**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 2021**

**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 December 31, 2021, 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: December 31, 2021

**INDEX TO EXHIBITS**

| Item | |
|---|---|
| 99.1 | Press release of Mesoblast Ltd, dated December 31, 2021. |

asx announcement

mesoblast
the regenerative medicine company

**MESOBLAST PROVIDES UPDATE FOLLOWING MEETING WITH FDA'S OTAT ON REMESTEMCEL-L FOR CHILDREN WITH ACUTE GRAFT VERSUS HOST DISEASE**

**Key Points:**

- Meeting held with the US Food and Drug Administration's (FDA) Office of Tissues and Advanced Therapies (OTAT) to address potency assay and chemistry, manufacturing and controls (CMC) items identified in the complete response letter (CRL) for remestemcel-L in the treatment of steroid-refractory acute graft versus host disease (SR-aGVHD) in children
- OTAT indicated that Mesoblast's approach to address the outstanding CMC items is reasonable
- OTAT indicated that the *in vitro* immunomodulatory activity Mesoblast intends to measure for potency is a reasonable critical quality attribute (CQA) for the product, and the relevance of this activity to clinical outcomes should be established
- Mesoblast has now generated substantial new data that it believes establish the relevance of the proposed *in vitro* immunomodulatory activity of remestemcel-L to the *in vivo* clinical effect of the product in the Phase 3 trial in children with SR-aGVHD, including survival and biomarkers of *in vivo* activity
- Mesoblast will provide these new data to OTAT, and address other outstanding items as required for the Biologics License Application (BLA) resubmission

**Melbourne, Australia; December 31, and New York, USA; December 30, 2021:** Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today provided a regulatory update on remestemcel-L for steroid-refractory acute graft versus host disease in children following its recent meeting with the FDA's OTAT. Mesoblast requested the meeting to address the appropriateness of a potency assay related to remestemcel-L's proposed immunomodulatory mechanism of action as well as the approach to outstanding CMC items identified in the CRL.

OTAT indicated that Mesoblast's approach to address outstanding CMC items is reasonable, that the *in vitro* immunomodulatory activity of remestemcel-L proposed by Mesoblast as a measure of its potency is a reasonable CQA for the product in the treatment of children with SR-aGVHD, and the relevance of this immunomodulatory activity to clinical outcomes should be established.

Mesoblast has now generated substantial new data which it believes establish the relevance of the proposed *in vitro* immunomodulatory activity of remestemcel-L to the clinical effect of the product in the completed Phase 3 trial in pediatric SR-aGVHD, including to survival outcomes and biomarkers of the product's *in vivo* activity. Mesoblast will provide these new data to OTAT and address other remaining CRL items as required for the BLA resubmission.

By demonstrating the relevance of the *in vitro* potency assay to clinical outcomes, Mesoblast believes it will be able to show that the remestemcel-L product used in the Phase 3 trial in pediatric SR-aGVHD was standardized as to identity, strength, quality, purity, and dosage form, and that this will address OTAT's recommendation for an additional adequate and well-controlled study.

Mesoblast continues to be in a well-established process with FDA's Center for Biologics Evaluation and Research (CBER), and if the resubmission is accepted, CBER will consider the adequacy of the clinical data in the context of the related CMC issues noted above.

**About Steroid-Refractory Acute Graft Versus Host Disease (SR-aGVHD)**
GVHD is a severe inflammation in the bloodstream caused by complications of bone marrow transplants. The disease occurs in up to 50% of the 30,000 patients who receive an allogeneic bone marrow transplant each year, primarily during treatment for blood cancers. In patients with the most severe form of GVHD, mortality can be as high as 90%. There are no therapies approved for treating SR-aGVHD in children under the age of 12.

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**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 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 moderate to severe 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

**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.


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Release authorized by the Chief Executive.

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