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 December, 2017

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 December 21, 2017, 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.

INDEX TO EXHIBITS

Item	
99.1	Press release of Mesoblast Ltd, dated December 21, 2017.

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: December 21, 2017

Exhibit 99.1

asx announcement

mesoblast
the regenerative medicine company

MESOBLAST RECEIVES FDA REGENERATIVE MEDICINE ADVANCED THERAPY DESIGNATION FOR ITS CELL THERAPY IN HEART FAILURE PATIENTS WITH LEFT VENTRICULAR ASSIST DEVICES

New York, USA; and Melbourne, Australia; December 21, 2017: Mesoblast Limited (ASX:MSB; Nasdaq: MESO) today announced that the United States Food and Drug Administration (FDA) has granted Regenerative Medicine Advanced Therapy (RMAT) designation for its novel mesenchymal precursor cell (MPC) therapy in the treatment of heart failure patients with left ventricular systolic dysfunction and left ventricular assist devices (LVADs). The RMAT designation under the 21st Century Cures Act aims to expedite the development of regenerative medicine therapies intended for the treatment of serious diseases and life-threatening conditions.

This RMAT designation allows for multi-disciplinary, comprehensive interactions with the FDA to support the efficient development of and potential accelerated approval pathway for Mesoblast's allogeneic MPCs in the treatment of heart failure patients with LVADs. The RMAT designation also offers eligibility for priority review. Once the biologics license application (BLA) for a product is approved, the FDA can require various post-approval confirmatory commitments.

Mesoblast Chief Executive Silviu Itescu stated, "The RMAT designation speaks to the strength of the clinical data generated to date using our cell-based therapy in these heart failure patients with LVADs who are at risk of high mortality and have extremely limited treatment options. We are looking forward to working closely with the FDA in advancing this program with the aim of providing a new therapeutic option for these patients with exceptionally high unmet clinical need."

The basis of this RMAT designation grant came from the completed study data set of a 30-patient randomized, blinded, placebo-controlled pilot trial of Mesoblast's MPCs at a dose of 25 million cells in heart failure patients with LVADs, and related analyses. These preliminary clinical data suggest that Mesoblast's MPC product:

- improved native heart function,
- prolonged the time post LVAD implantation of a first hospitalization for a non-surgical major gastrointestinal (GI) bleeding event, and
- improved early survival rates in these LVAD recipients.

The results of the pilot study were published in the American Heart Association Journal *Circulation* and can be found here.

A Phase 2b trial of MPCs at a dose of 150 million cells is currently being conducted in 159 patients with heart failure and LVADs and is funded by the NIH and the Canadian Institute of Health Research. This trial has completed enrollment and the primary endpoint will be reached in Q1 CY 2018.

FDA has invited Mesoblast to have a multidisciplinary comprehensive discussion as soon as possible regarding the development strategy and the evidence needed to achieve an approval in an efficient manner.

For more information on RMAT designation, please see https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ucm537670.htm

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About Heart Failure Requiring LVAD
New York Heart Association Class IV heart failure affects more than 250,000 patients in the United States alone, with over 50,000 having end-stage disease. The number of end-stage heart failure patients is expected to rise in line with the 25% projected increase in total heart failure patients between 2010 and 2030[1,2]. There are currently very few medical options for end-stage heart failure patients, as only around 2,000 heart transplants can be performed in the U.S. every year due to limited donor availability[3]. LVADs have significantly improved survival for end-stage heart failure patients, and are increasingly being used as a destination therapy[4,5]. However, the 12-month mortality rates remain high, and repeated hospitalizations are very common. The complications arising from LVAD implantation have severely restricted their use by the vast majority of the end-stage heart failure population, as well as reducing its cost-effectiveness as a treatment.

About Mesoblast's Allogeneic MPC Product Candidate for the Treatment of Heart Failure:
Mesoblast's MPC-150-IM product candidate at a dose of 150 million cells is currently being evaluated in the following two ongoing randomized placebo-controlled trials in patients with either advanced or end-stage heart failure.

- A Phase 2b trial of MPC-150-IM at a dose of 150 million cells in 159 patients with end-stage heart failure and LVADs. This trial, which is funded by the United States National Institutes of Health (NIH) and the Canadian Institute of Health Research and sponsored by the Icahn School of Medicine at Mount Sinai Hospital, New York, has completed enrollment. The primary endpoint will be reached in Q1 CY 2018.
- A Phase 3 trial of MPC-150-IM at the same 150 million cell dose in up to 600 patients with advanced heart failure. This trial is expected to complete enrolment at the end of 2018.

The mechanism of action (MOA) by which MPC-150-IM is thought to exert its effects in these patient populations is through secretion of potent biomolecules which reduce damaging inflammation and strengthen the native heart by induction of a mature blood vessel network.

1 Heidenreich PA, et al. Forecasting the future of cardiovascular disease in the United States: A policy statement form the American Heart Association. Circulation 2011;123:933-944
2 Heidenreich PA, et al. Forecasting the impact of heart failure in the United States: a policy statement from the American Heart Association. Circ Heart Fail 2013;6:606–619
3 http://healthresearchfunding.org/24-heart-transplant-waiting-list-statistics
4 Miller LW, Guglin M. Patient selection for ventricular assist devices: a moving target. J Am Coll Cardiol 2013;61:1209–1221
5 Gustafsson G, Rogers JG. Left ventricular assist device therapy in advanced heart failure: patient selection and outcomes. European Journal of Heart Failure 2017;19,595-602

About Mesoblast
Mesoblast Limited (ASX:MSB; Nasdaq:MESO) is a global leader in developing innovative cell-based medicines. The Company has leveraged its proprietary technology platform, which is based on specialized cells known as mesenchymal lineage adult stem cells, to establish a broad portfolio of late-stage product candidates. Mesoblast's allogeneic, 'off-the-shelf' cell product candidates target advanced stages of diseases with high, unmet medical needs including cardiovascular conditions, orthopedic disorders, immunologic and inflammatory disorders and oncologic/hematologic conditions.

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 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

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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.

For further information, please contact:

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