

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 2020

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 27, 2020, 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: August 28, 2020

INDEX TO EXHIBITS

Item

- 99.1 Press release of Mesoblast Ltd, dated August 27, 2020.
- 99.2 Investor presentation of Mesoblast Ltd, dated August 27, 2020.

MESOBLAST REPORTS SUBSTANTIAL OPERATIONAL PROGRESS AND FINANCIAL RESULTS FOR THE YEAR ENDED JUNE 30, 2020
Mesoblast Well Prepared Ahead of First Potential US Product Launch

Melbourne, Australia, August 27, 2020 and New York, USA, August 26, 2020: Mesoblast Limited (ASX:MSB; Nasdaq:MESO) today reported operational highlights and financial results for the fourth quarter and full-year ended June 30, 2020 (FY2020).

Mesoblast Chief Executive Dr Silviu Itescu stated: "We are very pleased to report the significant corporate progress made by the Company over the last financial year. The most notable achievement was the successful FDA Advisory Committee meeting held this month which resulted in an overwhelmingly positive vote in favor of the efficacy of our lead product candidate remestemcel-L (RYONCIL™) for children with steroid-refractory acute graft versus host disease (aGVHD). We are working closely with the FDA ahead of next month's approval action date and are well prepared for a potential US launch during Q4 2020, with inventory build and a commercial organization in place.

"In parallel, based on its anti-inflammatory effects in aGVHD, we have positioned remestemcel-L to address the most significant inflammatory complications in children and adults infected with COVID-19. Our randomized controlled Phase 3 trial continues to enroll adults in the US with acute respiratory distress syndrome, aiming to reduce the primary cause of mortality due to COVID-19 infection. We have also made remestemcel-L available to physicians for treatment of COVID-19 infected children with multisystem inflammatory syndrome (MIS-C) involving the heart under our Expanded Access Program.

"We look forward to the upcoming results of our COVID-19 studies and the Phase 3 trials for chronic advanced heart failure and discogenic low back pain."

Financial Highlights

- 92% increase in revenues to US\$32.2 million for FY2020, compared with US\$16.7 million for FY2019.
 - 127% increase in milestone revenue from strategic partnerships, to US\$25.0 million for FY2020.
 - 32% increase in royalty revenue on TEMCELL® HS. Inj.¹ sales in Japan by licensee JCR Pharmaceuticals (JCR), to US\$6.6 million for FY2020.
- 13% reduction in loss after tax (US\$77.9 million for FY2020 compared with US\$89.8 million for FY2019), even after US\$13.8 million increased investment in commercial readiness for the potential US launch of RYONCIL (US\$8.8 million for commercial manufacturing activities and US\$5.0 million for sales/marketing).
- US\$129.3 million (A\$188.4 million)² cash on hand at June 30, 2020, after US\$90 million (A\$138 million)³ capital raise from global institutional investors in May 2020.
- May have access to up to an additional US\$67.5 million over the next 12 months through existing financing facilities and strategic partnerships.

US Market Opportunity for RYONCIL™

- The market adoption and sales of TEMCELL in Japan for SR-aGVHD by JCR provides insight into potential market adoption and sales of RYONCIL in the US.
- As announced by JCR on July 31, production capacity for TEMCELL is being increased as JCR has received orders far in excess of its initial forecasts since the product's 2016 launch.

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- Mesoblast estimates that the US addressable market opportunity for remestemcel-L in SR-aGVHD in children and adults is approximately eight times larger than Japan given differences in population size, incidence of aGVHD, and relative pharmacoeconomics.⁴⁻⁷ This represents a significant commercial opportunity for Mesoblast's first potential product launch in the US.
- The Company's commercial and strategic execution capabilities have been further strengthened with the appointment of Chief Operating Officer, Dagmar Rosa-Bjorkeson, who has more than 25 years of global experience in the pharmaceutical industry, including executive leadership in operational execution, market development, and corporate strategy.

Operational Highlights for Phase 3 Product Candidates

Mesoblast is developing culture expanded allogeneic cellular medicines based on its proprietary remestemcel-L and rexlemestrocel mesenchymal lineage cell technology platforms. The product candidates derived from these cell platforms share mechanisms of action that counteract the cytokine storms implicated in various inflammatory conditions by reducing pro-inflammatory cytokines, increasing anti-inflammatory cytokines, and recruiting anti-inflammatory cells to involved tissues.

Remestemcel-L (RYONCIL) for Pediatric SR-aGVHD

On August 13, 2020, the Oncologic Drugs Advisory Committee (ODAC) of the United States Food and Drug Administration (FDA) voted 9-1⁸ in favor that the available data support the efficacy of remestemcel-L (RYONCIL) in pediatric patients with steroid-refractory acute graft versus host disease (SR-aGVHD), a life-threatening complication of a bone marrow transplant. The ODAC is an independent panel of experts that evaluates efficacy and safety of data and makes appropriate recommendations to the FDA. Although the FDA will consider the recommendation of the panel, the final decision regarding the approval of the product is made by the FDA solely, and the recommendations by the panel are non-binding.

The Biologics License Application (BLA) for RYONCIL is under Priority Review by the FDA with an action date of September 30, 2020, under the Prescription Drug User Fee Act (PDUFA). If approved by the PDUFA date, Mesoblast plans to launch RYONCIL in the US in Q4 CY2020 in children and adolescents up to 18 years old. There are currently no FDA-approved treatments in the US for children under 12 with SR-aGVHD.

Remestemcel-L for Adults With SR-aGVHD

Beyond pediatric SR-aGVHD, Mesoblast will seek to obtain approval for RYONCIL in adults with the most severe forms of SR-aGVHD. In an earlier randomized placebo-controlled Phase 3 trial, a post-hoc analysis showed that remestemcel-L was associated with an increased Day 28 overall response in steroid-refractory patients with Grade C/D disease. This patient population continues to represent a high-risk population with poor overall survival, and in August 2020 Mesoblast convened an advisory meeting with key opinion leaders to develop a clinical trial design for a post-market study evaluating remestemcel-L in this patient population.

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Remestemcel-L for Adults with COVID-19 Acute Respiratory Distress Syndrome (ARDS)

Despite improvements in the treatment of COVID-19, mortality remains high, particularly in patients with cytokine storm and ARDS who require mechanical ventilation. A pilot study in 12 COVID-19 patients with moderate to severe ARDS treated with remestemcel-L under emergency compassionate use at Mt Sinai Hospital in New York demonstrated promising results, with 75% of patients successfully taken off a ventilator and discharged from hospital within a median of 10 days. In order to definitively determine the safety and efficacy of these data, a Phase 3 randomized controlled trial is being conducted in 300 ventilator-dependent patients with moderate to severe COVID-19 ARDS.⁹ Up to 30 leading medical centers across the US are taking part in the trial, which is expected to complete recruitment during Q4 CY2020.

Patients in the Phase 3 trial are randomized 1:1 to receive either two intravenous infusions of remestemcel-L within five days or placebo on top of maximal care. The primary endpoint is all-cause mortality within 30 days of randomization, with the key secondary endpoint being the number of days off mechanical ventilator support.

An independent Data Safety Monitoring Board (DSMB) has set a review date of early September for its first interim analysis of the Phase 3 trial of remestemcel-L in ventilator-dependent COVID-19 patients with moderate to severe ARDS. The DSMB will review safety and efficacy data from the first 90 patients after they have all completed 30 days of follow up and will inform Mesoblast on whether to proceed as planned to full enrollment of 300 patients or to stop the trial early.

Remestemcel-L Expanded Access Program (EAP) for Children With COVID-19 Multisystem Inflammatory Syndrome (MIS-C)

Children hospitalized with COVID-19 infection are at risk of both ARDS, seen in 22% of children,¹⁰ and a life-threatening inflammation called MIS-C which in approximately 50% of cases is associated with significant cardiovascular complications resulting in decreased heart function and dilation of coronary arteries.^{11-13.}

Mesoblast has established an EAP which provides physicians with access to use remestemcel-L in COVID-19 infected children aged between two months and 17 years with cardiovascular and other complications of MIS-C under the Company's existing Investigational New Drug (IND) application with the FDA.¹⁴ The first patient has received treatment under the EAP and has been discharged from the hospital. Mesoblast will continue to monitor the outcome in all MIS-C patients treated under the EAP to establish the safety and effectiveness of the protocol in children with this potentially life-threatening complication of COVID-19.

Rexlemestrocel (REVASCOR®) for Advanced Chronic 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.¹⁵ The objective of treatment with Mesoblast's allogeneic cell therapy REVASCOR is to reduce or reverse the severe inflammatory process in the damaged heart of these patients, and thereby prevent or delay further progression of heart failure or death. Mesoblast's 566-patient Phase 3 randomized controlled trial of REVASCOR for advanced heart failure has completed patient follow-up and all events have been independently adjudicated. While the COVID-19 pandemic has delayed completion of data quality review at the study sites, the Phase 3 trial data readout is expected during Q4 CY2020.

In parallel, Mesoblast's partner in China, Tasly Pharmaceuticals, is leveraging the results of this trial in its discussions with the Chinese regulatory authority.

In an earlier randomized placebo-controlled 60-patient Phase 2 trial, a single intra-myocardial injection of REVASCOR at the dose administered in the subsequent Phase 3 trial prevented any hospitalizations or deaths over three years of follow-up in patients with advanced chronic heart failure.

Additionally, in results presented at the 2020 American College of Cardiology Virtual Scientific Sessions from 70 patients with end-stage ischemic heart failure and a Left Ventricular Assist Device (LVAD), a sub-study of 159 patients randomized to either REVASCOR or saline, a single intra-myocardial injection of REVASCOR at the dose administered in the Phase 3 trial resulted in a beneficial effect on LVAD weaning, hospital readmissions for heart failure, and major mucosal bleeding events. These end-stage ischemic heart failure patients closely resemble the

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majority of patients enrolled in the Phase 3 randomized controlled trial of REVASCOR for advanced chronic heart failure.

Rexlemestrocel (MPC-06-ID) for Chronic Low Back Pain

Mesoblast's MPC-06-ID development program targets over 3.2 million patients in the United States and 4 million in the E.U.5 with chronic low back pain due to moderate to severe inflammatory disc degeneration.¹⁶ Back pain causes more disability than any other condition and inflicts substantial direct and indirect costs on the healthcare system, including excessive use of opioids in this patient population. There is a significant need for a safe, efficacious and durable treatment in patients with chronic low back pain due to severely inflamed degenerative disc disease.

While the COVID-19 pandemic has delayed completion of data quality review at the study sites, data readout for the 2:1 randomized placebo-controlled US Phase 3 trial in 404 patients is expected during Q4 CY2020. Mesoblast continues to collaborate closely with Grünenthal on the clinical protocol for a confirmatory Phase 3 trial in Europe for MPC-06-ID in chronic low back pain due to degenerative disc disease, with the results of this and the US Phase 3 trial expected to support both FDA and European Medicines Agency regulatory approvals.

Manufacturing

During fiscal 2020, Mesoblast established a commercial supply agreement with Lonza ahead of the potential FDA approval and commercial launch of RYONCIL. This agreement has facilitated inventory build in preparation for the potential product launch. Manufacturing is also being scaled-up to meet projected increase in capacity requirements for potential label extensions of RYONCIL such as COVID-19 ARDS.

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

Intellectual Property

Mesoblast has an extensive patent portfolio with over 1,100 patents and patent applications across 82 patent families, and patent terms extending through 2040. These patents cover composition of matter, manufacturing, and therapeutic applications of mesenchymal lineage cells, and provide strong commercial protection for our products in all major markets, including the United States, Europe, Japan and China.

Licensing agreements with JCR, Grünenthal, 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.

Financial Results for the Year Ended June 30, 2020 (FY2020):

Loss after tax reduced by US\$11.9 million to US\$77.9 million for FY2020 compared to US\$89.8 million for FY2019 as detailed below:

Revenues increased US\$15.4 million to US\$32.2 million for FY2020, compared to US\$16.7 million for FY2019.

- Milestone revenue increased by US\$14.0 million due to the upfront milestone payment of US\$15.0 million received for the strategic partnership with Grünenthal GmbH in FY2020. In FY2019 we recognized US\$1.0 million of cumulative sales milestones for sales of TEMCELL in Japan. Additionally, we recognized US\$10.0 million of milestone revenue in FY2020 and FY2019 in relation to our partnership with Tasly in China.
- Royalty revenue on sales of TEMCELL in Japan increased US\$1.6 million (32%) to US\$6.6 million for FY2020 compared with US\$5.0 million for FY2019.

Research and Development expenses decreased by US\$3.6 million to US\$56.2 million for FY2020, compared to US\$59.8 million for FY2019. The total reduction in overall R & D costs due to savings on Phase 3 clinical trials was

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US\$8.6 million, offset by our investment in pre-commercial activities as we prepare for the potential launch of RYONCIL in the United States.

Manufacturing expenses increased by US\$9.9 million to US\$25.3 million for FY2020, compared to US\$15.4 million for FY2019 due to increased expenditure on pre-launch inventory for the potential launch of RYONCIL and clinical supply for the COVID-19 ARDS phase 3 trial offset by a reduction in manufacturing activities related to filing the Biologics License Application (BLA) for this product.

Management and Administration expenses increased US\$4.0 million to US\$25.6 million for FY2020, compared with US\$21.6 million for FY2019, primarily due to non-cash share-based payments to employees and consultants.

Finance Costs for borrowing arrangements with Hercules and NovaQuest were US\$13.3 million for FY2020, compared to US\$11.3 million for FY2019, an increase of US\$2.0 million.

Income tax benefit increased by US\$0.5 million to US\$9.4 million for FY2020, compared with US\$8.9 million for FY2019 in relation to deferred tax liabilities recognized on the balance sheet during the period.

The net loss attributable to ordinary shareholders was 14.74 US cents per share for FY2020, compared with 18.16 US cents per share for FY2019.

Conference Call Details

There will be a webcast today on the financial results beginning at 8am AEST (Thursday, August 27, 2020); 6pm EDT (Wednesday, August 26, 2020). It can be accessed via <https://webcast.boardroom.media/mesoblast-limited/20200826/NaN5f2ba898ed347b00198de987>

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

References

1. TEMCELL HS. Inj.® is a registered trademark of JCR Pharmaceuticals Co. Ltd.
2. Cash on hand at June 30, 2020 has been translated from US\$ to A\$ at a spot rate of 1.457.
3. Proceeds from the May 13, 2020 placement have been translated from A\$ to US\$ at a spot rate of 0.651.
4. Japanese Data Center for Hematopoietic Cell Transplantation (JDCHCT) - Activities and Outcomes of Hematopoietic Cell Transplantation in Japan 2018.
5. Westin, J., Saliba, R.M., Lima, M. (2011) Steroid-refractory acute GVHD: predictors and outcomes. *Advances in Hematology*.
6. 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.
7. Risk factors for acute GVHD and survival after hematopoietic cell transplantation - *Blood* 2012 119:296-307; Madan Jagasia et al.
8. This vote includes a change to the original vote by one of the ODAC panel members after electronic voting closed.
9. <https://clinicaltrials.gov/ct2/show/NCT04456439>
10. Chao JY et al. *J Pediatr* 2020;223:14-9
11. *Lancet* 2020; May 7. DOI: [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)31094-1](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31094-1)
12. *Lancet* 2020; May 13 DOI: [https://doi.org/10.1016/S0140-6736\(20\)31103-X](https://doi.org/10.1016/S0140-6736(20)31103-X)
13. <https://www.nejm.org/doi/full/10.1056/NEJMoa2021756>
14. <https://clinicaltrials.gov/ct2/show/NCT04456439>
15. AHA's 2017 Heart Disease and Stroke Statistics
16. Decision Resources: Chronic Pain December 2015.

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 mesenchymal lineage cell therapy technology platform to establish a broad portfolio of commercial products and late-stage product candidates. Mesoblast has a strong and extensive global intellectual property (IP) portfolio with protection extending through to at least 2040 in all major markets. The Company's proprietary manufacturing processes yield industrial-scale, cryopreserved, off-the-shelf, cellular medicines. These cell therapies, with defined pharmaceutical release criteria, are planned to be readily available to patients worldwide.

Mesoblast's Biologics License Application to seek approval of its product candidate RYONCIL™ (remestemcel-L) for pediatric steroid-refractory acute graft versus host disease has been accepted for priority review by the United

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States Food and Drug Administration (FDA), and if approved, product launch in the United States is expected in 2020. Remestemcel-L is also being developed for other inflammatory diseases in children and adults including moderate to severe acute respiratory distress syndrome (ARDS). Mesoblast is completing Phase 3 trials for its product candidates for advanced heart failure and chronic low back pain. Two products have been commercialized in Japan and Europe by Mesoblast's licensees, and the Company has established commercial partnerships in Europe and China for certain Phase 3 assets.

Mesoblast has locations in Australia, the United States and Singapore and is listed on the Australian Securities Exchange (MSB) and on the Nasdaq (MESO). For more information, please see 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.

Release authorized by the Chief Executive, as approved by the Board of Directors.

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(in U.S. dollars, in thousands, except per share amount)	Year Ended June 30,	
	2020	2019
Revenue	32,156	16,722
Research & development	(56,188)	(59,815)
Manufacturing commercialization	(25,309)	(15,358)
Management and administration	(25,609)	(21,625)
Fair value remeasurement of contingent consideration	1,380	(6,264)
Other operating income and expenses	(455)	(1,086)
Finance costs	(13,330)	(11,328)
Loss before income tax	(87,355)	(98,754)
Income tax benefit	9,415	8,955
Loss attributable to the owners of Mesoblast Limited	(77,940)	(89,799)
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:	Cents	Cents
Basic - losses per share	(14.74)	(18.16)
Diluted - losses per share	(14.74)	(18.16)

Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	Year Ended June 30,	
	2020	2019
Loss for the period	(77,940)	(89,799)
Other comprehensive (loss)/income		
<i>Items that may be reclassified to profit and loss</i>		
Financial assets at fair value through other comprehensive income	(446)	(4)
Exchange differences on translation of foreign operations	1,146	(137)
Other comprehensive (loss)/income for the period, net of tax	700	(141)
Total comprehensive losses attributable to the owners of Mesoblast Limited	(77,240)	(89,940)

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(in U.S. dollars, in thousands)	As of June 30,	
	2020	2019
Assets		
Current Assets		
Cash & cash equivalents	129,328	50,426
Trade & other receivables	1,574	4,060
Prepayments	5,646	8,036
Total Current Assets	136,548	62,522
Non-Current Assets		
Property, plant and equipment	2,293	826
Right-of-use assets	7,978	—
Financial assets at fair value through other comprehensive income	1,871	2,317
Other non-current assets	3,311	3,324
Intangible assets	581,601	583,126
Total Non-Current Assets	597,054	589,593
Total Assets	733,602	652,115
Liabilities		
Current Liabilities		
Trade and other payables	24,972	13,060
Provisions	29,197	7,264
Borrowings	32,455	14,007
Lease liabilities	3,519	—
Deferred consideration	—	10,000
Total Current Liabilities	90,143	44,331
Non-Current Liabilities		
Deferred tax liability	730	11,124
Provisions	27,563	48,329
Borrowings	57,023	67,279
Lease liabilities	6,317	—
Deferred consideration	2,500	—
Total Non-Current Liabilities	94,133	126,732
Total Liabilities	184,276	171,063
Net Assets	549,326	481,052
Equity		
Issued Capital	1,051,450	910,405
Reserves	46,634	40,638
(Accumulated losses)/retained earnings	(548,758)	(469,991)
Total Equity	549,326	481,052

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(in U.S. dollars, in thousands)	Year ended June 30,	
	2020	2019
Cash flows from operating activities		
Commercialization revenue received	7,676	4,359
Upfront and milestone payments received	17,500	26,409
Government grants and tax incentives received	1,577	1,654
Payments to suppliers and employees (inclusive of goods and services tax)	(77,711)	(86,294)
Interest received	546	726
Interest and other costs of finance paid	(5,947)	(4,641)
Income taxes (paid)	(7)	(3)
Net cash (outflows) in operating activities	(56,365)	(57,790)
Cash flows from investing activities		
Investment in fixed assets	(2,096)	(279)
Payments for contingent consideration	(1,027)	(721)
Payments for licenses	(150)	—
Net cash (outflows) in investing activities	(3,273)	(1,000)
Cash flows from financing activities		
Proceeds from borrowings	512	43,572
Repayment of borrowings	(512)	—
Payments of transaction costs from borrowings	—	(1,614)
Proceeds from issue of shares	144,946	30,258
Payments for share issue costs	(6,277)	(608)
Payments for lease liabilities	(1,625)	—
Net cash inflows by financing activities	137,044	71,608
Net increase/(decrease) in cash and cash equivalents	77,406	12,818
Cash and cash equivalents at beginning of period	50,426	37,763
FX gain/(losses) on the translation of foreign bank accounts	1,496	(155)
Cash and cash equivalents at end of period	129,328	50,426

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Global Leader in Allogeneic Cellular Medicines for Inflammatory Diseases

Financial Year Ended June 30, 2020

ASX: MSB; Nasdaq: MESO

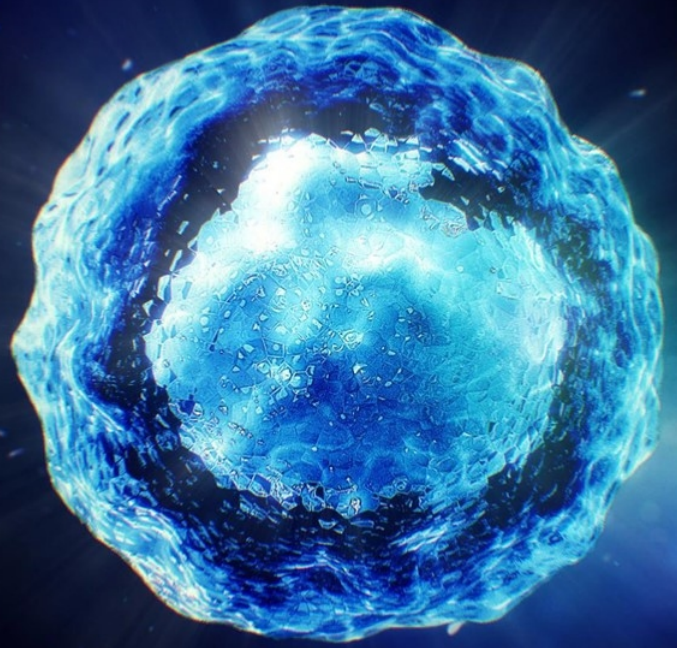


CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This presentation includes forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this presentation are forward-looking statements. Words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "intend," "plan," "targets," "likely," "will," "would," "could," and similar expressions or phrases identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and future events, recent changes in regulatory laws, and financial trends that we believe may affect our financial condition, results of operation, business strategy and financial needs. These statements may relate to, but are not limited to: expectations regarding the safety or efficacy of, or potential applications for, Mesoblast's adult stem cell technologies; expectations regarding the strength of Mesoblast's intellectual property, the timeline for Mesoblast's regulatory approval process, and the scalability and efficiency of manufacturing processes; expectations about Mesoblast's ability to grow its business and statements regarding its relationships with current and potential future business partners and future benefits of those relationships; statements concerning Mesoblast's share price or potential market capitalization; and statements concerning Mesoblast's capital requirements and ability to raise future capital, among others. Forward-looking statements should not be read as a guarantee of future performance or results, and actual results may differ from the results anticipated in these forward-looking statements, and the differences may be material and adverse. You should read this presentation together with our financial statements and the notes related thereto, as well as the risk factors, in our most recently filed reports with the SEC or on our website. Uncertainties and risks that may cause Mesoblast's actual results, performance or achievements to be materially different from those which may be expressed or implied by such statements, include, without limitation: risks inherent in the development and commercialization of potential products; uncertainty of clinical trial results or regulatory approvals or clearances; government regulation; the need for future capital; dependence upon collaborators; and protection of our intellectual property rights, among others. Accordingly, you should not place undue reliance on these forward-looking statements. We do not undertake any obligations to publicly update or revise any forward-looking statements, whether as a result of new information, future developments or otherwise.

Our Mission

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



Allogeneic Cellular Medicines for Inflammatory Diseases

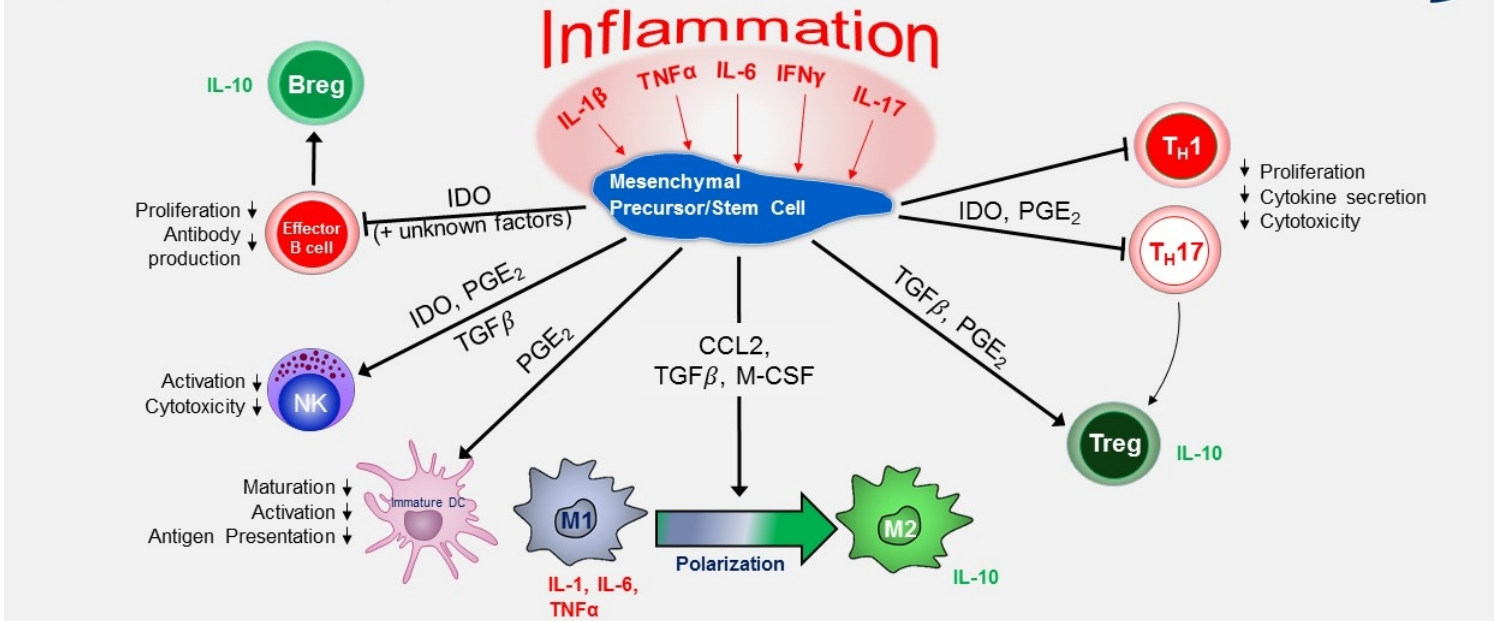


Innovative Technology Platform	Lead Product Candidate	Pipeline of Phase 3 Product Candidates
<ul style="list-style-type: none"> ▪ Allogeneic mesenchymal precursor cells (MPCs) and their progeny, mesenchymal stem cells (MSCs) ▪ Well characterized immunomodulatory mechanisms of action ▪ Targeting severe and life-threatening inflammatory conditions ▪ Underpinned by extensive, global intellectual property estate 	<ul style="list-style-type: none"> ▪ RYONCIL™ (remestemcel-L) BLA filed with US FDA for pediatric steroid-refractory acute GVHD ▪ Targeted US commercial team for potential launch ▪ If approved, launch planned for 2020 ▪ Industrial-scale manufacturing in place to meet commercial demand ▪ Continued growth in royalty revenues from Japan sales of licensee product for acute GVHD¹ 	<ul style="list-style-type: none"> ▪ Lifecycle expansion of remestemcel-L for pediatric and adult inflammatory diseases ▪ Phase 3 trial of 300 patients using remestemcel-L in acute respiratory distress syndrome (ARDS) due to COVID-19 ▪ Two additional product candidates in Phase 3 trials, heart failure and back pain, with near-term US readouts

1. 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.

Platform Technology – Mechanism of Action

Our cellular therapies are activated by multiple inflammatory cytokines through surface receptors, resulting in orchestration of an anti-inflammatory cascade



Source: data on file

Pipeline of Phase 3 Product Candidates



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

* Mesoblast has the right to use data generated by JCR Pharmaceuticals Co Ltd in Japan to support its development and commercialization plans for remestemcel-L in the US and other major healthcare markets, including for GVHD, Hypoxic Ischemic Encephalopathy and Epidermolysis Bullosa

Commercial Scale Manufacturing Capability

- Scalable allogeneic “off-the-shelf” cellular platforms
- Manufacturing meets stringent criteria of international regulatory agencies
- Robust quality assurance processes ensure final product with batch-to-batch consistency and reproducibility
- Current capacity sufficient for RYONCIL GVHD launch



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- Projected increase in capacity requirements for maturing pipeline, including GVHD label extensions and COVID-19 ARDS
 - Proprietary xeno-free technologies will increase yields and output
 - Moving to 3D bioreactors will reduce labor and improve manufacturing efficiencies
 - These innovations will significantly reduce cost of goods

Global IP Estate Provides Substantial Competitive Advantage

- Extensive patent portfolio with protection extending through 2040 in all major markets
- Over 1,100 patents and patent applications (82 patent families) across all major jurisdictions
- Covers composition of matter, manufacturing, and therapeutic applications of mesenchymal lineage cells
- Provides strong global protection in areas of our core commercial focus
- Grant rights to third parties who require access to our patent portfolio to commercialize their products, when outside our core commercial areas
- Mesoblast receives royalty income from its patent licensee TiGenix, S.A.U., a wholly owned subsidiary of Takeda, on its worldwide sales of its product Alofisel® for the treatment of complex perianal fistulas in adult patients with Crohn's disease, as well as milestone payments



**Mesenchymal
Lineage
Cells**

Markets
Global coverage
including U.S.,
Europe, China,
and Japan

Sources
Allogeneic / Autologous
(Bone Marrow, Adipose,
Dental Pulp, Placental),
Pluripotent (iPS)

Therapeutic Areas
Core commercial and
non-core indications

Recent Highlights: Remestemcel-L for Children



Children with Steroid-Refractory Acute Graft Versus Host Disease (SR-aGVHD)

- FDA Oncologic Drugs Advisory Committee (ODAC) of the FDA voted overwhelmingly (9-1*) in favor that the available data support the efficacy of RYONCIL in pediatric patients with SR-aGVHD
- The Biologics License Application (BLA) for RYONCIL is under Priority Review by the FDA with an action date of September 30, 2020, under the Prescription Drug User Fee Act (PDUFA)
- If approved by the PDUFA date, Mesoblast plans RYONCIL launch in US in Q4 2020 in children and adolescents up to 18 years old
- Preparations advanced for potential launch, with product inventory and commercial team in place

Children with COVID-19 Multisystem Inflammatory Syndrome (MIS-C)

- Established an expanded access protocol (EAP) in the US for compassionate use of remestemcel-L in the treatment of COVID-19 infected children with cardiovascular and other complications of MIS-C
- The first patient has received treatment under the EAP and has been discharged from the hospital

** This vote includes a change to the original vote by one of the ODAC panel members after electronic voting closed*

Recent Highlights: Remestemcel-L for Adults



Adults With Acute Respiratory Distress Syndrome (ARDS) due to COVID-19

- FDA cleared IND application to treat patients with COVID-19 ARDS, providing a pathway for use under both EAP and in a randomized controlled trial
- Under emergency compassionate care at Mt Sinai Hospital in New York, 75% of patients (9/12) with moderate to severe ARDS who received two infusions of remestemcel-L were successfully taken off a ventilator and discharged from hospital within a median of 10 days
- Ongoing Phase 3 randomized, placebo-controlled trial of remestemcel-L in up to 300 ventilator-dependent patients with moderate to severe COVID-19 ARDS, objective is reduction in mortality within 30 days
- Trial expected to complete recruitment during Q4 CY2020
- Independent DSMB has set a review date of early September for first interim analysis of the Phase 3 trial from the first 90 patients after they have all completed 30 days of follow up

Adults With Steroid-Refractory Acute Graft Versus Host Disease (SR-aGVHD)

- Patients with most severe forms of SR-aGVHD continue to have high unmet need and poor survival
- August 2020 convened advisory meeting with key opinion leaders to develop clinical trial design for post-market study evaluating remestemcel-L in these high-risk patients



Financials

ASX
Nasdaq

Financial Highlights



Full Year FY2020 Compared to Full Year FY2019

- 92% increase in total revenue to US\$32.2m
- 127% increase in milestone revenues from strategic partnerships to US\$25.0m
- 32% growth in commercialization revenue from sales of TEMCELL to US\$6.6m
- 13% (US\$11.9m) reduction in loss after tax, even after US\$13.8 million increased investment in commercial readiness for potential US launch of RYONCIL
- Total reduction in clinical trial expenditure of US\$8.6m, inclusive of new Phase 3 COVID-19 ARDS trial

Figures are rounded

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

Continued Growth in Revenues from Sales of TEMCELL in Japan for SR-aGVHD

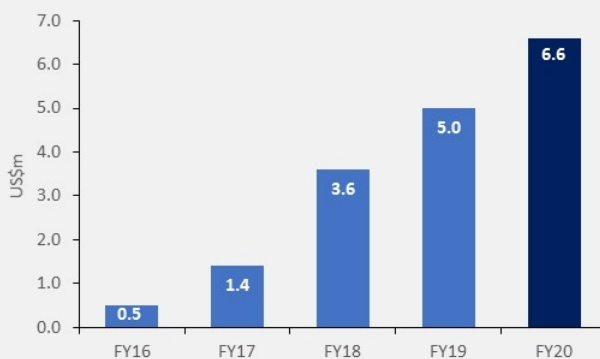
TEMCELL® HS Inj.¹



ACUTE GRAFT VERSUS HOST DISEASE + OTHER INDICATIONS

- JCR Pharmaceuticals has exclusive rights to Mesoblast's MSC technology for acute GVHD in Japan
- US\$6.6 million royalties received in last 12 months
- Production capacity for TEMCELL is currently being increased as JCR has received orders far in excess of its initial forecasts since the product's 2016 launch²
- Product adoption and reimbursement informs Mesoblast US commercial strategy for RYONCIL in acute GVHD
- US addressable market for acute GVHD in children and adults is ~ eight-fold larger than Japan due to greater patient numbers, incidence and pharmacoeconomics

ANNUAL REVENUE FROM TEMCELL ROYALTIES IN JAPAN



Success of TEMCELL by Mesoblast Licensee JCR Informs Potential US Market for RYONCIL

1. TEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co Ltd.
2. JCR Pharmaceuticals News Release: *Notice regarding Capital Expenditures to Increase Production Capacity at the Seishin Plant*, July 31, 2020

Substantial Increase in Revenues and Reduced Loss After Tax

Profit and Loss for the full year ending (US\$m)	June 30, 2020	June 30, 2019
Commercialization revenue	6.6	5.0
Milestone revenue	25.0	11.0
Interest revenue	0.5	0.7
Total Revenue	32.2	16.7
Research and development	(56.2)	(59.8)
Manufacturing	(25.3)	(15.4)
Management & administration	(25.6)	(21.6)
Contingent consideration	1.4	(6.3)
Other operating income & expenses	(0.5)	(1.1)
Finance costs	(13.3)	(11.3)
Loss before tax	(87.3)	(98.8)
Income tax benefit	9.4	9.0
Loss after tax	(77.9)	(89.8)

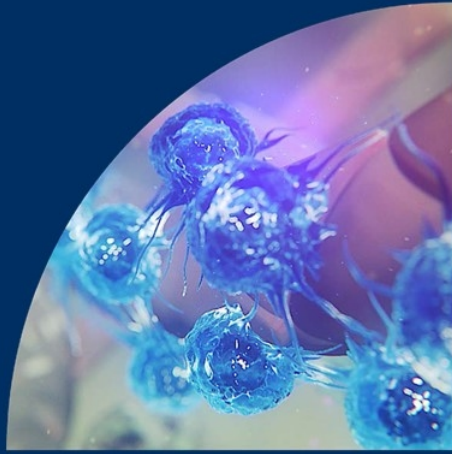
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Strengthened Balance Sheet



- At June 30, 2020, cash on hand was US\$129.3 million
- Mesoblast completed a US\$90 million capital raise from global institutional investors in May 2020
- Up to an additional US\$67.5 million may be available through existing financing facilities and strategic partnerships over next 12 months
- Capital will be used for
 - Commercial launch of RYONCIL for acute GVHD
 - Scale-up of manufacturing for projected increase in capacity requirements for maturing pipeline, including GVHD label extensions and COVID-19 ARDS
 - Clinical programs supporting label extension strategies and regulatory approvals of Phase 3 assets

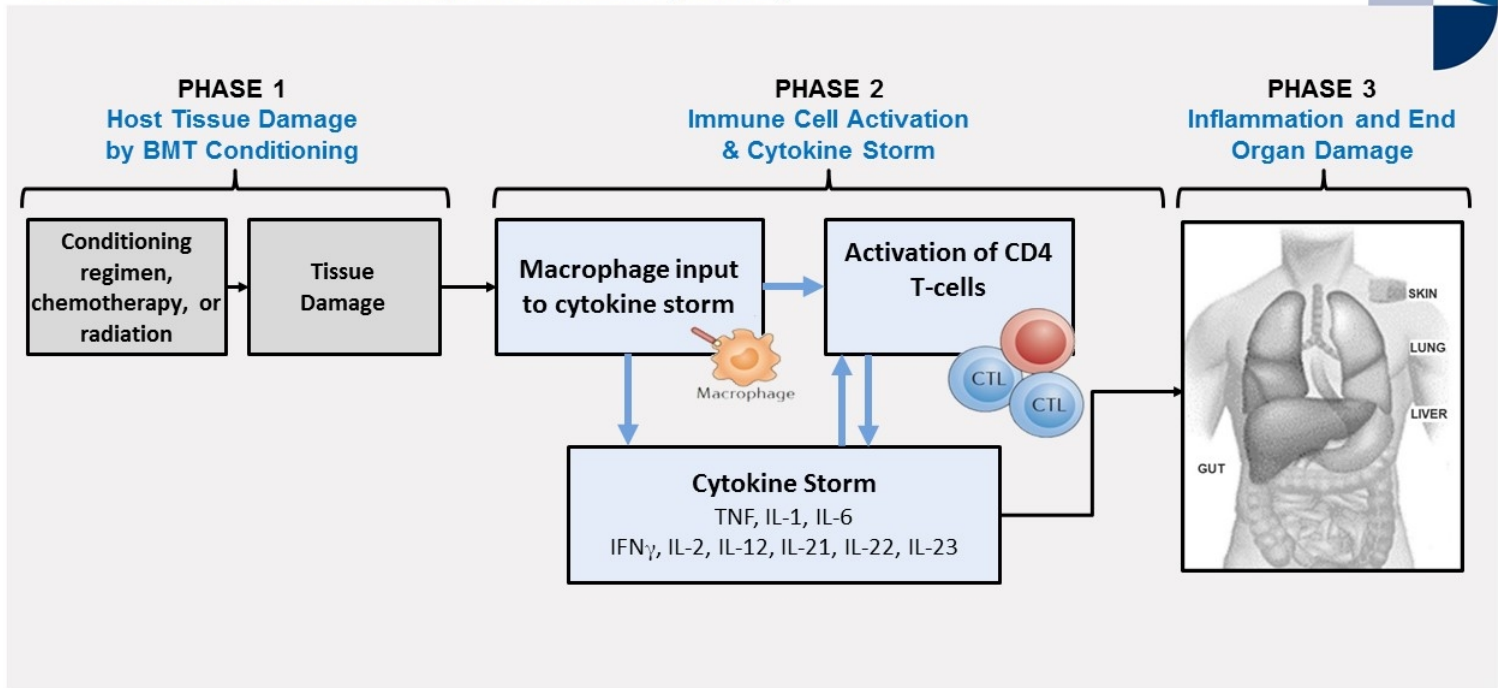
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**RYONCIL (remestemcel-L):
Acute Graft Versus Host Disease**

ASX
Nasdaq

Acute GVHD: Serious and Fatal Complication of Allogeneic Bone Marrow Transplantation (BMT)



Modified from Blazar et al., *Nature Reviews Immunology* 12: 443 – 458

Children with Steroid-Refractory Acute GVHD at High Risk of Treatment Failure and Death

Extremely high unmet medical need

- More than 2,000 allogeneic BMTs in children and adolescents in US annually¹
- Despite prophylaxis, ~50% will develop aGVHD²
- First-line treatment is corticosteroids
- Response rate is ~50%
- Children < 12 years of age have no approved treatment for steroid-refractory acute GVHD

Acute GVHD Primarily Affects Skin, GI Tract, and Liver

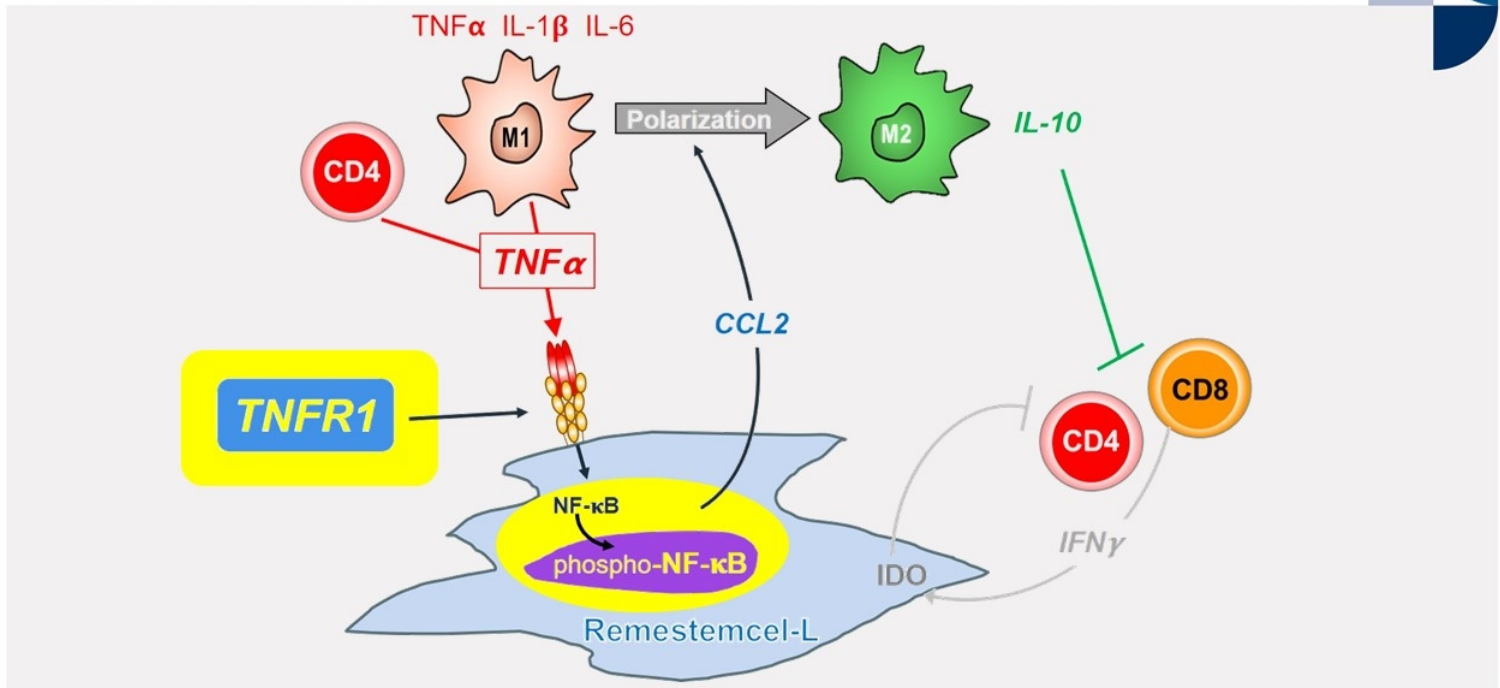
- Classic skin rash; Abdominal cramps; Large volumes of diarrhea
- Rising serum bilirubin (indicative of liver damage or disease)
- Mortality as high as 70 – 90%²⁻⁵ when involving gut and liver



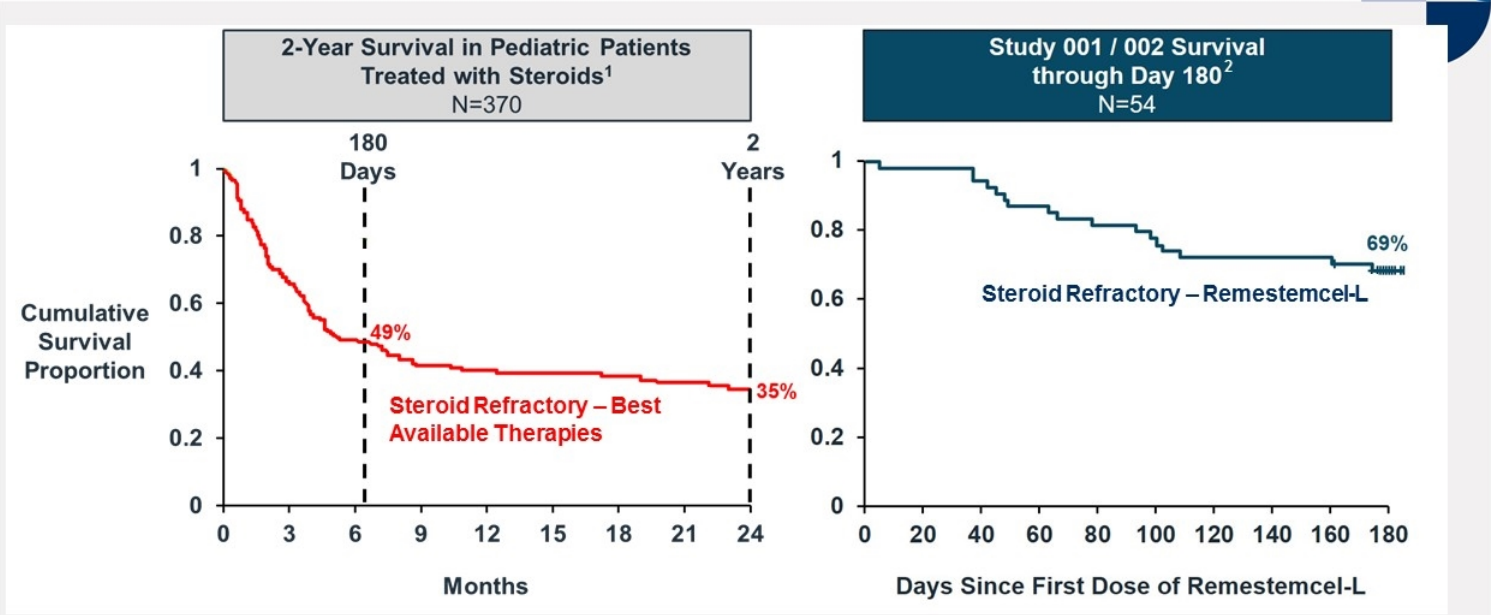
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1. HRSA Transplant Activity Report, CIBMTR, 2019; 2. Westin, J., Saliba, RM., Lima, M. (2011) Steroid-refractory acute GVHD: predictors and outcomes. *Advances in Hematology*; 3. MacMillan, M.L. et al. Pediatric acute GVHD: clinical phenotype and response to upfront steroids. *Bone Marrow Transplant* 55, 165–171 (2020); 4. Jagasia, M. et al. Risk factors for acute GVHD and survival after hematopoietic cell transplantation. *Blood* (2012) 119 (1): 296-307; 5. 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*

Immunomodulatory Activities of Remestemcel-L in Response to Inflammation



Remestemcel-L Improved Dismal Survival in Children with SR-aGVHD



1. Adapted and redrawn from Figure 2 of MacMillan, M.L. et al. Pediatric acute GVHD: clinical phenotype and response to upfront steroids. Bone Marrow Transplant 55, 165–171 (2020); 2. Kurtzberg, J. et al. A Phase 3, Single-Arm, Prospective Study of Remestemcel-L, Ex Vivo Culture-Expanded Adult Human Mesenchymal Stromal Cells for the Treatment of Pediatric Patients Who Failed to Respond to Steroid Treatment for Acute Graft-versus-Host Disease. Biol Blood Marrow Transplant 26 (2020) 845-854

RYONCIL: Anticipated FDA Approval in 2020



- Results from three studies using RYONCIL in children and adults with SR-aGVHD support the FDA BLA filing
 - RYONCIL was used as salvage therapy in an expanded access program in 241 children with SR-aGVHD (80% Grade C/D) who failed institutional standard of care
 - RYONCIL was used as first-line therapy in Mesoblast's open-label Phase 3 trial in 55 children with SR-aGVHD, 89% of whom had Grade C/D disease
 - RYONCIL was used as first-line therapy in a randomized controlled Phase 3 trial of 260 adults and children with SR-aGVHD
- BLA filing for RYONCIL was accepted by the US FDA for priority review for the treatment of SR-aGVHD in children
- ODAC of the FDA voted overwhelmingly in favour (9:1)* that the available data support the efficacy of remestemcel-L in pediatric patients with SR-aGVHD
- The FDA has set a Prescription Drug User Fee Act (PDUFA) action date of September 30, 2020
- If approved, RYONCIL launch in the US planned for Q4 CY2020

** This vote includes a change to the original vote by one of the ODAC panel members after electronic voting closed*

RYONCIL: U.S. Regulatory and Commercial Strategy



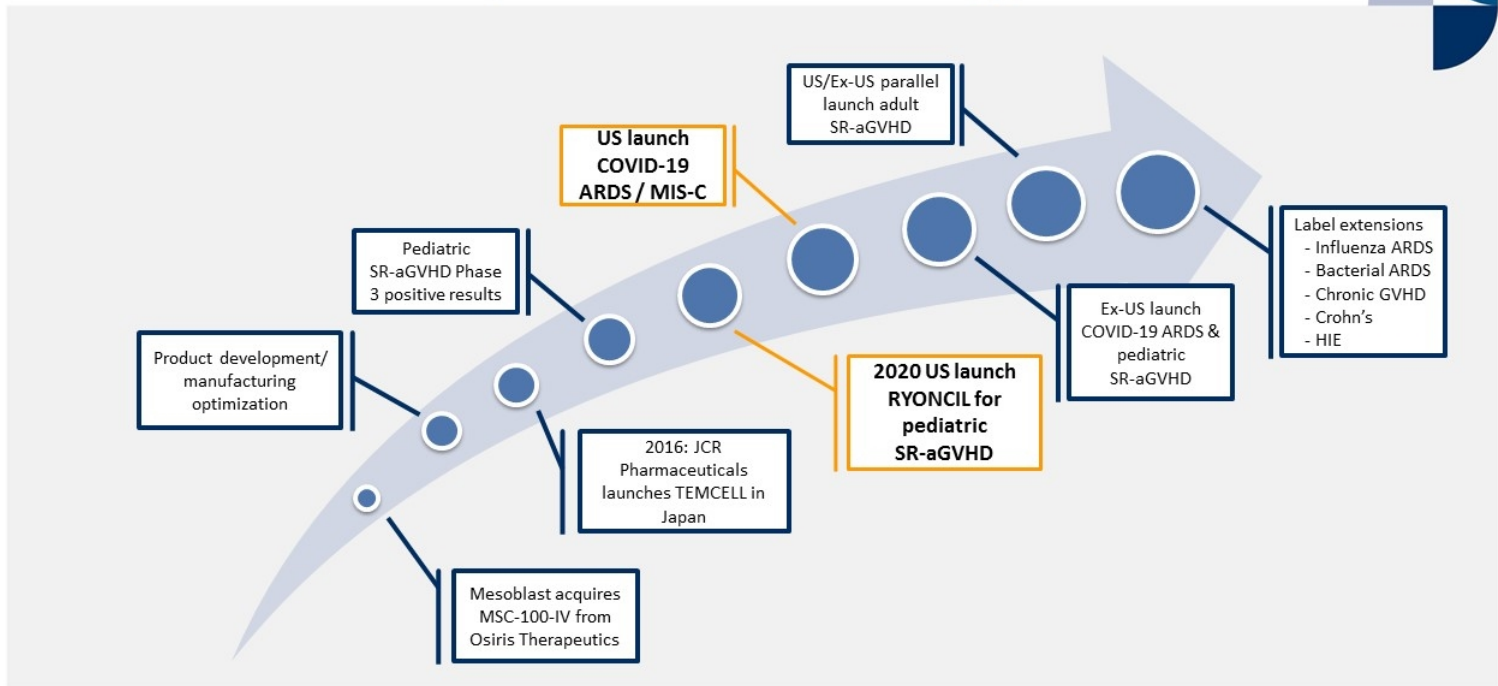
- FDA action date set for September 30, 2020
- Commercialization strategy in place for product launch
- Ramp-up for inventory build
- Building out efficient, targeted sales force - 15 centers account for ~50% of patients
- Label extension planned for treatment of adult SR-aGVHD
- Lifecycle strategy

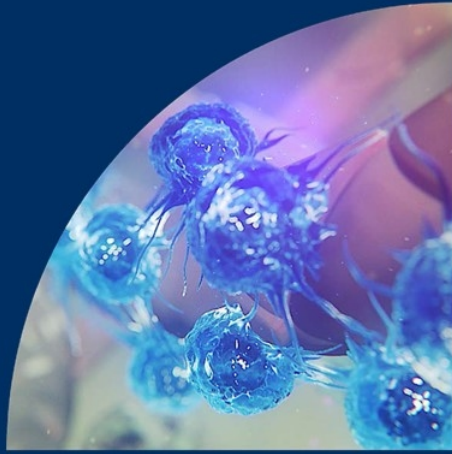


Post-marketing Study in Adults with SR-aGVHD

- Utilize remestemcel-L manufactured using optimized process
- Advisory Board of GVHD experts convened August 2020
- Planning underway for randomized controlled trial of remestemcel-L vs standard of care in adult SR-aGVHD patients
 - Designed to demonstrate improved overall response and survival
 - Focus on adults with continued high unmet need despite approved therapies or who have not responded to existing therapies

Remestemcel-L: Lifecycle Extension Strategy





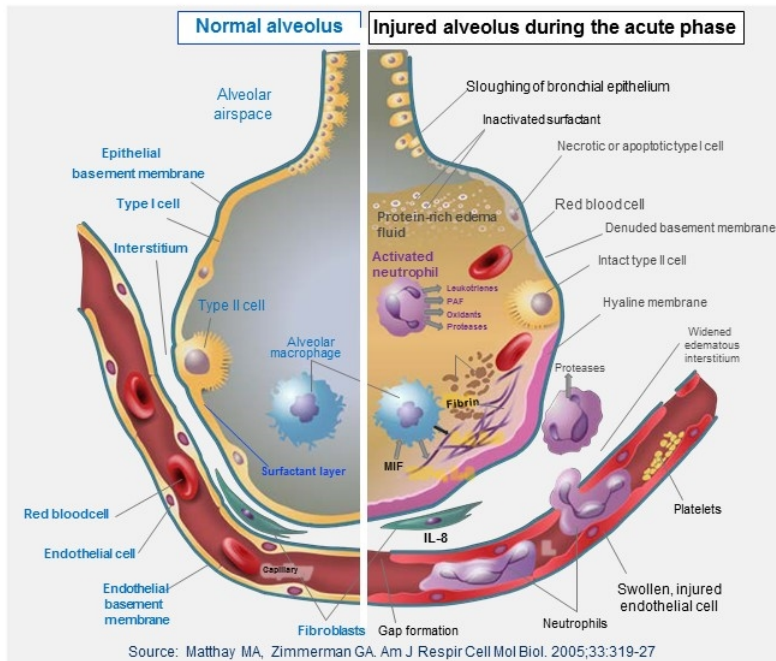
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Remestemcel-L: Potential New Treatment Paradigm in Adults & Children with COVID-19

Overview – Remestemcel-L for ARDS due to COVID-19



- COVID-19 is a respiratory virus with a high mortality due to a severe inflammatory condition of the lungs called acute respiratory distress syndrome (ARDS)
- ARDS is caused by cytokine storm in lungs of patients infected with COVID-19 and is the primary cause of death
- The extensive safety data of remestemcel-L and its anti-inflammatory effects in aGVHD makes a compelling rationale for evaluating remestemcel-L in COVID-19 ARDS
- Intravenous delivery of remestemcel-L results in selective migration to the lungs making inflammatory lung disease an ideal target for this therapy
- Remestemcel-L has the potential to tame the cytokine storm in ARDS and may offer a life-saving treatment for those suffering from COVID-19



Acute respiratory distress syndrome (ARDS)

- A major area of unmet medical need
- Multiple triggers including viral/bacterial infections such as coronavirus or influenza
- Typically requires extended ICU hospitalization and intervention by ventilation
- ~40-80% mortality in viral induced ARDS (influenza & COVID-19, respectively)¹⁻⁴

Pathophysiology

- Activation of alveolar M1 macrophages results in cytokine storm
- Influx of neutrophils results in proteolytic destruction
- Aberrant secretion of fluid by alveolar cells
- Interstitial edema, cell death and influx of inflammatory cells

1. Matthay MA, et al. Acute Respiratory Distress Syndrome. Nature 2019 5:18. doi: [10.1038/s41572-019-0069-0](https://doi.org/10.1038/s41572-019-0069-0); 2. Bellani G, Laffey JG, Pham T, et al. Epidemiology and patterns of care, and mortality for patients with acute respiratory distress syndrome in intensive care units in 50 countries. JAMA 2016;315:788-800; 3. Petrilli CM et al. Factors associated with hospitalization and critical illness among 4,103 patients with Covid-19 disease in New York City. MedRxiv 2020; 4. Gibson PG., et al. COVID-19 ARDS: clinical features and differences to "usual" pre-COVID ARDS. Med J Aust. 24 April 2020



Compassionate Use Data from Emergency IND

- 12 patients with moderate or severe ARDS received two infusions of remestemcel-L at Mt. Sinai Hospital in New York City
- Nine patients (75%) successfully came off ventilator support at a median of 10 days and were discharged from hospital
- This contrasts with only 9% of COVID-19 patients able to be extubated and a 12% survival rate in two major NY hospital networks during same time period^{1,2}
- This pilot data informed design of the ongoing 300-patient randomized controlled clinical trial
- Trial is being conducted at up to 30 teaching hospitals in the US

1 Petrilli CM et al. Factors associated with hospitalization and critical illness among 4,103 patients with Covid-19 disease in New York City. MedRxiv 2020 doi: <https://www.medrxiv.org/content/10.1101/2020.04.08.20057794v1.full.pdf>

2. Richardson S et al. Presenting characteristics, comorbidities, and outcomes among 5700 patients hospitalized with COVID-19 in the New York City area. JAMA 2020. doi:10.1001/jama.2020.6775

Phase 3 Trial of 300 Patients with ARDS due to COVID-19



- Multi-center, randomized, controlled, blinded study to assess safety and efficacy of remestemcel-L plus standard of care (SOC) versus placebo plus SOC in subjects with moderate/severe ARDS on ventilator due to COVID-19
- Up to 300 patients randomized 1:1 to receive SOC with placebo or remestemcel-L
- Primary endpoint all cause mortality up to 30 days, key secondary days alive off ventilator within 60 days
- Recruitment expected to complete during Q4 CY2020, with interim analyses planned which could result in early stoppage for efficacy or futility

Key Milestones for Remestemcel-L in COVID-19 ARDS

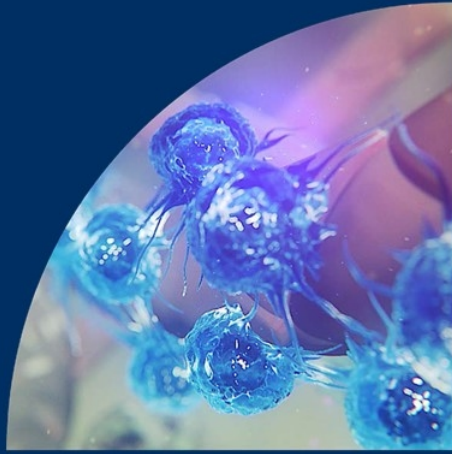


- Interim analyses planned which could result in stopping the trial early for efficacy or futility
- First interim analysis is due early September after 30% of patients reach the primary endpoint
- Seek expedited regulatory approval subject to positive data read-out
- Manufacturing scale-up to meet projected increase in capacity requirements for maturing pipeline, including GVHD label extensions and COVID-19 ARDS
 - Increase manufacturing footprint for capacity expansion
 - Implement proprietary xeno-free technologies to increase yields and output
 - Plan for long-term move to 3D bioreactors to reduce labor and improve manufacturing efficiencies
- Establish further manufacturing and commercialization partnerships

Remestemcel-L for Children With COVID-19



- Children hospitalized with COVID-19 develop both ARDS (22%) and a life-threatening inflammation called Multisystem inflammatory Syndrome (MIS-C) which involves multiple critical organs and their vasculature
- In approximately 50% of cases, MIS-C is associated with significant cardiovascular complications that directly involve heart muscle and may result in decreased cardiac function
- These children often show no evidence of active COVID-19 infection, but have antibodies against COVID-19, indicating prior infection and suggesting an autoimmune process as the cause of MIS-C
- Mesoblast has established an EAP filed with the FDA which provides physicians with access to remestemcel-L in COVID-19 infected children aged 2 months-17 years with cardiovascular and other complications of MIS-C
- The first patient has received treatment under the EAP and has been discharged from the hospital
- Mesoblast will continue to monitor the outcome in all MIS-C patients treated under the EAP to establish the safety and effectiveness of the protocol in children with this potentially life-threatening complication of COVID-19



Update on Other Phase 3 Product Candidates

- Heart Failure
- Chronic Low Back Pain

Partnerships and License Agreements

Phase 3 Product Candidates for Heart Failure and Chronic Low Back Pain



MPC-06-ID



- Strategic partnership to develop and commercialize MPC-06-ID in Europe & Latin America
- Mesoblast will receive up to US\$150 million in upfront and milestone payments prior to product launch
- Milestone payments could exceed US\$1 billion depending on patient adoption
- Mesoblast will also receive tiered double digit royalties on product sales

CHRONIC LOW BACK PAIN - DEGENERATIVE DISC

PREVALENCE
EUROPE
~7.0 MILLION



REVASCOR™



- Exclusive cardiovascular rights in China
- Mesoblast received US\$40 million in an upfront payment and equity placement
- Eligible for additional milestones and royalties

CARDIOVASCULAR – CHRONIC HEART FAILURE

PREVALENCE
CHINA
~4.5 MILLION



REVASCOR® for Advanced and End-Stage Heart Failure



- In December 2019, the Phase 3 trial in advanced heart failure surpassed the number of primary endpoint events required for trial completion
 - Final study visits for all surviving patients have been completed
 - Ongoing quality review of all data is being completed at the study sites
 - Data readout expected during Q4 CY2020
 - Results may support regulatory approval in the US

- Results from a sub-study of 70 patients with end-stage ischemic heart failure and a Left Ventricular Assist Device (LVAD), of 159 randomized patients who received either REVASCOR or saline, were presented at the American College of Cardiology (ACC) Virtual Scientific Sessions
 - Conclusions from the study included MPCs had a beneficial effect on LVAD weaning, major mucosal bleeding, serious adverse events, and readmissions in ischemic heart failure patients
 - End-stage ischemic heart failure patients with LVADs are older and have co-morbidities such as diabetes, thereby closely resembling the majority of patients in Mesoblast's 566-patient Phase 3 trial of REVASCOR for advanced chronic heart failure

MPC-06-ID for Chronic Low Back Pain



- Phase 3 trial of MPC-06-ID for chronic low back pain in 404 patients:
 - Final study visits for all patients have been completed
 - Ongoing quality review of all data is being completed at the study sites
 - Data readout expected during Q4 CY2020
- Continued operational progress in strategic partnership for chronic lower back pain with Grünenthal in Europe to complete clinical protocol design, obtain regulatory input, and receive clearance 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 in Europe

Major Operational Milestones for the Next 12 Months



Remestemcel-L for SR-aGVHD

- RYONCIL Priority Review for pediatric SR-aGVHD underway with PDUFA date set for September 30, 2020
- If approved, US launch of RYONCIL planned for 2020
- Commence trial in adults with SR-aGVHD to expand label

Remestemcel-L for Acute Respiratory Distress Syndrome (ARDS) in COVID-19

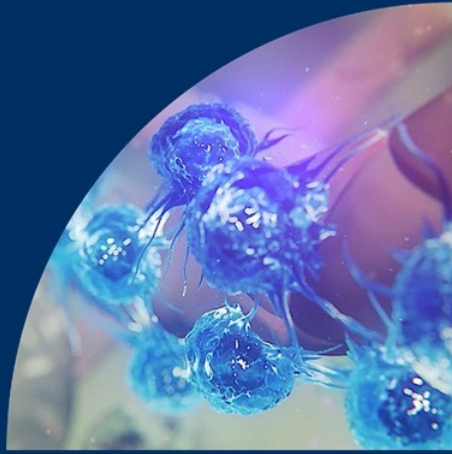
- Ongoing recruitment for Phase 3 multicenter, randomized controlled trial in North America
- Trial completion expected during Q4 CY2020
- Establish strategic partnerships for manufacturing and commercialization

REVASCOR for Advanced and End-Stage Heart Failure

- Data readout for advanced chronic heart failure Phase 3 trial during Q4 CY2020
- Initiate confirmatory trial in end-stage heart failure

MPC-06-ID for Chronic Low Back Pain

- Data readout for Phase 3 trial during Q4 CY2020
- Obtain clearance from European regulatory authorities to begin European Phase 3 trial



 **mesoblast**



Thank You

ASX
Nasdaq

