asx announcement

MESOBLAST QUARTERLY CASH FLOW REPORT

Continued Revenue Growth in Japan Provides Framework for First Product Commercialization in United States

Melbourne, Australia, January 29, 2020 and New York, USA, January 28, 2020: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today reported its quarterly cash flows and operational highlights for the second quarter FY2020.

Mesoblast Chief Executive Dr Silviu Itescu said: "We are pleased by the continued growth in revenues from sales of the allogeneic cell therapy product TEMCELL®[1] HS Inj. for steroid-refractory acute graft versus host disease (aGVHD) by our licensee in Japan. We view market adoption in Japan as an important indicator for the potential United States (US) market opportunity of our own cell therapy product candidate for aGVHD, Ryoncil™, the commercial brand name agreed to with the Food and Drug Administration (FDA)."

Key Highlights for the Quarter

- Revenues from sales of TEMCELL by Mesoblast's licensee for steroid-refractory acute graft versus host disease (aGVHD) in Japan continued to increase and were US$2.0 million for the quarter ended December 31, 2019, a growth of 61% over the comparative quarter of 2018. On a rolling 12-month basis to December 31, 2019, revenues were US$6.6 million, an increase of 53% relative to the prior corresponding period.
- Total cash receipts from operating activities were US$19.4 million which comprised:
  - US$17.5 million in upfront and milestone payments from Grünenthal under the strategic partnership.
  - US$1.9 million in royalties.
- Total cash payments for operating activities were reduced by 16% to US$4.0 million relative to the comparative quarter of 2018, reflecting reduced spend of US$6.7 million on clinical programs. This was partially offset by investment in manufacturing and commercial activities for the expected US launch of Ryoncil.
- Cash on hand at the end of the quarter was US$81.3 million (A$116.1 million). Over the next 12 months, Mesoblast may have access to an additional US$62.5 million (A$89.3 million) through existing financing facilities and strategic partnerships.
- Clinical efficacy and safety data were filed for Ryoncil in the Company's rolling Biologics License Application (BLA). This included analyses of 309 children with aGVHD who have received Ryoncil across three separate studies and new data in control pediatric subjects from the contemporaneous database of the Mount Sinai Acute GVHD International Consortium (MAGIC).
- The results demonstrate the effectiveness of Ryoncil in this patient population, with particular efficacy and survival benefit in patients with the most severe forms of aGVHD. If approved, Mesoblast plans US launch of Ryoncil in 2020.

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- Mesoblast's Phase 3 trial evaluating Revascor in advanced chronic heart failure surpassed the number of primary endpoint events required for trial completion. At completion all surviving patients will have been followed for at least 12 months, with a mean follow up period of approximately 30 months. The results from this pivotal trial are expected to be read out by mid-2020.
- The independent Data Monitoring Committee (DMC) overseeing this Phase 3 trial held its 10th and final scheduled meeting in December 2019 with the recommendation that the trial continue as planned. The DMC reviewed available data from the 566 randomized patients, including components of the trial's primary and secondary endpoints, and all safety data.
- Continued operational progress in strategic partnerships for heart failure in China with Tasly Pharmaceuticals and for chronic lower back pain with Grünenthal in Europe, including plans to leverage US Phase 3 trial data read outs; Mesoblast continues to be in active discussions with additional pharmaceutical companies with regard to further potential global and regional strategic partnerships[2].

Commentary on Appendix 4C Cash Flow Report

Upfronts and Milestone receipts were US$17.5 million for the second quarter FY2020. Mesoblast received a US$15.0 million upfront payment and a US$2.5 million milestone payment under the Grünenthal strategic partnership for the development of Mesoblast's Phase 3 allogeneic product candidate for the treatment of chronic low back pain due to degenerative disc disease.

Royalty receipts received in the second quarter FY2020 from JCR Pharmaceuticals Co. Ltd for the sales of TEMCELL in Japan for the treatment of aGVHD were US$1.9 million. The royalty receipt does not include US$2.0 million of revenues recognized for the current quarter, which are expected to be received in February 2020.

Research and Development payments were US$7.5 million for the second quarter FY2020 in relation to our Phase 3 programs in aGVHD, advanced heart failure and chronic low back pain due to degenerative disc disease.

Manufacturing payments were US$3.2 million for the second quarter FY2020 for commercial manufacturing investment to support potential launch of Ryoncil.

Total Operating Activities resulted in net cash usage of US$1.3 million for the second quarter as upfront and milestone payments under the Grünenthal strategic partnership offset operating expenditure.

A copy of the Appendix 4C – Quarterly Cash Flow Report for the second quarter FY2020 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 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

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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.

Release authorized by the Chief Executive.

1.TEMCELL HS. Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd. We received royalty revenues on sales of TEMCELL in Japan for steroid-refractory acute graft versus host disease (SR-aGVHD) by Mesoblast licensee JCR Pharmaceuticals Co. Ltd.

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

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+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	31 December 2019

Consolidated statement of cash flows		**Current quarter US$'000**	**Year to date (6 months) US$'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers		
	- royalty receipts from JCR Pharmaceuticals Co.,Ltd	1,872	3,611
	- upfronts and milestones from Grünenthal	17,500	17,500
1.2	Payments for		
	(a) research and development	(7,468)	(15,290)
	- 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		
	(b) manufacturing commercialization	(3,206)	(6,204)
	(c) product manufacturing and operating costs	(1,205)	(1,668)
	(d) advertising & marketing	(701)	(1,150)
	(e) staff costs	(3,084)	(4,981)
	(f) other expenses from ordinary activities	(3,362)	(6,604)
	(g) other:		
	- intellectual property portfolio expenses	(552)	(1,223)
1.3	Dividends received (see note 3)	—	—
1.4	Interest received	240	413
1.5	Interest and other costs of finance paid	(1,361)	(2,788)
1.6	Income taxes paid	(3)	(3)
1.7	Government grants and tax incentives	—	1,499
1.8	Other (provide details if material)	—	—
1.9	**Net cash from / (used in) operating activities**	**(1,330)**	**(16,888)**

Consolidated statement of cash flows		Current quarter US$'000	Year to date (6 months) US$'000
2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) property, plant and equipment	(458)	(612)
	(b) businesses (see item 10)	—	—
	(c) investments	—	—
	(d) intellectual property	—	(100)
	(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	—	—
2.6	**Net cash from / (used in) investing Activities**	**(458)**	**(712)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issue of shares	50,663	50,663
3.2	Proceeds from issue of convertible notes	—	—
3.3	Proceeds from exercise of share options	91	390
3.4	Transaction costs related to issues of shares, convertible notes or options	(2,164)	(2,164)
3.5	Proceeds from borrowings	—	—
3.6	Repayment of borrowings	—	—
3.7	Transaction costs related to loans and borrowings	—	—
3.8	Dividends paid	—	—
3.9	Other (provide details if material)	—	—
	(a) Payments for lease liabilities	(360)	(695)
3.10	**Net cash from / (used in) financing activities**	**48,230**	**48,194**

Consolidated statement of cash flows		**Current quarter US$'000**	**Year to date (6 months) US$'000**
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of quarter (October 1, 2019)/beginning of year (July 1, 2019)	34,536	50,426
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,330)	(16,888)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(458)	(712)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	48,230	48,194
4.5	Effect of movement in exchange rates on cash held	370	328
4.6	**Cash and cash equivalents at end of quarter**	**81,348**	**81,348**

5.	**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**
5.1	Bank balances	80,928	34,131
5.2	Call deposits	—	—
5.3	Bank overdrafts	—	—
5.4	Other (Term deposits)	420	405
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**81,348**	**34,536**

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	340
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$340,000

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.

Hercules extended the final tranche under the facility so that a further US$25.0 million may potentially be drawn on or before Q4 CY2020.

As at December 31, 2019, in line with the decreases in the U.S prime rate in the quarter, the interest rate on the loan decreased from 9.95% to 9.70%.

__*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 Ryoncil by the United States Food and Drug Administration (FDA).

Prior to maturity in July 2026, the loan is only repayable from net sales of Ryoncil 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.

9.	Estimated cash outflows for next quarter	US$'000
9.1	Research and development	(8,463)
9.2	Manufacturing commercialization	(3,593)
9.3	Product manufacturing and operating costs	(1,200)
9.4	Advertising and marketing	(1,339)
9.5	Leased assets	—
9.6	Staff costs	(2,456)
9.7	Other expenses from ordinary activities	(3,539)
9.8	Other (provide details if material)	
	(a) intellectual property portfolio expenses	(892)
	(b) interest expenses	(1,318)
9.9	Total estimated operating cash outflows	(22,800)*

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

- US$2.0 million royalty receipts earned on sales of TEMCELL® HS. Inj.[1] in Japan; and
- interest income receipts.

The company is in active negotiations regarding potential commercial 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.

Additional future payments from Grünenthal may include milestones up to US$27.5 million within the first year comprising US$20.0 million on receiving regulatory approval to begin a confirmatory Phase 3 trial in Europe, and US$7.5 million on certain clinical and manufacturing outcomes.

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	Name of entity	—	—
10.2	Place of incorporation or registration	—	—
10.3	Consideration for acquisition or disposal	—	—
10.4	Total net assets	—	—
10.5	Nature of business	—	—

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: 29 January 2020

(Company secretary)

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.