
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 May 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 May 28, 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: May 28, 2020

INDEX TO EXHIBITS

Item

- 99.1 Press release of Mesoblast Ltd, dated May 28, 2020.
- 99.2 Investor presentation of Mesoblast Ltd, dated May 28, 2020.

MESOBLAST REPORTS STRONG FINANCIAL POSITION AND SUBSTANTIAL OPERATIONAL PROGRESS FOR THE PERIOD ENDED MARCH 31, 2020

Melbourne, Australia, May 28, 2020 and New York, USA, May 27, 2020: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today reported financial, corporate and operational highlights for the nine months ended March 31, 2020. Cash on hand at March 31, 2020 was US\$60.1 million (A\$97.3 million) and in May 2020, pro forma cash on hand was approximately US\$150 million (A\$235 million) after adjusting for a US\$90 million (A\$138 million) capital raise.

Mesoblast Chief Executive Dr Silviu Itescu stated: "This past quarter has underscored the value of our lead product candidate remestemcel-L and the experience we have gained in its use over recent years in patients with severe cytokine release syndromes.

"Our Biologics License Application for marketing approval of RYONCIL™ (remestemcel-L) in children with steroid-refractory acute graft versus host disease is currently under priority review by the United States Food and Drug Administration (FDA), and we hope to be able to make the product available to patients suffering with this life-threatening inflammatory condition during 2020. We are also proud to be developing remestemcel-L as a potential very important therapy in the battle against COVID-19. A Phase 3 randomized controlled trial in the United States is underway to confirm the remarkable pilot data from compassionate use of remestemcel-L in COVID-19 infected patients with moderate to severe acute respiratory distress syndrome (ARDS), and to definitively determine whether this product candidate can contribute meaningfully to this urgent, unmet medical need."

Financial Highlights for the Nine Months of FY2020 Compared with the Nine Months of FY2019:

- 113% increase in revenues to US\$31.5 million, compared with US\$14.8 million, comprising:
 - 81% growth in royalty revenues to US\$5.9 million from sales of TEMCELL HS Inj.®1 by Mesoblast's licensee for steroid-refractory acute graft versus host disease (SR-aGVHD) in Japan, compared with US\$3.3 million.
 - 127% increase in milestone revenues to US\$25.0 million from strategic partnerships compared to US\$11.0 million.
- 34% reduction in loss after tax (US\$45.3 million compared with US\$69.1 million) driven by:
 - 113% increase in total revenues
 - 15% decrease in research and development spend (US\$40.9 million compared with US\$48.4 million)
- Cash on hand at March 31, 2020 was US\$60.1 million
- Pro forma cash on hand is approximately US\$150 million, with the additional US\$90 million capital raised 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 the:
 - 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

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Operational and Corporate Highlights for the Nine Months of FY2020:

- The United States Food and Drug Administration (FDA) accepted for priority review the Company's Biologics License Application (BLA) to seek approval of its lead allogeneic cell therapy remestemcel-L² for steroid-refractory acute graft versus host disease (SR-aGVHD) in children under the brand name RYONCIL™.³
- The FDA set a Prescription Drug User Fee Act (PDUFA) action date of September 30, 2020, and if approved, Mesoblast will make RYONCIL immediately available in the United States.
- Mesoblast continues to build a targeted commercial team and inventory for potential launch of RYONCIL in the United States, with the continued increase in revenues from sales of TEMCELL in Japan informing the projected uptake of RYONCIL.
- Based on the extensive safety and efficacy data for remestemcel-L in SR-aGVHD and similar cytokine release in both SR-aGVHD and ARDS, Mesoblast submitted an Investigational New Drug (IND) application for use of remestemcel-L in the treatment of patients with moderate to severe ARDS caused by COVID-19, which was cleared by the FDA.
- Promising results were seen with remestemcel-L under FDA-sanctioned emergency compassionate use in COVID-19 patients with moderate to severe ARDS, where nine of 12 ventilator-dependent patients were able to come off ventilators within a median of 10 days and were discharged from hospital.
- On the back of these results, a 300-patient Phase 3 randomized controlled trial in patients with moderate to severe ARDS from COVID-19 was initiated in up to 30 sites across North America, with planned interim analyses that may result in stopping the trial early for efficacy or futility.
- Results 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, were presented at the 2020 American College of Cardiology Virtual Scientific Sessions, and showed a beneficial effect on LVAD weaning, hospital readmissions for heart failure, and major mucosal bleeding events.
- In the Phase 3 randomized controlled trial of Revascor for advanced heart failure, final study visits for all surviving patients have been completed, ongoing quality review of all data is being completed at the study sites, with a data readout planned for mid-2020.
- Mesoblast continues to collaborate 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.

Major Operational Milestones for the Next 12 Months

Remestemcel-L for SR-aGVHD and Other Inflammatory Diseases

- FDA has set a Prescription Drug User Fee Act (PDUFA) action date for RYONCIL in the treatment of pediatric SR-aGVHD of September 30, 2020
- If approved, US launch of RYONCIL planned for Q4 2020
- Execute lifecycle extension strategy with investigator-initiated and sponsored clinical trials for pediatric and adult systemic inflammatory diseases.

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

- Complete recruitment of Phase 3 trial
- Interim analyses planned which could result in stopping the trial early for efficacy or futility. First interim analysis when 30% of patients reach the primary endpoint
- Expansion into additional causes of ARDS including influenza and bacterial infection
- Establish strategic partnerships for manufacturing and commercialization.⁴

REVASCOR for Advanced and End-Stage Heart Failure

- In the Phase 3 randomized controlled trial of Revascor for advanced heart failure, final study visits for all surviving patients have been completed, ongoing quality review of all data is being completed at the study sites, with a data readout planned for mid-2020
- Initiate confirmatory trial in ischemic end-stage heart failure patients.

MPC-06-ID for Chronic Low Back Pain

- In the Phase 3 randomized controlled trial of MPC-06-ID for chronic low back pain due to degenerative disc disease, final study visits for all patients have been completed, ongoing quality review of all data is being completed at the study sites, with a data readout planned for mid-2020
- Work together with Grünenthal to complete clinical protocol design, obtain regulatory input, and receive clearance from European regulatory authorities to begin European Phase 3 trial.

Manufacturing

- Scale up of manufacturing to meet projected increase in capacity requirements for maturing pipeline, including GVHD label extensions and COVID-19 ARDS
- 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

Lead Program Updates

RYONCIL™ (remestemcel-L) for Steroid-refractory Acute GVHD in Children

- The FDA has accepted for priority review the BLA for RYONCIL under the product candidate's existing Fast Track designation. If approved, this product is expected to be launched in the US in Q4 2020.
- Three peer-reviewed articles on distinct clinical trials of RYONCIL for the treatment of acute GVHD were published in the May issue of Biology of Blood and Marrow Transplantation, the official publication of the American Society for Transplantation and Cellular Therapy.
- Results from these three trials show a consistent pattern of safety and efficacy for RYONCIL (remestemcel-L) in patients with the greatest levels of inflammation and the most severe grades of acute GVHD. These clinical outcomes provide a compelling rationale for use of remestemcel-L in children and adults with other conditions associated with severe inflammation and cytokine release, including acute respiratory distress syndrome (ARDS) and systemic vascular manifestations of COVID-19 infection.

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Remestemcel-L for COVID-19 ARDS

- During the period March-April 2020, 12 ventilator-dependent COVID-19 patients with moderate/severe COVID-19 ARDS were treated with two infusions of remestemcel-L within the first five days under emergency compassionate use at New York City's Mt Sinai hospital. Nine patients successfully came off ventilator support at a median of 10 days and were discharged from hospital.
- These results contrast with only 9% of ventilator-dependent COVID-19 patients being able to come off ventilators with standard of care treatment at two major referral hospital networks in New York during the same time period. This compassionate use treatment experience has informed the design of the clinical protocol for the randomized, placebo-controlled Phase 3 trial of remestemcel-L in ventilator-dependent COVID-19 moderate/severe ARDS patients in Northern America.⁵⁻⁶
- First patients have been dosed in the Phase 3 randomized placebo-controlled trial in the United States of remestemcel-L in COVID-19 infected patients with moderate to severe ARDS on ventilator support. Enrollment is underway in up to 30 leading medical centers across North America and is expected to complete within three to four months, with interim analyses planned which could result in stopping the trial early for efficacy or futility.
- The trial will randomize up to 300 ventilator-dependent patients in intensive care units to either remestemcel-L or placebo (1:1) on top of maximal care, in line with specific guidance provided by the FDA for robust statistical analysis. The primary endpoint is all-cause mortality within 30 days of randomization, with the key secondary endpoint being the number of days alive and off mechanical support.

REVASCOR for Advanced and End-stage Heart Failure

- Results of 70 patients with end-stage ischemic heart failure and a Left Ventricular Assist Device (LVAD), from 159 patients randomized to either Revascor® or saline, were presented at the 2020 American College of Cardiology Virtual Scientific Sessions, and showed a beneficial effect on LVAD weaning, hospital readmissions for heart failure, and major mucosal bleeding events. The trial's independent investigators concluded that these findings may reflect the effect of Revascor on angiogenesis, inflammation and endothelial dysfunction, and warranted further clinical research. 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 the 566-patient Phase 3 trial for advanced heart failure. The full results from these 70 patients will be published in a peer-reviewed journal.
- Final study visits for all patients enrolled in the 566-patient Phase 3 randomized controlled trial of Revascor for advanced heart failure have been completed, ongoing quality review of all data is being completed at the study sites, and data readout is planned for mid-2020.
- 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 a clinical protocol for a confirmatory Phase 3 trial of REVASCOR in the treatment of patients with end-stage ischemic heart failure and a left ventricular assist device (LVAD), in line with FDA guidance. This product is being developed for these patients under existing FDA Regenerative Medicine Advanced Therapy (RMAT) and Orphan Drug Designations.

MPC-06-ID for Chronic Low Back Pain

- Final study visits for all patients have been completed in the Phase 3 trial with ongoing quality review of all data being completed at the study sites. More than 400 patients were randomized in this United States trial, with a data readout planned for mid-2020.
- Grünenthal and Mesoblast continue to collaborate on the clinical protocol for a confirmatory Phase 3 trial in Europe, with the results of the two Phase 3 trials expected to support both FDA and European Medicines Agency regulatory approvals for MPC-06-ID in chronic low back pain due to degenerative disc disease.

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Financial Results for the Nine Months Ended March 31, 2020 (nine months of FY2020):

Loss after tax reduced by US\$23.7 million to US\$45.3 million for the nine months of FY2020 compared to US\$69.1 million for the nine months of FY2019 as detailed below:

- **Revenues** increased US\$16.7 million to US\$31.5 million for the nine months of FY2020, compared to US\$14.8 million for the nine months of FY2019.
 - Milestone revenue increased by US\$14.0 million due to the up-front milestone payment of US\$15.0 million received for the strategic partnership with Grünenthal GmbH in the nine months of FY2020. In the nine months of 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 the nine months of FY2020 and FY2019 in relation to our partnership with Tasty in China.
 - Royalty revenue on sales of TEMCELL in Japan increased US\$2.7 million (81%) to US\$5.9 million for the nine months of FY2020 compared with US\$3.3 million for the nine months of FY2019.
- **Research and Development** expenses decreased by US\$7.5 million to US\$40.9 million for the nine months of FY2020, compared to US\$48.4 million for the nine months of FY2019. This US\$7.5 million decrease was due to a reduction in third party costs for our Phase 3 advanced heart failure, chronic low back pain and GVHD clinical trials as enrolment is now complete and activities are decreasing.
- **Manufacturing** expenses increased by US\$2.5 million to US\$15.4 million for the nine months of FY2020, compared to US\$12.9 million for the nine months of FY2019 due to increased expenditure on pre-launch inventory for the potential launch of RYONCIL.
- **Management and Administration** expenses increased US\$2.0 million to US\$18.0 million for the nine months of FY2020, compared with US\$16.0 million for the nine months of FY2019.
- **Finance Costs** for our borrowing arrangements with Hercules and NovaQuest were US\$9.8 million for the nine months of FY2020, compared to US\$7.9 million for the nine months of FY2019, an increase of US\$1.9 million.
- **Income tax benefit** increased by US\$0.4 million to US\$6.2 million in the nine months of FY2020, compared with US\$5.8 million in the nine months of FY2019 in relation to deferred tax liabilities recognized on the balance sheet during the period.

Additional components of loss after income tax also include movements in other items which did not impact current cash reserves, including fair value remeasurement of contingent consideration for which we recognized a gain on remeasurement of US\$1.3 million in the nine months of FY2020 compared to a loss of US\$3.4 million in the nine months of FY2019 due to the revaluation of contingent consideration in each relevant period.

The net loss attributable to ordinary shareholders was 8.66 US cents per share for the nine months of FY2020, compared with 14.02 US cents per share for the nine months of FY2019.

Financial Results for the Three Months Ended March 31, 2020 (third quarter FY2020):

Loss after tax reduced by US\$9.7 million to US\$15.3 million for the third quarter FY2020 compared to US\$25.0 million for the third quarter FY2019 as detailed below:

- **Revenues** increased US\$11.0 million to US\$12.2 million for the third quarter FY2020, compared to US\$1.2 million for the third quarter FY2019.
 - US\$10.0 million milestone revenue recognized in the third quarter FY2020 in relation to our partnership with Tasty in China.
 - Royalty revenue on sales of TEMCELL in Japan increased US\$1.0 million (99%) to US\$2.1 million for the third quarter FY2020 compared with US\$1.0 million for the third quarter FY2019.

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- **Research and Development** expenses of US\$14.4 million remained consistent for the third quarter FY2020 compared with the third quarter FY2019.
- **Manufacturing** expenses increased by US\$4.4 million to US\$7.6 million for the third quarter FY2020, compared to US\$3.2 million for the third quarter FY2019 due to increased expenditure on pre-launch inventory for the potential launch of RYONCIL.
- **Management and Administration** expenses increased US\$0.5 million to US\$5.7 million for the third quarter FY2020, compared with US\$5.2 million for the third quarter FY2019.
- **Finance Costs** for our borrowing arrangements with Hercules and NovaQuest were US\$3.4 million for the third quarter FY2020, compared to US\$2.8 million for the third quarter FY2019, an increase of US\$0.6 million.
- **Income tax benefit** decreased by US\$0.3 million to US\$1.9 million in the third quarter FY2020, compared with US\$2.2 million in the third quarter FY2019 in relation to deferred tax liabilities recognized on the balance sheet during the period.

Additional components of loss after income tax also include movements in other items which did not impact current cash reserves, including fair value remeasurement of contingent consideration for which we recognized a gain on remeasurement of US\$2.2 million in the third quarter FY2020 compared to a loss of US\$2.7 million in the third quarter FY2019 due to the revaluation of contingent consideration in each relevant period.

The net loss attributable to ordinary shareholders was 2.84 US cents per share for the third quarter FY2020, compared with 5.00 US cents per share for the third quarter FY2019.

Webcast

There will be a webcast today on the financial results beginning at 8am, Thursday May 28 AEST and 6pm, Wednesday, May 27, 2020 EDT.

The live webcast can be accessed via <https://webcast.boardroom.media/mesoblast-limited/20200526/NaNmesoblast-q3-financial-results>

To access the call only, dial 1 855 881 1339 (US), 1800 870 643 or 1800 809 971 (Australia) or +61 2 9007 3187 (outside of the US and Australia). The conference identification code is 10007263.

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. United States Adopted Name (USAN) assigned to Mesoblast's *ex vivo* cultured allogeneic human mesenchymal stem cells.
3. RYONCIL has been accepted by the FDA as the brand name for Mesoblast's remestemcel-L product.
4. Mesoblast does not make any representation or give any assurance that such partnering transactions will be concluded.
5. 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>
6. 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.

About Mesoblast

Mesoblast Limited (Nasdaq:MESO; ASX:MSB) 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. 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.

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Mesoblast's Biologics License Application to seek approval of its product candidate RYONCIL™ (remestemcel-L) for pediatric steroid-refractory acute graft versus host disease (acute GVHD) has been accepted for priority review by the United 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. 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 a strong and extensive global intellectual property (IP) portfolio with protection extending through to at least 2040 in all major markets. This IP position is expected to provide the Company with substantial commercial advantages as it develops its product candidates for these conditions.

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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Consolidated Income Statement

(in U.S. dollars, in thousands, except per share amount)	Three Months Ended March 31,		Nine Months Ended March 31,	
	2020	2019	2020	2019
Revenue	12,201	1,249	31,455	14,755
Research & development	(14,379)	(14,407)	(40,922)	(48,380)
Manufacturing commercialization	(7,612)	(3,193)	(15,456)	(12,910)
Management and administration	(5,730)	(5,256)	(17,960)	(15,998)
Fair value remeasurement of contingent consideration	2,158	(2,718)	1,276	(3,352)
Other operating income and expenses	(442)	(82)	(28)	(1,060)
Finance costs	(3,414)	(2,768)	(9,853)	(7,906)
Loss before income tax	(17,218)	(27,175)	(51,488)	(74,851)
Income tax benefit	1,955	2,205	6,158	5,778
Loss attributable to the owners of Mesoblast Limited	(15,263)	(24,970)	(45,330)	(69,073)
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:	Cents	Cents	Cents	Cents
Basic - losses per share	(2.84)	(5.00)	(8.66)	(14.02)
Diluted - losses per share	(2.84)	(5.00)	(8.66)	(14.02)

Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	Three Months Ended March 31,		Nine Months Ended March 31,	
	2020	2019	2020	2019
Loss for the period	(15,263)	(24,970)	(45,330)	(69,073)
Other comprehensive (loss)/income				
<i>Items that may be reclassified to profit and loss</i>				
Financial assets at fair value through other comprehensive income	94	85	(551)	280
Exchange differences on translation of foreign operations	(361)	79	(405)	(104)
Other comprehensive income/(loss) for the period, net of tax	(267)	164	(956)	176
Total comprehensive losses attributable to the owners of Mesoblast Limited	(15,530)	(24,806)	(46,286)	(68,897)

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Consolidated Balance Sheet

(in U.S. dollars, in thousands)	As of March 31, 2020	As of June 30, 2019
Assets		
Current Assets		
Cash & cash equivalents	60,077	50,426
Trade & other receivables	3,001	4,060
Prepayments	6,315	8,036
Total Current Assets	69,393	62,522
Non-Current Assets		
Property, plant and equipment	1,965	826
Right-of-use assets	7,479	—
Financial assets at fair value through other comprehensive income	1,766	2,317
Other non-current assets	3,244	3,324
Intangible assets	581,943	583,126
Total Non-Current Assets	596,397	589,593
Total Assets	665,790	652,115
Liabilities		
Current Liabilities		
Trade and other payables	19,478	13,060
Provisions	27,152	7,264
Borrowings	27,000	14,007
Lease liabilities	3,059	—
Deferred consideration	—	10,000
Total Current Liabilities	76,689	44,331
Non-Current Liabilities		
Deferred tax liability	4,966	11,124
Provisions	28,109	48,329
Borrowings	59,951	67,279
Lease liabilities	5,762	—
Deferred consideration	2,500	—
Total Non-Current Liabilities	101,288	126,732
Total Liabilities	177,977	171,063
Net Assets	487,813	481,052
Equity		
Issued Capital	960,447	910,405
Reserves	43,514	40,638
(Accumulated losses)/retained earnings	(516,148)	(469,991)
Total Equity	487,813	481,052

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Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	Nine Months Ended	
	2020	2019
Cash flows from operating activities		
Commercialization revenue received	5,579	3,321
Upfront and milestone payments received	17,500	26,409
Research and development tax incentive received	1,499	1,654
Payments to suppliers and employees (inclusive of goods and services tax)	(57,722)	(67,672)
Interest received	533	493
Interest and other costs of finance paid	(4,165)	(2,906)
Income taxes (paid)/refunded	(7)	(3)
Net cash (outflows) in operating activities	(36,783)	(38,704)
Cash flows from investing activities		
Investment in fixed assets	(1,305)	(202)
Payments for licenses	(100)	—
Net cash (outflows) in investing activities	(1,405)	(202)
Cash flows from financing activities		
Proceeds from borrowings	—	43,572
Payments of transaction costs from borrowings	—	(1,582)
Proceeds from issue of shares	51,559	30,258
Payments for share issue costs	(2,211)	(607)
Payment of lease liabilities	(1,219)	—
Net cash inflows by financing activities	48,129	71,641
Net increase in cash and cash equivalents	9,941	32,735
Cash and cash equivalents at beginning of period	50,426	37,763
FX gains/(losses) on the translation of foreign bank accounts	(290)	(113)
Cash and cash equivalents at end of period	60,077	70,385

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Global Leader in Allogeneic Cellular Medicines for Inflammatory Diseases

Financial and Operational Highlights for the Third Quarter Ended March 31, 2020

ASX: MSB; Nasdaq: MESO

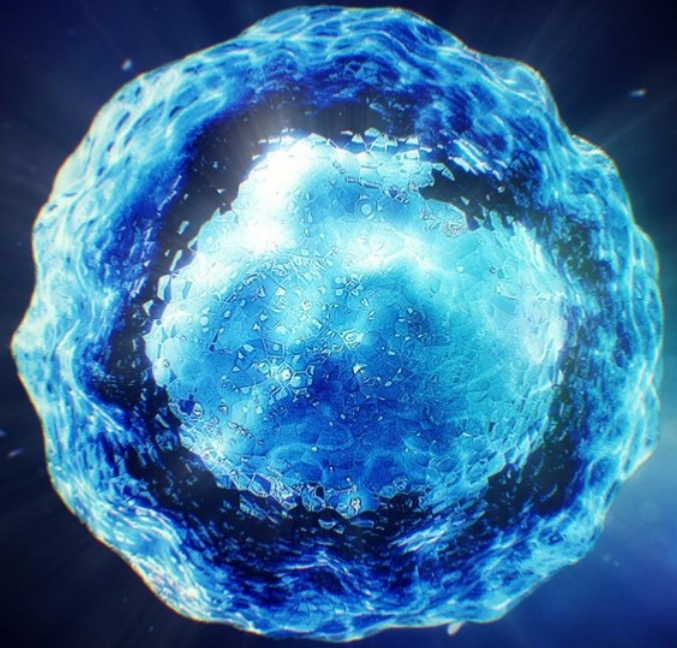


CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

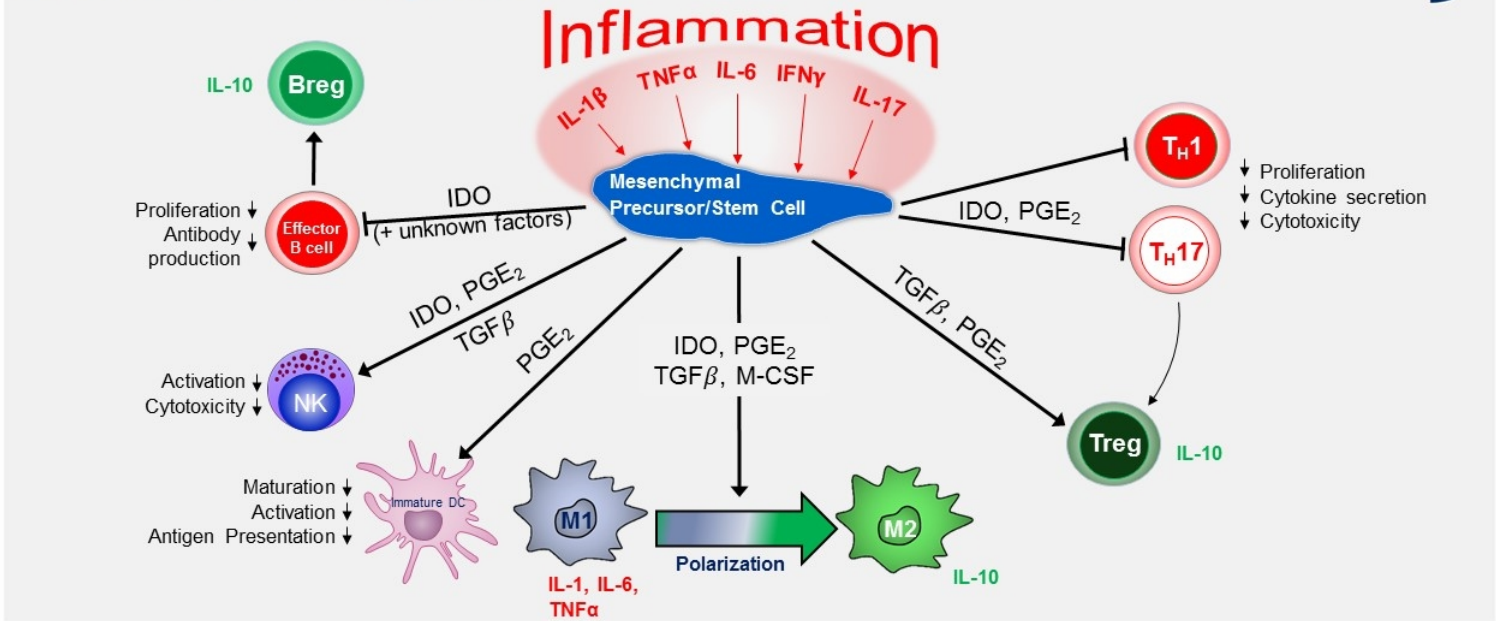


Innovative Technology Platform	Lead Product Candidate	Pipeline of Phase 3 Product Candidates
<ul style="list-style-type: none">▪ Allogeneic mesenchymal precursor cells (MPCs) and their progeny, mesenchymal stem cells (MSCs)▪ Well characterized immunomodulatory mechanisms of action▪ Targeting severe and 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, HIE and EB

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 1,000 patents and patent applications (68 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

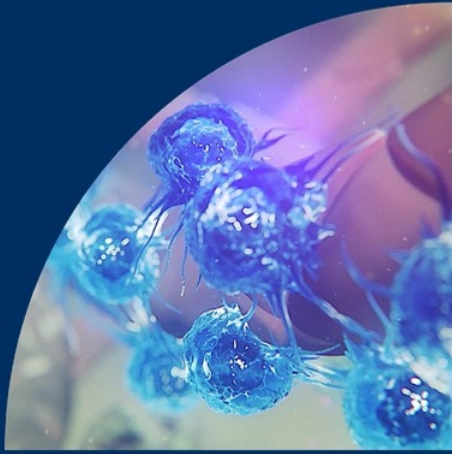


Mesenchymal Lineage Cells

Therapeutic Areas
Core commercial and non-core indications

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

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



ASX
Nasdaq

Financials

Financial Highlights



First Nine Months FY2020 Compared to First Nine Months FY2019

- 113% increase in total revenue to US\$31.5m from US\$14.8m
- 81% growth in commercialization revenue from sales of TEMCELL to US\$5.9m from US\$3.3m
- 127% increase in milestone revenues from strategic partnerships to US\$25.0m from US\$11.0m
- 34% (US\$23.7m) reduction in loss after tax
- 15% (US\$7.5m) decrease in R&D spend

Third Quarter FY2020 Compared to Third Quarter FY2019

- 10-fold increase in total revenue to US\$12.2m from US\$1.2m
- 99% growth in commercialization revenue from sales of TEMCELL to US\$2.1m

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

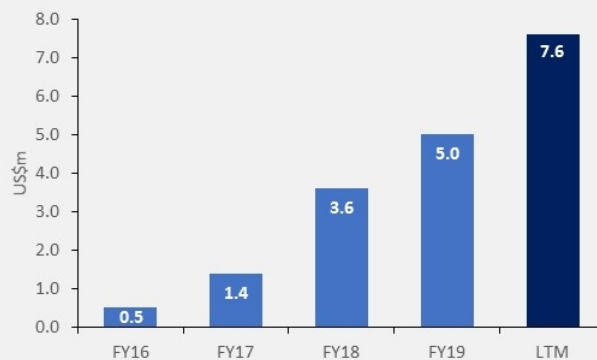
TEMCELL®



ACUTE GRAFT VERSUS HOST DISEASE + OTHER INDICATIONS

- JCR Pharmaceuticals has exclusive rights to Mesoblast's MSC technology for acute GVHD in Japan
- US\$7.6 million royalties received in last 12 months
- 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
- License expanded to cover:
 - Epidermolysis bullosa (EB), a highly debilitating and sometimes lethal skin disease; and
 - Hypoxic ischemic encephalopathy (HIE) in newborns, a disease with a high frequency of mortality

ANNUAL REVENUE FROM TEMCELL ROYALTIES IN JAPAN



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

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

Substantial Increase in Revenues and Reduced Loss After Tax

Profit and Loss for the nine months ending (US\$m)	March 31, 2020	March 31, 2019
Commercialization revenue	5.9	3.3
Milestone revenue	25.0	11.0
Interest revenue	0.5	0.5
Total Revenue	31.5	14.8
Research and development	(40.9)	(48.4)
Manufacturing	(15.5)	(12.9)
Management & administration	(18.0)	(16.0)
Contingent consideration	1.3	(3.4)
Other operating income & expenses	(0.0)	(1.1)
Finance costs	(9.9)	(7.9)
Loss before tax	(51.5)	(74.9)
Income tax benefit	6.2	5.8
Loss after tax	(45.3)	(69.1)

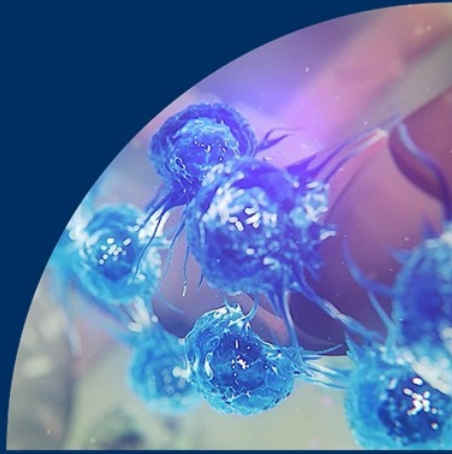
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Strengthened Balance Sheet After Capital Raise



- Cash on hand at March 31, 2020 was US\$60.1m
- Pro forma cash on hand is approximately US\$150m, with the additional US\$90m capital raised 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

Figures are rounded



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

ASX
Nasdaq

Acute Graft Versus Host Disease (aGVHD)

Significant market opportunity for RYONCIL



Burden of Illness

- aGVHD is a life-threatening complication that occurs in ~50% of patients receiving allogeneic bone marrow transplants (BMTs)¹
- Steroid-refractory aGVHD is associated with **mortality rates as high as 90%^{1,7} and significant extended hospital stay costs²**

Minimal Treatment Options

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

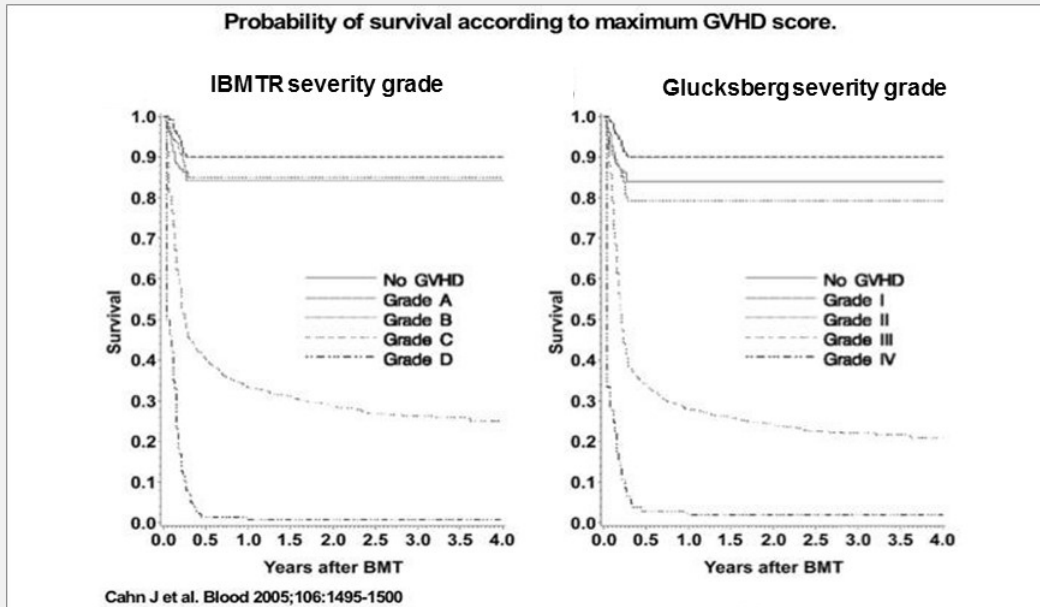
Market Opportunity

- >30,000 allogeneic BMTs performed globally (>20K US/EU) annually, ~20% pediatric^{3,4}
- Our licensee JCR Pharmaceuticals Co., Ltd launched TEMCELL® HS Inj.⁵ in Japan for SR-aGVHD in 2016; reimbursed up to ~\$USD195k⁶
- **SR-aGVHD represents \$USD > 700m US/EU market opportunity^{4,8}**



1. Westin, J., Saliba, RM., Lima, M. (2011) Steroid-refractory acute GVHD: predictors and outcomes. *Advances in Hematology*. 2. Anthem-HealthCore/Mesoblast claims analysis (2016). Data on file 3. Niederwieser D, Baldomero H, Szer J. (2016) Hematopoietic stem cell transplantation activity worldwide in 2012 and a SWOT analysis of the Worldwide Network for Blood and Marrow Transplantation Group including the global survey. 4. Source: CIBMTR Current Uses and Outcomes of Hematopoietic Cell Transplantation 2017 Summary. Passweg JR, Baldomero H (2016) Hematopoietic stem cell transplantation in Europe 2014: more than 40,000 transplants annually. 5. TEMCELL is the registered trademark of JCR 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

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



RYONCIL: Phase 3 Trial compared to MAGIC Database

Improved Day 28 Overall Response and Day 100 Survival relative to matched controls



- A comparative analysis performed between Mesoblast's open-label Phase 3 study and contemporaneous controls receiving institutional standard of care
- Phase 3 trial of RYONCIL (GVHD001) in 55 children, 89% of whom had Grade C/D disease
- A cohort of 30 pediatric patients with SR-aGVHD from the MAGIC consortium matched for inclusion criteria and disease severity (80% Grade C/D)

Outcomes*	MSB-GVHD001 (n=54) ²	MAGIC SR-aGVHD (n=30) ³
Day 28 Overall Response	70%	43%
Day 100 Survival	74%	57%

*rounded to nearest %

RYONCIL has demonstrated efficacy and survival benefit in children with SR-aGVHD including those with the most severe grades of the disease

1. Mount Sinai Acute GVHD International Consortium (MAGIC) - a group of ten BMT centers throughout the US and Europe whose purpose is to conduct ground-breaking clinical trials in GVHD, including developing informative biorepositories that assist in developing treatments that can guide GVHD therapy.

2. GVHD001 had 55 randomized patients, however one patient dropped out before receiving any dose of remestemcel-L

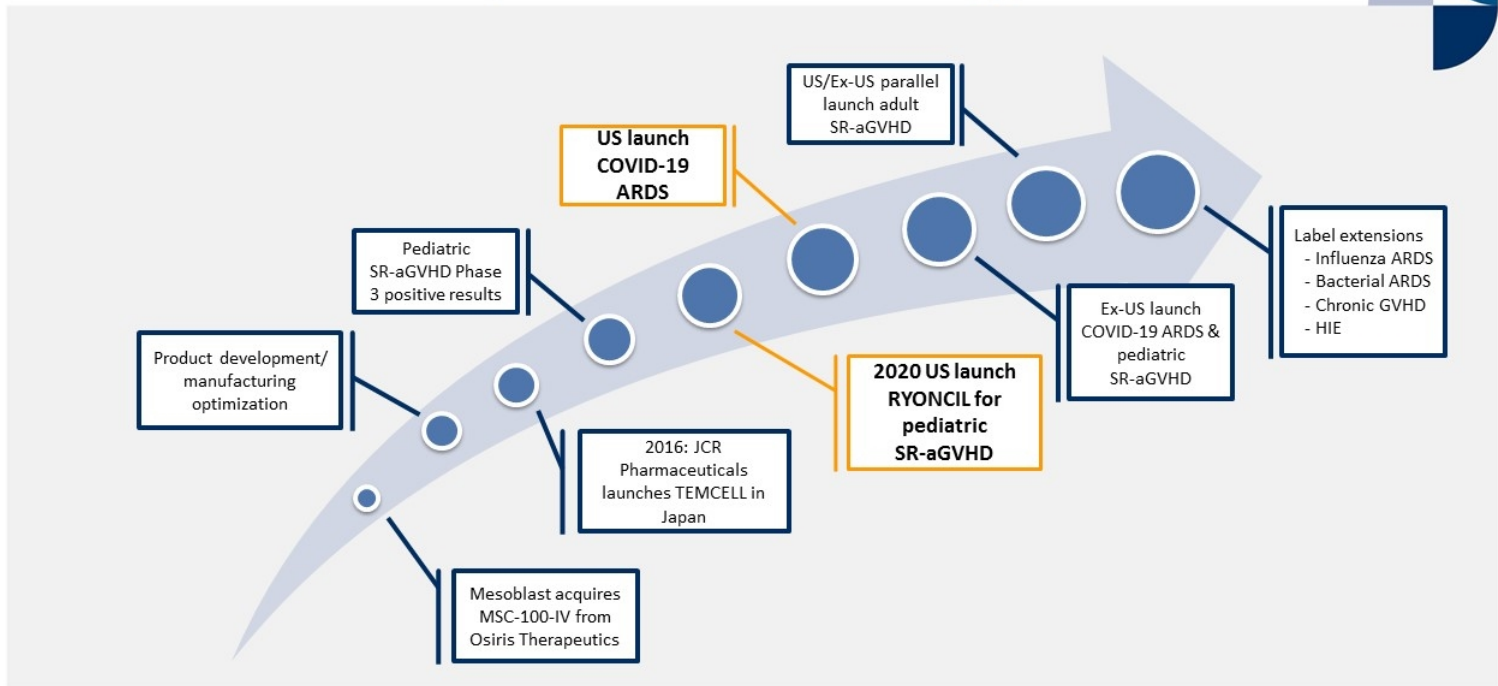
3. Two subjects in the MAGIC cohort had follow-up <100 days; these subjects are excluded from the respective survival analyses.

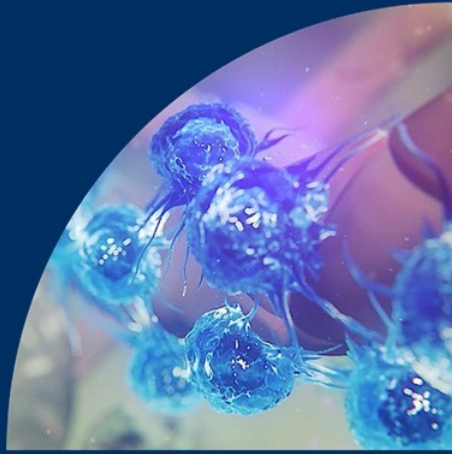
RYONCIL: Anticipated FDA Approval in 2020



- 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
- 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

Remestemcel-L: Lifecycle Extension Strategy





**Remestemcel-L:
Acute Respiratory Distress Syndrome
(ARDS) due to COVID-19**

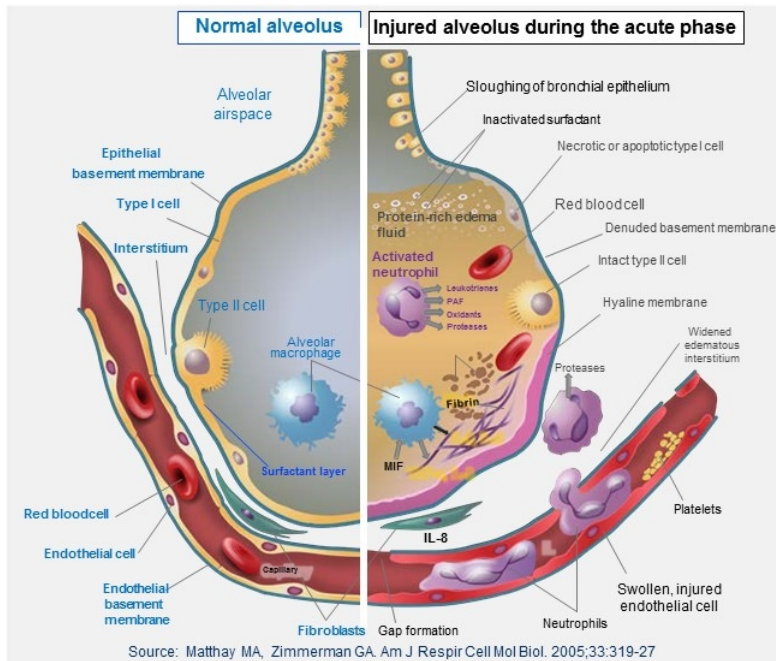


Overview – Remestemcel-L for COVID-19 ARDS



- COVID-19 is a respiratory virus with a high mortality due to a severe inflammatory condition of the lungs called acute respiratory disease 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

ARDS due to COVID-19, Influenza & Bacterial Infection – Major Unmet Need



Source: Matthay MA, Zimmerman GA. Am J Respir Cell Mol Biol. 2005;33:319-27

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

Rationale for Remestemcel-L Treatment of ARDS



- The COVID-19 virus stimulates a cytokine storm in the lung, increasing inflammatory cytokines and biomarkers such as TNF α , IL-6, IL-8, hepatocyte growth factor, and IL-2R leading to ARDS¹⁻³
- When remestemcel-L arrives in the inflamed lung, its surface receptors are activated by major pro-inflammatory cytokines including TNF α and IL-6
- Engagement of these receptors results in secretion by remestemcel-L of multiple anti-inflammatory factors that switch off macrophages, B-cells and T-cells
- This results in reduction of the cytokine storm that causes ARDS and associated inflammatory biomarkers including TNF α , IL-8, hepatocyte growth factor, and IL-2R⁴
- The anti-inflammatory and additional reparative factors produced by remestemcel-L have the potential to reverse ARDS, protect alveolar epithelial cells, and improve lung function

1. Yuki K. et al. COVID-19 pathophysiology: A review. *Clinical Immunology* 215 (2020) 108427; 2. van de Veerdonk FL. et al. A systems approach to inflammation identifies therapeutic targets in SARS CoV-2 infection. *medRxiv preprint* doi: <https://doi.org/10.1101/2020.05.23.20110916>; 3. Gong J. et al. Correlation Analysis Between Disease Severity and Inflammation-related Parameters in Patients with COVID-19 Pneumonia. *medRxiv preprint* doi: <https://doi.org/10.1101/2020.02.25.20025643>; 4. Kutrzberg J. et al. A Phase 3, Single-Arm, Prospective Study of Remestemcel-L, ExVivo 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* Volume 26, Issue 5, May 2020, Pages 845-854

Pilot Data From Emergency IND Provides Rationale for Randomized Controlled Phase 3 Trial of Remestemcel-L in COVID-19 ARDS

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 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}

Confirmatory Phase 3 Trial

- Up to 300 patients randomized 1:1 to remestemcel-L or placebo
- Primary endpoint Day 30 mortality; Key secondary endpoint days alive off ventilator support
- First patients randomized and dosed in early May

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



Objective:

- Multi-center, randomized, controlled, blinded study to assess safety and efficacy of remestemcel-L versus standard of care (SOC) treatment in subjects with moderate/severe ARDS on ventilator due to COVID-19
- The trial will be conducted at up to 30 major teaching hospitals across North America

Trial design:

- 300 patients 1:1 randomized (150 SOC + remestemcel-L : 150 SOC + placebo)
- Dose is two infusions of remestemcel-L (2×10^6 cells/kg/dose) in the first week

Primary endpoint: all cause mortality up to 30 days post randomization

Key secondary endpoint: days alive off ventilator within 60 days

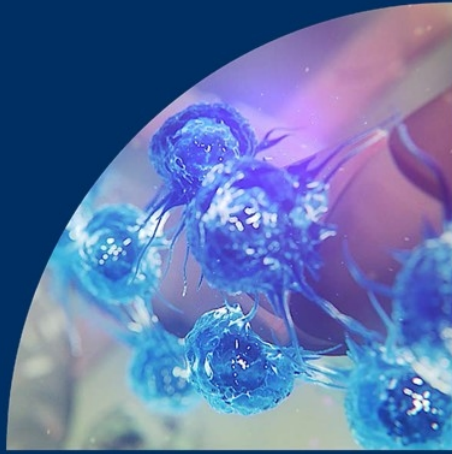
Additional information:

- Recruitment is expected to complete within three to four months, with interim analyses planned which could result in stopping the trial early for efficacy or futility

Key Milestones for Remestemcel-L in COVID-19 ARDS



- Recruitment is expected to take three to four months
- Interim analyses planned which could result in stopping the trial early for efficacy or futility. First interim analysis when 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 manufacturing and commercialization partnerships



Update on Phase 3 Product Candidates

- Heart Failure
- Chronic Low Back Pain

Partnerships and License Agreements

Phase 3 Product Candidates

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

REVASCOR™



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

CHRONIC LOW BACK PAIN - DEGENERATIVE DISC

PREVALENCE
EUROPE
~7.0 MILLION



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 planned for mid-2020
 - 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 Mesoblast's product candidate 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 planned for mid-2020

- 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 & Other Rare Diseases

- RYONCIL Priority Review underway with PDUFA date set for September 30, 2020
- If approved, US launch of RYONCIL planned for 2020
- Expand investigator-initiated clinical trials for chronic GVHD and other indications

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

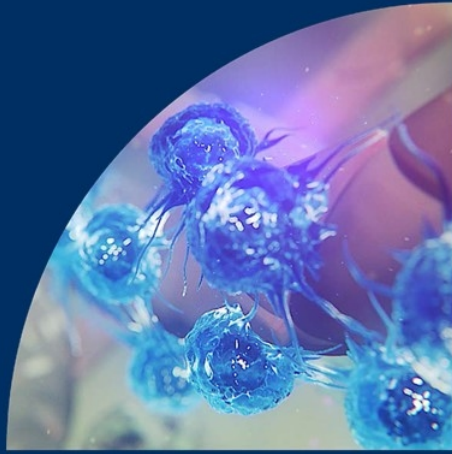
- Ongoing recruitment for Phase 3 multicenter, randomized controlled trial in North America
- Trial completion expected in approximately 3-4 months
- Establish strategic partnerships for manufacturing and commercialization

REVASCOR for Advanced and End-Stage Heart Failure

- Data readout for advanced chronic heart failure Phase 3 trial in mid-2020
- Initiate confirmatory trial in end-stage heart failure

MPC-06-ID for Chronic Low Back Pain

- Data readout for Phase 3 trial in mid-2020
- Obtain clearance from European regulatory authorities to begin European Phase 3 trial



 **mesoblast**



Thank You



