12 Oct 2020

ASX Announcement

QUARTERLY CASH FLOW STATEMENT – SEPTEMBER QUARTER 2020

Quarter highlights

- **Four of seven healthy volunteer cohorts treated in Part A of Phase I human clinical trials of AD-214**
  - **No dose limiting adverse events reported through first four dose levels**
- **$1.15 million revenue earned to date from GE Healthcare (GEHC) collaboration**
  - **Collaboration progressed to Stage 4 (lead optimisation)**
- **$8.12 million raised (before costs) from fully subscribed Placement and Entitlement Offer**
- **Strong $10.30 million cash position as at 30 September 2020 ($3.37 million at 30 June 2020) to fund new growth trajectory**

"The September quarter saw exciting and substantial progress for our Company. Treating the first participants in clinical trials of AD-214 and progressing our collaboration with GE Healthcare to lead optimisation were operational highlights. Strong support from existing and new shareholders indicated confidence in our strategy and we now have the financial resources to accelerate our growth through 2021. I am very pleased with the momentum our team has built," commented AdAlta's CEO and Managing Director, Dr Tim Oldham.

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 and Interstitial Lung Disease. The first participants in the AD-214 Phase I clinical trial are healthy volunteers (Part A) and began to receive AD-214 at CMAX's clinical trial unit in Adelaide in July. Participants have now received AD-214 (or placebo) at the first four dose levels (of seven planned) in Part A.

No dose limiting adverse events have been observed to date. Blinded data appears consistent with expectations established by simulations based on previous non-human primate toxicology studies.

Development of a radiolabelled version of AD-214 for PET imaging to measure the distribution and time in which AD-214 remains in the lungs of Idiopathic Pulmonary Fibrosis (IPF) and other Interstitial Lung Disease (ILD) patients progressed well. Development is on track for administration to patients during Part B of the Phase I program that is due to commence in the first half of 2021. The development of processes to attach the radiolabel to AD-214 is complete and preparation for pre-clinical studies in mice commencing during the December quarter are well advanced.

During the quarter, research conducted in collaboration with The Alfred Hospital and Monash University was published that is supportive of a wider and even more important role for AD-214 in pulmonary fibrosis than previously thought. The research showed that AD-214's target, the receptor known as CXCR4, is highly expressed in a wide range of ILDs, not just IPF, supporting the inclusion of ILD patients in the Phase I program. The research also showed that CXCR4 was expressed significantly in the epithelial cells lining the lung airways and blood vessels as well as in sites of fibrotic injury. As epithelial cells may be driving fibrosis, this finding increases the potential importance of blocking CXCR4 in anti-fibrotic therapy, which is the approach AdAlta is taking with AD-214.

GE Healthcare (GEHC) partnership

AdAlta's collaboration with GEHC to discover i-body candidates as diagnostic imaging agents successfully completed Stage 3 of the planned 8-11 month discovery process. On the basis of the properties of the panel of i-body candidates identified, GEHC elected to progress to an optional Stage 4 during which the lead i-bodies will be further optimised prior to GEHC assuming responsibility for pre-clinical and clinical development (subject to technical success at each stage).

Since announcing the GEHC collaboration in September 2019, AdAlta has earned cumulative milestones and research fees of $1.15 million ($0.79 million has been received to 30 September 2020).

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.

Recruitment rates of healthy volunteers in Part A the Phase I, being conducted in Adelaide, are closely monitored and remain on track to deliver top line safety data in early 2021 despite some trends towards a tighter recruiting environment.

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

Organisation and leadership

Dr David Fuller was appointed as a Non-executive Director of the Board in July 2020, bringing substantial clinical development and Asian market experience to the Company.

Non-executive Director fees, which were suspended from 1 April 2020 as part of the Company's COVID-19 response, were reinstated from 1 September 2020.

Financial position

During the quarter, AdAlta completed a full subscribed Placement and Entitlement Offer, issuing 81,230,240 ordinary shares at $0.10 to raise $8.12 million before costs. The Placement and Entitlement Offer were strongly supported by existing shareholders with 69 per cent of funds raised from existing shareholders or their related parties.

AdAlta expects to receive its Research and Development Tax Incentive (RDTI) refund for the FY2020 year during the December quarter. The RDTI refund is expected to exceed

the advances drawn down to date under the Radium Capital loan facility which was established during FY2019. The injection of funds will further strengthen AdAlta's cash position and the loan facility is expected to be settled in full during the December quarter on receipt of the RDTI refund.

AdAlta received operating cash inflows of A$249,271 during the September quarter ($0 in the prior quarter). This included research fees from GEHC, grant income under the Biomedical Translation Bridge Grant from MTPConnect that is part funding the development and clinical trial use of the PET tracer version of AD-214, and income from prospective partners purchasing i-bodies for evaluation as part of ongoing partnering discussions.

Operating cash outflows for the quarter were A$1,316,708 (A$1,157,452 in the prior quarter), including clinical trial, cell line license fees and research costs including those associated with the GEHC collaboration and the development of the PET tracer version of AD-214 for use in Part B of the AD-214 clinical trial. Quarterly operating cash outflows are expected to increase in subsequent quarters due to the implementation of the strategic plan as outlined in the Offer Document associated with the Entitlement Offer. This plan will see continued investment in AD-214 Phase I clinical trials, additional pre-clinical activity associated with AD-214 indication expansion and PET imaging, new internal pipeline product discovery and AD-214 manufacturing and i-body platform continuous improvement.

The cash balance at the end of the quarter was $10.30 million, up from $3.37 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 and salary (including superannuation and short-term incentive payments) for CEO and Managing Director and related parties.

AdAlta is now 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
October 2020

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.

AdAlta is conducting a Phase 1 clinical trial for its lead i-body candidate, AD-214. AD-214 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.

The Company is also entering collaborative partnerships to advance the development of its i-body platform. It has an agreement with multi-national company GE Healthcare for discovery of a diagnostic imaging agent against Granzyme B 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:

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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 2020

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	249	249
1.2	Payments for		
	(a) research and development	(851)	(851)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(244)	(244)
	(f) administration and corporate costs	(223)	(223)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	1	1
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	57	57
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(1,011)**	**(1,011)**

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	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
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	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	(176)	(176)
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)	-	-
3.10	**Net cash from / (used in) financing activities**	**7,947**	**7,947**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	3,367	3,367
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,011)	(1,011)
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)	7,947	7,947
4.5	Effect of movement in exchange rates on cash held	(2)	(2)
4.6	**Cash and cash equivalents at end of period**	**10,301**	**10,301**

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	844	13
5.2	Call deposits	9,457	3,354
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)**	**10,301**	**3,367**

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	121
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	2,077	2,077
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	**2,077**	**2,077**

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 financial year ending 30 June 2020. The interest rate for the loan facility is 15% per annum. Repayment is timed to coincide with receipt of AdAlta's 2020FY RDTI refund. The facility has been in place since 20 December 2019. An initial advance under the facility of $960,231 was received on 20 December 2019, a second advance of $805,118 received on 23 March 2020, and a further $311,970 received on 24 June 2020 (total amount borrowed: $2,077,319). The Company expects the loan facility to be settled in full in October 2020 upon receipt of 2020FY RDTI refund.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (Item 1.9)	(1,011)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	10,301
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	10,301
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	**10.2**

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.

12 October 2020

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.