asx announcement

mesoblast
the regenerative medicine company

MESOBLAST PROVIDES CORPORATE UPDATE AND FINANCIAL RESULTS FOR THE FIRST QUARTER ENDED SEPTEMBER 30, 2016

Melbourne, Australia; November 15, 2016; and New York, USA, November 14, 2016: Mesoblast Limited (ASX: MSB; Nasdaq: MESO) today provided a quarterly corporate update on its operational highlights, including its key milestone achieved in its acute graft versus host disease Phase 3 clinical trial. Mesoblast also reported its consolidated financial results for the three months ended September 30, 2016.

In line with previous guidance, the Company implemented operational streamlining measures during the quarter while achieving, and continuing to maintain progress towards, key milestones in its Tier 1 clinical programs.

In recognition of the Company's continued clinical achievements, it was recently awarded the Frost & Sullivan Asia Pacific 2016 Cell Therapy Company of the Year award. The Frost & Sullivan awards identify and honor the best-in-class companies that have demonstrated excellence in their industry.

Financial Highlights

At September 30, 2016, the Company had cash reserves of $60.4 million. As previously announced, a fully discretionary equity facility has been established for up to $A120 million/$US90 million over 36 months.

In order to absorb the incremental costs of the MPC-150-IM program in advanced heart failure in FY17, the Company has executed its planned operational streamlining and re-prioritization of projects. Cash outflows for Q1 FY17 were $21.2 million, a reduction of 28% from $29.4 million in the comparable FY16 quarter. This was achieved principally through reduced spend on commercial manufacturing, deprioritized Tier 2 clinical projects and reduced labor costs.

Operational Highlights

MSC-100-IV for steroid-refractory acute graft versus host disease (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 conducted by the independent Data Safety Monitoring Board (DSMB).
- 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 ongoing across multiple sites in the United States, trial completion is expected in the first half of 2017, and commercial launch activities are underway.
- Based on guidance from the United States Food and Drug Administration, 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 its use in adult patients with high-risk steroid-refractory aGVHD.

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

- The Phase 2 trial of Mesoblast's intravenous product candidate, MPC-300-IV, in biologic refractory rheumatoid arthritis has completed enrollment and results of the 12 week primary endpoint were released in August 2016. An intravenous infusion of allogeneic MPCs was well tolerated in biologic refractory RA patients, without serious adverse events over 12 weeks.

- A single intravenous MPC infusion in biologic refractory RA patients resulted in dose-related improvements in clinical symptoms, function, and disease activity, with the 2 million MPCs/kg dose providing the greatest benefit.

- The responses to date in this 48-patient, randomized, placebo-controlled Phase 2 trial provide support for the potential of Mesoblast's allogeneic MPCs to be positioned early as a treatment option in RA patients who have previously received a prior anti-TNF or other biologic agent.

- Given the large market opportunity, the Company believes that MPC-300-IV is well-positioned to advance through a strategic partnership into Phase 3 development for biologic refractory rheumatoid arthritis.

- With respect to other indications of the MPC-300-IV product candidate, positive results from the randomized, placebo-controlled Phase 2 trial of MPC-300-IV in patients with diabetic nephropathy were published in the peer-reviewed journal *EBioMedicine.*

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

- More than 300 patients have been enrolled to date in the Phase 3 trial evaluating MPC-150-IM in advanced CHF patients. After reviewing patient data in April and October 2016, the trial's DSMB has maintained its recommendation that the study should continue as planned.

- The 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 control.

- Based on observed HF-MACE event rates in the trial to date, the Company has decided to bring forward to Q1 CY2017 a previously planned Interim Analysis to assess the trial's primary endpoint.

MPC-06-ID for chronic low back pain:

- The current 360 patient Phase 3 trial is actively recruiting across US sites.

- 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.

Vice Chair: Mr William (Bill) A. Burns, former CEO of Roche Pharmaceuticals was appointed Vice Chair of Mesoblast after serving as a Mesoblast Non-Executive Director since 2014. In this new role, he will focus his considerable pharmaceutical industry expertise on activities relating to execution of major strategic partnerships and corporate transactions.

Intellectual Property: The Company's intellectual property portfolio was further strengthened by the granting of a key patent by the United States Patent and Trademark Office covering the use of its MPCs in the treatment of rheumatic diseases.

Upcoming Milestones

- During the first half of CY2017, the Company expects to have interim analyses from its Phase 3 trials in advanced heart failure and chronic low back pain trials, and to complete enrollment in the Phase 3 acute graft versus host disease trial.

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- The Company is in advanced discussions to establish potential strategic partnerships to commercialize its lead products.

Financial Results for the Three Months Ended September 30, 2016 (first quarter) (in U.S. Dollars)

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

- **Research and Development:** Research and development (R&D) expenses increased by $2.9 million. This increase was driven by increased costs for the MPC-150-IM chronic heart failure product. Within R&D expenses, labor costs have been reduced through a 28% reduction in FTEs from a labor restructure, as well as additional cost reductions in consultancy and travel. Additionally there has been a reduction in certain clinical trial costs due to the completion of enrollment for the Company's heart attack study using MPC-25-IC, and the deprioritization of the previously-specified Tier 2 clinical programs.

- **Manufacturing Commercialization:** Manufacturing commercialization expenses were $3.3 million for the first quarter of FY2017 compared with $6.2 million for the first quarter of FY2016, a decrease of $2.9 million as the Company had sufficient clinical grade product on hand to enable it to manage costs by reducing the number of production runs in the period.

- **Revenue:** The decrease in revenue for the first quarter of FY2017 compared with the first quarter of FY2016 was due to a decrease in non-cash commercialization revenue, as the Company had fully recognized its remaining deferred revenue balance for its MPC-150-IM product in June 2016, and to having received a one-time milestone payment for TEMCELL® HS Inj. in the first quarter of FY2016.

The overall increase in loss before income tax also includes movements in other items which did not impact the Company's current cash reserves, such as: remeasurement of contingent consideration, R&D tax incentive revenue and foreign exchange movements within other operating income and expenses.

Conference Call Details

Australia: 9:00 am AEDT on Tuesday, November 15, 2016

T: 1800 558 698 and 1800 809 971 (toll-free Australia)

USA: 5:00 pm ET on Monday, November 14, 2016
T: 1855 8811 339 (toll-free US)

Ex USA and Australia: +612 9007 3187

Passcode: 912575

The live webcast can be accessed via
http://webcasting.boardroom.media/broadcast/58214386d5f1311b35bd36a6

The archived webcast will be available in the Events and Presentations section of the Investor page in the Mesoblast website.

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.

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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.

For further information, please contact:

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Consolidated Income Statement

(in thousands, except per share amount)	Note	Three Months Ended September 30, 2016	2015
Revenue	3	395	7,513
Research & development		(14,004)	(11,089)
Manufacturing commercialization		(3,295)	(6,203)
Management and administration		(5,459)	(5,535)
Fair value remeasurement of contingent consideration		24	3,729
Other operating income and expenses		473	849
Finance costs		(1,037)	(2,424)
Loss before income tax	3	**(22,903)**	**(13,160)**
Income tax benefit/(expense)	4	3,105	—
Loss attributable to the owners of Mesoblast Limited		**(19,798)**	**(13,160)**
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:		**Cents**	**Cents**
Basic - losses per share		(5.24)	(3.94)
Diluted - losses per share		(5.24)	(3.94)

Consolidated Statement of Comprehensive Income

(in thousands)	Note	Three Months Ended September 30, 2016	2015
(Loss)/profit for the year		**(19,798)**	**(13,160)**
Other comprehensive income			
Items that may be reclassified to profit and loss			
Changes in the fair value of available-for-sale financial assets		31	—
Exchange differences on translation of foreign operations		703	(3,593)
Other comprehensive (loss)/income for the period, net of tax		**734**	**(3,593)**
Total comprehensive (loss)/income is attributable to the owners of Mesoblast Limited		**(19,064)**	**(16,753)**

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Consolidated Statement of Balance Sheet

(in thousands)	Note	As of September 30, 2016	As of June 30, 2016
Assets			
Current Assets			
Cash & cash equivalents	5(a)	60,355	80,937
Trade & other receivables	5(b)	4,583	4,054
Prepayments	5(b)	5,759	3,832
Total Current Assets		**70,697**	**88,823**
Non-Current Assets			
Property, plant and equipment		2,925	3,063
Available-for-sale financial assets	5(d)	1,997	1,966
Other non-current assets		2,362	2,343
Intangible assets	6(a)	587,463	587,823
Total Non-Current Assets		**594,747**	**595,195**
Total Assets		**665,444**	**684,018**
Liabilities			
Current Liabilities			
Trade and other payables	5(c)	28,119	27,155
Provisions		3,202	2,260
Total Current Liabilities		**31,321**	**29,415**
Non-Current Liabilities			
Deferred tax liability	6(b)	59,588	62,693
Provisions		64,663	63,749
Total Non-Current Liabilities		**124,251**	**126,442**
Total Liabilities		**155,572**	**155,857**
Net Assets		**509,872**	**528,161**
Equity			
Issued Capital	8	770,289	770,272
Reserves		27,468	25,976
(Accumulated losses)/retained earnings		(287,885)	(268,087)
Total Equity		**509,872**	**528,161**

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Consolidated Statement of Cash Flows

(in thousands)	Note	Three months ended September 30, 2016	2015
Cash flows from operating activities			
Commercialization revenue received		361	—
Payments to suppliers and employees (inclusive of goods and services tax)		(21,369)	(28,355)
Interest received		181	288
Net cash (outflows) in operating activities	7(b)	**(20,827)**	**(28,067)**
Cash flows from investing activities			
Payments for investments		—	(805)
Payments for licenses		—	(200)
Investment in fixed assets		(290)	(502)
Net cash (outflows) in investing activities		**(290)**	**(1,507)**
		—	
Cash flows from financing activities			
Proceeds from issue of shares		—	169
Payments for share issue costs	8	(55)	—
Net cash (outflows) / inflows by financing activities		**(55)**	**169**
Net (decrease)/increase in cash and cash equivalents		(21,172)	(29,405)
Cash and cash equivalents at beginning of period		80,937	110,701
FX (losses)/gains on the translation of foreign bank accounts		590	(3,535)
Cash and cash equivalents at end of period	7(a)	**60,355**	**77,761**

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