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 November 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 November 15, 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: November 16, 2021

INDEX TO EXHIBITS

Item	
99.1	Press release of Mesoblast Ltd, dated November 15, 2021.

asx announcement

mesoblast
the regenerative medicine company

LATE BREAKING PRESENTATION AT AMERICAN HEART ASSOCIATION ANNUAL MEETING OF LANDMARK PHASE 3 TRIAL OF REXLEMESTROCEL-L IN CHRONIC HEART FAILURE

Trial Results Highlighted Reduction in Cardiovascular Mortality, Heart Attacks and Strokes, with Greatest Effect Seen in Setting of Inflammation

Melbourne, Australia; November 15, and New York, USA; November 14, 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 reduced ejection fraction (HFrEF) were presented as a late breaking presentation at the American Heart Association (AHA) annual Scientific Sessions during a featured program 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, presented new results from the landmark study showing a significant relationship between presence of systemic inflammation as quantified by high-sensitivity C-reactive protein (hs-CRP) and treatment benefit with rexlemestrocel-L on risk of cardiovascular mortality, heart attacks or strokes.

In a release by the American Heart Association, Dr Perin said: "Cell therapy has the potential to change how we treat heart failure. This study addresses the inflammatory aspects of heart failure, which go mostly untreated, despite significant pharmaceutical and device therapy development."

Key findings of pre-specified outcomes were:

- A single dose of rexlemestrocel-L on top of standard of care reduced the incidence of heart attacks or strokes by 65% across all 537 NYHA class II or class III treated patients compared with standard of care alone, p=0.001[1]
- Across 301 NYHA class II and class III treated patients with high levels of inflammation (hs-CRP ≥ 2mg/L), rexlemestrocel-L reduced the incidence of heart attacks or strokes by 79% compared with standard of care alone, p<0.001[1]
- In NYHA class II patients with high levels of inflammation (hs-CRP ≥ 2mg/L), a single dose of rexlemestrocel-L reduced the incidence of cardiovascular death by 80% compared with standard of care alone, p=0.005[1]
- Compared with standard of care alone, a single dose of rexlemestrocel-L on top of standard of care reduced the incidence of cardiovascular death, heart attacks or strokes by 33% across all 537 NYHA class II or class III patients, p=0.02[1], and by 45% in the 301 patients with high levels of inflammation (hs-CRP ≥ 2mg/L), p=0.012[1]
- Compared with standard of care alone, addition of rexlemestrocel-L did not further reduce the frequency of hospitalization for worsening HF symptoms as previously reported

In a release from Texas Heart Institute, President & CEO Dr. Joseph G. Rogers said that the Texas Heart Institute prides itself upon consistently striving to uncover The Next First in cardiovascular discovery and treatment.

Whereas most traditional treatments address the congestion or fluid overload associated with heart failure, rexlemestrocel-L addresses the inflammation that is at the centre of advanced chronic heart failure – widely regarded as the leading cause of death in the developed world.

The ability of rexlemestrocel-L to significantly impact cardiac death, heart attacks and strokes on top of maximal HFrEF therapy reflects the unique mechanisms-of-action of this allogeneic cellular therapy

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on reduction of inflammation and improved microvasculature. The unchecked intra-cardiac inflammation in HFrEF patients causes progressive loss of heart muscle, replacement with scar tissue, and death. Persistent inflammation in the blood circulation also results in accelerated atherosclerosis with plaque progression and instability resulting in plaque rupture and potential blockage of major arteries, resulting in high rates of heart attacks and strokes in chronic HFrEF patients.

Rexlemestrocel-L reduces inflammatory cytokine production by immune cells, generating improved local networks of blood vessels within the damaged heart and reducing risk of plaque rupture in major arteries. The observed relationship between systemic inflammation and degree of benefit from treatment with rexlemestrocel-L supports the importance of the anti-inflammatory mechanism-of-action of rexlemestrocel-L in addressing the high-risk of mortality and morbidity in HFrEF patients.

In addition to Dr. Perin, the DREAM-HF study co-authors are Drs Barry Greenberg, MD, Kenneth Borow, MD, Timothy Henry, MD, Farrell Mendelsohn, MD, Les Miller, MD, Elizabeth Swiggum, MD, Eric Adler, MD, Christopher James, PA, and Silviu Itescu, MD. The study's findings have been submitted for publication.

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.[2-4]

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.

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 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 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

Footnotes

1. All p-values are descriptive and not adjusted for multiplicity

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2. AHA's 2017 Heart Disease and Stroke Statistics
3. Ponikowski P., et al. Heart Failure: Preventing disease and death worldwide. *European Society of Cardiology*. 2014; 1: 4-25
4. Virani SS, Alonso A, Benjamin EJ, et al. American Heart Association Council on Epidemiology and Prevention Statistics Committee and Stroke Statistics Subcommittee. Heart Disease and Stroke Statistics - 2020 update: a report from the American Heart Association.
Circulation 2020;141:e139-e596.

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.

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