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 July 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 July 1, 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: July 1, 2021

INDEX TO EXHIBITS

Item	
99.1	Press release of Mesoblast Ltd, dated July 1, 2021.

asx announcement

mesoblast
the regenerative medicine company

MESOBLAST PROVIDES UPDATE ON PROGRAM FOR CHRONIC LOW BACK PAIN DUE TO DEGENERATIVE DISC DISEASE

Melbourne, Australia; July 1, and New York, USA; June 30, 2021: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today provided an update on the strategy for bringing rexlemestrocel-L to patients in the United States (US) with chronic low back pain (CLBP) due to degenerative disc disease (DDD) refractory to available therapies, including opioids. Excessive use of opioids in this patient population continues to be a major focus for US healthcare policymakers, regulatory authorities, patients and physicians, with more than 50% of US opioid prescriptions being for the treatment of CLBP.[1,6,7]

Mesoblast has filed a request and expects to hold a Type C meeting with the US Food & Drug Administration (FDA) during the current quarter to discuss the pathway to US regulatory approval for rexlemestrocel-L following the recently completed 404 patient Phase 3 trial in patients with chronic inflammatory back pain due to degenerative disc disease.

“We look forward to discussing with the FDA the most efficient path forward given the durable pain reduction for at least two years and the opioid-sparing activity from a single administration of rexlemestrocel-L that was observed in the recent Phase 3 trial” said Dr Fred Grossman, Chief Medical Officer of Mesoblast.

Mesoblast plans to leverage the results from a planned US trial to support potential product approvals in both US and EU by including 20% EU patients in order to provide regulatory harmonization, cost efficiencies and streamlined timelines, without initiating an EU trial. In line with this strategy, Mesoblast and its partner in Europe and Latin America, Grünenthal, have amended their collaboration agreement, with Mesoblast being eligible to receive payments up to US$112.5 million prior to product launch in the EU, inclusive of US$17.5 million already received, if certain clinical and regulatory milestones are satisfied and reimbursement targets are achieved. Cumulative milestone payments could reach US$1 billion depending on the final outcome of Phase 3 studies and patient adoption. Mesoblast will also receive tiered double-digit royalties on product sales as per the original agreement.

About Chronic Low Back Pain due to Degenerative Disc Disease

Chronic low back pain (CLBP) affects approximately 10-15% of the adult population, equivalent to more than 30 million people in the United States and almost 40 million people across the EU5.[1] Degenerative disc disease (DDD) causing discogenic pain is the most common etiology of CLBP in adults.[4,5] Over 7 million patients in each of the United States and E.U.5 are thought to suffer from CLBP caused by degenerative disc disease,[4-6] a disease which involves inflammation and degeneration of the intervertebral discs due to various factors including age, trauma or genetic pre-disposition.

Back pain causes more disability than any other condition and inflicts substantial direct and indirect costs on the healthcare system[6], including excessive use of opioids in this patient population. There are few treatment options for patients with CLBP who fail conservative therapy, including opioids, spinal injections and surgery (e.g., spinal fusion or total disk arthroplasty).[7] More than 50% of US opioid prescriptions are for the treatment of CLBP,[1-3] despite the fact that opioids are associated with serious and potentially life-threatening side effects and have not demonstrated efficacy in the treatment of CLBP.[3,8,9] In 2018, more than 67,000 drug overdose deaths occurred in the United States[10] of which almost 47,000 (70%) were opioid related.

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.

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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

References

1. Decision Resources: Chronic Pain Report 2015.
2. Abdel Shaheed C, Maher CG, Williams KA, Day R, McLachlan AJ. Efficacy, tolerability, and dose-dependent effects of opioid analgesics for low back pain: a systematic review and meta-analysis. *JAMA Intern Med* 2016;176(7):958–68
3. Hudson TJ, Edlund MJ, Steffick DE, Tripathi SP, Sullivan MD. Epidemiology of regular prescribed opioid use: results from a national, population-based survey. *J Pain Symptom Manage* 2008;36(3):280–8
4. DePalma MJ, et al. What Is the Source of Chronic Low Back Pain and Does Age Play a Role? *Pain Med*. 2011; 12: 224–233
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7. Zigler J, et al. Comparison of lumbar total disc replacement with surgical spinal fusion for the treatment of single-level degenerative disc disease: a meta-analysis of 5-year outcomes from randomized controlled trials. *Glob Spine J*. 2018;8(4):413–23
8. Chaparro LE, Furlan AD, Deshpande A, Mailis-Gagnon A, Atlas S, Turk DC. Opioids compared to placebo or other treatments for chronic low-back pain. *Cochrane Database Syst Rev* 2013(8):CD004959
9. Chou R, Turner JA, Devine EB, Hansen RN, Sullivan SD, Blazina I, et al. The effectiveness and risks of long-term opioid therapy for chronic pain: a systematic review for a National Institutes of Health Pathways to Prevention Workshop. *Ann Intern Med* 2015;162 (4):276–86
10. Annual surveillance report of drug-related risks and outcomes United States, 2019. Centers for Disease Control and Prevention

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 potential milestone and royalty payments that may be received pursuant to the agreement with Grunenthal, 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;

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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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