

## MESOBLAST REPORTS 2019 FULL YEAR RESULTS

### ***Strong Operational Progress and Continued Growth in Revenues from Royalties***

**Melbourne, Australia; August 30, 2019; and New York, USA, August 29, 2019:** Mesoblast Limited (ASX: MSB; Nasdaq: MESO) today reported strong operational progress and financial highlights for the fourth quarter and full-year ended June 30, 2019 (FY2019).

Mesoblast Chief Executive Dr Silviu Itescu stated: "The Company is well positioned to deliver substantial shareholder value in the coming year. Our expenditure over the 2019 financial year has been specifically targeted at advancing our lead cell therapy candidates towards commercialization. We are excited about the planned readouts of our major Phase 3 trials in chronic heart failure and low back pain, and are also especially pleased with the growth in revenues on graft versus host disease (GVHD) product sales in Japan as we progress the United States Food and Drug Administration (FDA) filing process to seek approval of our GVHD product in the United States market."

### **Continued Growth in Revenues from Japan Royalties**

The Company is pleased to report continued growth in revenues from royalties on sales of TEMCELL® HS. Inj.<sup>1</sup> in Japan for steroid-refractory acute graft versus host disease (aGVHD) by Mesoblast licensee JCR Pharmaceuticals Co. Ltd. Revenues from royalties on TEMCELL sales increased by 37% to US\$5.0 million for the fiscal year. In the most recent quarter, revenues from royalties increased by 54% to US\$1.7 million. Total revenue was stable at US\$16.7 million in FY2019 compared with US\$17.3 million in FY2018.

### **Capital Strategy**

Cash on hand was US\$50.4 million (A\$71.9 million) at June 30, 2019.

In addition, Mesoblast may have access to additional sources of capital, as follows:

- Under its agreements with Hercules Capital, Inc. and NovaQuest Capital Management, LLC., the Company has up to US\$35.0 million available subject to achievement of certain milestones.
- Mesoblast has entered into a Subscription Commitment Letter with its largest institutional shareholder, M&G Investment Management, for US\$15.0 million in Mesoblast ordinary shares, exercisable by the Company on or before 31 December 2019, subject to customary diligence and with pricing to be agreed at the time Mesoblast gives notice
- The Company will receive further milestone and royalty payments from its existing strategic partners JCR, Takeda Pharmaceuticals Company Ltd. and Tasly Pharmaceutical Group.
- Mesoblast remains in advanced negotiations with a number of additional potential commercial partners regarding transactions and access to non-dilutive capital<sup>2</sup>.
- Mesoblast has extended its fully discretionary equity facility with Kentgrove Capital of up to A\$120.0 million (approximately US\$82.0 million) for the next 24 months.

### **Graft Versus Host Disease**

There are more than 30,000 allogeneic bone marrow transplants performed annually worldwide<sup>3</sup>, primarily in patients being treated for blood cancers. The most severe forms of the disease, Grades C/D or III/IV, are frequently refractory to steroid therapy and associated with mortality rates as high as 90%<sup>4,5</sup>.

There are no approved therapies for aGVHD in the United States for children under 12.

**Mesoblast Limited**  
ABN 68 109 431 870  
[www.mesoblast.com](http://www.mesoblast.com)

**Corporate Headquarters**  
Level 38  
55 Collins Street  
Melbourne 3000  
Victoria Australia

T +61 3 9639 6036  
F +61 3 9639 6030

**United States Operations**  
505 Fifth Avenue  
Third Floor  
New York, NY 10017  
USA

T +1 212 880 2060  
F +1 212 880 2061

**Asia**  
20 Biopolis Way  
#05-01 Centros  
Biopreneur 3  
SINGAPORE 138668

T +65 6570 0635  
F +65 6570 0176

In Mesoblast's Phase 3 trial of 55 children with aGVHD - 89% of whom had Grade C/D disease - treatment with remestemcel-L resulted in a six-month survival of 69%. In addition, achievement of an Overall Response at Day 28, which occurred in 69% of patients, predicted highest survival at Day 100 and Day 180, which was 85% and 79%, respectively. The trial successfully met its primary endpoint of increased Day 28 Overall Response compared with a protocol-defined historical control rate of 45% (p=0.0003). These data are consistent with prior results from an Expanded Access Program in 241 children where remestemcel-L was used as salvage therapy after failure of steroids and other agents.

Remestemcel-L is administered to patients in a series of intravenous infusions. Remestemcel-L has demonstrated immunomodulatory properties to counteract the inflammatory processes that are implicated in aGVHD by down-regulating the production of pro-inflammatory cytokines, increasing production of anti-inflammatory cytokines, and enabling recruitment of naturally occurring anti-inflammatory cells to involved tissues.

### **Potential United States Market for Remestemcel-L**

The product adoption and reimbursement seen in the Japan GVHD market for TEMCELL informs Mesoblast's United States commercial strategy for remestemcel-L in aGVHD. The Company believes that the United States addressable market opportunity for remestemcel-L in aGVHD in children and adults is approximately eight times larger than Japan given differences in population size, incidence of aGVHD, and relative pharmacoeconomics<sup>6,7,8,9</sup>.

Mesoblast is preparing for potential product launch in the United States of remestemcel-L for aGVHD in children. Health economics and outcomes research data presented by Mesoblast at the 24<sup>th</sup> European Hematology Association Congress indicated that pediatric aGVHD may result in significant deterioration in quality of life and additional direct healthcare costs of an average of up to US\$500,000 per patient. This represents a significant commercial opportunity for Mesoblast's first potential product launch in the United States.

### **Filing for FDA approval**

The rolling Biologics License Application (BLA) submission to the FDA is underway and we expect to complete the filing in CY2019. Remestemcel-L has received Fast Track designation for aGVHD and under this designation Mesoblast can request a priority review once its BLA filing is accepted by the FDA.

### **Commercial Activities for Potential Launch in United States**

In line with our expected timelines for potential United States launch of remestemcel-L, Mesoblast has increased expenditure on commercial manufacturing activities and commercial team ramp up in parallel with its FDA filing activities.

### **Life Cycle Strategy for Remestemcel-L**

Mesoblast intends to expand its clinical program into the adult aGVHD segment. In addition, an investigator-initiated study evaluating remestemcel-L in children is planned in the United States for chronic GVHD.

Mesoblast has the right to use all safety and efficacy data generated by JCR in Japan for TEMCELL to support its life cycle strategy for remestemcel-L in the United States and other major healthcare markets. JCR has filed to extend marketing approval for TEMCELL in wound healing in patients with Epidermolysis Bullosa, and is evaluating the use of TEMCELL for the treatment of newborns who lack sufficient blood supply and oxygen to the brain, a condition termed hypoxic ischemic encephalopathy.

### **Chronic Heart Failure**

#### **Advanced Heart Failure**

In the United States alone, of more than 6.5 million patients with chronic heart failure, there are more than 1.3 million patients with advanced stage of the disease who have high rates of morbidity and mortality despite maximal existing therapies<sup>10</sup>. This well-defined major treatment gap in these needy patients is a potential multi-billion dollar market opportunity for Mesoblast. The objective of treatment with Mesoblast's allogeneic cell therapy Revascor is to prevent or delay further progression of heart failure or death.

**Mesoblast Limited**  
ABN 68 109 431 870  
[www.mesoblast.com](http://www.mesoblast.com)

**Corporate Headquarters**  
Level 38  
55 Collins Street  
Melbourne 3000  
Victoria Australia

T +61 3 9639 6036  
F +61 3 9639 6030

**United States Operations**  
505 Fifth Avenue  
Third Floor  
New York, NY 10017  
USA

T +1 212 880 2060  
F +1 212 880 2061

**Asia**  
20 Biopolis Way  
#05-01 Centros  
Biopreneur 3  
SINGAPORE 138668

T +65 6570 0635  
F +65 6570 0176

The American Heart Association journal *Circulation Research*<sup>11</sup> recently published a Special Article highlighting the important potential clinical benefits of Revascor as an immunotherapy in patients with advanced chronic heart failure, stating that there is a biologic rationale for the use of Revascor in targeting cardiac inflammation in order to improve heart failure outcomes.

In a post-hoc analysis of an earlier Phase 2 trial published in *Circulation Research*<sup>12</sup>, it was found that control patients with very enlarged hearts (left ventricular end systolic volume >100ml) deteriorated most rapidly, while similar patients receiving Revascor were protected against disease progression. These Phase 2 findings identified the patient population most likely to benefit from Revascor and guided the clinical trial design for the subsequent Phase 3 study.

In Mesoblast's randomized, placebo-controlled Phase 3 trial, enrollment of 566 patients has been completed across 55 centers in North America. The trial's primary endpoint is reduction in heart failure-related hospital admissions, and the key secondary endpoint is reduction in terminal cardiac events.

Revascor was successful in April 2017 in a pre-specified futility analysis of the Phase 3 trial's primary efficacy endpoint in the first 270 patients enrolled in the trial.

Currently, approximately 90% of events in this Phase 3 trial have been accrued and validated. Mesoblast expects the trial to accrue all the requisite primary events by the end of CY2019 with readouts planned during the first half of CY2020.

### ***End-stage Heart Failure***

In the United States, over 60,000 patients annually suffer from end-stage heart failure<sup>13</sup>, and despite optimal medical therapy these patients have a one-year mortality exceeding 50%<sup>14</sup>. The only options to increase survival in these patients are the use of heart transplants or left ventricular assist devices (LVADs). The use of LVADs is gaining momentum, with approximately 5,500 LVADs implanted annually in the United States<sup>15,16,17</sup>.

In patients implanted with an LVAD, endothelial dysfunction and reduced blood flow caused by severe inflammation result in a compensatory abnormal network of blood vessels in the gastrointestinal tract, with potentially life-threatening bleeding in up to 40% of patients<sup>17,18</sup>. Mesoblast believes that Revascor may address the severe inflammation that leads to these major bleeding complications.

In November 2018, United States National Institutes of Health investigators presented results of a 159-patient randomized placebo-controlled Phase 2 clinical trial at the American Heart Association Scientific Sessions. In the Phase 2 trial, a single intra-myocardial injection of Revascor at the time of LVAD implantation resulted in a 76% reduction in major GI bleeding events and 65% reduction in related hospitalizations in the overall patient population studied. In a post-hoc analysis in patients with an ischemic cause of their heart failure, these effects of Revascor were even greater, as well as an observed significant increase in the ability to wean off device support, suggesting strengthening of the native heart muscle.

The FDA recently provided guidance on the pathway for marketing authorization of Revascor in this indication.

Key outcomes were:

- FDA reiterated that a reduction in major gastrointestinal bleeding events and/or epistaxis, collectively termed major mucosal bleeding events, is an important clinical outcome in patients implanted with an LVAD.
- FDA confirmed that data from the recently completed 159-patient placebo-controlled trial showing that Revascor reduced major mucosal bleeding events can support product marketing authorization through a BLA, with confirmatory clinical trial data.
- FDA agreed on a confirmatory Phase 3 trial of Revascor in LVAD patients, with a primary endpoint of reduction in major mucosal bleeding events, and key secondary endpoints demonstrating improvement in various parameters of cardiovascular function.

**Mesoblast Limited**  
ABN 68 109 431 870  
[www.mesoblast.com](http://www.mesoblast.com)

**Corporate Headquarters**  
Level 38  
55 Collins Street  
Melbourne 3000  
Victoria Australia

T +61 3 9639 6036  
F +61 3 9639 6030

**United States Operations**  
505 Fifth Avenue  
Third Floor  
New York, NY 10017  
USA

T +1 212 880 2060  
F +1 212 880 2061

**Asia**  
20 Biopolis Way  
#05-01 Centros  
Biopreneur 3  
SINGAPORE 138668

T +65 6570 0635  
F +65 6570 0176

Revascor is being developed for these patients under existing FDA Regenerative Medicine Advanced Therapy (RMAT) and Orphan Drug designations.

The confirmatory trial is planned to be conducted with the International Center for Health Outcomes Innovation Research (InCHOIR) at the Icahn School of Medicine at Mount Sinai in New York, in line with an existing Memorandum of Understanding. It is expected to be initiated before the end of CY2019.

## Chronic Low Back Pain

Approximately 3.2 million patients in the United States alone suffer from chronic low back pain due to moderate degenerative disc disease<sup>19</sup>. After failure of conservative measures (medication, injections, epidural steroid, physical therapy etc.), there is a need for treatments that both reduce pain and improve function over a sustained period of time.

In post-hoc results from an earlier randomized, placebo-controlled Phase 2 trial in 100 patients, data showed that a single intra-discal injection of MPC-06-ID resulted in over a three-fold increase relative to saline controls in successfully achieving a composite endpoint consisting of 50% improvement in low back pain and 15 point improvement in function at both 12 and 24 months with no treatment or surgical interventions at the treated level through 24 months. In this study, 37% of patients treated with MPC-06-ID compared with 10% in the control group achieved this composite endpoint over two years.

This composite endpoint is the primary endpoint in the Phase 3 clinical trial for chronic low back pain which completed enrollment in March 2018 with 404 patients randomized 2:1 to receive either MPC-06-ID or saline control. Follow-up of patients in the Phase 3 trial of MPC-06-ID is continuing to a 24-month assessment of safety and efficacy. All patients will have completed 24 months of follow-up by the first quarter of CY 2020, with readouts planned mid-CY2020.

## Board and Senior Executive Appointments in Line with Commercialization Plans

As Mesoblast transitions to a commercial stage company, there have been two key additions to its Board of Directors and the appointment of a new Chief Medical Officer.

Joseph R. Swedish has been appointed as Mesoblast's non-executive Chairman and Shawn Tomasello as a non-executive Director.

Mr Swedish most recently served as Chairman, President and CEO of Anthem Inc., a Fortune 29 company and the leading health benefits provider in the U.S. He also serves on the boards of IBM Corporation, CDW Corporation, Proteus Digital Health, and Centrexion Therapeutics. Ms Tomasello was Chief Commercial Officer at leading immuno-oncology cell therapy company Kite Pharma, where she played a pivotal role in its acquisition in 2017 by Gilead Sciences. Prior to this she served as Chief Commercial Officer at Pharmacyclics, Inc., which was acquired in 2015 by AbbVie, Inc. Ms Tomasello previously was President of the Americas, Hematology and Oncology at Celgene Corporation. Ms Tomasello currently serves on the Board of Directors of Centrexion Therapeutics, Oxford BioTherapeutics and Diplomat Rx.

Mesoblast's new Chief Medical Officer, Dr Fred Grossman, brings a wealth of commercial experience gained from numerous leadership roles at global pharmaceutical companies. He has over 20 years of industry experience, and has held key leadership positions at major global pharmaceutical companies, including Eli Lilly, Johnson & Johnson (J&J), Bristol Myers Squibb (BMS), Sunovion, and Glenmark. During his career, he has managed global clinical development, pharmacovigilance, medical affairs and clinical operations for innovative product development, as well as FDA approvals and post-market support for numerous blockbuster, specialty and generic products. Dr Grossman has led and built teams in the United States, Europe and Japan with responsibility for global medical affairs, global clinical development, health economics and outcomes research and global drug safety.

**Mesoblast Limited**  
ABN 68 109 431 870  
[www.mesoblast.com](http://www.mesoblast.com)

**Corporate Headquarters**  
Level 38  
55 Collins Street  
Melbourne 3000  
Victoria Australia

T +61 3 9639 6036  
F +61 3 9639 6030

**United States Operations**  
505 Fifth Avenue  
Third Floor  
New York, NY 10017  
USA

T +1 212 880 2060  
F +1 212 880 2061

**Asia**  
20 Biopolis Way  
#05-01 Centros  
Biopreneur 3  
SINGAPORE 138668

T +65 6570 0635  
F +65 6570 0176

## Manufacturing

Mesoblast is developing patent-protected product candidates for a range of inflammatory and immune-mediated conditions using a scalable, allogeneic (off-the-shelf) cellular medicine platform technology.

The Company's manufacturing activities meet stringent criteria set by international regulatory agencies, including the FDA and EMA. Mesoblast's product candidates contain well-characterized cell populations, and our robust quality assurance processes ensures final product with batch-to-batch consistency and reproducibility as measured by well-established product release assays.

Mesoblast has proprietary technology that facilitates the increase in yields necessary for the long-term commercial supply of our product candidates, and next generation manufacturing processes using three-dimensional bioreactors to reduce labour and drive down cost of goods.

## Intellectual Property

Mesoblast continues to protect and expand its extensive estate of patent rights and intellectual property with approximately 995 patents and patent applications across 68 patent families. These patents relate principally to compositions of matter, methods of manufacture, and uses/indications of mesenchymal lineage cells.

More specifically, the Company's patent estate includes issued patent and patent applications in major markets, including, but not limited to, the United States, Europe, Japan and China. The patents that Mesoblast has obtained, and continue to apply for, cover mesenchymal lineage cell technologies and product candidates derived from these technologies, irrespective of the tissue source, including bone marrow, adipose, placenta, umbilical cord and dental pulp.

Among the indication-specific issued or pending patents covering product candidates derived from the Company's mesenchymal lineage cells are those which are directed to its lead product candidates for aGVHD, advanced heart failure, chronic low back pain, as well as chronic auto-immune conditions such as rheumatoid arthritis. Mesoblast also has issued and pending patents covering other pipeline indications, including diabetic kidney disease, inflammatory bowel disease (e.g. Crohn's disease), neurologic diseases, eye diseases and additional orthopedic diseases. In addition, the Company has in-licensed patents covering complementary technologies, such as other types of mesenchymal lineage cells, cell surface modification technologies, pay-loading technology and protein and gene technologies, as part of its strategy to expand its targeted disease applications and manage the life cycle of its current lead programs.

Licensing agreements with JCR, Tasly and Takeda highlight the strength of Mesoblast's extensive intellectual property portfolio covering mesenchymal lineage cells. Mesoblast will continue to use its patents to prosecute its commercial rights as they relate to its core strategic product portfolio. When consistent with the Company's strategic objectives, it may consider providing third parties with commercial access to its patent portfolio.

## Detailed Financial Results for the Year Ended June 30, 2019

- **Revenues** were US\$16.7 million for FY2019, compared to US\$17.3 million for FY2018. Revenues comprised:
  - US\$10.0 million revenue recognized in FY2019 in relation to establishing a partnership with Tasly in China, compared with US\$11.8 million revenue recognized in FY2018 in relation to the patent license agreement with Takeda Pharmaceutical Company Limited.
  - US\$6.0 million royalties and milestone revenues recognized in FY2019 from sales of TEMCELL by JCR compared with US\$5.1 million in FY2018, an increase of US\$0.9 million. Royalty revenue on sales of TEMCELL increased by 37% for FY2019 compared to FY2018.
- **Research and Development** expenses were US\$59.8 million for FY2019, compared to US\$65.9 million for FY2018. This US\$6.1 million decrease was due to a reduction in third party costs in our Phase 3 clinical trials.

**Mesoblast Limited**  
ABN 68 109 431 870  
[www.mesoblast.com](http://www.mesoblast.com)

**Corporate Headquarters**  
Level 38  
55 Collins Street  
Melbourne 3000  
Victoria Australia

T +61 3 9639 6036  
F +61 3 9639 6030

**United States Operations**  
505 Fifth Avenue  
Third Floor  
New York, NY 10017  
USA

T +1 212 880 2060  
F +1 212 880 2061

**Asia**  
20 Biopolis Way  
#05-01 Centros  
Biopreneur 3  
SINGAPORE 138668

T +65 6570 0635  
F +65 6570 0176

- **Manufacturing** expenses were US\$15.4 million for FY2019, compared to US\$5.5 million for FY2018, an increase of US\$9.9 million for commercial manufacturing investment primarily to support the potential launch of remestemcel-L.
- **Management and Administration** expenses were US\$21.6 million for FY2019, compared to US\$21.9 million for FY2018, a decrease of US\$0.3 million.
- **Finance Costs** of US\$11.3 million in interest expenses were recognized for FY2019, of which US\$4.6 million was paid in cash, compared with US\$1.8 million for FY2018, in relation to financial agreements with Hercules and NovaQuest.

Additional components of loss after income tax also include movements in other items which did not impact current cash reserves, such as income tax benefits, fair value remeasurement of contingent consideration, remeasurement of borrowing arrangements and foreign exchange movements within other operating income and expenses.

In FY2019, the net loss attributable to ordinary shareholders was 18.16 cents per share for FY2019, compared with a loss per share of 7.58 cents for FY2018. There was an after tax loss of US\$89.8 million in FY2019, compared to US\$35.3 million for FY2018. The increase in the loss is primarily due to commercial manufacturing investment of US\$9.9 million to support potential launch of remestemcel-L, and an increase of US\$9.5 million in finance costs. Additionally, in the FY2018 comparative period, the Company recognized a one-off non-cash income tax benefit of US\$23.0 million primarily due to a revaluation of tax liabilities given changes in tax rates and a non-cash US\$10.5 million gain on remeasurement of contingent consideration for reduction of future payments to third parties.

## Conference Call Details

There will be a webcast today on the financial results beginning at 8am AEST (Friday August 30, 2019); 6pm EDT (Thursday August 29, 2019). It can be accessed via <https://s1.c-conf.com/diamondpass/mesoblast-10001891-invite.html>

To access the call only, dial 1800 558 698 (toll-free Australia), 1 855 881 1339 (toll-free U.S.), or +61 2 9007 3187 (outside of the U.S. and Australia). The conference identification code is 10001891.

The archived webcast will be available on the Investor page of the Company's website: [www.mesoblast.com](http://www.mesoblast.com)

## About Mesoblast

Mesoblast Limited (ASX: MSB; Nasdaq: MESO) is a world leader in developing allogeneic (off-the-shelf) cellular medicines. The Company has leveraged its proprietary technology platform to establish a broad portfolio of late-stage product candidates with three product candidates in Phase 3 trials – acute graft versus host disease, chronic heart failure and chronic low back pain due to degenerative disc disease. Through a proprietary process, Mesoblast selects rare mesenchymal lineage precursor and stem cells from the bone marrow of healthy adults and creates master cell banks, which can be industrially expanded to produce thousands of doses from each donor that meet stringent release criteria, have lot to lot consistency, and can be used off-the-shelf without the need for tissue matching. Mesoblast has facilities in Melbourne, New York, Singapore and Texas and is listed on the Australian Securities Exchange (MSB) and on the Nasdaq (MESO). [www.mesoblast.com](http://www.mesoblast.com)

## References

1. TEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.
2. Mesoblast does not make any representation or give any assurance that such a partnering transaction will be concluded.
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. Westin, J., Saliba, RM., Lima, M. (2011) Steroid-refractory acute GVHD: predictors and outcomes. *Advances in Hematology*.
5. 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*.
6. Japanese Data Center for Hematopoietic Cell Transplantation (JDCHCT) - [Activities and Outcomes of Hematopoietic Cell Transplantation in Japan 2018](#).
7. Westin, J., Saliba, RM., Lima, M. (2011) Steroid-refractory acute GVHD: predictors and outcomes. *Advances in Hematology*.

**Mesoblast Limited**  
ABN 68 109 431 870  
[www.mesoblast.com](http://www.mesoblast.com)

**Corporate Headquarters**  
Level 38  
55 Collins Street  
Melbourne 3000  
Victoria Australia

T +61 3 9639 6036  
F +61 3 9639 6030

**United States Operations**  
505 Fifth Avenue  
Third Floor  
New York, NY 10017  
USA

T +1 212 880 2060  
F +1 212 880 2061

**Asia**  
20 Biopolis Way  
#05-01 Centros  
Biopreneur 3  
SINGAPORE 138668

T +65 6570 0635  
F +65 6570 0176

8. CIBMTR Current Uses and Outcomes of Hematopoietic Cell Transplantation 2017 Summary. Passweg JR, Baldomero, H (2016) Hematopoietic stem cell transplantation in Europe 2014: more than 40,000 transplants annually.
9. Risk factors for acute GVHD and survival after hematopoietic cell transplantation - Blood 2012 119:296-307; Madan Jagasia et al.
10. AHA's 2017 Heart Disease and Stroke Statistics.
11. Phase 3 DREAM-HF Trial of Mesenchymal Precursor Cells in Chronic Heart Failure; A Review of Biological Plausibility and Implementation of Flexible Clinical Trial Design; *Circulation Research*, July 2019
12. A Phase II Dose-Escalation Study of Allogeneic Mesenchymal Precursor Cells in Patients with Ischemic or Non-ischemic Heart Failure; *Circulation Research*, July 2015.
13. Gustafsson F, Rogers JG. Left ventricular assist device therapy in advanced heart failure: patient selection and outcomes. *European Journal of Heart Failure* 2017; 19:595-602.
14. United Network for Organ Sharing.
15. Agency for Healthcare Research and Quality–Healthcare Cost and Utilization Project–Claims Analysis ICD- 37.
16. Data on file.
17. Chatterjee A, Feldmann C, Hanke JS (2018); The momentum of HeartMate 3: a novel active magnetically levitated centrifugal left ventricular assist device (LVAD). *J Thorac Dis* 10 (Suppl 15): S1790-S1793.
18. Mehra, MR Salerno C, Cleveland JC (2018) Health care resources use and cost implications in the MOMENTUM 3 long-term outcome study: a randomized controlled trial of a magnetically levitated cardiac pump in advanced heart failure.
19. Decision Resources: Chronic Pain December 2015.

### Forward-Looking Statements

This announcement 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, and ability to access, 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.

*For further information, please contact:*

Julie Meldrum  
Corporate Communications  
Mesoblast  
T: +61 3 9639 6036  
E: [julie.meldrum@mesoblast.com](mailto:julie.meldrum@mesoblast.com)

Schond Greenway  
Investor Relations  
Mesoblast  
T: +1 212 880 2060  
E: [schond.greenway@mesoblast.com](mailto:schond.greenway@mesoblast.com)

**Mesoblast Limited**  
ABN 68 109 431 870  
[www.mesoblast.com](http://www.mesoblast.com)

**Corporate Headquarters**  
Level 38  
55 Collins Street  
Melbourne 3000  
Victoria Australia

T +61 3 9639 6036  
F +61 3 9639 6030

**United States Operations**  
505 Fifth Avenue  
Third Floor  
New York, NY 10017  
USA

T +1 212 880 2060  
F +1 212 880 2061

**Asia**  
20 Biopolis Way  
#05-01 Centros  
Biopreneur 3  
SINGAPORE 138668

T +65 6570 0635  
F +65 6570 0176

## Consolidated Income Statement

(in U.S. dollars, in thousands, except per share amount)	(unaudited) Three Months Ended June 30,		(audited) Year Ended June 30,	
	2019	2018	2019	2018
Revenue	1,967	1,700	16,722	17,341
Research & development	(11,435)	(17,539)	(59,815)	(65,927)
Manufacturing commercialization	(2,448)	(2,121)	(15,358)	(5,508)
Management and administration	(5,627)	(5,219)	(21,625)	(21,907)
Fair value remeasurement of contingent consideration	(2,912)	2,661	(6,264)	10,541
Other operating income and expenses	(26)	69	(1,086)	1,312
Finance costs	(3,422)	(1,406)	(11,328)	(1,829)
<b>Loss before income tax</b>	<b>(23,903)</b>	<b>(21,855)</b>	<b>(98,754)</b>	<b>(65,977)</b>
Income tax benefit	3,177	1,021	8,955	30,687
<b>Loss attributable to the owners of Mesoblast Limited</b>	<b>(20,726)</b>	<b>(20,834)</b>	<b>(89,799)</b>	<b>(35,290)</b>
<b>Losses per share from continuing operations attributable to the ordinary equity holders of the Group:</b>	<b>Cents</b>	<b>Cents</b>	<b>Cents</b>	<b>Cents</b>
Basic - losses per share	(4.15)	(4.39)	(18.16)	(7.58)
Diluted - losses per share	(4.15)	(4.39)	(18.16)	(7.58)

## Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	(unaudited) Three Months Ended June 30,		(audited) Year Ended June 30,	
	2019	2018	2019	2018
<b>Loss for the period</b>	<b>(20,726)</b>	<b>(20,834)</b>	<b>(89,799)</b>	<b>(35,290)</b>
<b>Other comprehensive (loss)/income</b>				
<i>Items that may be reclassified to profit and loss</i>				
Changes in the fair value of financial assets	(284)	183	(4)	324
Exchange differences on translation of foreign operations	(33)	(334)	(137)	(903)
Other comprehensive (loss)/income for the period, net of tax	<b>(317)</b>	<b>(151)</b>	<b>(141)</b>	<b>(579)</b>
<b>Total comprehensive losses attributable to the owners of Mesoblast Limited</b>	<b>(21,043)</b>	<b>(20,985)</b>	<b>(89,940)</b>	<b>(35,869)</b>

**Mesoblast Limited**  
ABN 68 109 431 870  
[www.mesoblast.com](http://www.mesoblast.com)

**Corporate Headquarters**  
Level 38  
55 Collins Street  
Melbourne 3000  
Victoria Australia

T +61 3 9639 6036  
F +61 3 9639 6030

**United States Operations**  
505 Fifth Avenue  
Third Floor  
New York, NY 10017  
USA

T +1 212 880 2060  
F +1 212 880 2061

**Asia**  
20 Biopolis Way  
#05-01 Centros  
Biopreneur 3  
SINGAPORE 138668

T +65 6570 0635  
F +65 6570 0176

## Consolidated Balance Sheet

(in U.S. dollars, in thousands)	(audited) As of June 30,	
	2019	2018
<b>Assets</b>		
<b>Current Assets</b>		
Cash & cash equivalents	50,426	37,763
Trade & other receivables	4,060	50,366
Prepayments	8,036	12,942
<b>Total Current Assets</b>	<b>62,522</b>	<b>101,071</b>
<b>Non-Current Assets</b>		
Property, plant and equipment	826	1,084
Financial assets at fair value through other comprehensive income	2,317	2,321
Other non-current assets	3,324	3,361
Intangible assets	583,126	584,606
<b>Total Non-Current Assets</b>	<b>589,593</b>	<b>591,372</b>
<b>Total Assets</b>	<b>652,115</b>	<b>692,443</b>
<b>Liabilities</b>		
<b>Current Liabilities</b>		
Trade and other payables	13,060	18,921
Provisions	7,264	5,082
Borrowings	14,007	—
Deferred consideration	10,000	—
<b>Total Current Liabilities</b>	<b>44,331</b>	<b>24,003</b>
<b>Non-Current Liabilities</b>		
Deferred tax liability	11,124	20,079
Provisions	48,329	42,956
Borrowings	67,279	59,397
<b>Total Non-Current Liabilities</b>	<b>126,732</b>	<b>122,432</b>
<b>Total Liabilities</b>	<b>171,063</b>	<b>146,435</b>
<b>Net Assets</b>	<b>481,052</b>	<b>546,008</b>
<b>Equity</b>		
Issued Capital	910,405	889,481
Reserves	40,638	36,719
(Accumulated losses)/retained earnings	(469,991)	(380,192)
<b>Total Equity</b>	<b>481,052</b>	<b>546,008</b>

Mesoblast Limited  
ABN 68 109 431 870  
[www.mesoblast.com](http://www.mesoblast.com)

**Corporate Headquarters**  
Level 38  
55 Collins Street  
Melbourne 3000  
Victoria Australia

T +61 3 9639 6036  
F +61 3 9639 6030

**United States Operations**  
505 Fifth Avenue  
Third Floor  
New York, NY 10017  
USA

T +1 212 880 2060  
F +1 212 880 2061

**Asia**  
20 Biopolis Way  
#05-01 Centros  
Biopreneur 3  
SINGAPORE 138668

T +65 6570 0635  
F +65 6570 0176

## Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	(audited) Year ended June 30,	
	2019	2018
<b>Cash flows from operating activities</b>		
Commercialization revenue received	4,359	3,019
Milestone payment received	26,409	7,125
Research and development tax incentive received	1,654	—
Payments to suppliers and employees (inclusive of goods and services tax)	(86,294)	(84,682)
Interest received	726	367
Interest and other costs of finance paid	(4,641)	(816)
Income taxes (paid)	(3)	(25)
<b>Net cash (outflows) in operating activities</b>	<b>(57,790)</b>	<b>(75,012)</b>
<b>Cash flows from investing activities</b>		
Investment in fixed assets	(279)	(201)
Payments for contingent consideration	(721)	(952)
Rental deposits received	—	—
<b>Net cash inflows/(outflows) in investing activities</b>	<b>(1,000)</b>	<b>(1,153)</b>
<b>Cash flows from financing activities</b>		
Proceeds from borrowings	43,572	31,704
Payments of transaction costs from borrowings	(1,614)	(392)
Proceeds from issue of shares	30,258	40,566
Payments for share issue costs	(608)	(3,265)
<b>Net cash inflows by financing activities</b>	<b>71,608</b>	<b>68,613</b>
Net increase/(decrease) in cash and cash equivalents	12,818	(7,552)
Cash and cash equivalents at beginning of period	37,763	45,761
FX gain/(losses) on the translation of foreign bank accounts	(155)	(446)
<b>Cash and cash equivalents at end of period</b>	<b>50,426</b>	<b>37,763</b>

**Mesoblast Limited**  
ABN 68 109 431 870  
[www.mesoblast.com](http://www.mesoblast.com)

**Corporate Headquarters**  
Level 38  
55 Collins Street  
Melbourne 3000  
Victoria Australia

T +61 3 9639 6036  
F +61 3 9639 6030

**United States Operations**  
505 Fifth Avenue  
Third Floor  
New York, NY 10017  
USA

T +1 212 880 2060  
F +1 212 880 2061

**Asia**  
20 Biopolis Way  
#05-01 Centros  
Biopreneur 3  
SINGAPORE 138668

T +65 6570 0635  
F +65 6570 0176