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 February 2023

Commission File Number 001-37626

Mesoblast Limited

(*Exact name of Registrant as specified in its charter*)

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

Australia
(*Jurisdiction of incorporation or organization)*

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

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

Form 20-F ☑ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes ☐ No ☑

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes ☐ No ☑

INFORMATION CONTAINED ON THIS REPORT ON FORM 6-K

On February 28, 2023, 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.

On February 28, 2023, Mesoblast Limited filed with the Australian Securities Exchange a new release announcement which is attached hereto as Exhibit 99.3, and is 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: February 28, 2023

INDEX TO EXHIBITS

Item	
99.1	Press release of Mesoblast Ltd, dated February 28, 2023.
99.2	Investor presentation of Mesoblast Ltd, dated February 28, 2023.
99.3	Press release of Mesoblast Ltd, dated February 28, 2023.

asx announcement

mesoblast

MESOBLAST REPORTS OPERATIONAL AND FINANCIAL HIGHLIGHTS FOR QUARTER ENDED DECEMBER 31, 2022

Melbourne, Australia: February 28 and New York, USA: February 27, 2023: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today reported operational highlights and financial results for the period ended December 31, 2022.

Dr. Silviu Itescu, Chief Executive of Mesoblast, commenting on the results said, "There is an urgent need for a therapy that improves the dismal survival outcomes in children with steroid-refractory acute graft versus host disease (SR-aGVHD),[1,2] a potentially life-threatening complication of an allogeneic bone marrow transplant for the treatment of blood cancers. With the resubmission of the BLA filing for remestemcel-L we are one step closer to bringing this important product candidate to the market."

"In addition, Mesoblast has been granted Regenerative Medicine Advanced Therapy (RMAT) designation for rexlemestrocel-L for chronic lower back pain (CLBP) associated with degenerative disc disease and we look forward to further interactions with FDA, aiming to enroll the first patients in the pivotal trial by the middle of this year.

I am also pleased to announce that results from our Phase 3 chronic heart failure trial, DREAM-HF, in patients with reduced ejection fraction (HFrEF) was today published in the world's leading cardiology journal - the *Journal of the American College of Cardiology (JACC)*,[4] highlighting the potential for rexlemestrocel-L to make a key difference in patient outcomes including mortality, heart attack or stroke."

FINANCIAL HIGHLIGHTS

Revenue from royalties on sales of TEMCELL® HS Inj.[4,5] sold in Japan by our licensee were US$1.9 million for the quarter ended December 31, 2022. On a constant currency basis, sales for the quarter ended December 31, 2022, were US$2.1 million[5], compared with US$2.3 million for the quarter ended December 31, 2021.

Net cash usage for operating activities was US$16.5 million for the quarter ended December 31, 2022. This represents a 9% reduction (US$1.7 million) from the comparative quarter in FY2022, and a 46% reduction (US$14.1 million) from the comparative quarter in FY2021.

Cash on hand at the end of the quarter was $67.6 million. Up to an additional US$40.0 million may be drawn from existing financing facilities subject to achieving certain milestones.

OPERATIONAL HIGHLIGHTS

Biologics License Application (BLA) resubmitted for remestemcel-L in treatment of children with steroid-refractory graft versus host disease (SR-aGVHD) to the US Food and Drug Administration (FDA) on January 31, 2023.

Presentations of peer-reviewed studies at Tandem Meeting of the American Society for Transplantation and Cellular Therapy (ASTCT) and the Center for International Blood and Marrow Transplant Research (CIBMTR). The data from both studies formed key components of the BLA resubmission

- Long-term survival in children treated with remestemcel-L for SR-aGVHD
- The immunomodulatory activity of remestemcel-L on T cell activation *in vitro* is a direct measure of product potency and correlates with clinical outcomes in pediatric patients with SR-aGVHD.

Regenerative Medicine Advanced Therapy (RMAT) designation granted by FDA for rexlemestrocel-L in the treatment of chronic low back pain (CLBP) associated with disc degeneration, in combination with hyaluronic acid (HA) as delivery agent for injection into the lumbar disc. Preparations underway to commence pivotal study.

DREAM-HF Phase 3 trial results published in the premier peer-reviewed journal for cardiovascular medicine, the *Journal of the American College of Cardiology (JACC)*.

OPERATIONAL RESULTS AND NEAR-TERM MILESTONES

Mesoblast Limited
ABN 68 109 431 870

www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
Melbourne 3000
Victoria Australia

T +61 3 9639 6036
F +61 3 9639 6030

United States Operations
505 Fifth Avenue
Third Floor
New York, NY 10017
USA

T +1 212 880 2060
F +1 212 880 2061

Asia
21 Biopolis Road
#01-22 Nucleos (South Tower)
SINGAPORE 138567

T +65 6570 0635
F +65 6570 0176

Remestemcel-L

Activities regarding remestemcel-L for steroid resistant acute graft versus host disease (SR-aGVHD) in children

Mesoblast filed the Biologics License Application (BLA) resubmission with the US Food and Drug Administration (FDA) at the end of January. The resubmission contains substantial new information in response to the Complete Response Letter (CRL) received in September 2020 to the BLA for remestemcel-L. Specifically, the resubmission contains the following:

- new long-term survival data for children enrolled in the Phase 3 trial showing durability of treatment effect through at least four years,
- new data showing remestemcel-L's treatment benefit in high-risk disease activity and on survival in propensity-matched studies of children in the Phase 3 trial and controls stratified by validated biomarkers for high-risk disease,
- new analyses of data obtained prospectively showing that the validated potency assay which was in place and used to release product for the 54-patient Phase 3 clinical trial measures a key product attribute which reflects the primary mechanism of action of remestemcel-L in children with SR-aGVHD, correlates with the product's *in vivo* bioactivity, and predicts overall survival outcomes,
- new analyses of data obtained prospectively relating to manufacturing changes implemented during product development, prior to Phase 3, to progressive increases in potency and to improved survival outcomes in larger studies of remestemcel-L under expanded access in children with SR-aGVHD,
- new data showing that the validated potency assay has low variability and can adequately demonstrate manufacturing consistency and reproducibility, and
- establishment of a new specification for release of commercial product based on extensive clinical data which provides assurance that future batches of remestemcel-L will have attributes supportive of expected survival outcomes.

Data related to the long-term survival benefit and validated potency assay were presented at the 2023 Tandem Meetings (ASTCT-CIBMTR) held this month. The new results come from a four-year observational survival study performed by the Center for International Blood and Marrow Transplant Research (CIBMTR) on 51 evaluable patients with SR-aGVHD who were enrolled in Mesoblast's phase 3 clinical trial of remestemcel-L.

Overall survival in the remestemcel-L cohort was 63% at 1 year, 51% at 2 years, and 49% at 4 years, while across four recently published studies of children or adults with SR-aGVHD who received best available therapy (BAT) or the only FDA-approved agent for adults, survival rates of 40-49% at 1 year and 25%-38% at 2 years were seen.[6-9]

Rexlemestrocel-L

Activities regarding rexlemestrocel-L for discogenic chronic low back pain (CLBP)

This month the FDA granted RMAT designation for rexlemestrocel-L in the treatment of CLBP associated with degenerative disc disease, in combination with hyaluronic acid (HA) as delivery agent for injection into the lumbar disc.

RMAT designations aim to expedite the development of regenerative medicine therapies intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition where preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for the disease or condition. An RMAT designation for rexlemestrocel-L provides all the benefits of Breakthrough and Fast Track designations, including rolling review and eligibility for priority review on filing of a BLA.

There is a significant need for a safe, effective, and durable opioid-sparing treatment in patients with CLBP associated with degenerative disc disease. Mesoblast has previously gained alignment with the FDA on the key metrics for a pivotal Phase 3 study of rexlemestrocel-L which seeks to replicate the significant reduction in pain seen in the first Phase 3 trial. FDA has confirmed that 12-month reduction in pain is an approvable indication, with key secondary measures of improvement in function and reduced opioid usage. Preparations underway to initiate a pivotal Phase 3 trial by mid-CY2023.

Activities regarding rexlemestrocel-L for chronic heart failure with reduced ejection fraction (HFrEF) [13]

Today's publication of the DREAM-HF Phase 3 trial results[3] in the premier peer-reviewed journal for cardiovascular medicine, the *Journal of the American College of Cardiology (JACC)* showed that rexlemestrocel-L strengthened heart function at 12 months, as measured by left ventricular ejection fraction (LVEF), and decreased cardiovascular death, myocardial infarction or stroke in patients with chronic HFrEF over a mean follow-up of 30 months.

The study enrolled patients across 51 sites in North America and the results showed that a single intra-myocardial injection of 150 million cells of rexlemestrocel-L

- improved LVEF from baseline to 12 months to a significantly greater extent than controls across all patients with available echocardiograms (p=0.021), with maximal benefit seen in patients with active inflammation as measured by the presence of baseline hsCRP ≥2mg/L (p=0.008)
- reduced risk of MI or stroke by 57% (HR 0.43; 95% CI [0.23, 0.78]) in all treated patients compared with controls
- reduced risk of MI or stroke by 75% (HR 0.25; 95% CI [0.09, 0.68]) in patients with inflammation (baseline hsCRP ≥2mg/L) compared with controls
- reduced risk for time-to-first Major Adverse Cardiac Event (MACE), defined as cardiovascular death, MI or stroke, by 28% (HR 0.72; 95% CI: [0.51, 1.03]) in all-treated patients compared with controls
- reduced risk for time-to-first MACE by 37% (HF 0.63; 95% CI: [0.39, 1.02]) in patients with inflammation (baseline hsCRP≥2mg/L) compared with controls

Results from three randomized controlled trials of rexlemestrocel-L in class II/III and in end-stage HFrEF with left ventricular assist devices (LVADs) support the hypothesis that rexlemestrocel-L acts by a common mechanism of action to reverse inflammation-related endothelial dysfunction, thereby reducing adverse clinical outcomes across the spectrum of HFrEF patients.

Improvement in LVEF at 12 months in patients with HFrEF may be an appropriate early surrogate endpoint for long term reduction in major adverse cardiovascular events (MACE).

Mesoblast plans to meet with the FDA next quarter under its existing RMAT designation for end-stage HFrEF patients with LVADs to discuss common mechanisms- of-action across the spectrum of HFrEF patients from NYHA class II/III to those with an implanted LVAD, and potential pathway to marketing approval.

FINANCIAL RESULTS FOR THE PERIOD ENDED DECEMBER 31, 2022 (SECOND QUARTER FY2023)

- **Cash reserves** as of December 31, 2022 were US$67.6 million. Up to an additional US$40.0 million may be drawn from existing financing facilities subject to achieving certain milestones.
- **Financing Facilities**, in December 2022 we announced that funds managed by Oaktree Capital Management, L.P. ("Oaktree") extended to Mesoblast the availability of up to an additional US$30 million of its US$90 million five-year facility subject to achieving certain milestones on or before September 30, 2023.
- **Net cash usage** for operating activities was US$16.5 million for the second quarter FY2023. This represents a 9% reduction (US$1.7 million) from the second quarter FY2022, and a 46% reduction (US$14.1 million) from the second quarter FY2021.
- **Revenue** from royalties on sales of TEMCELL® HS Inj.[4] sold in Japan by our licensee for the second quarter FY2023 were US$1.9 million. On a constant currency basis, sales for the second quarter FY2023, were US$2.1 million,[5] compared with US$2.3 million for the second quarter FY2022.
- **Research & Development** expenses reduced by US$2.5 million (25%), down to US$7.7 million for the second quarter FY2023 compared to US$10.2 million for the second quarter FY2022. R&D expenses primarily supported preparations for the remestemcel-L BLA re-submission and preparations for pivotal studies for rexlemestrocel-L, as clinical trial activities for our product candidates are reduced since clinical trial recruitment and data analysis are now complete.

- **Manufacturing expenses** were US$7.9 million for the second quarter FY2023 compared to US$6.6 million for the second quarter FY2022. During the quarter we continued pre-launch manufacturing activities and product testing for remestemcel-L to support the potential commercial launch for SR-aGVHD.

  We expect to recognize the US$30.4 million balance of remestemcel-L pre-launch inventory, and the balance of any further production completed at that time, on our balance sheet if we receive FDA approval.
- **Management and Administration** expenses reduced by US$1.4 million (18%), down to US$6.4 million for the second quarter FY2023 compared to US$7.8 million for the second quarter FY2022 primarily due to decreased legal and professional fees associated with a one-off adjustment in legal expenses during the period.
- **Remeasurement of Contingent Consideration** recognized gains of US$1.5 million in the second quarter FY2023 reflecting a reduction in future third party payments compared to a loss of US$0.4 million in the second quarter FY2022.
- **Fair value movement of warrants** recognized a loss of US$0.3 million in the second quarter FY2023 compared to a gain of US$2.2 million in the second quarter FY2022.
- **Finance Costs for borrowing arrangements** include US$5.0 million of non-cash expenditure for the second quarter FY2023 comprising accruing interest and borrowing costs.

Loss after tax for the second quarter FY2023 was US$24.5 million compared to US$25.9 million for the second quarter FY2022. The net loss attributable to ordinary shareholders was 3.32 US cents per share for the second quarter FY2023, compared with 4.00 US cents per share for the second quarter FY2022.

Conference Call
There will be a webcast today, beginning at 8.30am AEDT (Tuesday, February 28); 4.30pm ET (Monday, February 27). It can be accessed via: https://webcast.openbriefing.com/msb-qtr-2023/

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

About Mesoblast
Mesoblast 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. Westin, J., Saliba, RM., Lima, M. (2011) Steroid-refractory acute GVHD: predictors and outcomes. Advances in Hematology.
2. 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.
3. Perin EC. Et al. Randomized Trial of Targeted Transendocardial Mesenchymal Precursor Cell Therapy in Patients With Heart Failure. *JACC* Vol. 81, No. 9, 2023. https://doi.org/10.1016/j.jacc.2022.11.061
4. TEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.
5. 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:116.02 Yen for the 3 months ended December 31, 2021 to 1USD:133.70 Yen for the 3 months ended December 31, 2022.
6. Rashidi A et al. Outcomes and predictors of response in steroid-refractory acute graft-versus-host disease: single-center results from a cohort of 203 patients. *Biol Blood Bone Marrow Transplant* 2019; 25(11):2297-2302
7. MacMillan ML et al. Pediatric acute GVHD: clinical phenotype and response to upfront steroids. *Bone Marrow Transplant* 2020; 55(1): 165-171
8. Zeiser R et al. Ruxolitinib for Glucocorticoid-Refractory Acute Graft-versus-Host Disease. *N Engl J Med* 2020;382:1800-10
9. 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

Forward-Looking Statements

This press release includes forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Forward-looking statements should not be read as a guarantee of future performance or results, and actual results may differ from the results anticipated in these forward-looking statements, and the differences may be material and adverse. Forward-looking statements include, but are not limited to, statements about: the initiation, timing, progress and results of Mesoblast's preclinical and clinical studies, and Mesoblast's research and development programs; Mesoblast's ability to advance product candidates into, enroll and successfully complete, clinical studies, including multi-national clinical trials; Mesoblast's ability to advance its manufacturing capabilities; the timing or likelihood of regulatory filings and approvals, manufacturing activities and product marketing activities, if any; the commercialization of Mesoblast's 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:

Corporate Communications / Investors
Paul Hughes
T: +61 3 9639 6036
E: investors@mesoblast.com

Media
BlueDot Media
Steve Dabkowski
T: +61 419 880 486
E: steve@bluedot.net.au

Rubenstein
Tali Mackay
E: tmackay@rubenstein.com

Consolidated Income Statement

(in U.S. dollars, in thousands, except per share amount)	Three Months Ended December 31,		Six Months Ended December 31,	
	2022	2021	2022	2021
Revenue	2,134	2,383	3,636	5,977
Research & development	(7,683)	(10,198)	(13,430)	(19,526)
Manufacturing commercialization	(7,894)	(6,590)	(12,760)	(14,127)
Management and administration	(6,386)	(7,814)	(13,281)	(13,692)
Fair value remeasurement of contingent consideration	1,520	(351)	5,989	(71)
Fair value remeasurement of warrant liability	(311)	2,152	(712)	2,152
Other operating income and expenses	251	(227)	(253)	(405)
Finance costs	(6,188)	(5,380)	(10,685)	(9,040)
Loss before income tax	**(24,557)**	**(26,025)**	**(41,496)**	**(48,732)**
Income tax benefit/(expense)	71	80	126	142
Loss attributable to the owners of Mesoblast Limited	**(24,486)**	**(25,945)**	**(41,370)**	**(48,590)**
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:	**Cents**	**Cents**	**Cents**	**Cents**
Basic - losses per share	(3.32)	(4.00)	(5.78)	(7.50)
Diluted - losses per share	(3.32)	(4.00)	(5.78)	(7.50)

Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	Three Months Ended December 31,		Six Months Ended December 31,	
	2022	2021	2022	2021
Loss for the period	**(24,486)**	**(25,945)**	**(41,370)**	**(48,590)**
Other comprehensive (loss)/income				
Items that may be reclassified to profit and loss				
Exchange differences on translation of foreign operations	259	166	100	(183)
Items that will not be reclassified to profit and loss				
Financial assets at fair value through other comprehensive income	106	112	192	266
Other comprehensive (loss)/income for the period, net of tax	**365**	**278**	**292**	**83**
Total comprehensive losses attributable to the owners of Mesoblast Limited	**(24,121)**	**(25,667)**	**(41,078)**	**(48,507)**

Consolidated Balance Sheet

(in U.S. dollars, in thousands)	As of December 31, 2022	As of June 30, 2022
Assets		
Current Assets		
Cash & cash equivalents	67,619	60,447
Trade & other receivables	5,115	4,403
Prepayments	5,399	4,987
Total Current Assets	**78,133**	**69,837**
Non-Current Assets		
Property, plant and equipment	1,556	2,045
Right-of-use assets	6,598	7,920
Financial assets at fair value through other comprehensive income	1,949	1,758
Other non-current assets	1,922	1,930
Intangible assets	577,902	578,652
Total Non-Current Assets	**589,927**	**592,305**
Total Assets	**668,060**	**662,142**
Liabilities		
Current Liabilities		
Trade and other payables	22,992	23,079
Provisions	17,853	17,906
Borrowings	5,938	5,017
Lease liabilities	3,860	3,186
Warrant liability	3,933	2,185
Total Current Liabilities	**54,576**	**51,373**
Non-Current Liabilities		
Provisions	8,998	12,523
Borrowings	96,984	91,617
Lease liabilities	5,000	7,085
Deferred consideration	2,500	2,500
Total Non-Current Liabilities	**113,482**	**113,725**
Total Liabilities	**168,058**	**165,098**
Net Assets	**500,002**	**497,044**
Equity		
Issued Capital	1,207,714	1,165,309
Reserves	72,574	70,651
(Accumulated losses)/retained earnings	(780,286)	(738,916)
Total Equity	**500,002**	**497,044**

Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	Six Months Ended December 31, 2022	2021
Cash flows from operating activities		
Commercialization revenue received	3,667	5,531
Government grants and tax incentives received	18	24
Payments to suppliers and employees (inclusive of goods and services tax)	(34,633)	(41,977)
Interest received	207	4
Net cash (outflows) in operating activities	**(30,741)**	**(36,418)**
Cash flows from investing activities		
Investment in fixed assets	(187)	(103)
Payments for intellectual property	(50)	(26)
Net cash (outflows) in investing activities	**(237)**	**(129)**
Cash flows from financing activities		
Proceeds from borrowings	—	51,919
Repayment of borrowings	—	(55,458)
Payment of transaction costs from borrowings	(217)	(5,453)
Interest and other costs of finance paid	(2,807)	(2,951)
Proceeds from issue of shares	45,065	209
Proceeds from issue of warrants	—	8,081
Payments for share issue costs	(2,646)	(216)
Payments for lease liabilities	(1,109)	(1,214)
Net cash inflows/(outflows) by financing activities	**38,286**	**(5,083)**
Net increase/(decrease) in cash and cash equivalents	7,308	(41,630)
Cash and cash equivalents at beginning of period	60,447	136,881
FX gain/(losses) on the translation of foreign bank accounts	(136)	(402)
Cash and cash equivalents at end of period	**67,619**	**94,849**

Exhibit 99.2

mesoblast

Global Leader in Allogeneic Cellular Medicines for Inflammatory Diseases

Operational Highlights and Financial Results for the Quarter Ended December 31, 2022

February 2023

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.

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 SR-aGVHD	Remestemcel-L BLA resubmitted to FDA for children with steroid-refractory acute graft versus host disease (SR-aGVHD) January 31, 2023
Rexlemestrocel-L for CLBP	First Phase 3 completed for discogenic chronic low back pain (CLBP). RMAT granted by FDA. Progressing towards initiation of a second pivotal Phase 3 study commencing mid-CY2023
Rexlemestrocel-L for HFrEF	First Phase 3 completed for heart failure with reduced ejection fraction (HFrEF) Class II/III patients. RMAT granted by FDA for end-stage HFrEF patients with an LVAD
Finances	Annualized revenue of US$7.6 million from royalties on sales MSC products; US$67.6 million in cash plus up to an additional US$40 million from existing financing facilities, subject to certain milestones. Potential for commercial partnering and royalty sharing transactions

Late-Stage Clinical Pipeline

Based on the Proprietary Allogeneic Mesenchymal Stromal Cell Platforms

Product	Indication	Phase 2	Phase 3	Regulatory Filing	Approved	Status/Next Steps
Remestemcel-L	SR-aGVHD					• BLA resubmitted Jan 2023
Rexlemestrocel-L	CLBP					• RMAT granted • Planning to start pivotal Phase 3 trial mid-CY2023
Rexlemestrocel-L	HFrEF					• RMAT granted for End-Stage/LVAD • FDA meeting planned for H1 CY2023
Remestemcel-L	ARDS and other applications					• Clinical collaborations, investigator studies

Mesoblast's Proprietary Stromal Cell Technology

Based on mesenchymal lineage adult stromal cells (MLCs/SCs)

Mesenchymal Lineage

MLCs are **derived** from healthy bone marrow, **present** around blood vessels and **responsive** to signals associated with tissue damage / inflammation

Defined Stromal Cells

Biologically-defined, optimized for results:
Remestemcel-L: based on mesenchymal stromal cells (MSCs)

Rexlemestrocel-L: based on mesenchymal precursor cells (MPCs)

Allogenic Properties

Expanded **without differentiation**

No expression of cell surface co-stimulatory molecules

Scalable Production

Scalable "off-the-shelf" cellular platforms

Validated potency assay to ensure batch-to-batch consistency and reproducibility

Manufacturing Remestemcel-L

Financial Results

for the Period Ended December 31, 2022

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Financial Highlights

Royalty Revenue	Revenue from royalties on sales of TEMCELL® HS Inj.[1] sold in Japan by our licensee were US$1.9 million for the quarter ended December 31, 2022. On a constant currency basis, sales for the quarter ended December 31, 2022, were US$2.1 million[2], compared with US$2.3 million for the quarter ended December 31, 2021.
Cash Burn	Net cash usage for operating activities in the second quarter FY2023 was US$16.5 million; this represented a 9% reduction (US$1.7 million) on the second quarter FY2022, and a 46% reduction (US$14.1 million) on the second quarter FY2021.
Cash Reserves	At December 31, 2022, cash-on-hand was US$67.6 million. Up to an additional US$40.0 million may be drawn from existing financing facilities subject to achieving certain milestones.

1. TEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.
2. 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:116.02 Yen for the 3 months ended December 31, 2021 to 1USD:133.70 Yen for the 3 months ended December 31, 2022.

Reduction in Expenditure on R&D, Improved Loss Before Tax

P&L for the quarter ended (US$m)	Dec 31, 2022	Dec 31, 2021
Total Revenue	**2.1**	**2.4**
Research and development	(7.7)	(10.2)
Manufacturing	(7.9)	(6.6)
Management & administration	(6.4)	(7.8)
Revaluation of contingent consideration	1.5	(0.4)
Revaluation of warrant liability	(0.3)	2.2
Other operating income & expenses	0.3	(0.2)
Finance costs	(6.2)	(5.4)
Loss before tax	**(24.6)**	**(26.0)**
Income tax benefit	0.1	0.1
Loss after tax	**(24.5)**	**(25.9)**

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

Reduction in R&D Expenditure: reduced by US$2.5 million (25%), down to US$7.7 million for the quarter ended December 31, 2022. R&D expenses primarily supported preparations for the remestemcel-L BLA re-submission and preparations for pivotal studies for rexlemestrocel-L, as clinical trial activities for our product candidates are reduced since clinical trial recruitment and data analysis are now complete.

Continued Investment in Manufacturing: continued manufacturing activities to support the potential commercial launch for SR-aGVHD. On FDA approval US$30.4 million of remestemcel-L pre-launch inventory will be recognized on the balance sheet.

Finance Costs include US$5.0 million of non-cash expenditure for the quarter ended December 31, 2022 comprising accruing interest and borrowing costs.

Figures have been rounded.

1. TEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd. 2. 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.

Remestemcel-L

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

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

SR-aGVHD is associated with mortality rates as high as 90%

Treatment Options

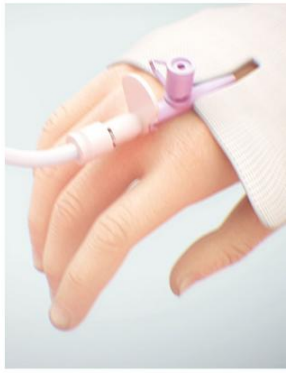
- Corticosteroids are first-line therapy for aGVHD
- There is only one approved treatment for disease refractory to steroids and no approved treatment in the US for children under 12 years old
- In Japan, Mesoblast's licensee has received the only product approval for SR-aGVHD in both children and adults

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%[1,5] and significant extended hospital stay costs[2]

Market Opportunity

- More than 30,000 allogeneic BMTs performed globally (>20K US/EU) annually, ~20% pediatric[3,4]
- Approx. 1,500 allogeneic BMTs in children and adolescents in US[4]



1. Westin, J., Saliba, RM., Lima, M. (2011) Steroid-refractory acute GVHD: predictors and outcomes. Advances in Hematology. 2. Anthem-HealthCore/Mesoblast claims analysis (2016). Data on file 3. 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. 4. HRSA Transplant Activity Report, CIBMTR, 2019 5. 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.

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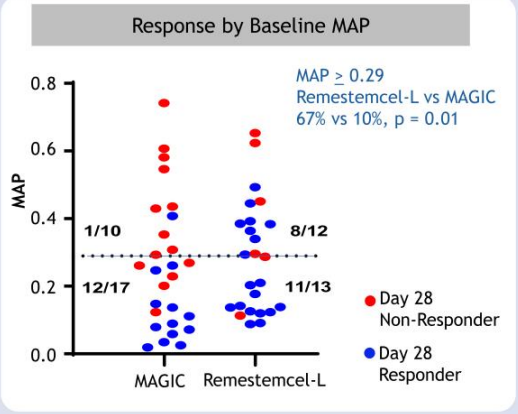
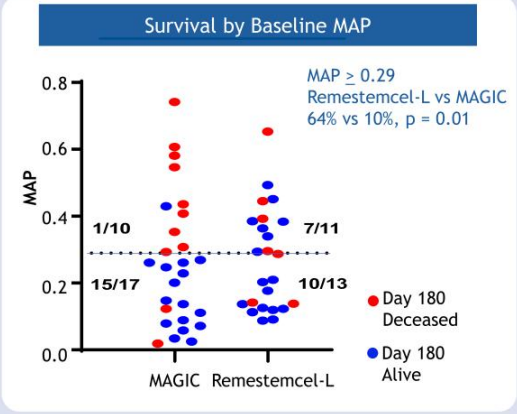
BLA Resubmission Contains New Data on Product Potency and Clinical Outcomes in Pediatric Patients with SR-aGVHD

- New data showing remestemcel-L's treatment benefit in high-risk disease activity and on survival in propensity-matched studies of children in the Phase 3 trial and controls stratified by validated biomarkers for high-risk disease
- New long-term survival data for children enrolled in the Phase 3 trial showing durability of treatment effect through at least four years
- New analyses of data from Phase 3 trial and the Expanded Access Program showing that the validated potency assay reflects the primary mechanism of action of remestemcel-L in children with SR-aGVHD, correlates with the product's in vivo bioactivity, and predicts overall survival outcomes
- New data showing that the validated potency assay has low variability and can adequately demonstrate manufacturing consistency and reproducibility

Use of Validated Biomarker for Assessment of Treatment Effect in Severe SR-aGVHD

Remestemcel-L Results in Significantly Greater Day 28 Overall Responses and Day 180 Survival in Highest-Risk Patients (Baseline MAP ≥ 0.29)





Kasikis S et al. Bone Marrow Transplantation 2021; 56:2869-2870.

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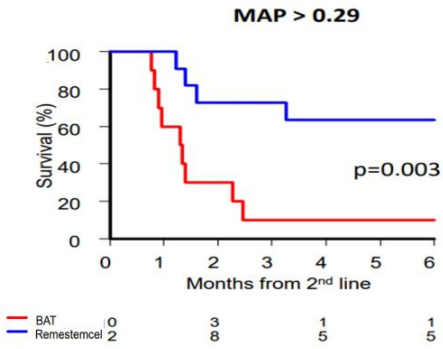
Remestemcel-L Treatment Outcomes

Significantly Greater Survival in Steroid-Refractory Patients with Baseline MAP ≥ 0.29

Kaplan-Meier Estimates of 6-month Overall Survival for the Two Patient Cohorts by Baseline MAP



Abbreviations:
MAP: MAGIC algorithm probability;
BAT: best available therapy.

Kasikis S et al. Bone Marrow Transplantation 2021; 56:2869-2870.

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Remestemcel-L for SR-aGVHD

Improved Early Survival in Children Across Three Studies

Day 100 Survival			
Remestemcel-L Protocol	**Remestemcel-L**	**Matched Controls**	**Matched Control Protocol**
First Line Therapy after Steroids Treatment Setting			
Pediatric Subset of Protocol 280: randomized controlled P3, n=27 w/SR-aGVHD	79%	54%	Study Control Arm (n=13)
Study 001, open-label P3, n=54[1] with 89% Grade C/D disease	74%	57%	**MAGIC[2] cohort**, n=30[3] propensity-controlled subset
Salvage Therapy Treatment Setting			
Expanded Access Protocol (EAP275), n=241	66%	na	
EAP275, n=51 Grade D subset	51%	31%	**CIBMTR dbase**, n=327[4] propensity controlled subset

1. GVHD001 had 55 randomized patients, however one patient dropped out before receiving any dose of remestemcel-L; 2. Mount Sinai Acute GVHD International Consortium (MAGIC) - a group of ten BMT centers throughout the US and Europe whose purpose is to conduct ground-breaking clinical trials in GVHD, including developing informative biorepositories that assist in developing treatments that can guide GVHD therapy; 3. Two subjects in the MAGIC cohort had follow-up <100 days; these subjects are excluded from the respective survival analyses; 4. Data on file

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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]	Zeiser et al[3]	REACH2[3]	REACH1[4]
Treatment	Remestemcel-L	BAT[5]	BAT[5]	BAT[5]	Ruxolitinib	Ruxolitinib
N=	51	128	203	155	154	71
Subjects	Children	Children	Adults	Adults	Adults	Adults
aGVHD Grade	88% Grade C/D	22% Grade 3/4	54% Grade 3/4	63% Grade 3/4	63% Grade 3/4	68% Grade 3/4
Year 1 Survival	63%	40%	--	44%	49%	43%
Year 2 Survival	51%	35%	25%	36%	38%	--
Year 3 Survival	49%					
Year 4 Survival	49%					

1. MacMillan ML et al. Pediatric acute GVHD: clinical phenotype and response to upfront steroids. Bone Marrow Transplant 2020; 55(1): 165-171
2. Rashidi A et al. Outcomes and predictors of response in steroid-refractory acute graft-versus-host disease: single-center results from a cohort of 203 patients. Biol Blood Bone Marrow Transplant 2019; 25(11):2297-2302.
3. Zeiser R et al. Ruxolitinib for Glucocorticoid-Refractory Acute Graft-versus-Host Disease. N Engl J Med 2020;382:1800-10.
4. Jagasia M et al. Ruxolitinib for the treatment of steroid-refractory acute GVHD (REACH1): a multicenter, open-label phase 2 trial. Blood. 2020 May 14; 135(20): 1739–1749
5. BAT = Best Available Treatment

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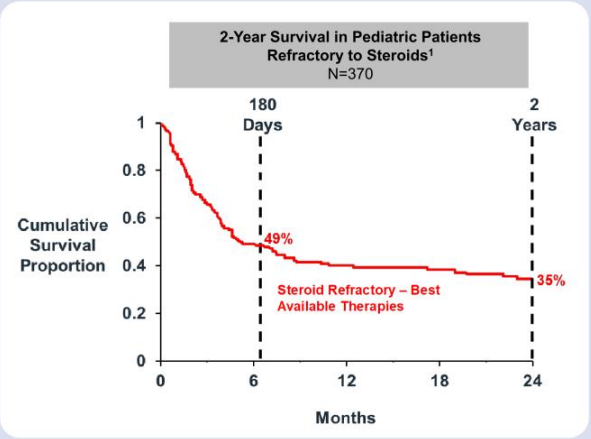
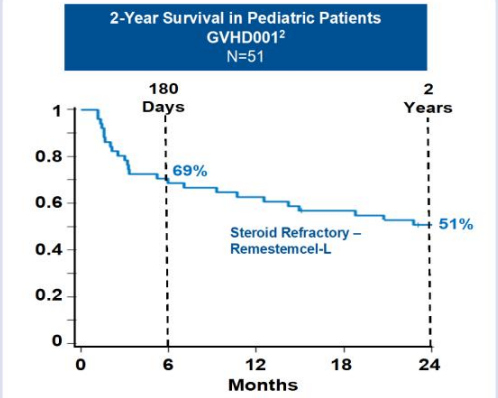
Long term Survival in Pediatric Patients with SR-aGVHD Treated with Remestemcel-L

Presented at the 2023 Tandem Meeting of ASTCT and CIBMTR





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

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Rexlemestrocel-L

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

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Chronic Low Back Pain Due to Degenerative Disc Disease (CLBP) Impacts 7M+

Rexlemestrocel-L represents a potential new paradigm for the treatment of CLBP

Burden of Illness

- Back pain causes more disability than any other condition[1]
- 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 CLBP[2]
- Durable improvement in pain has potential to reduce opioid use and prevent surgical intervention

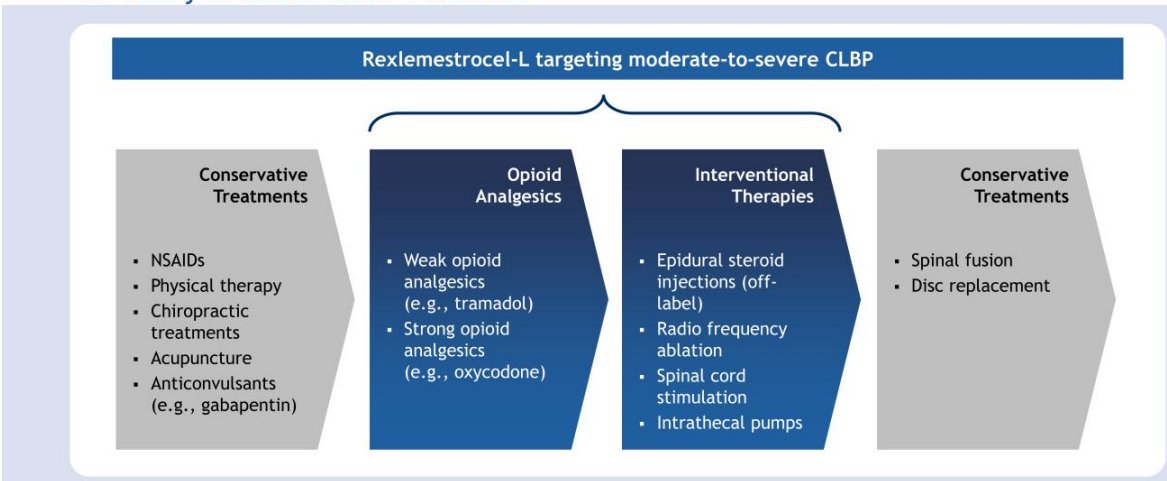
Market Opportunity

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

Patients with CLBP Refractory to Standard Treatment Have Minimal Options

Rexlemestrocel-L has the Potential to be First-Line Treatment for Patients with CLBP Refractory to Conservative Treatment



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:

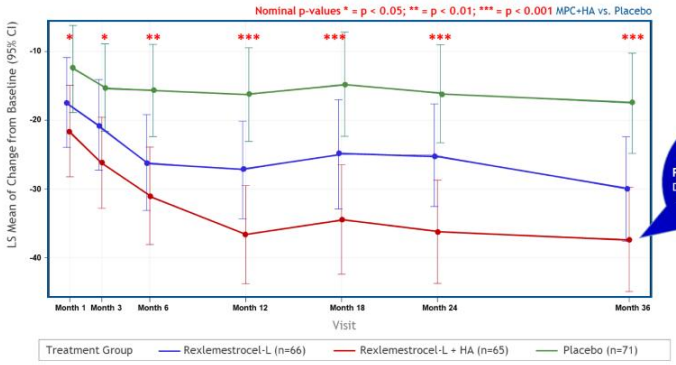
- A single injection of rexlemestrocel-L+HA into the lumbar disc resulted in significant reduction in pain compared with saline control at 12 and 24 months across all subjects (n=404)
- Pain reduction through 36 months was seen in the subset of patients using opioids at baseline (n=168) with the rexlemestrocel-L+HA 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

LS Mean VAS Change in Low Back Pain from Baseline - Duration CLBP < 68 Month Median Baseline Duration (n=202)



Duration < Median

Rexlemestrocel-L +HA Demonstrated significant reductions in pain over 36-months

VAS=Visual Analog Score; HA=Hyaluronic Acid

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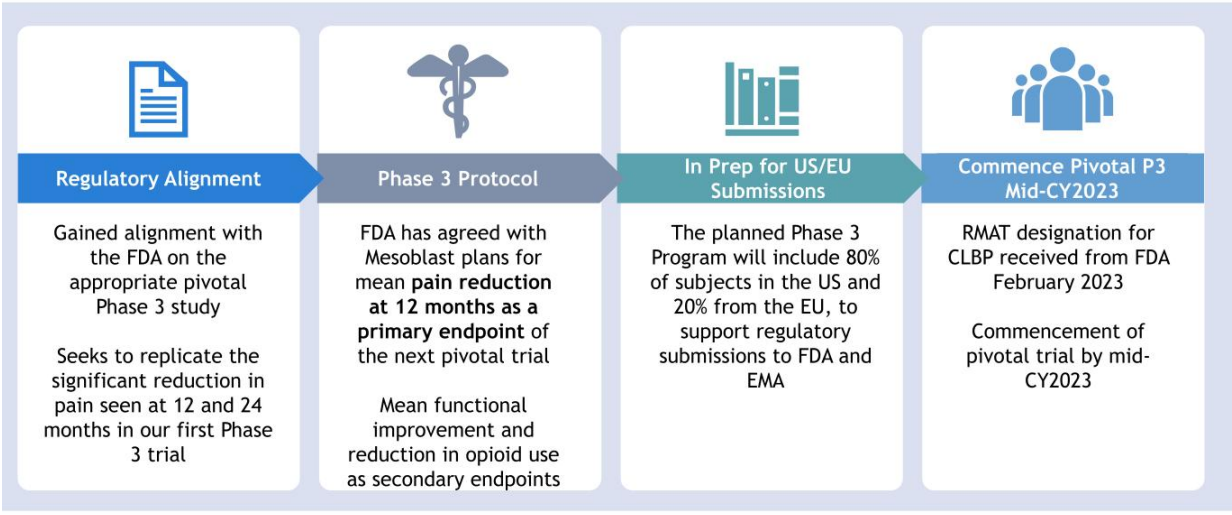
Rexlemestrocel-L / CLBP



Rexlemestrocel-L

Chronic Heart Failure Reduced Ejection Fraction (HFrEF)

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Chronic Heart Failure (CHF): Rising Incidence and High Mortality

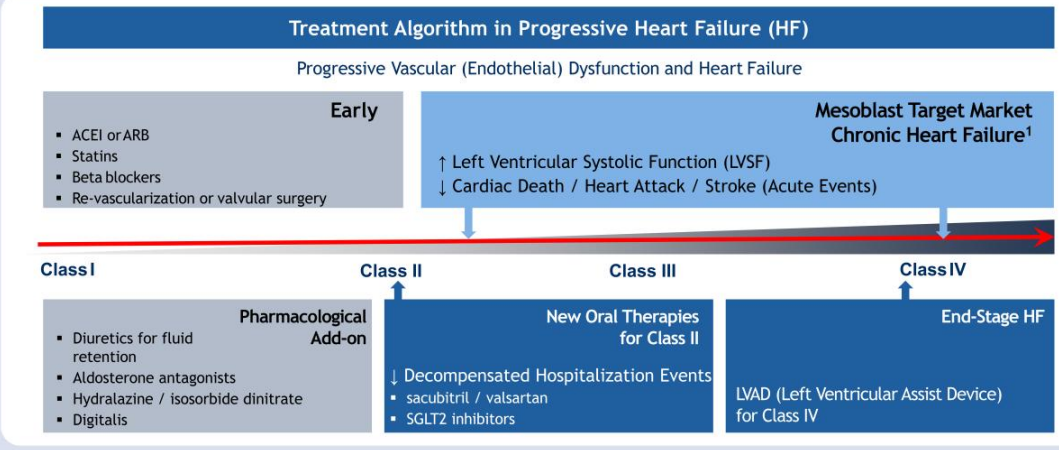
New therapies reduce recurrent hospitalization but do not materially improve mortality or major ischemic event rates

- Cardiovascular disease remains the leading cause of death in the United States[1]
- Heart failure affects 6.5 million patients in the US and 26 million patients globally. As populations age, the prevalence is increasing[2]
- Chronic heart failure is a progressive disease with a high mortality that approaches 50% at 5 years[2,3] and at least 75% after an initial hospitalization[4]
- Patients with heart failure are also at high risk of recurrent major adverse cardiac events involving large vessels (heart attacks / strokes)

1. Muntner BEJ, et al. Heart Disease and Stroke Statistics-2019 Update: A Report From the American Heart Association. Circulation. Feb 19, 2019. 2. United States Food & Drug Administration. Treatment for Heart Failure: Endpoints for Drug Development. Draft Guidance. June 2019. 3. Taylor CJ, et al. Trends in survival after a diagnosis of heart failure in the United Kingdom 2000-2017: population based cohort study. BMJ. 2019;364:l223. 4. Shah KS, et al. Heart Failure with Preserve, Borderline, and Reduced Ejection Fraction; 5-Year Outcomes. JACC. 2017;Nov12.

Patients Experience Progressive Vascular Dysfunction and Heart Failure

Rexlemestrocel-L has the potential to improve endothelial dysfunction in patients from Class II thru IV



1. GlobalData-PharmaPoint Heart Failure (2016); McMurray et al., 2012;Yancy et al., 2013, 2016 ACC/AHAHFSA Focused Update on New Pharmacological Therapy for Heart Failure: An Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure.

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ORIGINAL INVESTIGATIONS

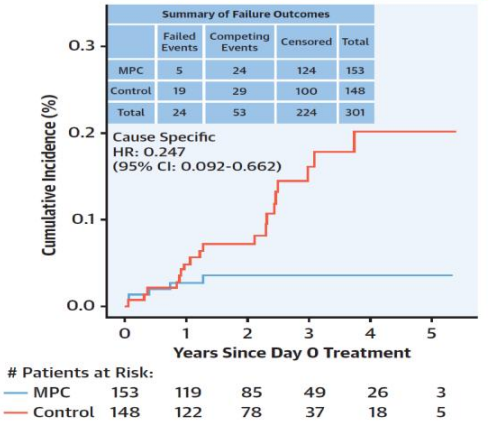
Randomized Trial of Targeted Transendocardial Mesenchymal Precursor Cell Therapy in Patients With Heart Failure

Emerson C. Perin, MD, PhD,[a] Kenneth M. Borow, MD,[b] Timothy D. Henry, MD,[c] Farrell O. Mendelsohn, MD,[d] Leslie W. Miller, MD,[e] Elizabeth Swiggum, MD,[f] Eric D. Adler, MD,[g] David H. Chang, MD,[h] R. David Fish, MD,[d] Alain Bouchard, MD,[d] Margaret Jenkins, BSc (Hons),[i] Alex Yaroshinsky, PhD,[j] Jack Hayes, MA,[k] Olga Rutman, PhD,[k] Christopher W. James, PA,[c] Eric Rose, MD,[c] Silviu Itescu, MD,[l] Barry Greenberg, MD[m]

Randomized, double-blind, controlled, 537 patient Phase 3 trial of rexlemestrocel-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



Patients at Risk:

MPC	153	119	85	49	26	3
Control	148	122	78	37	18	5

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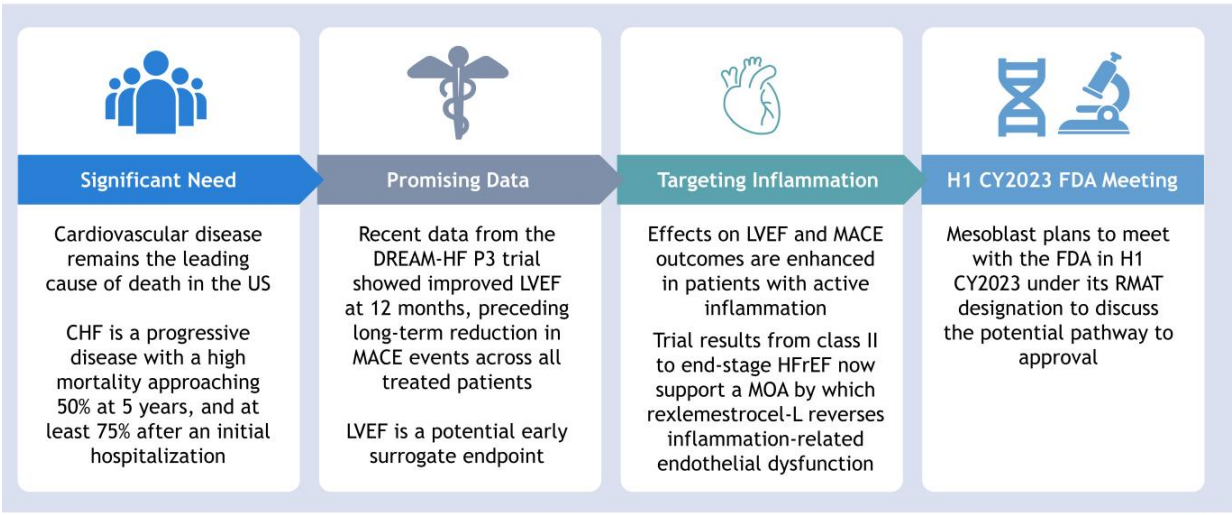
Rexlemestrocel-L / HFrEF

Defining the Regulatory Path to FDA Approval



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Thank You

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asx announcement

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DREAM-HF PHASE 3 TRIAL RESULTS FOR MESOBLAST CELL THERAPY IN HEART FAILURE PUBLISHED IN JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY (JACC)

Single Intra-Myocardial Intervention with Rexlemestrocel-L Reduced Cardiovascular Death, Myocardial Infarction or Stroke Over Mean Follow-Up of 30 Months in High-Risk Patients with Chronic Heart Failure

Melbourne, Australia; February 28 and New York, USA; February 27, 2023: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today announced publication of the DREAM-HF Phase 3 trial results in the premier peer-reviewed journal for cardiovascular medicine, the *Journal of the American College of Cardiology* (JACC). The results of the randomized, double-blind, controlled study in 537 patients showed that Mesoblast's mesenchymal precursor cell therapy (MPCs; rexlemestrocel-L) strengthened heart function at 12 months, as measured by left ventricular ejection fraction (LVEF) and decreased cardiovascular death, myocardial infarction (MI) or stroke in patients with chronic heart failure (CHF) due to reduced ejection fraction (HFrEF) over a mean follow-up of 30 months.[1]

DREAM-HF's lead investigator, Dr. Emerson C. Perin, MD, PhD, FACC, Medical Director at The Texas Heart Institute, said "The cells appear to work by reducing inflammation, increasing microvascular flow, and strengthening heart muscle. Locally, in the heart, the MPCs can protect cardiac muscle cells from dying and can improve blood flow and energetics. In large blood vessels throughout the body, the reduced inflammation resulting from the activation of MPCs may decrease plaque instability, which is what leads to heart attacks and strokes. The cells seem to have a systemic immune modulatory and anti-inflammatory effect."

"MPC therapy could change the future of cardiovascular care for patients with heart failure due to inflammation," according to Dr. Joseph G. Rogers, CEO and President of The Texas Heart Institute and advanced heart failure specialist.

The study enrolled patients across 51 sites in North America and the results showed that a single intra-myocardial injection of 150 million cells of rexlemestrocel-L:

- improved LVEF from baseline to 12 months to a significantly greater extent than controls across all patients with available echocardiograms (p=0.021), with maximal benefit seen in patients with active inflammation as measured by the presence of baseline hsCRP ≥2mg/L (p=0.008)
- reduced risk of MI or stroke by 57% (HR 0.43; 95% CI [0.23, 0.78]) in all treated patients compared with controls
- reduced risk of MI or stroke by 75% (HR 0.25; 95% CI [0.09, 0.68]) in patients with inflammation (baseline hsCRP ≥2mg/L) compared with controls
- reduced risk for time-to-first Major Adverse Cardiac Event (MACE), defined as cardiovascular death, MI or stroke, by 28% (HR 0.72; 95% CI: [0.51, 1.03]) in all-treated patients compared with controls
- reduced risk for time-to-first MACE by 37% (HF 0.63; 95% CI: [0.39, 1.02]) in patients with inflammation (baseline hsCRP≥2mg/L) compared with controls
- did not further reduce the frequency of recurrent hospitalizations for worsening HF symptoms when added to maximal standard of care medicines for heart failure.

"These provocative results may usher in new directions for the field of cell-based regenerative therapies in the coming decade," stated PV Johnston et al commenting on the DREAM-HF results in a recently published[2] review in American Heart Journal Plus: Cardiology Research. "Using the knowledge gained from DREAM-HF along with the trials that preceded it, the potential for breakthrough cell-based therapies for heart failure in the coming decade is immense."

Mesoblast Limited
ABN 68 109 431 870

www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
Melbourne 3000
Victoria Australia

T +61 3 9639 6036
F +61 3 9639 6030

United States Operations
505 Fifth Avenue
Third Floor
New York, NY 10017
USA

T +1 212 880 2060
F +1 212 880 2061

Asia
21 Biopolis Road
#01-22 Nucleos (South Tower)
SINGAPORE 138567

T +65 6570 0635
F +65 6570 0176

“We are very encouraged by these study data that indicate the potential of our allogeneic cellular therapy to address the major areas of unmet need in heart failure patients where conventional treatments are not effective,” said Mesoblast CEO Dr. Silviu Itescu. “Improvement in LVEF at 12 months may be a functional surrogate endpoint for rexlemestrocel-L’s subsequent benefits on long-term MACE outcomes and survival in this high-risk patient population with chronic heart failure.”

“These findings suggest an important mechanism of action is the anti-inflammatory effect of MPCs, but perhaps more importantly, these effects are systemic and not limited to their site of delivery in the heart” added PV Johnston et al. “The results of DREAM-HF suggest those patients with heart failure with preserved ejection fraction (HFpEF) and other cardiomyopathies could potentially benefit from MPC therapy as well. The results of DREAM-HF in this way mirror the prior Cardiothoracic Surgical Trials Network studies of intramyocardial MPCs in left ventricular assist device (LVAD) patients.”

In an earlier randomized, controlled trial in 159 patients with end-stage chronic HFrEF, inflammation and LVAD implantation, a single intervention with rexlemestrocel-L injected directly into the left ventricle at the time of LVAD insertion resulted in significantly reduced cumulative incidence of life-threatening non-surgical major mucosal bleeding events requiring hospitalization through 6 months (GI or epistaxis) compared with controls (p=0.02).

Mesoblast plans to meet with the US Food & Drug Administration (FDA) next quarter under its existing regenerative medicine advanced therapy (RMAT) designation to discuss common mechanisms- of-action across the spectrum of chronic HFrEF patients from NYHA class II/III to those with an implanted LVAD, and potential pathway to marketing approval.

About Chronic Heart Failure
Chronic heart failure (CHF) is characterized by poor heart function resulting in insufficient blood flow to the body’s vital organs and extremities. This condition affects approximately 6.5 million people in the United States and 26 million people globally with increasing prevalence and incidence. CHF patients are commonly classified according to the New York Heart Association (NYHA) categories based on the patient’s physical limitations. Class I (mild) patients have no limitations while Class IV patients (severe/end stage) experience symptoms even at rest.

The mortality rate approaches 50% at 5 years as patients progress beyond NYHA early class II disease in parallel with increasing inflammation in the heart and in the circulation.[3,4] Despite recent approvals of new therapies for HFrEF, NYHA class II/III HFrEF patients with inflammation remain at high risk for cardiac death, heart attacks and strokes.

Over 60,000 patients annually in the US progress to end-stage heart failure (NYHA class IIIB/IV) and these patients have a one-year mortality exceeding 50%.[5] Use of LVADs in end-stage heart failure patients to improve survival is gaining momentum, with approximately 5,500 LVADs implanted annually in the US.[6-8] However, systemic inflammation associated with major life-threatening gastrointestinal bleeding high rates of rehospitalization remain a major obstacle to greater LVADs use.[9,10]

About Mesoblast
Mesoblast 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

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Forward-Looking Statements

This press release includes forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Forward-looking statements should not be read as a guarantee of future performance or results, and actual results may differ from the results anticipated in these forward-looking statements, and the differences may be material and adverse. Forward-looking statements include, but are not limited to, statements about: the initiation, timing, progress and results of Mesoblast's preclinical and clinical studies, and Mesoblast's research and development programs; Mesoblast's ability to advance product candidates into, enroll and successfully complete, clinical studies, including multi-national clinical trials; Mesoblast's ability to advance its manufacturing capabilities; the timing or likelihood of regulatory filings and approvals, manufacturing activities and product marketing activities, if any; the commercialization of Mesoblast's 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:

Corporate Communications / Investors
Paul Hughes
T: +61 3 9639 6036
E: investors@mesoblast.com

Media
BlueDot Media
Steve Dabkowski
T: +61 419 880 486
E: steve@bluedot.net.au

Rubenstein
Tali Mackay
E: tmackay@rubenstein.com