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asx announcement

mesoblast

UPDATE ON REMESTEMCEL-L FOR THE TREATMENT OF COVID-19 ARDS AND STEROID-REFRACTORY ACUTE GVHD

Quarterly Activity Report

Melbourne, Australia, October 29, and New York; USA; October 28, 2020: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today provided an update on the potential pathway to marketing approval for its lead product candidate remestemcel-L. It also provided a financial report for the first quarter ended September 30, 2020.

Mesoblast Chief Executive Dr Silviu Itescu stated: "We believe the immunomodulatory properties of remestemcel-L position this potential therapy at the forefront of treatment for severe and life-threatening inflammatory conditions, including COVID-19 acute respiratory distress syndrome (ARDS) and steroid-refractory acute graft versus host disease (SR-aGVHD). We are pursuing an accelerated approval pathway for remestemcel-L in the treatment of children with SR-aGVHD, and a parallel approval pathway for COVID-19 ARDS if the randomized controlled Phase 3 trial is positive."

Children with Steroid-Refractory Acute Graft Versus Host Disease

In August, the Oncologic Drugs Advisory Committee (ODAC)[1] of the United States Food and Drug Administration (FDA) voted 9:1 that the available data from a single-arm Phase 3 trial and evidence from additional studies support the efficacy of remestemcel-L in pediatric patients with SR-aGVHD. Despite the overwhelming ODAC vote, in September the FDA recommended that Mesoblast conduct at least one additional randomized, controlled study in adults and/or children to provide further evidence of the effectiveness of remestemcel-L for SR-aGVHD.

Mesoblast believes that remestemcel-L meets the criteria for accelerated approval as there are currently no approved treatments for this life-threatening condition in children under 12. Mesoblast has formally requested a Type A meeting with the FDA to discuss a potential accelerated approval of the Biologics License Application (BLA) for remestemcel-L for the treatment of SR-aGVHD in children, with an additional randomized controlled study in patients 12 years and older as a post-approval requirement. Mesoblast expects this meeting will occur in November.

Adults with COVID-19 ARDS

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. It is now evident that in both adults and children COVID-19 causes severe inflammation of other organ systems in addition to the lungs, including the heart, brain and kidneys. The immunomodulatory mechanism of action of remestemcel-L may be beneficial in the treatment of ARDS as well as in involvement of other organ systems.

Indeed, nine of 12 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. Additionally, two COVID-19 infected children with multisystem inflammatory syndrome (MIS-C) who received remestemcel-L for severe heart failure fully recovered heart function and were discharged within 30 hours of the second dose.

To confirm these pilot data, remestemcel-L is being evaluated for its potential to reduce mortality in a Phase 3 randomized controlled trial of up to 300 ventilator-dependent adults with moderate or severe COVID-19 ARDS. The dosing regimen in the Phase 3 is the same as in the pilot trial. Trial enrollment across more than 20 hospitals in the United States has surpassed 50% of the total 300 patient target. The trial's first 135 patients will complete 30 days of follow up during October, after which the independent Data Safety Monitoring Board (DSMB) will perform an interim analysis of the trial's primary endpoint of all-cause mortality within 30 days of randomization. The DSMB is expected to

inform Mesoblast in early November on whether the trial should proceed as planned, or should stop early. A further interim analysis is planned after 60% of the trial has been enrolled.

Crohn's Disease

According to recent estimates, more than three million people (1.3%) in the United States alone have inflammatory bowel disease, with more than 33,000 new cases of Crohn's disease and 38,000 new cases of ulcerative colitis diagnosed every year.[2-4] Despite recent advances, 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,[5] which can have a devastating impact on quality of life.

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 disease and 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. The investigator-initiated study at Cleveland Clinic is the first in humans using local cell delivery in 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.

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.[6] 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. 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. Results from Mesoblast's randomized placebo-controlled Phase 3 trial in patients with advanced forms of New York Heart Association Class II or Class III disease are expected during Q4 CY2020.

Chronic Low Back Pain

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, affecting over 3.2 million patients in the United States and approximately 4 million in the EU5.[7] Results from a Phase 3 randomized placebo-controlled trial evaluating Mesoblast's product candidate in patients with chronic low back pain due to degenerative disc disease are expected during Q4 CY2020. In parallel, Mesoblast and its partner Grünenthal GmbH are collaborating on the clinical protocol for a confirmatory Phase 3 trial in Europe.

Cash Flow Report for the First Quarter FY2021

Cash on hand at the end of the quarter was US$108.1 million. Over the next 12 months, Mesoblast may have access to an additional US$67.5 million through existing financing facilities and strategic partnerships.

Total Operating Activities excluding product inventory resulted in net cash usage of US$23.0 million in the quarter ended September 30, 2020. In addition, $5.2 million was invested in RYONCIL® (remestemcel-L) commercial inventory in anticipation of product launch for either children with SR-aGVHD or COVID-19 patients with moderate to severe ARDS.

- Research and Development payments were US$9.9 million for the current quarter compared to US$7.8 million for quarter ended September 30, 2019. The increase was primarily due to recruitment activities for our Phase 3 trial of remestemcel-L in COVID-19 patients with moderate to severe ARDS.

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- Product manufacturing and operating costs were US$5.2 million for the current quarter compared to US$3.5 million for quarter ended September 30, 2019. The increase was primarily due to investment in scale-up and increased capacity requirements of remestemcel-L in parallel to development for COVID-19 ARDS.
- Royalty receipts received from JCR Pharmaceuticals Co. Ltd for the sales of TEMCELL HS Inj.(R)8 in Japan for the treatment of aGVHD were US$0.7 million for the current quarter compared to US$1.7 million for the quarter ended September 30, 2019. 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 Pharmaceuticals on July 31, 2020).
- Payments to Related Parties, detailed in Item 6 of the Appendix 4C cash flow report for the quarter, comprise approximately US$387,000 in Non-executive Director fees and Executive Director's salary.

A copy of the Appendix 4C – Quarterly Cash Flow Report for the first quarter FY2021 is attached.

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

1.This vote includes a change to the original vote by one of the ODAC panel members after electronic voting closed.
2.CDC Facts and Figures 2015.
3.Globaldata Pharmapoint 2018.
4.Dahlhamer JM, MMWR Morb Mortal Wkly Rep. 2016;65(42):1166–1169.
5.Crohn's and Colitis Foundation
6.AHA's 2017 Heart Disease and Stroke Statistics
7.Decision Resources: Chronic Pain December 2015
8.TEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.

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

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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.

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Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

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Name of entity	
Mesoblast Limited	
ABN	**Quarter ended ("current quarter")**
68 109 431 870	30 September 2020

Consolidated statement of cash flows		**Current quarter $US'000**	**Year to date (3 months) $US'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers - royalty receipts	682	682
1.2	Payments for		
	(a) research and development	(9,906)	(9,906)
	(b) manufacturing commercialization	(5,218)	(5,218)
	(c) product manufacturing and operating costs	(5,229)	(5,229)
	(d) advertising and marketing	(1,756)	(1,756)
	(e) leased assets	—	—
	(f) staff costs	(1,908)	(1,908)
	(g) other expenses from ordinary activities	(2,503)	(2,503)
	(h) other:		
	- Intellectual property portfolio expenses	(964)	(964)
1.3	Dividends received (see note 3)	—	—
1.4	Interest received	13	13
1.5	Interest and other costs of finance paid	(1,389)	(1,389)
1.6	Income taxes paid	(6)	(6)
1.7	Government grants and tax incentives	17	17
1.8	Other (provide details if material)	—	—
1.9	**Net cash from / (used in) operating activities**	**(28,167)**	**(28,167)**

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Consolidated statement of cash flows		Current quarter $US'000	Year to date (3 months) $US'000
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(i) entities	—	—
	(j) businesses	—	—
	(k) property, plant and equipment	(81)	(81)
	(l) investments	—	—
	(m) intellectual property	—	—
	(n) other non-current assets	—	—
2.2	Proceeds from disposal of:		
	(o) entities	—	—
	(p) businesses	—	—
	(q) property, plant and equipment	—	—
	(r) investments	—	—
	(s) intellectual property	—	—
	(t) other non-current assets	—	—
2.3	Cash flows from loans to other entities	—	—
2.4	Dividends received (see note 3)	—	—
2.5	Other	—	—
2.6	**Net cash from / (used in) investing activities**	**(81)**	**(81)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	1,429	1,429
3.2	Proceeds from issue of convertible debt securities	—	—
3.3	Proceeds from exercise of options	6,705	6,705
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(897)	(897)
3.5	Proceeds from borrowings	—	—
3.6	Repayment of borrowings	—	—

Consolidated statement of cash flows		Current quarter $US'000	Year to date (3 months) $US'000
3.7	Transaction costs related to loans and borrowings	—	—
3.8	Dividends paid	—	—
3.9	Other (payment of lease liability)	(695)	(695)
3.10	**Net cash from / (used in) financing activities**	**6,542**	**6,542**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of quarter (July 1, 2020)/beginning of year (July 1, 2020)	129,328	129,328
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(28,167)	(28,167)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(81)	(81)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	6,542	6,542
4.5	Effect of movement in exchange rates on cash held	501	501
4.6	**Cash and cash equivalents at end of period**	**108,123**	**108,123**

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5.	**Reconciliation of cash and cash equivalents** at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	**Current quarter $US'000**	**Previous quarter $US'000**
5.1	Bank balances	107,697	128,916
5.2	Call deposits	—	—
5.3	Bank overdrafts	—	—
5.4	Other (Term deposits)	426	412
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**108,123**	**129,328**

6.	**Payments to related parties of the entity and their associates**	**Current quarter $US'000**
6.1	Aggregate amount of payments to related parties and their associates included in item 1	387
6.2	Aggregate amount of payments to related parties and their associates included in item 2	—

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

Payments to directors (for the current quarter) = US$387,000

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7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $US'000**	**Amount drawn at quarter end $US'000**
7.1	Loan facilities	115,000*	80,000*
7.2	Credit standby arrangements	—	—
7.3	Other (please specify)	—	—
7.4	**Total financing facilities**	115,000*	80,000*

7.5	**Unused financing facilities available at quarter end**	35,000*

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

*__Loan facility with Hercules Capital, Inc.__

On March 6, 2018, Mesoblast entered into a Loan and Security Agreement with Hercules Capital, Inc. ("Hercules Capital") for a US$75.0 million secured four-year credit facility. Mesoblast drew the first tranche of US$35.0 million on closing. An additional US$15.0 million was drawn during Q1 CY2019.

A further US$25.0 million may potentially be drawn on or before Q4 CY2020 subject to certain conditions.

As at September 30, 2020, the interest rate on the loan was 9.70%.

__*Loan facility with NovaQuest Capital Management, L.L.C.__

On June 29, 2018, Mesoblast entered into a Loan and Security Agreement with NovaQuest Capital Management, L.L.C. ("NovaQuest") for a non-dilutive US$40.0 million secured eight-year term loan. Mesoblast drew the first tranche of US$30.0 million of the loan on closing. An additional US$10.0 million from the loan will be drawn on marketing approval of RYONCIL by the United States Food and Drug Administration (FDA).

Prior to maturity in July 2026, the loan is only repayable from net sales of RYONCIL in the treatment of pediatric patients who have failed to respond to steroid treatment for acute Graft versus Host Disease (aGvHD), in the United States and other geographies excluding Asia. Interest on the loan will accrue at a rate of 15% per annum with the interest only period lasting 4 years. Interest payments will be deferred until after the first commercial sale. The financing is subordinated to the senior creditor, Hercules Capital.

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8.	Estimated cash available for future operating activities	$US'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(28,167)
8.2	Cash and cash equivalents at quarter end (item 4.6)	108,123
8.3	Unused finance facilities available at quarter end (item 7.5)	35,000*
8.4	Total available funding (item 8.2 + item 8.3)	143,123
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	5.1

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

*Under the Hercules Capital loan facility, a further US$25.0 million may potentially be drawn on or before Q4 CY2020 subject to certain conditions. Under the NovaQuest loan facility, an additional US$10.0 million from the loan will be drawn on marketing approval of RYONCIL by the United States Food and Drug Administration (FDA).

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: Not applicable

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: Not applicable

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: Not applicable

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: 29 October 2020

Authorised by: .....Chief Executive.....
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.

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