

**22 October 2021**

**ASX Announcement**

**ADALTA PRESENTATIONS AT AUSBIOTECH INVEST AND BIO-EUROPE**

**MELBOURNE Australia, 22 October 2021:** AdAlta Limited (ASX:1AD), the clinical stage drug discovery company developing novel therapeutic products from its i-body platform is pleased to announce that CEO and Managing Director, Dr Tim Oldham, will present at the upcoming AusBiotech Invest and BIO-Europe Digital conferences taking place virtually from 25-29 October 2021.

Dr Oldham's presentations will draw on AdAlta's corporate overview (attached), incorporating results from most recent quarterly report. The presentations focus on AdAlta's wholly owned fibrosis/inflammation pipeline and co-developed immuno-oncology pipeline that demonstrate the power of the i-body platform for drug discovery. The video presentations will be available on demand throughout the conferences. The AusBiotech Invest presentation can also be found on the Company's website at: <https://adalta.com.au/investors/presentations/>.

Potential investors or partners attending either conference are invited to make contact to arrange 1:1 discussions on AdAlta's i-body platform, its fibrosis or oncology assets, or for a company introduction. Contact information for Dr Tim Oldham is available at the bottom of this announcement.

**About the conferences**

*AusBiotech Invest 2021*

AusBiotech is the leading Australian industry body representing and advocating for organisations doing business in and with the global life sciences economy. AusBiotech Invest is the largest life sciences conference in Australia. Networking and one-to-one meetings for the global life science network are available via this forum. In 2021 AusBiotech Invest will be held virtually from 25-29 October. <https://www.ausbiotechnc.org/>

*BIO-Europe Digital*

BIO-Europe Digital is one of the largest biotech partnering conference in Europe. BIO-Europe Digital plays a pivotal role in bringing global biopharma and investment leaders together, to build partnerships that facilitate innovation and medical breakthroughs. In 2021 BIO-Europe will be held digitally from 25-28 October. <https://informaconnect.com/bioeurope/>.

Authorised for lodgement by:

**Tim Oldham**  
**CEO and Managing Director**  
**October 2021**

## **Notes to editor**

### **About AdAlta**

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 protein 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 antigenbinding 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 has completed Phase I clinical studies for its lead i-body candidate, AD-214, that is being developed for the treatment of Idiopathic Pulmonary Fibrosis (IPF) and other human fibrotic diseases for which current therapies are sub-optimal and there is a high unmet medical need.

The Company is also entering collaborative partnerships to advance the development of its i-body platform. It has an agreement with GE Healthcare to co-develop i-bodies as diagnostic imaging agents against Granzyme B, a biomarker of response to immuno-oncology drugs, a program now in preclinical development. It also has a collaboration with Carina Biotech to co-develop precision engineered, i-body enabled CAR-T cell therapies to bring new hope to patients with cancer.

AdAlta's strategy is to maximise the products developed using its next generation i-body platform by internally discovering and developing selected i-body enabled product candidates against GPCRs implicated in fibrosis, inflammation and cancer and partnering with other biopharmaceutical companies to develop product candidates against other classes of receptor, in other indications, and in other product formats.

Further information can be found at: <https://adalta.com.au>

### **For more information, please contact:**

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# Corporate overview

October 2021

## 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's purpose

To use our unique i-body technology to create multiple novel therapeutics for debilitating diseases that have proven difficult to drug with traditional antibodies

## AdAlta today



- **i-body platform:** can create therapeutics addressing targets underserved by traditional antibodies



- **Fibrosis/inflammation: Lead asset AD-214** preparing for Phase II
  - US\$3b IPF market today, multiple indication potential
- **Second target in discovery**



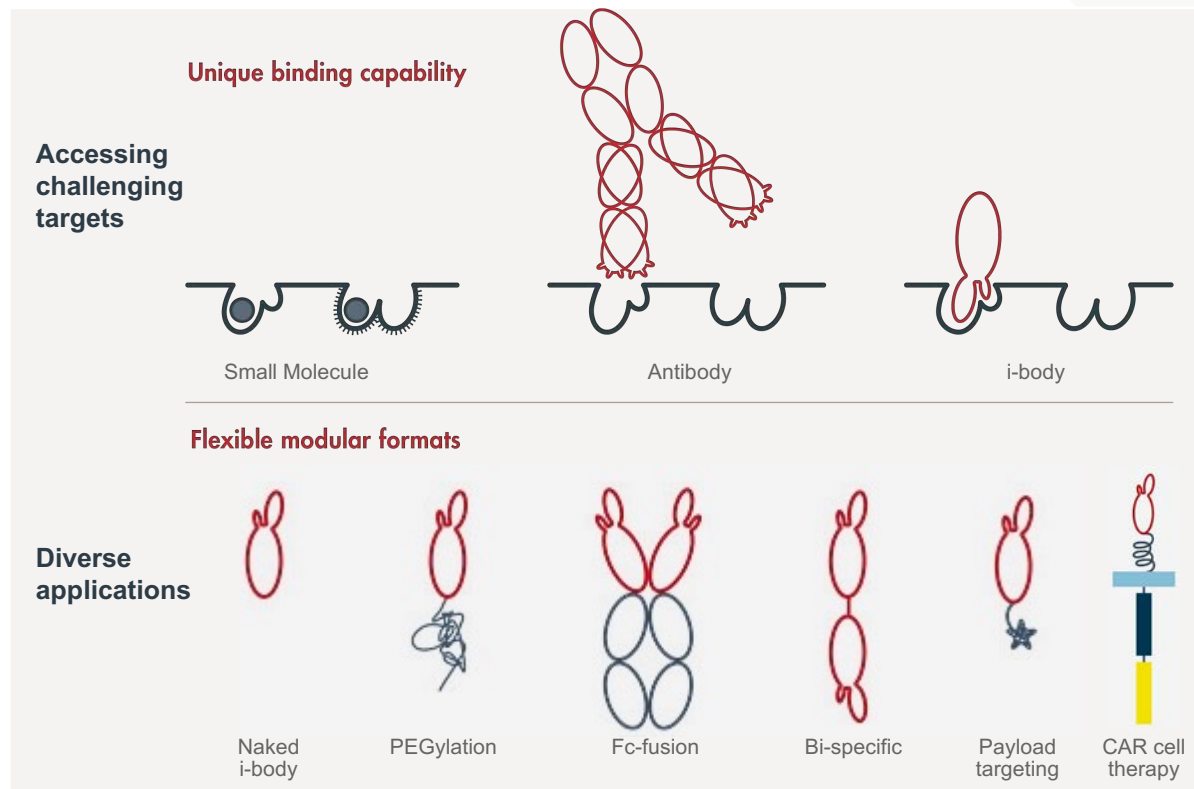
- **Immuno-oncology: two co-development collaborations**
  - GZMB PET imaging agent with **GE Healthcare**: US\$6.4b PET imaging agent market
  - i-body enabled CAR-T with **Carina Biotech**: US\$20b market by 2028



- **Continuing to build out pipeline** with additional programs: targeting 10 by 2023

# What is the i-body advantage?

All the selectivity and specificity of antibodies with greater versatility and tunability



## Small size, flexible binding domain

Confers unique binding capability for targets challenging traditional antibodies; enables modular drug design across diverse applications

## Minimising off-target side effects

Unique binding capability potentially allows greater selectivity and specificity, tunable affinity

## Multiple drug administration routes

Amenable to multiple administration routes (e.g. injection, inhalation and topical)

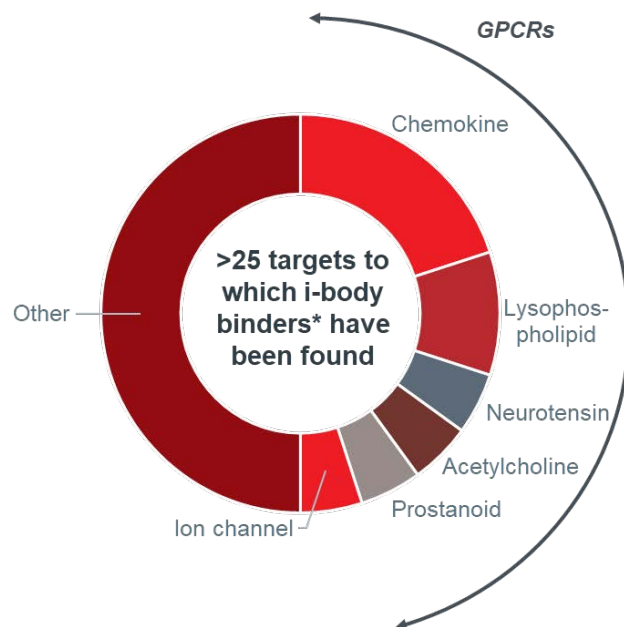
## Robust

Resilient to pH and temperature cycling

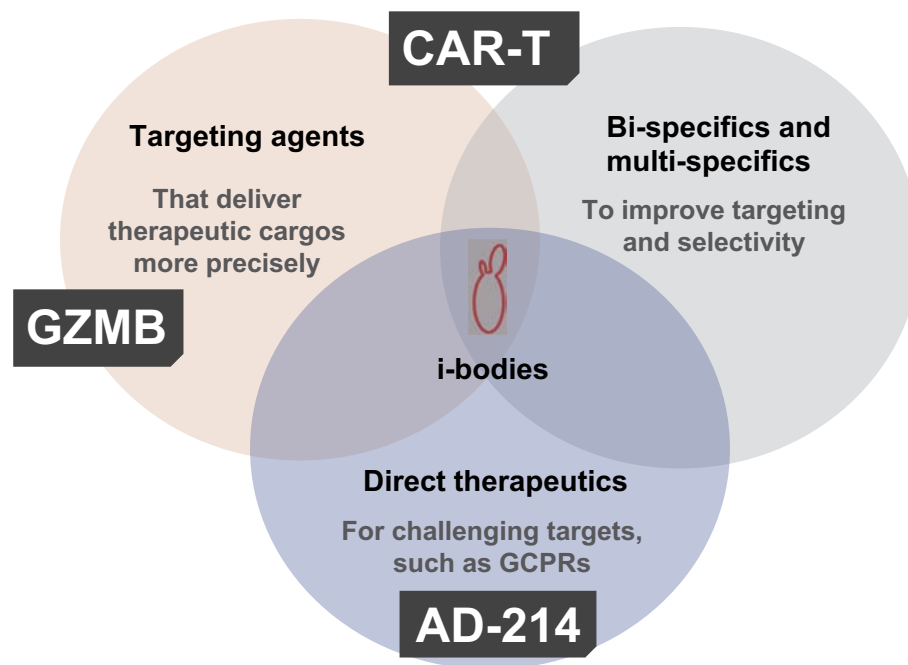
# An immensely powerful drug discovery platform

i-body technology can enable a wide range of therapeutic and diagnostic products

## Wide range of target classes



## Wide range of product formats





## Idiopathic Pulmonary Fibrosis (IPF)

AdAlta's first target, already a \$3b market, is a degenerative, fatal disease in dire need of improved treatment options: i-bodies have been designed to target a novel mode of action to address this medical need



In IPF, scarring and stiffening of the lungs **progressively and irreversibly reduces lung function**

Despite being poorly tolerated and having difficult side effects, the two current therapies sell **\$3b per year**

**3.8 years**  
median survival after diagnosis

**>300,000**  
people living with IPF,  
It is irreversible

**40,000**  
people die from IPF every year

**Burden of fibrotic lung disease  
following COVID-19 likely to be high.\***

**“Long COVID” is a developing issue – potentially further  
increasing the need for better anti-fibrotic drugs.**

\* PM George, et al, “Pulmonary fibrosis and COVID-19: the potential role for antifibrotic therapy”, Lancet published online May 15, 2020.

# AD-214: first in class treatment for fibrosis

## AD-214's initial focus is IPF

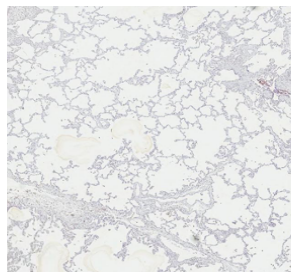
**First-in-class** (novel mode of action) treatment

Targets a receptor called **CXCR4**

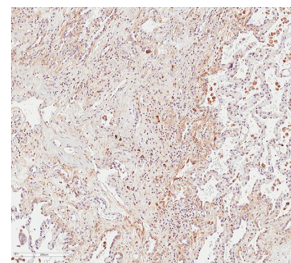
Initial focus is **Idiopathic Pulmonary Fibrosis (IPF)**, one of a group of **Interstitial Lung Diseases (ILDs)**

**Blocking CXCR4** reduces fibrosis in animal models

**Human Lung Tissue**



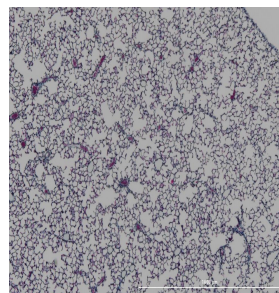
Normal



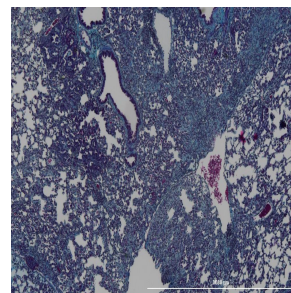
Diseased

*Brown stain shows increased amount of CXCR4 in fibrotic lung tissue*

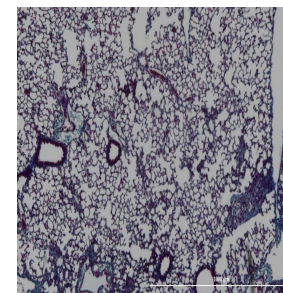
**Mouse model of lung fibrosis**



Normal mouse lung tissue



IPF mouse lung tissue\*



IPF mouse lung tissue + AD-214\*

*Purple stain shows amount of collagen (fibrosis)*

\* IPF tissue images taken 21 days after bleomycin (BLM) was administered to induce fibrosis; mouse treated with AD-214 received 10 mg/kg AD-214 every 4 days from day 8 after bleomycin administration.

## Phase I clinical and PET imaging inform dosing and route of administration

AD-214 is well tolerated in Phase I studies; PET imaging with radiolabelled AD-214 supports early transition to inhaled route of administration

### Intravenous AD-214 is well tolerated in single and multiple doses

- ▶ Phase I healthy volunteers: 42 single dose participants to 20 mg/kg; 8 multiple dose participants at 5 mg/kg
- ▶ No concerning immune responses, clinical sign or organ function results

### Target (CXCR4) binding observed with extended duration

- ▶ Clear markers of CXCR4 engagement observed (Phase I and PET imaging)
- ▶ Receptor occupancy sustained at high levels for extended periods

### Rapid liver distribution and clearance reduces bioavailability

- ▶ Consistent with pharmacokinetics and a first pass clearance mechanism
- ▶ More than half administered dose not available at target site of action

### Liver distribution does not appear to affect safety, efficacy profile

- ▶ Consistent with lack of localization to hepatocytes, observed changes in liver function or toxicity in toxicology and clinical studies
- ▶ Consistent with observed bleomycin mouse efficacy data


**Direct lung delivery (inhalation) of AD-214 could achieve a therapeutic dose at lower levels than intravenous delivery**

Alternate intravenous formulations to be evaluated for other indications



## Phase II planned with inhaled formulation

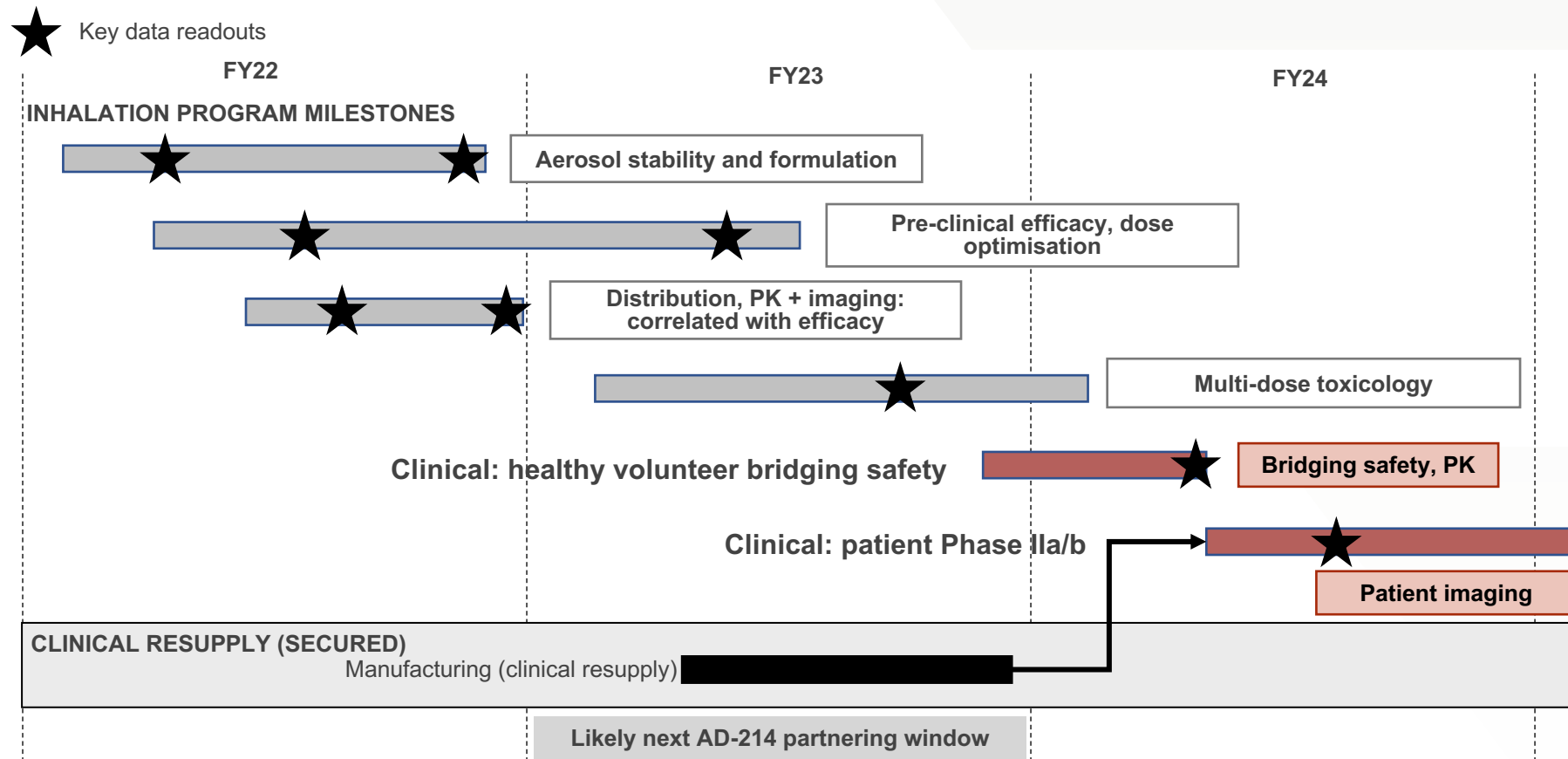
Delivery of AD-214 by inhalation has potential to improve bioavailability, be more convenient for patients, be more cost effective, and improve partnering flexibility



<b>Improved bioavailability</b>	<ul style="list-style-type: none"> <li>• AD-214 delivered direct to fibrotic areas</li> <li>• First pass liver clearance avoided</li> <li>• Dosing schedule flexibility to optimise receptor coverage</li> </ul>
<b>Greater patient convenience</b>	<ul style="list-style-type: none"> <li>• Self administration (no scheduled clinic visits; freedom of movement)</li> <li>• Less invasive</li> </ul>
<b>Enhanced cost effectiveness</b>	<ul style="list-style-type: none"> <li>• Lower drug dose means lower cost of goods</li> <li>• Lower healthcare costs for administration</li> </ul>
<b>Diversified partnering options</b>	<ul style="list-style-type: none"> <li>• Potential to partner AD-214 by indication using different routes of administration - broadens potential long term options</li> </ul>

## Key milestones to de-risk AD-214 development

Quarterly milestones to de-risk asset; extensive use of pre-clinical imaging; AD-214 partnering window from FY23



## AD-214: multiple indication extension options

Each additional indication could address multiple markets with U\$ billion potential

Data in tissue and animal models show that AD-214 may improve fibrosis across a range of fibrotic diseases and cancer:

**multiple indication extension potential**

**Indication specific formulations and routes of administration may enhance partnering potential**

- **LUNG (lead indication - inhaled):** Idiopathic Pulmonary Fibrosis with natural extension to Interstitial Lung Disease
- **EYE (intravitreal injection):** Wet-Age Related Macular Degeneration
- **CANCER:** 23 different cancers, enhancement of I/O drugs\*
- **KIDNEY:** Chronic kidney disease\*
- **LIVER:** NASH\*
- **SKIN (topical, local injection):** Hypertrophic scars



### Lung

IPF/ILD

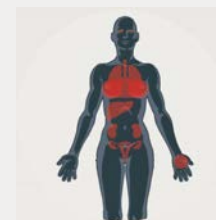
>US\$3b



### Eye

Wet-AMD

>\$15b



### Cancer

23 different cancers, I/O

>\$1b ea



### Kidney

RENAL FIBROSIS

>US\$10b



### Liver

NASH & CIRRHOSIS



### Skin

SCLERODERMA

\* Subject to development of a satisfactory, improved intravenous formulation.



## IPF partnering: valuable options as early as Phase I

IPF assets have recently yielded attractive deal terms at early stages of development – first partnering window for AD-214 in FY2023



Feb-21: License by Graviton  
*Phase I*  
**US\$517.5m milestones**



Jul-19 license by Boehringer Ingelheim  
*Phase I*  
**€45m upfront + €1.1b milestones**



Nov-20: Galapagos collaboration  
*Phase II ready*  
**€320m milestones**



Nov-19 acquired by Roche – *Phase II*  
**US\$390m upfront + US\$1b milestones**  
*[Aug-15 BMS option to buy*  
**US\$150m upfront + US\$1.25b milestones]**



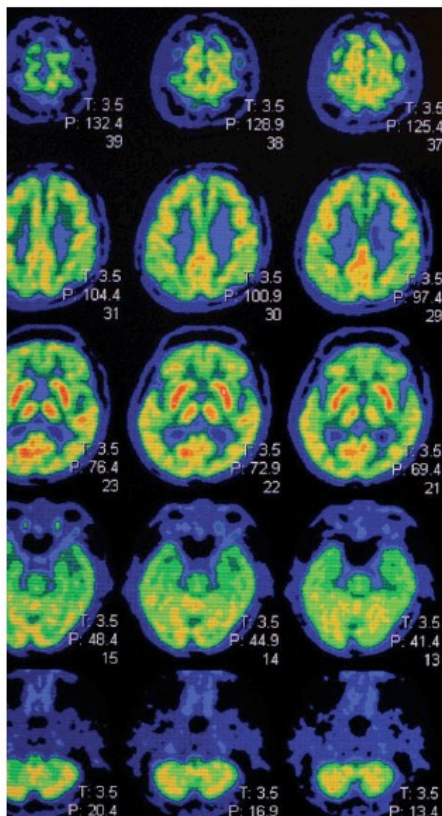
Aug-20: License by AstraZeneca  
*Preclinical*  
**Upfront US\$17m + milestones US\$360m**



Jan-20 platform license by Boehringer Ingelheim  
*Preclinical*  
**upfront undisclosed + US\$1b milestones**

## Immuno-oncology (I/O) PET imaging

**US\$6.4b PET imaging market: could help identify the 20-40% of patients who will respond to revolutionary I/O drugs faster**



Immuno-oncology (I/O) drugs  
**reactivate the patient's own  
immune system** to fight cancer

**US\$95 billion** I/O market<sup>1</sup>

Only **20-40%** of patients respond to I/O drugs<sup>2</sup>

**Granzyme B (GZMB)** is produced  
by immune cells to kill cancer

**Potential biomarker** of immune system  
activated by I/O drugs

PET imaging GZMB can help  
**identify responders early**

PET imaging agents have  
**short development time**

**US\$6.4 billion**  
PET imaging agent market<sup>3</sup>  
Largest products >US\$400m<sup>4</sup>

1. 2026 forecast by ResearchandMarkets.com, Immuno-Oncology - Market Analysis, Trends, Opportunities and Unmet Needs - Thematic Research, March 2021
2. P Sharma, et al, Cell 168(4) 707 (2017)
3. 2027 forecast by Global Industry Analysts, Imaging Agents: Global Market Trajectory and Analytics, April 2021
4. AD Nunn, J Nucl Med (2007) 169



## GZMB i-body asset: GE Healthcare co-development collaboration

**Second asset in pre-clinical development; and could generate royalty revenue sooner than a therapeutic due to shorter diagnostic development timelines**



### Unique i-body platform

- i-body discovery
- Manufacturing process development



GE Healthcare

### Leading global supplier of PET imaging equipment and tracers

- $^{18}\text{F}$  chemistry, final product manufacture
- Pre-clinical, clinical proof of concept
- Commercialisation

### Pipeline asset at no financial cost to AdAlta

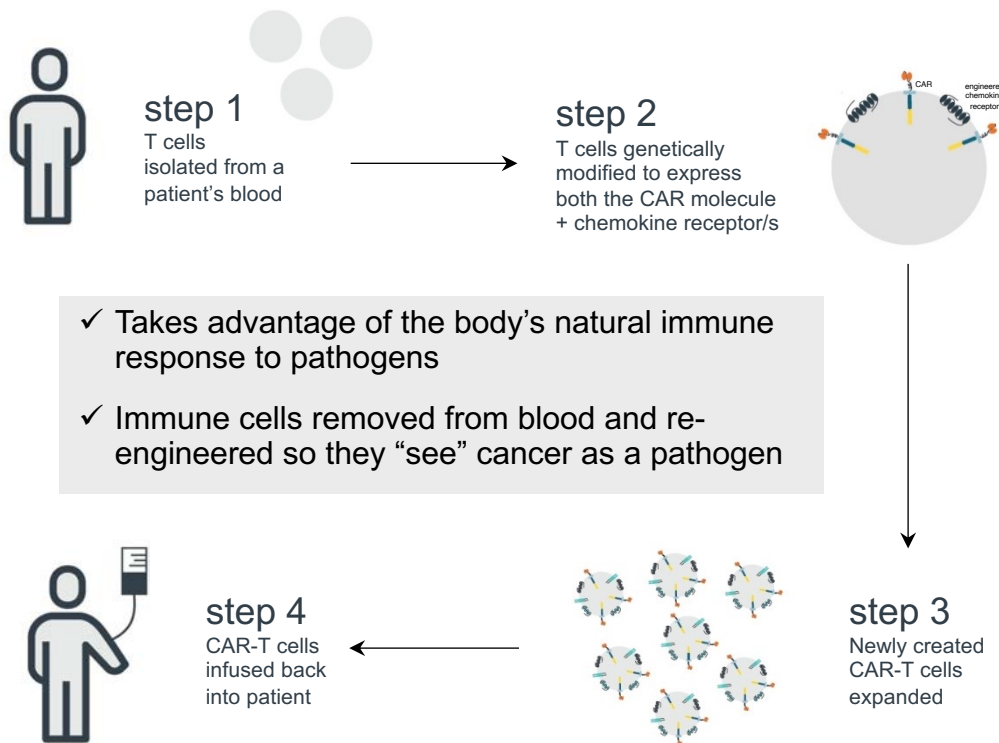
- AdAlta earns research fees, development and sales milestone payments and royalties on product sales
- A\$1.5 million revenue (milestones and research fees) earned to June 2021

### October 2021 status

- Panel of GZMB specific i-bodies identified
- Pre-clinical proof of concept studies underway
- Manufacturing development underway

# CAR-T therapies are revolutionising cancer treatment

Reprogramming a patient's own immune system to fight cancer is a fast growing market at the cutting edge of medicine



- ✓ Takes advantage of the body's natural immune response to pathogens
- ✓ Immune cells removed from blood and re-engineered so they "see" cancer as a pathogen

**>US\$1b** earned by CAR-T therapy products in 2020<sup>3</sup>

**2m** addressable patient population within next 10 years<sup>1</sup>

**US\$20.3b** revenue forecast for 2028<sup>1</sup>

**50%** solid tumour share of revenues by 2030<sup>2</sup>

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

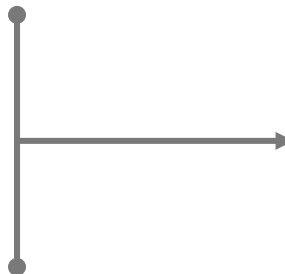
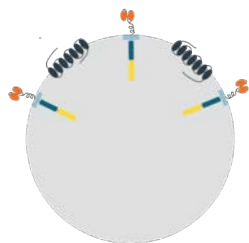
2. Polaris Market Research, "CAR-T Cell Therapy Market Share, Size Trends, Industry Analysis Report", June 2021

3. Yescarta and Kymriah market size estimates calculated from various publicly available sources. Estimates vary and different analyses may give different results.

## i-body enabled CAR-T assets: Carina collaboration

**Third program entering discovery to generate precision engineered CAR-T products providing new hope for patients with cancer**

**World-leading**  
proprietary **CAR-T**  
technologies for superior  
**access, potency and**  
**persistence**



To develop precision engineered, i-body enabled, CAR-T therapies, including bi-specific and dual CAR-T products, that provide new hope for patients with cancer

**Unique i-body** platform  
for exceptional **reach and**  
**targeting** capability



## Carina collaboration details

AdAlta and Carina will jointly develop up to 5 targets to create CAR-T, bi-specific CAR-T and dual CAR-T cell therapy products

### Up to 5 targets

- **Proof of principle already achieved** (*in vitro*)
- Targets not yet disclosed
- **Combine targets for bi-specific and dual-targeted CARs**



### Significant new, shared IP

- Share costs, research to *in vivo* proof of concept
- AdAlta + Carina will **jointly own collaboration IP**



### Post proof of concept commercialisation options

- Can continue to develop products together, progress independently or out license
- **Products** emerge from the collaboration at proof of concept



### Attractive deal space

- Biotech and immuno-oncology segment: very attractive deal space
- **Large biotech and pharma companies are actively sourcing CAR-T products**



## AdAlta assets and business model

Current strategy is based on leveraging the i-body platform to create i-body enabled assets that are wholly owned or co-developed. The pipeline is expanding to plan

### Co-developed assets



GE Healthcare

**Granzyme B** i-body enabled **PET imaging** agents for use in immuno-oncology

Pre-clinical



Precision engineered, i-body enabled **CAR-T** cells providing new hope for patients with cancer

Discovery

### Immuno-oncology theme

### Wholly owned assets



**Lead candidate: AD-214**  
First in class anti-fibrotic targeting CXCR4

Phase I  
Orphan Drug Designation for IPF



**Undisclosed target: GPCR for fibrotic disease**  
Discovery

One more target to be added in 2021

### Fibrosis and inflammation theme

### Platform



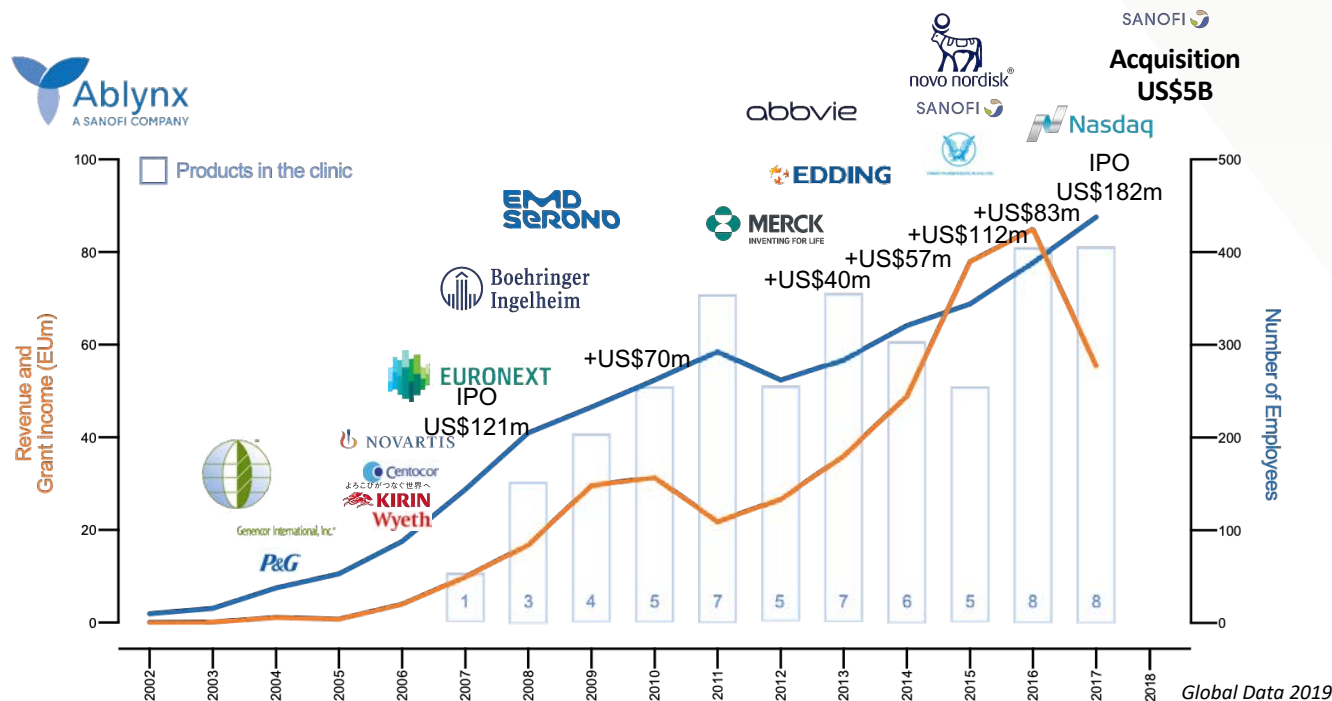
Patented, diverse i-body discovery platform:  
20 billion different i-bodies for drugging undruggable targets

## An expanding pipeline of i-body enabled products



# The potential of our strategy: Ablynx case study

Multiple internal and external assets drive value, attract partners



AdAlta is embarking on a similar journey

## GPCR platform exits

**HEPTARES**  
therapeutics

Feb-15 acquired by Sosei  
Phase Ib + 7 preclinical leads  
**US\$400m**

**receptos**

Jul-15 acquired by Celgene  
Ph II/III + GPCR platform

**US\$7.8b**

**Ablynx**  
A SANOFI COMPANY

Feb-18 acquired by Sanofi  
8 clinical, 37 preclinical candidates  
**€3.9b**

# Milestones for remainder of FY2022

## Milestones extended through end of FY2022

	AD-214	Other Assets
H1 2021	<ul style="list-style-type: none"> <li>✓ Orphan Drug Designation for AD-214 in IPF</li> <li>✓ Results of Phase I single dose studies in healthy volunteers</li> <li>✓ Phase I multi-dose studies in healthy volunteers commence</li> <li>✓ Japanese patent covering AD-214 granted</li> <li>✓ PET tracer pre-clinical development results</li> </ul>	<ul style="list-style-type: none"> <li>✓ Progressing the GE Healthcare collaboration from discovery to pre-clinical development</li> </ul>
H2 2021	<ul style="list-style-type: none"> <li>✓ Top line results of multi-dose studies in healthy volunteers</li> <li>✓ Pre-clinical data in additional indications</li> <li>• Preliminary stability of AD-214 following nebulisation</li> </ul>	<ul style="list-style-type: none"> <li>✓ Entering a second collaboration agreement (Carina Biotech)</li> <li>• Finalise research project outlines for initial Carina targets</li> <li>• Commencing development of two new i-body enabled internal pipeline assets (one commenced, one to go)</li> </ul>
H1 2022	<ul style="list-style-type: none"> <li>• Initial efficacy of inhaled AD-214 in IPF animal model</li> <li>• Imaging inhaled AD-214 in the lungs of healthy and fibrotic disease model animals</li> <li>• Inhaled dose and dose scheduling optimisation</li> </ul>	<ul style="list-style-type: none"> <li>• New i-body 2.0 IP filed</li> <li>• GE Healthcare preclinical update</li> <li>• First experimental results from Carina collaboration</li> </ul>



## Industry experienced leadership and advisors

Team with experience from discovery through manufacturing, clinical and commercialisation

Board	Executive	Scientific Advisory Board
 <p><b>Dr Paul MacLeman</b> <i>Chair</i></p>  	 <p><b>Tim Oldham, PhD</b> <i>CEO &amp; Managing Director</i></p>  	 <p><b>Brian Richardson</b> <i>Drug discovery and development expert</i></p> 
 <p><b>Liddy McCall</b> <i>Director (alt: Dr James Williams)</i></p>  	 <p><b>Dallas Hartman, PhD</b> <i>Chief Operating Officer</i></p>  	 <p><b>Steve Felstead</b> <i>Clinical development</i></p> 
 <p><b>Tim Oldham, PhD</b> <i>CEO &amp; Managing Director</i></p>  	 <p><b>Claudia Gregorio-King, PhD</b> <i>VP Clinical Product Development</i></p>  	 <p><b>John Westwick</b> <i>Pulmonary drug discovery and development</i></p> 
 <p><b>Dr Robert Peach</b> <i>Independent Director</i></p> 	 <p><b>Mick Foley, PhD</b> <i>Founding Chief Scientist</i></p>  	
 <p><b>Dr David Fuller</b> <i>Independent Director</i></p>  	 <p><b>Michael Rasmussen</b> <i>Consultant Medical Expert</i></p>  	

## Corporate snapshot

### Key financial details (18 Oct 2021)

ASX code	1AD
<b>Market capitalisation</b>	<b>A\$21.33m</b>
Share price (12 month closing range)	A\$0.087 (\$0.081 - 0.195)
12 month return	(33)%
Ordinary Shares (daily volume)	245,179,578 (497,778)
Unlisted Options	7,514,067
<b>Cash (30 Sep 2021)</b>	<b>A\$6.77m</b>

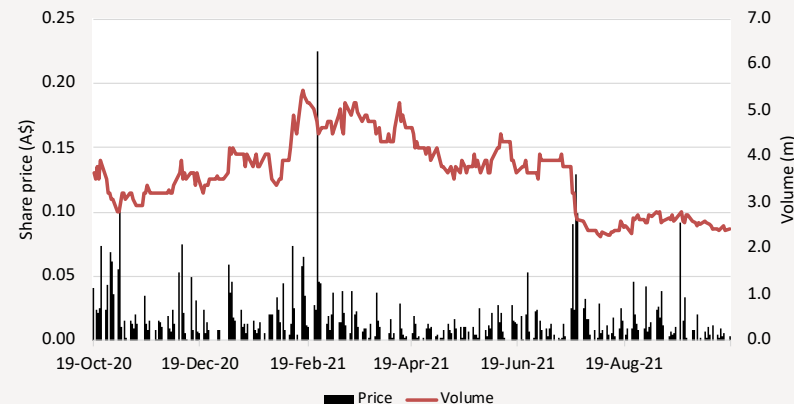
### Major shareholders (18 Oct 2021)

	%
Yuuwa Capital LP	22.0
Platinum Asset Management	11.6
Meurs Holdings Pty Ltd	7.3
Radiata Super Pty Ltd	3.1
Sacavic Pty Ltd	1.8
Other (1,567 total holders)	54.2
<b>Total</b>	<b>100%</b>

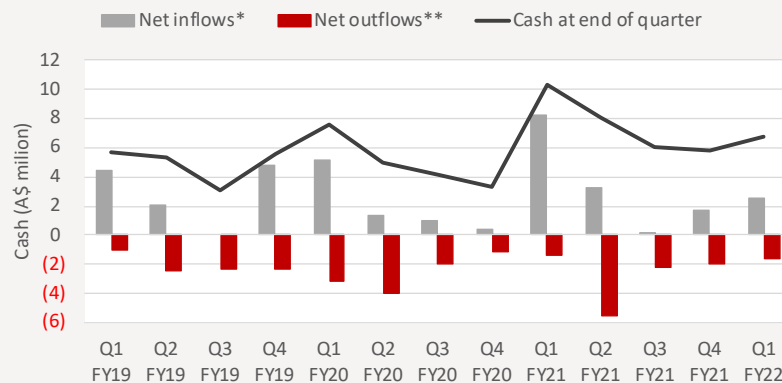
### Analyst Coverage

Edison  
Pitt Street Research  
Securities Vault

### Share price performance (last 12 months)



### Quarterly cash flows (A\$ million)



# Investment proposition



## i-body platform to create value

Patented, validated i-body platform for asset creation: designed for “difficult” targets, multiple modalities



## Fibrosis/inflammation

### Lead asset advancing to Phase II

AD-214: first-in-class, multiple indications  
*Phase I complete; clear path to Phase II in IPF*  
>\$3b market potential in first indication

+

**Discovery initiated on 2<sup>nd</sup> target**



## Immuno-oncology

### 2 x co-development collaborations to leverage platform

- ✓ GE Healthcare: PET imaging in I/O  
\$6b market
- ✓ Carina Biotech: CAR-T \$20b market



## Clear vision for growth

Build on existing clinical and commercial validation of platform and therapeutic knowledge to add internal programs, expand collaborations



## Leading expertise

Experienced drug development team in place



## Regular near-term news flow

AdAlta substantially undervalued relative to peers  
Regular near milestones advance and derisk pipeline

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[www.adalta.com.au](http://www.adalta.com.au)