
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 October 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 October 7, 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: October 8, 2021

INDEX TO EXHIBITS

Item

99.1 Press release of Mesoblast Ltd, dated October 7, 2021.

REXLEMESTROCEL-L PHASE 3 TRIAL RESULTS IN CHRONIC HEART FAILURE SELECTED AS LATE BREAKING PRESENTATION AT AMERICAN HEART ASSOCIATION ANNUAL MEETING

Melbourne, Australia; October 7, and New York, USA; October 6, 2021: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today announced that results from the randomized, controlled Phase 3 trial of rexlemestrocel-L in 565 patients with New York Heart Association (NYHA) class II and class III chronic heart failure (CHF) with low ejection fraction (HFrEF) have been selected through peer review as a late breaking presentation at the American Heart Association (AHA) annual meeting occurring November 13th- 15th. The featured session is titled 'Building on the Foundations of Treatment: Advances in Heart Failure Therapy'.

The trial's co-principal investigator Dr Emerson Perin, Medical Director of Texas Heart Institute, and Clinical Professor, Baylor College of Medicine, will give the presentation titled '*Randomized Trial of Targeted Transendocardial Delivery of Mesenchymal Precursor Cells in High-Risk Chronic Heart Failure Patients with Reduced Ejection Fraction*'. The session will also feature late breaking results from two additional heart failure trials with SGLT-2 Inhibitors.

Late-Breaking Science sessions are innovative and provide the latest breakthroughs in clinical science. These sessions provide notable exposure and recognition for studies likely to have a significant impact on clinical practice and/or to make significant advances in a scientific field.

About Chronic Heart Failure

Heart failure affects approximately 6.5 million people in the US and 26 million people globally, with increasing prevalence and incidence. The mortality rate approaches 50% at 5 years as patients progress beyond NYHA class II disease in parallel with increasing intra-cardiac and systemic inflammation.^{1,2}

Despite recent approvals of new therapies for HFrEF, including SGLT2 inhibitors, that have reduced hospitalizations due to reversible volume-related events, NYHA class II/III HFrEF patients with inflammation remain at high risk for cardiac death, heart attacks and strokes. Rexlemestrocel is being developed as an immunomodulatory therapy to address the high degree of intra-cardiac and systemic inflammation in chronic heart failure in order to reduce the high rate of major cardiac events (MACE) in these patients.

About the American Heart Association (AHA)

The American Heart Association is the US's oldest and largest voluntary organization dedicated to fighting heart disease and stroke. Its scientific journals include *Circulation*, *Stroke*, and *Journal of the American Heart Association* (JAHA). The AHA's Scientific Sessions is regarded as the world's most prestigious cardiovascular meeting and has been running since 1925. The conference attracts more than 15,000 attendees, with the majority being physicians and other cardiology professionals.

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.

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Mesoblast has completed Phase 3 trials of rexllestrocel-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

Footnotes

1. AHA's 2017 Heart Disease and Stroke Statistics
2. Ponikowski P., et al. Heart Failure: Preventing disease and death worldwide. *European Society of Cardiology*. 2014; 1: 4-25

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. All statements other than statements of historical fact, including our intention to discuss a regulatory pathway with the FDA, are forward-looking statements, which are often indicated by terms such as "anticipate," "believe," "could," "estimate," "expect," "goal," "intend," "likely," "look forward to," "may," "plan," "potential," "predict," "project," "should," "will," "would" and similar expressions and variations thereof. 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. The risks, uncertainties and other factors that may impact our forward-looking statements include, but are not limited to: 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; whether the FDA agrees to a regulatory pathway; 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. Unless required by law, 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 more information, please contact:

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