21 Jul 2020

ASX Announcement

QUARTERLY CASH FLOW STATEMENT – JUNE QUARTER 2020

Quarter highlights

- AdAlta became a clinical stage company
- Approval to commence Phase I human clinical studies of AD-214
- First participants to be treated late July 2020
- Supportive US Food and Drug Administration (FDA) advice received and incorporated into development plans
- GE Healthcare (GEHC) collaboration and radiolabelled PET imaging version of AD-214 continue to progress
- $3.37 million cash position as at 30 June 2020 ($4.14 million at 31 March 2020)

Operations overview

The June quarter was transformational for AdAlta, marking the transition from pre-clinical stage to clinical stage, a coming of age moment for any biotech company.

AD-214 operating developments

During the quarter, a Human Research Ethics Committee (HREC) gave approval for AdAlta to commence a Phase I clinical trial of its lead product, AD-214, in healthy volunteers (Part A) and Interstitial Lung Disease (ILD) patients including Idiopathic Pulmonary Fibrosis (IPF) patients (Parts B and C). Participant screening commenced for Part A of the trial, being conducted at CMAX's clinical trial unit in Adelaide.

The Company also received supportive advice and responses to a pre-Investigational New Drug application (pre-IND) meeting with the US Food and Drug Administration (FDA). In response to questions posed by AdAlta, the FDA indicated that the panel of preclinical studies conducted to date on AD-214 would be sufficient to support an IND application in the US and that AdAlta's Phase I trial design is reasonable. Specific FDA guidance has now (post quarter end) been incorporated into the protocol for the Phase I trial and the ongoing development plans for AD-214.

Confirmation that the first trial participants have received AD-214 is expected in late July. Part A investigating AD-214 in healthy volunteers is expected to be complete by the end of 2020 with top line safety results in January 2021. Part B of the Phase I trial is expected to commence in patients in early 2021.

To enhance the information available from the Phase I program, AdAlta is developing a radiolabelled version of AD-214 for PET imaging to measure the distribution and residence time of AD-214 in the lungs of ILD/IPF patients. Development restarted during the quarter after a collaborator laboratory was closed in March in response to COVID-19. Chelation agents to bind the radiolabel have been successfully added to AD-214 and shown not to affect binding to the biological target CXCR4 in *in vitro* assays. Radiolabelling for process development and pre-clinical studies will commence shortly.

GE Healthcare (GEHC) partnership operating developments

AdAlta's collaboration with GEHC to discover i-body candidates as diagnostic imaging agents progressed to Stage 3 of an originally planned 8-11 month discovery process. Stage 3 involves small scale expression of the most prospective individual i-bodies to verify the binding affinity, selectivity and specificity seen in Stage 2. Stage 3 progress has been delayed slightly by the effect of COVID-19 on reagent and material lead times. The research fee for Stage 3 will be invoiced in instalments through the September quarter.

COVID-19 operating environment

The recent increase of COVID-19 restrictions in Victoria has not currently affected operations. The Company's laboratories remain open, as do those of our collaborators in the development of the AD-214 PET imaging agent. Part A of the Phase I clinical trial is being conducted in Adelaide and is unaffected by the Victorian operating environment.

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

Investor updates

AdAlta participated in several investor briefings to discuss the approval for the Phase I clinical trial of AD-214 and the transformation to clinical stage company, a milestone that the Company has been working towards for many years. AdAlta was also selected to present at BIO2020, the largest annual biotechnology industry conference, which this year was fully digital for the first time.

Copies of the materials and videos from the briefings can be found on the Company's website (http://adalta.com.au/investors/news-media/; http://adalta.com.au/investors/asx-announcements/).

Financial update

AdAlta received A$311,970 during the quarter as the third advance against its accrued R&D Tax Incentive (RDTI) rebate under the facility with Radium Capital.

Operating cash outflows for the period remained modest at A$1.1 million (A$1.9 million in the prior quarter) as the Company focussed on preparations for the Phase I clinical trial and were primarily for payments related to stability studies of AD-214, clinical trial start-up costs and research costs, including those associated with the GE Healthcare collaboration. Future quarter outflows are expected to increase as Phase I clinical trial costs increase.

The cash balance at the end of the quarter was $3.37 million, down from $4.14 million at the end of the previous quarter.

With prudent cash management actions in place and the deferral of the initiation of the strategic growth initiatives which were announced in March, AdAlta is confident that existing cash resources are sufficient to achieve its forecast AD-214 milestones (top line safety results from the healthy volunteer part of the Phase I program and development of

the radio-labelled PET imaging agent version of AD-214, currently anticipated by early 2021).

In accordance with Listing Rule 4.7C, payments made to related parties and their associates included in items 6.1 of the Appendix 4C includes Director fees and salary (including superannuation) for executive director and related parties.

Authorised for lodgement by:

Tim Oldham
CEO and Managing Director
July 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 GE Healthcare for diagnostic imaging agents against several drug targets, including Granzyme B.

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: http://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	30 June 2020

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	-	616
1.2	Payments for		
	(a) research and development	(722)	(8,063)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(208)	(859)
	(f) administration and corporate costs	(136)	(1,078)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	19
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	68	3,567
1.8	Other (provide details if material)	(90)	(90)
1.9	**Net cash from / (used in) operating activities**	**(1,088)**	**(5,888)**

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

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

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	1,780
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	-	(154)
3.5	Proceeds from borrowings	312	2,077
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	(1)	(2)
3.8	Dividends paid	-	-
3.9	Other – (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**311**	**3,701**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	4,144	5,556
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,088)	(5,888)
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)	311	3,701
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**3,367**	**3,367**

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	13	10
5.2	Call deposits	3,354	4,134
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)**	**3,367**	**4,144**

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	96
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 executive director and related parties.

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).

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (Item 1.9)	(1,088)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	3,367
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	3,367
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	**3.1**

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

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:

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:

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.

21 July 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.