asx announcement

mesoblast

APPENDIX 4C QUARTERLY ACTIVITY REPORT

Mesoblast Operational and Financial Highlights for Quarter Ended March 31, 2022

Melbourne, Australia; April 29 and New York, USA; April 28, 2022: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today provided an activity report for the third quarter ended March 31, 2022.

Financial highlights

- Net cash usage for operating activities in the quarter was reduced by 40%, or US$10.3 million, to US$15.5 million compared with US$25.8 million in the comparative quarter last year
- Net cash usage for operating activities, excluding inventory for the planned remestemcel-L product launch, was reduced by 50% to US$11.2 million from US$22.2 million in the comparative quarter
- Cash on hand at the end of the quarter was US$76.8 million, with up to an additional US$40 million available to be drawn down from existing financing facilities subject to certain milestones
- Revenues in the quarter were US$2.1 million, including US$1.9 million from TEMCELL® HS Inj.[1] royalties on sales for SR-aGvHD in Japan, an increase of 5% on the comparative quarter last year

New appointments to the Board and Management:

- Philip R. Krause, M.D. joined the Board of Directors in March. Dr. Krause was for the past decade Deputy Director, Office of Vaccines Research and Review (OVRR) at the United States Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER). Dr. Krause is currently Chair of the World Health Organization COVID Vaccines Research Expert Group, and most recently he shared responsibility for regulatory authorizations of COVID-19 vaccines in the US. Dr. Krause's deep insights and knowledge of regulatory processes will be invaluable to Mesoblast as it prepares its resubmission of the Biologics License Application (BLA) to the FDA for remestemcel-L in the treatment of children with steroid-refractory acute graft versus host disease (SR-aGVHD)
- Eric Rose, M.D. was appointed as the Company's Chief Medical Officer (CMO), having been a non-executive director of Mesoblast since 2013. Previously Chairman of Surgery at Columbia University's School of Medicine, Dr. Rose brings to his new role an extensive record of excellence in clinical development and successful interactions at the highest levels with key regulatory, industry and government stakeholders including the United States FDA, the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA)

Key updates on remestemcel-L:

BLA resubmission to the FDA for the treatment of children with SR-aGVHD

- Detailed data requirements and documentation being finalized for resubmission of the Biologics License Application (BLA) to the FDA for remestemcel-L in the treatment of children with SR-aGVHD
- Mesoblast has generated substantial new data, as previously discussed, that it believes establish the relevance of the proposed potency assay measuring remestemcel-L's *in vitro* anti-inflammatory and immunomodulatory activity to the *in vivo* clinical effect of the product

in the Phase 3 trial in children with SR-aGVHD, including survival and biomarkers of *in vivo* activity

- Mesoblast will provide these new data to FDA and address all chemistry, manufacturing and controls (CMC) outstanding items as required for the planned BLA resubmission. If the resubmission is accepted, CBER will consider the adequacy of the clinical data in the context of the related CMC issues noted above

Inflammatory Bowel Disease

- The results of the first cohort of patients from the randomized, controlled study of remestemcel-L by direct endoscopic delivery to areas of inflammation in patients with medically refractory ulcerative colitis or Crohn's colitis were presented at the 17th Congress of European Crohn's and Colitis Organisation (ECCO) by the trial's lead investigator Dr. Amy L. Lightner, Associate Professor of Surgery in the Department of Colon and Rectal Surgery at Cleveland Clinic

- Results from an interim analysis of the first twelve patient cohort were published in the *Journal of Crohn's and Colitis.*[2,3] A single local delivery of remestemcel-L by colonoscopy resulted in rapid mucosal healing, improved clinical and endoscopic scores as early as two weeks following remestemcel-L, and a high incidence of disease remission by six weeks. Dr. Lightner is scheduled to present results from additional patients at the world's premier meeting for physicians, researchers and industry professionals in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery, Digestive Disease Week® (DDW) next month

COVID-19 acute respiratory distress syndrome (ARDS)

- Clinical outcomes from the pilot study of remestemcel-L in 11 ventilator-dependent COVID-19 patients with ARDS treated under emergency investigational new drug (eIND) applications at Mt Sinai Hospital in New York, was published in the peer-reviewed journal *Cytotherapy* this month. The manuscript[4] titled 'Mesenchymal Stromal Cell Therapy for Acute Respiratory Distress Syndrome due to COVID-19' provides the pilot experience with remestemcel-L in 11 ventilator-dependent patients (10/11 were < 65 years) in the intensive care unit (ICU) with moderate/severe ARDS, 82% of whom were successfully discharged from the ICU. The authors noted that there are currently no approved therapies for COVID-19 ARDS and concluded that the case series demonstrated remestemcel-L infusions to treat moderate to severe COVID-19 ARDS were safe, well-tolerated, and resulted in improved clinical outcomes including liberation from mechanical ventilation and discharge from the ICU and/or hospital. These data formed the dosing strategy for a subsequent randomized controlled trial in 222 patients with moderate-severe COVID ARDS. Mesoblast continues to be in discussions with its collaborators to begin a trial to confirm the observed outcomes in patients < 65, with a potential pathway to seek Emergency Use Authorization

Key updates on rexlemestrocel-L:

Chronic Heart Failure

- Dr. Eugene Braunwald who has often been called the father of modern cardiology and the most frequently cited author in cardiology,[5] this month published an article in European Heart Journal titled *Cardiac cell therapy: a call for action*.[6] The paper highlighted next generation mesenchymal stromal (bone marrow-derived) cells as attractive candidates for cardiac cell therapy (CCT). He specifically highlighted the clinical outcomes observed in Mesoblast's DREAM-HF Phase 3 trial and pointed out the company's commercial leadership globally in the field of CCT for heart failure

- Mesoblast received feedback last quarter from FDA confirming that reduction in major adverse cardiovascular events (MACE) of cardiovascular mortality or irreversible morbidity (non-fatal heart attack or stroke) is an acceptable clinically meaningful endpoint for determining the treatment benefit of rexlemestrocel-L for patients with chronic heart failure

and low ejection fraction (HFrEF). Subsequently provided FDA with top-line results of new analyses in pre-specified high-risk groups in the DREAM-HF Phase 3 trial of rexlemestrocel-L in HFrEF which showed that the greatest treatment benefit is in patients with diabetes and/or myocardial ischemia (72% of total treated population), a target population at very high risk for mortality and irreversible morbidity due to micro- and macro-vascular disease despite receiving optimal standard of care therapies [7]

- Mesoblast expects to receive guidance from FDA on a potential pathway to approval following detailed review of the outcomes identified in high-risk HFrEF patients with diabetes and/or myocardial ischemia

Chronic Low Back Pain

- Presented 36-month follow-up results from the 404-patient Phase 3 trial of rexlemestrocel-L (MPC-06-ID) in patients with chronic low back pain (CLBP) associated with degenerative disc disease (DDD) which showed durable reduction in back pain lasting at least three years from a single intra-discal injection of rexlemestrocel-L+hyaluronic acid (HA) carrier
- Mesoblast received feedback last quarter from FDA on the Phase 3 program for CLBP and plans to conduct an additional US Phase 3 trial which may support submissions for potential approval in both the US and EU. Following review of the completed Phase 3 trial data, FDA agreed with Mesoblast's proposal for pain reduction at 12 months as the primary endpoint of the next trial, with functional improvement and reduction in opioid use as secondary endpoints

Other:

Salary payments to full-time Executive Directors were US$289,088 and fees to Non-Executive Directors were US$207,296, detailed in Item 6 of the Appendix 4C cash flow report for the quarter.(1)

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

(1) As required by ASX listing rule 4.7 and reported in Item 6 of the Appendix 4C, reported are the aggregated total payments to related parties being Executive Directors and Non-Executive Directors

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 is developing product candidates for distinct indications based on its remestemcel-L and rexlemestrocel-L allogeneic stromal cell technology platforms. Remestemcel-L is being developed for inflammatory diseases in children and adults including steroid refractory acute graft versus host disease, biologic-resistant inflammatory bowel disease, and acute respiratory distress syndrome. Rexlemestrocel-L is in development for advanced chronic 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
References / Footnotes

1. TEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.
2. Lightner A., et al. A Phase IB/IIA study of remestemcel-L, an allogeneic bone marrow derived mesenchymal stem cell product, for the treatment of medically refractory Crohn's colitis: A preliminary analysis. *Journal of Crohn's and Colitis*, Volume 16, Issue Supplement_1, January 2022, Pages i412–i413, https://doi.org/10.1093/ecco-jcc/jjab232.555
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4. Whittaker Brown S., et al. Mesenchymal Stromal Cell Therapy for Acute Respiratory Distress Syndrome due to COVID-19. *Cytotherapy*, April 2022, https://doi.org/10.1016/j.jcyt.2022.03.006
5. Dunlay SM., et al. *Circulation*. 2019;140:e294–e324
6. Neill US. Conversations with Giants in Medicine – A conversation with Eugene Braunwald. *J Clin Invest.* 2013;123(1):1-2. https://doi.org/10.1172/JCI67778
7. Braunwald E. Cardiac cell therapy: a call for action. *European Heart Journal* (2022) 00, 1–2, https://doi.org/10.1093/eurheartj/ehac188

Forward-Looking Statements

This press release 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 (including BLA resubmission), 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	31 March 2022

Consolidated statement of cash flows		**Current quarter $US'000**	**Year to date (9 months) $US'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers - royalty receipts	2,438	7,969
1.2	Payments for		
	(a) research and development	(5,030)	(19,567)
	(b) manufacturing commercialization	(4,002)	(8,432)
	(c) product manufacturing and operating costs	(2,889)	(11,232)
	(d) advertising and marketing	(205)	(666)
	(e) leased assets	—	—
	(f) staff costs	(1,801)	(7,122)
	(g) other expenses from ordinary activities	(3,226)	(10,673)
	(h) other: - Intellectual property portfolio expenses	(725)	(2,163)
1.3	Dividends received (see note 3)	—	—
1.4	Interest received	1	5
1.5	Interest and other costs of finance paid	—	—
1.6	Income taxes paid	(31)	(31)
1.7	Government grants and tax incentives	—	24
1.8	Other (provide details if material)	—	—
1.9	**Net cash from / (used in) operating activities**	**(15,470)**	**(51,888)**

Consolidated statement of cash flows		Current quarter $US'000	Year to date (9 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	(7)	(110)
	(l) investments	—	—
	(m) intellectual property	(49)	(75)
	(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**	**(56)**	**(185)**

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	—	209
3.4	Transaction costs related to issues of equity securities or convertible debt securities	—	(216)
3.5	Proceeds from borrowings	—	51,919
	Proceeds from issue of warrants	—	8,081
3.6	Repayment of borrowings	—	(55,458)
3.7	Transaction costs related to loans and borrowings	(60)	(5,513)
	Interest and other costs of finance paid	(1,366)	(4,317)

Consolidated statement of cash flows		Current quarter $US'000	Year to date (9 months) $US'000
3.8	Dividends paid	—	—
3.9	Other (payment of lease liability)	(1,145)	(2,359)
3.10	**Net cash from / (used in) financing activities**	**(2,571)**	**(7,654)**

Change in Accounting Policy
The Group routinely reviews the financial statements for opportunities to improve the quality of financial reporting. In November 2021, the Group refinanced its existing senior debt facility with a new US$90.0 million five-year facility provided by funds managed by Oaktree Capital Management, L.P. ("Oaktree") and as a result in the six months ended December 31, 2021, the Group received proceeds from borrowings and repaid the Hercules loan. In connection with the Group refinance, substantial balances related to payment of transaction costs from borrowings and charges on repayment of borrowings were recorded in the Statement of Cash Flows.

During the subsequent preparation of the Appendix 4D for the six month period ended December 31, 2021, management revised the accounting policy relating to the classification of the Interest and other costs of finance paid, previously classified within the operating activities of the Statement of Cash Flows. The Group has changed its accounting policy to classify cash flows from interest and other costs of finance paid as a financing activity because it improves the relevance of the cash flows paid from obtaining capital resources. This change in accounting policy also diminishes the mismatch in operating cash flows from the profit and loss and improves the reliability of the operating cash flow balance. This revised accounting policy has been retrospectively applied to this Appendix 4C to classify Interest and other costs of finance paid as a financing activity for the current quarter and year to date.

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of quarter (January 1, 2022)/beginning of year (July 1, 2021)	94,849	136,881
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(15,470)	(51,888)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(56)	(185)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(2,571)	(7,654)
4.5	Effect of movement in exchange rates on cash held	8	(394)
4.6	**Cash and cash equivalents at end of period**	**76,760**	**76,760**

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	76,311	94,414
5.2	Call deposits	—	—
5.3	Bank overdrafts	—	—
5.4	Other (Term deposits)	449	435
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**76,760**	**94,849**

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	496
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$496,000

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	130,000*	90,000*
7.2	Credit standby arrangements	—	—
7.3	Other (please specify)	—	—
7.4	**Total financing facilities**	130,000*	90,000*

7.5	**Unused financing facilities available at quarter end**	40,000*

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 Oaktree Capital Management, Inc.__

On November 19, 2021, Mesoblast refinanced its senior debt facility with a new US$90.0 million secured five-year credit facility provided by funds managed by Oaktree Capital Management, L.P. ("Oaktree"). Mesoblast drew the first tranche of US$60.0 million on closing, the remaining $30.0 million is available prior to December 31, 2022, subject to certain milestones.

The loan has an initial interest only period of three years, at a fixed rate of 9.75% per annum, after which time 40% of the principal is payable over two years and a final payment due no later than November 2026. Proceeds from the Oaktree facility have been used to discharge Mesoblast's obligations under the Hercules loan.

The loan interest rate is fixed and as at March 31, 2022 the interest rate was 9.75%. In the current quarter, 8% interest was paid in cash, while 1.75% interest was not paid in cash, instead it was paid in kind (PIK) and accrued onto the loan balance outstanding.

***__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, Oaktree.

8.	Estimated cash available for future operating activities	$US'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(15,470)
8.2	Cash and cash equivalents at quarter end (item 4.6)	76,760
8.3	Unused finance facilities available at quarter end (item 7.5)	40,000*
8.4	Total available funding (item 8.2 + item 8.3)	116,760
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	7.5

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 Oaktree senior debt facility $30.0 million is available prior to December 31, 2022, subject to certain milestones. 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 April 2022.....

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.