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 October 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 October 2, 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: October 2, 2020

INDEX TO EXHIBITS

Item	
99.1	Press release of Mesoblast Ltd, dated October 2, 2020.

asx announcement

mesoblast
the regenerative medicine company

MESOBLAST RECEIVES COMPLETE RESPONSE LETTER FROM THE FDA FOR BIOLOGICS LICENSE APPLICATION FOR STEROID-REFRACTORY ACUTE GRAFT VERSUS HOST DISEASE IN CHILDREN

Melbourne, Australia; October 2, 2020 and New York, USA; October 1, 2020: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, announced today that the US Food and Drug Administration (FDA) has issued a Complete Response Letter to its Biologics License Application (BLA) for remestemcel-L for the treatment of pediatric steroid-refractory acute graft versus host disease (SR-aGVHD). While the Oncologic Drugs Advisory Committee (ODAC)[1] of the FDA voted 9:1 that the available data support the efficacy of remestemcel-L in pediatric patients with SR-aGVHD, the FDA recommended that Mesoblast conduct at least one additional randomized, controlled study in adults and/or children to provide further evidence of the effectiveness of remestemcel-L for SR-aGVHD. As there are currently no approved treatments for this life-threatening condition in children under 12, Mesoblast will urgently request a Type A meeting with the FDA, expected within 30 days, to discuss a potential accelerated approval with a post-approval condition for an additional study.

Joanne Kurtzberg, MD, Jerome Harris Distinguished Professor of Pediatrics, Director, Pediatric Blood and Marrow Transplant Program, and Co-Director, Stem Cell Transplant Laboratory Duke University Medical Center, said: "The Phase 3 trial results showed that remestemcel-L provides a meaningful treatment for children with SR-aGVHD who have a very dismal prognosis. I look forward to having this much-needed therapy available to our patients."

Mesoblast is currently conducting a randomized, controlled Phase 3 trial evaluating remestemcel-L in up to 300 ventilator-dependent adults with moderate to severe acute respiratory distress syndrome (ARDS) due to COVID-19. A second interim analysis by the trial's independent Data Safety Monitoring Board is expected in early November, with completion of patient enrollment expected in December. COVID-19 ARDS is an inflammatory disease with a similar profile of damaging inflammatory cytokines as is seen in children with SR-aGVHD, and is the primary cause of death in COVID-19 infection. The trial's primary endpoint is reduction of all-cause mortality within 30 days of randomization.

The FDA also identified a need for further scientific rationale to demonstrate the relationship of potency measurements to the product's biologic activity. Assays measuring the potency of remestemcel-L will continue to be refined to provide further scientific rationale for its use in severe inflammatory diseases with high mortality risk, such as SR-aGVHD and COVID-19 ARDS.

Mesoblast Chief Executive Dr Silviu Itescu stated: "We are working tirelessly to bring remestemcel-L to patients with life threatening inflammatory conditions, including SR-aGVHD and COVID-19 ARDS."

About 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, and these numbers are increasing.[2] In patients with the most severe form of acute GVHD (Grade C/D or III/IV) mortality is as high as 90% despite optimal institutional standard of care.[3,4] There are currently no FDA-approved treatments in the United States for children under 12 with SR-aGVHD, a potentially life-threatening complication of an allogeneic bone marrow transplant for blood cancer.

About Remestemcel-L
Mesoblast's lead allogeneic cell therapy product candidate, remestemcel-L, is an investigational therapy comprising culture-expanded mesenchymal stem 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 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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References

1. This vote includes a change to the original vote by one of the ODAC panel members after electronic voting closed.
2.Niederwieser D, Baldomero H, Szer J. 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. Bone Marrow Transplant 2016; 51(6):778-85.
3. Westin, J., Saliba, RM., Lima, M. (2011) Steroid-refractory acute GVHD: predictors and outcomes. Advances in Hematology 2011;2011:601953.
4. 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 2019;54(11):1805-1814

Conference Call

An audio webcast will begin at 9.15am Friday, October 2 AEST / 7.15pm Thursday, October 1, 2020 EDT. The audio webcast can be accessed via https://webcast.boardroom.media/mesoblast-limited/20200930/NaN5f7147e5581a8100190f7687 or Webcast link

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

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 (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); 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.

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Release authorized by the Board.

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