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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 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

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**INFORMATION CONTAINED ON THIS REPORT ON FORM 6-K**

On November 27, 2019, Mesoblast Limited filed with the Australian Securities Exchange the Chairman's Annual General Meeting address, presentation to Annual General Meeting and results of Annual General Meeting, which are attached hereto as [Exhibit 99.1](#), [Exhibit 99.2](#) and [Exhibit 99.3](#), and are incorporated herein by reference.

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**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 29, 2019

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INDEX TO EXHIBITS

Item

- 99.1 Chairman's Annual General Meeting address, dated November 27, 2019.
- 99.2 Presentation to Annual General Meeting, dated November 27, 2019.
- 99.3 Results of Annual General Meeting, dated November 27, 2019.



**INTERVIEW WITH MESOBLAST CHAIRMAN JOSEPH R. SWEDISH**  
**2019 MESOBLAST ANNUAL GENERAL MEETING**  
**November 27, 2019**

*Joseph R. Swedish was Executive Chairman, President and CEO of Anthem Inc., a Fortune 33 company and the leading health benefits provider in the United States. For 12 consecutive years, Modern Healthcare named Mr Swedish as one of the 100 Most Influential People in Healthcare. He also sits on the Board of Directors of technology leaders IBM and CDW.*

**What attracted you to join Mesoblast, and then become Chairman of the Board?**

Mesoblast's business strategy to deliver innovative, clinically superior and cost-effective therapeutic solutions to some of the largest healthcare challenges today is the reason I chose to join the Board.

I believe Mesoblast is on the cusp of transforming the way we think about treating life-threatening diseases and unmet medical conditions that have eluded the pharmaceutical industry. In my view, the clinical study data to date showing that these cellular medicines work best in the more advanced stages of diseases in contrast to standard of care drugs gives great hope to millions of patients around the world.

Importantly, Mesoblast's platform technology potentially has broad implications beyond its Phase 3 assets. I believe that all going well, Mesoblast will maintain its leadership and first mover status in targeting blockbuster markets.

This broad portfolio of Phase 3 and Phase 2 assets are just the tip of the innovation iceberg for Mesoblast. I consider it a privilege to be part of this important company.

**How do you see Mesoblast's platform technology as an engine for innovative cellular medicines to potentially transform the therapeutic landscape?**

Diseases such as graft versus host disease, advanced and end-stage heart failure and chronic low back pain are some of the most complex disease challenges we face. The classic drug development approach to treat these multifactorial diseases has relied on a single target or single disease pathway model. What is so exciting about the multi-factorial mechanisms of action inherent in the Mesoblast technology platform is that for the first time we may be able to address the underlying causes of these complex diseases to bring meaningful quality of life improvement to millions of patients.

**How does your experience assist Mesoblast's objective to successfully commercialize its cellular medicines?**

As Mesoblast transitions to a commercial stage company, I would like to think that my long-term experience in healthcare resource allocation and reimbursement metrics will be an asset, especially as we plan our first product launch in the United States.

**Is the United States reimbursement system supportive of new medicines that provide potential life-saving outcomes for patients?**

I know first-hand that the US reimbursement system is highly supportive of new therapeutic approaches that deliver cost efficiencies while providing superior clinical outcomes. As we know, the advanced stages of the diseases that Mesoblast technology may address represent an escalating and unsustainable economic burden on payers and state and federal governments. I am personally very excited by the prospects of helping contribute to the reduction in cost of care while delivering much improved clinical outcomes to millions of patients who need these next generation medicines.

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

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## Since you joined the Board, how have you seen Mesoblast's commercial prospects evolving?

I've been very impressed by the high calibre of people who under the leadership of our CEO, Dr Silviu Itescu, are laser focused on delivering commercial outcomes. The business strategy developed by the Board has been honed and is being very well executed.

### 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 cell therapy technology platform to establish a broad portfolio of commercial products and late-stage product candidates. Two products have been commercialized in Japan and Europe by its licensees, and it has established commercial partnerships in Europe and China for certain Phase 3 assets. In the United States, Mesoblast has initiated submission of a rolling Biologics License Application to the FDA to seek approval of its product candidate for acute graft versus host disease following a successful Phase 3 trial, and is completing Phase 3 trials for its advanced heart failure and chronic low back pain product candidates. Mesoblast's proprietary manufacturing process yields industrial-scale, frozen, off-the-shelf, cellular medicines based on its mesenchymal lineage cell platform technology. These cell therapies, with defined pharmaceutical release criteria, are planned to be readily available to patients worldwide. Mesoblast has locations in Melbourne, New York, Singapore and Texas and is listed on the Australian Securities Exchange (MSB) and on the Nasdaq (MESO). For more information, please see [www.mesoblast.com](http://www.mesoblast.com).  
LinkedIn: Mesoblast Limited and Twitter: @Mesoblast

### 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 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.

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**Global Leader in Allogeneic Cellular  
Medicines for Inflammatory Diseases**

**First Quarter Ended September 30, 2019**

Nasdaq: MESO ASX: MSB

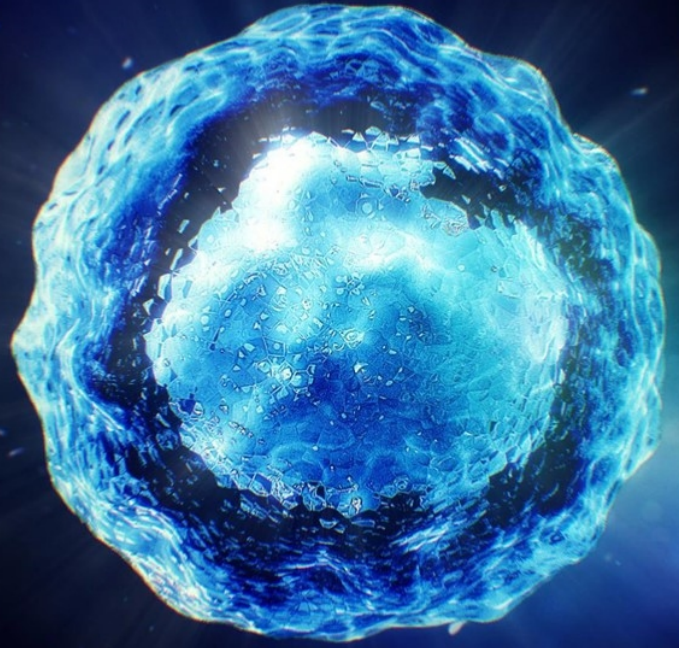


## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

*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.*

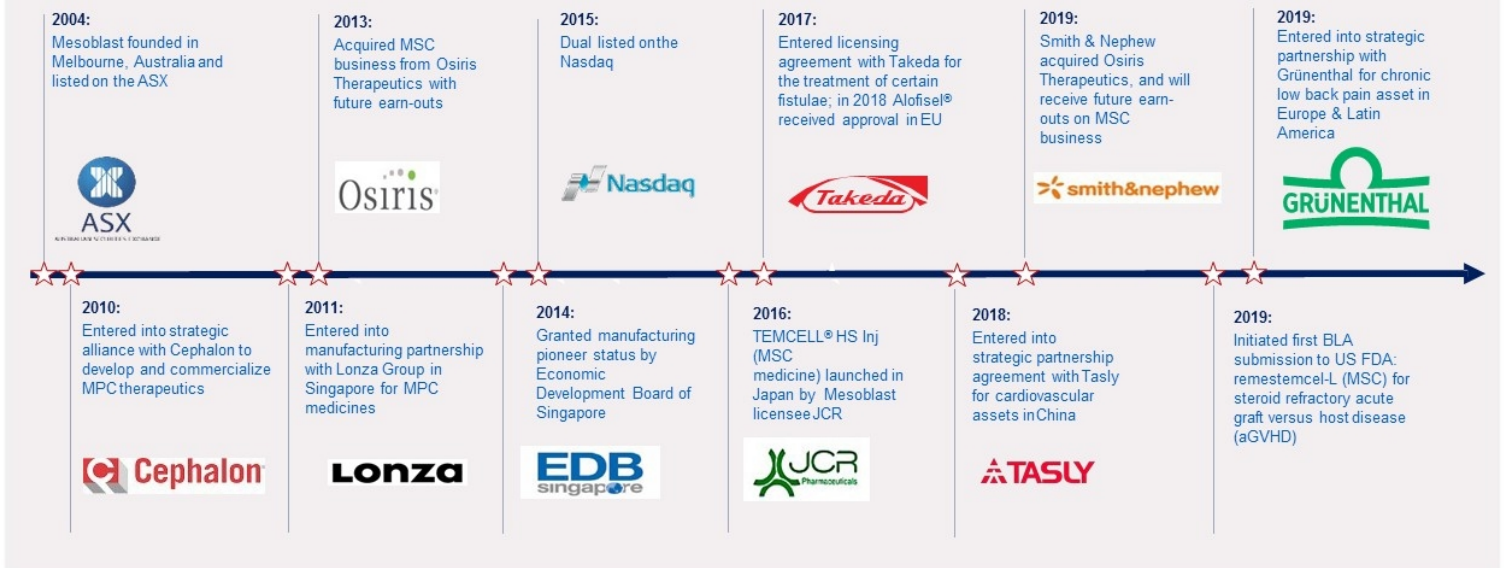
## Our Mission

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







Innovative Technology Platform <sup>1</sup>	Late Stage Pipeline	Commercialization
<ul style="list-style-type: none"> <li>▪ Innovative technology targets some of the most severe disease states refractory to conventional therapies</li> <li>▪ Well characterized multimodal mechanisms of action</li> <li>▪ Underpinned by extensive, global IP estate</li> </ul>	<ul style="list-style-type: none"> <li>▪ Initiated rolling filing with US FDA for approval for steroid-refractory aGVHD</li> <li>▪ Two Phase 3 product candidates – heart failure and back pain – with near term US trial readouts</li> <li>▪ Back pain Phase 3 product candidate partnered in Europe &amp; Latin America with Grünenthal</li> <li>▪ Heart failure Phase 3 product candidate partnered in China</li> </ul>	<ul style="list-style-type: none"> <li>▪ Building US sales force for potential aGVHD product launch</li> <li>▪ Industrial-scale manufacturing to meet commercial demand</li> <li>▪ First approved products commercialized by licensees in Japan<sup>2</sup> and Europe<sup>3</sup></li> <li>▪ Continued growth in royalty revenues from strategic partnerships</li> </ul>

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 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

- ~1,000 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



**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 and Late-Stage Product Pipeline

PLATFORM	PRODUCT	THERAPEUTIC AREA	APPROVAL	COMMERCIAL RIGHTS
MSC (Bone Marrow)	TEMCELL® HS Inj <sup>1</sup>	Acute Graft Versus Host Disease	1st allogeneic regen med approved in Japan	JCR Japan
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	
MSC suite	Remestemcel-L	Acute Graft Versus Host Disease	[Progress bars]			BLA submission to FDA underway	mesoblast the regenerative medicine company
		Crohn's Disease	[Progress bars]				
		Knee Osteoarthritis	[Progress bars]				
MPC suite	Revascor	Advanced HF (Class II/III)	[Progress bars]			TASLY China mesoblast ROW	
		End-Stage HF (Class III/IV)	[Progress bars]				
	MPC-06-ID	Chronic Low Back Pain	[Progress bars]			GRUNENTHAL Europe Lat Am mesoblast ROW	
	MPC-300-IV	Rheumatoid Arthritis Diabetic Nephropathy	[Progress bars]			mesoblast the regenerative medicine company	

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

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

# Partnerships and License Agreements



- Strategic partnership to develop and commercialize MPC-06-ID for chronic low back pain due to degenerative disc disease in patients who have exhausted conservative treatment options
- Grünenthal will have exclusive commercialization rights for Europe and Latin America
- Mesoblast will receive up to US\$150 million in upfront and milestone payments prior to product launch, as well as further commercialization milestone payments
- Cumulative milestone payments could exceed US\$1 billion depending on the final outcome of Phase III studies and patient adoption. Mesoblast will also receive tiered double digit royalties on product sales



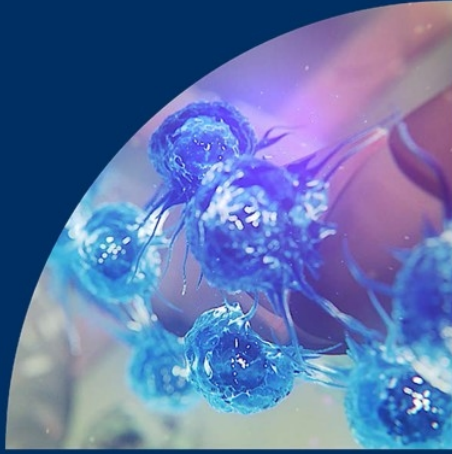
- JCR has rights to use our MSC technology to treat acute GVHD in Japan
- Its product TEMCELL® HS Inj. was the first fully approved allogeneic cellular medicine in Japan
- Royalties and milestones received in last 12 months exceed US\$6.0 million
- License expanded to cover use in epidermolysis bullosa (EB), a highly debilitating and sometimes lethal skin disease and hypoxic ischemic encephalopathy (HIE) in newborns



- 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



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



ASX  
Nasdaq

Financials  
First Quarter FY2020



## Substantial Increase in Revenues

For the quarter ending (US\$m)	September 30, 2019	September 30, 2018	September 30, 2017
Upfront/milestone revenue	15.0	10.5	0.5
Commercialization revenue	1.9	1.0	0.6
Interest revenue	0.1	0.1	0.1
<b>Total revenue</b>	<b>17.0</b>	<b>11.6</b>	<b>1.2</b>

- Strategic partnerships drive upfront and milestone revenues
  - US\$15.0 million for an upfront milestone payment for the strategic partnership with Grünenthal GmbH in the first quarter FY2020
  - US\$10.0 million from licensee Tasly Pharmaceutical Group in the first quarter FY2019
  - US\$0.5 million from licensee JCR in the first quarter FY2019
- 85% growth in commercialization revenue from royalty income on sales of TEMCELL® HS. Inj.<sup>1</sup>

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

## Loss After Tax Reduced by 72% (US\$14.0 million)

Profit and Loss for the quarter ending (US\$m)	September 30, 2019	September 30, 2018
<b>Total Revenue</b>	17.0	11.6
Research and development	(12.4)	(18.5)
Manufacturing	(2.7)	(4.3)
Management & administration	(5.4)	(5.6)
Contingent consideration	(0.3)	(0.6)
Other operating income & expenses	(0.2)	(0.2)
Finance costs	(3.4)	(2.6)
<b>Loss before tax</b>	(7.4)	(20.2)
Income tax benefit	1.9	0.7
<b>Loss after tax</b>	(5.5)	(19.5)

Loss after tax reduced by US\$14.0 million (72%) predominantly due to:

- US\$6.1 million reduction in R&D expenditure; and
- US\$5.4 million increase in milestone revenues from strategic partnerships and increased commercialization revenues from product sales in Japan.

## Strong Balance Sheet and 20% Reduction in Operating Net Cash Outflows

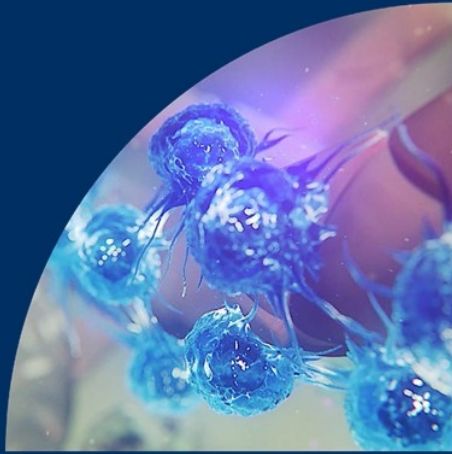
As of (US\$m)	September 30, 2019	June 30, 2019
Cash on Hand	34.5	50.4
Pro forma cash on hand	100.0	50.4

- Pro forma cash on hand at September 30, 2019 includes a US\$15.0 million upfront payment for the strategic partnership with Grünenthal received on October 1, 2019 and US\$50.5 million of gross cash proceeds from an institutional capital raise received on October 3, 2019.
- Over the next 12 months, we may receive up to an additional US\$30.0 million in milestone payments under the strategic partnership with Grünenthal and a further US\$35.0 million under the arrangements with Hercules Capital and NovaQuest, subject to achievement of certain milestones.

For the quarter ending (US\$m)	September 30, 2019	September 30, 2018	September 30, 2017
Operating net cash outflows	(15.6)	(19.5)	(20.4)

- 20% (US\$3.9 million) reduction in net operating cash outflows for the three months ended September 30, 2019.





Operational Highlights  
First Quarter FY2020

ASX  
Nasdaq

# 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)<sup>1</sup>
- Steroid-refractory aGVHD is associated with **mortality rates as high as 90%<sup>1,7</sup> and significant extended hospital stay costs<sup>2</sup>**

## 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<sup>3,4</sup>
- Our licensee, JCR Pharmaceuticals Co., Ltd launched TEMCELL® HS Inj.<sup>5</sup> in Japan for SR-aGVHD in 2016; reimbursed up to ~\$USD195k<sup>6</sup>
- **SR-aGVHD represents \$USD > 700m US/EU market opportunity<sup>4,8</sup>**



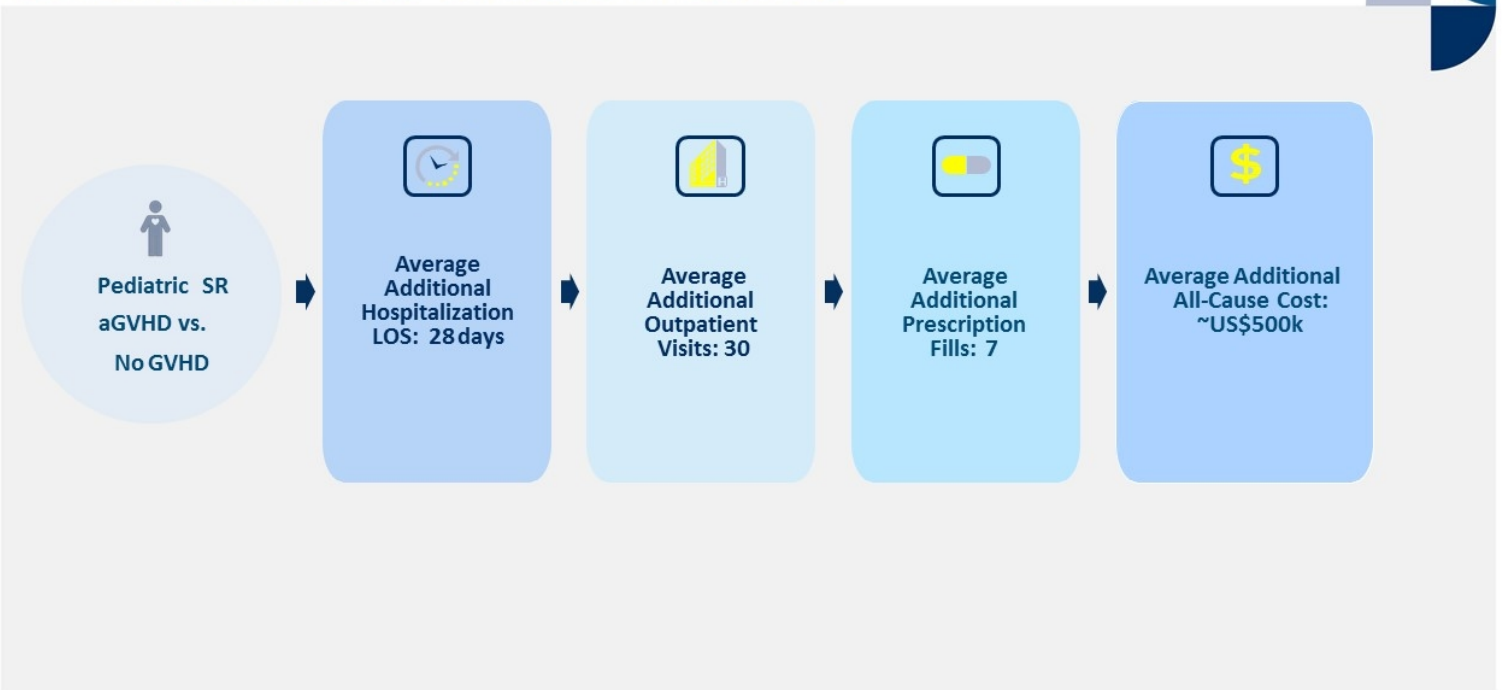
1. Westin, J., Saliba, RM., Lima, M. (2011) Steroid-refractory acute GVHD: predictors and outcomes. *Advances in Hematology*. 2. Anthem-HealthCore/Mesoblast claims analysis (2016). Data on file 3. Niederwieser D, Baldomero H, Szer J. (2016) Hematopoietic stem cell transplantation activity worldwide in 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. 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*. 8. Data on file

## 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
- Fast Track designation provides eligibility for FDA priority review
- Commercialization strategy in place for product launch
- Ramp-up for inventory build
- Building out efficient, targeted sales force - 15 centers account for ~50% of patients

# Remestemcel-L: SR-aGVHD is Associated with Significant Burden of Illness in Children in the U.S.<sup>1</sup>



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<sup>1</sup>



(n=20)

0

Reaction to  
Tested Target Profile<sup>2</sup>

Median  
Response

6

7

Max Rating Product  
Attributes

## 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.

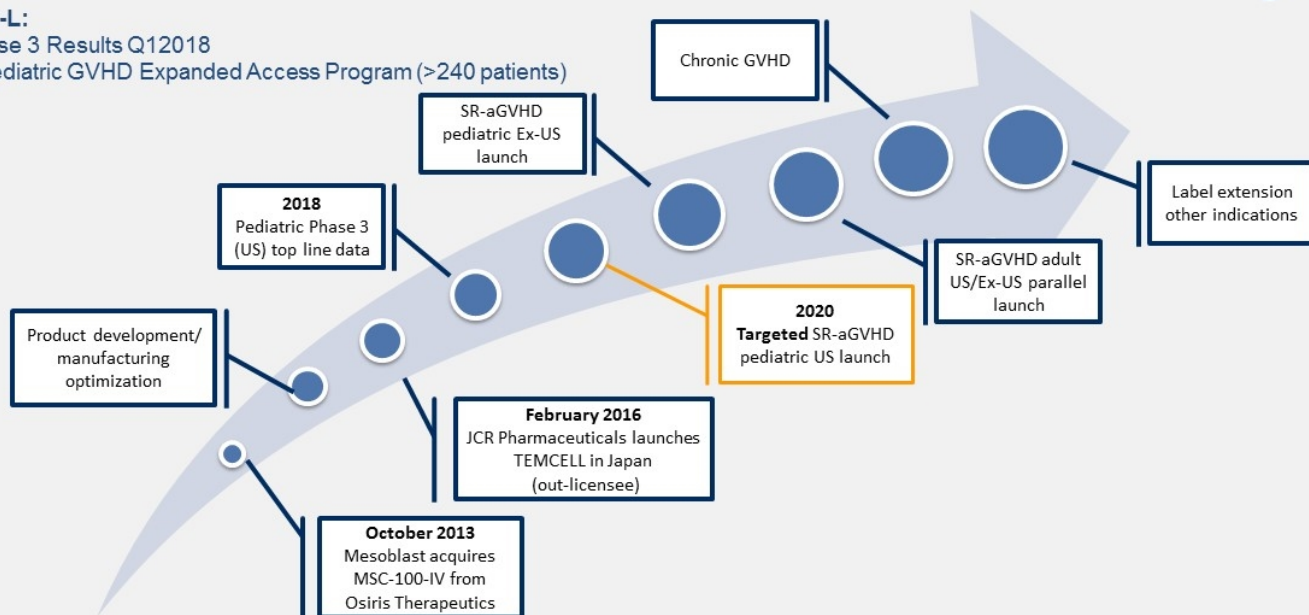
2. ZS Associates June 2018 Qualitative Market Research: MCO Medical Directors n=5, Transplant Center Directors n=5, Hospital Pharmacy Directors n=5, AMC-based Hem/Oncs / KOLs n=3

# Remestemcel-L: Life Cycle Strategy

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)





# Remestemcel-L for Acute GVHD



## Recent Highlights

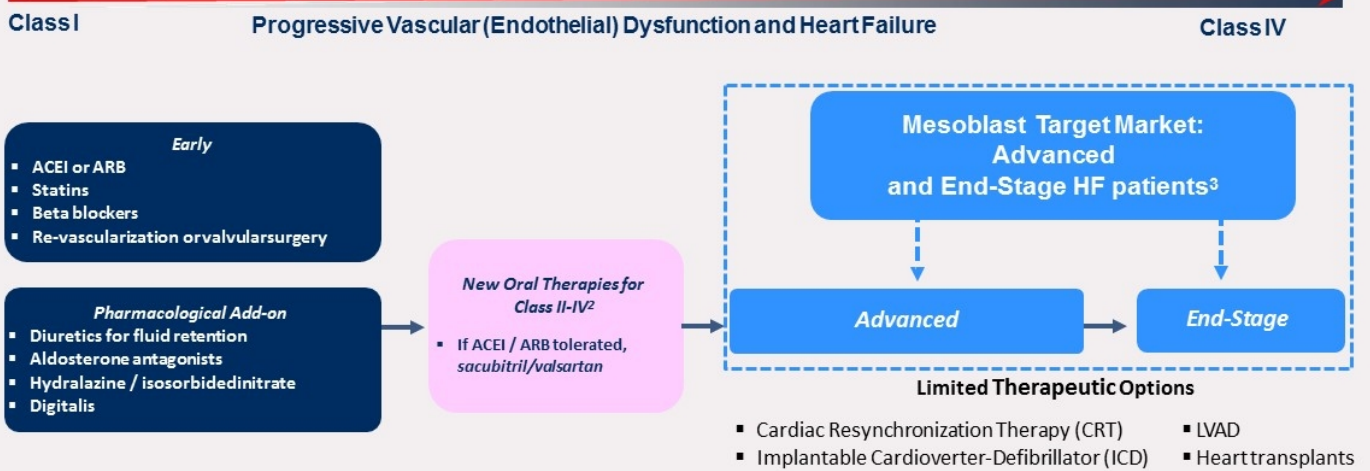
- Continued growth in revenues from royalties on sales of TEMCELL in Japan for steroid refractory aGVHD
  - Product adoption and reimbursement seen in the Japan GVHD market for TEMCELL informs Mesoblast US commercial strategy for remestemcel-L in aGVHD
  - US addressable market for SR aGVHD in children and adults is expected to be approximately 8-fold larger than Japan, a major commercial opportunity due to greater patient numbers, incidence and pharmacoeconomics
- Mesoblast entered into an agreement with Lonza for commercial product manufacture in line with the corporate strategy to facilitate appropriate inventory build ahead of the planned launch of remestemcel-L

## Key milestones

- Upcoming filing of completed Biologic License Application (BLA) submission to the US Food and Drug Administration (FDA)
- Within a maximum of 60 days after receipt of the complete application, Mesoblast will be informed by FDA of acceptance of the filing, and whether the BLA has received Priority Review under its existing Fast Track designation
- If approved, the US launch of remestemcel-L is expected to occur next year

# Advanced and End-Stage Heart Failure

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



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

2. Corlanort® (vabradine) approved by FDA (April 2015), ENTRESTO® (sacubitril/valsartan) approved by FDA (July 2015).

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



# Advanced Heart Failure

## Revascor – Commercial opportunity

### Burden of Illness

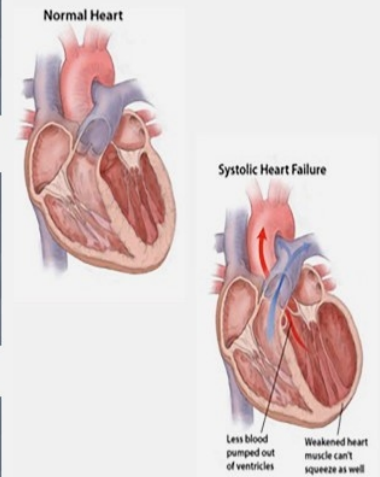
- ~ 8 million patients with chronic heart failure by 2030 in US alone<sup>1</sup>
- 17-45% globally die within 1 year of hospital admission<sup>1</sup>
- Majority of advanced heart failure patients die within 5 years<sup>1</sup>

### Limited Options / Unmet Need

- Despite recent advances in newly approved drugs, limited treatment options are available for patients with advanced heart failure<sup>2</sup>
- 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<sup>4</sup>
- Hospitalizations account for ~69% of expenditure<sup>3-5</sup>
- **Multi-billion dollar annual market opportunity in US**<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. Gunvitz JH, Magid DJ, Smith DH, et al. Contemporary Prevalence and Correlates of Incident Heart Failure with Preserved Ejection Fraction. The American Journal of Medicine. 2013;126(5):393-400. Derived by applying a HF-REF prevalence rate of 32.6% to the U.S. rate of 5.7m U.S. patients., 4. A. Reevaluation of the Costs of Heart Failure and its Implications for Allocation of Health Resources in the United States. Voigt J. Clin.Cardiol. 37, 5, 312-321 (2014)., 5. The Medical and Socioeconomic Burden of Heart Failure: A Comparative Delineation with Cancer. Dimitrios, F. International Journal of Cardiology (2015), doi: 10.1016/j.ijcard.2015.10.172.

# 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

# Revascor for Advanced Heart Failure



## Key milestones

- Full accrual of primary endpoints events in the Phase 3 trial of Revascor for advanced heart failure around the end of CY19
- Data read-out for this Phase 3 trial planned in H1 CY20
- Results will be considered pivotal to support regulatory approval in the US, as well as China through the Tasly partnership

# End-Stage Heart Failure

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

### Burden of Illness

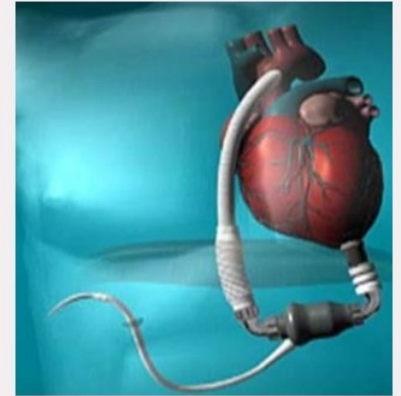
- In the US there are ~ 250,000–300,000 patients annually who suffer from advanced systolic heart failure (NYHA Class III–IV)<sup>1</sup>
- Despite optimal medical therapy, mortality exceeds 50% in class IV patients<sup>1</sup>

### Ongoing Unmet Need

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

### Market Opportunity

- ~ 4,500 – 5,500 assist devices are implanted annually in the US<sup>3, 4</sup>
- **US LVAD market is growing double-digit CAGR and represents significant market growth opportunity<sup>3,4</sup>**
- US targeted commercial footprint provides low cost market entry

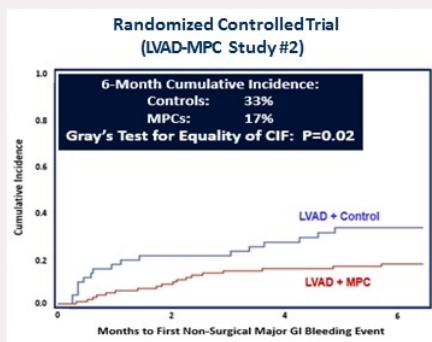
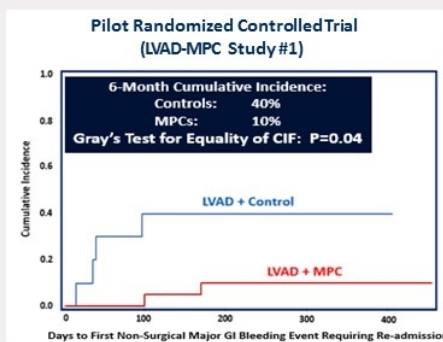


<sup>1</sup>Gustafsson G, Rogers J. (2017) Left ventricular assist device therapy in advanced heart failure: patient selection and outcomes, <sup>2</sup>Mehra, MR Salerno C, Cleveland JC (2018) Health care resources use and cost implications in the MOMENTUM 3 long-term outcome study: a randomized controlled 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-9 37.6 implantation of heart and circulatory assist systems, <sup>4</sup>Data on File

# End-Stage Heart Failure in LVAD Patients

Revascor reduced GI bleeding events causing hospitalizations in two randomized trials

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



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

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.



# Revascor for End-Stage Heart Failure in LVAD Patients



## Recent Highlights

- Mesoblast and the International Center for Health Outcomes Innovation Research (InCHOIR) at the Icahn School of Medicine at Mount Sinai in New York have agreed on the protocol for a confirmatory Phase 3 trial of Revascor
- In line with FDA guidance, the primary endpoint will be reduction in major mucosal bleeding events, and key secondary endpoints will be 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

## Key milestones

- Initiation of confirmatory Phase 3 trial of Revascor for the reduction of mucosal bleeding in end-stage heart failure patients implanted with an LVAD
  - Results will be considered pivotal to support regulatory approval in the US

# MPC-06-ID: A New Paradigm for Treatment of 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>1,2</sup>, including excessive use of opioids in this patient population

## Minimal Treatment Options

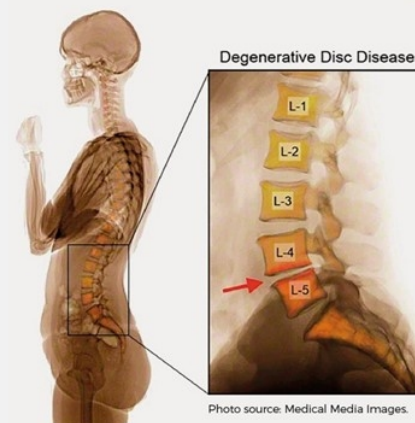
- Minimal treatment options for patients with chronic low back pain (CLBP) who fail conservative therapy include opioids and surgery
- 50% of opioid prescriptions are for CLBP

## Unmet Need

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

## Market Opportunity

- Over 7m patients are estimated to suffer from CLBP due to degenerative disc disease (DDD) in each of the U.S. and E.U.<sup>3-6</sup>
- MPC-06-ID development program targets over 3.2m patients in U.S. and 4m in E.U.5 with moderate to severe disease



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

## MPC-06-ID – Development Strategy for US & Europe



- Phase 3 trial in chronic low back pain completed enrolment in March 2018 with 404 patients randomized to receive MPC-06-ID or placebo
- Initiate confirmatory Phase 3 trial in Europe in partnership with Grünenthal
- Complete commercial manufacturing in partnership with Grünenthal
- Results of confirmatory Phase 3 clinical trials in US and Europe, together with commercial manufacturing, expected to support regulatory approval and commercial launches in both Europe and US for MPC-06-ID in chronic low back pain due to degenerative disc disease



# Key Terms of the Strategic Partnership with Grünenthal



## Grünenthal has obtained

- An exclusive license for Europe and Latin America to develop and commercialize MPC-06-ID in the treatment of chronic low back pain due to degenerative disc disease

## In consideration, Mesoblast will receive

- Up to US\$150 million in upfront and milestone payments prior to product launch, as well as further commercialization milestone payments
- Payments include commitments up to US\$45 million within the first year comprising US\$15 million on signing, US\$20 million on receiving regulatory approval to begin a confirmatory Phase 3 trial in Europe, and US\$10 million on certain clinical and manufacturing outcomes
- Cumulative milestone payments could exceed US\$1 billion depending on the final outcome of Phase 3 studies and patient adoption
- Mesoblast will also receive tiered double digit royalties on product sales
- Mesoblast retains the rights for the rest of world, including the US and Japan markets

# Transaction Benefits to Mesoblast



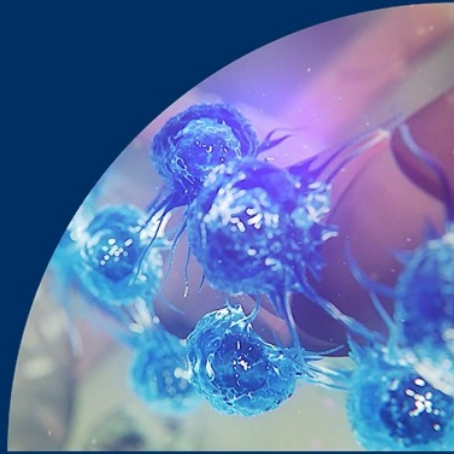
- ✓ **Strong commercial partner**
  - Delivers commercialization, distribution, sales & marketing
  - Field force comprises around 1,600 people across Europe, Latin America & US – overall focus is on pain – visited nearly 300,000 stakeholders in 2018 (physicians, pharmacists & health administrators)
  - Provides knowledge and knowhow in manufacturing, regulatory affairs (Europe in particular)
- ✓ **Advances approval pathway**
  - Provides funding for Phase 3 trial in Europe reducing Mesoblast cash outflow
  - Mesoblast and Grünenthal will collaborate on the study design for a confirmatory Phase 3 trial in Europe
  - Confirmatory European and US (currently ongoing) Phase 3 trials are expected to support regulatory approval in both Europe and US
- ✓ **Transaction focuses on Europe**
  - Mesoblast maintains rights to all other geographic markets, including US, Japan and China for additional partnering opportunities to maximize shareholder return
- ✓ **Third party endorsement provides validation of technology platform**

# MPC-06-ID for Chronic Low Back Pain



## Key Milestones

- Last patient last visit at 24-months of follow up in the Phase 3 trial of MPC-06-ID for chronic low back pain H1 CY20, with the primary endpoint being a composite outcome of pain and function at 12 and 24 months
- Obtain clearance in CY20 from European regulatory authorities to begin European Phase 3 trial
- Results from the Phase 3 trials will be considered pivotal to support regulatory approval in the US, as well as Europe through the Grünenthal partnership



 **mesoblast**



Questions

27 November 2019

**Mesoblast Limited (MSB)**  
**Results of Annual General Meeting Held 27 November 2019**

In accordance with Listing Rule 3.13.2 and section 251AA of the Corporations Act 2001, we advise details of the resolutions and the proxies received in respect of each resolution as per the attached report.

Yours faithfully

Charlie Harrison  
Company Secretary

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**Mesoblast Limited**  
ABN 68 109 431 870

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As required by section 251AA(2) of the Corporations Act 2001 (Commonwealth) the following statistics are provided in respect of each resolution on the agenda.

Resolution	Manner in which the securityholder directed the proxy vote (as at proxy close):					Manner in which votes were cast in person or by proxy on a poll (where applicable)			Resolution Result
	Votes For	Votes Against	Discretionary Chairman of Meeting Other Nominated Persons	Total Votes Discretionary	Votes Abstain	For	Against	Abstain **	
2 ADOPTION OF THE REMUNERATION REPORT	164,637,727	34,781,277	749,317 306,631	1,055,948	992,269	166,495,247 82.72%	34,782,677 17.28%	1,165,259	Carried
3A RE-ELECTION OF DR ERIC ROSE AS A DIRECTOR	262,662,551	6,441,862	773,567 306,631	1,079,528	734,260	266,918,241 97.58%	6,612,752 2.42%	734,260	Carried
3B RE-ELECTION OF MR WILLIAM BURNS AS A DIRECTOR	266,872,209	2,256,708	766,567 306,631	1,074,528	734,796	271,272,389 96.17%	2,258,108 0.83%	734,796	Carried
4A APPROVAL OF PROPOSED ISSUE OF OPTIONS TO NEWLY-APPOINTED NON-EXECUTIVE CHAIR, MR JOSEPH R. SWEDISH	153,459,463	27,706,233	756,657 306,631	1,063,288	9,808,237	164,897,965 85.32%	28,381,981 14.68%	9,808,237	Carried
4B APPROVAL OF PROPOSED ISSUE OF OPTIONS TO NON-EXECUTIVE DIRECTORS, DR ERIC ROSE AND MR WILLIAM BURNS	153,375,190	27,804,996	817,847 306,631	1,124,478	9,732,567	164,874,882 85.27%	28,480,734 14.73%	9,732,567	Carried
5 APPROVAL OF PROPOSED ISSUE OF OPTIONS TO CEO, DR SILVIU ITCESCU, IN CONNECTION WITH HIS REMUNERATION FOR FY18/19 & FY19/20	186,068,638	5,025,879	800,307 306,631	1,106,938	9,815,766	188,232,038 97.39%	5,040,379 2.61%	9,815,766	Carried
6 APPROVAL OF EMPLOYEE SHARE OPTION PLAN FOR EMPLOYEES FOR THE PURPOSE OF LISTING RULE 7.2	185,905,145	5,222,139	790,957 306,631	1,097,588	9,812,349	187,868,705 97.20%	5,407,129 2.80%	9,812,349	Carried
7 RATIFICATION OF ISSUE OF SHARES TO EXISTING AND NEW INSTITUTIONAL INVESTORS	98,219,155	282,030	820,717 306,631	1,127,348	306,655	102,456,665 99.56%	452,920 0.44%	306,655	Carried

\*\* - Note that votes relating to a person who abstains on an item are not counted in determining whether or not the required majority of votes were cast for or against that item