ASX Announcement | 24 October 2024

AdAlta Limited (ASX:1AD)

QUARTERLY ACTIVITIES REPORT – SEPTEMBER QUARTER 2024

Preparing for clinical activity; partnering advancing in two business units

Key highlights

- Clinical Advisory Board and Consultant CMO-AdSolis appointed to support preparation for further clinical studies of AD-214
- Consultant CMO-AdCella appointed to support asset selection and preparation for cellular immunotherapy clinical studies
- First non-binding term sheet executed for AdCella
- Post end-of-quarter fund inflows strengthen cash position

AdAlta Limited (ASX:1AD) ("AdAlta" or **"the Company")**, developer of the clinical stage i-body® platform and other novel protein and cell therapeutic products is pleased to announce its Appendix 4C cash flow report for the quarter ended 30 September 2024 (Q1 FY25), along with the following financial and operational update.

The quarter was focused on preparing AD-214 for further clinical studies, securing the partnerships for AdSolis Pty Ltd to finance those studies, and advancing due diligence on a pipeline of novel cellular immunotherapy assets for AdCella Pty Ltd to advance AdAlta's "East to West" cellular immunotherapy strategy. As a direct consequence of these activities, early October 2024 saw both a non-binding term sheet executed for the AdCella pipeline, and AdAlta's leadership team further enhanced - the latter via the appointment of a Clinical Advisory Board for AD-214 and Consultant Chief Medical Officers ("CMOs") for each of the AdSolis and AdCella business units.

The Company's cash balance as at the end of September 2024 was $1.91 million (compared to the cash position at 30 June 2024 of $3.13 million). The Company forecasts financing inflows of up to $1.07 million during the December 2024 quarter (Q2 FY25) from R&D Tax Incentive (RDTI) rebates and existing investment facilities net of repayment of the Victorian Government R&D Cash Flow Loan Facility.

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

"AdAlta took further steps toward the realisation of two core priorities over the September 2024 quarter. The first involved our team's progress advancing due diligence on AD-214 with partners and investors, a prerequisite to further clinical trials involving this exciting AdAlta drug candidate. The second priority progressed was due diligence on an initial pipeline of differentiated cellular immunotherapy products, the next step in the execution of our "East to West" cellular immunotherapy strategy.

"Recent months has also seen AdAlta take deliberate steps to enhance its leadership team that will give the implementation of our AdSolis and AdCella strategies extra impetus. We now have in place a high-calibre AD-214 Clinical Advisory Board, a Translational Science Advisor for AD-214 and highly experienced Consultant CMOs for each of our AdSolis and AdCella units. Their confidence in our strategies means a great deal to us, and their undoubted expertise in their respective fields supports our ability to execute the best possible clinical trials programs. We welcome them to the AdAlta team,

We are also very pleased to have executed our first non-binding term sheet to in-license an asset for AdCella, enabling deep due diligence to begin and additional investors in the AdCella opportunity to engage. And, from a look ahead perspective, further term sheets are currently under negotiation for both AdSolis and AdCella."

A. Operational updates

1. AdSolis – a new approach to fibrotic disease

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

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
- Some cancers.

The Company's priority is to finance progression of AD-214 into Phase II clinical studies in IPF or kidney fibrosis, through out-licensing or co-development partnerships with its AdSolis subsidiary.

Execution capability enhanced as expert advisors support AD-214 development

In addition to partnering efforts during Q1 FY25, AdAlta worked on building execution capability.

In early October, AdAlta announced the appointment of leading IPF clinicians, Professors Tamera Coorte, 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. This group of eminent physicians will help finalise the design of the Phase II clinical trial of AD-214 to optimise recruitment and maximise probability of a definitive result. The appointment of leading IPF researcher Professor Gisli Jenkins as Translational Science Advisor will further strengthen the design of biomarker and other mode of action indicator studies that can be incorporated into the Phase II clinical trial program.

Also in October, the Company announced that it is appointing a Consultant CMO-AdSolis. This engagement will fully commence in 2025, however AdSolis will have the benefit of immediate advice during a transitional period while the consultant completes other engagements. This individual, based in USA, has more than 30 years' experience as a board certified and practicing pulmonary physician including faculty appointments at Stanford University, Johns Hopkins and Washington University School of Medicine. They bring over 20 years of clinical development, regulatory and medical affairs experience almost exclusively in respiratory and/or orphan diseases. They held leadership roles supporting approval, post-approval and indication extension clinical studies and medical affairs for both currently marketed drugs for IPF.

In addition, tender processes have been prepared to procure a range of regulatory, clinical operations, subcutaneous formulation development and other services necessary to advance our development strategy for AD-214.

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.

2. AdCella – "East to West" cellular immunotherapies

AdAlta announced the creation of AdCella Pty Ltd (AdCella) in April 2024. AdCella will focus on cellular immunotherapies (living drugs based on engineered human cells), a rapidly growing market that is transforming outcomes in blood cancer and is now poised to do so in solid cancers and non-cancer indications. Asia, and China in particular, is leading innovation in this field with around half 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.

AdCella's objective is to 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, AdCella could add significant value to these assets for both it as well as its licensing partners.

AdAlta will provide operational and execution services in return for equity in AdCella and will also be able to provide capital alongside private investors. For investors in AdCella, including AdAlta, the business model offers assets with existing clinical efficacy and safety data acquired at low upfront cost and offering a relatively short (3-4 years) time to value inflection and potential onward transactions ensuring efficient use of capital and recycling of investments.

AdAlta and its strategic partners SYNthesis BioVentures ("SYNBV") and Cell Therapies Pty Ltd are conducting due diligence on a pipeline of more than ten differentiated T cell immunotherapies for solid cancers.

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 sets out the proposed financial terms under which AdCella would license the product, subject to assumptions to now be tested during a detailed due diligence period, and several other conditions being met. The Company anticipates executing additional non-binding term sheets during the December 2024 quarter (Q2 FY25). These are allowing AdAlta and SYNBV to engage with additional investors to finance AdCella's growth.

Also in October 2024, AdAlta announced the appointment of Dr Kevin Lynch MD as Consultant CMO-AdCella. 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.

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

AdAlta's i-body® platform continues to enable early discovery and preclinical development programs across a range of drug formats and targets. AdAlta's discovery business includes:

- Ongoing immuno-oncology co-development programs with Carina Biotech (i-CAR-T), GE Healthcare (i-PET imaging) and GPCR Therapeutics (CXCR4 i-body® combination therapies)
- Internal discovery programs supporting AdCella
- Potential applications of the new anti-malarial i-body® discovered with La Trobe University (see ASX announcement dated 19 December 2023).

Progress on internal discovery programs has been intentionally slowed to increase focus on AdSolis and AdCella partnering programs.

4. Near term objectives

AdAlta's objectives for the next six months include:

Goal	Target as at 30 Jun 2024	Target as at 30 Sep 2024
AdSolis		
Full safety and tolerability results for AD-214 Phase I extension study	Achieved (Mar-24)	Achieved (Mar-24)
Securing licensing or financing partnerships to finance Phase II clinical studies	Near-term goal[1]	Near-term goal[1]
AdCella		
Complete establishment of AdCella under SYNBV MoU – license initial asset(s)	Q4 CY24	Near-term goal[1]
i-body discovery		
In vivo proof of concept results of A-i-CAR-T cells (Carina collaboration)	H2 CY24	Intentionally slowed to increase focus on AdSolis and AdCella partnering programs
Discovery programs for targets B and C continue (Carina collaboration)	Initial binder panel H2 CY24	
Commence discovery on two new "catalogue" targets for i-CAR-T	Initial binder panel TBD	

[1] For competitive and practical reasons, AdAlta is not explicitly forecasting the timing or value of any future potential partnering or licensing deal for AD-214 or in-licensing deal for AdCella.

B. Corporate and organization updates

On 29 April 2024, AdAlta entered institutional investment agreements with New Life Sciences Capital, LLC ("NLSC") and an entity associated with the Meurs Group, under which NLSC and Meurs Group would, subject to conditions described in the ASX announcement of 29 April 2024, invest up to $3.0 million and $0.7 million respectively. A first investment of $0.8 million and $0.4 million respectively ($1.2 million total) was 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. The Meurs Group second investment was approved by an Extraordinary General Meeting held on 23 July 2024 (which also ratified the first investment under both investment agreements).

Also during the September 2024 quarter, the Company issued 10,582,011 million shares to NLSC on conversion of $200,000 of the First Subscription Amount. AdAlta anticipates receiving up to $0.7 million by 2 November 2024 as the second investment under an institutional investment agreement with New Life Sciences Capital, LLC ("NLSC") (see ASX announcement dated 29 April 2024). The Company utilised its existing and available placement capacity under Listing Rule 7.1 to approve the second NLSC Investment and a third investment of up to $0.7 million by NLSC, should they elect to make the latter investment 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.

C. Financial position

Net operating cash outflows for Q1 FY25 were $1,416,135, near the prior quarter outflows figure of $1,386,654. Operating cash outflows for Q1 FY25 included a continued reduction in research and development expenditure following the completion of the Phase I extension study of AD-214, offset by

increased business development and due diligence costs and one-time payments in respect of new lease and occupancy arrangements for the Company laboratories at La Trobe University that relate to prior periods. Future cash requirements are anticipated to be comparable to the September 2024 quarter or continue to decline until the potential transactions in respect of AdSolis and AdCella become reality.

The cash balance at the end of the September 2024 quarter was A$1.91 million (versus A$3.13 million at the end of the previous quarter). Post period end, the Company received a $1.77 million R&D Tax Incentive (RDTI) rebate in respect of the FY24 financial year and repaid 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. As noted in the above **Corporate and organization updates** section, the Company anticipates receiving up to $0.7 million as the second investment under the New Life Sciences Capital (NLSC) investment agreement during the December 2024 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 $121,755 which include Director Fees plus the salary (including superannuation) for the CEO and Managing Director.

D. Summary

The first quarter of AdAlta's FY2025 has seen the Company make solid progress on both its AdSolis and AdCella strategies. Progress here was demonstrated by:

- Executing a non-binding term sheet to in-license what could be, subject to final diligence, AdCella's first asset (with additional term sheets under negotiation for both AdCella and AdSolis)
- The appointment of Consultant CMOs for both the AdSolis and AdCella subsidiaries and a Clinical Advisory Board and translational science advisor for AD-214.

For a video summary of this release and opportunity to engage in a virtual discussion see: https://investorhub.adalta.com.au/link/LeoZYy

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

For further information, please contact:

AdAlta Limited (ASX:1AD)
Tim Oldham
CEO & Managing Director
P: +61 3 9479 5159
E: t.oldham@adalta.com.au

Media & Investor Enquiries
The Capital Network
Julia Maguire
P: +61 2 8999 3699
E: julia@thecapitalnetwork.com.au

About AdAlta Limited

AdAlta Limited (ASX:1AD) 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 creates 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's strategy is to maximise the products developed using its next generation i-body® platform by discovering and developing selected i-body®-enabled product candidates useful in fibrosis, inflammation and cancer; and partnering with other biopharmaceutical companies to develop these and other product candidates in a range of indications and product formats

AdAlta's current lead i-body® enabled candidate is AD-214, which is taking a wholly new approach to treat lung fibrosis (IPF) and other fibrotic diseases. In accord with its business model, AdAlta is creating a private, unlisted subsidiary called AdSolis to advance AD-214 into Phase II clinical trials through licensing and/or third-party investment.

AdAlta believes that the i-body® technology is ideally suited for use in the creation of advanced cellular immunotherapies for cancer and that this field represents an opportunity to expand its clinical stage pipeline. It has entered a Memorandum of Understanding with SYNthesis BioVentures to investigate the formation of a jointly owned entity, to be called AdCella, that, once established, will provide innovative cellular immunotherapies originating in Asia with a pathway to western regulated markets via Australian clinical trials and further enhancement with AdAlta's i-body® technology.

The Company is also entering collaborative discovery 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.

For more information

Join our InvestorHub

Follow us on Twitter

Follow us on LinkedIn

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	30 September 2024

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(335)	(335)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(401)	(401)
	(f) administration and corporate costs	(657)	(657)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	8	8
1.5	Interest and other costs of finance paid	(30)	(30)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(1,415)**	**(1,415)**

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 (3 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	300	300
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)		
	- Security deposit	(31)	(31)
	- Rental payments under AASB16 (interest expense of lease included in item 1.5 interest expense under AASB16)	(73)	(73)
3.10	**Net cash from / (used in) financing activities**	**196**	**196**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 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	3,133	3,133
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,415)	(1,415)
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)	196	196
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**1,914**	**1,914**

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	147	89
5.2	Call deposits	1,767	3,044
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)**	**1,914**	**3,133**

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	122
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	1,400	1,400
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	**1,400**	**1,400**

7.5	**Unused financing facilities available at quarter end**	-

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

Loan facility in place as at 30 September 2024 is a non-dilutive funding facility with Treasury Corporation of Victoria (TCV) as part of the Victorian Government's R&D Cash Flow Loan Initiative.

The table below outlines the terms of the Facility as announced on 29 April 2024 following amendments agreed by AdAlta Limited and Invest Victoria. Full repayment of the facility is to be upon receipt of AdAlta's Research and Development Tax Incentive (RDTI) rebate in respect of FY2024.

	Endorsed Amended Terms
Facility amount as at date of announcement	$1,400,000
Repayment	By 31 October 2024*
Interest rate	TCV 11am loan interest rate (currently 4.515%)**
Security	FY24 RDTI refund

* To be repaid upon receipt of RDTI rebate in respect of FY2024 year
** Any overdue instalment payments may also attract an additional 2% interest.

As at the date of this announcement the loan has been fully repaid.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (Item 1.9)	(1,415)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	1,914
8.3	Unused finance facilities available at quarter end (Item 7.5)	
8.4	Total available funding (Item 8.2 + Item 8.3)	1,914
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	**1.4**

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: Quarterly cash requirements before transaction costs are anticipated to continue to decline until the potential execution of transaction in respect of AdSolis and AdCella.

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: As announced on 29 April 2024, the Company has an institutional investment of up to $3.7million. As at 30 September 2024, the Company had received investment of $1.5million.

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: Yes, for reasons outlined above

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.

24 October 2024

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.