# **APPENDIX 4C**

Quarter Ended 30 June 2023

**An Alternate Future** 



Alterity Therapeutics Limited ACN 080 699 065

Lodged with the ASX under Listing Rule 4.3A.
This information should be read in conjunction with the Annual report.



## Appendix 4C – Q4 FY23 Quarterly Cash Flow Report

#### Highlights:

- ATH434-201 Phase 2 study on track to complete enrollment in Q3 2023 with top-line data expected by the end of 2024 in individuals with Multiple System Atrophy (MSA)
- ATH434–201 Phase 2 Data Monitoring Committee recommends continuing clinical trial as planned
- Initiated ATH434-202 Phase 2 Biomarker study in individuals with more advanced MSA
- Promising wearable sensor data from the bioMUSE Natural History Study presented at the AAN Annual Meeting
- Cash balance on 30 June 2023 of \$15.8M

MELBOURNE, AUSTRALIA AND SAN FRANCISCO, USA – 31 July 2023. Alterity Therapeutics Limited (ASX: ATH, NASDAQ: ATHE) ("Alterity" or "the Company"), a biotechnology company dedicated to developing disease modifying treatments for neurodegenerative diseases, releases its Appendix 4C Quarterly Cash Flow Report and update on company activities for the quarter ending 30 June 2023 (Q4 FY23).

"The last several months have been extremely productive for Alterity as we hit several milestones and made significant progress advancing ATH434," said David Stamler, M.D., Chief Executive Officer, Alterity. "With the clearance by the Data Monitoring Committee to continue the ATH434-201 trial as planned and the enthusiasm for the trial from physicians around the world, the trial remains on track to complete enrollment in the third quarter of 2023 with top-line data expected by the end of 2024."

Dr. Stamler, continued, "We also initiated a second Phase 2 study, ATH434-202, in participants with more advanced MSA. Importantly, this Biomarker study gives us the opportunity to get an early indication of efficacy before the ATH434-201 Phase 2 study reads out. Individuals with more advanced MSA may also benefit from ATH434 and measuring key biomarkers will permit us to evaluate drug activity in this population. The data derived from the Biomarker study have the potential to accelerate the overall development program."

"An important element of our ATH434-201 trial is the use of wearable sensors to determine the impact of ATH434 on motor impairment and gait stability. During the quarter, data from the bioMUSE natural history study reinforced this measure by showing that wearable sensors can be used to assess disease progression that may not be captured by neurological examination," concluded Dr. Stamler.

The Company's cash position on 30 June 2023 was A\$15.8M with operating cash outflows for the quarter of A\$6.2M. The company anticipates the cash position will be boosted in the coming weeks with the receipt of the A\$4.7M R&D Tax incentive for the 2022 fiscal year.

#### **Operational Activities**

ATH434-201 Phase 2 Clinical Trial

Subsequent to the quarter, on 26 July, Alterity announced that the independent Data Monitoring Committee (DMC) for the ATH434-201 Phase 2 study recommended the trial continue as planned. The DMC conducted a prespecified review of unblinded clinical data from an initial cohort of study participants. The DMC expressed no concerns about safety and recommended that the study continue without modification.

This randomized, double blind, placebo controlled clinical trial continues to progress with participants in both Australia and the United Kingdom now being treated. The trial is enrolling participants with early stage MSA at over 15 sites in three regions — Australia/New Zealand, the United States, and Europe. The trial is being well received by physicians across the board with feedback positive as they implement Alterity's state of the art methods to diagnose and track the disease.

#### ATH434-202 Phase 2 Clinical Trial

Alterity initiated enrollment in a second Phase 2 trial of ATH434 during the quarter in participants with MSA. This open label, single arm study, entitled "A Biomarker Study of ATH434 in participants with MSA" (ATH434-202), allows Alterity to evaluate the effect of ATH434 on a MSA population more advanced than that being investigated in the randomized study. The design of the Biomarker study will allow the Company to perform interim analyses of biomarker data during conduct, with potential to provide early indications of efficacy before the randomized study reads out.

The key aim of the study is to assess the efficacy of ATH434 on objective biomarkers that measure target engagement and are relevant to the underlying pathology of disease. Clinical measures important in MSA will also be assessed.

Promising wearable sensor data from the bioMUSE Natural History Study

During the quarter, analysis from the Biomarkers of Progression in Multiple System Atrophy (bioMUSE) natural history study demonstrated that wearable sensors can quantify motor impairment in individuals with MSA that is not captured by neurological examination. This means that wearable sensors can be used to assess disease progression and inform clinical trials. These data were presented at the American Academy of Neurology Annual Meeting. As a result of the study, Alterity has incorporated wearable sensor data into its Phase 2 clinical trial for ATH434 as one of its secondary endpoints to determine the effect of treatment on gait parameters.

The ongoing bioMUSE study will continue to provide vital information on early stage MSA, inform the selection of biomarkers suitable to evaluate target engagement and preliminary efficacy, and deliver clinical data to characterize disease progression in a population that mirrors those being studied in Alterity's ATH434-201 trial.

#### **About Alterity Therapeutics Limited**

Alterity Therapeutics is a clinical stage biotechnology company dedicated to creating an alternate future for people living with neurodegenerative diseases. The Company's lead asset, ATH434, has the potential to treat various Parkinsonian disorders. Alterity also has a broad drug discovery platform generating patentable chemical compounds to intercede in disease processes. The Company is based in Melbourne, Australia, and San Francisco, California, USA. For further information please visit the Company's web site at <a href="https://www.alteritytherapeutics.com">www.alteritytherapeutics.com</a>.

**END** 

#### **Authorisation & Additional information**

This announcement was authorised by David Stamler, CEO of Alterity Therapeutics Limited.

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#### **Forward Looking Statements**

This press release contains "forward-looking statements" within the meaning of section 27A of the Securities Act of 1933 and section 21E of the Securities Exchange Act of 1934. The Company has tried to identify such forward-looking statements by use of such words as "expects," "intends," "hopes," "anticipates," "believes," "could," "may," "evidences" and "estimates," and other similar expressions, but these words are not the exclusive means of identifying such statements.

Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements are described in the sections titled "Risk Factors" in the Company's filings with the SEC, including its most recent Annual Report on Form 20-F as well as reports on Form 6-K, including, but not limited to the following: statements relating to the Company's drug development program, including, but not limited to the initiation, progress and outcomes of clinical trials of the Company's drug development program, including, but not limited to, ATH434, and any other statements that are not historical facts. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to the difficulties or delays in financing, development, testing, regulatory approval, production and marketing of the Company's drug components, including, but not limited to, ATH434, the ability of the Company to procure additional future sources of financing, unexpected adverse side effects or inadequate therapeutic efficacy of the Company's drug compounds, including, but not limited to, ATH434, that could slow or prevent products coming to market, the uncertainty of obtaining patent protection for the Company's intellectual property or trade secrets, the uncertainty of successfully enforcing the Company's patent rights and the uncertainty of the Company freedom to operate.

Any forward-looking statement made by us in this press release is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

# **Appendix 4C**

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

### Name of entity

| Alterity Therapeutics Limited |   |
|-------------------------------|---|
| Ĺ                             | j |

## ABN Quarter ended ("current quarter")

37 080 699 065 30 June 2023

| Con | solidated statement of cash flows              | Current quarter<br>\$A'000 | Year to date (12<br>months)<br>\$A'000 |
|-----|--|----------------------------|--|
| 1.  | Cash flows from operating activities           |                            |  |
| 1.1 | Receipts from customers                        | -                          | -                                      |
| 1.2 | Payments for                                   |                            |  |
|     | (a) research and development                   | (4,180)                    | (13,253)                               |
|     | (b) product manufacturing and operating costs  | -                          | -                                      |
|     | (c) advertising and marketing                  | (98)                       | (449)                                  |
|     | (d) leased assets                              | -                          | -                                      |
|     | (e) staff costs                                | (832)                      | (3,867)                                |
|     | (f) administration and corporate costs         | (1,116)                    | (2,403)                                |
| 1.3 | Dividends received (see note 3)                | -                          | -                                      |
| 1.4 | Interest received                              | 1                          | 9                                      |
| 1.5 | Interest and other costs of finance paid       | -                          | -                                      |
| 1.6 | Income taxes paid                              | -                          | (102)                                  |
| 1.7 | Government grants and tax incentives           | -                          | -                                      |
| 1.8 | Other (provide details if material)            | -                          | -                                      |
| 1.9 | Net cash from / (used in) operating activities | (6,225)                    | (20,065)                               |

| <b></b> |                                      |   | ·   |
|---------|--------------------------------------|---|-----|
| 2.      | Cash flows from investing activities |   |     |
| 2.1     | Payments to acquire or for:          |   |     |
|         | (a) entities                         | - | -   |
|         | (b) businesses                       | - | -   |
|         | (c) property, plant and equipment    | - | (5) |
|         | (d) investments                      | - | -   |
|         | (e) intellectual property            | - | -   |
|         | (f) other non-current assets         | - | -   |

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| Con | solidated statement of cash flows              | Current quarter<br>\$A'000 | Year to date (12<br>months)<br>\$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 | -                          | (5)                                    |

| 3.   | Cash flows from financing activities  |      |       |
|------|---|------|-------|
| 3.1  | Proceeds from issues of equity securities (excluding convertible debt securities)       | -    | 311   |
| 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 | (40) | (133) |
| 3.5  | Proceeds from borrowings  | -    | -     |
| 3.6  | Repayment of borrowings   | -    | -     |
| 3.7  | Transaction costs related to loans and borrowings                                       | -    | -     |
| 3.8  | Dividends paid  | -    | -     |
| 3.9  | Other (provide details if material)   | -    | -     |
| 3.10 | Net cash from / (used in) financing activities  | (40) | 178   |

| 4.  | Net increase / (decrease) in cash and cash equivalents for the period |         |          |
|-----|---|---------|----------|
| 4.1 | Cash and cash equivalents at beginning of period                      | 21,944  | 34,807   |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above)       | (6,225) | (20,065) |
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above)       | -       | (5)      |

| Consolidated statement of cash flows |  | Current quarter<br>\$A'000 | Year to date (12<br>months)<br>\$A'000 |
|--------------------------------------|--|----------------------------|--|
| 4.4                                  | Net cash from / (used in) financing activities (item 3.10 above) | (40)                       | 178                                    |
| 4.5                                  | Effect of movement in exchange rates on cash held                | 94                         | 858                                    |
| 4.6                                  | Cash and cash equivalents at end of period                       | 15,773                     | 15,773                                 |

| 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<br>\$A'000 | Previous quarter<br>\$A'000 |
|-----|---|----------------------------|-----------------------------|
| 5.1 | Bank balances   | 15,773                     | 21,944                      |
| 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)   | 15,773                     | 21,944                      |

| 6.  | Payments to related parties of the entity and their associates  | Current quarter<br>\$A'000 |
|-----|---|----------------------------|
| 6.1 | Aggregate amount of payments to related parties and their associates included in item 1                             | 132                        |
| 6.2 | Aggregate amount of payments to related parties and their associates included in item 2                             | -                          |
|     | if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include ation for, such payments. | e a description of, and an |

The amount at 6.1 includes payment of director's fees and salaries and consulting fees, excluding GST where applicable.

| 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<br>amount at quarter<br>end<br>\$A'000 | Amount drawn at<br>quarter end<br>\$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 qu   | uarter end  | -   |
| 7.6 | •   |   |   |
|     |   |   |   |

| 8.  | Estimated cash available for future operating activities                                    | \$A'000                  |
|-----|---|--------------------------|
| 8.1 | Net cash from / (used in) operating activities (item 1.9)                                   | (6,225)                  |
| 8.2 | Cash and cash equivalents at quarter end (item 4.6)   | 15,773                   |
| 8.3 | Unused finance facilities available at quarter end (item 7.5)                               | -                        |
| 8.4 | Total available funding (item 8.2 + item 8.3)   | 15,773                   |
| 8.5 | Estimated quarters of funding available (item 8.4 divided by item 8.1)                      | 2.5                      |
|     | Note: if the entity has reported positive net operating cash flows in item 1.9. answer item | 8 5 as "N/A" Otherwise a |

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: |  |  |  |
|---------|--|--|--|
|         |  |  |  |

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: |  |  |  |
|---------|--|--|--|
|         |  |  |  |

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:   |  |
|---|--|
|   |  |
|   |  |
| Note: where item 9.5 is less than 2 quarters, all of questions 9.6.1. | 9.6.2 and 9.6.2 above must be answered |

### **Compliance statement**

- 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 July 2023

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Authorised by: Phillip Hains - Company Secretary

(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.
- 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.