
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 May 2023

Commission File Number 001-37626

Mesoblast Limited

(Exact name of Registrant as specified in its charter)

Not Applicable

(Translation of Registrant's name into English)

Australia

(Jurisdiction of incorporation or organization)

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

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

Form 20-F Form 40-F

INFORMATION CONTAINED ON THIS REPORT ON FORM 6-K

On May 26, 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.

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: May 26, 2023

INDEX TO EXHIBITS

Item

- [99.1](#) Press release of Mesoblast Ltd, dated May 26, 2023
- [99.2](#) Investor presentation of Mesoblast Ltd, dated May 26, 2023.

MESOBLAST REPORTS OPERATIONAL AND FINANCIAL HIGHLIGHTS FOR QUARTER ENDED MARCH 31, 2023

Melbourne, Australia: May 26 and New York, USA: May 25, 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 March 31, 2023.

OPERATIONAL HIGHLIGHTS

Remestemcel-L BLA filing accepted by FDA, PDUFA goal date set

US Food and Drug Administration (FDA) accepted Mesoblast's filing of the Biologics License Application (BLA) for remestemcel-L in the treatment of children with steroid-refractory graft versus host disease (SR-aGVHD) as being complete and has set a Prescription Drug User Fee Act (PDUFA) goal date of August 2, 2023.

FDA pre-license inspection of remestemcel-L manufacturing conducted

As part of its ongoing review of the BLA, FDA has now conducted the Pre-License Inspection (PLI) of the manufacturing process for remestemcel-L.

The FDA inspection did not result in the issuance of a Form 483, which must be provided at the conclusion of an inspection if investigators have observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic Act and related Acts.

According to FDA procedures, an Establishment Inspection Report (EIR) is expected to be issued by FDA in the coming weeks providing a detailed summary and final assessment of the inspection.

Key studies presented at 2023 Tandem Meetings of the American Society for Transplantation and Cellular Therapy (ASTCT) and the Center for Blood and Marrow Transplant Research (CIBMTR) in support of remestemcel-L BLA

The presentations were titled "Long-Term Survival in Children Treated with Remestemcel-L for SR-aGVHD" and "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 Steroid-Refractory Acute GVHD".

Regenerative Medicine Advanced Therapy (RMAT) designation granted by FDA for rexiemestroccl-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. FDA has cleared the pivotal trial protocol, and we expect enrolment to commence during the third quarter of this year.

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)*.¹

FINANCIAL HIGHLIGHTS

Successful completion of a global private placement primarily to Mesoblast's existing major US, UK, and Australian shareholders raising approximately US\$40.0 million, net of transaction costs.

Cash on hand at the end of the quarter of US\$48.8 million, pro-forma cash after adjusting for US\$40.0 million of proceeds raised in April is US\$88.8 million, with up to an additional US\$40.0 million available to be drawn down from existing financing facilities subject to certain milestones.

Revenue from royalties on sales of TEMCELL® HS Inj.^{2,3} sold in Japan by our licensee were US\$1.8 million for the quarter ended March 31, 2023. On a constant currency basis, royalties on sales grew 4% quarter on quarter to US\$2.0 million³ for the quarter ended March 31, 2023, compared with US\$1.9 million for the quarter ended March 31, 2022.

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Net cash usage for operating activities in the quarter was US\$16.2 million; this represented an increase of US\$0.7 million, or 4%, on the comparative quarter in FY2022, and a reduction of US\$8.3 million, or 34%, on the comparative quarter in FY2021.

OPERATIONAL RESULTS AND NEAR-TERM MILESTONES

Remestemcel-L

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

- Resubmitted to the FDA the BLA for approval of remestemcel-L in the treatment of children with SR-aGVHD.
- The resubmission contains new information developed since the Complete Response Letter (CRL) received in September 2020, including the generation of new data and analyses which we believe provide substantial evidence of remestemcel-L's effectiveness in pediatric SR-aGVHD.
- FDA accepted Mesoblast's BLA resubmission for remestemcel-L, considering the resubmission to be a complete response and set a Prescription Drug User Fee Act (PDUFA) goal date of August 2, 2023.
- As part of its ongoing review of the BLA, FDA has now conducted the Pre-License Inspection (PLI) of the manufacturing process for remestemcel-L.
- The FDA inspection did not result in the issuance of a Form 483, which is provided at the conclusion of an inspection if investigators have observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic Act and related Acts.
- According to FDA procedures, an Establishment Inspection Report (EIR) is expected to be issued by FDA in the coming weeks providing a detailed summary and final assessment of the inspection.
- Two studies on the remestemcel-L development program for the treatment of children with SR-aGVHD were selected by peer review and presented at the 2023 Tandem Meetings of the American Society for Transplantation and Cellular Therapy (ASTCT) and the Center for Blood and Marrow Transplant Research (CIBMTR).
- The data from these studies formed key components of Mesoblast's recent resubmission of its remestemcel-L BLA to FDA for children with SR-aGVHD.

Rexlemestrocel-L

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

- FDA granted Mesoblast a Regenerative Medicine Advanced Therapy (RMAT) designation for treatment of discogenic chronic low back pain.
- FDA has confirmed that a 12-month reduction in pain alone is an approvable indication. Key secondary endpoints will be improvement in function and reduced opioid usage. Mesoblast will use this primary endpoint of pain reduction in its next Phase 3 trial under the RMAT designation.
- FDA has cleared the pivotal trial protocol, and we expect enrolment to commence during the third quarter of this year.

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.

Activities regarding rexllestrocel-L for chronic heart failure with reduced ejection fraction (HFrEF)

- 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; rexllestrocel-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

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 rexllestrocel-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 $\geq 2\text{mg/L}$ ($p=0.008$)
- 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 $\geq 2\text{mg/L}$) 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% (HR 0.63; 95% CI: [0.39, 1.02]) in patients with inflammation (baseline hsCRP $\geq 2\text{mg/L}$) compared with controls.

Results from three randomized controlled trials of rexllestrocel-L in class II/III and in end-stage HFrEF with left ventricular assist devices (LVADs) support the hypothesis that rexllestrocel-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 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 MARCH 31, 2023 (THIRD QUARTER FY2023)

- **Cash reserves** on hand at the end of the quarter of US\$48.8 million, pro-forma cash after adjusting for US\$40.0 million of proceeds raised in April is US\$88.8 million, with up to an additional US\$40.0 million available to be drawn down from existing financing facilities subject to certain milestones.
- **Net cash usage** for operating activities was US\$16.2 million for the third quarter FY2023. This represents a 4% increase (US\$0.7 million) from the third quarter FY2022, and a 34% reduction (US\$8.3 million) from the third quarter FY2021.
- **Revenue** from royalties on sales of TEMCELL[®] HS Inj.² sold in Japan by our licensee for the third quarter FY2023 were US\$1.8 million. On a constant currency basis, sales for the third quarter FY2023 grew 4% to US\$2.0 million,³ compared with US\$1.9 million for the third quarter FY2022.
- **Research & Development** expenses reduced by US\$1.2 million (14%), down to US\$7.0 million for the third quarter FY2023 compared to US\$8.2 million for the third quarter FY2022. R&D expenses primarily supported preparations for the rexllestrocel-L BLA re-submission and preparations for pivotal studies for rexllestrocel-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\$6.2 million for the third quarter FY2023 compared to US\$5.6 million for the third 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\$31.0 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\$1.2 million (15%), down to US\$6.4 million for the third quarter FY2023 compared to US\$7.6 million for the third quarter FY2022 primarily due to professional fees associated with a one-off corporate activity incurred during the prior period.
- **Remeasurement of Contingent Consideration** recognized gains of US\$1.3 million in the third quarter FY2023 reflecting a reduction in future third party payments compared to a gain of US\$0.7 million in the third quarter FY2022.
- **Fair value movement of warrants** recognized a loss of US\$0.5 million in the third quarter FY2023 compared to a gain of US\$0.9 million in the third quarter FY2022.
- **Other operating income** in the third quarter FY2023 includes R&D tax incentive income of US\$3.1 million. The income recorded in this quarter pertains to the eligible expenditure refundable under the Australian governments incentive program for the years ended June 30, 2021 and 2022 and the nine months ended March 31, 2023.
- **Finance Costs for borrowing arrangements** include US\$3.8 million of non-cash expenditure for the third quarter FY2023 comprising accruing interest and borrowing costs.

Loss after tax for the third quarter FY2023 was US\$18.6 million compared to US\$21.3 million for the third quarter FY2022. The net loss attributable to ordinary shareholders was 2.53 US cents per share for the third quarter FY2023, compared with 3.28 US cents per share for the third quarter FY2022.

Conference Call

There will be a webcast today, beginning at 8.30am AEST (Friday, May 26); 6.30pm EDT (Thursday, May 25). It can be accessed via: <https://webcast.openbriefing.com/msb-qtr1-2023/>

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. 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>
2. TEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.
3. 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:123.41 Yen for the 3 months ended March 31, 2022 to 1USD:134.54 Yen for the 3 months ended March 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 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.

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Consolidated Income Statement

(in U.S. dollars, in thousands, except per share amount)	Three Months Ended March 31,		Nine Months Ended March 31,	
	2023	2022	2023	2022
Revenue	1,939	2,011	5,362	7,987
Research & development	(7,066)	(8,250)	(20,496)	(27,776)
Manufacturing commercialization	(6,246)	(5,590)	(19,006)	(19,717)
Management and administration	(6,407)	(7,567)	(19,688)	(21,259)
Fair value remeasurement of contingent consideration	1,318	672	7,307	601
Fair value remeasurement of warrant liability	(517)	896	(1,229)	3,048
Other operating income and expenses	3,317	392	3,278	(12)
Finance costs	(4,984)	(3,911)	(15,670)	(12,951)
Loss before income tax	(18,646)	(21,347)	(60,142)	(70,079)
Income tax benefit/(expense)	46	45	172	187
Loss attributable to the owners of Mesoblast Limited	(18,600)	(21,302)	(59,970)	(69,892)
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:	Cents	Cents	Cents	Cents
Basic - losses per share	(2.53)	(3.28)	(8.29)	(10.78)
Diluted - losses per share	(2.53)	(3.28)	(8.29)	(10.78)

Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	Three Months Ended March 31,		Nine Months Ended March 31,	
	2023	2022	2023	2022
Loss for the period	(18,600)	(21,302)	(59,970)	(69,892)
Other comprehensive (loss)/income				
<i>Items that may be reclassified to profit and loss</i>				
Exchange differences on translation of foreign operations	152	(333)	252	(516)
<i>Items that will not be reclassified to profit and loss</i>				
Financial assets at fair value through other comprehensive income	83	(314)	275	(48)
Other comprehensive (loss)/income for the period, net of tax	235	(647)	527	(564)
Total comprehensive losses attributable to the owners of Mesoblast Limited	(18,365)	(21,949)	(59,443)	(70,456)

Consolidated Balance Sheet

(in U.S. dollars, in thousands)	As of March 31, 2023	As of June 30, 2022
Assets		
Current Assets		
Cash & cash equivalents	48,799	60,447
Trade & other receivables	8,393	4,403
Prepayments	4,173	4,987
Total Current Assets	61,365	69,837
Non-Current Assets		
Property, plant and equipment	1,484	2,045
Right-of-use assets	5,641	7,920
Financial assets at fair value through other comprehensive income	2,032	1,758
Other non-current assets	2,388	1,930
Intangible assets	577,531	578,652
Total Non-Current Assets	589,076	592,305
Total Assets	650,441	662,142
Liabilities		
Current Liabilities		
Trade and other payables	20,972	23,079
Provisions	17,576	17,906
Borrowings	7,314	5,017
Lease liabilities	3,605	3,186
Warrant liability	4,450	2,185
Total Current Liabilities	53,917	51,373
Non-Current Liabilities		
Provisions	8,167	12,523
Borrowings	99,043	91,617
Lease liabilities	4,646	7,085
Deferred consideration	2,500	2,500
Total Non-Current Liabilities	114,356	113,725
Total Liabilities	168,273	165,098
Net Assets	482,168	497,044
Equity		
Issued Capital	1,207,500	1,165,309
Reserves	73,554	70,651
(Accumulated losses)/retained earnings	(798,886)	(738,916)
Total Equity	482,168	497,044

Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	Nine Months Ended	
	2023	2022
Cash flows from operating activities		
Commercialization revenue received	5,646	7,969
Government grants and tax incentives received	—	24
Payments to suppliers and employees (inclusive of goods and services tax)	(53,032)	(59,855)
Interest received	399	5
Income taxes paid	(4)	(31)
Net cash (outflows) in operating activities	(46,991)	(51,888)
Cash flows from investing activities		
Investment in fixed assets	(227)	(110)
Receipts from investment in sublease	67	—
Payments for intellectual property	(50)	(75)
Net cash (outflows) in investing activities	(210)	(185)
Cash flows from financing activities		
Proceeds from borrowings	—	51,919
Repayment of borrowings	—	(55,458)
Payment of transaction costs from borrowings	(412)	(5,513)
Interest and other costs of finance paid	(4,244)	(4,317)
Proceeds from issue of shares	45,065	209
Proceeds from issue of warrants	—	8,081
Payments for share issue costs	(2,873)	(216)
Payments for lease liabilities	(1,791)	(2,359)
Net cash inflows/(outflows) by financing activities	35,745	(7,654)
Net increase/(decrease) in cash and cash equivalents	(11,456)	(59,727)
Cash and cash equivalents at beginning of period	60,447	136,881
FX gain/(losses) on the translation of foreign bank accounts	(192)	(394)
Cash and cash equivalents at end of period	48,799	76,760



Global Leader in Allogeneic Cellular Medicines for Inflammatory Diseases

Operational Highlights and Financial Results
for the Quarter Ended March 31, 2023

May 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	FDA review of BLA with PDUFA goal date August 2, 2023, for children with steroid-refractory acute graft versus host disease (SR-aGVHD). FDA has now conducted the Pre-License Inspection (PLI) of the manufacturing process for remestemcel-L
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 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	Last 12 months revenue of US\$7.6 million from royalties; Cash-on-hand was US\$48.8 million, pro-forma cash after adjusting for US\$40 million placement is US\$88.8 million plus up to an additional US\$40m from existing financing facilities, subject to certain milestones.

Late-Stage Clinical Pipeline

Based on the Proprietary Allogeneic Mesenchymal Stromal Cell Platform

Product	Indication	Phase 2	Phase 3	Regulatory Filing	Approved	Status/Next Steps	
Remestemcel-L	Pediatric SR-aGVHD						<ul style="list-style-type: none"> • BLA accepted for review • PDUFA goal date August 2, 2023 • FDA PLI conducted
Remestemcel-L	Adult SR-aGVHD; ARDS; IBD						<ul style="list-style-type: none"> • Label extension • Clinical collaborations • Investigator-initiated trials
Rexlemestrocel-L	CLBP						<ul style="list-style-type: none"> • RMAT granted • Planning to start pivotal Phase 3 trial mid-CY2023
Rexlemestrocel-L	HFrEF						<ul style="list-style-type: none"> • RMAT granted for End-Stage / LVAD • FDA meeting planned for CY2023

SR-aGVHD = Steroid-Refractory Acute Graft Versus Host Disease
 CLBP = Chronic Low Back Pain
 IBD = Inflammatory Bowel Disease

HFrEF = Heart Failure with Reduced Ejection Fraction
 LVAD = Left Ventricular Assist Device
 ARDS = Acute Respiratory Distress Syndrome

RMAT = Regenerative Medicines Advanced Therapy designation
 PLI = Pre-Licensure Inspection





Financial Results

for the Period Ended March 31, 2023

Manufacturing Remestemcel-L
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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\$1.8 million for the quarter ended March 31, 2023. On a constant currency basis, royalties on sales grew 4% quarter on quarter to US\$2.0 ² million for the quarter ended March 31, 2023, compared with US\$1.9 million for the quarter ended March 31, 2022. Last 12-months revenue of US\$7.6 million from royalties on product sales.
Cash Burn	Net cash usage for operating activities in the third quarter FY2023 was US\$16.2 million; this represented a 4% increase (US\$0.7 million) on the third quarter FY2022, and a 34% reduction (US\$8.3 million) on the third quarter FY2021.
Capital	Successful completion of a global private placement primarily to Mesoblast's existing major US, UK, and Australian shareholders raising approximately US\$40.0 million, net of transaction costs.
Cash Reserves	At March 31, 2023, cash-on-hand was US\$48.8 million, pro-forma cash after adjusting for proceeds of US\$40.0 million raised in April private placement is US\$88.8 million, with up to an additional US\$40.0 million available to be drawn down from existing financing facilities subject to achieving certain milestones.

7

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:123.41 Yen for the 3 months ended March 31, 2022 to 1USD:134.54 Yen for the 3 months ended March 31, 2023.

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

P&L for the quarter ended (US\$m)	Mar 31, 2023	Mar 31, 2022
Total Revenue	1.9	2.0
Research and development	(7.0)	(8.2)
Manufacturing	(6.2)	(5.6)
Management & administration	(6.4)	(7.6)
Revaluation of contingent consideration	1.3	0.7
Revaluation of warrant liability	(0.5)	0.9
Other operating income & expenses	3.3	0.4
Finance costs	(5.0)	(3.9)
Loss before tax	(18.6)	(21.3)
Income tax benefit	-	-
Loss after tax	(18.6)	(21.3)

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\$1.2 million (14%), down to US\$7.0 million for the quarter ended March 31, 2023. R&D expenses primarily supported preparations for the remestemcel-L BLA re-submission and preparations for pivotal studies for rexlemestrocel-L.

Continued Investment in Manufacturing: continued manufacturing activities to support the potential commercial launch for SR-aGVHD. On FDA approval US\$31.0 million of remestemcel-L pre-launch inventory will be recognized on the balance sheet.

Finance Costs include US\$3.8 million of non-cash expenditure for the quarter ended March 31, 2023 comprising accruing interest and borrowing costs.

Figures have been rounded.

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

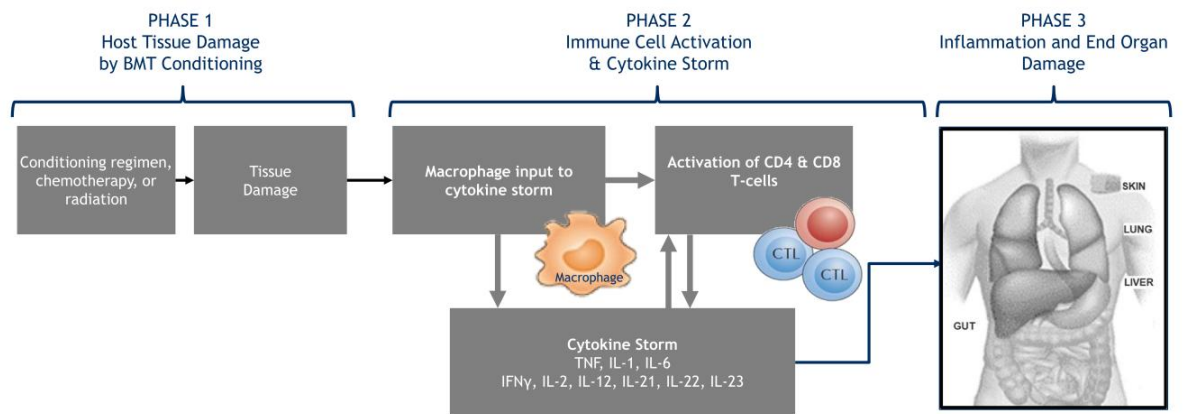


Remestemcel-L

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

Acute Graft Versus Host Disease (aGVHD)

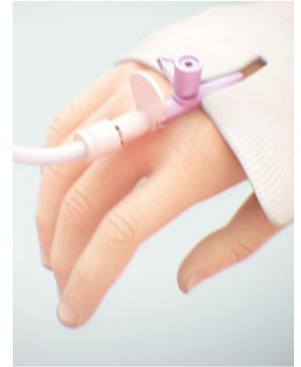
Serious and Fatal Complication of Allogeneic Bone Marrow Transplantation (BMT)



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
<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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 costs² 	<ul style="list-style-type: none"> 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 US⁴



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*.

Remestemcel-L for Children with SR-aGVHD

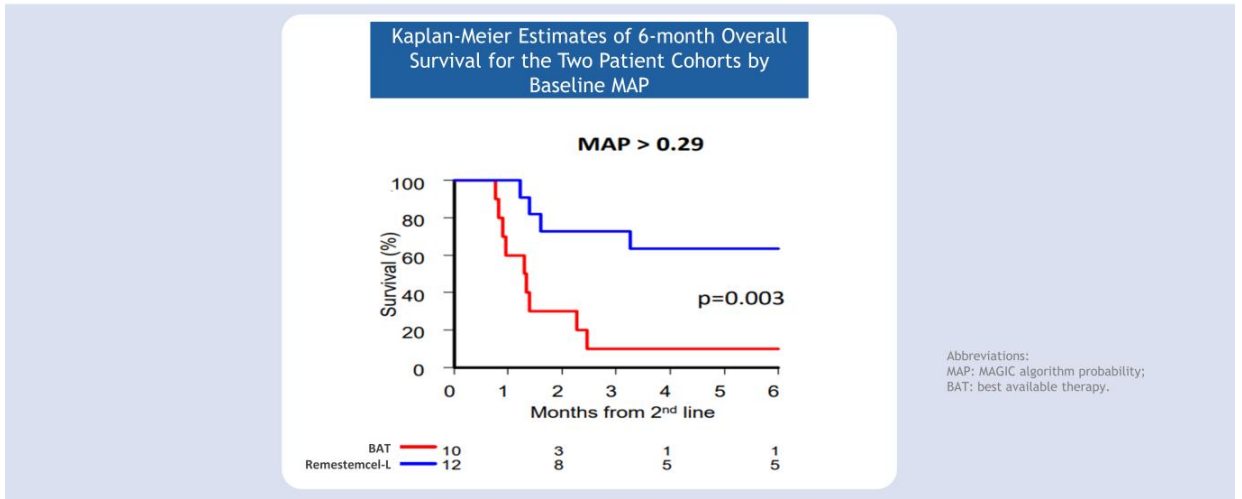
Improved Early Survival Across Three Studies involving more than 300 Treated Children

Day 100 Survival			
Remestemcel-L Protocol	Remestemcel-L	Matched Controls	Matched Control Protocol
First Line Therapy after Steroids Treatment Setting			
Pediatric Subset of Protocol 280: randomized controlled P3, n=27 w/SR-aGVHD	79%	54%	Study Control Arm (n=13)
Study 001, open-label P3, n=54¹ with 89% Grade C/D disease	74%	57%	MAGIC² cohort, n=30³ 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=327⁴ 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

Remestemcel-L Treatment Outcomes

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



Status of BLA for Remestemcel-L in Pediatric Patients with SR-aGVHD

New Data Under Review

- ▣ BLA resubmitted Jan 30, 2023
- ▣ BLA file considered by FDA to be a complete response, accepted for review, with PDUFA goal date August 2, 2023
- ▣ New data under review shows:
 - Durable long-term survival of patients in Phase 3 trial
 - Increased survival in high-risk patients compared with propensity matched controls
 - Positive correlation between *in vitro* potency assay and survival
 - That the validated potency assay has low variability and can adequately demonstrate manufacturing consistency and reproducibility

Status of BLA for Remestemcel-L in Pediatric Patients with SR-aGVHD

Manufacturing Inspection Conducted

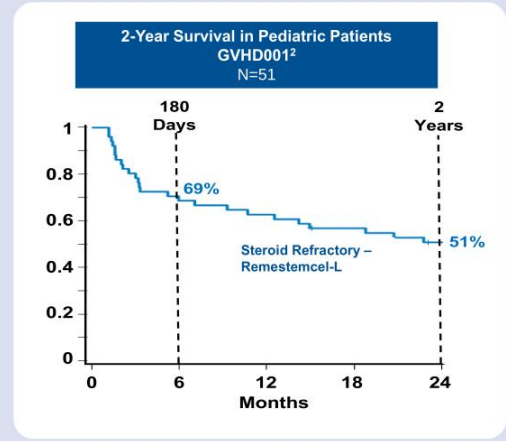
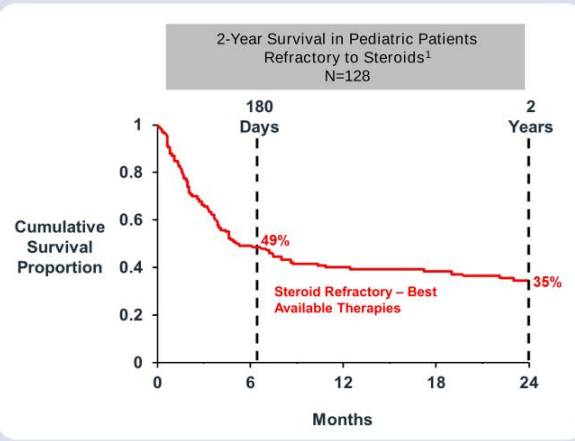
- FDA has now conducted the Pre-License Inspection (PLI) of the manufacturing process for remestemcel-L
- FDA inspection did not result in the issuance of a Form 483, which is provided at the conclusion of an inspection if investigators have observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic Act and related Acts
- Establishment Inspection Report (EIR) is expected to be issued by FDA in the coming weeks providing a detailed summary and final assessment of the inspection

Remestemcel-L: Long-Term Survival Data a Cornerstone of BLA Resubmission to FDA for SR-aGVHD

- ▀ Mesoblast provided new results 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
- ▀ The new long-term survival data provide assurance that the short-term day 28 responses and early survival through 180 days in the 54-patient Phase 3 trial in children with SR-aGVHD previously presented to FDA in the original BLA submission are unlikely to have arisen by chance
- ▀ These long-term survival outcomes are a cornerstone of the BLA resubmission

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

Extended Survival Data in Children with SR-aGVHD

Remestemcel-L Treatment Resulted in Durable Survival Over 4 Years

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

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

The Immunomodulatory Activity of Remestemcel-L on T Cell Activation *in vitro* is a Direct Measure of Product Potency and Correlates with Survival in Pediatric Patients with SR-aGVHD

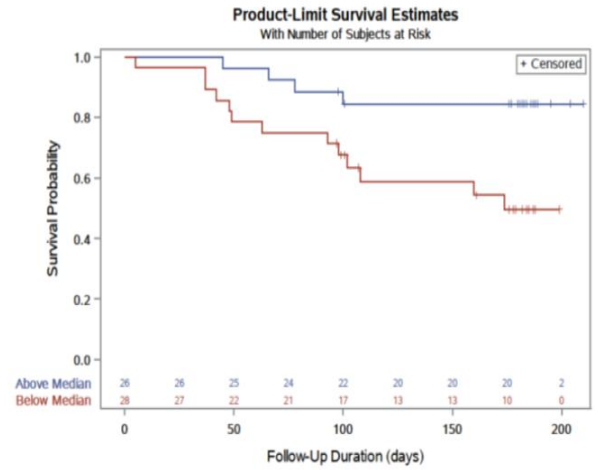
- The clinical benefits of remestemcel-L in SR-aGVHD are likely due to its immunomodulatory effects on alloreactive T cell activation/proliferation and inflammatory cytokine production
- An *in vitro* assay measuring inhibition of T-cell activation was established during development, prior to the Phase 3 trial, as a potential measure of product potency
- Assay was used to measure the ability of individual remestemcel-L lots to inhibit T cell activation prior to their use in EAP 275 and the Phase 3 trial GVHD 001
- Correlations between survival outcomes in EAP 275 and the Phase 3 trial GVHD 001 and potency of lots received as measured by inhibition of T-cell activation were performed

Correlation of Remestemcel-L (Ryoncil) Lot Potency and 6-Month Survival

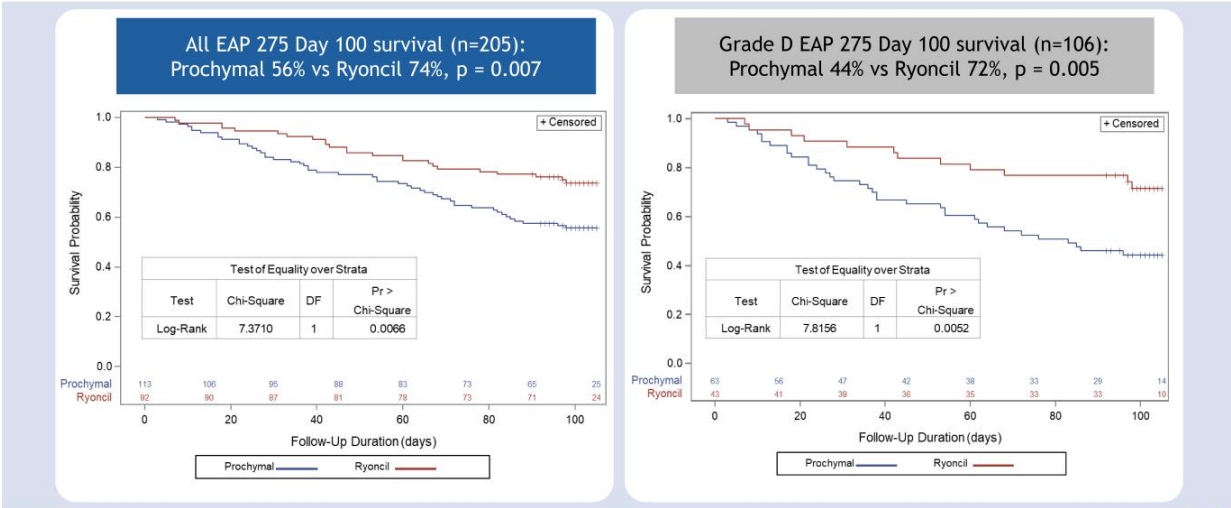
Analyses were performed evaluating *in vitro/in vivo* relationships in relation to inhibition of T-cell activation by product lots administered

- There was an association between higher inhibition of T-cell activation by product lots received and Day 180 survival (85% Day 180 OS > median vs. 54% Day 180 OS ≤ median, p=0.01)
- The relationship between greater survival and level of inhibition of T-cell activation > median vs. ≤ median was most evident in patients with the most severe form of the disease and at highest risk for death:
 - Minnesota high risk (Day 180 OS 89% vs 50%, p=0.01)
 - MAGIC Algorithm Probability (MAP) ≥0.29 (Day 180 OS 100% vs. 17%, p=0.003)
 - IBMTR Grade D disease (Day 180 OS 91% vs. 50%, p=0.03)

Note that expected Day 180 survival for Grade D treated with best available therapy in CIBMTR registry is ~30%



Survival Significantly Improved in EAP 275 aGVHD Patients Receiving Higher Potency Ryoncil Product Made After 2008 Compared with Lower Potency Prochymal Product Made Before 2008
Greatest Effect Seen In Patients With Grade D Disease



Go to Market Strategy - Remestemcel-L in Pediatric Patients

Pre-Launch: Engagement of Highest Transplant Volume Centers with Experience Using Ryoncil

- ▀ Non-promotional activities including profiling centers, educate on disease awareness & unmet needs, and support payer engagement

- ▀ Hiring of select positions to build out commercial team has commenced

- ▀ Key Activities:
 - Market Access initiates payer outreach
 - Medical provides education to payers
 - Corporate leadership initiates engagement with Top 15 centers
 - Regional sales directors lead center profiling

- ▀ Manufacturing preparation has been ongoing with US\$31.0 million of remestemcel-L pre-launch inventory in-hand

Go to Market Strategy - Remestemcel-L in Pediatric Patients

Post-Approval Launch: Staged Approach Initially Targeting Highest Transplant Volume Centers

- ▀ Staged approach to launch based on centers with highest volume and experience with product
- ▀ Building out efficient, targeted sales force - 15 highest volume centers account for ~50% of patients
- ▀ Key Activities:
 - Initiate commercial onboarding & logistics at centers
 - MSLs engage centers around medical & scientific needs
 - Logistical and reimbursement support offered as needed
 - Center certification for remestemcel-L administration



Rexlemestrocel-L

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

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

Burden of Illness

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

Treatment Options

- ▶ Minimal treatment options for patients with chronic low back pain (CLBP) who fail conservative therapy include opioids and surgery
- ▶ 50% of opioid prescriptions are for CLBP²
- ▶ Durable improvement in pain has potential to reduce opioid use and prevent surgical intervention

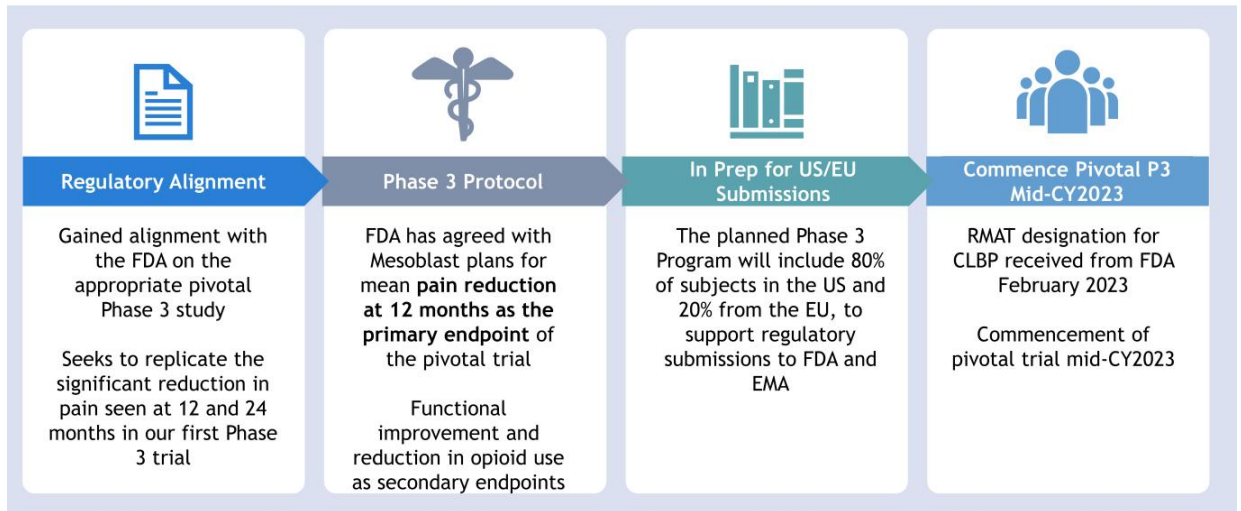
Market Opportunity

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



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

Rexlemestrocel-L / CLBP - Program Summary



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)

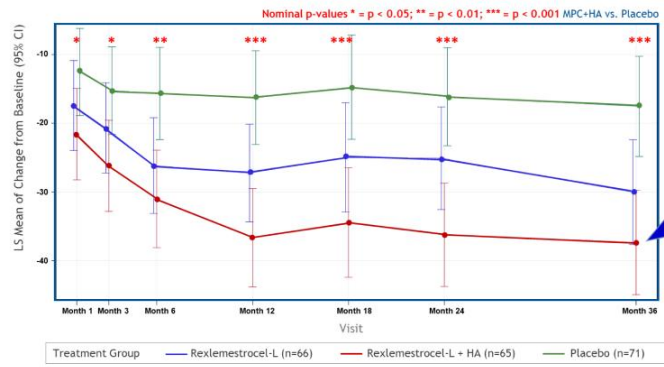
Results from the trial showed that:

- ▶ 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

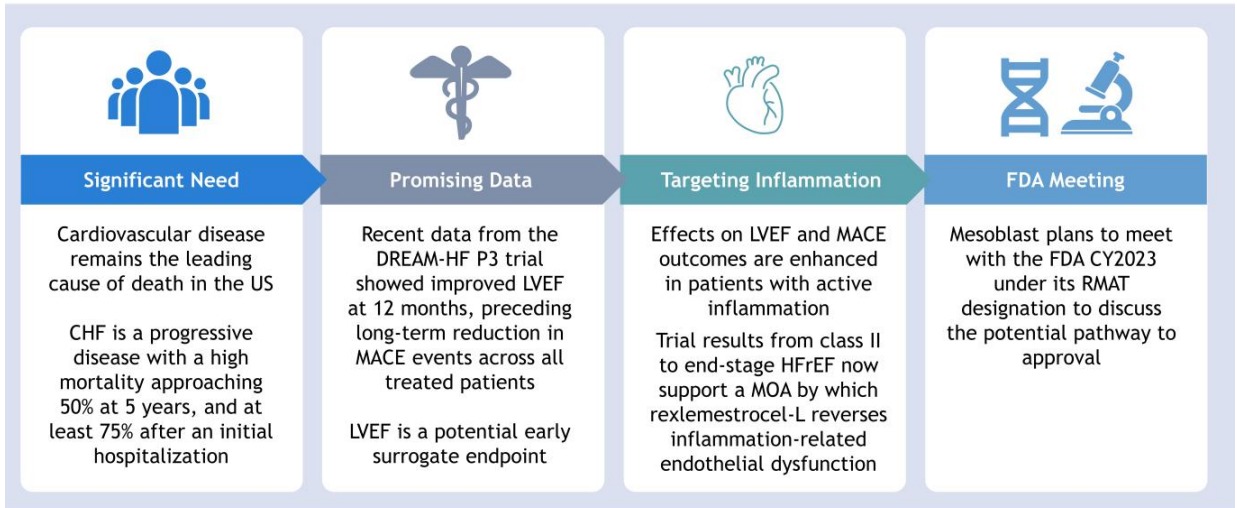


Rexlemestrocel-L

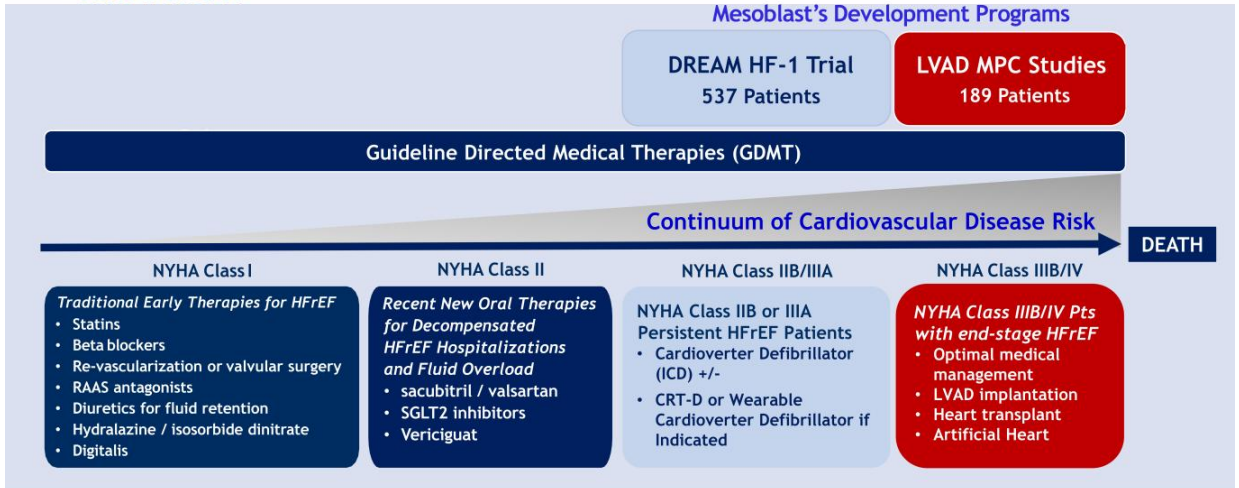
Chronic Heart Failure Reduced Ejection Fraction (HFrEF)

Rexlemestrocel-L / HFREF - Program Summary

Defining the Regulatory Path to FDA Approval



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



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

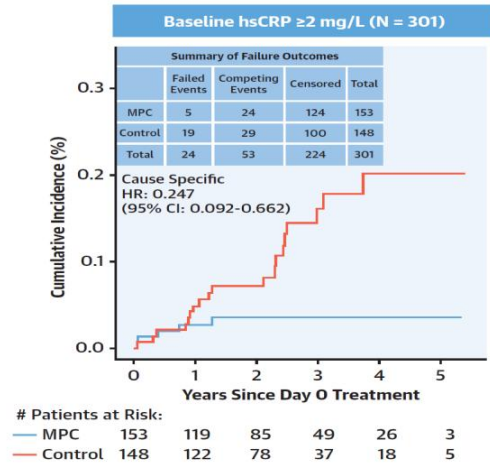


Emerson C. Perin, MD, PhD,¹ Kenneth M. Borow, MD,² Timothy D. Henry, MD,³ Farrell O. Mendelsohn, MD,⁴ Leslie W. Miller, MD,⁵ Elizabeth Swiggum, MD,⁶ Eric D. Adler, MD,⁷ David H. Chang, MD,⁸ R. David Fish, MD,⁹ Alain Bouchard, MD,¹⁰ Margaret Jenkins, BSc (Hons), Alex Yaroshinsky, PhD,¹¹ Jack Hayes, MA,¹² Olga Rutman, PhD,¹³ Christopher W. James, PA,¹⁴ Eric Rose, MD,¹⁵ Silviu Itescu, MD,¹⁶ Barry Greenberg, MD¹⁷

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



Rexlemestrocel-L - Two Pivotal Studies in Chronic Heart Failure (CHF)
Mesoblast's Development Programs Assess the Impact of Intra-cardiac Administration of Rexlemestrocel-L Across the Continuum of Disease from Mild/Moderate to End-stage Severity

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



Thank You



