

## APPENDIX 4C QUARTERLY ACTIVITY REPORT FOR QUARTER ENDED DECEMBER 31, 2023

**Melbourne, Australia; January 31 and New York, USA; January 30, 2024:** 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, 2023.

Mesoblast Chief Executive Silviu Itescu said: "It has been a very busy quarter in which we have made substantial operational progress across our three lead Phase 3 assets. We have generated significant new potency and characterization data for our lead product Ryoncil® (remestemcel-L) for children with acute GVHD, as requested by FDA, and will submit these data ahead of our planned meeting with FDA this quarter."

"Our second Phase 3 back pain trial with rexlemestrocil-L, aiming to confirm the durable pain reduction that was seen in the first Phase 3 trial, is underway. Finally, we were very pleased to have received a Rare Pediatric Disease (RPD) Designation from FDA for our cardiovascular product Revascor® in children with life-threatening congenital heart disease, and plan to discuss the trial results in the context of a regulatory approval pathway."

Dr Itescu added: "We raised additional capital during the quarter to support these important Phase 3 programs, and I would like to thank all shareholders that participated in the placement and entitlement offer. In combination with our previously announced cost reduction strategies and operational streamlining, which are on-track, this new capital will provide added balance sheet strength."

### ACTIVITY REPORT

#### Graft versus Host Disease – Pediatric and Adult Phase 3 Programs

- Mesoblast has requested a meeting with FDA this quarter to provide additional potency and characterization data for its product RYONCIL which it believes demonstrate that the product used as second-line after corticosteroids in the pivotal Phase 3 trial GVHD001 in children with SR-aGVHD, which successfully met its primary endpoint of Day 28 Overall Response, was made to a standard supporting the trial as being adequate and well controlled.
- The new potency assay data show that the RYONCIL product made with the current manufacturing process that has undergone successful inspection by FDA, demonstrates greater potency than the earlier generation product, providing context to its greater impact on survival.
- Showing that the product used in the completed pediatric Phase 3 trial was standardized as to potency and characterization could provide support for approval of the pediatric indication given the absence of any approved therapies for children.
- Survival in adults with SR-aGVHD who have failed at least one additional agent, such as ruxolitinib, remains as low as 20-30% by 100 days.<sup>1,2</sup> In contrast, 100-day survival was 63% after remestemcel-L treatment was used under expanded access in 71 patients aged 12 and older with SR-aGVHD who failed to respond to at least one additional agent, such as ruxolitinib.
- The Blood and Marrow Transplant Clinical Trials Network (BMT CTN) in the United States, a body that is funded by the National Institutes of Health (NIH) and is responsible for approximately 80% of all US allogeneic BMTs, has agreed to develop and execute a pivotal trial of RYONCIL in adults who are refractory to both corticosteroids and a second line agent such as ruxolitinib.
- Mesoblast will provide the Phase 3 trial protocol to FDA ahead of the upcoming meeting this quarter.

#### Cardiovascular – Program in Pediatric Congenital Heart Disease, Adult Phase 3 Program in Chronic Heart Failure with Reduced Ejection Fraction (HFrEF)

- This month FDA granted Mesoblast a Rare Pediatric Disease (RPD) Designation for Revascor® (rexlemestrocil-L) following submission of results from the randomized controlled trial in children with hypoplastic left heart syndrome (HLHS), a potentially life-threatening congenital heart condition.

- The results from the blinded, randomized, placebo-controlled prospective trial of REVASCOR conducted in the United States in children with HLHS were published in the December 2023 issue of the peer reviewed the *Journal of Thoracic and Cardiovascular Surgery Open (JTCVS Open)*.<sup>3</sup> In the HLHS trial, a single intramyocardial administration of REVASCOR at the time of staged surgery resulted in the desired outcome of significantly increased left ventricular (LV) end-systolic and end-diastolic volumes over 12 months compared with controls as measured by 3D echocardiography, (p=0.009 & p=0.020 respectively), facilitating life-saving biventricular surgery to be achievable in 100% of REVASCOR-treated children vs only 57% of controls.
- RPD Designation is granted by the FDA for certain serious or life-threatening diseases which primarily affect children.
- On FDA approval of a Biologics Licensing Application (BLA) for REVASCOR for the treatment of HLHS, Mesoblast may be eligible to receive a Priority Review Voucher (PRV) that can be redeemed for any subsequent marketing application or may be sold or transferred to a third party.
- REVASCOR® has shown the potential to reduce major adverse cardiac events such as heart attack and cardiovascular death in high risk patients with HFrEF. Mesoblast will meet with FDA this quarter to address potential pathways to approval for REVASCOR under our Regenerative Medicine Advanced Therapies (RMAT) designation.

### Chronic Low Back Pain – Phase 3 Program

- Second Phase 3 trial underway for rexlamestrocel-L in the treatment of chronic low back pain (CLBP) due to inflammatory disc degeneration– a condition affecting at least seven million people in both the US and Europe alone.
- Phase 3 trial activities, investigators and trial sites across the United States are being managed by a leading contract research organisation (CRO) specializing in pain trials.
- The trial’s primary endpoint is reduction in pain at 12 months after a single intra-discal injection of rexlamestrocel-L.
- First Phase 3 trial showed significant pain reduction at 12 and 24 months, and confirmation of these results will provide FDA with a clinical data package that may result in product approval.

### FIANANCIAL REPORT

#### Strengthened Balance Sheet

Institutional Placement and Entitlement Offer completed raising A\$60.3 million at an issue price of A\$0.30 per share, including the completed retail component and top-up facility of the Entitlement Offer. The offer was well supported by existing shareholders, new institutional investors, and by Directors. Mesoblast Founder and Chief Executive Officer, Dr Silviu Itescu strongly supported the Entitlement Offer subscribing for A\$3.0 million.

Cash balance at the end of the quarter was A\$113.4 million (US\$77.6 million).<sup>4</sup>

#### Cost containment strategy on-track

Cost containment strategies and payroll reductions have been enacted by management and the Board enabling continuation of Phase 3 programs for SR-aGVHD and CLBP in the quarter whilst still achieving reductions in net operating cash spend:

- Net operating cash spend of US\$12.3 million for the quarter.
- 25% reduction in net operating cash spend from the comparative quarter in FY2023.
- 32% reduction in net operating cash spend from the comparative quarter in FY2022.
- On target to achieve a 23% (\$15m) reduction in net operating spend in FY2024 compared to FY2023 which will be partially offset by investment in our Phase 3 programs for SR-aGVHD and CLBP.

We will maintain our focus on cutting costs and preserving cash in the remainder of the year whilst complimenting that with initiatives currently underway to increase cash inflows which would by design enable us to prudently invest in our Phase 3 programs for SR-aGVHD and CLBP. In this regard, we are working on corporate initiatives to strengthen our balance sheet, including royalty monetization and

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strategic partnerships to both access existing commercial distribution channels and supplement costs of development.

### Revenues

Revenue from royalties on sales of TEMCELL® HS Inj.<sup>5</sup> sold in Japan by our licensee for the quarter were US\$1.5 million. On a constant currency basis, royalties on sales were US\$3.3 million for the six-month period ended December 31, 2023, a growth of 3% compared with US\$3.2 million in the comparative period in FY2023.<sup>6</sup>

### Other

Fees to Non-Executive Directors were nil, consulting payments to Non-Executive Directors were US\$144,700 and salary payments to full-time Executive Directors were US\$226,288, detailed in Item 6 of the Appendix 4C cash flow report for the quarter.<sup>7</sup> From 1 August 2023, Non-Executive directors have voluntarily deferred 50% cash payment of their director fees and agreed to receive the remaining 50% of their fees in equity-based incentives and Executive Directors (our Chief Executive and Chief Medical Officers) have voluntarily reduced their base salaries for FY24 by 30% in lieu of accepting equity-based incentives.

A copy of the Appendix 4C – Quarterly Cash Flow Report for the second quarter FY2024 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](http://www.mesoblast.com), LinkedIn: Mesoblast Limited and Twitter: @Mesoblast

### References / Footnotes

1. 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.
2. Abedin S, et al. Ruxolitinib resistance or intolerance in steroid-refractory acute graft-versus-host disease — a real-world outcomes analysis. *British Journal of Haematology*, 2021;195:429–43.
3. Wittenberg RE, Gauvreau K, Leighton J, Moleon-Shea M, Borow KM, Marx GR, Emani SM, Prospective randomized controlled trial of the safety and feasibility of a novel mesenchymal precursor cell therapy in hypoplastic left heart syndrome, *JTCVS Open* Volume 16, Dec 2023, doi: <https://doi.org/10.1016/j.xjon.2023.09.031>
4. Using Reserve Bank of Australia (RBA) published exchange rate from December 31, 2023 of 1A\$:0.6840US\$.
5. TEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.
6. TEMCELL sales by our Licensee are recorded in Japanese Yen before being translated into USD for the purposes of calculating the royalty paid to Mesoblast. Results have been adjusted for the

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movement of the USD to Japanese Yen exchange rate from 1USD:133.70 Yen for the 6 months ended December 31, 2022 to 1USD:142.82 Yen for the 6 months ended December, 2023.

7. 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, 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 2023

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$US'000</b>	<b>Year to date (6 months) \$US'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	1,727	3,971
- royalty receipts		
1.2 Payments for		
(a) research and development	(3,586)	(7,549)
(b) manufacturing commercialization, product manufacturing and operating costs	(6,913)	(15,296)
(c) advertising and marketing	(687)	(1,583)
(d) leased assets	—	—
(e) staff costs	(1,293)	(2,998)
(f) other expenses from ordinary activities	(1,804)	(5,210)
(g) other:		
- Intellectual property portfolio expenses	(113)	(1,358)
1.3 Dividends received (see note 3)	—	—
1.4 Interest received	342	887
1.5 Interest and other costs of finance paid	—	—
1.6 Income taxes paid	(1)	(1)
1.7 Government grants and tax incentives and credits	—	2,565
1.8 Other (provide details if material)	—	—
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(12,328)</b>	<b>(26,572)</b>

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$US'000</b>	<b>Year to date (6 months) \$US'000</b>
<b>2.</b>	<b>Cash flows from investing activities</b>		
2.1	Payments to acquire or for:		
	(i) entities	—	—
	(j) businesses	—	—
	(k) property, plant and equipment	(19)	(194)
	(l) investments	—	—
	(m) intellectual property	—	(10)
	(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	58	116
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>39</b>	<b>(88)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	39,708	39,708
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	(2,143)	(2,578)
3.5	Proceeds from borrowings	—	—
	Proceeds from issue of warrants	—	—
3.6	Repayment of borrowings	—	—
3.7	Transaction costs related to loans and borrowings	(169)	(540)
	Interest and other costs of finance paid	(1,479)	(2,845)

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$US'000</b>	<b>Year to date (6 months) \$US'000</b>
3.8	Dividends paid	—	—
3.9	Other (payment of lease liability)	(1,099)	(2,145)
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>34,818</b>	<b>31,600</b>
<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of quarter (July 1, 2023)/beginning of year (July 1, 2023)	53,177	71,318
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(12,328)	(26,572)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	39	(88)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	34,818	31,600
4.5	Effect of movement in exchange rates on cash held	1,848	1,296
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>77,554</b>	<b>77,554</b>

<b>5. Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$US'000</b>	<b>Previous quarter \$US'000</b>
5.1 Bank balances	77,144	52,790
5.2 Call deposits	—	—
5.3 Bank overdrafts	—	—
5.4 Other (Term deposits)	410	387
<b>5.5 Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>77,554</b>	<b>53,177</b>

<b>6. Payments to related parties of the entity and their associates</b>	<b>Current quarter \$US'000</b>
6.1 Aggregate amount of payments to related parties and their associates included in item 1	371
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.*

Consulting payments to Non-Executive Directors and salary payments to full-time Executive Directors (for the current quarter) =US\$370,988



7.	<b>Financing facilities</b>	<b>Total facility amount at quarter end \$US'000</b>	<b>Amount drawn at quarter end \$US'000</b>
	<i>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.</i>		
7.1	Loan facilities	100,000*	90,000*
7.2	Credit standby arrangements	—	—
7.3	Other (please specify)	—	—
7.4	<b>Total financing facilities</b>	100,000*	90,000*
7.5	<b>Unused financing facilities available at quarter end</b>		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.		
	<p><b><u>*Loan facility with Oaktree Capital Management, Inc.</u></b></p> <p>On November 19, 2021, Mesoblast refinanced its senior debt facility with a secured five-year credit facility provided by funds managed by Oaktree Capital Management, L.P. ("Oaktree") and drew down US\$60.0 million on closing.</p> <p>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.</p> <p>The loan interest rate is fixed and as at June 30, 2023 the interest rate was 9.75%. For the first two years to November 19, 2023, 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.</p> <p><b><u>*Loan facility with NovaQuest Capital Management, L.L.C.</u></b></p> <p>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 included an interest only period of approximately four years through until July 8, 2022.</p> <p>All interest and principal payments (i.e. the amortization period) are 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.</p>		

<b>8. Estimated cash available for future operating activities</b>	<b>\$US'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	(12,328)
8.2 Cash and cash equivalents at quarter end (item 4.6)	77,554
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)	87,554
<b>8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<b>7.1</b>

*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 remestemcel-L for the treatment in pediatric patients with steroid-refractory acute graft versus host disease by the United States Food and Drug Administration.

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 2024.....

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.