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 2023

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 9, 2023, 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 14, 2023

INDEX TO EXHIBITS

Item	
99.1	Press release of Mesoblast Ltd, dated February 9, 2023.

asx announcement

mesoblast

FDA GRANTS REGENERATIVE MEDICINE ADVANCED THERAPY (RMAT) DESIGNATION FOR REXLEMESTROCEL-L IN CHRONIC LOW BACK PAIN

Melbourne, Australia; February 9 and New York, USA; February 8, 2023: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today announced that the United States Food and Drug Administration's (FDA) Office of Tissues and Advanced Therapies (OTAT) has granted Regenerative Medicine Advanced Therapy (RMAT) designation for rexlemestrocel-L in the treatment of chronic low back pain (CLBP) associated with disc degeneration, in combination with hyaluronic acid (HA) as delivery agent for injection into the lumbar disc.

RMAT designations aim to expedite the development of regenerative medicine therapies intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition where preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for the disease or condition. An RMAT designation for rexlemestrocel-L provides all the benefits of Breakthrough and Fast Track designations, including rolling review and eligibility for priority review on filing of a Biologics License Application (BLA).

There is a significant need for a safe, effective, and durable opioid-sparing treatment in patients with CLBP associated with degenerative disc disease. Data from the completed 404-patient randomized, blinded placebo-controlled Phase 3 trial of rexlemestrocel-L combined with HA formed the basis for FDA's determination that Mesoblast's allogeneic cell therapy has the potential to address unmet medical needs for patients suffering from CLBP due to disc degeneration. Results from the trial showed that:

- A single injection of rexlemestrocel-L+HA into the lumbar disc resulted in significant reduction in pain compared with saline control at 12 and 24 months across all subjects (n=404).
- The reduction in low back pain observed in all subjects was substantially enhanced in the pre-specified population with CLBP of shorter duration than the median of 68 months for the study (n=194).
- Significant improvement in function and quality of life measures were observed in subjects with a shorter duration of CLBP at baseline.
- Pain reduction through 36 months was seen in the subset of patients using opioids at baseline (n=168) with the rexlemestrocel-L+HA group having substantially greater reduction at all time points compared with saline controls.
- Among patients on opioids at baseline, despite instructions to maintain existing therapies throughout the trial, at 36 months 28% who received rexlemestrocel-L + HA were not taking an opioid compared with 8% of saline treated controls.

"We are pleased to receive RMAT designation for our cellular therapy to treat CLBP due to disc degeneration" said Mesoblast Chief Executive Silviu Itescu. "We look forward to working closely with FDA to efficiently generate the additional data needed to support marketing approval of rexlemestrocel-L for the treatment of this serious and debilitating condition."

About Chronic Low Back Pain

CLBP is a serious condition with an annual prevalence of low back pain in the general US adult population of 10-30% and a lifetime prevalence in US adults as high as 65-80%.[1] Overall, low back pain is the fifth most common reason for visiting a US doctor.[2] In the last 3 months alone, approximately 25% of adults in the USA experienced low back pain for at least 24 hours.[3] In the first 3 months, recovery is observed in 33% of patients, but 1 year after onset, 65% still report pain.[4] CLBP is one of the leading causes of disability in the United States, and it is associated with impaired quality of life, severe limitations in ability to perform activities of daily living, reduced ability to work, and negative impacts on mental health. In fact, back pain is the leading cause of disability in Americans under 45 years old with more than 26 million Americans between the ages of 20-64 experiencing frequent back pain.[5] Back pain is listed as a cause of limitations in activities of daily living by 15% to 31% of those persons with limitations.[6] When considering both death and disability,

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musculoskeletal conditions such as CLBP are the second greatest cause of disability and have the fourth greatest impact on the overall health of the world population.[7]

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 2041 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 is developing product candidates for distinct indications based on its remestemcel-L and rexlemestrocel-L allogeneic stromal cell technology platforms. Remestemcel-L is being developed for inflammatory diseases in children and adults including steroid refractory acute graft versus host disease, biologic-resistant inflammatory bowel disease, and acute respiratory distress syndrome. Rexlemestrocel-L is in development for advanced chronic 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 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. Urits I, Burshtein A, Sharma M, et al. Low Back Pain, a Comprehensive Review: Pathophysiology, Diagnosis, and Treatment. Current Pain and Headache Reports. 2019;23(3):1-10. doi:10.1007/s11916-019-0757-1.
2. Atlas SJ, Deyo RA. Evaluating and managing acute low back pain in the primary care setting. J Gen Intern Med, Springer. 2001;16: 120–31.
3. Petering RC, Webb C. Treatment options for low back pain in athletes. Sports Health, SAGE Publications. 2011;3:550–5.
4. Itz CJ, Geurts JW, Kleef M, Nelemans P. Clinical course of non-specific low back pain: A systematic review of prospective cohort studies set in primary care. European Journal of Pain. 2012;17(1):5-15. doi:10.1002/j.1532-2149.2012.00170.x.
5. American Academy of Pain Medicine - Get the Facts on Pain. The American Academy of Pain Medicine. http://www.painmed.org/patientcenter/facts-on-pain/ Accessed on June 28, 2017.
6. United States Bone and Joint Initiative: The Burden of Musculoskeletal Diseases in the United States (BMUS), Third Edition, 2014. Rosemont, IL. Available at http://www.boneandjointburden.org. Accessed on August 23, 2017.
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Forward-Looking Statements
This press release 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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