ASX Announcement | 31 January 2024
AdAlta Limited (ASX:1AD)

QUARTERLY ACTIVITIES REPORT – DECEMBER QUARTER 2023

Delivered strong AD-214 Phase I extension study interim results, a new i-body® for malaria treatment, and a stronger balance sheet.

Key highlights

- AD-214 Phase I extension study interim data reinforces safety profile, dose selection
- AD-214 and i-CAR cell therapy partnering discussions advanced during JPMorgan week and Advanced Therapies Week
- i-body® enabled potential breakthrough in malaria treatment discovered with La Trobe University
- Oversubscribed Placement Offer raised A$1.65 million
- Reduced debt while maintaining a strong cash position of $3.68 million as at 31 December 2023 ($3.57 million as at 30 September 2023)

AdAlta Limited (ASX:1AD) ("AdAlta" or "the Company") is pleased to announce its December quarter 2023 results. The quarter featured further encouraging clinical data and continued partnering interest for lead asset, AD-214. AdAlta also announced the discovery of a new i-body® with potentially world first anti-malarial properties. The Company improved its cash position while reducing debt, reporting a balance of $3.68 million at 31 December ($3.57 million at 30 September).

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

"The interim data from AD-214's Phase I extension study reported during the December quarter of 2023 was in line with our expectations, continued to reinforce the safety profile and dose selection for Phase II. These results were well received during our partnering discussions at JPMorgan Healthcare week in San Francisco in January 2024. We are grateful for the additional funds contributed by shareholders during the quarter that will allow us to further those partnering discussions once final results from this study are received at end of February 2024. We continue to aggressively pursue both out-licensing and fully funded co-development collaborations to progress AD-214 into Phase II clinical trials and ff we are able to successfully convert any of the pipeline of collaborations these could deliver a material financial impact for AdAlta in the near term.

"We enter 2024 with momentum on AD-214 and our i-CAR cell therapy programs, the excitement of an i-body® that is a world first pan-species inhibitor of malaria invasion further demonstrating the versatility of the i-body® platform, and with a strengthened balance sheet."

A. Operations overview

1. AD-214 safety profile and dose selection reinforced, supporting partnering

Priority: generate a return on investment by securing non-dilutive financing of Phase II clinical studies that realises value created by AdAlta

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 is to finance progression of AD-214 into Phase II clinical studies in IPF or kidney fibrosis. AdAlta plans to achieve this either by fully licensing-out to larger biopharmaceutical companies or co-developing in an asset specific investment vehicle financed by a third party strategic or financial investor.

Interim data from Phase I extension study reinforces safety profile and Phase II dose selection, de-risking Phase II studies

As previously announced (August 2023), AdAlta commenced a Phase I extension clinical study of AD-214 in healthy volunteers to establish the safety of multiple 10 mg/kg doses of AD-214 and confirm this as the target dosing regimen for Phase II clinical efficacy studies. During the December 2023 quarter, all participants received a third dose of AD-214 (or placebo), the same number as previously administered at 5 mg/kg doses, enabling comparison with these prior studies and AdAlta's dose simulation models.

The bioavailability of AD-214 and the blocking of its target receptor, CXCR4 (receptor occupancy) was in line with prior single dose studies, consistent across all three doses and, most significantly, in line with the predictions of previously announced dose simulation models (September 2023).

The immune response to AD-214, as measured by the number of participants in which anti-drug antibodies were detected and the level of these antidrug antibodies, was lower at this time point than observed in prior multi-dose studies.

Study investigators have reported no dose limiting toxicity, no need to interrupt doses and no requirement to administer medication to manage infusion reactions. The frequency of mild infusion related reactions appears lower than that observed at 5 mg/kg in the original Phase I study.

Post quarter end (January 2023), the Company advised that all participants had now received their fourth and final dose of AD-214 (or placebo) and that final results are on track to be received by end of February 2024.

Partnering momentum continues to build through January 2024 partnering events, offering near term upside if successful

AdAlta attended Biotech Showcase™ and BIOPartnering@JPM Week as part of JPMorgan Healthcare Week (8-11 January in San Francisco, USA), one of the most significant industry events for partnering and investment each year, followed by Advanced Therapies Week (16-19 January, Miami, USA) a key gathering of developers of, investors in and service providers to the cell and gene therapy industry. Across the two weeks of partnering events, the Company participated in 20 meetings related to AD-214. With many additional partners already in AdAlta's out-licensing pipeline waiting for the results of the ongoing Phase I extension study, the Company was pleased to field several new licensing enquiries. Of note were:

- A new confidentiality agreement request from a top 20 global pharmaceutical company.
- Approximately half the discussions were new interest from investors exploring co-developing/asset financing of Phase II clinical trials of AD-214.

2. **Immuno-oncology: AdAlta's role in next generation cell and gene therapies continues to be well received**

AdAlta has identified the potential for the i-body® platform to become a key building block of advanced cell and gene therapy products, and particularly i-body® enabled Chimeric Antigen Receptor-T cell (i-CAR-T cell) therapies for solid tumours. Building on AdAlta's i-CAR-T collaboration with Carina Biotech, a clear opportunity is emerging to use the i-body® platform as the smallest available tool to help direct these transformational therapies specifically to cancer and/or to enhance their function when they arrive. During Advanced Therapies Week, the Company was able to further test this strategy with potential co-development partners, investors, and owners of clinic ready assets that AdAlta could potentially license.

The strategy and positioning were well received, increasing confidence in the potential to develop a robust and valuable clinical stage pipeline of assets after AD-214 and expanding the potential applications of i-bodies beyond CAR-T cell therapy to include gene and mRNA delivered therapies.

AdAlta's existing immuno-oncology co-development programs, with Carina Biotech (i-CAR-T) and GE Healthcare (i-PET imaging), continued to progress without achieving material milestones during the quarter.

3. **Malaria: Potential i-body® enabled breakthrough in malaria treatment discovered with La Trobe University**

In collaboration with La Trobe University, AdAlta has discovered an i-body® believed to be the first ever antibody-like molecule capable of high potency inhibition of malaria parasite invasion of red blood cells and liver cells across multiple strains of the parasite. Variability between strains has plagued all previous attempts to produce a single antibody that can inhibit malaria parasite invasion. When combined with protecting cells from invasion at two different life cycle stages of the parasite, the new i-body® confers the real possibility AdAlta may be able to bring forward a new approach to treating malaria, a disease with 247 million cases each year resulting in 619,000 deaths and with local infections reappearing in Europe and USA. The results were published in December 2023 following applications for new intellectual property protection and will be progressed further through collaborators and grant funding.

This discovery demonstrates the versatility of the i-body® platform and the value of our collaboration with La Trobe University.

4. **Near term milestones**

AdAlta's milestones and data read-outs for the next six months include:

Goal	Status as at 30 Jun 2023	Status as at 31 Dec 2023
AD-214		
First HV participant first visit for AD-214 Phase I extension clinical study	On track (Aug'23)	Achieved
First HV headline results from AD-214 Phase I extension clinical study	On track (Q4'23)	Achieved (Nov'23)
Final HV participant visit for AD-214 Phase I extension study	On track (Q4'23)	Achieved (Jan'24)
Full safety and tolerability results for AD-214 Phase I extension study	Q1'23	On track
Carina collaboration		

Goal	Status as at 30 Jun 2023	Status as at 31 Dec 2023
In vivo proof of concept results of A-i-CAR-T cells	On track (H2 2023)	H1'24
Discovery programs for targets B and C continue	Commencing	On track
i-body® platform and pipeline		
Commence discovery on two new "catalogue" targets for i-CAR-T	Planned	Commenced

AdAlta is not forecasting the timing or value of any future partnering or licensing deal for AD-214, and notes that the Phase I extension study results anticipated in the March quarter of 2024 are important to advancing existing partnering discussions.

B. Corporate and organization updates – oversubscribed Placement Offer and well supported AGM

In October 2023, the Company conducted a series of briefings for investors that featured IPF survivor Bill van Nierop discussing the physiological and mental impacts of IPF, the inadequacies of current treatments and the desperate need for improved therapies. AdAlta plans to make Bill's comments available to a wider audience shortly.

During the quarter, AdAlta completed an oversubscribed Placement Offer, raising A$1.65 million prior to costs to fund completion of Phase I extension clinical study of AD 214 and to progress ongoing partnering discussions across the pipeline. This resulted in the issue of approximately 83 million New Shares at $0.02 per New Share and 83 million New Options with an exercise price of $0.03 expiring 29 May 2024. A further 12 million New Options were issued to Peak Asset Management under their engagement as lead manager.

The Company's Annual General Meeting was held in November 2023. All resolutions passed with support of more than 98% of shares voted.

C. Financial position – cash reserves maintained and balance sheet strengthened

Net cash inflows from operating activities for the quarter were $572,789 (outflows of $2,822,872 in the prior quarter. The Company received operating in flows of $2,350,940 as its R&D Tax Incentive (RDTI) rebate for the FY23 fiscal year (Nil in the prior quarter). Operating cash outflows for the quarter were also substantially lower at A$1,795,033(A$2,839,336 in the prior quarter), reflecting planned lower clinical site activity associated with the Phase I extension study of AD-214, no product manufacturing costs, and reduced staff costs following payment of annual short term incentives in the prior quarter.

Net cash outflows from financing activities were $457,164 (inflows of $1,662,389 in prior quarter). AdAlta maintains a loan facility under the Victorian Government R&D Tax Cash Flow Incentive scheme (Facility). Fuds drawn under the Facility as at 31 December 2023 were $2.0million ($4.0million as at 30 September 2023). In accordance with the terms of the Facility (as described in item 7.6 of the Appendix 4C accompanying this report), $2.0 million was repaid during the quarter from the proceeds of the RDTI rebate in respect of the FY23 year. A further repayment of $0.6 million was made in January 2024, post period end. This outflow was partially offset by net proceeds after costs from the Placement Offer conducted during the period of $1,542,836.

The cash balance at the end of the quarter was slightly improved at A$3.68 million, (A$3.57 million at the end of the previous quarter). The Company is actively evaluating and progressing multiple activities to raise additional

funds, including out-licensing AD-214 and the i-body platform, project financing ongoing development of AD-214 and grants to progress other pipeline projects.

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 $120,885 which include Director fees plus the salary (including superannuation) for the CEO and Managing Director.

D. Summary

AdAlta enters 2024 on track to deliver the results of the Phase I extension study of AD-214 in the first quarter, representing a key milestone in its efforts to partner or asset finance AD-214 into Phase II studies. By strengthening its balance sheet through retiring debt while maintaining its cash reserves, the Company has maintained the financial resources necessary to progress these partnering discussions. During the last quarter of 2023, the Company also added a potential new weapon in the fight against malaria into its inventory of partnerable i-body® candidates, further demonstrating the versatility and power of its i-body® platform.

This ASX announcement has been authorised for release by the Board of AdAlta Limited (ASX:1AD).

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About AdAlta Limited

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 enabled protein and cell 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 is extending 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. Preparation for Phase II clinical studies is also underway.

The Company is also entering collaborative partnerships to advance the development of its i-body® platform. It has a collaboration with Carina Biotech to codevelop 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 preclinical 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.

For more information

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To learn more about AdAlta please click here: www.adalta.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	31 December 2023

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	-	-
1.2	Payments for		
	(a) research and development	(900)	(2,656)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(385)	(990)
	(f) administration and corporate costs	(475)	(910)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	17	33
1.5	Interest and other costs of finance paid	(36)	(79)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	2,351	2,351
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**572**	**(2,251)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	(63)
	(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**	-	**(63)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	1,660	3,532
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	(117)	(270)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(2,000)	(2,000)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other – (provide details if material)	-	(56)
3.10	**Net cash from / (used in) financing activities**	**(457)**	**1,206**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	3,567	4,790
4.2	Net cash from / (used in) operating activities (item 1.9 above)	572	(2,251)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(63)

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)	(457)	1,206
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	3,682	3,682

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	443
5.2	Call deposits	3,570	3,124
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)**	**3,682**	**3,567**

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).

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	2,000	2,000
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	**2,000**	**2,000**

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 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.

The table below outlines the current terms of the Facility as agreed by AdAlta Limited and Invest Victoria.

In October 2023, $2million of the facility was repaid.

	Terms as announced on 18 October 2023
Facility amount as at date of announcement	$4,000,000
Repayment	50% by 31 October 2023 15% by 31 January 2024 35% by 30 April 2024
Interest rate	TCV 11am loan interest rate (currently 4.515%)*
Security	FY24 RDTI refund

* Any overdue instalment payments may also attract an additional 2% interest.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (Item 1.9)	
8.2	Cash and cash equivalents at quarter end (Item 4.6)	
8.3	Unused finance facilities available at quarter end (Item 7.5)	
8.4	Total available funding (Item 8.2 + Item 8.3)	
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: 31 January 2024

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.