ASX Announcement/Press Release | 6 February 2025

AdAlta Limited (ASX:1AD)

"East to West" cellular immunotherapy strategy prioritized

AdAlta's "East to West" strategy validated and accelerated with additional term sheets

Investment highlights

- AdAlta's "East to West" cellular immunotherapy strategy confirmed as key driver of future pipeline growth and value creation in strategic review and is core growth priority for the company
- AdAlta will in-license highly differentiated cell therapies for solid cancers from Asian originators and build value by conducting first Phase I clinical trials.
- This strategy provides a pathway for "Eastern" innovation to reach "Western" regulated markets and patients and aligns with a key driver of the global biopharma industry
- Two new non-binding term sheets now signed following a disciplined asset selection process, bringing total products in advanced in-licensing discussions to three
- Following a strategic review AdAlta's first in class antifibrotic molecule, AD-214, will continue to be advanced only via third party transactions and the Company will cease internal discovery R&D activities to focus resources on the "East to West" growth strategy.

AdAlta Limited (ASX:1AD) ("AdAlta" or "the Company") is pleased to announce the acceleration of its "East to West" cellular immunotherapy growth strategy with the execution of two further non-binding term sheets to in-license clinical stage CAR-T products, bringing total products in advanced due diligence to three. This growing opportunity pipeline is expected to quickly re-shape AdAlta into a leader in cellular immunotherapy for solid cancer patients, enhancing the Company's value creation opportunities. This strategy is aligned with a global biopharma trend: biopharma innovation emerging from China and Asia is reshaping the global biopharma landscape.[1]

Following a strategic review of its pipeline, AdAlta has determined that it will continue to advance its first in class antifibrotic drug, AD-214, being developed for fatal diseases such as Idiopathic Pulmonary Fibrosis (IPF), only through external partners and investors and it will cease internal discovery R&D to focus resources on its now validated "East to West" growth strategy.

AdAlta CEO and Managing Director, Tim Oldham said:

"Our decision to accelerate AdAlta's "East to West" strategy represents a substantial opportunity for the Company. This strategy is already providing us access to "Eastern" advances in cellular immunotherapies and will, in turn, help drug candidates flowing from biotech innovation in that region reach "Western" regulated markets.

We believe AdAlta can make a series of modest investments, leveraged with third party capital and focused on single clinical trials per asset, that could see value realisation in relatively short time periods. The strategy is already receiving positive feedback from strategic and financial investors who are potential sources of non-dilutive funding and from our Asian in-licensing partners. The alignment of the strategy with industry growth trends was validated at JPMorgan Week and by the signing of these two new term sheets.

[1] BioCentury, commenting on JPMorgan Healthcare Week 2025 when promoting the 4th East-West Biopharma Summit 2025

We are streamlining and simplifying the rest of our business to create focus. We'll continue to seek transactions to advance AD-214 however we will cease internal R&D: we can develop a diverse clinical stage pipeline that is important for shareholder value creation much faster and more efficiently with our "East to West" strategy.

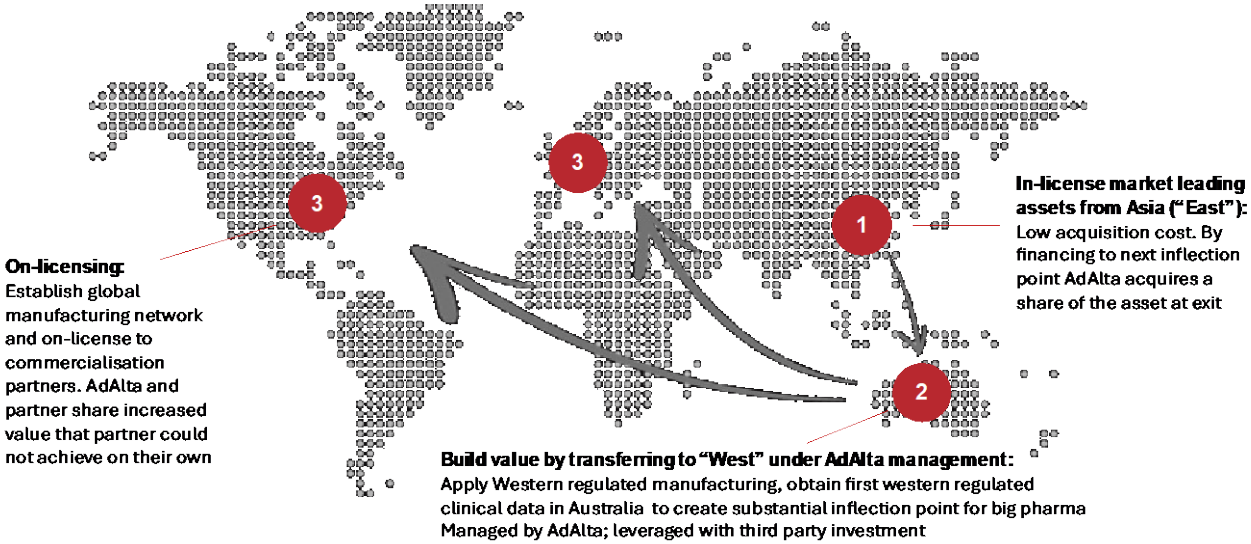
I am very excited about the potential of our "East to West" strategy and look forward to providing investors with further updates as we finalise selection and acquisition of the first assets."

BACKGROUND

AdAlta's "East to West" strategy provides leverage to Asian health care sector innovation

AdAlta's "East to West" cellular immunotherapy strategy is to in-license clinical stage, highly differentiated cellular immunotherapies for solid cancers from the "East" (Asia) and provide a pathway for these groundbreaking products to access "Western" markets by establishing manufacturing and conducting first clinical trials under a USA FDA IND in Australia. This then prepares these products for on-licensing to larger biopharmaceutical companies at substantially enhanced valuations. AdAlta acts as a force multiplier for Asian innovators. The business model is illustrated in Figure 1.

Figure 1: *Valuation upside from becoming a force multiplier for Asian partners*



This strategy leverages the rich innovation in Asia in biotechnology generally and cellular therapies in particular. Global efforts to tap this innovation was a key theme at the recent JPM Morgan Healthcare Week[2] (see box). 41% of global cellular immunotherapy developers and 61% of all clinical trials are located in Asia.[3] Making this innovation available to Western patients remains challenging: large biopharma companies resist

[2] A series of linked conferences held in San Francisco, USA 13-16 January 2025

[3] Alliance for Regenerative Medicine, Developer Data Report Q3 2023. Includes all companies developing gene modified cell therapies and cell-based immuno-oncology products by headquarter region; GlobalData, Pharma Intelligence Centre, Clinical Trials Database (accessed 5 April 2024). Includes all adoptive cell therapies (T cell immunotherapies, NK cell immunotherapies and tumour infiltrating lymphocytes. Includes all ongoing clinical trials. Multinational trials are included in each country in which they are conducted

the opportunity costs and complexity of transacting with Asia and want clinical data in more diverse populations, and many Asian companies lack the financial and operational skills to deliver this.

AdAlta's "East to West" strategy aims to provide a pathway across this gap, leveraging Australia's specific advantages in cell therapy manufacturing and clinical translation and utilizing AdAlta's clinical translation skills and a unique business model. Conducting a single clinical trial, if successful, makes each asset substantially more attractive to larger biopharmaceutical companies, thereby creating significant value for both AdAlta and our Asian partners.

Rise of Asian innovation highlighted at JPM Week

If you attended JPM Week, you couldn't miss it: the biopharma innovation emerging from China and Asia was the *topic of conversation. From in-licensing to newcos, deals are closing every week — reshaping the global biopharma landscape.*

BioCentury, 23 January 2025

This year's China story is going to be about the explosion of high-quality, fast-follow assets that are being picked up by richly-funded startup consolidators and by pharma companies hunting for better deals. It's a trend that has the potential to upend the venture capital investment thesis and how we value innovation.

Drew Armstrong, Endpoints News, 10 January 2025

The "East to West" strategy has multiple advantages

AdAlta's "East to West" cellular immunotherapy strategy seeks to bring the same transformative outcomes seen in blood cancers to patients with solid tumors. Using a disciplined asset selection process, AdAlta is identifying highly differentiated T cell immunotherapies designed to overcome the challenges of accessing and treating solid cancers and with potential to be significantly better than current best in class treatments. The solid cancer market is larger and less competitive than the blood cancer market.

Importantly, the "East to West" strategy provides AdAlta with a clear pathway to more effectively create a clinical pipeline via a growing catalogue of in-licensing agreements. These will see the creation of multiple capital efficient, short investment horizon assets, all with frequent clinical milestones. The Company believes that the valuation upside potential for each asset is substantial

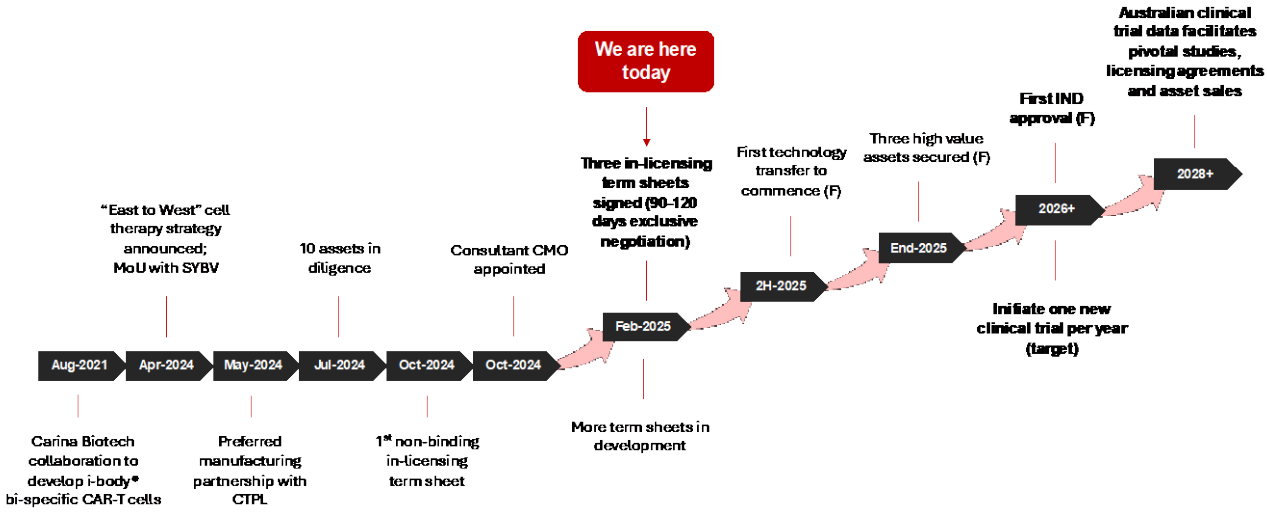
The "East to West" strategy is highly scalable, with the deep opportunity pipeline available providing a runway for AdAlta to evolve into a powerhouse in cellular immunotherapy through replicating product licensing by becoming a force multiplier for Asian partners. Interest from international investors indicates that AdAlta can own and manage these assets while leveraging significant third party capital to finance value creation.

"East to West" strategy momentum and future goals

AdAlta's "East to West" to West" cellular immunotherapy strategy was launched in the second quarter of calendar year 2024, when AdAlta announced collaborations with SYNthesis BioVentures (SYBV) and Cell Therapies Pty Ltd (CTPL).[4] A Chief Medical Officer has been appointed and the first non-binding term sheet was executed in October 2024.[5] The two non-binding term sheets announced today, in addition to the term sheet executed in October, mean the Company now has three clinical stage CAR-T cell therapy assets in advanced due diligence. Figure 2 summarises AdAlta's progress to date and target deliverables in the near term.

[4] See ASX announcements dated 8 April 2024 and 13 May 2024
[5] See ASX 4C in respect of September quarter 2024 dated 24 October 2024

Figure 2: *"East to West" strategy – progress and potential*



The drug candidates covered in these three term sheets were all developed in China and are:

- Term sheet 1: Armored CAR-T for lung, mesothelioma, ovarian, pancreatic and colorectal cancers, with clinical data from 32 patients showing efficacy substantially superior to current second line care and a rapid, non-viral vector manufacturing process;
- Term sheet 2: First-in-class CAR-T for advanced colorectal, lung and gastric cancers, with clinical data from 9 heavily pre-treated colorectal cancer patients including two cases of completely resolved malignant ascites, a safety "kill" switch and potential for multi-dosing without lymphodepletion;
- Term sheet 3: first-in-class CAR-T for gastric and gynaecological cancers with clinical data from ten patients suggesting superiority over current third line care.

Under these term sheets, AdAlta has between 90-120 days of exclusivity to complete confirmatory due diligence and negotiate definitive licensing agreements. Under definitive agreements, AdAlta will typically make upfront and milestone payments to partners of US$2-6.5 million, such payments to include supply of viral vectors and other raw materials and in some cases payment for further clinical studies in Asia. AdAlta will be responsible for completing technology transfer to Cell Therapies Pty Ltd or another suitable contract manufacturing organization, securing a US IND approval and conducting a Phase I clinical trial, most likely in Australia, to prepare each asset for Phase II studies (which could support regulatory approval depending on the results and indication). AdAlta will receive between 45-60% of the economic proceeds of a licensing transaction at the end of this Phase I study and will have the option to progress development itself or in co-operation with its partners. Each term sheet may or may not result in a definitive license agreement and terms may vary materially as a result of due diligence findings. Full details about each asset, including licensing terms, will be communicated when definitive agreements are executed.

AdAlta anticipates that further term sheets will be executed. The Company's aspirational targets are for three assets to be secured by the end of calendar year 2025, the first to commence technology transfer in the second half of 2025 and for one new asset to progress into clinical trials each year from calendar year 2026.

Strategic review has decided to accelerate "East to West" strategy, continue to monetise AD-214 through external investment and cease internal discovery research

The substantial momentum generated behind the "East to West" cellular immunotherapy strategy combined with the market sentiment and specific investor and partner feedback during JPMorgan Healthcare Week have validated the potential for this strategy to become a core growth driver for AdAlta. In addition to in-licensing discussions, AdAlta is positively advancing discussions with multiple venture capital firms and other investors in addition to SYNBV to finance this strategy through direct co-investment in a subsidiary.

Following a strategic review, the Board has determined that resources should be focused on executing this strategy as the most effective and capital efficient way to build a valuable clinical stage pipeline.

AdAlta's lead fibrosis disease drug candidate AD-214 will continue to be advanced into Phase II clinical trials through external partnerships and financing. AD-214 has been shown to be safe in Phase I clinical studies, effective in multiple animal and laboratory models of lung fibrosis (IPF, ILD) and kidney fibrosis (eg FSGS, lupus nephritis, Alport Syndrome) and has patent and market exclusivity protection beyond 2036. The next phase of the development program will prioritise completing development of a market preferred subcutaneous formulation of AD-214 and generating clinical efficacy data in patients. The Company continues to advance licensing discussions with regional and global biopharmaceutical companies for both lung and kidney indications as well as with financial investors in a potential spin-out company. While these discussions are progressing more slowly than hoped, the Company notes that interest in fibrosis assets remains high, as evidenced by Eli Lilly's license of MTX-463 (entering Phase II for IPF) from Mediar Therapeutics for US$99 million in upfront and near term payments and up to US$687 million in contingent milestones.[6]

AdAlta has also made the decision to cease internal R&D. This move will free A$0.7-0.85 million per year of cash operating costs that can be directed towards the Company's "East to West" cell therapy strategy from April 2025. Cash restructuring costs are not material. Other existing external partnerships will continue until expiry and do not require material AdAlta resources.

The acceleration of the "East to West" cellular immunotherapy strategy and the reallocation of R&D resources to support this strategy represents a significant growth for AdAlta beyond and in addition to the value already created in AD-214.

To view engage in discussion about this announcement visit AdAlta's InvestorHub here:
https://investorhub.adalta.com.au/link/vPnple

AdAlta will host a webinar to discuss this announcement on Tuesday, 11 February 2025 at 1200 AEST. Further details will be advised to ASX separately. Advance registration is required:
https://us02web.zoom.us/webinar/register/WN_RNWwB4MRRaeLxrjeb7ujOw

This ASX announcement has been authorised by the Board of AdAlta Limited.

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About AdAlta

AdAlta (ASX: 1AD) is a clinical stage biotechnology business addressing the need for effective cellular immunotherapies for the treatment of solid cancers.

Through its 'East to West' strategy, the Company is integrating Asia's prowess in T cell therapy development with the efficiency and quality of Australia's clinical and manufacturing ecosystem to create a pathway connecting 'Eastern' innovation in cellular immunotherapies with 'Western' regulated markets and patients.

[6] 10 January 2025 https://www.mediartx.com/wp-content/uploads/2025/01/MediarTx-PRESS-RELEASE_1-10-25.pdf

AdAlta in-licenses products from Asian originators and invests to establish US FDA regulated manufacturing and conduct Phase I clinical studies with potential to position each product for on-licensing to larger biopharmaceutical companies for potential registrational studies and commercialization.

AdAlta implements a disciplined approach to asset selection focused on highly differentiated T cell therapy products supported by clinical data in solid cancers. The company adopts a capital efficient business model delivering a rapid return on investment in each project that is replicable and provides opportunities to scale across multiple products.

Solid tumours account for 90% of cancers yet remain underserved by current cellular immunotherapies. AdAlta aims to dominate this high-growth segment. The cellular immunotherapy market is projected to grow at a compound annual growth rate of 34% to reach US$20.3 billion by 2028.

AdAlta's first in class fusion protein, AD-214, takes a whole new approach to fibrotic diseases of the lung and kidney, such as the degenerative and fatal Idiopathic Pulmonary Fibrosis. Following demonstration of efficacy in multiple animal models of disease and two successful Phase I clinical studies, AD-214 is available for partnering.

To learn more, please visit: www.adalta.com.au

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