
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 6-K

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16 under the Securities Exchange Act of 1934

For the month of November 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 November 20, 2020, Mesoblast Limited filed with the Australian Securities Exchange a new release announcement, which is attached hereto as Exhibit 99.1, and is incorporated herein by reference.

On November 20, 2020, Mesoblast Limited filed with the Australian Securities Exchange a new release announcement and investor presentation, which are attached hereto as Exhibit 99.2 and Exhibit 99.3, 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/ Niva Sivakumar

Niva Sivakumar
Company Secretary

Dated: November 23, 2020

INDEX TO EXHIBITS

Item

- 99.1 Press release of Mesoblast Ltd, dated November 20, 2020.
- 99.2 Press release of Mesoblast Ltd, dated November 20, 2020.
- 99.3 Investor presentation of Mesoblast Ltd, dated November 20, 2020.

MESOBLAST ENTERS GLOBAL COLLABORATION FOR DEVELOPMENT, MANUFACTURE AND COMMERCIALIZATION OF REMESTEMCEL-L
Initial Focus on Acute Respiratory Distress Syndrome, including COVID-19

Melbourne, Australia; November 20, and New York, USA; November 19, 2020: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), today announced that it has entered into an exclusive worldwide license and collaboration agreement with Novartis for the development, manufacture and commercialization of Mesoblast's mesenchymal stromal cell (MSC) product remestemcel-L, with an initial focus on the development of the treatment of acute respiratory distress syndrome (ARDS), including that associated with COVID-19.

Mesoblast Chief Executive Dr Silviu Itescu stated: "Our collaboration with Novartis will help ensure that remestemcel-L could become available to the many patients suffering from ARDS, the principal cause of mortality in COVID-19 infection. This agreement is in line with our corporate strategy to collaborate and partner with world-leading major pharma companies in order to maximize market access for our innovative cellular medicines."

The demonstrated ability of Novartis to rapidly move from clinical to commercial scale with cell-based therapies will play a role in the successful development and potential commercialization of remestemcel-L, as will the nearly two decades of experience Novartis has in delivering first-in-class products that address areas of unmet respiratory need.

ARDS is an area of significant unmet need, with a high mortality rate despite current standard of care, which includes prolonged ICU treatment and mechanical ventilation. As the potential first ARDS therapy, remestemcel-L will be evaluated to treat this deadly condition and improve outcomes. Remestemcel-L is currently being studied in COVID-19-related ARDS in an ongoing 300-patient Phase 3 study, where even with maximal existing therapies, mortality is estimated to be even higher. Novartis intends to initiate a Phase 3 study in non-COVID-19-related ARDS after the anticipated closing of the license agreement and successful completion and outcome of the current study.

Key transaction terms:

- Novartis will make a US\$50 million upfront payment including US\$25 million in equity.
- From the initiation of a Phase 3 trial in all-cause ARDS, Novartis will fully fund global clinical development for all-cause ARDS and potentially other respiratory indications.
- Mesoblast may receive a total of US\$505 million pending achievement of pre-commercialization milestones for ARDS indications.
- Mesoblast may receive additional payments post-commercialization of up to US\$750 million based on achieving certain sales milestones and tiered double-digit royalties on product sales.
- Mesoblast will retain full rights and economics for remestemcel-L for graft versus host disease (GVHD), and Novartis has an option to, if exercised, become the commercial distributor outside of Japan.
- For most non-respiratory indications, the parties may co-fund development and commercialization on a 50:50 profit-share basis.
- Mesoblast will be responsible for clinical and commercial manufacturing and Novartis will purchase commercial product under agreed pricing terms. Novartis will reimburse Mesoblast up to US\$50 million on the achievement of certain milestones related to the successful implementation of its next-generation manufacturing processes using its proprietary media and three-dimensional bioreactors aimed at delivering substantial manufacturing efficiencies. Novartis will be responsible for any capital expenditure required to meet increased capacity requirements for manufacture of remestemcel-L.

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The closing of the license agreement is subject to the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and certain other conditions.

About Mesenchymal Stromal Cells (MSCs)

MSCs have immunomodulatory properties which may facilitate their effective use in life-threatening conditions associated with systemic inflammation. Key inherent characteristics of MSCs are their capacity for significant expansion in culture and their relative lack of immunogenicity. These properties facilitate their use as allogeneic or “off-the-shelf” therapeutics with specific release criteria and batch-to-batch reproducibility.

About Remestemcel-L

Remestemcel-L is an investigational therapy comprising culture-expanded MSCs derived from the bone marrow of an unrelated donor. Remestemcel-L is thought to have immunomodulatory properties to counteract the cytokine storms that are implicated in various inflammatory conditions by down-regulating the production of pro-inflammatory cytokines, increasing production of anti-inflammatory cytokines, and enabling recruitment of naturally occurring anti-inflammatory cells to involved tissues. Remestemcel-L is being developed for inflammatory diseases in children and adults including steroid-refractory acute graft versus host disease (SR-aGVHD) and moderate to severe acute respiratory distress syndrome.

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.

Remestemcel-L is being developed for inflammatory diseases in children and adults including steroid-refractory acute graft versus host disease and 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 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

Conference Call

There will be a webcast today beginning at 9.00am AEDT (Friday, November 20); 5.00pm EST (Thursday, November 19, 2020). It can be accessed via <https://webcast.boardroom.media/mesoblast-limited/20201119/NaN5fb59c68f297810019932232>

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

Mesoblast’s 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 potential milestone and royalty payments that may be received pursuant to the agreement with Novartis, 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

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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 Board.

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OPERATIONAL AND FINANCIAL RESULTS FOR THE PERIOD ENDED SEPTEMBER 30, 2020

Melbourne, Australia, November 20, and New York, USA, November 19, 2020: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today reported operational and financial results for the first quarter ended September 30, 2020 (FY2021).

Mesoblast has entered into an exclusive worldwide license and collaboration agreement with Novartis for the development, manufacture and commercialization of its lead mesenchymal stromal cell (MSC) product candidate, remestemcel-L, with an initial focus on the treatment of acute respiratory distress syndrome (ARDS), including that associated with COVID-19. Details of this transaction have been lodged in a separate announcement with the ASX and Nasdaq today.

As foreshadowed following the capital raising in May 2020, Mesoblast increased its investment in both clinical development and manufacturing to facilitate the potential availability of remestemcel-L for patients with COVID-19. These activities led to the strategic collaboration with Novartis which will open new opportunities in respiratory indications. This collaboration will also provide the commercial and manufacturing strength to bring this important cellular medicine to the many patients with COVID-19 and its life-threatening complication of ARDS.

Cash on hand at September 30, 2020 was US\$108.1 million (A\$152.1 million)¹ and, on transaction closing,² pro-forma cash on hand is US\$158.1 million (A\$222.4 million).

Remestemcel-L for COVID-19 Complications in Adults and Children

As cases of COVID-19 surge in the United States and globally, deaths continue to increase from ARDS in ventilator-dependent patients as a result of an overactive immune response in the lungs to COVID-19. Remestemcel-L is being evaluated for its potential to reduce 30-day mortality on top of maximal care in a Phase 3 randomized controlled trial of up to 300 ventilator-dependent adults with moderate or severe COVID-19 ARDS. The key secondary endpoint is the number of days off mechanical ventilator support.

After two prior interim analyses reviewing safety and efficacy data, the trial's independent Data Safety Monitoring Board (DSMB) recommended trial continuation as planned. Trial enrollment has now surpassed 180 patients.

The trial aims to confirm pilot data where nine of 12 (75%) ventilator-dependent adult patients with COVID-19 ARDS who received two doses of remestemcel-L under emergency compassionate use at New York's Mt Sinai Hospital were successfully discharged within a median of 10 days.

Children hospitalized with COVID-19 infection are at risk of a life-threatening inflammatory condition called multi-system inflammatory syndrome (MIS-C) which involves multiple critical organs and their vasculature, is associated with COVID-19 antibodies, and is thought to be a post-viral autoimmune process. In approximately 50% of cases this inflammation is associated with significant cardiovascular complications resulting in decreased heart function and dilation of coronary arteries.³⁻⁵

Mesoblast's existing Investigational New Drug (IND) application provides physicians with access to use remestemcel-L in COVID-19 infected children aged between two months and 17 years with MIS-C.⁶ Two COVID-19 infected children with MIS-C who received remestemcel-L for severe heart failure fully recovered heart function and were discharged within 30 hours of the second dose.



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

As part of the broad license and collaboration agreement with Novartis for remestemcel-L, Mesoblast will retain full rights and economics for graft versus host disease (GVHD).

On August 13, 2020, results from 309 children with steroid-refractory acute graft versus host disease (SR-aGVHD) treated with remestemcel-L were presented to the Oncologic Drugs Advisory Committee (ODAC) of the United States Food and Drug Administration (FDA). The ODAC panel voted 9:1 that the available data support the efficacy of remestemcel-L in pediatric patients with SR-aGVHD⁷. Despite the overwhelming ODAC vote, on September 30, the FDA provided Mesoblast with a Complete Response Letter.

On November 17, a Type A meeting was held with the FDA to discuss the review of the Biologics License Application for remestemcel-L and a potential pathway for accelerated approval with a post-approval requirement to conduct an additional randomized controlled study in patients 12 years and older. At the current time it appears that the FDA review team will not agree to accelerated approval. However, the definitive outcome of the Type A meeting will not be known until Mesoblast receives the formal minutes which are expected within 30 days of the meeting. If the current review team does not agree to accelerated approval, Mesoblast will request a further Type A meeting to initiate the well-established FDA dispute resolution pathway.

Under the terms of the license and collaboration agreement, Novartis has an option to become the commercial distributor for remestemcel-L in SR-aGVHD outside of Japan.

Remestemcel-L for Inflammatory Bowel Disease

A randomized, controlled study of remestemcel-L delivered by an endoscope directly to the areas of inflammation and tissue injury in up to 48 patients with medically refractory Crohn's or ulcerative colitis has commenced at Cleveland Clinic. Mesoblast's objective is to confirm the potential for remestemcel-L to induce luminal healing and early remission in a wider spectrum of diseases with severe inflammation of the gut, in addition to SR-aGVHD.

Despite recent advances in the treatment of inflammatory bowel disease, approximately 30% of patients are primarily unresponsive to anti-TNF α agents and even among responders, up to 10% will lose their response to the drug every year. Up to 80% of patients with medically-refractory Crohn's disease eventually require surgical treatment of their disease,⁸ which can have a devastating impact on quality of life. This investigator-initiated study is the first in humans using local cell delivery directly into the gut, and will enable Mesoblast to compare clinical outcomes using this delivery method with results from an ongoing randomized, placebo-controlled trial in patients with biologic-refractory Crohn's disease where remestemcel-L was administered intravenously.

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.⁹ The objective of treatment with Mesoblast's allogeneic cellular product candidate 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 randomized placebo-controlled Phase 3 trial in 566 patients with advanced forms of New York Heart Association Class II or Class III disease 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 in the current quarter.

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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.

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.¹⁰ 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 in the current quarter.

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 United States Phase 3 trial expected to support both FDA and European Medicines Agency regulatory approvals.

Financial Results for the First Quarter Ended September 30, 2020 (FY2021)

- **Revenues** decreased US\$15.7 million to US\$1.3 million for first quarter FY2021, compared to US\$17.0 million for first quarter FY2020.
 - Milestone revenue decreased by US\$15.0 million due to the upfront milestone payment of US\$15.0 million received for the strategic partnership with Grünenthal GmbH in first quarter FY2020, compared to nil milestone income in first quarter FY2021.
 - Royalty revenue on sales of TEMCELL HS Inj.(R)¹¹ in Japan decreased US\$0.6 million to US\$1.3 million for first quarter FY2021 compared with US\$1.9 million for first quarter FY2020. The decrease was due to a temporary shutdown in production as JCR expands its facility capacity to meet increasing demand far in excess of its initial forecast (as announced by JCR on July 31, 2020).
- **Research and Development** expenses increased by US\$6.9 million to US\$19.3 million for first quarter FY2021, compared to US\$12.4 million for the first quarter FY2020. This was due to increased clinical trial costs relating to the Phase 3 trial for COVID-19 ARDS, non-cash share-based payments to employees and consultants, and pre-commercial activities for remestemcel-L.
- **Manufacturing** expenses increased by US\$9.2 million to US\$11.9 million for first quarter FY2021, compared to US\$2.7 million for first quarter FY2020 due to increased expenditure on clinical supply for the COVID-19 ARDS Phase 3 trial and inventory for the potential launch of RYONCIL (remestemcel-L).
- **Management and Administration** expenses increased US\$2.2 million to US\$7.7 million for first quarter FY2021, compared with US\$5.5 million for first quarter FY2020 primary due to non-cash share-based payments to employees and consultants and increased in other corporate overheads.
- **Finance Costs** for borrowing arrangements with Hercules and NovaQuest were US\$4.8 million for first quarter FY2021, compared to US\$3.5 million for first quarter FY2020.

As a result of the above, loss after tax for the first quarter FY2021 was US\$24.5 million compared to US\$5.5 million for first quarter FY2020. The net loss attributable to ordinary shareholders was 4.21 US cents per share for first quarter FY2021, compared with 1.10 US cents per share for first quarter FY2020.

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Conference Call Details

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

References

- 1.Cash on hand at September 30, 2020 has been translated from US\$ to AS\$ at a spot rate of 1.407.
- 2.The closing of the license agreement is subject to the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and certain other conditions. The pro-forma cash is inclusive of a US\$25 million equity purchase at a 15% premium to the volume weighted average price calculated over 30 trading days as of today, subject to the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and certain other conditions.
- 3.www.clinicaltrials.gov; NCT04456439
- 4.Lancet2020; May 7. DOI: [https://doi.org/10.1016/S0140-6736\(20\)31094-12](https://doi.org/10.1016/S0140-6736(20)31094-12)
- 5.Lancet. 2020; (May 13) [https://doi.org/10.1016/S0140-6736\(20\)31103-X](https://doi.org/10.1016/S0140-6736(20)31103-X)
- 6.<https://www.nejm.org/doi/full/10.1056/NEJMoa2021756>
- 7.This vote includes a change to the original vote by one of the ODAC panel members after electronic voting closed.
- 8.Crohn's and Colitis Foundation.
- 9.AHA's 2017 Heart Disease and Stroke Statistics.
- 10.Decision Resources: Chronic Pain December 2015.
- 11.TEMCELL HS Inj.(R) is a registered trademark of JCR Pharmaceuticals Co. Ltd.

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.

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Forward-Looking Statements

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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 Board.

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Consolidated Income Statement

(in U.S. dollars, in thousands, except per share amount)	Three Months Ended September 30,	
	2020	2019
Revenue	1,305	17,048
Research & development	(19,278)	(12,389)
Manufacturing commercialization	(11,924)	(2,698)
Management and administration	(7,680)	(5,463)
Fair value remeasurement of contingent consideration	15,107	(288)
Other operating income and expenses	2,018	(169)
Finance costs	(4,822)	(3,457)
Loss before income tax	(25,274)	(7,416)
Income tax benefit	730	1,932
Loss attributable to the owners of Mesoblast Limited	(24,544)	(5,484)
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:	Cents	Cents
Basic - losses per share	(4.21)	(1.10)
Diluted - losses per share	(4.21)	(1.10)

Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	Three Months Ended September 30,	
	2020	2019
Loss for the period	(24,544)	(5,484)
Other comprehensive (loss)/income		
<i>Items that may be reclassified to profit and loss</i>		
Financial assets at fair value through other comprehensive income	81	(365)
Exchange differences on translation of foreign operations	408	(332)
Other comprehensive (loss)/income for the period, net of tax	489	(697)
Total comprehensive losses attributable to the owners of Mesoblast Limited	(24,055)	(6,181)

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Consolidated Balance Sheet

(in U.S. dollars, in thousands)	As of September 30, 2020	As of June 30, 2020
Assets		
Current Assets		
Cash & cash equivalents	108,123	129,328
Trade & other receivables	2,446	1,574
Prepayments	5,168	5,646
Total Current Assets	115,737	136,548
Non-Current Assets		
Property, plant and equipment	2,294	2,293
Right-of-use assets	8,038	7,978
Financial assets at fair value through other comprehensive income	1,952	1,871
Other non-current assets	3,334	3,311
Intangible assets	581,217	581,601
Total Non-Current Assets	596,835	597,054
Total Assets	712,572	733,602
Liabilities		
Current Liabilities		
Trade and other payables	27,602	24,972
Provisions	22,218	29,197
Borrowings	34,893	32,455
Lease liabilities	2,984	3,519
Total Current Liabilities	87,697	90,143
Non-Current Liabilities		
Deferred tax liability	—	730
Provisions	20,723	27,563
Borrowings	56,098	57,023
Lease liabilities	7,048	6,317
Deferred consideration	2,500	2,500
Total Non-Current Liabilities	86,369	94,133
Total Liabilities	174,066	184,276
Net Assets	538,506	549,326
Equity		
Issued Capital	1,063,005	1,051,450
Reserves	48,803	46,634
(Accumulated losses)/retained earnings	(573,302)	(548,758)
Total Equity	538,506	549,326

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Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	Three Months Ended	
	2020	September 30, 2019
Cash flows from operating activities		
Commercialization revenue received	682	1,739
Upfront and milestone payments received	—	—
Government grants and tax incentives received	17	1,499
Payments to suppliers and employees (inclusive of goods and services tax)	(27,484)	(17,539)
Interest received	13	173
Interest and other costs of finance paid	(1,389)	(1,427)
Income taxes (paid)	(6)	(3)
Net cash (outflows) in operating activities	(28,167)	(15,558)
Cash flows from investing activities		
Investment in fixed assets	(81)	(153)
Payments for licenses	—	(100)
Net cash (outflows) in investing activities	(81)	(253)
Cash flows from financing activities		
Proceeds from issue of shares	8,134	299
Payments for share issue costs	(897)	—
Payments for lease liabilities	(695)	(335)
Net cash inflows by financing activities	6,542	(36)
Net increase/(decrease) in cash and cash equivalents	(21,706)	(15,847)
Cash and cash equivalents at beginning of period	129,328	50,426
FX gain/(losses) on the translation of foreign bank accounts	501	(43)
Cash and cash equivalents at end of period	108,123	34,536

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**Financial Results for First Quarter Ended
September 30, 2020**

Strategic Collaboration with Novartis

ASX: MSB; Nasdaq: MESO

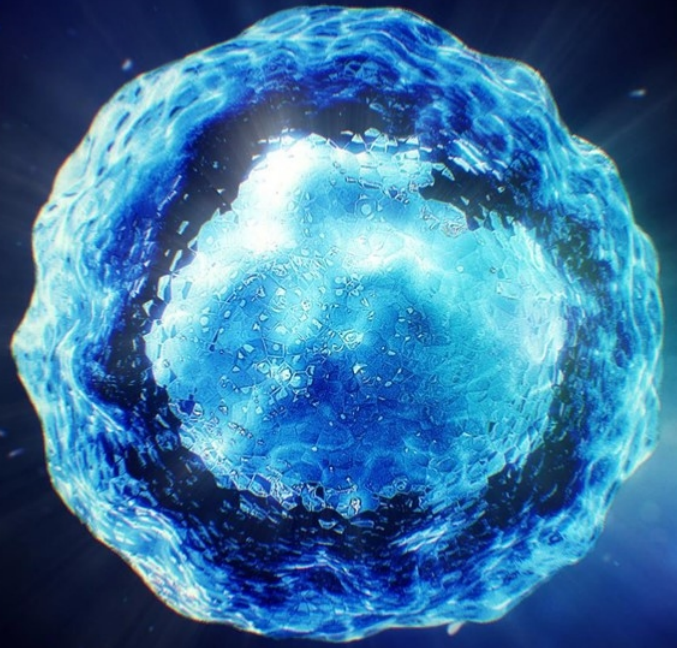


CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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



Strategic Collaboration with Novartis, Initial Focus on Respiratory Indications



- In early 2020, Mesoblast recognized that the extensive safety data of remestemcel-L and its anti-inflammatory mechanism of action made a compelling rationale for evaluating its potential to reduce the high mortality due to severe inflammation in COVID-19 ARDS
- Capital raised in May 2020 allowed increased investment in both clinical development and manufacturing to facilitate the potential availability of remestemcel-L for patients with COVID-19 ARDS
- Ongoing Phase 3 randomized, placebo-controlled trial of remestemcel-L in up to 300 ventilator-dependent patients with moderate to severe COVID-19 ARDS aims to show a reduction in mortality within 30 days
- The trial's independent data safety monitoring board (DSMB), recommended the continuation of the trial after each of two interim analyses
- Enrollment has now surpassed 180 patients
- Novartis will provide the commercial and manufacturing strength to bring this important cellular medicine to the many patients with COVID-19 and its life-threatening complication of ARDS
- The collaboration establishes a new respiratory focus targeting inflammatory lung conditions

Overview of Collaboration with Novartis for Remestemcel-L



- Worldwide license and collaboration agreement with Novartis for the development, manufacture and commercialization of remestemcel-L
 - Initial focus is on the treatment of ARDS, including that associated with COVID-19, and other respiratory conditions
 - ARDS is an area of significant unmet need, with a high mortality rate despite current standard of care, which includes prolonged ICU treatment and mechanical ventilation.
 - Novartis intends to initiate a Phase 3 study in non-COVID-19-related ARDS after the anticipated closing of the license agreement and successful completion and outcome of the current COVID-19 ARDS study
 - Mesoblast will retain full rights and economics for remestemcel-L for graft versus host disease (GVHD), and Novartis has an option to, if exercised, become the commercial distributor outside of Japan
 - For most non-respiratory indications, the parties may co-fund development and commercialization on a 50:50 profit-share basis
-

Key Terms of Collaboration with Novartis



- Novartis will make a US\$50 million upfront payment including US\$25 million in equity*
- Mesoblast may receive a total of US\$505 million pending achievement of pre-commercialization milestones for ARDS indications
- Mesoblast may receive additional payments post-commercialization of up to US\$750 million based on achieving certain sales milestones and tiered double-digit royalties on product sales
- From the initiation of a Phase 3 trial in all-cause ARDS, Novartis will fully fund global clinical development for all-cause ARDS and potentially other respiratory indications
- Mesoblast will be responsible for clinical and commercial manufacturing and Novartis will purchase commercial product under agreed pricing terms
- Novartis will reimburse Mesoblast up to US\$50 million on the achievement of certain milestones related to the successful implementation of its next-generation manufacturing processes using its proprietary media and three-dimensional bioreactors aimed at delivering substantial manufacturing efficiencies
- Novartis will be responsible for any capital expenditure required to meet increased capacity requirements for manufacture of remestemcel-L

* The closing of the license agreement is subject to the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and certain other conditions

Product Pipeline

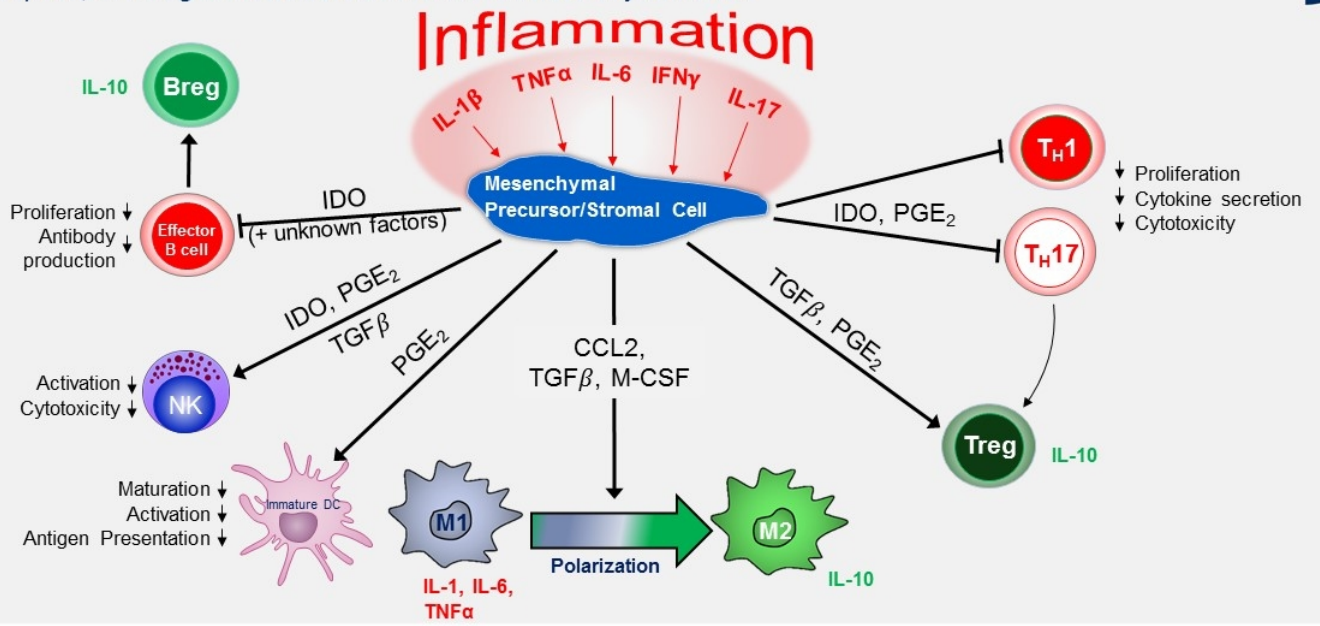


This chart is figurative and does not purport to show individual trial progress within a clinical program

* 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

Platform Technology – Mechanism of Action

Our mesenchymal precursor/stromal cells respond to and are activated by multiple inflammatory cytokines through surface receptors, resulting in orchestration of an anti-inflammatory cascade



Source: data on file

Commercial Scale Manufacturing Capability

Manufacturing Remestemcel-L

- 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
- Projected increase in capacity requirements for maturing pipeline, including 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



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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

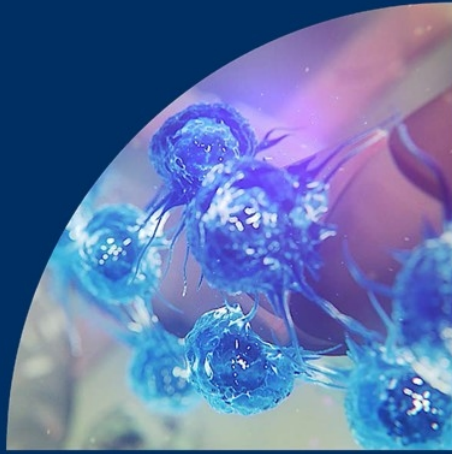


**Mesenchymal
Lineage
Cells**

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



ASX
Nasdaq

Financial Results for the Quarter Ended September 30, 2020

Strengthened Balance Sheet



- At September 30, 2020, cash on hand was US\$108.1 million
- Proforma cash on hand of US\$158.1 million includes an additional US\$50 million upfront payment from the collaboration with Novartis*
- Over the next 12 months Mesoblast, pending achievement of certain milestones, may receive additional payments under the collaboration with Novartis
- Up to an additional US\$67.5 million may be available through existing financing facilities and other strategic partnerships over next 12 months

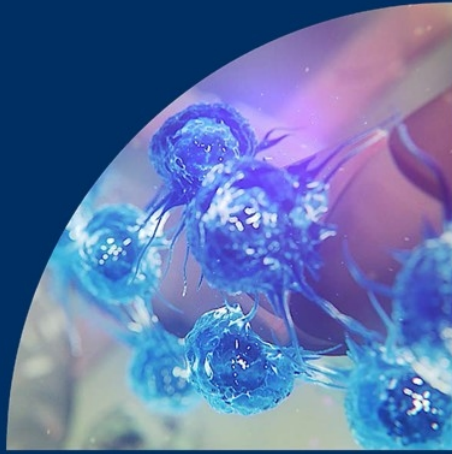
Figures are rounded

* The closing of the license agreement is subject to the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and certain other conditions

Capital Raised in May 2020 Supported Increased Investment in COVID-19 Related R&D and Manufacturing

Profit and Loss for the three months ending (US\$m)	September 30, 2020	September 30, 2019
Commercialization revenue	1.3	1.9
Milestone revenue	-	15.0
Interest revenue	-	0.2
Total Revenue	1.3	17.0
Research and development	(19.3)	(12.4)
Manufacturing	(11.9)	(2.7)
Management & administration	(7.7)	(5.5)
Contingent consideration	15.1	(0.3)
Other operating income & expenses	2.0	(0.2)
Finance costs	(4.8)	(3.5)
Loss before tax	(25.3)	(7.4)
Income tax benefit	0.7	1.9
Loss after tax	(24.5)	(5.5)

Figures are rounded



**Remestemcel-L:
Potential New Treatment Paradigm in
Inflammatory Respiratory Conditions**

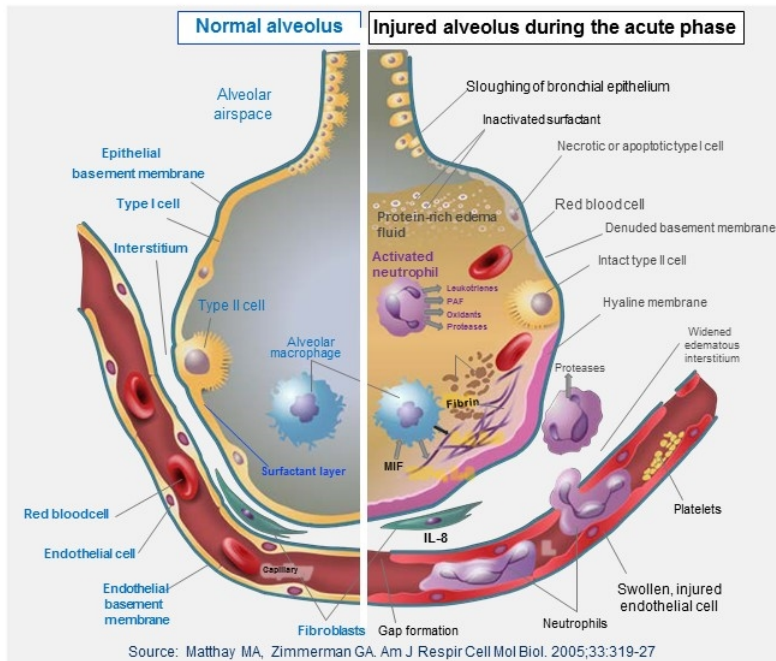
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Overview – Remestemcel-L for ARDS due to COVID-19



- 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

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)

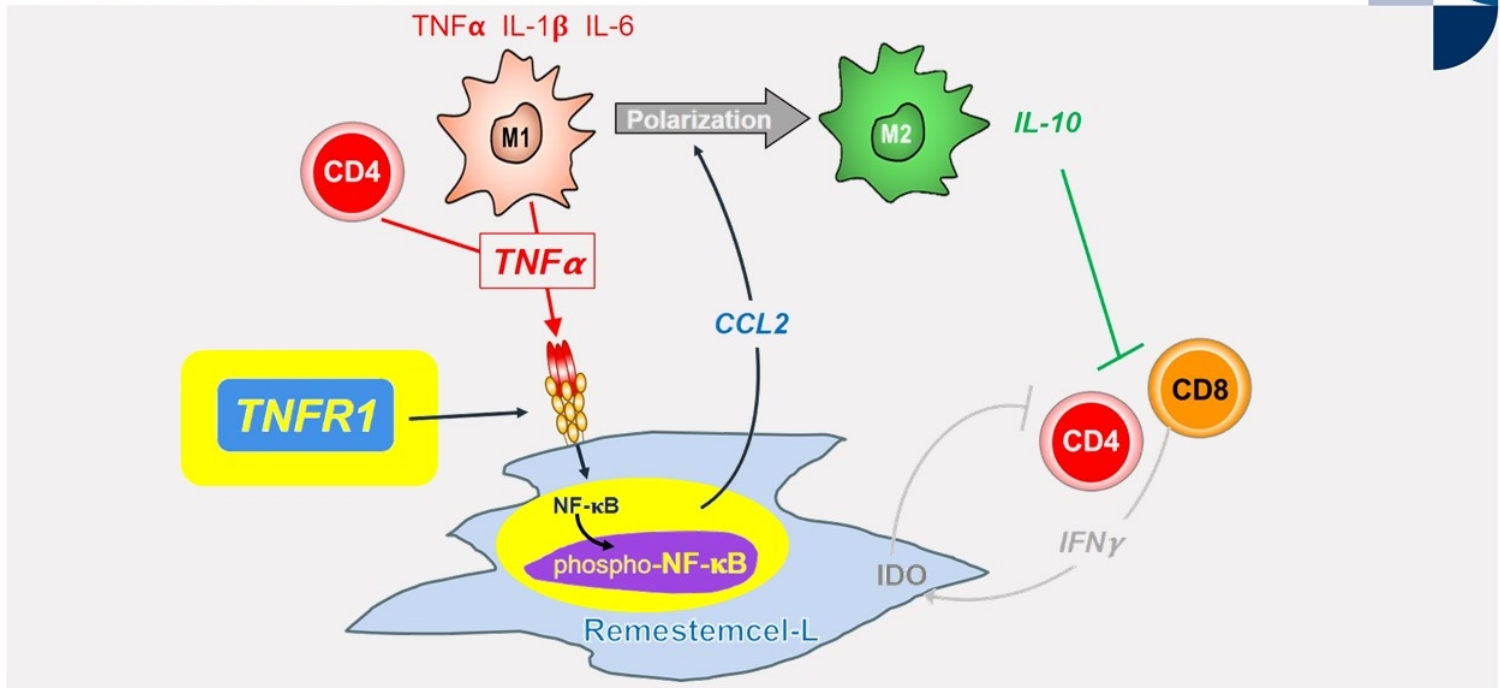
- A major area of unmet medical need
- Multiple triggers including viral/bacterial infections such as coronavirus or influenza
- Typically requires extended ICU hospitalization and intervention by ventilation
- ~40-80% mortality in viral induced ARDS (influenza & COVID-19, respectively)¹⁻⁴

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

Immunomodulatory Activities of Remestemcel-L in Response to Inflammation



Promising Pilot Data in Adults & Children with COVID-19



Compassionate Use Emergency IND in Ventilator-Dependent Adults with COVID-19 ARDS

- 12 patients with moderate or severe ARDS received two infusions of remestemcel-L within five days 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 all COVID-19 patients able to be extubated and a 12% survival rate in two major NY hospital networks during same time period^{1,2}

Children with Multisystem inflammatory Syndrome (MIS-C) due to COVID-19

- 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
- Mesoblast has established an EAP 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
- Two children with significant cardiac dysfunction, normalized after two infusions and discharged from the hospital

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

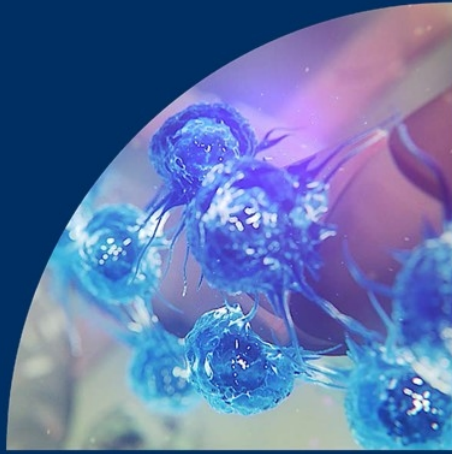
Remestemcel-L: Phase 3 Randomized Controlled Trial in COVID-19 ARDS

- Multi-center, randomized, controlled, blinded study to assess safety and efficacy of remestemcel-L versus placebo in ventilator-dependent patients with moderate/severe ARDS due to COVID-19
- Up to 300 patients randomized 1:1 to receive placebo or two infusions of remestemcel-L within 3-5 days
- Primary endpoint all cause mortality up to 30 days; key secondary endpoint days alive off ventilator within 60 days
- Trial designed to have three interim analyses for potential early stoppage due to futility or overwhelming efficacy
- Full recruitment expected to complete during Q1 CY2021

Key Milestones for Remestemcel-L in COVID-19 ARDS



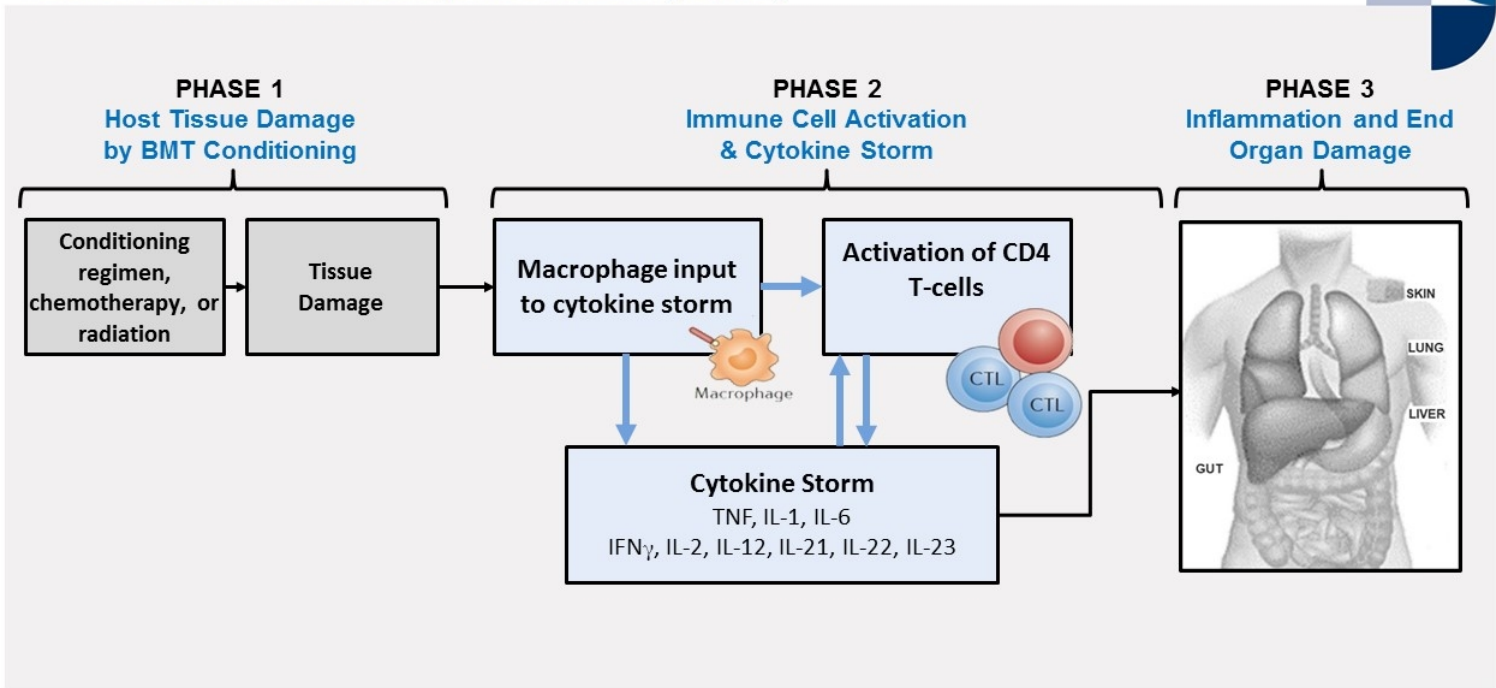
- DSMB recommended continuation of the trial after reaching first (30%) and second (45%) interim analyses
- Trial enrollment has now surpassed 180 patients
- Plan to seek Emergency Use Authorization (EUA) subject to positive data read-out
- Manufacturing scale-up to meet projected increase in capacity requirements for maturing pipeline, including ARDS due to COVID-19 and other causes, additional respiratory indications
 - 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



**Remestemcel-L:
Acute Graft Versus Host Disease**

ASX
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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*

Remestemcel-L: Prior Clinical Data in Children with SR-aGVHD



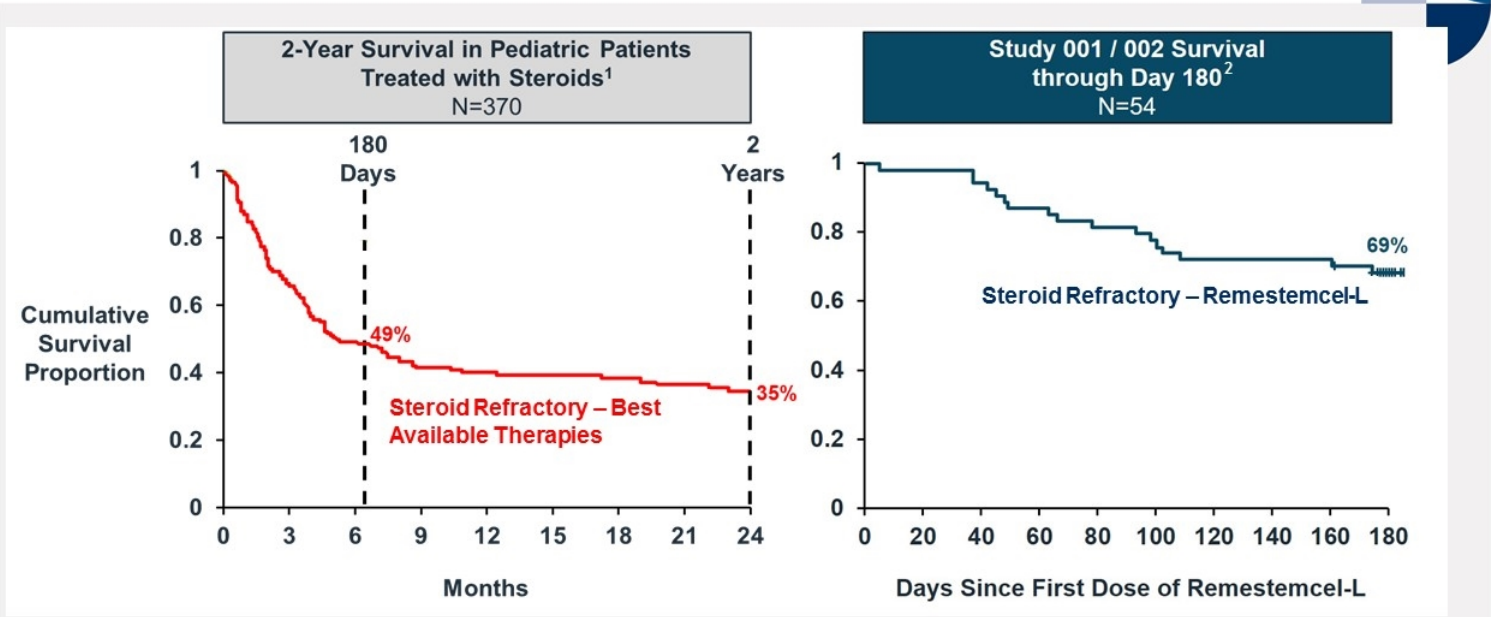
- Consistent efficacy and safety outcomes in a total of 309 children from three studies:
 - Remestemcel-L was used as first-line therapy in a randomized controlled Phase 3 trial of 260 patients, with SR-aGVHD, including 27 children
 - Remestemcel-L was used as salvage therapy in an expanded access program in 241 children with SR-aGVHD, 80% of whom had Grade C/D disease, and failed institutional standard of care
 - Remestemcel-L was used as first-line therapy in Mesoblast's open-label Phase 3 trial in 54 children with SR-aGVHD, 89% of whom had Grade C/D disease

	MAGIC ¹ N=30 ²	Protocol 280 (pediatric)		EAP 275	Study 001
		Placebo N=13	Remestemcel-L N=14	Remestemcel-L N=241	Remestemcel-L N=54 ³
Day 28 Overall Response	43%	38%	64%	65%	69%
Day 100 Survival	57%	54%	79%	66%	74%

Source: ODAC Advisory Committee Briefing Document and Presentation August 2020.

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. Two subjects in the MAGIC cohort had follow-up <100 days; these subjects are excluded from the respective survival analyses.
 3. GVHD001 had 55 randomized patients, however one patient dropped out before receiving any dose of remestemcel-L.

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



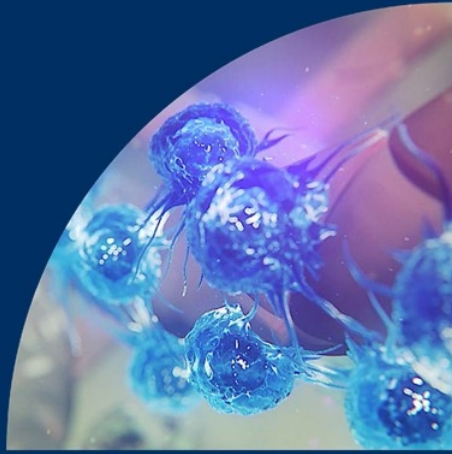
1. Adapted and redrawn from Figure 2 of MacMillan, M.L. et al. Pediatric acute GVHD: clinical phenotype and response to upfront steroids. Bone Marrow Transplant 55, 165–171 (2020); 2. Kurtzberg, J. et al. A Phase 3, Single-Arm, Prospective Study of Remestemcel-L, Ex Vivo Culture-Expanded Adult Human 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

SR-aGVHD Regulatory & Commercial Update



- As part of the broad license and collaboration agreement with Novartis for remestemcel-L, Mesoblast will retain full rights and economics for GVHD
- On August 13 2020, results from 309 children with SR-aGVHD treated with remestemcel-L were presented to the Oncologic Drugs Advisory Committee (ODAC) of the United States Food and Drug Administration (FDA).
- The ODAC panel voted 9:1 that the available data support the efficacy of remestemcel-L in pediatric patients with SR-aGVHD.* Despite the overwhelming ODAC vote, on September 30, the FDA provided Mesoblast with a Complete Response Letter
- On November 17, a Type A meeting was held with the FDA to discuss the review of the Biologics License Application for remestemcel-L and a potential pathway for accelerated approval with a post-approval requirement to conduct an additional randomized controlled study in patients 12 years and older. At the current time it appears that the FDA review team will not agree to accelerated approval. However, the definitive outcome of the Type A meeting will not be known until Mesoblast receives the formal minutes which are expected within 30 days of the meeting
- If the current review team does not agree to accelerated approval, Mesoblast will request a further Type A meeting to initiate the well-established FDA dispute resolution pathway
- Under the terms of the license and collaboration agreement, Novartis has an option to become the commercial distributor for remestemcel-L in SR-aGVHD outside of Japan

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



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



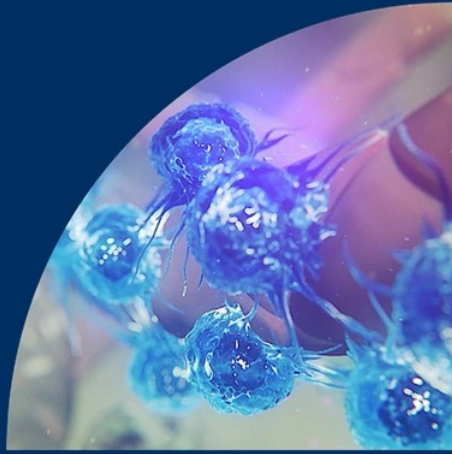
- In December 2019, the Phase 3 trial in advanced heart failure surpassed the number of primary endpoint events required for trial completion
 - Final study visits for all surviving patients have been completed
 - Ongoing quality review of all data is being completed at the study sites
 - Data readout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



 **mesoblast**



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Nasdaq

