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 2020

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 18, 2020, 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 18, 2020

INDEX TO EXHIBITS

Item	
99.1	Press release of Mesoblast Ltd, dated December 18, 2020.

asx announcement

mesoblast
the regenerative medicine company

MESOBLAST UPDATE ON COVID-19 ARDS TRIAL

Melbourne, Australia; December 18, and New York, USA; December 17, 2020: Mesoblast Limited (ASX:MSB; Nasdaq:MESO) today provided an update on the randomized controlled trial of remestemcel-L in ventilator-dependent patients with moderate to severe acute respiratory distress syndrome (ARDS) due to COVID-19 infection after the Data Safety Monitoring Board (DSMB) performed a third interim analysis on the trial's first 180 patients. The trial was powered to achieve a primary endpoint of 43% reduction in mortality at 30 days for treatment with remestemcel-L on top of maximal care in a trial of 300 patients. This projected mortality reduction was based on pilot data observed during the initial stages of the pandemic when control mortality rates were exceedingly high and prior to new evolving treatment regimens that have reduced disease mortality in ventilated patients. The DSMB reported that there were no safety concerns and noted that the trial is not likely to meet the 30-day mortality reduction endpoint at the planned 300 patient enrolment. The DSMB recommended that the trial complete with the currently enrolled 223 patients, and that all be followed-up as planned.

Notably, the trial has not yet accrued data on the secondary endpoints, which include days alive off mechanical ventilation at 60 days post randomization, overall survival, days in intensive care, duration of hospitalization, and cardiac, neurological, and pulmonary organ damage. Additionally, measures of circulating cytokines and inflammatory markers will be evaluated. None of these were included in the interim analysis. As such, the trial will evaluate all 223 enrolled patients through 60 days of follow-up to study potential treatment effects on these outcomes. Mesoblast and Novartis will both analyse these results to identify meaningful clinical outcomes that may guide decisions on the development program for remestemcel-L in non-COVID ARDS.

During the course of the trial, as the pandemic has evolved, numerous changes in the treatment regimens for COVID-19 patients occurred, including both prior to and while on mechanical ventilation that may have an effect on the mortality endpoint in the trial. These include extended management of patients prior to ventilator support, and use of experimental therapies such as dexamethasone, anti-virals, and re-purposed immunomodulatory agents. All of these may have changed the natural course of ventilated patients and reduced overall mortality rates during the trial compared to the early stages of the pandemic.

Mesoblast entered into a license and collaboration agreement with Novartis on November 20, 2020 for the development, manufacture and commercialization of remestemcel-L, with an initial focus on the treatment of ARDS, including that associated with COVID-19, and other indications. The closing of the agreement is subject to the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and certain other conditions.

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 Limited (ASX:MSB; Nasdaq:MESO) is a world leader in developing allogeneic (off-the-shelf) cellular medicines. The Company has leveraged its proprietary mesenchymal lineage cell therapy technology platform to establish a broad portfolio of late-stage product candidates. 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. For more information, please see www.mesoblast.com, LinkedIn: Mesoblast Limited and Twitter: @Mesoblast

Mesoblast Limited
ABN 68 109 431 870

www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
Melbourne 3000
Victoria Australia

T +61 3 9639 6036
F +61 3 9639 6030

United States Operations
505 Fifth Avenue
Third Floor
New York, NY 10017
USA

T +1 212 880 2060
F +1 212 880 2061

Asia
21 Biopolis Road
#01-22 Nucleos (South Tower)
SINGAPORE 138567

T +65 6570 0635
F +65 6570 0176

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 include, but are not limited to, statements about the potential closing of the agreement with Novartis and its timing, 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, 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.

Corporate Communications / Investors

Schond Greenway
T: +212 880 2060
E: schond.greenway@mesoblast.com

Paul Hughes
T: +61 3 9639 6036
E: paul.hughes@mesoblast.com

Media

Kristen Bothwell
T: +1 917 613 5434
E:kbothwell@rubenstein.com