asx announcement

mesoblast

MESOBLAST PROVIDES REMESTEMCEL-L UPDATE AND QUARTERLY ACTIVITY REPORT

Melbourne, Australia, July 30, 2020, and New York; USA; July 29, 2020: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today provided an update on upcoming milestones for its lead product candidate remestemcel-L, and an activity report for the fourth quarter ended June 30, 2020.

Mesoblast Chief Executive Dr Silviu Itescu stated: "Remestemcel-L has two imminent major milestones, the interim analysis in the ongoing Phase 3 trial of remestemcel-L in COVID-19 patients with acute respiratory distress syndrome and the FDA advisory committee panel review of our submission for potential approval of RYONCIL™ (remestemcel-L) in children with steroid-refractory acute graft versus host disease. Together with the upcoming Phase 3 read-outs in chronic heart failure and back pain, these key milestones will take the Company into the most significant period in its history."

Remestemcel-L Phase 3 Trial for COVID-19 Acute Respiratory Distress Syndrome

The independent Data Safety Monitoring Board (DSMB) has set a date for early September to complete the first interim analysis of the Phase 3 trial of remestemcel-L in ventilator-dependent COVID-19 patients with moderate to severe acute respiratory distress syndrome (ARDS). The trial's first 90 patients will have completed 30 days of follow up during August, after which the DSMB will perform an interim analysis review of the safety and efficacy data. The DSMB will then inform Mesoblast on whether the trial should proceed as planned, or should stop early.

There are currently no approved treatments for COVID-19 ARDS, the primary cause of death in patients infected with COVID-19.

The clinical protocol evaluating remestemcel-L in patients in the Phase 3 trial was based on results from a pilot study using remestemcel-L under emergency compassionate care at Mt Sinai Hospital in New York, with 75% (nine of 12) of patients with moderate to severe ARDS successfully taken off a ventilator and discharged from hospital within a median of 10 days.

The placebo-controlled, double-blinded trial commenced enrollment in the reporting quarter of ventilator-dependent patients in intensive care units with moderate to severe COVID-19 ARDS randomized (1:1) to receive either two intravenous infusions of remestemcel-L three to five days apart or placebo on top of maximal care. The primary endpoint is all-cause mortality within 30 days of randomization, with the key secondary endpoint being the number of days off mechanical ventilator support.

Up to 30 leading medical centers across the United States are expected to participate in the trial, which is expected to complete recruitment in September 2020.

Remestemcel-L for Steroid-Refractory Acute Graft Versus Host Disease

The Oncologic Drugs Advisory Committee (ODAC) of the United States Food and Drug Administration (FDA) has scheduled a meeting for August 13, 2020 to review data supporting the Company's Biologics License Application (BLA) for approval of RYONCIL in the treatment of steroid-refractory acute graft versus host disease (SR-aGVHD) in children.

There are currently no FDA-approved treatments in the United States for children under 12 with SR-aGVHD, a potentially life-threatening complication of an allogeneic bone marrow transplant for blood cancer.

Although the FDA will consider the recommendation of the panel, the final decision regarding the approval of the product is made by the FDA solely, and the recommendations by the panel are non-binding.

RYONCIL has been accepted for Priority Review by the FDA with an action date of September 30, 2020, under the Prescription Drug User Fee Act (PDUFA). If approved, RYONCIL is planned for launch in the United States in 2020 with product inventory in place.

Cash Flow Report for the Fourth Quarter FY2020

Cash on hand at the end of the quarter was US$129.3 million (A$188.4 million). Mesoblast completed a US$90 million (A$138 million) capital raise from global institutional investors in May 2020. Over the next 12 months, Mesoblast may have access to an additional US$67.5 million through existing financing facilities and strategic partnerships.

Total Operating Activities resulted in net cash usage of US$19.6 million in the quarter ended June 30, 2020, as the Company continues to prepare for the potential approval and commercial launch of RYONCIL in the United States.

- Research and Development payments were US$6.7 million, primarily for our Phase 3 programs.
- Manufacturing payments were US$7.4 million for commercial manufacturing investment to support potential launch of RYONCIL.
- Royalty receipts received from JCR Pharmaceuticals Co. Ltd for the sales of TEMCELL HS Inj.[(R)1] in Japan for the treatment of aGVHD were US$2.1 million.
- Payments to Related Parties, detailed in Item 6 of the Appendix 4C cash flow report for the quarter, comprise approximately US$361,000 in Non-executive Director fees and Executive Director's salary.

A copy of the Appendix 4C – Quarterly Cash Flow Report for the fourth 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 has a strong and extensive global intellectual property (IP) portfolio with protection extending through to at least 2040 in all major markets. The Company'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 pediatric steroid-refractory acute graft versus host disease has been accepted for priority review by the United States Food and Drug Administration (FDA), and if approved, product launch in the United States is expected in 2020. Remestemcel-L is also being developed for other inflammatory diseases in children and adults including moderate to severe acute respiratory distress syndrome (ARDS). Following positive pilot trial results under compassionate care use, remestemcel-L is being evaluated in a Phase 3 randomized controlled trial in 300 patients with COVID-19 ARDS in the United States. 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 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[®1] HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.

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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.

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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	30 June 2020

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		
	- royalty receipts	2,096	7,676
	- upfronts and milestones from Grünenthal	—	17,500
1.2	Payments for		
	(a) research and development	(6,619)	(31,092)
	(b) manufacturing commercialization	(5,604)	(13,342)
	(c) product manufacturing and operating costs	(1,799)	(4,654)
	(d) advertising and marketing	(1,334)	(4,260)
	(e) leased assets	—	—
	(f) staff costs	(1,980)	(9,716)
	(g) other expenses from ordinary activities	(1,938)	(12,089)
	(h) other:		
	- Intellectual property portfolio expenses	(763)	(2,605)
1.3	Dividends received (see note 3)	—	—
1.4	Interest received	13	546
1.5	Interest and other costs of finance paid	(1,732)	(5,897)
1.6	Income taxes paid	—	(7)
1.7	Government grants and tax incentives	78	1,577
1.8	Other (provide details if material)	—	—
1.9	**Net cash from / (used in) operating activities**	**(19,582)**	**(56,365)**

Consolidated 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 or for:		
	(a) entities	—	—
	(b) businesses	—	—
	(c) property, plant and equipment	(791)	(2,096)
	(d) investments	—	—
	(e) intellectual property	(50)	(150)
	(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	—	—
	- payment for contingent consideration	(1,027)	(1,027)
2.6	**Net cash from / (used in) investing activities**	**(1,868)**	**(3,273)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	89,923	140,586
3.2	Proceeds from issue of convertible debt securities	—	—
3.3	Proceeds from exercise of options	3,464	4,360
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(4,066)	(6,277)
3.5	Proceeds from borrowings	512	512
3.6	Repayment of borrowings	(512)	(512)
3.7	Transaction costs related to loans and borrowings		
3.8	Dividends paid	—	—

Consolidated statement of cash flows		Current quarter $US'000	Year to date (12 months) $US'000
3.9	Other (payment of lease liability)	(406)	(1,625)
3.10	**Net cash from / (used in) financing activities**	**88,915**	**137,044**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of quarter (April 1, 2020)/beginning of year (July 1, 2019)	60,077	50,426
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(19,582)	(56,365)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(1,868)	(3,273)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	88,915	137,044
4.5	Effect of movement in exchange rates on cash held	1,786	1,496
4.6	**Cash and cash equivalents at end of period**	**129,328**	**129,328**

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	128,916	59,707
5.2	Call deposits	—	—
5.3	Bank overdrafts	—	—
5.4	Other (Term deposits)	412	370
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**129,328**	**60,077**

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	361
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$361,000

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 June 30, 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)	(19,582)
8.2	Cash and cash equivalents at quarter end (item 4.6)	129,328
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)	164,328
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	8.4

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

*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:

8.6.1 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

8.6.2 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

8.6.3 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

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

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: .....30 July 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.