28 July 2021

ASX Announcement

QUARTERLY CASH FLOW STATEMENT – JUNE QUARTER 2021

Quarter highlights

- **Multiple doses of AD-214 well tolerated in healthy volunteers; Phase I trial concluded having achieved its objectives**
- **Pre-clinical PET imaging of AD-214 distribution informs decision to progress inhaled version of AD-214 into future clinical trials**
- **Resupply agreement for clinical AD-214 material secured with KBI Biopharma**
- **Clinical studies in patients to commence on KBI resupply**
- **GE Healthcare progresses panel of granzyme B i-bodies into preclinical development; extends research agreement with AdAlta**
- **Radium Capital provide $1.68 million R&D Tax Incentive Advance loan facility**
- **Solid $5.79 million cash position at 30 June 2021 ($6.05 million at 31 March 2021)**

Reflecting on June 2021 quarter progress, AdAlta's CEO and Managing Director, Dr Tim Oldham commented:

"The final quarter of FY2021 was very significant for AdAlta. Our Phase I clinical and PET imaging programs achieved their objectives and enabled us to determine a clear pathway to patient clinical studies for AD-214. The 5 mg/kg intravenous multidose cohort of our Phase I clinical study of AD-214 yielded results consistent with single dose studies and continued to support the excellent safety profile of AD-214 by the intravenous route. Our PET imaging program found that a substantial portion of intravenously administered doses of AD-214 were distributed rapidly to the liver where it was unavailable for therapeutic effect, thus bringing forward our plans to develop an inhaled version of AD-214 for idiopathic pulmonary fibrosis. We also secured resupply of AD-214 clinical material for mid-2023 and are planning for clinical trials in IPF patients to commence shortly after that, ensuring no slowing of corporate timelines to clinical efficacy data.

Separately, we were delighted that GE Healthcare has not only selected a panel of granzyme B binding i-bodies to move into clinical development, but have also extended our collaboration to include manufacturing and in vitro *testing support, generating additional research fees. Additionally, we also made significant progress towards securing our next co-development collaboration."*

Operations overview

AD-214

AdAlta is progressing the development of its lead product, AD-214, 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 first cohort of healthy volunteers receiving multiple doses of AD-214 at 5 mg/kg via intravenous administration successfully completed treatment during the quarter, with results reported after the quarter end. The data suggests that the AD-214 molecule fully engages its target receptor in humans with no dose limiting safety issues. The pharmacokinetic and safety results were consistent with prior single dose results, except

for three moderate infusion related reactions (one placebo and two treated participants from a total of eight) linked to the formulation. Although the supervising Human Research Ethics Committee (HREC) has granted approval to progress to the next, 10 mg/kg, cohort, based on other results including pre-clinical PET imaging, AdAlta has elected to conclude the trial early.

Separately, after the quarter's end, AdAlta announced it had completed development of a radiolabelled version of AD-214 (RL-AD-214) for PET imaging to inform dose levels and optimal routes of administration for various fibrotic indications. Pre-clinical imaging studies identified that rapid liver distribution is likely to significantly increase the intravenous dose of AD-214 required for therapeutic effect. AdAlta acknowledges support for this work in the form of a grant with total value of $999,600 provided by MTPConnect's Biomedical Translation Bridge (BTB) Program[1] and support from UniQuest.

Post the quarter, AdAlta announced that it had entered an AD-214 resupply agreement with KBI Biopharmaceuticals, securing the next batch of clinical AD-214 for the first half of 2023.

No liver toxicity has been observed in any pre-clinical or clinical studies to date and pre-clinical studies by intravenous administration have demonstrated efficacy in relevant animal models. However, delivery of AD-214 by inhalation directly to the site of fibrosis in IPF and ILD patients is expected to significantly reduce the required dose of the drug, deliver greater patient and clinician convenience, enhance cost effectiveness and diversify AdAlta's partnering options.

AdAlta believes that it can develop the inhaled formulation within the timeframe for delivery of the next clinical AD-214 material and has initiated discussions with contract research organisations with expertise in inhaled drug delivery, access to approved delivery devices and with capability to execute preclinical inhalation studies. The AD-214 molecule remains unchanged, so existing drug substance manufacturing processes remain unchanged and safety data from our Phase I study supports the safety of the much lower systemic exposure likely via inhalation. The time to Phase II efficacy data is therefore largely unchanged relative to the intravenous route, but with a more convenient formulation.

The current Phase I clinical program will now conclude, with cash and AD-214 drug substance savings supporting the inhaled development program for IPF and extending current cash runway.

AdAlta also continues to plan for studies in ILD patients with the inhaled formulation (a market potentially twice the size of the IPF market), to develop pre-clinical data in other fibrosis indications such as eye fibrosis that also require local administration, and to explore intravenous formulation modifications that may reduce liver localization.

During the quarter, the Japanese Patent Office granted Japan Patent Number 6863897 entitled "CXCR4 binding molecules and methods of use thereof" with an expiration date

[1] 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.

of 8 January 2036. This patent includes the composition of AD-214 and its use in therapeutic and diagnostic applications, including IPF.

GE Healthcare (GEHC) partnership

AdAlta's commercial agreement with GE Healthcare progressed to pre-clinical development during the quarter, following the successful identification of multiple i-bodies binding to the enzyme granzyme B to be advanced to this stage for use as a potential PET diagnostic imaging agent.

The PET diagnostic under development by AdAlta and GE Healthcare will combine an i-body binding to granzyme B with GE Healthcare's PET imaging technology and is designed to show whether immune cells produce an enzyme called granzyme B in tumours, and therefore whether cancer immunotherapies, such as checkpoint inhibitors are working effectively to reactivate the patient's immune system to fight tumours.

GE Healthcare and AdAlta also agreed an amendment to their collaboration agreement under which AdAlta will now provide support for i-body manufacturing for both pre-clinical and clinical testing of these candidates, as well as conducting certain pre-clinical studies. AdAlta will earn additional research fees, funding this extra support ahead of the next milestone payment due on achieving pre-clinical proof of concept.

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,[2] with the largest PET imaging agents generating annual sales of more than US$400 million.[3]

Additional pipeline assets

AdAlta is aiming to add three additional assets into its pipeline during calendar 2021.

Development plans are in final stages of development for the next internal pipeline target and two further G-protein coupled receptor targets are under evaluation using the Company's comprehensive target evaluation process.

AdAlta also continues to progress co-development discussions with third parties to expand its external pipeline by combining AdAlta's i-bodies with third party targets or technology, with good progress made towards securing a second co-development partner. This milestone is currently on track to be achieved during the September quarter of 2021.

AdAlta is also continuing research 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.

Corporate updates

The Company held an Investor Briefing on 19 July 2021 to discuss the results of Phase I multiple dose studies of AD-214 in healthy volunteers and pre-clinical imaging results. Videos and presentation materials can be found on the Company website.

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[2] Global Industry Analysts, Imaging Agents: Global Market Trajectory and Analytics, April 2021

[3] AD Nunn, J Nucl Med (2007) 169

3,725 ordinary shares were issued on exercise of listed options post quarter end for gross proceeds to the Company of $925.66. A total of 23,345,078 listed options expired unexercised on 30 June 2021. The listed options had an exercise price of $0.2485 each.

50,000 unlisted options were cancelled during the quarter due to vesting conditions either not being achieved or becoming unable to be achieved.

The issued capital of the Company post the expiry and issuance of ordinary shares in relation to the listed options comprised 245,179,578 ordinary shares and 7,879,595 unlisted options with exercise prices ranging from $A0.0835 - $0.9985.

Financial position

During the quarter, AdAlta received operating cash inflows of $211,121 ($111,257 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$2,177,999 (A$2,138,571 in the prior quarter), including AD-214 clinical trial costs, other research costs including those associated with the GE Healthcare collaboration, product development costs, continuous manufacturing improvement initiatives and corporate costs which included costs associated with the strategic reviews of AD-214 indications and new i-body targets and business development initiatives.

During the quarter, AdAlta received an advance of $1.68 million under a loan facility with Innovation Structured Finance Co., LLC serviced via Radium Capital. The facility is an advance on 80% of the Company's R&D Tax Incentive (RDTI) for the period 1 July 2020 to 31 March 2021. The interest rate for the loan facility is 14% per annum. Repayment is timed to coincide with receipt of AdAlta's FY2021 RDTI refund.

The cash balance at the end of the quarter was $5.79 million, down from $6.05 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 ($136,674) includes Director fees as well as salary (including superannuation) for the CEO and Managing Director.

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AdAlta has a clear pathway to progress AD-214 into patient clinical studies in IPF using a preferred inhaled formulation, continues to progress additional its collaboration with GE Healthcare and remains on track to add three additional assets to its pipeline as its growth trajectory accelerates through 2021.

Authorised for lodgement by:

Tim Oldham
CEO and Managing Director
July 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.

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:

Investors

Tim Oldham, CEO & Managing Director
Tel: +61 403 446 665
E: t.oldham@adalta.com.au

Media

IR Department
Tel: +61 411 117 774
E: jane.lowe@irdepartment.com.au

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 June 2021

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	221	1,002
1.2	Payments for		
	(a) research and development	(1,629)	(7,202)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(318)	(997)
	(f) administration and corporate costs	(231)	(967)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	3
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	3,286
1.8	Other (provide details if material)	-	92
1.9	**Net cash from / (used in) operating activities**	**(1,957)**	**(4,783)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	(2)
	(d) investments	-	-
	(e) intellectual property	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 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**	**-**	**(2)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	8,123
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	-	(327)
3.5	Proceeds from borrowings	1,683	1,683
3.6	Repayment of borrowings	-	(2,284)
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**	**1,683**	**7,195**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	6,049	3,367
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,957)	(4,783)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(2)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	1,683	7,195
4.5	Effect of movement in exchange rates on cash held	16	14
4.6	**Cash and cash equivalents at end of period**	**5,791**	**5,791**

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	877	656
5.2	Call deposits	4,914	5,393
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)**	**5,791**	**6,049**

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	137
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 salary (including superannuation) for the CEO and Managing Director.

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	1,683	1,683
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	**-**	**-**

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 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 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 AdAlta's 2021FY RDTI refund. An advance of $1,682,890 was received in June 2021.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (Item 1.9)	(1,957)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	5,791
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	5,791
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	**3.0**

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: 28 July 2021

Authorised 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.