10 May 2022

ASX Announcement

AdAlta presentation at Bioshares Biotech Summit

MELBOURNE Australia, 10 May 2022: AdAlta Limited (ASX:1AD), the clinical stage biotechnology company developing novel therapeutic products from its i-body platform, is pleased to advise that CEO and Managing Director, Dr Tim Oldham, will be presenting at the 16th Bioshares Biotech Summit in Albury, NSW on 11 May 2022.

The Bioshares Biotech Summit's unique format brings together biotechnology companies and equity capital markets participants to explore not just what biotechnology companies do but just as importantly how they do it. In keeping with this purpose, Dr Oldham's presentation will focus on how AdAlta makes big strategic and portfolio decisions to guide development of its i-body drug discovery platform, including a case study of the decision in 2021 to add an intravenous formulation of AD-214 to enhance the convenience and cost effectiveness of the product.

A copy of the presentation is attached.

Authorised for lodgement by:

Tim Oldham
CEO and Managing Director
May 2022

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Notes to Editors

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. AdAlta has a second target in discovery research, also in the field of fibrosis and inflammation.

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 immunooncology 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

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AdAlta
next generation protein therapeutics

Developing i-body enabled drugs for challenging diseases

Tim Oldham PhD, CEO and Managing Director

BioShares Conference, 11 May 2022

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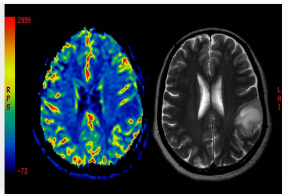
AdAlta at a glance

Building out pipeline

Targeting 10 internal and external programs by end 2023

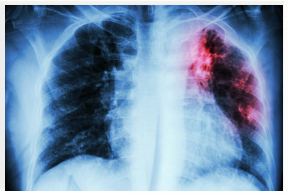
Immuno-oncology: two co-development collaborations

1. GZMB PET imaging agent with **GE Healthcare**: US$6.4b market
2. i-body enabled CAR-T with **Carina Biotech**: US$20b market by 2028



Fibrosis/inflammation: wholly owned pipeline

1. Lead asset AD-214 preparing for Phase II clinical trials
2. Second target in discovery



i-body platform

Powerful drug discovery tool for creating drugs against challenging diseases underserved by traditional antibodies

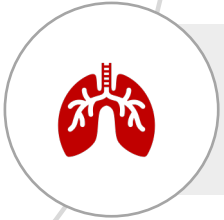
Today's objective: explore AdAlta's approach to "big" drug development decisions

Realising novel i-body platform potential

Focus, investment in platform, multiple "proof of principle" examples, balanced pipeline

Taking big decisions

Align with strategy, deliver target product profile, follow the data, invest to increase options and/or reduce risk



Inhaled protein therapeutics: AD-214 for IPF

A case study in realising platform potential and taking big decisions

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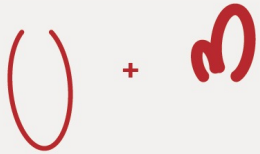
Maximising i-body platform potential

i-bodies: a powerful drug discovery engine for next generation protein therapeutics

1

Shark single domain antibody (sdAb): small size and long binding loops enable unique target and epitope access

2



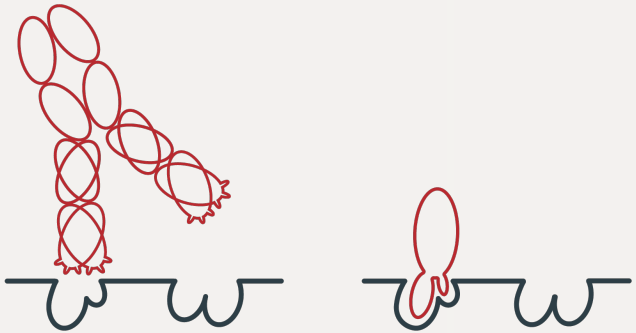
A **human** protein that is structurally equivalent to the shark sdAb backbone with two engineered binding loops

3

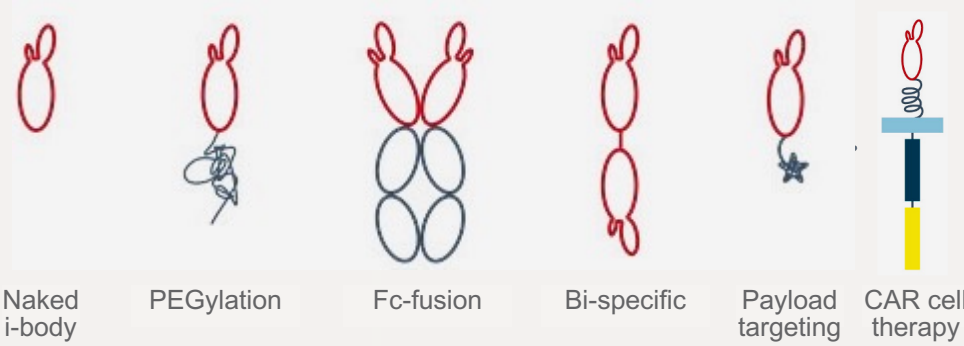
AdAlta's i-body library has 10^{10} unique i-bodies

AdAlta **i-bodies** mimic the structural, stability and unique binding features of the shark sdAb system on a human protein backbone

Unique binding capability



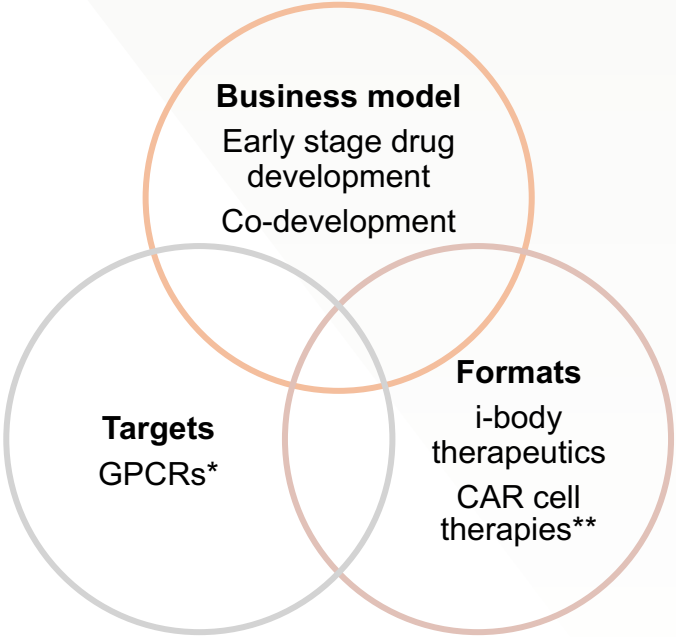
Flexible modular formats



Focus is very important for platform companies facing large opportunities

Benefits of focus	
Organisation expertise	• Repeat projects build experience, expertise • Defines required skills and knowledge
R&D	• Focus for platform technology development
Target selection	• Faster qualitative filtering • Deeper domain expertise
Business development	• Fewer marketing messages • Faster qualitative opportunity filtering
Investor relations	• Clarity of purpose • Simplicity of messaging

AdAlta's current focus choices



* G-protein coupled receptors: GPCRs are one of the largest classes of drug targets that is poorly served by antibody therapeutics
** Chimeric antigen receptor cell therapies: immune cells such as T cells (CAR-T) and NK cells (CAR-NK) engineered to include a receptor (chimeric antigen receptor) that binds to tumour antigens the immune cells would otherwise not see and then activating the immune cell, enabling it to kill the tumour cells

Requirements to move beyond a single product and realise platform value

AdAlta in 2019

Continuous platform improvements

Learning and ideas

Expanding library of proof of principle "use cases"

1 product
1 partnership

Maximise i-body platform value

~25 targets "hit"

Inventory of target and product ideas

2 programs
- Preclinical
- Discovery

Balanced pipeline

AdAlta in 2022

Continuous platform improvements

i-body2.0 program
Shorter screening cycle

Expanding library of proof of principle "use cases"

3 product formats
2 partnerships
1 clinical stage asset

Maximise i-body platform value

Robust selection process
Growing library of GPCR ideas

Inventory of target and product ideas

4 programs
- **Clinical**
- **Preclinical**
- **Discovery**

Balanced pipeline

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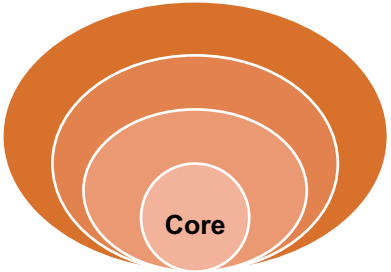
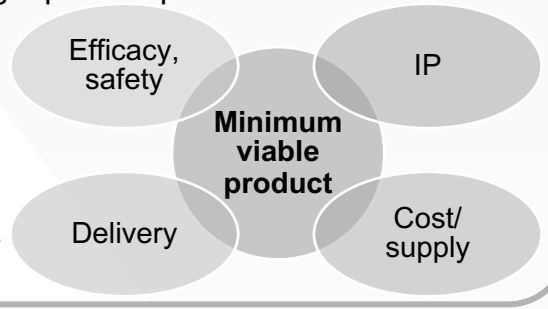
Taking big decisions during i-body drug development

Lenses for making big decisions

Strategic alignment

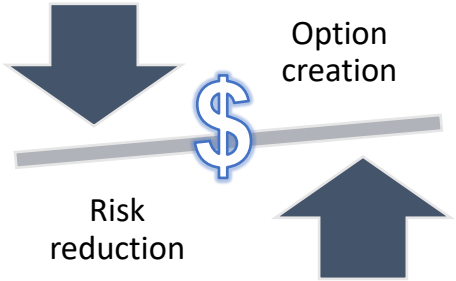


Target product profile

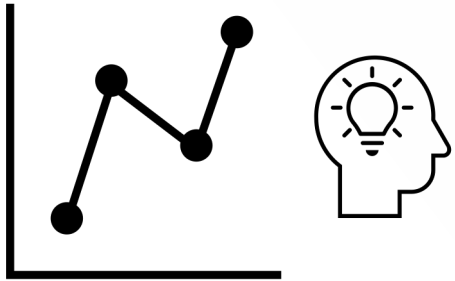


Decision?

Value creation/ ROI



Data, information, insight



Recent “big” decisions at AdAlta

Case study in next section

Decision	Strategic alignment	Target product profile	Data & information	Value creation
• Defining focus for platform	+++	+	++	+++
• Selecting targets for pipeline	++	++	+++	+++
• Expanding team, pipeline	+++		+	+++
• Format: AD-114 to AD-214		+++	+++	+++
• Adding inhalation route of administration to AD-214		+++	+++	+++
• Adding indications to AD-214	++	++	+++	+++

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A big decision case study: inhaled AD-214

AD-214 | Completed Phase I, preparing superior inhalation format for Phase II

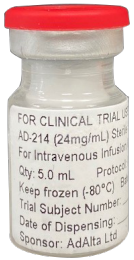
New data, additional time, and knowledge of minimum viable and optimum target product profiles gave AdAlta the opportunity to consider investment in an inhaled form of AD-214 alongside the intravenous form

Phase I intravenous (iv) clinical study successfully completed[1]

- AD-214 (iv) is well tolerated, binds its target (CXCR4) well
- Preclinical animal data supports potential iv efficacy

Drug substance manufacturing secured for next clinical studies in 2021[2]

- Delivery mid 2023
- Next clinical studies to commence second half of 2023



What are best investments to make ahead of next clinical studies?

Direct lung delivery (inhalation) could be a superior format for IPF[3] and add significant value to AD-214

- *Data*: PET imaging shows rapid liver distribution
- *TPP*: Direct lung delivery could reduce dose, costs
- *TPP*: At home inhalation more flexible, convenient than iv
- *Value creation*: Differentiated routes of administration enable partnering AD-214 by indication – potentially prior to next clinical studies

Preclinical development of inhaled formulation now well advanced

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

Inhalation precedents | IPF and protein therapeutics

Information from precedents and experts informed initial feasibility and selection of risk mitigation strategies

Inhalation used regularly in IPF and other respiratory diseases

Inhaled IPF pipeline

United Therapeutics CORPORATION (Ph III)

Galecto (Ph IIb)

Avalyn PHARMA (Ph I/II)

pieris (Preclin) (biologic)

- Patients routinely inhale salbutamol, steroids for symptom relief
- Inhaled therapeutics also marketed for asthma, COPD, cystic fibrosis

Substantial number of biologics in development for inhalation*

- 2 marketed biologics

Pulmozyme dornase alfa INHALATION SOLUTION

afrezza (insulin human) Inhalation Powder

- 19 clinical stage biologics

Ablynx A SANOFI COMPANY

NOVARTIS

gsk

ucb

Genentech A Member of the Roche Group

- Most 15-80 kDa (AD-214 73 kDa)
- Most solutions for inhalation

Off-the-shelf devices for nebulization of liquid formulations

OMRON PHILIPS

VECTURA

PARI

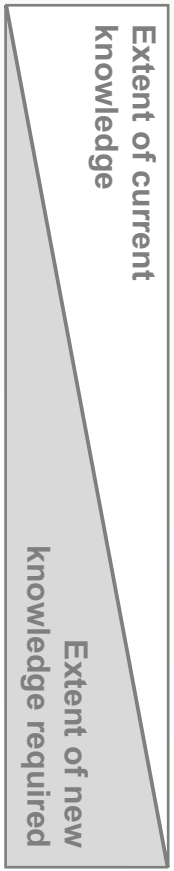
- Smart, hand held, mesh nebulisers assist compliance, accuracy, drug efficiency
- Low shear forces: designed for biologics
- Liquid formulations: minimal modification to intravenous formulation

* W Liang *et al*, Pulmonary delivery of biological drugs, *Pharmaceuticals* 2020, 12, 1025

Company brands do not represent endorsement of AdAlta programs; Pulmozyme (dornase alpha, 37 kDa) is a trademark of Genentech; Afrezza (insulin, 6 kDa) is a trademark of MannKind Corp

AdAlta's approach to the factors to consider when developing inhaled biologics

Factor	AdAlta approach for AD-214 decision
Benefit of inhaled route of administration	• Improves IPF target product profile • Continued IV investment adds options for partnering by indication
Formulation	• Liquid for nebulization – speed, development cost and time
Delivery	• Use commercially available nebulisers: stability of AD-214 demonstrated
Deposition	• Chosen nebulisers produce <5 mm particles: high alveolar deposition
Mucociliary clearance	• Predominant in upper airway where AD-214 is not required
Macrophage clearance	• Predominant in alveolar region; size, formulation and aggregation dependent • Chosen nebulisers show very low levels of aggregation
Tissue transport	• Transport to blood for systemic distribution is not required • Fc-domain of AD-214 could enhance alveolar epithelial transport
Immunogenicity	• No concerning systemic immunogenicity to date, however … • … different mechanisms of immunogenicity in the lung



Inhaled AD-214 | Milestones to gain new knowledge and opportunities in 2022

June 2022 quarter

- Antifibrotic effects in cultured human lung airway cells

Through mid CY 2022

- Antifibrotic effects in cultured human lung tissue
- Imaging distribution, retention in sheep
- Manufacturing AD-214 for toxicology studies

September 2022 quarter

- Efficacy in bleomycin mouse model*
- Inhaled AD-214 formulation selected
- Partnering discussions accelerate

December 2022 quarter

- Preparation for inhalation toxicology studies
- cGMP manufacturing commences for Phase Ib/II clinical trials

Aim of pre-clinical studies

1. Demonstrate nebulised AD-214 can reach lower airways of sheep lungs (similar to human)
2. Demonstrate that AD-214 reaching the lower airways is retained in fibrotic tissue (bleomycin mice, sheep, cultured lung tissue)
3. Demonstrate AD-214 delivered to fibrotic tissue can moderate disease progression (bleomycin mice, cultured lung tissues and cells)

Preclinical success anticipated to accelerate existing partnering discussions

I/O assets | Other AdAlta milestones and opportunities in 2022

GE Healthcare

carina biotech

Through mid CY 2022

- GZMB iPET imaging agent preclinical proof of concept

Through mid CY 2022

- Initial *in vitro* cancer cell killing screening assays completed for iCAR-T target A

September 2022 quarter

- iCAR-T targets B and C selected

December 2022 quarter

iCAR-T Target A

- *in vitro* cancer cell killing assays complete
- *in vivo* proof of concept studies commenced

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