UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 6-K

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16 under the Securities Exchange Act of 1934

For the month of February 2023

Commission File Number 001-37626

Mesoblast Limited

(*Exact name of Registrant as specified in its charter*)

Not Applicable
(*Translation of Registrant's name into English)*

Australia
(*Jurisdiction of incorporation or organization)*

Silviu Itescu
Chief Executive Officer and Executive Director
Level 38
55 Collins Street
Melbourne 3000
Australia
(*Address of principal executive offices*)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F:

Form 20-F ☑ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes ☐ No ☑

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes ☐ No ☑

INFORMATION CONTAINED ON THIS REPORT ON FORM 6-K

On January 31, 2023, Mesoblast Limited filed with the Australian Securities Exchange a quarterly report for entities admitted on the basis of commitments (Appendix 4C) for the quarter ended December 31, 2022, which is attached hereto as Exhibit 99.1, and is incorporated herein by reference.

On January 31, 2023, Mesoblast Limited filed with the Australian Securities Exchange a new release announcement which is attached hereto as Exhibit 99.2, and is incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly organized.

MESOBLAST LIMITED

/s/ Niva Sivakumar
Niva Sivakumar
Company Secretary

Dated: February 1, 2023

INDEX TO EXHIBITS

Item	
99.1	Appendix 4C of Mesoblast Ltd, dated January 31, 2023.
99.2	Press release of Mesoblast Ltd, dated January 31, 2023.

asx announcement

APPENDIX 4C QUARTERLY ACTIVITY REPORT

Mesoblast Operational and Financial Highlights for Quarter Ended December 31, 2022

Melbourne, Australia and New York, USA; January 31, 2023: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today provided an activity report for the second quarter ended December 31, 2022.

Financial Highlights

- Revenue from royalties on sales of TEMCELL® HS Inj.[1] sold in Japan by our licensee for the quarter increased 36% to US$1.9 million from US$1.4 million for the quarter ended September 30, 2022.
- Net cash usage for operating activities in the quarter was US$16.5 million; this represented a reduction of US$1.7 million, or 9%, on the comparative quarter in FY2022, and a reduction of US$14.1 million, or 46%, on the comparative quarter in FY2021.[2]
- In December 2022 we announced that funds managed by Oaktree Capital Management, L.P. (“Oaktree”) extended to Mesoblast the availability of up to an additional US$30 million of its US$90 million five-year facility subject to achieving certain milestones on or before September 30, 2023.
- Cash on hand at the end of the quarter was US$67.6 million, with up to an additional US$40 million available to be drawn down from existing financing facilities subject to certain milestones.

Operational Highlights

- The Biologics License Application (BLA) resubmission documents for remestemcel-L in the treatment of children with steroid-refractory graft versus host disease (SR-aGVHD) are complete and expected to be filed with FDA shortly.
- Survival outcomes have not improved over the past two decades for children or adults with the most severe forms of SR-aGVHD.[3-5] The lack of any approved treatments for children under 12 means that there is an urgent need for a therapy that improves the dismal survival outcomes in children.
- Long-term survival results were received for remestemcel-L from Mesoblast’s pivotal Phase 3 clinical trial (GVHD-001) in children with SR-aGVHD. The results showed durable survival through 4 years of follow-up. These new long-term survival data are a key component of the Company’s BLA resubmission to the FDA.

  The study was performed by the Center for International Blood and Marrow Transplant Research (CIBMTR) on 51 evaluable children with SR-aGVHD who were enrolled in the phase 3 trial across 20 centers in the US.

  Overall survival in the remestemcel-L cohort was 63% at 1 year, 51% at 2 years, and 49% at 4 years, with median survival of 2 to 3 years. In recently published studies of children or adults with SR-aGVHD who received best available therapy (BAT) or the only FDA-approved agent for adults, ruxolitinib, 1 year survival was 40-49% and 2 year survival was 25%-38%.[3,6-8]
- Mesoblast has previously gained alignment with the FDA on key metrics for a pivotal Phase 3 study of rexlemestrocel-L in patients with chronic low back pain (CLBP) with degenerative disc disease which seeks to replicate the significant reduction in pain seen in the first Phase 3 trial.
- FDA has confirmed that 12-month reduction in pain is an approvable indication, with key secondary measures of improvement in function and reduction in opioid usage.
- Preparation underway to commence the pivotal Phase 3 clinical trial by mid-CY2023.

- Results from three randomized controlled trials of rexlemestrocel-L in class II/III heart failure with reduced ejection fraction (HFrEF) and in end-stage HFrEF with left ventricular assist devices (LVADs) support the idea of a common mechanism of action (MOA) by which rexlemestrocel-L reverses inflammation-related endothelial dysfunction and reduces adverse clinical outcomes across the spectrum of HFrEF patients.

- Improvement in left ventricular ejection fraction (LVEF) at 12 months in patients with HFrEF may be an appropriate early surrogate endpoint for long term reduction in major adverse cardiovascular events (MACE).

- Mesoblast plans to meet with FDA under its existing regenerative medicine advanced therapy (RMAT) designation to discuss data and the evidence of a common MOA across the broader HFrEF spectrum, including LVAD patients.

Other

Salary payments to full-time Executive Directors were US$324,678 and fees to Non-Executive Directors were US$192,164, detailed in Item 6 of the Appendix 4C cash flow report for the quarter.[9]

A copy of the Appendix 4C – Quarterly Cash Flow Report for the second quarter FY2023 is attached.

About Mesoblast

Mesoblast is a world leader in developing allogeneic (off-the-shelf) cellular medicines for the treatment of severe and life-threatening inflammatory conditions. The Company has leveraged its proprietary mesenchymal lineage cell therapy technology platform to establish a broad portfolio of late-stage product candidates which respond to severe inflammation by releasing anti-inflammatory factors that counter and modulate multiple effector arms of the immune system, resulting in significant reduction of the damaging inflammatory process.

Mesoblast has a strong and extensive global intellectual property portfolio with protection extending through to at least 2041 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 is developing product candidates for distinct indications based on its remestemcel-L and rexlemestrocel-L allogeneic stromal cell technology platforms. Remestemcel-L is being developed for inflammatory diseases in children and adults including steroid refractory acute graft versus host disease, biologic-resistant inflammatory bowel disease, and acute respiratory distress syndrome. Rexlemestrocel-L is in development for advanced chronic 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

References / Footnotes

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

2. The Appendix 4C for the quarter ended December 31, 2021 reported net cash usage for operating activities of US$19.8 million which was subsequently revised to US$18.2 million, and the quarter ended December 31, 2020 reported net cash usage for operating activities of US$32.0 million which was subsequently revised to US$30.6 million. These revisions were due to a change in accounting policy adopted at December 31, 2021.

3. Rashidi A et al. Outcomes and predictors of response in steroid-refractory acute graft-versus-host disease: single-center results from a cohort of 203 patients. *Biol Blood Bone Marrow Transplant* 2019; 25(11):2297-2302.

4. Berger M, Pessolano R, Carraro F, Saglio F, Vassallo E, Fagioli F. Steroid-refractory acute graft-versus-host disease graded III-IV in pediatric patients. A mono-institutional experience with a long-term follow-up. *Pediatric Transplantation*. 2020; 24(7):e13806

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

5. Biavasco F, Ihorst G, Wasch R, Wehr C, Bertz H, Finke J, Zeiser R. Therapy response of glucocorticoid-refractory acute GVHD of the lower intestinal tract. *Bone Marrow Transplantation.* 2022

6. MacMillan ML et al. Pediatric acute GVHD: clinical phenotype and response to upfront steroids. *Bone Marrow Transplant* 2020; 55(1): 165-171

7. Zeiser R et al. Ruxolitinib for Glucocorticoid-Refractory Acute Graft-versus-Host Disease. *N Engl J Med* 2020;382:1800-10.

8. Jagasia M et al. Ruxolitinib for the treatment of steroid-refractory acute GVHD (REACH1): a multicenter, open-label phase 2 trial. *Blood.* 2020 May 14; 135(20): 1739–1749.

9. As required by ASX listing rule 4.7 and reported in Item 6 of the Appendix 4C, reported are the aggregated total payments to related parties being Executive Directors and Non-Executive Directors

Forward-Looking Statements

This press release 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 (including BLA resubmission), 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.

For more information, please contact:

Corporate Communications / Investors
Paul Hughes
T: +61 3 9639 6036
E: investors@mesoblast.com

Media
BlueDot Media
Steve Dabkowski
T: +61 419 880 486
E: steve@bluedot.net.au

Rubenstein
Tali Mackay
E: tmackay@rubenstein.com

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 December 2022

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	1,448	3,667
1.2	Payments for		
	(a) research and development	(5,487)	(11,049)
	(b) manufacturing commercialization	(3,662)	(7,679)
	(c) product manufacturing and operating costs	(1,670)	(2,465)
	(d) advertising and marketing	(573)	(1,006)
	(e) leased assets	—	—
	(f) staff costs	(3,069)	(5,205)
	(g) other expenses from ordinary activities	(3,131)	(6,169)
	(h) other:		
	- Intellectual property portfolio expenses	(527)	(1,112)
1.3	Dividends received (see note 3)	—	—
1.4	Interest received	147	207
1.5	Interest and other costs of finance paid	—	—
1.6	Income taxes paid	—	—
1.7	Government grants and tax incentives	18	18
1.8	Other (provide details if material)	—	—
1.9	**Net cash from / (used in) operating activities**	**(16,506)**	**(30,793)**

+ See chapter 19 of the ASX Listing Rules for defined terms.

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 or for:		
	(i) entities	—	—
	(j) businesses	—	—
	(k) property, plant and equipment	(34)	(187)
	(l) investments	—	—
	(m) intellectual property	—	(50)
	(n) other non-current assets	—	—
2.2	Proceeds from disposal of:		
	(o) entities	—	—
	(p) businesses	—	—
	(q) property, plant and equipment	—	—
	(r) investments	—	—
	(s) intellectual property	—	—
	(t) other non-current assets	—	—
2.3	Cash flows from loans to other entities	—	—
2.4	Dividends received (see note 3)	—	—
2.5	Other	—	—
2.6	**Net cash from / (used in) investing activities**	**(34)**	**(237)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	—	45,065
3.2	Proceeds from issue of convertible debt securities	—	—
3.3	Proceeds from exercise of options	—	—
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(81)	(2,646)
3.5	Proceeds from borrowings	—	—
	Proceeds from issue of warrants	—	—
3.6	Repayment of borrowings	—	—
3.7	Transaction costs related to loans and borrowings	(65)	(216)
	Interest and other costs of finance paid	(1,375)	(2,756)
3.8	Dividends paid	—	—
3.9	Other (payment of lease liability)	(439)	(1,109)
3.10	**Net cash from / (used in) financing activities**	**(1,960)**	**38,338**

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, 2022)/beginning of year (July 1, 2022)	85,502	60,447
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(16,506)	(30,793)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(34)	(237)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(1,960)	38,338
4.5	Effect of movement in exchange rates on cash held	617	(136)
4.6	**Cash and cash equivalents at end of period**	**67,619**	**67,619**

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	67,213	85,112
5.2	Call deposits	—	—
5.3	Bank overdrafts	—	—
5.4	Other (Term deposits)	406	390
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**67,619**	**85,502**

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	517
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 for Non-executive Director fees and Executive Director's salary (for the current quarter) = US$516,842

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	130,000*	90,000*
7.2	Credit standby arrangements	—	—
7.3	Other (please specify)	—	—
7.4	**Total financing facilities**	130,000*	90,000*

7.5	**Unused financing facilities available at quarter end**	40,000*

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 Oaktree Capital Management, Inc.__

On November 19, 2021, Mesoblast refinanced its senior debt facility with a new US$90.0 million secured five-year credit facility provided by funds managed by Oaktree Capital Management, L.P. ("Oaktree"). Mesoblast drew the first tranche of US$60.0 million on closing, the remaining US$30.0 million is available subject to achieving certain milestones on or before September 30, 2023.

The loan has an initial interest only period of three years, at a fixed rate of 9.75% per annum, after which time 40% of the principal is payable over two years and a final payment due no later than November 2026.

The loan interest rate is fixed and as at December 31, 2022 the interest rate was 9.75%. In the year to date at December 31, 2022, 8% interest was paid in cash, while 1.75% interest was not paid in cash, instead it was paid in kind (PIK) and accrued onto the loan balance outstanding.

__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 for the treatment in pediatric patients with steroid-refractory acute graft versus host disease ("SR-aGVHD") by the United States Food and Drug Administration (FDA). The loan term includes an interest only period of approximately four years through until July 8, 2022, then a four-year amortization period through until maturity.

All interest and principal payments will be deferred until after the first commercial sale of remestemcel-L in the treatment of pediatric patients with SR-aGVHD. Principal is repayable in equal quarterly instalments over the amortization period of the loan based on a percentage of net sales and are limited by a payment cap. The loan has a fixed interest rate of 15% per annum. The financing is subordinated to the senior creditor, Oaktree.

8.	**Estimated cash available for future operating activities**	**$US'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(16,506)
8.2	Cash and cash equivalents at quarter end (item 4.6)	67,619
8.3	Unused finance facilities available at quarter end (item 7.5)	40,000*
8.4	Total available funding (item 8.2 + item 8.3)	107,617
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	6.5

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 Oaktree senior debt facility US$30.0 million is available subject to achieving certain milestones on or before September 30, 2023. 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: 31 January 2023

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.

asx announcement

MESOBLAST RESUBMITS BIOLOGIC LICENSE APPLICATION (BLA) TO FDA FOR REMESTEMCEL-L IN CHILDREN WITH STEROID-REFRACTORY ACUTE GRAFT VERSUS HOST DISEASE (SR-aGVHD)

Validation of Remestemcel-L Potency Assay used in the Phase 3 Trial which Measures In-Vivo Activity based on Mechanism of Action

Assay Identifies High-Potency Product Lots Associated with Enhanced Survival

New Data Show that Remestemcel-L Improves Inflammatory Biomarkers and Survival in Children at Highest Risk of Mortality

New 4-Year Data from the Phase 3 Trial Shows Durable Long-Term Survival Outcomes

BLA Resubmission will have a Review Period up to Six-Months from Filing upon Acceptance by FDA

If Approved, Remestemcel-L would be the First Treatment Available for Children Under 12 Years Old with SR-aGVHD, a Devastating Disease with Very High Mortality

New York, USA; January 31, 2023 and Melbourne, Australia: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, announced today it has resubmitted to the U.S. Food and Drug Administration (FDA) its Biologics License Application (BLA) for approval of remestemcel-L in the treatment of children with steroid-refractory acute graft versus host disease (SR-aGVHD).

Survival outcomes have not improved over the past two decades for the most severe forms of SR-aGVHD, a life-threatening complication of an allogeneic bone marrow transplant following treatment for blood cancers and other conditions.[1-3] The lack of any approved treatments for children under 12 means that there is an urgent need for a therapy that improves the dismal survival outcomes. If remestemcel-L receives FDA approval, it will be the first allogeneic "off-the-shelf" cellular medicine to be approved in the United States, and the first therapy for children under 12 years old with SR-aGVHD.

The resubmission contains substantial new information as required by FDA in the Complete Response Letter (CRL) received in September 2020 to the BLA for remestemcel-L. Mesoblast has maintained an active dialogue with FDA since receiving the CRL and in October 2022 provided a high-level synopsis of the substantial new information under its Investigational New Drug (IND) application for remestemcel-L. FDA granted remestemcel-L Fast Track designation, a process to facilitate the development and expedited review of therapies for serious conditions that fill unmet medical needs, and Priority Review designation, which is given to drugs that treat a serious condition and provide a significant improvement in safety or effectiveness over existing treatments. The BLA resubmission will have a review period up to six months from filing upon acceptance by FDA.

Mesoblast has responded to the CRL and the further guidance it has received from the FDA and has generated and provided new data and analyses in the resubmission which we believe provide substantial evidence of remestemcel-L's effectiveness in pediatric SR-aGVHD. Specifically, the resubmission contains the following:

- new long-term survival data of children enrolled in the Phase 3 trial showing durability of treatment effect through at least four years,
- new data showing remestemcel-L's treatment benefit in high-risk disease activity and on survival in propensity-matched studies of children in the Phase 3 trial and controls stratified by validated biomarkers for high-risk disease,

- new analyses of data obtained prospectively showing that the validated potency assay which was in place and used to release product for the 54-patient Phase 3 clinical trial measures a key product attribute which reflects the primary mechanism of action of remestemcel-L in children with SR-aGVHD, correlates with the product's *in vivo* bioactivity, and predicts overall survival outcomes,

- new analyses of data obtained prospectively relating manufacturing changes during product development prior to Phase 3 to progressive increases in potency and to improved survival outcomes in larger studies of remestemcel-L under expanded access in children with SR-aGVHD,

- new data showing that the validated potency assay has low variability and can adequately demonstrate manufacturing consistency and reproducibility, and

- establishment of a new specification for release of commercial product based on extensive clinical data which provides assurance that future batches of remestemcel-L will have attributes supportive of expected survival outcomes.

"There is an urgent need for a therapy that improves the dismal survival outcome in children with SR-aGVHD" said Dr. Silviu Itescu, Chief Executive of Mesoblast. "Our team has worked tirelessly over the past two years to provide a comprehensive response to the FDA. We are grateful for the agency's active dialogue and constructive feedback that will ensure a high bar is met in terms of product consistency and predictability of clinical outcomes."

About Steroid-Refractory Acute Graft Versus Host Disease

Survival outcomes have not improved over the past two decades for children or adults with the most severe forms of SR-aGVHD.[1-3] The lack of any approved treatments for children under 12 means that
there is an urgent need for a therapy that improves the dismal survival outcomes in children.

Acute GVHD occurs in approximately 50% of patients who receive an allogeneic bone marrow transplant (BMT). Over 30,000 patients worldwide undergo an allogeneic BMT annually, primarily during treatment for blood cancers, including about 20% in pediatric patients.[4,5] SR-aGVHD is associated with mortality as high as 90% and significant extended hospital stay costs.[6,7] There are currently no FDA-approved treatments in the US for children under 12 with SR-aGVHD.

About Remestemcel-L

Mesoblast's lead product candidate, Remestemcel-L, is an investigational therapy comprising culture expanded mesenchymal stromal cells derived from the bone marrow of an unrelated donor. It is administered to patients in a series of intravenous infusions. Remestemcel-L is believed to have immunomodulatory properties to counteract the inflammatory processes that are implicated in SR-aGVHD by down-regulating the production of pro-inflammatory cytokines, increasing production of anti-inflammatory cytokines, and enabling recruitment of naturally occurring anti-inflammatory cells to involved tissues.

The original BLA submission contained clinical outcomes of 309 children with SR-aGVHD treated with remestemcel-L showing consistent treatment responses and survival across three separate trials. The data were reviewed by the agency's panel of the Oncologic Drugs Advisory Committee (ODAC) which voted in favor 9:1 that the available data support the efficacy of remestemcel-L in pediatric patients with SR-aGVHD.

The BLA resubmission now contains additional clinical and biomarker data, including from a propensity-matched study of children with high-risk disease, based on the validated MAP biomarker score, comparing outcomes in 25 children from Mesoblast's Phase 3 trial and 27 control children treated with various biologics, including ruxolitinib, from the Mount Sinai Acute GvHD International Consortium (MAGIC) database. The study showed that 67% of high-risk children treated with remestemcel responded positively to treatment within 28 days and were alive after 180 days compared to just 10% in both categories in the MAGIC group.

The BLA resubmission also contains results of a 4-year survival study performed by the Center for International Blood and Marrow Transplant Research (CIBMTR) on 51 evaluable patients with SR-aGVHD who were enrolled in the Phase 3 trial. The results demonstrated durability of the early day 180 survival benefits, with 63% survival at 1 year and 51% at 2 years in a group of children with predominantly grade C/D disease (89%) and with expected 2 year survival of just 25-38% using best available therapy.[1,8-9]

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 is a world leader in developing allogeneic (off-the-shelf) cellular medicines for the treatment of severe and life-threatening inflammatory conditions. The Company has leveraged its proprietary mesenchymal lineage cell therapy technology platform to establish a broad portfolio of late-stage product candidates which respond to severe inflammation by releasing anti-inflammatory factors that counter and modulate multiple effector arms of the immune system, resulting in significant reduction of the damaging inflammatory process.

Mesoblast has a strong and extensive global intellectual property portfolio with protection extending through to at least 2041 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 is developing product candidates for distinct indications based on its remestemcel-L and rexlemestrocel-L allogeneic stromal cell technology platforms. Remestemcel-L is being developed for inflammatory diseases in children and adults including steroid refractory acute graft versus host disease, biologic-resistant inflammatory bowel disease, and acute respiratory distress syndrome. Rexlemestrocel-L is in development for advanced chronic 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

References / Footnotes

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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

Forward-Looking Statements

This press release 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 (including BLA resubmission), 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.

For more information, please contact:

Corporate Communications / Investors
Paul Hughes
T: +61 3 9639 6036
E: investors@mesoblast.com

Media
BlueDot Media
Steve Dabkowski
T: +61 419 880 486
E: steve@bluedot.net.au

Rubenstein
Tali Mackay
E: tmackay@rubenstein.com