

**31 January 2020**

**ASX Announcement**

## **QUARTERLY CASH FLOW STATEMENT**

### **Quarter highlights**

- Cash position of \$5.02m as at 31 December 2019 (\$7.59m as at 30 September 2019)
- Pre-clinical toxicology study results demonstrating positive safety profile for lead anti-fibrotic candidate, AD-214, reported
- GMP manufacture of bulk AD-214 drug substance completed
- A\$1 million Biomedical Translation Bridge (BTB) grant awarded to enable development of a radiolabeled PET imaging agent version of AD-214
- Stage 1 milestones achieved in GE Healthcare collaboration, Stage 2 research fees to be paid in March 2020 quarter

### **Post quarter end developments**

- John Chiplin retired as Non-Executive Director of the Board
- Phase I initial human clinical trial program for AD-214 announced to now incorporate patients and the BTB grant funded PET imaging agent version of AD-214. Trial to commence in mid-2020 to incorporate these changes and enable an additional pre-clinical study
- US patent protecting AD-214 issued

### **Key operating developments – internal pipeline**

Significant progress was made in advancing AdAlta's lead product candidate, AD-214, towards initial human clinical trials in fibrotic disease during the quarter.

#### *Key toxicology results and manufacture of bulk AD-214 drug substance*

The Company announced the results of a key toxicology study conducted to enable Phase I human clinical studies which showed that AD-214 was well-tolerated and did not result in any evident signs of toxicity when administered intravenously up to a dose level of 100mg/kg. There were no AD-214 related adverse events, nor any changes in body weight, respiratory, neurology, cardiovascular and ophthalmology tests that were performed as part of the safety assessment. Transient changes in white blood cell counts and blood proteins returned to baseline levels within study analysis timeframes.

Bulk AD-214 drug substance for use in clinical trials was manufactured under Good Manufacturing Practice (GMP) conditions by our contract manufacturing partner, KBI BioPharma in the USA. The bulk AD-214 drug substance is now being filled into vials for the Phase I clinical trial at PCI Pharma Services in Melbourne.

*Grant awarded under the Medical Research Futures Fund (MRFF) Biomedical Translation Bridge (BTB) program*

During the quarter, AdAlta was awarded a A\$1 million grant under the MRFF's BTB program, managed by MTPConnect. The grant will allow AdAlta to develop and clinically evaluate a radio-labelled version of AD-214 for positron emission tomography (PET) imaging of the cell surface receptor CXCR4 in patients with Interstitial Lung Disease (ILD), including Idiopathic Pulmonary Fibrosis (IPF). This will verify that AD-214 binds to CXCR4 receptors in fibrotic lung tissue in patients and determine the kinetics of binding, substantially improving the information generated during clinical evaluation of AD-214 and enabling the early introduction of patients into the Phase I clinical program. AdAlta is collaborating with leading radiochemistry, PET imaging and IPF experts at the Alfred Hospital, Monash University, Olivia Newton-John Cancer Research Institute/Austin Health and University of Melbourne.

*Strategic review of AD-214 program and Phase I trial*

Post quarter's end, AdAlta announced the results of a strategic review of the AD-214 development program and the Phase I clinical trial strategy. Commencement of the Phase I clinical trial has been delayed from first quarter until mid-2020 to enable incorporation of patient cohorts and the radio-labelled PET imaging version of AD-214 in the study design, and the completion of an additional pre-clinical study to better inform dose levels and intervals.

The Company is now working to propose a Phase I program to ethics committees that incorporates an initial single dose component in healthy volunteers to confirm the safety and pharmacokinetic profile of AD-214, followed by single and multi-dose components in patients where the radio-labelled version of AD-214 may be used to image disease and track the homing of AD-214 to diseased tissue. The patient components are being designed to include patients with a range of fibrotic ILDs of which IPF is one the most common. Broadening the range of eligible patients will improve recruitment and potentially extend the market opportunity for AD-214. Including patients and the radio-labelled version of AD-214 will significantly improve the partnering and further development value of the Phase I program.

*Engagement of key clinical trial service providers*

To prepare for the commencement of its Phase I clinical program for AD-214 and following an extensive selection process, AdAlta has now engaged key service providers.

Clinical Network Services Pty Ltd (CNS) has been engaged as the Contract Research Organisation (CRO) to provide clinical program management, medical writing, data management and biostatistics. CNS is an Australian company that has conducted more than 900 projects (the majority being Phase I studies) for more than 350 clients from around the world. CNS is now finalising the trial protocol and investigator brochure and preparing the documents necessary to obtain ethics approval for the Phase I program.

*AdAlta has* executed a letter of intent with CMAX Clinical Research Pty Ltd (CMAX), one of Australia's most experienced clinical trial centres, to conduct the healthy volunteer

component of the Phase I program. The definitive clinical trial research agreement is dependent on receiving ethics approval to commence the trial.

Laboratory testing and analysis of samples from trial subjects will be conducted by 360biolabs Pty Ltd, substantially increasing the value of the Phase I program for both future development and also partnering.

#### *US patent protecting AD-214 issued*

Post quarter's end, the United States Patent and Trademark Office granted AdAlta patent number 10,538,596 entitled "CXCR4 binding molecules and methods of use thereof" with an expiration date of 8 January 2036. This patent includes the composition and use in therapeutic and diagnostic applications of AD-214.

### **Key operating developments – partnerships**

AdAlta successfully completed Stage 1 and commenced Stage 2 of its collaboration with global medical technology and diagnostics firm, GE Healthcare, during the quarter. Under the agreement, the companies are collaborating to identify a pre-clinical target binding to Granzyme B for cancer diagnostics applications.

AdAlta received A\$387,000 under the collaboration agreement during the quarter comprising an upfront payment and Stage 1 research fees. Stage 2 research fees will be received during the March 2020 quarter.

### **Corporate developments**

Post the end of the quarter, AdAlta announced the retirement of John Chiplin as a Non-Executive Director of the Company, following many years of distinguished service that included guiding the Company through its initial public offering in 2016.

### **Financial update**

The Company received its first ever licensing revenue and initial collaborative research fee payments totalling A\$387,000 during the quarter.

The Company also entered a loan facility with Radium Capital under which AdAlta is able to access up to 80% of its accrued R&D Tax Incentive (RDTI) rebate each quarter. The Company received A\$960,000 under the facility during the quarter.

Operating cash outflows for the period were A\$3.9 million (A\$3.1 million in the prior quarter) primarily for payments related to GMP manufacturing of AD-214, completion of the toxicology study and other pre-clinical studies and research costs, including those associated with the GE Healthcare collaboration. Outflows were A\$1.3 million lower than forecast for the period (A\$5.2 million) due primarily to delays in the receipt of invoices for

ongoing stability and pre-clinical studies and slower than anticipated clinical trial start-up costs.

The cash balance at the end of the quarter was \$5.02 million, down from \$7.59 million at the end of the previous quarter.

The Company expects cash outflows over the March quarter to be approximately \$2.6 million, offset by inflows from GE Healthcare and the Radium facility of A\$1.0m (net estimated cash outflow of \$1.6 million.) The cash outflows include costs associated with Phase I clinical trial design and start-up costs, pre-clinical studies, vialling costs for AD-214 at PCI, ongoing stability studies at KBI and research under the GE Healthcare license agreement.

The Company considers that it has sufficient existing cash resources, including access to the Radium facility, to complete development of the radio-labelled AD-214, an additional pre-clinical study for AD-214 and the healthy volunteer component of the AD-214 Phase I program. The latter is projected to commence in mid-2020 and is expected to be completed by the end of 2020. The GE Healthcare collaboration is fully funded by advance payments of research fees. The Company plans to continue to invest in the development of AD-214 and other products from its i body platform.

Authorised for lodgement by:

**Tim Oldham**  
**CEO and Managing Director**

## Notes to Editors

### About AdAlta

AdAlta Limited is an Australian-based drug development company headquartered in Melbourne. The Company is using its proprietary technology platform to generate a promising new class of single domain antibody protein therapeutics, known as i-bodies, that have the potential to treat some of today's most challenging medical conditions. The technology mimics the shape and stability of a crucial antigen-binding domain, that was discovered initially in sharks and then developed as a human protein. The result is a range of unique compounds, capable of uniquely interacting with previously difficult to access targets such as G-protein coupled receptors and ion channels that are implicated in many serious diseases.

AdAlta is currently preparing for its Phase 1 clinical studies for its lead i-body candidate, AD-214. The clinical program is expected to commence in mid-2020 following clinical trial design finalisation and completion of a pre-clinical study to inform dose levels. AD-214 is being developed for the treatment of Idiopathic Pulmonary Fibrosis (IPF) and other human fibrotic diseases, for which current therapies are sub-optimal and there is a high-unmet medical need. The Company is also in collaborative partnerships to advance the development of its i-body platform. It has an agreement with UK-based research organisation, Excellerate Bioscience to collaborate on an undisclosed target of commercial interest and an agreement with GE Healthcare for diagnostic imaging agents against several drug targets, including Granzyme B.

AdAlta plans to continue further drug discovery and development directed towards other drug targets and diseases.

Further information can be found at: [www.adalta.com.au](http://www.adalta.com.au)

### For more information, please contact:

#### Investors

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## Appendix 4C

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

+Rule 4.7B

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

Name of entity

**ADALTA LIMITED**

ABN

**92 120 332 925**

Quarter ended ("current quarter")

**31/12/19**

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
<b>1.0</b>	<b>Cash flows from operating activities</b>		
1.1	Receipts from customers	387	387
1.2	Payments for	-	-
	(a) research and development	(3,308)	(5,856)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(269)	(469)
	(f) administration and corporate costs	(336)	(694)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	8	18
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	3,499
1.8	Other		
<b>1.9</b>	<b>Net cash from / (used in) operating activities</b>	<b>(3,518)</b>	<b>(3,115)</b>

<b>2.0</b>	<b>Cash flows from investing activities</b>		
2.1	Payments to acquire:		
	(a) property, plant and equipment	(2)	(2)
	(b) businesses (see item 10)	-	-
	(c) investments	-	-
	(d) intellectual property	-	-
	(e) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) property, plant and equipment	-	-
	(b) businesses (see item 10)	-	-
	(c) investments	-	-
	(d) intellectual property	-	-
	(e) 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>(2)</b>	<b>(2)</b>

  

<b>3.0</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of shares	-	1,780
3.2	Proceeds from issue of convertible notes	-	-
3.3	Proceeds from exercise of share options	-	-
3.4	Transaction costs related to issues of shares, convertible notes or options	-	(154)
3.5	Proceeds from borrowings	960	960
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other	-	-
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>960</b>	<b>2,586</b>

  

<b>4.0</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of quarter/year to date	7,585	5,556
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,518)	(3,115)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(2)	(2)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	960	2,586
4.5	Effect of movement in exchange rates on cash held	-	-
<b>4.6</b>	<b>Cash and cash equivalents at end of quarter</b>	<b>5,025</b>	<b>5,025</b>

5.0	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	Previous quarter
		\$A'000	\$A'000
5.1	Bank balances	21	84
5.2	Call deposits	5,004	7,501
5.3	Bank overdrafts		
5.4	Other (provide details)		
5.5	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>5,025</b>	<b>7,585</b>

6.0	Payments to directors of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to these parties included in item 1.2	161
6.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	
6.3	Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2	
Directors fees paid (includes amounts paid to CEO and Managing Director Tim Oldham)		

7.0	Payments to related entities of the entity and their associates	Current quarter \$A'000
7.1	Aggregate amount of payments to these parties included in item 1.2	
7.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	
7.3	Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2	

8.0	Financing facilities available	Total facility amount at quarter end	Amount drawn at quarter end
	<i>Add notes as necessary for an understanding of the position</i>	\$A'000	\$A'000
8.1	Loan facilities	960	960
8.2	Credit standby arrangements		
8.3	Other (please specify)		
8.4	Include below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include details of those facilities as well.		

The loan facility is with Innovation Structured Finance Co., LLC serviced via Radium Capital and is an advance on 80% of the Company's R&D Tax Incentive (RDTI) for the financial year ending 30 June 2020. The interest rate for the loan facility is 15% per annum. Repayment is timed to coincide with receipt of AdAlta's 2020FY RDTI refund. The facility has been in place since 20 December 2019, an initial advance under the facility of \$960,231 has been recieved (total amount borrowed: \$960,231).



9.0	Estimated cash outflows for next quarter	\$A'000
9.1	Research and development	2,064
9.2	Product manufacturing and operating costs	-
9.3	Advertising and marketing	-
9.4	Leased assets	-
9.5	Staff costs	211
9.6	Administration and corporate costs	291
9.7	Other (Inflows - GE Healthcare & Radium Facility)	(1,000)
9.8	<b>Total estimated cash outflows</b>	<b>1,566</b>

10.0	Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)	Acquisitions	Disposals
10.1	Name of entity		
10.2	Place of incorporation or registration		
10.3	Consideration for acquisition or disposal		
10.4	Total net assets		
10.5	Nature of business		

#### 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.

Sign here:



Company secretary

Date: 31 January 2020

Print name:

Cameron Jones

#### Notes

- 1 The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.
- 2 If this quarterly 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 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.