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 March 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 February 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/ Paul Hughes

Paul Hughes Company Secretary

Dated: March 1, 2024

INDEX TO EXHIBITS

Item

- <u>.99.1</u> Press release of Mesoblast Ltd, dated February 29, 2024.
- <u>.99.2</u> Investor presentation of Mesoblast Ltd, dated February 29, 2024.

mesoblast

asx announcement

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

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

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

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

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

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

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

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

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

GRAFT VERSUS HOST DISEASE - PEDIATRIC AND ADULT PHASE 3 PROGRAMS

- Mesoblast has an upcoming meeting scheduled for March with the United States Food and Drug Administration (FDA) and has provided the agency with new data from a second potency assay for its product Ryoncil[®] (remestemcel-L) that provides additional product characterization as requested by FDA.
- The new data show that the RYONCIL product made with the current manufacturing process that
 has undergone successful inspection by FDA, demonstrates greater potency than the earlier
 generation product, providing context to its greater impact on survival.

- Survival in adults with SR-aGVHD who have failed at least one additional agent, such as ruxolitinib, remains as low as 20-30% by 100 days.^{2,3} In contrast, 100-day survival was 67% after RYONCIL treatment was used under expanded access in 51 adults and children with SR-aGVHD who failed to respond to at least one additional agent, such as ruxolitinib.
- These additional clinical data, together with the proposed Phase 3 trial protocol in adults with SRaGVHD have also been provided to FDA. Mesoblast is collaborating with Blood and Marrow Transplant Clinical Trials Network (BMT CTN) in the United States, a body that is funded by the National Institutes of Health (NIH) and is responsible for approximately 80% of all US allogeneic BMTs, to conduct a pivotal trial in adults with SR-aGVHD.

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

- During the quarter FDA granted Mesoblast's cardiovascular product, Revascor[®] (rexlemestrocel-L), both Rare Pediatric Disease Designation (RPDD) and Orphan-Drug Designation (ODD). This followed submission of results from the randomized controlled trial in children with hypoplastic left heart syndrome (HLHS), a potentially life-threatening congenital heart condition.
- Results from a blinded, randomized, placebo-controlled prospective trial of REVASCOR conducted in the United States in children with HLHS were published in the December 2023 issue of the peer reviewed The Journal of Thoracic and Cardiovascular Surgery Open (JTCVS Open).⁴
- In the HLHS trial conducted in 19 children, a single intramyocardial administration of REVASCOR at the time of staged surgery resulted in the desired outcome of significantly larger increases in left ventricular (LV) end-systolic and end-diastolic volumes over 12 months compared with controls as measured by 3D echocardiography, (p=0.009 & p=0.020 respectively).
- These changes are indicative of clinically important growth of the small left ventricle, facilitating the
 ability to have a successful surgical correction, known as full biventricular (BiV) conversion, which
 allows for a normal two ventricle circulation with the surgically repaired left ventricle taking over
 circulatory support to the body. Without full BiV conversion the right heart chamber is under
 excessive strain with increased risk of heart failure and death.
- As noted in the JTCVS publication the fact that 100% of REVASCOR-treated children compared with 57% of controls had large enough LVs to accommodate the full BiV conversion suggests that REVASCOR treatment may help increase the ability to 'better grow' the HLHS LV after LV recruitment surgery.
- The FDA's ODD Program provides orphan status to drugs and biologics which are defined as those
 intended for the safe and effective treatment, diagnosis or prevention of rare diseases. ODD qualifies
 the drug for various development incentives, including eligibility for seven years of market
 exclusivity upon regulatory approval, exemption from FDA application fees, tax credits for qualified
 clinical trials, and other potential assistance in the drug development process.
- RPD Designation is granted by the FDA for certain serious or life-threatening diseases which
 primarily affect children. On FDA approval of a Biologics Licensing Application (BLA) for REVASCOR
 for the treatment of HLHS, Mesoblast may be eligible to receive a Priority Review Voucher (PRV)
 that can be redeemed for any subsequent marketing application or may be sold or transferred to a
 third party.
- Mesoblast plans to meet with FDA to discuss the regulatory path to approval for REVASCOR in children with this life-threatening condition.

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

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

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

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

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

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

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

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

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

Conference Call

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

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

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About Mesoblast

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

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

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

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

References / Footnotes

- 1. Using Reserve Bank of Australia (RBA) published exchange rate from December 31, 2023 of 1A\$:0.6840US\$.
- Jagasia M et al. Ruxolitinib for the treatment of steroid-refractory acute GVHD (REACH1): a multicenter, open-label phase 2 trial. *Blood*. 2020 May 14; 135(20): 1739–1749
- Abedin S, et al. Ruxolitinib resistance or intolerance in steroid-refractory acute graft versus-host disease – a real-world outcomes analysis. *British Journal of Haematology*, 2021;195:429-43.
- 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: <u>https://doi.org/10.1016/j.xjon.2023.09.031</u>
- 5. TEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.
- 6. TEMCELL sales by our Licensee are recorded in Japanese Yen before being translated into USD for the purposes of calculating the royalty paid to Mesoblast. Results have been adjusted for the movement of the USD to Japanese Yen exchange rate from 1USD:139.10 Yen for the six months ended December 31, 2022 to 1USD:146.94 Yen for the six months ended December 31, 2023.

Forward-Looking Statements

This press release includes forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements completed 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, including multi-national clinical trials; Mesoblast's ability to advance its manufacturing capabilities; the timing or likelihood of regulatory filings and approvals (including our request to have a Type A meeting with the FDA, the outcome of such a meeting, and any future decision that the FDA may make on the BLA for remestemcel-L for pediatric patients with SR-

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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

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

Losses per share from continuing operations attributable to the ordinary equity

holders of the Group:	Cents	Cents
Basic - losses per share	(3.82)	(5.64)
Diluted - losses per share	(3.82)	(5.64)

Consolidated Statement of Comprehensive Income

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

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Consolidated Balance Sheet	As of December 31,	As of June 30,
(in U.S. dollars, in thousands)	2023	2023
Assets Current Assets		
Cash & cash comivalents	77.554	71.318
Trade & other receivables	3,998	6.998
Prenavments	3,602	3,342
Total Current Assets	85,154	81,658
Non-Current Assets		
Property, plant and equipment	1,171	1,357
Right-of-use assets	4,329	5,134
Financial assets at fair value through other comprehensive income	826	1,757
Other non-current assets	2,241	2,326
Intangible assets	576,564	577,183
Total Non-Current Assets	585,131	587,757
Total Assets	670,285	669,415
Liabilities		
Current Liabilities		
Trade and other payables	10,760	20,145
Provisions	8,230	6,399
Borrowings	8,534	5,952
Lease liabilities	2,851	4,060
Warrant liability	992	5,426
Total Current Liabilities	31,367	41,982
Non-Current Liabilities		
Provisions	17,073	16,612
Borrowings	107,228	102,811
Lease liabilities	3,386	3,672
Deferred consideration	2,500	2,500
Total Non-Current Liabilities	130,187	125,595
Total Liabilities	161,554	167,577
Net Assets	508,731	501,838
Fanity		
Issued Capital	1,286,229	1,249,123
Reserves	75.846	73,520
(Accumulated losses)	(853,344)	(820,805)
Total Equity	508,731	501,838
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Consolidated Statement of Cash Flow

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

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Global Leader in Allogeneic Cellular Medicines for Inflammatory Diseases

Financial Results and Operational Update for the Half-Year Ended December 31, 2023



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 expressed or implied by these forward-looking statements 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. Were have based these forward-looking statements are provard-looking statements were have based these forward-looking statements are provard-looking statements and efficiency of manifacturing processes; expectations, basines strategy and financial needs. These statements may relate to, but rent timeted in the are not timited to: expectations regarding the strategy of protential applications for, Mesoblast's adult sence cell technologies; expectations regarding the strength of Mesoblast's intellectual property, the timeline for Mesoblast's explaitancy approval process, and the beneficiency of manufacturing processes; expectations about Assoblast's intellectual 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 there to note readiation these strategy and risks that may cause event individue free motions and ability to raise future capital, among others. Forward-looking statements onderning Mesoblast's actual requirements, and the differences may be readiations and vatere performance or results and texture to be material and adverse. You should read this presentation together with our financial statements and the differ from the results anticipatec

Our Mission

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



Investment Highlights

Novel Allogeneic Cell Therapy Platform	Developing off-the-shelf, allogeneic cellular medicines based on proprietary mesenchymal stromal cell (MSC) technology platforms to enable treatment without the need for donor matching or immunosuppression.
Remestemcel-L for Pediatric SR-aGVHD	Single-arm pivotal Phase 3 trial completed; primary endpoint successfully met. Long-term data shows durability of survival benefit >4 years. New data from second potency assay provided to FDA, meeting scheduled Q1 CY2024.
Remestemcel-L for Adult SR-aGVHD	Market size for adult population approx. 5-fold larger than pediatric. Mesoblast is collaborating with BMT CTN, a body responsible for approximately 80% of all US transplants, to conduct a pivotal trial in adults with SR-aGVHD.
Rexlemestrocel-L for Heart Disease	First Phase 3 completed for heart failure with reduced ejection fraction (HFrEF) Class II/III patients. FDA RMAT for end-stage HFrEF patients with an LVAD. Randomized controlled trial in pediatric congenital heart disease published. RPDD & ODD granted by FDA.
Rexlemestrocel-L for CLBP	First randomized controlled Phase 3 trial completed, RMAT granted by FDA for discogenic pain Agreement in place for confirmatory trial, 12-month pain reduction endpoint for FDA approval. Pivotal trial activities have commenced.
SR-aGVHD = Steroid-Refractory Graft v Host Dis MBMT CTN = Bone Marrow Transplant Clinical Tria CLBP = Chronic Low Back Pain	ease FDA = U.S. Food & Drug Administration LVAD = Left Ventricular Assist Device RNAT = Regenerative Medicine Advanced Therapy RPDD - Rare Pediatric Disease Designation ODD - Orphan Drug Designation Medical Sector Secto

Global Intellectual Property (IP) Estate Provides Substantial Competitive Advantage

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





Commercial-scale Manufacturing Process and Facilities

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

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3D bioreactors for high volume indications







Our mesenchymal precursor/stromal cells respond to and are activated by multiple inflammatory cytokines through surface receptors, resulting in orchestration of an anti-inflammatory cascade Inflammation IL-10 Proliferation IDO IDO, PGE2 Mesenchymal Precurso Stromal Cell Cytokine secretion Proliferation Antibody production Cytotoxicity T_H17) PGE 00 00 TGEB Activation IDO, PGE2 Cytotoxicity 🕇 TGF β , M-CSF, CCL2 Treg **▲** IL-10 Maturation Activation Antigen Presentation mmatt 🕈 IL-1 M1 † IL-6 ▼ TNFα Polar mesoblast Source: data on file 7

Platform Technology - Shared Mechanism of Action Across Our Products

Late-Stage Clinical Pipeline

Based on the Proprietary Allogeneic Mesenchymal Stromal Cell Platform



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

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



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Clinical Program Milestones - 2024

Clinical Progra	IIII Milescones - 2024	Target Date	<u>Status</u>
RYONCIL	Additional potency assay data provided to FDA	Q1 CY2024	Achieved
Adult & Pediatric SR-aGVHD	FDA meeting regarding potency assay data for the pediatric BLA	Q1 CY2024	Scheduled
(remestemcel-L)	Completion and submission to FDA of protocol for adult SR-aGVHD Phase 3 trial in partnership with BMT CTN	Q1 CY2024	Achieved
	Commence patient enrollment for adult SR-aGVHD trial	Q2 CY2024	Planned
REVASCOR Adult & Pediatric	Meet with the FDA under RMAT to discuss the potential pathway to approval in adults with HFrEF based on LVAD and DREAM-HF trials	Q1 CY2024	Achieved
Heart Disease (rexlemestrocel-L)	Meet with FDA on congenital heart disease pathway to approval in pediatric patients based on results of randomized, controlled trial	Q2 CY2024	Planned
Inflammatory Pain	CLBP Phase 3 trial start-up activities with investigators, trial sites & contract research organization (CRO)	Q4 CY2023	Achieved
(rexlemestrocel-L)	Phase 3 CLBP patient screening/enrollment initiates and completes	Q1-Q4 CY2024	Ongoing
9 SR-aGVHD = Steroid-Refracto FDA = United States Food and	ry Graft v Host Disease BMT CTN = Bone Marrow Transplant Clinical Trials Network LVAD = Left Ventricular Assist d Drug Administration RMAT = Regenerative Medicine Advanced Therapy HFrRF = Heart Failure with Re	Device duced Ejection Fraction	mesoblast

Regulatory Status for RYONCIL in Pediatric Patients with SR-aGVHD

FDA Meeting Scheduled for March

Mesoblast has an upcoming meeting scheduled for March with the United States Food and Drug Administration (FDA).

Mesoblast has provided the agency with new data from a second potency assay for its product Ryoncil® (remestemcel-L) that provides additional product characterization as requested by FDA.

The new data show that the RYONCIL product made with the current manufacturing process that has undergone successful inspection by FDA, demonstrates greater potency than the earlier generation product, providing context to its greater impact on survival.



Pathway to Approval for RYONCIL in Adult Patients with SR-aGVHD

- Survival in adults with SR-aGVHD who have failed at least one additional agent, such as ruxolitinib, remains as low as 20-30% by 100 days, a patient population with no approved therapies.^{1,2}
- In contrast, 100-day survival was 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 intends to commence a Phase 3 trial of RYONCIL in adults and adolescents, a market approx. 5-fold larger than pediatric, who are refractory to both corticosteroids and a second line agent such as ruxolitinib, for whom there are no approved therapies.
- Mesoblast is collaborating with the Blood and Marrow Transplant Clinical Trials Network (BMT CTN), a body responsible for approximately 80% of all US transplants, to conduct the trial.

 Jagasia M et al. Ruxolitinib for the treatment of steroid-refractory acute GVHD (REACH1): a multicenter, open-label phase 2 trial. Blood. 2020 May 14; 135(20): 1739-1749. Abedin S, et al. Ruxolitinib resistance or intolerance in steroid-refractory acute graft versus-host disease – a real-world outcomes analysis. British Journal of Haematology, 2021;195:429-43.
 m e s o b l a s t

REV (HF	ASCOR in Adults with Chronic Heart Failure with Reduced Ejection Fraction rEF), Including End-Stage Patients with a Left Ventricular Assist Device (LVAD)
FDA	Meeting Regarding Regulatory Path to Approval
-	REVASCOR has shown the potential to reduce major adverse cardiac events (MACE) such as heart attack and cardiovascular death in high-risk patients with HFrEF and inflammation.
-	REVASCOR has also shown the potential to improve major outcomes in high-risk patients with end-stage HFrEF, inflammation and LVADs.
7	Mesoblast met with FDA this quarter to address potential pathways to approval for REVASCOR under our Regenerative Medicine Advanced Therapies (RMAT) designation. The discussion covered both Class II/III HFrEF ischemic patients with inflammation from the Phase 3 DREAM-HF 565 patient study and Class IV ischemic LVAD patients with inflammation from the 159 patient LVAD study.
7	Mesoblast discussed with FDA the mechanism of action by which REVASCOR is able to improve major outcomes, including mortality, across the continuum of heart failure with inflammation.
-	Minutes of the meeting are expected from FDA next month.
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Pediatric Congenital Heart Disease - Hypoplastic Left Heart Syndrome (HLHS)

Awarded FDA Rare Pediatric Disease Designation (RPDD) and Orphan Drug Designation (ODD)

During the quarter FDA granted Mesoblast's cardiovascular product, REVASCOR, both RPDD and 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 US in children with HLHS were published in the December 2023 issue of the peer reviewed *The Journal of Thoracic and Cardiovascular Surgery Open (JTCVS Open)*.¹

As noted in the JTCVS publication the fact that 100% of REVASCOR-treated children compared with 57% of controls had large enough LVs to accommodate the full BiV conversion suggests that REVASCOR treatment may help increase the ability to 'better grow' the HLHS LV after LV recruitment surgery.

Mesoblast plans to meet with FDA to discuss the regulatory path to approval for REVASCOR in children with this life-threatening condition.





Financial Highlights

Cash Reserves	At December 31, 2023, cash-on-hand was US\$77.6 million (A\$113.5 million), after completing Institutional Placement and Entitlement Offer of A\$60.3 million. Strengthened Balance Sheet through delivering on cost containment strategies.
Cash Burn	 Reduction in net cash usage for operating activities: For the three months ended December 31, 2023, net cash usage was US\$12.3 million, a 25% reduction versus the comparative quarter in FY2023. For the six months ended December 31, 2023, net cash usage was US\$26.6 million, a 14% reduction versus the comparative period in FY2023.
Reduction in Loss	Loss after tax reduced by 21% for the six months ended December 31, 2023, versus the comparative period to December 31, 2022.



Reduction in Manufacturing, R&D and Management Administration; Improved Loss Before Tax

P&L for the six months ended (US\$m)	Dec 31, 2023	Dec 31, 2022
Total Revenue	3.4	3.4
Research and development	(12.6)	(13.4)
Manufacturing	(6.7)	(12.8)
Management & administration	(11.5)	(13.3)
Revaluation of contingent consideration	(0.3)	6.0
Revaluation of warrant liability	4.4	(0.7)
Other operating income & expenses	1.1	(0.0)
Finance costs	(10.3)	(10.7)
Loss before tax	(32.6)	(41.5)
Income tax benefit	0.1	0.1
Loss after tax	(32.5)	(41.4)

Revenue: Revenue predominately from royalties on sales of TEMCELL® HS Inj.¹ sold in Japan by our licensee.

Reduction in Manufacturing Expenditure: reduced by 47% for the six months ended December 31, 2023, from \$12.8 million to \$6.7 million. Costs in the current period include new potency and characterization data for the remestemcel-L product, as requested by FDA, which have been submitted ahead of our upcoming meeting with FDA next month.

Finance Costs include \$6.9 million of non-cash expenditure for the six months ended December 31, 2023 comprising accruing interest and borrowing costs.

Figures have been rounded.

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ded. 1. TEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.





Remestemcel-L

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



Acute Graft Versus Host Disease (aGVHD)

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



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

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

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

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Remestemcel-L for Children with SR-aGVHD

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

Day 100 Survival						
Remestemcel-L Protocol	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				

1. GVHD001 had 55 randomized patients, however one patient dropped out before receiving any dose of remestencel-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 control tad lot(dow-) of 00 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

Presented at the 2023 Tandem Meeting of ASTCT and CIBMTR



Extended Survival Data in Children with SR-aGVHD

Remestemcel-L Treatment Resulted in Durable Survival Over 4 Years

Survival Outcomes in Pediatric & Adult SR-aGVHD (Remestemcel-L data from the Center for International Blood and Marrow Transplant Research (CIBMTR) dbase)							
Study	GVHD001	MacMillan et al ¹	Rashidi et al ²	REACH2 ³	REACH2 ³	REACH1 ⁴	
Treatment	Remestemcel-L	BAT ⁵	BAT ⁵	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%						

... MacMillan ML et al. Pediatric acut Rashidi A et al. Outcomes and pred Zeiser R et al. Ruxolitinib for Glucos Jagasia M et al. Ruxolitinib for the * BAT = Best Austic * ront steroids. Bone Marrow Transplant 2020; 55(1): 165-171 aft-versus-host disease: single-center results from a cohort of 203 patients. Biol Blood Bone Marrow Transplant 2019; 25(11):2297-2302. ease. K Feigl J Med 2020;382: 1800-10. CKH1): a multicenter, open-label phase 2 trial. Blood. 2020 May 14; 135(20): 1739–1749

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Regulatory Status for RYONCIL in Pediatric Patients with SR-aGVHD

FDA Meeting Scheduled for March

Mesoblast has an upcoming meeting scheduled for March with the United States Food and Drug Administration (FDA).

Mesoblast has provided the agency with new data from a second potency assay for its product Ryoncil® (remestemcel-L) that provides additional product characterization as requested by FDA.

The new data show that the RYONCIL product made with the current manufacturing process that has undergone successful inspection by FDA, demonstrates greater potency than the earlier generation product, providing context to its greater impact on survival.



RYONCIL for Adults with SR-aGVHD

- Commercial strategy is to progress to adults who have failed steroids and a first-line agent, including ruxolitinib.
- Market opportunity approximately five times larger than pediatric.
- Approximately 45% of ruxolitinib patients are non-responders.¹
- Survival in adults with SR-aGVHD who have failed at least one additional agent, such as ruxolitinib, is 20-30% by 100 days.^{1,2}
- In contrast, 100-day survival was 67% after remestemcel-L treatment was used under expanded access in 51 children and adults with SR-aGVHD who failed to respond to at least one additional agent, such as ruxolitinib.
- Mesoblast is collaborating with the Blood and Marrow Transplant Clinical Trials Network (BMT CTN), a body responsible for approximately 80% of all US transplants, to conduct a pivotal trial in this patient population.
- Jagasia M et al. Ruxolitinib for the treatment of steroid-refractory acute GVHD (REACH1): a multicenter, open-label phase 2 trial. Blood. 2020 May 14; 135(20): 1739-1749
 Abedin S, et al. Ruxolitinib resistance or intolerance in steroid-refractory acute graft versus-host disease a real-world outcomes analysis. British Journal of Haematology, 2021;195:429-43
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Rexlemestrocel-L

Chronic Heart Failure Reduced Ejection Fraction (HFrEF)



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

	*	A B	22
Significant Need	Promising Data	Targeting Inflammation	FDA Meeting
Cardiovascular disease remains the leading cause of death in the US CHF is a progressive disease with a high mortality approaching 50% at 5 years, and at least 75% after an initial hospitalization	Recent data from the DREAM-HF P3 trial showed improved LVEF at 12 months, preceding long-term reduction in MACE events across all treated patients LVEF is a potential early surrogate endpoint	Effects on LVEF and MACE outcomes are enhanced in patients with active inflammation Trial results from class II to end-stage HFrEF now support a MOA by which rexlemestrocel-L reverses inflammation-related endothelial dysfunction	Mesoblast met with the FDA under its RMAT designation to discuss the potential pathway to approval FDA formal minutes due in March
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Patients Experience Progressive Vascular Dysfunction and Heart Failure Rexlemestrocel-L has the potential to improve endothelial dysfunction in patients from Class II thru IV

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

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

JACC JUURNALS

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

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

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



REVASCOR As Treatment For Severe Congenital Heart Disease Awarded FDA Rare Pediatric Disease Designation and Orphan Drug Designation

- REVASCOR has multiple mechanisms-of-action that may be beneficial to children with congenital heart disease including neovascularization, anti-fibrosis, and reduction in inflammation.
 Wester connecting strated quinters and pulmong artery
- 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.



29 1. Kritzmire, S. M, et al. (2022). Hypoplastic left heart syndrome. https://www.ncbi.nlm.nih.gov/books/NBK554576/#



REVASCOR As Treatment For Severe Congenital Heart Disease Awarded FDA Rare Pediatric Disease Designation and Orphan Drug Designation s In the HLHS randomized controlled single-center US trial in 19 patients, a single intramyocardial administration of REVASCOR at the time of staged surgery resulted in significantly increased LV systolic and diastolic volumes over 12 months compared with control.¹ 🐴 These changes are indicative of clinically important growth of the small left ventricle that can help facilitate a subsequent surgical correction allowing for a normal two ventricle circulation. 🐴 Improvement in left ventricular functional outcomes with REVASCOR may encourage more widespread use of surgical procedures to create a functioning left ventricle in children with HLHS resulting in reduction in long-term morbidity and mortality compared with other medical and/or surgical approaches. 🐴 A Rare Pediatric Disease (RPD) designation 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 Biologics Licensing Application (BLA) for REVASCOR for the treatment of HLHS, Mesoblast may be eligible to receive a Priority Review Voucher (PRV) that can be redeemed for any subsequent marketing application or may be sold or transferred to a third party. Wittenberg RE, Gauvreau K, Leighton J, Moleon-Shea M, Borow KM, Marx GR, Emani SM, Prospective randomized controlled trial of the safety and feasibility of a novel mesenchymal precursor cell therapy in hypoplastic left heart syndrome, JTCVS Open (2023), doi: https://doi.org/10.1016/j.xjon.2023.09.031. mesoblast 1.

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Rexlemestrocel-L

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



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

Burder	n of Illness	Tre	atment Options	Ma	rket Opportunity	
 Bac dis cor Inf and hea inc opi poj 	ck pain causes more sability than any other ndition ¹ Ticts substantial direct d indirect costs on the althcare system, ¹ cluding excessive use of ioids in this patient pulation	1	Minimal treatment options for patients with chronic low back pain (CLBP) who fail conservative therapy include opioids and surgery 50% of opioid prescriptions are for CLBP ² Durable improvement in pain has potential to reduce opioid use and prevent surgical intervention	4	Over 7m patients are estimated to suffer from CLBP due to degenerative disc disease (DDD) in each of the U.S. and E.U.5 ²⁻⁴	

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.

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Rexlemestrocel-L / CLBP - Program Summary

Phase 3 Protocol	Product Manufacturing	Pivotal P3 Trial
FDA has agreed with Mesoblast plans for mean pain reduction at 12 months as the primary endpoint of the pivotal trial Functional improvement and reduction in opioid use as secondary endpoints	Product has been manufactured for use in the pivotal Phase 3 study Potency assays are in place for product release	RMAT designation for CLBP received from FDA Pivotal trial activities, including investigators, trial sites & CRO have commenced
	Phase 3 Protocol FDA has agreed with Mesoblast plans for mean pain reduction at 12 months as the primary endpoint of the pivotal trial Functional improvement and reduction in opioid use as secondary endpoints	Phase 3 Protocol Product Manufacturing FDA has agreed with Mesoblast plans for mean pain reduction at 12 months as the primary endpoint of the pivotal trial Product Manufacturing Functional improvement and reduction in opioid use as secondary endpoints Potency assays are in place for product release

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

RMAT designation provides all the benefits of Breakthrough and Fast Track designations, including rolling review and eligibility for priority review on filing of a Biologics License Application (BLA)

Results from the trial showed that:

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



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

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







Thank You

