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mesoblast
the regenerative medicine company

MESOBLAST PRESENTS CORPORATE UPDATE AND FINANCIAL RESULTS FOR THE HALF YEAR PERIOD ENDED DECEMBER 31, 2016

Melbourne, Australia; February 27, 2017; and New York, USA, February 26, 2017: Mesoblast Limited (ASX: MSB; Nasdaq: MESO) today provided the market with a strategic update, financial results for the half-year period ended December 31, 2016 (half-year FY2017), and operational highlights.

Strategic Update

Our corporate vision is to bring to market disruptive cellular medicines to treat serious and life-threatening illnesses.

We are developing lead product candidates, based on our proprietary mesenchymal lineage cell technology platform, which have shown a strong safety profile and consistent signals of efficacy in difficult to treat patient segments, reflective of the unique mechanisms of action of our cells.

To achieve our corporate vision, Mesoblast has prioritized its pipeline to focus its resources on four Tier 1 product candidates that represent the nearest-term revenue opportunities and/or potential blockbuster target markets.

These product candidates are well positioned to meet objectives of the recently enacted 21st Century Cures Act. This Act provides an accelerated approval pathway in the United States, the world's largest healthcare market, for cell-based medicines designated as regenerative advanced therapies.

Mesoblast intends to enter into strategic alliances with partners who share our corporate vision and can leverage their existing strengths and capabilities to maximize the commercial value of our lead assets.

In line with this objective, Mesoblast recently entered into a period of exclusivity to negotiate a commercial and development partnership with Mallinckrodt Pharmaceuticals for two Tier 1 product candidates in consideration for an equity purchase of 20 million shares. Mallinckrodt is a global specialty pharmaceutical company with a major focus within the hospital acute and critical care settings, including pain management, autoimmune and rare diseases, and specialty generic pharmaceuticals.

Financial Highlights

At December 31, 2016, the Group had cash reserves of US$55.6 million after adjusting for the committed capital of US$21.7 million from the equity purchase agreement with Mallinckrodt Pharmaceuticals announced on December 23, 2016, the proceeds of which were subsequently received on January 6, 2017.

During the half-year FY2017, the Company has executed its planned operational streamlining and re-prioritization of projects to successfully absorb the incremental costs of the MPC-150-IM program in advanced chronic heart failure (CHF). In line with this objective, operating cash outflows for the half-year FY2017 excluding MPC-150-IM for CHF were reduced by 22% (US$11.5 million) compared with the half-year period ended December 31, 2015 (half–year FY2016). After absorbing the incremental R&D costs associated with the CHF program, total operating cash outflows were US$47.3 million, still a reduction of 9% (US$4.6 million) compared with the half-year FY2016.

The US$11.5 million in savings was achieved principally through reduced spend on commercial manufacturing, labor costs within R&D and management & administration.

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As previously announced, a fully discretionary equity facility has been established for up to $A120 million/$US90 million over 36 months.

Key Upcoming Milestones

- During CY2017, the Company expects to report multiple clinical, regulatory and commercial outcomes.

- The Company expects to:

    - report on the Phase 3 interim analysis in patients with advanced chronic heart failure (CHF)
    - report on the Phase 2B top line results for end-stage CHF
    - release 12 month data on its biologic refractory rheumatoid arthritis (RA) program
    - complete enrollment in the chronic low back pain (CLBP) Phase 3 trial, and
    - complete enrollment and read out top-line results in the Phase 3 acute graft versus host disease (aGVHD) trial.

- The Company expects to report on discussions with the FDA on the potential for certain of its product candidates to be designated as regenerative advanced therapies under the 21st Century Cures Act.

- Mesoblast intends to enter into strategic alliances with partners who share our corporate vision and can leverage their existing strengths and capabilities to maximize the commercial value of our lead assets.

Operational Highlights

MPC-150-IM for advanced chronic heart failure (CHF):

1. Mesoblast is currently conducting a Phase 3 trial of MPC-150-IM in New York Heart Association (NYHA) Class II-III advanced CHF patients.

- This trial's primary endpoint is a comparison of recurrent heart failure-related major adverse cardiovascular events (HF-MACE) in advanced CHF patients receiving either MPC-150-IM by catheter injection into the left ventricular heart muscle or sham control.

- More than 300 advanced CHF patients have been enrolled to date.

- After reviewing patient data at two timepoints, in April and October 2016, the trial's Data Monitoring Committee maintained its recommendation that the study should continue as planned.

- An interim analysis of the trial's primary endpoint is planned for Q1 CY2017.

2. MPC-150-IM is also currently being evaluated in a Phase 2b trial in patients with end-stage heart failure who have received a left ventricular assist device (LVAD). This program is sponsored and funded by the United States National Institutes of Health (NIH).

- Enrollment of this trial comprising approximately 150 patients is expected to be completed during 1H CY2017 with a data read-out planned in 2H CY2017.

The results of these trials will be used to guide the Company's discussions with the United States Food and Drug Administration (FDA) in line with the 21st Century Cures Act for potential accelerated approval pathways for MPC-150-IM.

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

- Results of a new study were published in the peer-reviewed journal *Stem Cell Research & Therapy*, 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.

- Recent results from this 48-patient placebo-controlled, randomized Phase 2 trial evaluating two dosing regimens against placebo in RA patients resistant to anti-Tumor Necrosis Factor (TNF) agents showed that a single intravenous infusion of MPC-300-IV resulted in durable responses through nine months (39 weeks). All three cohorts 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.

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

    - Continuous variables ACR-N, HAQ-DI and DAS-28 were used in line with the FDA Guidance For Industry Rheumatoid Arthritis: Developing Drug Products For Treatment, May 2013, and identified the 2 million MPC/kg dose as the most effective over 39 weeks.

    - The 2 million MPC/kg dose showed the earliest and most sustained treatment benefit.

    - The RA population resistant to anti-TNF agents constitutes about one-third of patients treated with these agents, is the fastest growing branded market segment within the $19 billion global RA biologics market, and is set to grow further as multiple anti-TNF biosimilars become available; the goal of therapy in these patients is to achieve early and sustained low disease activity which correlates with prevention of structural joint damage in RA.

Given the serious nature of anti-TNF resistant RA, MPC-300-IV is well-positioned to be developed as a regenerative advanced therapy to target this major unmet medical need.

MPC-06-ID for Chronic Low Back Pain (CBLP):

- During the reporting period Mesoblast entered into exclusive negotiations with Mallinckrodt for a commercial and development partnership for MPC-06-ID in the treatment or prevention of CLBP.

- The current 360 patient Phase 3 trial is actively recruiting across US and Australian sites with enrollment expected to complete this year.

- The 24-month results from the Company's 100-patient Phase 2 trial of MPC-06-ID for treatment of chronic low back pain were presented at the 24th Annual Scientific Meeting of the Spine Intervention Society and received the 2016 Best Basic Science Abstract award.

MSC-100-IV for Acute Graft Versus Host Disease (aGVHD):

- During the reporting period Mesoblast entered into exclusive negotiations with Mallinckrodt for a commercial and development partnership for developing product candidates for pediatric and adult aGVHD.

- The Phase 3 trial of Mesoblast's intravenous product candidate MSC-100-IV, used as front-line therapy in children with steroid-resistant aGVHD, was successful in a pre-specified interim futility analysis.

- The interim analysis showed that the predefined Bayesian futility rule used to determine the probability of the trial's success using the trial's primary endpoint of Day 28 overall response had been passed. The analysis method determined the likelihood of obtaining a statistically significant treatment effect at study completion, based on the data observed at this interim time point.

- Enrollment in the 60-patient open label Phase 3 trial is expected to complete mid-2017 with a read out in 2H CY 2017.

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

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

Financial Results for the Six Months Ended 31 December 2016 (the half-year) (in U.S. Dollars)

The Company has executed a range of cost reduction initiatives in order to offset the incremental costs of the MPC-150-IM program in FY2017. In line with this objective, operating cash outflows for the half-year FY2017 excluding MPC-150-IM for CHF were reduced by 22% (US$11.5 million) compared with the half-year FY2016. These reductions comprised: $3.4 million within Research and Development; $7.2 million in Manufacturing Commercialization; and $0.9 million within Management and Administration.

Loss before income tax for the half-year FY2017 increased by $10.6 million primarily due to non-cash revenue items that do not affect our cash reserves, compared with the half-year FY2016.

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

- **Revenues** for the half-year were reduced by $10.6 million, of which $7.5 million was a reduction in a non-cash item. This non-cash item was deferred revenue recognized in half-year FY2016 related to our MPC-150-IM product. The remaining decrease reflects a one-off $3.5 million milestone payment in the half-year 2016 for TEMCELL® HS Inj.

- **Research and Development** expenses increased by $5.4 million, and were $29.0 million for the half-year FY2017 compared with $23.6 million for the half-year FY2016. This net $5.4 million increase was driven by increased costs for our MPC-150-IM heart failure product candidate, offset by Operational Streamlining savings of $3.4 million within R&D achieved through a 31% reduction in FTEs and a 29% reduction in product support costs.

- **Manufacturing Commercialization** expenses were $7.1 million for the half-year FY2017 compared with $14.3 million for the half-year FY2016, a decrease of $7.2 million (51%): Costs were reduced as the Company had sufficient clinical grade product on hand to reduce the number of production runs in this period; as well as savings arising from the labor restructure, combined with cost containment of consultants and travel.

- **Management and Administration** expenses were $10.3 million for the half-year FY2017 compared with $11.3 million for the half-year FY2016, a decrease of $1.0 million. This decrease was primarily due to reductions in full time equivalents, consultancy expenses, and reductions in corporate overhead expenses such as rent, legal and professional fees and other office expenses.

The overall increase in loss before income tax also includes movements in other items which did not impact our current cash reserves, such as: contingent consideration, finance costs and foreign exchange movements within other operating income and expenses. Our net loss attributable to ordinary shareholders was $39.8 million, or 10.50 cents per share, for the half-year FY2017, compared with $35.5 million, or 10.31 cents per share, for the half-year FY2016.

Financial Results for the Three Months Ended 31 December 2016 (second quarter) (in U.S. Dollars)

Loss before income tax increased by $0.9 million (4%) for the second quarter of FY2017 compared with the second quarter of FY2016. This overall increase in loss before income tax was primarily impacted by non-cash items that do not affect our cash reserves.

From August 2016, the Company executed a range of cost reduction initiatives in order to offset the incremental costs of the MPC-150-IM program in FY2017. Progress on these initiatives is explained above in the Financial Results for the Six Months Ended 31 December 2016 (the half-year).

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

- **Revenues** were $0.6 million for the second quarter of FY2017 compared with $4.0 million for the second quarter of FY2016, a decrease of $3.4 million. This decrease was due to a decrease in a non-cash item. This non-cash item was deferred revenue recognized in the second quarter of FY2016 related to our MPC-150-IM product.

- **Research and Development** expenses were $15.0 million for the second quarter of FY2017 compared with $12.5 million for the second quarter of FY2016, an increase of $2.5 million. This $2.5 million increase was driven by increased costs for our MPC-150-IM product.

- **Manufacturing Commercialization** expenses were $3.8 million for the second quarter of FY2017 compared with $8.1 million for the second quarter of FY2016, a decrease of $4.3 million as we had sufficient clinical grade product on hand to enable us to manage costs by reducing the number of production runs in the period.

- **Management and Administration** expenses were $4.9 million for the second quarter of FY2017 compared with $5.7 million for the second quarter of FY2016, a decrease of $0.8 million. This decrease was primarily due to a savings in labour and associated adjustments to short term incentive costs, a reduction in consultancy expenses and a reduction in rent and other office expenses as management reduced costs in line with our corporate strategy.

The overall increase in loss before income tax also includes movements in other items which did not impact our current cash reserves, such as: contingent consideration, finance costs and foreign exchange movements within other operating income and expenses. Our net loss attributable to ordinary shareholders was $20.1 million, or 5.27 cents per share, for the second quarter of FY2017, compared with $22.3 million, or 6.29 cents per share, for the second quarter of FY2016.

Conference Call Details

Mesoblast will be hosting a conference call beginning at 9.00am AEDT on February 27, 2017 / 5.00pm EST on February 26, 2017. The conference identification code is 638112.

The live webcast can be accessed via:
http://webcasting.boardroom.media/broadcast/58af4d2b196ffa2970ec979c

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
International	+61 2 9007 3187

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. 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 thousands, except per share amount)	Three Months Ended December 31, 2016	2015	Six Months Ended December 31, 2016	2015
Revenue	550	4,014	945	11,527
Research & development	(15,043)	(12,515)	(29,047)	(23,604)
Manufacturing commercialization	(3,790)	(8,118)	(7,085)	(14,321)
Management and administration	(4,879)	(5,716)	(10,338)	(11,251)
Fair value remeasurement of contingent consideration	288	541	312	4,271
Other operating income and expenses	311	1,495	784	2,343
Finance costs	(614)	(2,026)	(1,651)	(4,450)
Loss before income tax	**(23,177)**	**(22,325)**	**(46,080)**	**(35,485)**
Income tax benefit/(expense)	3,126	—	6,231	—
Loss attributable to the owners of Mesoblast Limited	**(20,051)**	**(22,325)**	**(39,849)**	**(35,485)**
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:	**Cents**	**Cents**	**Cents**	**Cents**
Basic - losses per share	(5.27)	(6.29)	(10.50)	(10.31)
Diluted - losses per share	(5.27)	(6.29)	(10.50)	(10.31)

Consolidated Statement of Comprehensive Income

(in thousands)	Three Months Ended December 31, 2016	2015	Six Months Ended December 31, 2016	2015
(Loss)/profit for the year	**(20,051)**	**(22,325)**	**(39,849)**	**(35,485)**
Other comprehensive income				
Items that may be reclassified to profit and loss				
Changes in the fair value of available-for-sale financial assets	(1)	(185)	31	(185)
Exchange differences on translation of foreign operations	(1,277)	1,742	(574)	(1,851)
Other comprehensive (loss)/income for the period, net of tax	**(1,278)**	**1,557**	**(543)**	**(2,036)**
Total comprehensive (loss)/income is attributable to the owners of Mesoblast Limited	**(21,329)**	**(20,768)**	**(40,392)**	**(37,521)**

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Consolidated Statement of Balance Sheet

(in thousands)	As of December 31, 2016	As of June 30, 2016
Assets		
Current Assets		
Cash & cash equivalents	33,902	80,937
Trade & other receivables	27,133	4,054
Prepayments	5,966	3,832
Total Current Assets	**67,001**	**88,823**
Non-Current Assets		
Property, plant and equipment	2,485	3,063
Available-for-sale financial assets	1,997	1,966
Other non-current assets	2,325	2,343
Intangible assets	587,072	587,823
Total Non-Current Assets	**593,879**	**595,195**
Total Assets	**660,880**	**684,018**
Liabilities		
Current Liabilities		
Trade and other payables	26,259	27,155
Provisions	2,840	2,260
Total Current Liabilities	**29,099**	**29,415**
Non-Current Liabilities		
Deferred tax liability	56,462	62,693
Provisions	64,802	63,749
Total Non-Current Liabilities	**121,264**	**126,442**
Total Liabilities	**150,363**	**155,857**
Net Assets	**510,517**	**528,161**
Equity		
Capital	791,788	770,272
Reserves	26,665	25,976
(Accumulated losses)/retained earnings	(307,936)	(268,087)
Total Equity	**510,517**	**528,161**

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Consolidated Statement of Cash Flows

(in thousands)	Six months ended December 31, 2016	2015
Cash flows from operating activities		
Commercialization revenue received	579	—
Milestone revenue received	—	3,500
Payments to suppliers and employees (inclusive of goods and services tax)	(47,252)	(51,881)
Interest received	309	508
Net cash (outflows) in operating activities	**(46,364)**	**(47,873)**
Cash flows from investing activities		
Payments for investments	—	(805)
Payments for licenses	—	(200)
Investment in fixed assets	(292)	(613)
Net cash (outflows) in investing activities	**(292)**	**(1,618)**
Cash flows from financing activities		
Proceeds from issue of shares	—	68,549
Payments for share issue costs	(60)	(6,618)
Net cash (outflows) / inflows by financing activities	**(60)**	**61,931**
Net (decrease)/increase in cash and cash equivalents	(46,716)	12,440
Cash and cash equivalents at beginning of period	80,937	110,701
FX (losses)/gains on the translation of foreign bank accounts	(319)	(2,358)
Cash and cash equivalents at end of period	**33,902**	**120,783**

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