asx announcement

mesoblast

APPENDIX 4C QUARTERLY ACTIVITY REPORT

Mesoblast Financial and Operational Highlights for Quarter Ended March 31, 2023

Melbourne, Australia; April 28 and New York, USA; April 27, 2023: 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, 2023.

Financial Highlights

- Successful completion of a global private placement primarily to Mesoblast's existing major US, UK, and Australian shareholders raising approximately US$40 million, net of transaction costs.
- In addition to cash on hand at the end of the quarter of US$48.8 million, pro-forma cash after proceeds raised in April is US$88.8 million, with up to an additional US$40 million available to be drawn down from existing financing facilities subject to certain milestones.
- Net cash usage for operating activities in the quarter was US$16.2 million; this represented an increase of US$0.7 million, or 4%, on the comparative quarter in FY2022, and a reduction of US$8.3 million, or 34%, on the comparative quarter in FY2021.
- Revenue from royalties on sales of TEMCELL® HS Inj.[1] sold in Japan by our licensee for the quarter were US$1.8 million. On a constant currency basis, royalties on sales grew 4% quarter on quarter from US$2.0 million[2] for the quarter ended March 31, 2023, compared with US$1.9 million for the quarter ended March 31, 2022.

Operational Highlights

Remestemcel-L

- Resubmitted to the U.S. Food and Drug Administration (FDA) the Biologics License Application (BLA) for approval of remestemcel-L in the treatment of children with steroid-refractory acute graft versus host disease (SR-aGVHD).
- The resubmission contains new information developed since the Complete Response Letter (CRL) received in September 2020, including the generation of new data and analyses which we believe provide substantial evidence of remestemcel-L's effectiveness in pediatric SR-aGVHD.
- FDA accepted Mesoblast's BLA resubmission for remestemcel-L, considering the resubmission to be a complete response and set a Prescription Drug User Fee Act (PDUFA) goal date of August 2, 2023.
- As part of the ongoing review of the BLA for remestemcel-L FDA scheduled a Pre-License Inspection (PLI) of Mesoblast's cell therapy manufacturing operations at Lonza Bioscience in Singapore.
- Two studies on the remestemcel-L development program for the treatment of children with SR-aGVHD were selected by peer review and presented at the 2023 Tandem Meetings of the American Society for Transplantation and Cellular Therapy (ASTCT) and the Center for Blood and Marrow Transplant Research (CIBMTR).
- The studies are titled "The Immunomodulatory Activity of Remestemcel-L on T Cell Activation in vitro is a Direct Measure of Product Potency and Correlates with Clinical Outcomes in Pediatric Patients with Steroid-Refractory Acute GVHD" and "Long-Term Survival in Children Treated with Remestemcel-L for SR-aGVHD". The data from both studies formed key components of Mesoblast's recent resubmission of its remestemcel-L BLA to FDA for children with SR-aGVHD.

Rexlemestrocel-L

- FDA granted Regenerative Medicine Advanced Therapy (RMAT) designation for rexlemestrocel-L in the treatment of chronic low back pain (CLBP) associated with disc degeneration, in combination with hyaluronic acid (HA) as delivery agent for injection into the lumbar disc.
- FDA has confirmed that a 12-month reduction in pain is an approvable indication and Mesoblast will use this endpoint in its confirmatory Phase 3 trial under the RMAT designation.
- Publication of the DREAM-HF Phase 3 trial results in the premier peer-reviewed journal for cardiovascular medicine, the Journal of the American College of Cardiology (JACC). The results of the randomized, double-blind, controlled study in 537 patients showed that Mesoblast's mesenchymal precursor cell therapy (MPCs; rexlemestrocel-L) strengthened heart function at 12 months, as measured by left ventricular ejection fraction (LVEF) and decreased cardiovascular death, myocardial infarction (MI) or stroke in patients with chronic heart failure (CHF) due to reduced ejection fraction (HFrEF) over a mean follow-up of 30 months.[3]

Other
Salary payments to full-time Executive Directors were US$330,756 and fees to Non-Executive Directors were US$197,365, detailed in Item 6 of the Appendix 4C cash flow report for the quarter.[4]

A copy of the Appendix 4C – Quarterly Cash Flow Report for the third 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. 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 movement of the USD to Japanese Yen exchange rate from 1USD:123.41 Yen for the 3 months ended March 31, 2022 to 1USD:134.54 Yen for the 3 months ended March 31, 2023.
3. Perin EC. Et al. Randomized Trial of Targeted Transendocardial Mesenchymal Precursor Cell Therapy in Patients With Heart Failure. *JACC* Vol. 81, No. 9, 2023. https://doi.org/10.1016/j.jacc.2022.11.061

4. 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	**Quarter ended ("current quarter")**
68 109 431 870	31 March 2023

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	1,979	5,646
1.2	Payments for		
	(a) research and development	(5,026)	(16,075)
	(b) manufacturing commercialization	(4,470)	(12,149)
	(c) product manufacturing and operating costs	(3,742)	(6,207)
	(d) advertising and marketing	(789)	(1,795)
	(e) leased assets	—	—
	(f) staff costs	(1,271)	(6,476)
	(g) other expenses from ordinary activities	(2,270)	(8,439)
	(h) other: - Intellectual property portfolio expenses	(779)	(1,891)
1.3	Dividends received (see note 3)	—	—
1.4	Interest received	192	399
1.5	Interest and other costs of finance paid	—	—
1.6	Income taxes paid	—	—
1.7	Government grants and tax incentives	(22)	(4)
1.8	Other (provide details if material)	—	—
1.9	**Net cash from / (used in) operating activities**	**(16,198)**	**(46,991)**

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	(40)	(227)
	(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	67	67
2.6	**Net cash from / (used in) investing activities**	**27**	**(210)**

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	(227)	(2,873)
3.5	Proceeds from borrowings	—	—
	Proceeds from issue of warrants	—	—
3.6	Repayment of borrowings	—	—
3.7	Transaction costs related to loans and borrowings	(196)	(412)
	Interest and other costs of finance paid	(1,488)	(4,244)

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)	(682)	(1,791)
3.10	**Net cash from / (used in) financing activities**	**(2,593)**	**35,745**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of quarter (January 1, 2023)/beginning of year (July 1, 2022)	67,619	60,447
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(16,198)	(46,991)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	27	(210)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(2,593)	35,745
4.5	Effect of movement in exchange rates on cash held	(56)	(192)
4.6	**Cash and cash equivalents at end of period**	**48,799**	**48,799**

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	48,396	67,213
5.2	Call deposits	—	—
5.3	Bank overdrafts	—	—
5.4	Other (Term deposits)	403	406
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**48,799**	**67,619**

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	528
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$528,121

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 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 March 31, 2023 the interest rate was 9.75%. Since the loan's inception, 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$40.0million 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)	(16,198)
8.2	Cash and cash equivalents at quarter end (item 4.6)	48,799
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)	88,799
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	5.5

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 bedrawn 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: .....28 April 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.