
**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 September 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 September 15, 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: September 16, 2020

INDEX TO EXHIBITS

Item

99.1 Press release of Mesoblast Ltd, dated September 15, 2020.

MESOBLAST WINS 2020 FIERCE BIOTECH INNOVATION OF THE YEAR AWARD FOR REMESTEMCEL-L

Melbourne, Australia; September 15 and New York; USA; September 14, 2020: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today announced that its lead product candidate remestemcel-L has been selected as the winner of the Fierce Innovation Awards - Life Sciences Edition 2020 for Biotech Innovation. The Fierce Innovation Awards is a peer-reviewed program from the publisher of *FierceBiotech* and *FiercePharma*.

Mesoblast Chief Executive Dr Silviu Itescu stated: "This important award is recognition of Mesoblast's leadership as an innovator in the cell therapy industry, and of the potential for remestemcel-L to profoundly impact the lives of children suffering with steroid-refractory acute graft versus host disease (SR-aGVHD)."

Remestemcel-L is under priority review by the United States Food and Drug Administration (FDA) for pediatric SR-aGVHD and, if approved, product launch in the United States is expected in 2020. The FDA has set a Prescription Drug User Fee Act (PDUFA) action date of September 30, 2020.

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.

Given the extensive inflammatory response in COVID-19 infection, remestemcel-L is also being evaluated in a randomized, controlled Phase 3 trial in up to 300 ventilator-dependent adults with moderate to severe acute respiratory distress syndrome (ARDS), the primary cause of mortality in COVID-19 patients. The trial aims to confirm results from a pilot study at New York's Mt Sinai hospital which showed that nine of 12 patients (75%) were successfully discharged from hospital a median of 10 days after receiving two intravenous doses of remestemcel-L within five days. The trial's independent Data Safety Monitoring Board (DSMB) recently completed an interim analysis of the trial's first 30% enrolled patients and recommended that the trial should continue as planned after reviewing all safety data and results for the trial's primary endpoint of all-cause mortality within 30 days of randomization. The DSMB will perform a second interim analysis when 45% of the enrollment target has completed 30 days of follow-up.

About Fierce Innovation Awards – Life Sciences Edition 2020

These awards highlight companies that demonstrate innovative solutions, technologies, and services that have the potential to make the greatest impact for biotech and pharma companies. The evaluation criteria are effectiveness, technical innovation, competitive advantage, financial impact, and true innovation. The awards program's applications were reviewed by a panel of executives from major biotech and pharma companies including Astellas, Accenture, AstraZeneca, Angiocrine Bioscience, Biotech Research Group, NIHR Clinical Research Network, Medidata Solutions and PPD.

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. Mesoblast's Biologics License Application to seek approval of its product candidate RYONCIL™ (remestemcel-L) for pediatric steroid-refractory acute graft versus host disease has been accepted for priority review by the United States Food and Drug Administration (FDA), and if approved, product launch in the United States is expected in 2020. Remestemcel-L is also being developed for other inflammatory diseases in children and adults including moderate to severe acute respiratory distress syndrome (ARDS). 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 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

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. 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; 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. 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.

For further information, please contact:

Media

Julie Meldrum
T: +61 3 9639 6036
E: julie.meldrum@mesoblast.com

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

Investors

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

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

Mesoblast Limited
ABN 68 109 431 870
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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