asx announcement



MESOBLAST QUARTERLY CASH FLOW REPORT

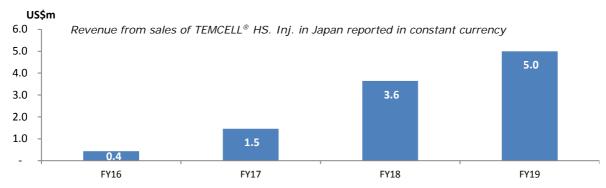
RECORD REVENUES FROM JAPAN PRODUCT SALES FOR THE PERIOD ENDED JUNE 30, 2019

Melbourne, Australia, July 31, 2019 and New York, USA, July 30, 2019: Mesoblast Limited (ASX:MSB; Nasdaq:MESO) today reported its operational highlights and its quarterly cash flows for the fourth quarter (fourth quarter FY2019) and 12 months ended June 30, 2019 (FY2019).

Mesoblast Chief Executive Dr Silviu Itescu stated: "It is pleasing to see the growth in revenues achieved by our Japanese partner in the treatment of acute graft versus host disease in the first three years post launch. This augurs well for the potential uptake of remestemcel-L in the treatment of GVHD, if approved, in the United States."

Key Highlights

 Increased revenues⁽¹⁾ of 54%⁽²⁾ for the quarter and 37%⁽³⁾ for the year on sales of TEMCELL® HS. Inj.⁽⁴⁾ in Japan steroid-refractory acute graft versus host disease (SR-aGVHD) by Mesoblast licensee JCR Pharmaceuticals Co. Ltd.



- Mesoblast initiated a rolling Biologics License Application (BLA) with the United States Food and Drug Administration (FDA) for remestemcel-L in the treatment of pediatric aGVHD; in preparation for product launch, focus is on inventory and commercial team ramp up.
- The FDA has granted Orphan Drug Designation for the use of rexlemestrocel-L (Revascor) for the prevention of post implantation mucosal bleeding in heart failure patients implanted with a left ventricular assist device (LVAD).
- In late July Mesoblast had a positive meeting with the FDA to further define the registration pathway for the use of Revascor in the treatment of heart failure in patients with an LVAD, with formal minutes expected in coming weeks.
- Cash on hand at June 30, 2019 was US\$50.4 million (A\$71.9 million); additional capital of US\$35.0 million may be available under existing arrangements with Hercules Capital, Inc. and NovaQuest Capital Management, L.L.C.
- The Kentgrove Capital equity facility for up to A\$120.0 million (approx. US\$85.0 million), which can be used at Mesoblast's discretion, has been extended for two years.
- The Company remains in advanced negotiations with a number of potential commercial partners regarding potential transactions and access to non-dilutive capital. (5)

⁽¹⁾ Unaudited

⁽²⁾ fourth quarter FY2019 compared to the fourth quarter FY2018. Reported in constant currency.

⁽³⁾ FY2019 year compared to the FY2018 year. Reported in constant currency.

⁽⁴⁾ TEMCELL HS. Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.

⁽⁵⁾ Mesoblast does not make any representation or give any assurance that such a partnering transaction will be concluded.

Commentary on Appendix 4C Cash Flow Report

Milestone receipts of US\$26.4 million received for FY2019 comprised:

- o US\$20.0 million receipts from milestones received in relation to establishing a partnership with Tasly Pharmaceutical Group in China.
- o US\$5.4 million (€5 million) receipts from milestones received in relation to a patent license agreement with Takeda Pharmaceutical Company Limited.
- o US\$1.0 million receipts from milestones received for JCR reaching cumulative net sales milestones for sales of TEMCELL® in Japan.

Royalty receipts received from sales of TEMCELL in Japan for the treatment of aGVHD were US\$1.0 million for the fourth quarter FY2019 and US\$4.4 million for FY2019. Royalty income recognized as revenue for the fourth quarter FY2019 and FY2019 was US\$1.7 million and US\$5.0 million respectively. The amounts recognized as revenue in the periods are higher than the amounts reported as cash received as royalty income recognized as revenue in the fourth quarter will not be received until July 2019.

Research and Development payments of US\$8.3 million for the fourth quarter and US\$48.5 million in FY2019, with costs being incurred in relation to Phase 3 programs in aGVHD, advanced chronic heart failure and chronic low back pain due to degenerative disc disease.

Manufacturing payments of US\$4.3 million for the fourth quarter and US\$13.4 million for FY2019 for commercial manufacturing investment to support potential launch of remestemcel-L.

Total Operating Activities net cash usage was US\$19.1 million for the fourth quarter and US\$57.8 million for FY2019.

A copy of the Appendix 4C – Quarterly Cash Flow Report for the fourth quarter FY2019 and FY2019 is attached.

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 technology platform to establish a broad portfolio of late-stage product candidates with three product candidates in Phase 3 trials – acute graft versus host disease, chronic heart failure and chronic low back pain due to degenerative disc disease. Through a proprietary process, Mesoblast selects rare mesenchymal lineage precursor and stem cells from the bone marrow of healthy adults and creates master cell banks, which can be industrially expanded to produce thousands of doses from each donor that meet stringent release criteria, have lot to lot consistency, and can be used off-the-shelf without the need for tissue matching. Mesoblast has facilities in Melbourne, New York, Singapore and Texas and is listed on the Australian Securities Exchange (MSB) and on the Nasdag (MESO). www.mesoblast.com

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

> Mesoblast Limited ABN 68 109 431 870

www.mesoblast.com

Corporate Headquarters Level 38 55 Collins Street Melbourne 3000 Victoria Australia

т +61 3 9639 6036 ғ +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 20 Biopolis Way #05-01 Centros Biopreneur 3 SINGAPORE 138668

т +65 6570 0635 в +65 6570 0176 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

Mesoblast Limited ABN 68 109 431 870

www.mesoblast.com

Corporate Headquarters Level 38 55 Collins Street Melbourne 3000

т +61 3 9639 6036 г +61 3 9639 6030

Victoria Australia

United States Operations 505 Fifth Avenue Third Floor New York, NY 10017 USA

т +1 212 880 2060 **F** +1 212 880 2061 Asia 20 Biopolis Way #05-01 Centros Biopreneur 3 SINGAPORE 138668

т +65 6570 0635 г +65 6570 0176

+Rule 4.7B

Appendix 4C

Quarterly report for entities subject to Listing Rule 4.7B

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

Name of entity

Mesoblast Limited	
ABN	Quarter ended ("current quarter")
68 109 431 870	30 June 2019

Consolidated statement of cash flows		Current quarter US\$'000	Year to date (12 months) US\$'000
1.	Cash flows from operating activities		
1.1	Receipts from customers - milestone receipts from Tasly Pharmaceutical Group - milestone receipts from Takeda Pharmaceutical Company Limited - milestone receipts from JCR Pharmaceuticals Co., Ltd. - royalty receipts	 1,038	20,000 5,409 1,000 4,359
1.2	Payments for		
	(a) research and development - includes the costs of the three Tier 1 Phase 3 programs in advanced chronic heart failure, chronic low back pain and acute graft vs host disease.	(8,280)	(48,526)
	(b) manufacturing commercialization	(4,330)	(13,441)
	(c) advertising and marketing	_	_
	(d) leased assets	_	_
	(e) staff costs	(1,795)	(9,496)
	(f) other expenses from ordinary activities (g) other:	(3,215)	(12,203)
4.0	- intellectual property portfolio expenses	(1,000)	(2,627)
1.3	Dividends received (see note 3)	_	_
1.4	Interest received	232	726
1.5	Interest and other costs of finance paid	(1,735)	(4,641)
1.6	Income taxes paid	-	(3)
1.7	Government grants and tax incentives	-	1,654
1.8	Other (provide details if material)	-	_
1.9	Net cash from / (used in) operating activities	(19,085)	(57,789)

⁺ See chapter 19 for defined terms

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Cons	solidated statement of cash flows	Current quarter US\$'000	Year to date (12 months) US\$'000
2.	Cash flows from investing activities		
2.1	Payments to acquire:		
	(a) property, plant and equipment	(77)	(279)
	(b) businesses (see item 10)	_	_
	(c) investments	_	_
	(d) intellectual property	_	_
	(e) other non-current assets	_	_
2.2	Proceeds from disposal of:		
	(a) property, plant and equipment	_	_
	(b) businesses (see item 10)	_	_
	(c) investments	_	_
	(d) intellectual property	_	_
	(e) other non-current assets	_	_
2.3	Cash flows from loans to other entities	_	_
2.4	Dividends received (see note 3)	_	_
2.5	Other (provide details if material):	_	_
	(a) Payments for contingent consideration	(721)	(721)
2.6	Net cash from / (used in) investing Activities	(798)	(1,000)
3.	Cash flows from financing activities		
3.1	Proceeds from issue of shares		
	- NovaQuest Capital Management, L.L.C.	_	10,000
	- Tasly Pharmaceutical Group	_	20,000
3.2	Proceeds from issue of convertible notes	_	_
3.3	Proceeds from exercise of share options	_	258
3.4	Transaction costs related to issues of shares, convertible notes or options	_	(608)
3.5	Proceeds from borrowings		
	- NovaQuest Capital Management, L.L.C.	_	28,950
	- Hercules Capital, Inc.	_	14,622
3.6	Repayment of borrowings	_	_
3.7	Transaction costs related to loans and borrowings	(32)	(1,614)
3.8	Dividends paid	_	_
3.9	Other (provide details if material)	_	_
3.10	Net cash from / (used in) financing activities	(32)	71,608

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Consolidated statement of cash flows		Current quarter US\$'000	Year to date (12 months) US\$'000
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of quarter (April 1, 2019)/beginning of year (July 1, 2018)	70,385	37,763
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(19,085)	(57,789)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(798)	(1,000)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(32)	71,608
4.5	Effect of movement in exchange rates on cash held	(44)	(156)
4.6	Cash and cash equivalents at end of quarter	50,426	50,426

Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter US\$'000	Previous quarter US\$'000
Bank balances	50,002	69,961
Call deposits	_	_
Bank overdrafts		
Other (Term deposits)	424	424
Cash and cash equivalents at end of quarter (should equal item 4.6 above)	50,426	70,385
	equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts Bank balances Call deposits Bank overdrafts Other (Term deposits) Cash and cash equivalents at end of	equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts Bank balances Call deposits Bank overdrafts Other (Term deposits) Cash and cash equivalents at end of U\$\$,000 50,002

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6.	Payments to directors of the entity and their associates	Current quarter US\$'000
6.1	Aggregate amount of payments to these parties included in item 1.2	381
6.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	_

6.3 Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2

Payments to directors (For the Current Quarter) = US\$381,000

7.	Payments to related entities of the entity and their associates	Current quarter US\$'000
7.1	Aggregate amount of payments to these parties included in item 1.2	
7.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	_

7.3 Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2

8.	Financing facilities available Add notes as necessary for an understanding of the position	Total facility amount at quarter end US\$'000	Amount drawn at quarter end US\$'000
8.1	Loan facilities	115,000*	80,000*
8.2	Credit standby arrangements	_	_
8.3	Other (please specify)	_	_

8.4 Include below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include details of those facilities as well.

*Loan facility with Hercules Capital, Inc.

On March 6, 2018, Mesoblast entered into a Loan and Security Agreement with Hercules Capital, Inc. ("Hercules Capital") for a US\$75.0 million secured four-year credit facility. Mesoblast drew the first tranche of US\$35.0 million on closing. An additional US\$15.0 million was drawn during Q1 CY2019, and a further US\$25.0 million may be drawn on or before Q4 CY2019, as certain milestones are met.

As at June 30, 2019, the interest rate remains at 10.45% as reported in the last quarter there was no change in the U.S prime rate in the quarter.

*Loan facility with NovaQuest Capital Management, L.L.C.

On June 29, 2018, Mesoblast entered into a Loan and Security Agreement with NovaQuest Capital Management, L.L.C. ("NovaQuest") for a non-dilutive US\$40.0 million secured eight-year term loan. Mesoblast drew the first tranche of US\$30.0 million of the loan on closing. An additional US\$10.0 million from the loan will be drawn on marketing approval of remestemcel-L by the United States Food and Drug Administration (FDA).

Prior to maturity in July 2026, the loan is only repayable from net sales of remestemcel-L (MSC-100-IV) in the treatment of pediatric patients who have failed to respond to steroid treatment for acute Graft versus Host Disease (aGvHD), in the United States and other geographies excluding Asia. Interest on the loan will accrue at a rate of 15% per annum with the interest only period lasting 4 years. Interest payments will be deferred until after the first commercial sale. The financing is subordinated to the senior creditor, Hercules Capital.

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9.	Estimated cash outflows for next quarter	US\$'000
9.1	Research and development	(6,317)
9.2	Product manufacturing and operating costs	(2,031)
9.3	Manufacturing commercialization	(3,362)
9.4	Advertising and marketing	(684)
9.5	Leased assets	_
9.6	Staff costs	(1,759)
9.7	Other expenses from ordinary activities	(3,658)
9.8	Other (provide details if material)	
	(a) intellectual property portfolio expenses	(636)
	(b) interest expenses	(1,341)
9.9	Total estimated operating cash outflows	(19,788)*

^{*} In the next quarter, Mesoblast's cash and cash equivalents will be augmented by the following cash receipts:

- R&D tax incentive (US\$1.5 million was received from the Australian Government in July 2019).
- royalty receipts earned on sales of TEMCELL® HS. Inj. 1 in Japan; and
- interest income receipts.

The company remains in advanced negotiations with a number of potential commercial partners regarding potential transactions and access to non-dilutive capital. Mesoblast does not make any representation or give any assurance that such a partnering transaction will be concluded.

Up to an additional US\$35.0 million is available to Mesoblast subject to achievement of certain milestones, under the financing arrangements with Hercules Capital and NovaQuest. Refer to 8.4 for further details.

Mesoblast has extended its equity facility with Kentgrove Capital for an additional 2 years on similar terms to the original agreement from 2016. The facility provides for up to A\$120.0 million (approximately US\$85.0 million) over the next 2 years to be used at Mesoblast's discretion to provide additional funds as required.

1 TEMCELL HS. Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.

10.	Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)	Acquisitions	Disposals
10.1		_	
10.2	registration	_	_
10.3	Consideration for acquisition or disposal	_	_
	Total net assets	_	_
	Nature of business	_	_

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Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Sign here: Date: 31 July 2019

(Company secretary)

Matter

Print name: Charlie Harrison

Notes

- 1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.
- 2. If this quarterly report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
- 3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

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