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 May 2024

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 \square Form 40-F \square

INFORMATION CONTAINED ON THIS REPORT ON FORM 6-K

On April 30, 2024, 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 March 31, 2024, which is attached hereto as <u>Exhibit 99.1</u>, and is incorporated herein by reference.

On April 30, 2024, 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/ Paul Hughes

Paul Hughes
Company Secretary

Dated: May 1, 2024

INDEX TO EXHIBITS

Item

- 99.1 Appendix 4C of Mesoblast Ltd, dated April 30, 2024.
- 99.2 Press release of Mesoblast Ltd, dated April 30, 2024.



asx announcement

APPENDIX 4C QUARTERLY ACTIVITY REPORT FOR QUARTER ENDED MARCH 31, 2024

FDA Provides Clarity on Path to Licensure for Remestemcel-L in SR-aGVHD and Rexlemestrocel-L in End-Stage Heart Failure

Melbourne, Australia; April 30 and New York, USA; April 29, 2024: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today provided an activity report for the third quarter ended March 31, 2024.

Mesoblast Chief Executive Silviu Itescu said: "We are very pleased with the positive interactions we had last quarter with the FDA, having received clarity on the path to licensure for our product candidates in pediatric acute graft versus host disease and in ischemic patients with chronic heart failure."

"Based on the clear responses and guidance from FDA we intend this quarter to resubmit our Biologics License Application (BLA) for approval of remestemcel-L in children with SR-aGVHD," said Mesoblast CEO Dr. Silviu Itescu. "In addition, FDA informed us that the results from our pivotal study of rexlemestrocel-L in end-stage heart failure patients may support an accelerated approval, and we intend to have a pre-BLA meeting to discuss the data that will be provided and the timing for an accelerated approval filing."

ACTIVITY REPORT

Graft versus Host Disease - Pediatric and Adult Indications

- United States Food and Drug Administration (FDA) informed Mesoblast after its Type C meeting during the quarter that following additional consideration the available clinical data from its Phase 3 study MSB-GVHD001 appears sufficient to support submission of the proposed Biologics License Application (BLA) for remestemcel-L for treatment of pediatric patients with steroid-refractory acute graft versus host disease (SR-aGVHD).
- Mesoblast intends to file the resubmission this quarter, potentially resulting in an approval for Ryoncil® (remestemcel-L) in the second half of CY2024.
- Mesoblast will now focus on its original strategy to first gain pediatric approval for RYONCIL, followed by label extension in the larger adult population.

Cardiovascular - Chronic Heart Failure with Reduced Ejection Fraction (HFrEF) in Adults

- FDA informed the Company in formal minutes following the Type B meeting held in February under Mesoblast's existing Regenerative Medicine Advanced Therapy (RMAT) designation, that it supports an accelerated approval pathway for Revascor® (rexlemestrocel-L), Mesoblast's allogeneic mesenchymal precursor cell (MPC) product, in patients with end-stage ischemic heart failure with reduced ejection fraction (HFrEF) and a left ventricular assist device (LVAD).
- In these patients, a single administration of REVASCOR reduced inflammation, strengthened left ventricular function, reduced right ventricular failure, reduced hospitalizations and reduced mortality.
- REVASCOR has also shown the potential to reduce major adverse cardiac events (MACE) such as cardiovascular death, heart attacks and strokes in ischemic HFrEF patients with NYHA class II /III disease and inflammation.
- Mesoblast intends to request a pre-BLA meeting with FDA to discuss data presentation, timing and FDA expectations for an accelerated approval filing in ischemic HFrEF patients with end-stage heart failure.

Cardiovascular - Pediatric Congenital Heart Disease

- During the quarter FDA granted Mesoblast a Rare Pediatric Disease (RPD) Designation for Revascor® (rexlemestrocel-L) following submission of results from the randomized controlled trial in children with hypoplastic left heart syndrome (HLHS), a potentially life-threatening congenital heart condition.
- On FDA approval of a BLA for REVASCOR for the treatment of HLHS, Mesoblast may be eligible to receive a Priority Review Voucher (PRV) that can be redeemed for any subsequent marketing application or may be sold or transferred to a third party.

Chronic Low Back Pain - Phase 3 Program

 Second Phase 3 trial underway for rexlemestrocel-L in the treatment of chronic low back pain (CLBP) due to inflammatory disc degeneration— a condition affecting at least seven million people in both the US and Europe alone.

FINANCIAL REPORT

Strengthened Balance Sheet

Completed the pro-rata accelerated non-renounceable entitlement offer that was launched on 4 December, 2023 (Entitlement Offer). Together the entitlement offer and institutional placement raised gross proceeds of A\$97 million, including A\$36.7 million during the quarter on the same terms as the Entitlement Offer. As part of its active approach to efficient balance sheet management, during the quarter Mesoblast reduced debt under its five-year facility, and its minimum cash balance requirement under that facility, by US\$10 million. Cash balance at the end of the quarter was A\$117.0 million (US\$76.4 million).

Cost containment strategy on-track

Cost containment strategies and payroll reductions have been enacted by management and the Board enabling continuation of Phase 3 programs for SR-aGVHD and CLBP in the quarter whilst still achieving reductions in net operating cash spend:

- Net operating cash spend of US\$11.7 million for the quarter.
- 28% reduction in net operating cash spend from the comparative quarter in FY2023.
- On target to achieve a 23% (\$15m) reduction in net operating spend in FY2024 compared to FY2023 which will be partially offset by investment in our commercial and clinical activities for SR-aGVHD and CLBP, respectively.

We will maintain our focus on cutting costs and preserving cash in the remainder of the year whilst we continue to work on corporate and strategic initiatives to access commercial distribution channels, supplement costs of development, and strengthen our balance sheet.

Other

Fees to Non-Executive Directors were nil, consulting payments to Non-Executive Directors were US\$77,217 and salary payments to full-time Executive Directors were US\$228,769, detailed in Item 6 of the Appendix 4C cash flow report for the quarter. From 1 August 2023, Non-Executive directors have voluntarily deferred 50% cash payment of their director fees and agreed to receive the remaining 50% of their fees in equity-based incentives and Executive Directors (our Chief Executive and Chief Medical Officers) have voluntarily reduced their base salaries for FY24 by 30% in lieu of accepting equity-based incentives.

A copy of the Appendix 4C - Quarterly Cash Flow Report for the third quarter FY2024 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 Limited ABN 68 109 431 870 www.mesoblast.com Corporate Headquarters Level 38 55 Collins Street Melbourne 3000 Victoria Australia United States Operations 505 Fifth Avenue Third Floor New York, NY 10017 USA

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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 remestencel-L and rexlemestrocel-L allogeneic stromal cell technology platforms. Remestencel-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

- Using Reserve Bank of Australia (RBA) published exchange rate from March 31, 2024 of 1A\$:0.6532US\$.
- 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, 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 2024

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	1,661	5,632
1.2	Payments for		
	(a) research and development	(4,102)	(11,651)
	(b) manufacturing commercialization, product manufacturing and operating costs	(4,415)	(19,711)
	(c) advertising and marketing	(243)	(1,826)
	(d) leased assets	_	_
	(e) staff costs	(826)	(3,824)
	(f) other expenses from ordinary activities	(2,887)	(8,097)
	(g) other:		
	 Intellectual property portfolio expenses 	(1,275)	(2,633)
1.3	Dividends received (see note 3)	-	
1.4	Interest received	437	1,324
1.5	Interest and other costs of finance paid	_	_
1.6	Income taxes refunded	5	4
1.7	Government grants and tax incentives and credits		2,565
1.8	Other (provide details if material)	_	_
1.9	Net cash from / (used in) operating activities	(11,645)	(38,217)



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 or for:			
	(i) entities	_	_	
	(j) businesses	_	_	
	(k) property, plant and equipment	(41)	(235)	
	(I) investments	_	-	
	(m) intellectual property	_	(10)	
	(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)	_	<u></u> -	
2.5	Other	60	176	
2.6	Net cash from / (used in) investing activities	19	(69)	
3.	Cash flows from financing activities			
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	25,691	65,399	
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	(1,500)	(4,078)	
3.5	Proceeds from borrowings	_	· <u>-</u> -	
	Proceeds from issue of warrants	_	.—	
3.6	Repayment of borrowings	(10,000)	(10,000)	
3.7	Transaction costs related to loans and borrowings	(463)	(1,003)	
	Interest and other costs of finance paid	(1,556)	(4,401)	

Page 2



Consolidated statement of cash flows		Current quarter \$US'000	Year to date (9 months) \$US'000
3.8	Dividends paid	_	_
3.9	Other (payment of lease liability)	(503)	(2,648)
3.10	Net cash from / (used in) financing activities	11,669	43,269
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of quarter (December 1, 2023)/beginning of year (July 1, 2023)	77,554	71,318
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(11,645)	(38,217)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	19	(69)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	11,669	43,269
4.5	Effect of movement in exchange rates on cash held	(1,233)	63
4.6	Cash and cash equivalents at end of	76,364	76,364

period



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	75,972	77,144
5.2	Call deposits	_	_
5.3	Bank overdrafts	_	(
5.4	Other (Term deposits)	392	410
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	76,364	77,554

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	306
6.2	Aggregate amount of payments to related parties and their associates included in item 2	_

explanation for, such payments.

Consulting payments to Non-Executive Directors and salary payments to full-time Executive Directors (for the current quarter) =US\$305,986



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	90,000*	80,000*
7.2	Credit standby arrangements		_
7.3	Other (please specify)	_	_
7.4	Total financing facilities	90,000*	*000,008
7.5	Unused financing facilities available at qu	arter end	10,000*

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.

Mesoblast refinanced its senior debt facility on November 19, 2021 with a secured five-year credit facility provided by funds managed by Oaktree Capital Management, L.P. ("Oaktree").The balance of funds drawn down is currently US\$50.0 million.

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 June 30, 2023 the interest rate was 9.75%. For the first two years to November 19, 2023, 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 NovaOuest 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\$40.0million 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 included an interest only period of approximately four years through until July 8, 2022.

All interest and principal payments (i.e. the amortization period) are 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)	(11,645)		
8.2	Cash and cash equivalents at quarter end (item 4.6)	76,364		
8.3	Unused finance facilities available at quarter end (item 7.5)	10,000*		
8.4	Total available funding (item 8.2 + item 8.3)	86,364		
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	7.4		
	if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 a tted quarters of funding available must be included in item 8.5.	s "N/A". Otherwise, a figure for the		
	If item 8.5 is less than 2 quarters, please provide answers to the following questions:			
United	If item 8.5 is less than 2 quarters, please provide answers to the fol	lowing questions:		
	If item 8.5 is less than 2 quarters, please provide answers to the fol	lowing questions:		
	If item 8.5 is less than 2 quarters, please provide answers to the fol 8.6.1 Does the entity expect that it will continue to have the curr	lowing questions:		
	If item 8.5 is less than 2 quarters, please provide answers to the fol 8.6.1 Does the entity expect that it will continue to have the curr cash flows for the time being and, if not, why not?	lowing questions: ent level of net operating any steps, to raise further		
	If item 8.5 is less than 2 quarters, please provide answers to the fol 8.6.1 Does the entity expect that it will continue to have the curr 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 cash to fund its operations and, if so, what are those steps and how	lowing questions: ent level of net operating any steps, to raise further		
	If item 8.5 is less than 2 quarters, please provide answers to the fol 8.6.1 Does the entity expect that it will continue to have the curr 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 cash to fund its operations and, if so, what are those steps and how that they will be successful?	lowing questions: ent level of net operating any steps, to raise further vikely does it believe		
	If item 8.5 is less than 2 quarters, please provide answers to the fol 8.6.1 Does the entity expect that it will continue to have the curr 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 cash to fund its operations and, if so, what are those steps and how that they will be successful? Answer: Not applicable 8.6.3 Does the entity expect to be able to continue its operation.	lowing questions: ent level of net operating any steps, to raise further vikely does it believe		

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 April 2024
	by:Chief Executive



Notes

- 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.
- 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.
- 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 CHAIR TRANSITION

Melbourne, Australia; April 30 and New York, USA; April 29, 2024: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today announced that Joseph R. Swedish has chosen to transition from Chair and will remain on the Board until completion of his term at the Annual General Meeting later this year. The Board has unanimously appointed Jane Bell AM to the role of non-executive Chair effective today. The Board acknowledges and thanks Mr Swedish for his dedicated service as Chair of Mesoblast having seen the company emerge from a challenging period to the point of potential first product commercialisation.

Mr Swedish said "It has been an honour serving on the Board and witnessing first-hand the tremendous dedication and commitment it takes to bring a cutting-edge product to market. I feel we are on the verge of achieving that goal and I am confident that the Board, working with Silviu and the management team will achieve this milestone and capitalize on the building blocks established to date".

Ms Bell said. "Mesoblast is a very exciting company. I am honoured to have the opportunity to step up at this important juncture in order to maximise shareholder value as the Company seeks to commercialise its valuable product pipeline," Ms Bell said.

Mesoblast Chief Executive Dr Silviu Itescu said: "I am grateful for Joe's leadership as Chair these past years. I welcome Jane who brings to the Board deep finance, commercial and healthcare skills and look forward to working together to bring our important products to patients."

Ms Bell is an experienced leader with a corporate career spanning chair, director and executive roles as a banking and finance lawyer with 30 years of corporate finance expertise focussing on international investment transactions in the United States, Canada, Australia and the United Kingdom, including funds management, mergers, acquisitions, and divestments. She has served as a non-executive Director in a diverse range of highly regulated sectors including delivery of healthcare, life sciences, medical research, and funds management.

As Mesoblast Chair, Ms Bell will step down as Chair of the Audit and Risk Committee and will continue as a member of this committee. Mr Philip Facchina has been appointed by the Board as Chair of the Audit and Risk Committee in her place.

About Mesoblast

Mesoblast (the Company) 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.

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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 any future decision that the FDA may make on the BLA for remestemcel-L for pediatric patients with SR-aGVHD), 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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