asx announcement

mesoblast
the regenerative medicine company

MESOBLAST OPERATIONAL HIGHLIGHTS AND FINANCIAL RESULTS FOR THE FOURTH QUARTER AND FOR THE YEAR ENDED 30 JUNE 2017

Melbourne, Australia; August 30, 2017; and New York, USA, August 29, 2017: Mesoblast Limited (ASX: MSB; Nasdaq: MESO) today reported its consolidated financial results and operational highlights for the three months ended June 30, 2017 (fourth quarter of 2017) and year ended June 30, 2017 (FY2017).

The Company has just completed an oversubscribed institutional entitlement offer for a fully underwritten capital raise of approximately A$50.7 million (US$40.0 million). At June 30, 2017, the Company had cash reserves of US$45.8 million, and US$84.0 million on a pro-forma basis after adjusting for total net proceeds from the entitlement offer.

In FY2017, cost savings of US$20.7 million (28%) were delivered in comparison with the prior financial year. These savings enabled the Company to substantially offset the incremental costs of its Phase 3 clinical program in advanced chronic heart failure (CHF).

Mesoblast's cash reserves will be used to achieve significant outcomes in FY18 for the Phase 2b/3 trials in end-stage CHF, acute graft versus host disease (aGVHD) and chronic low back pain (CLBP). These value inflection points will provide Mesoblast with multiple commercialization options going forward, including the potential for accelerated market entry.

Key Operational Highlights for FY17

Mesoblast has prioritized its resources on those product candidates that are in Phase 3 development and have the potential to address serious and life threatening conditions or impact the use of opioids, in line with the United States 21st Century Cures Act.

The release of clinical results from several important Phase 3 and Phase 2 clinical trials during the year provided further support of safety, efficacy and durability across multiple Mesoblast product candidates.

MPC-150-IM for cardiovascular disease in adults and children

- In Mesoblast's randomized, placebo-controlled Phase 3 trial, evaluating MPC-150-IM in moderate/severe advanced CHF, a successful pre-specified interim futility analysis of the efficacy endpoint was achieved in the first 270 patients in April 2017. The trial's Independent Data Monitoring Committee formally recommended that the trial be continued as planned.
- In this Phase 3 trial over 400 of the anticipated approximately 600 total patients have been enrolled to date.
- A 159-patient randomized, placebo-controlled Phase 2b trial funded by the National Institutes of Health (NIH) and the Canadian Institutes for Health Research (CIHR) evaluating MPC-150-IM in end-stage heart failure patients with left ventricular assist devices (LVAD) neared completion of enrollment.
- An additional Phase 2 externally funded 24-patient trial evaluating MPC-150-IM in children under the age of 5 with hypoplastic left heart syndrome (HLHS) undergoing corrective surgery was cleared by the FDA to commence at Boston Children's Hospital.

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MSC-100-IV for steroid refractory acute Graft Versus Host Disease in children

- The United States Food and Drug Administration (FDA) granted a Fast Track designation for the use of MSC-100-IV to improve overall response rate in children with steroid refractory aGVHD.
- The pre-specified interim futility analysis of the overall response primary endpoint of Mesoblast's Phase 3 aGVHD trial was successful in November 2016.

MPC-06-ID for chronic low back pain in degenerative disc disease

- Results from our 100-patient randomized, placebo-controlled Phase 2 trial in patients with chronic low back pain showed that a single injection of MPC-06-ID cells resulted in meaningful improvements in both pain and function that were durable for at least 36 months.
- Alignment with the FDA regarding the Phase 3 program with confirmation that the trial's primary endpoint is acceptable for product approval.

MPC-300-IV for biologic refractory rheumatoid arthritis

- Mesoblast's 48-patient randomized, placebo-controlled Phase 2 trial in patients with biologic refractory rheumatoid arthritis (RA) showed a dose-related effect on clinical outcomes, and that a single 2m/kg injection of Mesoblast's MPC-300-IV cells resulted in the earliest and most sustained treatment responses through 39 weeks.

MPC-75-IA for prevention of radiographic and clinical features of knee osteoarthritis after traumatic injury

- Results from the Phase 2a trial of MPC-75-IA for the prevention of radiographic and clinical features of knee osteoarthritis after traumatic injury were published in the peer-reviewed journal *Arthritis Research & Therapy*. The results showed that a single intra-articular injection of MPC-75-IA reduced cartilage loss and bone changes by six months, and improved pain and function for over two years, when compared to controls.

FY18 Outlook

- Mesoblast intends to pursue RMAT designation as outlined in the 21st Century Cures Act in the United States for a number of its product candidates. The designation allows for an expedited approval path for cellular medicines designated as regenerative advanced therapies, which may help shorten clinical development time, shorten timeframes to FDA approval, reduce costs of development and increase the prospect of near-term revenue
- The Phase 2b trial using MPC-150-IM in 159 end-stage CHF patients with a LVAD is expected to complete enrollment in Q3 CY17
- The top-line results are expected in Q1 CY18
- The Phase 3 trial using MPC-150-IM in patients with Class II/III CHF is continuing to enrol through FY18, with full enrollment expected to occur in 2H CY18
- The Phase 3 trial using MSC-100-IV in children with steroid refractory acute GVHD is expected to complete enrollment with top-line data readout expected in 2H CY17
- The Phase 3 trial using MPC-06-ID in patients with CLBP is expected to complete enrollment in Q4 CY17
- 12-month results for the Phase 2 trial using MPC-300-IV in patients with biologic-refractory RA are expected in Q3 CY17
- Potential corporate partnerships for a number of Mesoblast's product candidates
- Cost containment measures remain in force

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Financial Highlights

At June 30, 2017, the Company had cash reserves of US$45.8 million, and US$84.0 million on a pro-forma basis after adjusting for proceeds from the entitlement offer.

The Company successfully achieved targeted cost savings of US$20-25 million for FY2017 as a result of its operational streamlining program as previously announced in August 2016. Cost savings of US$20.7 million (28%) were delivered from R&D product support costs, manufacturing, and management & administration for the year ended FY2017 in comparison with the prior financial year. For the fourth quarter of FY2017, the Company's cost savings for these activities were US$4.2 million (24%) compared with the fourth quarter of FY2016.

These operational streamlining savings enabled the Company to re-allocate funds for the incremental costs of the MPC-150-IM CHF Phase 3 trial through to and beyond the successful interim futility analysis of the trial's efficacy endpoint in early April 2017. The net result of the savings from the operational streamlining program, the incremental costs of the MPC-150-IM CHF Phase 3 trial, and reduction of cash inflows in operating activities led to total net operating cash flows increasing by US$7.5 million (9%) as compared with FY2016.

The Company intends to partner one or more of its four Tier 1 product candidates in order to increase cash reserves and further reduce cash burn.

As previously announced, Mesoblast retains an equity facility for up to A$120 million/US$90 million, to be used at its discretion over the next two years to provide additional funds as required.

Operational Update

MPC-150-IM is being developed for advanced and end-stage chronic heart failure (CHF) in New York Heart Association (NYHA) Class II/III and Class IV patients:

Advanced CHF in patients with New York Heart Association (NYHA) Class III/IV is a major unmet medical need due to the high rates of morbidity and mortality despite existing therapies.

Intramyocardial administration of MPCs in animal models of heart failure has resulted in improved cardiac function and attenuated pathological ventricular remodelling. These effects were attributable, at least in part, to MPC secretion of biomolecules that reduce damaging inflammation and stimulate reparative processes in the failing heart including new blood vessel formation, cardiac muscle cell survival, and reduction in tissue fibrosis.

MPC-150-IM is being evaluated in two ongoing randomized placebo-controlled Phase 2b/3 trials in patients with either severe or end-stage advanced CHF.

The mechanism of action (MOA) by which MPC-150-IM is thought to exert its effects in these patient populations is through immunomodulation and cardiac repair. Positive clinical signals supporting a common underlying MOA have been previously published in Phase 2 trials of Mesoblast's allogeneic MPC therapy in moderate/severe and end-stage heart failure.

In Phase 2 results, a single injection of MPC-150-IM by catheter into the endo-myocardium of patients with moderate to advanced CHF prevented any HF-related hospitalizations or cardiac deaths over three years of follow-up.

Under the United States 21st Century Cures Act, MPC-150-IM may be eligible for regenerative medicine advanced therapy (RMAT) designation for treatment of advanced and/or end-stage CHF in adults and children. Such designation may facilitate accelerated approval pathways for this product candidate.

- MPC-150-IM, injected by catheter into the endo-myocardium, is being evaluated in a Phase 3 trial targeting predominantly advanced CHF patients who have severe left ventricular systolic dysfunction.
    - In April 2017, the pre-specified interim futility analysis of the efficacy endpoint was successful in the trial's first 270 patients. After notifying the Company of the interim analysis results, the trial's Independent Data Monitoring Committee formally recommended the trial be continued as planned

- More than 400 of the anticipated approximately 600 NYHA Class II/III CHF patients have been randomized to date

- The trial's primary efficacy endpoint is a comparison of recurrent non-fatal HF-related major adverse cardiac events (HF-MACE) between either MPC-treated patients or sham-treated controls

- MPC-150-IM, injected directly into the epicardium, is being evaluated in a Phase 2b trial in patients with NYHA Class IV/end-stage heart failure who have received a LVAD.

    - The study is being conducted in North America by a team of researchers within the NIH-funded Cardiothoracic Surgical Trials Network. The trial is also supported by the National Institute of Neurological Disorders and Stroke and the CIHR

    - The trial is evaluating the safety and efficacy of MPC-150-IM injected into the native heart muscle of end-stage CHF patients whose circulation is being supported by a LVAD

    - Given that high rates of mortality and recurrent hospitalizations continue to be seen in end-stage CHF patients even with LVAD implants, this trial has the potential to support an accelerated approval pathway for MPC-150-IM

    - The primary efficacy endpoint of the study is the number of temporary weans from LVAD tolerated over the 6 months post-randomization, indicating strengthening of the native heart muscle. Additional efficacy endpoints include patient survival, adverse events and rehospitalization rates over 12 months

    - Enrollment of this trial is expected to be completed shortly with top-line results for the trial's primary endpoint expected in Q1 CY2018

- MPC-150-IM has also been cleared by the FDA to be evaluated in a 24-patient trial combining MPCs with corrective heart surgery in children under the age of 5 with HLHS. The trial is sponsored and funded by the Boston Children's Hospital, the pediatric teaching hospital of Harvard University, with support from Bulens and Capozzi Foundation and the Ethan Lindberg Foundation.

MSC-100-IV is being developed for steroid-refractory acute Graft Versus Host Disease (aGVHD):

Currently there are no approved therapies for patients with aGVHD in the United States and off-label options have demonstrated mixed efficacy with high toxicity. As such, there is a significant need for an effective treatment with a favorable risk/benefit profile. We are developing our allogeneic mesenchymal stem cell (MSC) product candidate MSC-100-IV for children and adults with steroid-refractory aGVHD.

In Japan, our licensee JCR Pharmaceuticals Ltd. has already obtained regulatory approval and launched the MSC-based product TEMCELL® HS Inj. for the treatment of aGVHD in children and adults[1].

In the United States, Canada and several European countries MSC-100-IV has been used for the treatment of aGVHD in children under an expanded access program. This program enrolled more than 240 patients suffering from aGVHD and MSC-100-IV was used either as front-line or as salvage therapy.

In line with guidance from the FDA, we are currently completing an open-label trial in up to 60 children with steroid-refractory aGVHD to evaluate MSC-100-IV as front-line therapy in these children.

- This Phase 3 is expected to complete enrollment in 2H CY 2017.

- The pre-specified interim futility analysis of the primary endpoint of the ongoing trial was successful in November 2016.

- The FDA has granted a Fast Track designation for the use of MSC-100-IV to achieve improved overall response rate in children with steroid-refractory aGVHD.

- Fast Track designation has the potential to shorten the time to FDA approval of MSC-100-IV for this indication through priority review (shortened FDA review process from 10 to 6 months) and a streamlined rolling review process (completed modules of the Biologics License Application, BLA, can be submitted to FDA when available, instead of waiting for all to be completed and submitted together)

- The product candidate's existing Orphan Indication designation may additionally lead to potential commercial benefits following FDA approval

- Based on guidance from the FDA, Mesoblast believes that data from this Phase 3 trial may be sufficient for filing for accelerated conditional approval of MSC-100-IV in the United States.

- Mesoblast plans to broaden the use of its technology platform with a Phase 3 trial in adult patients with high-risk steroid-refractory acute GVHD.

- In December 2016, Mesoblast and Mallinckrodt Pharmaceuticals entered into an agreement to exclusively negotiate a commercial and development partnership for MSC-100-IV in the treatment of acute GVHD.

MPC-06-ID is being developed for chronic low back pain (CLBP) due to degenerative disc disease (DDD):

In 2016, over 7 million people in the United States alone were estimated to suffer from CLBP caused by DDD, of which 3.2 million patients have moderate disease. After failure of conservative measures (medication, injections, epidural steroid physical therapy, etc.), there is no treatment that prevents progression of disc degeneration, reduces pain and improves function over a sustained period of 6 to 12 months.

The United States 21st Century Cures Act includes a focus on reducing the growing opioid epidemic. In 2017 it is thought that more than 30,000 Americans will die as a result of opioid overdoses[2]. We believe that MPC-06-ID may have the potential to reduce and/or eliminate the need for the use of opioids in the treatment of this disease, and accordingly are evaluating the product in this light in our Phase 3 program.

- The ongoing 360-patient Phase 3 trial for MPC-06-ID in patients with CLBP due to intervertebral disc degeneration is actively recruiting across U.S. and Australian sites with enrollment targeted to complete this year. The primary endpoint composite is a 50% reduction in the Visual Analog Scale (VAS) pain score and a 15-point reduction in the Oswestry disability index (ODI), with no additional intervention, at both 12 and 24 months.

- The Phase 3 trial using MPC-06-ID in patients with CLBP is expected to complete enrollment Q4 CY17.

- In line with FDA guidance, the Phase 3 trial's 24-month primary endpoint composite is being analyzed using an intent to treat (ITT) population.

- The 36-month analysis from March 2017 of the randomized, placebo-controlled, 100-patient Phase 2 trial of MPC-06-ID aimed to determine the proportion of patients who maintained treatment success beyond the 24-month primary evaluation. Key trial results using the ITT analysis were:

    - 38% of the 6 million MPC group achieved the primary endpoint composite over 24 months compared with 10% of the saline group ($p<0.05$)
    - 82% of the 6 million MPC group who achieved the primary endpoint composite over 24 months maintained treatment success using this composite endpoint at 36 months
    - 86% of the 6 million MPC group who successfully met the pain responder criteria (50% pain reduction with no additional intervention at both 12 and 24 months) remained pain responders through 36 months
    - 92% of the 6 million MPC group who met the functional responder criteria (15-point reduction in ODI and no additional intervention at both 12 and 24 months) remained functional responders through 36 months

- there were no significant differences in measurements of safety between cell-treated patients and controls over 36 months

- The 36-month Phase 2 trial results support the ongoing 360-patient Phase 3 trial of Mesoblast's product candidate MPC-06-ID for CLBP by reinforcing the rationale for MPC dose selection, use of saline control, and the trial's primary endpoint composite over 24 months. If similar clinical durability is seen in the Phase 3 program, it is anticipated such data will translate into meaningful health economic benefits including increased productivity that may support attractive product reimbursement.

- In December 2016, Mesoblast and Mallinckrodt Pharmaceuticals entered into an agreement to exclusively negotiate a commercial and development partnership for MPC-06-ID in the treatment of CLBP.

MPC-300-IV is being developed for biologic refractory rheumatoid arthritis (RA):

Major advances in the treatment of RA using biologic agents have resulted in a $19 billion global market in 2016, predominantly Tumor Necrosis Factor (TNF)-inhibitors. Despite these advances, approximately one third of patients either do not respond sufficiently to TNF-inhibitors or other biologic agents, or cannot tolerate them due to infectious or other complications. In the United States, the anti-TNF refractory population is the fastest growing branded market segment, projected to increase by 8% annually and potentially higher with the expected market entry and greater availability of anti-TNF biosimilars.

Mesoblast's Phase 2 trial recruited a total of 48 patients with active RA who were on a stable regimen of methotrexate and had an inadequate prior clinical response to at least one anti-TNF agent.

- Results of a study were published in the peer-reviewed journal *Stem Cell Research & Therapy* in February 2017, showing that a single intravenous infusion of 150 million of the Company's proprietary allogeneic "off-the-shelf" STRO-3 immunoselected MPCs significantly improved clinical disease severity, reduced joint cartilage erosions, and improved synovial inflammation and histopathology in a large animal model of early RA.

- This study provides mechanistic and translational support for the clinical outcomes reported in the ongoing Phase 2 trial of MPC-300-IV for biologic refractory RA.

- Results from this 48-patient placebo-controlled, randomized Phase 2 trial evaluating two dosing regimens against placebo in RA patients resistant to anti-TNF agents showed that single intravenous infusion of MPC-300-IV resulted in durable responses through nine months (39 weeks). All three cohorts (2m MPCs/KG; 1m/MPCs/KG and placebo) were well matched for disease activity and other demographics at baseline. The results showed that:

    - The safety profile over 39 weeks was comparable among the placebo and both MPC treatment groups, with no cell-related serious adverse events reported

    - Both MPC doses outperformed placebo at the week 39 follow-up in each of ACR20/50/70 responses, as well as by median ACR-N analysis

    - The 2 million MPC/kg dose showed the earliest and most sustained treatment responses in this Phase 2 trial in the period assessed

- 52-week results are expected in Q3 CY17.

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Financial Results for the Three Months Ended June 30, 2017 (fourth quarter) (in U.S. Dollars)

The Company continued to execute its planned operational streamlining and re-prioritization of projects to offset the incremental costs of the MPC-150-IM Phase 3 program in CHF. Due to these measures, the Company had cost savings of $4.2 million (24%) for R&D product support costs, manufacturing, and management & administration for the fourth quarter of FY2017, compared with the fourth quarter of FY2016. This cost savings comprised: $6.6 million within manufacturing which was offset by non-cash increases of $1.0 million within R&D product support costs and $1.3 million within management & administration.

There was an improvement of $3.0 million (9%) in the loss before income tax for the fourth quarter of FY2017, compared with the fourth quarter of FY2016. This overall decrease in loss before income tax was primarily due to non-cash items that do not affect cash reserves.

The main items which impacted the loss before income tax movement were:

- **Revenues** from sales of TEMCELL increased by $0.1 million in the fourth quarter of FY2017 compared with the fourth quarter of FY2016 and the Company also received its first sales milestone on sales of TEMCELL in the fourth quarter of FY2017. There was a non-cash decrease of $26.3 million in total revenues for the fourth quarter of FY2017 compared with the fourth quarter of FY2016, primarily due to a significant deferred revenue item of $22.5 million being recognized in FY2016 related to regaining control of the Company's MPC-150-IM product.

- **Manufacturing** expenses were $1.2 million for the fourth quarter of FY2017, compared with $7.7 million for the fourth quarter of FY2016, a decrease of $6.6 million primarily due to a reduction in manufacturing activity because sufficient quantities of clinical grade product were previously manufactured for ongoing clinical trials.

- **Research and Development:** After absorbing the incremental R&D costs associated with the CHF program, total R&D costs were $15.9 million, an increase of $1.5 million versus the comparative quarter in FY2016.

- **Management and Administration** expenses were $7.1 million for the fourth quarter of FY2017, compared with $5.8 million for the fourth quarter of FY2016, an increase of $1.3 million primarily due to a non-cash increase of $1.0 million in share-based payment expenses.

The overall decrease in loss before income tax also includes movements in other items which did not impact current cash reserves, such as: fair value remeasurement of contingent consideration, impairment of intangible assets and foreign exchange movements within other operating income and expenses. The net loss attributable to ordinary shareholders was $27.2 million, or 6.40 cents losses per share, for the fourth quarter of FY2017, compared with a net profit of $48.3 million, or 12.78 cents earnings per share, for the fourth quarter of FY2016.

Financial Results for the Year Ended June 30, 2017 (in U.S. Dollars)

The Company successfully achieved targeted savings of US$20-25 million for FY2017 as a result of its operational streamlining program as previously announced in August 2016. Cost savings of US$20.7 million (28%) were delivered from R&D product support costs, manufacturing, and management & administration for the year ended FY2017 in comparison with the prior financial year. For the fourth quarter of FY2017, the Company's cost savings for these activities were US$4.2 million (24%) compared with the fourth quarter of FY2016. These cost savings comprised: $17.7 million in manufacturing, $3.5 million within R&D product support costs offset by a non-cash increase of $0.5 million within management & administration.

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These operational streamlining savings enabled the Company to re-allocate funds for the incremental costs of the MPC-150-IM CHF Phase 3 trial through to and beyond the successful interim futility analysis of the trial's efficacy endpoint in early April 2017. The net result of the savings from the operational streamlining program, the incremental costs of the MPC-150-IM CHF Phase 3 trial, and reduction of cash inflows in operating activities led to total net operating cashflows increasing by US$7.5 million (9%) as compared with FY2016.

There was a decrease of $0.6 million (1%) in the loss before income tax for FY2017, compared with FY2016. This overall decrease in loss before income tax was primarily due to non-cash items that do not affect cash reserves.

The main items which impacted the loss before income tax movement were:

- **Revenues** from royalties on sales of TEMCELL increased by $1.0 million in FY2017, compared to FY2016, and the Company also received its first sales milestone on sales of TEMCELL in FY2017. There was a decrease of $40.1 million in total revenues in FY2017, compared to FY2016, primarily due to a non-cash deferred revenue items of $37.5 million recognized in FY2016 related to regaining control of the Company's MPC-150-IM product.

- **Manufacturing** expenses were $12.1 million for FY2017, compared with $29.8 million for FY2016, a decrease of $17.7 million due to a reduction in manufacturing activity because sufficient quantities of clinical grade product were previously manufactured for all ongoing clinical trials.

- **Research and Development:** After absorbing the incremental R&D costs associated with the CHF program, total R&D costs were $58.9 million, an increase of $8.9 million versus the comparative period in FY2016.

- **Management and Administration** expenses were relatively stable at $23.0 million for FY2017, compared with $22.5 million for FY2016, an increase of $0.5 million. This movement was due to increased legal & professional fees of $0.7 million; an increase of $1.4 million in non-cash share based payment expenses; offset by a decrease of $1.6 million in corporate overhead expenses resulting from the planned operational streamlining activities.

The overall decrease in loss before income tax also includes movements in other items which did not impact current cash reserves, such as fair value remeasurement of contingent consideration, impairment of intangible assets, and foreign exchange movements within other operating income and expenses. The net loss attributable to ordinary shareholders was $76.8 million, or 19.43 cents per share, for the twelve months of FY2017, compared with $4.1 million, or 1.14 cents per share, for the twelve months of FY2016.

1. TEMCELL® HS. Inj is a registered trademark of JCR Pharmaceuticals Co., Ltd.
2. https://www.cdc.gov/drugoverdose/epidemic/index.html

Conference Call Details

Mesoblast will be hosting a conference call beginning at 8am AEST on August 30, 2017 / 6pm EDT on August 29, 2017. The conference identification code is 850 866**.**

The live webcast can be accessed via: http://webcasting.boardroom.media/broadcast/597052f22298ed20a06fa42e

To access the call, please dial:

Australia Toll Free	1 800 558 698
Australia Alternate	1 800 809 971
United States	1 855 881 1339
United Kingdom	0800 051 8245
Japan	0053 116 1281
Singapore	800 101 2785
Hong Kong	800 966 806
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About Mesoblast
Mesoblast Limited (ASX:MSB; Nasdaq:MESO) is a global leader in developing innovative cell-based medicines. The Company has leveraged its proprietary technology platform, which is based on specialized cells known as mesenchymal lineage adult stem cells, to establish a broad portfolio of late-stage product candidates. Mesoblast's allogeneic, 'off-the-shelf' cell product candidates target advanced stages of diseases with high, unmet medical needs including cardiovascular conditions, orthopedic disorders, immunologic and inflammatory disorders and oncologic/hematologic conditions.

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 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.

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Consolidated Income Statement

(in U.S. dollars, in thousands, except per share amount)	(unaudited) Three Months Ended June 30, 2017	2016	(audited) Year Ended June 30, 2017	2016
Revenue	566	26,879	2,412	42,548
Research & development	(15,939)	(14,395)	(58,914)	(50,013)
Manufacturing commercialization	(1,150)	(7,721)	(12,065)	(29,763)
Management and administration	(7,148)	(5,834)	(23,007)	(22,500)
Fair value remeasurement of contingent consideration	(7,908)	28,954	(130)	28,112
Impairment of intangible assets	—	(61,919)	—	(61,919)
Other operating income and expenses	321	(177)	1,489	2,714
Loss before income tax	**(31,258)**	**(34,213)**	**(90,215)**	**(90,821)**
Income tax benefit/(expense)	4,076	82,504	13,400	86,694
(Loss)/profit attributable to the owners of Mesoblast Limited	**(27,182)**	**48,291**	**(76,815)**	**(4,127)**
(Losses)/earnings per share from continuing operations attributable to the ordinary equity holders of the Group:	**Cents**	**Cents**	**Cents**	**Cents**
Basic - (losses)/earnings per share	(6.40)	12.78	(19.43)	(1.14)
Diluted - (losses)/earnings per share	(6.40)	12.78	(19.43)	(1.14)

Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	(unaudited) Three Months Ended June 30, 2017	2016	(audited) Year Ended June 30, 2017	2016
(Loss)/profit for the year	**(27,182)**	**48,291**	**(76,815)**	**(4,127)**
Other comprehensive income/(loss)				
Items that may be reclassified to profit and loss				
Changes in the fair value of available-for-sale financial assets	86	(186)	31	(334)
Exchange differences on translation of foreign operations	(52)	(381)	316	(705)
Other comprehensive income/(loss) for the period, net of tax	**34**	**(567)**	**347**	**(1,039)**
Total comprehensive (loss)/income attributable to the owners of Mesoblast Limited	**(27,148)**	**47,724**	**(76,468)**	**(5,166)**

Mesoblast Limited
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Consolidated Statement of Balance Sheet

(in U.S. dollars, in thousands)	As of June 30, 2017	2016
Assets		
Current Assets		
Cash & cash equivalents	45,761	80,937
Trade & other receivables	3,743	4,054
Prepayments	14,105	3,832
Total Current Assets	**63,609**	**88,823**
Non-Current Assets		
Property, plant and equipment	1,814	3,063
Available-for-sale financial assets	1,997	1,966
Other non-current assets	1,916	2,343
Intangible assets	586,350	587,823
Total Non-Current Assets	**592,077**	**595,195**
Total Assets	**655,686**	**684,018**
Liabilities		
Current Liabilities		
Trade and other payables	21,805	27,155
Provisions	14,865	2,260
Total Current Liabilities	**36,670**	**29,415**
Non-Current Liabilities		
Deferred tax liability	49,293	62,693
Provisions	52,957	63,749
Total Non-Current Liabilities	**102,250**	**126,442**
Total Liabilities	**138,920**	**155,857**
Net Assets	**516,766**	**528,161**
Equity		
Issued Capital	830,425	770,272
Reserves	31,243	25,976
(Accumulated losses)/retained earnings	(344,902)	(268,087)
Total Equity	**516,766**	**528,161**

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Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	Year ended June 30, 2017	2016
Cash flows from operating activities		
Commercialization revenue received	1,332	99
Milestone revenue received	500	3,500
Research and development tax incentive received	2,813	4,466
Payments to suppliers and employees (inclusive of goods and services tax)	(100,598)	(97,190)
Interest received	483	1,129
Income taxes (paid)/refunded	(1)	—
Net cash (outflows) in operating activities	**(95,471)**	**(87,996)**
Cash flows from investing activities		
Payments for investments	—	(805)
Payments for licenses	—	(200)
Investment in fixed assets	(311)	(722)
Rental deposits received	453	—
Net cash inflows/(outflows) in investing activities	**142**	**(1,727)**
Cash flows from financing activities		
Proceeds from issue of shares	61,932	68,549
Payments for share issue costs	(1,927)	(6,483)
Net cash inflows by financing activities	**60,005**	**62,066**
Net (decrease) in cash and cash equivalents	(35,324)	(27,657)
Cash and cash equivalents at beginning of period	80,937	110,701
FX gains/(losses) on the translation of foreign bank accounts	148	(2,107)
Cash and cash equivalents at end of period	**45,761**	**80,937**

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