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 December 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 ☑ Form 40-F ☐

INFORMATION CONTAINED ON THIS REPORT ON FORM 6-K

On December 19, 2024, Mesoblast Limited filed with the Australian Securities Exchange a new release announcement, which is attached hereto as Exhibit 99.1, 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: December 20, 2024

INDEX TO EXHIBITS

Item	
99.1	Press release of Mesoblast Ltd, dated December 19, 2024.

asx announcement

mesoblast

MESOBLAST'S RYONCIL® IS THE FIRST U.S. FDA-APPROVED MESENCHYMAL STROMAL CELL (MSC) THERAPY

- *RYONCIL (remestemcel-L) is the first MSC product approved by FDA for any indication.*
- *RYONCIL is the first FDA-approved therapy for children aged 2 months and older, including adolescents and teenagers, with steroid-refractory acute graft versus host disease (SR-aGvHD), a life-threatening condition with high mortality rates.*
- *In a single-arm, multi-center, Phase 3 trial of children with SR-aGvHD, 89% of whom had high severity Grade C or Grade D disease, 70% achieved an overall response by Day 28 of treatment with RYONCIL, a measure that predicts survival in aGVHD.*
- *RYONCIL'S immunomodulatory effects, including inhibition of T cell activation and secretion of pro-inflammatory cytokines, position the therapy for potential other indications in diseases with excessive inflammation.*

Melbourne, Australia; December 19 and New York, USA; December 18, 2024: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today announced the Food and Drug Administration (FDA) approved Ryoncil® (remestemcel-L) as the first mesenchymal stromal cell (MSC) therapy in the United States. RYONCIL is the only MSC therapy approved in the U.S. for any indication, and the only approved therapy for steroid-refractory acute graft versus host disease (SR-aGvHD) in children 2 months and older, including adolescents and teenagers.

Transplant physician Dr Joanne Kurtzberg, the Jerome Harris Distinguished Professor of Pediatrics and Professor of Pathology, and Director, Marcus Center for Cellular Cures at Duke University Medical Center (DUMC), said: "Steroid-refractory acute graft versus host disease is a devastating condition with an extremely poor prognosis. From today we are able to offer RYONCIL, the first FDA-approved treatment which will be life saving for so many children and will have a great impact on their families."

Annually in the United States approximately 10,000 patients undergo an allogeneic bone marrow transplant, 1,500 of whom are children. Approximately 50% develop aGvHD and almost half of those do not respond to steroids, the recognized first-line treatment.[1-5] In a single-arm multi-center Phase 3 trial of children with SR-aGvHD, 89% of whom had high severity Grade C or Grade D disease, 70% achieved an overall response by Day 28 of treatment with RYONCIL, a measure that predicts survival in aGVHD. RYONCIL treatment was not discontinued or interrupted in any patient for any laboratory abnormality, and the full course was completed without interruption in more than 85% of patients. The full Phase 3 clinical study results are available in *Biology of Blood and Marrow Transplantation*.[6]

"We are very pleased that the FDA has granted approval of RYONCIL® and are proud of the company's commitment to the GVHD community in bringing this important new treatment to children and families with no other acceptable options," said Dr. Silviu Itescu, Chief Executive of Mesoblast. "With RYONCIL approval by FDA, Mesoblast has demonstrated the ability to bring the first MSC product to market. We will continue to work closely with FDA to obtain approval of our other late-stage products, including REVASCOR® for cardiovascular diseases and rexlemestrocel-L for inflammatory pain indications, as well as expanding the indications for RYONCIL in both children and adults with inflammatory conditions."

RYONCIL will be available in the United States at transplant centers and other treating hospitals.

Please see the full Prescribing Information at www.ryoncil.com. The FDA's approval press release is available here.

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What is RYONCIL (remestemcel-L)
RYONCIL is an allogeneic bone marrow-derived mesenchymal stromal cell (MSC) therapy indicated for the treatment of steroid-refractory acute graft versus host disease (SR-aGvHD) in pediatric patients 2 months of age and older.

The recommended dosage of RYONCIL is 2×10^6 MSC /kg body weight per intravenous infusion given twice per week for 4 consecutive weeks. Response is assessed 28 ± 2 days after the first dose and further treatment administered as appropriate.

Important Safety Information

Contraindications: Known hypersensitivity to dimethyl sulfoxide (DMSO) or porcine and bovine proteins.

Adverse reactions: Serious adverse reactions included pyrexia (9%), respiratory failure (9%), pneumatosis intestinalis (7%) and staphylococcal bacteremia infection (<5%). Adverse reactions of Grade 3 occurring in ≥10% of patients were viral infectious disorders (15%), bacterial infectious disorders (19%), and infections pathogen unspecified (15%). No grade 4 or 5 adverse reactions occurred in the study. Eight patients had discontinuation of RYONCIL treatment due to the following: acute infusion reactions (n=3), hypotension (n=1), gastroenteritis (n=1), and death (n=3).

You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Mesoblast at toll-free phone #1-844-889-MESO (6376)

Please see the RYONCIL full Prescribing Information for additional Important Safety Information.

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 therapies from the Company's proprietary mesenchymal lineage cell therapy technology platform 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's RYONCIL® (remestemcel-L) for the treatment of steroid-refractory acute graft versus host disease (SR-aGvHD) in children 2 months and older is the first FDA-approved mesenchymal stromal cell (MSC) therapy.

Mesoblast is committed to developing additional cell therapies for distinct indications based on its remestemcel-L and rexlemestrocel-L allogeneic stromal cell technology platforms. RYONCIL is being developed for additional inflammatory diseases including SR-aGvHD in adults and biologic-resistant inflammatory bowel disease. Rexlemestrocel-L is being developed for heart failure and chronic low back pain. The Company has established commercial partnerships in Japan, Europe and China.

About Mesoblast intellectual property: Mesoblast has a strong and extensive global intellectual property portfolio, with over 1,000 granted patents or patent applications covering mesenchymal stromal cell compositions of matter, methods of manufacturing and indications. These granted patents and patent applications provide commercial protection extending through to at least 2041 in all major markets.

About Mesoblast manufacturing: 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 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. 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.
2. 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
3. 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
4. Niederwieser D, Baldomero H, Szer J. (2016) Hematopoietic stem cell transplantation activity worldwide in 2012 and a SWOT analysis of the Worldwide Network for Blood and Marrow Transplantation Group including the global survey.
5. HRSA Transplant Activity Report, CIBMTR, 2019
6. Kurtzberg, J. et al. A Phase 3, Single-Arm, Prospective Study of Remestemcel-L, Ex Vivo Culture-Expanded Adult Human Mesenchymal Stromal Cells for the Treatment of Pediatric Patients Who Failed to Respond to Steroid Treatment for Acute Graft-versus-Host Disease. Biol Blood Marrow Transplant 26 (2020) 845-854 https://doi.org/10.1016/j.bbmt.2020.01.018

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 in relation to remestemcel-L for 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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