# **APPENDIX 4C**

Quarter Ended 31 December 2022

**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 – Q2 FY23 Quarterly Cash Flow Report

#### Highlights:

- Expanded participation in ATH434 Phase 2 clinical trial with sites opened for recruitment in Australia, the United States, and Italy
- Presented compelling bioMUSE data at two prestigious industry conferences
- Granted a 20-year patent for 100 new compounds targeting Parkinson's and Alzheimer's disease
- Cash balance on 31 December 2022 of A\$25.3M

**MELBOURNE, AUSTRALIA AND SAN FRANCISCO, USA – 31 January 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 31<sup>st</sup> December 2022 (Q2 FY23).

In this quarter, Alterity continued to focus its efforts on running and expanding the Phase 2 clinical trial (the "Trial" or "Study") for its lead drug candidate ATH434 in Multiple System Atrophy (MSA), now enrolling patients across the globe. The Company's cash position on 31 December 2022 was A\$25.3M with operating cash outflows of A\$5.2M.

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.

David Stamler, M.D., Chief Executive Officer, Alterity, commented, "We are excited about the progress of our Phase 2 clinical trial which is now actively recruiting participants with early-stage MSA in three regions globally. We remain committed to bringing our potential disease modifying therapy to individuals living with this devastating condition. During the quarter, we also presented key bioMUSE data, grew our intellectual property portfolio, and published preclinical data giving us the opportunity to expand our pipeline into other neurodegenerative diseases."

#### **Operational Activities**

ATH434 Phase 2 Clinical Trial

During the second quarter of FY23, Alterity launched in its Phase 2 clinical trial of ATH434 in Sydney, Australia after successfully securing ethics approval from the Human Research Ethics Committee (HREC) at St. Vincent's Hospital, Melbourne.

After the quarter closed, in January 2023, the Company also announced further expansion of the trial with sites now open form enrollment in the United States and Italy. With these additions, the Company is now actively enrolling patients for the Study in three regions (Europe, Asia-Pacific, and North America), and five countries (New Zealand, Australia, United Kingdom, U.S., and Italy). Alterity's clinical team is providing ongoing support to the investigators at each site working toward the goal of recruiting 60 patients globally.

bioMUSE (Biomarkers of progression in Multiple System Atrophy)

The bioMUSE Natural History study continues to deliver valuable data to de-risk Alterity's Phase 2 trial by providing insight into the diagnosis and biomarkers of MSA to characterize disease

#### progression.

In October, and in conjunction with collaborators at Vanderbilt University Medical Center, the Company gave a poster presentation at the 147th Annual Meeting of the American Neurological Association (ANA) on different methods of measuring the volume of brain structures affected in individuals with MSA, Parkinson's disease, and healthy controls. The poster, *Deep Learning Segmentation Improves Precision of Volume Assessment of Subcortical Structures in early MSA*, found meaningful differences in the accuracy of three different techniques for measuring the volume of subcortical brain structures on MRI scans of patients with MSA and Parkinson's disease. The Deep Learning method provides the basis for measuring brain iron with high precision in the Phase 2 study.

In November, Alterity also presented data from bioMUSE at the American Autonomic Society (AAS) 2022 Annual Conference. This poster, entitled *Urinary Symptom Profile in Early Multiple System Atrophy*, evaluated early stage MSA patients urinary symptoms with the Urinary Symptom Profile (USP). The study results indicate that the USP can be used for comprehensive evaluation of urinary complaints, a symptom which can have a profound negative impact on quality of life, in a group of patients similar to those being studied in the Phase 2 trial.

#### **Publication**

In October 2022, a preclinical investigation of ATH434 was published in the journal *Neurotherapeutics* and demonstrated efficacy in an animal model of Parkinson's disease. The publication, entitled, "ATH434 Rescues Pre-motor Hyposmia in a Mouse Model of Parkinsonism" assessed the impact of ATH434 on motor and non-motor manifestations in experimentally induced Parkinson's disease. The investigation showed that treatment with ATH434 prevented the development of motor impairment, which was associated with a reduction in iron levels and preservation of nerve cells in the brain region affected in Parkinson's. This study adds to the weight of evidence regarding ATH434 as a potential disease modifying therapy for Parkinsonian disorders.

### **Intellectual Property**

Strengthening its IP portfolio, Alterity secured a new composition of matter patent from the United States Patent and Trademark Office (USPTO) in December. The patent, entitled, "Compounds for and methods of treating diseases", is based on a new scaffold that includes more than 100 novel compounds, at least one of which has demonstrated efficacy in an animal model of dementia.

The new patent covers iron chaperones, small molecules capable of binding and redistributing excess iron in the central nervous system, implicated in the pathology of many important neurodegenerative diseases, including Alzheimer's and Parkinson's diseases. Alterity will have 20 years of exclusivity for these compounds, expanding the company's intellectual property estate for treating major neurodegenerative diseases.

#### Corporate

Subsequent to the end of the quarter on 24 January 2023, Alterity received formal notification from The Nasdaq Stock Market LLC confirming that the Company had regained compliance with the minimum bid price requirement under Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Rule"), which requires that the Company's American Depositary Shares ("ADS") maintain a minimum bid price of at least US\$1.00 per ADS, and that the matter is now closed.

#### **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>.

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#### **Authorization & 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, 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 December 2022

Consolidated statement of cash flows **Current quarter** Year to date (6 \$A'000 months) \$A'000 1. Cash flows from operating activities 1.1 Receipts from customers 1.2 Payments for (a) research and development (3,604)(6,784)(b) product manufacturing and operating (c) advertising and marketing (173)(253)(d) leased assets (e) staff costs (955)(1,863)(444)(f) administration and corporate costs (940)1.3 Dividends received (see note 3) 1.4 Interest received 6 6 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)

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	-	

(5,170)

1.9

activities

(9,936)

Net cash from / (used in) operating

Con	solidated 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)	_	129
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	(28)	(36)
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	(28)	93

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	31,850	34,807
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(5,170)	(9,936)
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 (6 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(28)	93
4.5	Effect of movement in exchange rates on cash held	(1,302)	386
4.6	Cash and cash equivalents at end of period	25,350	25,350

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	25,350	31,850
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)	25,350	31,850

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	131
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 includ nation 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.

<b>7.</b>	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	arter 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.		itional financing

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(5,170)
8.2	Cash and cash equivalents at quarter end (item 4.6)	25,350
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	25,350
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	4.9
	Note: if the entity has reported positive net operating cash flows in item 1.9, answer item figure for the estimated quarters of funding available must be included in item 8.5.	8.5 as "N/A". Otherwise, a

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?

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 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: 31 January 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.
- 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.