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 March 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 March 31, 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/ Charlie Harrison

Charlie Harrison
Company Secretary

Dated: April 1, 2021

INDEX TO EXHIBITS

Item	
99.1	Press release of Mesoblast Ltd, dated March 31, 2021.

asx announcement

mesoblast
the regenerative medicine company

MESOBLAST OPERATIONAL HIGHLIGHTS AND UPCOMING MILESTONES

Melbourne, Australia; March 31 and New York, USA; March 30, 2021: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today provided an overview of the Company's recent operational highlights, as well as upcoming milestones.

Operational highlights included:

- Successful completion of US$110 million private placement, with pro-forma cash balance at December 31, 2020, of US$187.5 million
- Private placement was led by US investor group SurgCenter Development (SurgCenter), one of the largest private operators of ambulatory surgical centers (ASC) in the US specializing in spine, orthopaedic and total joint procedures.
- Appointment of Philip J. Facchina, Chief Strategy Officer of SurgCenter, to the Mesoblast Board of Directors
- Results from Phase 3 trial of rexlemestrocel-L (MPC-06-ID) in 404 patients with chronic low back pain (CLBP) due to degenerative disc disease (DDD) showed that a single injection of rexlemestrocel-L + hyaluronic acid (HA) carrier may provide at least two years of pain reduction, with opioid sparing activity in patients using opioids at baseline
- Significant and durable reductions in CLBP through 24 months were seen across the entire evaluable study population, and greatest pain reduction was observed in the pre-specified population with CLBP of shorter duration than the study median of 68 months
- The results indicate that treatment benefit may be greatest when inflammation is high and before irreversible fibrosis has occurred in the intervertebral disc
- Results from Phase 3 trial of rexlemestrocel-L (REVASCOR®) in 537 patients with chronic heart failure (CHF) with reduced left ventricular ejection fraction (HFrEF) showed that a single dose of rexlemestrocel-L resulted in substantial reductions in heart attacks and strokes across the entire evaluable study population of NYHA class II and III patients and in significant and durable reduction in cardiac death in patients with New York Heart Association (NYHA) class II disease
- The results indicate that treatment benefit in patients with chronic heart failure may be greatest when inflammation is high and before irreversible heart muscle loss and fibrosis has occurred
- Commencement of an investigator-led randomized, controlled study of remestemcel-L delivered by an endoscope directly to the areas of inflammation and tissue injury in up to 48 patients with medically refractory Crohn's disease or ulcerative colitis
- License and collaboration agreement with Novartis for the development, manufacture, and commercialization of remestemcel-L, with an initial focus on the development of the treatment of acute respiratory distress syndrome (ARDS), including that associated with COVID-19. The agreement remains subject to certain closing conditions, including time to analyze the results from the COVID-19 ARDS trial

Key initiatives and upcoming milestones for the next two quarters:

- Mesoblast's strengthened balance sheet will underpin the Company's operational preparedness and its ongoing discussions with potential strategic partners to develop and commercialize rexlemestrocel-L and remestemcel-L for the large market opportunities of chronic heart failure, chronic lower back pain, and respiratory diseases
- Mesoblast expects to meet with the United States Food and Drug Administration (FDA) under a well-established regulatory process to discuss the fastest pathway to licensure of remestemcel-L in the treatment of children with steroid-refractory acute graft versus host disease
- Clinical results from remestemcel-L trials in COVID-19 ARDS and medically refractory Crohn's disease or ulcerative colitis
- Mesoblast intends to meet with FDA to discuss a potential pathway for approval of rexlemestrocel-L in patients with chronic heart failure based on the observed reduction in mortality and morbidity in the chronic heart failure Phase 3 trial

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- Mesoblast intends to meet with FDA to discuss a potential pathway for approval of rexlemestrocel-L in patients with chronic discogenic lower back pain based on the observed durable reduction in pain and opioid sparing activity in the CLBP Phase 3 trial

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.

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 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.

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Release authorized by the Chief Executive.

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