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 September 2019

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 September 27, 2019, 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/ Charlie Harrison

Charlie Harrison
Company Secretary

Dated: October 2, 2019

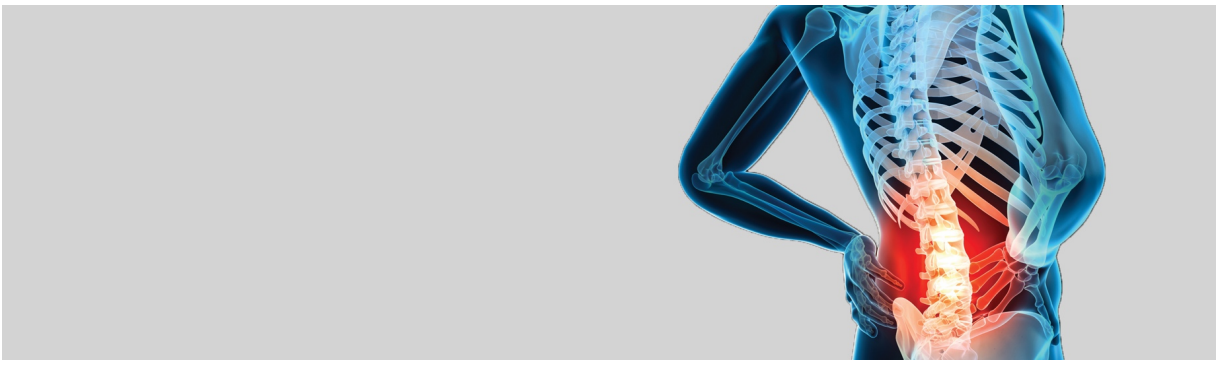
INDEX TO EXHIBITS

Item	
99.1	Press release of Mesoblast Ltd, dated September 27, 2019.

mesoblast

Newsletter

September 2019



Chronic Low Back Pain Associated With Degenerative Disc Disease – A Major Unmet Medical Need

Grünenthal, a global leader in pain management, and Mesoblast have entered into a strategic partnership to develop and commercialize MPC-06-ID, Mesoblast's Phase 3 allogeneic cell therapy candidate for the treatment of chronic low back pain associated with degenerative disc disease in patients who have exhausted conservative treatment options.*

What is the burden of illness of chronic low back pain from degenerative disc disease?

Approximately 10-15% of the adult population across the United States and Europe suffers from chronic low back pain[2], a leading cause of disability with substantial direct and indirect costs on the healthcare system.

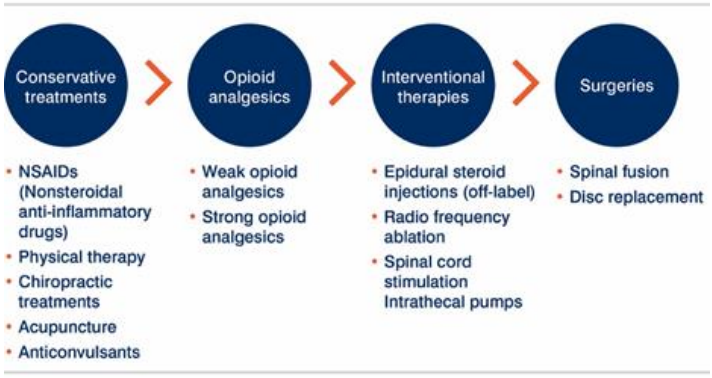
Moderate to severe disc degeneration as a cause of chronic low back pain occurs in over 3.2 million patients in the United States[3] and approximately 4 million in Europe[4,5,6,7], and is responsible for about 50% of total opioid prescriptions[8]. Excessive use of opioids in this patient population is a major public health issue.

What is the mechanism of action of MPC-06-ID in patients with chronic low back pain from degenerative disc disease?

Key to the mechanisms of action of Mesoblast's mesenchymal lineage cells is their ability to be activated by and then counter severe inflammation at various disease sites[9]. It is now well recognized that inflammation plays a key role in the development of chronic low back pain accompanying degenerative disc disease[10]. The multi-modal mechanisms of action of Mesoblast's mesenchymal lineage cell platform could represent a fundamental advantage over other therapies in disease modification, resulting in symptomatic relief as well as tissue repair and regeneration.

In response to the specific inflammatory signature that typifies chronic low back pain, our proprietary cells respond by producing a wide variety of biomolecules that not only target the underlying inflammation (immunomodulation) but also suppress pain in degenerated discs, inhibit nerve ingrowth, and enhance disc repair[9,11,12, 13, 14, 15,16].

What is the current treatment journey for these patients?



While opioids may be effective in temporarily treating the symptoms of the disease, they are not disease-modifying and thus do not address the underlying biological cause. There is a critical need for a novel therapeutic approach that provides durable improvement in pain and function and is capable to modify the disease without the adverse event profile of opioids.

Mesoblast believes that its proprietary cell therapy may meet this urgent need, with the potential for multi-billion dollar markets in the United States and Europe if successful through Phase 3 trials[17,18,19,20].

What is the pathway to marketing authorization in the United States and Europe?

In a randomized, placebo-controlled Phase 2 trial of 100 patients, a post-hoc analysis demonstrated that a single intra-discal injection of MPC-06-ID using a unit dose of six million allogeneic mesenchymal precursor cells (MPCs) resulted in meaningful and durable improvements for patients in pain intensity and functionality for up to three years. The safety profile for cell-treated patients and those treated with a placebo was similar.

These results led to Mesoblast conducting a Phase 3 trial predominantly in the United States
in 404 patients with moderate to severe chronic low back pain associated with degenerative disc disease. This three-arm study comparing 6 million MPCs with or without hyaluronic acid against saline control is designed to show efficacy for either treatment arm. This Phase 3 trial will read out in 2020.

Grünenthal and Mesoblast have agreed on an overall development plan for MPC-06-ID to meet regulatory requirements for marketing in both Europe and the United States. As part of this plan, the companies will collaborate on the study design for a confirmatory Phase 3 trial in Europe.

Positive results of the two confirmatory Phase 3 trials are expected to support regulatory approval of MPC-06-ID for this patient population in both the United States and Europe.

What are the key terms of the partnership with Grünenthal GmbH?

Grünenthal obtained an exclusive license to develop and commercialize MPC-06-ID for chronic low back pain and/or functional disability associated with disc degeneration in Europe and Latin America. In consideration, Mesoblast will receive from Grünenthal up to US$150 million (~AU$220 million) in upfront and milestone payments prior to product launch, including commitments up to US$45 million (~AU$66 million) in the first year. Cumulative milestone payments could exceed US$1 billion (~AU$1.5 billion), depending on the final outcome of the Phase 3 studies and patient adoption. Additionally Mesoblast will receive tiered, double-digit royalties on product sales.

This partnership is in line with Mesoblast's corporate strategy to partner with leading healthcare companies to maximize market access to its portfolio of innovative cellular medicines across major healthcare jurisdictions.

What are the strategic benefits of this partnership?

Firstly, the partnership provides third party validation of Mesoblast's proprietary technology platform. Grünenthal brings 50 years' experience in pain research and a long track record of commercialization, distribution, sales and marketing.

Secondly, Grünenthal provides an excellent commercial channel for Mesoblast's pain product in Europe. The company employs approximately 4,900 people worldwide with its pain-focused salesforce comprising 1,600 people. It has a revenue base of approximately US$1.5 billion (~AU$2.2 billion), with products sold in 100 countries.

Thirdly, the Grünenthal partnership is expected to advance the approval pathways for MPC-06-ID in both the United States and Europe. Specifically, Grünenthal provides funding for a second Phase 3 trial, and know-how in manufacturing and regulatory affairs, especially in Europe.

Finally, Mesoblast retains the rights to fully capitalize on the commercial opportunities for the product in the United States, Japan and other markets.

References

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17 Decision Resources : Chronic Back Pain December 2015.
18 LEK & NCI opinion leader interviews, and secondary analysis.
19 Navigant: Commercial Assessment for a Proprietary Cell-Based Therapy for DDD in the U.S. and the EU3 – August 2014.
20 Data on file.

***MPC-06-ID is Mesoblast's cell therapy that comprises six million mesenchymal precursor cells. In an outpatient procedure, it is delivered via a single injection directly into the damaged disc.**