20 April 2021

ASX Announcement

QUARTERLY CASH FLOW STATEMENT – MARCH QUARTER 2021

Quarter highlights

- **Single doses of AD-214 very well tolerated in healthy volunteers**
- **AD-214 binds to its target receptor at higher levels and for longer than expected**
- **Two weekly repeat dose studies of AD-214 in healthy volunteers commenced**
- **Data set to support Phase II IND applications to be in hand by end 2021**
- **Orphan Drug Designated granted by FDA for AD-214 in IPF**
- **Solid progress on pipeline expansion initiatives**
- **Strong $6.05 million cash position at 31 March 2021 ($8.06 million at 31 December 2020)**

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

"First formal results from our Phase I trial of AD-214 were undoubtedly the highlight of our quarter. Demonstrating the AD-214 is very well tolerated in single doses is an important milestone for bit AD-214 and the i-body platform more generally and we anticipate will generate increased partner interest. The higher and longer than expected duration of binding to the target receptor also supports longer and more convenient dosing intervals that are now being incorporated in future parts of the Phase I program. Taken together, these results have enabled us to redesign the remainder of the Phase I program to achieve more data more rapidly, adding to the momentum behind our lead asset."

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.

During the quarter AdAlta completed dosing healthy volunteers in Part A of the Phase I clinical study. 42 participants have received a single dose of AD-214 or placebo at doses ranging from 0.01 mg/kg to 20 mg/kg, the highest planned dose. AD-214 was very well tolerated, with no serious or dose limiting adverse events and no other adverse events of note. Anti-drug antibodies were detected, mostly at low levels, in 11 participants with no associated clinical symptoms (a not unexpected observation for a biological drug). Pharmacokinetic parameters increased linearly or more than linearly with dose.

Analysis of peripheral blood (where target receptors are predominantly found in healthy individuals) showed clear evidence of target engagement and high levels of receptor occupancy for substantially longer than predicted from results of pre-clinical studies in non-human primates and substantially longer than the time taken for AD-214 to be eliminated from free circulation in the blood. High levels of receptor occupancy are generally required for therapeutic effect of drugs such as AD-214 that are designed to inhibit target receptor activity. The time over which receptor occupancy remains high is a

key indicator of likely therapeutic dosing intervals (with longer intervals generally more convenient and lower cost). If repeated in IPF patients, these results are strongly supportive of longer dosing intervals than the weekly interval currently planned in future clinical studies.

Taken together with emerging pre-clinical data in other indications supporting a broader role for AD-214 beyond IPF, these results have enabled AdAlta to further optimise the design of remainder of the Phase I clinical trial program to generate more data more rapidly and for similar cost.

The next part of the Phase I program will now explore the safety of repeat doses of AD-214 up to 15 mg/kg in healthy volunteers. The first cohort has received their first dose of 5 mg/kg in early April with top line results from this part expected by the end of 2021. This will provide AdAlta with a safety data package capable of supporting Phase II clinical trial applications to the US Food and Drug Administration (FDA) during 2022, substantially earlier than originally anticipated.

The final part of the Phase I program is anticipated to commence during the September quarter 2021 and will explore the safety and distribution of AD-214 in IPF and ILD patients, including the use of the radio-labelled version of AD-214 being developed for PET imaging with support from the Medical Research Future Fund Biomedical Technology Bridge Program. This will provide important information about the effect of higher levels of AD-214's target in patients, as well as safety data in combination with standard of care treatments which was not previously anticipated.

Development of a radiolabelled version of AD-214 for PET imaging to measure the tissue distribution and receptor occupancy time of AD-214 in IPF and ILD patients progressed during the quarter, with final pre-clinical studies scheduled for the June 2021 quarter.

During the quarter, the FDA granted Orphan Drug Designation (ODD) to AD-214 for use in IPF. ODD entitles AD-214 to certain benefits during development for IPF including eligibility for seven years market exclusivity post approval, tax credits of 50% of qualified clinical drug testing costs awarded upon approval, additional protocol assistance, reduced review times and waiver of certain marketing authorisation application fees. In addition to bringing novel therapies to sufferers of rare diseases more rapidly, these benefits add additional economic value to AD-214 for AdAlta and its eventual commercialisation partners.

There continue to be a number of Asian region and multinational pharmaceutical companies actively monitoring the Company's progress as Phase I data becomes available.

GE Healthcare (GEHC) partnership

AdAlta's collaboration with GEHC to discover i-body candidates against granzyme B as diagnostic imaging agents in immuno-oncology has now almost completed lead optimisation. GEHC is anticipated to assume responsibility for pre-clinical and clinical development during the June quarter 2021.

Additional pipeline assets

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

A strategic review of G-protein Coupled Receptor (GPCR) targets implicated in fibrosis, inflammation and/or oncology has identified a short-list of potential targets to add to the Company's internal pipeline (wholly owned) targets. Further evaluation of this shortlist is underway, with results expected to be announced in the second half of 2021.

AdAlta 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. The Company continues to forecast securing a second co-development partner in the middle 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 governance

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

Financial position

During the quarter, AdAlta received operating cash inflows of $111,257 ($456,957 in the prior quarter), comprising primarily research fees from GE Healthcare and proceeds of an export market development grant.

Operating cash outflows for the quarter were A$2,138,571 (A$3,531,275 in the prior quarter), including AD-214 clinical trial costs, other research costs including those associated with the GEHC 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.

The cash balance at the end of the quarter was $6.05 million, down from $8.06 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 ($114,174) includes Director fees as well as salary (including superannuation) for the CEO and Managing Director.

AdAlta continues to progress AD-214 through Phase I trials, with multidose studies in healthy volunteers underway and preparations patient studies considerably advanced. Additional internal and external (collaborator) assets are on track for addition to AdAlta's pipeline as its growth trajectory accelerates through 2021.

Authorised for lodgement by:

Tim Oldham
CEO and Managing Director
April 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 is well progressed in Phase I clinical trials.

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 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 is well tolerated in single doses in healthy volunteers and demonstrates high and sustained duration of CXCR4 receptor occupancy. Repeat dose studies in healthy volunteers have commenced. Safety and biodistribution (PET imaging) studies are in advanced planning.

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

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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	31 March 2021

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (9 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	75	781
1.2	Payments for		
	(a) research and development	(1,747)	(5,573)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(209)	(679)
	(f) administration and corporate costs	(183)	(736)
1.3	Dividends received (see note 3)	-	
1.4	Interest received	1	3
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	36	3,286
1.8	Other (provide details if material)	-	92
1.9	**Net cash from / (used in) operating activities**	**(2,027)**	**(2,826)**

2.	**Cash flows from investing activities**		
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 (9 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)**	**(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	-	-
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**	**-**	**5,512**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	8,064	3,367
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,027)	(2,826)
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 (9 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	5,512
4.5	Effect of movement in exchange rates on cash held	14	(2)
4.6	**Cash and cash equivalents at end of period**	**6,049**	**6,049**

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	656	622
5.2	Call deposits	5,393	7,442
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)**	**6,049**	**8,064**

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	114
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	-	-
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.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (Item 1.9)	(2,027)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	6,049
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	6,049
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:

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:

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:

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: 20 April 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.