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mesoblast

MESOBLAST REPORTS FINANCIAL RESULTS AND OPERATIONAL UPDATE FOR FISCAL YEAR ENDED JUNE 30, 2023

Melbourne, Australia; August 31 and New York, USA; August 30, 2023: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today reported financial results and an operational update for the period ended June 30, 2023, and provided an overview of upcoming milestones.

Mesoblast Chief Executive Silviu Itescu said: "We had anticipated that remestemcel-L would have been approved by the United States Food and Drug Administration (FDA) for the treatment of pediatric steroid-refractory acute graft versus host disease (SR-aGVHD), a condition with a high mortality where there are no approved therapies for children under 12 years old. During the six-month BLA review we made substantial progress towards bringing this cutting-edge product to market with completion of a comprehensive FDA inspection of our manufacturing process. Following the complete response, a Type A meeting with FDA has been scheduled for mid-September and we will discuss the potential paths to approval via additional potency assay data or new clinical data in adults. We remain committed to making available this life-saving therapy to patients suffering with this devastating disease."

Dr Itescu continued "We have implemented a significant cost containment strategy and enacted substantial payroll reduction to protect our cash reserves and ensure that we are fiscally prudent. Leading by example, I have deferred my entire short term incentives (STI) and reduced my annual salary by 30%, and the same initiatives have been agreed to by our CMO Dr Eric Rose. I am also pleased that our Non-Executive Directors have agreed to defer all cash compensation."

"These cost reduction strategies together with operational streamlining will enable the company to conserve cash while at the same time drive value as we progress our Phase 3 programs in adults with SR-aGVHD and in chronic inflammatory low back pain."

FINANCIAL RESULTS FOR THE PERIOD ENDED JUNE 30, 2023 (FY2023)

- **Cash reserves** at June 30, 2023 were US$71.3 million, with up to an additional US$40 million from our existing financing facilities subject to both certain milestones being met and the extension of timeline to achieve them.
- **Net cash usage** for operating activities was US$63.3 million for FY2023, a 37% reduction compared with FY2021 and 4% reduction compared with FY2022.
- **Revenues** were US$7.5 million for FY2023, compared to US$10.2 million for FY2022, a reduction primarily due to a one-off milestone of US$1.2 million from Takeda for Japan approval of Alofisel® (darvadstrocel) for perianal fistulas in FY2022.
- **Royalties** on sales of TEMCELL® HS Inj.[1] sold in Japan by our licensee for FY2023 were, on a constant currency basis, US$8.1 million, compared with US$8.7 million for FY2022.[2]

COST CONTAINMENT PLAN FOR NEXT 12 MONTHS AND REDUCTION IN SPEND ON OPERATIONAL ACTIVITIES AND PAYROLL

- Net operating cash usage in FY2023 was a 37% reduction compared with FY2021 and 4% reduction compared with FY2022.
- Further targeted 23% reduction (US$15 million) from US$63.3 million in FY2023 to US$48.3 million in projected FY2024 annual net operating cash spend through reduced spend across research, sales & marketing, commercial inventory, and payroll, which will be partially offset by investment in our Phase 3 programs for SR-aGVHD and CLBP.
- Targeted 40% annualized reduction in payroll by February 2024 which includes base salaries, short-term incentives (STIs) payments and contractor fees.
- CEO and CMO have deferred their entire FY23 short-term incentives (STI), have voluntarily reduced their base salaries for FY24 by 30% to preserve cash, and will instead receive long-term non-cash incentives (LTIs) to further align with shareholders, subject to required shareholder approval.

- FY23 short-term incentives (STIs) have been entirely deferred for all employees.
- Management are eligible to receive LTIs in lieu of a 30% reduction in salary.
- Non-Executive Directors have voluntarily deferred 100% of the cash payment of their director fees and agreed to receive 50% of their fees in LTIs, subject to required shareholder approval.

REMESTEMCEL-L STRATEGY UPDATE

- FDA provided a complete response requiring Mesoblast to demonstrate that product used in the phase 3 trial is similar to product intended for commercial release, as measured by a standardized potency assay.
- FDA indicates that an additional clinical trial would be needed to establish this link if the company is not able to do so via additional potency assay work.
- Type A meeting with US FDA scheduled to be held mid-September for SR-aGVHD indication.
- Mesoblast proposes providing FDA with additional potency assay data to provide link between Phase 3 product and commercial inventory.
- Mesoblast proposes providing FDA with new clinical trial data in adults, which could also support the pediatric indication.
- In line with our overall commercial strategy to progress to adult patient populations, which make up approximately 5-fold larger numbers than children,[3] Mesoblast intends to conduct a targeted, controlled study in adults with high mortality risk.
- Survival in adults with SR-aGVHD who have failed at least one additional agent, such as ruxolitinib, remains as low as 20-30% by 100 days.[4,5]
- In contrast, 100-day survival was 63% after remestemcel-L treatment was used under expanded access in 71 patients aged 12 and older with SR-aGVHD who failed to respond to at least one additional agent, such as ruxolitinib.
- Mesoblast is in discussions with world-leading investigators at the Blood and Marrow Clinical Trials Network (BM CTN), a body responsible for 80% of all US transplants, to conduct the new clinical trial.
- The costs of this targeted study are expected to be covered by the spending reduction described above.

REXLEMESTROCEL-L STRATEGY UPDATE

- Product has been manufactured for use in a pivotal study recruiting patients across the United States to support potential marketing approval of rexlemestrocel-L in chronic low back pain (CLBP) due to degenerative disc disease.
- Pivotal trial start-up activities have commenced and recruitment is expected to begin next quarter.
- Primary endpoint is reduction in pain at 12 months compared to placebo.
- Rexlemestrocel-L has received Regenerative Medicine Advanced Therapy (RMAT) designation for CLBP.
- Rexlemestrocel-L has additionally received RMAT designation for treatment of heart failure in patients with Left Ventricular Assist Devices (LVADs).
- Mesoblast to meet with FDA to seek to extend RMAT to HFrEF patients without LVADs based on common mechanism of action, and potential pathway to marketing approval.

DETAILS OF FINANCIAL RESULTS FOR THE PERIOD ENDED JUNE 30, 2023 (FY2023)

- **Research & Development** expenses reduced by US$5.6 million (17%), down to US$27.2 million for FY2023 compared to US$32.8 million for 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 reduced by US$3.0 million (10%), down to US$27.7 million for FY2023 compared to US$30.7 million for FY2022. During the year we continued pre-launch manufacturing activities and product testing for remestemcel-L.
- **Management and Administration** expenses reduced by US$1.8 million (7%), down to US$25.4 million for FY2023 compared to US$27.2 million for FY2022 primarily due to a one-off adjustment in legal expenses in FY2023 and increased professional fees associated with a one-off corporate activity incurred in FY2022.
- **Remeasurement of Contingent Consideration** recognized gains of US$8.8 million in FY2023 reflecting a reduction in future third party payments compared to a gain of US$0.9 million in FY2022 primarily as a result of revaluing future third party payments.
- **Fair value movement of warrants** recognized a loss of US$2.2 million in FY2023 compared to a gain of US$5.9 million in FY2022.
- **Other operating income** in FY2023 includes R&D tax incentive income of US$3.5 million. The income recorded in this period pertains to the eligible expenditure refundable under the Australian governments incentive program for the years ended June 30, 2021, 2022 and 2023.
- **Finance Costs** for borrowing arrangements include US$15.2 million of non-cash expenditure for FY2023 comprising accruing interest and borrowing costs.

Loss after tax for FY2023 was US$81.9 million compared to US$91.3 million for FY2022. The net loss attributable to ordinary shareholders was 11.08 US cents per share for FY2023, compared with 14.08 US cents per share for FY2022.

Conference Call
There will be a webcast today, beginning at 8.30am AEST (Thursday, August 31); 6.30pm EDT (Wednesday, August 30). It can be accessed via: https://webcast.openbriefing.com/msb-fyr-2023/

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

About Mesoblast
Mesoblast (the Company) 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:122.14 Yen for the year ended June 30, 2022 to 1USD:139.76 Yen for the year ended June 30, 2023.
3. HRSA Transplant Activity Report, CIBMTR, 2020
4. Jagasia M et al. Ruxolitinib for the treatment of steroid-refractory acute GVHD (REACH1): a multicenter, open-label phase 2 trial. *Blood.* 2020 May 14; 135(20): 1739–1749
5. Abedin S, et al. Ruxolitinib resistance or intolerance in steroid-refractory acute graft versus-host disease — a real-world outcomes analysis. *British Journal of Haematology*, 2021;195:429–43.

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 our request to have a Type A meeting with the FDA, the outcome of such a meeting, and any future decision that the FDA may make on the BLA for remestemcel-L for pediatric patients with SR-aGVHD), 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, 2023	2022
Revenue	7,501	10,211
Research & development	(27,189)	(32,815)
Manufacturing commercialization	(27,733)	(30,757)
Management and administration	(25,374)	(27,210)
Fair value remeasurement of contingent consideration	8,771	913
Fair value remeasurement of warrant liability	(2,205)	5,896
Other operating income and expenses	4,250	(536)
Finance costs	(20,122)	(17,288)
Loss before income tax	**(82,101)**	**(91,586)**
Income tax benefit/(expense)	212	239
Loss attributable to the owners of Mesoblast Limited	**(81,889)**	**(91,347)**

Losses per share from continuing operations attributable to the ordinary equity holders of the Group:	**Cents**	**Cents**
Basic - losses per share	(11.08)	(14.08)
Diluted - losses per share	(11.08)	(14.08)

Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	Year Ended June 30, 2023	2022
Loss for the period	**(81,889)**	**(91,347)**
Other comprehensive (loss)/income		
Items that may be reclassified to profit and loss		
Exchange differences on translation of foreign operations	(573)	91
Items that will not be reclassified to profit and loss		
Financial assets at fair value through other comprehensive income	(1)	(322)
Other comprehensive (loss)/income for the period, net of tax	**(574)**	**(231)**
Total comprehensive losses attributable to the owners of Mesoblast Limited	**(82,463)**	**(91,578)**

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Consolidated Balance Sheet

(in U.S. dollars, in thousands)	As of June 30, 2023	2022
Assets		
Current Assets		
Cash & cash equivalents	71,318	60,447
Trade & other receivables	6,998	4,403
Prepayments	3,342	4,987
Total Current Assets	**81,658**	**69,837**
Non-Current Assets		
Property, plant and equipment	1,357	2,045
Right-of-use assets	5,134	7,920
Financial assets at fair value through other comprehensive income	1,757	1,758
Other non-current assets	2,326	1,930
Intangible assets	577,183	578,652
Total Non-Current Assets	**587,757**	**592,305**
Total Assets	**669,415**	**662,142**
Liabilities		
Current Liabilities		
Trade and other payables	20,145	23,079
Provisions	6,399	17,906
Borrowings	5,952	5,017
Lease liabilities	4,060	3,186
Warrant liability	5,426	2,185
Total Current Liabilities	**41,982**	**51,373**
Non-Current Liabilities		
Provisions	16,612	12,523
Borrowings	102,811	91,617
Lease liabilities	3,672	7,085
Deferred consideration	2,500	2,500
Total Non-Current Liabilities	**125,595**	**113,725**
Total Liabilities	**167,577**	**165,098**
Net Assets	**501,838**	**497,044**
Equity		
Issued Capital	1,249,123	1,165,309
Reserves	73,520	70,651
Accumulated losses	(820,805)	(738,916)
Total Equity	**501,838**	**497,044**

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Consolidated Statement of Cash Flow

(in U.S. dollars, in thousands)	Year Ended June 30, 2023	2022
Cash flows from operating activities		
Commercialization revenue received	7,480	9,980
Government grants and tax incentives received	1,118	24
Payments to suppliers and employees (inclusive of goods and services tax)	(72,683)	(75,769)
Interest received	796	7
Income taxes received /(paid)	20	(24)
Net cash (outflows) in operating activities	**(63,269)**	**(65,782)**
Cash flows from investing activities		
Investment in fixed assets	(264)	(157)
Receipts from investment in sublease	120	—
Payments for licenses	(50)	(75)
Net cash (outflows) in investing activities	**(194)**	**(232)**
Cash flows from financing activities		
Proceeds from borrowings	—	51,919
Repayment of borrowings	—	(55,458)
Payment of transaction costs from borrowings	(574)	(5,527)
Interest and other costs of finance paid	(6,014)	(6,084)
Proceeds from issue of shares	88,635	209
Proceeds from issue of warrants	—	8,081
Payments for share issue costs	(4,889)	(222)
Payments for lease liabilities	(2,656)	(2,788)
Net cash inflows/(outflows) by financing activities	**74,502**	**(9,870)**
Net increase/(decrease) in cash and cash equivalents	11,039	(75,884)
Cash and cash equivalents at beginning of period	60,447	136,881
FX (loss)/gain on the translation of foreign bank accounts	(168)	(550)
Cash and cash equivalents at end of period	**71,318**	**60,447**

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