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 2024

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 ☐

INFORMATION CONTAINED ON THIS REPORT ON FORM 6-K

On March 11, 2024, 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/ Paul Hughes

Paul Hughes
Company Secretary

Dated: March 13, 2024

INDEX TO EXHIBITS

Item	
99.1	Press release of Mesoblast Ltd, dated March 11, 2024.

asx announcement

mesoblast

UNITED STATES FOOD & DRUG ADMINISTRATION (FDA) SUPPORTS ACCELERATED APPROVAL PATHWAY FOR REXLEMESTROCEL-L IN END-STAGE HEART FAILURE PATIENTS WITH A LEFT VENTRICULAR ASSIST DEVICE (LVAD)

Melbourne, Australia; March 11 and New York, USA; March 10, 2024: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today announced that U.S. FDA supports an accelerated approval pathway for rexlemestrocel-L, Mesoblast's allogeneic mesenchymal precursor cell (MPC) product, in patients with end-stage ischemic heart failure with reduced ejection fraction (HFrEF) and a left ventricular assist device (LVAD). FDA provided this feedback in formal minutes to the company following the Type B meeting held with FDA on February 21, 2024 for rexlemestrocel-L (Revascor®) under the existing Regenerative Medicine Advanced Therapy (RMAT) designation.

"We are very pleased with FDA's feedback that the presented results from our pivotal study of rexlemestrocel-L in end-stage HFrEF patients with LVADs may support an accelerated approval," said Mesoblast CEO Dr. Silviu Itescu. "We intend to request a pre-Biologics License Application (BLA) meeting to discuss data presentation, timing and FDA expectations for an accelerated approval filing."

Every year in the United States over 100,000 patients progress to end-stage HFrEF. In these patients, more than 2,500 life prolonging LVADs are implanted in the US annually, of whom approximately 80% undergo the procedure as destination or permanent therapy.[1] Most patients receiving LVADs as destination therapy have an ischemic HFrEF etiology. Compared to patients with non-ischemic HFrEF, patients with ischemic HFrEF have a 76% lower likelihood of LV functional recovery following LVAD implantation,[2] and increased mortality over the initial 1-2 years.[3] Resistance to functional recovery in ischemic HFrEF patients is thought to be due to excessive inflammation and microvascular insufficiency in the ischemic myocardium.[4]

In the placebo-controlled LVAD-MPC Study #2, 70 patients with end-stage ischemic HFrEF were randomized at the time of LVAD implantation surgery to either a single intervention with rexlemestrocel-L (150 million STRO3-immunoselected and culture-expanded allogeneic cells) or placebo injected directly into the left ventricular myocardium. Key findings were:

- Ischemic controls were characterized by persistently elevated levels of the inflammatory cytokine IL-6, by reduced ability to be weaned from LVAD support, and by high mortality.
- In contrast, in ischemic patients treated with rexlemestrocel-L, IL-6 levels returned to normal by 2 months and remained low through 12 months.
- 63% of ischemic patients who received a single administration of rexlemestrocel-L successfully underwent temporary weaning from full LVAD support as early as month 2 as compared with 36% of controls ($p = 0.008$).
- The cumulative incidence of successful temporary weans off the LVAD device over 6 months was also increased by 1.55-fold over control in ischemic patients who received rexlemestrocel-L ([95% CI 1.01, 2.36]; $p=0.02$).
- Only 4.9% of ischemic patients treated with a single administration of rexlemestrocel-L died from month 2 through month 12, as compared with 26.9% of ischemic controls, an 82% reduction ($p = 0.02$).

In feedback provided to Mesoblast regarding potential pathways to licensure for rexlemestrocel-L, FDA's comments indicated that the presented results may support a reasonable likelihood of clinical benefit of MPCs against mortality in LVAD patients, consistent with the criteria for accelerated approval.

Mesoblast intends to request a pre-BLA meeting with FDA to discuss data presentation, timing and FDA expectations for an accelerated approval filing in end-stage ischemic HFrEF patients with LVAD implantation.

About Revascor® (rexlemestrocel-L) in Heart Disease
REVASCOR is an allogeneic preparation of immunoselected and culture-expanded mesenchymal precursor cells (MPC) and is being developed as an immunomodulatory therapy to address the high degree of inflammation in the heart and in the circulation that is present across the spectrum of heart failure and reduced ejection fraction (HFrEF) patients, from New York Heart Association (NYHA) class II through end-stage CHF, in order to reduce the high rate of major cardiac events and complications. This investigational therapy has been trialled in two large placebo-controlled randomized studies in patients with CHF, a 565-patient trial in NYHA class II/III HFrEF patients and a 159-patient trial in end-stage HFrEF patients implanted with a left ventricular assist device (LVAD).

Rexlemestrocel-L has US Food and Drug Administration (FDA) Regenerative Medicine Advanced Therapy (RMAT) and Orphan Drug designations for patients with end-stage HFrEF implanted with an LVAD.

About Chronic Heart Failure
Chronic heart failure (CHF) is characterized by poor heart function resulting in insufficient blood flow to the body's vital organs and extremities. This condition affects approximately 6.5 million people in the United States and 26 million people globally with increasing prevalence and incidence. CHF patients are commonly classified according to the New York Heart Association (NYHA) categories based on the patient's physical limitations. Class I (mild) patients have no limitations while Class IV patients (severe/end stage) experience symptoms even at rest.

The mortality rate approaches 50% at 5 years as patients progress beyond NYHA early class II disease in parallel with increasing inflammation in the heart and in the circulation.[5,6] Despite recent approvals of new therapies for HFrEF, NYHA class II/III HFrEF patients with inflammation remain at high risk for cardiac death, heart attacks and strokes.

Over 100,000 patients annually in the US progress to end-stage heart failure (NYHA class IIIB/IV) and these patients have a one-year mortality exceeding 50%.[7] Use of LVADs in end-stage heart failure patients to improve survival is gaining momentum, with approximately 2,000 LVADs implanted as destination therapy annually in the US,[1] the majority of whom have an ischemic etiology.

About Mesoblast
Mesoblast (the Company) 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. Yuzefpolskaya M et al. Ann Thorac Surg 2023; 115:311-28

Mesoblast Limited
ABN 68 109 431 870
www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
Melbourne 3000
Victoria Australia
T +61 3 9639 6036
F +61 3 9639 6030

United States Operations
505 Fifth Avenue
Third Floor
New York, NY 10017
USA
T +1 212 880 2060
F +1 212 880 2061

Asia
21 Biopolis Road
#01-22 Nucleos (South Tower)
SINGAPORE 138567
T +65 6570 0635
F +65 6570 0176

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3. Mehra MR, Goldstein DJ, Cleveland JC, et. al. Five-year outcomes in patient with fully magnetically levitated vs axial-flow left ventricular assist devices in the MOMENTUM 3 randomized trial. JAMA 2022; doi:10.1001/jama.2022.161972.
4. Symons JD, Deeter L, Deeter N, et al. Effect of continuous-flow left ventricular assist device support on coronary artery endothelial function in ischemic and nonischemic cardiomyopathy. Cir Heart Fail 2019; 12:e006085. DOI: 10.1161/CIRCHEARTFAILURE.119.006085.
5. AHA's 2017 Heart Disease and Stroke Statistics
6. Ponikowski P., et al. Heart Failure: Preventing disease and death worldwide. *European Society of Cardiology*. 2014; 1: 4-25
7. Gustafsson F, Rogers JG. Left ventricular assist device therapy in advanced heart failure: patient selection and outcomes. European Journal of Heart Failure 2017;19:595-602.

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 (including any future decision that the FDA may make on the BLA for remestemcel-L for pediatric patients with SR-aGVHD), 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.

For more information, please contact:

Corporate Communications / Investors
Paul Hughes
T: +61 3 9639 6036
E: investors@mesoblast.com

Media
BlueDot Media
Steve Dabkowski
T: +61 419 880 486
E: steve@bluedot.net.au