asx announcement

mesoblast
the regenerative medicine company

MESOBLAST PROVIDES STRATEGIC UPDATE AND REPORTS ON FIRST QUARTER FINANCIAL RESULTS

Materially Strengthened Cash Reserves

First Royalties From TEMCELL Product Sales Expected In Q1 2016

Resources Prioritized On Tier 1 Product Candidates

Cash Managed To Extend Runway And Achieve Tier 1 Value Inflexion Points

Major Focus Is FDA Filing For Our First US Product Approval In Acute Graft Versus Host Disease

Melbourne, Australia; and New York, USA; 17 December 2015: Mesoblast Limited (ASX: MSB; Nasdaq: MESO) today reported first quarter 2016 results for the three months ended 30 September 2015 and provided a corporate update. At 30 September 2015, the Company had cash reserves of $77.8 million. This was further augmented by $63.5 million net proceeds raised in a public financing in November.

“We are entering 2016 with a clear strategy, strong balance sheet, and focus on cost-effective delivery of our tier 1 product candidates,” said Silviu Itescu, CEO of Mesoblast.

“We have materially strengthened our cash position, and at the same time implemented tight fiscal control that will result in a reduction of approximately 20-25% of quarterly operating cash burn in comparison with the last 2 quarters (Q1 FY2016 / Q4 FY2015).

“As a result, we have sufficient runway to deliver on 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.

“Mesoblast’s visibility and liquidity will increase in the largest market for biotech companies as a result of our US listing.

“In addition, we intend to conclude additional and appropriate strategic partnerships,” Itescu said.

Financial Highlights

As of 30 September 2015, the Company had cash and cash equivalents of $77.8 million. A further net $63.5 million was raised as a result of the recent US listing and financing.

Loss after income tax was reduced by 15% ($2.3 million): $13.2 million for the three months ended 30 September 2015 compared with $15.5 million for the three months ended 30 September 2014. This included 20% ($1.4 million) reduction in management and administration costs and 14% ($1.8 million) lower expenditure in research and development.

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Recent Highlights

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

- 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.

Upcoming Milestones During The Next 12 Months

Mesoblast expects to make significant advances in the next 12 months towards commercialization of its late stage, Tier 1 product candidates.

- In the coming weeks, Mesoblast expects to announce top-line results from the first cohort in the Phase 2 trial of our product candidate for biologic-refractory rheumatoid arthritis. Full trial results, including the second cohort, are expected during the first half of 2016.

- During the first quarter of 2016, the Company anticipates that its licensee will launch TEMCELL, its mesenchymal stem cell product for aGVHD in Japan.

- During the first quarter of 2016, Mesoblast expects to announce the outcome of the first interim analysis of safety and efficacy from a Phase 3 trial of its product candidate for advanced chronic heart failure with its development and commercial partner, Teva Pharmaceutical Industries Ltd.

- During the third quarter of 2016, the Company expects to announce top-line results from an interim analysis of a Phase 3 trial of its product candidate for steroid refractory aGVHD. We expect to complete recruitment of this Phase 3 trial and to have top-line results in the fourth quarter 2016, and full results of the trial to be released in the first quarter 2017. A positive interim analysis may support a 2016 filing with the FDA for product approval.

- During the third quarter of 2016, enrollment of the first Phase 3 trial of our product candidate for chronic low back pain due to degenerative disc disease is expected to be completed.

Financial Results for the Three Months Ended 30 September 2015

Revenues were $7.5 million for the three months ended 30 September 2015, compared with $7.0 million in the same period in 2014, an increase of $0.5 million. The Company recorded $3.5 million in milestone revenue in the three months ended 30 September 2015. In the same period in 2014, Mesoblast received milestone revenue of $2.0 million.

Commercialization revenue of $3.8 million in the three months ended 30 September 2015 was unchanged compared with the three months ended 30 September 2014.

Interest revenue decreased $1.0 million in the three months ended 30 September 2015 when compared to the same period in 2014 as a result of decreased cash reserves and by the Company retaining a higher proportion of cash reserves in US$ compared with A$ in the three months ended 30 September 2015, when compared with the three months ended 30 September 2014.

Research and development expenses were $11.1 million for the three months ended 30 September 2015, compared with $12.9 million for the three months ended 30 September 2014, a decrease of $1.8 million. This decrease in research and development expenses reflects a reduction in expenditures in our Tier 2 products and product support costs.

Manufacturing commercialization expenses, which consist of fees paid to contract manufacturing organizations and laboratory supplies used in manufacturing commercialization of our mesenchymal lineage cell product candidates, increased by $0.3 million for the three months ended 30 September 2015 compared to the three months ended 30 September 2014. This rise was due to an increase in the number of production runs to meet the clinical supply demands of our Tier 1 products. The manufacturing program continues to represent a significant commitment by the Company.

Management and administration expenses were $5.5 million for the three months ended 30 September 2015, compared with $6.9 million for the three months ended 30 September 2014, a decrease of 20% or $1.4 million. The decrease was driven by management restraining such costs and benefits from exchange rate fluctuations as the US$ strengthened.

Conference Call Details

Mesoblast will host a conference call beginning at 5:00pm Eastern Time on Wednesday 16 December/ 9:00 am Australian Eastern Daylight Time on Thursday 17 December. To access the call, please dial 855-298-3404 (toll-free US), 1800-801-825 (toll-free Australia) or +1 631-514-2526 (outside of the US). The passcode is 6205376. A live webcast will be available through http://investorsmedia.mesoblast.com/phoenix.zhtml?c=187006&p=irol-calendar. The conference call will be accompanied by a slide presentation. The archived webcast will be available in the Events and Presentations section of the Company's website.

About Mesoblast

Mesoblast Limited (ASX: MSB; Nasdaq: MESO) is a global leader in 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 where there are highly unmet medical needs, including cardiovascular conditions, orthopedic disorders, immunologic and inflammatory disorders and oncology/hematology 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.

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Consolidated Income Statement
(unaudited)

(in thousands, except per share amounts)	Three Months Ended September 30,	
	2015	2014
Revenue	7,513	6,967
Research and development	(11,089)	(12,893)
Manufacturing commercialization	(6,203)	(5,899)
Management and administration	(5,535)	(6,942)
Fair value remeasurement of contingent consideration	3,729	(1,648)
Other operating income and expenses	849	6,806
Finance costs	(2,424)	(1,936)
Loss before income tax	(13,160)	(15,545)
Income tax expense	-	-
Loss attributable to the owners of Mesoblast Limited	(13,160)	(15,545)
Losses per share attributable to the ordinary equity holders of the Group:	Cents	Cents
Basic – losses per share	(3.94)	(4.90)
Diluted – losses per share	(3.94)	(4.90)

Due to recent developments in the business, including listing on the NASDAQ and changing our presentation currency from AUD to USD a wider review was triggered on the presentation of our recently completed financial results. The Company therefore performed a benchmarking study against other seasoned filers to understand best practice in presenting financial information to the users of the financial statements.

The impact of this analysis was to collapse Other Income with Other Expenses into one line item 'Other operating income and expenses' and present all fair value measurements of contingent consideration within one line item 'Fair value remeasurement of contingent consideration' within the Consolidated Income Statement.

(in thousands)	Three Months Ended September 30,	
	2015	2014
Loss for the period	(13,160)	(15,545)
Other comprehensive income/(loss)		
Items that may be reclassified to profit and loss		
Exchange differences on translation of foreign operations	(3,593)	(11,314)
Income tax relating to these items	-	-
Other comprehensive income /(loss) for the period, net of tax	(3,593)	(11,314)
Total comprehensive loss attributable to the owners of Mesoblast Limited	(16,753)	(26,859)

Consolidated Balance Sheet

(unaudited) (in thousands)	As of September 30, 2015	As of June 30, 2015
Assets		
Current assets		
Cash and cash equivalents	77,761	110,701
Trade and other receivables	8,371	3,972
Prepayments	7,872	7,787
Total current assets	94,004	122,460
Non-current assets		
Property, plant and equipment	3,990	4,398
Available-for-sale financial assets	2,300	2,300
Other non-current assets	2,302	2,367
Intangible assets	650,271	650,241
Total non-current assets	658,863	659,306
Total assets	752,867	781,766
Liabilities		
Current liabilities		
Trade and other payables	23,558	28,242
Deferred revenue	15,004	15,004
Provisions	1,838	5,161
Total current liabilities	40,400	48,407
Non-current liabilities		
Deferred revenue	18,754	22,505
Deferred tax liability	149,387	149,387
Provisions	91,500	93,480
Total non-current liabilities	259,641	265,372
Total liabilities	300,041	313,779
Net assets	452,826	467,987
Equity		
Issued capital	709,593	709,191
Reserves	20,353	22,756
Accumulated losses	(277,120)	(263,960)
Total equity	452,826	467,987

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