
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 August 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 August 29, 2024, Mesoblast Limited filed with the Australian Securities Exchange a new release announcement and investor presentation, which are attached hereto as [Exhibit 99.1](#) and [Exhibit 99.2](#) 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: August 29, 2024

INDEX TO EXHIBITS

Item

- [99.1](#) Press release of Mesoblast Ltd, dated August 29, 2024.
- [99.2](#) Investor presentation of Mesoblast Ltd, dated August 29, 2024.

asx announcement



MESOBLAST REPORTS FINANCIAL RESULTS AND OPERATIONAL UPDATE FOR FISCAL YEAR ENDED JUNE 30, 2024

Potential first product approval and preparing for commercial launch

Melbourne, Australia; August 29 and New York, USA; August 28, 2024: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today provided an operational update and reported financial results for the period ended June 30, 2024.

Mesoblast Chief Executive Silviu Itescu said: "During the past year we have built significant momentum in our interactions with the United States Food and Drug Administration (FDA) across each of our Phase 3 products.

I am very pleased that our Biologics License Application (BLA) resubmission for approval of Ryoncil® (remestemcel-L) in the treatment of children with steroid-refractory acute graft versus host disease (SR-aGVHD) was accepted by the FDA. We are in active discussions with the agency and anticipate a decision prior to or on the Prescription Drug User Fee Act (PDUFA) goal date of January 7, 2025. Concurrently we are implementing a go-to-market plan to bring RYONCIL to the many children suffering with this devastating disease, picking up the substantial amount of work completed last year."

"We have commenced enrolling patients across multiple U.S. sites in our confirmatory Phase 3 trial for inflammatory back pain which is in alignment with FDA, we have received a Rare Pediatric Disease Designation from FDA for Revascor® (rexlemestrocil-L) in children with a congenital heart disease, and have additionally been notified that FDA supports a potential accelerated approval pathway for REVASCOR in end-stage heart failure patients."

OPERATIONAL RESULTS FOR THE FULL-YEAR ENDED JUNE 30, 2024 (FY2024)

1. RYONCIL (REMESTEMCEL-L) FOR ACUTE GRAFT VERSUS HOST DISEASE IN CHILDREN

Potential FDA Approval

- Mesoblast resubmitted its BLA for approval of RYONCIL on July 8, 2024, addressing remaining CMC (Chemistry, Manufacturing, and Controls) items in the August 2023 Complete Response Letter (CRL).
- FDA previously informed Mesoblast that the available clinical data from its Phase 3 study appears sufficient to support resubmission of the BLA.
- FDA accepted the BLA resubmission within two weeks, considering it to be a complete response.
- Mesoblast and FDA are in ongoing interactions in relation to the active BLA review.
- 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.
- Mesoblast anticipates a decision prior to or on the FDA's Prescription Drug User Fee Act (PDUFA) goal date of January 7, 2025.

Activities For Go to Market Strategy

- Hiring of select senior positions to build targeted commercial team has commenced.
- Key Pre-Launch Activities include:
 - Market Access initiates payer outreach
 - Medical provides education to payers
 - Corporate leadership initiates engagement with Top 15 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 - 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.

2. RYONCIL (REMESTEMCEL-L) FOR ACUTE GRAFT VERSUS HOST DISEASE IN ADULTS

- Mesoblast strategy is to first gain pediatric approval for RYONCIL, followed by label extension in the larger adult population.
- As part of its label extension strategy for RYONCIL, Mesoblast is planning to conduct a study in the larger adult population once it has gained pediatric approval.
- 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.^{1,2} In contrast, 100-day survival was 67% after RYONCIL treatment was used under expanded access in 51 adults and children with SR-aGVHD who failed to respond to at least one additional agent, such as ruxolitinib.
- Mesoblast is collaborating with Blood and Marrow Transplant Clinical Trials Network (BMT CTN) in the United States, a body that is funded by the National Institutes of Health (NIH) and is responsible for approximately 80% of all US allogeneic BMTs, to conduct a pivotal trial in adults with SR-aGVHD.

3. REXLEMESTROCEL-L FOR CHRONIC LOW BACK PAIN ASSOCIATED WITH DEGENERATIVE DISC DISEASE

- The confirmatory Phase 3 trial of Mesoblast's second generation allogeneic, STRO3-immunoselected, and industrially manufactured stromal cell product rexllestrocel-L in patients with chronic low back pain (CLBP) due to inflammatory degenerative disc disease (DDD) of less than five years duration has commenced enrollment at multiple sites across the United States.
- FDA has previously agreed on the design of this 300-patient randomized, placebo-controlled confirmatory Phase 3 trial, and the 12-month primary endpoint of pain reduction as an approvable indication.
- This endpoint was successfully met in Mesoblast's first Phase 3 trial.
- Key secondary measures include improvement in quality of life and function.
- A particular focus is on treatment of patients on opioids, since discogenic back pain accounts for approximately 50% of prescription opioid usage in the US.
- Significant pain reduction and opioid cessation were observed in Mesoblast's first Phase 3 trial.
- FDA has designated rexllestrocel-L a Regenerative Medicine Advanced Therapy (RMAT) for the treatment of chronic low back pain. RMAT designation provides all the benefits of Breakthrough and Fast Track designations, including rolling review and eligibility for priority review on filing of a BLA.

4. REVASCOR (REXLEMESTROCEL-L) FOR PEDIATRIC CONGENITAL HEART DISEASE: HYPOPLASTIC LEFT HEART SYNDROME (HLHS)

- During the year FDA granted REVASCOR both Rare Pediatric Disease Designation (RPDD) and Orphan-Drug Designation (ODD). This followed submission of results from the randomized controlled trial in children with hypoplastic left heart syndrome (HLHS), a potentially life-threatening congenital heart condition.
- Results from a blinded, randomized, placebo-controlled prospective trial of REVASCOR conducted in the United States in children with HLHS were published in the December 2023 issue of the peer reviewed *The Journal of Thoracic and Cardiovascular Surgery Open (JTCSV Open)*.³
- In the HLHS trial conducted in 19 children, a single intramyocardial administration of REVASCOR at the time of staged surgery resulted in the desired outcome of significantly larger increases in left

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ventricular (LV) end-systolic and end-diastolic volumes over 12 months compared with controls as measured by 3D echocardiography, (p=0.009 & p=0.020 respectively).

- These changes are indicative of clinically important growth of the small left ventricle, facilitating the ability to have a successful surgical correction, known as full biventricular (BiV) conversion, which allows for a normal two ventricle circulation. Without full BiV conversion the right heart chamber is under excessive strain with increased risk of heart failure and death.
- 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.

5. REVASCOR (REXLEMESTROCEL-L) FOR CHRONIC HEART FAILURE WITH REDUCED EJECTION FRACTION (HFrEF) AND PERSISTENT INFLAMMATION

- Heart failure with low ejection fraction (HFrEF) occurs in approximately 50% of all heart failure patients and is associated with high mortality.
- 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 reduced major adverse cardiac events (MACE) (cardiovascular death, heart attacks and strokes) in a completed randomized controlled Phase 3 trial in ischemic HFrEF patients with NYHA class II /III disease and inflammation.
- Over 100,000 patients in the US progress annually to end-stage HFrEF and more than 2,500 life prolonging LVADs are implanted annually in these patients.
- Resistance to functional recovery in ischemic HFrEF patients with LVADs is thought to be due to excessive inflammation and microvascular insufficiency in the ischemic myocardium.⁴
- In a randomized controlled trial, a single administration of REVASCOR reduced inflammation, strengthened left ventricular function, reduced right ventricular failure, and reduced hospitalizations in end-stage ischemic HFrEF patients with a left ventricular assist device (LVAD).
- In March FDA informed Mesoblast that it supports an accelerated approval pathway for its second generation allogeneic, STRO3-immunoselected, and industrially manufactured stromal cell product rexlemestrocel-L (Revascor[®]), for patients with end-stage ischemic HFrEF and an LVAD.
- Mesoblast has received RMAT designation for rexlemestrocel-L in the treatment of end-stage heart failure in LVAD patients and intends to meet with FDA to discuss data presentation, timing and FDA expectations for an accelerated approval filing in these patients.

FINANCIAL RESULTS FOR THE FULL-YEAR ENDED JUNE 30, 2024 (FY2024)

- Cash balance at June 30, 2024 was US\$63.3 million (A\$95.0 million),⁵ with additional US\$10.0 million available from an existing facility on FDA approval of RYONCIL.
- Reduction in net cash usage for operating activities:
 - 23% reduction (US\$14.8 million) for FY2024 compared with FY2023 (US\$48.5 million vs US\$63.3 million).
 - 37% reduction (US\$6.1 million) for Q4 FY2024 compared with Q4 FY2023 (US\$10.2 million vs US\$16.3 million).
 - Reduction in cash usage predominantly driven by reduced manufacturing activities and lowered payroll.

Continued focus on prudent cash management for operational activities as we undertake targeted commercial rollout and supply chain activities for RYONCIL (remestemcel-L).

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COST CONTAINMENT TARGETS ACHIEVED FOR FY2024 AND CONTINUING IN FY2025

- Achievement of 23% reduction (US\$14.8 million) in net cash usage for operating activities in FY2024 was due in large part to successful execution of our payroll reduction strategy.
- Continued focus on cost containment of headcount and payroll to be maintained in FY2025.
- Alignment of management salaries and incentives with shareholders as outlined below.

Initiatives	FY2024	FY2025
CEO and CMO voluntarily reduced their base salaries by 30% to preserve cash, replaced with non-cash incentives (LTIs) to further align with shareholders	✓	✓
Additional management have voluntarily reduced their base salaries, replaced with non-cash incentives (LTIs)	✓	✓
Cash payment of STI earned during FY2023 & FY2024 (payable in subsequent 12 month period) deferred until FDA BLA approval of SR-aGVHD for all employees	✓	✓
Management to be offered non-cash LTIs to replace cash payment of STIs earned during FY2023 & FY2024 (payable in subsequent 12 month period) to preserve cash and align with shareholders	✓	✓
Deferred 100% of the cash payment of Non-Executive Director Fees until an FDA decision on the BLA, with 50% of their fees in non-cash LTIs	✓	✓

DETAILS OF FINANCIAL RESULTS FOR THE TWELVE MONTHS ENDED JUNE 30, 2024 (FY2024)

- **Royalties** primarily on sales of TEMCELL® HS Inj.⁶ sold in Japan by our licensee for the FY2024 were US\$5.9 million and US\$6.3 million on a constant currency basis, down 17% compared with US\$7.1 million for the comparative period in FY2023.⁷
- **Research & Development** expenses reduced by US\$1.8 million (7%), down to US\$25.4 million for FY2024 compared with US\$27.2 million for the comparative period in FY2023. R&D expenses primarily supported preparations for the remestemcel-L BLA re-submission and preparations for pivotal studies for CLBP associated with DDD and adult SR-aGVHD.
- **Manufacturing** reduced by US\$12.0 million (43%), down from US\$27.7 million to US\$15.7 million due to decreased inventory build and one-off FY2023 spend on FDA Pre-License Inspection (PLI).
- **Management and Administration** expenses reduced by US\$1.7 million (7%), to US\$23.6 million for FY2024.
- **Revaluation of Contingent Consideration** recognized in FY2024 reflects a greater probability of approval of remestemcel-L for the treatment of SR-aGVHD as compared to FY2023 which reflected the 2023 CRL. In FY2024 we recognized a loss of US\$9.7 million compared to a gain of US\$8.8 million in FY2023.
- **Fair value movement of warrants** recognized a gain of US\$0.8 million in FY2024 on a revaluation of warrants to market value compared to a loss of US\$2.2 million in FY2023.
- **Other operating income** in FY2024 was US\$2.6 million compared with US\$4.2 million in FY2023 due to a reduction tax incentives.
- **Finance Costs** for borrowing arrangements include US\$17.2 million of non-cash expenditure for FY2024 comprising accruing interest and borrowing costs.

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Loss after tax for FY2024 was US\$88.0 million, a 7% increase compared to US\$81.9 million for FY2023. The net loss attributable to ordinary shareholders was 8.91 US cents per share for FY2024, compared with 10.53 US cents per share for FY2023.

Conference Call

There will be a webcast today, beginning at 8.30am AEST (Thursday, August 29); 6.30pm EDT (Wednesday, August 28). It can be accessed via: <https://webcast.openbriefing.com/msb-fyr-2024/>

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

About Mesoblast

Mesoblast (the Company) is a world leader in developing allogeneic (off-the-shelf) cellular medicines for the treatment of severe and life-threatening inflammatory conditions. The Company has leveraged its proprietary mesenchymal lineage cell therapy technology platform to establish a broad portfolio of late-stage product candidates which respond to severe inflammation by releasing anti-inflammatory factors that counter and modulate multiple effector arms of the immune system, resulting in significant reduction of the damaging inflammatory process.

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

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

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

References / Footnotes

1. 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.
3. Wittenberg RE, Gauvreau K, Leighton J, Moleon-Shea M, Borow KM, Marx GR, Emani SM, Prospective randomized controlled trial of the safety and feasibility of a novel mesenchymal precursor cell therapy in hypoplastic left heart syndrome, *JTCVS Open* Volume 16, Dec 2023, doi: <https://doi.org/10.1016/j.xjon.2023.09.031>
4. Symons JD, Deeter L, Deeter N, et al. Effect of continuous-flow left ventricular assist device support on coronary artery endothelial function in ischemic and nonischemic cardiomyopathy. *Cir Heart Fail* 2019; 12:e006085. DOI: 10.1161/CIRCHEARTFAILURE.119.006085.
5. Using Reserve Bank of Australia (RBA) published exchange rate from June 30, 2024 of 1A\$:0.6624US\$.
6. TEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.
7. TEMCELL sales by our Licensee are recorded in Japanese Yen before being translated into USD for the purposes of calculating the royalty paid to Mesoblast. Results have been adjusted for the movement of the USD to Japanese Yen exchange rate from 1USD:140.01 Yen for the twelve months ended June 30, 2023 to 1USD:151.75 Yen for the twelve months ended June 30, 2024.

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

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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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Consolidated Income Statement

(in U.S. dollars, in thousands, except per share amount)	Year Ended June 30,	
	2024	2023
Revenue	5,902	7,501
Research & development	(25,353)	(27,189)
Manufacturing commercialization	(15,717)	(27,733)
Management and administration	(23,626)	(25,374)
Fair value remeasurement of contingent consideration	(9,693)	8,771
Fair value remeasurement of warrant liability	779	(2,205)
Other operating income and expenses	2,570	4,250
Finance costs	(23,009)	(20,122)
Loss before income tax	(88,147)	(82,101)
Income tax benefit/(expense)	191	212
Loss attributable to the owners of Mesoblast Limited	(87,956)	(81,889)

Losses per share from continuing operations attributable to the ordinary equity holders of the Group:

	Cents	Cents
Basic - losses per share	(8.91)	(10.53)
Diluted - losses per share	(8.91)	(10.53)

Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	Year Ended June 30,	
	2024	2023
Loss for the period	(87,956)	(81,889)
Other comprehensive (loss)/income		
<i>Items that may be reclassified to profit and loss</i>		
Exchange differences on translation of foreign operations	51	(573)
<i>Items that will not be reclassified to profit and loss</i>		
Financial assets at fair value through other comprehensive income	(743)	(1)
Other comprehensive (loss)/income for the period, net of tax	(692)	(574)
Total comprehensive losses attributable to the owners of Mesoblast Limited	(88,648)	(82,463)

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Consolidated Balance Sheet

(in U.S. dollars, in thousands)	As of June 30,	
	2024	2023
Assets		
Current Assets		
Cash & cash equivalents	62,960	71,318
Trade & other receivables	20,952	6,998
Prepayments	2,551	3,342
Total Current Assets	86,463	81,658
Non-Current Assets		
Property, plant and equipment	1,106	1,357
Right-of-use assets	2,732	5,134
Financial assets at fair value through other comprehensive income	1,014	1,757
Other non-current assets	2,102	2,326
Intangible assets	575,736	577,183
Total Non-Current Assets	582,690	587,757
Total Assets	669,153	669,415
Liabilities		
Current Liabilities		
Trade and other payables	7,070	20,145
Provisions	45,038	6,399
Borrowings	13,862	5,952
Lease liabilities	2,626	4,060
Warrant liability	4,647	5,426
Total Current Liabilities	73,243	41,982
Non-Current Liabilities		
Provisions	10,620	16,612
Borrowings	100,483	102,811
Lease liabilities	1,952	3,672
Deferred consideration	2,500	2,500
Total Non-Current Liabilities	115,555	125,595
Total Liabilities	188,798	167,577
Net Assets	480,355	501,838
Equity		
Issued Capital	1,310,813	1,249,123
Reserves	78,303	73,520
Accumulated losses	(908,761)	(820,805)
Total Equity	480,355	501,838

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Consolidated Statement of Cash Flow

(in U.S. dollars, in thousands)	Year Ended June 30,	
	2024	2023
Cash flows from operating activities		
Commercialization revenue received	6,776	7,480
Government grants and tax incentives and credits received	3,819	1,118
Payments to suppliers and employees (inclusive of goods and services tax)	(60,835)	(72,683)
Interest received	1,778	796
Income taxes received /(paid)	4	20
Net cash (outflows) in operating activities	(48,458)	(63,269)
Cash flows from investing activities		
Investment in fixed assets	(271)	(264)
Receipts from investment in sublease	234	120
Payments for licenses	(60)	(50)
Net cash (outflows) in investing activities	(97)	(194)
Cash flows from financing activities		
Proceeds from borrowings	—	—
Repayment of borrowings	(10,000)	—
Payment of transaction costs from borrowings	(1,559)	(574)
Interest and other costs of finance paid	(5,717)	(6,014)
Proceeds from issue of shares	65,406	88,635
Proceeds from issue of warrants	—	—
Payments for share issue costs	(4,356)	(4,889)
Payments for lease liabilities	(3,522)	(2,656)
Net cash inflows/(outflows) by financing activities	40,252	74,502
Net increase/(decrease) in cash and cash equivalents	(8,303)	11,039
Cash and cash equivalents at beginning of period	71,318	60,447
FX (loss)/gain on the translation of foreign bank accounts	(55)	(168)
Cash and cash equivalents at end of period	62,960	71,318

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Global Leader in Allogeneic Cellular Medicines for Inflammatory Diseases

Financial Results and Operational Update for
the Year Ended June 30, 2024

August 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



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



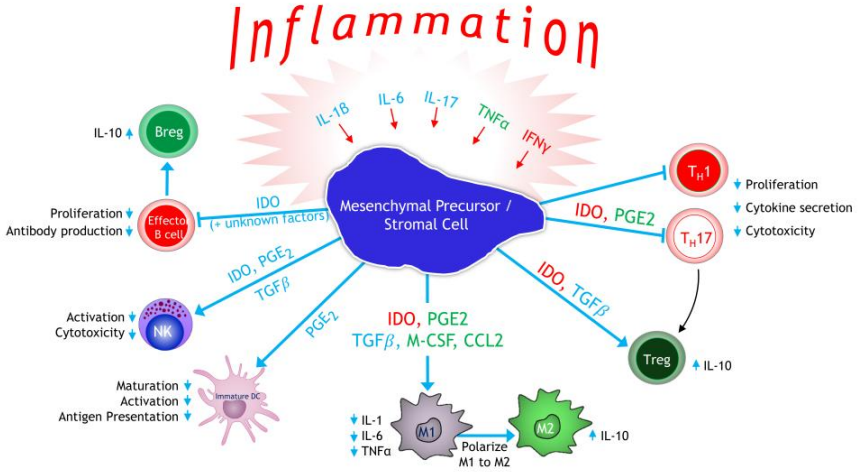
Phase 3 trials
in **THREE**
major
indications

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



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	Progress bar with >> icon			
	Adult SR-aGVHD	Progress bar with >> icon			
RYONCIL® remestemcel-L	IBD / Crohn's	Progress bar with >> icon			
REVASCOR® rexlemestrocel-L (STRO3+)	Pediatric HLHS	Progress bar with >> icon			
	Adult HFrEF End-stage	Progress bar with >> icon			
	Adult HFrEF Class II/III	Progress bar with >> icon			
Rexlemestrocel-L (STRO3+)	CLBP	Progress bar with >> icon			

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>



Financial Results

for the Period Ended June 30, 2024

Manufacturing Remestemcel-L
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Financial highlights

- ▢ Cash balance at June 30, 2024 was US\$63.3 million (A\$95.0 million),¹ with additional US\$10.0 million available from an existing facility on FDA approval of RYONCIL.
- ▢ Reduction in net cash usage for operating activities:
 - 23% reduction (US\$14.8 million) for FY2024 compared with FY2023 (US\$48.5 million vs US\$63.3 million).
 - 37% reduction (US\$6.1 million) for Q4 FY2024 compared with Q4 FY2023 (US\$10.2 million vs US\$16.3 million).
 - Reduction in cash usage predominantly driven by reduced manufacturing activities and lowered payroll (as outlined in next slide).
- ▢ Continued focus on prudent cash management for operational activities as we undertake targeted commercial rollout and supply chain activities for remestemcel-L (RYONCIL).

Headcount and payroll cost containment targets achieved for F2024 and continuing in FY2025

- Achievement of 23% reduction (US\$14.8 million) in net cash usage for operating activities in FY2024 from FY2023 was due in large part to successful execution of our payroll reduction strategy.
- Continued focus on cost containment of headcount and payroll to be maintained in FY2025.
- Alignment of management salaries and incentives with shareholders as outlined below.

Initiatives	FY2024	FY2025
CEO and CMO voluntarily reduced their base salaries by 30% to preserve cash, replaced with non-cash incentives (LTIs) to further align with shareholders	✓	✓
Additional management have voluntarily reduced their base salaries, replaced with non-cash incentives (LTIs)	✓	✓
Cash payment of STI earned during FY2023 & FY2024 (payable in subsequent 12 month period) deferred until FDA BLA approval of SR-aGVHD for all employees	✓	✓
Management to be offered non-cash LTIs to replace cash payment of STIs earned during FY2023 & FY2024 (payable in subsequent 12 month period) to preserve cash and align with shareholders	✓	✓
Deferred 100% of the cash payment of Non-Executive Director Fees until an FDA decision on the BLA, with 50% of their fees in non-cash LTIs	✓	✓

Reduction in key categories of expenditure

P&L for the year ended (US\$m)	June 30, 2024	June 30, 2023
Total Revenue	5.9	7.5
Research and development	(25.4)	(27.2)
Manufacturing	(15.7)	(27.7)
Management & administration	(23.6)	(25.4)
Revaluation of contingent consideration	(9.7)	8.8
Revaluation of warrant liability	0.8	(2.2)
Other operating income & expenses	2.6	4.2
Finance costs	(23.0)	(20.1)
Loss before tax	(88.1)	(82.1)
Income tax benefit	0.2	0.2
Loss after tax	(88.0)	(81.9)
Adjusted Loss after tax¹	(78.3)	(90.7)

Revenue: Revenue predominately from royalties on sales of TEMCELL® HS Inj.² sold in Japan by our licensee.

Reduction in Manufacturing Expenditure: reduced by US\$12.0 million (43%) due to decreased inventory build and one-off FY2023 expenditure on FDA Pre-License Inspection (PLI).

Finance Costs include US\$17.3 million of non-cash expenditure for the year ended June 30, 2024 comprising accruing interest and borrowing costs.

Revaluation of Contingent Consideration: greater probability of GVHD approval assumed in FY2024 valuation versus the FY2023 valuation which reflected the 2023 CRL.

Loss after tax of US\$88.0 million for FY2024. After adjusting for revaluation of contingent consideration¹ our Loss after tax for FY2024 is US\$78.3 million, a US\$12.4 million improvement on FY2023.

Figures have been rounded.

1. Adjusted Loss after tax is our statutory Loss after Tax less the revaluation of contingent consideration, a loss of \$9.7m for FY2024 and a gain of \$8.8m in FY2023.
2. TEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.





Remestemcel-L

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

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

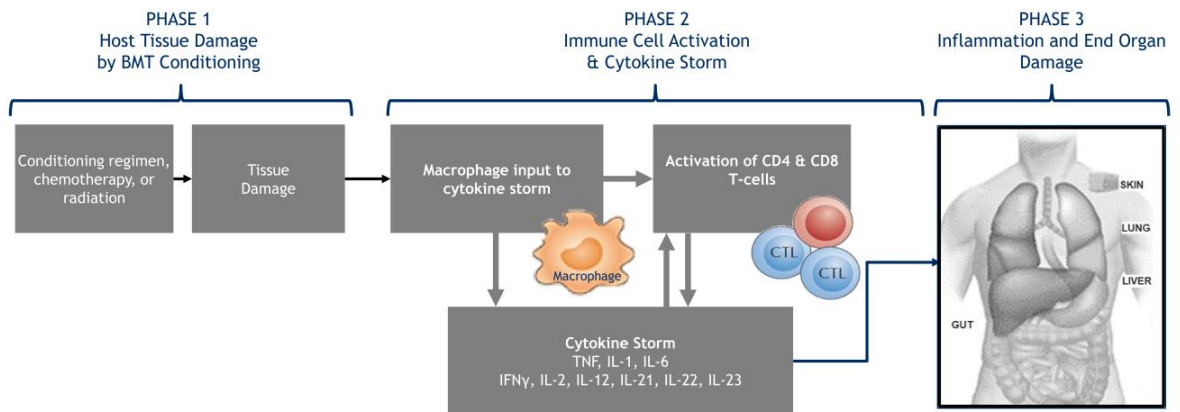
Product	Indication	Phase 2	Phase 3	Regulatory Filing	Approved
RYONCIL® remestemcel-L	Pediatric SR-aGVHD				
	Adult SR-aGVHD				

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

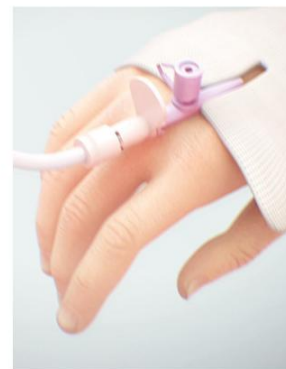
- Corticosteroids are first-line therapy for aGVHD
- There is only one approved treatment for disease refractory to steroids and no approved treatment in the US for children under 12 years old
- In Japan, Mesoblast's licensee received the first product approval for SR-aGVHD in both children and adults

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*.

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

- ▀ Mesoblast resubmitted its BLA for approval of RYONCIL on July 8, 2024, addressing remaining CMC (Chemistry, Manufacturing, and Controls) items in the August 2023 Complete Response Letter (CRL).
- ▀ FDA previously informed Mesoblast that the available clinical data from its Phase 3 study appears sufficient to support resubmission of the BLA.
- ▀ FDA accepted the BLA resubmission within two weeks, considering it to be a complete response.
- ▀ Mesoblast and FDA in ongoing interactions in relation to active BLA review.
- ▀ Mesoblast anticipates a decision prior to or on the FDA's Prescription Drug User Fee Act (PDUFA) goal date of January 7, 2025.
- ▀ 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 Top 15 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 67% after RYONCIL treatment was used under expanded access in 51 adults and children with SR-aGVHD who failed to respond to at least one additional agent, such as ruxolitinib.
- 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

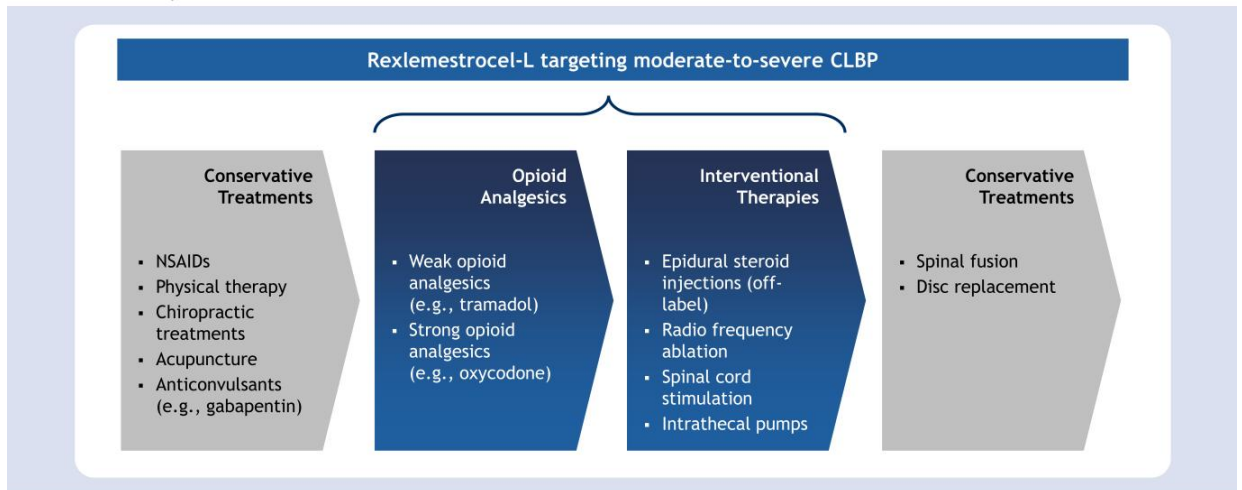
- ▶ Over 7m patients are estimated to suffer from CLBP due to degenerative disc disease (DDD) in each of the U.S. and E.U.³⁻⁴



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.

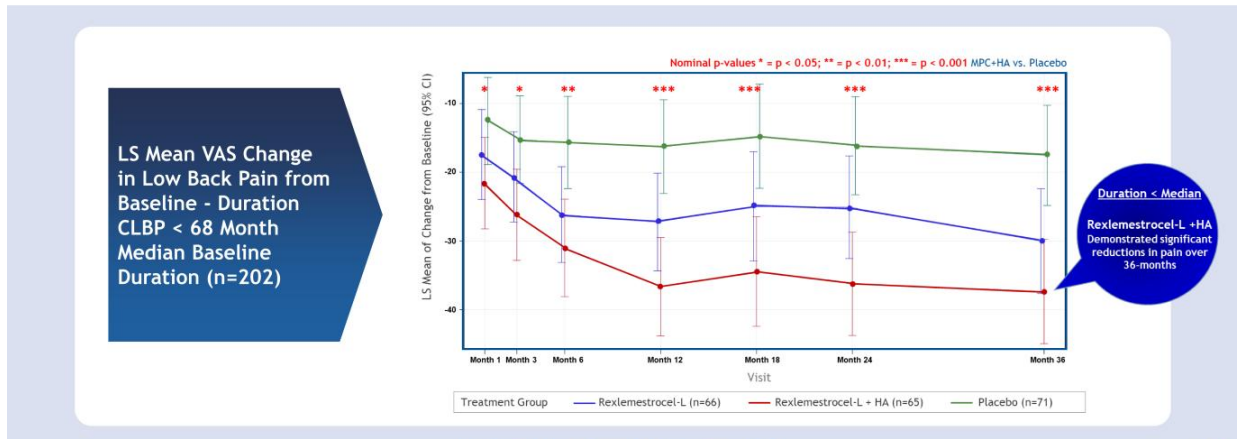
Patients with CLBP refractory to standard treatment have minimal options

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



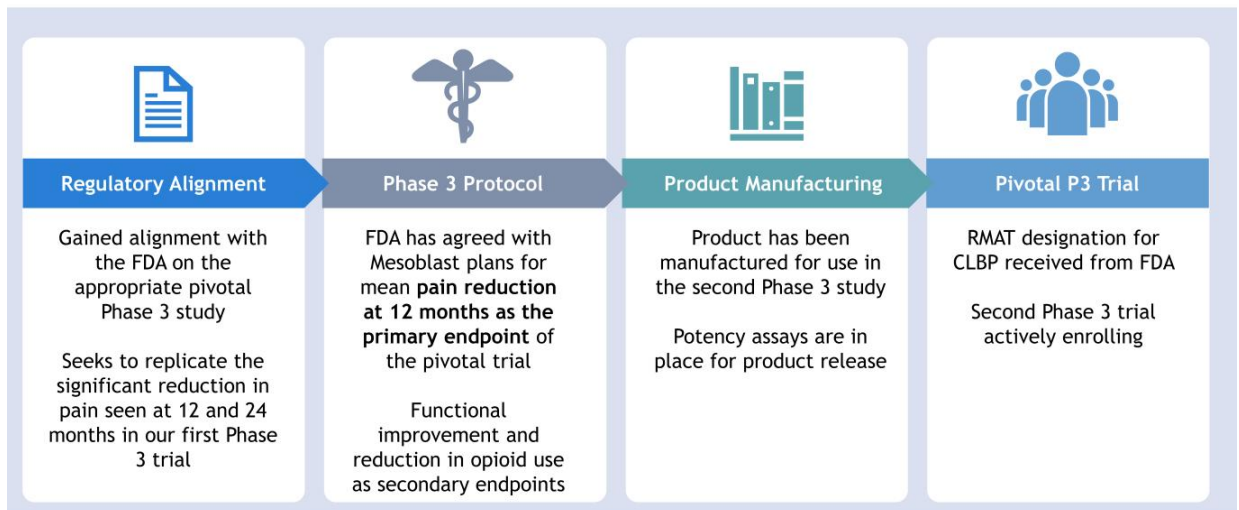
Phase 3 trial outcomes based on a single injection of rexlemestrocel-L + HA showed more than three years of pain reduction

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

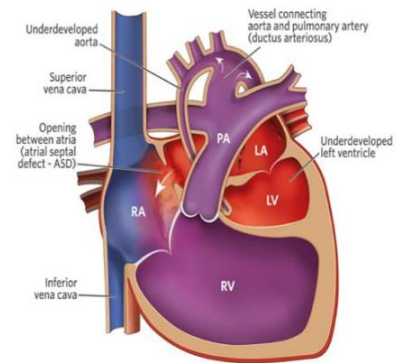
Product	Indication	Phase 2	Phase 3	Regulatory Filing	Approved
REVASCOR® rexlimestrocel-L (STRO3+)	Pediatric HLHS				
	Adult HFrEF End-stage				
	Adult HFrEF Class II/III				

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 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.
- Achievement of life-saving surgery creating 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 limited by the inability in most patients for the left ventricle to grow sufficiently to support the circulation to the body.
- Clinical trial at Boston Children's Hospital evaluated whether REVASCOR could enhance LV size to support circulation to the body.

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 and death. 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.

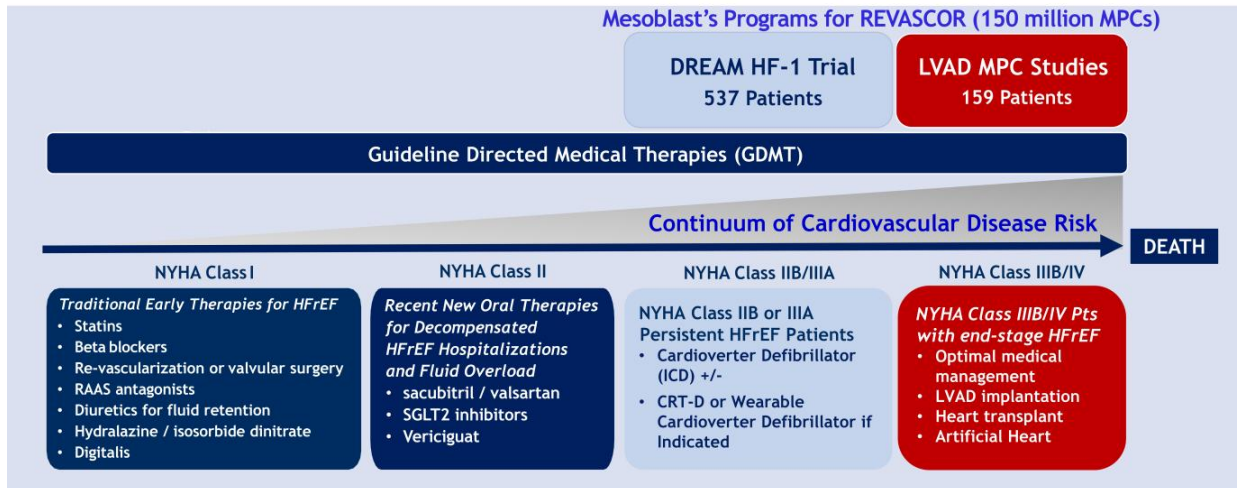
Pediatric: FDA awarded Rare Pediatric Disease designation and Orphan Drug designation to REVASCOR for hypoplastic left heart syndrome

- 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)



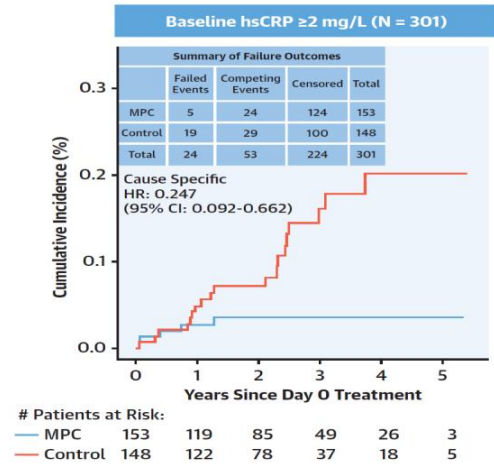
Randomized Trial of Targeted Transcatheter Mesenchymal Precursor Cell Therapy in Patients With Heart Failure



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

