

**20 January 2022**

**ASX Announcement**

**ADALTA UPDATED CORPORATE PRESENTATION AND INVESTOR WEBINAR**

**MELBOURNE Australia, 20 January 2022:** AdAlta Limited (ASX:1AD), the clinical stage biotechnology company developing novel therapeutic products from its i-body platform is pleased to announce its participation in the ShareCafe Small Cap "Hidden Gems" Webinar, to be held on Friday 21 January 2022 from 12:30pm AEDT / 9:30am AWST.

Through the session, CEO and Managing Director, Dr Tim Oldham will provide an overview of progress on the company's programs in the areas of fibrosis/inflammation and oncology; discuss the recent data read out on the nebulised version of AD-214, as well as plans for the year ahead.

This webinar is able to be viewed live via Zoom. To access further details of the event, please copy and paste the following link into your internet browser:

[https://us02web.zoom.us/webinar/register/5416151767246/WN\\_vGZ5UY\\_pRcWUx2OIFRG9QQ](https://us02web.zoom.us/webinar/register/5416151767246/WN_vGZ5UY_pRcWUx2OIFRG9QQ)

The investor presentation to be delivered during the webinar is attached. A recorded copy of the webinar will be made available via AdAlta's website at [www.adalta.com.au](http://www.adalta.com.au) following the event.

Authorised for lodgement by:

**Tim Oldham**  
**CEO and Managing Director**  
**January 2022**

**Notes to Editors**

**About AdAlta**

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 generate a promising new class of medicines with the potential to treat some of today's most challenging diseases.

The Company's lead asset, called AD-214, is a first-in-class product being developed for the treatment of Idiopathic Pulmonary Fibrosis (IPF) and other human fibrotic diseases and potentially cancers, for which current therapies are sub-optimal and there is a high unmet medical need. AD-214 has progressed through Phase I clinical trials in healthy volunteers.



AdAlta is also entering collaborative partnerships to co-develop i-body enabled therapeutics. The Company has a revenue generating partnership agreement with GE Healthcare which is designed to discover a diagnostic imaging agent for use in immuno-oncology.

AdAlta's growth strategy is to add value to its existing assets and build a pipeline of wholly owned and co-developed therapeutic products enabled by i-bodies.

### **About i-bodies**

Traditional monoclonal antibodies transformed the pharmaceutical industry's ability to address drug targets selectively and specifically. There remain many targets and applications they have been unable to address. i-bodies are designed to solve these challenging drug targeting problems.

i-bodies are single domain antibodies that mimic 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. These unique proteins are capable of interacting with high selectivity, specificity and affinity with 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.

### **About AD-214**

AD-214 is being developed for the treatment of Idiopathic Pulmonary Fibrosis (IPF) and other human fibrotic diseases and potentially cancers, for which current therapies are sub-optimal and there is a high unmet medical need. AD-214 targets a GPCR called CXCR4 and has been specifically engineered to include features making it suitable for chronic use in fibrosis. It is the only agent against CXCR4 being developed for fibrotic diseases, giving it first-in-class status.

AD-214 has demonstrated efficacy in animal models of IPF and kidney fibrosis and studies in eye fibrosis and metastatic cancer are underway.

In Phase I clinical trials, AD-214 was well tolerated in single and multiple intravenous doses in healthy volunteers and demonstrates high and sustained duration of CXCR4 receptor occupancy. A radiolabelled version of AD-214 for safety and biodistribution (PET imaging) studies has also been developed. AdAlta is developing a more convenient inhaled formulation for future clinical studies.

AD-214 has Orphan Drug Designation (ODD) from the US Food and Drug Administration.

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

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

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# Corporate overview

January 2022

## AdAlta today

AdAlta is building significant growth momentum while retaining agility to respond and adapt to data and opportunities



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



- **Fibrosis/inflammation: lead asset AD-214** preparing for Phase II clinical trial
  - US\$3b Idiopathic Pulmonary Fibrosis (IPF) market today,<sup>1</sup> multiple US\$b indication potential
- **Second target in discovery**




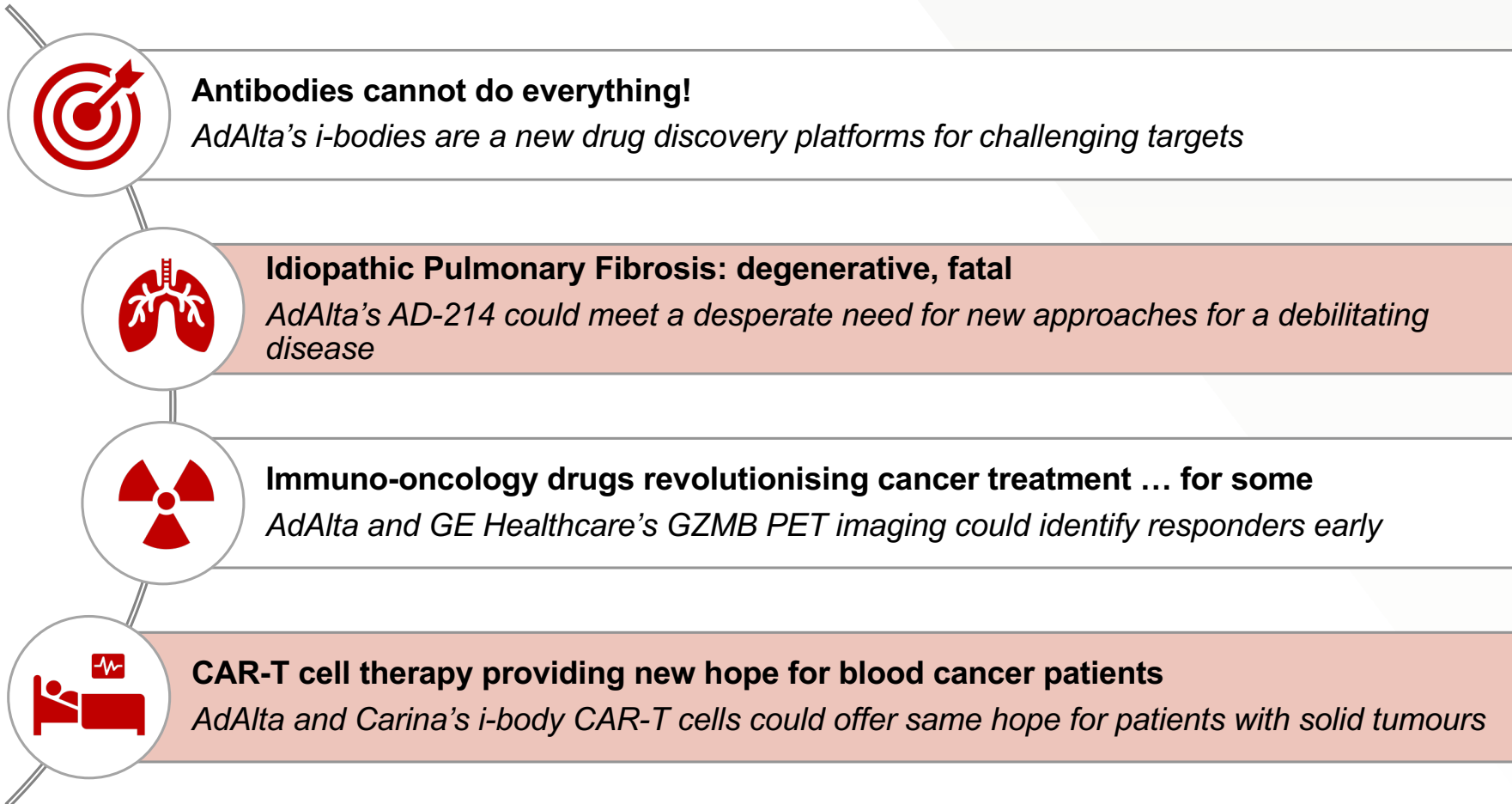
- **Immuno-oncology: two co-development collaborations**
  - GZMB PET imaging agent with **GE Healthcare**: US\$6.4b PET imaging agent market<sup>2</sup>
  - i-body enabled CAR-T with **Carina Biotech**: US\$20b market by 2028<sup>3</sup>



- **Continuing to build out pipeline** with additional internal and external programs: targeting 10 by 2023
  - \$3.75m Placement completed Dec 2021; \$2.2m Entitlement Offer closes 31 Jan 2022

1. GlobalData, Idiopathic Pulmonary Fibrosis Opportunity Analysis and Forecasts to 2029, November 2020  
2. 2027 forecast by Global Industry Analysts, Imaging Agents: Global Market Trajectory and Analytics, April 2021  
3. 2028 forecast by Grandview Research, "T-cell Therapy Market Size, Share & Trends Analysis" Feb 2021

## Four human health needs AdAlta is addressing today

 Focus today



# AD-214: first in class treatment for fibrosis

AD-214's initial focus is IPF

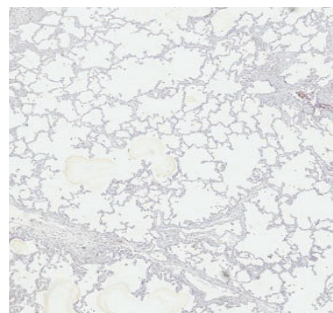
**First-in-class** (novel mode of action) treatment

Targets a receptor called **CXCR4**

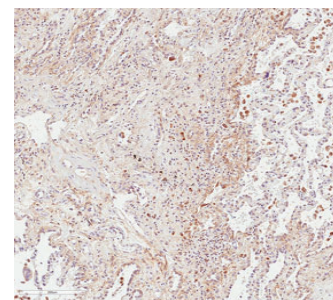
Initial focus is **Idiopathic Pulmonary Fibrosis (IPF)**, one of a group of **Interstitial Lung Diseases (ILDs)**

**Blocking CXCR4 reduces fibrosis** in animal models

**Human Lung Tissue**



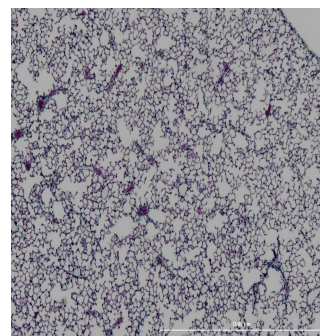
Normal



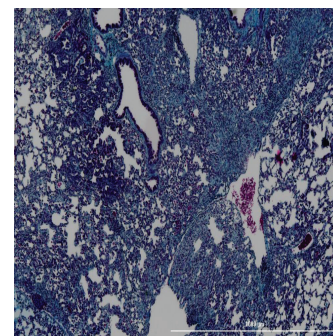
Diseased

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

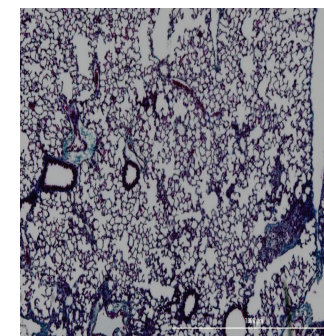
**Mouse model of lung fibrosis**



Normal mouse lung tissue



IPF mouse lung tissue\*

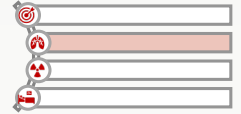


IPF mouse lung tissue + AD-214\*

*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.





## 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

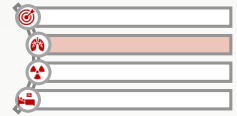
**>300,000**  
people living with IPF,  
It is irreversible

**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.



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

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

## Phase I clinical study successfully completed<sup>1</sup>

- Intravenous AD-214 is well tolerated in single and multiple doses
- Target (CXCR4) binding observed with extended duration

## Resupply of AD-214 clinical material secured<sup>2</sup>

- Defines timeline for Phase II clinical study

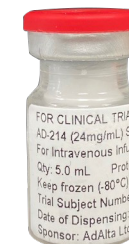
## Pre-clinical intravenous studies inform optimal administration<sup>3</sup>

- PET imaging shows rapid liver distribution (reduced bioavailability)
- Preclinical animal data supports potential iv safety, efficacy profile

**Direct lung delivery (inhalation) of AD-214: a superior format for IPF**

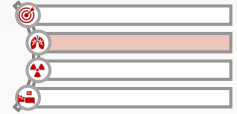
**Phase II studies in IPF scheduled for 2H 2023 with superior formulation**

**Improved intravenous formulation for other indications, derisks IPF**



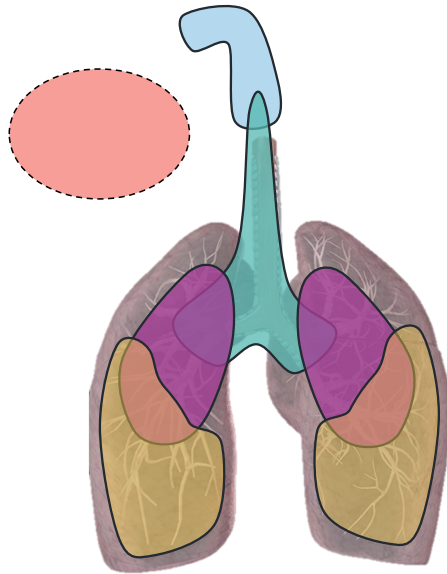
1. ASX Releases 10 Mar 2021 and 19 Jul 2021  
2. ASX Release 1 July 2021  
3. ASX Release 19 July 2021; these studies were part supported by a Biomedical Translational Bridge grant, a program of Australia's Medical Research Future Fund administered by MTPConnect and supported by UniQuest





## Predicted regional deposition of AD-214 in human lungs

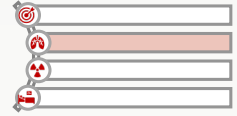
The ICRP66<sup>1</sup> model predicts that 17-46% of AD-214 delivered from commercial nebulisers will be delivered to the smallest (alveolar/interstitial) airways of the lungs where most IPF is found



- Exhaled fraction
- Extra thoracic fraction
- Tracheobronchial fraction
- Bronchiolar fraction
- Alveolar/interstitial fraction

	Device A	Device B
<b>Aerosol particle size</b> (volume mean diameter)	4.8 µm	4.4 µm
<b>Fine particle fraction</b> (% particles ≤ 5 µm)	55%	60%
<b>Deposition fraction</b>		
Extra thoracic	17%	23%
Tracheobronchial	8%	11%
Bronchiolar	15%	11%
<b>Alveolar / interstitial</b>	<b>46%</b>	<b>17%</b>
<b>Total lung (BB, bb, Al)</b>	<b>69%</b>	<b>38%</b>
<b>Exhaled</b>	14%	38%

1. International Commission for Radiation Protection



## AD-214: multiple indication extension options

Each additional indication could address multiple markets with US\$ 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

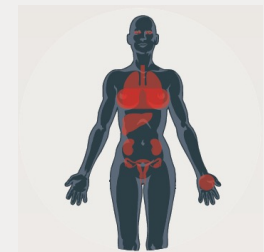
>US\$3b



**Eye**

Wet-AMD

>US\$15b



**Cancer**

23 different cancers, I/O

>US\$1b ea



**Kidney**

RENAL FIBROSIS

>US\$10b



**Liver**

NASH & CIRRHOSIS



**Skin**

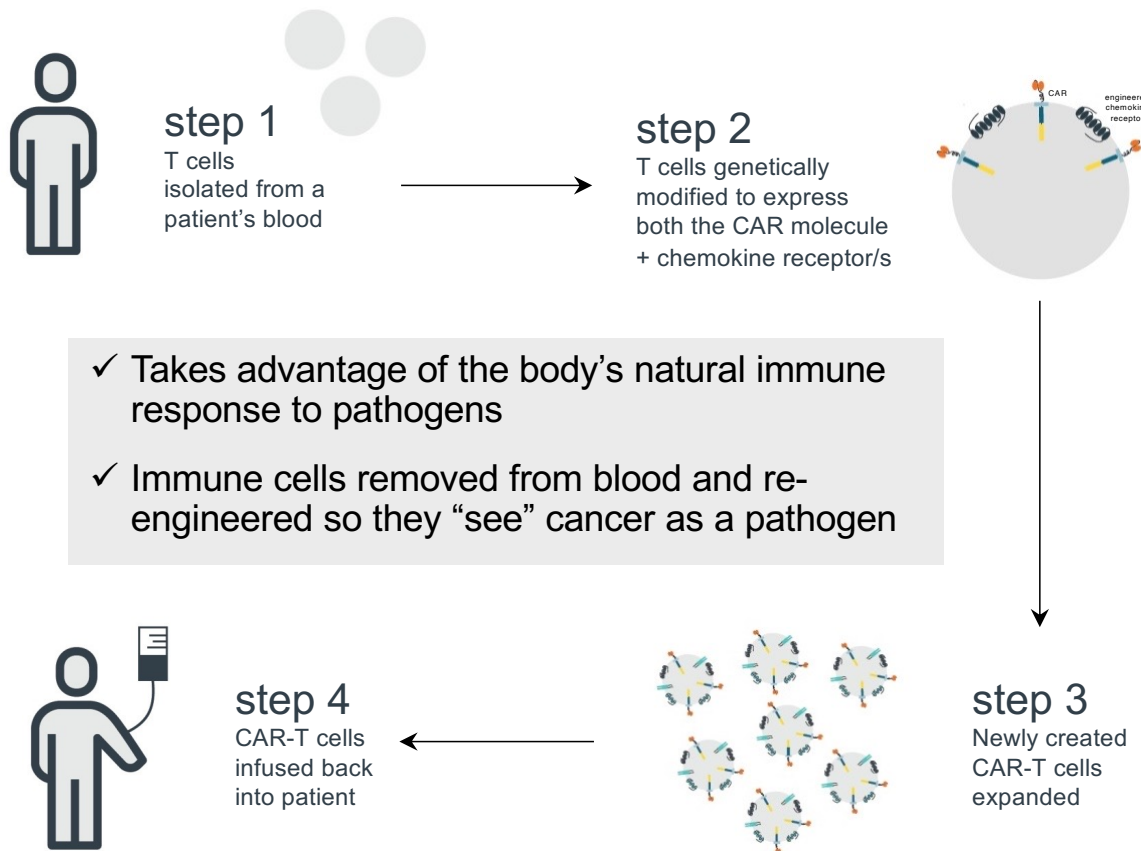
SCLERODERMA

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



# 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



>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>

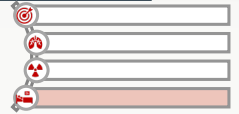
50%

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

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

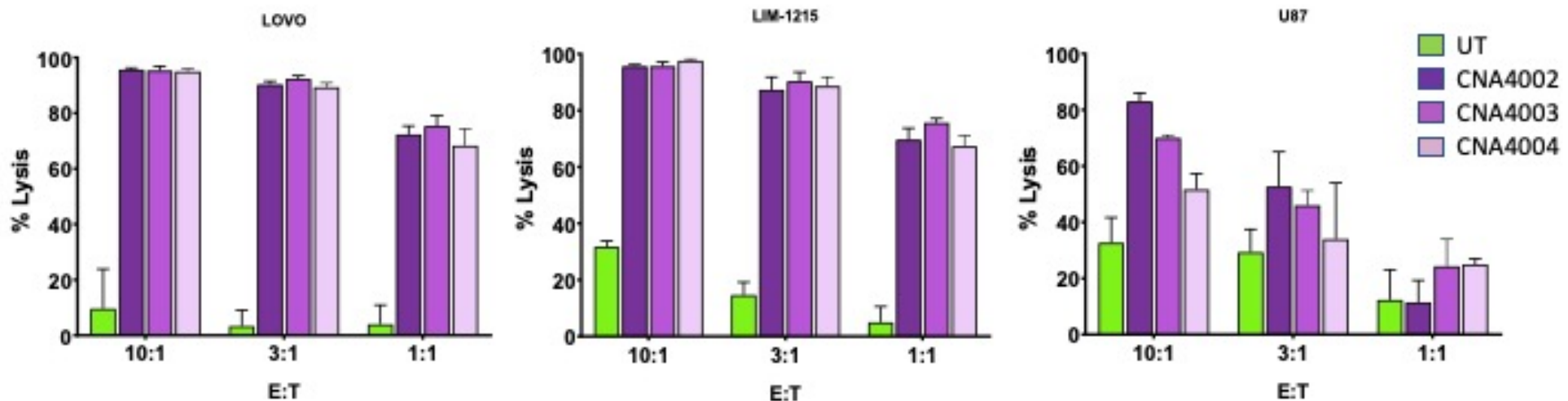
2. Polaris Market Research, "CAR-T Cell Therapy Market Share, Size Trends, Industry Analysis Report", June 2021

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



# Building the first iCAR-T cell therapy: proof of principle results

i-body enabled CAR-T (iCAR-T) cells have been successfully generated by Carina and demonstrate *in vitro* cell killing (lysis)<sup>1</sup>



## Experimental details

- LOVO and LIM1215 are colorectal cancer cell lines; U87 is a glioblastoma cell line
- 3 different Carina CAR-T constructs incorporating i-body against a single target “X” (CNA4002/CNA4003/CNA4004)
- UT is an unmodified T-cell that does not result in significant killing (lysis) of these cell lines
- i-CAR-T cells manufactured with 97% transduction (i-body CAR insertion) efficiency
- i-CAR-T cells included 60-70% CD4+ (helper) and 20-30% CD8+ (cytotoxic – killer) T cells

1. 210921 Carina iBody Datapack SB (2021) – previously unpublished data

## Calendar 2022 goals

Significant progress anticipated on both existing core programs and further pipeline expansion



### AD-214 – first in class anti-fibrotic

- Inhaled formulation development: nebulisation feasibility, efficacy in animal model of IPF (Q1); lung distribution imaging in healthy and disease model animals (Q1); dose finding and clinical formulation (Q2)
- Intravenous formulation development (Q3)
- GLP toxicology with inhaled formulation (commences 2H22)
- Continuing partnering discussions (Q1); selection of next indication



### GE Healthcare – GZMB PET imaging

- Pre-clinical proof of concept – milestone payment (mid-22)



### Carina Biotech – i-body enabled CAR-T cells

- 1st experimental results on Target #1
- Commence i-body discovery on Target #2



### Internal pipeline and platform development

- Initial functional data on i-body binders against internal Target #2 (2H22)
- i-body2.0: new intellectual property filed (end'22)
- 7 programs in pipeline (end'22)
- Additional patent filings, grants on individual i-body enabled products



## Corporate snapshot

### Key financial details (22 Dec 2021)

ASX code	1AD
<b>Market capitalisation</b>	<b>A\$24.32m</b>
Share price (12 month closing range)	A\$0.082 (\$0.074 - 0.195)
12 month return	(38)%
Ordinary Shares (daily volume)	296,549,441 (426,207)
Unlisted Options	13,804,595
<b>Cash (30 Nov 2021)</b>	<b>A\$6.46m</b>
<b>Proceeds of placement (14 Dec 2021)</b>	<b>A\$3.75m</b>

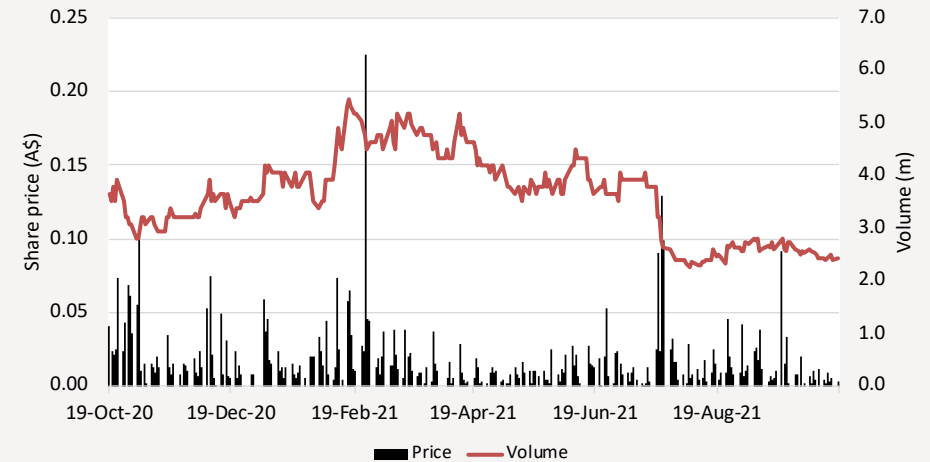
### Major shareholders (22 Dec 2021)

	%
Yuuwa Capital LP	18.2
Platinum Asset Management	16.6
Meurs Holdings Pty Ltd	6.0
Radiata Super Pty Ltd	3.7
Sacavic Pty Ltd	2.5
Other (~1,600 total holders)	53.0
<b>Total</b>	<b>100%</b>

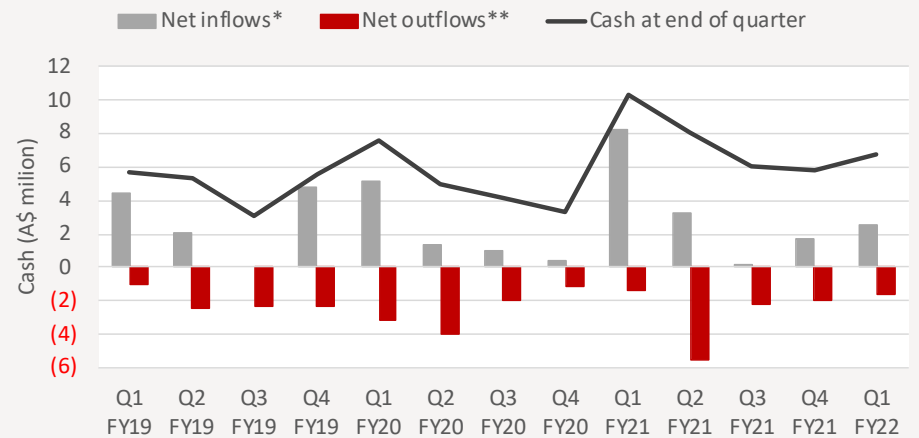
### Analyst Coverage

Pitt Street Research  
Lodge Partners

### Share price performance (last 12 months)



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



## Investment proposition



**i-body platform to create value**



**Fibrosis/inflammation**  
**Lead asset advancing to Phase II**  
>\$3b market potential in first indication<sup>1</sup>

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



**Immuno-oncology**  
**2 x co-development collaborations to leverage platform**

- ✓ GE Healthcare: \$6b PET market<sup>2</sup>
- ✓ Carina Biotech: \$20b CAR-T market<sup>3</sup>



**Clear vision for growth**



**Leading expertise**



**Regular near-term news flow**

1. GlobalData, Idiopathic Pulmonary Fibrosis Opportunity Analysis and Forecasts to 2029, November 2020
2. 2027 forecast by Global Industry Analysts, Imaging Agents: Global Market Trajectory and Analytics, April 2021
3. 2028 forecast by Grandview Research, "T-cell Therapy Market Size, Share & Trends Analysis" Feb 2021

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