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mesoblast

APPENDIX 4C QUARTERLY ACTIVITY REPORT FOR QUARTER ENDED JUNE 30, 2024

Ryoncil BLA Submission Under FDA Review for Approval in Children with SR-aGVHD

Melbourne, Australia; July 31 and New York, USA; July 30, 2024: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today provided highlights of its recent activities for the fourth quarter ended June 30, 2024.

Mesoblast Chief Executive Silviu Itescu said: "We are very pleased with the strong relationship we have built with FDA across our product pipeline and the positive outcomes over the past six months."

"Our BLA resubmission for approval of Ryoncil® (remestemcel-L) in the treatment of children with acute graft versus host disease (SR-aGVHD) was accepted as a complete response, we received feedback from FDA on the potential accelerated approval pathway for Revascor® (rexlemestrocel-L) in end-stage heart failure patients, and our confirmatory Phase 3 trial in inflammatory back pain is actively enrolling with a primary endpoint of pain reduction aligned with FDA."

"We are executing on our go-to-market plan to bring Ryoncil to the many children suffering with the devastating disease of acute GVHD. I look forward to an activity update at our full year financials and investor call on August 28th 6.30pm EDT (August 29th 8.30am AEST)."

KEY HIGHLIGHTS

Graft versus Host Disease – Pending Decision on FDA Approval

- FDA informed Mesoblast at the end of March 2024 that, following additional consideration, the available clinical data from the Phase 3 study MSB-GVHD001 appears sufficient to support submission of the proposed BLA for remestemcel-L (RYONCIL) for treatment of pediatric patients with SR-aGVHD.
- Mesoblast resubmitted its BLA for approval of RYONCIL on July 8, 2024, addressing remaining CMC (Chemistry, Manufacturing, and Controls) items in the August 2023 Complete Response Letter (CRL).
- FDA accepted the BLA resubmission within two weeks, considering it to be a complete response.
- Mesoblast anticipates a decision prior to or on the FDA's Prescription Drug User Fee Act (PDUFA) goal date of January 7, 2025.
- FDA has already conducted the Pre-License Inspection (PLI) of the manufacturing process for RYONCIL in May 2023 and this did not result in the issuance of any Form 483.
- RYONCIL is being reviewed under Priority Review, a designation given to drugs that treat a serious condition and provide a significant improvement in safety or effectiveness over existing treatments.

Chronic Inflammatory Low Back Pain – Phase 3 Program

- The confirmatory Phase 3 trial of Mesoblast's second generation allogeneic, immunoselected, and industrially manufactured stromal cell product rexlemestrocel-L in patients with chronic low back pain (CLBP) due to inflammatory degenerative disc disease of less than five years duration has commenced enrollment at multiple sites across the United States.
- FDA has previously confirmed alignment with Mesoblast on the design of the 300-patient randomized, placebo-controlled trial and the 12-month primary endpoint of pain reduction as an approvable indication. Key secondary measures include improvement in quality of life, function, and reduced opioid usage.
- FDA has designated rexlemestrocel-L a Regenerative Medicine Advanced Therapy (RMAT) for the treatment of chronic low back pain. RMAT designation provides all the benefits of Breakthrough and Fast Track designations, including rolling review and eligibility for priority review on filing of a Biologics License Application (BLA).

Chronic Heart Failure with Reduced Ejection Fraction (HFrEF) and Persistent Inflammation

- FDA informed Mesoblast that it supports an accelerated approval pathway for its second generation allogeneic, immunoselected, and industrially manufactured stromal cell product rexlemestrocel-L (Revascor®), for patients with end-stage ischemic heart failure with reduced ejection fraction (HFrEF) and a left ventricular assist device (LVAD).
- In these patients, a single administration of REVASCOR reduced inflammation, strengthened left ventricular function, reduced right ventricular failure, and reduced hospitalizations.
- REVASCOR has also reduced major adverse cardiac events (MACE) (cardiovascular death, heart attacks and strokes) in a completed Phase 3 trial in ischemic HFrEF patients with NYHA class II /III disease and inflammation.
- Mesoblast has received RMAT designation for rexlemestrocel-L in the treatment of end-stage heart failure in LVAD patients and intends to meet with FDA to discuss data presentation, timing and FDA expectations for an accelerated approval filing in these patients.

FINANCIAL REPORT

We will take a measured approach to preparing for the commercial launch of RYONCIL for treatment of children with SR-aGVHD in anticipation of potential FDA BLA approval and ensure prudent cash management. The successful implementation of the cost containment plan from August 2023 and the re-prioritization of projects has enabled us to reduce cash expenditure whilst still making significant strides forward on key programs as outlined above. We continue to work on corporate and strategic initiatives to access commercial distribution channels and optimize our balance sheet.

Fourth Quarter and Full Year Results

- Cash balance at June 30, 2024 is US$63.0 million, with additional US$10.0 million available from an existing facility on FDA approval of RYONCIL.
- Net operating cash spend of US$10.2 million for the fourth quarter FY2024.
- 37% (US$6.0 million) reduction in net operating cash spend for the fourth quarter FY2024 versus the prior comparative quarter in FY2023.
- 23% (US$14.8 million) reduction in net operating cash spend in FY2024 compared to FY2023.

Cost containment strategy achieved

On completion of the FY2024 financial year we are pleased to report the results of the successful cost containment plan announced in August 2023 as follows:

FY2024 Objectives & Outcomes	Achieved
Reduce Net Operating Cash Usage 23% Achieved 23% reduction (US$14.8 million) from US$63.3 million in FY2023 to US$48.5 million in projected FY2024	✓
Reduce annualized payroll by 40% by February 2024 CEO and CMO deferred their FY23 short-term incentives (STI), and voluntarily reduced their base salaries for FY24 by 30% to preserve cash and instead receive long-term non-cash incentives (LTIs) to further align with shareholders	✓
FY23 STI was entirely deferred beyond FY2024 for all employees	✓
Program was introduced for management to receive LTIs in lieu of a portion of salary	✓
Defer Non-Executive Director Fees Deferred 100% of the cash payment of Non-Executive Director Fees beyond FY2024, with 50% of their fees in LTIs	✓

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Other
Fees to Non-Executive Directors were nil, consulting payments to Non-Executive Director were US$102,783 and salary payments to full-time Executive Directors were US$228,506, detailed in Item 6 of the Appendix 4C cash flow report for the quarter.[1] 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 fourth quarter FY2024 is attached.

About Mesoblast
Mesoblast (the Company) 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, and biologic-resistant inflammatory bowel disease. Rexlemestrocel-L is being developed 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. 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

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benefits of strategic collaboration agreements and Mesoblast's ability to enter into and maintain established strategic collaborations; Mesoblast's ability to establish and maintain intellectual property on its product candidates and Mesoblast's ability to successfully defend these in cases of alleged infringement; the scope of protection Mesoblast is able to establish and maintain for intellectual property rights covering its product candidates and technology; estimates of Mesoblast's expenses, future revenues, capital requirements and its needs for additional financing; Mesoblast's financial performance; developments relating to Mesoblast's competitors and industry; and the pricing and reimbursement of Mesoblast's product candidates, if approved. You should read this press release together with our risk factors, in our most recently filed reports with the SEC or on our website. Uncertainties and risks that may cause Mesoblast's actual results, performance or achievements to be materially different from those which may be expressed or implied by such statements, and accordingly, you should not place undue reliance on these forward-looking statements. We do not undertake any obligations to publicly update or revise any forward-looking statements, whether as a result of new information, future developments or otherwise.

Release authorized by the Chief Executive.

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Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

Mesoblast Limited

ABN	**Quarter ended ("current quarter")**
68 109 431 870	30 June 2024

Consolidated statement of cash flows		**Current quarter $US'000**	**Year to date (12 months) $US'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers - royalty receipts	1,144	6,776
1.2	Payments for		
	(a) research and development	(3,902)	(15,553)
	(b) manufacturing commercialization, product manufacturing and operating costs	(4,921)	(24,632)
	(c) advertising and marketing	(7)	(1,833)
	(d) leased assets	—	—
	(e) staff costs	(1,172)	(4,996)
	(f) other expenses from ordinary activities	(2,200)	(10,297)
	(g) other: - Intellectual property portfolio expenses	(891)	(3,524)
1.3	Dividends received (see note 3)	—	—
1.4	Interest received	454	1,778
1.5	Interest and other costs of finance paid	—	—
1.6	Income taxes refunded	—	4
1.7	Government grants and tax incentives and credits	1,254	3,819
1.8	Other (provide details if material)	—	—
1.9	**Net cash from / (used in) operating activities**	**(10,241)**	**(48,458)**

Consolidated statement of cash flows		Current quarter $US'000	Year to date (12 months) $US'000
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(i) entities	—	—
	(j) businesses	—	—
	(k) property, plant and equipment	(36)	(271)
	(l) investments	—	—
	(m) intellectual property	(50)	(60)
	(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	234
2.6	**Net cash from / (used in) investing activities**	**(28)**	**(97)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	—	65,399
3.2	Proceeds from issue of convertible debt securities	—	—
3.3	Proceeds from exercise of options	7	7
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(278)	(4,356)
3.5	Proceeds from borrowings	—	—
	Proceeds from issue of warrants	—	—
3.6	Repayment of borrowings	—	(10,000)
3.7	Transaction costs related to loans and borrowings	(556)	(1,559)
	Interest and other costs of finance paid	(1,316)	(5,717)

Consolidated statement of cash flows		Current quarter $US'000	Year to date (12 months) $US'000
3.8	Dividends paid	—	—
3.9	Other (payment of lease liability)	(874)	(3,522)
3.10	**Net cash from / (used in) financing activities**	**(3,017)**	**40,252**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of quarter (April 1, 2024)/beginning of year (July 1, 2023)	76,364	71,318
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(10,241)	(48,458)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(28)	(97)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(3,017)	40,252
4.5	Effect of movement in exchange rates on cash held	(118)	(55)
4.6	**Cash and cash equivalents at end of period**	**62,960**	**62,960**

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	62,563	75,972
5.2	Call deposits	—	—
5.3	Bank overdrafts	—	—
5.4	Other (Term deposits)	397	392
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**62,960**	**76,364**

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	331
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 Director and salary payments to full-time Executive Directors (for the current quarter) =US$331,289

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $US'000**	**Amount drawn at quarter end $US'000**
7.1	Loan facilities	90,000*	80,000*
7.2	Credit standby arrangements	—	—
7.3	Other (please specify)	—	—
7.4	**Total financing facilities**	90,000*	80,000*

7.5	**Unused financing facilities available at quarter end**	10,000*

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

***Loan facility with Oaktree Capital Management, Inc.**

Mesoblast refinanced its senior debt facility on November 19, 2021 with a secured five-year credit facility provided by funds managed by Oaktree Capital Management, L.P. ("Oaktree").The balance of funds drawn down is currently US$50.0 million.

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 June 30, 2024 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.

***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 included an interest only period of approximately four years through until July 8, 2022.

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.

8.	**Estimated cash available for future operating activities**	**$US'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(10,241)
8.2	Cash and cash equivalents at quarter end (item 4.6)	62,960
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)	72,960
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	7.1

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

* Under the NovaQuest loan facility, an additional US$10.0 million from the loan will be drawn on marketing approval of 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 July 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.