

## Appendix 4C – Q2 FY22 Quarterly Cash Flow Report

### Highlights:

- NZ's regulator Medsafe authorizes Phase 2 clinical trial for ATH434; more jurisdictions to follow
- New poster presentation and publications provide further evidence of potential of ATH434 to treat neurodegenerative diseases
- New US composition of matter patent secures exclusivity for a new class of compounds targeting Parkinson's and Alzheimer's diseases
- Active investor relations program in Australia and US
- Cash balance on 31 December 2021 of A\$37M

**MELBOURNE, AUSTRALIA AND SAN FRANCISCO, USA – 27 January 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 31<sup>st</sup> December 2021 (Q2 FY22).

The Company's cash position on 31 December 2021 was \$37M with operating cash outflows of \$4M. This was consistent with company expectations and largely due to the preparation for the Phase 2 clinical trial for Alterity's lead drug candidate ATH434 in Multiple System Atrophy (MSA), a Parkinsonian disorder with no approved therapy.

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

Alterity continues to identify new drug candidates to expand its portfolio and protect its therapeutic approach to address neurodegeneration.

On 14th December, Alterity announced that the New Zealand Medicines and Medical Devices Safety Authority (Medsafe) had authorized Alterity's Phase 2 clinical trial for ATH434 in MSA to be recruited in that country. This is the first jurisdiction to authorize the trial with further countries to follow this year. Alterity expects to launch the trial in the first quarter of 2022.

The Phase 2 clinical trial is a randomized, double-blind, placebo-controlled investigation of ATH434 in patients with early-stage MSA. The study will explore the effect of ATH434 treatment on imaging and protein biomarkers such as aggregating  $\alpha$ -synuclein and excess iron, which are important contributors to MSA pathology. Clinical endpoints and other biomarkers will permit comprehensive assessment of ATH434 efficacy along with characterization of safety and pharmacokinetics. Patients will receive treatment for 12 months which will provide an opportunity to detect changes in efficacy endpoints to optimize design of a definitive Phase 3 study.

In November, Alterity gave a poster presentation at the American Autonomic Society 32<sup>nd</sup> Annual International Symposium. The poster, entitled, "Cardiovascular safety and pharmacokinetics of ATH434, a novel small molecule inhibitor of  $\alpha$ -synuclein aggregation, in adults and older adults", described results from the Company's Phase 1 clinical trial conducted in healthy volunteers. In the Phase 1 trial, ATH434 was well tolerated in adult and  $\geq$  65-year-old volunteers and demonstrated

no cardiac adverse event signal and no clinically significant changes in blood pressure or heart rate at any dose. ATH434 also demonstrated dose dependent pharmacokinetics (PK) after single and multiple oral doses and a half-life that supports twice-daily dosing.

Alterity's profile continues to bolster with the publication of two preclinical studies demonstrating the potential of ATH434 to treat Parkinsonian disorders. Non-motor symptoms are common in patients with Parkinsonian disorders, such as Parkinson's disease and MSA. Parkinson's disease patients experience gastrointestinal complications, cognitive deficits, autonomic dysfunction, and mood disturbance and these non-motor manifestations are an important source of morbidity and reduced quality of life. As published in the *Journal of Parkinson's Disease*, "ATH434 Reverses Colorectal Dysfunction in the A53T Mouse Model of Parkinson's Disease" presents results from a preclinical study investigating the effect of ATH434 on gastrointestinal complications. Alterity also announced the publication in *Plos One* of an in vitro study concluding that the novel mechanism of action of ATH434 provides a compelling case for its continued development as a therapeutic agent in neurodegenerative diseases associated with iron accumulation.

Activity is also increasing within the investment community in Australia and the US with Alterity's Chief Executive Officer, David Stamler, MD, presenting at the MST Financial Lifesciences & Biotech Forum and the Benchmark Company Discovery One-On-One Investor Conference in 2021. Dr. Stamler also presented at the H.C. Wainwright BIOCONNECT Virtual Conference during the annual JP Morgan Healthcare Conference in January 2022.

Post the reporting period, the Company announced the United States Patent and Trademark Office granted a composition of matter patent that was issued a Notice of Allowance in August 2021. The patent covers more than 80 novel compounds and secures exclusivity for a new class of iron chaperones designed to redistribute the excess iron implicated in many neurodegenerative diseases, including Parkinson's and Alzheimer's diseases.

"This past quarter has been highly active as we move toward the initiation of our Phase 2 clinical trial for MSA with our profile significantly bolstered within the investment, patient, clinical and research communities," said Dr Stamler. "It's an exciting time for our company, but more importantly for clinicians and patients who understand intimately the devastation of the diseases we are targeting and understand the urgent need to develop new treatments that address the underlying pathology of these diseases."

## 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  $\alpha$ -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.<sup>1</sup>

<sup>1</sup>National Institute of Health: Neurological Disorders and Stroke, [Multiple System Atrophy Fact Sheet](#)

## 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  $\alpha$ -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.

## 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](http://www.alteritytherapeutics.com).

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### Authorization & Additional information

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

### Contact: Investor Relations

Australia

Rebecca Wilson

E: WE-AUAlterity@we-worldwide.com

Tp: +61 417 382 391

US

Remy Bernarda

E: remy.bernarda@iradvisory.com

Tp: +1 (415) 203-6386

### 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 patent protection for the Company's intellectual property or trade secrets, including, but not limited to, the intellectual property relating to ATH434.*

*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**

37 080 699 065

**Quarter ended ("current quarter")**

31 December 2021

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (6 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(2,815)	(6,115)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(110)	(191)
(d) leased assets	-	-
(e) staff costs	(873)	(1,676)
(f) administration and corporate costs	(354)	(1,290)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	1	1
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	103	329
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(4,048)</b>	<b>(8,942)</b>
<b>2. Cash flows from investing activities</b>		
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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>-</b>	<b>-</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
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	(23)	(587)
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)	-	-
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>(23)</b>	<b>16,589</b>

<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	41,335	28,116
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,048)	(8,942)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

Appendix 4C  
Quarterly cash flow report for entities subject to Listing Rule 4.7B

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(23)	16,589
4.5	Effect of movement in exchange rates on cash held	(262)	1,239
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>37,002</b>	<b>37,002</b>

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	35,002	38,335
5.2	Call deposits	2,000	3,000
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>37,002</b>	<b>41,335</b>

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	166
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.

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

<b>7. Financing facilities</b>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
<i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i>		
<i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>		
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
<b>7.4 Total financing facilities</b>	-	-
<b>7.5 Unused financing facilities available at quarter end</b>		-
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.	-	

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	<b>(4,048)</b>
8.2 Cash and cash equivalents at quarter end (item 4.6)	<b>37,002</b>
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	<b>37,002</b>
<b>8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<b>9.1</b>
<i>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.</i>	
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	
<i>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.</i>	

## 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: 27 January 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.