

APPENDIX 4C QUARTERLY ACTIVITY REPORT

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

Melbourne, Australia and New York, USA; January 31, 2023: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today provided an activity report for the second quarter ended December 31, 2022.

Financial Highlights

- Revenue from royalties on sales of TEMCELL® HS Inj.¹ sold in Japan by our licensee for the quarter increased 36% to US\$1.9 million from US\$1.4 million for the quarter ended September 30, 2022.
- Net cash usage for operating activities in the quarter was US\$16.5 million; this represented a reduction of US\$1.7 million, or 9%, on the comparative quarter in FY2022, and a reduction of US\$14.1 million, or 46%, on the comparative quarter in FY2021.²
- In December 2022 we announced that funds managed by Oaktree Capital Management, L.P. ("Oaktree") extended to Mesoblast the availability of up to an additional US\$30 million of its US\$90 million five-year facility subject to achieving certain milestones on or before September 30, 2023.
- Cash on hand at the end of the quarter was US\$67.6 million, with up to an additional US\$40 million available to be drawn down from existing financing facilities subject to certain milestones.

Operational Highlights

- The Biologics License Application (BLA) resubmission documents for remestemcel-L in the treatment of children with steroid-refractory graft versus host disease (SR-aGVHD) are complete and expected to be filed with FDA shortly.
- Survival outcomes have not improved over the past two decades for children or adults with the most severe forms of SR-aGVHD.³⁻⁵ The lack of any approved treatments for children under 12 means that there is an urgent need for a therapy that improves the dismal survival outcomes in children.
- Long-term survival results were received for remestemcel-L from Mesoblast's pivotal Phase 3 clinical trial (GVHD-001) in children with SR-aGVHD. The results showed durable survival through 4 years of follow-up. These new long-term survival data are a key component of the Company's BLA resubmission to the FDA.

The study was performed by the Center for International Blood and Marrow Transplant Research (CIBMTR) on 51 evaluable children with SR-aGVHD who were enrolled in the phase 3 trial across 20 centers in the US.

Overall survival in the remestemcel-L cohort was 63% at 1 year, 51% at 2 years, and 49% at 4 years, with median survival of 2 to 3 years. In recently published studies of children or adults with SR-aGVHD who received best available therapy (BAT) or the only FDA-approved agent for adults, ruxolitinib, 1 year survival was 40-49% and 2 year survival was 25%-38%.^{3,6-8}

- Mesoblast has previously gained alignment with the FDA on key metrics for a pivotal Phase 3 study of rexlemestrocet-L in patients with chronic low back pain (CLBP) with degenerative disc disease which seeks to replicate the significant reduction in pain seen in the first Phase 3 trial.
- FDA has confirmed that 12-month reduction in pain is an approvable indication, with key secondary measures of improvement in function and reduction in opioid usage.

- Preparation underway to commence the pivotal Phase 3 clinical trial by mid-CY2023.
- Results from three randomized controlled trials of rexlemestrocel-L in class II/III heart failure with reduced ejection fraction (HFrEF) and in end-stage HFrEF with left ventricular assist devices (LVADs) support the idea of a common mechanism of action (MOA) by which rexlemestrocel-L reverses inflammation-related endothelial dysfunction and reduces adverse clinical outcomes across the spectrum of HFrEF patients.
- Improvement in left ventricular ejection fraction (LVEF) at 12 months in patients with HFrEF may be an appropriate early surrogate endpoint for long term reduction in major adverse cardiovascular events (MACE).
- Mesoblast plans to meet with FDA under its existing regenerative medicine advanced therapy (RMAT) designation to discuss data and the evidence of a common MOA across the broader HFrEF spectrum, including LVAD patients.

Other

Salary payments to full-time Executive Directors were US\$324,678 and fees to Non-Executive Directors were US\$192,164, detailed in Item 6 of the Appendix 4C cash flow report for the quarter.⁹

A copy of the Appendix 4C – Quarterly Cash Flow Report for the second quarter FY2023 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 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. The Appendix 4C for the quarter ended December 31, 2021 reported net cash usage for operating activities of US\$19.8 million which was subsequently revised to US\$18.2 million, and the quarter ended December 31, 2020 reported net cash usage for operating activities of US\$32.0 million which was subsequently revised to US\$30.6 million. These revisions were due to a change in accounting policy adopted at December 31, 2021.
3. Rashidi A et al. Outcomes and predictors of response in steroid-refractory acute graft-versus-host disease: single-center results from a cohort of 203 patients. *Biol Blood Bone Marrow Transplant* 2019; 25(11):2297-2302.
4. Berger M, Pessolano R, Carraro F, Saglio F, Vassallo E, Fagioli F. Steroid-refractory acute graft-versus-host disease graded III-IV in pediatric patients. A mono-institutional experience with a long-term follow-up. *Pediatric Transplantation*. 2020; 24(7):e13806

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5. Biavasco F, Ihorst G, Wasch R, Wehr C, Bertz H, Finke J, Zeiser R. Therapy response of glucocorticoid-refractory acute GVHD of the lower intestinal tract. *Bone Marrow Transplantation*. 2022
6. MacMillan ML et al. Pediatric acute GVHD: clinical phenotype and response to upfront steroids. *Bone Marrow Transplant* 2020; 55(1): 165-171
7. Zeiser R et al. Ruxolitinib for Glucocorticoid-Refractory Acute Graft-versus-Host Disease. *N Engl J Med* 2020;382:1800-10.
8. Jagasia M et al. Ruxolitinib for the treatment of steroid-refractory acute GVHD (REACH1): a multicenter, open-label phase 2 trial. *Blood*. 2020 May 14; 135(20): 1739–1749.
9. 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

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

68 109 431 870

Quarter ended ("current quarter")

31 December 2022

Consolidated statement of cash flows	Current quarter \$US'000	Year to date (6 months) \$US'000
1. Cash flows from operating activities		
1.1 Receipts from customers	1,448	3,667
- royalty receipts		
1.2 Payments for		
(a) research and development	(5,487)	(11,049)
(b) manufacturing commercialization	(3,662)	(7,679)
(c) product manufacturing and operating costs	(1,670)	(2,465)
(d) advertising and marketing	(573)	(1,006)
(e) leased assets	—	—
(f) staff costs	(3,069)	(5,205)
(g) other expenses from ordinary activities	(3,131)	(6,169)
(h) other:		
- Intellectual property portfolio expenses	(527)	(1,112)
1.3 Dividends received (see note 3)	—	—
1.4 Interest received	147	207
1.5 Interest and other costs of finance paid	—	—
1.6 Income taxes paid	—	—
1.7 Government grants and tax incentives	18	18
1.8 Other (provide details if material)	—	—
1.9 Net cash from / (used in) operating activities	(16,506)	(30,793)

Consolidated statement of cash flows		Current quarter \$US'000	Year to date (6 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	(34)	(187)
	(l) investments	—	—
	(m) intellectual property	—	(50)
	(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	(34)	(237)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	—	45,065
3.2	Proceeds from issue of convertible debt securities	—	—
3.3	Proceeds from exercise of options	—	—
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(81)	(2,646)
3.5	Proceeds from borrowings	—	—
	Proceeds from issue of warrants	—	—
3.6	Repayment of borrowings	—	—
3.7	Transaction costs related to loans and borrowings	(65)	(216)
	Interest and other costs of finance paid	(1,375)	(2,756)

Consolidated statement of cash flows		Current quarter \$US'000	Year to date (6 months) \$US'000
3.8	Dividends paid	—	—
3.9	Other (payment of lease liability)	(439)	(1,109)
3.10	Net cash from / (used in) financing activities	(1,960)	38,338

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of quarter (October 1, 2022)/beginning of year (July 1, 2022)	85,502	60,447
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(16,506)	(30,793)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(34)	(237)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(1,960)	38,338
4.5	Effect of movement in exchange rates on cash held	617	(136)
4.6	Cash and cash equivalents at end of period	67,619	67,619

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	67,213	85,112
5.2 Call deposits	—	—
5.3 Bank overdrafts	—	—
5.4 Other (Term deposits)	406	390
5.5 Cash and cash equivalents at end of quarter (should equal item 4.6 above)	67,619	85,502

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	517
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\$516,842

7. Financing facilities		
<i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i> <i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>		
	Total facility amount at quarter end \$US'000	Amount drawn at quarter end \$US'000
7.1	Loan facilities	130,000*
7.2	Credit standby arrangements	—
7.3	Other (please specify)	—
7.4	Total financing facilities	130,000*
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.	
	<u>*Loan facility with Oaktree Capital Management, Inc.</u> 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 US\$30.0 million is available subject to achieving certain milestones on or before September 30, 2023. 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. The loan interest rate is fixed and as at December 31, 2022 the interest rate was 9.75%. In the year to date at December 31, 2022, 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. <u>*Loan facility with NovaQuest Capital Management, L.L.C.</u> 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\$40.0million 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 remestemcel-L for the treatment in pediatric patients with steroid-refractory acute graft versus host disease ("SR-aGVHD") by the United States Food and Drug Administration (FDA). The loan term includes an interest only period of approximately four years through until July 8, 2022, then a four-year amortization period through until maturity. All interest and principal payments will be deferred until after the first commercial sale of remestemcel-L in the treatment of pediatric patients with SR-aGVHD. Principal is repayable in equal quarterly instalments over the amortization period of the loan based on a percentage of net sales and are limited by a payment cap. The loan has a fixed interest rate of 15% per annum. 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)	(16,506)
8.2	Cash and cash equivalents at quarter end (item 4.6)	67,619
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)	107,617
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	6.5

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 US\$30.0 million is available subject to achieving certain milestones on or before September 30, 2023. 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:31 January 2023.....

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.