

4 January 2022

ASX Announcement

ADALTA PRESENTING AT JANUARY BIOTECH CONFERENCES

MELBOURNE Australia, 4 January 2022: AdAlta Limited (ASX:1AD), the clinical stage drug discovery company developing novel therapeutic products from its i-body platform is participating virtually at Biotech Showcase™ 2022 Virtual conference during “J.P. Morgan Week 2022” and at H.C. Wainwright BioConnect. Highlights from its latest investor presentation (attached) will be presented by CEO and Managing Director, Dr Tim Oldham. Dr Oldham and COO, Dr Dallas Hartman, will be participating in partnering and networking programs at both events.

Biotech Showcase™ 2022 Virtual conference

Biotech Showcase, produced by Demy-Colton and EBD Group, will be held virtually on January 10–12, 2022 & January 17–19, 2022. Biotech Showcase is an investor conference focused on driving advances in therapeutic development by providing a sophisticated networking platform for executives and investors that fosters investment and partnership opportunities. The conference takes place each year during what’s known as JP Morgan Healthcare week - one of the industry's largest gatherings and busiest weeks.

Further details of the conference can be found at: <https://informaconnect.com/biotech-showcase/>.

The pre-recorded video of Dr Oldham’s presentation will be made available on AdAlta’s website. <https://adalta.com.au/investors/presentations/>

H.C. Wainwright Bioconnect Conference.

The H.C. Wainwright Bioconnect Conference will be held on January 10-13, 2022.

Further details of the conference can be found at: <https://hcwevents.com/bioconnect/>.

Authorised for lodgement by:

Tim Oldham
CEO and Managing Director
January 2022

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 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 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>

About Biotech Showcase

Biotech Showcase is an investor and networking conference devoted to providing private and public biotechnology and life sciences companies with an opportunity to present to, and meet with, investors and pharmaceutical executives in one place. Investors and biopharmaceutical executives from around the world gather at Biotech Showcase during this bellwether week which sets the tone for the coming year. Now in its 14th year, this well-established, highly respected conference features multiple tracks of presenting companies, plenary sessions, workshops, networking, and an opportunity to schedule one-to-one meetings. Biotech Showcase is produced by Demy-Colton and EBD Group. Both organizations have a long history of producing high-quality programs that support the biotechnology and broader life sciences industry.

Further information can be found at: <https://informaconnect.com/biotech-showcase/>

About H.C. Wainwright & Co.

H.C. Wainwright & Co. is one of America's oldest and most trusted financial institutions. H.C. Wainwright blends traditional values with innovative services, operating with integrity and offering leading-edge investment banking, corporate finance, and strategic advisory services to public and private growth companies across multiple sectors and regions. H.C. Wainwright Bioconnect Conference offers presenting companies, fireside discussions, meetings with H.C. Wainwright investment banking & research teams, and evenings of virtual entertainment.

Further information can be found at: <https://hcwevents.com/bioconnect/>



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Corporate overview

December 2021

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,¹ 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 market²
 - i-body enabled CAR-T with **Carina Biotech:** US\$20b market by 2028³



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

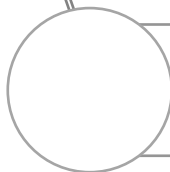
1. GlobalData, Idiopathic Pulmonary Fibrosis Opportunity Analysis and Forecasts to 2029, November 2020
2. 2027 forecast by Global Industry Analysts, Imaging Agents: Global Market Trajectory and Analytics, April 2021
3. 2028 forecast by Grandview Research, "T-cell Therapy Market Size, Share & Trends Analysis"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

Four human health needs AdAlta is addressing today



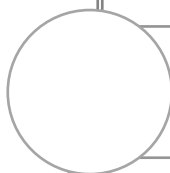
Antibodies cannot do everything!

AdAlta's i-bodies are a new drug discovery platforms for challenging targets



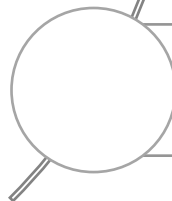
Idiopathic Pulmonary Fibrosis: degenerative, fatal

AdAlta's AD-214 could meet a desperate need for new approaches for a debilitating disease



Immuno-oncology drugs revolutionising cancer treatment ... for some

AdAlta and GE Healthcare's GZMB PET imaging could identify responders early

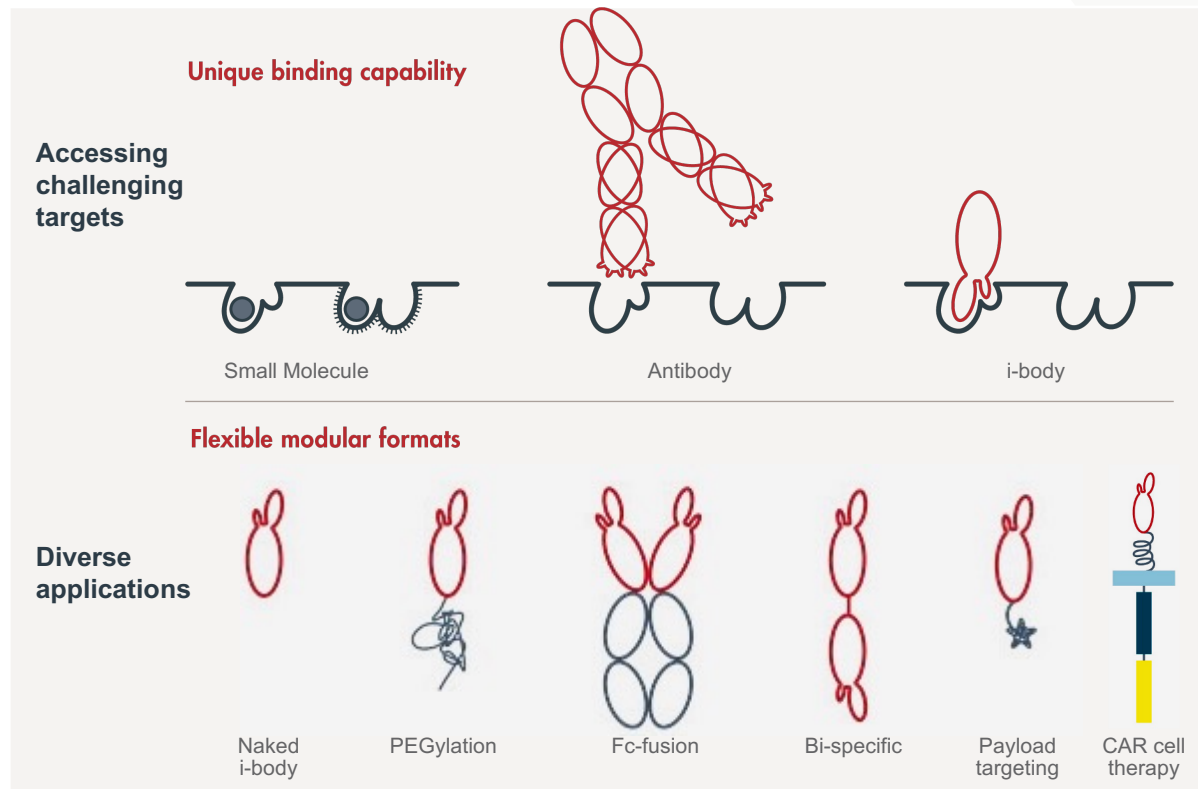


CAR-T cell therapy providing new hope for blood cancer patients

AdAlta and Carina's i-body CAR-T cells could offer same hope for patients with solid tumours

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)

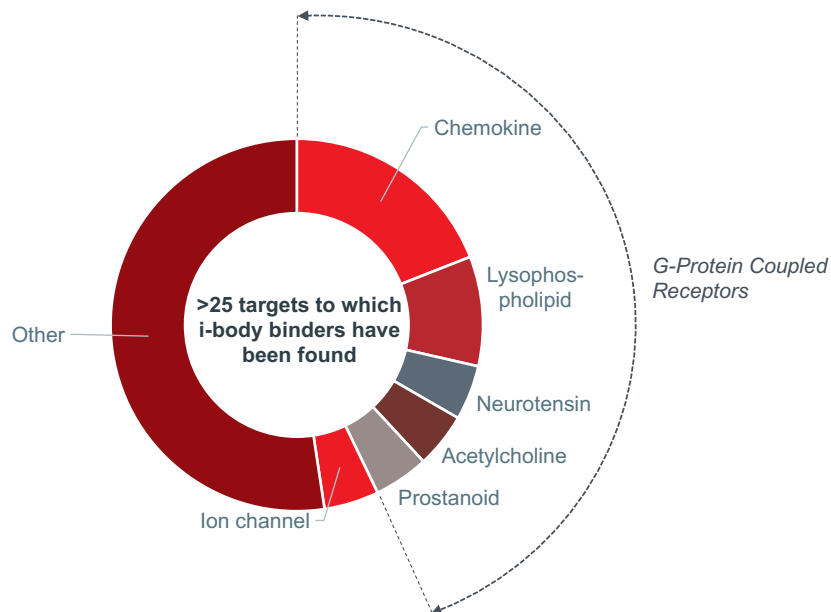
Robust

Resilient to pH and temperature cycling

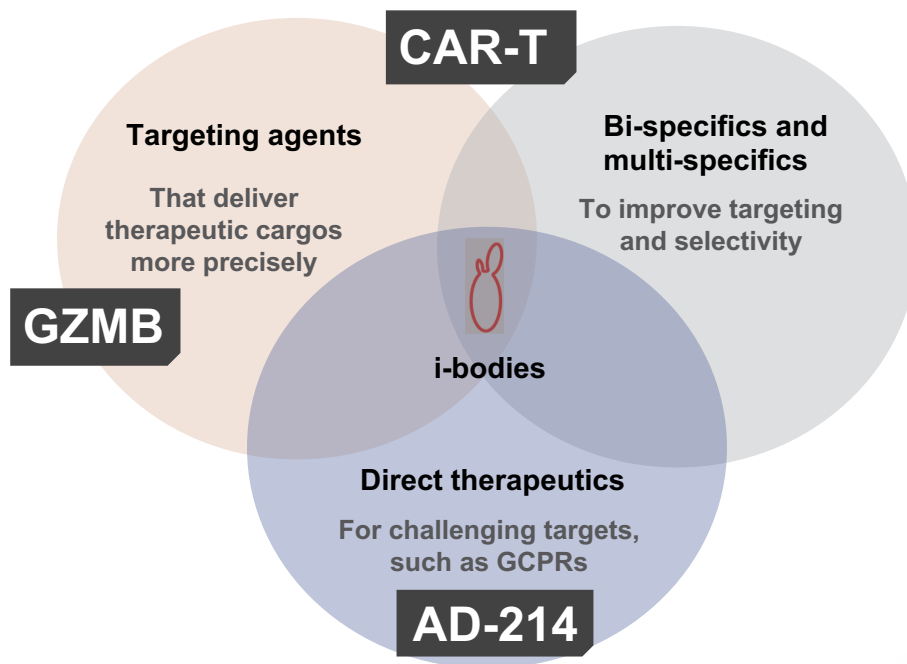
An immensely powerful drug discovery platform

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

Wide range of target classes



Wide range of product formats



AD-214: first in class treatment for fibrosis

AD-214's initial focus is IPF

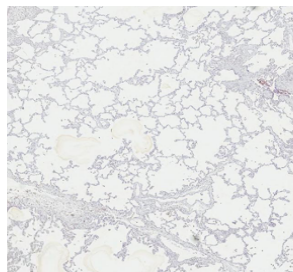
First-in-class (novel mode of action) treatment

Targets a receptor called **CXCR4**

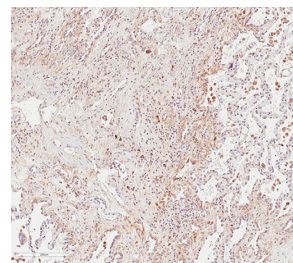
Initial focus is **Idiopathic Pulmonary Fibrosis (IPF)**, one of a group of **Interstitial Lung Diseases (ILDs)**

Blocking CXCR4 reduces fibrosis in animal models

Human Lung Tissue



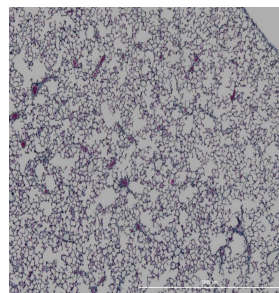
Normal



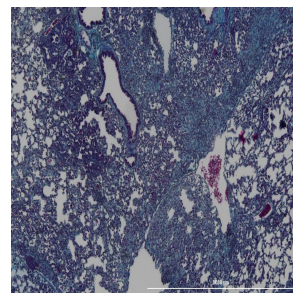
Diseased

Brown stain shows increased amount of CXCR4 in fibrotic lung tissue

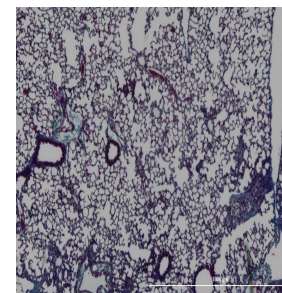
Mouse model of lung fibrosis



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.

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

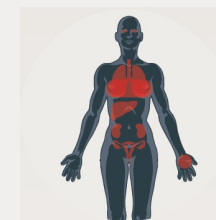
>US\$3b



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.

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 completed¹

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

Resupply of AD-214 clinical material secured²

- Defines timeline for Phase II clinical study

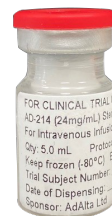
Pre-clinical intravenous studies inform optimal administration³

- 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



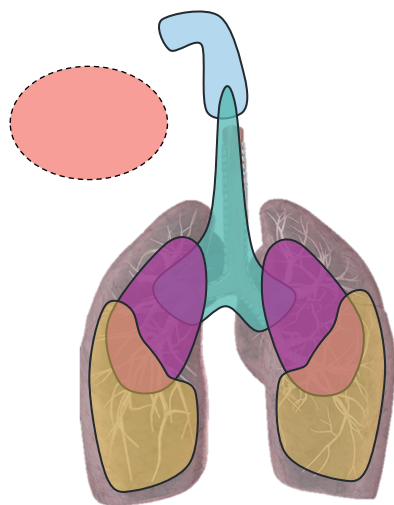
1. ASX Releases 10 Mar 2021 and 19 Jul 2021

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 ICRP66¹ 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



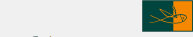
- Exhaled fraction
- Extra thoracic fraction
- Tracheobronchial fraction
- Bronchiolar fraction
- Alveolar/interstitial fraction

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

1. International Commission for Radiation Protection

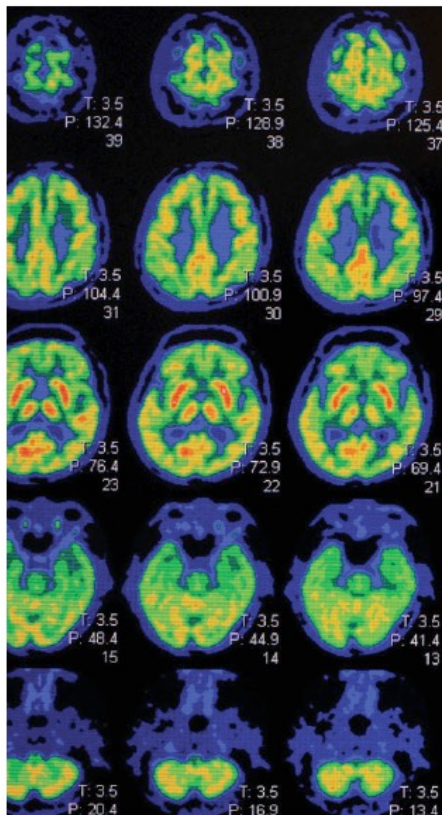
IPF partnering: valuable options as early as Phase I

IPF assets have recently yielded attractive deal terms at early stages of development

Date	Licensee	Licensor	Transaction Terms	Asset/Mode of Action	Clinical Phase	Additional Comments
Nov-21			US\$254m upfront	Cudetaxestat <i>Autotaxin inhibitor</i>	2 (Ready)	SPAC merger; Deal includes cudetaxestat (lead product) + calpain inhibitor products
Nov-21			€320m milestones	OATD-01 <i>Chitotriosidase/acidic mammalian chitinase (CHIT1/AMCase) inhibitor</i>	2 (Ready)	Single product license
Sep-21			US\$152m upfront +US\$602m milestones	Axatilimab <i>CSF-1R inhibitor</i>	2 (Ready)	Lead indication cGVHD
Nov-19			US\$390m upfront +US\$1b milestones	PRM-151 <i>Recombinant form of human pentraxin-2 (PTX-2) protein.</i>	2	Deal includes PRM-151 (IPF lead asset) + multiple assets for fibrotic diseases
Feb-21			US\$517.5m milestones	TDI01 <i>Rho containing protein kinase 2 (ROCK2) inhibitor</i>	1	Single product license
Jul-19			€45m upfront +€1.1b milestones	BBT-877 <i>Autotaxin inhibitor</i>	1	Single product license

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 market¹

Only **20-40%** of patients respond to I/O drugs²

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 market³
Largest products >US\$400m⁴

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}F chemistry, final product manufacture
- Pre-clinical, clinical proof of concept
- Commercialisation

Pipeline asset generating revenue for AdAlta

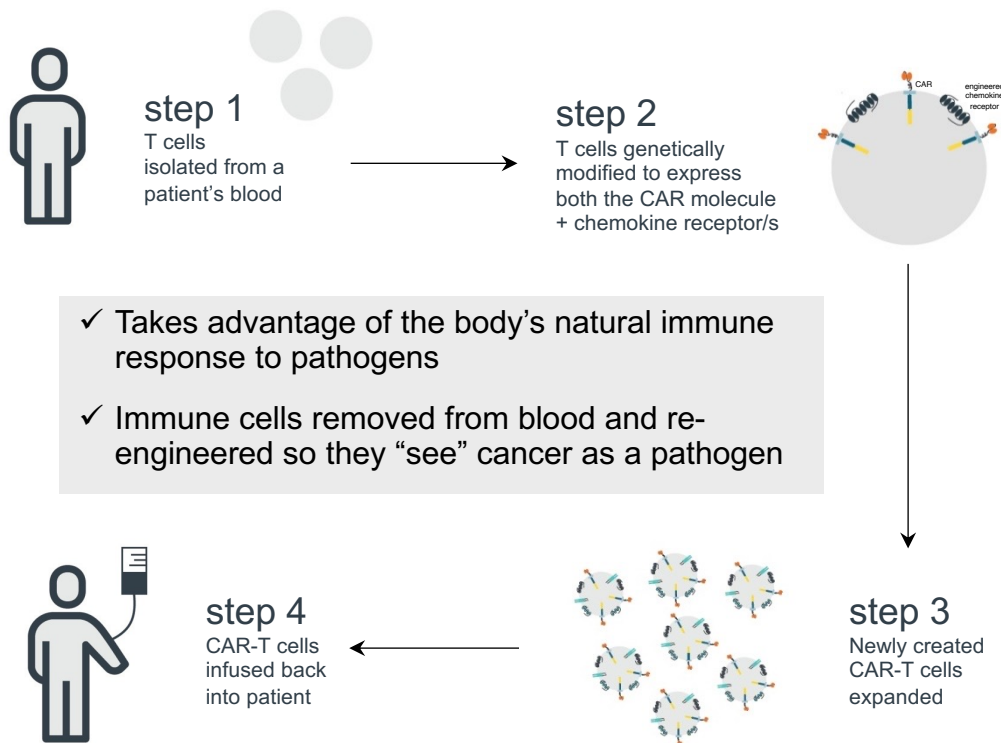
- AdAlta earns research fees, development and sales milestone payments and royalties on product sales
- A\$1.5 million revenue (milestones and research fees) earned to June 2021

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



>US\$1b earned by CAR-T therapy products in 2020³

2m addressable patient population within next 10 years¹

US\$20.3b revenue forecast for 2028¹

50% solid tumour share of revenues by 2030²

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

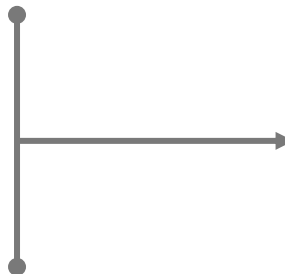
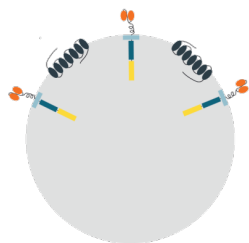
2. Polaris Market Research, "CAR-T Cell Therapy Market Share, Size Trends, Industry Analysis Report", June 2021

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



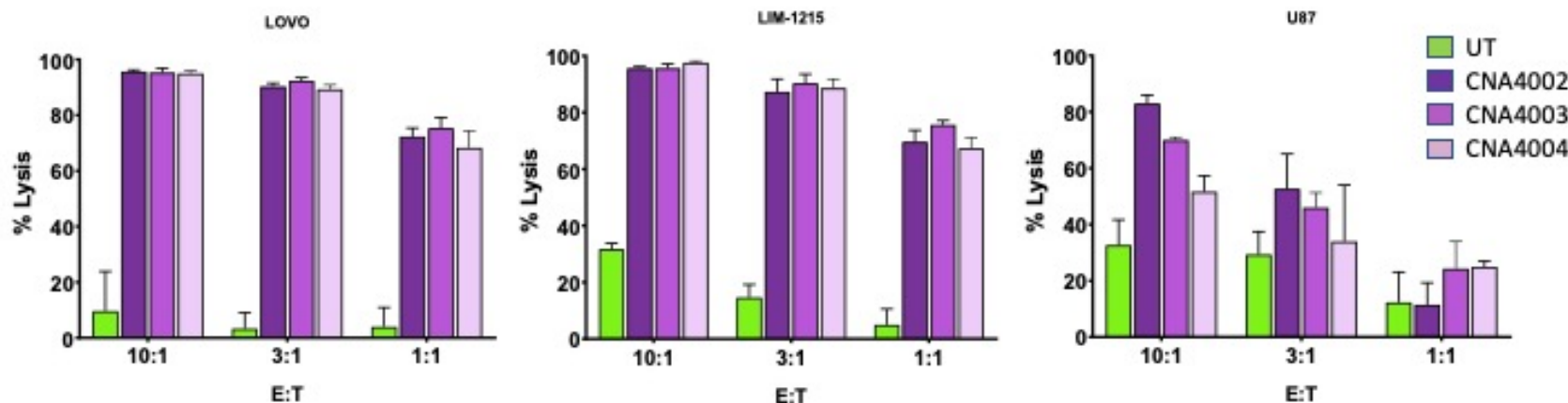
To develop precision engineered, i-body enabled, CAR-T therapies, including bi-specific and dual CAR-T products, that provide new hope for patients with cancer

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



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)¹



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

AdAlta assets and business model

AdAlta's pipeline is expanding to plan. The i-body platform is creating wholly owned or co-developed assets. Our team is building skills in fibrosis/inflammation and immuno-oncology.

Co-developed assets



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

Pre-clinical



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

Discovery

Immuno-oncology theme

One more target to be added in early 2022

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

Fibrosis and inflammation theme

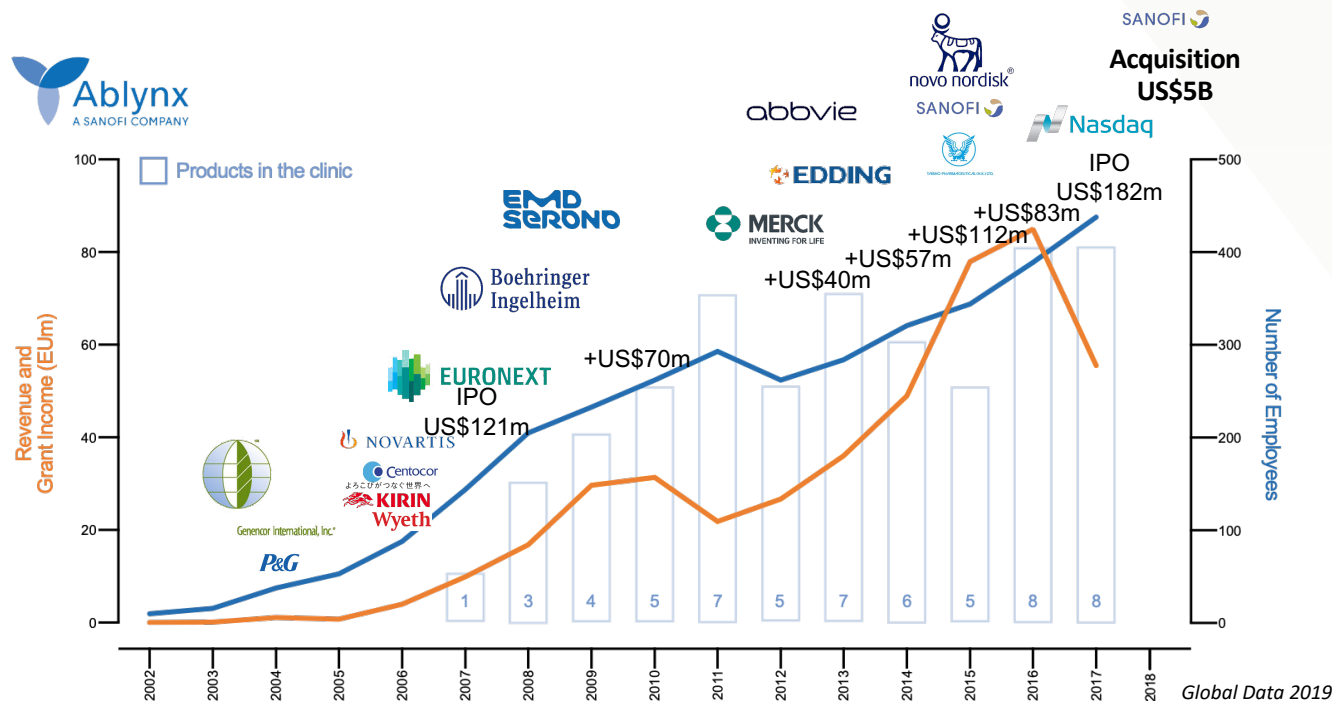
Platform



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

The potential of our strategy: Ablynx case study

Multiple internal and external assets drive value, attract partners



AdAlta is embarking on a similar journey
Target: 10 programs in development by 2023

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

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

Industry experienced leadership and advisors

Team with experience from discovery through manufacturing, clinical and commercialisation

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

Corporate snapshot

Key financial details (22 Dec 2021)

ASX code	1AD
Market capitalisation	A\$24.32m
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
Cash (30 Nov 2021)	A\$6.46m
Proceeds of placement (14 Dec 2021)	A\$3.75m

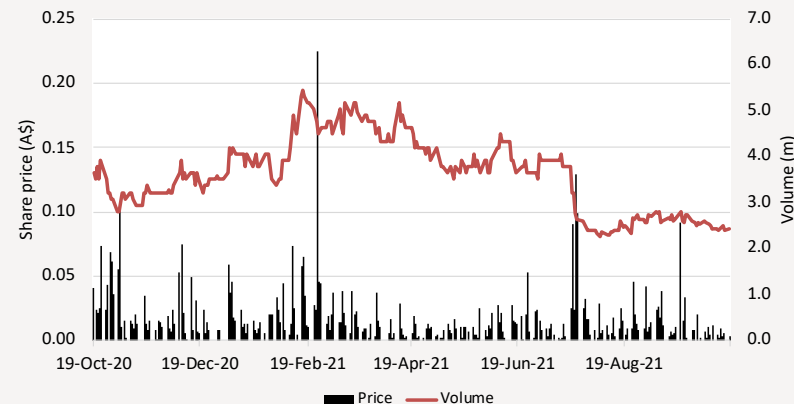
Major shareholders (22 Dec 2021)

	%
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
Total	100%

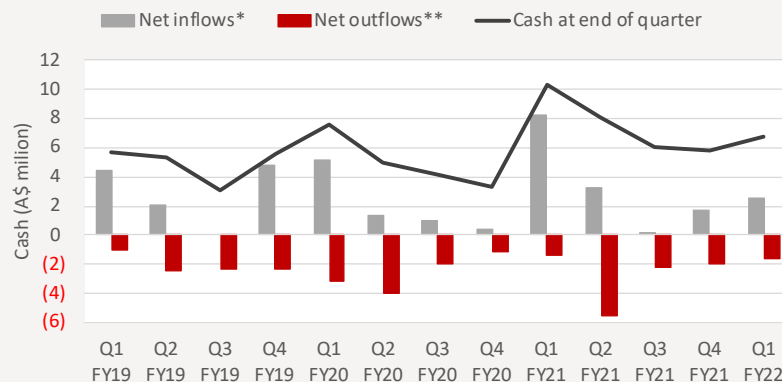
Analyst Coverage

Pitt Street Research
Lodge Partners

Share price performance (last 12 months)



Quarterly cash flows (A\$ million)



Partner and investor proposition



**Powerful i-body discovery platform
to create value**



**Fibrosis/inflammation
Lead asset advancing to Phase II
>\$3b market potential in first indication¹**

Discovery initiated on 2nd target



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

- ✓ GE Healthcare: \$6b PET market²
- ✓ Carina Biotech: \$20b CAR-T market³



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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