ASX Announcement | 31 January 2025
AdAlta Limited (ASX:1AD)

QUARTERLY ACTIVITIES REPORT – DECEMBER QUARTER 2024

Board renewal and recently assembled clinical advisory team enhance leadership capabilities as "East-to-West" strategy and AD-214 are progressed

Key highlights

- Expanded advisor network engaged to support "East to West" cellular therapy strategy
- First non-binding term sheet executed for "East to West" cellular therapy strategy
- AD-214 partnering to be supported by new advisors, stronger execution capabilities and new data from continuous manufacturing improvement program
- New AdAlta Board members appointed, strategic review nearing completion

AdAlta Limited (ASX:1AD) ("AdAlta" or **"the Company")**, developer of next generation protein and cell therapeutic products, is pleased to announce its Appendix 4C cash flow report for the quarter ended 31 December 2024 (Q2 FY25), along with the following financial and operational update.

The quarter focussed on increasing the Company's "bench strength" with two new Non-executive Directors appointed to the AdAlta Board and additional advisors engaged. This enhanced leadership team will bolster AdAlta's ability to execute growth plans for both the Company's "East to West" cellular immunotherapy strategy and AD-214, its first in class anti-fibrotic drug candidate.

At the same time, AdAlta executed its first non-binding term sheet to in-license its first cellular immunotherapy asset, and new data from the Company's continuous manufacturing improvement program has meaningfully added to the AD-214 value proposition for partners.

The Company's cash balance as at the end of December 2024 was $1.63 million (compared to the cash position at 30 September 2024 of $1.91 million). AdAlta repaid its Victorian Government R&D Cash Flow Loan Facility in full during Q2 FY25.

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

"The December 2024 quarter saw AdAlta successfully undertake Board renewal and assemble a world-class clinical advisory team. All the new appointees have joined to help realise the patient impact and upside potential in both our lead drug candidate AD-214 and the Company's exciting "East to West" strategy. These highly qualified individuals enhance the Company's ability to further progress its growth strategy.

"The clinical advisory team now includes two very well credentialled consultant Chief Medical Officers who will help AdAlta deliver on its oncology cell therapy and fibrosis strategies.. Board renewal adds additional positive momentum, with recently appointed Directors Michelle Burke and Iain Ross further strengthening our strategy and change capabilities. Collectively, all are already helping review and refine our strategy.

"The signing of our first non-binding term sheet to in-license an asset as part of our "East to West" cell therapy strategy was a crucial step in building this business. We are now focussing our efforts on securing additional term sheets to build our pipeline and validate the potential scalability of this exciting growth strategy.

"While AD-214 partnering is taking longer than we had hoped, we continue positive discussions with a number of new and continuing parties and are encouraged by the recent licensing of Mediar Therapeutic's IPF candidate by Eli Lilly. Data generated during the December quarter showed the potential both for

AD-214 to be formulated for subcutaneous administration and for our continuous manufacturing improvement strategies to further drive down cost of goods. This will support partnering discussions for this important drug candidate.

A. Operational updates

1. "East to West" cellular immunotherapies

AdAlta announced its "East to West" cellular immunotherapy strategy in April 2024 (see ASX announcement dated 8 April 2024). Cellular immunotherapies (living drugs based on engineered human cells) are a rapidly growing market that is transforming outcomes in blood cancer. During 2024, the US Food & Drug Administration (US FDA) approved the first T cell immunotherapies for solid cancers, opening up this much larger market. Asia, and China in particular, is leading innovation in this field with around 40% of all companies and 60% of all clinical trials found in Asia. Australia has specific and globally recognised expertise in cellular immunotherapy manufacturing and clinical trials.

AdAlta will be a force multiplier for Asian innovators by providing a pathway for clinic ready assets to access Western-regulated markets. By licensing or acquiring global (outside Asia) commercialisation rights to these products in return for conducting initial clinical trials for Western-regulated markets in Australia, AdAlta could add significant value to these assets for both it as well as its licensing partners.

In October 2024, AdAlta signed a non-binding term sheet with a Chinese company in respect of a CAR-T cell therapy product that has demonstrated safety and potential efficacy in small clinical trials in advanced gastric cancers. The product also has potential application in other gastro-intestinal cancers. The non-binding term sheet provides for an exclusive negotiation period during which detailed due diligence is conducted. As a result of initial findings, AdAlta and its partner are further refining the collaboration model and extending the exclusive due diligence period.

The Company maintains an active deal pipeline with more than ten products being actively monitored. Two new deal candidates were added during Q2 FY25. Two other discussions were terminated prior to executing term sheets because they failed to meet AdAlta's investment criteria. The Company anticipates executing additional non-binding term sheets during the March 2025 quarter (Q3 FY25). These term sheets are allowing AdAlta and seed investor SYNBV to engage with additional investors to finance AdAlta's growth.

In October 2024, AdAlta announced the appointment of Dr Kevin Lynch MD as Consultant CMO supporting the Company's cell therapy strategy. Dr Lynch brings more than 25 years' clinical development experience in oncology and haematology across multiple markets, including China at Antengene, Celgene, and Novartis. His experience and networks will support AdCella's asset selection and associated execution strategies.

2. AD-214 – a new approach to fibrotic disease

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)) and kidney fibrosis. The Company is focussed on securing third party partners or investors to finance progression of AD-214 into Phase II clinical studies in IPF or kidney fibrosis and development of a patient preferred subcutaneous format.

Execution capability enhanced as expert advisors support AD-214 development

In early October 2024, AdAlta announced the appointment of leading IPF clinicians, Professors Tamera Corte, Toby Maher, Philip Molyneaux, and Marlies Wijsenbeek-Lourens to join existing Scientific Advisory Board member, Dr Steve Felstead, on a new AD-214 Clinical Advisory Board and the appointment of leading IPF researcher Professor Gisli Jenkins as Translational Science Advisor. The Company also appointed a USA-based consultant Chief Medical Officer for AD-214, bringing more than 30 years' experience as a board-certified and practicing pulmonary physician including at Stanford, Johns Hopkins and Washington Universities and over 20 years of clinical development, regulatory and medical affairs experience almost exclusively in respiratory and/or orphan diseases, including leadership roles supporting approval, post-approval and indication extension for both currently marketed drugs for IPF. This engagement will fully commence in 2025.

New formulation and continuous manufacturing improvement data supports AD-214 product profile

AD-214 is currently delivered by intravenous infusion every two weeks. A weekly, subcutaneous injection would be more convenient for patients and reduce health care system costs. AdAlta's scientists have now demonstrated that AD-214 can be successfully concentrated to the level required so that an effective dose can be delivered in a sufficiently small volume for subcutaneous administration.

AdAlta also has designed a continuous manufacturing improvement program to ensure that the cost of producing AD-214 continues to be lowered. During Q2 FY25, AdAlta's scientists completed proof of principle experiments identifying a method of reducing losses during initial harvesting from the primary fermentation step in production. This demonstrates the feasibility of one of the major yield improvement strategies.

Partnering momentum continues

The Company continues to maintain a robust and active pipeline of potential investors and licensing partners for AD-214. Investment term sheets are being actively discussed with several parties.

These discussions are all-encompassing, meaning they take time. In addition, each of the potential partnerships currently being explored are all advancing at different paces and with different structures. For competitive and practical reasons, AdAlta is unable to forecast when, or even if, specific partnership agreements and the transactions that flow from them may close.

The value large pharma companies place on novel fibrosis assets was further reinforced by the announcement on 10 January 2025 that Eli Lilly would pay Mediar Therapeutics US$99 million in upfront and near-term payments and up to US$687 million for IPF asset MTX-463 that is, like AD-214, poised to enter Phase II clinical trials.

3. i-body discovery – going where antibody drugs cannot

Progress on internal discovery programs has been intentionally slowed to increase focus on "East to West" cell therapy and AD-214 partnering programs.

4. Near-term objectives

AdAlta's objectives for the next six months are focussed on transactions enabling advancement of AD-214 and validation of the "East to West" cellular immunotherapy strategy. For competitive and practical reasons, AdAlta is not explicitly forecasting the timing or value of any future potential partnering or licensing deal(s) for AD-214 or cellular immunotherapy in-licensing deal(s).

Following AdAlta's recent Board renewal, the Company is nearing completion of a strategic review of its asset portfolio of assets and growth opportunities. The Company anticipates that results of the review will be released imminently.

B. Corporate and organization updates

Mid-way through Q2 FY25, AdAlta announced the retirement of Dr Robert Peach as non-executive director and the appointment of Michelle Burke and Iain Ross as non-executive directors (see ASX announcement dated 18 November 2024). The skill sets of the new directors in cell therapies, strategy, corporate transformation and capital markets will be invaluable as AdAlta's development strategy continues to evolve.

Back in late-April 2024, AdAlta entered institutional investment agreements with New Life Sciences Capital, LLC ("NLSC") and an entity associated with the Meurs Group (see ASX announcement dated 29 April 2024). Under these agreements, NLSC and Meurs Group would, subject to conditions described in the abovementioned ASX announcement, invest up to $3.0 million and $0.7 million respectively. Initial investments of $0.8 million and $0.4 million respectively ($1.2 million total) were received during the June 2024 quarter. During the September 2024 quarter, AdAlta received $0.3 million as the second investment under the Meurs Group investment agreement and called the second investment under the NLSC investment agreement.

During the December 2024 quarter, AdAlta received $0.58 million as the second investment under the institutional investment agreement with NLSC. NLSC may elect to make a third investment of up to $0.7 million prior to 7 May 2025. A fourth investment under the NLSC investment agreement would only be made by mutual agreement between the parties prior to 7 May 2025, and would be undertaken only if placement capacity under Listing Rule 7.1 is available. On 4 November 2024, 25,252,525 shares were issued to the Meurs Group under the institutional investment agreement.

At AdAlta's FY24 Annual General Meeting held on 20 November 2024, all resolutions, including the adoption of the remuneration report, were passed with greater than 97% support. As a result, 1,396,999 STI Performance Rights and 757,195 LTI Options were issued to CEO and Managing Director, Tim Oldham during Q2 FY25. 1,695,380 Performance Rights were also issued to employees during the period.

C. Financial position

Q2 FY25 saw net operating cash inflows of $568,912, comprising $1,774,530 inflows from the R&D Tax Incentive rebate in respect of FY24 and normal operating outflows of $1,205,618, which were lower than the prior quarter outflows of $1,416,135. Operating cash outflows for Q2 FY25 included a continued reduction in research and development (R&D) expenditure and increased business development and due diligence costs. Future cash requirements are anticipated to continue to decline until potential transactions in respect of AD-214 and the "East to West" cellular immunotherapy strategy become reality.

Financing cash flows include repayment in full the $1.4 million balance of the Victorian Government R&D Cash Flow Loan Facility, resulting in a net cash inflow of $0.37 million following receipt of the R&D Tax Incentive Rebate, and receipt of the $0.58 million second investment under the NLSC institutional investment agreement.

The cash balance at the end of the December 2024 quarter was $1.63 million (versus A$1.91 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 $124,225, which include Director Fees plus the salary (including superannuation) for the CEO and Managing Director.

D. Summary

AdAlta's Q2 FY25 reporting period has seen the Company build execution capabilities in both its strategic businesses as well as its Board. New data has added to the AD-214 product profile and the Company's "East to West" cellular immunotherapy strategy continues to be validated, including by execution of the first in-licensing term sheet.

For an opportunity to engage in a virtual discussion of this report see:
https://investorhub.adalta.com.au/link/WrvX4y

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

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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 December 2024

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	(147)	(482)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(366)	(767)
	(f) administration and corporate costs	(686)	(1,343)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	7	15
1.5	Interest and other costs of finance paid	(14)	(44)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	1,775	1,775
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**569**	**(846)**

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

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	576	876
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	(1,400)	(1,400)
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)		
	- Security deposit	-	(31)
	- Rental payments under AASB16 (interest expense of lease included in item 1.5 interest expense under AASB16)	(32)	(105)
3.10	**Net cash from / (used in) financing activities**	**(856)**	**(660)**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	1,914	3,133
4.2	Net cash from / (used in) operating activities (item 1.9 above)	569	(846)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(856)	(660)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**1,627**	**1,627**

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	149	147
5.2	Call deposits	1,478	1,767
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)**	**1,627**	**1,914**

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	124
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	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	**-**	**-**

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.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (Item 1.9)	569
8.2	Cash and cash equivalents at quarter end (Item 4.6)	1,627
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	1,627
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:

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:

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:

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.

31 January 2025

Date: .....

The Board

Authorised by: .....
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.