

**5 June 2020**

**ASX Announcement**

**ADALTA TO PRESENT AT BIO DIGITAL 2020**

**MELBOURNE Australia, 5 June 2020:** AdAlta Limited (ASX:1AD), the biotechnology company developing novel therapeutic products against challenging drug targets using its i-body platform will present at BIO Digital 2020. The BIO International Convention is one of the largest biotechnology industry conferences each year. This years' conference is being conducted virtually from 8-12 June. AdAlta's on-demand company presentation will be available to more than 5,000 registered delegates and 2,800 companies during the conference and for the following month. AdAlta will also participate in virtual partnering meetings through the week.

A copy of AdAlta's company presentation is attached and a link to the video of CEO and Managing Director, Tim Oldham, delivering the presentation will be available on AdAlta's website: <http://adalta.com.au/investors/presentations/>

Authorised for lodgement by:

**Tim Oldham**  
**CEO and Managing Director**  
**June 2020**

**Notes to Editors**  
**About AdAlta**

AdAlta Limited is a biotechnology 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 compounds, 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.

AdAlta is preparing to conduct Phase 1 clinical studies for its lead i-body candidate, AD-214. AD-214 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 for diagnostic imaging agents against several drug targets, including Granzyme B.

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: <http://adalta.com.au>

**For more information, please contact:**

**Investors**

Tim Oldham, CEO & Managing Director  
Tel: +61 403 446 665  
E: [t.oldham@adalta.com.au](mailto:t.oldham@adalta.com.au)

**Media**

IR Department  
Tel: +61 411 364 382  
E: [gabriella.hold@irdepartment.com.au](mailto:gabriella.hold@irdepartment.com.au)



# AdAlta

next generation protein therapeutics

## **i-bodies: drugging difficult targets for next generation protein therapeutics**

BIO2020, 8-12 June 2020



**AdAlta Limited (ASX:1AD)**

**Tim Oldham, CEO and Managing Director**

[t.oldham@adalta.com.au](mailto:t.oldham@adalta.com.au)



# 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.



**“Next generation protein therapeutics”**  
**“Drugging difficult targets”**

AdAlta Limited (ASX:1AD) is using its unique i-body platform to discover and develop next generation protein therapeutics acting on your most challenging drug targets

# AdAlta's defining features

## Multi-dimensional growth strategy

Additional: AD-214 indications; pipeline products; discovery and development partnerships

## Discovery collaboration with GE Healthcare

Partner target + AdAlta i-body discovery engine = targeting challenge solved  
Validates partnering capability and platform diversity

## AD-214 anti-fibrotic product entering Phase I

First in class (anti-CXCR4) for IPF (high unmet need, orphan indication)  
Validates platform capability, safety and our drug development capability

## i-body platform

Unique single domain antibody platform capable of drug discovery against "difficult" targets

# Opportunities for our partners

## Product partners

- License to AD-214 (and future products)

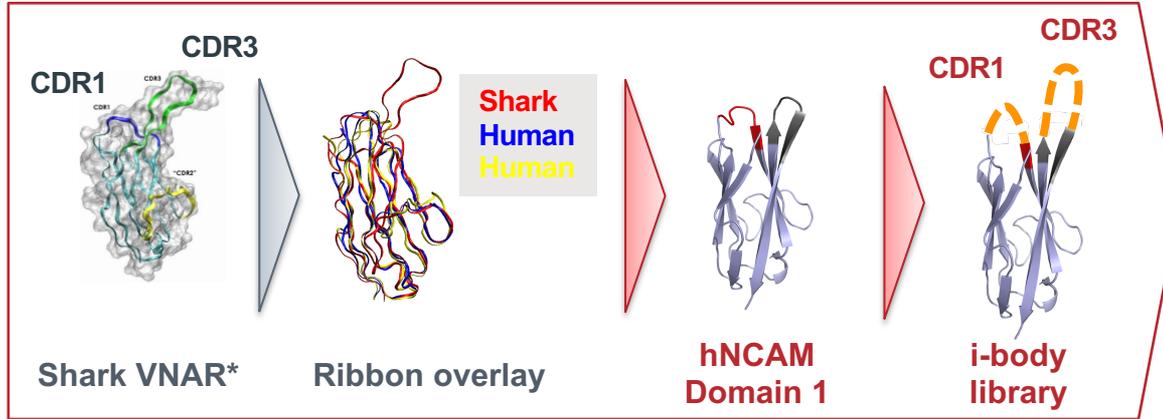
## Platform partners

- Co-develop solutions to drug targeting challenges

## Financial partners

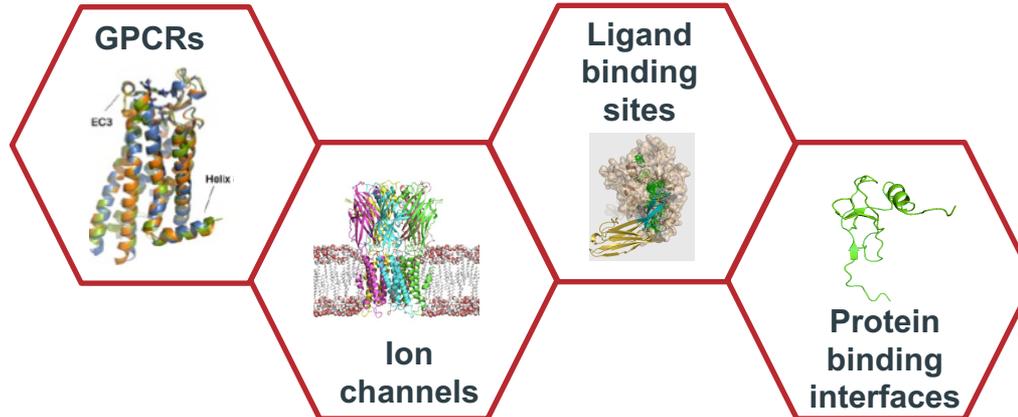
- Buy platform potential at single product price

# i-bodies: designed for “difficult to drug” targets



## Unique i-body properties

- Small + long loop = unique epitopes
- Novel, tunable pharmacology
- Flexible half-life
- Stable under pH, temperature cycling
- Multiple routes of administration



# Market opportunity for IPF (lung fibrosis)

**Idiopathic Pulmonary Fibrosis (IPF) is an irreversible, unpredictable and incurable disease**

## THE STATISTICS

People living with IPF  
**300,000**

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

Median length of survival after IPF diagnosis  
**3.8 years**

### IPF incidence



of sufferers die within 2 to 3 years following diagnosis



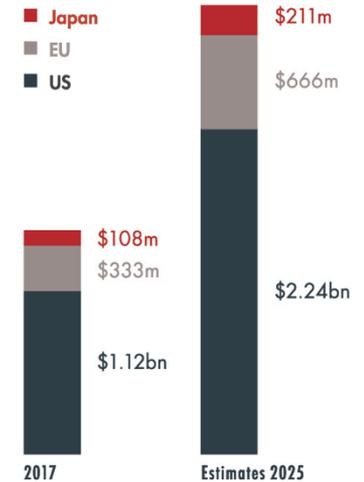
### Current IPF treatments

Pirfenidone

Nintedanib

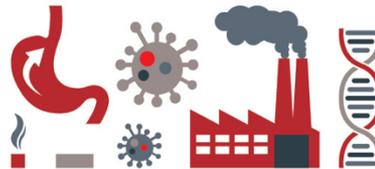


### IPF Therapy Sales (US\$)



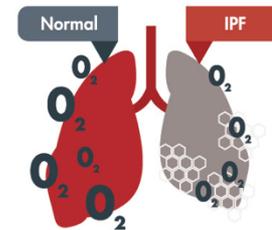
Source: GlobalData 2018

### Causes



The cause is unknown but risk factors may include: smoking, environmental exposures, chronic viral infections, abnormal acid reflux and family history of the disease.

### Pathology



Resultant scarring/honeycombing in the lung restricts breathing and oxygen exchange.

*Burden of fibrotic lung disease following SARS-CoV-2 infection is likely to be high*

*Antifibrotic therapies could have value in preventing severe COVID-19 in IPF patients, preventing fibrosis after SARS-CoV-2 infection<sup>1</sup>*

Source: GlobalData

1. PM George, AU Wells, RG Jenkins, "Pulmonary fibrosis and COVID-19: the potential role for antifibrotic therapy", Lancet published online May 15, 2020 [https://doi.org/10.1016/S2213-2600\(20\)30225-3](https://doi.org/10.1016/S2213-2600(20)30225-3)

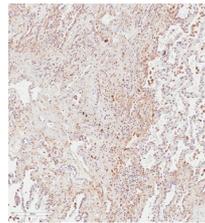
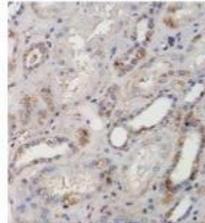
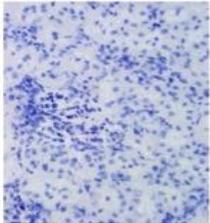
# AD-214: first in-class anti-fibrotic with potential in multiple indications

AD-214 targets CXCR4 which is:

- ▶ Important in maintaining stem cells in bone marrow
- ▶ Used by HIV-1 as a co-receptor for viral entry into cells
- ▶ Associated with more than 23 types of cancers
- ▶ ***Recognised as a biomarker, critical player in development of fibrosis in many organs***

Human kidney tissue

Human lung tissue



Normal

Diseased

Normal

Diseased

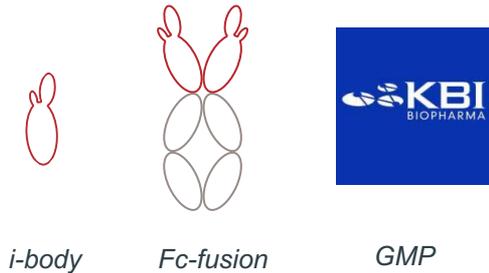
*Brown stain is an indicator of CXCR4 expression*

**AD-214 is a potential first-in-class anti-fibrotic**

- ▶ Inhibits inflammation, fibrocyte recruitment, collagen deposition
- ▶ Does not mobilise stem cells
- ▶ Developed for chronic use
- ▶ Potential in multiple fibrotic diseases, metastatic and other cancers

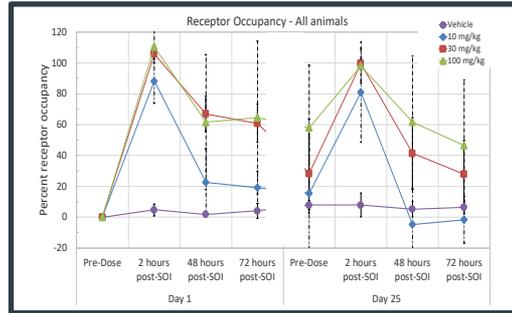
# Recent AD-214 achievements

## Product development, GMP manufacturing



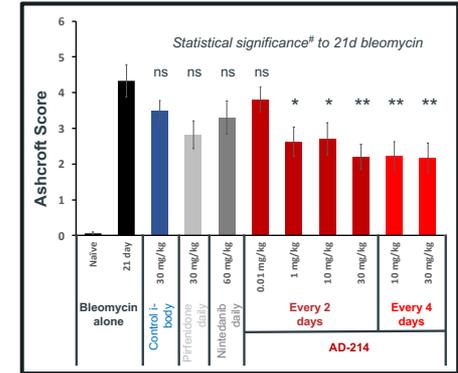
- ▶ i-body-Fc-fusion for manufacturing, half-life
- ▶ Continuous manufacturing improvement strategy
- ▶ **cGMP clinical trial production complete**

## Toxicology, pharmacokinetics and pharmacodynamics: non-human primate



- ▶ High receptor binding >3 days
- ▶ Supports  $\geq$  weekly dosing
- ▶ Clean tox profile
- ▶ **Phase I study includes potential therapeutic window**

## Pre-clinical efficacy: mouse bleomycin model



- ▶ Efficacy demonstrated in gold standard animal model of IPF
- ▶ **Enables progression to Phase I in mid-2020**

# AD-214 next steps

## Phase I clinical study: safety, tolerability, PK, PD (mid-2020)

**Part C ILD/IPF MAD**  
12-24 subjects, 1-20 mg/kg

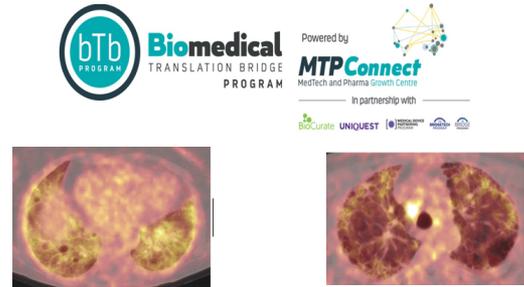
**Part B ILD/IPF SAD**  
15-30 subjects, 0.1-20 mg/kg

**Part A HV SAD**  
40 subjects, 1-20 mg/kg



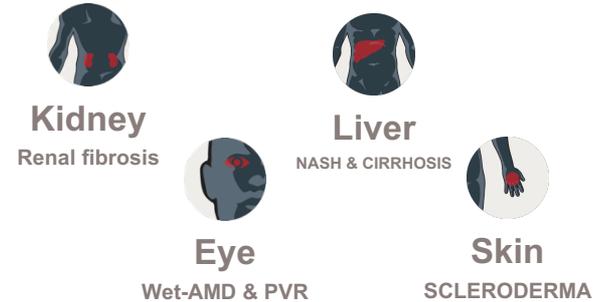
- ▶ Early safety, PK/PD read out
- ▶ Impact of disease on PK/PD established with PET tracer
- ▶ A partnering window opens with first patient data

## Radiolabelled AD-214 for PET imaging (Q1 2021)



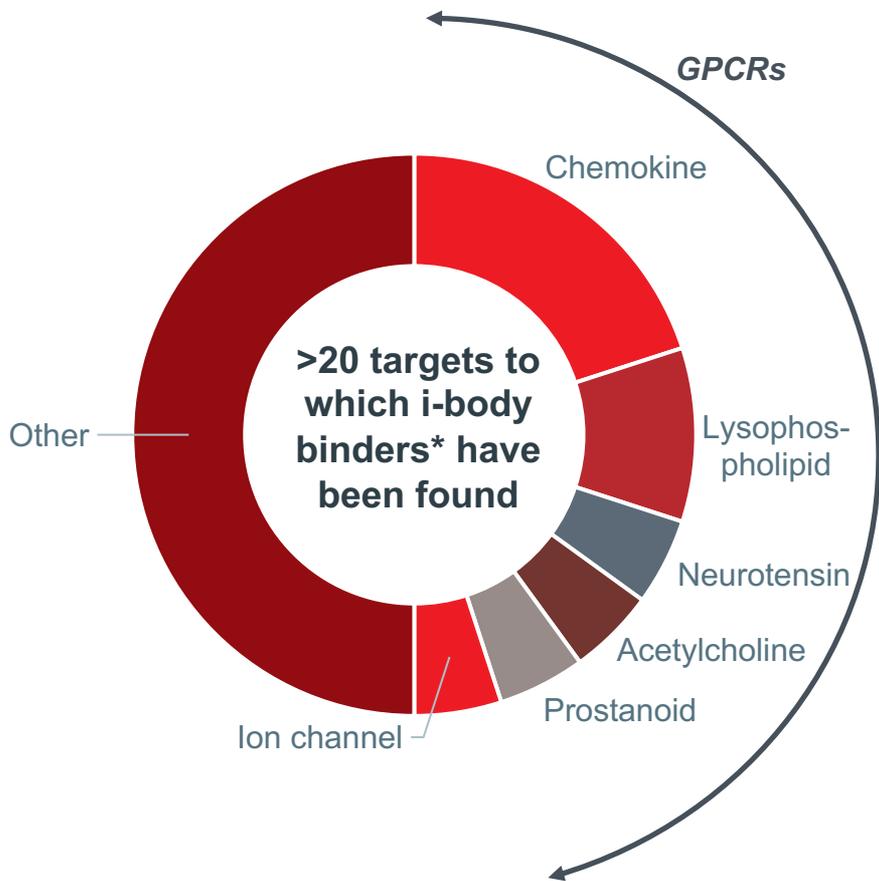
- ▶ A\$1m grant funding
- ▶ AD-214 distribution and target engagement
- ▶ Potential diagnostic
- ▶ Adds significant commercial and clinical value to Phase I

## Indication extension options (proof of concept 2021)



- ▶ Emerging proof of concept in multiple fibrotic diseases
- ▶ Cancer program planned
- ▶ Attractive additional options to progress to Phase II

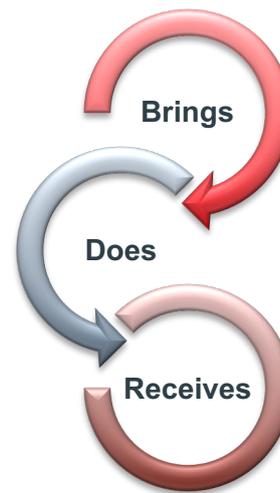
# Diverse target capability supports multiple platform partnerships



- i-body libraries
- Platform IP

- Discovery, validation

- Milestones
- Research fees
- Royalties

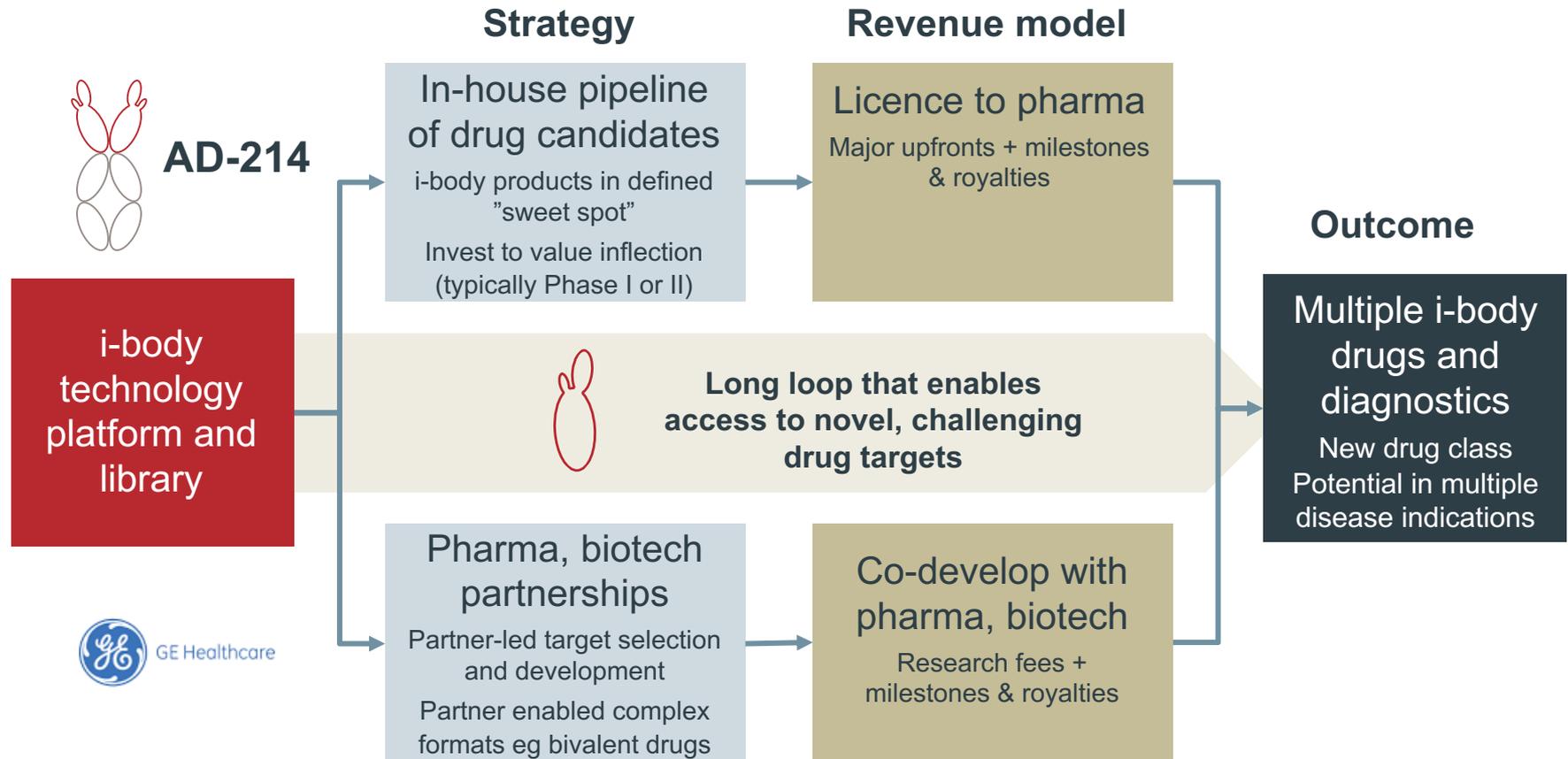


- Target
- i-body performance specs

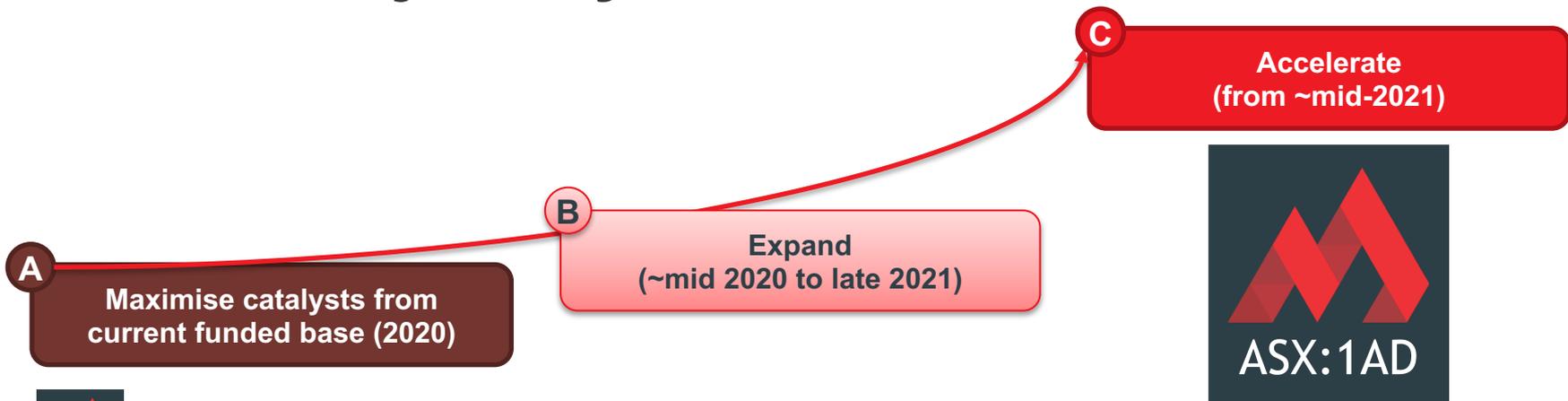
- Pre-clinical, clinical development

- Binder IP
- Exclusive commercialisation rights

# AdAlta's strategy, business model to create value



# Growth trajectory to build value



 **Market Cap: A\$14 million**  
(26 May 2020)

## From ...

- Single product, single indication, single partner
- Validating platform with AD-214 trial and GE partnership

**Expand**  
(~mid 2020 to late 2021)

## Via ...

- Laying the foundations
- AD-214 Phase I in patients
- New platform partnerships
- Continuous platform improvement

**Accelerate**  
(from ~mid-2021)



**Market Cap: ????**

## Towards 2023 ...

- Multi-product, multi-partner platform company
- AD-214 partnering, new indications
- ~5 internal GPCR programs
- >3 co-development partnerships

Supported by financing strategy

# Market benchmarks: reaching for the stars!

## Fibrosis pipelines



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



Promedior

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



Jan-20 platform license by Boehringer Ingelheim \$?m + \$1b milestones Preclinical

## Micro-antibody platforms



April-16 license by Abbvie \$40m upfront + \$645m milestones & royalties



Feb-18 collaboration with Seattle Genetics (3 targets) \$30m upfront + \$1.2b milestones & royalties



Feb-18 acquired by Sanofi €3.9b

## GPCR platforms



Feb-15 acquired by Sosei \$400m Phase Ib asset + 7 pre-clinical leads



Jul-15 acquired by Celgene \$7.8b Ph III, Ph II and GPCR platform



April-16 license with Boehringer €8m + €125m milestones Phase I GPCR nanobody

# Diverse, experienced team

## Executive



**Tim Oldham, PhD**  
CEO & Managing Director



**Mick Foley, PhD**  
Chief Scientific Officer



**Dallas Hartman, PhD**  
Chief Operating Officer



**Claudia Gregorio-King, PhD**  
VP Clinical Product Development



**Kevin Lynch, MD**  
Consultant Medical Expert



## Board



**Dr Paul MacLeman**  
Chair



**Liddy McCall**  
Director



**Dr Robert Peach**  
Independent Director



**Dr James Williams**  
Alternate to Liddy McCall



## Scientific Advisory Board



**Brian Richardson**  
Drug discovery and development expert



**Steve Felstead**  
Clinical development

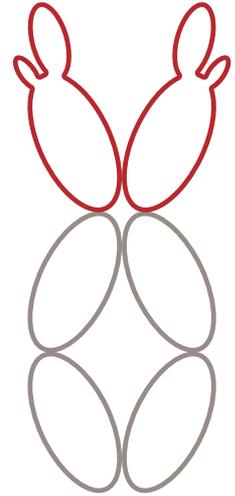


**John Westwick**  
Pulmonary drug discovery and development



# AdAlta (ASX:1AD) summary

- ▶ **i-body platform for generating multiple products against “difficult” targets**
  - Internal pipeline focused on GPCRs implicated in fibrotic and inflammatory disease and cancer
  - External pipeline leveraging partner expertise to pursue wider range of targets, indications
- ▶ **First in class lead asset, AD-214, entering human Phase 1 clinical trials provides catalyst for growth**
  - Efficacy demonstrated in gold-standard animal model of IPF; receptor occupancy data supportive of desired weekly dosing and potential therapeutic window within Phase I dose range
  - Multiple additional indications with emerging proof of concept data
- ▶ **Clear plan to use the i-body platform to accelerate pipeline expansion**
  - Bring AD-214 to the clinic and expand indications; first partnering window at end of Phase I
  - Add new internal pipeline candidates in a clearly defined “sweet spot”
  - Add external pipeline candidates by replicating the recent GE deal
  - Support growth with continuous improvements to i-body platform and AD-214 product
- ▶ **Experienced drug development team driving strategic focus on the foundation**
  - Developing network of partners and investors to share in the opportunity ahead



**AD-214**



**Contacts for more information:**

**Tim Oldham, CEO and Managing Director**

[t.oldham@adalta.com.au](mailto:t.oldham@adalta.com.au)

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

