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 February 2021

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 February 17, 2021, 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/ Niva Sivakumar

Niva Sivakumar
Company Secretary

Dated: February 19, 2021

INDEX TO EXHIBITS

Item	
99.1	Press release of Mesoblast Ltd, dated February 17, 2021.

asx announcement

mesoblast
the regenerative medicine company

POSITIVE OUTCOMES OF FIRST CHILDREN TREATED WITH REMESTEMCEL-L FOR MULTISYSTEM INFLAMMATORY SYNDROME (MIS-C) AND HEART FAILURE POST-COVID-19 PUBLISHED IN PEDIATRICS

Melbourne, Australia; February 17, and New York, USA; February 16, 2021: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today announced that *Pediatrics* (Journal of the American Academy of Pediatrics) has published a paper on the first two children treated with Mesoblast's mesenchymal stromal cell (MSC) product candidate remestemcel-L for life-threatening multisystem inflammatory syndrome (MIS-C) associated with COVID-19.

The manuscript, titled 'Remestemcel-L Therapy for COVID-19-Associated Multisystem Inflammatory Syndrome in Children,' was based on two children admitted to the Medical University of South Carolina's MUSC Shawn Jenkins Children's Hospital, who were the first ever to be treated with remestemcel-L for MIS-C. Its authors include Allison Ross Eckard, MD, Professor of Pediatrics and Medicine and Division Chief of Infectious Diseases and Dr. Andrew M. Atz, Professor and Chair of the Department of Pediatrics at the Medical University of South Carolina. The article can be accessed at https://doi.org/10.1542/peds.2020-046573

MIS-C, a potentially life-threatening inflammatory condition which involves multiple critical organs and their vasculature, is associated with prior rather than active COVID-19 infection. It is thought to be a post-viral autoimmune process where the body's over-zealous reaction to the virus causes the damage, rather than the virus itself. In approximately 50% of cases this inflammation is associated with significant cardiovascular complications resulting in decreased heart function and the presence of clinically important cardiovascular symptoms.[1-3]

The two patients detailed in the paper were previously exposed to COVID-19 infection and later developed MIS-C. Despite receiving standard of care for MIS-C, they continued to display severe heart failure and significantly elevated inflammatory biomarkers. When treated with two intravenous doses of remestemcel-L separated by 48 hours, normalization of left ventricular ejection fraction, notable reductions in biomarkers of systemic and cardiac inflammation, and improved clinical status occurred. There were no safety signals associated with the remestemcel-L treatment. Both patients were subsequently discharged from hospital.

The authors noted: There are currently no standardized or approved treatments for MIS-C. Remestemcel-L exhibits beneficial effects relative to the cardiac and vascular pathophysiology associated with this inflammatory disease state in children. This therapy holds promise as a novel treatment for MIS-C.

Mesoblast's existing Investigational New Drug (IND) application provides physicians with access to their MSC investigational product candidate, remestemcel-L, under its Intermediate-Size Expanded Access Program in COVID-19 infected children aged between two months and 17 years with MIS-C.[4]

About Mesoblast

Mesoblast is a world leader in developing allogeneic (off-the-shelf) cellular medicines for the treatment of severe and life-threatening inflammatory conditions. The Company has leveraged its proprietary mesenchymal lineage cell therapy technology platform to establish a broad portfolio of late-stage product candidates which respond to severe inflammation by releasing anti-inflammatory factors that counter and modulate multiple effector arms of the immune system, resulting in significant reduction of the damaging inflammatory process.

Mesoblast has a strong and extensive global intellectual property 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 has completed Phase 3 trials of rexlemestrocel-L for advanced chronic heart failure and chronic low back pain. 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. 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.

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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

References / Footnotes

1. Riphagen S, Gomez X, et al. Hyperinflammatory shock in children during COVID-19 pandemic. *Lancet* 2020; 395:1607-1608
2. Verdoni L, et al. An outbreak of severe Kawasaki-like disease at the Italian epicentre of the SARS-CoV-2 epidemic: an observational cohort study. *Lancet* 2020; 395:1771-1778
3. Dufort EM, et al. Multisystem Inflammatory Syndrome in Children in New York State. *N Eng J Med* 2020; 383:347-358
4. www.clinicaltrials.gov; NCT04456439

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 initiation, timing, progress and results of Mesoblast's preclinical and clinical studies, and Mesoblast's research and development programs; Mesoblast's ability to advance product candidates into, enroll and successfully complete, clinical studies, including multi-national clinical trials; Mesoblast's ability to advance its manufacturing capabilities; the timing or likelihood of regulatory filings and approvals, manufacturing activities and product marketing activities, if any; the commercialization of Mesoblast's product candidates, if approved; regulatory or public perceptions and market acceptance surrounding the use of stem-cell based therapies; the potential for Mesoblast's product candidates, if any are approved, to be withdrawn from the market due to patient adverse events or deaths; the potential benefits of strategic collaboration agreements and Mesoblast's ability to enter into and maintain established strategic collaborations; 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; the scope of protection Mesoblast is able to establish and maintain for intellectual property rights covering its product candidates and technology; estimates of Mesoblast's expenses, future revenues, capital requirements and its needs for additional financing; Mesoblast's financial performance; developments relating to Mesoblast's competitors and industry; 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.

Release authorized by the Chief Executive.

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