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 August 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 ☐

INFORMATION CONTAINED ON THIS REPORT ON FORM 6-K

On August 4, 2023, 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/ Niva Sivakumar

Niva Sivakumar
Company Secretary

Dated: August 4, 2023

INDEX TO EXHIBITS

Item	
99.1	Press release of Mesoblast Ltd, dated August 4, 2023.

asx announcement

mesoblast

MESOBLAST RECEIVES COMPLETE RESPONSE FROM U.S. FOOD AND DRUG ADMINISTRATION FOR BIOLOGICS LICENSE APPLICATION FOR STEROID-REFRACTORY ACUTE GRAFT VERSUS HOST DISEASE IN CHILDREN

Melbourne, Australia; August 4 and New York, USA; August 3, 2023: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today announced that the US Food and Drug Administration (FDA) has provided a complete response to its Biologics License Application (BLA) resubmission for remestemcel-L for the treatment of pediatric steroid-refractory acute graft versus host disease (SR-aGVHD) and requires more data to support marketing approval. To obtain the data required, Mesoblast will conduct a targeted, controlled study in the highest-risk adults with the greatest mortality. This adult study is in line with our overall commercial strategy, which envisioned a sequenced progression from pediatric to adult SR-aGVHD indications. Adults comprise 80% of the SR-aGVHD market.

Mesoblast Chief Executive Silviu Itescu said: "FDA's inspection of our manufacturing process resulted in no observed concerns, the Agency raised no safety issues across more than 1300 patients who have received remestemcel-L to date, and acknowledged improvements to our potency assay. We remain steadfast in making remestemcel-L available to both children and adults suffering from this devastating disease, and have received substantial clarity in how to bring this much-needed product to these patients".

Mesoblast intends to enroll adult patients at highest mortality risk with SR-aGVHD where existing therapy has not improved outcomes and 90-day survival remains as low as 20-30%.[1] Mesoblast has generated pilot data through its emergency IND program in adults showing a survival benefit with remestemcel-L in this target population. In line with our overall commercial strategy to expand into the adult SR-aGVHD indication, Mesoblast has already been working with leading investigators at various US centers of excellence to establish the adult follow-on study protocol, potentially utilizing established clinical trials networks. The company will seek alignment with FDA on the trial design for the adult study at a Type A meeting within 45 days.

Prior to the resubmission, FDA guided Mesoblast to resolve outstanding chemistry, manufacturing and controls (CMC) issues before initiating any additional clinical trial. FDA completed the Pre-License Inspection (PLI) of the manufacturing facility, did not issue any Form 483, and found no objectionable conditions. In addition, FDA acknowledged in the resubmission review that changes implemented appear to improve assay performance relative to the original version of the assay used in the pediatric Phase 3 trial.

Mesoblast has successfully met the pre-specified primary endpoint, prospectively agreed with FDA, of a single-arm Phase 3 trial in 54 children with SR-aGvHD. While the Oncologic Drugs Advisory Committee of FDA in August 2020 voted 9:1 in favor of remestemcel-L's efficacy in a pediatric patient population, in September 2020 FDA recommended further steps be undertaken to obtain approval. The BLA resubmission of January 2023 included long-term follow-up data from the Phase 3 trial by the Center for International Blood and Marrow Transplant Research (CIBMTR) showing 50% survival through more than 4 years of follow-up for remestemcel-L treated patients in the Phase 3 trial for whom less than 20% survival at two years was expected based on disease severity. The resubmission also included a post-hoc propensity matched study showing 6 month survival was 67% with remestemcel-L vs 10% with other unapproved therapies in highest-risk patients as identified using the Mount Sinai Acute GVHD International Consortium (MAGIC). These pediatric data provide further support for use of remestemcel-L in the proposed study in high-risk adults with SR-aGVHD.

Conference Call
There will be a webcast today, beginning at 10.00am AEST (Friday, August 4); 8.00pm EDT (Thursday, August 3). It can be accessed via: https://webcast.openbriefing.com/msb-mu-2023/

The archived webcast will be available on the Investor page of the Company's website: www.mesoblast.com

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.[2,3]

First-line treatment involves systemic corticosteroids. A significant proportion of patients have severe disease that is refractory to steroids. SR-aGVHD is associated with mortality as high as 90% and significant extended hospital stay costs.[4,5]

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, 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. 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
2. 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.
3. HRSA Transplant Activity Report, CIBMTR, 2019
4. Westin, J., Saliba, RM., Lima, M. (2011) Steroid-refractory acute GVHD: predictors and outcomes. *Advances in Hematology*.
5. 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*.

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

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advance its manufacturing capabilities; the timing or likelihood of regulatory filings and approvals (including our request to have a Type A meeting with the FDA, the outcome of such a meeting, and 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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