asx announcement

mesoblast
the regenerative medicine company

MESOBLAST FINANCIAL AND OPERATIONAL HIGHLIGHTS FOR THE QUARTER ENDED MARCH 31, 2020

Melbourne, Australia, April 29, 2020 and New York, USA, April 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 third quarter ended March 31, 2020.

During the reporting quarter, Mesoblast achieved a significant milestone when its Biologics License Application (BLA) for RYONCIL™ (remestemcel-L) was accepted by the United States Food and Drug Administration (FDA) for priority review in the treatment of children with steroid-refractory acute graft versus host disease (SR-aGVHD).

The Company has identified a second major inflammatory condition with a high mortality rate, acute respiratory distress syndrome (ARDS) caused by COVID-19 infection, where remestemcel-L could be of benefit given similar immune activation and cytokine storm as occurs in aGVHD. The extensive body of safety data accumulated for remestemcel-L to date supported Mesoblast's evaluation of remestemcel-L under an Investigational New Drug (IND) application to the FDA in treating the cytokine storm of COVID-19 ARDS. A randomized, placebo-controlled Phase 2/3 trial of remestemcel-L in COVID-19 ARDS is expected to commence soon to confirm the initial signals of efficacy observed in the compassionate use program.

Key Financial Highlights for the Quarter

- Revenues from sales of TEMCELL®1 HS Inj. by Mesoblast's licensee for aGVHD in Japan continued to increase and were US$2.1 million for the quarter ended March 31, 2020, a growth of 99% over the comparative quarter of 2019. On a rolling 12-month basis to March 31, 2020, revenues were US$7.6 million, an increase of 75% relative to the prior corresponding period.
- Cash on hand at the end of the quarter was US$60.1 million (A$97.3 million). Over the next 12 months, Mesoblast may have access to an additional US$62.5 million (A$101.2 million) through existing financing facilities and strategic partnerships.
- Total cash payments for operating activities was US$22.0 million, a reduction of 2.8% relative to the comparative quarter of 2019. Spending on clinical programs reduced by US$4.2 million during the period compared to the comparative quarter of 2019. This was partially offset by investment in manufacturing and commercial activities for the expected US launch of RYONCIL (remestemcel-L) in SR-aGVHD.
- Mesoblast is in active discussions with US and other government authorities as well as potential pharmaceutical partners with respect to its plans for ramp-up of commercial manufacturing for remestemcel-L in COVID-19 ARDS.[2]

Key Operational Highlights for the Quarter

- Remestemcel-L for Steroid-Refractory Acute Graft Versus Host Disease (SR-aGVHD):
  - Mesoblast's BLA for RYONCIL™ (remestemcel-L) was accepted by the FDA for priority review for the treatment of SR-aGVHD in children. The FDA has set a Prescription Drug User Fee Act (PDUFA) action date of September 30, 2020.
  - If approved, we plan to launch RYONCIL in the US in 2020; product inventory is in place and a targeted commercial team is being built.
- Remestemcel-L for Acute Respiratory Distress Syndrome in COVID-19 patients:
  - ARDS is caused by cytokine storm in lungs of patients infected with COVID-19 and is the primary cause of death in these patients.
  - Extensive body of safety data for remestemcel-L, and similar potential mechanism of action for remestemcel-L in modulating cytokine storm associated with both aGVHD and ARDS, makes

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compelling rationale for evaluating remestemcel-L in COVID-19 ARDS. A post-hoc analysis of a randomized, placebo-controlled study in 60 patients with chronic obstructive pulmonary disease demonstrated that remestemcel-L significantly improved respiratory function in patients with the same elevated inflammatory biomarkers that are also observed in patients with COVID-19 ARDS.

  - Consequently, an IND application was submitted to and cleared by the FDA for intravenous infusions of remestemcel-L to treat patients with COVID-19 ARDS.
  - Initial data from patients who were treated under emergency compassionate use at New York City's Mt Sinai hospital showed 83% (10/12) survival in COVID-19 patients with moderate/severe ARDS treated during the period March-April 2020 with two intravenous infusions of remestemcel-L; 75% (9/12) have successfully come off ventilator support at a median of 10 days, and seven of these patients have been discharged from hospital.
  - These results contrast with only 9% of ventilator-dependent COVID-19 patients being able to come off ventilators with standard of care treatment and only 12% survival in ventilator-dependent COVID-19 patients at two major referral hospital networks in New York during the same time period.[3,4] These poor outcomes are consistent with earlier published data from China where mortality rates of over 80% were reported in patients with COVID-19 and moderate/severe ARDS.[5]
  - This compassionate use treatment experience has informed the design of the clinical protocol for a multi-center, randomized, placebo-controlled Phase 2/3 trial of remestemcel-L in ventilator-dependent COVID-19 moderate/severe ARDS patients across North America.
  - This trial will be conducted as a public-private partnership in a collaboration with the Cardiothoracic Surgical Trials Network (CTSN), which was established by the United States National Institutes of Health's National Heart, Lung and Blood Institute (NHLBI) as a flexible platform for conducting collaborative trials.

- Revascor® for Chronic Heart Failure
  - Results from a sub-study of 70 patients with end-stage ischemic heart failure and a Left Ventricular Assist Device (LVAD), of 159 randomized patients who received either Mesoblast's allogeneic mesenchymal precursor cell (MPC) product candidate Revascor® or saline, were presented at the American College of Cardiology (ACC) Virtual Scientific Sessions. Conclusions from the study included MPCs had a beneficial effect on LVAD weaning, major mucosal bleeding, serious adverse events, and readmissions in ischemic heart failure patients.
  - End-stage ischemic heart failure patients with LVADs are older and have co-morbidities such as diabetes, thereby closely resembling the majority of patients in Mesoblast's 566-patient Phase 3 trial of Revascor for advanced chronic heart failure, planned to read out in mid-2020.
  - Continued operational progress in strategic partnership for heart failure in China with Tasly Pharmaceuticals, leveraging US Phase 3 trial data read out.
- MPC-06-ID for Chronic Low Back Pain
  - 404-patient Phase 3 trial in chronic low pain planned to read out in mid-2020.
  - Continued operational progress in strategic partnership for chronic lower back pain with Grünenthal GmBH in Europe, leveraging US Phase 3 trial data read out.

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Commentary on Appendix 4C Cash Flow Report

Royalty receipts received in the third quarter FY2020 from JCR Pharmaceuticals Co. Ltd for the sales of TEMCELL in Japan for the treatment of aGVHD were US$2.0 million. The royalty receipt does not include US$2.1 million of revenues recognized for the current quarter, which are expected to be received in May 2020.

Research and Development payments were US$9.2 million for the third quarter FY2020 due to our Phase 3 programs in aGVHD, advanced heart failure and chronic low back pain due to degenerative disc disease.

Manufacturing payments were US$2.7 million for the third quarter FY2020 for commercial manufacturing investment to support potential launch of RYONCIL.

Total Operating Activities resulted in net cash usage of US$19.9 million for the third quarter as the Company continues to prepare for the potential approval and commercial launch of RYONCIL in the US.

A copy of the Appendix 4C – Quarterly Cash Flow Report for the third 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 mesenchymal lineage cell therapy technology platform to establish a broad portfolio of commercial products and late-stage product candidates. Mesoblast's proprietary manufacturing processes yield industrial-scale, cryopreserved, off-the-shelf, cellular medicines. These cell therapies, with defined pharmaceutical release criteria, are planned to be readily available to patients worldwide.

Mesoblast's Biologics License Application to seek approval of its product candidate RYONCIL™ (remestemcel-L) for steroid-refractory acute graft versus host disease (acute GVHD) has been accepted for priority review by the United States Food and Drug Administration (FDA). If approved, RYONCIL is expected to be launched in the United States in 2020 for pediatric steroid-refractory acute GVHD. Remestemcel-L is also being developed for other rare diseases. Mesoblast is completing Phase 3 trials for its product candidates for advanced heart failure and chronic low back pain. Two products have been commercialized in Japan and Europe by Mesoblast's licensees, and the Company has established commercial partnerships in Europe and China for certain Phase 3 assets.

Mesoblast has a strong and extensive global intellectual property (IP) portfolio with protection extending through to at least 2040 in all major markets. This IP position is expected to provide the Company with substantial commercial advantages as it develops its product candidates for these conditions.

Mesoblast has locations in Australia, the United States and Singapore 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

[1]TEMCELL HS. Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd. Mesoblast receives royalty revenues on sales of TEMCELL in Japan for aGVHD.

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

[3] Petrilli CM et al. Factors associated with hospitalization and critical illness among 4,103 patients with Covid-19 disease in New York City. MedRxiv 2020 doi: https://www.medrxiv.org/content/10.1101/2020.04.08.20057794v1.full.pdf

[4] Richardson S et al. Presenting characteristics, comorbidities, and outcomes among 5700 patients hospitalized with COVID-19 in the New York City area. JAMA 2020. doi:10.1001/jama.2020.6775

[5]Liu Y et al. Clinical features and progression of acute respiratory distress syndrome in coronavirus disease 2019. Medrxiv 2020; https://www.medrxiv.org/content/10.1101/2020.04.08.20057794v1.full.pdf

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 include, but are not limited to, statements

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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.

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Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

Mesoblast Limited

ABN	**Quarter ended ("current quarter")**
68 109 431 870	31 March 2020

Consolidated statement of cash flows		**Current quarter $US'000**	**Year to date (9 months) $US'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers		
	- royalty receipts from JCR Pharmaceuticals Co.,Ltd	1,968	5,579
	- upfronts and milestones from Grünenthal	—	17,500
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	(9,183)	(24,473)
	(b) manufacturing commercialization	(1,534)	(7,738)
	(c) product manufacturing and operating costs	(1,187)	(2,855)
	(d) advertising and marketing	(1,776)	(2,926)
	(e) leased assets	—	—
	(f) staff costs	(2,755)	(7,736)
	(g) other expenses from ordinary activities	(3,548)	(10,152)
	(h) other: -Intellectual property portfolio expenses	(619)	(1,842)
1.3	Dividends received (see note 3)	—	—
1.4	Interest received	120	533
1.5	Interest and other costs of finance paid	(1,377)	(4,165)
1.6	Income taxes paid	(4)	(7)
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**	**(19,895)**	**(36,783)**

Consolidated statement of cash flows		Current quarter $US'000	Year to date (9 months) $US'000
2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	—	—
	(b) businesses	—	—
	(c) property, plant and equipment	(693)	(1,305)
	(d) investments	—	—
	(e) intellectual property	—	(100)
	(f) other non-current assets	—	—
2.2	Proceeds from disposal of:		
	(a) entities	—	—
	(b) businesses	—	—
	(c) property, plant and equipment	—	—
	(d) investments	—	—
	(e) intellectual property	—	—
	(f) 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)	—	—
2.6	**Net cash from / (used in) investing activities**	**(693)**	**(1,405)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	—	50,663
3.2	Proceeds from issue of convertible debt securities	—	—
3.3	Proceeds from exercise of options	506	896
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(47)	(2,211)
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 (payment of lease liability)	(524)	(1,219)
3.10	**Net cash from / (used in) financing activities**	**(65)**	**48,129**

Consolidated statement of cash flows		Current quarter $US'000	Year to date (9 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 (January 1, 2020)/beginning of year (July 1, 2019)	81,348	50,426
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(19,895)	(36,783)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(693)	(1,405)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(65)	48,129
4.5	Effect of movement in exchange rates on cash held	(618)	(290)
4.6	**Cash and cash equivalents at end of period**	**60,077**	**60,077**

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	59,707	80,928
5.2	Call deposits	—	—
5.3	Bank overdrafts	—	—
5.4	Other (Term deposits)	370	420
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**60,077**	**81,348**

6.	Payments to related parties of the entity and their associates	Current quarter $US'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	364
6.2	Aggregate amount of payments to related parties and their associates included in item 2	—

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments

Payments to directors (for the current quarter) = US$364,000

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $US'000**	**Amount drawn at quarter end $US'000**
7.1	Loan facilities	115,000*	80,000*
7.2	Credit standby arrangements	—	—
7.3	Other (please specify)	—	—
7.4	**Total financing facilities**	115,000*	80,000*

7.5	**Unused financing facilities available at quarter end**	35,000*

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing 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.

A further US$25.0 million may potentially be drawn on or before Q4 CY2020 subject to certain conditions.

As at March 31, 2020, the interest rate on the loan was 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.

8.	Estimated cash available for future operating activities	$US'000
8.1	Net cash from / (used in) operating activities (Item 1.9)	(19,895)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	60,077
8.3	Unused finance facilities available at quarter end (Item 7.5)	35,000*
8.4	Total available funding (Item 8.2 + Item 8.3)	95,077
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	4.8

*Under the Hercules Capital loan facility, a further US$25.0 million may potentially be drawn on or before Q4 CY2020 subject to certain conditions. Under the NovaQuest loan facility, 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).

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

1. Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: Not applicable

2. Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: Not applicable

3. Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: Not applicable

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.

Date: .....29 April 2020.....

Authorised by: .....Chief Executive.....
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow 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 cash flow 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.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.