asx announcement

mesoblast
the regenerative medicine company

MESOBLAST REPORTS ON FIRST HALF AND SECOND QUARTER FINANCIAL RESULTS

Melbourne, Australia (17 February 2016); and New York, USA (16 February 2016): Mesoblast Limited (ASX: MSB; Nasdaq: MESO) today reported financial results and operational highlights for the 1H/2Q ended 31 December 2015.

Financial Highlights (USD)

At 31 December 2015, the Company had cash reserves of $120.8 million.

Operating cash outflow for the second quarter of 2016 was US$19.8 million, a reduction of over 25% in comparison to the first quarter of 2016 (US$28.1 million) and the fourth quarter of 2015 (US$27.3 million). This reduction was implemented in line with previous guidance regarding fiscal control measures designed to reduce quarterly cash burn by approximately 20-25%.

For the six months ended 31 December 2015, the Company's loss before income tax improved by 18% ($7.9 million) as compared to the comparative period in FY2015. This improvement was principally due to a 23% reduction in research and development expenditure and a 22% reduction in management and administration expenditure.

Operational Highlights

- Recruitment of all three Tier 1 Phase 3 Clinical trials is progressing well across sites in the United States, including MPC-150-IM for Chronic Heart Failure (CHF), MPC-06-ID for Chronic Low Back Pain (CLBP), and MSC-100-IV for Acute Graft Versus Host Disease (aGVHD) in children.

- MPC-150-IM: Phase 3 trial size was significantly reduced from 1,165 to approximately 600 subjects following communications between our commercial partner, Teva Pharmaceutical Industries Ltd., and the United States Food and Drug Administration (FDA).

    - Phase 3 trial is targeting patients with advanced heart failure and high rates of hospitalization or death, a significant unmet need

    - Updated timelines for this trial will be provided in conjunction with Teva

- Mesoblast's licensee in Japan, JCR Pharmaceuticals Co. Ltd., received full approval for the first allogeneic regenerative medicine in Japan, TEMCELL® HS Inj. for aGVHD in children and adults.

    - Licensee JCR Pharmaceuticals Co. expected to launch TEMCELL® HS Inj. in Japan in the first quarter of the 2016 calendar year.

    - Japan's National Health Insurance (NHI) has set reimbursement for TEMCELL® HS Inj. at ¥868,680 (US$7,200) for 72 million cells.

    - A four-week, multi-dose treatment course of TEMCELL for an average adult is expected to be reimbursed at ¥13,898,880 (US$115,000), or at ¥20,848,320 (US$172,000) if symptoms persist and additional dosing is required.

    - Mesoblast is entitled to receive royalties and other payments at pre-defined thresholds of net sales.

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- MPC-300-IV: top-line results released from the first cohort of Phase 2 trial in rheumatoid arthritis (RA) patients who have previously failed one or more biologic agents. Results show that a single intravenous infusion of the lower dose of MPC-300-IV was safe and resulted in early and sustained clinical responses.

- Phase 2 trial results in CHF and Type 2 Diabetes published in leading peer reviewed journals, Circulation Research and Diabetes Care, respectively.

Financial Results for the three months ended 31 December 2015 (the second quarter) (USD)

- **Revenue:** Revenue was $4.0 million for the second quarter of 2016 compared with $4.4 million for the second quarter of 2015, a decrease of $0.4 million. This decrease was primarily due to a decrease in interest income as the result of increased proportion of cash reserves held in U.S. dollars in line with our needs ensuring currency risk is mitigated.

- **Research and Development:** Research and development (R&D) expenses were $12.5 million for the second quarter of 2016 compared with $17.8 million for the second quarter of 2015, a decrease of $5.3 million. This decrease primarily reflects a reduction in expenditures of our Tier 2 products and product support costs as management reduced costs in line with our corporate strategy.

- **Manufacturing Commercialization:** Manufacturing commercialization expenses were $8.1 million for the second quarter of 2016 compared with $5.6 million for the second quarter of 2015, an increase of $2.5 million. This increase was primarily driven by increased Phase 3 clinical supply demands.

- **Management and Administration:** Management and administration expenses were $5.7 million for the second quarter of 2016 compared with $7.5 million for the second quarter of 2015, a decrease of $1.8 million. This decrease was primarily due to lower share based payment expenses and favourable exchange rate movements as the U.S. dollar strengthened against the Australian dollar. The majority of management and administration expenses were incurred in Australian dollars.

- **Net Loss:** Loss attributable to ordinary shareholders was $22.3 million, or 6.29 cents per share, for the second quarter of 2016, compared with $27.9 million, or 8.78 cents per share, for the second quarter of 2015.

Financial Results for the six months ended 31 December 2015 (the half-year) (USD)

- **Revenue:** Revenue was $11.5 million for the half-year of 2016 compared with $11.3 million for the half-year of 2015, an increase of $0.2 million. This increase was due to increased milestone revenue recognised in the half-year as a $3.5 million milestone revenue was recognised in the half-year of 2016 for the regulatory approval of MSC product TEMCELL® in Japan, compared to a $2.0 million milestone revenue being recognised in the half-year 2015 for marketing approval for TEMCELL® in Japan.

- **Research and Development:** Research and development (R&D) expenses were $23.6 million for the half-year of 2016 compared with $30.7 million for the half-year of 2015, a decrease of $7.1 million. This decrease primarily reflects a reduction in expenditures of our Tier 2 products and product support costs as management reduced costs in line with our corporate strategy.

- **Manufacturing Commercialization:** Manufacturing commercialization expenses were $14.3 million for the half-year of 2016 compared with $11.4 million for the half-year of 2015, an increase of $2.9 million. This increase was primarily driven by increased Phase 3 clinical supply demands.

- **Management and Administration:** Management and administration expenses were $11.3 million for the half-year of 2016 compared with $14.5 million for the half-year of 2015, a decrease of $3.2 million. This decrease was primarily due to lower share based payment expenses and favourable exchange rate movements as the U.S. dollar strengthened against the Australian dollar. The majority of management and administration expenses were incurred in Australian dollars.

- **Net Loss:** Loss attributable to ordinary shareholders was $35.5 million, or 10.31 cents per share, for the half-year of 2016, compared with $43.4 million, or 13.68 cents per share, for the half-year of 2015.

2016 Financial Guidance

Mesoblast maintains last quarter's guidance, namely that quarterly operating cash burn will reduce by approximately 20-25% in comparison with Q1 FY2016 / Q4 FY2015 while still achieving timelines for important value inflexion points for our heart failure, back pain and rheumatoid arthritis programs, and to file with the FDA for approval of our pediatric graft versus host disease product candidate.

Conference Call Details

Australia: 9:00 am AEDT on Wednesday, 17 February 2016 1800-005-989 (toll-free Australia)

USA: 5:00 pm ET on Tuesday, 16 February 2016 877-456-0438 (toll-free US)

Ex USA and Australia: +1 262-558-6163

Passcode: 49888069

The live webcast can be accessed by clicking here, or by clicking here.

The archived webcast will be available in the Events and Presentations section of the Investor page on the Mesoblast website http://investorsmedia.mesoblast.com/phoenix.zhtml?c=187006&p=irol-calendar

About Mesoblast

Mesoblast Limited (ASX: MSB; Nasdaq: MESO) is a world leader in developing innovative cellular medicines. We have established what we believe is the industry's most clinically advanced and diverse portfolio of cell-based products with five programs, two of which are partnered, in active Phase 3 clinical studies or Phase 3-ready, and four programs in Phase 2. All our clinical programs target significant, under-served therapeutic areas including cardiac diseases, spine orthopedic disorders, oncology and hematology diseases, and immune-mediated and inflammatory conditions.

Forward Looking Statements

This press release contains forward-looking statements which are subject to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements are based on estimates and information available to us at the time of this press release and are not guarantees of future performance. Statements in this release involve risks, uncertainties and assumptions. If the risks or uncertainties ever materialize or the assumptions prove incorrect, our results may differ materially from those expressed or implied by such forward-looking statements. All statements other than statements of historical fact could be deemed forward-looking statements, including, but not limited to: the initiation, timing, progress and results of our preclinical and clinical studies, and our research and development programs; our ability to advance product candidates into, enroll and successfully complete, clinical studies, including multi-national clinical trials; our ability to advance our manufacturing capabilities; the timing or likelihood of regulatory filings and approvals, manufacturing activities and product marketing activities, if any; the commercialization of our product candidates, if approved; regulatory or public perceptions and market acceptance surrounding the use of stem-cell based therapies; the potential for our 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 our ability to enter into and maintain established strategic collaborations; our ability to establish and maintain intellectual property on our product candidates and our ability to successfully defend these in cases of alleged infringement; the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology; estimates of our expenses, future revenues, capital requirements and our needs for additional financing; our financial performance; developments relating to our competitors and our industry; and the pricing and reimbursement of our product candidates, if approved.

Additional risks and uncertainties that could affect Mesoblast's financial results are included under the captions "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in the Mesoblast's most recent filings with the SEC, which are available on Mesoblast's website at http://www.mesoblast.com in the Investors and Media section and on the SEC's website at www.sec.gov. Additional information will also be set forth in other filings that the Company makes with the SEC from time to time. All forward-looking statements in this press release are based on information available to the Company as of the date hereof, and Mesoblast does not assume any obligation to update the forward-looking statements provided to reflect events that occur or circumstances that exist after the date on which they were made.

For further information, please contact:

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Consolidated Income Statement (unaudited)

(US dollars in thousands, except per share amounts)	Three Months Ended 31 December		Six Months Ended 31 December	
	2015	2014	2015	2014
Revenue	**4,014**	**4,377**	**11,527**	**11,344**
Research and development	(12,515)	(17,839)	(23,604)	(30,732)
Manufacturing commercialization	(8,118)	(5,551)	(14,321)	(11,450)
Management and administration	(5,716)	(7,546)	(11,251)	(14,486)
Fair value remeasurement of contingent consideration	541	(2,834)	4,271	(4,482)
Other operating income and expenses	1,495	4,173	2,343	10,978
Finance costs	(2,026)	(2,662)	(4,450)	(4,597)
Loss before income tax	**(22,325)**	**(27,882)**	**(35,485)**	**(43,425)**
Income tax expense	-	-	-	-
Loss attributable to the owners of Mesoblast Limited	**(22,325)**	**(27,882)**	**(35,485)**	**(43,425)**
Losses per share attributable to the ordinary equity holders of the Group:	**Cents**	**Cents**	**Cents**	**Cents**
Basic – losses per share	(6.29)	(8.78)	(10.31)	(13.68)
Diluted – losses per share	(6.29)	(8.78)	(10.31)	(13.68)

Consolidated Statement of Comprehensive Income (unaudited)

(in thousands)	Three Months Ended 31 December		Six Months Ended 31 December	
	2015	2014	2015	2014
Loss for the period	**(22,325)**	**(27,882)**	**(35,485)**	**(43,425)**
Other comprehensive income/(loss)				
Items that may be reclassified to profit and loss				
Changes in the fair value of available-for-sale financial assets	(185)	-	(185)	-
Exchange differences on translation of foreign operations	1,742	(8,310)	(1,851)	(19,624)
Income tax relating to these items	-	-	-	-
Other comprehensive income /(loss) for the period, net of tax	**1,557**	**(8,310)**	**(2,036)**	**(19,624)**
Total comprehensive loss attributable to the owners of Mesoblast Limited	**(20,768)**	**(36,192)**	**(37,521)**	**(63,049)**

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Consolidated Balance Sheet
(unaudited)

(US dollars - in thousands)	As of 31 December 2015	As of 30 June 2015
Assets		
Current assets		
Cash and cash equivalents	120,783	110,701
Trade and other receivables	7,833	3,972
Prepayments	3,903	7,787
Total current assets	**132,519**	**122,460**
Non-current assets		
Property, plant and equipment	3,742	4,398
Available-for-sale financial assets	2,115	2,300
Other non-current assets	2,331	2,367
Intangible assets	650,246	650,241
Total non-current assets	**658,434**	**659,306**
Total assets	**790,953**	**781,766**
Liabilities		
Current liabilities		
Trade and other payables	23,980	28,242
Deferred revenue	15,004	15,004
Provisions	2,695	5,161
Total current liabilities	**41,679**	**48,407**
Non-current liabilities		
Deferred revenue	15,003	22,505
Deferred tax liability	149,387	149,387
Provisions	92,130	93,480
Total non-current liabilities	**256,520**	**265,372**
Total liabilities	**298,199**	**313,779**
Net assets	**492,754**	**467,987**
Equity		
Issued capital	768,832	709,191
Reserves	23,367	22,756
Accumulated losses	(299,445)	(263,960)
Total equity	**492,754**	**467,987**

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Consolidated Statement of Cash Flows
(unaudited)

	Six months Ended 31 December	
(in thousands)	**2015**	**2014**
Cash flows from operating activities		
Milestone payment received	3,500	2,000
Research and development tax incentive received	-	1
Payments to suppliers and employees (inclusive of goods and services tax)	(51,881)	(54,849)
Interest received	508	2,163
Income taxes (paid)/refunded	-	(67)
Net cash (outflows) in operating activities	**(47,873)**	**(50,752)**
Cash flows from investing activities		
Payments for financial derivatives	-	(851)
Payments for investments	(805)	-
Payments for licenses	(200)	(70)
Investment in fixed assets	(613)	(1,730)
Net cash (outflows) in investing activities	**(1,618)**	**(2,651)**
Cash flows from financing activities		
Proceeds from issue of shares	68,549	990
Payments for share issue costs	(6,618)	-
Net cash inflows by financing activities	**61,931**	**990**
Net (decrease)/increase in cash and cash equivalents	12,440	(52,413)
Cash and cash equivalents at beginning of period	110,701	185,003
FX (losses)/gains on the translation of foreign bank accounts	(2,358)	(10,220)
Cash and cash equivalents at end of period	**120,783**	**122,370**