PARADIGM BIOPHARMA

ASX RELEASE 31 January 2024

DECEMBER 2023 QUARTERLY ACTIVITIES REPORT

Key Highlights

- **Phase 3 PARA_OA_002 Stage 1 Completion**: The first stage of the harmonised phase 3 trial was completed during the period. 120 sites were activated across seven countries completing the randomisation of 579 subjects demonstrating the effectiveness of Paradigm's recruitment initiatives. Global clinical trial sites remain on standby for the commencement of the final stage of the phase 3 trial.
- **Phase 3 Optimal Dose**: Following the completion of Stage 1 of the Phase 3 clinical trial PARA_OA_002 and the release of the 12-month durability and 6-month quantitative MRI data from the Phase 2 clinical trial PARA_OA_008, the optimal dosing regimen was determined to be 2mg/kg injectable pentosan polysulfate sodium (iPPS) twice weekly and this dosing is intended for use in the next stage of the Phase 3 Osteoarthritis (OA) clinical program.
- **PARA_OA_008 Completion**: The PARA_OA_008 trial completed during the quarter. The phase 2 trial successfully achieved its primary endpoint of a change from baseline at Day 56 in one or more synovial fluid biomarkers, and met several secondary endpoints of objective (MRI) and subjective (patient reported) measures out to 1 year.
- **IPPS demonstrates 1 year durability in OA**: During the December quarter Paradigm reported significant new phase 2 PARA_OA_008 data demonstrating improvements in patient-reported outcomes of WOMAC pain, function and patient global impression of change (PGIC) scores for participants receiving 2mg/kg twice weekly iPPS compared to placebo at Day 365 in the phase 2 PARA_OA_008 clinical trial.
- **Structural improvements at 6-months:** Paradigm reported exciting new analysis from the phase 2 PARA_OA_008 clinical trial showing the preservation of cartilage in knee OA subjects. A 6-week twice weekly course of subcutaneous iPPS was shown to increase cartilage thickness and volume and to reduce bone marrow lesions and synovitis from baseline on MRI follow-up at 6 months.
- **Capital Raise**: Paradigm announced a $30.1 million capital raise (before costs) comprising a fully underwritten $18m placement and $12m accelerated non renounceable entitlement offer.
- **Cash Runway**: 31 December 2023 cash balance of $33.5m, which provides sufficient runway for CY2024, including commencement stage 2 of the phase 3 OA program. The funding runway could be further extended by approximately $33m via exercise of outstanding options (Nov 2024 expiry) and a regional partnering deal.
- **Milestones and Outlook:** Paradigm is preparing the protocol for the next stage of the phase 3 clinical trial for the US FDA and the determination application for the TGA Provisional Approval pathway. Both are expected to be submitted in Q1 this calendar year.

Paradigm Biopharmaceuticals Ltd. (ASX:PAR) ("Paradigm" or "the Company") is pleased to provide its quarterly update for the three months ended 31 December 2023 to accompany its Appendix 4C cash flow report for the period.

- Cash balance as of 31 December 2023 was $33.5m (on 30 September 2023 it was $33.6m).
- During the period Paradigm announced a $30.1 million capital raise (before costs) comprising a fully underwritten $18m placement and $12m accelerated non renounceable entitlement offer.
- Paradigm has lodged its R&D Tax Incentive refund claim for FY23 and is awaiting receipt of the $7.2m refund, expected during Q1 CY24.
- Research and development expenditure for the quarter was $27.06m compared to the previous quarter of $21.9m. This spend in Q2 FY24 was largely related to costs incurred during the prior quarter on the Stage 1 dose finding activities of Phase 3 clinical trial, including recruitment, screening, dosing and follow-up of the final patients enrolled in the study. The cost also includes activities related to the close-out of stage 1 of the PARA_OA_ 002 phase 3 clinical program. Close-out procedures for clinical trials require all sites to be monitored by Paradigm's clinical research organization and Paradigm staff, to comply with the clinical trial regulations.
- The costs of the interim analysis performed on initial 300 participants on PARA_OA_002 are also included in the December quarter. Since completing stage 1 of the phase 3 PARA_OA_002 study in late November 2023, the December spending for new patient activity costs has significantly reduced. It is forecast that costs going forward will continue to decline, as study closure completes. All ongoing and future activities will focus on delivering the next phase of the phase 3 OA trial.
- R&D spend during the December quarter also related to clinical and quantitative MRI data analysis and completion of the PARA_OA_008 phase 2 clinical trial activities. The spend also included end of study analysis and shut down cost for the MPS VI phase 2 study, and an ongoing New Drug Application required nonclinical studies relating to our OA clinical program.
- The quarter also saw payments related to continuing activities described in the outlook below.
- In accordance with Listing Rule 4.7C.3 and as noted in item 6 of the Appendix 4C Cashflow Statement, payments to related parties and their associates during the quarter ended 31 December 2023 were fees of $57K, which includes $52K for payment of Director fees, and $5K for legal fees to BioMeltzer (a company related to Paradigm NED, Amos Meltzer).

QUARTERLY ACTIVITIES & OUTLOOK

Paradigm is pleased to provide an update on continuing activities.

Phase 3 Clinical Program

Paradigm reported in October 2023 findings from an interim analysis conducted once the first 300 participants from the PARA_OA_002 clinical trial reached day 56 of the study.

The doses (less than 2 mg/kg twice weekly) included in the dose determination part of phase 3 trial did not meet the prespecified performance threshold, which was based on prior outcome data produced with the 2mg/kg twice weekly dosing regimen. Following these findings, Paradigm has prepared a new protocol for the next stage of the phase 3 clinical program using the 2mg/kg twice weekly dose regimen of iPPS which has demonstrated consistent positive data in the PARA_OA_008, PARA_005 (previous phase 2b) studies and the TGA Special Access Scheme.

Stage 1 activities for the PARA_OA_002 phase 3 clinical trial concluded during the quarter with the study completing the randomisation of 579 subjects demonstrating Paradigm's ability to enrol suitable study participants through the many recruitment initiatives implemented for the global phase 3 study.

Paradigm remains on track for the protocol review by the US FDA to implement the 2mg/kg twice weekly dosing regimen into the next stage of the OA phase 3 program, anticipated in Q1 CY2024. Enrolment activities for next stage of the phase 3 OA clinical program are expected to commence in Q2 CY 2024.

R&D Expenditure

Paradigm's expenditure over the last three quarters has been unusually high as Paradigm has invested heavily in the first stage of the phase 3 clinical program. The activities relating to the spend include:

- Increased clinical trial site activations and initiatives to support subject recruitment,
- PARA_OA_002 Interim Analysis,
- Close out of stage 1 PARA_OA_002 and PARA_OA_006 studies.

Subject Recruitment

Through the second half of CY2023, Paradigm increased its target clinical trial sites from 80 to 120 clinical trial site activations to support the recruitment increased initiatives undertaken by the Company. The Phase 3 clinical program has activated sites across seven countries, comprising Australia, the US and Canada in North America, and the UK, Belgium, Poland, and Czechia in the EU. The additional trial sites activated aided to Paradigm to meet the reported 100% enrolment target of June 2023 which was reported at the beginning of July 2023. The significant one-off upfront investment in the trial setup costs in the stage 1 of the phase 3 trial ensures trial sites are trained and available to commence with next stage of the phase 3 clinical program, thus streamlining the recruitment and enrolment process.

As Paradigm reached the increased target for site activation and these clinical trial sites became familiar with the study design, it enabled an increase in the number of participants directed to these sites through the utilisation of several recruitment initiatives. The implemented initiatives include the introduction of 1nHealth, SubjectWell, and Paradigm's partnership with NFL Alumni Health, which together increased the volume of potential participants to study sites for screening and randomisation. Paradigm also launched a dedicated clinical trial website www.Hope4OA.com, an ethics-approved easy-to-use public-facing website for providing trial information and access Paradigm's OA clinical trials. The implementation of these recruitment initiatives in stage 1 have enabled identification of potential participants for stage 2 of the phase 3 study.

Paradigm expects the investment in these activities upfront to enhance the efficiency of the next stage of the phase 3 clinical trial and mitigate any potential delays.

Interim Analysis

An interim analysis was conducted ahead of schedule to determine the performance of the three iPPS doses in stage 1 of PARA_OA_002 clinical trial against placebo. This was conducted following reported data from the phase PARA_OA_008 clinical trial demonstrating the once weekly iPPS dosing regimen was not providing sufficient clinical results to that of the 2mg/kg twice weekly Paradigm has reported across multiple programs. Costs associated with the interim analysis included Clinical Research Organisation (CRO) and Data Monitoring Committee to analyse data on the first 300 participants who had reached Day 56. The interim analysis provided Paradigm an earlier indication of the optimal dose and aided the preparation of the clinical protocol for the next stage of the phase 3 OA program ahead of schedule.

Phase 3 Stage 1 close out activities

Paradigm completed activities associated with the close out of stage 1 of PARA_OA_002 clinical trial and the PARA_OA_006 extension study. Close-out is a process to ensure all clinical trial related activities are appropriately reconciled, recorded, and reported at the end of a trial in accordance with the protocol, standard operating procedures (SOPs) good clinical practice (GCP), and all other applicable regulatory requirements. Close-out is integral to the quality control of a clinical trial and is designed to ensure quality of the study according to Sponsor requirements and to ensure that all necessary documents are in place should it be necessary for the trial information to be retrieved or inspected, by regulatory agencies, in the future. Paradigm required the close-out to be conducted in accordance with the said SOPs and with GCP so that the clinical data could be used in discussion with the US FDA regarding the minimal effective dose discussions and the revised clinical trial protocol and at the time of Paradigm's New Drug Application (NDA) submission.

Cost Containment Measures

As discussed during the capital raise, aggressive cost containment measures have been implemented to ensure capital is being directed toward completion of the phase 3 OA clinical trial. Paradigm's financial commitment to the MPS clinical program has now completed with a reduced headcount in the MPS clinical team implemented following the completion of the phase 2 studies in MPS I and VI. Paradigm is actively seeking to partner this clinical asset to progress iPPS for treatment of MPS toward commercialisation. Ongoing overheads have been reduced throughout this cost containment phase by over $1m per quarter which will come into effect from January 2024, with further reductions planned over the coming months.

Forecast cash outflow for the March 2024 quarter is expected to be $8 - $11m (including R&D refund) and the June 2024 quarter expected to be in the $6m - $8m range which is inclusive of phase 3 stage 2 restart costs.

Paradigm has issued short term options (Nov 2024 expiry) as a part of the 2023 capital raise exercisable at $0.65. Exercise of the outstanding options is expected to add an additional $33m (approximate).

PARA_OA_008 Phase 2 Clinal Trial

Paradigm's PARA_OA_008 clinical trial concluded during the December quarter with the significant data from the 12-month clinical data and 6-month quantitative analysis reported. The PARA_OA_008 clinical trial phase 2 trial data showing efficacy of iPPS on both objective (MRI analysis) and subjective measures (patient reported outcomes) compared to placebo, demonstrates that iPPS both treats the symptoms of OA and has the potential to preserve and/or regenerate joint tissues.

OBJECTIVE DATA MEASURES	**Reported (Day)**
Improvement in synovial fluid biomarkers associated with OA disease progression.	56 & 168
Improvement in structural changes in the knee determined by MRI.	168
SUBJECTIVE DATA MEASURES	**Reported**
Significant improvement in mean change from baseline in WOMAC pain, function, and overall scores.	56, 168 & 365
Significant improvement in Patient Global Impression of Change (PGIC)	365

During the December quarter Paradigm reported durable and significant responses in WOMAC scores for pain (p=0.054), function (p=0.048), stiffness and overall (p=0.054) were observed for iPPS twice weekly compared to placebo control through to Day 365. The outstanding results for iPPS compared to placebo were strengthened through the reporting that cumulative rescue pain medication use was over five times higher in the placebo group compared to iPPS group at Day 365.

This data is a significant outcome for Paradigm as no OA drug has previously shown durable and meaningful improvements in pain and function at 12 months after a single course of treatment.

The Company also reported in October quantitative MRI analysis results at the day 168 follow-up from the phase 2 PARA_OA_008 clinical trial, demonstrated that a single 6-week treatment of iPPS treatment at 2mg/kg twice weekly results in an increase in overall cartilage thickness (p=0.05) and cartilage volume (p=0.07) compared to a decrease in the placebo group. Bone marrow lesions (-17%) and synovitis (-1%) were also decreased in the knee joint following iPPS administration to day 168 compared to small increases in the placebo group.

The above results of the successful phase 2 clinical trial demonstrate that iPPS both treats the symptoms of OA and preserves and/or regenerates joint tissues. This is significant from a commercial perspective because the disease modifying effects of iPPS observed in the PARA_OA_008 phase 2 clinical trial are expected to support a greater reimbursement compared to that which would be expected for a therapeutic that only treat the symptoms of OA.

OA remains the most prevalent form of joint disease, affecting up to 16% of the population in the developed world, with more than 72 million people in the US, EU5, Canada and Australia suffering from osteoarthritis.[1] The prevalence of OA is increasing in line with the aging population and increasing rates of obesity. By 2030 the number of people suffering from OA in the US is predicted to increase by 86% to 67 million.[2]

OA has a significant impact on day-to-day functioning and, although the levels of pain and disability may fluctuate, it has no known cure or spontaneous remission and is associated with irreversible structural damage and progression over time. Presently there are no drugs approved that can prevent, stop, or even restrain progression of OA. Moreover, the available medications that claim to mitigate the pain of OA have numerous risk/benefit considerations and market research indicates that only 19% of knee OA patients are satisfied with currently available treatments. [2,3]

There is an urgent unmet need for a new therapy for OA. This successful phase 2 clinical trial has provided important data for Paradigm to progress with the TGA Provisional Approval application, which would expedite the pathway to marketing approval of iPPS in Australia.

Capital Raising

Paradigm announced on the 30th of October, a fully underwritten $30.1 million (before costs of $1.76m) capital raising, comprising:

- a placement to institutional investors of approximately 42 million Shares at an issue price of $0.43 per Share raising approximately $18 million;
- an accelerated non-renounceable Entitlement Offer of 1 Share for every 10 Shares held by eligible shareholders at an issue price of $0.43 per Share raising approximately $12.1 million; and
- 3 free-attaching Options for every 4 Shares subscribed for and issued under the Entitlement Offer and Placement.

The proceeds from the capital raise are being utilised for the Company's phase 3 OA clinical program.

Paradigm Board Changes

During the December quarter Non-Executive Director, Mr John Gaffney stepped down from the Paradigm board following 9-years of service. Non-Executive Director, Helen Fisher also informed the Paradigm Board during the period that she will be stepping down from the position as Non-Executive Director on the appointment of a replacement Non-Executive Director, to focus on other commitments going forward. The Paradigm Board commenced a search for an Independent Non-Executive Director with commercial experience and financial expertise and an Independent Chair during the December quarter. Paradigm expects to make an announcement on additions to the board during H1 CY2024.

Mucopolysaccharidosis VI

The MPS VI study has completed however, the MPS VI data analysis encountered an unforeseen delay with the service provider conducting the GAG analysis for the phase 2 clinical trial. This is a highly specialised analytical technique with only a small number of

service providers available globally. Paradigm expects to release the top-line data next week.

Global Conferences

American College of Rheumatology (ACR) Convergence 2023: In November Dr Mukesh Ahuja, Paradigm Global Head of Osteoarthritis, presented a poster at the ACR Convergence 2023 held November 10–15 at the San Diego Convention Centre in San Diego, California. The poster detailing data from the PARA_OA_008 clinical trial on the therapeutic effects of iPPS on clinical and disease modifying outcomes in subjects with knee osteoarthritis.

Company Outlook

Phase 3 OA Clinical Program

Paradigm met with US FDA on the 10th of January 2024 to discuss outstanding requirements for the next stage of the Phase 3 clinical program in Osteoarthritis. Paradigm's clinical and regulatory teams are preparing the documentation for submission of updated nonclinical data to the Agency ahead of the submission of the clinical protocol to the FDA. The program has FDA granted Fast-track designation and the timeline for the review is expected in Q1 CY2024. Paradigm plans to proceed with the dose of 2mg/kg twice weekly for registration studies. Enrolment activities for next stage of the phase 3 OA program are expected to commence in Q2 CY2024.

TGA Provisional Approval Application

Paradigm is progressing with its TGA Provisional marketing approval in Australia for iPPS, which is expected to expedite the pathway to revenues. The next stage of the TGA Provisional Approval pathway, the determination application remains on track with the determination application planned to be submitted to the TGA toward the end of the current quarter (Q1 CY2024). Should this prove successful, Paradigm will prepare a full dossier for submission to the final stage of the TGA provisional approval application process.

Business Development

Paradigm continues to progress business development activities with regional partnering companies with the aim to have at least one regional partnering by the end of June 2024. Discussions are ongoing with a number of potential partners. Updates will be provided when appropriate.

Other Activities

- Paradigm's PARA_OA_008 phase 2 clinical data has been selected for podium presentations at two global orthopedic and OA conference. Dr Mukesh Ahuja, Paradigm's Global Head of Osteoarthritis will present data from the phase 2 clinical trial evaluating the clinical and disease modifying outcomes of iPPS in knee OA at the:
    - Orthopedic Research Society (**ORS**) Annual Meeting 2024, 2–6 February: Paradigm submitted a late-breaking abstract to the ORS selection committee following the release of the PARA_OA_008 12-month clinical and 6-month quantitative MRI data. The abstract titled "*The therapeutic effects of pentosan polysulfate sodium on clinical and disease modifying outcomes in moderate*

to severe knee osteoarthritis" was selected for a presentation during the late-breaking podium session; and

- Osteoarthritis Research Society International (**OARSI**) 2024, 18–21 April: Paradigm's recent clinical and disease modifying outcome data from the PARA_OA_008 phase 2 clinical trial was reviewed by the OARSI panel and selected for a podium presentation during the conference.

- Paradigm has lodged the FY23 R&D Tax Incentive Scheme refund claim. The refund of approximately $7.2m was anticipated to be received during Q4 CY2023, however it is now expected in Q1 CY2024.

- The overall results produced in the PARA_OA_008 phase 2 clinical trial and MPS-I study are currently being compiled into a manuscript for peer review and publication. Both are expected to be published during CY2024.

About Paradigm Biopharmaceuticals

Paradigm Biopharmaceuticals Ltd. (ASX:PAR) is a late-stage drug development company driven by a purpose to improve patients' health and quality of life by discovering, developing, and delivering pharmaceutical therapies. Paradigm's current focus is developing iPPS for the treatment of diseases where inflammation plays a major pathogenic role, indicating a need for the anti-inflammatory and tissue regenerative properties of PPS, such as in osteoarthritis (phase 3) and mucopolysaccharidosis (phase 2).

Forward Looking Statements

This Company announcement contains forward-looking statements, including statements regarding anticipated commencement dates or completions dates of preclinical or clinical trials, regulatory developments, and regulatory approval. These forward-looking statements are not guarantees or predictions of future performance, and involve known and unknown risks, uncertainties and other factors, many of which are beyond our control, and which may cause actual results to differ materially from those expressed in the statements contained in this presentation. Readers are cautioned not to put undue reliance on forward-looking statements.

References

[1] Global Health Data Exchange, Institute for Health and Metrics Evaluation, University of Washington. Accessed June 2021 http://ghdx.healthdata.org/gbd-results-tool.
[2] OARSI. Osteoarthritis: A Serious Disease, Submitted to the U.S. Food and Drug Administration December 1, 2016.
[3] Matthews GL, Hunter DJ. Emerging drugs for osteoarthritis. Expert Opin Emerg Drugs. 2011;16(3):479-491. doi:10.1517/14728214.2011.576670.

Authorised for release by the Paradigm Board of Directors.

FOR FURTHER INFORMATION PLEASE CONTACT:

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Appendix 4C

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

Name of entity	
Paradigm Biopharmaceuticals Limited	
ABN	**Quarter ended ("current quarter")**
94 169 346 963	31 December 2023

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	30
1.2	Payments for		
	(a) research and development	(27,064)	(49,004)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(137)	(137)
	(d) leased assets	(26)	(37)
	(e) staff costs	(641)	(1,204)
	(f) administration and corporate costs	(772)	(1,300)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	86	635
1.5	Interest and other costs of finance paid	(3)	(6)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(28,557)**	**(51,023)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	**Net cash from / (used in) investing activities**	**-**	**-**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	30,117	30,117
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	(1,763) -	(1,763) -
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings (lease liabilities)	(8)	(51)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (Limited recourse loan repaid under ESP)	-	-
3.10	**Net cash from / (used in) financing activities**	**28,346**	**28,303**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	**33,559**	**56,379**
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(28,557)	(51,023)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-
4.4	Net cash from / (used in) financing activities (item 3.10 above)	28,346	28,303
4.5	Effect of movement in exchange rates on cash held	203	(108)
4.6	**Cash and cash equivalents at end of period**	**33,551**	**33,551**

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 $A'000	Previous quarter $A'000
5.1	Bank balances	33,551	33,559
5.2	Call deposits		
5.3	Bank overdrafts		
5.4	Other (provide details)		
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**33,551**	**33,559**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	57
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.

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 $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	-	-

7.5	**Unused financing facilities available at quarter end**	-

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.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(28,557)
8.2	Cash and cash equivalents at quarter end (item 4.6)	33,551
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	33,551
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	1.17

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.

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: No, the company has implemented a range of cost containment strategies, and has also closed down Stage I of the Phase III clinical trial as the company prepares to proceed with Stage 2 in the coming months.

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: The Company recently conducted a capital raise, and is also awaiting payment of approximately $7.2m from the ATO for the FY2023 R&D tax incentive refund.

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: Yes, in light of the cost containment and the further funds available via the refund.	

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 January 2024.....

Authorised by: ...By the board.....
(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.