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MESOBLAST SETS RYONCIL® PRICE BASED ON ECONOMIC VALUE OF TREATMENT WITH PLANNED PRODUCT AVAILABILITY THIS QUARTER

Financial Results and Operational Update for Half-Year Ended December 31, 2024

Melbourne, Australia; February 27 and New York, USA; February 26, 2025: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today provided financial results and an operational update for the period ended December 31, 2024,

"Our FDA approved product Ryoncil® will be available in the coming weeks to the children with SR-aGvHD in need of life-saving therapy," said Dr. Silviu Itescu, Chief Executive of Mesoblast. "The treatment has delivered long-term survival outcomes in these very high-risk patients and we are pleased with the benefits and value that this treatment brings to patients and their healthcare providers at specialized transplant centers across the U.S."

Ryoncil® (remestemcel-L) U.S. Launch for Steroid-Refractory Acute Graft Versus Host Disease

On December 18, 2024, Ryoncil® (remestemcel-L) became the first mesenchymal stromal cell (MSC) therapy approved by U.S. FDA for any indication.

FDA approved Ryoncil® as the first and only therapy for pediatric patients 2 months and older, including adolescents and teenagers, with steroid-refractory acute graft versus host disease (SR-aGvHD), a life-threatening condition with high mortality rates.

Each year, approximately 375 pediatric patients in the U.S. are diagnosed with SR-aGvHD. The cost of treating a child who dies of SR-aGvHD within 12 months of transplant is approximately US$2.5 million and is US$1.8M higher than for those with SR aGvHD who remain alive.[1]

In the Phase 3 trial of 54 children with SR aGvHD (89% grades C/D), treatment with Ryoncil® resulted in a 70% overall response rate (ORR) at day 28. Survival through 4 years was 49%, with only 14% of patients dying due to aGvHD.

Based on health economic models for lifetime ultra rare disease and high-impact short-term therapies, including Quality of Life Years (QALYs) gained, total benefits of patient outcomes using Ryoncil® ranged from US$3.2 million to US$4.1 million (comprising long-term survival benefit, cost-offset, and cost-savings).

The recommended dosage of Ryoncil® for treatment of pediatric SR-aGvHD is 2×10^6 MSC/kg body weight per intravenous infusion given twice per week for 4 consecutive weeks. The wholesale acquisition cost (WAC) of Ryoncil® is US$194,000 per intravenous infusion, irrespective of body weights. To assist patients and institutions with insurance coverage, financial assistance, and access programs, ensuring that no patient is left behind in receiving this potentially life-saving therapy, Mesoblast has established *MyMesoblast*™, a comprehensive patient services hub where Ryoncil® will be available for ordering.

Our commercial execution is well underway engaging with the top 45 centers which represent 80% of pediatric transplants in the U.S. Ryoncil will be distributed by Cencora, leveraging its cryogenic logistics capabilities and state-of-the art cryogenic storage infrastructure to enable the efficient and secure delivery of cryopreserved product to U.S. treatment centers.

Corporate and Financial Highlights

Cash balance at December 31, 2024 was US$38 million (A$61 million)[2] with pro-forma cash of approximately US$200 million (A$322 million) after successful completion of a global private placement which raised US$161 million (A$260 million). Net operating cash spend was US$20.7 million for the first half FY2025, a 22% reduction on the first half FY2024.
This month Dr. Gregory George MD PhD, Mesoblast's largest shareholder, was appointed to its Board of Directors. Dr. George founded and managed the largest privately owned ambulatory surgical center company in the United States, SurgCenter Development. Dr. George brings to the Board his background

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as a medical scientist with unique operational experience having built a start-up company in the medical field and turning it into a highly-efficient multi-billion-dollar commercial organization. Dr. George will not be accepting any Director's fees as a board member, instead leaving these funds in the Company to contribute to the operational success of the business.

Ryoncil® Lifecycle Extension in Pediatric & Adult Inflammatory Diseases

Inflammatory bowel disease (IBD), including Crohn's disease (CD) remains a major unmet need across the adult and pediatric population where early and durable remission remains especially challenging. The age of onset is bimodal with a major first peak between 15 to 30 years (20-30 % patients diagnosed before age 20 years) and a smaller second peak between the ages of 60 and 70 years. In the U.S. pediatric prevalence is approximately 60,000-80,000 and the annual pediatric incidence of the disease is approximately 7,000 children. More than 60% of adult and pediatric CD patients are unable to achieve remission on anti-TNF agents, the only approved class of biologics in children.[3-6]

A recent pilot study in adults demonstrated positive outcomes (rapid mucosal healing and disease remission) in biologic refractory patients receiving remestemcel-L by direct endoscopic injection to areas of inflammation. This extends , Mesoblast data showing that intravenously delivered remestemcel-L can induce early remission in CD adults who have failed a single anti-TNF agent.

Given the effectiveness of Ryoncil® in treating children with GI-related SR-aGvHD, and the existing data on adult CD, Mesoblast plans to further evaluate the immunomodulatory effects of Ryoncil on GI inflammation in treating medically-refractory pediatric CD patients.

For adult patients with SR-aGvHD, 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.

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.[7,8] In contrast, 100-day survival was 73% after Ryoncil® treatment was used under expanded access in 25 adults with SR-aGvHD who failed to respond to at least one additional agent, such as ruxolitinib.

Revascor® (rexlemestrocel-L) for Chronic Heart Failure with Reduced Ejection Fraction (HFrEF) and Persistent Inflammation

In 2024 FDA informed Mesoblast that it supports an accelerated approval pathway for REVASCOR, Mesoblast's second generation allogeneic, STRO3-immunoselected, and industrially manufactured stromal cell therapy, in patients with end-stage ischemic HFrEF kept alive with a left ventricular assist device (LVAD).

Accelerated approval to market REVASCOR, if received, will require Mesoblast to commit to a post-approval confirmatory study in NYHA Class II/III HFrEF patients which could result in full approval in the broader HFrEF population.

In November 2024 a publication in the prestigious peer-reviewed European Journal of Heart Failure (EJHF) reported that a single intramyocardial injection of REVASCOR results in improved survival in high-risk NYHA Class II/III patients with ischemic heart failure and inflammation.[9] This identifies the HFrEF population that is responsive to REVASCOR and will be the target of a confirmatory trial after accelerated approval, if received.

Under its Regenerative Medicine Advanced Therapy (RMAT) designation Mesoblast intends to meet with FDA to discuss data presentation, timing and FDA expectations for an accelerated approval filing in these patients.

Revascor® for Pediatric Congenital Heart Disease - Hypoplastic Left Heart Syndrome

U.S. FDA granted REVASCOR a RMAT designation following submission of results from the randomized controlled trial in children with hypoplastic left heart syndrome (HLHS), a potentially life-threatening congenital heart condition.

Earlier in 2024, FDA granted REVASCOR both Rare Pediatric Disease Designation (RPDD) and Orphan-Drug Designation (ODD) for treatment of children with HLHS. On FDA approval of a BLA for REVASCOR for the treatment of HLHS, if received, Mesoblast may be eligible to receive a Priority Review Voucher

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(PRV) that can be redeemed for any subsequent marketing application or may be sold or transferred to a third party.

Rexlemestrocel-L for Chronic Low Back Pain associated with Degenerative Disc Disease – Phase 3 Program

The confirmatory Phase 3 trial of Mesoblast's second generation allogeneic, STRO3-immunoselected, and industrially manufactured stromal cell product candidate rexlemestrocel-L in patients with chronic low back pain (CLBP) due to inflammatory degenerative disc disease (DDD) of less than five years duration has commenced enrollment and treatment at multiple sites across the U.S.

The capital raise concluded last month will facilitate expansion of sites enrolling in the trial and acceleration of patient accrual.

FDA has previously agreed on the design of this 300-patient randomized, placebo-controlled confirmatory Phase 3 trial, and the 12-month primary endpoint of pain reduction as an approvable indication.

This endpoint was successfully met in Mesoblast's first Phase 3 trial. Key secondary measures include improvement in quality of life and function.

A particular focus is on treatment of patients on opioids, since discogenic back pain accounts for approximately 50% of prescription opioid usage in the US. Significant pain reduction and opioid cessation were observed in Mesoblast's first Phase 3 trial.

Rexlemestrocel-L has received RMAT designation from FDA for the treatment of chronic low back pain.

Details of Financial Results for Half-Year Ended December 31, 2024 (H1 FY2025)

- **Royalties** from sales by our licensees for H1 FY2025 were US$3.2 million compared with US$3.4 million for the comparative period in FY2024.
- **Research & Development** expenses were US$20.6 million in H1 FY2025, of which US$8.2 million was due to non-cash share-based payments primarily for STI in lieu of cash-based payments. This compares with US$12.6 million for the comparative period H1 FY2024, of which US$1.1 million was non-cash share-based payments.
- **Manufacturing:** As a result of FDA approval of RYONCIL in December 2024, the US$23.0 million provision against the value of inventory manufactured and expensed in prior periods was reversed and is now recognized as an inventory asset on the balance sheet. This resulted in a gain in manufacturing of US$14.7 million for H1 FY2025.
- **Management and Administration** expenses were US$17.2 million for H1 FY2025 of which US$6.3 million was due to non-cash share-based payment expenses primarily for STI in lieu of cash-based payments. This compares with US$11.5 million for the comparative period H1 FY2024, of which US$1.0 million was non-cash share-based payments.
- **Contingent Consideration:** As a result of FDA approval of RYONCIL in December 2024, the probability of success of pediatric GVHD increased to 100% and resulted in an increase in non-cash remeasurement increased by US$4.0 million to US$4.3 million for H1 FY2025 compared to US$0.3 million for H1 FY2024.
- **Fair value movement of warrants:** As a result of FDA approval of RYONCIL in December 2024 and the consequential share price appreciation, our warrant remeasurement increased by US$16.4 million to US$12.0 million for H1 FY2025 compared to a gain of US$4.4 million for H1 FY2024.
- **Other operating income & expenses** for H1 FY2025 was an expense of US$0.7 million compared with a US$1.1 million gain in H1 FY2024 due increased FX losses and withholding tax.
- **Finance Costs** of US$10.8 million for H1 FY2025 for borrowing arrangements include US$7.8 million of non-cash expenditure comprising accruing interest and other borrowing costs.

Operating Cash Flow: Net Cash Outflow was US$20.7 million for H1 FY2025, a reduction of US$5.9 million versus US$26.6 million in H1 FY2024.

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Loss after tax for H1 FY2025 was US$47.9 million compared to US$32.5 million for H1 FY2024. The net loss attributable to ordinary shareholders was 4.20 US cents per share for H1 FY2025, compared with 3.72 US cents per share for H1 FY2024.

Conference Call
There will be a webcast today, beginning at 9.00am AEDT (Thursday, February 27); 5.00pm EST (Wednesday, February 26). It can be accessed via: https://webcast.openbriefing.com/msb-hyr-2025/

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

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 therapies from the Company's proprietary mesenchymal lineage cell therapy technology platform 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's RYONCIL® (remestemcel-L) for the treatment of steroid-refractory acute graft versus host disease (SR-aGvHD) in pediatric patients 2 months and older is the first FDA-approved mesenchymal stromal cell (MSC) therapy. Please see the full Prescribing Information at www.ryoncil.com.

Mesoblast is committed to developing additional cell therapies for distinct indications based on its remestemcel-L and rexlemestrocel-L allogeneic stromal cell technology platforms. RYONCIL is being developed for additional inflammatory diseases including SR-aGvHD in adults and biologic-resistant inflammatory bowel disease. Rexlemestrocel-L is being developed for heart failure and chronic low back pain. The Company has established commercial partnerships in Japan, Europe and China.

About Mesoblast intellectual property: Mesoblast has a strong and extensive global intellectual property portfolio, with over 1,000 granted patents or patent applications covering mesenchymal stromal cell compositions of matter, methods of manufacturing and indications. These granted patents and patent applications are expected to provide commercial protection extending through to at least 2041 in major markets.

About Mesoblast manufacturing: 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 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

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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 RYONCIL for pediatric SR-aGVHD and any other 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, 2024	2023
Revenue	3,156	3,388
Research & development	(20,649)	(12,647)
Manufacturing commercialization	14,740	(6,746)
Management and administration	(17,188)	(11,482)
Fair value remeasurement of contingent consideration	(4,303)	(337)
Fair value remeasurement of warrant liability	(11,978)	4,434
Other operating income and expenses	(673)	1,068
Finance costs	(10,827)	(10,319)
Loss before income tax	**(47,722)**	**(32,641)**
Income tax benefit/(expense)	(212)	102
Loss attributable to the owners of Mesoblast Limited	**(47,934)**	**(32,539)**

Losses per share from continuing operations attributable to the ordinary equity holders of the Group:	**Cents**	**Cents**
Basic - losses per share	(4.20)	(3.72)
Diluted - losses per share	(4.20)	(3.72)

Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	Six Months Ended December 31, 2024	2023
Loss for the period	**(47,934)**	**(32,539)**
Other comprehensive (loss)/income		
Items that may be reclassified to profit and loss		
Exchange differences on translation of foreign operations	(113)	1,164
Items that will not be reclassified to profit and loss		
Financial assets at fair value through other comprehensive income	194	(931)
Other comprehensive (loss)/income for the period, net of tax	**81**	**233**
Total comprehensive losses attributable to the owners of Mesoblast Limited	**(47,853)**	**(32,306)**

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Consolidated Balance Sheet

(in U.S. dollars, in thousands)	As of December 31, 2024	As of June 30, 2024
Assets		
Current Assets		
Cash & cash equivalents	38,029	62,960
Trade & other receivables	2,996	20,952
Prepayments	4,460	2,551
Inventory	24,194	—
Total Current Assets	**69,679**	**86,463**
Non-Current Assets		
Property, plant and equipment	1,004	1,106
Right-of-use assets	5,215	2,732
Financial assets at fair value through other comprehensive income	1,208	1,014
Other non-current assets	1,333	2,102
Intangible assets	574,879	575,736
Total Non-Current Assets	**583,639**	**582,690**
Total Assets	**653,318**	**669,153**
Liabilities		
Current Liabilities		
Trade and other payables	11,860	7,070
Provisions	27,567	45,038
Borrowings	17,505	13,862
Lease liabilities	2,381	2,626
Warrant liability	13,437	4,647
Total Current Liabilities	**72,750**	**73,243**
Non-Current Liabilities		
Provisions	10,581	10,620
Borrowings	101,475	100,483
Lease liabilities	4,750	1,952
Deferred consideration	2,500	2,500
Total Non-Current Liabilities	**119,306**	**115,555**
Total Liabilities	**192,056**	**188,798**
Net Assets	**461,262**	**480,355**
Equity		
Issued Capital	1,320,207	1,310,813
Reserves	97,750	78,303
(Accumulated losses)	(956,695)	(908,761)
Total Equity	**461,262**	**480,355**

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Consolidated Statement of Cash Flow

(in U.S. dollars, in thousands)	Six Months Ended December 31, t 2024	2023
Cash flows from operating activities		
Commercialization revenue received	3,063	3,971
Government grants and tax incentives and credits received	2	2,565
Payments to suppliers and employees (inclusive of goods and services tax)	(24,159)	(33,994)
Interest received	441	887
Income taxes paid	(2)	(1)
Net cash (outflows) in operating activities	**(20,655)**	**(26,572)**
Cash flows from investing activities		
Payments for property, plant and equipment	(106)	(194)
Receipts from investment in sublease	124	116
Payments for intellectual property	—	(10)
Receipt of security deposits	609	—
Net cash inflows/(outflows) in investing activities	**627**	**(88)**
Cash flows from financing activities		
Repayment of borrowings	(2,608)	—
Payment of transaction costs from borrowings	(644)	(540)
Interest and other costs of finance paid	(2,720)	(2,845)
Proceeds from exercise of options	1,341	—
Proceeds from exercise of warrants	1,362	—
Proceeds from issue of shares	—	39,708
Payments for share issue costs	(24)	(2,578)
Payments for lease liabilities	(971)	(2,145)
Net cash (outflows)/inflows by financing activities	**(4,264)**	**31,600**
Net (decrease)/increase in cash and cash equivalents	(24,292)	4,940
Cash and cash equivalents at beginning of period	62,960	71,318
Foreign exchange (losses)/gains on the translation of foreign bank accounts	(639)	1,296
Cash and cash equivalents at end of period	**38,029**	**77,554**

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