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MESOBLAST REPORTS FINANCIAL RESULTS AND OPERATIONAL UPDATE FOR HALF-YEAR ENDED DECEMBER 31, 2023

Melbourne, Australia; February 29 and New York, USA; February 28, 2024: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today provided an operational update and reported financial results for the period ended December 31, 2023.

Mesoblast Chief Executive Silviu Itescu said: "We were very busy operationally during the last quarter and continued to have positive engagement with the United States Food and Drug Administration (FDA) across our lead programs. We have strengthened our balance sheet while maintaining overall spending constraint in line with our corporate objectives.

For our product Ryoncil® (remestemcel-L) for life-threatening steroid-refractory acute graft-versus-host disease (SR-aGVHD) ahead of our upcoming meeting in March we have provided the FDA with new data from a second potency assay that provides additional product characterization as requested by FDA.

"For our cardiovascular product Revascor®, we had a very productive meeting with the FDA this month which included discussion of a unifying mechanism of action across the continuum of heart failure with inflammation in adults, and potential approval pathways in these patients. The FDA will provide written minutes from the meeting in March.

"We were also very pleased during this quarter to have received both a Rare Pediatric Disease Designation and Orphan Drug Designation from FDA for Revascor® in children with hypoplastic left heart syndrome and plan to discuss the results of the completed randomized controlled trial in the context of a regulatory approval pathway."

"Finally, our second Phase 3 back pain trial with rexlemestrocel-L, aiming to confirm the durable pain reduction that was seen in the first Phase 3 trial, is underway."

FINANCIAL RESULTS FOR THE SIX MONTHS ENDED DECEMBER 31, 2023 (FIRST HALF FY2024)

- **Strengthened balance sheet** through delivering on cost containment strategies and access to capital markets enacted by management and the Board.
- **Reduction in net cash usage** for operating activities:
  - For the three months ended December 31, 2023, net cash usage was US$12.3 million, a 25% reduction versus the comparative quarter in FY2023.
  - For the six months ended December 31, 2023, net cash usage was US$26.6 million, a 14% reduction versus the comparative period in FY2023.
  - For FY2024, on target to achieve a 23% reduction (US$15 million) in net cash usage compared to FY2023, partially offset by investment in our Phase 3 programs for SR-aGVHD and CLBP.
- **Cash Reserves** at December 31, 2023 were US$77.6 million (A$113.5 million) after completing an Institutional Placement and Entitlement Offer of A$60.3 million.[1]

GRAFT VERSUS HOST DISEASE – PEDIATRIC AND ADULT PHASE 3 PROGRAMS

- Mesoblast has an upcoming meeting scheduled for March with the United States Food and Drug Administration (FDA) and has provided the agency with new data from a second potency assay for its product Ryoncil® (remestemcel-L) that provides additional product characterization as requested by FDA.
- The new 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.

- 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.[2,3] In contrast, 100-day survival was 67% after RYONCIL treatment was used under expanded access in 51 adults and children with SR-aGVHD who failed to respond to at least one additional agent, such as ruxolitinib.
- These additional clinical data, together with the proposed Phase 3 trial protocol in adults with SR-aGVHD have also been provided to FDA. Mesoblast is collaborating with 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, to conduct a pivotal trial in adults with SR-aGVHD.

PEDIATRIC CONGENITAL HEART DISEASE - HYPOPLASTIC LEFT HEART SYNDROME (HLHS)

- During the quarter FDA granted Mesoblast's cardiovascular product, Revascor® (rexlemestrocel-L), both Rare Pediatric Disease Designation (RPDD) and Orphan-Drug Designation (ODD). This followed submission of results from the randomized controlled trial in children with hypoplastic left heart syndrome (HLHS), a potentially life-threatening congenital heart condition.
- Results from a 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)*.[4]
- In the HLHS trial conducted in 19 children, a single intramyocardial administration of REVASCOR at the time of staged surgery resulted in the desired outcome of significantly larger increases in 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).
- These changes are indicative of clinically important growth of the small left ventricle, facilitating the ability to have a successful surgical correction, known as full biventricular (BiV) conversion, which allows for a normal two ventricle circulation with the surgically repaired left ventricle taking over circulatory support to the body. Without full BiV conversion the right heart chamber is under excessive strain with increased risk of heart failure and death.
- As noted in the JTCVS publication the fact that 100% of REVASCOR-treated children compared with 57% of controls had large enough LVs to accommodate the full BiV conversion suggests that REVASCOR treatment may help increase the ability to 'better grow' the HLHS LV after LV recruitment surgery.
- The FDA's ODD Program provides orphan status to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases. ODD qualifies the drug for various development incentives, including eligibility for seven years of market exclusivity upon regulatory approval, exemption from FDA application fees, tax credits for qualified clinical trials, and other potential assistance in the drug development process.
- 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.
- Mesoblast plans to meet with FDA to discuss the regulatory path to approval for REVASCOR in children with this life-threatening condition.

FDA MEETING REGARDING REGULATORY PATH TO APPROVAL FOR REXLEMESTROCEL-L IN ADULTS WITH CHRONIC HEART FAILURE WITH REDUCED EJECTION FRACTION (HFrEF), INCLUDING END-STAGE PATIENTS WITH A LEFT VENTRICULAR ASSIST DEVICE (LVAD)

- REVASCOR has shown the potential to reduce major adverse cardiac events (MACE) such as heart attack and cardiovascular death in high-risk patients with HFrEF and inflammation.
- REVASCOR has also shown the potential to improve major outcomes in high-risk patients with end-stage HFrEF, inflammation and LVADs.
- Mesoblast met with FDA this quarter to address potential pathways to approval for REVASCOR under our Regenerative Medicine Advanced Therapies (RMAT) designation. The discussion covered

both Class II/III HFrEF ischemic patients with inflammation from the Phase 3 DREAM-HF 565 patient study and Class IV ischemic LVAD patients with inflammation from the 159 patient LVAD study.

- Mesoblast discussed with FDA the mechanism of action by which REVASCOR is able to improve major outcomes, including mortality, across the continuum of heart failure with inflammation.
- Minutes of the meeting are expected from FDA next month.

CHRONIC LOW BACK PAIN (CLBP) ASSOCIATED WITH DEGENERATIVE DISK DISEASE (DDD)

- Product has been manufactured for use in a pivotal study recruiting patients across the United States to support potential marketing approval of rexlemestrocel-L in chronic low back pain due to degenerative disc disease.
- Primary endpoint is reduction in pain at 12 months compared to placebo.
- Rexlemestrocel-L has received Regenerative Medicine Advanced Therapy (RMAT) designation for CLBP.

DETAILS OF FINANCIAL RESULTS FOR THE SIX MONTHS ENDED DECEMBER 31, 2023 (FIRST HALF FY2024)

- **Royalties** on sales of TEMCELL® HS Inj.[5] sold in Japan by our licensee for the first half FY2024 were, on a constant currency basis, US$3.3 million, a growth of 3% compared with US$3.2 million for the comparative period in FY2023.[6]
- **Research & Development** expenses reduced by US$0.8 million (6%), down to US$12.6 million for the first half FY2024 compared with US$13.4 million for the comparative period in FY2023. R&D expenses primarily supported preparations for the remestemcel-L BLA re-submission and preparations for pivotal studies for CLBP associated with DDD and adult SR-aGVHD.
- **Manufacturing** reduced by 47% for the six months ended December 31, 2023, from US$12.8 million to US$6.7 million. Costs in the current period include new potency and characterization data for the remestemcel-L product, as requested by FDA, which have been submitted ahead of our upcoming meeting with FDA next month. During the prior comparative period costs were elevated as we completed activities associated with the FDA Pre-License Inspection (PLI) of the manufacturing process for remestemcel-L.
- **Management and Administration** expenses reduced by US$1.8 million, to US$11.5 million for the first half FY2024.
- **Remeasurement of Contingent Consideration** recognized a minor loss of US$0.3 million in the first half FY2024 compared to a gain of US$6.0 million in the comparative period in FY2023 reflecting a reduction in future third party payments.
- **Fair value movement of warrants** recognized a gain of US$4.4 million in the first half FY2024 on a revaluation of warrants to market value compared to a minor loss of US$0.7 million in the comparative period in FY2023.
- **Other operating income** in the first half FY2024 was US$1.1 million compared with Nil in the comparative period in FY2023.
- **Finance Costs** for borrowing arrangements include US$6.9 million of non-cash expenditure for the first half FY2024 comprising accruing interest and borrowing costs.

Loss after tax for the first half FY2024 was US$32.5 million, a 21% reduction compared to US$41.4 million for the comparative period in FY2023. The net loss attributable to ordinary shareholders was 3.82 US cents per share for the first half FY2024, compared with 5.64 US cents per share for the comparative period in FY2023.

Conference Call
There will be a webcast today, beginning at 9.00am AEST (Thursday, February 29); 5.00pm EDT (Wednesday, February 28). It can be accessed via: https://webcast.openbriefing.com/msb-hyr-2024/

The archived webcast will be available on the Investor page of the Company's website: www.mesoblast.com

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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, 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. Using Reserve Bank of Australia (RBA) published exchange rate from December 31, 2023 of 1A$:0.6840US$.
2. 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
3. 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.
4. 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
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 movement of the USD to Japanese Yen exchange rate from 1USD:139.10 Yen for the six months ended December 31, 2022 to 1USD:146.94 Yen for the six months ended December 31, 2023.

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 our request to have a Type A meeting with the FDA, the outcome of such a meeting, and any future decision that the FDA may make on the BLA for remestemcel-L for pediatric patients with SR-

aGVHD), 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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Consolidated Income Statement

(in U.S. dollars, in thousands, except per share amount)	Six Months Ended December 31, 2023	2022
Revenue	3,388	3,422
Research & development	(12,647)	(13,430)
Manufacturing commercialization	(6,746)	(12,760)
Management and administration	(11,482)	(13,281)
Fair value remeasurement of contingent consideration	(337)	5,989
Fair value remeasurement of warrant liability	4,434	(712)
Other operating income and expenses	1,068	(39)
Finance costs	(10,319)	(10,685)
Loss before income tax	**(32,641)**	**(41,496)**
Income tax benefit/(expense)	102	126
Loss attributable to the owners of Mesoblast Limited	**(32,539)**	**(41,370)**
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:	**Cents**	**Cents**
Basic - losses per share	(3.82)	(5.64)
Diluted - losses per share	(3.82)	(5.64)

Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	Six Months Ended December 31, 2023	2022
Loss for the period	**(32,539)**	**(41,370)**
Other comprehensive (loss)/income		
Items that may be reclassified to profit and loss		
Exchange differences on translation of foreign operations	1,164	100
Items that will not be reclassified to profit and loss		
Financial assets at fair value through other comprehensive income	(931)	192
Other comprehensive (loss)/income for the period, net of tax	**233**	**292**
Total comprehensive losses attributable to the owners of Mesoblast Limited	**(32,306)**	**(41,078)**

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Consolidated Balance Sheet
(in U.S. dollars, in thousands)

	As of December 31, 2023	As of June 30, 2023
Assets		
Current Assets		
Cash & cash equivalents	77,554	71,318
Trade & other receivables	3,998	6,998
Prepayments	3,602	3,342
Total Current Assets	**85,154**	**81,658**
Non-Current Assets		
Property, plant and equipment	1,171	1,357
Right-of-use assets	4,329	5,134
Financial assets at fair value through other comprehensive income	826	1,757
Other non-current assets	2,241	2,326
Intangible assets	576,564	577,183
Total Non-Current Assets	**585,131**	**587,757**
Total Assets	**670,285**	**669,415**
Liabilities		
Current Liabilities		
Trade and other payables	10,760	20,145
Provisions	8,230	6,399
Borrowings	8,534	5,952
Lease liabilities	2,851	4,060
Warrant liability	992	5,426
Total Current Liabilities	**31,367**	**41,982**
Non-Current Liabilities		
Provisions	17,073	16,612
Borrowings	107,228	102,811
Lease liabilities	3,386	3,672
Deferred consideration	2,500	2,500
Total Non-Current Liabilities	**130,187**	**125,595**
Total Liabilities	**161,554**	**167,577**
Net Assets	**508,731**	**501,838**
Equity		
Issued Capital	1,286,229	1,249,123
Reserves	75,846	73,520
(Accumulated losses)	(853,344)	(820,805)
Total Equity	**508,731**	**501,838**

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Consolidated Statement of Cash Flow

(in U.S. dollars, in thousands)	Six Months Ended December 31, 2023	2022
Cash flows from operating activities		
Commercialization revenue received	3,971	3,667
Government grants and tax incentives and credits received	2,565	18
Payments to suppliers and employees (inclusive of goods and services tax)	(33,994)	(34,633)
Interest received	887	207
Income taxes paid	(1)	—
Net cash (outflows) in operating activities	**(26,572)**	**(30,741)**
Cash flows from investing activities		
Investment in fixed assets	(194)	(187)
Receipts from investment in sublease	116	—
Payments for intellectual property	(10)	(50)
Net cash (outflows) in investing activities	**(88)**	**(237)**
Cash flows from financing activities		
Payment of transaction costs from borrowings	(540)	(217)
Interest and other costs of finance paid	(2,845)	(2,807)
Proceeds from issue of shares	39,708	45,065
Payments for share issue costs	(2,578)	(2,646)
Payments for lease liabilities	(2,145)	(1,109)
Net cash inflows by financing activities	**31,600**	**38,286**
Net increase in cash and cash equivalents	4,940	7,308
Cash and cash equivalents at beginning of period	71,318	60,447
FX gains/(losses) on the translation of foreign bank accounts	1,296	(136)
Cash and cash equivalents at end of period	**77,554**	**67,619**

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