

asx announcement

APPENDIX 4C QUARTERLY ACTIVITY REPORT

Mesoblast Operational and Financial Highlights for Quarter Ended December 31, 2020

Melbourne, Australia; January 29 and New York, USA; January 28, 2021: Mesoblast Limited (ASX: MSB; Nasdaq: MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today provided an update on its pipeline of late-stage product candidates, and an activity report for the second quarter ended December 31, 2020.

Mesoblast Chief Executive Dr Silviu Itescu stated: 'We were very pleased to see the significant reduction in cardiac mortality and major vascular events in our Phase 3 trial of rexlemestrocel-L for advanced chronic heart failure. The high-risk New York Heart Association class II patient population is particularly important since it represents a very large unmet need and existing therapies have not materially reduced mortality in these patients.

These results continue to reinforce the strength of our platform technology in targeting the most serious and life-threatening diseases caused by excessive inflammation. The strong data from this randomized controlled Phase 3 trial underpin our discussions with potential strategic partners and provide support for our interactions with the United States Food and Drug Administration."

Key Highlights:

- Sales of TEMCELL® HS Inj. 13 in Japan for the treatment of aGVHD have recovered rapidly from the effects of the temporary shutdown in production during mid-2020 which was undertaken in order to increase capacity to meet growing demand for the product
- Revenues from royalties on TEMCELL® HS Inj. sales for the quarter ended December 31, 2020 were US\$2.1 million compared to US\$2.0 million in the quarter ended December 31, 2019
- Mesoblast has amended its existing agreement with Hercules to extend the interest-only period of the loan up to March 2022, subject to achieving certain milestones
- Cash on hand at December 31, 2020 was US\$77.5 million. Over the next 12 months,
 Mesoblast may receive up to an additional US\$92.5 million through existing financing facilities and strategic partnerships
- During Q4 2020, Phase 3 trial results of rexlemestrocel-L (REVASCOR®) in patients with chronic heart failure with reduced left ventricular ejection fraction (HFrEF) showed that a single dose of rexlemestrocel-L resulted in substantial and durable reductions in heart attacks, strokes, and cardiac deaths. Mesoblast plans to meet with the FDA to discuss how the results may support a pathway to approval
- When the 60-day results of the COVID-19 ARDS trial become available during Q1 2021, they will be analysed by Mesoblast and Novartis to identify meaningful clinical outcomes that may guide decisions on the development program for remestemcel-L in non-COVID ARDS
- Mesoblast intends to meet with the FDA during Q1 2021 through a well-established process to have further discussions on the potential for accelerated approval of remestemcel-L in the treatment of children with steroid-refractory acute graft-versus-host disease (SR-aGVHD)
- Results from the Phase 3, 404-patient, randomized placebo-controlled trial evaluating MPC-06-ID (rexlemestrocel-L) in patients with chronic low back pain due to degenerative disc disease are expected shortly
- Mesoblast is actively exploring additional strategic initiatives with a number of global pharma companies across its advanced-stage pipeline of product candidates

Rexlemestrocel-L

Revascor for Chronic Heart Failure

The results from the landmark DREAM-HF randomized controlled Phase 3 trial in 537 treated patients with chronic heart failure with reduced left ventricular ejection fraction (HFrEF) who received rexlemestrocel-L (REVASCOR®) or control sham, demonstrated that a single dose of rexlemestrocel-L resulted in substantial and durable reductions in heart attacks, strokes, and cardiac deaths. The results of this trial identify New York Heart Association (NYHA) class II HFrEF patients as the optimal target population for greatest rexlemestrocel-L treatment effect, and therefore a focus for registration and commercialization of rexlemestrocel-L in the largest market in heart failure.

The incidence of heart attacks and strokes were reduced by 60% over a median follow-up period of 30 months following a single dose of rexlemestrocel-L in the entire population of 537 treated patients (5% vs 13%, p=0.002). The incidence of death from cardiovascular causes was reduced by 60% in the 206 patients with NYHA class II disease (8% vs 20%, p=0.037), a significant reduction which was evident in both ischemic and non-ischemic subgroups as well as diabetic and nondiabetic patients.

The results also show that the NYHA class II patients in the control group, following an initial period of approximately 20 months of disease stability, progressed to cardiac death rates in-line with NYHA class III patients. NYHA class II patients treated with a single dose of rexlemestrocel-L did not show such cardiac death progression (p=0.004 compared to class II control patients).

The combination of the three pre-specified outcomes of cardiac death, heart attack or stroke into a single composite outcome - called the three-point major adverse cardiovascular events (MACE) is a well-established endpoint used by the United States Food and Drug Administration (FDA) to determine cardiovascular risk. Rexlemestrocel-L significantly reduced this three-point MACE by 30% compared to controls across the entire population of 537 treated patients (20.6% vs 30%, p=0.027). In the NYHA class II subgroup of 206 patients, rexlemestrocel-L reduced the three-point MACE by 55% compared to controls (13% vs 29%, p=0.009).

Heart failure affects approximately 6.5 million people in the US and 26 million people globally, with increasing prevalence and incidence. Chronic heart failure is a progressive disease associated with cardiac and systemic inflammation and a high mortality rate that approaches 50% at 5 years as patients progress beyond NYHA class II disease. In addition, these patients are at high risk of recurrent heart attacks and strokes, reflecting the high degree of systemic inflammation and progressive atherosclerosis associated with chronic heart failure. The high rate of cardiac death, heart attacks and strokes accompanying disease progression continues to be the most significant unmet need in this patient population since new therapies that have reduced recurrent hospitalizations due to cardiac decompensation have not materially impacted these MACE outcomes.

Based on the observed reduction in mortality and morbidity in this Phase 3 trial, Mesoblast intends to meet with the FDA to discuss a potential approval pathway. Concurrently, Mesoblast will also explore potential strategic initiatives with a number of global pharma companies who have existing interests in cardiovascular disease and/or major vascular complications of diabetes.

MPC-06-ID for Chronic Low Back Pain due to Degenerative Disc Disease

Chronic low back pain (CLBP) affects approximately 10-15% of the adult population, equivalent to more than 30 million people in the United States and almost 40 million people across the EU5.¹ Degenerative disc disease (DDD) causing discogenic pain is the most common etiology of chronic low back pain in adults.^{2,3} Over 7 million patients in each of the United States and EU5 are thought to suffer from CLBP caused by degenerative disc disease,²⁻⁴ a disease which involves inflammation and degeneration of the intervertebral discs due to various factors including age, trauma, or genetic predisposition.

Back pain causes more disability than any other condition and inflicts substantial direct and indirect costs on the healthcare system.⁴ For patients with CLBP who fail conservative therapy there are few alternatives treatments, including opioids, spinal injections and surgery (eg, spinal fusion or total disk

arthroplasty).⁵ Excessive use of opioids in this patient population constitutes a major concern in the US, with more than 50% of US opioid prescriptions being for the treatment of CLBP.^{1,6,7}

There is consequently a significant need for a safe, efficacious, and durable opioid-sparing treatment in patients with chronic low back pain due to severely inflamed degenerative disc disease. Results from the Phase 3, 404-patient, randomized placebo-controlled trial evaluating MPC-06-ID (rexlemestrocel-L) in patients with chronic low back pain due to degenerative disc disease are expected shortly.

Remestemcel-L

Collaboration with Novartis

Mesoblast has entered into a worldwide license and collaboration agreement with Novartis for the development, manufacture, and commercialization of Mesoblast's mesenchymal stromal cell (MSC) product remestemcel-L, with an initial focus on the development of the treatment of acute respiratory distress syndrome (ARDS), including that associated with COVID-19. The closing of the license agreement is subject to certain conditions.

Mesoblast has enrolled 223 patients in its randomized controlled trial of remestemcel-L in ventilator-dependent patients with moderate to severe ARDS due to COVID-19 infection. Following the third interim analysis on the trial's first 180 patients last month, the Data Safety Monitoring Board (DSMB) reported that there were no safety concerns but noted that the trial was not likely to meet the 30-day mortality reduction endpoint at the planned 300 patient enrolment. The trial was powered to achieve a primary endpoint of 43% reduction in mortality at 30 days for treatment with remestemcel-L on top of maximal care. The DSMB recommended that the trial complete with the currently enrolled 223 patients, and that all be followed-up as planned.

Notably, the trial has not yet accrued data on the secondary endpoints, which include days alive off mechanical ventilation at 60 days post randomization, overall survival, days in intensive care, duration of hospitalization, and cardiac, neurological, and pulmonary organ damage. Additionally, measures of circulating cytokines and inflammatory markers will be evaluated. None of these were included in the interim analysis. As such, the trial will evaluate all 223 enrolled patients through 60 days of follow-up to study potential treatment effects on these outcomes. Mesoblast and Novartis will both analyse these results to identify meaningful clinical outcomes that may guide decisions on the development program for remestemcel-L in non-COVID ARDS.

Steroid-Refractory Acute Graft Versus Host Disease

On August 13, 2020, results from 309 children with steroid-refractory acute graft versus host disease (SR-aGVHD) treated with remestemcel-L were presented to the Oncologic Drugs Advisory Committee (ODAC) of the United States Food and Drug Administration (FDA). The ODAC panel voted 9:1 that the available data support the efficacy of remestemcel-L in pediatric patients with SR-aGVHD⁸. Despite the overwhelming ODAC vote, on September 30, the FDA provided Mesoblast with a Complete Response Letter.

Mesoblast held a Type A meeting with the FDA in November 2020 to discuss the review of the Biologics License Application for remestemcel-L. The current review team have not agreed to accelerated approval. However, there was consensus with the review team on the proposed optimization of potency assays and on use of biomarkers to demonstrate the product's bioactivity invivo.

Mesoblast intends to meet with the FDA during Q1 2021 through a well-established process for continuing discussions on the potential for accelerated approval with a post-approval commitment to conduct an additional randomized controlled study in patients 12 years and older.

Inflammatory Bowel Disease - Crohn's Disease and Ulcerative Colitis

A randomized, controlled study of remestemcel-L delivered by an endoscope directly to the areas of inflammation and tissue injury in up to 48 patients with medically refractory Crohn's disease and ulcerative colitis has commenced at Cleveland Clinic in October 2020. The investigator-initiated study is the first in humans using local cell delivery in the gut and will enable Mesoblast to compare clinical outcomes using this delivery method with results from an ongoing randomized, placebo-controlled trial in patients with biologic-refractory Crohn's disease where remestemcel-L was administered intravenously.

According to recent estimates, more than three million people (1.3%) in the United States alone have inflammatory bowel disease, with more than 33,000 new cases of Crohn's disease and 38,000 new cases of ulcerative colitis diagnosed every year. Despite recent advances, approximately 30% of patients are primarily unresponsive to anti-TNFa agents and even among responders, up to 10% will lose their response to the drug every year. Up to 80% of patients with medically refractory Crohn's disease eventually require surgical treatment of their disease, which can have a devastating impact on quality of life.

Cash Flow Report for the Second Quarter FY2021

Cash on hand at the end of the quarter was US\$77.5 million. Over the next 12 months, Mesoblast may receive up to an additional US\$92.5 million through existing financing facilities and strategic partnerships. Mesoblast has amended its existing agreement with Hercules to extend the interest-only period of the loan up to March 2022, subject to achieving certain milestones.

Total Operating Activities resulted in net cash usage of US\$31.9 million in the quarter ended December 31, 2020. This included investment of US\$4.3 million in commercial manufacturing and inventory build in anticipation for product launch of remestercel-L for SR-aGVHD, and US\$9.6 million associated with the COVID-19 ARDS development program and the annual employee short term incentive plan. Specifically:

- Sales of TEMCELL® HS Inj. 13 in Japan for the treatment of aGVHD continue to recover from the effects of the temporary shutdown in production during mid-2020 which was undertaken in order to increase capacity to meet growing demand for the product
- Revenues from TEMCELL® royalties for the quarter ended December 31, 2020 were US\$2.1 million compared to US\$2.0 million in the quarter ended December 31, 2019. Royalty receipts for the quarter were US\$1.3 million, reflecting revenues recognized in the prior quarter
- Research and Development payments were US\$13.5 million for the current quarter. This
 comprises payments for the CHF and CLBP Phase 3 trials, as well as the COVID-19 ARDS trial
- Product manufacturing & operating costs and manufacturing commercialization payments were US\$7.8 million for the current quarter, this included investment of US\$4.3 million in commercial manufacturing and inventory build in anticipation for product launch of remestemcel-L for SR-aGVHD
- Payments to Related Parties, detailed in Item 6 of the Appendix 4C cash flow report for the quarter, comprise approximately US\$397,000 in Non-Executive Director fees and Executive Director's salary

A copy of the Appendix 4C – Quarterly Cash Flow Report for the second quarter FY2021 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 2040 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.

Remestemcel-L is being developed for inflammatory diseases in children and adults including steroid refractory acute graft versus host disease and moderate to severe acute respiratory distress syndrome. Mesoblast has completed Phase 3 trials of rexlemestrocel-L 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 entered into global and regional strategic partnerships 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. Decision Resources: Chronic Pain Report 2015
- 2. DePalma MJ, et al. What Is the Source of Chronic Low Back Pain and Does Age Play a Role? Pain Med. 2011; 12: 224–233
- 3. Peng BG. Pathophysiology, diagnosis, and treatment of discogenic low back pain. World J Orthop. 2013 April 18; 4(2): 42-52
- 4. Williams, J., NG, Nawi, Pelzter, K. Risk factors and disability associated with low back pain in older adults in low-and middle-income countries. Results from the WHO Study on global ageing and adult health (SAGE). PloS One. 2015; 10(6): e0127880
- 5. Zigler J, et al. Comparison of lumbar total disc replacement with surgical spinal fusion for the treatment of single-level degenerative disc disease: a meta-analysis of 5-year outcomes from randomized controlled trials. Glob Spine J. 2018;8(4):413–23
- 6. Abdel Shaheed C, Maher CG, Williams KA, Day R, McLachlan AJ. Efficacy, tolerability, and dose-dependent effects of opioid analgesics for low back pain: a systematic review and meta-analysis. JAMA Intern Med 2016;176(7):958–68
- 7. Hudson TJ, Edlund MJ, Steffick DE, Tripathi SP, Sullivan MD. Epidemiology of regular prescribed opioid use: results from a national, population-based survey. J Pain Symptom Manage 2008;36(3):280–8
- 8. This vote includes a change to the original vote by one of the ODAC panel members after electronic voting closed
- 9. CDC Facts and Figures 2015
- 10. Globaldata Pharmapoint 2018
- 11. Dahlhamer JM, MMWR Morb Mortal Wkly Rep. 2016;65(42):1166-1169
- 12. Crohn's and Colitis Foundation
- 13. TEMCELL® HS Inj. is a 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 forwardlooking 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. Forwardlooking 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 Quarter ended ("current quarter")			
68 109 431 870		31 December 2020	

Con	solidated statement of cash flows	Current quarter \$US'000	Year to date (6 months) \$US'000
1.	Cash flows from operating activities		
1.1	Receipts from customers - royalty receipts	1,290	1,972
1.2	Payments for		
	(a) research and development	(13,530)	(23,436)
	(b) manufacturing commercialization	(2,908)	(8,126)
	(c) product manufacturing and operating costs	(4,911)	(10,140)
	(d) advertising and marketing	(2,130)	(3,886)
	(e) leased assets	_	_
	(f) staff costs	(4,177)	(6,085)
	(g) other expenses from ordinary activities	(3,613)	(6,116)
	(h) other:		
	Intellectual property portfolio expenses	(604)	(1,568)
1.3	Dividends received (see note 3)	_	_
1.4	Interest received	3	16
1.5	Interest and other costs of finance paid	(1,382)	(2,771)
1.6	Income taxes paid	_	(6)
1.7	Government grants and tax incentives	_	17
1.8	Other (provide details if material)	_	_
1.9	Net cash from / (used in) operating activities	(31,962)	(60,129)

Con	solidated statement of cash flows	Current quarter \$US'000	Year to date (6 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	(407)	(488)
	(I) investments	-	_
	(m) intellectual property	-	_
	(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	_	_
2.6	Net cash from / (used in) investing activities	(407)	(488)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	_	1,429
3.2	Proceeds from issue of convertible debt securities	_	_
3.3	Proceeds from exercise of options	1,431	8,136
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(8)	(905)
3.5	Proceeds from borrowings	_	_
3.6	Repayment of borrowings	_	_

Consolidated statement of cash flows		Current quarter \$US'000	Year to date (6 months) \$US'000
3.7	Transaction costs related to loans and borrowings	_	_
3.8	Dividends paid	_	_
3.9	Other (payment of lease liability)	(785)	(1,480)
3.10	Net cash from / (used in) financing activities	638	7,180

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of quarter (October 1, 2020)/beginning of year (July 1, 2020)	108,123	129,328
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(31,962)	(60,129)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(407)	(488)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	638	7,180
4.5	Effect of movement in exchange rates on cash held	1,136	1,637
4.6	Cash and cash equivalents at end of period	77,528	77,528

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	77,065	107,697
5.2	Call deposits	_	<u> </u>
5.3	Bank overdrafts	_	_
5.4	Other (Term deposits)	463	426
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	77,528	108,123

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	397
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.		

Payments for Non-executive Director fees and Executive Director's salary (for the current quarter) =

7.	Financing facilities 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.	Total facility amount at quarter end \$US'000	Amount drawn at quarter end \$US'000
7.1	Loan facilities	90,000*	80,000*
7.2	Credit standby arrangements	_	_
7.3	Other (please specify)	_	_
7.4	Total financing facilities	90,000*	80,000*
7.5	Unused financing facilities available at qu	arter end	10,000*

7.6 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.

*Loan facility with Hercules Capital, Inc.

On March 6, 2018, Mesoblast entered into a Loan and Security Agreement with Hercules Capital, Inc. ("Hercules Capital") for a US\$75.0 million secured four-year credit facility. Mesoblast drew the first tranche of US\$35.0 million on closing. An additional US\$15.0 million was drawn during Q1 CY2019.

As at December 31, 2020, the interest rate on the loan was 9.70%.

*Loan facility with NovaQuest Capital Management, L.L.C.

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\$40.0 million 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 RYONCIL by the United States Food and Drug Administration (FDA).

Prior to maturity in July 2026, the loan is only repayable from net sales of RYONCIL in the treatment of pediatric patients who have failed to respond to steroid treatment for acute Graft versus Host Disease (aGvHD), in the United States and other geographies excluding Asia. Interest on the loan will accrue at a rate of 15% per annum with the interest only period lasting 4 years. Interest payments will be deferred until after the first commercial sale. The financing is subordinated to the senior creditor, Hercules Capital.

8.	Estimated cash available for future operating activities	\$US'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(31,962)
8.2	Cash and cash equivalents at quarter end (item 4.6)	77,528
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)	87,528
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	2.7
	Note: if the entity has reported positive net operating cash flows in item 1.9, answer item figure for the estimated quarters of funding available must be included in item 8.5.	n 8.5 as "N/A". Otherwise, a
	*Under the NovaQuest loan facility, an additional US\$10.0 million from the loan will approval of RYONCIL by the United States Food and Drug Administration (FDA).	be drawn on marketing

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:	29 January 2021
Authorised by:	Chief Executive

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.
- 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.