
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 October 2023

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

INFORMATION CONTAINED ON THIS REPORT ON FORM 6-K

On October 31, 2023, 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 September 30, 2023, 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/ Paul Hughes

Paul Hughes
Company Secretary

Dated: October 31, 2023

INDEX TO EXHIBITS

Item

[99.1](#) Appendix 4C of Mesoblast Ltd, dated October 31, 2023.

asx announcement



**APPENDIX 4C QUARTERLY ACTIVITY REPORT FOR QUARTER ENDED
SEPTEMBER 30, 2023**

Melbourne, Australia; October 31 and New York, USA; October 30, 2023: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today provided an activity report for the first quarter ended September 30, 2023.

Mesoblast Chief Executive Silviu Itescu said: "During the period we had a very productive meeting with the United States Food and Drug Administration (FDA), which has allowed us to establish the path forward for potential pediatric and adult approvals of Ryoncil® (remestemcel-L) in steroid-refractory acute graft versus host disease (SR-aGVHD)."

Dr Itescu added: "I am very confident that the cost reduction strategies we have implemented, together with operational streamlining and access to additional sources of capital, will facilitate the balance sheet strength needed to complete our Phase 3 programs for adults with SR-aGVHD and for chronic inflammatory low back pain through to product approvals and commercialization."

ACTIVITY REPORT

At the Type A meeting in September, Mesoblast presented clinical data indicating that treatment with the improved RYONCIL product version of remestemcel-L, manufactured using the current process inspected by FDA, resulted in consistently high survival rates in children with SR-aGVHD, whether using product made for the Phase 3 clinical trial MSB-GVHD001 between 2015-2018 or made with the validated manufacturing process proposed for commercial release and used under Emergency Investigational New Drug (EIND) protocol through 2023. Mesoblast believes that the totality of these clinical studies, together with additional data using the IL-2R alpha inhibition potency assay in place during the pediatric Phase 3 trial, will both support approval for the pediatric indication and provide a link between the RYONCIL product that was used in the pediatric Phase 3 trial and available commercial inventory.

In its September 2023 draft guidance to industry for development of agents to treat aGVHD,¹ the FDA stated that a marketing application in a population with refractory aGVHD where there are no available therapies might be supported by positive results from a single-arm trial. Mesoblast intends to commence a Phase 3 trial of RYONCIL in adults and adolescents, a market 5-fold larger than pediatric, who are refractory to both corticosteroids and a second line agent such as ruxolitinib, for whom there are no approved therapies. The trial is expected to be conducted by the Blood and Marrow Transplant Clinical Trials Network (BMT CTN), a body responsible for approximately 80% of all US transplants, at a fraction of the cost of a traditional contract research organization (CRO).

FIANANCIAL REPORT

Management and the Board have undertaken a detailed review of expenditures and have put in place a plan that focuses on preservation of cash by implementing significant cost containment strategies and enacting substantial payroll reductions. We have already managed to reduce net operating cash usage over the past two years by 37%, and the cost containment that we have now put in place ensure that we will be operating in an even more fiscally prudent manner which is expected to reduce spend by a further 23% year on year.

These activities to preserve cash are complemented by initiatives currently underway to increase cash inflows which would by design enable us to prudently invest in our Phase 3 programs for SR-aGVHD and back pain. In this regard, we are working on corporate initiatives to strengthen our balance sheet, including royalty monetization and strategic partnerships to both access existing commercial distribution channels and supplement costs of development.

Cash balance at the end of the quarter was US\$53.2 million, with net operating cash spend of US\$14.2 million. We have implemented a cost containment plan to achieve a targeted 23% reduction (US\$15 million) in projected FY2024 annual net operating cash spend compared with FY2023, which will be partially offset by investment in our Phase 3 programs for SR-aGVHD and CLBP.

Revenue from royalties on sales of TEMCELL® HS Inj.² sold in Japan by our licensee for the quarter were US\$1.6 million. On a constant currency basis, royalties on sales were US\$1.7 million for the quarter ended September 30, 2023, a growth of 24% compared with US\$1.4 million in the comparative quarter in FY2023.³

Other

Fees to Non-Executive Directors were US\$83,121, consulting payments to Non-Executive Directors were US\$76,200 and salary payments to full-time Executive Directors were US\$293,834, detailed in Item 6 of the Appendix 4C cash flow report for the quarter.⁴ From 1 August 2023, Non-Executive directors have voluntarily deferred 50% cash payment of their director fees and agreed to receive the remaining 50% of their fees in equity-based incentives and Executive Directors (our Chief Executive and Chief Medical Officers) have voluntarily reduced their base salaries for FY24 by 30% in lieu of accepting equity-based incentives.

A copy of the Appendix 4C – Quarterly Cash Flow Report for the first quarter FY2024 is attached.

About Mesoblast

Mesoblast is a world leader in developing allogeneic (off-the-shelf) cellular medicines for the treatment of severe and life-threatening inflammatory conditions. The Company has leveraged its proprietary mesenchymal lineage cell therapy technology platform to establish a broad portfolio of late-stage product candidates which respond to severe inflammation by releasing anti-inflammatory factors that counter and modulate multiple effector arms of the immune system, resulting in significant reduction of the damaging inflammatory process.

Mesoblast has a strong and extensive global intellectual property portfolio with protection extending through to at least 2041 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 is developing product candidates for distinct indications based on its remestemcel-L and rexlemestrocet-L allogeneic stromal cell technology platforms. Remestemcel-L is being developed for inflammatory diseases in children and adults including steroid refractory acute graft versus host disease, biologic-resistant inflammatory bowel disease, and acute respiratory distress syndrome. Rexlemestrocet-L is in development for advanced chronic 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

References / Footnotes

1. United States Food & Drug Administration. Graft-versus-Host Diseases: Developing Drugs, Biological Products, and Certain Devices for Prevention or Treatment Guidance for Industry. Draft Guidance. September 2023.
2. TEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.
3. TEMCELL sales by our Licensee are recorded in Japanese Yen before being translated into USD for the purposes of calculating the royalty paid to Mesoblast. Results have been adjusted for the movement of the USD to Japanese Yen exchange rate from 1USD:145.81 Yen for the 3 months ended September 30, 2022 to 1USD:150.58 Yen for the 3 months ended September 30, 2023.
4. As required by ASX listing rule 4.7 and reported in Item 6 of the Appendix 4C, reported are the aggregated total payments to related parties being Executive Directors and Non-Executive Directors.

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

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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 initiation, timing, progress and results of Mesoblast's preclinical and clinical studies, and Mesoblast's research and development programs; Mesoblast's ability to advance product candidates into, enroll and successfully complete, clinical studies, including multi-national clinical trials; Mesoblast's ability to advance its manufacturing capabilities; the timing or likelihood of regulatory filings and approvals, manufacturing activities and product marketing activities, if any; the commercialization of Mesoblast's product candidates, if approved; regulatory or public perceptions and market acceptance surrounding the use of stem-cell based therapies; the potential for Mesoblast's product candidates, if any are approved, to be withdrawn from the market due to patient adverse events or deaths; the potential benefits of strategic collaboration agreements and Mesoblast's ability to enter into and maintain established strategic collaborations; 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; the scope of protection Mesoblast is able to establish and maintain for intellectual property rights covering its product candidates and technology; estimates of Mesoblast's expenses, future revenues, capital requirements and its needs for additional financing; Mesoblast's financial performance; developments relating to Mesoblast's competitors and industry; 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.

Release authorized by the Chief Executive.

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Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

Mesoblast Limited

ABN

68 109 431 870

Quarter ended ("current quarter")

30 September 2023

Consolidated statement of cash flows	Current quarter \$US'000	Year to date (3 months) \$US'000
1. Cash flows from operating activities		
1.1 Receipts from customers	2,244	2,244
- royalty receipts		
1.2 Payments for		
(a) research and development	(3,963)	(3,963)
(b) manufacturing commercialization	(8,244)	(8,244)
(c) product manufacturing and operating costs	(139)	(139)
(d) advertising and marketing	(896)	(896)
(e) leased assets	—	—
(f) staff costs	(1,705)	(1,705)
(g) other expenses from ordinary activities	(3,405)	(3,405)
(h) other:		
- Intellectual property portfolio expenses	(1,245)	(1,245)
1.3 Dividends received (see note 3)	—	—
1.4 Interest received	545	545
1.5 Interest and other costs of finance paid	—	—
1.6 Income taxes paid	—	—
1.7 Government grants and tax incentives and credits	2,565	2,565
1.8 Other (provide details if material)	—	—
1.9 Net cash from / (used in) operating activities	(14,244)	(14,244)



Consolidated statement of cash flows		Current quarter \$US'000	Year to date (3 months) \$US'000
2.	Cash flows from investing activities		
2.1	Payments to acquire or for:		
	(i) entities	—	—
	(j) businesses	—	—
	(k) property, plant and equipment	(175)	(175)
	(l) investments	—	—
	(m) intellectual property	(10)	(10)
	(n) other non-current assets	—	—
2.2	Proceeds from disposal of:		
	(o) entities	—	—
	(p) businesses	—	—
	(q) property, plant and equipment	—	—
	(r) investments	—	—
	(s) intellectual property	—	—
	(t) other non-current assets	—	—
2.3	Cash flows from loans to other entities	—	—
2.4	Dividends received (see note 3)	—	—
2.5	Other	58	58
2.6	Net cash from / (used in) investing activities	(127)	(127)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	—	—
3.2	Proceeds from issue of convertible debt securities	—	—
3.3	Proceeds from exercise of options	—	—
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(435)	(435)
3.5	Proceeds from borrowings	—	—
	Proceeds from issue of warrants	—	—
3.6	Repayment of borrowings	—	—
3.7	Transaction costs related to loans and borrowings	(371)	(371)
	Interest and other costs of finance paid	(1,366)	(1,366)



Consolidated statement of cash flows		Current quarter \$US'000	Year to date (3 months) \$US'000
3.8	Dividends paid	—	—
3.9	Other (payment of lease liability)	(1,046)	(1,046)
3.10	Net cash from / (used in) financing activities	(3,218)	(3,218)
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of quarter (July 1, 2023)/beginning of year (July 1, 2023)	71,318	71,318
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(14,244)	(14,244)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(127)	(127)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(3,218)	(3,218)
4.5	Effect of movement in exchange rates on cash held	(552)	(552)
4.6	Cash and cash equivalents at end of period	53,177	53,177



5. Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$US'000	Previous quarter \$US'000
5.1 Bank balances	52,790	70,920
5.2 Call deposits	—	—
5.3 Bank overdrafts	—	—
5.4 Other (Term deposits)	387	398
5.5 Cash and cash equivalents at end of quarter (should equal item 4.6 above)	53,177	71,318

6. Payments to related parties of the entity and their associates	Current quarter \$US'000
6.1 Aggregate amount of payments to related parties and their associates included in item 1	453
6.2 Aggregate amount of payments to related parties and their associates included in item 2	—

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

Fees and consulting payments to Non-Executive Directors and salary payments to full-time Executive Directors (for the current quarter) =US\$453,155



7.	Financing facilities <i>Note: the term "facility" includes all forms of financing arrangements available to the entity. Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	Total facility amount at quarter end \$US'000	Amount drawn at quarter end \$US'000
7.1	Loan facilities	100,000*	90,000*
7.2	Credit standby arrangements	—	—
7.3	Other (please specify)	—	—
7.4	Total financing facilities	100,000*	90,000*
7.5	Unused financing facilities available at quarter end		10,000*
7.6	<p>Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.</p> <div style="border: 1px solid black; padding: 10px;"> <p><u>*Loan facility with Oaktree Capital Management, Inc.</u></p> <p>On November 19, 2021, Mesoblast refinanced its senior debt facility with a secured five-year credit facility provided by funds managed by Oaktree Capital Management, L.P. ("Oaktree") and drew down US\$60.0 million on closing.</p> <p>The loan has an initial interest only period of three years, at a fixed rate of 9.75% per annum, after which time 40% of the principal is payable over two years and a final payment due no later than November 2026.</p> <p>The loan interest rate is fixed and as at June 30, 2023 the interest rate was 9.75%. Since the loan's inception, 8% interest was paid in cash, while 1.75% interest was not paid in cash, instead it was paid in kind (PIK) and accrued onto the loan balance outstanding.</p> <p><u>*Loan facility with NovaQuest Capital Management, L.L.C.</u></p> <p>On June 29, 2018, Mesoblast entered into a Loan and Security Agreement with NovaQuest Capital Management, L.L.C. ("NovaQuest") for a non-dilutive US\$40.0million secured eight-year term loan. Mesoblast drew the first tranche of US\$30.0 million of the loan on closing. An additional US\$10.0 million from the loan will be drawn on marketing approval of remestemcel-L for the treatment in pediatric patients with steroid-refractory acute graft versus host disease ("SR-aGVHD") by the United States Food and Drug Administration ("FDA"). The loan term includes an interest only period of approximately four years through until July 8, 2022, then a four-year amortization period through until maturity.</p> <p>All interest and principal payments will be deferred until after the first commercial sale of remestemcel-L in the treatment of pediatric patients with SR-aGVHD. Principal is repayable in equal quarterly instalments over the amortization period of the loan based on a percentage of net sales and are limited by a payment cap. The loan has a fixed interest rate of 15% per annum. The financing is subordinated to the senior creditor, Oaktree.</p> </div>		



8.	Estimated cash available for future operating activities	\$US'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(14,244)
8.2	Cash and cash equivalents at quarter end (item 4.6)	53,177
8.3	Unused finance facilities available at quarter end (item 7.5)	10,000*
8.4	Total available funding (item 8.2 + item 8.3)	63,177
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	4.4

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

* Under the NovaQuest loan facility, an additional US\$10.0 million from the loan will be drawn on marketing approval of remestemcel-L for the treatment in pediatric patients with steroid-refractory acute graft versus host disease by the United States Food and Drug Administration.

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: Not applicable

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: Not applicable

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: Not applicable

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date:31 October 2023.....

Authorised by:Chief Executive.....
(Name of body or officer authorising release – see note 4)



Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, AASB 107: Statement of Cash Flows apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's Corporate Governance Principles and Recommendations, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.



