asx announcement

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-aGVHD[7]. 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-TNFα 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.

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.

Conference Call Details
There will be a webcast today on the financial results 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

References

1.Cash on hand at September 30, 2020 has been translated from US$ to A$ 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
5.Lancet. 2020; (May 13) 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.

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

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 Board.

For further information, please contact:

Media

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

Kristen Bothwell
T: +1 917 613 5434
E:kbothwell@rubenstein.com

Investors

Schond Greenway
T: +212 880 2060
E: schond.greenway@mesoblast.com

Paul Hughes
T: +61 3 9639 6036
E: paul.hughes@mesoblast.com

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		
Items that may be reclassified to profit and loss		
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)**

Mesoblast Limited
ABN 68 109 431 870
www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
Melbourne 3000
Victoria Australia
T +61 3 9639 6036
F +61 3 9639 6030

United States Operations
505 Fifth Avenue
Third Floor
New York, NY 10017
USA
T +1 212 880 2060
F +1 212 880 2061

Asia
21 Biopolis Road
#01-22 Nucleos (South Tower)
SINGAPORE 138567
T +65 6570 0635
F +65 6570 0176

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**

Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	Three Months Ended September 30, 2020	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**