asx announcement

mesoblast
the regenerative medicine company

MESOBLAST FINANICAL RESULTS FOR THE QUARTER ENDED SEPTEMBER 30, 2019

Continued Increase in Revenues and Strong Balance Sheet

Melbourne, Australia, November 26, 2019 and New York, USA, November 25, 2019: Mesoblast Limited (ASX:MSB; Nasdaq:MESO) today reported operational highlights and financial results for the first quarter ended September 30, 2019.

Mesoblast Chief Executive Dr Silviu Itescu stated: "The Company's financial results for the quarter reflect continued growth in revenues from product sales in Japan and ongoing strategic partnering activities, and a reduction in R&D expenditures. Our balance sheet positions us well as we prepare for first product approval and launch in the United States market."

Financial Highlights for the First Quarter FY2020

- 46% growth in revenues due to:
    - 43% increase in milestone revenues from strategic partnerships (US$15.0 million compared with US$10.5 million for the first quarter of FY2019).
    - 85% growth in revenues from sales of TEMCELL®[1] HS. Inj. by Mesoblast's licensee for steroid-refractory acute graft versus host disease (aGVHD) in Japan compared to the first quarter of FY2019.
- 72% reduction in loss after tax compared to the first quarter FY2019 (US$5.5 million compared with US$19.5 million) driven by:
    - 33% decrease in research and development spend (US$12.4 million compared with US$18.5 million for the first quarter FY2019).
    - 46% increase in revenues from milestones and commercialization, as noted above.
- At September 30, 2019, cash on hand was US$34.5 million and pro forma cash on hand was US$100.0 million. Pro forma cash on hand has been adjusted for US$15.0 million upfront received on October 1, 2019 from Grünenthal GmbH and US$50.5 million of gross cash proceeds from the capital raise on October 3, 2019.
- Over the coming 12 months, Mesoblast may have access to an additional US$65.0 million in non-dilutive capital under existing strategic partnerships and financial arrangements.

Operational Highlights for the First Quarter FY2020

- The continued growth in commercialization revenues reflects successful aGVHD market adoption in Japan and provides insight into the projected uptake of our product candidate remestemcel-L for aGVHD in the United States.
- In October, Mesoblast entered into an agreement with Lonza for commercial product manufacture in line with the corporate strategy to facilitate appropriate inventory build ahead of the planned launch of remestemcel-L.
- Mesoblast entered into a strategic partnership with Grünenthal, a global leader in pain management, to develop and commercialize MPC-06-ID, Mesoblast's Phase 3 allogeneic product candidate for the treatment of chronic low back pain due to degenerative disc disease. Under the partnership, Grünenthal will have exclusive commercialization rights to MPC-06-ID for Europe and Latin America.

Mesoblast Limited
ABN 68 109 431 870
www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
Melbourne 3000
Victoria Australia
T +61 3 9639 6036
F +61 3 9639 6030

United States Operations
505 Fifth Avenue
Third Floor
New York, NY 10017
USA
T +1 212 880 2060
F +1 212 880 2061

Asia
21 Biopolis Road
#01-22 Nucleos (South Tower)
SINGAPORE 138567
T +65 6570 0635
F +65 6570 0176

- Under the Grünenthal agreement, Mesoblast will receive up to US$150 million in upfront and milestone payments prior to product launch, as well as further commercialization milestone payments. Cumulative milestone payments could exceed US$1 billion depending on the outcome of Phase 3 studies and patient adoption. Mesoblast will also receive tiered double-digit royalties on product sales.

- Mesoblast and the International Center for Health Outcomes Innovation Research (InCHOIR) at the Icahn School of Medicine at Mount Sinai in New York have agreed on the protocol for a confirmatory Phase 3 trial of Revascor in the treatment of patients with end-stage heart failure and a left ventricular assist device (LVAD), in line with US Food and Drug Administration (FDA) guidance on a primary endpoint of reduction in major mucosal bleeding events, and key secondary endpoints demonstrating improvement in various parameters of cardiovascular function.

- Revascor is being developed for these patients under existing FDA Regenerative Medicine Advanced Therapy (RMAT) and Orphan Drug Designations.

Key Milestones

Remestemcel-L for aGVHD

- Upcoming filing of the completed Biologic License Application (BLA) submission to the US Food and Drug Administration (FDA).

- Within a maximum of 60 days after receipt of the complete application, Mesoblast will be informed by FDA of acceptance of the filing, and whether the BLA has received Priority Review under its existing Fast Track designation.

- If approved, the US launch of remestemcel-L is expected to occur next year.

Revascor for advanced and end-stage heart failure

- Full accrual of primary endpoints events in the Phase 3 trial of Revascor for advanced heart failure around the end of this year.

- Data read-out for this Phase 3 trial planned in H1 CY20.

- Results will be considered pivotal to support regulatory approval in the US, as well as China through the Tasly partnership.

- Initiation of confirmatory Phase 3 trial of Revascor for the reduction of mucosal bleeding in end-stage heart failure patients implanted with an LVAD.

MPC-06-ID for chronic low back pain

- Last patient last visit at 24-months of follow up in the Phase 3 trial of MPC-06-ID for chronic low back pain H1 CY20, with the primary endpoint being a composite outcome of pain and function at 12 and 24 months.

- Results will be considered pivotal to support regulatory approval in the US, as well as Europe through the Grünenthal partnership.

Strategic partnerships

- In active discussions to enter into further global and regional strategic partnering transactions.[2]

Financial Results for the Three Months Ended September 30, 2019 (first quarter FY2020)

Loss after tax reduced by US$14.0 million to US$5.5 million for the first quarter FY2020 compared to US$19.5 million for the first quarter FY2019 as detailed below:

- **Revenues** increased US$5.4 million to US$17.0 million for the first quarter FY2020, compared to US$11.6 million for the first quarter FY2019.
    - Milestone revenues increased by US$4.5 million as we recognized the up-front milestone payment of US$15.0 million for the strategic partnership with Grünenthal in first quarter FY2020. In the first quarter of FY2019 we recognized US$10.0 million of milestone revenue in relation to establishing a partnership with Tasly in China and US$0.5 million of cumulative sales milestones for sales of TEMCELL in Japan.
    - Royalty revenue on sales of TEMCELL in Japan increased US$0.9 million (85%) to US$1.9 million for the first quarter FY2020 compared with US$1.0 million for the first quarter FY2019.
- **Research and Development** expenses decreased by US$6.1 million to US$12.4 million for the first quarter FY2020, compared to US$18.5 million for the first quarter FY2019. This US$6.1 million decrease was due to a reduction in third party costs for our Phase 3 clinical trials as enrollment is now complete and activities are decreasing.
- **Manufacturing** expenses decreased by US$1.6 million to US$2.7 million for the first quarter FY2020, compared to US$4.3 million for the first quarter FY2019 due to a reduction in manufacturing activities related to filing the Biologics License Application (BLA) for remestemcel-L.
- **Management and Administration** expenses decreased US$0.1 million to US$5.5 million for the first quarter FY2020, compared with US$5.6 million for the first quarter FY2019.
- **Finance Costs** for our borrowing arrangements with Hercules and NovaQuest were US$3.5 million for the first quarter FY2020, compared to US$2.7 million for the first quarter FY2019, an increase of US$0.8 million.
- **Income tax benefit** increased by US$1.2 million to US$1.9 million in the first quarter FY2020, compared with US$0.7 million in the first quarter FY2019 in relation to deferred tax liabilities recognized on the balance sheet during the period.

The net loss attributable to ordinary shareholders was 1.10 cents per share for the first quarter FY2020, compared with 4.07 cents for the first quarter FY2019.

Cash on hand was US$34.5 million at September 30, 2019, pro forma cash on hand was US$100.0 million after adjusting for US$15.0 million upfront received on October 1, 2019 from Grünenthal GmbH and US$50.5 million of gross cash proceeds from the capital raise on October 3, 2019.

Webcast

There will be a webcast today on the financial results beginning at 8.30am on Tuesday November 26, 2019 AEDT; 4.30pm Monday November 25, 2019 EST.

The live webcast can be accessed via
https://webcasting.boardroom.media/broadcast/5dcdf529dbec873524b6116b

The archived webcast will be available on the Investor page of the Company's website: www.mesoblast.com

1.TEMCELL HS. Inj.® is a registered trademark of JCR Pharmaceuticals Co. Ltd.
2. Mesoblast does not make any representation or give any assurance that such partnering transactions will be concluded

Mesoblast Limited
ABN 68 109 431 870
www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
Melbourne 3000
Victoria Australia
T +61 3 9639 6036
F +61 3 9639 6030

United States Operations
505 Fifth Avenue
Third Floor
New York, NY 10017
USA
T +1 212 880 2060
F +1 212 880 2061

Asia
21 Biopolis Road
#01-22 Nucleos (South Tower)
SINGAPORE 138567
T +65 6570 0635
F +65 6570 0176

About Mesoblast

Mesoblast Limited (ASX: MSB; Nasdaq: MESO) is a world leader in developing allogeneic (off-the-shelf) cellular medicines. The Company has leveraged its proprietary cell therapy technology platform to establish a broad portfolio of commercial products and late-stage product candidates. Two products have been commercialized in Japan and Europe by its licensees, and it has established commercial partnerships in Europe and China for certain Phase 3 assets. In the United States, Mesoblast has initiated submission of a rolling Biologics License Application to the FDA to seek approval of its product candidate for acute graft versus host disease following a successful Phase 3 trial, and is completing Phase 3 trials for its advanced heart failure and chronic low back pain product candidates. Mesoblast's proprietary manufacturing process yields industrial-scale, frozen, off-the-shelf, cellular medicines based on its mesenchymal lineage cell platform technology. These cell therapies, with defined pharmaceutical release criteria, are planned to be readily available to patients worldwide. Mesoblast has locations in Melbourne, New York, Singapore and Texas and is listed on the Australian Securities Exchange (MSB) and on the Nasdaq (MESO). For more information, please see www.mesoblast.com, LinkedIn: Mesoblast Limited and Twitter: @Mesoblast

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.

For further information, please contact:

Julie Meldrum
Corporate Communications
Mesoblast
T: +61 3 9639 6036
E: julie.meldrum@mesoblast.com

Schond Greenway
Investor Relations
Mesoblast
T: +1 212 880 2060
E: schond.greenway@mesoblast.com

Consolidated Income Statement

(in U.S. dollars, in thousands, except per share amount)	Three Months Ended September 30, 2019	2018
Revenue	17,048	11,637
Research & development	(12,389)	(18,489)
Manufacturing commercialization	(2,698)	(4,317)
Management and administration	(5,463)	(5,614)
Fair value remeasurement of contingent consideration	(288)	(622)
Other operating income and expenses	(169)	(151)
Finance costs	(3,457)	(2,653)
Loss before income tax	**(7,416)**	**(20,209)**
Income tax benefit	1,932	711
Loss attributable to the owners of Mesoblast Limited	**(5,484)**	**(19,498)**
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:	**Cents**	**Cents**
Basic - losses per share	(1.10)	(4.07)
Diluted - losses per share	(1.10)	(4.07)

Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	Three Months Ended September 30, 2019	2018
Loss for the period	**(5,484)**	**(19,498)**
Other comprehensive (loss)/income		
Items that may be reclassified to profit and loss		
Changes in the fair value of financial assets	(365)	87
Exchange differences on translation of foreign operations	(332)	(23)
Other comprehensive income/(loss) for the period, net of tax	**(697)**	**64**
Total comprehensive losses attributable to the owners of Mesoblast Limited	**(6,181)**	**(19,434)**

Mesoblast Limited
ABN 68 109 431 870
www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
Melbourne 3000
Victoria Australia
T +61 3 9639 6036
F +61 3 9639 6030

United States Operations
505 Fifth Avenue
Third Floor
New York, NY 10017
USA
T +1 212 880 2060
F +1 212 880 2061

Asia
21 Biopolis Road
#01-22 Nucleos (South Tower)
SINGAPORE 138567
T +65 6570 0635
F +65 6570 0176

Consolidated Balance Sheet

(in U.S. dollars, in thousands)	As of September 30, 2019	As of June 30, 2019
Assets		
Current Assets		
Cash & cash equivalents	34,536	50,426
Trade & other receivables	17,857	4,060
Prepayments	8,200	8,036
Total Current Assets	**60,593**	**62,522**
Non-Current Assets		
Property, plant and equipment	978	826
Right-of-use assets	4,233	—
Financial assets at fair value through other comprehensive income	1,952	2,317
Other non-current assets	3,299	3,324
Intangible assets	582,731	583,126
Total Non-Current Assets	**593,193**	**589,593**
Total Assets	**653,786**	**652,115**
Liabilities		
Current Liabilities		
Trade and other payables	12,740	13,060
Provisions	26,977	7,264
Borrowings	18,851	14,007
Lease liabilities	1,524	—
Deferred consideration	10,000	10,000
Total Current Liabilities	**70,092**	**44,331**
Non-Current Liabilities		
Deferred tax liability	9,195	11,124
Provisions	30,555	48,329
Borrowings	64,881	67,279
Lease liabilities	3,916	—
Total Non-Current Liabilities	**108,547**	**126,732**
Total Liabilities	**178,639**	**171,063**
Net Assets	**475,147**	**481,052**
Equity		
Issued Capital	910,942	910,405
Reserves	40,507	40,638
(Accumulated losses)/retained earnings	(476,302)	(469,991)
Total Equity	**475,147**	**481,052**

Mesoblast Limited
ABN 68 109 431 870
www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
Melbourne 3000
Victoria Australia
T +61 3 9639 6036
F +61 3 9639 6030

United States Operations
505 Fifth Avenue
Third Floor
New York, NY 10017
USA
T +1 212 880 2060
F +1 212 880 2061

Asia
21 Biopolis Road
#01-22 Nucleos (South Tower)
SINGAPORE 138567
T +65 6570 0635
F +65 6570 0176

Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	Three months ended September 30, 2019	2018
Cash flows from operating activities		
Commercialization revenue received	1,739	1,095
Milestone payment received	—	500
Research and development tax incentive received	1,499	1,654
Payments to suppliers and employees (inclusive of goods and services tax)	(17,539)	(22,039)
Interest received	173	136
Interest and other costs of finance paid	(1,427)	(887)
Income taxes (paid)/refunded	(3)	(3)
Net cash (outflows) in operating activities	**(15,558)**	**(19,544)**
Cash flows from investing activities		
Investment in fixed assets	(153)	(39)
Payments for licenses	(100)	—
Net cash (outflows)/inflows in investing activities	**(253)**	**(39)**
Cash flows from financing activities		
Proceeds from borrowings	—	28,950
Payments of transaction costs from borrowings	—	(1,534)
Proceeds from issue of shares	299	10,048
Payments for share issue costs	—	(358)
Payment of lease liabilities	(335)	—
Net cash inflows by financing activities	**(36)**	**37,106**
Net increase/(decrease) in cash and cash equivalents	(15,847)	17,523
Cash and cash equivalents at beginning of period	50,426	37,763
FX (losses)/gains on the translation of foreign bank accounts	(43)	(143)
Cash and cash equivalents at end of period	**34,536**	**55,143**

Mesoblast Limited
ABN 68 109 431 870
www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
Melbourne 3000
Victoria Australia
T +61 3 9639 6036
F +61 3 9639 6030

United States Operations
505 Fifth Avenue
Third Floor
New York, NY 10017
USA
T +1 212 880 2060
F +1 212 880 2061

Asia
21 Biopolis Road
#01-22 Nucleos (South Tower)
SINGAPORE 138567
T +65 6570 0635
F +65 6570 0176