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 November 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 November 11, 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/ Charlie Harrison

Charlie Harrison
Company Secretary

Dated: November 12, 2020

INDEX TO EXHIBITS

Item	
99.1	Press release of Mesoblast Ltd, dated November 11, 2020.

asx announcement

mesoblast
the regenerative medicine company

SECOND INTERIM ANALYSIS OF CLINICAL OUTCOMES AFTER 135 PATIENTS RESULTS IN RECOMMENDATION TO CONTINUE REMESTEMCEL-L PHASE 3 TRIAL IN COVID-19 ARDS

Melbourne, Australia; November 11, and New York, USA; November 10, 2020: Mesoblast Limited (ASX: MSB; Nasdaq: MESO) today announced that the randomized controlled Phase 3 trial of remestemcel-L in patients with moderate to severe acute respiratory distress syndrome (ARDS) due to COVID-19 infection had received a recommendation to continue from the independent Data Safety Monitoring Board (DSMB) following completion of the trial's second interim analysis. The analysis was performed on the trial's first 135 patients, 45% of the total target of up to 300 randomized patients, with the DSMB recommending continuation after reviewing the trial's primary endpoint, all-cause mortality within 30 days of randomization and all safety data. The key secondary endpoint is days alive off mechanical ventilatory support within 60 days of randomization.

Mesoblast Chief Medical Officer Dr Fred Grossman said: "We are very pleased with the recommendation by the DSMB, as we seek to confirm whether remestemcel-L improves survival in ventilated COVID-19 patients with moderate to severe ARDS. Patients who have co-morbidities or are older are likely to continue to be at high risk of ARDS and death,[1-3] even if COVID-19 vaccines become available. This is why having a potential treatment that reduces mortality in these patients is so important."

ARDS is the principal cause of death in COVID-19 infection and is thought to be due to a dysregulated immune response in the lungs to COVID-19. Deaths continue to increase in ventilator-dependent ARDS patients as COVID-19 cases continue to surge globally. Despite improved treatment and earlier intervention in hospitalized COVID-19 patients overall, the mortality rate in COVID-19 ARDS patients who are over 60 years old remains more than 60%.[1] These patients appear to be particularly refractory to corticosteroids such as dexamethasone [4-5] and have not responded to single cytokine antagonists, anti-virals, or anti-malaria agents.

The Phase 3 trial aims to confirm findings from a pilot study at New York's Mt Sinai Hospital in March-April this year where nine of 12 ventilator-dependent patients (75%) were successfully discharged from hospital a median of 10 days after receiving two intravenous doses of remestemcel-L within five days. The ongoing Phase 3 trial, which is treating patients across more than 20 hospitals in the United States, uses the same dosing regimen.

Mesoblast holds an Investigational New Drug (IND) submission for remestemcel-L in COVID-19 ARDS, with trial size, protocol design, and endpoints developed with input from the United States Food and Drug Administration. The third and final interim analysis, when 60% of the randomized target has completed 30 days of follow-up, will occur in the coming weeks.

References

1.Mortality of COVID-19 Admitted Patients on Mechanical Ventilators. Epic Health Research Network. June 26, 2020
2. Harrison SL., et al. Comorbidities associated with mortality in 31,461 adults with COVID-19 in the United States: A federated electronic medical record analysis. PLOS Medicine. September 10, 2020. https://doi.org/10.1371/journal.pmed.1003321
3. Sanyaolu A., et al. Comorbidity and its Impact on Patients with COVID-19. SN Compr Clin Med. 2020 Jun 25: 1-8. doi: 10.1007/s42399-020-00363-4
4. Dexamethasone in Hospitalized Patients with Covid-19 — Preliminary Report. New England Journel of Medicine. July 17, 2020. DOI: 10.1056/NEJMoa2021436
5. Tomazini BM., et.al. Effect of Dexamethasone on Days Alive and Ventilator-Free in Patients With Moderate or Severe Acute Respiratory Distress Syndrome and COVID-19. JAMA 2020;324(13):1307-1316.

About Remestemcel-L

Mesoblast's lead product candidate, remestemcel-L, is an investigational therapy comprising culture-expanded mesenchymal stem cells derived from the bone marrow of an unrelated donor. It is thought to have immunomodulatory properties to counteract the cytokine storms that are implicated in various inflammatory conditions by down-regulating the production of pro-inflammatory cytokines, increasing production of anti-inflammatory cytokines, and enabling recruitment of naturally occurring anti-inflammatory cells to involved tissues.

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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 commercial products and late-stage product candidates. Mesoblast has a strong and extensive global intellectual property (IP) 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.

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. Mesoblast is completing Phase 3 trials for its product candidates for advanced 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 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; 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.

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