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 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 May 25, 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/ Charlie Harrison

Charlie Harrison
Company Secretary

Dated: May 26, 2021

INDEX TO EXHIBITS

Item	
99.1	Press release of Mesoblast Ltd, dated May 25, 2021.

asx announcement

mesoblast
the regenerative medicine company

IMPROVED OUTCOMES IN INFLAMMATORY LUNG DISEASE WITH REMESTEMCEL-L PUBLISHED IN RESPIRATORY RESEARCH JOURNAL

Melbourne, Australia; May 25 and New York, USA; May 24, 2021: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today announced that the peer-reviewed journal *Respiratory Research* has published results showing that Mesoblast's mesenchymal stromal cell (MSC) product candidate remestemcel-L significantly improved respiratory and functional clinical outcomes in patients with chronic obstructive pulmonary disease (COPD) and elevated levels of the inflammatory biomarker C-reactive protein (CRP). Patients with COPD and elevated CRP levels have increased rates of hospitalization and death.[1] These results provide further rationale for potential use of remestemcel-L in inflammatory lung diseases, including COVID-19 acute respiratory distress syndrome (ARDS).

The manuscript titled 'Effect of mesenchymal stromal cell infusions on lung function in COPD patients with high CRP levels' is based on a post-hoc analysis from a randomized, placebo-controlled 60-patient Phase 2 trial in patients with COPD where outcomes were compared over 12 months between patients who received either remestemcel-L, given in four monthly intravenous doses of 100 million cells, or saline injections. That paper can be accessed at https://doi.org/10.1186/s12931-021-01734-8

Key findings from the analysis were:

- The greater the degree of inflammation, as measured by elevated CRP levels, the greater the signal of efficacy of remestemcel-L treatment in improving moderate to severe lung disease
- Significant improvements were observed in each of the pre-specified endpoints of forced expiratory volume, and forced vital capacity, with maximal effects seen at four months (both $p < 0.01$)
- Significant increases were seen in six-minute walk test which is a major independent predictor of mortality in COPD[2]
- In patients with the highest level of CRP (>4mg/L), those who received remestemcel-L were able to walk 55 meters further than placebo-treated patients in the six-minute walk test at four months ($p=0.004$)

"The relationship between high CRP levels and the degree of improvement in respiratory function following administration of remestemcel-L is consistent with inflammation in the lung being a trigger for the immunomodulatory effects of remestemcel-L," said Dr Fred Grossman Mesoblast Chief Medical Officer. "This is the basis for our ongoing investigation of remestemcel-L in the treatment of the severe lung inflammation including ventilator-dependent patients with COVID-19 ARDS."

About Remestemcel-L

Remestemcel-L is an investigational therapy comprising culture-expanded mesenchymal stromal cells derived from the bone marrow of an unrelated donor. Remestemcel-L is thought to have immunomodulatory properties to counteract the cytokine storms that are implicated in various inflammatory conditions by downregulating the production of pro-inflammatory cytokines, increasing production of anti-inflammatory cytokines, and enabling recruitment of naturally occurring anti-inflammatory cells to involved tissues.

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 2040 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.

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Mesoblast has completed Phase 3 trials of rexlemestrocel-L for advanced chronic heart failure and chronic low back pain. 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. 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

Footnotes

1. Dahl,M, et al. C-reactive Protein As a Predictor of Prognosis in Chronic Obstructive Pulmonary Disease. *Am J Respir Crit Care Med.* Vol 175. pp 250–255, 2007.
2. Polkey MI, et al. Evaluation of COPD Longitudinally to Identify Predictive Surrogate Endpoints (ECLIPSE) Study Investigators. Six-minute-walk test in chronic obstructive pulmonary disease: minimal clinically important difference for death or hospitalization. *Am J Respir Crit Care Med.* 2013;187:382–386.

Forward-Looking Statements

This announcement 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. All statements other than statements of historical fact are forward-looking statements, which are often indicated by terms such as "anticipate," "believe," "could," "estimate," "expect," "goal," "intend," "likely," "look forward to," "may," "plan," "potential," "predict," "project," "should," "will," "would" and similar expressions and variations thereof. 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. The risks, uncertainties and other factors that may impact our forward-looking statements include, but are not limited to: the timing, progress and results of Mesoblast's preclinical and clinical studies; Mesoblast's ability to advance product candidates into, enroll and successfully complete, clinical studies; the timing or likelihood of regulatory filings and approvals; whether the FDA agrees to a path forward; and the pricing and reimbursement of Mesoblast's product candidates, if approved; 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. 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. Unless required by law, 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.

For more information, please contact:

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