asx announcement

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 rexlemestrocel-L in the treatment of chronic low back pain (CLBP) associated with disc degeneration, in combination with hyaluronic acid (HA) as delivery agent for injection into the lumbar disc. 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 million[3] 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 rexlemestrocel-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; rexlemestrocel-L) strengthened heart function at 12 months, as measured by left ventricular ejection fraction (LVEF) and decreased cardiovascular death, myocardial infarction (MI) or stroke in patients with chronic heart failure (CHF) due to reduced ejection fraction (HFrEF) over a mean follow-up of 30 months.[1]

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

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

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

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

Mesoblast plans to meet with the FDA 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 remestemcel-L BLA re-submission and preparations for pivotal studies for rexlemestrocel-L, as clinical trial activities for our product candidates are reduced since clinical trial recruitment and data analysis are now complete.
- **Manufacturing expenses** were US$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, 2023	Three Months Ended March 31, 2022	Nine Months Ended March 31, 2023	Nine Months Ended March 31, 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, 2023	Three Months Ended March 31, 2022	Nine Months Ended March 31, 2023	Nine Months Ended March 31, 2022
Loss for the period	**(18,600)**	**(21,302)**	**(59,970)**	**(69,892)**
Other comprehensive (loss)/income				
Items that may be reclassified to profit and loss				
Exchange differences on translation of foreign operations	152	(333)	252	(516)
Items that will not be reclassified to profit and loss				
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 March 31, 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**