AdAlta

next generation protein therapeutics

i-bodies: next generation protein therapeutics solving difficult drug target challenges

April 2020

AdAlta Limited (ASX:1AD)

Tim Oldham, CEO and Managing Director

t.oldham@adalta.com.au

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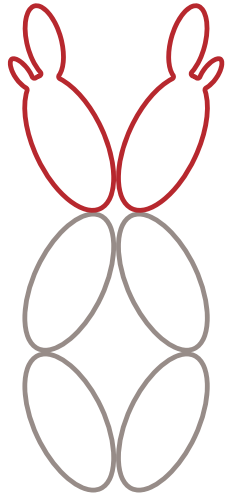
AdAlta's purpose

"Next generation protein therapeutics"
"Solving difficult drug target challenges"

AdAlta Limited (ASX:1AD) is a late pre-clinical stage biotechnology company using its i-body platform to discover and develop next generation protein therapeutics addressing drug targets that are challenging for other technologies

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, due to commence human Phase 1 clinical trial in mid-2020 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 fully use the i-body platform to expand pipeline, grow value**
  - Bring AD-214 to the clinic, expand indications ahead of 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

Executive leadership

Tim Oldham, PhD
CEO & Managing Director

- >20 years of international life sciences business development and commercialisation experience
- Significant ASX listed company experience

Mick Foley, PhD
Chief Scientific Officer

- Founding scientist of AdAlta and inventor of lead i-body candidate, AD-214
- Recognized expert in phage display; >70 scientific publications

Claudia Gregorio-King, PhD
VP Clinical Product Development

- 15 years experience in clinical operations, regulatory affairs and R&D program management

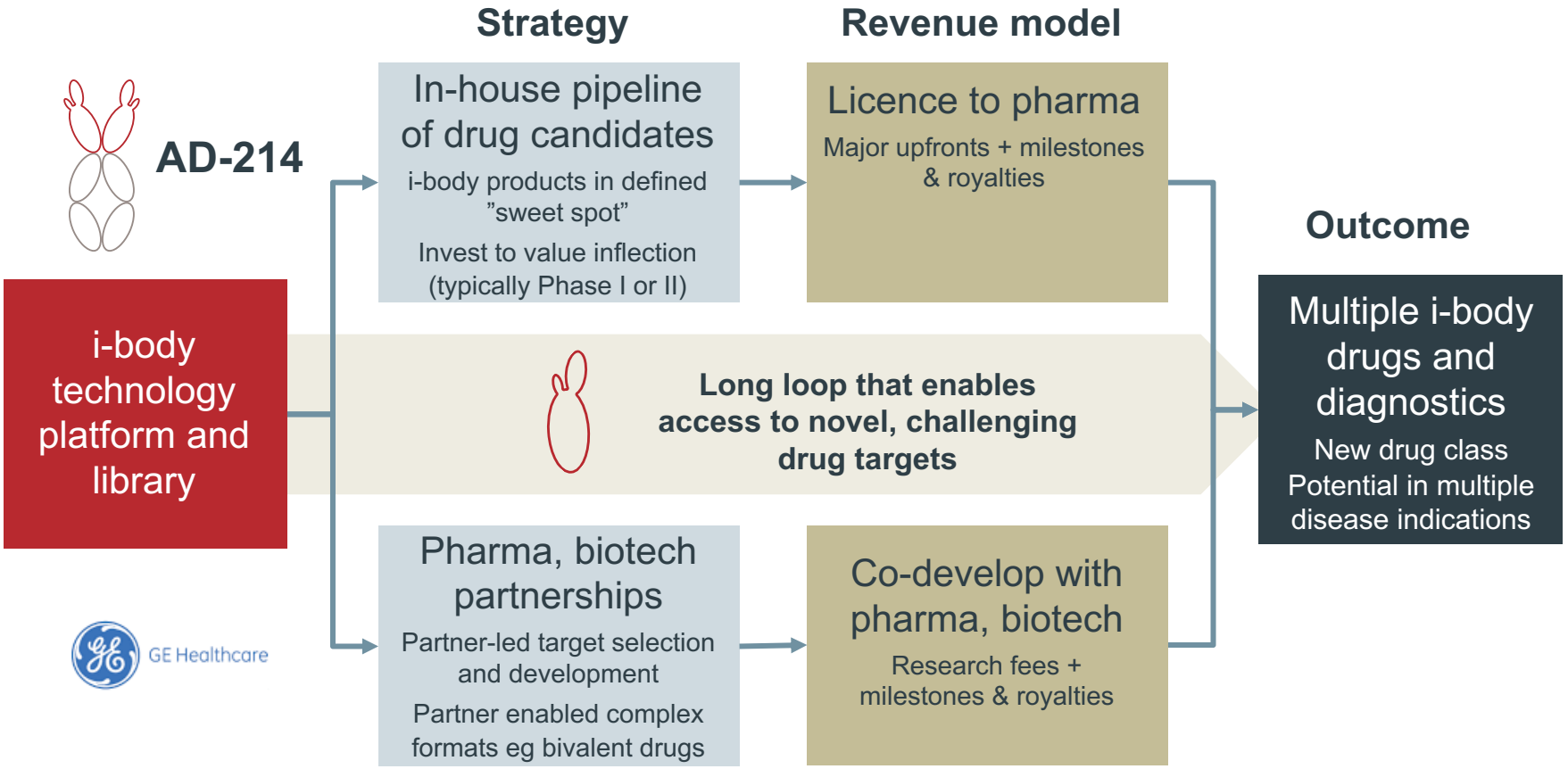
Dallas Hartman, PhD
Chief Operating Officer

- >20 years experience in protein product development and characterisation

Kevin Lynch, MD
Consultant Medical Expert

- >25 years experience across all phases of clinical development, regulatory and reimbursement approval and medical affairs

AdAlta's strategy, business model to create value



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Near term strategic priorities

Create value inflections for lead candidate AD-214

- Advance to clinic in Idiopathic Pulmonary Fibrosis
- Expand indications and licensing options

Build *internal* pipeline in our "sweet spot"

- G-protein coupled receptors (GPCRs)
- Fibrosis, inflammation, cancer

Build *external* pipeline through partnerships

- Earlier revenue; access to additional target expertise

Continuous i-body platform and AD-214 product improvement

Market opportunity for IPF (lung fibrosis)

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

THE STATISTICS

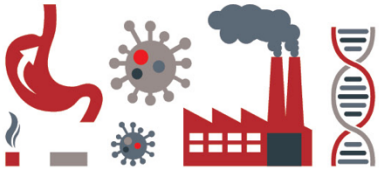
People living with IPF
300,000

People die from IPF every year
40,000

Median length of survival after IPF diagnosis
3.8 years

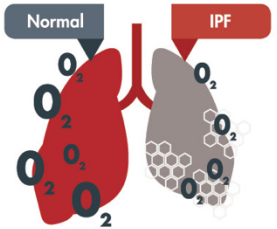
IPF incidence

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



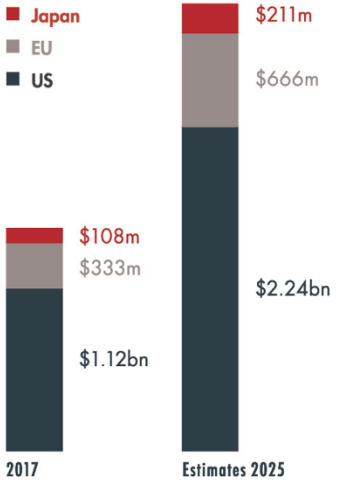
Resultant scarring/honeycombing in the lung restricts breathing and oxygen exchange.

Current IPF treatments

Pirfenidone — Roche

Nintedanib — Boehringer Ingelheim

IPF Therapy Sales (US$)



Source: GlobalData 2018

* AdAlta uses pirfenidone and nintedanib as positive controls in pre-clinical development
Source: GlobalData

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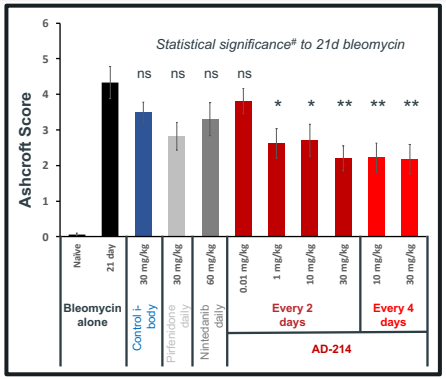
Significant recent AD-214 achievements

A$1m BTB grant to radiolabel AD-214 for PET imaging

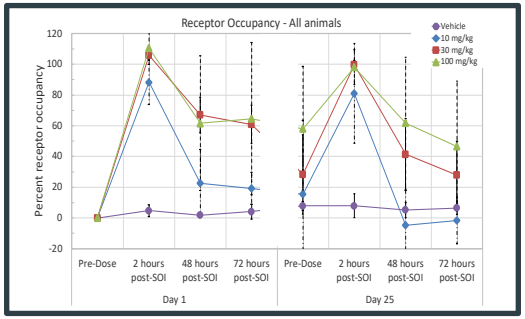
- AD-214 distribution and target engagement information in lungs of IPF patients earlier than planned
- **Adds significant commercial and clinical value to Phase I**
- Potential product in own right

Pre-clinical efficacy: mouse bleomycin model



- AD-214 efficacy demonstrated in gold standard animal model of IPF
- Adds to favorable NHP toxicity profile
- **Enables progression to Phase I in mid-2020**

Pharmacokinetics and pharmacodynamics: non-human primate



- AD-214 exhibits high target receptor binding for at least three days in NHP
- Supports potential therapeutic effect at weekly or every second week human dosing
- **Phase I study includes potential therapeutic window**

SUBJECT TO ETHICS APPROVAL

Proposed two-part phase I design

Phase I, dose-escalating study of the safety, tolerability, PK & PD of single and repeat doses of AD-214 in healthy volunteers (HVs) and patients with interstitial lung disease (ILD)

Part A (mid 2020)

Part B (early 2021; funding, PET tracer dependent)

Single dose, healthy volunteers (HV SAD)

- ~40 subjects
- 1-20 mg/kg iv
- 5 cohorts
- Randomized 3:1 drug:placebo
- 1 site

Single dose, ILD patients (Pax SAD)

- ~15-30 subjects*
- 0.1-20 mg/kg iv
- 5 cohorts
- Can begin after 5mg/kg cohort of HV SAD
- 2-3 sites

Multiple dose, ILD patients (Pax MAD)

- ~12-24 subjects*
- 1-20 mg/kg iv weekly over 4 weeks
- 4 cohorts
- Can begin after 5mg/kg cohort of Pax SAD
- 2-3 sites

Primary Objective

- Safety, tolerability of AD-214

Secondary Objectives

- PK, PD of AD-214
- Immunogenicity of AD-214

Exploratory Objectives

- Effect of AD-214 on respiratory function
- Localisation/distribution of ^{89}Zr-AD-214 by PET-CT

Contracted vendors

CNS Intelligent Development; CMAX Clinical Research; 360biolabs

Partners in development and clinical validation of PET tracer

Monash University; The University of Melbourne; theAlfred; Austin Health; Olivia Newton-John Cancer Research Institute

* Standard 3 + 3 safety design: up to 3 additional ILD pts will be recruited into one or more dose groups if required to provide additional safety.

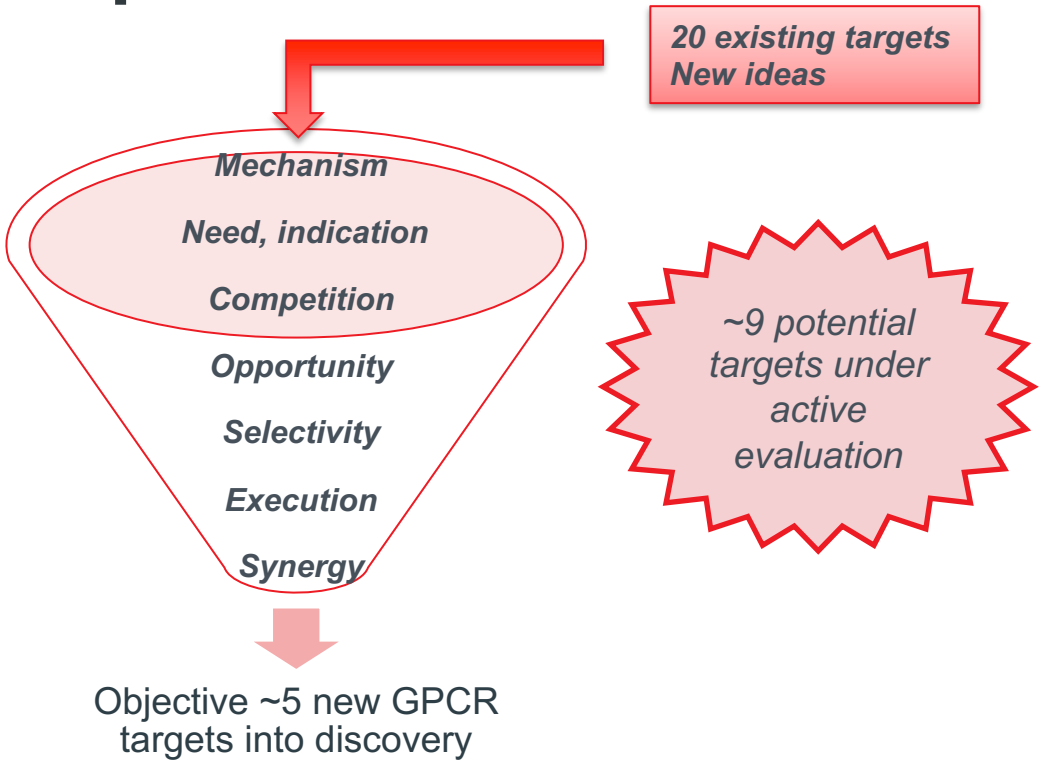
AdAlta's "sweet spot" facilitates more rapid screening of internal product ideas

AdAlta's internal development "sweet spot" – i-bodies to G-protein Coupled Receptors (GPCRs)

- Clinically validated
- Indications in fibrosis, inflammation or oncology
- Not adequately addressed with small molecule or conventional antibody approaches due to complex pharmacology

Partnering will enable platform to be deployed more widely including:

- Other "challenging to drug" targets needing new approaches eg ion channels
- Products that require complementary formatting technology eg bispecifics



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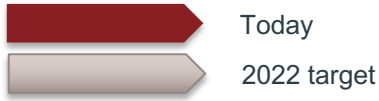
AdAlta target pipeline evolution

SUBJECT TO FINANCE, TECHNICAL SUCCESS



Target	Class of Target	Partner	Product/ Indication	Discovery	Preclinical, product dev	IND enabling studies	Phase I	Phase II
CXCR4	GPCR	AdAlta	**AD-214**: Idiopathic Pulmonary Fibrosis					
			AD-214: Indication 2					
			AD-214: Indication 3					
Target 2-3	GPCR	AdAlta	TBD					
Target 4-6	GPCR	AdAlta	TBD					
Granzyme B	Serine protease	GE Healthcare	PET imaging agents					
TBC		**3-5 Partners**						

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Market benchmarks

Breaking: Jan-20 Boehringer Ingelheim and Enleofen ink $1 Billion+ fibrosis deal

Fibrosis lead AD-214	adheron THERAPEUTICS Sep-15 acquired by Roche $105m + $475m milestones phase I	bridgebio therapeutics 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
Micro-antibodies	arGEN-X April-16 license by Abbvie $40m upfront + $645m milestones & royalties	pieris Feb-18 collaboration with Seattle Genetics (3 targets) $30m upfront + $1.2b milestones & royalties	Ablynx Feb-18 acquired by Sanofi €3.9b
GPCRs	HEPTARES therapeutics Feb-15 acquired by Sosei $400m Phase Ib asset + 7 pre-clinical leads	receptos Jul-15 acquired by Celgene $7.8b Ph III, Ph II and GPCR platform	Ablynx April-16 license with Boehringer €8m + €125m milestones PhI GPCR nanobody

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Growth trajectory to build value

Timing and rate of growth dependent on financial resources

A Maximise catalysts from current funded base (2020)

AD-214
- Phase I healthy subject single dose
- Develop PET imaging agent

Internal pipeline
- Target selection

External pipeline partners
- GE collaboration

Continuous platform improvement
- Design i-body2.0, AD-214 continuous improvement plan

B Expand (~mid 2020 to late 2021)

AD-214
- Phase I patient single dose + PET
- New indications: proof of concept

Internal pipeline
- Initiate discovery

External pipeline partners
- Fill, progress business development pipeline

Continuous platform improvement
- Build i-body2.0 libraries
- Lab scale AD-214 process improvements

C Accelerate (from ~mid-2021)

AD-214
- Phase I patient multi-dose + PET
- Phase I licensing window opens
- Next indication pre-clinical

Internal pipeline
- ~5 new internal targets in discovery and proof of concept

External pipeline partners
- 3-5 co-development contracts active

Continuous platform improvement
- File i-body2.0 IP
- Scale up AD-214 process improvements

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SUBJECT TO FINANCE

Building a diversified, valuable pipeline

Metric	From AD-214 focus today …	To multi-product by 2023 …
AD-214 development	▸ Pre-clinical in IPF	▸ Clinical in two indications ▸ Phase I partnering window
Internal pipeline	▸ Substantial “proof of principle” ▸ *Ad hoc* target selection	▸ GPCR target selection rigor ▸ 2 pre-clinical programs ▸ >3 discovery programs
Revenue generating partnerships	▸ 1 (GE Healthcare)	▸ 3-5 co-development partnerships in multiple target, product classes
News flow	▸ Large gaps between inflection points	▸ Frequent news flow, regular inflection points
Financing	▸ Primarily equity; frequent, small raises for “next steps” to date	▸ Partnerships: low double-digit share of annual costs ▸ >18 months cash to achieve inflections

Numerous milestones, inflection points and transactions along the way

GPCR = G-protein coupled receptor

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News flow

- **Early 2020**
  - ✓ Patent granted covering AD-214 granted in the US
  - ✓ Publication of role of CXCR4 in fibrosis
  - ✓ Pre-clinical efficacy and PK/PD of AD-214
  - ✓ AdAlta strategy update (AD-214 clinical development and i-body platform growth)
- **Mid-2020**
  - Ethics committee approval for Phase I human clinical studies
  - **Phase I healthy volunteer studies with AD-214 commence**
- **Late 2020**
  - PET tracer pre-clinical images in bleomycin mouse
  - **Phase I healthy volunteer studies – top line results (safety and PK)**
  - **Ethics approval to introduce PET tracer to Phase I patient single dose studies**
- **Early 2021**
  - **First patient image with PET tracer (early 2021)***
  - Proof of concept *in vitro* and *in vivo* (animal) data and in new AD-214 indications*

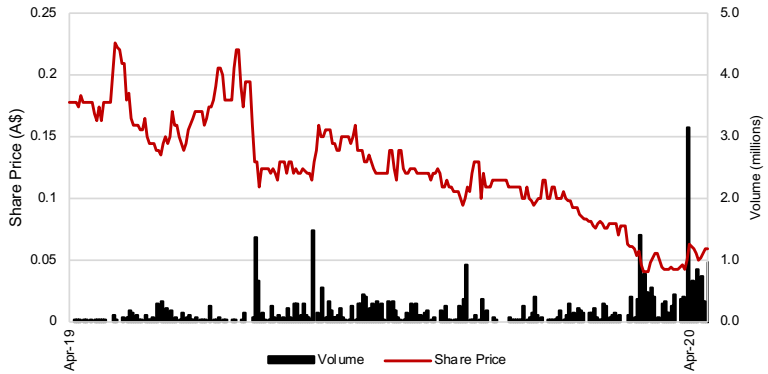
* Not currently funded

Financial position and results: funded to end of Phase I health volunteer study (late 2020)

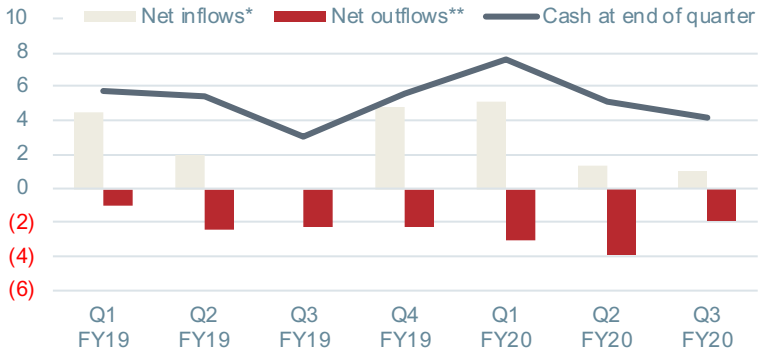
Key financial details	
ASX code	1AD
Share price (29 April 2020)	AUD$0.06
Market capitalisation	AUD$9.84m
Ordinary Shares	163,945,613
Listed Options	23,348,803
Unlisted Options	7,514,067
Current cash (31 March 2020)	AUD$4.14m
Trading range (last 12 months)	AUD$0.04 to $0.22
Average daily volume (last 6 months)	212,000

Major shareholders	%
Yuuwa Capital LP	32.97
Platinum Asset Management	8.54
CS Fourth Nominees Pty Ltd	3.07
Meurs Holdings Pty Ltd	3.05
Brispot Nominees Pty Ltd	2.21
Other shareholders	49.96
Total	100%

Share price performance (last 12 months)



Quarterly cash flows



* Net inflows include R&D Tax Incentive (RDTI) refund, proceeds of capital raising activity after capital raising costs, RDTI loan facility (Radium Capital), and platform licensing revenue (GE contract)

** Net outflows includes all operating expenses and equipment purchases

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International Board, Scientific Advisory Board

Extensive track record of drug, antibody development, capital raising and exits

Board

Dr Paul MacLeman
Chair

Liddy McCall
Director

Dr Robert Peach
Independent Director

Dr James Williams
Alternate to Liddy McCall

Scientific Advisory Board

Dr Mick Foley
AdAlta CSO
Expert in phage display

Brian Richardson
Drug discovery and development expert

Steve Felstead
Clinical development

John Westwick
Pulmonary drug discovery and development

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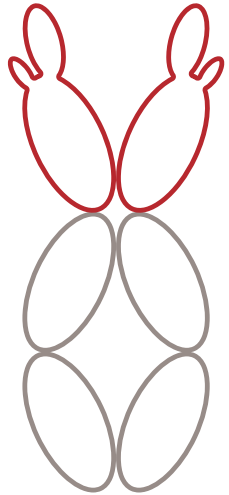

AD-214

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Contact us:

Tim Oldham, CEO and Managing Director

t.oldham@adalta.com.au

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