

**26 October 2022**

**ASX Announcement**

**QUARTERLY CASH FLOW STATEMENT – SEPTEMBER QUARTER 2022**

**Quarter highlights**

- **Important new data for inhaled AD-214 received**
- **New collaboration with GPCR Therapeutics to explore use of AD-214 in cancer**
- **AD-214 strategic priorities to be released, webinar to discuss week commencing 31 October 2022**
- **AbbVie's US\$225 million acquisition of preclinical stage DJS Antibodies highlights commercial potential of antifibrotic drugs**
- **R&D organisation changes**
- **\$7.16 million cash position as at 30 September 2022 (\$8.66 million as at 30 June 2022)**
- **\$1.58 million R&D Tax Incentive rebate received post quarter end**

**MELBOURNE Australia, 26 October 2022:** AdAlta Limited (ASX:1AD), the clinical stage drug discovery company developing novel therapeutic products from its i-body platform reports progress on the development of its lead asset, AD-214 and its other pipeline programs, and a cash balance of \$7.16 million as of 30 September 2022.

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

*"The September quarter of 2022 has been one of solid progress for AD-214. The planned program of preclinical and formulation experiments testing delivery and efficacy of AD-214 via inhalation for lung fibrosis have been completed and we entered a new collaboration with GPCR Therapeutics to explore the potential of AD-214 in oncology. The planned strategic review of AD-214 development priorities is underway and we look forward to providing an update to shareholders during the week of 31 October 2022.*

*"We are also pleased with the progress of our business and corporate development activities, with a number of exciting opportunities being evaluated."*

**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), kidney fibrosis, eye fibrosis and cancer. Multiple formulations and routes of administration are also being evaluated to optimise the target product profile and partnering potential.

During the September 2022 quarter, AdAlta completed the experimental part of a program of work to demonstrate the feasibility of inhalation as a route of administration for AD-214 in lung fibrosis. A radiolabelled version of AD-214 has been used to measure distribution of inhaled AD-214 in healthy and bleomycin treated sheep lungs using PET imaging. A

study was also conducted using inhaled and intratracheally administered AD-214 in the gold standard bleomycin mouse model of IPF. Initial results were received from mechanism of action studies of AD-214 on fibrotic mechanisms in *in vitro* cultured human lung tissue, with additional data expected during the current quarter. Contract development partner, Vectura, has identified an alternate formulation of AD-214 that appears suitable for inhalation and uses only components already approved for inhalation by the US FDA. Results of preliminary stability assessments were received after quarter's end. Full study reports are being finalised for all these studies.

AdAlta had hoped to receive updates from pre-clinical efficacy studies of AD-214 in eye fibrosis being conducted at University of Melbourne. While studies showing that AD-214 could be detected in mouse eyes up to 30 days following intra-ocular injection were received, generation of efficacy data will take longer than anticipated.

AdAlta now has sufficient data in hand to support the previously communicated strategic review and prioritisation of AD-214 indications and routes of administration, ahead of manufacturing batches planned for the first half of 2022 (as announced on 4 July 2022). The Company anticipates communicating the results of this review during the week of 31 October 2022, with a webinar for shareholders to follow.

The commercial potential of new fibrosis therapies was highlighted again in October via multinational pharmaceutical company, AbbVie's acquisition of preclinical stage British biotech DJS Antibodies for US\$255 million cash. DJS Antibodies discovers and develops antibody therapeutics against G-protein coupled receptors (GPCRs), an area of focus for AdAlta. The most advanced program is being developed as a potential first-in-class lysophosphatidic acid (LPA) receptor 1 antagonist antibody for IPF and other fibrotic diseases.

## **2. Other programs**

### ***Partnered 2 immune-oncology programs***

Carina Biotech (Carina) continued to progress the first collaborative i-CAR-T program with AdAlta against an undisclosed oncology target "A". "A-i-CAR-T" cells with varying binding strength (to target A) and length (i-body binding site to the T cell membrane) have been manufactured from two different donors and screened against three different tumour cell lines. AdAlta and Carina are now choosing three A-i-CAR-T cell candidates to screen against a wider range of cancer cell lines prior to *in vivo* testing in mice which is expected to commence in the first half of 2023. Research project plans are being finalised for two additional oncology targets, prior to discovery activities commencing at AdAlta.

The Company's business development campaign to identify additional partners who could benefit from, and potentially fund, the application of our i-bodies to their cellular immunotherapy programs is progressing well, with the potential benefits of AdAlta's smaller i-bodies over traditional CAR targeting molecules being well received. The Company is progressing several possible partnership discussions.

AdAlta continues to collaborate with GE Healthcare to develop i-body enabled PET imaging agents for use in immuno-oncology. Optimisation of the panel of i-bodies binding granzyme B continues to progress. Further updates for this program will be provided in consultation with GE Healthcare and as milestones are achieved.

### *Internal programs*

The Company's internal development program to screen its libraries to identify i-bodies with high specificity for an undisclosed G-protein coupled receptor (GPCR) implicated in fibrotic disease is also progressing.

### **3. Near term milestones**

AdAlta anticipates several milestones and data read-outs across its portfolio of programs. These include:

#### *2022 December quarter*

- AD-214 indication and route of administration prioritisation
- Preparation for AD-214 toxicology manufacturing
- *In vitro* cell killing of A-i-CAR-T cells against Target A completed
- Selection of targets B and C for Carina i-CAR-T collaboration

#### *2023 first half*

- Start of manufacturing campaign of AD-214 for extended dose toxicology studies
- Initiation of cGMP manufacturing of AD-214 for clinical studies
- Additional pre-clinical data supporting efficacy of AD-214 in eye and kidney fibrosis
- *In vivo* proof of concept studies of A-i-CAR-T cells commence

### **B. Corporate and organisation updates**

AdAlta's laboratories and those of its vendors and suppliers are generally operating at full capacity. Supplier cost increases and long lead times continued to affect toxicology and manufacturing campaigns most significantly. The strengthening US dollar is also having an impact on certain costs.

Dallas Hartman, AdAlta's Chief Operating Officer, resigned during the quarter to pursue interests as a chemistry, manufacturing and control (CMC) consultant.

AdAlta's CEO and Managing Director, Dr Tim Oldham commented:

*"During five years at AdAlta, Dallas has made significant contributions to the development of AD-214 manufacturing processes, the establishment of research excellence standards and the growth of our research team. He has also recruited product and platform development and program management leadership to provide continuity of leadership of our core programs. We thank Dallas for his service and wish him well for his future endeavours."*

The company has also engaged an experienced CMC consultant based close to manufacturing partner, KBI Biopharmaceuticals to assist in managing the manufacturing of the next batches of AD-214.

### **C. Financial position**

Operating cash outflows for the quarter were A\$2,181,380 (A\$2,039,824 in the prior quarter). The outflows are broadly in line with the prior quarter and include increased AD-214 preclinical study costs and annual short term incentive payments offset by reductions in AD-214 CMC costs.

During the quarter, AdAlta received operating cash inflows from customers of A\$684,659 (A\$194,962 in the prior quarter), being primarily final proceeds of the Medical Research Future Fund Biomedical Technology Bridge (BTB) grant plus revenue from GE Healthcare. In total, AdAlta has received over A\$1 million in matched funding from the BTB program (administered by MTPConnect) to develop a radiolabelled version of AD-214 for PET imaging and the development of the inhaled formulation of AD-214.

AdAlta maintains a \$4,000,000 fully drawn loan facility under the Victorian Government R&D Tax Cash Flow Incentive scheme (Facility). The Facility is repayable from the proceeds of the FY23 R&D Tax Incentive Rebate, expected by 31 October 2023. Interest on the Facility increased to 2.765% in line with changes in benchmark interest rates.

During the period 1,000,000 unlisted options over AdAlta ordinary shares expired unexercised.

The cash balance at the end of the quarter was A\$7.16 million, (A\$8.66 million at the end of the previous quarter). Following the quarter end, AdAlta received A\$1.58 million as part of its R&D Tax Incentive (RDTI) rebate pertaining to the FY22 financial year. An Advanced Overseas Finding has now also been approved and further A\$0.5 million is anticipated to be received. Part of the rebate may be used to make an advanced repayment of the Facility.

In accordance with Listing Rule 4.7C, payments made to related parties and their associates included in item 6.1 of the Appendix 4C (\$116,760) includes Director fees plus the salary (including superannuation and short term incentive payments) for the CEO and Managing Director.

Authorised for lodgement by:

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

## Notes to Editors

### About AdAlta

AdAlta Limited is a clinical stage drug development company headquartered in Melbourne, Australia. The Company is using its proprietary i-body technology platform to solve challenging drug targeting problems and generate a promising new class of single domain antibody protein therapeutics with the potential to treat some of today's most challenging medical conditions.

The i-body technology mimics 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. The result is a range of unique proteins capable of interacting with high selectivity, specificity and affinity with previously 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 and the first based on the shark motif to reach clinical trials.

AdAlta has completed Phase I clinical studies for its lead i-body candidate, AD-214, that 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. AdAlta has a second target in discovery research, also in the field of fibrosis and inflammation.

The Company is also entering collaborative partnerships to advance the development of its i-body platform. It has a collaboration with Carina Biotech to co-develop precision engineered, i-body enabled CAR-T cell therapies (i-CAR-T) to bring new hope to patients with cancer. It has an agreement with GE Healthcare to co-develop i-bodies as diagnostic imaging agents (i-PET imaging) against Granzyme B, a biomarker of response to immunology drugs, a program now in pre-clinical development.

AdAlta's strategy is to maximise the products developed using its next generation i-body platform by internally discovering and developing selected i-body enabled product candidates against GPCRs implicated in fibrosis, inflammation and cancer and partnering with other biopharmaceutical companies to develop product candidates against other classes of receptor, in other indications, and in other product formats.

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")**

30 September 2022

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	685	685
1.2 Payments for		
(a) research and development	(1,046)	(1,046)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(715)	(715)
(f) administration and corporate costs	(406)	(406)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	8	8
1.5 Interest and other costs of finance paid	(15)	(15)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(1,489)</b>	<b>(1,489)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(2)	(2)
(d) investments	-	-
(e) intellectual property	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 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</b>	<b>Net cash from / (used in) investing activities</b>	<b>(2)</b>	<b>(2)</b>
<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
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	-	-
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>-</b>	<b>-</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	8,661	8,661
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,489)	(1,489)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(2)	(2)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	(6)	(6)
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>7,164</b>	<b>7,164</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	334	482
5.2	Call deposits	6,830	8,179
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>7,164</b>	<b>8,661</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**

117

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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 and short term incentive).



**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.*

	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
7.1 Loan facilities	4,000	4,000
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
<b>7.4 Total financing facilities</b>	<b>4,000</b>	<b>4,000</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.

Loan facility in place as at 30 September 2022 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 was received in two tranches: the first of \$2.4 million was received in September 2021; and the second of \$1.6 million was received in the quarter ending 31 March 2022. Interest on Facility advances is variable at the "TCV 11am" loan interest rate (currently 2.765%). 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 2022 the total loan facility was \$4.0million, 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)	(1,489)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	7,164
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	7,164
<b>8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)</b>	<b>4.8</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.

26 October 2022

Date: .....

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.