14 October 2021

ASX Announcement

QUARTERLY CASH FLOW STATEMENT – SEPTEMBER QUARTER 2021

Quarter highlights

- **Strong $6.77 million cash position at 30 September 2021 ($5.79 million at 30 June 2021)**
- **Development of inhaled version of AD-214 progressing for next clinical trial**
- **$0.76 million BTB funds transferred to AD-214 inhalation program**
- **Further positive pre-clinical data for AD-214 in kidney fibrosis**
- **Collaboration established with Carina Biotech to create precision engineered, i-body enabled CAR-T cell therapies**
- **Discovery research commenced on our second GPCR target implicated in fibrotic disease**
- **Secured $4.0 million non-dilutive finance facility with Victorian Government**

MELBOURNE Australia, 14 October 2021: 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 September quarter, which ended with an improved cash balance of $6.77 million.

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

"In the first quarter of FY22 AdAlta achieved significant pipeline expansion milestones and an improved cash position. Building on the findings of our Phase I clinical trial and preclinical PET imaging program, development of a more cost effective and patient convenient inhaled formulation for use in our next clinical trials is underway. We are pleased to be able to reallocate BTB grant funding for this. We also reported positive new pre-clinical data for AD-214 in a mouse model of kidney fibrosis and we expanded our fibrosis/inflammation portfolio by initiating discovery against a new target.

Separately, we were delighted to establish a collaboration with Carina Biotech to develop precision engineered, i-body enabled CAR-T cell therapies to offer new hope to patients with cancer. Under the collaboration we will develop i-body enabled monospecific, bispecific and dual CAR-T products against five targets. This represents our second program in the fast-growing immuno-oncology field."

A. Operations overview

1. Fibrosis assets

i. 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.

The results of the Phase I clinical trial of AD-214 in healthy volunteers and of pre-clinical PET imaging studies of radiolabelled AD-214 (RL-AD-214) were reported in July and detailed in the previous quarterly report. Briefly, intravenous AD-214 clearly engaged its

target receptor and was well tolerated in healthy volunteers receiving single doses of AD-214 to 20 mg/kg and multiple doses of AD-214 at 5 mg/kg. After successful development of RL-AD-214, pre-clinical imaging studies identified that rapid liver distribution is likely to significantly increase the intravenous dose of AD-214 required for therapeutic effect when using the current formulation.

The supervising Human Research Ethics Committee (HREC) granted approval to progress the Phase I trial to the next, 10 mg/kg, cohort. AdAlta elected to conclude the trial and bring forward the development of an inhaled version of AD-214 for the next clinical trial. Inhalation has the potential to deliver the drug directly to the expected site of action at lower cost and in a more patient convenient form. Preliminary nebulization and pre-clinical efficacy and distribution results are expected around the end of 2021.

Separately, new pre-clinical data was reported during the quarter showing that AD-214 was effective in reducing collagen levels (a marker of fibrosis) in a mouse unilateral ureter obstruction (UUO) model of kidney fibrosis. This complements previous studies with the predecessor molecule, AD-114, showing efficacy in a mouse folic acid model of kidney fibrosis. Research has also progressed on improved intravenous formulations for indications such as kidney fibrosis.

ii. New Target

G-protein coupled receptors (GPCRs) are a very broad class of targets of high interest to the pharmaceutical industry. They have proven difficult to drug with traditional antibodies. AdAlta believes its i-bodies are particularly well suited to targeting GPCRs and has found binders to more than 10 different GPCRs, including CXCR4, the target of lead product, AD-214.

Following an extensive and rigorous target selection process, AdAlta commenced a new internal i-body discovery program against a second GPCR target implicated in fibrotic diseases. The target is one of several closely related GCPRs that all bind the same ligand but have different biological consequences. Previous attempts to drug the pathway by blocking synthesis of the ligand have failed to progress in clinical trials and AdAlta believes that an i-body blocking just the member of the family implicated in fibrosis could have greater success with fewer side effects.

Fibrosis is increasingly being considered as a disease that will require drugs acting via multiple modes of action so i-body enabled therapeutics against this target would represent an important addition to AdAlta's arsenal of antifibrotic therapeutics.

2. Immuno-oncology assets

a. GZMB PET imaging – GE Healthcare partnership

PET – or Positron Emission Tomography – imaging plays a vital role in the development and use of cancer immunotherapies by non-invasively measuring patient response before, during and after treatment. For this reason, the diagnostic radiopharmaceuticals market is forecast to be worth US$6.4 billion by 2027,[1] with the largest PET imaging agents generating annual sales of more than US$400 million.[2]

[1] Global Industry Analysts, Imaging Agents: Global Market Trajectory and Analytics, April 2021
[2] AD Nunn, J Nucl Med (2007) 169

AdAlta is collaborating with GE Healthcare to develop PET imaging reagents that can non-invasively detect the enzyme granzyme B (GZMB), a biomarker of immune checkpoint inhibitor drug effectiveness, that could help identify the 20-40% of patients who respond to these drugs (and just as importantly those that do not) much earlier than is possible today, significantly improving patient outcomes.

AdAlta continued with production of i-bodies binding granzyme B for pre-clinical development activities being conducted by both AdAlta and GE Healthcare. Production yields have been very encouraging. AdAlta earns fees for this work and potential future milestone payments on successful commercialisation of PET imaging agents. Initial pre-clinical proof of concept results are anticipated in the first half of 2022.

b. CAR-T cell therapy – Carina Biotech partnership

AdAlta and Carina Biotech Pty Ltd (Carina) announced a collaboration to develop precision engineered, i-body enabled Chimeric Antigen Receptor T (CAR-T) cell therapies against up to five solid tumour antigen targets. Carina will incorporate the i-bodies into CAR-T cells to generate *in vitro* proof of concept by killing cancer cell lines. The parties will jointly fund *in vivo* proof of concept studies in mice and will jointly own the CAR-T products that emerge. These may be out licensed or continue to be developed by either or both parties.

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.[3] Revenues from solid tumour CAR-T cell therapies are forecast to exceed revenues from blood cancer CAR-T cell therapies by 2030.[4]

Realising the potential of solid tumour CAR-T cells requires three challenges to be overcome. AdAlta's collaboration with Carina combines unique technologies of both companies to address these challenges. Carina's proprietary CAR-T cell manufacturing and development process very efficiently and rapidly produces robust, "young" CAR-T cells and its Chemokine Receptor Platform can enhance migration of T cells to and into a tumour. This addresses the challenges of "performance" (how well CAR-T cells reach and penetrate the tumour) and "persistence" (how well each CAR-T cell can survive to kill multiple cancer cells and enter the immune "memory"). The unique targeting capability of AdAlta's i-bodies addresses the third problem of "precision" (how well CAR-T cells can find all cancer cells and differentiate them from healthy tissue). i-bodies have potential to enable broader access to novel tumour antigens. Their small size makes them ideal for creating CAR-T cells capable of targeting two antigens. These dual

[3] Grandview Research, T-cell Therapy Market Size, Share & Trends Analysis Report 2021 – 2028, Feb 2021
[4] Polaris Market Research, CAR-T Cell Therapy Market Share, Size, Trends, Industry Analysis Report 2021 2028, June 2021

and bispecific CAR-T cells can be more specific for the tumour and reduce the chance of some tumour cells escaping.

3. i-body platform

AdAlta continues to enhance the productivity and efficiency of the i-body platform, with the aim of shortening the discovery cycle for future targets and enhancing the intellectual property protecting the i-body platform.

B. Corporate updates

The Company held an Investor Briefing on 19 July 2021 to discuss the results of Phase I clinical studies of AD-214 in healthy volunteers, pre-clinical imaging results and inhalation strategy. A further Investor Briefing was held on 25 August 2021 to discuss the CAR-T collaboration with Carina. Videos and presentation materials can be found at https://adalta.com.au.

AdAlta's laboratories have continued to operate under COVID-safe work practices during the Victorian COVID restrictions. The Company strongly encourages its employees to be vaccinated and is pleased to report that the Company has already achieved the Victorian Government requirements for authorised workers to have received one vaccination by 15 October 2021 and is on track to meet the requirements for authorised workers to be fully vaccinated by 26 November 2021.

C. Financial position

During the quarter, AdAlta received operating cash inflows of $176,414 ($221,121 in the prior quarter), comprising primarily research fees from GE Healthcare and proceeds of the BTB grant.

Operating cash outflows for the quarter were A$1,604,067 (A$2,177,999 in the prior quarter). The reduction reflected lower clinical costs associated with the completion of the Phase I clinical trial and lower consumables costs associated with the transition from i-body discovery to pre-clinical development of the GZMB program which were only partially offset by increases in the RL-AD-214 PET imaging costs under the BTB program. Research and development costs are expected to increase in the December 2021 quarter as initial costs are incurred for pre-clinical development of inhaled AD-214, preparation for manufacturing AD-214 drug substance, and new discovery programs.

AdAlta received an advance of $2.4 million under a $4.0 million loan facility with Treasury Corporation of Victoria (TCV) as part of the Victorian Government's R&D Cash Flow Loan Initiative. AdAlta's facility is believed to be one of the first awarded under the initiative. The facility is an advance of 80% of the Company's forecast R&D Tax Incentive (RDTI) for the FY2022 period, secured against the RDTI refunds for FY2022 and FY2023. 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. Interest on facility advances is variable at the "TCV 11am" loan interest rate (currently 0.265%). The facility differs from, and is in addition to, the previously announced (24 June 2021) Radium Capital facility which is secured against accrued RDTI rebates on already incurred (FY2021) R&D expenditure and is expected to be retired on receipt of FY2021 RDTI refund during the coming quarter.

After the end of the quarter, AdAlta announced an amendment to its funding agreement with MTPConnect under the Australian Government's Medical Research Future Fund's (MRFF) MTPConnect's Biomedical Translation Bridge (BTB) Program[5], with support from BTB partner, UniQuest. The amended BTB agreement will see A$0.76 million in matched funds, originally allocated to clinical studies using RL-AD-214, transferred during FY2022 to support the development of inhaled and improved intravenous formulations of AD-214.

The cash balance at the end of the quarter was $6.77 million, up from $5.79 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 ($191,039) includes Director fees plus the salary (including superannuation and short term incentive in respect of the FY2021 period) for the CEO and Managing Director.

Authorised for lodgement by:

Tim Oldham
CEO and Managing Director
October 2021

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.

[5] The BTB program is a $22.3 million initiative supported by the Australian Government's Medical Research Future Fund (MRFF) that provides up to $1 million in matched funding to nurture the translation of new therapies, technologies and medical devices through to proof of concept to turn innovative medical ideas into reality.

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	**Quarter ended ("current quarter")**
92 120 332 925	30 September 2021

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	176	176
1.2	Payments for		
	(a) research and development	(1,047)	(1,047)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(325)	(325)
	(f) administration and corporate costs	(232)	(232)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	-
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(1,428)**	**(1,428)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(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)	-	-
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)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	1	1
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	2,400	2,400
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**	**2,401**	**2,401**
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	5,791	5,791
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,428)	(1,428)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

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)	2,401	2,401
4.5	Effect of movement in exchange rates on cash held	10	10
4.6	**Cash and cash equivalents at end of period**	**6,774**	**6,774**

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	1,064	877
5.2	Call deposits	5,710	4,914
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)**	**6,774**	**5,791**

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	191
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 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.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities	4,149	4,149
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	**4,149**	**4,149**

7.5	**Unused financing facilities available at quarter 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.

The Company has two loan facilities as outlined below.

Loan facility #1 is with Innovation Structured Finance Co., LLC serviced via Radium Capital and is an advance on 80% of the Company's accrued R&D Tax Incentive (RDTI) refund for the period 1 July 2020 to 31 March 2021. The interest rate for the loan facility is 14% per annum. As announced on 25 June 2021, repayment is timed to coincide with receipt of the Company's 2021FY RDTI refund. An advance of $1,682,890 was received in June 2021. As at 30 September 2021 interest accrued on the facility was approximately $65,700 and the total loan facility was $1,748,568, being fully drawn.

Loan facility #2 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.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (Item 1.9)	(1,428)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	6,774
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	6,774
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	**4.7**

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.

Date: 14 October 2021

Authorised by: By the Board
(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.