
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 2018

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 13, 2018, 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 19, 2018, 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: December 20, 2018

INDEX TO EXHIBITS

Item

- 99.1 Press release of Mesoblast Ltd, dated December 13, 2018.
- 99.2 Press release of Mesoblast Ltd, dated December 19, 2018.

MEETINGS HELD WITH FDA SUPPORT MESOBLAST'S PLANNED REGULATORY FILING FOR COMMERCIALIZATION OF REMESTEMCEL-L IN ACUTE GVHD

New York, USA; and Melbourne, Australia; December 13, 2018: Mesoblast Limited (ASX:MSB; Nasdaq:MESO) today announced that recent meetings held with the United States Food and Drug Administration (FDA) support its planned regulatory filing for commercialization of remestemcel-L in pediatric patients with steroid refractory acute graft versus host disease (aGVHD).

Mesoblast gained agreement from the FDA on the proposed chemistry and manufacturing for commercialization. The FDA also provided guidance on the presentation of data from the completed 55-patient Phase 3 trial and the 241-patient Expanded Access Program to be included in the filing for the proposed indication. In the Phase 3 trial, Mesoblast met the pre-specified primary endpoint of improved Day 28 overall response and improved responder survival through Day 180.

Mesoblast plans to initiate the submission of the BLA with the FDA in early 2019 for the use of remestemcel-L in treating aGVHD in children. There are currently no approved products in the United States for aGVHD.

Mesoblast owns all commercial rights to remestemcel-L for all territories excluding Japan.

In Japan, Mesoblast's licensee, JCR Pharmaceuticals Co. Ltd., is marketing TEMCELL®1 HS. Inj. for the treatment of aGVHD in children and adults. Mesoblast receives royalty income on sales of TEMCELL in Japan as well as milestone payments.

In North America and EU5 countries, Mesoblast estimates that the addressable market opportunity is in excess of \$US700 million per annum.

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 technology platform to establish a broad portfolio of late-stage product candidates with three product candidates in Phase 3 trials – acute graft versus host disease, chronic heart failure and chronic low back pain due to degenerative disc disease. Through a proprietary process, Mesoblast selects rare mesenchymal lineage precursor and stem cells from the bone marrow of healthy adults and creates master cell banks, which can be industrially expanded to produce thousands of doses from each donor that meet stringent release criteria, have lot to lot consistency, and can be used off-the-shelf without the need for tissue matching. Mesoblast has facilities in Melbourne, New York, Singapore and Texas and is listed on the Australian Securities Exchange (MSB) and on the Nasdaq (MESO). www.mesoblast.com

1. TEMCELL® HS Inj. is the registered trademark of JCR Pharmaceuticals Co. Ltd.

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;

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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. 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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MESOBLAST MAKES EXECUTIVE APPOINTMENT TO DRIVE PRODUCT COMMERCIALIZATION

New York, USA; and Melbourne, Australia; December 19, 2018: Mesoblast Limited (ASX:MSB; Nasdaq:MESO) today announced that it has appointed Eric Strati, PhD, to the new position of Senior Vice President, Commercial. He will drive commercial launch activities of the Company's lead cell therapy product candidate remestemcel-L in the United States and Europe for the treatment of steroid-refractory acute graft versus host disease (aGVHD). Mesoblast estimates the annual peak sales for aGVHD to be approximately \$US700 million in the United States and EU5.

Dr Strati said: "My first priority is to build a highly efficient and targeted field sales team to leverage existing relationships with transplant centers in the United States. Key to rapid market penetration will be engagement with insurers and other reimbursement agencies as well as management of the product distribution process."

Prior to joining Mesoblast in 2015, Dr Strati held various leadership roles in global pharmaceutical companies, most recently at Novartis where he was Executive Director, Managed Markets, and a key member of the successful launch teams for the blockbuster drugs Entresto® in chronic heart failure and Cosentyx® in moderate to severe psoriasis.

Mesoblast's recently-appointed United States-based Directors Shawn Cline Tomasello and Joe Swedish will provide guidance to the commercial team, leveraging their combined extensive expertise in product launches, commercialization, pricing and reimbursement. Ms Tomasello most recently was Chief Commercial Officer at Kite Pharma and Pharmacyclics, and President of the Americas, Hematology and Oncology at Celgene. Mr Swedish was most recently President and CEO at Anthem, America's leading health benefits provider.

Mesoblast Chief Executive Dr Silviu Itescu stated: "Eric is well equipped to lead and execute on our product commercialization strategy as we transition to a fully integrated commercial stage company."

Mesoblast plans to submit a rolling Biologics License Application with the FDA for use of remestemcel-L in treating steroid-refractory aGVHD in children in early 2019. In order to make remestemcel-L available as soon as possible, Mesoblast will work diligently to provide all information required by the FDA. There are no FDA approved treatments for this disease with high mortality.

Remestemcel-L is already sold in Japan by Mesoblast's licensee, JCR Pharmaceuticals, under the registered trademark TEMCELL® HS Inj.

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For further information, please contact:

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