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mesoblast

OPERATIONAL HIGHLIGHTS AND FINANCIAL RESULTS FOR THE PERIOD ENDED MARCH 31, 2022

Substantial Reduction in Operational Spend while Maintaining Focus on BLA Resubmission

Melbourne, Australia; June 1 and New York, USA; May 31, 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 March 31, 2022.

Financial Highlights

- Net cash usage reported for operating activities in the quarter was reduced by 40%, or US$10.3 million, to US$15.5 million compared with US$25.8 million in the comparative quarter last year[1]
- For the quarter, net cash usage reported for operating activities, excluding inventory for the planned remestemcel-L product launch, was reduced by 50% to US$11.2 million from US$22.2 million in the comparative quarter
- For the nine-month period ended March 31, 2022, net cash usage reported for operating activities was reduced by 36%, or US$31.2 million, to US$54.8 million compared with US$86.0 million in the comparative period last year, and by 40% excluding inventory for the planned remestemcel-L product launch
- Revenues in the quarter were US$2.0 million, including US$1.9 million from TEMCELL® HS Inj.[2] royalties on sales for SR-aGvHD in Japan, an increase of 5% on the comparative quarter last year
- Revenues increased 46%, for the nine-month period ended March 31, 2022, to US$8.0 million compared with US$5.5 million in the comparative period last year
- Cash on hand at the end of the quarter was US$76.8 million, with up to an additional US$40 million available to be drawn down from existing financing facilities subject to certain milestones

Board and Management Highlights

- Philip R. Krause, M.D. joined the Board of Directors in March. Dr. Krause was for the past decade Deputy Director, Office of Vaccines Research and Review (OVRR) at the United States Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER). Dr. Krause is currently Chair of the World Health Organization COVID Vaccines Research Expert Group, and most recently he shared responsibility for regulatory authorizations of COVID-19 vaccines in the US. Dr. Krause's deep insights and knowledge of regulatory processes will be invaluable to Mesoblast as it prepares its resubmission of the Biologics License Application (BLA) to the FDA for remestemcel-L in the treatment of children with steroid-refractory acute graft versus host disease (SR-aGVHD)
- Eric Rose, M.D. was appointed as the Company's Chief Medical Officer (CMO), having been a non-executive director of Mesoblast since 2013. Previously Chairman of Surgery at Columbia University's School of Medicine, Dr. Rose brings to his new role an extensive record of excellence in clinical development and successful interactions at the highest levels with key regulatory, industry and government stakeholders including the United States FDA, the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA)

Operational Highlights for Remestemcel-L

Resubmission of the Biologics License Application (BLA) for remestemcel-L in the treatment of children with steroid-refractory graft versus host disease (SR-aGVHD) to the United States Food and Drug Administration (FDA)

- 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, and demonstrates relevance to the in vivo clinical effect of the product in the 54-patient Phase 3 trial in children with SR-aGVHD
- An investigator-initiated controlled study in children with SR-aGVHD stratified by baseline levels of inflammatory biomarkers, published late 2021 in the peer-reviewed journal *Bone Marrow Transplantation,*[3] showed that remestemcel-L provided a significant benefit in terms of both response and survival in children with the highest levels of inflammation and at greatest risk of death compared to best available therapy
- The study compared outcomes in 25 children from Mesoblast's Phase 3 trial of remestemcel-L in SR-aGVHD with 27 closely matched children from the Mount Sinai Acute GVHD International Consortium (MAGIC).[4] In children with baseline MAGIC Algorithm Probability (MAP) biomarker levels ≥0.29, a level associated with significant GI inflammation and damage, and which is predictive of poor treatment responses and very high mortality in SR-aGVHD, treatment with remestemcel-L resulted in 67% Day 28 Overall Response and 64% Day 180 overall survival compared with 10% Day 28 Overall Response and 10% Day 180 survival in the MAGIC cohort (both p=0.01) when treated with various biologics, including ruxolitinib
- The proposed potency assay 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
- While global supply chain constraints impacted supply of assay kits during the quarter, our GMP contractor is now well resourced allowing final testing of product inventory for the BLA resubmission
- In preparation for the expected FDA review, Mesoblast last week completed a successful 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 coming quarter. If the resubmission is accepted, CBER will consider the adequacy of the clinical data in the context of the related CMC issues

COVID-19 acute respiratory distress syndrome (ARDS)

- Provided an update on survival outcomes from the randomized controlled trial of remestemcel-L in ventilator-dependent COVID-19 patients with moderate/severe acute respiratory distress syndrome (ARDS) and plans for a pivotal trial with collaborative investigators
- Through the initial 90 days, remestemcel-L reduced mortality by 48% compared to controls in a pre-specified analysis of 123 patients below age 65 (26% vs 44%, p=0.038),[5,6] but not in 97 patients over age 65, as previously reported. In an exploratory analysis in 73 patients under age 65 who also received dexamethasone as part of their standard of care, remestemcel-L reduced 90-day mortality by 77% compared to controls (14% vs 48%, p=0.0037).[5,6] These early survival outcomes in the remestemcel-L group relative to controls

were maintained at later timepoints in those under age 65, with a 42% reduction in mortality through 12 months and with continued observed synergy with dexamethasone ($p<0.05$)[5,6]

- The Phase 2/3 trial in COVID ARDS randomized 1:1 to either standard of care alone or standard of care plus two doses of remestemcel-L 2 million cells/kg 3-5 days apart. This two-dose regimen of remestemcel-L was the same as in the earlier compassionate use program where 11 of 12 patients were younger than 65 and 75% successfully came off ventilatory support. These pilot study results were recently published in the peer-reviewed journal *Cytotherapy.*[7] In contrast, remestemcel-L is used at an eight-dose regimen of 2 million cells/kg over four weeks in patients with steroid-refractory acute graft versus host disease (SR-aGVHD). The established extended dosing regimen in SR-aGVHD, another severe inflammatory condition, provides a rationale for exploring an extended course of remestemcel-L in older patients with COVID ARDS who have higher levels of inflammation
- 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. Mesoblast is working together with investigators from a clinical trial network focused on acute lung injury at over 40 sites across the United States affiliated with Vanderbilt University Medical Center to design and implement a pivotal trial of remestemcel-L to reduce mortality in high-risk patients with ARDS

Inflammatory Bowel Disease

- Results from an interim analysis of the first cohort of patients from the randomized, controlled study of remestemcel-L by direct endoscopic delivery to areas of inflammation in patients with medically refractory ulcerative colitis or Crohn's colitis were published in the *Journal of Crohn's and Colitis.*[8,9] A single local delivery of remestemcel-L by colonoscopy resulted in rapid mucosal healing, improved clinical and endoscopic scores as early as two weeks following remestemcel-L, and a high incidence of disease remission by six weeks

Operational Highlights for Rexlemestrocel-L

Chronic Heart Failure

- Dr. Eugene Braunwald who has often been called the father of modern cardiology and the most frequently cited author in cardiology,[10] last month wrote an opinion piece in European Heart Journal titled *Cardiac cell therapy: a call for action*.[11] The paper highlighted next generation mesenchymal stromal (bone marrow-derived) cells as attractive candidates for cardiac cell therapy (CCT). He specifically highlighted the clinical outcomes observed in Mesoblast's DREAM-HF Phase 3 trial and pointed out the company's commercial leadership globally in the field of CCT for heart failure
- Mesoblast received feedback in Q4 CY2021 from FDA confirming that reduction in major adverse cardiovascular events (MACE) of cardiovascular mortality or irreversible morbidity (non-fatal heart attack or stroke) is an acceptable clinically meaningful endpoint for determining the treatment benefit of rexlemestrocel-L for patients with chronic heart failure and low ejection fraction (HFrEF). In December, following FDA guidance, Mesoblast presented additional top-line results in pre-specified high-risk groups in the DREAM-HF Phase 3 trial of rexlemestrocel-L in HFrEF which showed that the greatest treatment benefit is in patients with diabetes and/or myocardial ischemia (72% of total treated population), a target population at very high risk for mortality and irreversible morbidity due to micro- and macro-vascular disease despite receiving optimal standard of care therapies[12]
- Mesoblast expects to receive further guidance from FDA on a potential approval pathway following detailed review of the outcomes identified in high-risk HFrEF patients with diabetes and/or myocardial ischemia

Chronic Low Back Pain

- Presented 36-month follow-up results from the 404-patient Phase 3 trial of rexlemestrocel-L (MPC-06-ID) in patients with chronic low back pain (CLBP) associated with degenerative disc disease (DDD) which showed durable reduction in back pain lasting at least three years from a single intra-discal injection of rexlemestrocel-L+hyaluronic acid (HA) carrier
- Mesoblast received feedback in December 2021 from FDA on the Phase 3 program for CLBP and plans to conduct an additional US Phase 3 trial which may support submissions for potential approval in both the US and EU. Following review of the completed Phase 3 trial data, FDA agreed with Mesoblast's proposal for pain reduction at 12 months as the primary endpoint of the next trial, with functional improvement and reduction in opioid use as secondary endpoints

FINANCIAL RESULTS FOR THE PERIOD ENDED MARCH 31, 2022 (THIRD QUARTER FY2022)

- **Total Revenue** increased by 5% from the comparative quarter last year to US$2.0 million for the third quarter FY2022, including US$1.9 million from TEMCELL® HS Inj.[2] royalties on sales for SR-aGvHD in Japan
- **Cash on hand** at the end of the quarter was US$76.8 million, with up to an additional US$40 million available to be drawn down from existing financing facilities subject to certain milestones
- **Net cash usage** for operating activities in the quarter was reduced by 40%, or US$10.3 million, to US$15.5 million compared with US$25.8 million in the comparative quarter last year
- **Research & Development expenses** reduced by US$4.2 million (34%), down to US$8.2 million for the third quarter FY2022 from US$12.4 million for the third quarter 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 expense** were US$5.6 million for the third quarter FY2022, compared to US$7.3 million for the third quarter FY2021. During the quarter we continued to build our pre-launch inventory levels of remestemcel-L to support the commercial launch for SR-aGVHD

  We expect to recognize the US$29.7 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 decreased from US$8.1 million for the third quarter FY2021 to US$7.6 million for the third quarter FY2022; this decrease was predominantly due to one-off expenditure in legal and professional fees associated with regulatory and financing activities in the third quarter FY2021
- **Remeasurement of Contingent Consideration** reduced to a gain of US$0.7 million for the third quarter FY2022 whereas a gain of US$1.5 million was recognized in the third quarter FY2021 as a result of revaluing future third party payments
- **Fair value movement of warrants** we recognized a gain of US$0.9 million in the third quarter FY2022, compared to Nil for the third quarter FY2021
- **Finance Costs** for borrowing arrangements with Oaktree and NovaQuest were US$3.9 million for the third quarter FY2022, compared to US$3.2 million for the third quarter FY2021

Loss after tax for the third quarter FY2022 was US$21.3 million compared to US$26.5 million for the third quarter FY2021. The net loss attributable to ordinary shareholders was 3.28 US cents per share for the third quarter FY2022, compared with 4.39 US cents per share for the third quarter FY2021.

Conference Call

There will be a webcast today, beginning at 8.30am AEST (Wednesday, June 1); 6.30pm EDT (Tuesday, May 31). It can be accessed via: https://webcast.openbriefing.com/8756/

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

Reference / Footnotes

1. Accounting policy change resulted in a US$1.4 million benefit in the Mar 22 quarter.
2. TEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.
3. Kasikis S., et al. Mesenchymal stromal cell therapy induces high responses and survival in children with steroid refractory GVHD and poor risk. *Bone Marrow Transplantation* 2021; https://doi.org/10.1038/s41409-021-01442-3
4. 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
5. All p-values are descriptive and not adjusted for multiplicity
6. Hazard Ratios calculated using Cox regression proportional hazards model without adjustment; p-value from log rank test
7. Whittaker Brown S., et al. Mesenchymal Stromal Cell Therapy for Acute Respiratory Distress Syndrome due to COVID-19. *Cytotherapy*, April 2022, https://doi.org/10.1016/j.jcyt.2022.03.006
8. Lightner A., et al. A Phase IB/IIA study of remestemcel-L, an allogeneic bone marrow derived mesenchymal stem cell product, for the treatment of medically refractory Crohn's colitis: A preliminary analysis. *Journal of Crohn's and Colitis*, Volume 16, Issue Supplement_1, January 2022, Pages i412–i413, https://doi.org/10.1093/ecco-jcc/jjab232.555
9. Lightner A., et al. A Phase IB/IIA study of remestemcel-L, an allogeneic bone marrow derived mesenchymal stem cell product, for the treatment of medically refractory ulcerative colitis: An interim analysis. *Journal of Crohn's and Colitis*, Volume 16, Issue Supplement_1, January 2022, Pages i398–i399, https://doi.org/10.1093/ecco-jcc/jjab232.534

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10. Neill US. Conversations with Giants in Medicine – A conversation with Eugene Braunwald. *J Clin Invest.* 2013;123(1):1-2. https://doi.org/10.1172/JCI67778
11. Braunwald E. Cardiac cell therapy: a call for action. *European Heart Journal* (2022) 00, 1–2, https://doi.org/10.1093/eurheartj/ehac188
12. Dunlay SM., et al. *Circulation*. 2019;140:e294–e324

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 March 31, 2022	Three Months Ended March 31, 2021	Nine Months Ended March 31, 2022	Nine Months Ended March 31, 2021
Revenue	2,011	1,915	7,988	5,461
Research & development	(8,250)	(12,441)	(27,776)	(45,957)
Manufacturing commercialization	(5,590)	(7,332)	(19,717)	(25,706)
Management and administration	(7,567)	(8,087)	(21,259)	(23,633)
Fair value remeasurement of contingent consideration	672	1,534	601	18,103
Fair value remeasurement of warrant liability	896	—	3,048	—
Other operating income and expenses	392	1,025	(13)	1,420
Finance costs	(3,911)	(3,227)	(12,951)	(7,193)
Loss before income tax	**(21,347)**	**(26,613)**	**(70,079)**	**(77,505)**
Income tax benefit/(expense)	45	98	187	754
Loss attributable to the owners of Mesoblast Limited	**(21,302)**	**(26,515)**	**(69,892)**	**(76,751)**
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:	**Cents**	**Cents**	**Cents**	**Cents**
Basic - losses per share	(3.28)	(4.39)	(10.78)	(12.99)
Diluted - losses per share	(3.28)	(4.39)	(10.78)	(12.99)

Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	Three Months Ended March 31, 2022	Three Months Ended March 31, 2021	Nine Months Ended March 31, 2022	Nine Months Ended March 31, 2021
Loss for the period	**(21,302)**	**(26,515)**	**(69,892)**	**(76,751)**
Other comprehensive (loss)/income				
Items that may be reclassified to profit and loss				
Exchange differences on translation of foreign operations	(333)	(2,712)	(516)	(1,400)
Items that will not be reclassified to profit and loss				
Financial assets at fair value through other comprehensive income	(314)	81	(48)	109
Other comprehensive (loss)/income for the period, net of tax	**(647)**	**(2,631)**	**(564)**	**(1,291)**
Total comprehensive losses attributable to the owners of Mesoblast Limited	**(21,949)**	**(29,146)**	**(70,456)**	**(78,042)**

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Consolidated Balance Sheet

(in U.S. dollars, in thousands)	As of March 31, 2022	As of June 30, 2021
Assets		
Current Assets		
Cash & cash equivalents	76,760	136,881
Trade & other receivables	5,634	4,842
Prepayments	5,739	6,504
Total Current Assets	**88,133**	**148,227**
Non-Current Assets		
Property, plant and equipment	2,243	3,021
Right-of-use assets	8,363	9,119
Financial assets at fair value through other comprehensive income	2,032	2,080
Other non-current assets	1,973	1,724
Intangible assets	578,945	580,546
Total Non-Current Assets	**593,556**	**596,490**
Total Assets	**681,689**	**744,717**
Liabilities		
Current Liabilities		
Trade and other payables	18,983	19,598
Provisions	20,216	18,710
Borrowings	5,523	53,200
Lease liabilities	2,431	2,765
Warrant liability	5,033	—
Total Current Liabilities	**52,186**	**94,273**
Non-Current Liabilities		
Provisions	13,179	17,017
Borrowings	88,646	41,045
Lease liabilities	8,051	8,485
Deferred consideration	2,500	2,500
Total Non-Current Liabilities	**112,376**	**69,047**
Total Liabilities	**164,562**	**163,320**
Net Assets	**517,127**	**581,397**
Equity		
Issued Capital	1,165,309	1,163,153
Reserves	69,279	65,813
(Accumulated losses)/retained earnings	(717,461)	(647,569)
Total Equity	**517,127**	**581,397**

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Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	Nine Months Ended March 31, 2022	2021
Cash flows from operating activities		
Commercialization revenue received	7,969	4,162
Government grants and tax incentives received	24	56
Payments to suppliers and employees (inclusive of goods and services tax)	(59,855)	(86,029)
Interest received	5	17
Income taxes paid	(31)	(35)
Net cash (outflows) in operating activities	**(51,888)**	**(81,829)**
Cash flows from investing activities		
Investment in fixed assets	(110)	(1,424)
Payments for intellectual property	(75)	—
Net cash (outflows) in investing activities	**(185)**	**(1,424)**
Cash flows from financing activities		
Proceeds from borrowings	51,919	—
Repayment of borrowings	(55,458)	—
Payment of transaction costs from borrowings	(5,513)	(13)
Interest and other costs of finance paid	(4,317)	(4,122)
Proceeds from issue of shares	209	105,584
Proceeds from issue of warrants	8,081	12,969
Payments for share issue costs	(216)	(1,547)
Payments for lease liabilities	(2,359)	(2,100)
Net cash inflows/(outflows) by financing activities	**(7,654)**	**110,771**
Net increase/(decrease) in cash and cash equivalents	(59,727)	27,518
Cash and cash equivalents at beginning of period	136,881	129,328
FX gain/(losses) on the translation of foreign bank accounts	(394)	1,417
Cash and cash equivalents at end of period	**76,760**	**158,263**