asx announcement

mesoblast

APPENDIX 4C QUARTERLY ACTIVITY REPORT

Mesoblast Operational and Financial Highlights for Quarter Ended June 30, 2021

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

"During the quarter we made significant progress in both regulatory and clinical outcomes for our lead product candidate, remestemcel-L. FDA's CBER has recently recommended the next steps in the potential approval pathway for remestemcel-L in the treatment of steroid-refractory acute graft versus host disease in children" said Silviu Itescu, Chief Executive of Mesoblast. "Additionally, as COVID infections continue to surge, the 90-day survival outcomes from the remestemcel-L trial in adults with COVID ARDS demonstrated the potential for durable benefit of this therapy in certain segments experiencing the most extreme complication of this disease."

Key operational highlights:

- Mesoblast met with the United States Food & Drug Administration (FDA) on potential pathways to regulatory approval of its lead technology platform product remestemcel-L for steroid refractory acute graft versus host disease (SR-aGVHD) in children and acute respiratory distress syndrome (ARDS) in adults with COVID-19
- Regarding SR-aGVHD, FDA's Center for Biologics Evaluation and Research (CBER) recommended that Mesoblast as a next step discuss with CBER's review team at the Office of Tissue and Advanced Therapies (OTAT) our approach to address certain outstanding chemistry, manufacturing and controls (CMC) items, including potency assays, which could support a resubmission of the current Biologic License Application (BLA) with a six-month review period
- Regarding COVID ARDS, Mesoblast met with the FDA this week to determine the registration pathway for approval of remestemcel-L in this indication, with formal minutes expected in coming weeks
- Results from the randomized controlled trial of remestemcel-L in 222 ventilator-dependent COVID-19 patients with moderate/severe acute respiratory distress syndrome (ARDS) were recently highlighted at the biennial Stem Cells, Cell Therapies, and Bioengineering in Lung Biology and Diseases conference hosted by the University of Vermont, Burlington, VT, and at the International Society for Cell & Gene Therapy (ISCT) Scientific Signatures Series event on Cell and Gene-Based Therapies in Lung Diseases and Critical Illnesses
- The presented data included improved respiratory function in patients treated with remestemcel-L, as well as 90-day survival outcomes showing remestemcel-L significantly reduced mortality by 48% at 90 days compared to controls in a pre-specified analysis of 123 treated patients under 65 years old
- 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 acute respiratory distress syndrome (ARDS), including that associated with COVID-19. The agreement remains subject to certain closing conditions, including time to analyze the results from this COVID-19 ARDS trial
- Mesoblast filed requests and expects to hold meetings with the FDA during the next two quarters to discuss the pathways to US regulatory approvals for its second technology platform rexlemestrocel-L following the recently completed Phase 3 trials in patients with chronic heart failure and chronic inflammatory back pain due to degenerative disc disease

- Mesoblast and its partner in Europe and Latin America, Grünenthal, amended their collaboration agreement in line with a strategy to achieve regulatory harmonization, cost efficiencies and streamlined timelines aiming to leverage the results from a planned US trial in support of potential product approvals in both US and EU

Cash Flow Report for the Fourth Quarter FY2021

Cash on hand at the end of the quarter was US$136.4 million.

Total Operating Activities resulted in net cash usage of US$20.7 million in the quarter ended June 30, 2021. This included an investment of US$10.8 million associated with remestemcel-L for SR-aGVHD and COVID-19 ARDS. Specifically:

- Sales of TEMCELL® HS Inj.[1] in Japan for the treatment of aGVHD continue to recover from the effects of the temporary shutdown in production during mid-2020 which was undertaken in order to increase capacity to meet growing demand for the product
- Revenues from TEMCELL® royalties for the quarter ended June 30, 2021 were US$1.9 million compared to US$0.7 million in the quarter ended June 30, 2020. Royalty receipts for the quarter were US$1.9 million, reflecting revenues recognized in the prior quarter
- Research and Development payments were US$5.9 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$8.1 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$643,000 in Non-Executive Director fees and Executive Director's salary

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

About the Trial of Remestemcel-L in Acute Respiratory Distress Syndrome (ARDS) due to COVID-19

The trial enrolled 222 mechanically ventilated COVID-19 patients with moderate/severe ARDS across the US, of whom 217 were randomized 1:1 and received either standard of care alone or standard of care plus 2 intravenous infusions of remestemcel-L at a dose of 2 million cells/kg 3-5 days apart. This was the same remestemcel-L dosing regimen used in the earlier compassionate use program where 11 of 12 patients were younger than 65 and 75% successfully came off ventilatory support.

The trial was halted in December 2020 after the Data Safety Monitoring Board (DSMB) performed a third interim analysis on the trial's first 180 patients, noting that the trial was not likely to meet the 30-day mortality reduction endpoint at the planned 300 patient enrolment. The trial was powered to achieve a primary endpoint of 43% reduction in mortality at 30 days for treatment with remestemcel-L on top of maximal care. The DSMB recommended that the trial complete with the enrolled 222 patients, and that all be followed-up as planned.

At follow-up through day 60, remestemcel-L reduced overall mortality by 14% across the entire population of treated patients (n=217), and by 46% in the pre-specified population of patients under age 65 (n=123). In an exploratory analysis through day 60, remestemcel-L reduced mortality by 75% and increased days alive off mechanical ventilation in patients under age 65 when combined with dexamethasone, in comparison with controls on dexamethasone.

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 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.

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.

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 June 2021

Consolidated statement of cash flows		**Current quarter $US'000**	**Year to date (12 months) $US'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers		
	- royalty receipts	1,959	6,121
1.2	Payments for		
	(a) research and development	(5,900)	(41,084)
	(b) manufacturing commercialization	(3,346)	(14,324)
	(c) product manufacturing and operating costs	(4,729)	(17,868)
	(d) advertising and marketing	(352)	(6,175)
	(e) leased assets	—	—
	(f) staff costs	(2,161)	(10,241)
	(g) other expenses from ordinary activities	(3,787)	(14,305)
	(h) other:		
	- Intellectual property portfolio expenses	(616)	(2,923)
1.3	Dividends received (see note 3)	—	—
1.4	Interest received	—	17
1.5	Interest and other costs of finance paid	(1,810)	(5,932)
1.6	Income taxes paid	—	(35)
1.7	Government grants and tax incentives	12	68
1.8	Other (provide details if material)	—	—
1.9	**Net cash from / (used in) operating activities**	**(20,730)**	**(106,681)**

Consolidated statement of cash flows		Current quarter $US'000	Year to date (12 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	(223)	(1,647)
	(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**	**(223)**	**(1,647)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	—	110,014
3.2	Proceeds from issue of convertible debt securities	—	—
3.3	Proceeds from exercise of options	684	9,223
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(280)	(1,827)
3.5	Proceeds from borrowings	—	—
3.6	Repayment of borrowings	—	—
3.7	Transaction costs related to loans and borrowings	—	(13)
3.8	Dividends paid	—	—

Consolidated statement of cash flows		Current quarter $US'000	Year to date (12 months) $US'000
3.9	Other (payment of lease liability)	(831)	(2,931)
3.10	**Net cash from / (used in) financing activities**	**(427)**	**114,466**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of quarter (April 1, 2021)/beginning of year (July 1, 2020)	158,263	129,328
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(20,730)	(106,681)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(223)	(1,647)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(427)	114,466
4.5	Effect of movement in exchange rates on cash held	(2)	1,415
4.6	**Cash and cash equivalents at end of period**	**136,881**	**136,881**

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	136,430	157,807
5.2	Call deposits	—	—
5.3	Bank overdrafts	—	—
5.4	Other (Term deposits)	451	456
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**136,881**	**158,263**

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	643
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$643,000

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 June 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)	(20,730)
8.2	Cash and cash equivalents at quarter end (item 4.6)	136,881
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)	146,881
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	7.1

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 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: .....30 July 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.