APPENDIX 4C

**Quarter Ended 31 March 2022** 





**Alterity Therapeutics Limited** 

ACN 080 699 065



### Appendix 4C – Q3 FY22 Quarterly Cash Flow Report

MELBOURNE, AUSTRALIA AND SAN FRANCISCO, USA – 29 April 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> March 2022 (Q3 FY22).

The Company's cash position on 31 March 2022 was \$32.6M with operating cash outflows of \$3.4M. Consistent with the previous quarter, this was in line with company expectations and influenced primarily by preparations for the commencement of the Phase 2 clinical trial for Alterity's lead drug candidate ATH434 in Multiple System Atrophy (MSA), a Parkinsonian disorder with no approved therapy.

After the close of the quarter, Alterity provided an important update to its clinical sites for the Phase 2 trial with the United Kingdom Medicines & Healthcare products Regulatory Agency (MHRA) accepting Alterity's clinical trial authorisation (CTA) request to conduct the trial. The company expects to open its first clinical trial site for enrolment in New Zealand this quarter following approval in December 2021 by the New Zealand Medicines and Medical Devices Safety Authority (Medsafe). The global Phase 2 trial will also be expanded to the UK, other European countries, Australia, and the United States.

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**

The novel mechanism of action of ATH434 and its potential to treat the underlying pathology of multiple Parkinsonian diseases continues to capture the attention of clinicians and scientists around the world.

In January, the *Journal of Parkinson's Disease* published ATH434 data in an animal model of MSA from a study conducted by David I. Finkelstein, Ph.D., Head of Parkinson's Disease Laboratory at the Florey Institute of Neuroscience and Mental Health and the University of Melbourne. This study independently corroborated findings in a related study published last year.

The publication, entitled, "The Compound ATH434 Prevents Alpha-Synuclein Toxicity in a Murine Model of Multiple System Atrophy" reported the evaluation of the efficacy of ATH434 in genetically altered mice that develop manifestations of MSA. The investigation demonstrated that in the studied brain region, ATH434 treatment reduced both the toxic oligomeric and aggregated forms of  $\alpha$ -synuclein, a central nervous system protein important for normal function of nerve cells. At the same time, ATH434 treatment reduced the cardinal pathology of MSA (glial cell inclusions), reduced brain iron, preserved neurons and improved motor performance.

In March, Alterity's Chief Executive Officer David Stamler, M.D., was invited to speak at the Sachs Associates 5<sup>th</sup> Annual Neuroscience Innovation Forum as part of a panel discussion on the scientific progress of Parkinson's disease and movement disorders.

The company continues to strengthen its intellectual property portfolio with the United States Patent and Trademark Office (USPTO) granting a new patent (No. 11,155,547) entitled "Compounds and Methods for Treating Diseases", which covers more than 80 novel compounds and secures

exclusivity for a new class of iron chaperones designed to redistribute the excess of iron implicated in many neurodegenerative diseases including Parkinson's and Alzheimer's disease.

#### **Corporate activity**

During the period, Non-Executive Directors Dr David Sinclair and Mr Tristan Edwards resigned from the Board due to competing priorities and responsibilities within other organisations in which they are actively involved.

CEO Dr Stamler continues to position the current and future opportunities for investors presenting at the HC Wainwright conference in January. The company was also selected to present at the 34<sup>th</sup> Annual Roth Conference in March. Both investment banks are based in the US with their virtual conferences attracting investors from around the world.

Dr Stamler, CEO said: "2022 will be a transformational year for Alterity. We are growing awareness of our pipeline with clinicians, scientists, patient groups and investors as a potential solution to treating the underlying disease of people suffering from Parkinsonian diseases. We remain highly focussed on progressing towards the initiation of our first patient in the MSA Phase 2 clinical trial and then expanding the trial globally. We look forward to offering a potential treatment option to individuals living with MSA."

#### 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 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.  $^1$ 

#### 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

<sup>&</sup>lt;sup>1</sup> National Institute of Health: Neurological Disorders and Stroke, <u>Multiple System Atrophy Fact Sheet</u>

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.

#### **Contact: Investor Relations**

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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 31 March 2022

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(2,116)	(8,231)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(47)	(238)
	(d) leased assets	-	-
	(e) staff costs	(896)	(2,572)
	(f) administration and corporate costs	(581)	(1,871)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	1
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	228	557
1.8	Other (provide details if material)	-	-
1.9	Net cash from / (used in) operating activities	(3,412)	(12,354)

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	-

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Cons	solidated statement of cash flows	Current quarter \$A'000	Year to date (9 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)	-	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	1	(586)
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	1	16,590

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	37,002	28,116
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,412)	(12,354)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	1	16,590
4.5	Effect of movement in exchange rates on cash held	(956)	283
4.6	Cash and cash equivalents at end of period	32,635	32,635

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	31,635	35,002
5.2	Call deposits	1,000	2,000
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)	32,635	37,002

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	206
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		

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 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 qu	uarter 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)	(3,412)
8.2	Cash and cash equivalents at quarter end (item 4.6)	32,635
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	32,635
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	9.6

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: 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**

- This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 29 April 2022

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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.
- 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.