

**24 January 2022**

**ASX Announcement**

**QUARTERLY CASH FLOW STATEMENT – DECEMBER QUARTER 2021**

**Quarter highlights**

- **Strengthened \$9.08 million cash position as at 31 December 2021 (\$6.77 million as at 30 September 2021)**
- **AD-214 shown to be stable following nebulisation in pre-clinical and commercial devices; simulated to achieve better than expected distribution to lungs**
- **Pre-clinical efficacy studies of AD-214 by inhalation commenced – successful results in the March 2022 quarter may accelerate partnering discussions**
- **Three additional patents protecting AD-214 granted**
- **Proof of principle iCAR-T data reported; research plan agreed for first target in Carina collaboration**
- **\$3.75 million raised via private Placement with existing and new institutional and sophisticated investors; Entitlement Offer closes 31 January 2022**
- **\$0.89 million received as net proceeds of FY2021 R&D Tax Incentive rebate following repayment of Radium loan facility.**

**MELBOURNE Australia, 24 January 2022:** AdAlta Limited (ASX:1AD), the clinical stage drug discovery company developing novel therapeutic products from its i-body platform reports significant pipeline expansion and progress during the December quarter, which ended with an improved cash balance of \$9.08 million.

Reflecting on progress in the quarter, AdAlta's CEO and Managing Director, Dr Tim Oldham commented:

*"In the second quarter of FY22, we significantly strengthened AdAlta's cash position while making substantial progress on our AD-214 inhalation program and iCAR-T collaboration with Carina Biotech.*

*Most importantly we reported the successful nebulisation of AD-214 in commercial and preclinical inhalation devices, enabling us to commence pre-clinical efficacy studies of AD-214 in an inhaled format during the quarter. The results of inhalation efficacy studies, expected in the March 2022 quarter, and other development milestones planned for AD-214 during the first half of 2022 have the potential to steadily increase the value of AD-214 to partners and may accelerate partnering discussions.*

*We are grateful for the support of existing and new shareholders who participated in our \$3.75 million Placement, and for the ongoing support of the Australian Government and the Medical Research Future Fund via the R&D Tax Incentive and Biomedical Translational Bridge program that is supporting the development of our inhaled form of AD-214."*

## **A. Operations overview**

### **1. AD-214**

AdAlta is developing its lead product, AD-214, as a first in class, next generation antibody therapeutic for the treatment of Idiopathic Pulmonary Fibrosis (IPF) and Interstitial Lung Disease (ILD) with potential in other fibrotic diseases and cancer. An inhaled form of AD-214 is being prepared for Phase II studies in IPF, with development of this formulation accelerating during the quarter.

Feasibility studies showed that AD-214 could be aerosolised in the device used to administer AD-214 direct to the lungs of mice and still pass key product release tests. This device is now being used to test the comparative efficacy of intravenous versus inhaled AD-214 in the gold-standard bleomycin mouse model of pulmonary fibrosis. Initial results from these studies are anticipated to be received during the current quarter.

Further studies using commercially available nebulisers showed that AD-214 continued to meet key release tests related to target binding and lack of aggregation and degradation following nebulization. Average aerosol particle sizes were below the key 5  $\mu\text{m}$  threshold for efficient delivery to the alveoli (the smallest airways of the lungs, important for IPF treatment). Simulations show 17-46% deposition of the delivered dose of AD-214 in the alveolar region of the lungs. This result was better than anticipated, improving potential for dose reduction and cost savings relative to intravenous administration.

Studies planned during the first half of CY2022 will explore efficacy of inhaled AD-214, actual deposited dose, distribution and retention within the lungs and optimise dosing schedules. A number of partnering discussions relating to AD-214 are continuing and are anticipated to accelerate as results of these value-adding studies become available during the half.

AdAlta secured additional patent protection for AD-214 during the quarter, with issuance of a first patent in Singapore and second patents in Australia and USA. AdAlta now has patents protecting AD-214 granted in USA, Japan, Australia and Singapore and pending in other markets including Europe, China and India.

### **2. CAR-T cell therapy – Carina Biotech partnership**

In August 2021, AdAlta and Carina Biotech Pty Ltd (Carina) announced a collaboration to develop precision engineered, i-body enabled Chimeric Antigen Receptor T (iCAR-T) cell therapies against up to five solid tumour antigen targets.

CAR-T cell therapy harnesses the body's own immune system to fight cancer. A patient's immune cells (T cells) are collected, then genetically engineered in a laboratory to include a chimeric antigen receptor (CAR) that recognises a specific antigen on the surface of cancer cells. The CAR-T cells are expanded in a laboratory, then returned to the patient primed to locate and kill the cancer cells that have previously been invisible to the immune system.

The first CAR-T cells were approved for blood cancers in 2017 and now generate more than US\$1 billion per year. A total of five CAR-T cell products are approved for blood cancers by the FDA and the market is forecast to reach \$20.3 billion by 2027.<sup>1</sup> Revenues

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<sup>1</sup> Grandview Research, T-cell Therapy Market Size, Share & Trends Analysis Report 2021 – 2028, Feb 2021

from solid tumour CAR-T cell therapies are forecast to exceed revenues from blood cancer CAR-T cell therapies by 2030.<sup>2</sup>

During the quarter, AdAlta reported the results of proof of principle experiments showing that an i-body could be successfully incorporated into a CAR-T cell using Carina's technology with high efficiency. The resulting CAR-T cells were effective at killing cancer cell lines *in vitro* that were resistant to unmodified T-cells, providing proof of principle for the iCAR-T concept. AdAlta and Carina have now executed a research plan for the first target under the collaboration, with the first *in vitro* results from these iCAR-T cells expected in the second half of CY2022.

### **B. Corporate updates**

The Company held its Annual General Meeting on 29 November 2021. All resolutions were carried with more than 99% of votes cast in favour of each.

AdAlta's laboratories have continued to operate under COVID-safe work practices. The Company strongly encourages its employees to be vaccinated and is pleased to report that all staff have received at least two COVID-19 vaccinations.

### **C. Financial position**

Operating cash outflows for the quarter were A\$2,257,961 (A\$1,604,067 in the prior quarter). The increase reflected the commencement of several inhalation formulation development projects for AD-214, a deposit for cGMP AD-214 drug substance manufacturing for Phase II, increased salaries and wages associated with additional research staff to support AdAlta's expanding discovery pipeline and costs associated with external manufacturing of i-bodies for GE Healthcare.

During the quarter, AdAlta received operating cash inflows from customers of \$185,752 (\$176,414 in the prior quarter), comprising primarily research fees from GE Healthcare and proceeds of the BTB grant.

AdAlta also received a rebate of \$2,663,660 under the Commonwealth R&D Tax Incentive (RDTI) scheme. After full repayment of the Radium Capital loan facility secured over this rebate, net proceeds to AdAlta were \$894,329.

During the quarter, AdAlta issued 51,369,863 ordinary shares via a Placement to new and existing institutional and sophisticated investors. Shares were issued at \$0.073, a 9.9% discount to the last closing price and 10.4% discount to the volume weighted average price over the prior 15 trading days, raising \$3.75 million before costs. The Company also announced a 1 for 8 Entitlement Offer for existing shareholders on the same terms. The Entitlement Offer will raise approximately \$2.2 million if fully subscribed. The funds raised under the Placement will enable AdAlta to maximise the strategic options open to the Company following the development milestones scheduled in the first half of 2022. Proceeds from the Entitlement Offer will further expand these options.

**A reminder to any shareholders considering participating that the offer is due to close on Monday 31 January.**

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<sup>2</sup> Polaris Market Research, CAR-T Cell Therapy Market Share, Size, Trends, Industry Analysis Report 2021-2028, June 2021



A range of resources is available to shareholders via our Entitlement Offer webpage, available via [www.adalta.com.au](http://www.adalta.com.au) which includes details on how to access Entitlement & Acceptance forms.

730,000 unlisted options over AdAlta ordinary shares expired unexercised during the quarter.

The cash balance at the end of the quarter was \$9.08 million, up from \$6.77 million at the end of the previous quarter.

In accordance with Listing Rule 4.7C, payments made to related parties and their associates included in item 6.1 of the Appendix 4C (\$140,120) includes Director fees plus the salary (including superannuation) for the CEO and Managing Director.

Authorised for lodgement by:

**Tim Oldham**  
**CEO and Managing Director**  
**January 2022**

## **Notes to Editors**

### **About AdAlta**

AdAlta Limited (ASX:1AD) is a clinical stage drug development company headquartered in Melbourne, Australia. The Company is using its proprietary i-body technology platform to generate a promising new class of medicines with the potential to treat some of today's most challenging diseases.

The Company's lead asset, called AD-214, is a first-in-class product being developed for the treatment of Idiopathic Pulmonary Fibrosis (IPF) and other human fibrotic diseases and potentially cancers, for which current therapies are sub-optimal and there is a high unmet medical need. AD-214 has progressed through Phase I clinical trials in healthy volunteers.

AdAlta is also entering collaborative partnerships to co-develop i-body enabled therapeutics. The Company has a revenue generating partnership agreement with GE Healthcare which is designed to discover a diagnostic imaging agent for use in immuno-oncology.

AdAlta's growth strategy is to add value to its existing assets and build a pipeline of wholly owned and co-developed therapeutic products enabled by i-bodies.

### **About i-bodies**

Traditional monoclonal antibodies transformed the pharmaceutical industry's ability to address drug targets selectively and specifically. There remain many targets and applications they have been unable to address. i-bodies are designed to solve these challenging drug targeting problems.

i-bodies are single domain antibodies that mimic the shape and stability of a unique and versatile antigen-binding domain that was discovered initially in sharks and then



developed as a human protein. These unique proteins are capable of interacting with high selectivity, specificity and affinity with difficult to access targets such as G-protein coupled receptors (GPCRs) that are implicated in many serious diseases. i-bodies are the first fully human single domain antibody scaffold.

### **About AD-214**

AD-214 is being developed for the treatment of Idiopathic Pulmonary Fibrosis (IPF) and other human fibrotic diseases and potentially cancers, for which current therapies are sub-optimal and there is a high unmet medical need. AD-214 targets a GPCR called CXCR4 and has been specifically engineered to include features making it suitable for chronic use in fibrosis. It is the only agent against CXCR4 being developed for fibrotic diseases, giving it first-in-class status.

AD-214 has demonstrated efficacy in animal models of IPF and kidney fibrosis and studies in eye fibrosis and metastatic cancer are underway.

In Phase I clinical trials, AD-214 was well tolerated in single and multiple intravenous doses in healthy volunteers and demonstrates high and sustained duration of CXCR4 receptor occupancy. A radiolabelled version of AD-214 for safety and biodistribution (PET imaging) studies has also been developed. AdAlta is developing a more convenient inhaled formulation for future clinical studies.

AD-214 has Orphan Drug Designation (ODD) from the US Food and Drug Administration.

Further information can be found at: <https://adalta.com.au>

### **For more information, please contact:**

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## Appendix 4C

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

**Name of entity**

ADALTA LIMITED

**ABN**

92 120 332 925

**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	186	362
1.2 Payments for		-
(a) research and development	(1,331)	(2,378)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(542)	(867)
(f) administration and corporate costs	(386)	(618)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	-
1.5 Interest and other costs of finance paid	(88)	(88)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	2,664	2,664
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>503</b>	<b>(925)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(11)	(11)
(d) investments	-	-
(e) intellectual property	-	-

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
(f) other non-current assets	-	-
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 Net cash from / (used in) investing activities</b>	<b>(11)</b>	<b>(11)</b>
<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	3,750	3,750
3.2 Proceeds from issue of convertible debt securities	-	-
3.3 Proceeds from exercise of options	-	1
3.4 Transaction costs related to issues of equity securities or convertible debt securities	(252)	(252)
3.5 Proceeds from borrowings	-	2,400
3.6 Repayment of borrowings	(1,682)	(1,682)
3.7 Transaction costs related to loans and borrowings	-	-
3.8 Dividends paid	-	-
3.9 Other – (provide details if material)	-	-
<b>3.10 Net cash from / (used in) financing activities</b>	<b>1,816</b>	<b>4,217</b>
<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash and cash equivalents at beginning of period	6,774	5,791
4.2 Net cash from / (used in) operating activities (item 1.9 above)	503	(925)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(11)	(11)

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

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (6 months) \$A'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	1,816	4,217
4.5	Effect of movement in exchange rates on cash held	(4)	6
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>9,078</b>	<b>9,078</b>

<b>5. Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1 Bank balances	1,175	1,064
5.2 Call deposits	7,903	5,710
5.3 Bank overdrafts	-	-
5.4 Other (provide details)	-	-
<b>5.5 Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>9,078</b>	<b>6,774</b>

**6. Payments to related parties of the entity and their associates**

- 6.1 Aggregate amount of payments to related parties and their associates included in item 1
- 6.2 Aggregate amount of payments to related parties and their associates included in item 2

**Current quarter  
\$A'000**

140

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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 Director fees and CEO and Managing Director salary (including superannuation).



**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	2,400	2,400
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
<b>7.4 Total financing facilities</b>	<b>2,400</b>	<b>2,400</b>

**7.5 Unused financing facilities available at quarter end**

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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.

As at 31 December 2021, the Company has one loan facility in place as outlined below. A previous facility with Radium Capital was fully repaid in the quarter ending 31 December 2021.

Loan facility in place as at 31 December 2021 is a non-dilutive funding facility of up to \$4.0million with Treasury Corporation of Victoria (TCV) as part of the Victorian Government's R&D Cash Flow Loan Initiative. The Facility will be received in two tranches: the first of \$2.4 million was received in September 2021; and the second of up to \$1.6 million is expected to be received in the quarter ending 31 March 2022. The amount of the second tranche funding will be capped so as not to exceed a total Facility draw down of 80% of the Company's forecast R&D Tax Incentive (RDTI) rebate for FY2022. Interest on Facility advances is variable at the "TCV 11am" loan interest rate (currently 0.265%). Repayment of the Facility is timed to coincide with receipt of AdAlta's FY2023 RDTI refund, expected by 31 October 2023, but may be repaid earlier. The Facility is secured by the FY2022 and FY2023 RDTI refunds. As at 30 September 2021 the total loan facility was \$2.4million, being fully drawn.

<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)	503
8.2 Cash and cash equivalents at quarter end (Item 4.6)	9,078
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	9,078
<b>8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)</b>	<b>N/A</b>

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

## 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.

24 January 2022

Date: .....

By the Board

Authorised by: .....  
(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.