



**AdAlta**  
next generation protein therapeutics

## **CEO report**

Annual General Meeting

26 November 2019

**Tim Oldham, CEO and Managing Director**  
**AdAlta Limited (ASX:1AD)**



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# AdAlta overview

AdAlta Limited (ASX:1AD) is an Australian listed drug discovery and development company generating a promising new class of protein therapeutics, known as i-bodies, for treating a wide range of human diseases.

# Introducing new CEO, Tim Oldham PhD



cell therapies



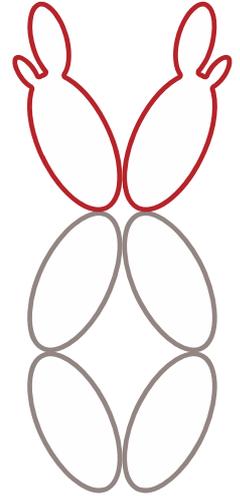
McKinsey  
& Company



- ▶ Commenced 14 October 2019
- ▶ 20 years' executive leadership experience in Australia, Europe and Asia
- ▶ Senior pharma and biotech roles in strategic planning, business development (licensing, M&A), commercial and manufacturing operations and alliance management in pharma and biotech
- ▶ Experience in complex and novel therapy commercialization pathways: biosimilars, modified antibodies, cell and gene therapies
- ▶ ASX Board experienced
- ▶ PhD, Imperial College, London; BSc/LLB, ANU

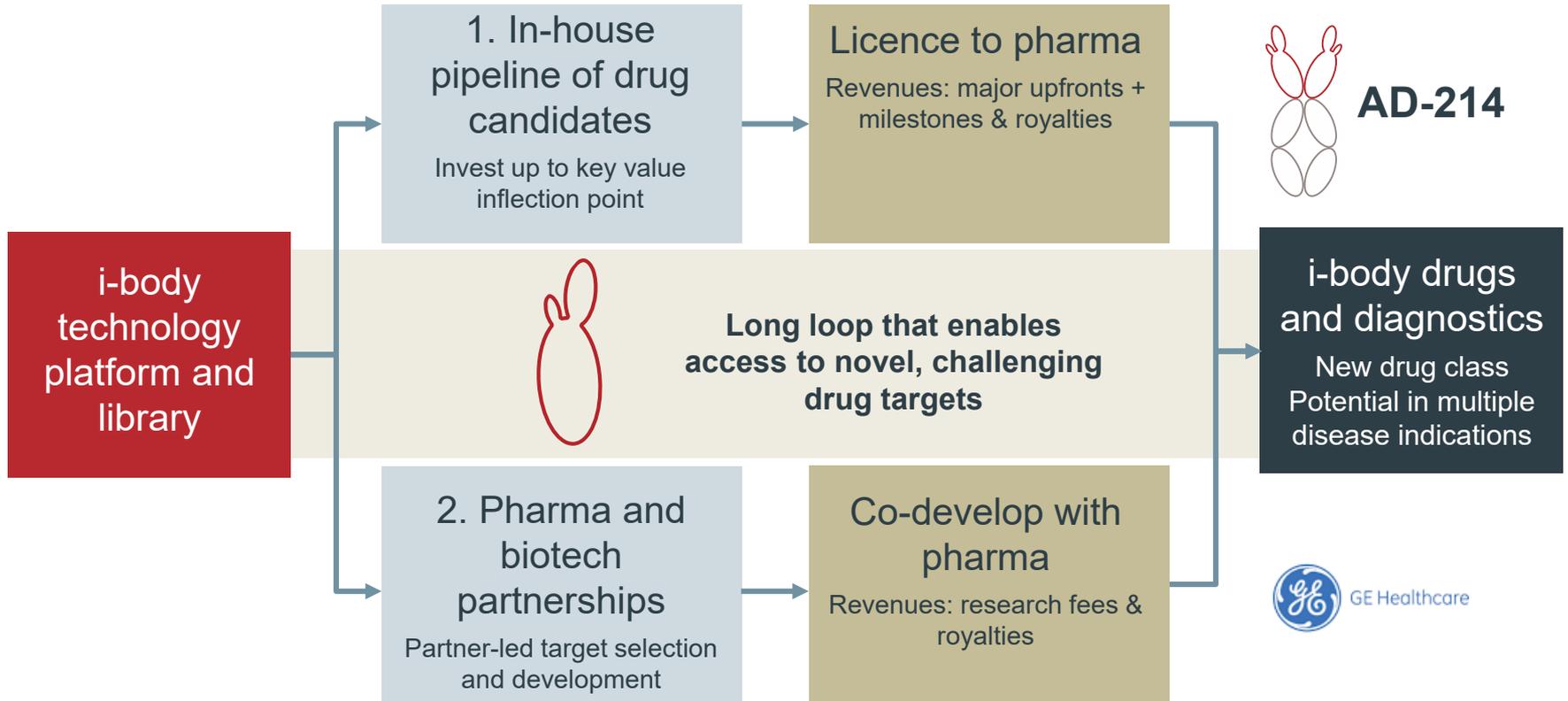
# AdAlta (1AD) investment summary

- ▶ **i-body platform for generating multiple products**
  - Novel structure provides new way to access important biological targets that can be difficult to access with conventional approaches
- ▶ **Lead internal program, AD-214, due to commence human Phase 1 clinical trial in early 2020**
  - Targeting fibrosis of the lungs (Idiopathic Pulmonary Fibrosis), a clinical indication with high unmet medical need and early transaction potential
  - USA FDA Orphan Drug Designation and strong pre-clinical data
- ▶ **Collaborations providing additional opportunities to leverage the i-body platform**
  - Recently secured licensing deal with global medical technology firm, GE Healthcare to develop i-bodies for diagnostic imaging
- ▶ **Experienced drug development team with track record of delivery**



**AD-214**

# AdAlta business model and strategy to create value



# AdAlta pipeline

	Partner	Product/ Indication	Target	Class of Target	Discovery	Preclinical	Manufacturing	IND enabling studies	Phase I
i-body discovery engine	 AdAlta <small>next generation protein therapeutics</small>	AD-214: Idiopathic Pulmonary Fibrosis	CXCR4	GPCR					
	 AdAlta <small>next generation protein therapeutics</small>	AD-214: Other fibrotic indications	CXCR4	GPCR					
	 AdAlta <small>next generation protein therapeutics</small>	Not disclosed	MCP-1	Novel ligand pocket					
	 AdAlta <small>next generation protein therapeutics</small>	Not disclosed	TRPV4	Ion channel					
	 Excellerate BIOSCIENCE	Not disclosed	Not disclosed	GPCR					
	 GE Healthcare	Diagnostic agents	Granzyme B + others	Serine protease					

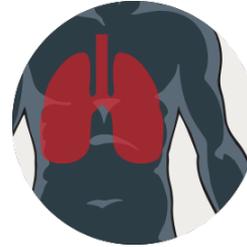
Binders obtained to 20 separate targets (10 are GPCRs and ion channels)

# AD-214 has broad application in treating fibrosis

AdAlta data in animal models and human tissue studies suggests that AD-214 can improve fibrosis and inflammation across a range of fibrotic diseases

- ▶ **LUNG:** Idiopathic Pulmonary Fibrosis
- ▶ **EYE:** Wet-Age Related Macular Degeneration
- ▶ **LIVER:** NASH
- ▶ **SKIN:** Hypertrophic scar
- ▶ **KIDNEY:** Chronic kidney disease

**Fibrotic diseases are recognised in almost every organ**



**Lung**  
IPF



**Eye**  
Wet-AMD & PVR



**Liver**  
NASH & CIRRHOSIS



**Kidney**  
RENAL FIBROSIS



**Skin**  
SCLERODERMA

# Market opportunity for IPF

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**

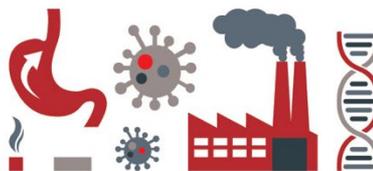
### IPF incidence



of sufferers die within 2 to 3 years following diagnosis

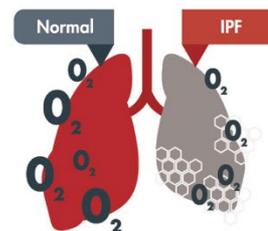


### Causes



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



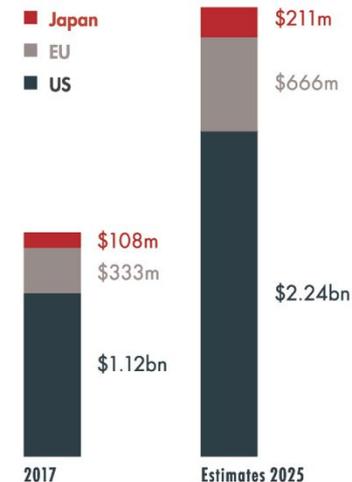
Resultant scarring/honeycombing in the lung restricts breathing and oxygen exchange.

### Current IPF treatments

Pirfenidone      Nintedanib



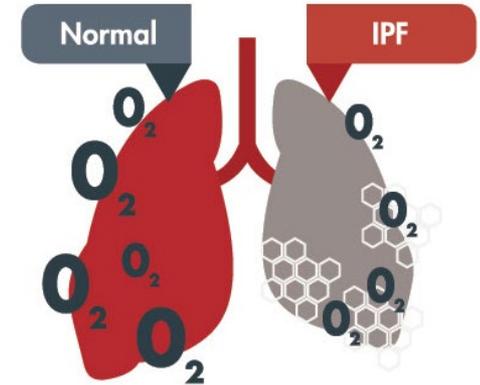
### IPF Therapy Sales (US\$)



Source: GlobalData 2018

# AdAlta's place in the IPF treatment landscape

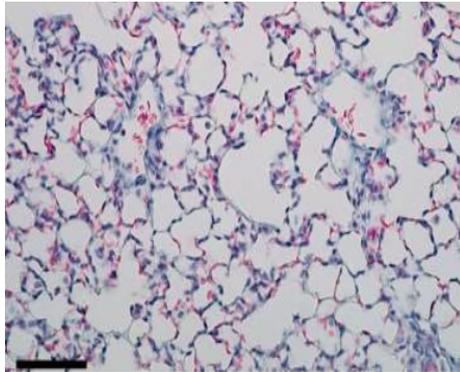
- ▶ FDA approvals of pirfenidone and nintedanib in 2014 has led to greater confidence in the development of drugs for IPF
  - Neither are optimal therapies - the disease process is slowed, not reversed
- ▶ A number of products in development
  - Provide pathway for Phase II and III trials
- ▶ No IPF treatments under development targeting CXCR4
  - Existing approved CXCR4 small molecule antagonist Mozobil very different pharmacology to AD-214 and toxic when provided in chronic setting



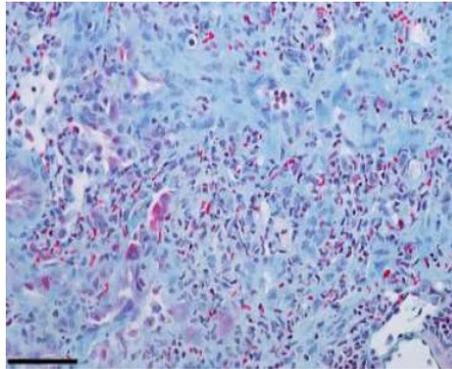
**High unmet medical need: there is a significant opportunity for multiple classes of drug to be clinically valuable and commercially successful for the management of IPF patients**

# AD-214 novel treatment for fibrosis – lung

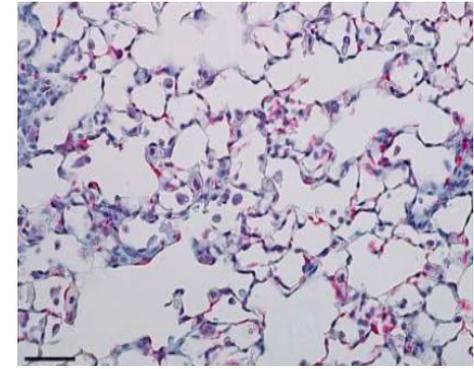
*AdAlta's lead i-body has demonstrated in vivo activity (reduced collagen content, reduced inflammatory cell infiltration, improved tissue architecture) in a Bleomycin-induced mouse model of lung fibrosis*



**Normal  
lung tissue**



**IPF lung tissue**  
(lung disease mouse model)



**IPF lung tissue + AdAlta  
anti-CXCR4 i-body dosed  
for 21 days**  
(lung disease mouse model)

*Blue staining represents collagen, a hallmark of fibrosis*

# AD-214 safe in 4-week toxicology study

## RECENT DATA

- ▶ 3 non-human primate studies completed
- ▶ Most recent: a Good Laboratory Practice (GLP) study to evaluate safety and toxicology prior to initial human studies
  - 10mg/kg, 30mg/kg and 100mg/kg multiple doses over four weeks plus recovery
  - AD-214 well tolerated with no deaths, no AD-214-related clinical signs, no changes in a panel of clinical observations, and only slight transient and completely reversible haematology changes

**Tox study results were in line with expectations and in keeping with previous studies**

# AD-214 development: key milestones



# GE Healthcare licensing deal – i-body platform

## Overview:

- ▶ Agreement with global medical technology and diagnostics firm, GE Healthcare
- ▶ AdAlta will screen its novel i-body library on a number of targets in order to identify i-bodies that GE can use as imaging agents, starting with Granzyme B

## Summary of commercial terms:

- ▶ First payment of GBP100,000 now due following target selection
- ▶ GE Healthcare will pay AdAlta for research costs
- ▶ Further milestone payments and royalties expected if development successful

**AdAlta aims to develop a range of therapeutic and diagnostic partnerships**

# Market benchmarks

## Fibrosis lead AD-214



Sep-15 acquired by Roche  
\$105m + \$475m milestones  
phase I



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



**Nov-19 acquired by Roche  
\$390m + \$1b – Phase II**

Aug-15 BMS option to buy  
\$150m + \$1.25b milestones

## Micro- antibodies



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

## GPCRs



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  
PhI GPCR nanobody

# Significant 2019 achievements

## AD-214

- ✓ Successfully completed AD-214 cell-line and manufacturing process development; completed manufacturing of clinical AD-214 bulk drug substance
- ✓ Completed Phase I-enabling non-human primate toxicity (safety) studies (pharmacology data pending)

## i-body platform partnerships

- ✓ Entered partnership with GE Healthcare to develop pre-clinical targets for diagnostic imaging – received first ever partnering revenue

## Pipeline research

- ✓ Key data published in *mABs* peer reviewed scientific journal, i-body half-life customisation
- ✓ Entered partnership with Excellerate Biosciences to accelerate characterization of GPCR binders

## Organisation

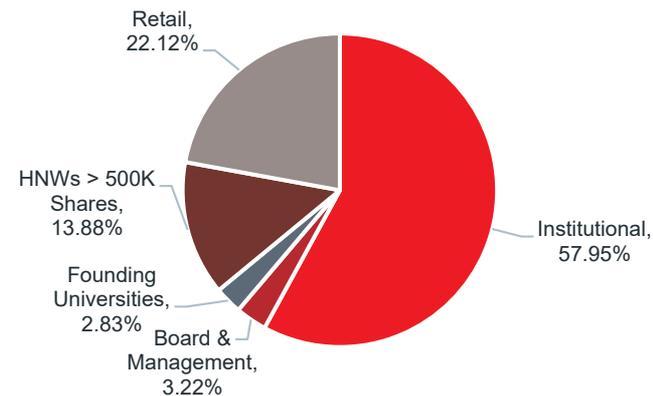
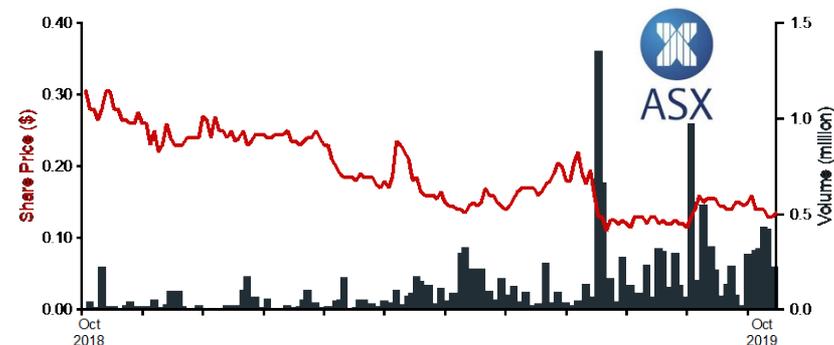
- ✓ Board skills expanded with appointment of Dr Ros Wilson
- ✓ Appointment of new CEO & Managing Director, Dr Tim Oldham

# Financial position

Key financial details	
ASX code	1AD
Share price (25 November 2019)	AUD\$0.12
Market capitalisation	AUD\$22.18m
Ordinary Shares	164,302,007
Listed Options	23,348,803
Unlisted Options	2,605,007
Current cash (30 September 2019)	AUD\$7.59m
Trading range (last 12 months)	AUD\$0.11 to \$0.30
Average daily volume	197,582

Major shareholders	%
Yuuwa Capital LP	32.90
Platinum Asset Management	8.64
Brispot Nominees Pty Ltd	4.65
Citycastle Pty Ltd	3.67
Meurs Holdings Pty Ltd	3.04
Other shareholders	47.09
<b>Total</b>	<b>100%</b>

## Share price performance (last 12 months)



# Financial results

AUD million

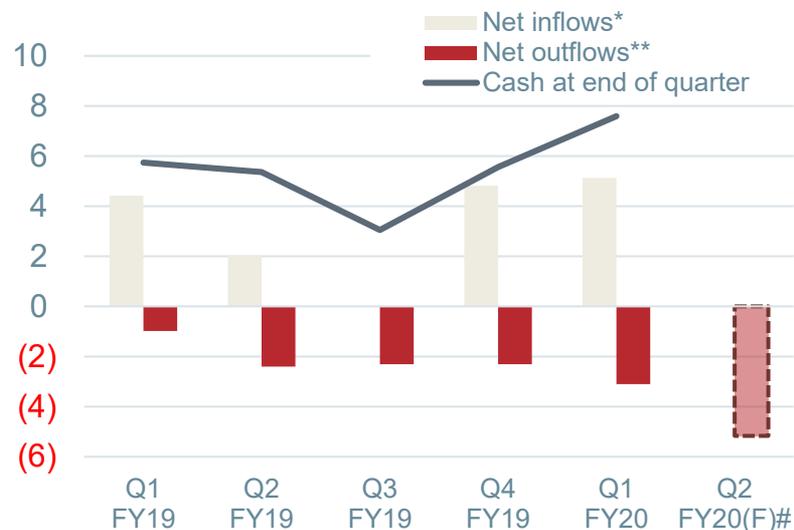
## Financial year cash flows

Cash	FY18 (AUD million)	FY19 (AUD million)
Operating inflows	1.86	2.11
Operating outflows	5.79	7.93
Financing cash flows	0.01	9.24
Starting cash	6.22	2.31
Ending cash	2.31	5.56

### Key drivers

- Capital raising Q1FY19 (\$4.3m) and mid-2019 (\$7.0m)
- R&D Tax refund Q2FY19 (\$2.0m) and Q1FY20 (\$3.5m)
- Outflows increasing due to external project costs associated with manufacturing process development, NHP toxicology study, GMP manufacturing

## Quarterly cash flows



### Outlook

- Q2FY20 is largest operating cash outflow of FY20
- Funded into Phase 1 clinical studies
- Cash balance plus cash management strategies fund the Company into Phase 1 clinical studies

# First month reflections

## Current CEO priorities

1. Commence AD-214 clinical program
2. Deliver GE contract
3. Develop growth/expansion strategy

### AD-214

- Busy but achievable plan to reach clinic Q1 2020
- Manufacturing
  - Clinical material available
  - Expected process improvement opportunities exist
- Data for numerous indication expansion options

### Platform

- Demonstrated ability to bind additional targets
  - Opens up additional product opportunities
- Opportunities to "industrialise" discovery
  - Improves productivity, IP extension potential

### Strategy

- Clear, confirmed opportunity to build a multi-product pipeline
- Major shareholders generally supportive of expanding development activity in an appropriately measured way
- Partnering: Company is "on the radar" of the industry based on inbound enquiries in first month

# FY20 news flow

*New milestones*

## ▶ H2 2019

- ✓ Partnership announcement – GE partnership September 2019
- ✓ Publication of key i-body data in well recognised, peer reviewed scientific journal, mAbs
- ✓ 4-week NHP toxicology study – completed October 2019 (plus GMP production of AD214 bulk for Phase I study)
- Publication of further key i-body/fibrosis data – *estimated February 2020*
- *Cash runway extension strategies*

## ▶ H1 2020

- *Additional pre-clinical PK/PD results*
- Update on i-body pipeline development and strategy
- **Phase I human clinical studies with AD-214 commence**
- *Initial single ascending dose component: dosing completed*

### To include

- AD-214 clinical development strategy
- New priority targets for i-body discovery and development

# AdAlta Limited (ASX:1AD) Summary

- ▶ **Platform technology for multiple pipeline products and partnerships**
- ▶ **Lead asset AD-214**
  - Has significant pre-clinical validation demonstrating broad anti-fibrotic and anti-inflammatory effects as well as safety.
  - Initial focus on treating Idiopathic Pulmonary Fibrosis (IPF). Market history of early commercialisation transactions in fibrosis
  - Key manufacturing and toxicology milestones achieved
  - Set to be in clinic by Q1 2020
- ▶ **Additional expansion opportunities through partnering**
  - Recent licensing deal with global medical technology firm, GE Healthcare, to develop i-bodies for diagnostic imaging: first licensing revenue received
- ▶ **Experienced leadership to drive AD-214 development, partnerships and pipeline expansion**
- ▶ **Cash balance and cash management strategies sufficient to fund the Company into Phase 1 clinical studies for AD-214**



# AdAlta

next generation protein therapeutics

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