

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."

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“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.”

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 currency² 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		
<i>Items that may be reclassified to profit and loss</i>		
Exchange differences on translation of foreign operations	91	(1,524)
<i>Items that will not be reclassified to profit and loss</i>		
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