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 July 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 July 9, 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: July 10, 2024

INDEX TO EXHIBITS

Item	
99.1	Press release of Mesoblast Ltd, dated July 9, 2024.

asx announcement

mesoblast

MESOBLAST RESUBMITS BIOLOGICS LICENSE APPLICATION (BLA) WITH UNITED STATES FOOD & DRUG ADMINISTRATION (FDA) FOR APPROVAL OF RYONCIL® IN CHILDREN WITH STEROID-REFRACTORY ACUTE GRAFT-VERSUS-HOST DISEASE (SR-aGVHD)

Melbourne, Australia; July 9 and New York, USA; July 8, 2024: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, announced today it has resubmitted its BLA for approval of Ryoncil® (remestemcel-L) in the treatment of children with SR-aGVHD.

The filing comes after Mesoblast was informed by FDA at the end of March that, following additional consideration, the available clinical data from the Phase 3 study MSB-GVHD001 appears sufficient to support submission of the proposed BLA for remestemcel-L for treatment of pediatric patients with SR-aGVHD. As a result, the filing addresses remaining CMC (Chemistry, Manufacturing, and Control) items.

"We have worked closely with the agency and thank them for their ongoing guidance, facilitating the potential approval of RYONCIL and addressing the urgent need for a therapy that improves the dismal survival outcome in children with SR-aGVHD," said Mesoblast CEO Dr. Silviu Itescu.

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 upon acceptance is expected to have a review period of between two and six months from receipt.

About Ryoncil® (remestemcel-L)
Mesoblast's lead product candidate, Ryoncil® (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. RYONCIL has immunomodulatory properties which counteract the inflammatory processes that are implicated in SR-aGVHD by inhibiting activation and proliferation of effector T cells, down-regulating the production of pro-inflammatory cytokines, and enabling recruitment of anti-inflammatory cells to involved tissues.

About the Phase 3 Trial of Ryoncil® (remestemcel-L) in Children with Steroid-Refractory Acute Graft Versus Host Disease
The Phase 3 Study GVHD001/002 was conducted in 54 children (89% Grade C/D) across 20 centers in the US where RYONCIL was used as the first line of treatment for children who failed to respond to steroids for acute GVHD.[1] The trial met its pre-specified primary endpoint, Day 28 Overall Response (OR), 70.4% versus 45%, p=0.0003. An overall response at day 28 was highly predictive of improved survival through day 100 (87% compared to 47% in patients that did not achieve day 28 OR p= 0.0001).

Compared with a matched control group of pediatric subjects from the contemporaneous database of the Mount Sinai Acute GVHD International Consortium (MAGIC) treated with best available therapy, treatment with Ryoncil achieved higher Day 28 OR (70% vs 43%) and higher Day 100 survival (74% vs 57%). A propensity-matched study of outcomes in 25 children from Mesoblast's Phase 3 trial and 27 control children who received best available treatment, including ruxolitinib, from the MAGIC database showed that 67% of high-risk children (MAP scores >0.29) who received Ryoncil achieved a Day 28 overall response and were alive after 180 days compared to just 10% in both categories in the MAGIC group.

In addition, 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, demonstrated durability of the survival benefits, with 67% survival at 6 months, 63%

survival at 1 year, 51% at 2 years, and 49% survival through 4 years in children with expected 2 year survival of just 25-38% using best available therapy.[2-4]

About Steroid-Refractory Acute Graft Versus Host Disease
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.[5,6] SR-aGVHD is associated with mortality as high as 90% and significant extended hospital stay costs.[7,8] There are currently no FDA-approved treatments in the US for children under 12 with SR-aGVHD.

Survival outcomes have not improved over the past two decades for children or adults with the most severe forms of SR-aGVHD.[2,9-10] 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.

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.

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, and biologic-resistant inflammatory bowel disease. Rexlemestrocel-L is being developed 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. 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
2. 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
3. MacMillan ML et al. Pediatric acute GVHD: clinical phenotype and response to upfront steroids. *Bone Marrow Transplant* 2020; 55(1): 165-171
4. Zeiser R et al. Ruxolitinib for Glucocorticoid-Refractory Acute Graft-versus-Host Disease. *N Engl J Med* 2020;382:1800-10.
5. 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.
6. HRSA Transplant Activity Report, CIBMTR, 2019
7. Westin, J., Saliba, RM., Lima, M. (2011) Steroid-refractory acute GVHD: predictors and outcomes. *Advances in Hematology*.
8. Axt L, Naumann A, Toennies J (2019) Retrospective single center analysis of outcome, risk factors and therapy in steroid refractory graft-versus-host disease after allogeneic hematopoietic cell transplantation. *Bone Marrow Transplantation*.

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10. 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

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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