asx announcement

mesoblast

APPENDIX 4C QUARTERLY ACTIVITY REPORT

Financial and Operational Highlights for Quarter Ended September 30, 2021

Melbourne, Australia; October 29 and New York, USA; October 28, 2021: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today provided an activity report for the first quarter ended September 30, 2021, and an update on its pipeline of late-stage product candidates.

Key highlights for the quarter:

- Revenues from TEMCELL® HS Inj.[1] royalties in Japan were US$2.4 million, an increase of 22% on the previous quarter, and of 90% on the comparative quarter last year
- Total Operating Activities resulted in net cash usage of US$19.6 million in the quarter, approximately 50% of which was to support the regulatory pathway to approval, manufacturing scale-up, and lifecycle management of the remestemcel-L platform
- Cash on hand at the end of the quarter was US$116.0 million
- Mesoblast is in active discussions to complete a refinancing of its existing senior secured debt facility by calendar year end
- Results published in the latest issue of the peer-reviewed journal *Bone Marrow Transplantation*[2] showed that children with steroid-refractory acute graft versus host disease (SR-aGVHD) and biomarkers predictive for highest mortality had 64% survival when treated with remestemcel-L compared with only 10% survival when treated with other available therapies, including ruxolitinib or other biologics
- These data provide further support for the proposed anti-inflammatory mechanism of action of remestemcel-L and its immunomodulatory activity in patients with SR-aGVHD, resulting in improved survival outcomes
- At its upcoming scheduled meeting with United States Food & Drug Administration's (FDA) Office of Tissue and Advanced Therapies (OTAT), Mesoblast will address the appropriateness of potency assays related to remestemcel-L's proposed anti-inflammatory mechanism of action as well as the outstanding chemistry, manufacturing and controls (CMC) items which could support a resubmission of the current Biologics License Application (BLA) for remestemcel-L in the treatment of SR-aGVHD in children
- The FDA advised Mesoblast that if an additional clinical study in acute respiratory distress syndrome (ARDS) due to COVID-19 showed statistically positive outcomes, it could provide a dataset in conjunction with the recently completed 222 patient clinical study that might be sufficient to support an emergency use authorization (EUA)
- Mesoblast has entered into a license and collaboration agreement with Novartis for the development, manufacture, and commercialization of remestemcel-L, with an initial focus on the treatment of ARDS, including that associated with COVID-19. The agreement remains subject to certain closing conditions, including time to analyze the results from the COVID-19 ARDS trial
- Results from the randomized, controlled Phase 3 trial of rexlemestrocel-L in 565 patients with New York Heart Association (NYHA) class II and class III chronic heart failure (CHF) with low ejection fraction (HFrEF) have been selected through peer review as a late breaking presentation at the American Heart Association (AHA) annual meeting occurring November 13th- 15th. The featured session is titled 'Building on the Foundations of Treatment: Advances in Heart Failure Therapy'
- The trial's co-principal investigator Dr Emerson Perin, Medical Director of Texas Heart Institute, and Clinical Professor, Baylor College of Medicine, will give the presentation titled

'Randomized Trial of Targeted Transendocardial Delivery of Mesenchymal Precursor Cells in High-Risk Chronic Heart Failure Patients with Reduced Ejection Fraction'

- Mesoblast expects to receive feedback from the FDA in the current quarter on the potential pathways to US regulatory approval for its rexlemestrocel-L technology platform following the recently completed Phase 3 trials in patients with chronic heart failure and chronic low back pain (CLBP) due to degenerative disc disease

Cash Flow Report for the First Quarter FY2022

Cash on hand at the end of the quarter was US$116.0 million.

Revenues from TEMCELL® HS Inj. royalties in Japan for the quarter ended September 30, 2021 were US$2.4 million. This represents a 22% increase compared to the previous quarter ended June 30, 2021, and a 90% increase compared to US$1.2 million in the comparative quarter ended September 30, 2020. Total royalty receipts for the quarter were US$2.0 million, reflecting revenues recognized in the prior quarter.

Total Operating Activities resulted in net cash usage of US$19.6 million in the quarter ended September 30, 2021.

Approximately 50% of the operating net cash usage, US$9.7 million was an investment in the remestemcel-L platform to support the regulatory pathway to approval, manufacturing scale-up, and lifecycle management. Mesoblast has an upcoming scheduled meeting with FDA's OTAT, to address outstanding CMC items which could support a resubmission of the current BLA in the treatment of SR-aGVHD in children.

Research and Development payments were US$7.0 million for the current quarter. This comprises payments for the recently completed trials in COVID-19 ARDS, CHF and CLBP, as well as potency assay work in support of these programs.

Product manufacturing & operating costs and manufacturing commercialization payments were US$7.1 million for the current quarter, the majority being for commercial manufacturing and inventory build in anticipation for product launch of remestemcel-L.

Payments to Related Parties, detailed in Item 6 of the Appendix 4C cash flow report for the quarter, comprise approximately US$425,000 in Non-Executive Director fees and Executive Director's salary.

A copy of the Appendix 4C – Quarterly Cash Flow Report for the first quarter FY2022 is attached.

About Mesoblast

Mesoblast is a world leader in developing allogeneic (off-the-shelf) cellular medicines for the treatment of severe and life-threatening inflammatory conditions. The Company has leveraged its proprietary mesenchymal lineage cell therapy technology platform to establish a broad portfolio of late-stage product candidates which respond to severe inflammation by releasing anti-inflammatory factors that counter and modulate multiple effector arms of the immune system, resulting in significant reduction of the damaging inflammatory process.

Mesoblast has a strong and extensive global intellectual property portfolio with protection extending through to at least 2041 in all major markets. The Company's proprietary manufacturing processes yield industrial-scale, cryopreserved, off-the-shelf, cellular medicines. These cell therapies, with defined pharmaceutical release criteria, are planned to be readily available to patients worldwide.

Mesoblast has completed Phase 3 trials of rexlemestrocel-L for advanced chronic heart failure and chronic low back pain. 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. 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

References / Footnotes

1. TEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.
2. Kasikis S., et al. Mesenchymal stromal cell therapy induces high responses and survival in children with steroid refractory GVHD and poor risk. *Bone Marrow Transplantation* 2021; https://doi.org/10.1038/s41409-021-01442-3

Forward-Looking Statements

This announcement includes forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Forward-looking statements should not be read as a guarantee of future performance or results, and actual results may differ from the results anticipated in these forward-looking statements, and the differences may be material and adverse. Forward-looking statements include, but are not limited to, statements about the initiation, timing, progress and results of Mesoblast's preclinical and clinical studies, and Mesoblast's research and development programs; Mesoblast's ability to advance product candidates into, enroll and successfully complete, clinical studies, including multi-national clinical trials; Mesoblast's ability to advance its manufacturing capabilities; the timing or likelihood of regulatory filings and approvals, manufacturing activities and product marketing activities, if any; the commercialization of Mesoblast's product candidates, if approved; regulatory or public perceptions and market acceptance surrounding the use of stem-cell based therapies; the potential for Mesoblast's product candidates, if any are approved, to be withdrawn from the market due to patient adverse events or deaths; the potential benefits of strategic collaboration agreements and Mesoblast's ability to enter into and maintain established strategic collaborations; Mesoblast's ability to establish and maintain intellectual property on its product candidates and Mesoblast's ability to successfully defend these in cases of alleged infringement; the scope of protection Mesoblast is able to establish and maintain for intellectual property rights covering its product candidates and technology; estimates of Mesoblast's expenses, future revenues, capital requirements and its needs for additional financing; Mesoblast's financial performance; developments relating to Mesoblast's competitors and industry; and the pricing and reimbursement of Mesoblast's product candidates, if approved. You should read this press release together with our risk factors, in our most recently filed reports with the SEC or on our website. Uncertainties and risks that may cause Mesoblast's actual results, performance or achievements to be materially different from those which may be expressed or implied by such statements, and accordingly, you should not place undue reliance on these forward-looking statements. We do not undertake any obligations to publicly update or revise any forward-looking statements, whether as a result of new information, future developments or otherwise.

Release authorized by the Chief Executive.

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Appendix 4C

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

Name of entity	
Mesoblast Limited	
ABN	**Quarter ended ("current quarter")**
68 109 431 870	30 September 2021

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	1,995	1,995
1.2	Payments for		
	(a) research and development	(7,007)	(7,007)
	(b) manufacturing commercialization	(2,208)	(2,208)
	(c) product manufacturing and operating costs	(4,872)	(4,872)
	(d) advertising and marketing	(282)	(282)
	(e) leased assets	—	—
	(f) staff costs	(2,232)	(2,232)
	(g) other expenses from ordinary activities	(2,895)	(2,895)
	(h) other: - Intellectual property portfolio expenses	(726)	(726)
1.3	Dividends received (see note 3)	—	—
1.4	Interest received	4	4
1.5	Interest and other costs of finance paid	(1,407)	(1,407)
1.6	Income taxes paid	—	—
1.7	Government grants and tax incentives	24	24
1.8	Other (provide details if material)	—	—
1.9	**Net cash from / (used in) operating activities**	**(19,606)**	**(19,606)**

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	(99)	(99)
	(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**	**(99)**	**(99)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	—	—
3.2	Proceeds from issue of convertible debt securities	—	—
3.3	Proceeds from exercise of options	147	147
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(104)	(104)
3.5	Proceeds from borrowings	—	—
3.6	Repayment of borrowings	—	—
3.7	Transaction costs related to loans and borrowings	(100)	(100)
3.8	Dividends paid	—	—

Consolidated statement of cash flows		Current quarter $US'000	Year to date (3 months) $US'000
3.9	Other (payment of lease liability)	(686)	(686)
3.10	**Net cash from / (used in) financing activities**	**(743)**	**(743)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of quarter (July 1, 2021)/beginning of year (July 1, 2021)	136,881	136,881
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(19,606)	(19,606)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(99)	(99)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(743)	(743)
4.5	Effect of movement in exchange rates on cash held	(477)	(477)
4.6	**Cash and cash equivalents at end of period**	**115,956**	**115,956**

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	115,524	136,430
5.2	Call deposits	—	—
5.3	Bank overdrafts	—	—
5.4	Other (Term deposits)	432	451
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**115,956**	**136,881**

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	425
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 for Non-executive Director fees and Executive Director's salary (for the current quarter) = US$425,000

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	90,000*	80,000*
7.2	Credit standby arrangements	—	—
7.3	Other (please specify)	—	—
7.4	**Total financing facilities**	90,000*	80,000*

7.5	**Unused financing facilities available at quarter end**	10,000*

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.

As at September 30, 2021 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.

8.	Estimated cash available for future operating activities	$US'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(19,606)
8.2	Cash and cash equivalents at quarter end (item 4.6)	115,956
8.3	Unused finance facilities available at quarter end (item 7.5)	10,000*
8.4	Total available funding (item 8.2 + item 8.3)	125,956
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	6.4

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 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 2021.....

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.