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 February 2016

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 February 16, 2016, Mesoblast Limited issued a press release, a copy of 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/ Scott Terrillion

Scott Terrillion
Vice President, Associate General Counsel and Head of Compliance

Dated: February 17, 2016

INDEX TO EXHIBITS

Item	
99.1	Press Release of Mesoblast Limited, dated February 16, 2016.

asx announcement

mesoblast
the regenerative medicine company

MESOBLAST CELL THERAPY SHOWS CLINICAL BENEFIT IN FIRST COHORT OF PATIENTS WITH BIOLOGIC REFRACTORY RHEUMATOID ARTHRITIS

New York; USA; and Melbourne, Australia; 16 February 2016: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), today announced results from the first cohort of its ongoing Phase 2 trial in rheumatoid arthritis (RA) patients who have previously failed one or more biologic agents. Top line results showed that a single intravenous infusion of the lower dose of Mesoblast's proprietary Mesenchymal Precursor Cell (MPC) product candidate, MPC-300-IV, was safe and resulted in early and sustained clinical responses.

MPC-300-IV (USAN: rexlemestrocel-L) is being evaluated in a double-blind, randomized, placebo-controlled, two-dose escalating trial in the United States. The trial is designed to evaluate safety and explore efficacy of MPC treatment in 48 patients with active RA randomized 2:1 to either placebo or a single intravenous infusion of 1 million or 2 million MPCs/kg. All recruited patients are on a stable regimen of methotrexate and have previously failed or had an adverse or inadequate clinical response to at least one biologic agent.

The lower MPC dose was evaluated in the first cohort of 24 patients, of whom 16 had failed 1-2 biologics. The second cohort of 24 patients, evaluating the higher dose of MPCs, is actively recruiting. Trial results for both cohorts are expected to be reported in Q3 2016.

The trial's primary endpoint is safety, with pre-specified efficacy endpoints at 12 weeks including the American College of Rheumatology (ACR) 20%, 50% and 70% response criteria (ACR20/50/70). ACR20 is a key validated primary endpoint in clinical trials which is accepted by the United States Food and Drug Administration for product approval in RA.

Key top line results for cohort 1 were:

- Cell infusions were well tolerated with no cell-related adverse events
- The trial's 12 week, pre-specified ACR20 efficacy endpoint was achieved by 47% of all MPC-treated patients and by 60% of MPC-treated patients who failed 1-2 biologics, vs 25% and 17%, respectively, of matched placebo-treated controls
- 71% of MPC-treated patients who achieved ACR20 responses did so as early as week 1
- At week 12, 27% of MPC-treated patients, but no placebo-treated controls, achieved ACR50 or ACR 70 responses
- Remission at week 12, as defined by Disease Activity Score (DAS28/CRP) <2.6, was seen in 20% of MPC-treated patients but in no controls.

In 2014, RA affected over 5.3 million people in the US, Japan, and the five major European markets (EU5), with 2.4 million in the US alone. Major advances using biologic agents in the treatment of RA have substantially increased the market size to $15.7 billion in 2014, with the market expected to grow to $18.4 billion in 2024.

Despite advances in the use of biologic agents, approximately one third of patients either do not sufficiently respond or cannot tolerate these agents. There is a clear need to deliver a safe and effective treatment, without the potential risk of opportunistic infections or malignancies.

Mesoblast Chief Executive Silviu Itescu said: "We are encouraged by the efficacy signals seen in the initial results using the lower dose of Mesoblast's cell therapy in biologic refractory patients with rheumatoid arthritis. They suggest that a single intravenous administration of our cell therapy may result in rapid and sustained responses in patients with active disease where disease remission remains the clear goal."

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About Rheumatoid Arthritis

RA is a chronic autoimmune disease of unknown etiology, affecting approximately one percent of the global population. The disease is attributed to chronic inflammation affecting the synovial membrane of multiple joints, which eventually leads to cartilage and bone destruction. The health-related quality of life in patients with RA is significantly impaired by pain, fatigue, and decline in musculoskeletal function. RA is associated with an increased risk of cardiovascular disease and mortality.

ACR response is a key endpoint used in clinical trials for agents in RA to measure improvement in signs and symptoms of the disease. ACR20 response is the percentage of patients achieving a 20% improvement in the number of tender and swollen joints, as well as a 20% improvement in three of the following five ACR core set measures: patient assessed global assessment, physician assessed global assessment, pain, disability, and level of acute phase reactant. ACR50 and ACR70 responses are similar to the ACR20 response, but denote 50% and 70% improvements, respectively.

DAS28-CRP is based on an examination of 28 joints for tenderness and swelling and concomitant measurement of C-reactive protein.

About Mesoblast

Mesoblast Limited (ASX:MSB; Nasdaq:MESO) is a global leader in 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 where there are highly unmet medical needs, including cardiovascular conditions, orthopedic disorders, immunologic and inflammatory disorders and oncologic/hematologic conditions.

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