

---

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 April 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 April 16, 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: April 23, 2019

---

INDEX TO EXHIBITS

Item

99.1 Press release of Mesoblast Ltd, dated April 16, 2019.

## FDA AGREES TO ROLLING REVIEW OF MESOBLAST'S BIOLOGIC LICENSE APPLICATION FOR ITS CELL THERAPY IN CHILDREN WITH STEROID-REFRACTORY ACUTE GRAFT VERSUS HOST DISEASE

**New York, USA; and Melbourne, Australia, April 16, 2019:** Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in cellular medicines for inflammatory diseases, announced today that the United States Food and Drug Administration (FDA) has agreed that Mesoblast can submit on a rolling basis a Biologics License Application (BLA) for its allogeneic cellular medicine remestemcel-L in children with steroid-refractory acute Graft Versus Host Disease (SR-aGVHD).

Mesoblast will submit each module of the BLA to the FDA on a rolling basis as it is completed. The rolling process will provide opportunity for ongoing and frequent communication, and during this process the Company expects it will be able to adequately address any substantial matters raised by the FDA.

Mesoblast has previously received Fast Track designation from the FDA for remestemcel-L in SR-aGVHD and is eligible for priority review once the BLA filing is completed and accepted by the FDA. Mesoblast expects to submit the first module shortly.

### About Steroid-refractory Acute Graft Versus Host Disease

SR-aGVHD is a life-threatening complication of a bone marrow transplant in patients primarily being treated for blood cancers. There are more than 30,000 allogeneic bone marrow transplants performed globally, with a total of over 20,000 in the United States and the EU5 annually. Approximately 20% occur in children. Currently, there are no approved products for SR-aGVHD in children outside Japan, where Mesoblast licensee JCR Pharmaceuticals markets TEMCELL®<sup>1</sup> HS Inj. for both children and adults with aGVHD.

### About Mesoblast

Mesoblast Limited (ASX:MSB; Nasdaq:MESO) has leveraged its proprietary immunomodulatory cellular technology platform to establish a broad portfolio of late-stage allogeneic (off-the-shelf) 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. Mesoblast has developed proprietary cell manufacturing processes, including use of immunoselection, master cell banks, industrialized culture expansion, potency assays, and stringent lot release criteria, to enable large-scale production of cellular therapies that can be used with off-the-shelf logistics from a single donor to thousands of unrelated recipients. 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. TEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.

### 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; 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. You should read this press release

**Mesoblast Limited**  
ABN 68 109 431 870

**Corporate Headquarters**  
Level 38  
55 Collins Street  
Melbourne 3000  
Victoria Australia

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

**Asia**  
20 Biopolis Way  
#05-01 Centros  
Biopreneur 3  
SINGAPORE 138668

[www.mesoblast.com](http://www.mesoblast.com)

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

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

T +65 6570 0635  
F +65 6570 0176

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

