**28 April 2023**

**ASX Announcement**

**QUARTERLY ACTIVITIES REPORT – MARCH QUARTER 2023**

**Quarter highlights**

- **Plans for early return to clinic for AD-214 to deliver valuable data and further inform partnering discussions**
- **Growing AD-214 partner interest supported by business development and preclinical activities**
- **Expansion of Carina i-CAR-T collaboration**
- **$5.57 million cash position as at 31 March 2023 ($7.34 million as at 31 December 2022)**
- **Rights Offer launched to raise $3.15 million, with $2.49 million in commitments**

**MELBOURNE Australia, 28 April 2023:** AdAlta Limited (ASX:1AD), the clinical stage drug discovery company developing novel therapeutic products from its i-body platform is pleased to report that it will take lead asset AD-214 back into clinical trials earlier than anticipated in order to develop valuable data to further inform discussions as partner interest builds. The Company reports a cash balance of $5.57 million as of 31 March 2023 before receipt of proceeds from a Rights Offer announced today which aims to raise up to $3.15 million.

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

*"The March quarter of 2023 saw us make significant progress towards implementing the AD-214 roadmap to Phase II studies that was presented in November 2022. We are pleased with the growing partner interest in this asset as exemplified by more potential partners asking deeper and more sophisticated questions. We are delighted to announce that we will bring AD-214 back to the clinic under a Phase I extension study. This means we can be in clinic making use of available resources and existing drug product earlier than previously anticipated, while cost effectively generating new data to build additional value in the program and for sharing with potential partners.*

*"We have also made great progress across the remainder of our pipeline, most significantly in relation to our i-CAR-T collaboration with Carina where we are poised to move the first product into animal studies and commence work on the next two products.*

*"Our major shareholders have been enormously supportive of AdAlta and the Rights Offer announced separately today provides all our existing shareholders with an attractively priced opportunity to help progress the Company towards transactions and transformational new therapies for fibrosis and cancer patients."*

## A. Operations overview

### *1. AD-214*

*Priorities*

AdAlta's lead product, AD-214, is a first in class, next generation antibody therapeutic for the treatment of fibrotic diseases including lung fibrosis (specifically Idiopathic Pulmonary Fibrosis (IPF) and Interstitial Lung Disease (ILD)), kidney fibrosis, eye fibrosis and some cancers. The Company's priority for AD-214 is to attract partnerships or other sources of non-dilutive capital to secure the funds necessary to progress Phase II clinical studies in IPF or kidney fibrosis. To enable this, AdAlta is making small investments in studies that generate new data which addresses key questions that partners are asking or will likely ask.

AdAlta is now planning to return AD-214 to the clinic under a Phase I extension study in the September quarter of 2023, more than a year earlier than previously forecast.

In tandem, the Company is securing suppliers for essential toxicology studies and manufacturing campaigns necessary to initiate Phase II studies, while deferring the substantial costs of these studies until appropriate funding is secured.

*Partnering status*

Partnering discussions are progressing well. During the quarter the number of potential partners who have expressed interest in undertaking a detailed technical review of AD-214 has increased. These include multinational pharmaceutical companies, US specialty pharmaceutical companies, and regional leaders in Japan and China.

*Return to clinic*

With partnering interest in AD-214 building, it is essential that the development program momentum be maintained. The Company has identified an opportunity to return AD-214 to clinical studies in the September quarter of 2023, at least 12 months earlier than would be possible for a full Phase II program.

Return to clinic will be via an extension of the previously completed Phase I study of AD-214 in healthy volunteers to evaluate the safety of higher doses of the product. This creates value for partners and enhances licensing transaction potential by extending the safety profile of multiple doses of AD-214 to doses that will likely be tested in Phase II. It also confirms trends in pharmacokinetics, receptor occupancy and adverse events that will support dose selection for Phase II, reducing the time required for dose escalation at the beginning of Phase II studies. The new study will utilise existing drug product inventory.

The Phase I extension clinical study, which remains conditional on Human Research Ethics Committee (HREC) approval and successfully completing the Rights Offer referred to below, is planned to commence in the September quarter and deliver initial top line results by the end of 2023.

*Preclinical results*

AdAlta's preclinical program continues to generate data in support of our partnering initiatives. In-house experiments are refining and confirming AdAlta's hypothesis about the links between AD-214 pharmacokinetics (clearance from the blood), durable and dose dependent receptor occupancy (essential for therapeutic activity) and therapeutic effect.

These experiments, which will continue in the June quarter, are providing new insights into dosing strategies for AD-214 and will help partners correlate preclinical efficacy and clinical results.

The Company has also received results from two additional encouraging preclinical efficacy studies. Prof Erica Fletcher's group at University of Melbourne previously studied the predecessor molecule, AD-114 in a mouse laser choroidal neovascularization (CNV) model of age-related macular degeneration (AMD) showing reduced blood vessel leakage and scarring (fibrosis), primary features of AMD. Preliminary results suggest that AD-214 may also be efficacious in this model and in a separate mouse model that spontaneously generates different features of AMD. These studies are continuing during the June quarter, however results to date provide encouragement that AdAlta might soon be able to progress separate partnering discussions in eye fibrosis.

Additional studies in a folic acid model of kidney fibrosis have been less successful. AdAlta's contract research organization was unable to achieve the consistency of response to folic acid between animals that our academic collaborators at University of Sydney observed, preventing conclusions being drawn about the dose dependence of AD-214 efficacy in this model.

### 2. *Other programs*

*Partnered immuno-oncology programs*

AdAlta is now working on three targets under its i-CAR-T collaboration with Carina Biotech (Carina). The companies have completed initial *in vitro* screening of multiple candidates targeting an undisclosed tumour antigen "A" and have selected three A-i-CAR-T cell candidates to progress. Pilot studies in mice are scheduled for the June 2023 quarter after which a single candidate will be selected to progress to *in vivo* proof of concept testing in mice, which is expected to occur in the second half of 2023. Discovery activities against two additional tumour antigens will also commence at AdAlta during the June 2023 quarter.

AdAlta continues to collaborate with GE Healthcare to develop i-body enabled granzyme B PET imaging agents for use in immuno-oncology with positive progress made on several work streams during the quarter. Further updates for this program will be provided in consultation with GE Healthcare and as milestones are achieved.

GPCR Therapeutics is now evaluating several CXCR4 i-bodies under the collaboration announced in October 2022.

*Internal programs*

As described in the previous quarterly report, during the March quarter, 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, a US$8 billion market.

The Company now has three discovery stage i-body programs that it is making available for partnering. Securing commercial interest is a priority for these programs before additional funds are allocated to them.

### 3. *Corporate development*

To ensure AdAlta maintains and grows a robust pipeline of assets, the team is continuously evaluating assets and technology platforms in, or approaching clinical trials, and where

there are clear synergies with the i-body platform and existing skills. The Company is encouraged by the progress of several of these opportunities and potential investor interest in them.

### *4. Intellectual property*

As described in the previous quarterly report, during the March quarter, AdAlta filed patent applications to protect the RANKL i-body and was awarded a second patent protecting AD-214 by the Japanese Patent Office.

### *5. Near term milestones*

Assuming success of the Rights Offer, AdAlta's milestones and data read-outs for the remainder of 2023 now include:

*2023 first half*

| Goal | Target as at 31 December 2022 | Status as at 31 March 2023 |
|---|---|---|
| *In vitro* cell killing of A-i-CAR-T cells against Target A completed | H1 2023 | On track |
| Selection of targets B and C for Carina i-CAR-T collaboration | H1 2023 | Achieved |
| Start of manufacturing campaign of AD-214 for extended dose toxicology studies | H1 2022 | Achieved |
| *Initiation of cGMP manufacturing of AD-214 for clinical studies – deferred subject to partnering/financing of Phase II study* | *Mid-2023* | *Deferred* |
| Additional pre-clinical data on efficacy of AD-214 in eye and kidney fibrosis | Q1-H2 2023 | Ongoing |
| Commence discovery of i-bodies for Carina targets B and C | N/A | New |

*2023 second half*

| Goal | Target as at 31 December 2022 | Status as at 31 March 2023 |
|---|---|---|
| Human Research Ethics Committee approval of AD-214 Phase I extension clinical study | N/A | New |
| First patient first visit for AD-214 Phase I extension clinical study | N/A | New |
| First headline results from AD-214 Phase I extension clinical study | N/A | New |
| Phase II protocol for AD-214 clinical study finalised and CRO selected | H1 2023 | H2 2023 |
| *In vivo* proof of concept results of A-i-CAR-T cells; discovery programs for targets B and C continue | H2 2023 | On track |
| *Extended dose toxicology studies for AD-214 commence* | *H2 2023* | *Deferred* |

## B. Corporate and organisation updates

Together with release of this report, the Company has announced a non-renounceable pro rata Rights Offer to AdAlta shareholders in Australia and New Zealand (**Eligible Shareholders**) to acquire 2 new ordinary shares (**New Shares**) at an issue price of 2.5 cents ($0.025) per New Share for every 5 shares held by Eligible Shareholders at 7:00 pm (Melbourne time) on Wednesday 3 May 2023 together with 1 option (**New Option**) for every 2 New Shares subscribed for. Each New Option will entitle the holder to subscribe for 1 additional ordinary share at an exercise price of 3 cents ($0.03) per share with an expiry date of 29 May 2024. The purpose of the Rights Offer is to raise approximately $3.15 million before costs (not including any proceeds received from exercise of the New Options) to enable the AD-214 Phase I extension clinical study described above. If fully subscribed, the Rights Offer will result in the issue of 126,150,371 New Shares together with approximately 63,075,186 New Options granted to subscribers for the New Shares as well as a further 15,000,000 options to be issued to the corporate advisor for the Rights Offer on the same terms as the New Options. The Company has received commitments to the Entitlement Offer or any Shortfall for $2.49 million of the target amount. Full details of the offer, including terms, timetable and use of funds can be found in today's Rights Offer announcement and related documents which are available at ASX or on the Company website at https://adalta.com.au/documents/.

As noted in the December 2022 quarterly report, substantial shareholder Yuuwa Capital LLC (Yuuwa) completed a planned wind up of its fund in January 2023. The shares of the Company previously held by Yuuwa have been distributed to its major shareholders. Following this, the Meurs Group advised that it has increased its substantial holding and a trust benefiting the Australian Commonwealth Government became a substantial holder.

During the quarter, 1,800,000 unlisted options were issued under the Company's Omnibus Equity Plan and 600,000 unlisted options were cancelled due to expiry or the vesting conditions becoming unable to be met.

## C. Financial position

Operating cash outflows for the quarter were A$1,785,322 (A$1,927,274 in the prior quarter). The outflows are broadly in line with the prior quarter and include costs associated with commencement of manufacturing of non-GMP batches of AD-214 for toxicology studies, offset by reduced corporate and business development costs. The volatile AUD-USD exchange rate has a potential impact on future costs. The Company has forward purchased approximately 100% 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.

AdAlta received no operating cash inflows from customers during the March 2023 or December 2022 quarters.

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 3.765% in line with changes in benchmark interest rates.

The cash balance at the end of the quarter was A$5.57 million, (A$7.34 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 were ($143,992) which include Director fees plus the salary (including superannuation) for the CEO and Managing Director.

Authorised for lodgement by:

**Tim Oldham**
**CEO and Managing Director**
**April 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 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 | 31 March 2023 |

| **Consolidated statement of cash flows** | | **Current quarter $A'000** | **Year to date (9 months) $A'000** |
|---|---|---|---|
| **1.** | **Cash flows from operating activities** | | |
| 1.1 | Receipts from customers | - | 685 |
| 1.2 | Payments for | | |
| | (a) research and development | (771) | (2,472) |
| | (b) product manufacturing and operating costs | - | - |
| | (c) advertising and marketing | - | - |
| | (d) leased assets | - | - |
| | (e) staff costs | (509) | (1,759) |
| | (f) administration and corporate costs | (472) | (1,588) |
| 1.3 | Dividends received (see note 3) | - | - |
| 1.4 | Interest received | 18 | 46 |
| 1.5 | Interest and other costs of finance paid | (33) | (75) |
| 1.6 | Income taxes paid | - | - |
| 1.7 | Government grants and tax incentives | - | 2,078 |
| 1.8 | Other (provide details if material) | - | - |
| **1.9** | **Net cash from / (used in) operating activities** | **(1,767)** | **(3,085)** |

| | | | |
|---|---|---|---|
| **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 (9 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 | 7,336 | 8,661 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | (1,767) | (3,085) |
| 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 (9 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 | - | (5) |
| **4.6** | **Cash and cash equivalents at end of period** | **5,569** | **5,569** |

| 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 | 157 | 112 |
| 5.2 | Call deposits | 5,412 | 7,224 |
| 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)** | **5,569** | **7,336** |

| 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 | 144 |
| 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**<br>*Note: the term "facility' includes all forms of financing arrangements available to the entity.*<br>*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 March 2023 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 3.765%). 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 March 2023 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) | (1,767) |
| 8.2 | Cash and cash equivalents at quarter end (Item 4.6) | 5,569 |
| 8.3 | Unused finance facilities available at quarter end (Item 7.5) | - |
| 8.4 | Total available funding (Item 8.2 + Item 8.3) | 5,569 |
| 8.5 | **Estimated quarters of funding available (Item 8.4 divided by Item 8.1)** | **3.2** |

*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: 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: 28 April 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.