25 July 2022

ASX Announcement

QUARTERLY CASH FLOW STATEMENT – JUNE QUARTER 2022

Quarter highlights

- **Preclinical program for inhaled AD-214 progressing; pivotal studies to report during September 2022 quarter**
- **AD-214 manufacturing and toxicology campaigns deferred to optimally align with partner preferences and the different needs of each potential indication**
- **European, Indian patents granted, protecting AD-214**
- **Partnered immuno-oncology programs progressing**
- **Business development campaigns building momentum**
- **$8.66 million cash position as at 30 June 2022 ($10.54 million as at 31 March 2022); cash runway extended via AD-214 program modification**

MELBOURNE Australia, 25 July 2022: AdAlta Limited (ASX:1AD), the clinical stage drug discovery company developing novel therapeutic products from its i-body platform reports progress on the development of lead assets AD-214 and its other pipeline programs, and a cash balance of $8.66 million as of 30 June 2022.

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

"The final quarter of FY22 has featured steady progress for inhaled AD-214. The pivotal experiments testing the ability to deliver AD-214 to the distant airways of the lungs and its effectiveness against fibrosis in animal models are underway with results expected in the coming quarter. Completion of the inhaled pre-clinical program provides key information for the growing partnering interest across multiple indications.

"Separately, and building on the progress of our partner, Carina Biotech, we launched a well-received and ongoing business development campaign at both the BIO International Convention in San Diego and in China to identify and engage potential additional partners who could benefit from, and fund, the application of our i-bodies to their cellular immunotherapy programs."

A. Operations overview

1. AD-214

AdAlta is developing its lead product, AD-214, as 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. An inhaled form of AD-214 is being prepared for the next planned IPF clinical study. Pre-clinical data exploring use in other fibrotic indications continues to be generated.

The pre-clinical development plan for the inhalation formulation of AD-214 addresses three questions:

1. Delivery: can nebulised AD-214 reach the lower airways of the lungs intact?

2. Distribution and retention: can AD-214, once in the lower airways of the lungs, reach and be retained in fibrotic tissue?
3. Efficacy: can AD-214 moderate fibrotic disease progression when delivered directly to fibrotic lung tissue?

During the June 2022 quarter, AdAlta completed pilot studies to establish methods of using radiolabelled AD-214 to measure inhaled AD-214 distribution and retention in sheep lungs using PET imaging. Initial images have now been collected from healthy sheep lungs and are undergoing analysis with additional studies planned in the coming quarter. These studies complete the program of work under a Biomedical Technology Bridge (BTB) grant from the Medical Research Future Fund (MRFF) administered by MTPConnect.

AdAlta also completed preparative work to enable AD-214 to be delivered via inhalation to mice to allow assessment of AD-214 efficacy in the gold standard bleomycin mouse model of IPF. This study commenced post period end with initial results expected by the end of the September quarter.

Separately, the Company received updates from pre-clinical studies of AD-214 in eye fibrosis being conducted at University of Melbourne. Studies assessing retention of AD-214 in mouse eyes following intra-ocular injection and the effect on blood vessel leakage and fibrosis in two different mouse models of eye fibrosis have been completed and analysis of data is ongoing. First results are expected during the September quarter. This ocular fibrosis data complements data published earlier this year in a leading peer reviewed journal, *JCI Insights*, demonstrating that AD-214 may play a role in protecting kidneys from fibrosis.[1]

AdAlta's ongoing program to engage with potential partners for the further development and commercialisation of AD-214 continued at the BIO International Convention 2022 in San Diego, USA in June. Several of these discussions have progressed to evaluation of confidential information. Significantly the interest in AD-214 from these potential partners extends to multiple fibrotic indications with each having different preferences for the lead indication. Each indication has different requirements for toxicology study design and clinical AD-214 supply.

As announced on 4 July 2022, AdAlta has modified the timing of AD-214 manufacturing campaigns and toxicology studies to better align these key activities with the emerging priorities of these potential partners, and the results of pre-clinical studies due in the September quarter 2022. The Company has been able to secure a six-month deferral of pre-booked manufacturing campaigns and toxicology studies, which also ensures that AdAlta can delay financial commitments to these studies, extending its existing cash runway.

AdAlta secured additional patent protection for AD-214 during the quarter, with the issuance of an Indian patent (conferring protection for a major global market and key manufacturing location) and European patent, ensuring AD-214 is now protected to 2036 by granted patents in the eight largest pharmaceutical markets.

[1] Qinghua Cao, Chunling Huang, Hao Yi, Anthony J. Gill, Angela Chou, Michael Foley, Chris Hosking, Kevin Lim, Cristina Triffon, Ying Shi, Xin-Ming Chen and Carol A. Pollock, *A single domain i-body (AD-114) attenuates renal fibrosis through blockade of CXCR4*, JCI Insight. 2022. https://doi.org/10.1172/jci.insight.143018

2. Other programs

Partnered immuno-oncology programs

Carina Biotech (Carina) continued to build CAR-T cells incorporating i-bodies directed against an undisclosed oncology target "A" (A-i-CAR-T cells), the first of five targets being developed in collaboration with AdAlta. A-i-CAR-T cells with varying binding strength (to target A) and length (i-body binding site to the T cell membrane) have been manufactured from two different donors. Cancer cell killing assays have been completed for one donor and are progressing for the second. The best A-i-CAR-T cell candidates will then be screened against a wider range of cancer cell lines prior to *in vivo* testing which is expected to commence in early 2023. Research project plans are being developed for two additional oncology targets prior to discovery activities commencing at AdAlta.

Based on the progress at Carina, during the quarter, the Company launched a business development campaign to identify additional partners who could benefit from, and potentially fund, the application of our i-bodies to their cellular immunotherapy programs. Discussions were initiated at the BIO International Convention in San Diego in June and via our business development partners Lingmed in China and MotionHall in San Francisco. The potential benefits of our smaller i-bodies over traditional CAR targeting molecules was well received and the Company is progressing several possible partnership discussions.

AdAlta continues to collaborate with GE Healthcare to develop i-body enabled PET imaging agents for use in immuno-oncology. We are continuing to work with them to optimise the panel of i-bodies to achieve GE Healthcare's target preclinical performance requirements. Further updates for this program will be provided in consultation with GE Healthcare and as milestones are achieved.

Internal programs

The Company's internal development program to screen its libraries to identify i-bodies with high specificity for an undisclosed G-protein coupled receptor (GPCR) implicated in fibrotic disease is also progressing

3. Near term milestones

AdAlta anticipates several milestones and data read-outs across its portfolio of programs. These include:

2022 September quarter

- *In vitro* studies investigating binding and anti-fibrotic effects of AD-214 in cultured human lung tissue
- Distribution and retention of inhaled AD-214 in sheep lung (PET imaging and pathology studies)
- Efficacy of inhaled AD-214 in the bleomycin mouse model of IPF
- Activity of AD-214 in mouse models of eye fibrosis
- Initial screening of A-i-CAR-T cell *in vitro* cancer cell killing capability at Carina
- Selection of lead clinical AD-214 inhalation formulations
- Selection of i-CAR-T targets to target B and C

2022 December quarter

- Preparation for AD-214 inhalation toxicology studies
- *In vitro* cell killing of A-i-CAR-T cells against Target A complete

2023 first half

- *In vivo* proof of concept studies of A-i-CAR-T cells commence
- Start of manufacturing campaign of AD-214 for toxicology studies
- Initiation of cGMP manufacturing of AD-214 for clinical studies

B. Corporate updates

AdAlta's laboratories have experienced some minor delays to in-house projects due to isolation of staff under COVID-safe protocols. Vendors and suppliers are experiencing similar delays. The impact of these delays has been incorporated, using the most current information available, in the anticipated program milestones above, however any future impacts of COVID-19 cannot be reliably predicted. Supplier cost increases affect toxicology and manufacturing campaigns most significantly and are being managed to the extent possible via advance booking. Known increases have been factored into financial planning however future changes cannot be accurately predicted nor completely mitigated.

C. Financial position

Operating cash outflows for the quarter were A$2,039,824 (A$2,134,791 in the prior quarter). The outflows are broadly in line with the prior quarter and include increased in AD-214 inhalation formulation development costs offset by reductions in clinical research organisation costs following completion of the initial Phase I clinical study of AD-214 and reduced professional services fees.

During the quarter, AdAlta received operating cash inflows from customers of $194,962 ($802,602 in the prior quarter), being primarily proceeds of the BTB grant. Final proceeds from the BTB grant are expected to be received during the September quarter.

AdAlta maintains a $4,000,000 fully drawn loan facility under the Victorian Government R&D Tax Cash Flow Incentive scheme (Facility). The Facility is repayable from the proceeds of the FY23 R&D Tax Incentive Rebate, expected by 31 October 2023. Interest on the Facility increased to 1.515% in line with changes in benchmark interest rates.

During the period 50,000 unlisted options were issued to employees with an exercise price of $0.076 and 50,000 unlisted options over AdAlta ordinary shares expired unexercised.

The cash balance at the end of the quarter was $8.66 million, ($10.54 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 ($144,981) includes Director fees plus the salary (including superannuation) for the CEO and Managing Director.

Authorised for lodgement by:

Tim Oldham
CEO and Managing Director
July 2022

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 has completed Phase I clinical studies for its lead i-body candidate, AD-214, that 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. AdAlta has a second target in discovery research, also in the field of fibrosis and inflammation.

The Company is also entering collaborative partnerships to advance the development of its i-body platform. It has a collaboration with Carina Biotech to co-develop precision engineered, i-body enabled CAR-T cell therapies (i-CAR-T) to bring new hope to patients with cancer. It has an agreement with GE Healthcare to co-develop i-bodies as diagnostic imaging agents (i-PET imaging) against Granzyme B, a biomarker of response to immuno-oncology drugs, a program now in pre-clinical development.

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 June 2022

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	195	1,360
1.2	Payments for	-	-
	(a) research and development	(944)	(4,294)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(645)	(2,104)
	(f) administration and corporate costs	(449)	(1,638)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	1	1
1.5	Interest and other costs of finance paid	(3)	(93)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	2,664
1.8	Other (provide details if material)		-
1.9	**Net cash from / (used in) operating activities**	**(1,845)**	**(4,104)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(12)	(25)
	(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**	**(12)**	**(25)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	5,003
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	1
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	(266)
3.5	Proceeds from borrowings	-	4,000
3.6	Repayment of borrowings	-	(1,682)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other – (provide details if material)	(20)	(20)
3.10	**Net cash from / (used in) financing activities**	**(20)**	**7,036**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	10,538	5,791
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,845)	(4,104)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(12)	(25)

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)	(20)	7,036
4.5	Effect of movement in exchange rates on cash held	-	(37)
4.6	**Cash and cash equivalents at end of period**	**8,661**	**8,661**

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	482	890
5.2	Call deposits	8,179	9,648
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)**	**8,661**	**10,538**

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	145
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).

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	4,000	4,000
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	**4,000**	**4,000**

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.

Loan facility in place as at 30 June 2022 is a non-dilutive funding facility of up to $4.0million with Treasury Corporation of Victoria (TCV) as part of the Victorian Government's R&D Cash Flow Loan Initiative. The Facility was received in two tranches: the first of $2.4 million was received in September 2021; and the second of $1.6 million was received in the quarter ending 31 March 2022. Interest on Facility advances is variable at the "TCV 11am" loan interest rate (currently 1.515%). Repayment of the Facility is timed to coincide with receipt of AdAlta's FY2023 RDTI refund, expected by 31 October 2023, but may be repaid earlier. The Facility is secured by the FY2022 and FY2023 RDTI refunds. As at 30 June 2022 the total loan facility was $4.0million, being fully drawn.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (Item 1.9)	(1,845)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	8,661
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	8,661
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	**4.7**

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: 25 July 2022

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.