
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 2024

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 15, 2024, Mesoblast Limited filed with the Australian Securities Exchange a Final Director's Interest Notice (Appendix 3Z), which is attached hereto as Exhibit 99.1, and is incorporated herein by reference.

On November 15, 2024, Mesoblast Limited filed with the Australian Securities Exchange the Chair'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/ Niva Sivakumar

Niva Sivakumar
Company Secretary

Dated: November 18, 2024

INDEX TO EXHIBITS

Item	
99.1	Final Director's Interest Notice, Joseph Swedish, dated November 15, 2024.
99.2	Chair's Annual General Meeting address, dated November 15, 2024.
99.3	CEO Presentation to Annual General Meeting, dated November 15, 2024.
99.4	Results of Annual General Meeting, dated November 15, 2024.

Appendix 3Z

Final Director's Interest Notice

Information or documents not available now must be given to ASX as soon as available. Information and documents given to ASX become ASX's property and may be made public.

Introduced 30/9/2001.

Name of entity Mesoblast Limited
ABN 68 109 431 870

We (the entity) give ASX the following information under listing rule 3.19A.3 and as agent for the director for the purposes of section 205G of the Corporations Act.

Name of director	Joseph Swedish
Date of last notice	15 January 2024
Date that director ceased to be director	15 November 2024

Part 1 – Director's relevant interests in securities of which the director is the registered holder

In the case of a trust, this includes interests in the trust made available by the responsible entity of the trust

Note: In the case of a company, interests which come within paragraph (i) of the definition of "notifiable interest of a director" should be disclosed in this part.

<p>Number & class of securities</p> <p>1,327,077 options*</p> <p>*Please note, Mr Swedish will be issued 28,510 options following shareholder approval received at the 2024 Annual General Meeting.</p>
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+ See chapter 19 for defined terms.

Appendix 3Z
Final Director's Interest Notice

Part 2 – Director's relevant interests in securities of which the director is not the registered holder

Note: In the case of a company, interests which come within paragraph (ii) of the definition of "notifiable interest of a director" should be disclosed in this part.

In the case of a trust, this includes interests in the trust made available by the responsible entity of the trust

Name of holder & nature of interest	Number & class of securities
<p>Note: Provide details of the circumstances giving rise to the relevant interest</p> <p>Interest in ordinary shares held in the form of American Depositary Shares ("ADSs") held by custodian JP Morgan Nominees Australia Pty Limited.</p> <p>Joseph R. Swedish Revocable Trust is the owner of the ADS (Joseph Swedish is the beneficial owner of these securities)</p>	<p>45,942 ADS, representing 459,420 ordinary shares</p>

Part 3 – Director's interests in contracts

Detail of contract	N/A
Nature of interest	N/A
Name of registered holder (if issued securities)	N/A
No. and class of securities to which interest relates	N/A

+ See chapter 19 for defined terms.

CHAIR'S ADDRESS TO SHAREHOLDERS

2024 ANNUAL GENERAL MEETING

Good afternoon shareholders. Welcome to the 2024 Mesoblast Annual General Meeting. It is a pleasure to deliver my first address to you as Chair of this innovative and exciting company.

This year has seen our Company make significant advances as a leading developer of innovative allogeneic cellular medicines with an extensive clinical-stage pipeline of therapeutic assets validated by clinical data that address serious and life-threatening inflammatory illnesses. Our key areas of focus remain cardiovascular disease, chronic low back pain, and acute life-threatening inflammatory conditions including graft versus host disease (GvHD).

Through the leadership of our Chief Executive Officer and Managing Director (CEO and MD), Dr Silviu Itescu and his team we have made tremendous strides in the past year in our engagement with regulators, in clinical development of our lead products, and in preparedness for product commercialization.

2024 has been pivotal in our journey toward commercializing our therapies. Our positive interactions with the United States Food and Drug Administration (FDA) allowed us to resubmit the Biologics License Application (BLA) for approval of Ryoncil® (remestemcel-L) for steroid-refractory acute GvHD in children, and work towards filing for accelerated approval of Revascor® (rexlemestrocel-L) in end-stage heart failure patients. As the current review for approval of RYONCIL progresses, our focus has turned to implementing the commercialization strategies that will allow us to successfully launch RYONCIL, a much-needed treatment for desperately ill children, upon FDA approval.

In addition, we received a number of important designations from the Agency for our program in congenital heart disease including a rare pediatric disease designation and we commenced a pivotal Phase 3 trial of rexlemestrocel-L for chronic low back pain and expect to accelerate patient enrollment across multiple centers in the U.S. over the coming year.

Our balance sheet has been well-managed, including recently securing access to US\$50 million to fund our planned commercial launch on approval of RYONCIL, while at the same time maintaining financial discipline through the implementation of cost reduction strategies to maximize our financial runway.

I would like to express my sincere gratitude to our shareholders for your continued trust and support. Furthermore, I would like to acknowledge the significant contribution from my predecessor and retiring board member Mr Joseph Swedish who admirably chaired the Company from 2019 to April 2024.

As we plan for 2025 and beyond, I am very optimistic about Mesoblast's future. The strength of our science, the dedication of our impressive team, and the support of our shareholders position us to achieve our goal of delivering transformative therapies to patients in need. Together, we are on the cusp of realizing the full potential of Mesoblast's transformative allogeneic cellular medicines, and I look forward to sharing our success with you in the year ahead.

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.

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Mesoblast has a strong and extensive global intellectual property portfolio with protection extending through to at least 2041 in all major markets. The Company's proprietary manufacturing processes yield industrial-scale, cryopreserved, off-the-shelf, cellular medicines. These cell therapies, with defined pharmaceutical release criteria, are planned to be readily available to patients worldwide.

Mesoblast is developing product candidates for distinct indications based on its remestemcel-L and rexlemestrocel-L allogeneic stromal cell technology platforms. Remestemcel-L is being developed for inflammatory diseases in children and adults including steroid refractory acute graft versus host disease, and biologic-resistant inflammatory bowel disease. Rexlemestrocel-L is being developed for advanced chronic heart failure and chronic low back pain. Two products have been commercialized in Japan and Europe by Mesoblast's licensees, and the Company has established commercial partnerships in Europe and China for certain Phase 3 assets.

Mesoblast has locations in Australia, the United States and Singapore and is listed on the Australian Securities Exchange (MSB) and on the Nasdaq (MESO). For more information, please see www.mesoblast.com, LinkedIn: Mesoblast Limited and Twitter: @Mesoblast

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 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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Mesoblast Limited
ABN 68 109 431 870

www.mesoblast.com



Global Leader in Allogeneic Cellular Medicines for Inflammatory Diseases

Annual General Meeting 2024

November 2024
ASX: MSB; Nasdaq: MESO



CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This presentation 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. All statements other than statements of historical facts contained in this presentation are forward-looking statements. Words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "intend," "plan," "targets," "likely," "will," "would," "could," and similar expressions or phrases identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and future events, recent changes in regulatory laws, and financial trends that we believe may affect our financial condition, results of operation, business strategy and financial needs. These statements may relate to, but are not limited to: expectations regarding the safety or efficacy of, or potential applications for, Mesoblast's adult stem cell technologies; expectations regarding the strength of Mesoblast's intellectual property, the timeline for Mesoblast's regulatory approval process, and the scalability and efficiency of manufacturing processes; expectations about Mesoblast's ability to grow its business and statements regarding its relationships with current and potential future business partners and future benefits of those relationships; statements concerning Mesoblast's share price or potential market capitalization; and statements concerning Mesoblast's capital requirements and ability to raise future capital, among others. 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. You should read this presentation together with our financial statements and the notes related thereto, as well as the 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, include, without limitation: risks inherent in the development and commercialization of potential products; uncertainty of clinical trial results or regulatory approvals or clearances; government regulation; the need for future capital; dependence upon collaborators; and protection of our intellectual property rights, among others. 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.

Mesoblast is committed to bringing to market innovative off-the-shelf allogeneic cellular medicines to treat serious and life-threatening inflammatory illnesses

Our Mission





Corporate Vision

To be the 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

Global Leader in allogeneic cellular medicines for inflammatory diseases

- ✓ World leader in developing allogeneic (off-the-shelf) cellular medicines for the treatment of severe and life-threatening inflammatory conditions
- ✓ Locations in Australia, the United States and Singapore
- ✓ Listed on the ASX (MSB) and NASDAQ (MESO)
- ✓ Developing product candidates for distinct indications based on its remestemcel-L and rexlemestrocel-L stromal cell technology platforms
- ✓ Extensive global intellectual property portfolio with protection extending through to at least 2041 in all major markets
- ✓ FDA-inspected commercial scale manufacturing process and facilities



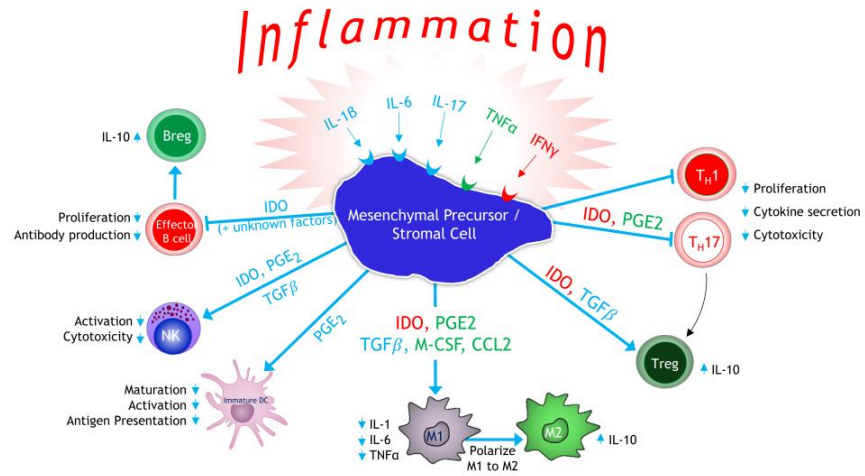
Phase 3 trials
in **THREE**
major
indications

more than
1,100
patents &
applications

TWO products
with clinical
data sufficient
for FDA
regulatory
review

Platform Technology - shared mechanism of action across our products

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



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



US patent exclusivity for use of mesenchymal precursor / stromal cells for all indications, and for acute GVHD specifically, provides a major commercial barrier against potential competitors

- “Composition of matter” and “method of treatment” US patents have been granted for RYONCIL and other mesenchymal precursor / stromal cell products to treat GVHD through to 2032.

Upon FDA approval patent term may be extended up to 5 years to 2037.

- Multiple “composition of matter”, “method of treatment” and “manufacturing” patent applications have recently been filed and are still undergoing examination.

These applications have the potential to extend coverage through to 2043 for the use of various types of mesenchymal precursor / stromal cells, including bone marrow or iPS derived for the treatment of various indications including GVHD.



Composition of Matter



Manufacturing



Method of Treatment

Late-Stage Clinical Pipeline based on proprietary allogeneic mesenchymal precursor / stromal cell platform

Product	Indication	Phase 2	Phase 3	Regulatory Filing	Approved
RYONCIL® remestemcel-L	Pediatric SR-aGVHD	▶▶			
	Adult SR-aGVHD	▶▶			
RYONCIL® remestemcel-L	IBD / Crohn's	▶▶			
REVASCOR® rexlemestrocel-L (STRO3+)	Pediatric HLHS	▶▶			
	Adult HFrEF End-stage	▶▶			
	Adult HFrEF Class II/III	▶▶			
Rexlemestrocel-L (STRO3+)	CLBP	▶▶			

SR-aGVHD = Steroid-Refractory Acute Graft Versus Host Disease;
 IBD = Inflammatory Bowel Disease; HLHS = Hypoplastic Left Heart Syndrome
 HFrEF = Heart Failure with Reduced Ejection Fraction;
 CLBP = Chronic Low Back Pain;

This chart is figurative and does not purport to show individual trial progress within a clinical program

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.
- Tasty Pharmaceuticals has exclusive rights for rexlemestrocel-L for the treatment or prevention of chronic heart failure in China.

Mesoblast expects to substantially advance its multiple product pipeline toward FDA approvals over the next six to twelve months

	Program	Key Objectives
1	RYONCIL Steroid-Refractory Acute-Graft versus Host Disease	<i>Resubmitted BLA for approval in pediatric patients with FDA accepting the submission within two weeks. PDUFA date Jan 7th 2025</i> <i>Study in adult patients for label extension to follow pediatric approval</i>
2	Rexlemestrol-L Chronic Low Back Pain	<i>CLBP Phase 3 trial actively enrolling at multiple sites across the U.S.</i> <i>The 300-patient randomized, placebo-controlled trial has a 12-month primary endpoint of pain reduction</i>
3	REVASCOR Heart Failure	<i>Heart failure in children with congenital heart disease, adults with low ejection fraction heart failure (HFrEF)</i> <i>Preparing for accelerated approval filing</i>

Financials

- ▀ Cash balance at September 30, 2024 is US\$51.1 million, with additional US\$60.0 million available from existing financing facilities on FDA approval of RYONCIL.
- ▀ Net operating cash spend of US\$10.5 million for the quarter ended September 30, 2024.
- ▀ 26% reduction in net operating cash spend for the quarter ended September 30, 2024 versus the comparative quarter in FY2024.
- ▀ On September 30, 2024 entered into a convertible note subscription agreement with our largest shareholder for issue, at Mesoblast's sole discretion, up to US\$50.0 million convertible notes on approval of RYONCIL by FDA.



Remestemcel-L

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

RYONCIL for steroid-refractory acute graft versus host disease (SR-aGVHD)

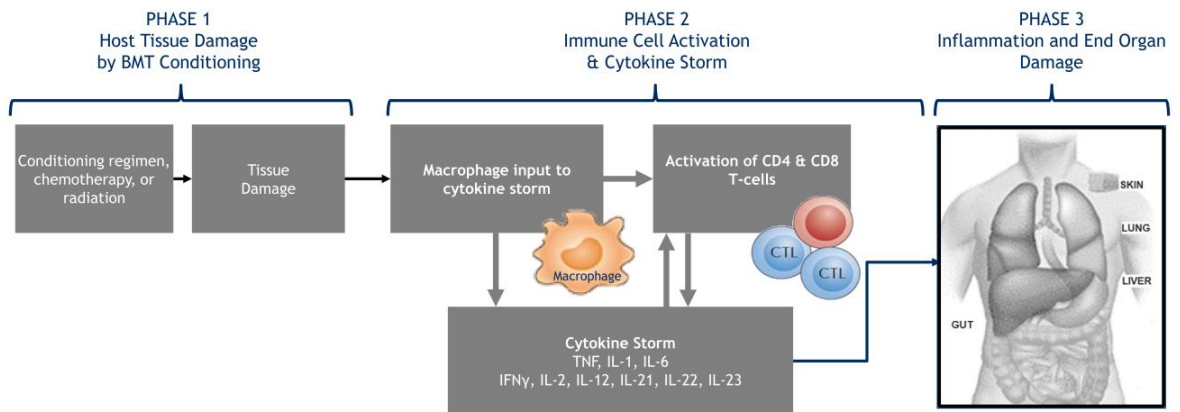
Product	Indication	Phase 2	Phase 3	Regulatory Filing	Approved
RYONCIL® remestemcel-L	Pediatric SR-aGVHD				
	Adult SR-aGVHD				

This chart is figurative and does not purport to show individual trial progress within a clinical program

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).

Acute Graft Versus Host Disease (aGVHD) is a serious and potentially fatal complication of allogeneic bone marrow transplantation (BMT)



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

Treatment Options

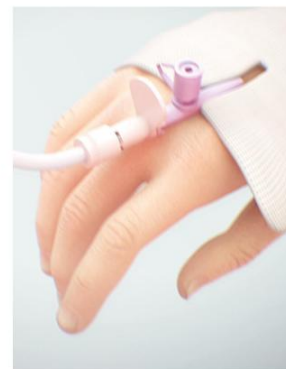
- Corticosteroids are first-line therapy for aGVHD
- There is only one approved treatment for disease refractory to steroids and no approved treatment in the US for children under 12 years old
- In Japan, Mesoblast's licensee received the first product approval for SR-aGVHD in both children and adults

Burden of Illness

- 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

Market Opportunity

- More than 30,000 allogeneic BMTs performed globally (>20K US/EU) annually, ~20% pediatric^{2,3}
- Approx. 10,000 allogeneic BMTs performed in the US annually
- Approx. 1,500 allogeneic 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, CIBMTR, 2020 4. Axt L, Naumann 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*.

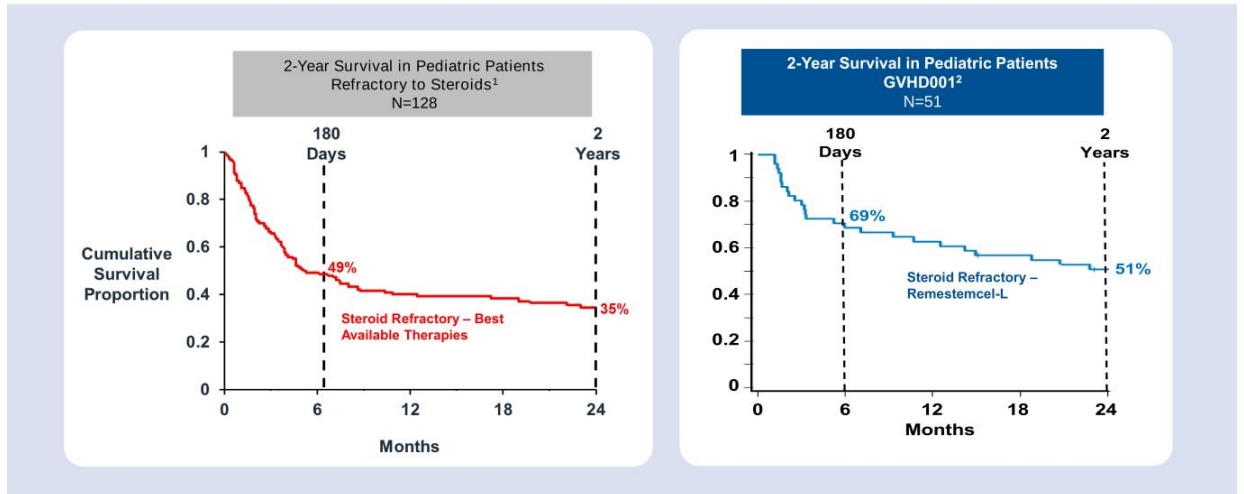
Remestemcel-L for Children with SR-aGVHD

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

Day 100 Survival			
Remestemcel-L Protocol	Remestemcel-L	Matched Controls	Matched Control Protocol
First Line Therapy after Steroids Treatment Setting			
1. Pediatric Subset of Protocol 280: randomized controlled P3, n=27 w/SR-aGVHD	79%	54%	Study Control Arm (n=13)
2. Study 001, open-label P3, n=54 ¹ with 89% Grade C/D disease	74%	57%	MAGIC ² cohort, n=30 ³ propensity-controlled subset
Salvage Therapy Treatment Setting			
3. Expanded Access Protocol (EAP275), n=241	66%	na	

16 1. GVHD001 had 55 randomized patients, however one patient dropped out before receiving any dose of remestemcel-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 therapy; 3. Two subjects in the MAGIC cohort had follow-up <100 days; these subjects are excluded from the respective survival analyses; 4. Data on file

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



1. Adapted and redrawn from Figure 2 of MacMillan, M.L. et al. Pediatric acute GVHD: clinical phenotype and response to upfront steroids. *Bone Marrow Transplant* 55, 165–171 (2020);
 2. CIBMTR – Center for International Blood & Bone Marrow Transplantation Research. Clinical Outcomes of Pediatric Patients Treated with Remestemcel-L for Steroid-Refractory Acute Graft Versus-Host Disease on a Phase 3, Single-Arm, Prospective Study (Nov 2022)
 ASTCT = American Society for Transplantation and Cellular Therapy; CIBMTR = Center for International Blood and Marrow Transplant Research

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	BAT ⁵	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%					

1. MacMillan ML et al. Pediatric acute GVHD: clinical phenotype and response to upfront steroids. Bone Marrow Transplant 2020; 55(1): 165-171
2. Rashidi A et al. Outcomes and predictors of response in steroid-refractory acute graft-versus-host disease: single-center results from a cohort of 203 patients. Biol Blood Bone Marrow Transplant 2019; 25(11):2297-2302.
3. Zeiser R et al. Ruxolitinib for Glucocorticoid-Refractory Acute Graft-versus-Host Disease. N Engl J Med 2020;382:1800-10.
4. 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
5. BAT = Best Available Treatment

Potential FDA approval of RYONCIL for pediatric patients with SR-aGVHD

- ▀ Mesoblast resubmitted its Biologics License Application (BLA) to FDA for approval of RYONCIL on July 8, 2024 and anticipates a decision prior to or on the FDA's Prescription Drug User Fee Act (PDUFA) goal date of January 7, 2025.
- ▀ Mesoblast and FDA continue to be engaged in active and ongoing interactions as part of the review process.
- ▀ FDA has already conducted the Pre-License Inspection (PLI) of the manufacturing process for RYONCIL in May 2023 and this did not result in the issuance of any Form 483.
- ▀ Inventory has been manufactured and there is an established supply chain to ensure cryopreserved product is available for delivery to meet the needs of each site immediately post approval, with ability to scale up as necessary going forward
- ▀ Mesoblast strategy is to first gain pediatric approval for RYONCIL, followed by label extension in the larger adult population.

Pre-Launch Activities For Go to Market Strategy - RYONCIL in Pediatric Patients

- ▣ Hiring of select senior positions to build targeted commercial team has commenced
- ▣ Key Activities:
 - Market Access initiates payer outreach
 - Medical provides education to payers
 - Corporate leadership initiates engagement with highest volume centers
 - Regional sales directors lead center profiling
- ▣ Ongoing KOL engagement with greatest experience using RYONCIL at highest volume centers
- ▣ Non-promotional activities including profiling high-volume centers, education on disease awareness & unmet needs, and payer engagement

Post-Launch Activities For Go to Market Strategy - RYONCIL in Pediatric Patients

- ▣ Post-launch - Staged approach based on centers with highest volume and experience with product.
- ▣ Targeted sales force with experience in bone marrow transplant centers - 15 highest volume centers account for ~50% of patients.
- ▣ Key Activities:
 - Initiate commercial onboarding & logistics at centers
 - MSAs engage centers around medical & scientific needs
 - Logistical and reimbursement support offered as needed
 - Center certification for remestemcel-L administration

Label extension strategy for RYONCIL in adult patients with SR-aGVHD

- Continued unmet need in adults with SR-aGVHD who fail ruxolitinib (>40% of treated patients).
- Survival in these patients who fail ruxolitinib remains a dismal 20-30% by 100 days, a patient population with no approved therapies.^{1,2}
- 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.
- Following approval in pediatric patients, Mesoblast intends to commence a Phase 3 trial of RYONCIL in adults and adolescents with SR-aGVHD who are refractory to a second line agent such as ruxolitinib.
- Mesoblast is collaborating with the Blood and Marrow Transplant Clinical Trials Network (BMT CTN), a NIH-funded body responsible for approximately 80% of all US transplants, to conduct the trial.


1. 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.
2. 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.



Rexlemestrocel-L

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

Rexlemestrocel-L for chronic low back pain

Product	Indication	Phase 2	Phase 3	Regulatory Filing	Approved
Rexlemestrocel-L (STRO3+)	CLBP				

This chart is figurative and does not purport to show individual trial progress within a clinical program

Notes:

- Grünenthal has an exclusive license to develop and commercialize rexlemestrocel-L for chronic low back pain in Europe and Latin America/Caribbean.

Chronic low back pain due to degenerative disc disease (CLBP) impacts 7M+

Burden of Illness

- ▶ Back pain causes more disability than any other condition¹
- ▶ Inflicts substantial direct and indirect costs on the healthcare system,¹ including excessive use of opioids in this patient population

Treatment Options

- ▶ 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 CLBP²
- ▶ Durable improvement in pain has potential to reduce opioid use and prevent surgical intervention

Market Opportunity

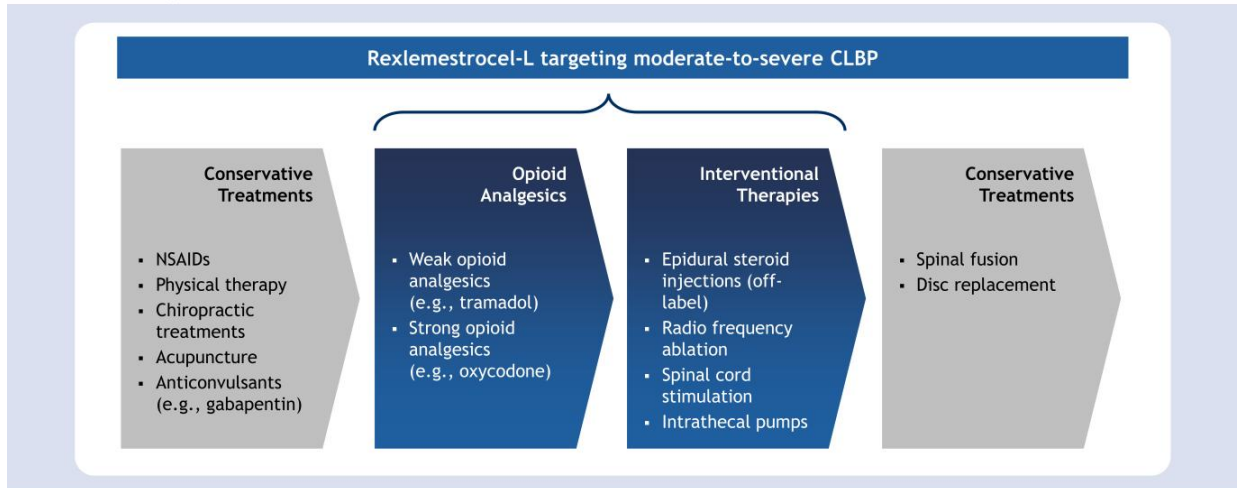
- ▶ Over 7m patients are estimated to suffer from CLBP due to degenerative disc disease (DDD) in each of the U.S. and E.U.³⁻⁴



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.

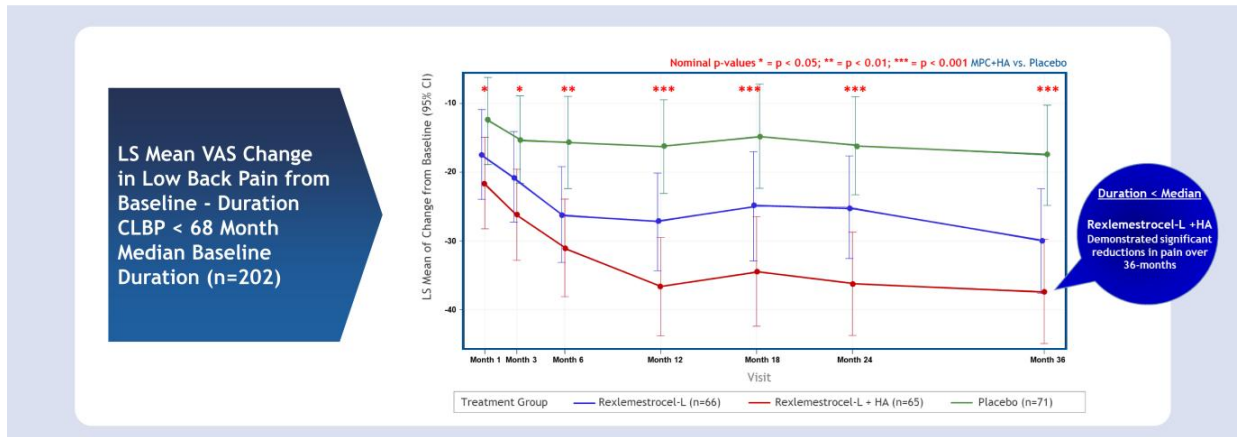
Patients with CLBP refractory to standard treatment have minimal options

Rexlemestrocel-L has potential to be first-line treatment for patients with moderate to severe CLBP, refractory to conservative treatment



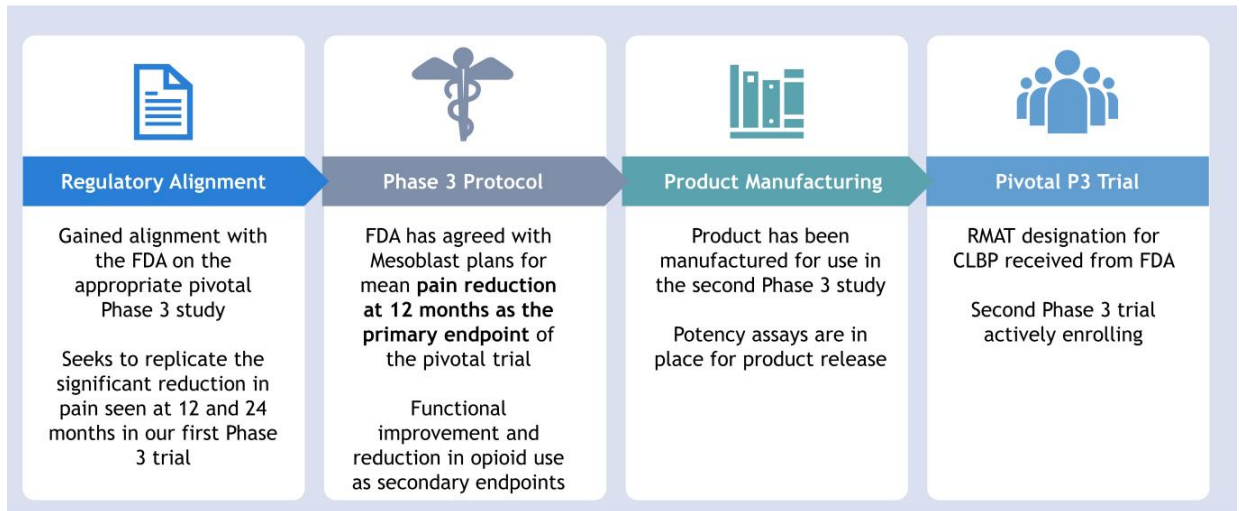
Phase 3 trial outcomes based on a single injection of rexlemestrocel-L + HA showed more than three years of pain reduction

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



VAS=Visual Analog Score; HA=Hyaluronic Acid

Rexlemestrocel-L / CLBP - program summary





Rexlemestrocel-L

Heart Failure

REVASCOR for pediatric congenital heart disease and adults with ischemic HFrEF

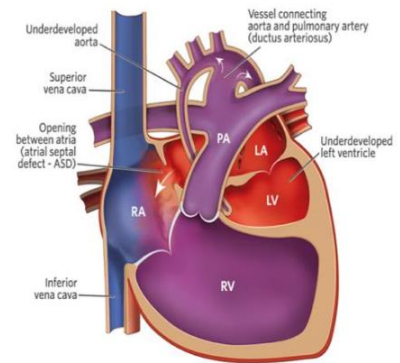
Product	Indication	Phase 2	Phase 3	Regulatory Filing	Approved
REVASCOR® rexlimestrocel-L (STRO3+)	Pediatric HLHS				
	Adult HFrEF End-stage				
	Adult HFrEF Class II/III				

This chart is figurative and does not purport to show individual trial progress within a clinical program

Pediatric: REVASCOR As treatment for severe congenital heart disease

- REVASCOR has multiple mechanisms-of-action that may be beneficial to children with congenital heart disease including neovascularization, anti-fibrosis, and reduction in inflammation.
- Hypoplastic left heart syndrome (HLHS) is a severe congenital heart disease in which the left ventricle (LV) is underdeveloped and cannot pump oxygenated blood to the rest of the body.
- Current definitive surgical procedure (Fontan) is life-saving, but maintains only a functional right ventricle (RV), resulting in progressive right heart failure, liver congestion, liver fibrosis and cirrhosis
- Creation of permanent two-ventricle circulation with LV pumping blood to the body would avoid the complications of Fontan procedure, but is limited to 30% whose LV is sufficiently large.
- Clinical trial at Boston Children's Hospital evaluated whether REVASCOR could increase LV size and increase the proportion of children capable of receiving permanent two-ventricle surgery.

Anatomy of hypoplastic left heart syndrome



Pediatric: REVASCOR as treatment for severe congenital heart disease

- 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, 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, liver cirrhosis, and death.
- The study showed 63% (5/8) of the REVASCOR treated HLS children vs 34% (4/11) of the controls went to full BiV conversion at 12 months post LV recruitment surgery. This represents a 75% increase in the rate of the optimal outcome.

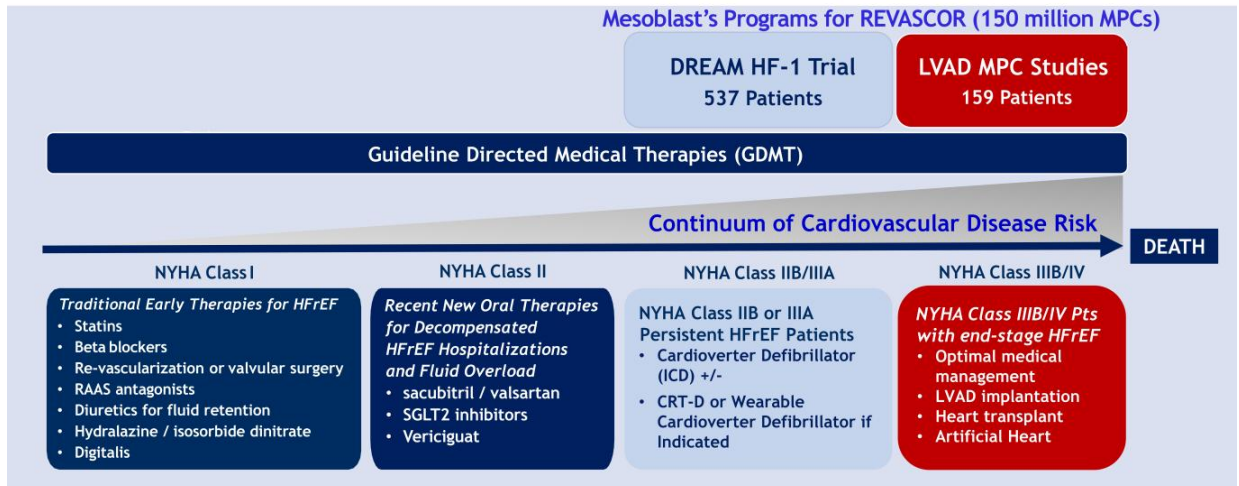
Pediatric: FDA awarded Rare Pediatric Disease designation and Orphan Drug designation to REVASCOR for hypoplastic left heart syndrome

- FDA granted Mesoblast's cardiovascular investigational product, REVASCOR, both Rare Pediatric Disease Designation (RPDD) and Orphan Drug Designation (ODD) this year. 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.
- 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.
- On FDA approval of a 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 whether the randomized controlled study can be used to obtain regulatory approval for REVASCOR in children with this life-threatening condition.

Adult: Heart failure with low ejection fraction (HFrEF) and underlying ischemia is increasing in prevalence and associated with high risk of mortality, heart attacks and strokes

- ▶ Heart failure affects 6.5 million patients in the US alone, with prevalence increasing.¹
- ▶ Chronic heart failure (CHF) is a progressive disease with a high mortality that approaches 50% at 5 years^{1,2} and at least 75% after an initial hospitalization.³
- ▶ Heart failure with low ejection fraction (HFrEF) is associated with greater mortality, occurs in approximately 50% of all patients.
- ▶ Over 60% of HFrEF patients have underlying ischemia and these are at highest risk of recurrent major adverse cardiac events involving large vessels (heart attacks / strokes).

REVASCOR has the potential to improve endothelial dysfunction in HFrEF patients across the spectrum of disease from mild-moderate to end-stage patients with a left ventricular assist device (LVAD)



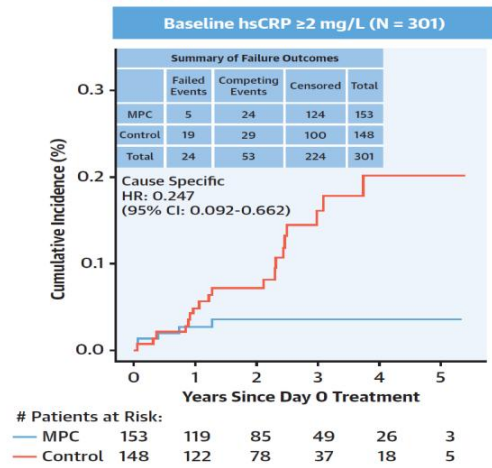
Randomized Trial of Targeted Transcatheter Mesenchymal Precursor Cell Therapy in Patients With Heart Failure



Perin EC, Borow KM, Henry TD, et al. Randomized Trial of Targeted Transcatheter 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 rexlumestrol-L over mean follow-up 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

FIGURE 4 Risk of Myocardial Infarction or Stroke



Pathway to accelerated approval for REVASCOR in adults with HFrEF

- DREAM-HF Trial over a mean follow-up of 30 months showed significant reduction in 3-Point MACE in ischemic HFrEF patients (n=158).
- LVAD-MPC Study #2, over 12 months of follow-up, showed significant increase in proportion of LVAD recipients with ischemic HFrEF etiology successfully weaned (n=70), with significant reduction in hospitalizations and mortality.
- At Type B meeting in Q1 2024, FDA informed Mesoblast that the totality of the trial results from these studies may support an accelerated approval pathway for REVASCOR in end-stage ischemic HFrEF patients with LVADs.
- Mesoblast intends to request a pre-BLA meeting with FDA to discuss data presentation, timing and FDA expectations for an accelerated approval filing in ischemic HFrEF patients with end-stage heart failure.



Thank You



15 November 2024

Mesoblast Limited (MSB)
Results of Annual General Meeting Held 15 November 2024

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.

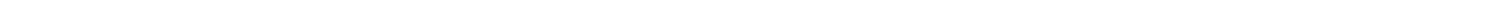
All resolutions were passed and decided by way of a poll.

Release authorized by the Chief Executive.

Yours faithfully

A handwritten signature in blue ink, appearing to read "Niva Sivakumar", written over a light blue horizontal line.

Niva Sivakumar
Company Secretary



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			Proxy 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	336,256,107 86.52%	49,830,936 12.82%	2,542,294 0.65%	1,098,531	347,641,785 87.26%	50,768,336 12.74%	1,098,531
03	RE-ELECTION OF DR PHILIP KRAUSE AS A DIRECTOR	NA	456,498,317 97.51%	8,973,589 1.92%	2,662,363 0.57%	1,095,374	468,886,464 98.11%	9,028,589 1.89%	1,095,374
04	PROPOSED ISSUE OF SHARES TO CHIEF MEDICAL OFFICER, DR ERIC ROSE, FOR HIS PARTICIPATION IN THE CAPITAL RAISING	NA	450,872,519 96.19%	15,327,732 3.27%	2,512,434 0.54%	513,552	461,692,463 96.56%	16,460,761 3.44%	853,797
05A	PROPOSED ISSUE OF OPTIONS TO DR SILVIU ITESCU IN CONNECTION WITH HIS LONG-TERM INCENTIVE REMUNERATION FOR THE 2024/2025 FINANCIAL YEAR	NA	356,877,801 91.71%	29,758,962 7.65%	2,500,374 0.64%	590,731	367,883,148 92.22%	31,034,773 7.76%	590,731
05B	PROPOSED ISSUE OF OPTIONS TO DR SILVIU ITESCU IN LIEU OF 30% OF BASE SALARY	NA	360,282,382 92.54%	26,486,318 6.80%	2,541,709 0.65%	417,459	371,657,475 93.13%	27,433,718 6.87%	417,459
05C	PROPOSED ISSUE OF OPTIONS TO DR SILVIU ITESCU IN CONNECTION WITH HIS SHORT-TERM INCENTIVE REMUNERATION FOR THE 2022/2023 AND 2023/2024 FINANCIAL YEARS	NA	334,447,425 86.04%	51,724,733 13.31%	2,550,374 0.66%	1,005,336	344,353,177 86.41%	54,150,139 13.59%	1,005,336
06A	PROPOSED ISSUE OF OPTIONS TO DR ERIC ROSE IN CONNECTION WITH HIS LONG-TERM INCENTIVE REMUNERATION FOR THE 2024/2025 FINANCIAL YEAR	NA	357,964,267 91.98%	28,691,581 7.37%	2,500,374 0.64%	571,646	369,147,025 92.53%	29,789,981 7.47%	571,646
06B	PROPOSED ISSUE OF OPTIONS TO DR ERIC ROSE IN LIEU OF 30% OF BASE SALARY	NA	360,214,155 92.55%	26,479,225 6.80%	2,508,384 0.64%	526,104	371,555,923 93.13%	27,426,625 6.87%	526,104
06C	PROPOSED ISSUE OF OPTIONS TO DR ERIC ROSE IN CONNECTION WITH HIS SHORT-TERM INCENTIVE REMUNERATION FOR THE 2022/2023 AND 2023/2024 FINANCIAL YEARS	NA	335,135,538 86.10%	51,595,306 13.26%	2,502,874 0.64%	494,150	344,856,343 86.43%	54,158,159 13.57%	494,150
07A	PROPOSED ISSUE OF MILESTONE-BASED OPTIONS TO DR PHILIP KRAUSE IN CONNECTION WITH HIS CONSULTANCY FEES FOR THE 2024/2025 FINANCIAL YEAR	NA	358,294,200 92.06%	28,363,304 7.29%	2,534,634 0.65%	545,730	369,596,129 92.64%	29,366,793 7.36%	545,730

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			Proxy 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 **
07B	PROPOSED ISSUE OF TIME-BASED OPTIONS TO DR PHILIP KRAUSE IN CONNECTION WITH HIS CONSULTANCY FEES	NA	364,351,460 93.63%	22,279,878 5.73%	2,527,134 0.65%	569,396	374,320,061 93.83%	24,599,195 6.17%	589,396
08	PROPOSED ISSUE OF OPTIONS TO INDEPENDENT NON-EXECUTIVE DIRECTORS	NA	359,328,448 92.45%	26,817,159 6.90%	2,527,134 0.65%	1,054,127	370,040,310 92.87%	28,413,215 7.13%	1,054,127
09	RATIFICATION OF ISSUE OF SECURITIES TO INSTITUTIONAL INVESTORS	NA	250,841,309 90.83%	22,799,016 8.26%	2,535,763 0.92%	36,514,579	260,561,950 91.28%	24,894,922 8.72%	37,014,579
10A	RATIFICATION OF GRANT OF WARRANTS RELATED TO CONVERTIBLE NOTE FINANCING	NA	269,542,800 97.35%	4,643,338 1.68%	2,690,670 0.97%	35,813,659	281,304,444 98.38%	4,643,338 1.62%	36,523,669
10B	PROPOSED ISSUE OF SECURITIES RELATED TO CONVERTIBLE NOTE FINANCING	NA	267,904,464 96.80%	6,166,205 2.23%	2,678,220 0.97%	35,941,778	279,653,458 97.84%	6,166,205 2.16%	36,651,788
11	RENEWAL OF PROPORTIONAL TAKEOVER APPROVAL PROVISIONS IN THE COMPANY'S CONSTITUTION	NA	461,465,855 98.85%	2,670,058 0.57%	2,686,999 0.58%	2,407,325	473,676,759 99.44%	2,670,058 0.56%	2,664,204

** - 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

