# 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 August 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 o

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 o 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 o No 🗵

### INFORMATION CONTAINED ON THIS REPORT ON FORM 6-K

On July 29, 2016, Mesoblast Limited filed with the Australian Securities Exchange a quarterly report for entities admitted on the basis of commitments (Appendix 4C) for the quarter ended June 30, 2016, which is attached hereto as Exhibit 99.1, and is incorporated herein by reference.

On August 1, 2016, Mesoblast Limited filed with the Australian Securities Exchange a new release announcement, which is attached hereto as <u>Exhibit 99.2</u>, 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: August 2, 2016

# INDEX TO EXHIBITS

Item

99.1 99.2

Appendix 4C, dated July 29, 2016. Press release of Mesoblast Ltd, dated August 1, 2016.

Rule 4.7B

# Appendix 4C

### Quarterly report for entities admitted on the basis of commitments

Introduced 31/03/010 Amended 30/09/01, 24/10/05, 17/12/10

Name of entity

Mesoblast Limited

ABN **68 109 431 870**  Quarter ended ("current quarter")
30 June 2016

Consolidated statement of cash flows

		Current quarter US\$ '000	Year to date (12 months) US\$ '000
	Cash flows related to operating activities		
1.1	Receipts from customers:		
	(a) Commercialization Revenue	99	99
	(b) Licensing Fee Revenue	_	3,500
	(c) R&D Tax Incentive received	4,466	4,466
1.2	Payments for:		
	(a) staff costs	(2,550)	(12,891)
	(b) research and development	(8,584)	(40,452)
	(c) manufacturing commercialisation	(8,312)	(26,859)
	(d) intellectual property portfolio expenses	(519)	(2,379)
	(e) other expenses from ordinary activities	(3,002)	(14,609)
1.3	Dividends received	_	_
1.4	Interest and other items of a similar nature received	313	1,129
1.5	Interest and other costs of finance paid	_	_
1.6	Income taxes paid	_	_
1.7	Other	_	_
	Net operating cash flows	(18,089)	(87,996)^

		Current quarter US\$ '000	Year to date (12 months) US\$ '000
8	Net operating cash flows (carried forward)	(18,089)	(87,996)^
	Cash flows related to investing activities		
9	Payment for acquisition of:		
	(a) businesses (item 5)	_	_
	(b) equity investments	_	_
	(c) intellectual property	_	(200)
	(d) physical non-current assets	(42)	(722)
	(e) other non-current assets	_	(805)
10	Proceeds from disposal of:		
	(a) businesses (item 5)	_	_
	(b) equity investments	_	_
	(c) intellectual property	_	_
	(d) physical non-current assets	_	_
	(e) other non-current assets	_	_
11	Loans to other entities	_	_
12	Loans repaid by other entities	_	_
13	Other:		
	(a) Payments for financial derivatives	_	_
	(b) Security deposits	<u></u>	_
	Net investing cash flows	(42)	(1,727)
14	Total operating and investing cash flows	(18,131)	(89,723)
	Cash flows related to financing activities		
15	Proceeds from issues of shares, options, etc.	_	68,549
16	Proceeds from sale of forfeited shares	_	_
17	Proceeds from borrowings	_	_
18	Repayment of borrowings	_	_
19	Dividends paid	_	_
20	Share issue costs	18	(6,483)
	Net financing cash flows		62,066
	Net increase / (decrease in cash held)	(18,113)	(27,657)
21	Cash at beginning of quarter / year to date	99,929	110,701
22	Exchange rate adjustments to item 1.21	(879)	(2,107)
23	Cash at end of quarter	80,937	80,937

^Within the year to date operating cash flows are share issue costs of \$315k associated with the November 2015 NASDAQ IPO equity raising incurred during the three months ended 30 September 2015.

<sup>+</sup> See chapter 19 for defined terms.

### Payments to directors of the entity and associates of the directors

### Payments to related entities of the entity and associates of the related entities

		Current quarter US\$ '000
1.24	Aggregate amount of payments to the parties included in item 1.2	440
1.25	Aggregate amount of loans to the parties included in item 1.11	_
1.26	Explanation necessary for an understanding of the transactions:	
	Payment to directors (for the current quarter) = \$440k	

### Non-cash financing and investing activities

2.1 Details of financing and investing transactions which have had a material effect on consolidated assets and liabilities but did not involve cash flows

n/a

2.2 Details of outlays made by other entities to establish or increase their share in businesses in which the reporting entity has an interest

n/a

### Financing facilities available

Add notes as necessary for an understanding of the position.

		Amount available USS '000	Amount used US\$ '000
3.1	Loan facilities		
3.2	Credit standby arrangements	_	_

+ See chapter 19 for defined terms.

### Reconciliation of cash

Reconciliation of cash at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts is as follows:

Date: 29 July 2016

		Current quarter US\$ '000	Previous quarter US\$ '000
4.1	Cash on hand and at bank	10,687	5,945
4.2	Deposits at call	58,969	46,992
4.3	Bank overdraft	_	_
4.4	Term deposits	11,281	46,992
	Total: cash at end of quarter (item 1.23)	80,937	99,929

### Acquisitions and disposals of business entities

		Current quarter US\$ '000	Previous quarter US\$ '000
5.1	Name of entity	n/a	n/a
5.2	Place of incorporation or registration	n/a	n/a
5.3	Consideration for acquisition or disposal	n/a	n/a
5.4	Total net assets	n/a	n/a
5.5	Nature of business	n/a	n/a

# Compliance statement

- This statement has been prepared under accounting policies which comply with accounting standards as defined in the Corporations Act (except to the extent that information is not required because of note 2) or other standards acceptable to ASX.
- This statement does give a true and fair view of the matters disclosed.

Sign here: /s/ Charlie Harrison

(Company Secretary)

Print name: Charlie Harrison

+ See chapter 19 for defined terms.

### Notes

- 1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity wanting to disclose additional information is encouraged to do so, in a note or notes attached to this report.
- 2. The definitions in, and provisions of, AASB 107: Statement of Cash Flows applies to this report except for any additional disclosure requirements requested by AASB 107 that are not already itemised in this report.
- 3. **Accounting Standards.** ASX will accept, for example, the use of International Financial Reporting Standards for foreign entities. If the standards used do not address a topic, the Australian standard on that topic (if any) must be complied with.

+ See chapter 19 for defined terms.

### asx announcement



### MESOBLAST'S FULL 24-MONTH TRIAL RESULTS FOR CHRONIC LOW BACK PAIN PRESENTED AT SPINE INTERVENTION SOCIETY ANNUAL MEETING, RECEIVE AWARD FOR BEST BASIC SCIENCE

#### Results Show Sustained Improvement In Pain And Function Over 24 Months Following A Single Intra-Disc Cell Injection

Melbourne, Australia; and New York, USA; 1 August 2016: Mesoblast Limited (ASX: MSB; Nasdaq: MESO) today announced that the 24-month results from the 100-patient, four-arm, randomized, placebo-controlled Phase 2 trial of its chronic low back pain (CLBP) product candidate MPC-06-ID were presented at the 24th Annual Scientific Meeting of the Spine Intervention Society (SIS) held in New Orleans 27-30 July, and received the 2016 Best Basic Science Abstract award at the meeting.

The trial results were selected following peer review for a podium presentation entitled "A Randomized, Controlled Trial Evaluating the Safety and Effectiveness of Immunoselected, Allogeneic, Mesenchymal Precursor Cells for Treatment of Chronic Low Back Pain".

Lead investigator and trial presenter Dr Michael J. DePalma, President and Medical Director of Virginia iSpine Physicians, stated: "The long term results from this study indicate that a single injection of Mesoblast's allogeneic Mesenchymal Precursor Cells (MPCs) into the disc of patients with moderate to severe CLBP due to degenerative disc disease was well tolerated and provided substantial improvement in pain and function over 24 months compared with control therapies."

#### Key trial results were:

- The procedure and treatment were well tolerated, without any significant differences in safety between cell-treated patients and controls.
- The 6 million MPC dose, currently used in the ongoing Phase 3 trial, resulted in the greatest proportion of patients meeting the Phase 3 primary endpoint of Overall Treatment Success (the composite of both pain and functional responder status) through 24 months.
- A significantly greater proportion of subjects who received 6 million MPCs achieved the pain responder criteria at both 12 and 24 months (50% pain reduction from baseline, as measured using a visual analog scale, with no intervention) than saline-treated controls (50.0% vs 12.5%, p=0.020); pain responder criteria were met by 36.0% of patients who received 18 million MPCs and by 23% who received hyaluronic acid.
- A significantly greater proportion of subjects who received 6 million MPCs achieved the functional responder criteria at both 12 and 24 months (15 point functional improvement from baseline, as measured by the Oswestry disability index, with no intervention) than saline-treated controls (46.2% vs 12.5%, p=0.042); functional responder criteria were met by 53.9% of patients who received 18 million MPCs (p=0.01 vs saline) and by 29.4% who received hyaluronic acid.
- Overall Treatment Success at 12 months was achieved by 50% of patients in the 6 million MPC group compared with 18.8% in the saline group (p=0.056); 77% of MPC-treated patients who achieved Overall Treatment Success at 12 months maintained this at 24 months (p=0.09 vs saline).
- Overall Treatment Success at both 12 and 24 months was achieved by 38.5% of the 6 million MPC group, 34.6% of the 18 million MPC group, 17.7% of the hyaluronic acid group, and 12.5% of the saline group

Dr DePalma added: "If findings from the ongoing Phase 3 trial are comparable, Mesoblast's MPCs could become a valuable treatment for a significant number of people suffering with chronic low back pain who currently have no other viable option."

Mesoblast Limited ABN 68 109 431 870

w.mesoblast.com

Corporate Headquarters Level 38 55 Collins Street

т +61 3 9639 6036 г +61 3 9639 6030

**United States Operations** 505 Fifth Avenu

Third Floor w York, NY 10017

т +1 212 880 2060 г +1 212 880 2061

Asia 20 Biopolis Way

#05-01 Centros Biopreneur 3 SINGAPORE 138668

т +65 6570 0635 в +65 6570 0176

Mesoblast's ongoing Phase 3 trial is recruiting 360 patients across 30 sites in the United States and Australia, randomized 2:1 to receive either 6 million MPCs or saline control. The trial's primary endpoint of Overall Treatment Success (using a composite of 50% improvement in lower back pain and 15 point improvement in function at both 12 and 24 months) is an acceptable endpoint for product approval, as per guidance from the United States Food and Drug Administration (FDA). Subject to further discussions with the FDA, Mesoblast anticipates being able to provide interim data from the trial in early 2017.

#### About Chronic Low Back Pain (CLBP) Caused By Degenerative Disc Disease

Approximately 5.7 million patients in the U.S. alone suffer from CLBP caused by degenerative disc disease, of which 4.0 million patients have moderate to severe disease. After failure of conservative measures (medication, injections, physical therapy, etc.), there is no treatment that prevents progression of disc degeneration, reduces pain and improves function over a sustained period of 6 to 12 months. When disc degeneration has progressed to a point that pain and loss of function can no longer be managed by conservative means, major invasive surgery such as spinal fusion is the only remaining option.

All therapies for progressive, severe and debilitating pain due to degenerating intervertebral discs treat the symptoms of the disease, but are not disease-modifying and thus do not address the underlying cause of the disease. Surgical intervention is not always successful in addressing the patient's pain and functional deficit. Surgeons estimate that between 50% to 70% of patients ultimately fail back surgery, with failure defined as either not achieving at least a 50% reduction of symptoms within four months or experiencing new-onset pain and spasm. Total costs of low back pain are estimated to be between US\$100 billion and US\$200 billion annually with two thirds of attributed to patients' decreased wages and productivity.

As a result, we believe that the most significant unmet need and commercial opportunity in the treatment of CLBP is a therapy that has the ability to reverse, halt or slow the progression of the disease. MPC-06-ID is being developed to target the population of patients suffering from moderate to severe CLBP due to moderately degenerated discs. The target patient population has exhausted conservative treatment options, may have failed epidural steroid injections to alleviate pain and has no treatment option other than invasive and costly surgical interventions.

#### About Mesoblast

Mesoblast Limited (ASX:MSB; Nasdaq:MESO) is a global leader in developing innovative 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 with high, unmet medical needs including cardiovascular conditions, orthopedic disorders, immunologic and inflammatory disorders and oncologic/hematologic conditions.

#### Forward-Looking Statements

This press release 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. 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.

Mesoblast Limited ABN 68 109 431 870

www.mesoblast.com

Corporate Headquarters Level 38 55 Collins Street Melbourne 3000 Victoria Australia

т +61 3 9639 6036 г +61 3 9639 6030 United States Operations 505 Fifth Avenue Third Floor New York, NY 10017 USA

т +1 212 880 2060 г +1 212 880 2061 Asia 20 Biopolis Way #05-01 Centros Biopreneur 3 SINGAPORE 138668

т +65 6570 0635 г +65 6570 0176 For further information, please contact:
Julie Meldrum
Corporate Communications
Mesoblast Limited
T: +61 3 9639 6036
E: julie.meldrum@mesoblast.com

Mesoblast Limited ABN 68 109 431 870

www.mesoblast.com

Corporate Headquarters Level 38 55 Collins Street Melbourne 3000 Victoria Australia

т +61 3 9639 6036 г +61 3 9639 6030 United States Operations 505 Fifth Avenue Third Floor New York, NY 10017 USA

т +1 212 880 2060 г +1 212 880 2061 Asia 20 Biopolis Way #05-01 Centros Biopreneur 3 SINGAPORE 138668

т +65 6570 0635 г +65 6570 0176