	67,279	59,397
Total Non-Current Liabilities	**126,732**	**122,432**
Total Liabilities	**171,063**	**146,435**
Net Assets	**481,052**	**546,008**
Equity		
Issued Capital	910,405	889,481
Reserves	40,638	36,719
(Accumulated losses)/retained earnings	(469,991)	(380,192)
Total Equity	**481,052**	**546,008**

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Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	(audited) Year ended June 30, 2019	2018
Cash flows from operating activities		
Commercialization revenue received	4,359	3,019
Milestone payment received	26,409	7,125
Research and development tax incentive received	1,654	—
Payments to suppliers and employees (inclusive of goods and services tax)	(86,294)	(84,682)
Interest received	726	367
Interest and other costs of finance paid	(4,641)	(816)
Income taxes (paid)	(3)	(25)
Net cash (outflows) in operating activities	**(57,790)**	**(75,012)**
Cash flows from investing activities		
Investment in fixed assets	(279)	(201)
Payments for contingent consideration	(721)	(952)
Rental deposits received	—	—
Net cash inflows/(outflows) in investing activities	**(1,000)**	**(1,153)**
Cash flows from financing activities		
Proceeds from borrowings	43,572	31,704
Payments of transaction costs from borrowings	(1,614)	(392)
Proceeds from issue of shares	30,258	40,566
Payments for share issue costs	(608)	(3,265)
Net cash inflows by financing activities	**71,608**	**68,613**
Net increase/(decrease) in cash and cash equivalents	12,818	(7,552)
Cash and cash equivalents at beginning of period	37,763	45,761
FX gain/(losses) on the translation of foreign bank accounts	(155)	(446)
Cash and cash equivalents at end of period	**50,426**	**37,763**

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mesoblast
the regenerative medicine company

Global Leader in Allogeneic Cellular Medicines for Inflammatory Diseases

FY Ended June 30, 2019

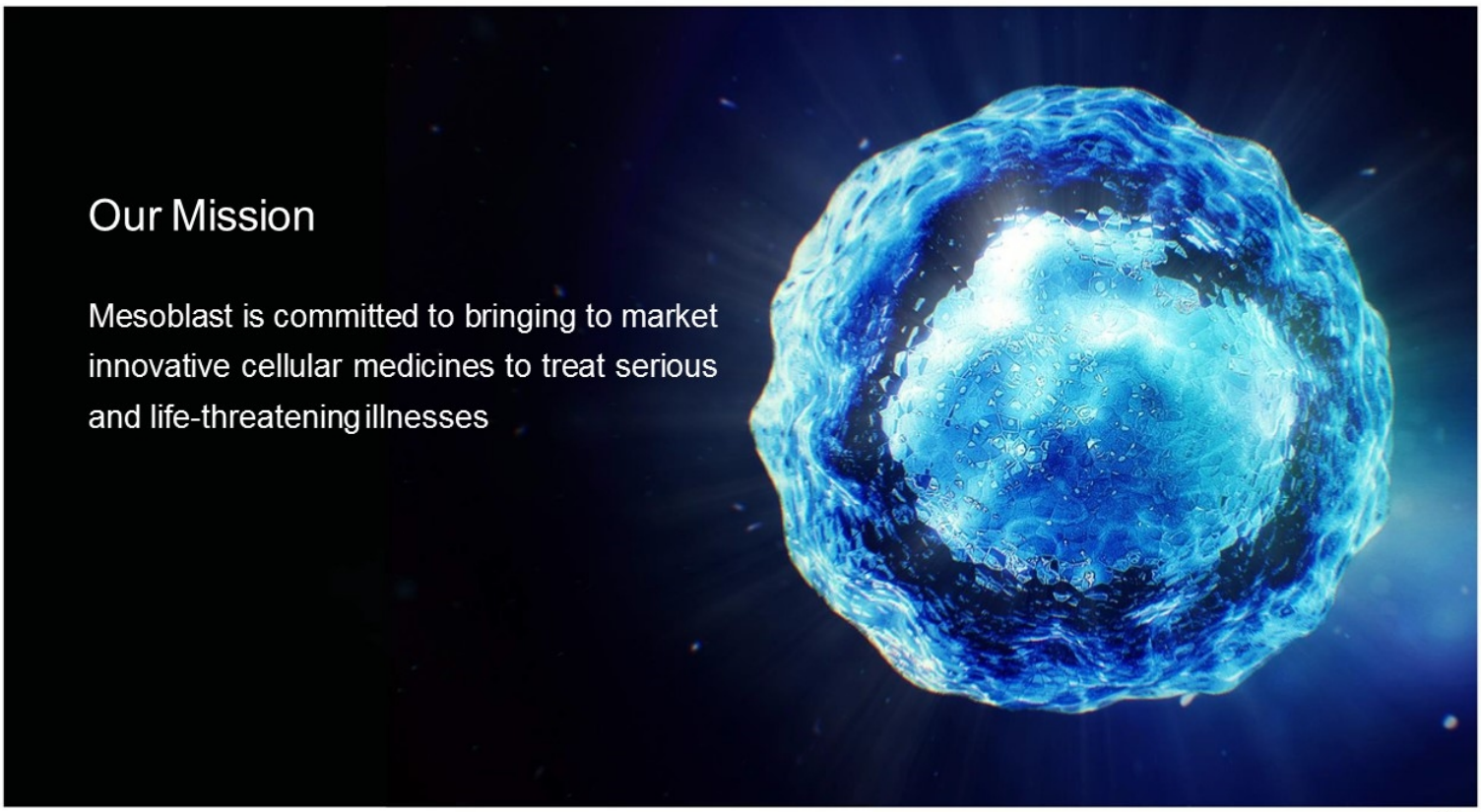
Nasdaq: MESO ASX: MSB

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 bringing to market innovative cellular medicines to treat serious and life-threatening illnesses



Corporate History

Over a decade of scientific, manufacturing, clinical development and corporate development experience targeted at bringing to market allogeneic, off-the-shelf cellular medicines for inflammatory diseases

2004:
Mesoblast founded in Melbourne, Australia and listed on the ASX

2010:
Entered into strategic alliance with Cephalon to develop and commercialize MPC therapeutics

2011:
Entered into manufacturing partnership with Lonza Group in Singapore for MPC medicines

2013:
Acquired MSC business from Osiris Therapeutics with trailing earn-out and milestone payments

2014:
Granted manufacturing pioneer status by Economic Development Board of Singapore

2015:
Dual listed on the Nasdaq

2016:
TEMCELL® HS Inj (MSC medicine) launched in Japan by Mesoblast licensee JCR

2017:
Entered licensing agreement with Takeda for the treatment of certain fistulae; in 2018 Alofisel® received approval in EU

2018:
Entered into partnership agreement with Tasly for cardiovascular assets in China

2019:
Smith & Nephew acquired Osiris Therapeutics, became Mesoblast's licensor for the MSC business

2019:
Initiated first BLA submission to US FDA: remestemcel-L (MSC) for steroid refractory acute graft versus host disease (aGVHD)

Premier Global Cellular Medicines Company

Innovative Technology Platform[1]	Late Stage Pipeline	Commercialization Plan
▪ Innovative technology targets some of the most severe disease states refractory to conventional therapies ▪ Well characterized multimodal mechanisms of action ▪ Underpinned by extensive, global IP estate	▪ Initiated filing with US FDA for approval for steroid-refractory aGVHD ▪ Two Phase 3 product candidates – heart failure and back pain – with near term US trial readouts ▪ Heart failure Phase 3 product candidate partnered in China	▪ Building US sales force for aGVHD launch, if approved ▪ Industrial-scale manufacturing to meet commercial demand ▪ First approved products commercialized by licensees in Japan[2] and Europe[3] ▪ Continued growth in royalty revenues from strategic partnerships

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®.

Commercial and Late-Stage Product Pipeline

PLATFORM	PRODUCT	THERAPEUTIC AREA		APPROVAL	COMMERCIAL RIGHTS	
MSC (Bone Marrow)	TEMCELL® HS Inj[1]	Acute Graft Versus Host Disease	1st allogeneic regen med approved in Japan	✓	JCR Japan	MARKETED
MSC (Adipose)	Alofisel®[2]	Perianal Fistula	1st allogeneic regen med approved in Europe	✓	Takeda Global	

PLATFORM	PRODUCT CANDIDATE	THERAPEUTIC AREA	PRE-CLINICAL / PHASE 2 / PHASE 3		COMMERCIAL RIGHTS	
MSC suite	Remestemcel-L	Acute Graft Versus Host Disease		BLA submission to FDA underway	mesoblast	IN DEVELOPMENT
	Remestemcel-L	Crohn's Disease				
	Remestemcel-L	Osteoarthritis/Cartilage Repair				
MPC suite	Revascor	Advanced HF (Class II/III) End-Stage HF (Class III/IV)[3]			TASLY China[4]	
	MPC-06-ID	Chronic Low Back Pain			mesoblast	
	MPC-300-IV	Rheumatoid Arthritis Diabetic Nephropathy				

1 Mesoblast receives royalty income from its licensee JCR Pharmaceuticals Co Ltd on sales of JCR's TEMCELL® Hs. Inj. product in Japan.
2 Mesoblast receives royalty income from its licensee Takeda Pharmaceuticals on Takeda's worldwide sales of its product Alofisel® in the local treatment of perianal fistulae.
3 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.
4 Tasly's rights are limited to China; Tasly also has rights to develop MPC-25-IC for Acute Cardiac Ischemia.

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

Partnerships and License Agreements

- JCR has rights to use our MSC technology to treat acute GVHD in Japan
- Its product TEMCELL® HS Inj. was the first fully approved allogeneic cellular medicine in Japan
- Royalties and milestones received in last 12 months exceed US$6.0 million
- License expanded in Oct 2018 to cover use in treatment of epidermolysis bullosa (EB), a highly debilitating and sometimes lethal skin disease; currently on file for approval in Japan
- License further expanded in June 2019 to cover use in hypoxic ischemic encephalopathy (HIE) in newborns; clinical trial initiated in July 2019

- Patent license agreement entered in Dec 2017 with Takeda (formerly TiGenix NV) providing exclusive access to certain IP for local treatment of perianal fistulae
- Mesoblast received €10 million in payments and is eligible to receive up to an additional €10 million in milestone payments (€20 million in total payments) plus royalties upon commercial sales of Alofisel® worldwide

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- Exclusive cardiovascular rights in China
- Mesoblast received US$40 million on closing, and is eligible to receive additional milestones and royalties

Recent Corporate Highlights

Remestemcel-L for Steroid-Refractory Acute Graft Versus Host Disease

- Continued growth in revenues from royalties on sales of TEMCELL in Japan for steroid refractory aGVHD.
- Product adoption and reimbursement seen in the Japan GVHD market for TEMCELL informs Mesoblast commercial strategy for rememstemcel-L in aGVHD.
- US addressable market for SR aGVHD in children and adults is expected to be approximately 8-fold larger than Japan, a major commercial opportunity.
- Rolling BLA submission to the US FDA is underway and we expect to complete the filing in CY2019.
- In line with expected timelines for potential US launch of remestemcel-L, spending has increased on commercial manufacturing activities and commercial team ramp up in parallel with the FDA filing.
- Mesoblast intends to expand its clinical program into the adult aGVHD segment.
- An investigator-initiated study evaluating remestemcel-L in children is planned in the US for *chronic* GVHD.
- Mesoblast has the right to use all safety and efficacy data generated by JCR in Japan for TEMCELL to support its life cycle strategy for remestemcel-L in the US and other major healthcare markets such as wound healing in patients with EB and HIE in newborns.

Recent Corporate Highlights (continued)

Revascor for Advanced Heart Failure

- Phase 3 trial in advanced heart failure has completed patient enrollment, with 566 patients randomized to receive Revascor or placebo across 55 centers in North America. The trial's primary endpoint is reduction in heart failure-related hospital admissions, and the key secondary endpoint is reduction in terminal cardiac events.
- Revascor was successful in April 2017 in a pre-specified futility analysis of the Phase 3 trial's primary efficacy endpoint in the first 270 patients enrolled in the trial.
- ~ 90% of events in this Phase 3 trial have been accrued and validated. The trial will complete when sufficient primary endpoint events have accrued, likely by end of CY 2019.

Revascor for End-Stage Heart Failure

- FDA meeting outcomes were:
  - FDA reiterated that a reduction in major gastrointestinal bleeding events and/or epistaxis, collectively termed major mucosal bleeding events, is an important clinical outcome in patients implanted with an LVAD.
  - FDA confirmed that data from the recently completed 159-patient placebo-controlled trial can support product marketing authorization through a BLA with confirmatory clinical trial data.
  - FDA agreed on a confirmatory Phase 3 trial with a primary endpoint of reduction in major mucosal bleeding events, and key secondary endpoints demonstrating improvement in various parameters of cardiovascular function.
- Revascor is being developed for these patients under existing FDA Regenerative Medicine Advanced Therapy (RMAT) and Orphan Drug designations.
- Confirmatory Phase 3 trial planned to be conducted with InCHOIR[1] under existing MoU.

1. InCHOIR = International Center for Health Outcomes and Innovation Research (inCHOIR) at the Icahn School of Medicine at Mount Sinai.

Recent Corporate Highlights (continued)

MPC-06-ID for Chronic Low Back Pain

- Phase 3 trial in chronic low back pain completed enrollment in March 2018 with 404 patients randomized to receive MPC-06-ID or placebo. All patients have now completed at least 12 months of safety and efficacy follow-up.
- Follow-up continuing to a 24-month assessment of safety and efficacy by the first quarter of CY 2020, with readouts planned mid-CY2020

Board and Senior Executive Appointments in Line with Commercialization Plans

- The Board appointed Joseph R. Swedish as Chairman in April 2019. As the former CEO of Anthem Inc., the second largest health insurance company in the US, he brings deep healthcare expertise and a track record in healthcare resource allocation and reimbursement metrics.
- Shawn Tomasello was appointed a non-executive Director. As former Chief Commercial Officer at Kite Pharma and Pharmacyclics, and President of the Americas, Hematology and Oncology at Celgene, she brings substantial commercial and transactional experience.
- Dr Fred Grossman joined as Chief Medical Officer, bringing a wealth of commercial experience gained from numerous leadership roles at Eli Lilly, Johnson & Johnson, Bristol Myers Squibb, Sunovion and Glenmark. The appointment aligns closely with the Company's near term commercial objectives for its lead products.

Commercial Scale Manufacturing Capability

- Scalable allogeneic “off-the-shelf” cellular medicine platform
- Manufacturing meets stringent criteria set by international regulatory agencies including FDA and EMA
- Robust quality assurance processes ensure final product with batch-to-batch consistency and reproducibility
- Culture expansion scalable for near term commercial needs
- Proprietary xeno-free technologies being developed to enable sufficient yields for long term global commercial supply
- Next generation processes using 3D bioreactors to reduce labor and drive down cost of goods

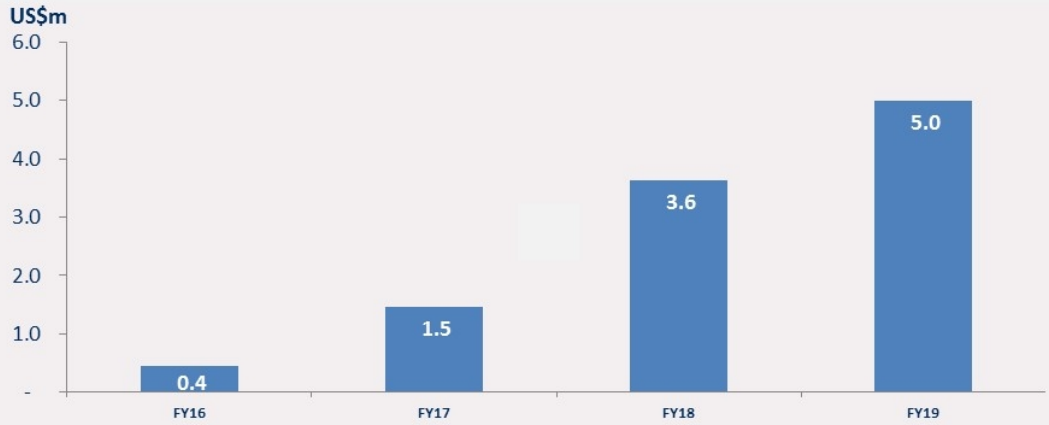
Lonza contract manufacturing facility in Singapore

Global IP Estate Provides Substantial Competitive Advantage

- ~995 patents and patent applications (68 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

Financials FY 2019

Revenues from Royalties on Japan Product Sales – 37% Year on Year Growth



- 37% growth in royalty revenue for the FY2019 year compared to FY2018 from sales of TEMCELL in Japan for SR-aGVHD by Mesoblast licensee JCR Pharmaceuticals Co. Ltd.
- 54% growth in royalty revenue for the quarter ended June 2019 compared to the quarter ended June 2018.

All results on this slide are reported in constant currency.

Revenues – Continued Growth in Royalties and Substantial Payments from Strategic Partnerships

For the year ending (US$m)	June 30, 2019	June 30, 2018
Upfront/milestone revenue	11.0	13.3
Commercialization revenue	5.0	3.6
Interest revenue	0.7	0.4
Total revenue	**16.7**	**17.3**

- Strategic partnerships drive revenues from upfront and milestone payments
  - US$10.0 million from licensee Tasly in FY2019
  - US$1.0 million from JCR in FY2019
  - US$11.8 million from licensee Takeda in FY2018
  - US$1.5 million from JCR in FY2018

Increased Investment in Commercial Manufacturing

Non-cash Gains in Comparable Period from Revaluation of Tax and Contingent Consideration

Profit and Loss for the year ending (US$m)	June 30, 2019	June 30, 2018
Total Revenue	16.7	17.3
Research and development	(59.8)	(65.9)
Manufacturing	(15.4)	(5.5)
Management & administration	(21.6)	(21.9)
Contingent consideration	(6.3)	10.5
Other operating income & expenses	(1.1)	1.3
Finance costs	(11.3)	(1.8)
(Loss)/Profit before tax	(98.8)	(66.0)
Income tax benefit	9.0	30.7
(Loss)/Profit after tax	(89.8)	(35.3)

Increase in loss primarily due to the following items:

- in the current period:
  - US$9.9 million increase in commercial manufacturing reflects investment to support potential launch for aGVHD product
  - US$9.5 million of increased finance costs on non-dilutive capital inflows from Hercules and NovaQuest
  - Partially offset by reduction in R&D
- and in the comparative period:
  - a one-off non-cash income tax benefit of US$23.0 million due to a revaluation of tax liabilities given changes in tax rates
  - non-cash US$10.5 million gain on contingent consideration for reduction of future payments to third parties

Reduction in Operating Net Cash Outflows for the Year Due to Increased Payments from Strategic Partnerships

For the year ending (US$m)	June 30, 2019	June 30, 2018
Operating net cash outflows	**(57.8)**	**(75.0)**
Investing net cash outflows	(1.0)	(1.2)
Financing net cash inflows	71.6	68.6
Net increase/(decrease) in cash	12.8	(7.6)

- 23% (US$17.2 million) reduction in net operating cash outflows for the year ended June 30, 2019, primarily due to increased payments from strategic partnerships during FY19.
- Cash reserves of US$50.4 million as at June 30, 2019.
- An additional US$35.0 million may be available under existing arrangements with Hercules Capital and NovaQuest, subject to achievement of certain milestones.
- In addition, Mesoblast has entered into a Subscription Commitment Letter with its largest institutional shareholder, M&G Investment Management, for US$15.0 million in Mesoblast ordinary shares, exercisable by the Company on or before 31 December 2019, subject to customary diligence and with pricing to be agreed at the time Mesoblast gives notice.

Lead Product Candidate
Remestemcel-L for aGVHD

Acute Graft Versus Host Disease (aGVHD)

Significant market opportunity for remestemcel-L

Burden of Illness

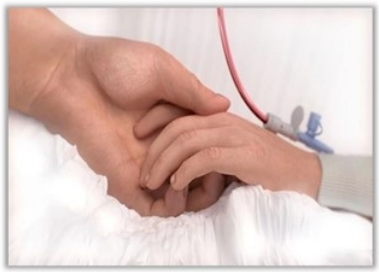
- aGVHD is a life-threatening complication that occurs in ~50% of patients receiving allogeneic bone marrow transplants (BMTs)[1]
- Steroid-refractory aGVHD is associated with **mortality rates as high as 90%[1,7] and significant extended hospital stay costs[2]**

Minimal Treatment Options

- There is only one approved treatment for SR-GVHD and **no approved treatment for children under 12 years old, outside Japan**
- In Japan, Mesoblast's licensee has received the only product approval for SR - aGVHD in both children and adults

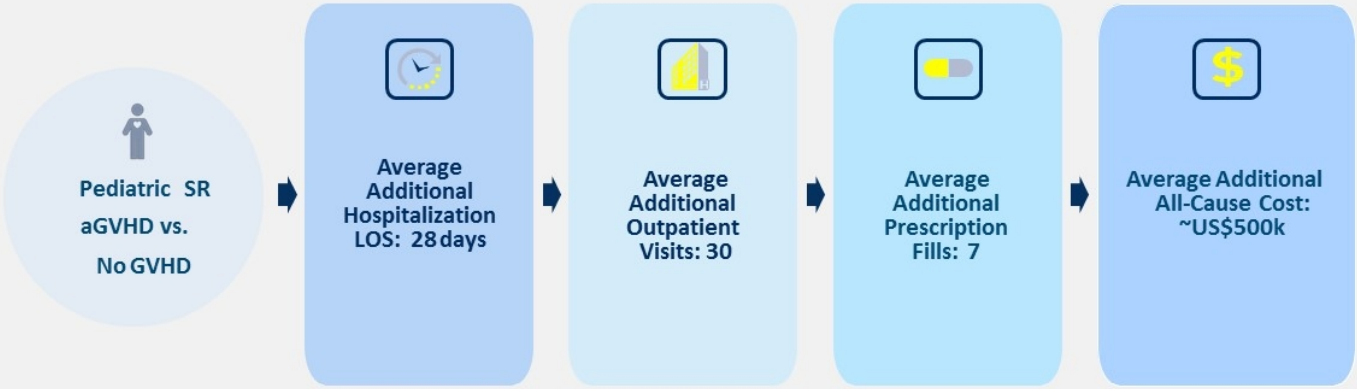
Market Opportunity

- >30,000 allogeneic BMTs performed globally (>20K US/EU) annually, ~20% pediatric[3,4]
- Our licensee, JCR Pharmaceuticals Co., Ltd launched TEMCELL® HS Inj.[5] in Japan for SR-aGVHD in 2016; reimbursed up to ~$USD195k[6]
- **SR-aGVHD represents $USD > 700m US/EU market opportunity[4,8]**



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 Pharmaceutcals 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. Axt L, Naumann A, Toennies J (2019) Retrospective single center analysis of outcome, risk factors and therapy in steroid refractory graft-versus-host disease after allogeneic hematopoietic cell transplantion. Bone Marrow Transplantation. 8. Data on file

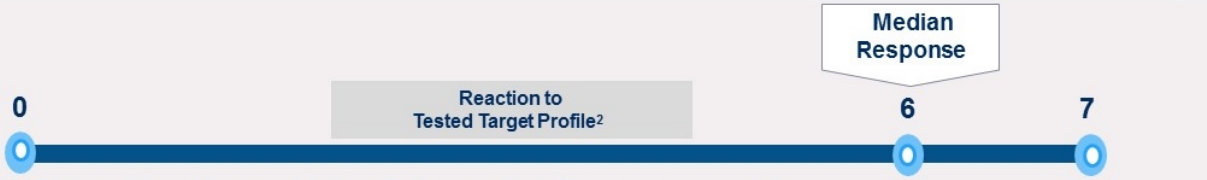
Remestemcel-L: SR-aGVHD is Associated with Significant Burden of Illness in Children in the U.S.[1]



1. European Hematology Association 2019 Congress Meeting: Abstract PF718, The economic and humanistic burden of graft-versus-host disease (GVHD) in pediatric patients: A systematic literature review (SLR)

Remestemcel-L: Results from Providers/Payers Indicate Near Maximal Rating on Product Attributes[1]

(n=20)



Most Significant Value Drivers for Remestemcel-L

- Day 28 overall response rate (especially grade C/D)
- Day 100 & Day 180 Survival rates
- No increase in infections
- Large clinical data set (n ~300)
- Ability to administer the drug outpatient
- Significant reduction in ICU stay

1. Data on file.
2. ZS Associates June 2018 Qualitative Market Research: MCO Medical Directors n=5, Transplant Center Directors n= 5, Hospital Pharmacy Directors n=5, AMC-based Hem/Oncs / KOLs n=3

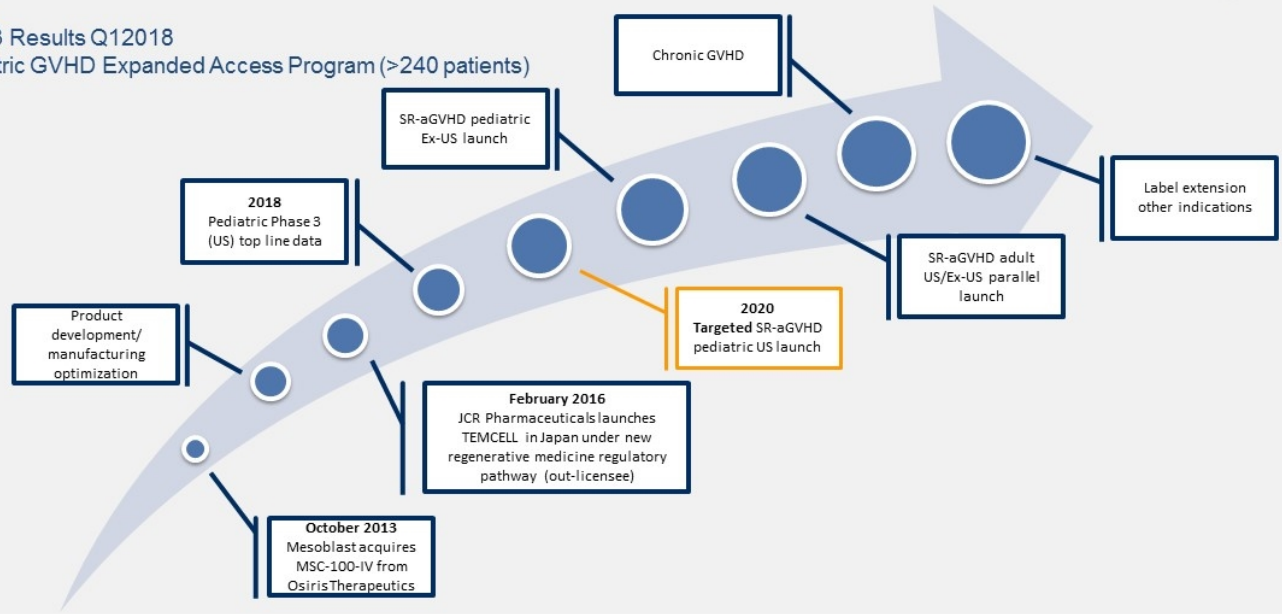
Remestemcel-L: U.S. Regulatory and Commercial Strategy

- US strategy for remestemcel-L informed by TEMCELL sales experience in Japan
- Rolling BLA submission to FDA initiated
- Fast Track designation provides eligibility for FDA priority review
- Ramp-up for inventory build is underway
- Commercialization strategy in place for product launch
- Building out efficient, targeted sales force - 15 centers account for ~50% of patients

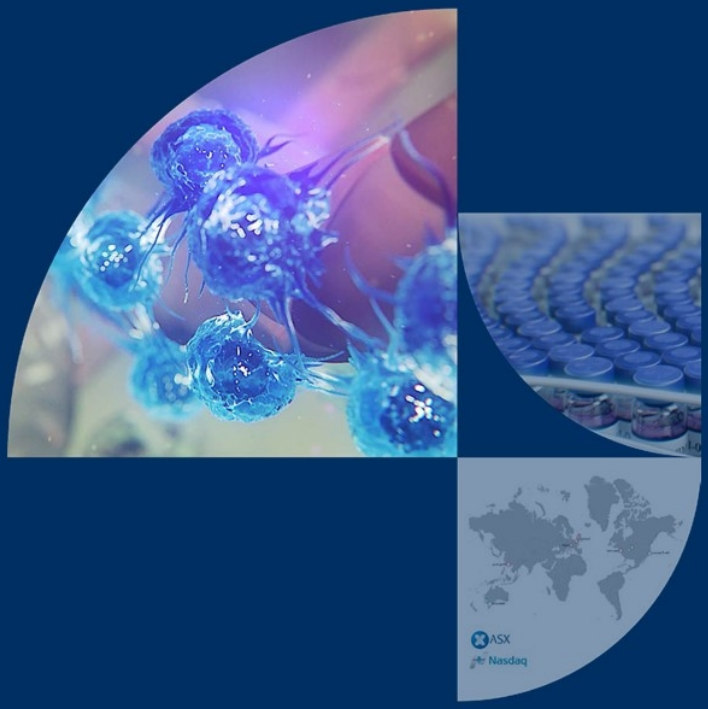
Remestemcel-L: Global GVHD Life Cycle Program

Mesoblast has over 10 years of experience in hematology-oncology space

Remestemcel-L:
- Positive Phase 3 Results Q12018
- Large US Pediatric GVHD Expanded Access Program (>240 patients)



Outlook



Anticipated FY2020 Milestones

Remestemcel-L for Steroid-Refractory Acute Graft Versus Host Disease

- Completion of BLA filing for remestemcel-L in the treatment of steroid refractory aGVHD in children (Q4 CY19)

Revascor for Advanced Heart Failure

- Phase 3 events-driven trial in advanced heart failure will complete when sufficient primary endpoints have accrued, likely by end CY19

Revascor for End-Stage Heart Failure

- Initiation of confirmatory Phase 3 trial of Revascor for the reduction of mucosal bleeding in end-stage heart failure patients implanted with a LVAD (Q4 CY19)

MPC-06-ID for Chronic Low Back Pain

- Patient follow up continues through 24-month assessment of safety and efficacy in Phase 3 trial for chronic lower back pain due to degenerative disc disease (H1 CY20) with readout planned (mid CY20)

Establish global and/or regional partnerships

- In advanced discussions on potential blockbuster products[1]

1. Mesoblast does not make any representation or give any assurance that such a partnering transaction will be concluded.

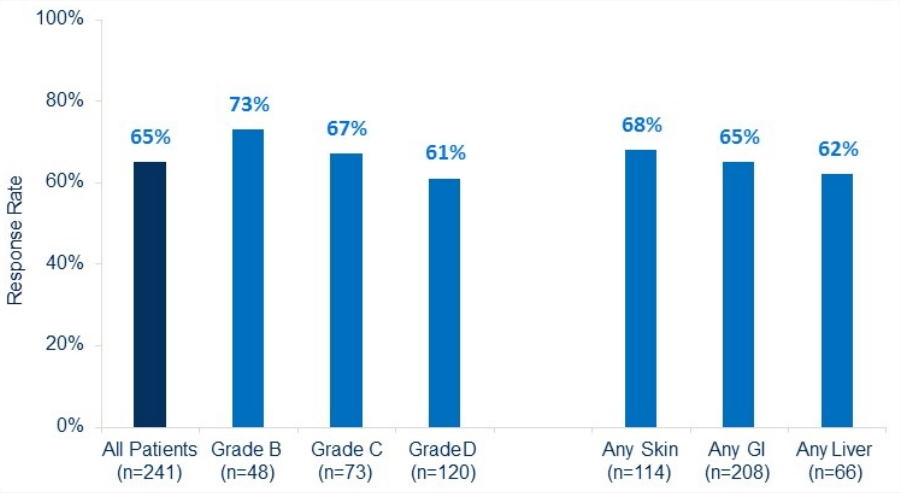
Additional Information
Development & Commercialization

Remestemcel-L: Expanded Access Program (Protocol 275)

Overall Day 28 Response in 241 Pediatric aGVHD Patients Receiving Remestemcel-L as First-line or Salvage Therapy After Failing Steroids[1]

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

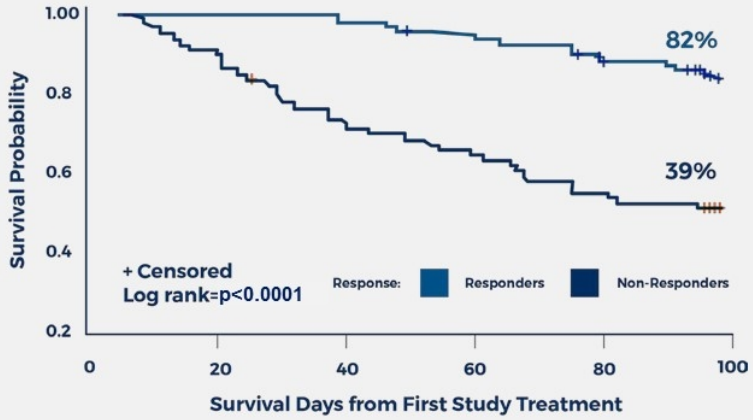
1. Kurtzberg et al: Presentation Tandem Feb 2016

Remestemcel-L: Expanded Access Program

Correlation of Day 28 Overall Response with Day 100 Survival, Using Remestemcel-L as First-line or Salvage Therapy After Failing Steroids and/or Additional Treatments[1]

Remestemcel-L in Children with SR-aGVHD who failed multiple other modalities

- Survival of Pediatric Patients Treated with Remestemcel-L 28-Day Responders vs Non-responders n=241



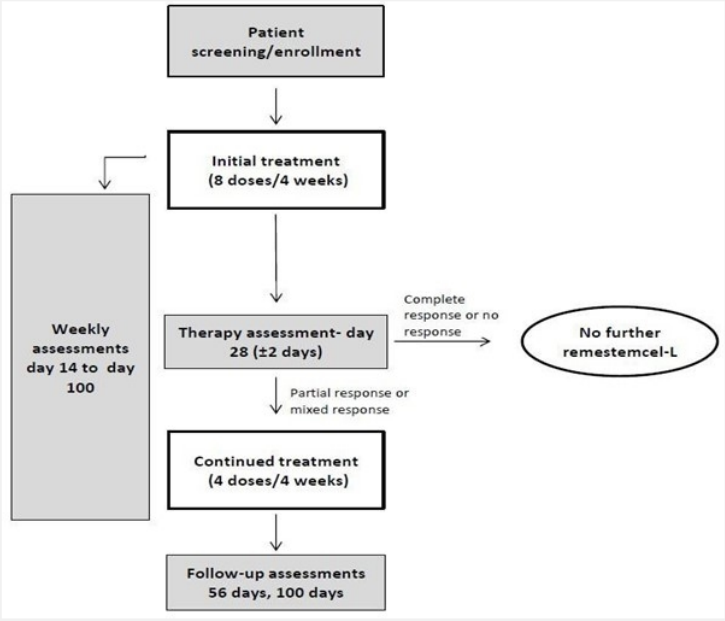
- In 241 children under EAP, **Overall Response** (CR+PR) at Day 28 was **65%** (95% CI: 58.9%, 70.9%)
- **Day 100 survival** correlated with overall response and was significantly improved in those who responded at Day 28 **(82% vs. 39%, p<0.0001)**

1. Kurtzberg et al: Presentation Tandem Feb 2016

Remestemcel-L:

Phase 3 Pediatric Trial (GVHD001) - First-line therapy in aGVHD after failing steroids[1]

- Multi-center, single-arm, open-label study to evaluate efficacy and safety to day 100 (GVHD001) and from day 100 to day 180 (GVHD002)
- 55 pediatric patients (2 months to 17 years)
- aGVHD following allogeneic HSCT failing systemic corticosteroid therapy
- Grade B aGVHD involving liver and/or GI tract with or without concomitant skin disease
- Grades C and D aGVHD involving skin, liver and/or GI tract
- Primary endpoint: **Overall response at Day 28**
- Key secondary endpoint: Survival at Day 100



1. Data on file.

Remestemcel-L: Phase 3 Trial

Protocol GVHD001 – Demographics[1]

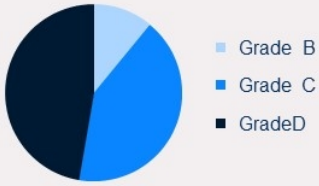
Subjects Enrolled	**55**
Age (years)	
Mean (SD)	**7.8 (5.44)**
Median (minimum, maximum)	**7.6 (0.6, 17.9)**
Gender	
Male	**35 (63.6%)**
Female	**20 (36.4%)**
Underlying Disease	
AML	**18 (32.7%)**
ALL	**12 (21.8%)**
Anemia	**5 (9.1%)**
CML	**4 (7.3%)**
SickleCell	**3 (5.5%)**
JML	**2 (3.6%)**
MDS	**2 (3.6%)**
Other	**9 (16.4%)**

1. Data on file.

Remestemcel-L: Phase 3 Trial

Protocol GVHD001 - Disease characteristics reflect aGVHD severity[1]

GVHD Grade at Baseline



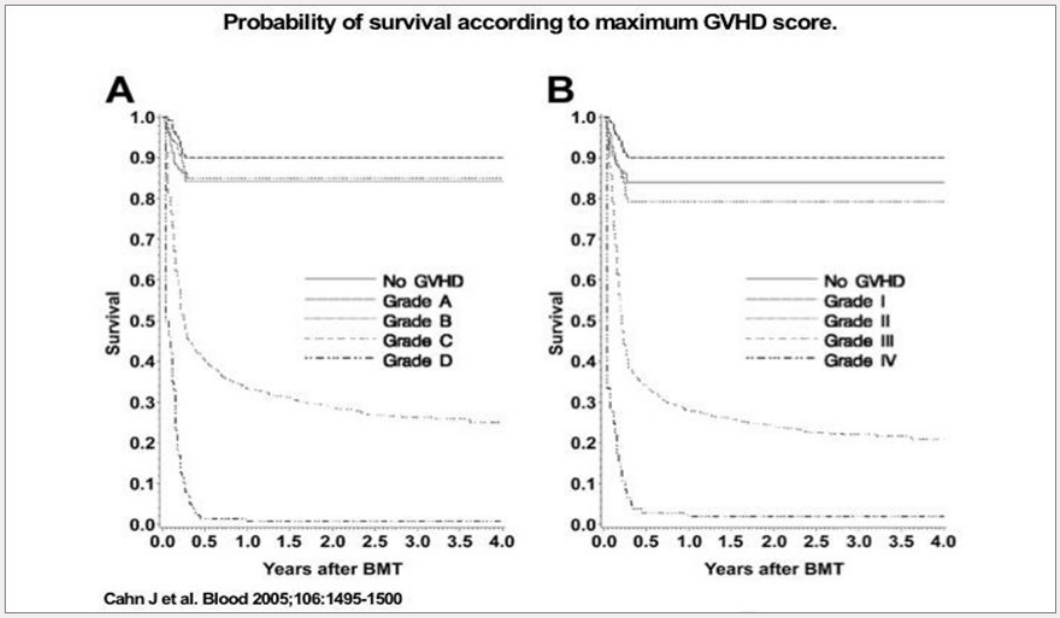
- 89% of subjects had Grade C/D disease at baseline
- 47% of subjects had Grade D disease at baseline

Baseline Organ Involvement

- 26% of subjects had Skin involvement only
  - All had stage 3 (n=10) or stage 4 (n=4) disease
- 38% of subjects had Lower GI involvement only
  - 16/21 had stage 3 (n=6) or stage 4 (n=10) disease
- 36% of subjects had multi-organ involvement, all with Lower GI
  - 6/20 had all three organs involved
  - 10/20 had Lower GI + Skin
  - 4/20 had Lower GI + Liver

1. Data on file.

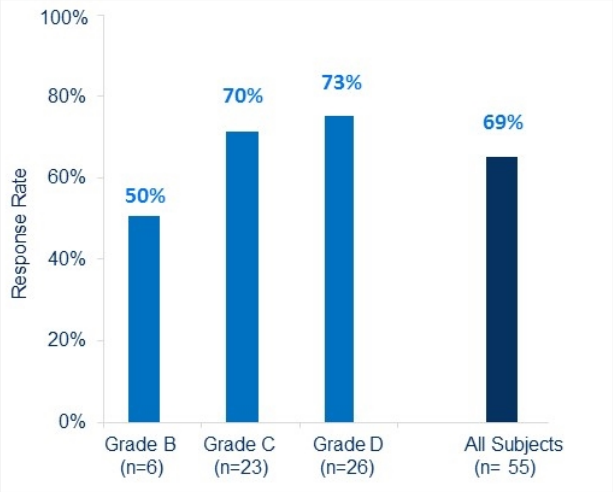
Grade C/D GVHD has Significantly Worse Survival than Grade A/B



Remestemcel-L: Phase 3 Trial

Protocol GVHD001 - Primary efficacy overall response at Day 28 was 69%, p=0.0003[1]

- 69% Overall Response rate at Day 28 (29% CR + 40% PR); (95% CI: 55%, 81%)
- p-value calculated from the binomial distribution, under the assumption of a 0.45 success rate under the null hypothesis



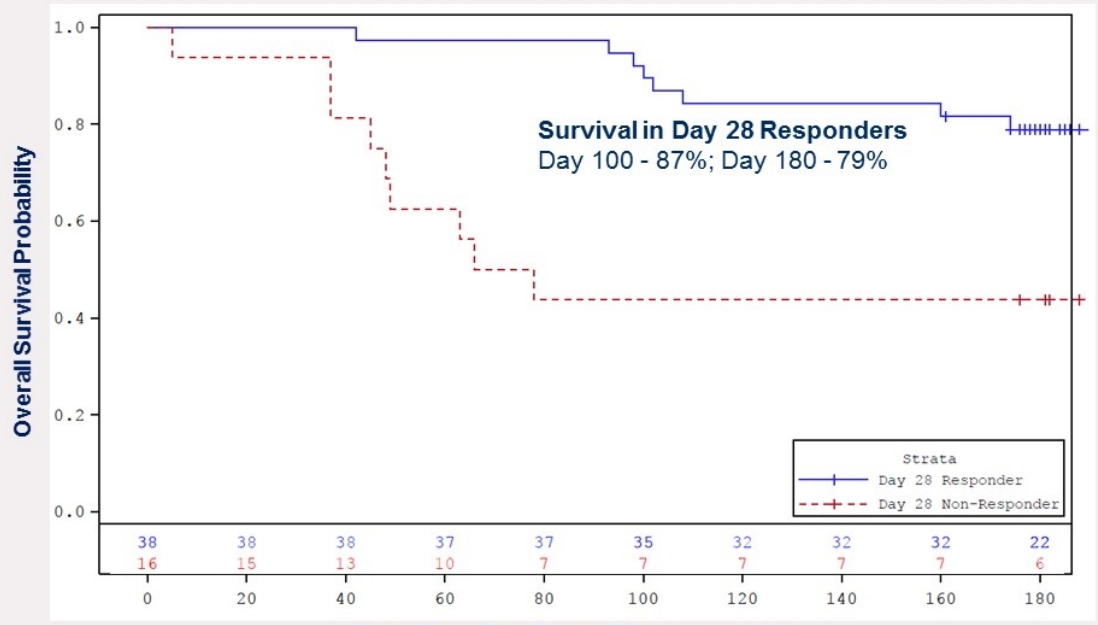
1. Data on file

Remestemcel-L: Phase 3 Trial[1]

- 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 90% mortality[2,3]
- 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[4]

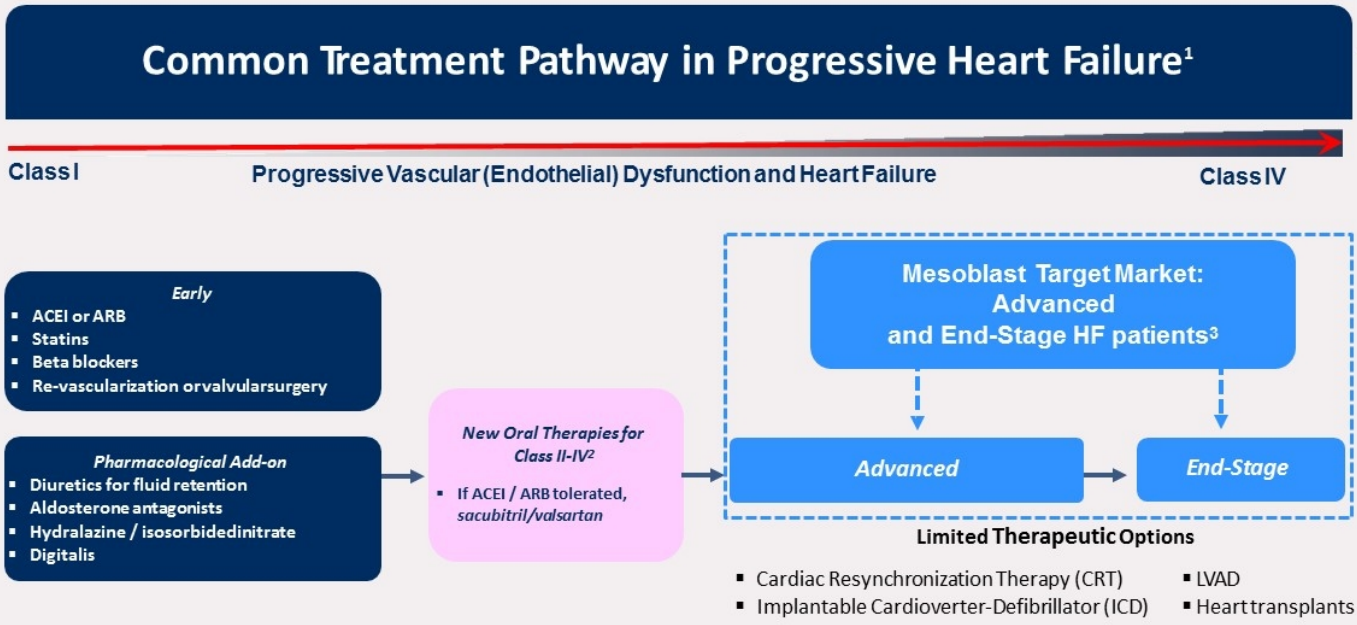
1. Data on file.
2. Westin, J., Saliba, RM., Lima, M. (2011) Steroid-refractory acute GVHD: predictors and outcomes. Advances in Hematology.
3. Axt L, Naumann A, Toennies J (2019) Retrospective single center analysis of outcome, risk factors and therapy in steroid refractory graft-versus-host disease after allogeneic hematopoietic cell transplantation. Bone Marrow Transplantation
4. 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.

Remestemcel-L: Protocol GVHD001/002 survival[1]



1. Data on file.

Advanced and End-Stage Heart Failure



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/AHAHFSA Focused Update on New Pharmacological Therapy for Heart Failure: An Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure.

Advanced Heart Failure

Revascor – Commercial opportunity

Burden of Illness

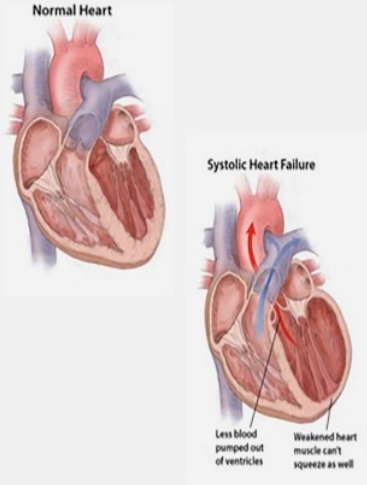
- Approx. 8 million patients with chronic heart failure by 2030 in US alone[1]
- 17-45% globally die within 1 year of hospital admission[1]
- Majority of advanced heart failure patients die within 5 years[1]

Limited Options / Unmet Need

- Despite recent advances in newly approved drugs, limited treatment options are available for patients with advanced heart failure[2]
- New therapies to reduce hospitalizations and mortality in patients with advanced heart failure who have failed other therapies
- Area of great need: NYHA class III-IV where event rate is highest

Market Opportunity

- US healthcare costs for NYHA class II-IV patients $US115bn/year[4]
- Hospitalizations account for ~69% of expenditure[3-5]
- **Multi-billion dollar annual market opportunity in US**[4,5]



1. Heart Failure: Preventing disease and death worldwide – European Society of Cardiology 2014., 2. ACC/AHAHFSA 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.ijard.2015.10.172.

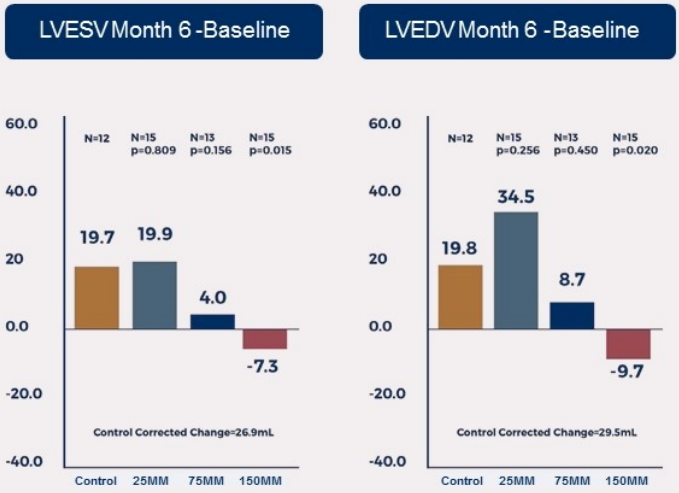
Revascor: Phase 2 Randomized, Controlled Trial Identified Optimal Therapeutic Dose and Target Patient Population for Phase 3

Objectives

- Identify a dose response and an optimal therapeutic dose
- Identify optimal target population for therapeutic effect
- Evaluate placebo vs. 25, 75, 150 million MPCs injected by endomyocardial catheter in 60 patients with class II/III heart failure and EF<40%

Results

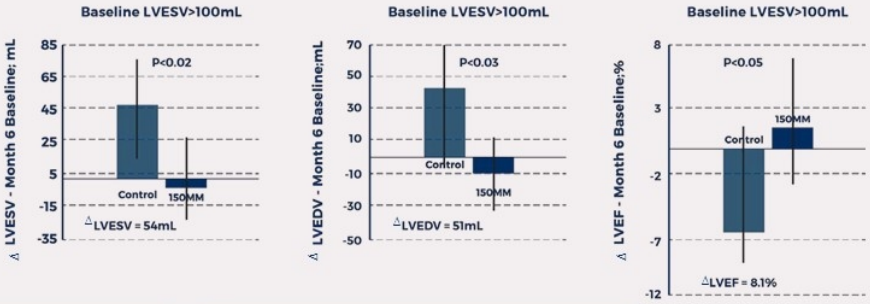
- At 6 months: Dose-dependent effect seen on left ventricular remodeling, with 150 million cell dose (MPC-150-IM) showing greatest effect vs. controls



Source: 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. LVESV = Left ventricular end systolic volume; LVEDV = Left Ventricular End-Diastolic Volume; EF = Ejection Fraction.

Revascor: Therapeutic Benefit on LV Remodeling in Phase 2 Subjects with LVESV>100ml[1]

- Placebo corrected benefit of 150MM cell dose on cardiac volumes and ejection fraction at 6 months was greatest in patients with more advanced heart failure as defined by baseline LVESV>100ml at baseline

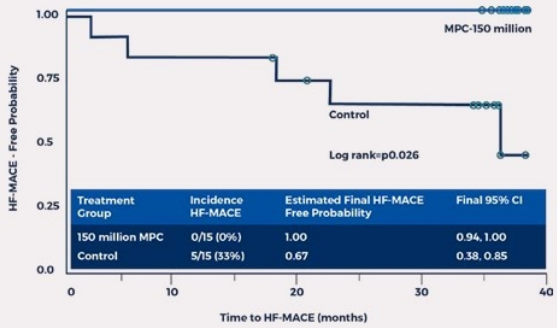


	Change (Entire cohort) Month 6 minusbaseline			Change (LVESV>100mL) Month 6 minusbaseline			
	PBO(n=15)	150M MPC (n=15)	Δ, PBO corrected	PBO (n=7)	150M MPC (n=11)	Δ, PBO corrected	P-values
LVESV	+20	-7	-27	+46	-8	-54	<0.02
LVEDV	+20	-10	-30	+41	-10	-51	<0.03
LVEF	-2.3	+0.6	+2.9	-6.4	+1.7	+8.1	<0.05

1. Source : Perin et al., Journal of Cardiac Failure 2015; Vol 21(8): S107; 19th Annual Scientific Meeting of the Heart Failure Society of America, Emerson et al. LVESV = Left ventricular end systolic volume; LVEDV = Left Ventricular End-Diastolic Volume; LVEF = Left Ventricular Ejection Fraction.

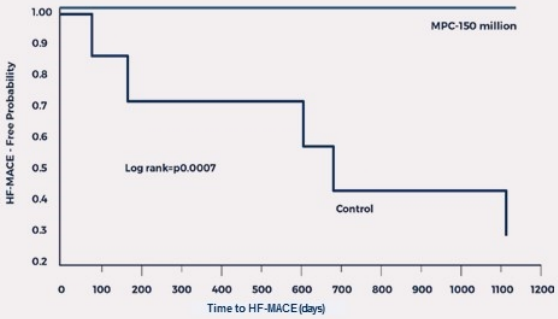
Revascor: Single Dose Prevented Any HF-MACE for 36 Months in Patients at Highest Risk of Recurrent Events and Death (Those with LVESV>100ml) in Phase 2

% HF-MACE Kaplan-Meier Curve over 36 months following treatment in all patients[1]



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

HF-MACE Kaplan-Meier Curve over 36 months following treatment in patients with LVESV>100ml[2]



- 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 logrank)
- 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.

Advanced Heart Failure

Revascor - Phase 3 trial fully enrolled

- Trial design is 1:1 randomized, controlled, double blinded; conducted over 55 sites across North America using 150 million cell dose vs control
- Events-driven Phase 3 trial completed enrollment of 566 patients in February 2019
- Primary endpoint: reduction in recurrent heart failure-related major adverse cardiac events such as heart failure-related hospitalizations and cardiac death
- Secondary endpoint: reduction in terminal cardiac events
- Target patient population enriched for those likely to be both highest risk for events and greatest responders to Revascor therapy
- ~ 90% of events in this Phase 3 trial have been accrued and validated

End-Stage Heart Failure

Revascor – Commercial opportunity in reducing GI bleeding in patients with LVADs

Burden of Illness

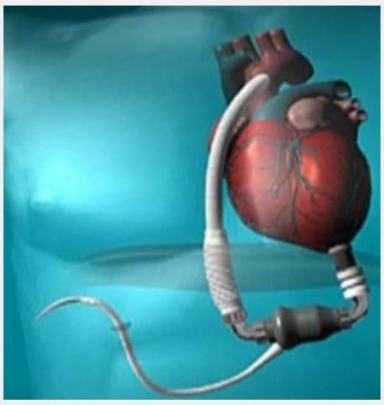
- In the US there are approx. 250,000–300,000 patients annually who suffer from advanced systolic heart failure (NYHA Class III–IV)[1]
- Despite optimal medical therapy, mortality exceeds 50% in class IV patients[1]

Ongoing Unmet Need

- LVADs have improved survival, but morbidity remains high with patients on average experiencing greater than two hospitalization annually[2]
- Gastrointestinal (GI) bleeding is the leading cause of non-surgical hospitalizations in LVAD patients[2]
- **Device attributable major adverse events (DAEs) can cost on average $USD46.5k per hospitalization[2]**

Market Opportunity

- Approx. 4,500 – 5,500 assist devices are implanted annually in the US[3, 4]
- **US LVAD market is growing double-digit CAGR and represents significant market growth opportunity[3,4]**
- US targeted commercial footprint provides low cost market entry



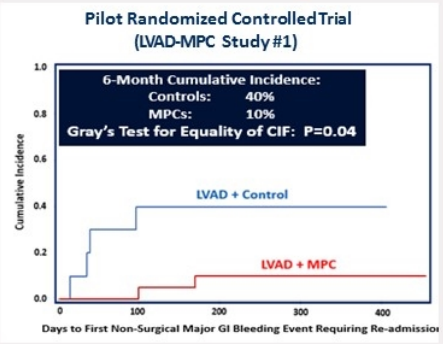
[1]Gustafsson G, Rogers J. (2017) Left ventricular assist device therapy in advanced heart failure: patient selection and outcomes, [2] Mehra, MR Salerno C, Cleveland JC (2018) Health care resources use and cost implications in the MOMENTUM 3 long-term outcome study: a randomized controlled trial of a magnetically levitated cardiac pump in advanced heart failure, [3]Agency for Healthcare Research and Quality – Healthcare Cost and Utilization Project – claims analysis using ICD-9 37.6 implantation of heart and circulatory assist systems, [4] Data on File

End-Stage Heart Failure

Revascor – Trials demonstrated reduced GI bleeding events in LVAD patients

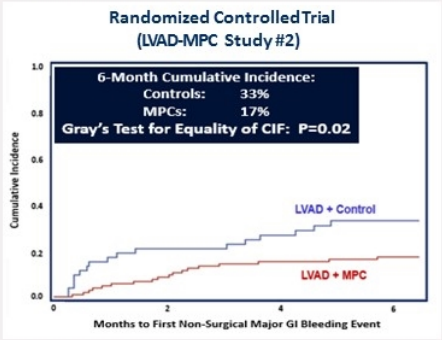
MPCs prolong time-to-first major GI bleeding event and reduced cumulative major GI bleeding events in two randomized controlled trials in LVAD patients[1,2]

Pilot Randomized Controlled Trial (LVAD-MPC Study #1)



MPC (n = 20)	Control (n = 10)	P-value
Event Rate (100-Pt-Months)	Event Rate (100-Pt-Months)	
4.2	**14.2**	**0.06**

Randomized Controlled Trial (LVAD-MPC Study #2)



MPC (n = 106)	Control (n = 53)	P-value
Event Rate (100-Pt-Months)	Event Rate (100-Pt-Months)	
3.8	**15.9**	**<0.001**

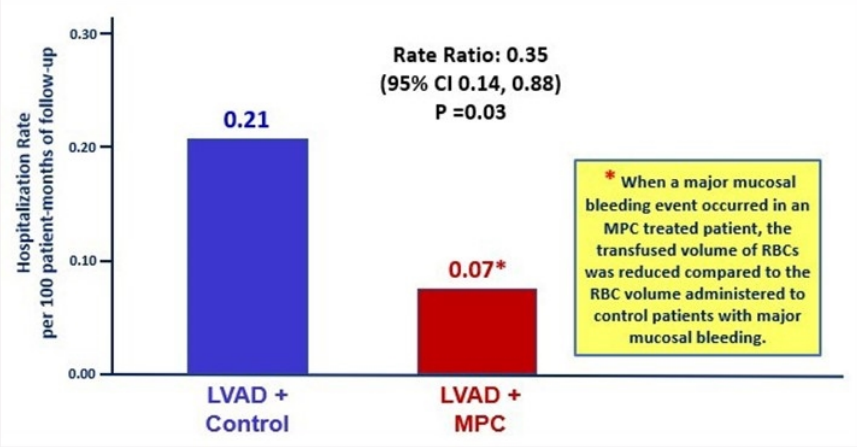
Rate of major GI bleeding events over six months in LVAD patients reduced by 70% and 76% with MPCs in two randomized controlled trials

1. Mesoblast internal data post-hoc analysis 2017 (clinicaltrials.gov; identifier: NCT01442129). 2. Presented at American Heart Association Scientific Sessions 2018.

End-Stage Heart Failure

Revascor—Reduced hospitalization rate from GI bleeding in Phase 2 trial

MPCs Reduce Hospitalization Rate from GI Bleeding by 65% in 159-Patient Phase 2 Trial[1]



1 Presented at American Heart Association Scientific Sessions 2018

Chronic Low Back Pain (CLBP)

MPC-06-ID – Market opportunity in CLBP due to disc degeneration

Burden of Illness

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

Minimal Treatment Options

- Treatment options for patients with CLBP who fail conservative therapy include opioids and surgery
- 50% of opioid prescriptions are for CLBP[2]

Unmet Need

- Novel therapeutic approach for durable improvement in pain and function
- Potential alternative for 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[3,4,5]
- **US market opportunity >$US $1 billion**[3,4,5,6]

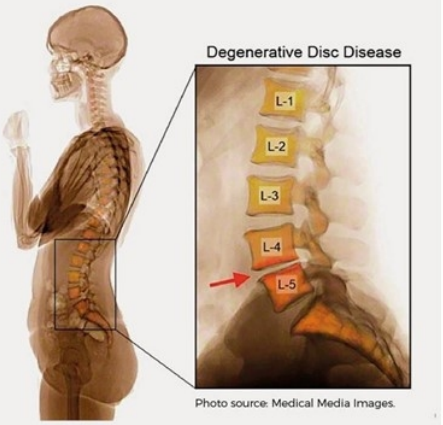


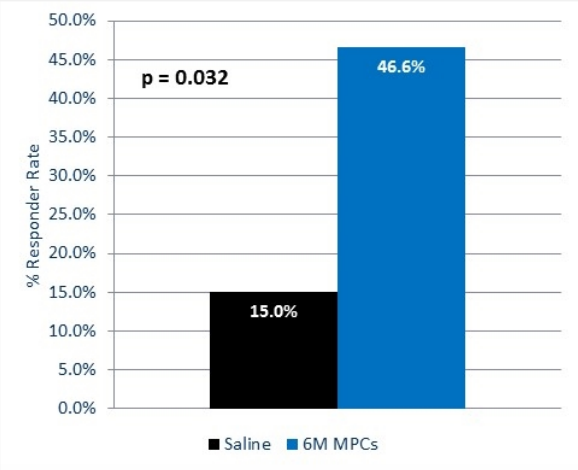
Photo source: Medical Media Images.

1. Williams, J., NG, Nawi, Pelzter, 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._

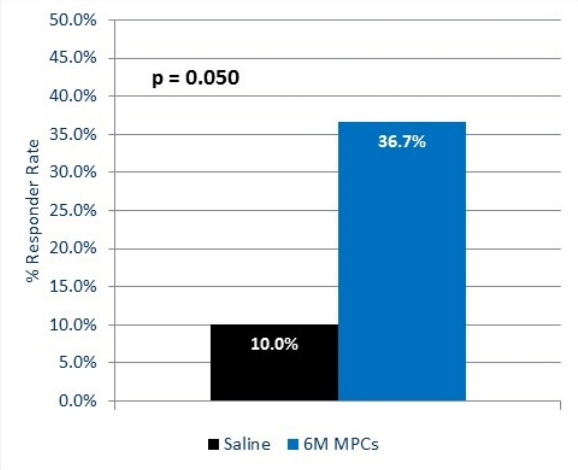
Chronic Low Back Pain

MPC-06-ID – Post-Hoc Phase 2 results provide target endpoints for Phase 3 trial

A: Phase 2: Treatment Success Responders[1,2] at 12 Months



B: Phase 2: Treatment Success Responders[1,2] at both 12 & 24 Months



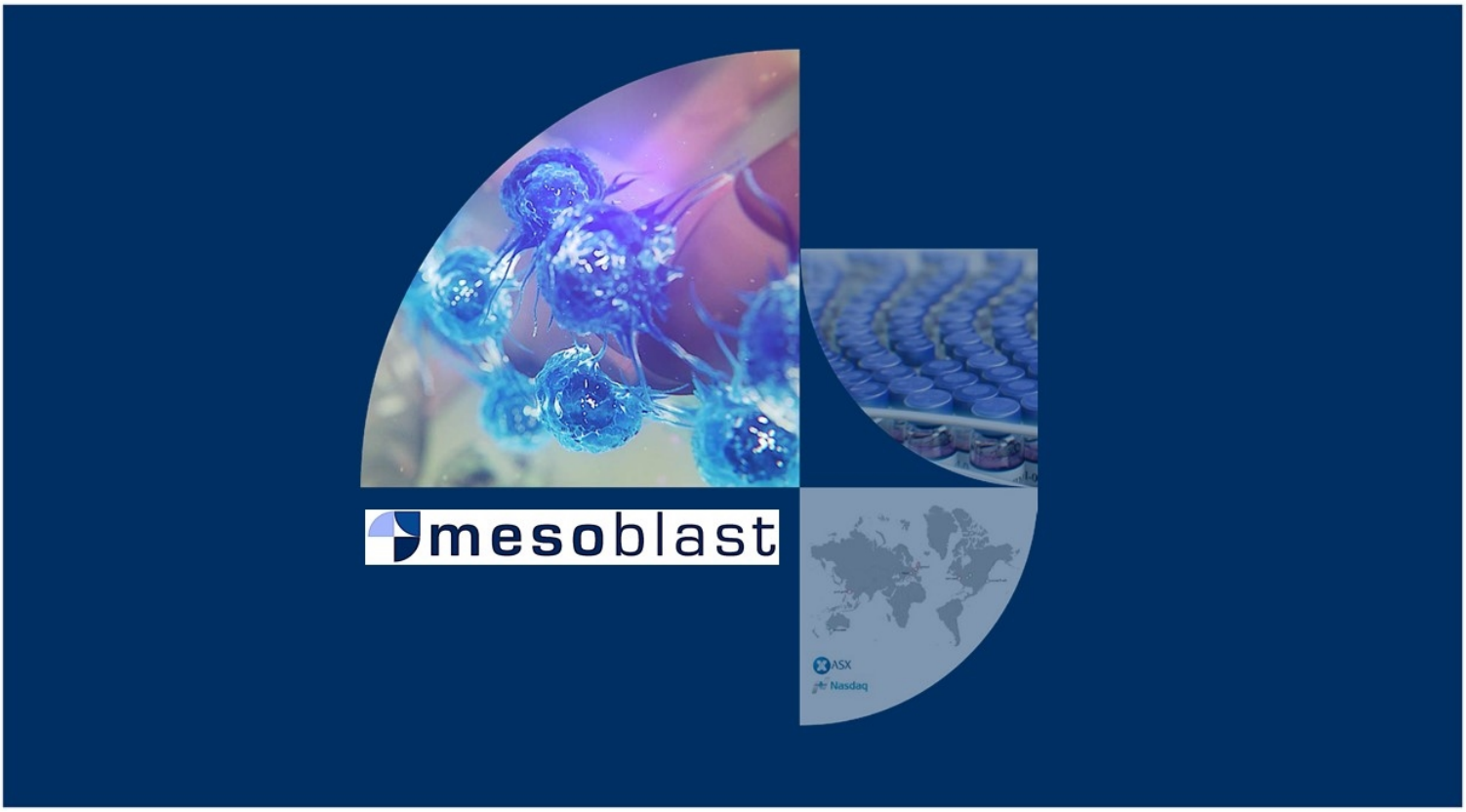
1. Subjects with missing data are classified as non-responders.
2. Treatment Success Responders have a 50% reduction in LBP as measured by VAS AND a 15 point improvement in function as measured by ODI at a) 12 months, and b) both 12 and 24 months and no intervention through 24 months.

Chronic Low Back Pain

MPC-06-ID – Ongoing Phase 3 Clinical Trial

- Three-arm study comparing 6-million MPC with or without hyaluronic acid (HA) against saline control
- Primary efficacy endpoint agreed to with FDA:
  - Overall Treatment Success Composite at both 12 and 24 months as measured by:
    - At least 50% reduction from baseline in Visual Analogue Scale (VAS) pain score at both 12 and 24 months post-treatment; and
    - At least a 15 point decrease from baseline in Oswestry Disability Index (ODI) function score at both 12 and 24 months post-treatment; and
    - No interventions affecting the treated disc through 24 months
- Study powered to show efficacy for both 6-million MPC arms (with and without HA)

404 patient 2:1 randomized Phase 3 trial completed enrollment March 2018; all patients have completed 12 month safety and efficacy follow-up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