

---

---

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 August 2019**

**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 August 14, 2019, 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: August 19, 2019

---

## INDEX TO EXHIBITS

### Item

99.1 Press release of Mesoblast Ltd, dated August 14, 2019.

## REMESTEMCEL-L TO BE EVALUATED AS TREATMENT FOR CHRONIC GRAFT VERSUS HOST DISEASE IN PLANNED INVESTIGATOR-INITIATED TRIAL

**Melbourne, Australia, August 14, 2019 and New York, USA, August 13, 2019:** Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in cellular medicines for inflammatory diseases, today announced that it intends to provide its allogeneic cell therapy product candidate remestemcel-L for evaluation under an investigator-initiated Investigational New Drug (IND) submission as a potential treatment in children with steroid-refractory *chronic* graft-versus-host disease (GVHD). The lead investigator will be Dr Joanne Kurtzberg, Jerome Harris Distinguished Professor of Pediatrics and Professor of Pathology, and Director, Pediatric Blood and Marrow Transplant Program at Duke University Medical Center.

In both *acute* and *chronic* forms of GVHD, the donated bone marrow stem cells view the recipient's body as foreign, and attack the body causing significant morbidity and mortality. *Acute* GVHD usually manifests within 100 days following a transplant while *chronic* GVHD generally manifests later (>100 days), and the two may occur separately or within the same patient.

The incidence of *chronic* GVHD is increasing and occurs in 30-70% of recipients of both related and unrelated bone marrow transplants.<sup>1,2</sup> There are no therapies approved by the United States Food and Drug Administration (FDA) in the 50% of children with *chronic* GVHD who fail steroids. Mesenchymal stem cells have been used successfully in patients with steroid-refractory *chronic* GVHD and have been reported to result in durable responses in up to 75% of patients.<sup>3-5</sup>

Dr Kurtzberg said: "Given my experience with achieving successful outcomes with remestemcel-L in children with steroid-refractory *acute* GVHD, I look forward to evaluating the treatment's potential as salvage therapy in *chronic* GVHD, where there remains a significant unmet need."

Earlier this year, Mesoblast initiated filing of a rolling submission for a Biologics License Application (BLA) to the FDA for the use of remestemcel-L in children with steroid-refractory *acute* GVHD. This BLA submission is based on a successful Phase 3 trial in 55 children with steroid-refractory *acute* GVHD and supporting results from an Expanded Access Program (EAP) in 241 children. Dr Kurtzberg was the Principal Investigator in both trials.

### 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 technology platform to establish a broad portfolio of late-stage product candidates with three product candidates in Phase 3 trials – acute graft versus host disease, chronic heart failure and chronic low back pain due to degenerative disc disease. Through a proprietary process, Mesoblast selects rare mesenchymal lineage precursor and stem cells from the bone marrow of healthy adults and creates master cell banks, which can be industrially expanded to produce thousands of doses from each donor without the need for tissue matching. Mesoblast has facilities in Melbourne, New York, Singapore and Texas and is listed on the Australian Securities Exchange (MSB) and on the Nasdaq (MESO). [www.mesoblast.com](http://www.mesoblast.com)

1. Arai et al. Biol Blood Marrow Transplant. 2015; 21(2): 266–274.
2. Grube et al. Biol Blood Marrow Transplant: 2016; 22 (11): 1781-179
3. Went et al. Bone Marrow Transplantation 2010; 45:1732-1740.
4. Shai et al. Blood 2013; 122:3294.
5. von Bahr et al. Blood 2015; 126:3138.

**Mesoblast Limited**  
 ABN 68 109 431 870  
[www.mesoblast.com](http://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**  
 20 Biopolis Way  
 #05-01 Centros  
 Biopreneur 3  
 SINGAPORE 138668

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. 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 timing, progress and results of Mesoblast's preclinical and clinical studies in aGVHD; Mesoblast's ability to advance its aGVHD product candidate into, enroll and successfully complete, clinical studies; the timing or likelihood of regulatory filings and approvals for aGVHD; 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.

*For further information, please contact:*

Julie Meldrum  
Corporate Communications  
T: +61 3 9639 6036  
E: [julie.meldrum@mesoblast.com](mailto:julie.meldrum@mesoblast.com)

Schond Greenway  
Investor Relations  
T: +1 212 880 2060  
E: [schond.greenway@mesoblast.com](mailto:schond.greenway@mesoblast.com)

**Mesoblast Limited**  
ABN 68 109 431 870  
[www.mesoblast.com](http://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**  
20 Biopolis Way  
#05-01 Centros  
Biopreneur 3  
SINGAPORE 138668

T +65 6570 0635  
F +65 6570 0176