28 January 2021

ASX Announcement

QUARTERLY CASH FLOW STATEMENT – DECEMBER QUARTER 2020

Quarter highlights

- **All healthy volunteer cohorts treated in Part A of Phase I human clinical trial of AD-214 (last cohort treated post quarter end)**
  - **No dose limiting adverse events reported**
  - **Encouraging receptor occupancy results being explored in modified final cohort**
  - **Top line results expected early March 2021**
- **Solid progress on all other strategic initiatives**
- **Strong $8.06 million cash position at 31 December 2020 ($10.30 million at 30 September 2020)**

Reflecting on December 2020 quarter progress, AdAlta's CEO and Managing Director, Dr Tim Oldham commented:

"Very encouraging results from higher doses of AD-214 administered in the healthy volunteer part of our Phase I clinical trials headline AdAlta's December quarter. These data support a very good safety profile and longer dosing intervals in the multi-dose patient part of the Phase I program. It was also pleasing to progress our overall strategy on multiple fronts, including our collaboration with GE Healthcare, the prioritisation of additional indications for AD-214 and the selection of the next targets for our i-body platform. Partnering discussions for both the i-body platform and AD-214 continue to build momentum ahead of potential partnering windows in mid- and late-2021 respectively."

Operations overview

AD-214

AdAlta is progressing the development of its lead product, AD-214, a next generation antibody therapeutic for the treatment of Idiopathic Pulmonary Fibrosis (IPF) and Interstitial Lung Disease (ILD).

AdAlta has now completed dosing healthy volunteers in Part A of the Phase I clinical study. 42 participants have received AD-214 or placebo at doses ranging from 0.01 mg/kg to 20 mg/kg, the highest planned dose. No adverse safety events of clinical concern have been reported.

A key secondary endpoint of the Phase I study is the extent and duration of receptor occupancy (the percentage of target receptors on certain circulating white blood cells that are occupied by AD-214). 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).

AD-214 has maintained 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. Blinded data from the 5 and 10 mg/kg cohorts showed that receptors remained saturated for three days after infusion of AD-214 and receptor occupancy remained at greater than 50% and 80% seven days after infusion respectively. If repeated in IPF patients, these results are strongly supportive of longer dosing intervals than the weekly interval currently planned in future clinical studies.

To further explore these findings and optimise the design of Part B of the Phase I study in IPF and ILD patients, AdAlta extended the final, 20 mg/kg, healthy volunteer cohort to investigate receptor occupancy at two and three weeks following infusion. This cohort was successfully treated in January 2021 and Part A top line results are expected in early March 2021, with full results in April and Part B of the Phase I clinical studies on track for initiation in the June 2021 quarter.

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 into pre-clinical development during the December quarter.

To add further value to AD-214, AdAlta is demonstrating the broad applicability of this product in indications beyond IPF/ILD. During the December quarter, AdAlta received encouraging results from studies of AD-214 in a mouse model of fibrosis in chronic kidney disease (being prepared for publication in the near future) and commenced studies in two mouse models of breast cancer to explore its potential in treating or preventing metastatic disease and improving the efficacy of checkpoint inhibitors. A strategic review of fibrosis, inflammation and cancer indications where AD-214 may be of benefit was also commenced to establish priorities for further pre-clinical and clinical investigations in additional indications.

The first partnering window for AD-214 is anticipated towards the end of 2021 when AdAlta anticipate having preliminary safety and PET imaging results from IPF/ILD patients. There continue to be a number of Asian region and multinational pharmaceutical companies actively monitoring the Company's progress ahead of this data becoming available.

GE Healthcare (GEHC) partnership

AdAlta's collaboration with GEHC to discover i-body candidates as diagnostic imaging agents progressed into lead optimisation during the December quarter. This stage is due to complete in the middle of the first half of calendar 2021 after which GEHC will assume responsibility for pre-clinical and clinical development. In line with forecast, $367,063 was received from GEHC as research fees during the December quarter.

Additional pipeline assets

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

A strategic review of targets to which i-bodies have been found in prior years has commenced to identify potential internal pipeline (wholly owned) targets that might progress more rapidly than discovery programs against a brand new target. This review is also refining the Company's target selection process. Results are 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. During the December quarter, income was received from supply of i-bodies for evaluation as part of these discussions.

COVID-19 operating environment

The Company's laboratories, and those of our collaborators in the development of the AD-214 PET imaging agent, remain open. Supply chain delays have impacted some projects however AdAlta remains confident of achieving key 2021 milestones.

To mitigate risks to recruitment rates of healthy volunteers in Part A of the Phase I study, and additional study site, Scientia, was opened in Sydney for the final two cohorts. There was no material impact on cost or timelines.

The Board continues to monitor the COVID-19 environment and has business and financial continuity and contingency plans in place.

Corporate governance

The Company's 2020 Annual General Meeting was held during the quarter. All resolutions, including approval of the remuneration report, election or re-election of directors, ratification of prior placements of shares under ASX Listing Rules 7.1 and 7.1A and amendments to the Constitution were passed with greater than 99% approval.

Financial position

During the quarter, AdAlta received operating cash inflows of $456,957 ($249,271 in the prior quarter). This included research fees from GE Healthcare, reimbursement of expenses under the Biomedical Translation Bridge (BTB) Grant pertaining to the AD-214 PET imaging agent and income from prospective partners purchasing i-bodies for evaluation as part of ongoing partnering discussions.

AdAlta also received $3,143,923 as its Research and Development Tax Incentive (RDTI) refund for the FY2020 year, a net inflow of $859,559 after repaying in full the Radium Capital loan facility which was established during FY2019. Other inflows totalled $142,973 and related to FX contract adjustments, government grants and interest.

Operating cash outflows for the quarter were A$3,531,275 (A$1,316,708 in the prior quarter), including clinical trial costs (the principal driver of the increase on prior quarters), other research costs including those associated with the GEHC collaboration, the development of the PET tracer version of AD-214 for use in Part B of the AD-214 clinical trial, continuous manufacturing improvement initiatives and corporate costs which included new costs associated with the strategic reviews of AD-214 indications and new i-body targets and the reinstatement of non-executive director fees.

The cash balance at the end of the quarter was $8.06 million, down from $10.30 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 includes Director fees as well as salary (including superannuation and short-term incentive payments) for the CEO and Managing Director.

AdAlta remains well placed to progress AD-214 into the patient part of Phase I trials and to add additional assets to its pipeline as it accelerates its growth trajectory through 2021.

Authorised for lodgement by:

Tim Oldham
CEO and Managing Director
January 2021

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 is conducting Phase 1 clinical studies for its lead i-body candidate, AD-214. AD-214 is a first in class product 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.

The Company is also entering collaborative partnerships to advance the development of its i-body platform. It has an agreement with GE Healthcare to discover i-bodies as diagnostic imaging agents for use in immuno-oncology.

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:

Investors

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

Media

IR Department
Tel: +61 411 364 382
E: gabriella.hold@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	31 December 2020

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	457	706
1.2	Payments for		
	(a) research and development	(2,975)	(3,826)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(226)	(470)
	(f) administration and corporate costs	(331)	(554)
1.3	Dividends received (see note 3)	-	
1.4	Interest received	2	3
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	3,193	3,250
1.8	Other (provide details if material)	92	92
1.9	**Net cash from / (used in) operating activities**	**212**	**(799)**

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 (6 months) $A'000
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
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)	-	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	(151)	(327)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(2,284)	(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**	**(2,435)**	**5,512**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	10,301	3,367
4.2	Net cash from / (used in) operating activities (item 1.9 above)	212	(799)
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 (6 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(2,435)	5,512
4.5	Effect of movement in exchange rates on cash held	(14)	(16)
4.6	**Cash and cash equivalents at end of period**	**8,064**	**8,064**

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	622	844
5.2	Call deposits	7,442	9,457
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)**	**8,064**	**10,301**

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	149
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)	212
8.2	Cash and cash equivalents at quarter end (Item 4.6)	8,064
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	8,064
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	**N/A**

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.

28 January 2021

Date: .....

By the Board

Authorised by: .....
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.