

30 January 2023

ASX Announcement

QUARTERLY CASH FLOW STATEMENT – DECEMBER QUARTER 2022

Quarter highlights

- **AD-214 strategic update and pathway to Phase II clinical trials, partnering**
- **Collaboration with GPCR Therapeutics to explore use of AD-214 in cancer**
- **Second Japanese patent for AD-214**
- **New collaborator publication supports potential of i-bodies in osteoporosis**
- **Yuuwa Capital completes planned end of fund wind-up**
- **\$7.34 million cash position as at 31 December 2022 (\$7.16 million as at 30 September 2022)**
- **\$2.08 million R&D Tax Incentive rebate received**

MELBOURNE Australia, 30 January 2023: 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 its lead asset, AD-214 and its other pipeline programs, and a cash balance of \$7.34 million as of 31 December 2022.

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

"The December quarter of 2022 saw us collate a year of preclinical and formulation study results and external market data to develop a roadmap to Phase II clinical trials and partnering for our lead asset, AD-214. Implementing that roadmap is already well underway."

"Our cash position improved as the receipt of our R&D Tax Incentive rebate more than offset our cash outflows, leaving us in a solid financial position moving into 2023."

"Post quarter end, our largest shareholder, Yuuwa Capital, completed the planned wind-up of its fund and we are very pleased to welcome the major shareholders of Yuuwa as new major shareholders of AdAlta. Yuuwa's support over many years is greatly appreciated by the Company and we thank Yuuwa's shareholders for their continued confidence in our long-term growth potential."

A. Operations overview

1. AD-214

AdAlta's lead product, AD-214, is a first in class, next generation antibody therapeutic for the treatment of fibrotic diseases. Since successful completion of a Phase I clinical trial in mid-2021, development of AD-214 has progressed in four indications: lung fibrosis (specifically Idiopathic Pulmonary Fibrosis (IPF) and Interstitial Lung Disease (ILD)), kidney fibrosis, eye fibrosis and cancer.

During the December 2022 quarter AdAlta reported that AD-214 could be successfully nebulised for inhalation, distributed throughout the lungs following inhalation and could reduce collagen deposition in an *in vitro* model of fibrotic human lung tissue, demonstrating proof of principle that AD-214 could be delivered clinically via inhalation.

The Company also announced a new collaboration with GPCR Therapeutics Inc who will evaluate a panel of AdAlta's anti-CXCR4 i-bodies, including AD-214, in combination with beta-blockers for treatment of cancer.

During the quarter, the Company completed a strategic review of the AD-214 development program and commercial landscape for anti-fibrotic therapies. Considering the pre-clinical data across all indications, the cost and time to progress each indication and route of administration to first demonstration of clinical efficacy, and partner demand, the Company has elected to progress injectable AD-214 into Phase II clinical trials in either lung or kidney fibrosis with a final decision on the indication to be made in the June quarter of 2023. Enabling manufacturing and toxicology programs are being implemented and are progressing in line with previous guidance to enable Phase II clinical studies to commence in mid-2024. Existing partnering discussions are being advanced to help fund the Phase II program and the availability of a potential inhalation route of administration for lung fibrosis is being well received for example by partners engaged at the annual JPMorgan/Biotech Showcase conference in San Francisco in January 2023.

Post quarter end, the Japanese Patent Office granted AdAlta a second patent protecting AD-214. This patent broadens the range of AD-214 sequence variants protected until 2036 in one of the largest pharmaceutical markets.

2. Other programs

Partnered immuno-oncology programs

Carina Biotech (Carina) continued to progress the first collaborative i-CAR-T program with AdAlta against an undisclosed oncology target "A". AdAlta and Carina are now choosing three A-i-CAR-T cell candidates to screen against a wider range of cancer cell lines in the first half of 2023 prior to *in vivo* testing in mice which is expected to commence in the second half of 2023. Research project plans are being finalised for two additional oncology targets, prior to discovery activities commencing at AdAlta during the first half of 2023.

The Company's 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 is progressing well, with the potential benefits of AdAlta's smaller i-bodies over traditional CAR targeting molecules being well received and market demand enabling prioritisation of a number of i-body targets. 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. Optimisation of the panel of i-bodies binding granzyme B continues to progress. Further updates for this program will be provided in consultation with GE Healthcare and as milestones are achieved.

Internal programs

The Company continues to progress programs to screen its libraries to identify i-bodies with high specificity for an undisclosed G-protein coupled receptor (GPCR) implicated in fibrotic disease and to develop a next generation i-body platform as resources allow.

Post quarter end, collaborators at University of Western Australia (UWA) published results of studies showing that an i-body binding to RANKL had potential as a new therapy for osteoporosis, an US\$8 billion market. AdAlta has filed patent applications to protect this invention and will continue to support the UWA team. This demonstrates further the board applicability of the i-body technology and opens potential new partnering discussions.

3. Near term milestones

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

2023 first half

- *In vitro* cell killing of A-i-CAR-T cells against Target A completed
- Selection of targets B and C for Carina i-CAR-T collaboration
- Start of manufacturing campaign of AD-214 for extended dose toxicology studies
- Initiation of cGMP manufacturing of AD-214 for clinical studies
- Additional pre-clinical data supporting efficacy of AD-214 in eye and kidney fibrosis

2023 second half

- *In vivo* proof of concept studies of A-i-CAR-T cells commence; discovery programs for targets B and C progressing
- Extended dose toxicology studies for AD-214 commence
- Phase II protocol for AD-214 clinical study finalised, CRO selected

B. Corporate and organisation updates

AdAlta's laboratories and those of its vendors and suppliers are generally operating at full capacity. Supplier long lead times continued to affect toxicology and manufacturing campaigns most significantly.

At the Company's Annual General Meeting held on 22 November, all resolutions were adopted with more than 98% support, including the Remuneration Report, Listing Rule 7.1A placement capacity and renewal of the Company's Omnibus Equity Plan. The Company thanks shareholders for their continued support.

Post the end of the quarter, substantial shareholder Yuuwa Capital LP (Yuuwa) completed a planned wind up of its fund. The shares of the Company previously held by Yuuwa have been distributed to its major shareholders. As a result, the Meurs Group advised that it has increased its substantial holding. The Company thanks Yuuwa for its support that was pivotal to the Company reaching its current position and look forward to continuing the long term association with Yuuwa's shareholders.

C. Financial position

Operating cash outflows for the quarter were A\$1,927,274 (A\$2,181,380 in the prior quarter). The outflows are broadly in line with the prior quarter and include increased one time corporate and business development costs offset by absence of annual short term incentive payments in the prior quarter. The volatile AUD-USD exchange rate has a potential impact on future costs. The Company has forward purchased approximately 50% of its near term contracted and forecast USD needs at rates close to long term historical averages. Supplier costs, particularly for manufacturing and toxicology studies, continue to increase and are being managed closely.

During the quarter, AdAlta received operating cash inflows from customers of A\$Nil (A\$684,659 in the prior quarter), with the reduction due to completion of the Medical Research Future Fund Biomedical Technology Bridge (BTB) project. AdAlta received an R&D Tax Incentive rebate of \$2,077,927 in respect of the FY22 financial year.

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 3.265% in line with changes in benchmark interest rates.

The cash balance at the end of the quarter was A\$7.34 million, (A\$7.16 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 (\$173,460) includes Director fees plus the salary (including superannuation) for the CEO and Managing Director.

Authorised for lodgement by:

Tim Oldham
CEO and Managing Director
January 2023

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 immunology 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

92 120 332 925

Quarter ended ("current quarter")

31 December 2022

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	-	685
1.2 Payments for		
(a) research and development	(655)	(1,701)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(535)	(1,250)
(f) administration and corporate costs	(710)	(1,116)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	20	28
1.5 Interest and other costs of finance paid	(27)	(42)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	2,078	2,078
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	171	(1,318)
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	-	-

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	-	(2)
3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
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	-	-
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	-	-
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	7,164	8,661
4.2	Net cash from / (used in) operating activities (item 1.9 above)	171	(1,318)
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 (6 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	1	(5)
4.6	Cash and cash equivalents at end of period	7,336	7,336

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	112	334
5.2	Call deposits	7,224	6,830
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)	7,336	7,164

6. Payments to related parties of the entity and their associates

- 6.1 Aggregate amount of payments to related parties and their associates included in item 1
- 6.2 Aggregate amount of payments to related parties and their associates included in item 2

**Current quarter
\$A'000**

173

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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 31 December 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 3.265%). 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 FY2023 RDTI refund. As at 31 December 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)	171
8.2 Cash and cash equivalents at quarter end (Item 4.6)	7,336
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	7,336
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: 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: 30 January 2023

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.