

#### ASX Announcement | 10 January 2025 AdAlta Limited (ASX:1AD)

# AdAlta to present at Biotech Showcase as part of JPMorgan Healthcare week

AdAlta Limited (ASX:1AD) ("AdAlta" or "the Company"), developer of the novel protein and cell therapeutic products for fatal diseases is presenting at Biotech Showcase 2025 in San Francisco as part of JPMorgan Healthcare Week. This is one of the year's biggest investment and partnering weeks for the biotech sector.

CEO and Managing Director, Dr Tim Oldham's presentation will highlight the substantial progress being made towards implementing AdAlta's "East to West" cellular immunotherapy growth strategy and showcase lead asset, AD-214, which is bringing a whole new approach to fibrotic diseases such as Idiopathic Pulmonary Fibrosis (IPF) and is now ready for partnering and co-development investment. Both these strategies will be further advanced during JPMorgan Healthcare Week from 13-16 January in San Francisco, USA.

Details of Dr Oldham's presentation are:

Title: Developing novel protein and cell therapeutics for fatal diseases

Time: 4:00PM US Pacific Time on 13 January 2025 (11:00AM AEST on 14 January)

Venue: Yosemite A, Hilton Hotel San Francisco Union Square

A copy of the presentation is attached.

For a video of the presentation and opportunity to engage in a virtual discussion see: <u>https://investorhub.adalta.com.au/link/oPBGOy</u>

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

#### For further information, please contact:

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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.

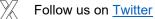
The i-body® technology mimics the shape and stability of a unique and versatile antigen binding domain that was discovered initially in sharks and then developed as a human protein. The result is a range of unique proteins capable of interacting with high selectivity, specificity and affinity with previously 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's lead i-body® enabled candidate is AD-214. At any time, 500,000 patients with lung fibrosis (IPF) face death from inability to breath, despite spending US\$4.3 billion per year on pharmaceutical therapies. Fibrosis can affect all organ systems and around 45% of all western country deaths have a fibrotic disease component. AD-214 is taking a wholly new approach to treat IPF and other fibrotic diseases. AD-214 is a first in class (first to utilize this mode of action) molecule and has been shown to be safe in Phase I clinical studies and effective in multiple animal and laboratory models of fibrotic disease. 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. It has appointed Cell Therapies Pty Ltd, Australia's leading manufacturer of cell and gene therapies, as AdCella's preferred manufacturer.

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

#### For more information



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# Developing next generation cell and protein therapeutics for fatal diseases

AdAlta Limited (ASX:1AD)

Next generation cell and protein therapeutics for fatal diseases

**Investor Presentation** 

January 2025



### **Disclaimer**



Investment in AdAlta is subject to investment risk, including possible loss of income and capital invested. AdAlta does not guarantee any particular rate of return or performance, nor do they guarantee the repayment of capital.

This presentation is not an offer or invitation for subscription or purchase of or a recommendation of securities. It does not take into account the investment objectives, financial situation and particular needs of the investor. Before making any investment in AdAlta, the investor or prospective investor should consider whether such an investment is appropriate to their particular investment needs, objectives and financial circumstances and consult an investment advisor if necessary.

This presentation may contain forward-looking statements regarding the potential of the Company's projects and interests and the development and therapeutic potential of the company's research and development. Any statement describing a goal, expectation, intention or belief of the company is a forward-looking statement and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those inherent in the process of discovering, developing and commercialising drugs that are safe and effective for use as human therapeutics and the financing of such activities.

There is no guarantee that the Company's research and development projects and interests (where applicable) will receive regulatory approvals or prove to be commercially successful in the future. Actual results of further research could differ from those projected or detailed in this presentation. As a result, you are cautioned not to rely on forward-looking statements. Consideration should be given to these and other risks concerning research and development programs referred to in this presentation.

### **AdAlta overview**



	Specialist in next- generation cell and protein therapeutics for fatal diseases	"East to West" cell therapy strategy to position company for scalable growth in a high value rapidly growing market	<ul> <li>Leading in cellular immune therapies for solid cancer</li> <li>First assets under late- stage due diligence</li> <li>Team and network in place</li> <li>Distinctive positioning and risk profile</li> </ul>	
14-Nov-23 14-Feb-24 14-May-24 14-Aug-24	14-Nov-24			
Volume ——Price	14-Nov-24 %	Attractive valuation		
				Phase I complete:
■ Volume — Price Largest shareholders (14 Nov 2024)**	%	Attractive valuation A\$11.0m market capitalization	AD-214, a new	Safety established
Largest shareholders (14 Nov 2024)** Sacavic Group	% 15.8	A\$11.0m market	AD-214, a new approach for fibrotic	<ul><li>Safety established</li><li>Compelling pre-clinical</li></ul>
Largest shareholders (14 Nov 2024)** Sacavic Group Meurs Group	% 15.8 14.5	A\$11.0m market capitalization (ASX:1AD)	· ·	Safety established
Volume Price  Largest shareholders (14 Nov 2024)**  Sacavic Group Meurs Group Platinum International Healthcare Fund	% 15.8 14.5 12.7	A\$11.0m market capitalization (ASX:1AD) A\$8.5m EV +	approach for fibrotic	<ul> <li>Safety established</li> <li>Compelling pre-clinical data</li> </ul>
Volume —Price      Largest shareholders (14 Nov 2024)**      Sacavic Group      Meurs Group      Platinum International Healthcare Fund      FMI Pty Ltd atf Commonwealth of Australia	% 15.8 14.5 12.7 4.3	A\$11.0m market capitalization (ASX:1AD)	approach for fibrotic diseases, available for	<ul> <li>Safety established</li> <li>Compelling pre-clinical data</li> <li>Competitively well</li> </ul>

\*Market capitalization A\$11.0m at 15 November 2024 less 30 Sep 2024 cash \$1.9m plus \$0.6m drawn down from NLSC facility \*\*Based on 631.5m issued ordinary shares; does not include effect of 27.1m unlisted options or resolutions at 2024 AGM \*\*\* Access to remaining \$1.5m subject to approval by NLSC

### AdAlta strategy

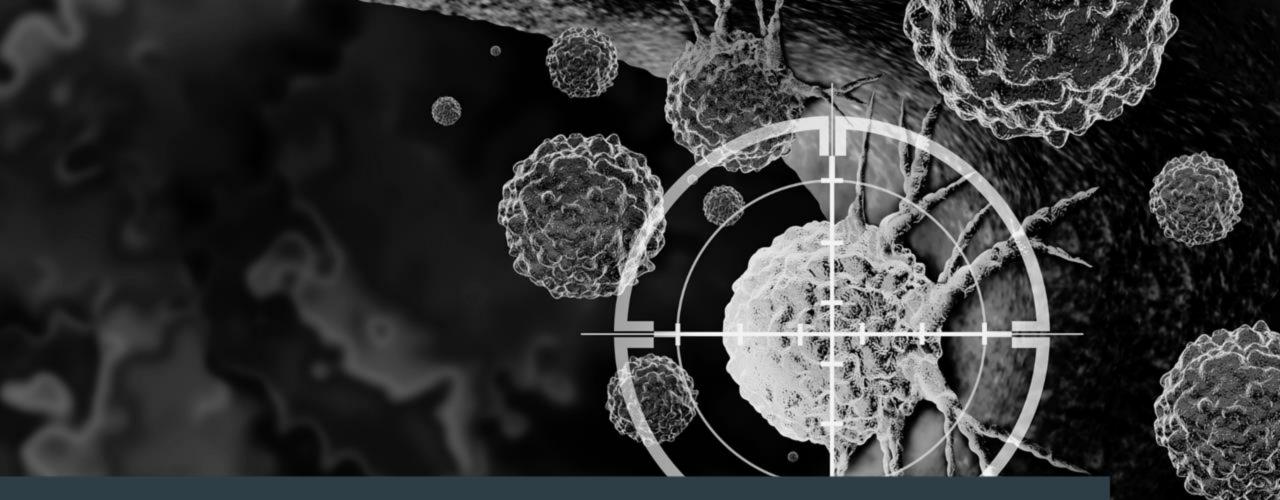


#### Description

- Addressing the need for effective cellular immunotherapies for solid cancers
- In-licensing first- or best-in-class, differentiated and clinical stage T cell therapies originating in Asia
- Generating first FDA-regulated clinical data using regional expertise in return for share of asset ownership
- Force multiplier for Asian partners
- De-risked, capital efficient, short investment cycle for investors seeking exposure to T cell therapies
- Seeking SPV investors
- Addressing the need for improved therapies for fibrotic diseases, including Idiopathic Pulmonary Fibrosis
- First-in-class molecule designed specifically for fibrosis using AdAlta's i-body® technology
- Extensive preclinical efficacy and mode of action data
- Demonstrated safety profile in Phase I clinical studies
- Seeking to out-license or co-invest to progress to Phase II clinical trials

"East to west" cellular immunotherapy strategy driving future growth and value creation

Transacting AD-214, a whole new approach to fibrotic disease, to unlock value created to date



# AdAlta's "east to west" cellular immunotherapy strategy

# "East to West" cellular immunotherapy strategic overview





- Cellular immunotherapy market projected to reach US\$20.3B by 2028 (34% CAGR)
- Solid tumours account for 90% of cancers yet remain underserved by current cellular immunotherapies
- Recent FDA approvals for solid tumour therapies have set the stage for growth
- Solid tumours projected to contribute >50% of revenues by 2030
- Asia leads in clinical trials (61%), providing a unique innovation pool
- AdAlta aims to dominate this high-growth segment with cutting-edge solutions

# Competitive Advantage

- Networks: Integrating Asia's rich innovation with the efficiency and quality of Australia's clinical and manufacturing ecosystem, and AdAlta's pre-IND to clinical translation skills
- Strategic sourcing: Disciplined asset selection
   focus on highly differentiated assets with clinical data in solid cancers
- Unique partnering model: asset financing for partners makes AdAlta a force multiplier and enables more valuable exit
- Capital efficient: modest investment focused on a single clinical trial for major inflection and short time to value realisation
- Scalable: replicable across multiple assets



- AdAlta's initial pipeline (under term sheet negotiation) features high-value assets targeting lung, colorectal, gastric cancer, and other solid tumours, leveraging advanced CAR-T technologies
- **Product A: Armored CAR-T** for lung, gynaecological, pleural and peritoneal cancers – IIT data shows ORR 40-75%
- Target B: First-in-class CAR-T for advanced colorectal and gastric cancers compelling preclinical results and efficacy signals in IIT studies
- **Target C: first-in-class CAR-T** for NPC, gastric and other epithelial cancers
- Pipeline includes over 10 high-potential therapies targeting various solid tumours

4.

## **Cellular immunotherapies are transforming cancer outcomes** New, multifunctional therapies are needed to address solid cancers

Therapy involves re-engineering patient's own immune cells to "see" cancer – living drug, single dose, potentially curative

**6 FDA-approved CAR-T** therapies since 2017 transforming outcomes:

Complete response rates: 83% r/r pALL, 51-65% r/r LBCL, 78% r/r MM<sup>4</sup>

... but so far only for blood cancers

CAR-T: >US\$2.6 billion earned in 2022,3 US\$20.3 billion forecast for 20281

>50% of CAR-T revenues from solid tumours by 2030<sup>2</sup>

90% of cancers are solid tumours: harder to target, harder to access, immune suppressive

Need new, multifunctional, cellular therapies

2024: FDA approved two cellular immunotherapies for solid cancer (melanoma, sarcoma)

Company websites and financial filings 3.

Kymriah, Yescarta and Carvytki prescribing information; r/r = relapsed/refractory; pAML - paediatric acute lymphoblastic leukemia, LBCL = large B cell lymphoma, MM = multiple myeloma

https://www.fda.gov/vaccines-blood-biologics/approved-blood-products/amtagvi; https://www.fda.gov/vaccines-blood-biologics/aucatzyl 5.



Chimeric Antigen Receptor (CAR) T cell therapy: A remarkable breakthrough in cancer treatment

#### CAR T-cell therapy in Southampton hailed by cancer patient

8 February 2024 By Alastair Fee, Health correspondent, BBC South

> The Boundless Potential of CAR T Cell Therapy, From Cancer to Chronic and Common Diseases: A Q&A with Carl June

August 22, 2023 | by Meagan Raeke

#### FORRES VINNOVATION VIEALTHCAR

Newly Approved Cell Therapy For Advanced Melanoma, Amtagvi, Is A Potential Breakthrough

> FDA signs off on Adaptimmune's Tecelra as the first engineered cell therapy for a solid tumor

Aug 2 2024 8-56a





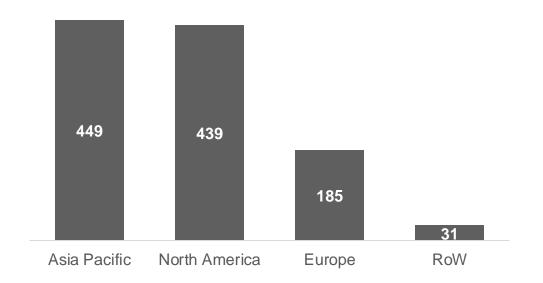
Grandview Research, "T-cell Therapy Market Size, Share & Trends Analysis" Feb 2021

Polaris Market Research, "CAR-T Cell Therapy Market Share, Size Trends, Industry Analysis Report", June 2021 2.

# The problem: The rich Eastern hemisphere cellular immunotherapy pipeline is not reaching western markets

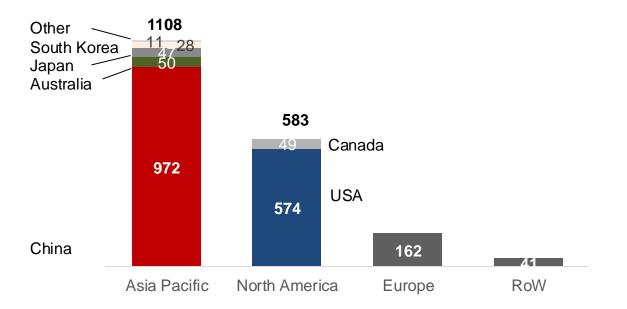






- 41% of developers, 61% of clinical trials in Asia Pacific
- Dominance of China in clinical trials reflects efficiency of Investigator Initiated Trials (IITs) to generate early clinical proof of concept
- Number of newly identified CAR-T therapies from Chinese developers has doubled every year since 2014

# **Cellular immunotherapy clinical trials 2024**<sup>2</sup> *n* = 1804



 Lack of capital, experience, networks plus geopolitical challenges are hampering flow of innovation from Asia to FDA and EMA regulated markets

<sup>1.</sup> 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

## Australia has a well-developed cell therapy delivery ecosystem<sup>1</sup>





#### **Clinical delivery capability**

- 138 cell and gene therapy trials to date
- **55** institutions treating patients with cell and gene therapies
- **25** sites approved for commercial CAR-T delivery
- 3 commercial approvals for CAR-T products
- Clinical trial costs 25-50% cheaper than US

#### Manufacturing and supply chain capability

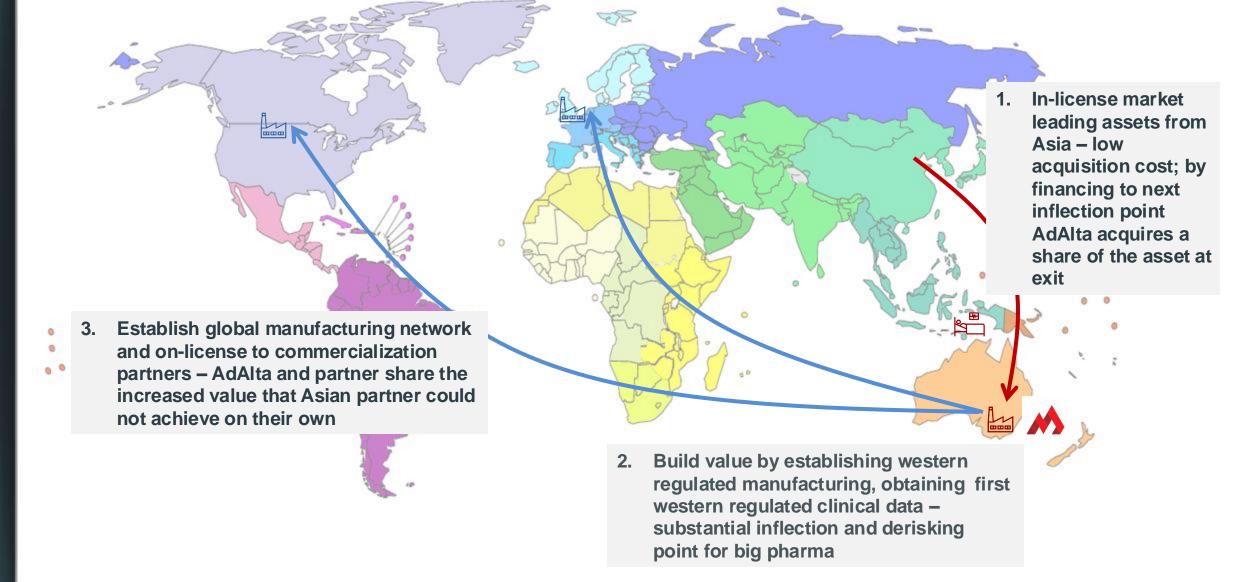
- Several cGMP cell therapy manufacturing facilities
- Cell Therapies Pty Ltd approved for commercial CAR-T supply by TGA and Japan PMDA
- Viral Vector Manufacturing Facility Pty Ltd being established
- Plasmid DNA (vector starting material) CDMO

#### Innovation and translation

- >20 companies developing advanced therapeutics
- Cell and Gene Catalyst to drive ecosystem
- R&D Tax Incentive to further leverage cost advantages

# AdAlta's solution and business model: be a force multiplier for Asian partners





# **Competitive advantage**

#### Strategic asset sourcing discipline

- T cell therapies for solid cancers
- Differentiated, multi-functional product design
- Clinical data in hand (safety, efficacy)
- Manufacturable at scale
- Best/first-in-class potential

#### Network and ecosystem advantages

- Mining Asian innovation
- Utilising Australian translational and manufacturing excellence
- Leveraging Australian cost advantage over US

Non-dilutive asset financing

Highly

scalable

- Generate all important FDA regulated clinical data at no cost to partner
- Partner maintain control of asset; benefits from value inflection

#### Capital efficient and risk managed



- Defined investment in clinically derisked asset
- Short timelines to value creation: ~3 year investment horizon per asset
- All funds used to add value to asset, not acquire historical IP
- Leveraging Australian R&D Tax Incentive

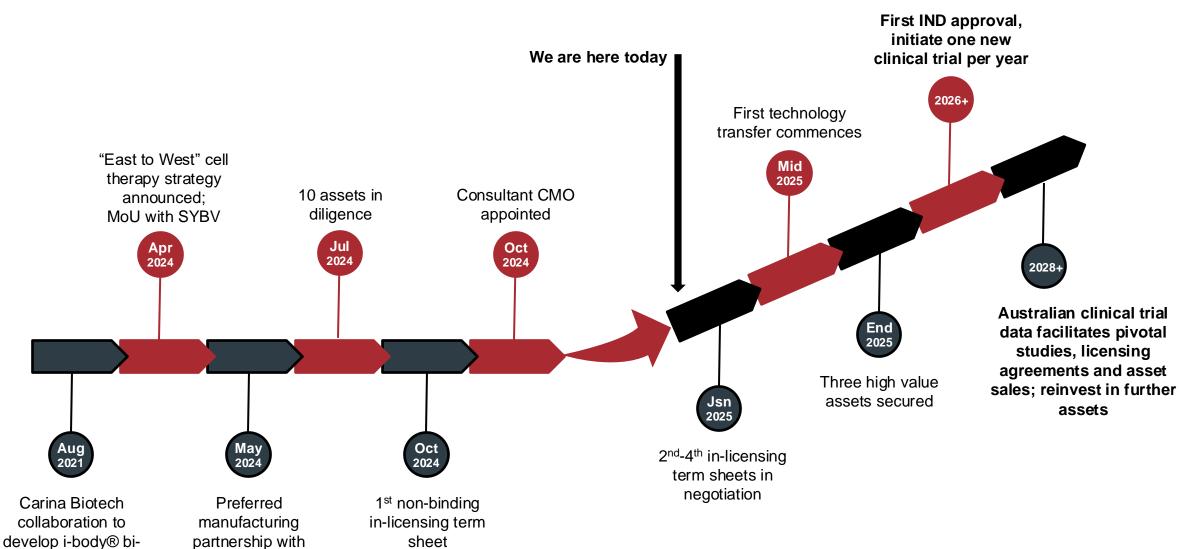
### **Progress and potential**

specific CAR-T

cells

CTPL





# The market: Phase I CAR-T cell therapy transactions (comparators at AdAlta exit)



Date	Drug(s)	Licensor	Licensee	Deal stage	Lead indications	Total value (US\$m)	Upfront (US\$m)
Nov-23	DLL3 targeting autologous CAR-T cell therapy	LEGEND BIOTECH	U NOVARTIS	Phase 1 (ongoing; US)	SCLC, LCNEC	1110	100
Aug-23	In vivo CD19 CAR-T cell therapy		₩ IMUGENE	Phase 1b (ongoing; US, AUS)	r/r B-cell ALL, r/r B-cell NHL	227	21
May-23	CD20 and CD19/20- directed autologous CAR-T cell therapy	Cellular Biomedicine Group	Janssen 🖌   Gehmen-Gehmen	Phase 1 (completed; China)	B-cell NHL, Follicular lymphoma, mantle cell Lymphoma, DLBCL	n/a	245
Jan-23	CART-ddBCMA	ARCELLX	Kite A GILEAD Company	Phase 2 (ongoing; US)	Multiple myeloma	n/a	325
Dec-20	Mesothelin-targeted autologous and allogeneic CAR-T cell therapy	\rm 🔥 Atara Bio	BAYER BAYER ER	Phase 1 (ongoing for autologous therapy; US)	Peritoneal / pleural mesothelioma	670	60
Sep-20	Chlorotoxin CAR T Cell Therapy	Cityof Hope	CHIMERIC THERAPEUTICS	Phase 1 (ongoing; US)	Astrocytoma, GBM	81.4	10

value 80
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# Building a powerhouse in cellular immunotherapy





# Providing a pathway for "Eastern" innovation in cellular immunotherapies to reach "Western" regulated markets and patients

Investing to establish first western manufacturing and clinical data creates a substantial value inflection for AdAlta and its partners



#### Focused exclusively on T cell therapies for solid cancers

First-in-class and best-in-class assets, less competitive and larger markets than hematology, T cells still the most potent and proven cellular immunotherapy platform



#### Capitalising on regional advantages

Asia's innovative T cell therapies designed to overcome the critical challenges accessing and treating solid cancers and Australia's specific advantages in manufacturing and clinical translation



#### Robust, disciplined asset selection

Focused on innovation and novelty, manufacturability, evidence of clinical activity in humans and US IND-readiness; first term sheet signed, three more in negotiation



#### Positioned for rapid return on investment

Establishing manufacturing and conducting a single clinical trial makes each asset substantially more attractive to larger industry partners



#### Highly scalable

Deep opportunity pipeline creates potential to build a powerhouse in cellular immunotherapy by replicating product licensing



# AD-214: a new approach to fibrosis available for partnering

# The need: fibrotic diseases, including Idiopathic Pulmonary Fibrosis (IPF) have no good outcomes today



#### IPF market is underserved today

- Two existing therapies generated US\$4.3b in 2022
- They slow but do not halt progression and do not significantly extend life expectancy
- Their side effects result in 30-50% of patients discontinuing therapy after one year

#### **IPF** market will grow

- 2% pa growth in prevalence
- 4-6% growth in market size
- US\$5.1b market by 2029
- US\$136,000 pa cost of treatment in US

"... sadly I am one of a few who can actually relate to the lived experience with and without IPF ..."

"You see our symptoms are basically an ongoing internal struggle to breathe freely ... and it's invisible to all, including family, friends and the general community."<sup>4</sup> THE LONG KAYAK **Current IPF treatments** 

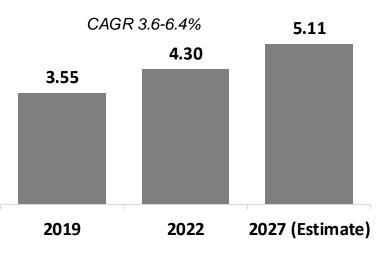


#### Esbriet" (pirfenidone) tablets 801mg reprovement of rokum Rooty 90 tablets Generative

Roche

Genentech

#### Global IPF sales (US\$ billion)<sup>1</sup>



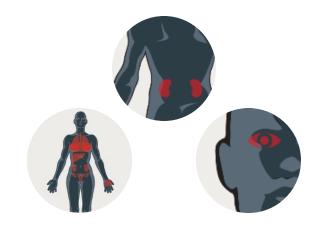
# Many other fibrosis market opportunities

Every organ vulnerable:

- Lung (US\$4b)
- Kidney (US\$10b)
- Eye (US\$15b)
- Cancer (US\$1b each)<sup>2</sup>

#### New drivers of incidence

- "Long COVID"3
- Re-emergence of silicosis



<sup>1</sup> GlobalData, Idiopathic Pulmonary Fibrosis: Competitive Landscape, April 2023; Roche and Boehringer Ingelheim financial reports, AdAlta analysis <sup>2</sup> GlobaData, disease analysis reports

<sup>3</sup> PM George, et al, "Pulmonary fibrosis and COVID-19: the potential role for antifibrotic therapy", Lancet published online May 15, 2020.

4 Bill van Nierop, https://www.facebook.com/kayakforlungs 28 September 2023

OR LUNGS II

# AD-214 has a compelling value proposition



#### Investment to date has built strong value proposition

# First in class molecule targeting established mode of action in fibrotic disease

 Competitively positioned as only antibody-like therapeutic entering late-stage development pipeline

# Pre-clinical efficacy in multiple animal models of fibrotic disease – derisks clinical studies in US\$b indications

- ✓ Led by Idiopathic Pulmonary Fibrosis (IPF): TAM US\$4.3b
- Multiple US\$b indication potential: kidney, eye, cancer

#### Phase I successfully completed (two studies)

✓ Well tolerated, evidence of target binding

#### Clinically viable dosing regimen

- Intravenous (IV) every 2 weeks established
- ✓ Subcutaneous (SC) every week feasible
- Models linking PK/PD and preclinical efficacy to establish dose

#### Strong intellectual property, regulatory position

- Patents protecting asset to 2036 and beyond
- ✓ US FDA Orphan Drug Designation for IPF
- ✓ 10-12 years market exclusivity (US, EU)

#### **Product development priorities**

# 1. Generate clinical proof of concept (efficacy)

- Demonstrate efficacy signals in patients
- IV or SC administration
- Substantially increases number of potential licensing partners

#### Design and execute clinical strategy in IPF patients

# 2. Develop market preferred formulation

- Weekly SC preferred over two weekly IV
- Enhanced market share, reduced COGS
- Achieves commercial ready COGS

# Develop formulation, integrate into clinical trials

Seeking out-licensing or third party investment to unlock next level of value

Advisors engaged; pipeline of active discussions

# AD-214 offers a competitive and differentiated product profile compared with leading disease modifying candidates



Product attributes	AD-214	BI-1015550	BMS-986278	Bexotegrast
Sponsor		Boehringer Ingelheim	( <sup>III</sup> ) Bristol Myers Squibb	PLIANT
Development stage	Phase I/II	Phase III	Phase III	Phase II
Format	Antibody IV every 2 weeks/SC weekly	Small molecule Oral twice daily	Small molecule Oral twice daily	Small molecule Oral once daily
Mode of action	CXCR4 antagonist	PDE4 inhibitor	LPAR1 antagonist	Dual avb1/6 integrin inhibitor
Novel pathway, no prior failures	$\bigcirc$	$\bigcirc$	$\bigotimes$	$\bigcirc$
Antibody precision	$\bigcirc$	$\bigotimes$	$\bigotimes$	$\bigotimes$
Potential synergies with marketed products	$\bigcirc$	$\bigotimes$	$\bigotimes$	$\bigotimes$
ODD (US FDA)	$\bigcirc$	$\bigcirc$	$\bigotimes$	$\bigcirc$
Available/ accessible for partnering	$\bigcirc$	$\bigotimes$	$\bigotimes$	$\bigcirc$

AD-214 difference:

- Novel mode of action set up for combination therapy with all other agents
- Safety profile supportive of combination use
- One of only three products targeting a novel disease modifying pathway with no prior clinical failures
- Only product offering antibodylike precision
- Evidence it can be more than additive to some therapies

# The value: pharma companies actively licensing IPF assets



Date	Licensor/target	Licensee/acquirer	Transaction	Upfront payment to licensor^^	Contingent milestones	Clinical Phase at transaction	
Aug-22	KINIKSA	Genentech A Member of the Roche Group	License	US\$100m	US\$600m	2 complete	
Apr-20		HORIZON	Acquisition*	US\$45m	Not disclosed	2a complete	
Nov-19	Promedior	Roche	Acquisition	US\$390m	US\$1,000m	2 complete	
Jan 23	Ҟ DAEWOONG	创新进中国 CSPharmaceuticals	China only license	US\$76m^	US\$240m	2 underway	
Feb 23	🔀 Redx	Jounce	Acquisition#	US\$425m	N/A	2a underway	
Nov-21		BIOTECH ACQUISITION COMPANY	Acquisition#	US\$353m	N/A	2 (Ready)	Pha
Nov-20	OncoArendi Therapeutics	<b>Galápa</b> gos	License	€25m	€295m	2 (Ready)	AD-214 is Phase II ready
Sep-21	Syndax 🌮	l cyte	License	US\$152m	US\$450m	2 (Ready)	is eady
Feb-21	東德制药		License	Not disclosed	US\$517.5m	1 underway	
Jul-19	bridgebio	Boehringer Ingelheim	License	€45m	€1,100m	1 underway	
Oct-22		abbvie	Acquisition	US\$255m	Not disclosed	Pre-clinical (+ platform)	
Pharma companies working on fibrosis (examples)       Boehringer Ingelheim       Genentech       Genentech       Genentech       Image Prizer       Image Prizer							

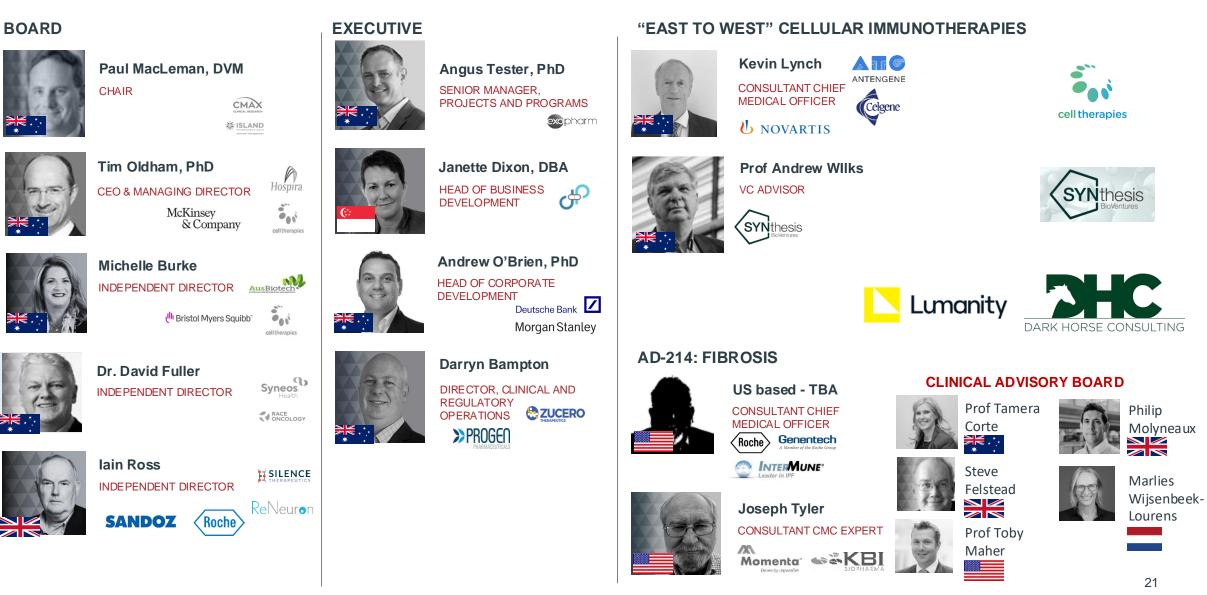
Source: Company press releases; \* Lead indication was diffuse cutaneous systemic sclerosis which usually evolves into IPF; # Did not complete; ^ Includes development milestones



# Summary

## **Experienced team with global reach**









"East to West" cellular immunotherapy growth strategy leveraging regional and business model advantages in high value, high growth sector; enabled by SYNthesis BioVentures and CTPL collaborations

AD-214, a new approach to fibrosis, available for partnering to unlock value created, heading to Phase II (US\$4.3b IPF market plus other indications), substantially de-risked by Phase I extension study clinical readouts



**Experienced team and global network**; differentiated discovery platform; established partnerships and pipeline



Strong and supportive institutional and large shareholder register, flexible financing



Attractive valuation relative to commercial potential of pipeline



Next generation cell and protein therapeutics for fatal diseases

AdAlta Ltd (ASX:1AD) Investor Presentation November 2024

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