
**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 July 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 July 21, 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 July 24, 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/ Charlie Harrison

Charlie Harrison
Company Secretary

Dated: July 27, 2020

INDEX TO EXHIBITS

Item

- 99.1 Press release of Mesoblast Ltd, dated July 21, 2020.
99.2 Press release of Mesoblast Ltd, dated July 24, 2020.

ASX announcement



FDA ADVISORY COMMITTEE SETS REVIEW DATE FOR MESOBLAST'S REMESTEMCEL-L IN PEDIATRIC STEROID-REFRACTORY ACUTE GRAFT VERSUS HOST DISEASE
Melbourne, Australia; July 21, 2020; and New York, USA; July 20, 2020: Mesoblast Limited (ASX:MSB; Nasdaq:MESO) today announced that the Oncologic Drugs Advisory Committee (ODAC) of the United States Food and Drug Administration (FDA) has scheduled a meeting on August 13, 2020 to review data supporting the Company's Biologics License Application (BLA) for approval of RYONCIL™ (remestemcel-L) for the treatment of steroid-refractory acute graft versus host disease (SR-aGVHD) in children.

There are currently no FDA-approved treatments in the United States for children under 12 with SR-aGVHD, a potentially life-threatening complication of an allogeneic bone marrow transplant for blood cancer. RYONCIL is under Priority Review by the FDA with an action date of September 30, 2020, under the Prescription Drug User Fee Act (PDUFA).

The ODAC is an independent panel of experts that provides advice and appropriate recommendations to the FDA based on potential issues highlighted by the FDA during their review of the efficacy and safety of marketed and investigational products for use in the treatment of cancer.

The ODAC review will comprise two separate sessions: a morning session which will discuss issues related to the characterization and critical quality attributes of remestemcel-L as they relate to clinical effectiveness, and an afternoon session which will discuss results from clinical trials included in the BLA.

Although the FDA will consider the recommendation of the panel, the final decision regarding the approval of the product is made by the FDA solely, and the recommendations by the panel are non-binding.

About RYONCIL™ (remestemcel-L)

Mesoblast's lead product candidate, RYONCIL (remestemcel-L), is an investigational therapy comprising culture-expanded mesenchymal stem cells derived from the bone marrow of an unrelated donor. It is administered to patients in a series of intravenous infusions. RYONCIL is believed to have immunomodulatory properties to counteract the inflammatory processes that are implicated in steroid-refractory acute graft versus host disease by down-regulating 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 (IP) 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.

Mesoblast's Biologics License Application to seek approval of its product candidate RYONCIL™ (remestemcel-L) for pediatric steroid-refractory acute graft versus host disease has been accepted for priority review by the United States Food and Drug Administration (FDA), and if approved, product launch in the United States is expected in

Mesoblast Limited
ABN 68 109 431 870

www.mesoblast.com

Corporate Headquarters
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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



2020. Remestemcel-L is also being developed for other inflammatory diseases in children and adults including moderate to severe acute respiratory distress syndrome. Mesoblast is completing Phase 3 trials for its product candidates for advanced 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

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New York, NY 10017
USA

T +1 212 880 2060
F +1 212 880 2061

Asia
20 Biopolis Way
#05-01 Centros
Biopreneur 3
SINGAPORE 138668

T +65 6570 0635
F +65 6570 0176

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 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. 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

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ASX announcement



EXECUTIVE LEADERSHIP EXPANDED AHEAD OF FIRST POTENTIAL U.S. PRODUCT LAUNCH

Melbourne, Australia, July 24, 2020, and New York; USA; July 23, 2020: Mesoblast Limited (ASX: MSB; Nasdaq: MESO), global leader in cellular medicines for inflammatory diseases, today announced the appointment of Dagmar Rosa-Bjorkeson to the role of Chief Operating Officer (COO), based in New York. Ms Rosa-Bjorkeson's responsibilities will include managing commercial operations, leading the business units, building out key strategic alliances, and overseeing product launches. She will be part of an expanded executive leadership structure that will deliver deep operational, commercial, and strategic pharmaceutical experience in line with the Company's transition to becoming a fully integrated commercial organization.

Mesoblast Chief Executive Dr Silviu Itescu stated: "I am pleased to welcome Ms Rosa-Bjorkeson to join our highly experienced and credentialed cross-functional executive leadership team. Mesoblast is very well positioned to build out our product portfolio and to be ready for the potential launch of RYONCIL™ in the United States market for pediatric steroid-refractory acute graft versus host disease."

Ms Rosa-Bjorkeson has more than 25 years of global experience in the pharmaceutical industry, including executive leadership in corporate and product strategy, market development and operational execution. She has led multiple successful product launches, including Gilenya® for multiple sclerosis at Novartis where she was Vice President and Head of its multiple sclerosis business unit, Vice President, Business Development and Licensing in the United States, and Country Head and President for Novartis Sweden. More recently, Ms Rosa-Bjorkeson served as Executive Vice President and President, Biosimilars, at Baxalta, now a wholly owned subsidiary of Takeda Pharmaceutical Company. She was also Executive Vice President and Chief Strategy and Development Officer at Mallinckrodt Pharmaceuticals. Ms Rosa-Bjorkeson is highly valued for her ability to deliver product launch excellence across mass markets, as well as specialty and rare disease brands.

Ms Rosa-Bjorkeson said: "I am very pleased to join Mesoblast at such an exciting and important time in the Company's history, and to be part of a cross-functional leadership team that is working towards bringing its cell therapies to patients with critical unmet needs."

About RYONCIL™ (remestemcel-L)

RYONCIL (remestemcel-L) is an allogeneic cell therapy product candidate believed to have immunomodulatory properties to counteract the cytokine storms that are implicated in various inflammatory conditions. The mechanism of action is thought to involve down-regulating the production of pro-inflammatory cytokines, increasing production of anti-inflammatory cytokines, and enabling recruitment of naturally occurring anti-inflammatory cells to involved tissues.

Mesoblast's Biologics License Application to seek approval of RYONCIL™ for pediatric steroid-refractory acute graft versus host disease has been accepted for priority review by the United States Food and Drug Administration (FDA), and if approved, product launch in the United States is expected in 2020. Remestemcel-L is also being developed for other inflammatory diseases in children and adults including moderate to severe acute respiratory distress syndrome (ARDS). Following positive pilot trial results under compassionate care use, remestemcel-L is being evaluated in a Phase 3 randomized controlled trial in 300 patients with COVID-19 ARDS in the United States.

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