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 2020

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 2, 2020, 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.

On December 7, 2020, Mesoblast Limited filed with the Australian Securities Exchange a new release announcement, which is attached hereto as Exhibit 99.2, 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: December 7, 2020

INDEX TO EXHIBITS

Item

99.1	Press release of Mesoblast Ltd, dated December 2, 2020.
99.2	Press release of Mesoblast Ltd, dated December 7, 2020.

asx announcement

mesoblast
the regenerative medicine company

FDA GRANTS FAST TRACK DESIGNATION FOR REMESTEMCEL-L IN THE TREATMENT OF ACUTE RESPIRATORY DISTRESS SYNDROME DUE TO COVID-19

Melbourne, Australia; December 2 and New York; USA; December 1, 2020: 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 (FDA) has granted Fast Track designation for remestemcel-L in the treatment of acute respiratory distress syndrome (ARDS) due to COVID-19 infection. Fast Track designation is granted if a therapy demonstrates the potential to address unmet medical needs for a serious or life-threatening disease.[1] ARDS is the primary cause of death in patients with COVID-19.

Fast Track designation by the FDA is intended to facilitate development and expedite review of therapies to treat serious and life-threatening conditions with no or limited treatment options so that an approved product can reach the market expeditiously.[1] Under Fast Track designation, a Biologic License Application (BLA) for remestemcel-L is eligible for both rolling submission and priority review.

Clinical data provided to the FDA supporting the potential of remestemcel-L to address the unmet medical need of COVID-19 ARDS included results from a pilot study of remestemcel-L under emergency compassionate use at New York's Mt Sinai Hospital in March-April this year. In this study, nine of 12 ventilator-dependent patients (75%) with moderate to severe COVID-19 ARDS were successfully discharged from hospital a median of 10 days after receiving two intravenous doses of remestemcel-L.

The ongoing randomized controlled Phase 3 trial of remestemcel-L in up to 300 ventilator-dependent patients with moderate to severe COVID-19 ARDS, under an FDA Investigational New Drug clearance, is approximately two-thirds enrolled. The trial's primary endpoint is overall mortality at Day 30, and the key secondary endpoint is days alive off ventilatory support through Day 60. Two interim analyses have been performed by the independent Data Safety Monitoring Board (DSMB), after 90 and 135 patients were enrolled, with recommendations to continue the trial as planned. A third and final interim analysis is planned to be performed by the DSMB when 180 patients have completed 30 days of follow-up.

Mesoblast recently entered into a license and collaboration agreement with Novartis for the development, manufacture and commercialization of remestemcel-L, with an initial focus on the treatment of ARDS, including COVID-19 ARDS. The closing of the agreement is subject to the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and certain other conditions.

About COVID-19 Acute Respiratory Distress Syndrome (ARDS)
ARDS is due to a dysregulated immune response in the lungs to various infectious agents including COVID-19. Deaths continue to increase in ventilator-dependent ARDS patients as COVID-19 cases continue to surge globally. Despite improved treatment and earlier intervention in hospitalized COVID-19 patients overall, the mortality rate in COVID-19 ARDS patients who are over 60 years old remains more than 60%.[2] These patients appear to be particularly refractory to corticosteroids such as dexamethasone[3,4] and have not responded to single cytokine antagonists, anti-virals, or anti-malaria agents.

About Remestemcel-L
Remestemcel-L is an investigational therapy comprising culture-expanded mesenchymal stromal cells derived from the bone marrow of an unrelated donor. Remestemcel-L is thought to have immunomodulatory properties to counteract the cytokine storms that are implicated in various inflammatory conditions by downregulating the production of pro-inflammatory cytokines, increasing production of anti-inflammatory cytokines, and enabling recruitment of naturally occurring anti-inflammatory cells to involved tissues.

About Mesoblast
Mesoblast Limited (ASX:MSB; Nasdaq:MESO) is a world leader in developing allogeneic (off-the-shelf) cellular medicines. The Company has leveraged its proprietary mesenchymal lineage cell therapy technology platform to establish a broad portfolio of commercial products and late-stage product candidates. Mesoblast has a strong and extensive global intellectual property portfolio with protection extending through to at least 2040 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. For more information, please see www.mesoblast.com, LinkedIn: Mesoblast Limited and Twitter: @Mesoblast

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

References

1.https://www.fda.gov/ForPatients/Approvals/Fast/ucm405399.htm
2.Rezoagli E, Fumagalli R, Bellani G. 2017. Definition and epidemiology of acute respiratory distress syndrome. Ann Transl Med. 5(14): 1- 12
3.Bellani G, Laffey J, Pham T. et. al. 2016. Epidemiology, patterns of care, and mortality for patients with acute respiratory distress syndrome in intensive care units in 50 countries. JAMA 315(8): 788-800
4.https://www.hopkinsguides.com/hopkins/view/Johns_Hopkins_ABX_Guide/540747/all/Coronavirus_COVID_19__SARS_CoV_2_

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 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; 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 further information, please contact:

Media

Julie Meldrum
T: +61 3 9639 6036
E:julie.meldrum@mesoblast.com

Kristen Bothwell
T: +1 917 613 5434
E:kbothwell@rubenstein.com

Investors

Schond Greenway
T: +212 880 2060
E: schond.greenway@mesoblast.com

Paul Hughes
T: +61 3 9639 6036
E: paul.hughes@mesoblast.com

asx announcement

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REMESTEMCEL-L REDUCES INFLAMMATORY BIOMARKERS PREDICTIVE OF HIGH MORTALITY IN ACUTE GRAFT VERSUS HOST DISEASE

Biomarker Study Results Presented at the 62nd American Society of Hematology Annual Meeting

Melbourne, Australia; December 7 and New York, USA; December 6, 2020: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today announced results presented at the 62nd annual meeting American Society of Hematology (ASH), which provide *in vivo* biomarker evidence linking remestemcel-L's immunomodulatory activity to survival outcomes in children with steroid-refractory acute graft versus host disease (SR-aGVHD). The results were presented on December 6, 2020 by the Phase 3 trial's lead investigator and pediatric transplant physician, Dr Joanne Kurtzberg, the Jerome Harris Distinguished Professor of Pediatrics and Professor of Pathology, and Director, Pediatric Blood and Marrow Transplant Program at Duke University Medical Center.

Key conclusions were:

- Clinically meaningful overall responses and survival in children with SR-aGVHD treated with remestemcel-L were associated with significant reductions in certain biomarkers of inflammation which have been validated as predictors of mortality risk
- These biomarkers provide evidence of *in vivo* bioactivity of remestemcel-L in pediatric SR-aGVHD, where children under 12 are at high-risk for mortality, with no approved therapies in the United States
- The durable reductions in blood levels of certain biomarkers associated with inflammatory diseases of the gut suggest that these could be more generally reflective of remestemcel-L activity *in vivo* in other inflammatory bowel diseases such as Crohn's disease and ulcerative colitis

Blood levels of soluble suppression of tumorigenicity 2 (ST2)[1,2] and MAGIC Biomarker Score (MBS)[3,4], validated biomarkers that predict high mortality in SR-aGVHD and active gut inflammation more broadly, were measured at baseline and sequentially over 180 days in 40 of the 54 children with SR-aGVHD who received at least four weeks of remestemcel-L treatment in the single-arm Phase 3 trial. Both the elevated baseline levels of ST2 and MBS were significantly reduced after remestemcel-L treatment at Days 100, 160 and 180 (all timepoints $p<0.001$ for both markers). This was accompanied by significant reductions in activated circulating T cells. Day 100 survival was 74% in the 54 remestemcel-L children with SR-aGVHD (89% with Grade C/D disease), which compares very favourably with a mortality approaching 70-90% in children of similar severity treated with other therapies.

Dr Kurtzberg said: "These results support the bioactivity of remestemcel-L in treating the severe inflammation in children with acute graft versus host disease refractory to steroids and provide evidence linking the immunomodulatory properties of remestemcel-L with the excellent responses and survival we see when treating these desperately ill children."

About Remestemcel-L

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1. Reichenbach DK et al. Bloo`d. 2015 May 14;125(20):3183-92.
2. Vander Lugt MT et al. New Engl J Med. 2013 Aug 8 369:529-39.
3. Hartwell MJ et al. JCI Insight. 2017;2(3):e89798.
4. Major-Monfried H et al. Blood. 2018;131(25):2846-2855.

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For more information, please contact:

Media

Julie Meldrum
T: +61 3 9639 6036
E:julie.meldrum@mesoblast.com

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T: +1 917 613 5434
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Investors

Schond Greenway
T: +212 880 2060
E: schond.greenway@mesoblast.com

Paul Hughes
T: +61 3 9639 6036
E: paul.hughes@mesoblast.com