UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

Form 6-K

Report of Foreign Private Issuer Pursuant to Rule 13a-16 or 15d-16 under the Securities Exchange Act of 1934

For the month of November 2023

Commission File Number 001-37626

Mesoblast Limited

(Exact name of Registrant as specified in its charter)

Not Applicable (Translation of Registrant's name into English)

Australia (Jurisdiction of incorporation or organization)

Silviu Itescu Chief Executive Officer and Executive Director Level 38 55 Collins Street Melbourne 3000 Australia (Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F: Form 20-F 🛛 Form 40-F 🗆

INFORMATION CONTAINED ON THIS REPORT ON FORM 6-K

On November 27, 2023, Mesoblast Limited filed with the Australian Securities Exchange a new release announcement, which is attached hereto as Exhibit 99.1, and is incorporated herein by reference.

On November 28, 2023, Mesoblast Limited filed with the Australian Securities Exchange the Chairman's Annual General Meeting address, CEO presentation to Annual General Meeting and results of Annual General Meeting, which are attached hereto as Exhibit 99.2, Exhibit 99.3, and Exhibit 99.4, and are incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly organized.

Mesoblast Limited /s/ Paul Hughes

Paul Hughes Company Secretary

Dated: November 30, 2023

INDEX TO EXHIBITS

Press release of Mesoblast Ltd, dated November 27, 2023. Chairman's Annual General Meeting address, dated November 28, 2023. CEO Presentation to Annual General Meeting, dated November 28, 2023. Results of Annual General Meeting, dated November 28, 2023

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asx announcement

MESOBLAST FILES FOR ORPHAN DRUG AND PEDIATRIC RARE DISEASE DESIGNATIONS FOR REXLEMESTROCEL-L AS TREATMENT FOR SEVERE CONGENITAL HEART DISEASE

Melbourne, Australia; November 27 and New York, USA; November 26, 2023: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today announced that it has filed for orphan drug designation (ODD) and rare pediatric disease designation (RPDD) with the United States Food and Drug Administration (FDA) for its allogeneic cell therapy Revascor[®] (rexlemestrocel-L) in the treatment of the congenital heart disease hypoplastic left heart syndrome (HLHS). The filings were based on results from a blinded, randomized, controlled prospective trial of REVASCOR conducted at a single center in the US in 19 children with HLHS and accepted for publication in an upcoming issue of the peer reviewed *The Journal of Thoracic and Cardiovascular Surgery Open (JTCVS Open).*¹

HLHS is a severe congenital heart disease in which the left side of the heart does not fully develop and effective pumping of oxygenated blood by the left ventricle to the rest of the body is reduced. Without immediate surgery after birth, the prognosis is dismal with HLHS overall being responsible for 25% to 40% of all neonatal cardiac mortality.² In the longer term, surgery that creates a two-ventricle series circulation with the left ventricle (LV) pumping blood to the body and the right ventricle pumping blood to the lungs is the ideal anatomic repair. Unfortunately, achievement of this objective is limited by the inability in most patients for the left ventricle to grow sufficiently to support the circulation to the body.

REVASCOR is an allogeneic preparation of immunoselected and culture-expanded mesenchymal precursor cells which have been shown previously to have multiple mechanisms-of-action that may be beneficial to children with HLHS including neovascularization, anti-fibrosis, anti-apoptosis, immunomodulation, reduction in inflammation, and reversal of endothelial dysfunction. In the DREAM-HF randomized sham-placebo controlled prospective trial of REVASCOR in 565 adult patients with heart failure with low ejection fraction (HFrEF), a single intramyocardial administration of REVASCOR into the left ventricle resulted in significant improvement in LV ejection fraction at 12 months,³ indicative of strengthened overall LV systolic function.

In the HLHS trial a single intramyocardial administration of REVASCOR at the time of staged surgery resulted in significantly increased LV systolic and diastolic volumes over 12 months compared with control. These changes are indicative of clinically important growth of the small left ventricle that can help facilitate a subsequent surgical correction allowing for a normal two ventricle circulation. Improvement in left ventriclar functional outcomes with REVASCOR may encourage more widespread use of surgical procedures to create a functioning left ventricle in children with HLHS resulting in reduction in long-term morbidity and mortality compared with other medical and/or surgical approaches.

The FDA has authority to grant orphan drug (OD) designation to a drug or biological product to prevent, diagnose or treat a rare disease or condition, defined as any disease or condition that affects less than 200,000 persons in the United States. An orphan drug designation (ODD) qualifies sponsors for incentives including tax credits for qualified clinical trials, exemption from user fees, and the potential for seven years of market exclusivity after approval. A rare pediatric disease designation (RPDD) demonstrates that the disease is serious or life-threatening and the manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents, and that the disease is a rare disease or condition.

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 latestage 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 remestencel-L and rexlemestrocel-L allogeneic stromal cell technology platforms. Remestencel-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

- 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 (2023), doi: https://doi.org/10.1016/j.xjon.2023.09.031.
- 2. Kritzmire, S. M, et al. (2022). Hypoplastic left heart syndrome.
- https://www.ncbi.nlm.nih.gov/books/NBK554576/#
- Perin EC, Borow KM, Henry TD, et al. Randomized Trial of Targeted Transendocardial Mesenchymal Precursor Cell Therapy in Patients With Heart Failure. Journal of the American College of Cardiology. 2023;81(9):849-863. doi:10.1016/j.jacc.2022.11.061

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 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

Mesoblast Limited ABN 68 109 431 870 www.mesoblast.com Corporate Headquarters Level 38 55 Collins Street Melbourne 3000 Victoria Australia **T** +61 3 9639 6036 **F** +61 3 9639 6030 United States Operations 505 Fifth Avenue Third Floor New York, NY 10017 USA **r** +1 212 880 2060 **r** +1 212 880 2061

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т +65 6570 0635 F +65 6570 0176 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.

For more information, please contact:

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CHAIRMAN'S ADDRESS TO SHAREHOLDERS

2023 ANNUAL GENERAL MEETING

Good afternoon shareholders. Welcome to the 2023 Mesoblast Annual General Meeting. It is a pleasure to get together with you once again.

A huge amount was accomplished during the year despite the disappointment of a further delay in gaining approval for our lead product candidate, Ryoncil® (remestemcel-L), in the treatment of children with steroid-refractory acute graft versus host disease (SR-aGVHD)- a devastating and life-threatening complication of a bone marrow transplant. The company continues to demonstrate the value of our technology and pipeline across the portfolio with the Board fully supportive of Mesoblast's corporate and commercial strategy led by our very capable Chief Executive, Dr Silviu Itescu.

The Mesoblast team continues to have very constructive interactions with United States Food and Drug Administration (FDA) in regard to RYONCIL for pediatric SR-aGVHD, including the recent Type A meeting, and understand the remaining issues that need to be addressed in order to gain FDA approval for RYONCIL as the first allogeneic mesenchymal stromal cell product in the United States. Additional potency assay work is being completed for presentation to the FDA, and last week we announced an agreement with the Blood and Marrow Transplant Clinical Trials Network to partner on a Phase 3 pivotal trial of RYONCIL in the treatment of adults with SR-aGVHD.

Indeed, as evidence for management's continued positive interactions with FDA, I am pleased to say that FDA granted Regenerative Medicine Advanced Therapy designation for our next generation potential blockbuster product rexlemestrocel-L for treatment of chronic low back pain associated with disc degeneration.

We also filed for orphan drug and rare pediatric disease designations with the FDA for Revascor® (rexlemestrocel-L) in the treatment of another devastating illness in children - severe congenital heart disease. The filings were based on results from a trial conducted at a single center in the United States in 19 children and accepted for publication in The Journal of Thoracic and Cardiovascular Surgery Open (JTCVS Open) which showed that a single administration of REVASCOR at the time of surgery resulted in a significant increase in the volume of the congenitally small left ventricular heart pumping chamber.

The Board is in alignment with the Chief Executive's outlined strategy for fiscal prudence and targeted reduction in payroll and quarterly spend. The management team has already successfully executed a substantial reduction in spend over the past two years, and the Board fully supports the new plan to preserve the Company's cash as well as strengthen the balance sheet through a number of planned initiatives.

In this regard, I would like to acknowledge the initiative taken by our Chief Executive and Chief Medical Officer to lead by example and defer the entire FY23 short-term incentives (STI), and voluntarily reduce their base cash payment by 30% in lieu of accepting equity-based incentives. I also thank my fellow directors for agreeing to voluntarily defer 50% cash payment of their director fees and to receive the remaining 50% of their fees in equity-based incentives.

In keeping with the Board's stated intention to maintain a program of renewal that generates regular rotation of Board membership, Ms Jane Bell joined the Board during the 2023 financial year. In September 2023, Ms Bell was appointed Chair of the Mesoblast Board Audit and Risk Committee, a role for which she is exceptionally well qualified to make a substantial contribution. I would like to thank our management team and all our employees who have put in a huge effort with respect to our FDA interactions and who continue to maintain their tremendous output toward the potential approval of our lead-product candidate.

Most importantly, I would like to thank our shareholders for their ongoing confidence in and support of Mesoblast as we continue our mission to obtain our first FDA product approval.

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Global Leader in Allogeneic Cellular Medicines for Inflammatory Diseases

Annual General Meeting 2023



CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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Our Mission

Mesoblast is committed to bringing to market innovative cellular medicines to treat serious and life-threatening illnesses





Corporate Vision

To be world's leading, most innovative, and highly respected cellular medicines company

To use our proprietary technologies to develop cellular medicine products that are life-saving and that improve quality of life

To establish an organization that attracts motivated people working towards achieving a common goal

To deliver appropriate returns for our shareholders

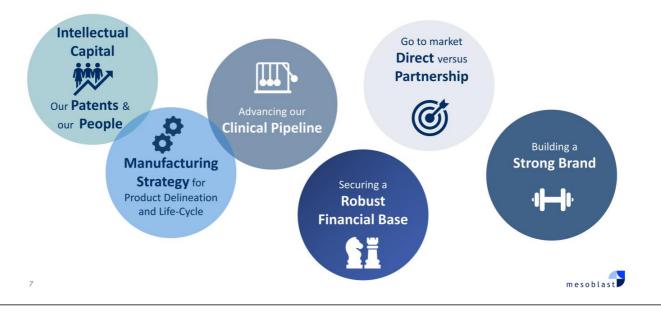
Investment Highlights

Novel Allogeneic Cell Therapy Platform	Developing off-the-shelf, allogeneic cellular medicines based on proprietary mesenchymal stromal cell (MSC) technology platforms to enable treatment without the need for donor matching or immunosuppression
Remestemcel-L for Pediatric SR-aGVHD	Single-arm pivotal Phase 3 trial completed; primary endpoint successfully met Long-term data shows durability of survival benefit >4 years Additional potency assay data to be presented to FDA
Remestemcel-L for Adult SR-aGVHD	Market size for adult population approx. 5-fold larger than pediatric The pivotal trial is expected to be conducted by BMT CTN, a body responsible for approximately 80% of all US transplants, at a fraction of the cost of a traditional CRO
Rexlemestrocel-L for CLBP	First randomized controlled Phase 3 trial completed, RMAT granted by FDA for discogenic pai Agreement on 12-month pain reduction endpoint for FDA approval, confirmatory trial needed Start-up activities for this trial significantly advanced with investigators, trial sites & CRO
Rexlemestrocel-L for Heart Disease	First Phase 3 completed for heart failure with reduced ejection fraction (HFrEF) Class II/III patients. RMAT granted by FDA for end-stage HFrEF patients with an LVAD. Randomized controlled trial in pediatric congenital heart disease patients published
SR-aGVHD = Steroid-Refractory Graf 5 FDA = United States Food and Drug /	

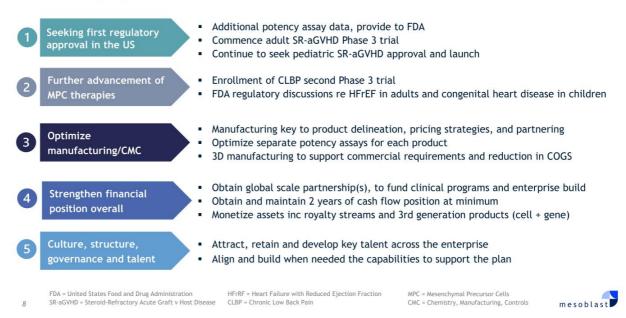
Corporate Level Strategic Options Evaluated and Set



Tactical Execution Of Corporate Strategy



Setting Key Strategic Priorities for 2024



Global Intellectual Property (IP) Estate Provides Substantial Competitive Advantage

- Extensive patent portfolio with protection extending through 2040
- Over 1,100 patents and patent applications (82 patent families) across all major jurisdictions
- Covers composition of matter, manufacturing, and therapeutic applications of mesenchymal lineage cells
- Provides strong global protection in areas of our core commercial focus against cell-based competitor products
- Outside our core areas, may grant rights to third parties requiring access to our patent portfolio to commercialize their products
- Track record of managing intellectual property
 - Royalty agreement and income received from JCR Pharmaceuticals in Japan for treatment of aGVHD
 - Patent license granted to TiGenix, S.A.U., a wholly owned subsidiary of Takeda, on its worldwide sales of its product Alofisel® for the treatment of complex perianal fistulas in Crohn's disease





Commercial-scale Manufacturing Process and Facilities

- Scalable allogeneic "off-the-shelf" cellular platforms
- Manufacturing meets stringent criteria of international regulatory agencies
- Robust quality assurance processes ensure final product with batch-to-batch consistency and reproducibility
- Manufacturing innovations to meet increasing capacity requirements, improve yields and reduce cost of goods
 - Proprietary xeno-free technologies
 - Scaled-up 2D manufacturing
 - 3D bioreactors for high volume indications

Manufacturing Remestemcel-L





Our mesenchymal precursor/stromal cells respond to and are activated by multiple inflammatory cytokines through surface receptors, resulting in orchestration of an anti-inflammatory cascade Inflammation IL-10 Proliferation IDO IDO, PGE2 Mesenchymal Precurso Stromal Cell Cytokine secretion Proliferation Antibody production Cytotoxicity T_H17) PGE 00 00 TGEB Activation IDO, PGE2 Cytotoxicity 🕇 TGF β , M-CSF, CCL2 Treg **▲** IL-10 Maturation Activation Antigen Presentation mmatt 🕈 IL-1 M1 † IL-6 ▼ TNFα Polar mesoblast Source: data on file 11

Platform Technology - Shared Mechanism of Action Across Our Products

Late-Stage Clinical Pipeline

Based on the Proprietary Allogeneic Mesenchymal Stromal Cell Platform



SR-aGVHD = Steroid-Refractory Acute Graft Versus Host Disease; CLBP = Chronic Low Back Pain; HFrEF = Heart Failure with Reduced Ejection Fraction

Notes: JCR Pharmaceuticals Co., Ltd. (JCR), has the right to develop mesenchymal stromal cells (MSCs) in certain fields for the Japanese market, including for the treatment of hematological malignancies, such as Graft vs Host Disease, and for hypoxic ischemic encephalopathy (HIE). Grünenthal has an exclusive license to develop and commercialize rexlemestrocel-L for chronic low back pain in Europe and Latin America/Caribbean. Tasly Pharmaceuticals has exclusive rights for rexlemestrocel-L for the treatment or prevention of chronic heart failure in China.

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Clinical Program Milestones - Next 12 Months

Clinical Progr	am Milestones - Next 12 Months	Target Date	<u>Status</u>
RYONCIL	Currently finalizing additional potency assay data on commercial inventory to provide to FDA	Q1 CY2024	In progress
Adult & Pediatric SR-aGVHD	Planned meeting with the FDA regarding potency assay data for the pediatric BLA	Q1 CY2024	Planned
(remestemcel-L)	Completion and submission to FDA of protocol for adult SR-aGVHD Phase 3 trial in partnership with BMT CTN	Q1 CY2024	In progress
	Commence patient enrollment for adult SR-aGVHD trial	Q2 CY2024	Planned
Pain	CLBP Phase 3 trial start-up activities with investigators, trial sites & contract research organization (CRO)	Q4 CY2023	In progress
(rexlemestrocel-L)	Phase 3 CLBP patient screening/enrollment initiates and completes	Q1-Q4 CY2024	Planned
Adult & Pediatric	Meet with the FDA under RMAT to discuss the potential pathway to approval in adults with HFrEF based on LVAD and DREAM-HF trials	Q1 CY2024	In progress
Heart Disease (rexlemestrocel-L)	Meeting with FDA on congenital heart disease pathway to approval in pediatric patients based on results of randomized, controlled trial	Q1 CY2024	Planned
13 SR-aGVHD = Steroid-Refra FDA = United States Food		sist Device n Reduced Ejection Fraction	mesoblast

P	athway to Approval for RYONCIL in Pediatric Patients with SR-aGVHD
7	During the Biologics License Application (BLA) review we made substantial progress towards bringing this cutting-edge product to market with a completed FDA inspection of our manufacturing process.
7	In August FDA provided a complete response requiring Mesoblast to provide additional potency assay data confirming that product used in the Phase 3 trial is similar to product intended for commercial release, as measured by a standardized potency assay.
7	At the Type A meeting in September, Mesoblast presented clinical data indicating that treatment with the improved RYONCIL product version of remestemcel-L, manufactured using the current process inspected by FDA, resulted in consistently high survival rates in children with SR-aGVHD.
7	Similarly high survival rates were seen whether using product made for the Phase 3 clinical trial MSB-GVHD001 between 2015-2018 or made with the validated manufacturing process proposed for commercial release and used under Emergency Investigational New Drug (EIND) protocol through 2023.
-	Mesoblast believes that the totality of these clinical studies, together with additional potency assay data currently being generated using the IL-2R alpha inhibition potency assay in place during the pediatric Phase 3 trial, will both support approval for the pediatric indication and provide a link between the RYONCIL product that was used in the pediatric Phase 3 trial and available commercial inventory.
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	P	athway to Approval for RYONCIL in Adult Patients with SR-aGVHD
		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, a patient population with no approved therapies. ^{1,2}
		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.
4		In its September 2023 draft guidance to industry for development of agents to treat aGVHD, the FDA stated that a marketing application in a population with refractory aGVHD where there are no approved therapies might be supported by positive results from a single-arm trial. ³
1		Mesoblast intends to commence a Phase 3 trial of RYONCIL in adults and adolescents, a market approx. 5-fold larger than pediatric, who are refractory to both corticosteroids and a second line agent such as ruxolitinib, for whom there are no approved therapies.
4		The trial is expected to be conducted by the Blood and Marrow Transplant Clinical Trials Network (BMT CTN), a body responsible for approximately 80% of all US transplants, at a fraction of the cost of a traditional contract research organization (CRO).
1. 2. 3. 15	Ab	gasia 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. edin 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. 5 FDA. Graft-versus-Host Diseases: Developing Drugs, Biological Products, and Certain Devices for Prevention or Treatment Guidance for Industry. Draft Guidance. Sep 2023 mesoblast

Financials

- Revenue from royalties, predominantly on sales of TEMCELL® HS Inj.¹ sold in Japan by our licensee, were US\$7.5 million for the year ended June 30, 2023.
- Cash balance at September 30, 2023 was US\$53.2 million, with net operating cash spend of US\$14.2 million for the quarter.

Management and the Board have put in place a plan that focuses on preservation of cash by implementing significant cost containment strategies and enacting substantial payroll reductions.

- Net operating cash usage over the past two years reduced by 37% to US\$63.3 million in FY2023. We have implemented a cost containment plan to achieve a further targeted 23% reduction (US\$15 million) in projected FY2024 annual net operating cash spend compared with FY2023, which will be partially offset by investment in our Phase 3 programs for adults with SR-aGVHD and CLBP.
- These activities to preserve cash are complemented by initiatives currently underway to increase cash inflows which would by design enable us to prudently invest in our Phase 3 programs. In this regard, we are working on corporate initiatives to strengthen our balance sheet, including royalty monetization and strategic partnerships to both access existing commercial distribution channels and supplement costs of development.

 TEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd. 16





Rexlemestrocel-L

Chronic Low Back Pain due to Degenerative Disc Disease (CLBP)



Chronic Low Back Pain Due to Degenerative Disc Disease (CLBP) Impacts 7M+ Rexlemestrocel-L represents a potential new paradigm for the treatment of CLBP

Burden of Illn	ness Tro	eatment Options	Market Opportunity
disability th condition ¹ Tinflicts subs and indirec healthcare	xcessive use of his patient	Minimal treatment options for patients with chronic low back pain (CLBP) who fail conservative therapy include opioids and surgery 50% of opioid prescriptions are for CLBP ² Durable improvement in pain has potential to reduce opioid use and prevent surgical intervention	CLBP due to degenerative

1. Williams, J., NG, Nawi, Pelzter, K. (2015) Risk factors and disability associated with low back pain in older adults in low-and middle-income countries. Results from the WHO Study on global ageing and adult health (SAGE). PloS One. 2015; 10(6): e0127880., 2.Decision Resources: Chronic Pain December 2015., 3. LEK & NCI opinion leader interviews, and secondary analysis., 4. Navigant: Commercial Assessment for a Proprietary Cell-Based Therapy for DDD in the U.S. and the EU3 - August 2014.

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Rexlemestrocel-L / CLBP - Program Summary

Gained alignment with the FDA on the appropriate pivotal Phase 3 studyFDA has agreed with Mesoblast plans for mean pain reduction at 12 months as the primary endpoint of the pivotal trialProduct has been manufactured for use in the pivotal Phase 3 studyRMAT desi CLBP receiv thisSeeks to replicate the significant reduction inFDA has agreed with Mesoblast plans for mean pain reduction at 12 months as the primary endpoint of the pivotal trialProduct has been manufactured for use in the pivotal Phase 3 studyRMAT desi CLBP receiv this	
the FDA on the appropriate pivotal Phase 3 studyMesoblast plans for mean pain reduction at 12 months as the primary endpoint ofmanufactured for use in the pivotal Phase 3 studyCLBP receiv thisSeeks to replicate the significant reduction inthe pivotal trialPotency assays are in place for product releaseStart-up a advance	al P3 Trial
	signation for ved from FDA s year activities for significantly ced with ors, trial sites CRO

Regenerative Medicine Advanced Therapy (RMAT) Designation Granted by FDA for Rexlemestrocel-L in the treatment of CLBP

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)

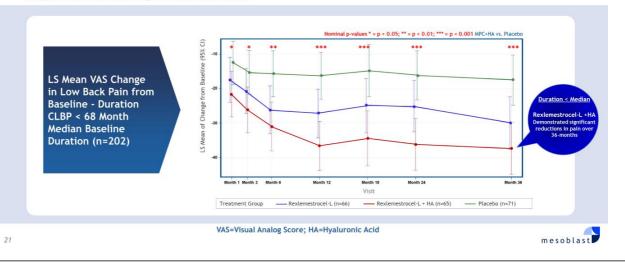
Results from the trial showed that:

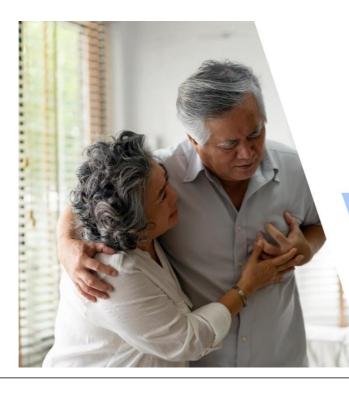
- A single injection of rexlemestrocel-L+HA into the lumbar disc resulted in significant reduction in pain compared with saline control at 12 and 24 months across all subjects (n=404)
- Pain reduction through 36 months was seen in the subset of patients using opioids at baseline (n=168) with the rexlemestrocel-L+HA group having substantially greater reduction at all time points compared with saline controls
- Among patients on opioids at baseline, despite instructions to maintain existing therapies throughout the trial, at 36 months 28% who received rexlemestrocel-L+HA were not taking an opioid compared with 8% of saline treated controls



Phase 3 Trial Outcomes based on a Single Injection of Rexlemestrocel-L + HA Results in More than Three Years of Pain Reduction

Greatest pain reduction was observed in the pre-specified population of subjects with CLBP duration shorter than the baseline study median of 68 months (n=202) with significantly greater reduction (nominal p-value < 0.05) at all time points analyzed over 36 months compared with saline controls





Rexlemestrocel-L

Chronic Heart Failure Reduced Ejection Fraction (HFrEF)



Rexlemestrocel-L / HFrEF - Program Summary Defining the Regulatory Path to FDA Approval

Promising Data	Targeting Inflammation	FDA Meeting
Recent data from the DREAM-HF P3 trial showed improved LVEF at 12 months, preceding long-term reduction in MACE events across all treated patients LVEF is a potential early surrogate endpoint	Effects on LVEF and MACE outcomes are enhanced in patients with active inflammation Trial results from class II to end-stage HFrEF now support a MOA by which rexlemestrocel-L reverses inflammation-related endothelial dysfunction	Mesoblast plans to meet with the FDA under its RMAT designation to discuss the potential pathway to approval
	DREAM-HF P3 trial showed improved LVEF at 12 months, preceding long-term reduction in MACE events across all treated patients LVEF is a potential early	DREAM-HF P3 trial showed improved LVEF at 12 months, preceding long-term reduction in MACE events across all treated patientsoutcomes are enhanced in patients with active inflammationTrial results from class II to end-stage HFrEF now support a MOA by which rexlemestrocel-L reverses inflammation-related

Patients Experience Progressive Vascular Dysfunction and Heart Failure Rexlemestrocel-L has the potential to improve endothelial dysfunction in patients from Class II thru IV

		Mesoblast's Deve	lopment Programs
		DREAM HF-1 Trial 537 Patients	LVAD MPC Studies 189 Patients
	Guideline Directed Medica	l Therapies (GDMT)	
		Continuum of Cardiova	ascular Disease Risk
NYHA Class I	NYHA Class II	NYHA Class IIB/IIIA	NYHA Class IIIB/IV
aditional Early Therapies for HFrEF Statins Beta blockers Re-vascularization or valvular surgery RAAS antagonists Diuretics for fluid retention Hydralazine / isosorbide dinitrate	Recent New Oral Therapies for Decompensated HFrEF Hospitalizations and Fluid Overload • sacubitril / valsartan • SGLT2 inhibitors • Vericiguat	NYHA Class IIB or IIIA Persistent HFrEF Patients • Cardioverter Defibrillator (ICD) +/- • CRT-D or Wearable Cardioverter Defibrillator if Indicated	NYHA Class IIIB/IV Pts with end-stage HFrEF • Optimal medical management • LVAD implantation • Heart transplant • Artificial Heart

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Rexlemestrocel-L - Two Pivotal Studies in Chronic Heart Failure (CHF)

Mesoblast's Development Programs Assess the Impact of Intra-cardiac Administration of Rexlemestrocel-L Across the Continuum of Disease from Mild/Moderate to End-stage Severity

MPC Study Design	LVAD-MPC Study #2	DREAM-HF Trial				
Treated Patients	159	537				
Study Design	Prospective, randomized, Multi-center, double-blinded & safety studies of allogeneic mes					
Pathologies of ↑ed Importance	LV Systolic Function, Inflammation, Mortality, Major Morbidities					
Product	Mesenchymal Precursor Cells with defin	ed Cardiac Potency (Rexlemestrocel-L)				
Cell Preparation, Manufacturing, Central Storage and Shipping	Same facilities and vendors in both studies					
Physical Location Used for Cell Administration at the Study Site	Operating room	Cardiac catheterization laboratory				
Patient Analysis Population	End-stage chronic HFrEF candidate for LVAD implant (NYHA Class IIIB or IV), ischemic or non-ischemic etiology (N=159: MPC=106, CTRL=53)	Chronic HFrEF (Late NYHA Class II or IIIA), ischemic or non-ischemic etiology (N=537: MPC=265, CTRL=272)				
Cell Dose in MPC	150 million cells administered as 15-20 indi	vidual injections during a single procedure				
Route of Cell Administration	te of Cell Administration Epicardial injection Transendocardial					
Target of Cell Administration	Mid-wall of left ventricle					

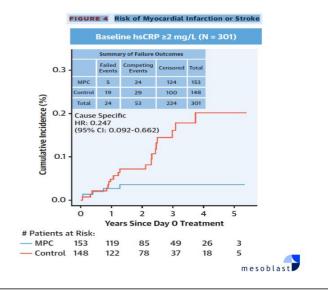
original investigations Randomized Trial of Targeted Transendocardial Mesenchymal Precursor Cell Therapy in Patients With Heart Failure

JACC JOURNALS

Perin EC, Borow KM, Henry TD, et al. Randomized Trial of Targeted Transendocardial Mesenchymal Precursor Cell Therapy in Patients With Heart Failure. Journal of the American College of Cardiology. 2023;81(9):849-863.

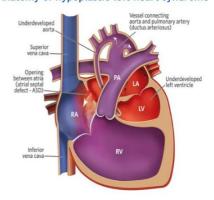
Randomized, double-blind, controlled, 537 patient Phase 3 trial of rexlemestrocel-L over mean followup of 30 months showed:

- Improved LVEF from baseline to 12 months in all patients - maximal benefit seen in patients with active inflammation
- Reduced risk of MI or stroke by 57% in all treated patients, and by 75% in patients with inflammation
- Reduced risk for time-to-first Major Adverse Cardiac Event (MACE), defined as cardiovascular death, MI or stroke, by 28% in all patients, and by 37% in patients with inflammation



REVASCOR As Treatment For Severe Congenital Heart Disease Filed with FDA For Orphan Drug And Pediatric Rare Disease Designations

- Hypoplastic left heart syndrome (HLHS) is a severe congenital heart disease in which the left side of the heart does not fully develop and effective pumping of oxygenated blood by the left ventricle to the rest of the body is reduced.
 Anatomy of hypoplastic left heart syndrome version of hypoplastic left heart synd
- Without immediate surgery after birth, the prognosis is dismal with HLHS overall being responsible for 25% to 40% of all neonatal cardiac mortality.¹
- In the longer term, surgery that creates a two-ventricle series circulation with the left ventricle (LV) pumping blood to the body and the right ventricle pumping blood to the lungs is the ideal anatomic repair. Unfortunately, achievement of this objective is limited by the inability in most patients for the left ventricle to grow sufficiently to support the circulation to the body.
- REVASCOR has multiple mechanisms-of-action that may be beneficial to children with HLHS including neovascularization, anti-fibrosis, anti-apoptosis, immunomodulation, reduction in inflammation, and reversal of endothelial dysfunction.
- 27 1. Kritzmire, S. M, et al. (2022). Hypoplastic left heart syndrome. https://www.ncbi.nlm.nih.gov/books/NBK554576/#





REVASCOR As Treatment For Severe Congenital Heart Disease

Filed with FDA For Orphan Drug And Pediatric Rare Disease Designations

- In the HLHS randomized controlled single-center US trial in 19 patients, a single intramyocardial administration of REVASCOR at the time of staged surgery resulted in significantly increased LV systolic and diastolic volumes over 12 months compared with control.¹
- These changes are indicative of clinically important growth of the small left ventricle that can help facilitate a subsequent surgical correction allowing for a normal two ventricle circulation.
- Improvement in left ventricular functional outcomes with REVASCOR may encourage more widespread use of surgical procedures to create a functioning left ventricle in children with HLHS resulting in reduction in long-term morbidity and mortality compared with other medical and/or surgical approaches.
- An orphan drug designation (ODD) qualifies sponsors for incentives including tax credits for qualified clinical trials, exemption from user fees, and the potential for seven years of market exclusivity after approval.
- A rare pediatric disease designation (RPDD) demonstrates that the disease is serious or life-threatening and the manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents, and that the disease is a rare disease or condition.
- 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 (2023), doi: https://doi.org/10.1016/j.xjon.2023.09.031.

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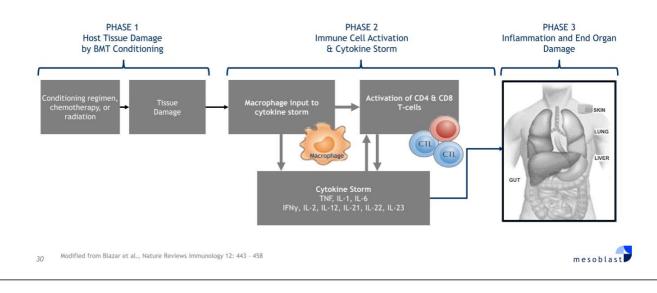
Remestemcel-L

Steroid-Refractory Acute Graft Versus Host Disease (SR-aGVHD)



Acute Graft Versus Host Disease (aGVHD)

Serious and Fatal Complication of Allogeneic Bone Marrow Transplantation (BMT)



Remestemcel-L: Steroid-Refractory Acute Graft Versus Host Disease (SR-aGVHD) SR-aGVHD is associated with mortality rates as high as 90%

Treatment Options	Burden of Illness	Market Opportunity	
 Corticosteroids are first-line therapy for aGVHD There is only one approved treatment for disease refractory to steroids and no approved treatment in the US for children under 12 years old In Japan, Mesoblast's licensee received the first product approval for SR-aGVHD in both children and adults 	 Acute GVHD is a life- threatening complication that occurs in -50% of patients receiving allogeneic bone marrow transplants (BMTs)¹ Acute GVHD primarily affects skin, GI tract, and liver Steroid-refractory aGVHD is associated with mortality rates as high as 90%^{1,4} and significant extended hospital stay costs² 	 More than 30,000 allogeneic BMTs performed globally (>20K US/EU) annually, -20% pediatric^{2,3} Approx. 9,000 -10,000 allogeneic BMTs performed in the US annually Approx. 1,500 allogenic BMTs are in children and adolescents in US³ 	

1. Westin, J., Saliba, RM., Lima, M. (2011) Steroid-refractory acute GVHD: predictors and outcomes. Advances in Hematology. 2. Niederwieser D, Baldomero H, Szer J. (2016) Hematopoietic stem cell transplantation activity worldwide in 2012 and a SWOT analysis of the Worldwide Network for Blood and Marrow Transplantation Group including the global survey. 3. HRSA Transplant Activity Report, CIBNTR, 2020 4. Act L, Namann A, Toennies J (2019) Retrospective single center analysis of outcome, risk factors and therapy in steroid refractory graft-versus-host disease after allogeneic hematopoietic cell transplantation. Bone Marrow Transplantation.

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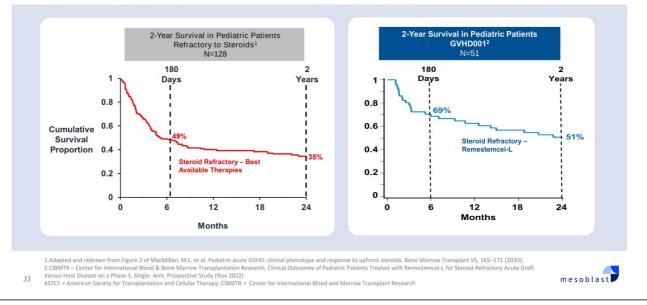
Remestemcel-L for Children with SR-aGVHD

Improved Early Survival Across Three Studies involving more than 300 Treated Children

Day 100 Survival											
Remestemcel-L Protocol	Matched Control Protocol										
First Line Therapy after Steroids Treatment Setting											
Pediatric Subset of Protocol 280: randomized controlled P3, n=27 w/SR-aGVHD	79%	54%	Study Control Arm (n=13)								
Study 001, open-label P3, n=541 with 89% Grade C/D disease	74%	57%	MAGIC ² cohort, n=30 ³ propensity- controlled subset								
	Salvage Therapy	Treatment Setting									
Expanded Access Protocol (EAP275), n=241	66%	na									
EAP275, n=51 Grade D subset	51%	31%	CIBMTR dbase, n=327 ⁴ propensity controlled subset								
1. GVHD001 had 55 randomized patients, however one patient dropped out before receiving any dose of remesterncel-L; 2. Mount Sinai Acute GVHD International Consortium (MAGIC) - a group of ten BMT centers throughout the US and Europe whose purpose is to conduct ground breaking clinical trials in GVHD, including developing informative biorepositories that assist in developing treatments that can guide GVHD as the provide the US and Europe whose purpose is to conduct ground breaking clinical trials in GVHD, including developing informative biorepositories that assist in developing treatments that can guide GVHD as the provide the US and Europe whose purpose is the MAGIC contrading to the subjects are excluded from the respective survival analyses; 4. Data on Title											

Long term Survival in Pediatric Patients with SR-aGVHD Treated with Remestemcel-L

Presented at the 2023 Tandem Meeting of ASTCT and CIBMTR



Extended Survival Data in Children with SR-aGVHD

Remestemcel-L Treatment Resulted in Durable Survival Over 4 Years

Survival Outcomes in Pediatric & Adult SR-aGVHD (Remestemcel-L data from the Center for International Blood and Marrow Transplant Research (CIBMTR) dbase)										
Study	GVHD001	MacMillan et al ¹	Rashidi et al ²	REACH2 ³	REACH2 ³	REACH1 ⁴				
Treatment	Remestemcel-L	BAT ⁵	BAT ⁵	BAT⁵	Ruxolitinib	Ruxolitinib				
N=	51	128	203	155	154	71				
Subjects	Children	Children	Adults	Adults	Adults	Adults				
aGVHD Grade	88% Grade C/D	22% Grade 3/4	54% Grade 3/4	63% Grade 3/4	63% Grade 3/4	68% Grade 3/4				
Year 1 Survival 63%		40%		44%	49%	43%				
Year 2 Survival	51%	35%	25%	36%	38%					
Year 3 Survival	49%									
Year 4 Survival	49%									

. MacMillan ML et al. Pediatric a .Rashidi A et al. Outcomes and p Zeiser R et al. Ruxolitinib for Glu Jagasia M et al. Ruxolitinib for th BAT = Best Aun^{3/2+1} ont steroids. Bone Marrow Transplant 2020; 55(1): 165-171 ff-verus-host disease: single-center results from a cohort of 203 patients. Biol Blood Bone Marrow Transplant 2019; 25(11):2297-2302. sess. R Furg JI Med 2020;382:1803-01 CH1): a multicenter, open-label phase 2 trial. Blood. 2020 May 14; 135(20): 1739–1749

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	Pa	athway to Approval for RYONCIL in Pediatric Patients with SR-aGVHD
	-	During the Biologics License Application (BLA) review we made substantial progress towards bringing this cutting-edge product to market with a completed FDA inspection of our manufacturing process.
	7	In August FDA provided a complete response requiring Mesoblast to provide additional potency assay data confirming that product used in the Phase 3 trial is similar to product intended for commercial release, as measured by a standardized potency assay.
	7	At the Type A meeting in September, Mesoblast presented clinical data indicating that treatment with the improved RYONCIL product version of remestemcel-L, manufactured using the current process inspected by FDA, resulted in consistently high survival rates in children with SR-aGVHD.
	7	Similarly high survival rates were seen whether using product made for the Phase 3 clinical trial MSB-GVHD001 between 2015-2018 or made with the validated manufacturing process proposed for commercial release and used under Emergency Investigational New Drug (EIND) protocol through 2023.
	-	Mesoblast believes that the totality of these clinical studies, together with additional potency assay data currently being generated using the IL-2R alpha inhibition potency assay in place during the pediatric Phase 3 trial, will both support approval for the pediatric indication and provide a link between the RYONCIL product that was used in the pediatric Phase 3 trial and available commercial inventory.
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RYONCIL for Adults with SR-aGVHD

- Commercial strategy is to progress to adults who have failed steroids and a first-line agent, including ruxolitinib
- Market opportunity approximately five times larger than pediatric
- Approximately 45% of ruxolitinib patients are non-responders ¹
- Survival in adults with SR-aGVHD who have failed at least one additional agent, such as ruxolitinib, is 20-30% by 100 days ^{1,2}
- In contrast, 100-day survival was 63% after remestemcel-L treatment was used under compassionate care in 71 patients aged 12 and older with SR-aGVHD who failed to respond to at least one additional agent, such as ruxolitinib
- In its September 2023 draft guidance to industry for development of agents to treat aGVHD, the FDA stated that a marketing application in a population with refractory aGVHD where there are no approved therapies might be supported by positive results from a single-arm trial.³
- The Blood and Marrow Transplant Clinical Trials Network (BMT CTN), a body responsible for approximately 80% of all US transplants, is expected to conduct the pivotal trial of RYONCIL in this adult population at a fraction of the cost of a traditional contract research organization (CRO)
- 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
 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
 US FDA. Graft-versus-Host Diseases: Developing Drugs, Biological Products, and Certain Devices for Prevention or Treatment Guidance for Industry. Draft Guidance. Sep 2023 m es oblast





Thank You



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28 November 2023

Mesoblast Limited (MSB) Results of Annual General Meeting Held 28 November 2023

In accordance with ASX Listing Rule 3.13.2 and section 251AA of the Corporations Act 2001 (Cth), we advise details of the resolutions and the proxies received in respect of each resolution as per the attached report.

All resolutions were passed and decided by way of a poll.

Release authorized by the Chief Executive.

Yours faithfully

Divashim

Niva Sivakumar Company Secretary

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MESOBLAST LIMITED

ANNUAL GENERAL MEETING Tuesday, 28 November, 2023

As required by section 251AA(2) of the Corporations Act 2001 (Commonwealth) the following statistics are provided in respect of each resolution on the agenda.

Resolution Voted on at the meeting			Pro	xy Votes (as at proxy	close)	Total votes cast in the poll (where applicable)			
No	Short Description	Strike Y/N/NA	For	Against	Discretionary (open votes)	Abstain	For	Against	Abstain **
02	ADOPTION OF THE REMUNERATION REPORT	N	149,477,371 93.88%	8,305,115 5.22%	1,440,491 0.90%	1,272,057	155,330,428 94.17%	9,618,269 5.83%	1,274,057
03	AMENDMENT TO THE CONSTITUTION	NA	224,442,048 98.44%	2,048,454 0.90%	1,503,898 0.66%	1,716,180	230,183,413 98.77%	2,857,390 1.23%	2,650,383
04A	RE-ELECTION OF MR PHILIP FACCHINA AS A DIRECTOR	NA	217,094,196 95.28%	9,294,475 4.08%	1,463,285 0.64%	1,858,624	223,557,605 95.68%	10,102,411 4.32%	2,031,170
04B	RE-ELECTION OF MR WILLIAM BURNS AS A DIRECTOR	NA	140,979,534 61.87%	85,530,397 37.54%	1,337,935 0.59%	1,862,714	146,975,404 62.86%	86,853,068 37.14%	1,862,714
05A	APPROVAL OF PROPOSED ISSUE OF OPTIONS TO DR SILVIU ITESCU IN CONNECTION WITH HIS LONG-TERM INCENTIVE REMUNERATION FOR THE 2023/2024 FINANCIAL YEAR	NA	137,170,523 86.44%	20,188,991 12.72%	1,332,046 0.84%	1,812,474	142,406,440 86.61%	22,012,840 13.39%	1,812,474
05B	APPROVAL OF PROPOSED ISSUE OF OPTIONS TO DR SILVIU ITESCU IN LIEU OF 30% OF BASE SALARY	NA	151,612,638 95.22%	6,277,596 3.94%	1,339,430 0.84%	1,274,370	156,973,939 95.16%	7,983,445 4.84%	1,274,370
06A	APPROVAL OF PROPOSED ISSUE OF OPTIONS TO DR ERIC ROSE IN CONNECTION WITH HIS LONG-TERM INCENTIVE REMUNERATION FOR THE 2023/2024 FINANCIAL YEAR	NA	136,735,754 86.17%	20,611,324 12.99%	1,337,930 0.84%	1,819,026	142,150,101 86.46%	22,262,627 13.54%	1,819,026
06B	APPROVAL OF PROPOSED ISSUE OF OPTIONS TO DR ERIC ROSE IN LIEU OF 30% OF BASE SALARY	NA	151,748,972 95.35%	6,034,788 3.79%	1,366,438 0.86%	1,353,836	167,309,827 95.41%	7,568,091 4.59%	1,353,836
07	APPROVAL OF PROPOSED ISSUE OF OPTIONS TO NON-EXECUTIVE DIRECTORS	NA	131,439,612 82.92%	25,680,553 16.20%	1,394,242 0.88%	1,989,627	136,526,295 83.13%	27,715,832 16.87%	1,989,627
08	APPROVAL OF PROPOSED ISSUE OF OPTIONS TO DIRECTOR, DR PHILIP KRAUSE	NA	137,744,446 86.65%	19,833,046 12.48%	1,388,538 0.87%	1,538,004	142,975,561 86.91%	21,542,566 13.09%	1,713,627

Printed: 28/11/2023

This report was produced from the Link Market Services Meeting System

MESOBLAST LIMITED



RESULT OF ANNUAL GENERA MEETING (ASX REPORT)

ANNUAL GENERAL MEETING Tuesday, 28 November, 2023

As required by section 251AA(2) of the Corporations Act 2001 (Commonwealth) the following statistics are provided in respect of each resolution on the agenda.

	Resolution Voted on at the meeting		Pro	xy Votes (as at proxy	close)	Total votes cast in the poll (where applicable)			
No	Short Description	Strike Y/N/NA	For	Against	Discretionary (open votes)	Abstain	For	Against	Abstain **
09	RATIFICATION OF ISSUE OF SECURITIES TO INSTITUTIONAL INVESTORS	NA	184,487,236 94.85%	8,563,242 4.40%	1,446,027 0.74%	21,507,994	190,886,855 95.22%	9,587,179 4.78%	21,511,071

** - Note that votes relating to a person who abstains on an item are not counted in determining whether or not the required majority of votes were cast for or against that item

Printed: 28/11/2023

This report was produced from the Link Market Services Meeting System