# APPENDIX 4C

## Quarter Ended 30 June 2022

**Alterity Therapeutics Limited**

ACN 080 699 065

# Appendix 4C – Q4 FY22 Quarterly Cash Flow Report

- Phase 2 clinical trial for ATH434 commences in New Zealand and patient enrolment begins
- Regulatory approval from the U.K. and Italian regulatory agencies to proceed with the Phase 2 trial
- A$4.1 million R&D Tax Incentive Scheme refund
- Cash balance on 30 June 2022 of A$34.8M

**MELBOURNE, AUSTRALIA AND SAN FRANCISCO, USA – 22 July 2022.** 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 30th June 2022 (Q4 FY22).

The Company's cash position at 30 June 2022 was A$34.8M with gross operating cash outflows of A$4.4M, which are aligned with Alterity's expectations as its progresses and expands its Phase 2 clinical trial of lead drug candidate ATH434 for the treatment of Multiple System Atrophy (MSA), a rare Parkinsonian disorder with no approved therapy.

Strengthening its cash position during the quarter, Alterity received a A$4.1 million refund from the Australian Taxation Office under the Australian Government's R&D Tax Incentive Scheme which will be used to further its research and development activities.

In accordance with ASX Listing Rule 4.7C, payments made to related parties and their associates included in item 6.1 of the Appendix 4C incorporates directors' fees, consulting fees, remuneration and superannuation at commercial rates.

**Operational Activities**

In a milestone clinical achievement, Alterity commenced its Phase 2 clinical trial for ATH434 during the quarter with the dosing of the first patient at its first global site at New Zealand's Brain Research Institute (NZBRI).

The randomized, double-blind, placebo-controlled study will enrol approximately 60 adult patients who will receive two dose levels of ATH434 or the placebo over a period of 12 months. Results will provide an opportunity to detect changes in efficacy endpoints to optimize design of a definitive Phase 3 study.

Initiation of the Phase 2 clinical trial is a significant achievement for the Company and the industry as Alterity progresses through its clinical pipeline aiming to bring the first known therapy for MSA to market.

The Company also received regulatory approval from the Italian Medicines Agency, or Agenzia Italiana del Farmaco (AIFA) to expand recruitment and clinical sites into Italy. This follows receipt of approval from the United Kingdom Medicines & Healthcare products Regulatory Agency (MHRA). The company is working closely with clinical sites in these countries to initiate patient recruitment.

Alterity also plans to further expand its Phase 2 trial into other European countries, Australia, and the United States and is exploring the addition of new drug candidates that address neurodegenerative disorders to its growing portfolio pipeline.

**Corporate activity**
Alterity continues to create awareness on the Company's work to develop therapeutic solutions for neurodegenerative diseases. Communication activities to investors, clinicians and patients ramped up during the quarter with greater engagement of the media to support awareness and recruitment of the Phase 2 clinical trials.

As part of the Company's wider exposure strategy, Chief Executive Officer David Stamler, M.D., presented at three investor focused events. Dr. Stamler was invited to participate in the Benchmark Company Healthcare House Call Conference, having the opportunity to introduce Alterity to Benchmark's clients in the US and beyond. He also presented at the VirtualInvestorConferences.com Life Sciences Investor Forum and at the Global Chinese Financial Forum (GCFF) Virtual Conference 2022 – Investing in Healthcare Conference.

In further support for Alterity's profile with clinicians and patient groups, a poster session was delivered on the Biomarkers of progression in Multiple System Atrophy (bioMUSE) study at the American Academy of Neurology (AAN) Annual Meeting in April.

Dr Stamler, CEO said: "We are delighted to see all the work we put into the progress of our Phase 2 clinical study coming to fruition with the start of recruitment in New Zealand. We are partnering with leading research institutions, clinicians, and scientists from around the globe to reach our goal of finding a treatment that can improve the lives of patients with MSA, and potentially reversing the grim outlook they face when receiving this diagnosis."

**IP**
In June, Alterity secured a patent (16/311,428) from the US Patent and Trademark Office on the method of treating immunoglobulin light chain amyloidosis, a rare blood disorder caused by the overproduction of abnormal protein known as amyloid.

## About ATH434

Alterity's lead candidate, ATH434, is the first of a new generation of small molecules designed to inhibit the aggregation of pathological proteins implicated in neurodegeneration. ATH434 has been shown preclinically to reduce α-synuclein pathology and preserve nerve cells by restoring normal iron balance in the brain. In this way, it has excellent potential to treat Parkinson's disease as well as various forms of atypical Parkinsonism such as Multiple System Atrophy (MSA). ATH434 has successfully completed a Phase 1 clinical trial demonstrating the agent is well tolerated, orally bioavailable, and achieved brain levels comparable to efficacious levels in animal models of MSA, with the objective of restoring function in patients with MSA and other Parkinsonian disorders. ATH434 has been granted Orphan designation for the treatment of MSA by the U.S. FDA and the European Commission. ATH434 is currently in a randomized, double-blind, placebo-controlled Phase 2 clinical trial of ATH434 in patients with early-stage MSA.

## About Multiple System Atrophy

Multiple System Atrophy (MSA) is a rare, neurodegenerative disease characterized by a combination of symptoms that affect both the autonomic nervous system and movement. The symptoms reflect the progressive loss of function and death of different types of nerve cells in the brain and spinal cord. It is a rapidly progressive disease and causes profound disability. MSA is a Parkinsonian disorder characterized by motor impairment, autonomic instability that affects involuntary functions such as blood pressure maintenance and bladder control, and impaired balance and/or coordination that predisposes to falls. A pathological hallmark of MSA is the accumulation of the protein α-synuclein within the support cells of the central nervous system and neuron loss in multiple brain regions. MSA affects approximately 15,000 individuals in the U.S., and while some of the symptoms of MSA can be treated with medications, currently there are no drugs that are able

to slow disease progression and there is no cure.[1]

[1] National Institute of Health: Neurological Disorders and Stroke, Multiple System Atrophy Fact Sheet

## 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 www.alteritytherapeutics.com.

## Authorization & Additional information

This announcement was authorized 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, uncertainties relating to the impact of the novel coronavirus (COVID-19) pandemic on the company's business, operations and employees, 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 | |
| **ABN** | **Quarter ended ("current quarter")** |
| 37 080 699 065 | 30 June 2022 |

| **Consolidated statement of cash flows** | | **Current quarter $A'000** | **Year to date (12 months) $A'000** |
|---|---|---|---|
| **1.** | **Cash flows from operating activities** | | |
| 1.1 | Receipts from customers | - | - |
| 1.2 | Payments for | | |
| | (a) research and development | (2,411) | (10,642) |
| | (b) product manufacturing and operating costs | - | - |
| | (c) advertising and marketing | (102) | (340) |
| | (d) leased assets | - | - |
| | (e) staff costs | (899) | (3,471) |
| | (f) administration and corporate costs | (971) | (2,842) |
| 1.3 | Dividends received (see note 3) | - | - |
| 1.4 | Interest received | 1 | 2 |
| 1.5 | Interest and other costs of finance paid | - | - |
| 1.6 | Income taxes paid | - | - |
| 1.7 | Government grants and tax incentives | 4,126 | 4,683 |
| 1.8 | Other (provide details if material) | - | - |
| **1.9** | **Net cash from / (used in) operating activities** | **(256)** | **(12,610)** |

| **2.** | **Cash flows from investing activities** | | |
|---|---|---|---|
| 2.1 | Payments to acquire or for: | | |
| | (a) entities | - | - |
| | (b) businesses | - | - |
| | (c) property, plant and equipment | (89) | (89) |
| | (d) investments | - | - |
| | (e) intellectual property | - | - |
| | (f) other non-current assets | - | - |

| Consolidated statement of cash flows | | Current quarter $A'000 | Year to date (12 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** | **(89)** | **(89)** |

| | | | |
|---|---|---|---|
| **3.** | **Cash flows from financing activities** | | |
| 3.1 | Proceeds from issues of equity securities (excluding convertible debt securities) | - | 17,176 |
| 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 | (29) | (615) |
| 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** | **(29)** | **16,561** |

| | | | |
|---|---|---|---|
| **4.** | **Net increase / (decrease) in cash and cash equivalents for the period** | | |
| 4.1 | Cash and cash equivalents at beginning of period | 32,635 | 28,116 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | (256) | (12,610) |
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above) | (89) | (89) |
| 4.4 | Net cash from / (used in) financing activities (item 3.10 above) | (29) | 16,561 |

| Consolidated statement of cash flows | | Current quarter $A'000 | Year to date (12 months) $A'000 |
|---|---|---|---|
| 4.5 | Effect of movement in exchange rates on cash held | 2,546 | 2,829 |
| **4.6** | **Cash and cash equivalents at end of period** | **34,807** | **34,807** |

| 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 | 34,807 | 31,635 |
| 5.2 | Call deposits | - | 1,000 |
| 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)** | **34,807** | **32,635** |

| 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 | 132 |
| 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.*

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

| 7. | **Financing facilities**<br>*Note: the term "facility' includes all forms of financing arrangements available to the entity.*<br>*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.

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| 8. | **Estimated cash available for future operating activities** | **$A'000** |
|---|---|---|
| 8.1 | Net cash from / (used in) operating activities (item 1.9) | **(4,382)*** |
| 8.2 | Cash and cash equivalents at quarter end (item 4.6) | **34,807** |
| 8.3 | Unused finance facilities available at quarter end (item 7.5) | **-** |
| 8.4 | Total available funding (item 8.2 + item 8.3) | **34,807** |
| 8.5 | **Estimated quarters of funding available (item 8.4 divided by item 8.1)** | **7.9** |

*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.*

**** The company has excluded the R&D tax incentive of $4.126M (item 1.7) from the calculation of 'Net cash from / (used in) operating activities' (item 8.1) to better reflect the 'Estimated quarters of funding available' (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: N/A

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: N/A

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: N/A

*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: 22 July 2022

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.

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.