UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 6-K

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16 under the Securities Exchange Act of 1934

For the month of August 2022

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 August 31, 2022, Mesoblast Limited filed with the Australian Securities Exchange a new release announcement and investor presentation, which are attached hereto as Exhibit 99.1 and Exhibit 99.2, and are incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly organized.

MESOBLAST LIMITED

/s/ Niva Sivakumar

Niva Sivakumar
Company Secretary

Dated: August 31, 2022

INDEX TO EXHIBITS

Item	
99.1	Press release of Mesoblast Ltd, dated August 31, 2022.
99.2	Investor presentation of Mesoblast Ltd, dated August 31, 2022.

asx announcement

mesoblast
the regenerative medicine company

MESOBLAST REPORTS FINANCIAL RESULTS AND OPERATIONAL HIGHLIGHTS FOR FISCAL YEAR ENDED JUNE 30, 2022

- *At June 30, 2022, cash-on-hand was US$60.4 million with pro-forma US$105.5 million after raising gross proceeds of US$45 million via a private placement in August, 2022*
- *Up to an additional US$40 million available from existing facilities subject to certain milestones*
- *Net operating spend of US$65.8 million for the 12 months ended June 2022, a 35% reduction on comparative year, with continued focus on cost control*
- *BLA resubmission for remestemcel-L in children with SR-aGVHD expected to be filed this quarter, with potential US approval Q1 CY2023*
- *Plan to meet with FDA next quarter under existing regenerative medicine advanced therapy (RMAT) designation to discuss common mechanism of action in HFrEF including those with LVADs, and potential pathway to marketing approval*
- *FDA clearance by year end 2022 to commence a pivotal study for potential marketing approval of rexlemestrocel-L in chronic lower back pain due to degenerative disc disease*

Melbourne, Australia; August 31 and New York, USA; August 30, 2022: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today reported financial results and operational highlights for the period ended June 30, 2022 and provided an update on upcoming milestones.

"I am pleased to report that calendar year 2022 is shaping up to be a transformational year for the Company", said Dr Silviu Itescu, Chief Executive of Mesoblast. "We are working towards the planned resubmission of the Biologics License Application (BLA) this quarter for remestemcel-L in children with steroid-refractory acute graft versus host disease (SR-aGVHD) and believe we have addressed the issues that were raised in the Complete Response Letter from the United States Food and Drug Administration (US FDA). Specifically, we have validated our key potency assay which has been in place throughout the extensive development phase of remestemcel-L and which reflects the mechanism of action by which remestemcel-L treatment results in a remarkable survival benefit in the most severely compromised children with SR-aGVHD."

"There continues to be no approved therapy in the US for SR-aGVHD in children under twelve with and we believe remestemcel-L can fill this significant unmet need as well as the continued need for treatments that deliver improved survival in adults with the most severe form of this disease" Dr. Itescu continued. "Royalty income from sales of our licensee's product TEMCELL® HS Inj.[1] in Japan increased 36% on the comparative year on a constant currency basis to almost US$10 million. This shows the continued growth in physician adoption of mesenchymal stromal cell therapy for this devastating disease and provides clear line of sight on the potential for remestemcel-L in the US market which we estimate to be up to ten times larger and in which we intend to market directly with our own targeted sales force."

Dr. Itescu commented further: "Our immunoselected next generation product, rexlemestrocel-L, is also at a pivotal stage in its development for patients with severe inflammation at high risk for death or other major adverse cardiac events (MACE) from chronic heart failure with reduced ejection fraction (HFrEF), and in patients with unremitting chronic low back pain from degenerative disc disease (CLBP). We have seen that rexlemestrocel-L improves left ventricular systolic function and subsequently reduces MACE events across high-risk HFrEF populations. Consequently, we plan to meet next quarter with FDA under our existing RMAT designation re a potential marketing approval pathway for rexlemestrocel-L in high-risk patients with HFrEF and inflammation."

"We are also pleased to have gained alignment with the FDA on the appropriate pivotal Phase 3 study in patients with CLBP which seeks to replicate the significant reduction in pain seen at 12 and 24 months in our first Phase 3 trial. Our Key Opinion Leader (KOL) event in June 2022 highlighted the urgent need for new treatment options in patients with CLBP, and we intend to have clearance from the FDA by year-end 2022 to commence the pivotal trial."

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NEAR-TERM MILESTONES

Remestemcel-L

- BLA resubmission for remestemcel-L in children with SR-aGVHD expected to be filed this quarter, with potential US approval Q1 CY2023
- Mesoblast and Vanderbilt University Medical Center, which coordinates a clinical trial network at over 40 sites across the US focused on ARDS, to jointly develop a trial protocol to confirm the previously observed reduction in mortality in COVID-19 ARDS patients under age 65

Rexlemestrocel-L

- Plan to meet with FDA next quarter under existing regenerative medicine advanced therapy (RMAT) designation to discuss common mechanism of action in HFrEF including those with LVADs, and potential pathway to marketing approval
- FDA clearance by year end 2022 to commence a pivotal study for potential marketing approval of rexlemestrocel-L in chronic lower back pain due to degenerative disc disease

PIPELINE UPDATE

Remestemcel-L

Steroid-refractory acute graft versus host disease:

- BLA resubmission to FDA expected by the end of Q3 CY2022
- FDA has indicated that Mesoblast's approach to address the outstanding CMC items is reasonable
- Mesoblast has optimized a potency assay that was in place at the time of the 54-patient Phase 3 trial in children with SR-aGVHD
- Mesoblast has now generated data from the expanded access program (EAP 275) of 241 children which confirm the ability of the *in-vitro* potency assay to measure product activity relevant to survival outcomes
- Development and validation work on the potency assay completed, key to the BLA resubmission
- Mock inspection affirmed BLA-submission readiness at manufacturing site

Acute respiratory distress syndrome:

- Mesoblast is working under a Memorandum of Understanding (MOU) with Vanderbilt University Medical Center, which coordinates and works closely with a clinical trial network of investigators at over 40 sites across the US focused on studying ARDS and other critical illnesses
- The MOU may lead to a collaboration on the design and execution of a second COVID-19 trial for remestemcel-L, including jointly developing a trial protocol to confirm the observed reduction in mortality in COVID-19 ARDS patients under 65 years of age in the earlier study
- We plan to provide an update on this potential collaboration by year-end CY2022

Inflammatory bowel disease:

- An investigator-initiated randomized, controlled study of remestemcel-L by direct endoscopic delivery to areas of inflammation is underway in patients with medically refractory ulcerative colitis or Crohn's colitis
- The first 12-patient cohort in this study showed rapid mucosal healing and disease remission compared to placebo in refractory patients at high risk of progression to surgery

Rexlemestrocel-L

Chronic heart failure with reduced ejection fraction (HFrEF) in NYHA class II/III patients through to end-stage III/IV patients with a left ventricular assist device (LVAD):

- Recent data from Phase 3 trial of 565 patients with HFrEF showed a single intervention with rexlemestrocel-L improves left ventricular ejection fraction (LVEF) at 12 months, preceding long-term reduction in major adverse cardiovascular events (MACE)
- LVEF improvement at 12 months may be an appropriate early surrogate endpoint for long term reduction in MACE

- Mesoblast now intends to meet with FDA next quarter under its existing RMAT designation to discuss data and the evidence of a common mechanism of action (MOA) across the broader HFrEF spectrum, including LVAD patients

Chronic low back pain associated with degenerative disc disease:

- Mesoblast gained alignment with the FDA on key metrics for pivotal Phase 3 study in patients with CLBP which seeks to replicate the significant reduction in pain seen at 12 and 24 months in first Phase 3 trial
- Pivotal trial will have as primary endpoint 12-month reduction in pain
- The Company plans to have clearance from the FDA by the year-end 2022 to commence the pivotal trial

FINANCIAL RESULTS FOR THE PERIOD ENDED JUNE 30, 2022 (FY2022)

- **Cash:** As of June 30, 2022, cash was US$60.4 million, with pro-forma US$105.5 million after raising gross proceeds of US$45 million via a private placement in August 2022. In addition, the Company has access to up to an additional US$40 million available to be drawn down from existing financing facilities, subject to certain milestones.
- **Total Revenue** increased 37% to US$10.2 million for FY2022 compared to US$7.5 million for FY2021. The increase of US$2.7 million was due to growth in royalties and US$1.2 million of milestone revenue from Takeda after it received approval to manufacture and market Alofisel® (darvadstrocel) in Japan for perianal fistulas in Crohn's Disease.

  Royalties from sales of TEMCELL® HS Inj.[1] sold in Japan by our licensee in FY2022, were US$8.7 million and US$9.8 million on a constant currency[2] basis, an increase of 21% and 36% respectively versus FY2021, predominantly due to increased volume of product sold.
- **Net cash usage** for operating activities for the 12 months ended June 2022 was US$65.8 million, a reduction of 35% relative to the comparative 12 months.
- **Research & Development expenses** reduced by US$20.2 million (38%), down to US$32.8 million for FY2022 compared to US$53.0 million for FY2021 as clinical trial activities for our COVID-19 ARDS, CLBP and CHF product candidates reduced given clinical trial recruitment and data analysis is now complete.
- **Manufacturing expenses** reduced by US$2.0 million (6%), down to US$30.8 million for FY2022 compared to US$32.7 million for FY2021. During the year we continued to build our pre-launch inventory levels of remestemcel-L to support the potential commercial launch for SR-aGVHD.

  We expect to recognize the US$28.9 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$3.7 million (12%), down to US$27.2 million for FY2022 compared to US$30.9 million for FY2021 primarily due to a reduction in employee compensation costs.
- **Remeasurement of Contingent Consideration** reduced to a gain of US$0.9 million in FY2022 compared to a gain of US$18.7 million for FY2021 as a result of revaluing future third party payments.
- **Fair value movement of warrants:** We recognized a gain of US$5.9 million in FY2022 compared to Nil in FY2021.
- **Finance Costs** for borrowing arrangements with our lenders, currently Oaktree and NovaQuest, were US$17.3 million (actual cash interest paid US$6.1 million) for FY2022, compared to US$10.7 million (actual cash interest paid US$5.9 million) for FY2021. The increase in reported Finance Costs was primarily due to the recognition of a non-cash gain on revaluation of our borrowings in the comparative year due to a reduction in expected value of future repayments.

Loss after tax for FY2022 was US$91.3 million compared to US$98.8 million for FY2021. The net loss attributable to ordinary shareholders was 14.08 US cents per share for FY2022, compared with 16.33 US cents per share for FY2021.

Conference Call
There will be a webcast today, beginning at 8.30am AEST (Wednesday, August 31); 6.30pm EDT (Tuesday, August 30). It can be accessed via: https://webcast.openbriefing.com/8875/

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. 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:108.7Yen for FY2021 to 1USD:122.0Yen for FY2022.

Forward-Looking Statements
This press release includes forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Forward-looking statements should not be read as a guarantee of future performance or results, and actual results may differ from the results anticipated in these forward-looking statements, and the differences may be material and adverse. Forward-looking statements include, but are not limited to, statements about: the initiation, timing, progress and results of Mesoblast's preclinical and clinical studies, and Mesoblast's research and development programs; Mesoblast's ability to advance product candidates into, enroll and successfully complete, clinical studies, including multi-national clinical trials; Mesoblast's ability to advance its manufacturing capabilities; the timing or likelihood of regulatory filings and approvals (including BLA resubmission), 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)	Year Ended June 30, 2022	2021
Revenue	10,214	7,456
Research & development	(32,815)	(53,012)
Manufacturing commercialization	(30,757)	(32,719)
Management and administration	(27,210)	(30,867)
Fair value remeasurement of contingent consideration	913	18,687
Fair value remeasurement of warrant liability	5,896	—
Other operating income and expenses	(539)	1,539
Finance costs	(17,288)	(10,714)
Loss before income tax	**(91,586)**	**(99,630)**
Income tax benefit/(expense)	239	819
Loss attributable to the owners of Mesoblast Limited	**(91,347)**	**(98,811)**
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:	**Cents**	**Cents**
Basic - losses per share	(14.08)	(16.33)
Diluted - losses per share	(14.08)	(16.33)

Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	Year Ended June 30, 2022	2021
Loss for the period	**(91,347)**	**(98,811)**
Other comprehensive (loss)/income		
Items that may be reclassified to profit and loss		
Exchange differences on translation of foreign operations	91	(1,524)
Items that will not be reclassified to profit and loss		
Financial assets at fair value through other comprehensive income	(322)	209
Other comprehensive (loss)/income for the period, net of tax	**(231)**	**(1,315)**
Total comprehensive losses attributable to the owners of Mesoblast Limited	**(91,578)**	**(100,126)**

Consolidated Balance Sheet

(in U.S. dollars, in thousands)	As of June 30, 2022	2021
Assets		
Current Assets		
Cash & cash equivalents	60,447	136,881
Trade & other receivables	4,403	4,842
Prepayments	4,987	6,504
Total Current Assets	**69,837**	**148,227**
Non-Current Assets		
Property, plant and equipment	2,045	3,021
Right-of-use assets	7,920	9,119
Financial assets at fair value through other comprehensive income	1,758	2,080
Other non-current assets	1,930	1,724
Intangible assets	578,652	580,546
Total Non-Current Assets	**592,305**	**596,490**
Total Assets	**662,142**	**744,717**
Liabilities		
Current Liabilities		
Trade and other payables	23,079	19,598
Provisions	17,906	18,710
Borrowings	5,017	53,200
Lease liabilities	3,186	2,765
Warrant liability	2,185	—
Total Current Liabilities	**51,373**	**94,273**
Non-Current Liabilities		
Provisions	12,523	17,017
Borrowings	91,617	41,045
Lease liabilities	7,085	8,485
Deferred consideration	2,500	2,500
Total Non-Current Liabilities	**113,725**	**69,047**
Total Liabilities	**165,098**	**163,320**
Net Assets	**497,044**	**581,397**
Equity		
Issued Capital	1,165,309	1,163,153
Reserves	70,651	65,813
(Accumulated losses)/retained earnings	(738,916)	(647,569)
Total Equity	**497,044**	**581,397**

Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	Year Ended June 30, 2022	2021
Cash flows from operating activities		
Commercialization revenue received	9,980	6,121
Upfront and milestone payments received	—	—
Government grants and tax incentives received	24	68
Payments to suppliers and employees (inclusive of goods and services tax)	(75,769)	(106,920)
Interest received	7	17
Income taxes paid	(24)	(35)
Net cash (outflows) in operating activities	**(65,782)**	**(100,749)**
Cash flows from investing activities		
Investment in fixed assets	(157)	(1,647)
Payments for contingent consideration	—	—
Payments for licenses	(75)	—
Net cash (outflows) in investing activities	**(232)**	**(1,647)**
Cash flows from financing activities		
Proceeds from borrowings	51,919	—
Repayment of borrowings	(55,458)	—
Payment of transaction costs from borrowings	(5,527)	(13)
Interest and other costs of finance paid	(6,084)	(5,932)
Proceeds from issue of shares	209	106,268
Proceeds from issue of warrants	8,081	12,969
Payments for share issue costs	(222)	(1,827)
Payments for lease liabilities	(2,788)	(2,931)
Net cash (outflows)/inflows by financing activities	**(9,870)**	**108,534**
Net (decrease)/increase in cash and cash equivalents	(75,884)	6,138
Cash and cash equivalents at beginning of period	136,881	129,328
FX (loss)/gain on the translation of foreign bank accounts	(550)	1,415
Cash and cash equivalents at end of period	**60,447**	**136,881**

Exhibit 99.2

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Global Leader in Allogeneic Cellular Medicines for Inflammatory Diseases

Operational Highlights & Financial Results for the Year Ended June 30, 2022

August 2022

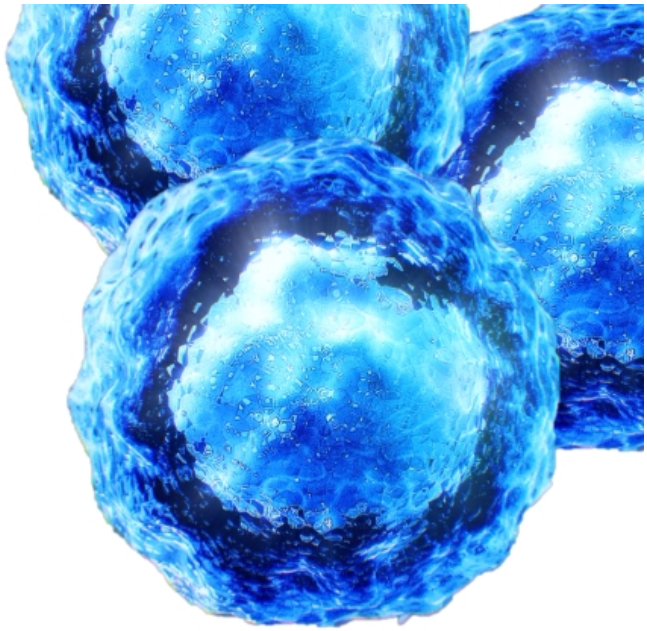
ASX: MSB; Nasdaq: MESO

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

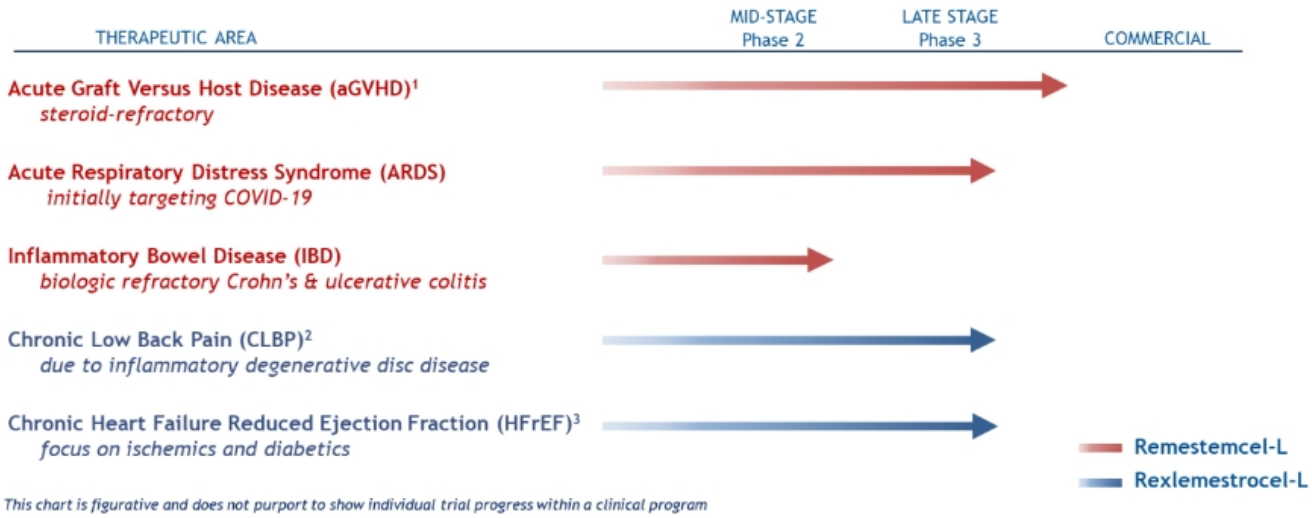
This presentation includes forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any 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



Late-Stage Clinical Pipeline



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

1. JCR Pharmaceuticals Co., Ltd. (JCR), has the right to develop mesenchymal stromal cells (MSCs) in certain fields for the Japanese market, including for the treatment of hematological malignancies, such as Graft vs Host Disease, and for hypoxic ischemic encephalopathy (HIE). Mesoblast has the right to use safety and efficacy data generated by JCR to support its development and commercialization plans for remestemcel-L in the US and other major healthcare markets, including for GVHD and HIE
2. Grünenthal has exclusive commercial rights to rexlemestrocel-L for chronic low back pain in Europe and Latin America/Caribbean
3. Tasly Pharmaceuticals has exclusive commercial rights to rexlemestrocel-L for the treatment or prevention of chronic heart failure in China

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Near Term Milestones

Remestemcel-L

- BLA resubmission for remestemcel-L in children with SR-aGVHD expected to be filed this quarter, with potential US approval Q1 CY2023
- Mesoblast and Vanderbilt University Medical Center, which coordinates a clinical trial network at over 40 sites across the US focused on ARDS, to jointly develop a trial protocol to confirm the previously observed reduction in mortality in COVID-19 ARDS patients under age 65.

Rexlemestrocel-L

- Plan to meet with FDA next quarter under existing regenerative medicine advanced therapy (RMAT) designation to discuss common mechanism of action in HFrEF including those with LVADs, and potential pathway to marketing approval
- FDA clearance by year end 2022 to commence a pivotal study for potential marketing approval of rexlemestrocel-L in chronic lower back pain due to degenerative disc disease

Manufacturing Remestemcel-L

Financial Results

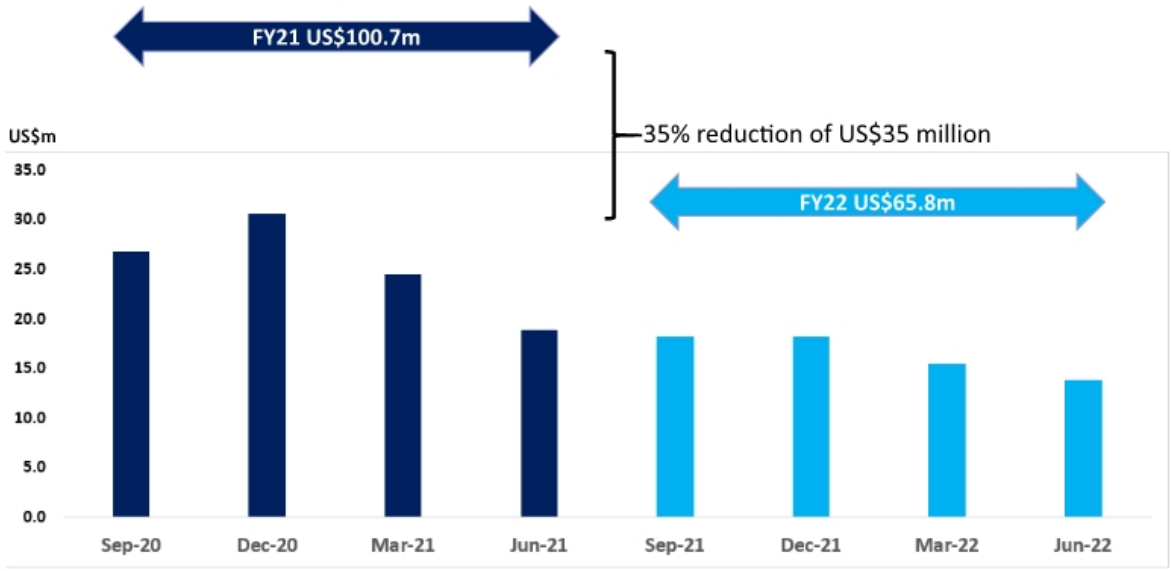
for the Period Ended June 30, 2022

mesoblast

Financial Highlights

- Total Revenue from royalties and milestones increased 37% to US$10.2 million for FY2022 compared to US$7.5 million for FY2021
- Royalties from sales of TEMCELL® HS Inj.[1] sold in Japan by our licensee in FY2022, were US$8.7 million and US$9.8 million on a constant currency[2] basis, an increase of 21% and 36% respectively versus FY2021, predominantly due to increased volume of product sold
- At June 30, 2022, cash-on-hand was US$60.4 million with pro-forma US$105.5 million after raising gross proceeds of US$45 million via a private placement in August 2022
- Up to an additional US$40 million available from existing facilities subject to certain milestones
- For the year ended June 30, 2022, net cash usage reported for operating activities was US$65.8 million, a reduction of 35% relative to the comparative period last year, with continued focus on cost control

Quarterly Net Operating Cash Burn has been significantly reduced



- Quarterly net operating cash burn has been reduced over the last 6 quarters.

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Reduction in R&D Spend; Steady Investment in Manufacturing

P&L for the 12 months ended (US$m)	Jun 30, 2022	Jun 30, 2021
Total Revenue	**10.2**	**7.5**
Research and development	(32.8)	(53.0)
Manufacturing	(30.8)	(32.7)
Management & administration	(27.2)	(30.9)
Revaluation of contingent consideration	0.9	18.7
Revaluation of warrant liability	5.9	-
Other operating income & expenses	(0.5)	1.5
Finance costs	(17.3)	(10.7)
Loss before tax	**(91.6)**	**(99.6)**
Income tax benefit	0.2	0.8
Loss after tax	**(91.4)**	**(98.8)**

- **Decreased R&D Spend:**
  38% reduction ($20.2m) predominantly due to reduced spend on clinical trial activities.

- **Steady Investment in Manufacturing:**
  Continued build of pre-launch inventory of remestemcel-L to support the launch of SR-aGVHD.

  On FDA approval, remestemcel-L inventory will be recognized on the balance sheet, currently at US$28.9 million.

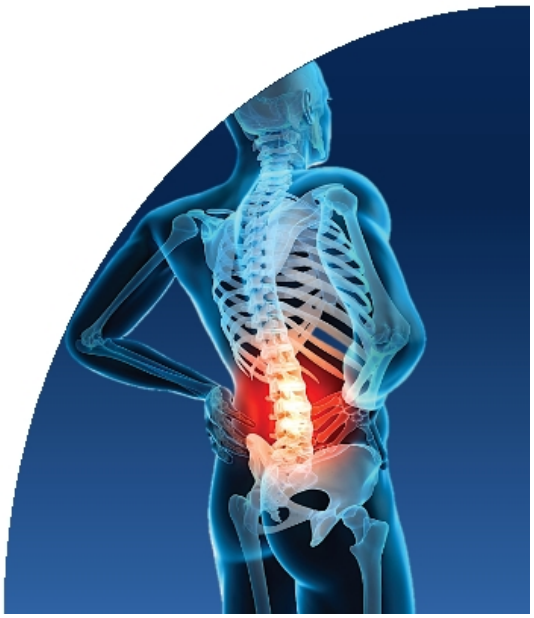
- **Finance Costs** included actual cash interest paid of US$6.1 million for FY2022, compared to US$5.9 million for FY2021.

  The increase in reported Finance Costs was primarily due to the recognition of a non-cash gain on revaluation of our borrowings in the comparative year due to a reduction in expected value of future repayments.

Figures have been rounded.

Clinical Pipeline

Current Status and Anticipated Milestones



Remestemcel-L: Steroid-Refractory Acute Graft Versus Host Disease

Significant Unmet Need with High Mortality

Treatment Options

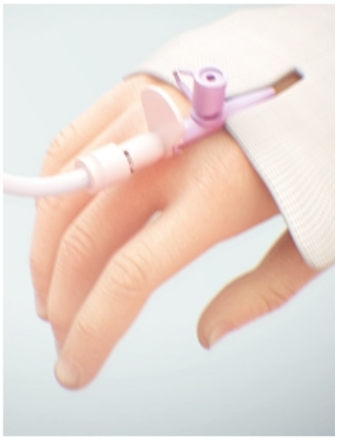
- Corticosteroids are first-line therapy for aGVHD
- There is only one approved treatment for disease refractory to steroids and no approved treatment in the US for children under 12 years old
- In Japan, Mesoblast's licensee has received the only product approval for SR-aGVHD in both children and adults

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 transplantion. Bone Marrow Transplantation.

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Remestemcel-L for Steroid-Refractory Graft Versus Host Disease

Consistent Efficacy and Safety Outcomes in a Total of 309 Children from Three Studies

- Remestemcel-L was used as first-line therapy in a randomized controlled Phase 3 trial of 260 patients, with SR-aGVHD, including 27 children
- Remestemcel-L was used as salvage therapy in an expanded access program in 241 children with SR-aGVHD, 80% of whom had Grade C/D disease, and failed institutional standard of care
- Remestemcel-L was used as first-line therapy in Mesoblast's open-label Phase 3 trial in 54 children with SR-aGVHD, 89% of whom had Grade C/D disease

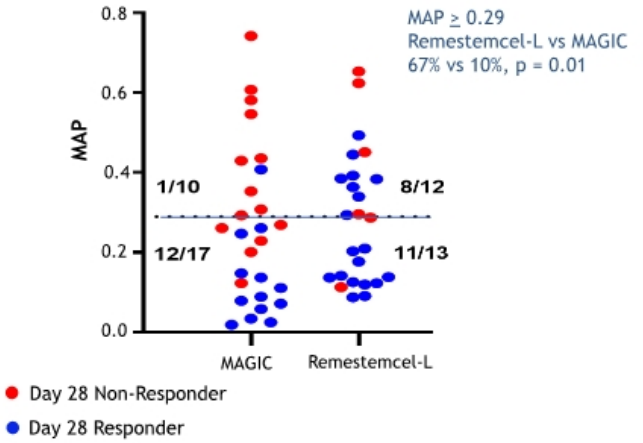
		Protocol 280 (pediatric)		EAP 275	Study 001
	MAGIC[1] N=30[2]	Placebo N=13	Remestemcel-L N=14	Remestemcel-L N=241	Remestemcel-L N=54[3]
Day 28 Overall Response	43%	38%	64%	65%	69%
Day 100 Survival	57%	54%	79%	66%	74%

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

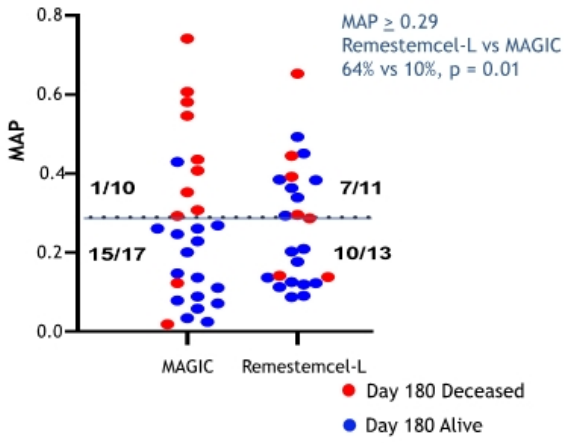
Remestemcel-L for Steroid-Refractory Graft Versus Host Disease

Significantly Greater Day 28 Overall Responses and Day 180 Survival in Steroid-Refractory Patients with Baseline MAP ≥ 0.29

Response by Baseline MAP



Survival by Baseline MAP



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

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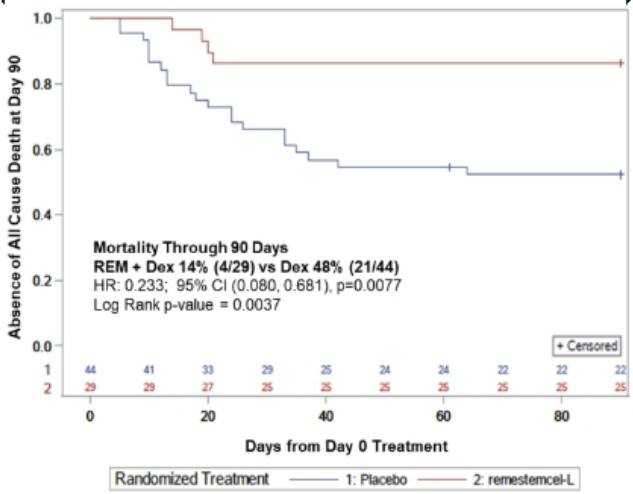
Remestemcel-L: Plan for BLA Resubmission for Steroid-Refractory Graft Versus Host Disease

- In response to FDA guidance, Mesoblast has optimized a potency assay that was in place at the time of the 54-patient Phase 3 trial in children with SR-aGVHD
- Mesoblast believes that the proposed potency assay measuring remestemcel-L's in vitro anti-inflammatory and immunomodulatory activity helps establish a clear understanding of remestemcel-L's mechanism of action in SR-aGVHD
- The potency assay from the Phase 3 trial demonstrates a relationship between the product's activity in vitro and its effects on survival in the Phase 3 trial, with the strongest correlation to survival in those patients at highest mortality risk as measured by clinical severity or high biomarker levels of inflammation
- Additionally, Mesoblast has now generated data from the expanded access program (EAP 275) of 241 children which confirm the ability of the in-vitro potency assay to measure product activity relevant to survival outcomes
- In preparation for the expected FDA review, during the last quarter Mesoblast completed a mock pre-approval inspection of its GMP manufacturing facility and process comprising both on-site and virtual inspections by external auditors
- Mesoblast will provide these new data to FDA and address all chemistry, manufacturing and controls (CMC) outstanding items as required for the planned BLA resubmission in the current quarter. If the resubmission is accepted, CBER will consider the adequacy of the clinical data in the context of the related CMC issues

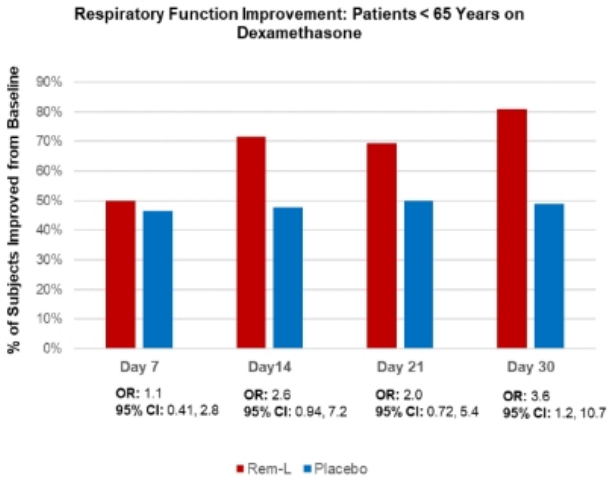
Remestemcel-L for Acute Respiratory Distress Syndrome (ARDS) due to COVID-19

Remestemcel-L Plus Dexamethasone Shows Synergy in Mortality Reduction and Improvement in ARDS Severity* in Exploratory Population < 65 years old

Treated Patients (mITT) < 65 years old on Dexamethasone (n=73) through 90-Days



Treated Patients (mITT) < 65 years old on Dexamethasone (n=73)



* Measured as resolution and/or improvement of ARDS as defined by the Berlin criteria at Days 7, 14, 21, and 30 post-randomizations

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Remestemcel-L: Regulatory Pathway to Potential EUA for COVID-19 ARDS

- Acute respiratory distress syndrome (ARDS) remains a major cause of mortality for COVID-19 patients who are immunocompromised, unvaccinated, or with comorbidities, as well as those with seasonal influenza and other pathogens
- FDA has advised Mesoblast that an additional clinical study in acute respiratory distress syndrome (ARDS) due to COVID19, if statistically positive, could provide sufficient evidence to support an emergency use authorization (EUA)
- Mesoblast has entered into a non-binding Memorandum of Understanding (MOU) with Vanderbilt University Medical Center, which coordinates and works closely with clinical investigators at over 40 sites across the United States focused on studying ARDS and other critical illnesses
- The MOU proposes a collaboration toward the design and execution of a second COVID-19 trial for remestemcel-L; to jointly develop a trial protocol; and seek FDA approval for the trial

Rexlemestrocel-L – Opportunity in Chronic Low Back Pain

A New Paradigm for Treatment of Chronic Low Back Pain due to Degenerative Disc Disease

Burden of Illness

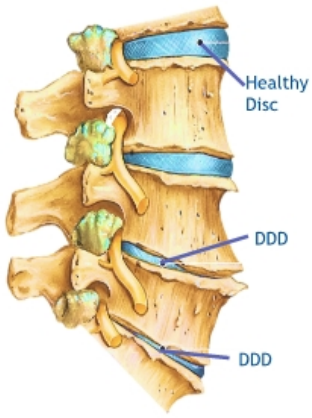
- Back pain causes more disability than any other condition[1]
- Inflicts substantial direct and indirect costs on the healthcare system,[1] including excessive use of opioids in this patient population

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[3]
- 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 [3,4,5]



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. Simon, J., McAuliffe, M., Shamim, F. (2015) Discogenic Low Back Pain. Phys Med Rehabil Clin N Am 25 (2014) 305-317., 3.Decision Resources: Chronic Pain December 2015., 4. LEK & NCI opinion leader interviews, and secondary analysis., 5. Navigant: Commercial Assessment for a Proprietary Cell-Based Therapy for DDD in the U.S. and the EU3 - August 2014., 6. HealthCare Utilization and Cost of Discogenic Lower Back Pain in the US - Anthem/HealthCore.

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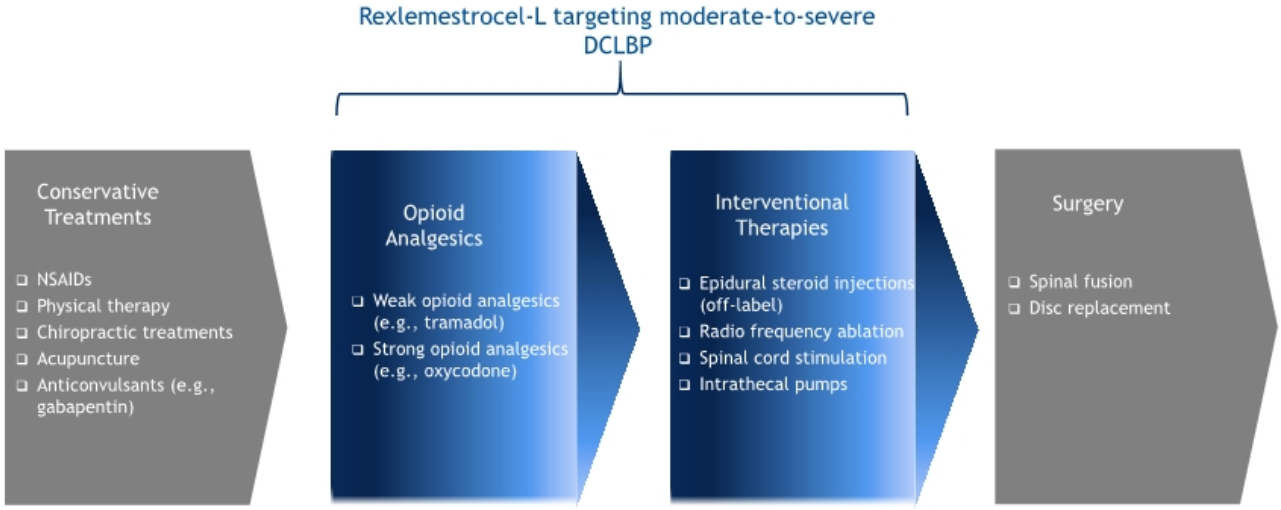
The Patient Treatment Journey

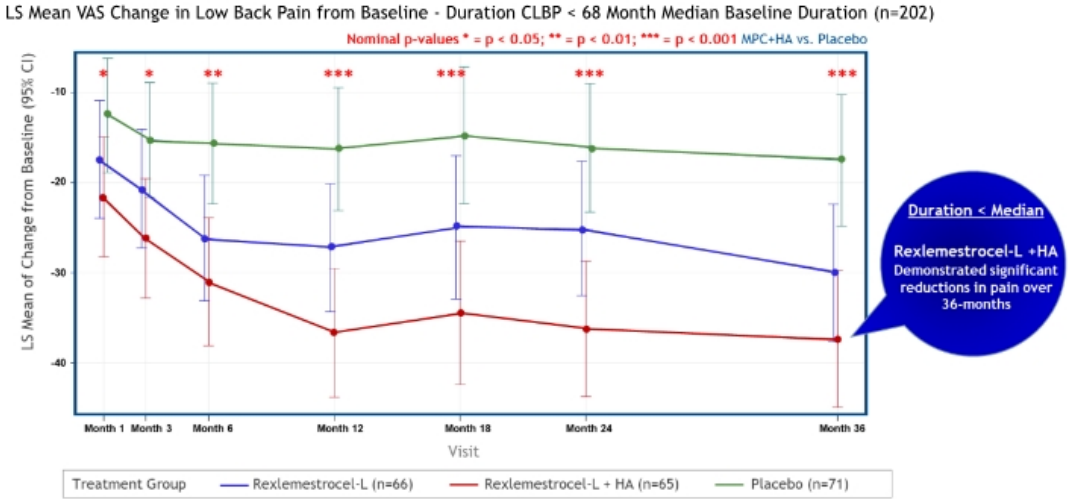
Rexlemestrocel-L Potential for First-Line CLBP associated with DDD, Refractory to Conservative Treatment



Phase 3 Trial Outcomes – Rexlemestrocel-L for Chronic Low Back Pain

Single Injection of Rexlemestrocel-L + HA Results in >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



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Market Access & Pricing Insights: Pricing will be Driven by Overall Value Offering; US Reference Pricing Suggests Higher Price Points for Disease Modifying Agents

- **Vivlodex® (meloxicam): $10.3k**
  - Osteoarthritis
- **Abuse-Deterrent Opioids**
  - OxyContin®: $1.2k - $6.8k+
  - Embeda®: $2.2k - $8.9k+
  - Xtampza ER®: $2.4k - $15.5k+
  - Hysingla ER®: $2.8k - $15.5k+

- **Teriparatide (Biosimilar to Forteo®)** Osteoporosis: ↓ incidence of hip fraction, ↑ bone mass

- **MACI® (autologous cultured chondrocytes on porcine collagen membrane)**
  - Indicated for the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults

- **Humira® (adalimumab)** Rheumatoid Arthritis: reduce signs and symptoms, improve physical function, inhibit the progression of structural damage

*Wholesale Acquisition Cost (WAC): Redbook 03/30/2021

Rexlemestrocel-L – Preparing for Next Phase 3 Trial in Chronic Low Back Pain

- FDA Office of Tissues and Advanced Therapies (OTAT) agreed with Mesoblast's proposal for mean pain reduction at 12 months to serve as the primary endpoint of the next trial, with mean functional improvement and reduction in opioid use as secondary endpoints
- A key objective is to demonstrate durable reduction in pain and position rexlemestrocel-L as a potential opioid-sparing agent
- The planned upcoming US trial will include at least 20% of subjects from the EU to support submissions to both FDA and EMA
- Active discussions ongoing with key investigators and advisors on final protocol design

Rexlemestrocel-L – Chronic Heart Failure

Rising Incidence & High Mortality

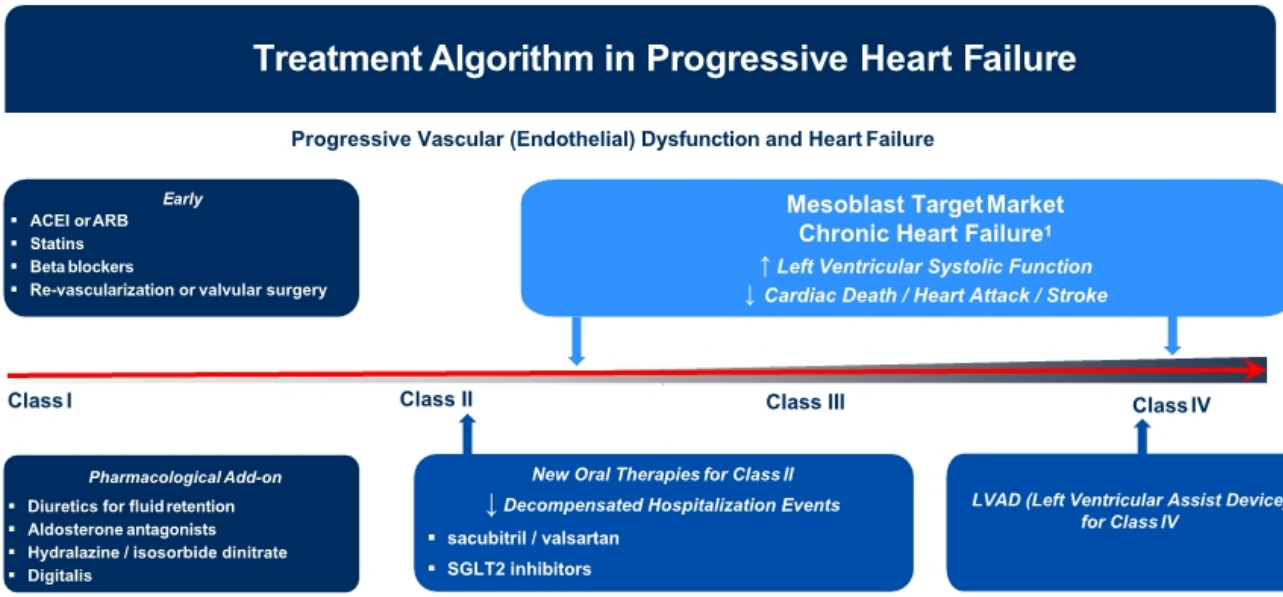
- Cardiovascular disease (CVD) remains the leading cause of death in the United States[1]
- Heart failure affects 6.5 million patients in the US and 26 million patients globally. As populations age, the prevalence is increasing[2]
- Chronic heart failure is a progressive disease with a high mortality 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)

New therapies for chronic heart failure reduce recurrent hospitalizations due to cardiac decompensation, however they do not materially improve cardiac mortality or major ischemic events (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.

The Patient Treatment Journey

Rexlemestrocel-L for Chronic Heart Failure



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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Rexlemestrocel-L: Phase 3 Trial in Heart Failure with Reduced Ejection Fraction (HFrEF)

Rexlemestrocel-L Improved Left Ventricular Systolic Function, as Measured by Left Ventricular Ejection Fraction (LVEF) at 12 Months: Potential Early Surrogate Endpoint

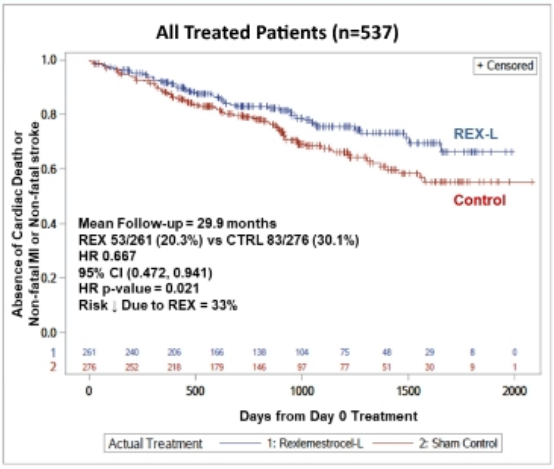
- In all treated patients (n=537) rexlemestrocel-L resulted in 52% greater increase in LVEF from baseline to 12 months compared with controls
- While both groups had similar LVEF at baseline (28.7% and 28.6%), at 12 months least squared mean change from baseline was 5.0 for the rexlemestrocel-L group and 3.3 for controls (p=0.021)
- In treated patients with CRP >2 (n=301) rexlemestrocel-L resulted in 86% greater increase in LVEF from baseline to 12 months compared with controls
- While both groups had similar LVEF at baseline (29.1% and 28.2%), at 12 months least squared mean change from baseline was 5.6 for the rexlemestrocel-L group and 2.9 for controls (p=0.005)

LVEF, 2-point MACE, and recurrent hospitalizations due to heart attack or stroke were pre-specified endpoints and the 3-point MACE was a post-hoc analysis of pre-specified endpoint components

DREAM-HF Phase 3 Trial in HFrEF

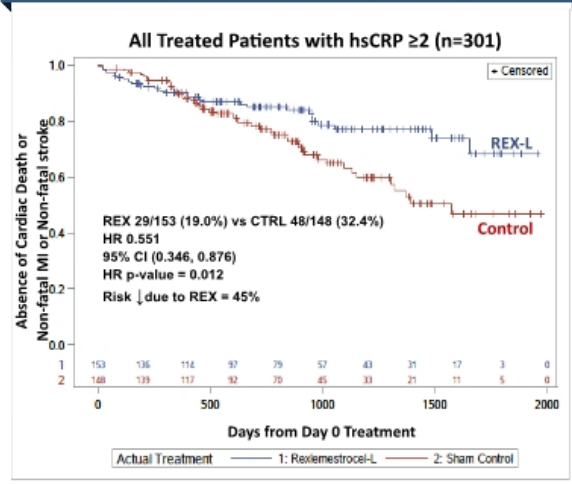
Rexlemestrocel-L Reduced Incidence of 3-Point Composite MACE - CV Death, MI or Stroke - Compared to Controls Across All 537 Treated Patients, with Enhanced Effect in Those with Active Inflammation as Measured by CRP >2

Time-to-First-Event (TTFE) for Cardiovascular Death or Non-fatal MI or Non-fatal Stroke (3P-MACE)



Kaplan-Meier log rank statistics

Time-to-First-Event (TTFE) for Cardiovascular Death or Non-fatal MI or Non-fatal Stroke



MACE=Major Adverse Cardiovascular Event; TTFE=Time To First Event; MI=Myocardial Infarction (Heart Attack)

LVEF, 2-point MACE, and recurrent hospitalizations due to heart attack or stroke were pre-specified endpoints and the 3-point MACE was a post-hoc analysis of pre-specified endpoint components

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Major Clinical & Regulatory Milestones Next 12 Months

Remestemcel-L

- FDA filing BLA this quarter for remestemcel-L in the treatment of SR-aGVHD
- Potential FDA approval of BLA six months after filing, and planned US product launch in Q1 CY2023
- Mesoblast and Vanderbilt University Medical Center, which coordinates a clinical trial network at over 40 sites across the US focused on ARDS, to jointly develop a trial protocol to confirm the previously observed reduction in mortality in COVID-19 ARDS patients under age 65.

Rexlemestrocel-L

- Plan to meet with FDA next quarter under existing RMAT designation to discuss common mechanism of action in HFrEF including those with LVADs, and potential pathway to marketing approval
- FDA clearance by year end 2022 to commence a pivotal study for potential marketing approval of rexlemestrocel-L in chronic low back pain due to degenerative disc disease


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Thank You