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mesoblast

MESOBLAST REPORTS FINANCIAL RESULTS AND OPERATIONAL HIGHLIGHTS FOR THE PERIOD ENDED SEPTEMBER 30, 2022

Durable long-term survival outcomes through 4 years for children with steroid-refractory graft versus host disease (SR-aGVHD) treated with remestemcel-L

These long-term survival outcomes are a cornerstone of the BLA resubmission to FDA for approval of remestemcel-L in the treatment of children with SR-aGVHD

Melbourne, Australia; November 23 and New York, USA; November 22, 2022: 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 September 30, 2022 and provided an update on upcoming milestones.

"The substantial and durable long-term survival over four years we have reported today in children with SR-aGVHD treated with remestemcel-L in our Phase 3 trial underscore the many lives that could potentially be saved by making this therapy available as soon as possible to children with the most common life-threatening complication after bone marrow transplantation" said Dr. Silviu Itescu, Chief Executive of Mesoblast.

"These new long-term survival data reaffirm the potential significance of remestemcel-L as a life-saving therapy for children with SR-aGVHD and are a cornerstone of the company's BLA resubmission to the FDA for approval of remestemcel-L in the treatment of children with SR-aGVHD. The lack of any approved treatments for children under 12 means that there is an urgent need for a therapy that improves the dismal survival outcomes in children. We are at a pivotal juncture, we believe we have appropriately addressed issues raised by FDA in the complete response, and we are well funded in preparation for a potential first product approval and launch by mid-year."

FINANCIAL HIGHLIGHTS

- **Cash:** Cash reserves as at September 30th were US$85.5 million. Up to an additional US$40.0 million may be drawn from existing financing facilities subject to achieving certain milestones, with current discussions to extend the period for the drawdown option.
- **Net cash usage** for operating activities in the quarter was US$14.3 million; this represented a 22% reduction (US$3.9 million) on the comparative quarter in FY2022, and a 47% reduction (US$12.5 million) on the comparative quarter in FY2021.
- **Revenue** from royalties on sales of TEMCELL® HS Inj.[1] sold in Japan by our licensee for the quarter were US$1.4 million. For the 12-month period ended September 30, 2022 royalties were US$7.7 million, and on a constant currency basis[2] US$9.0 million, a 9% increase on the comparative period.
- **Expenditure** for R&D, Manufacturing and Management & Administration inclusive of non-cash items, were US$17.5 million, a decrease of 23% (US$5.2 million) for the quarter ended September 30, 2022 on the comparative quarter.

OPERATIONAL HIGHLIGHTS AND NEAR-TERM MILESTONES

Remestemcel-L

Biologics License Application (BLA) resubmission to the US Food and Drug Administration (FDA) for the treatment of children with steroid-refractory graft versus host disease (SR-aGVHD)

- Survival outcomes have not improved over the past two decades for children or adults with the most severe forms of SR-aGVHD.[3-6] The lack of any approved treatments for children under 12 means that there is an urgent need for a therapy that improves the dismal survival outcomes in children.

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- In light of the unmet need, remestemcel-L has been granted Fast Track Designation and BLA Priority Review from the FDA.
- A major milestone in the Company's complete response to the FDA was the submission at the end of the last quarter of substantial new information on clinical and potency assay items to the Investigational New Drug (IND) file for remestemcel-L in the treatment of children with SR-aGVHD, as guided by FDA.
- Mesoblast has optimized a potency assay that was in place at the time of the Phase 3 trial and which demonstrates a relationship between the product's activity in-vitro and its effects on survival in the Phase 3 trial.
- 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.
- Today 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, while across four recently published studies of children or adults with SR-aGVHD who received best available therapy (BAT) or the only FDA-approved agent for adults survival rates of 40-49% at 1 year and 25%-38% at 2 years were seen. [7-10]
- 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 and are a cornerstone of the BLA resubmission.
- Mesoblast is working towards a potential US approval for remestemcel-L and first product launch in H1 CY2023.
- Additional indications for which remestemcel-L is being developed include acute respiratory distress syndrome and inflammatory bowel disease.

Rexlemestrocel-L

Chronic low back pain associated with degenerative disc disease:

- Working towards FDA clearance by year end 2022 to commence the second Phase 3 trial for potential marketing approval in chronic lower back pain due to degenerative disc disease.
- Mesoblast gained alignment with the FDA on key metrics for the Phase 3 study in patients with CLBP.
- The primary endpoint for the study will be reduction in pain at 12 months, in line with FDA discussions and feedback.

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.
- 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.

FINANCIAL RESULTS FOR THE PERIOD ENDED SEPTEMBER 30, 2022 (FIRST QUARTER FY2023)

- **Cash** reserves as at September 30th were US$85.5 million. Up to an additional US$40.0 million may be drawn from existing financing facilities subject to achieving certain milestones, with current discussions to extend the period for the drawdown option.
- **Net cash usage** for operating activities in the quarter was US$14.3 million; this represented a 22% reduction (US$3.9 million) on the comparative quarter in FY2022, and a 47% reduction (US$12.5 million) on the comparative quarter in FY2021.

- **Revenue** from royalties on sales of TEMCELL® HS Inj.[1] sold in Japan by our licensee for the quarter were US$1.4 million and US$1.8 million on a constant currency basis. For the 12-month period ended September 30, 2022 royalties were US$7.7 million, and on a constant currency basis[2] US$9.0 million, a 9% increase on the comparative period.

  In the comparative quarter, there was one-off milestone revenue of US$1.2 million from Takeda for Japan approval of Alofisel® (darvadstrocel) for perianal fistulas.

- **Research & Development expenses** reduced by US$3.6 million (38%), down to US$5.7 million for the first quarter FY2023 compared to US$9.3 million for the first quarter FY2022 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$2.7 million (35%), down to US$4.8 million for the first quarter FY2023 compared to US$7.5 million for the first 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$28.0 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** increased by US$1.0 million (17%), up to US$6.9 million for the first quarter FY2023 compared to US$5.9 million for the first quarter FY2022 primarily due to an increase in non-cash share-based payments and insurance costs.

- **Remeasurement of Contingent Consideration** gains increased to US$4.5 million in the first quarter FY2023 compared to a gain of US$0.3 million for the first quarter FY2022 reflecting a reduction in future third party payments.

- **Fair value movement of warrants:** recognized a loss of US$0.4 million in the first quarter FY2023 compared to Nil in the first quarter FY2022.

- **Finance Costs** for borrowing arrangements with our lenders, Oaktree and NovaQuest, were US$4.5 million (actual cash interest paid US$1.2 million) for the first quarter FY2023, compared to US$3.7 million (actual cash interest paid US$1.2 million) for the first quarter FY2022.

- **Loss after tax** for the first quarter FY2023 was US$16.9 million compared to US$22.6 million for the first quarter FY2022. The net loss attributable to ordinary shareholders was 2.43 US cents per share for the first quarter FY2023, compared with 3.49 US cents per share for the first quarter FY2022.

Conference Call
There will be a webcast today, beginning at 8.30am AEDT (Wednesday, November 23); 4.30pm ET (Tuesday, November 22). It can be accessed via: https://webcast.openbriefing.com/9143/

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:110.2Yen for the 12 months ended September 30, 2021 to 1USD:129.2Yen for the 12 months ended September 30, 2022.
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. Westin, J., Saliba, RM., Lima, M. (2011) Steroid-refractory acute GVHD: predictors and outcomes. *Advances in Hematology*.
6. 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*.
7. 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.
8. MacMillan ML et al. Pediatric acute GVHD: clinical phenotype and response to upfront steroids. *Bone Marrow Transplant* 2020; 55(1): 165-171
9. Zeiser R et al. Ruxolitinib for Glucocorticoid-Refractory Acute Graft-versus-Host Disease. *N Engl J Med* 2020;382:1800-10.
10. Jagasia M et al. Ruxolitinib for the treatment of steroid-refractory acute GVHD (REACH1): a multicenter, open-label phase 2 trial. *Blood.* 2020 May 14; 135(20): 1739–1749.

Forward-Looking Statements

This press release includes forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Forward-looking statements should not be read as a guarantee of future performance or results, and actual results may differ from the results anticipated in these forward-looking statements, and the differences may be material and adverse. Forward-looking statements include, but are not limited to, statements about: the initiation, timing, progress and results of Mesoblast's preclinical and clinical studies, and Mesoblast's research and development programs; Mesoblast's ability to advance product candidates into, enroll and successfully complete, clinical studies, including multi-national clinical trials; Mesoblast's ability to advance its manufacturing capabilities; the timing or likelihood of regulatory filings and approvals (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)	Three Months Ended September 30, 2022	2021
Revenue	1,503	3,594
Research & development	(5,744)	(9,328)
Manufacturing commercialization	(4,866)	(7,537)
Management and administration	(6,898)	(5,878)
Fair value remeasurement of contingent consideration	4,468	280
Fair value remeasurement of warrant liability	(401)	—
Other operating income and expenses	(504)	(178)
Finance costs	(4,497)	(3,660)
Loss before income tax	**(16,939)**	**(22,707)**
Income tax benefit/(expense)	55	62
Loss attributable to the owners of Mesoblast Limited	**(16,884)**	**(22,645)**
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:	**Cents**	**Cents**
Basic - losses per share	(2.43)	(3.49)
Diluted - losses per share	(2.43)	(3.49)

Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	Three Months Ended September 30, 2022	2021
Loss for the period	**(16,884)**	**(22,645)**
Other comprehensive (loss)/income		
Items that may be reclassified to profit and loss		
Exchange differences on translation of foreign operations	(159)	(349)
Items that will not be reclassified to profit and loss		
Financial assets at fair value through other comprehensive income	86	154
Other comprehensive (loss)/income for the period, net of tax	**(73)**	**(195)**
Total comprehensive losses attributable to the owners of Mesoblast Limited	**(16,957)**	**(22,840)**

Consolidated Balance Sheet

(in U.S. dollars, in thousands)	As of September 30, 2022	As of June 30, 2022
Assets		
Current Assets		
Cash & cash equivalents	85,502	60,447
Trade & other receivables	3,863	4,403
Prepayments	3,595	4,987
Total Current Assets	**92,960**	**69,837**
Non-Current Assets		
Property, plant and equipment	1,786	2,045
Right-of-use assets	7,730	7,920
Financial assets at fair value through other comprehensive income	1,843	1,758
Other non-current assets	1,902	1,930
Intangible assets	578,275	578,652
Total Non-Current Assets	**591,536**	**592,305**
Total Assets	**684,496**	**662,142**
Liabilities		
Current Liabilities		
Trade and other payables	17,663	23,079
Provisions	19,455	17,906
Borrowings	5,489	5,017
Lease liabilities	3,609	3,186
Warrant liability	2,586	2,185
Total Current Liabilities	**48,802**	**51,373**
Non-Current Liabilities		
Provisions	9,853	12,523
Borrowings	94,186	91,617
Lease liabilities	6,348	7,085
Deferred consideration	2,500	2,500
Total Non-Current Liabilities	**112,887**	**113,725**
Total Liabilities	**161,689**	**165,098**
Net Assets	**522,807**	**497,044**
Equity		
Issued Capital	1,207,734	1,165,309
Reserves	70,873	70,651
(Accumulated losses)/retained earnings	(755,800)	(738,916)
Total Equity	**522,807**	**497,044**

Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	Three Months Ended September 30, 2022	2021
Cash flows from operating activities		
Commercialization revenue received	2,219	1,995
Government grants and tax incentives received	—	24
Payments to suppliers and employees (inclusive of goods and services tax)	(16,566)	(20,222)
Interest received	60	4
Net cash (outflows) in operating activities	**(14,287)**	**(18,199)**
Cash flows from investing activities		
Investment in fixed assets	(153)	(99)
Payments for licenses	(50)	—
Net cash (outflows) in investing activities	**(203)**	**(99)**
Cash flows from financing activities		
Payment of transaction costs from borrowings	(151)	(100)
Interest and other costs of finance paid	(1,381)	(1,407)
Proceeds from issue of shares	45,065	147
Payments for share issue costs	(2,565)	(104)
Payments for lease liabilities	(670)	(686)
Net cash inflows/(outflows) by financing activities	**40,298**	**(2,150)**
Net increase/(decrease) in cash and cash equivalents	25,808	(20,448)
Cash and cash equivalents at beginning of period	60,447	136,881
FX (loss) on the translation of foreign bank accounts	(753)	(477)
Cash and cash equivalents at end of period	**85,502**	**115,956**