

**27 October 2020**

**ASX Announcement**

**ADALTA TO UPDATE ON PHASE I CLINICAL TRIAL DURING AUSBIOTECH INVEST 2020 CONFERENCE**

**MELBOURNE Australia, 27 October 2020:** AdAlta Limited (ASX:1AD), a clinical stage biopharmaceutical discovery and development company using i-body technology to address challenging drug targets advises that CEO and Managing Director, Dr Tim Oldham, will discuss the attached presentation at the AusBiotech Invest and Partnering Conference on 29 October 2020.

The presentation includes an update on the progress of the Company's Phase I clinical trial of its first in class anti-fibrotic product, AD-214. Twenty-one healthy participants have now received AD-214 or placebo in an approximately 3:1 ratio at doses ranging from 0.01 mg/kg to 5 mg/kg. In the four cohorts up to 1 mg/kg where full safety observations are available, there have been no safety events of clinical concern to the safety monitoring committee. The two participants so far to receive the highest dose of 5 mg/kg AD-214 or placebo have successfully passed the dose limiting adverse event observation period. The planned maximum dose for the healthy volunteer component of the Phase I trial is 20 mg/kg.

Investors wishing to view the presentation and live presenter Q&A at the conference may contact the Company at [enquiries@adalta.com.au](mailto:enquiries@adalta.com.au) for complimentary registration details. The presentation can also be found on the Company's website at: <https://adalta.com.au/investors/presentations/>

Authorised for lodgement by:

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

**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 is conducting 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 to discover i-bodies as diagnostic imaging agents against Granzyme B, a biomarker of response to immuno-oncology drugs.

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>

**For more information, please contact:**

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# AdAlta

next generation protein therapeutics

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

AusBiotechInvest October 2020



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

**Tim Oldham, CEO and Managing Director**

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# 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.

# A clinical stage drug discovery company advancing rapidly in 2020



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Grow by creating and advancing i-body-enabled assets

- Progress and partner AD-214
- Add 5 internal assets and 3-5 external partnerships
- \$8.1 million raised in fully subscribed placement and rights issue to accelerate growth trajectory



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Lead external asset: GE Healthcare target in lead optimisation

- \$1.15 million milestones and research fees earned to 30 Sept
- Lead optimization stage completes Q1'21

2

Lead internal asset: AD-214 a first in class anti-fibrotic in Phase I

- Pre-clinical efficacy, safety; BTB grant for PET tracer; US FDA pre-IND meeting
- Phase I clinical trial commenced; 4 of 7 dose levels in healthy subjects complete; safety data Q1'21



1

Patented i-body discovery platform: unique, validated capabilities against difficult targets

- First fully human single domain antibody platform; first based on shark motif to reach the clinic

# Opportunities for our partners

## Product partners

- License to first-in-class anti-fibrotic

## i-body platform partners

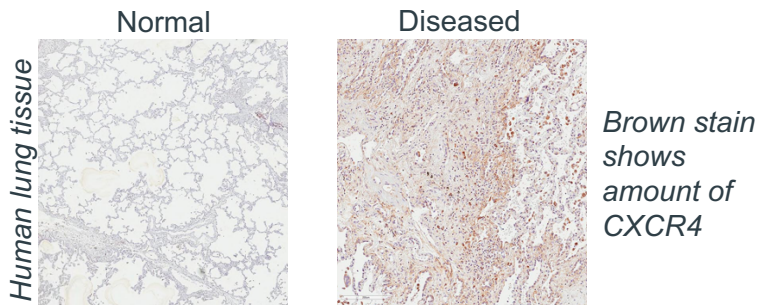
- Co-development solutions for challenging targets

## Financial partners

- Buy in to platform potential at single asset price

# Lead asset AD-214: first-in-class anti-fibrotic

**CXCR4 receptor is critical player in development of fibrosis in many organs**



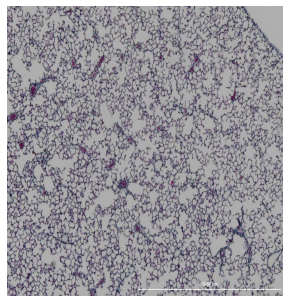
**AD-214 is first in class: the only CXCR4 antagonist being developed for fibrosis**

- ▶ *Potential in multiple fibrotic and cancer indications*

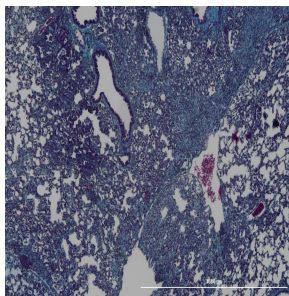
**AD-214 specifically designed for fibrosis**

- ▶ *Novel pharmacology*
- ▶ *Granted patents expire 2036*

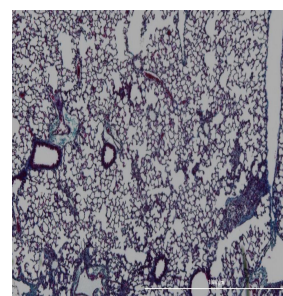
**Efficacy demonstrated in gold standard Idiopathic Pulmonary Fibrosis (IPF) mouse model**



**Normal mouse lung tissue**



**IPF mouse lung tissue**  
(21 days after bleomycin [BLM])



**IPF mouse lung tissue + AD-214**  
(21 days after BLM; AD-214 at 10mg/kg every 4 days from day 8)

# Lead indication IPF: \$3b market, poor options

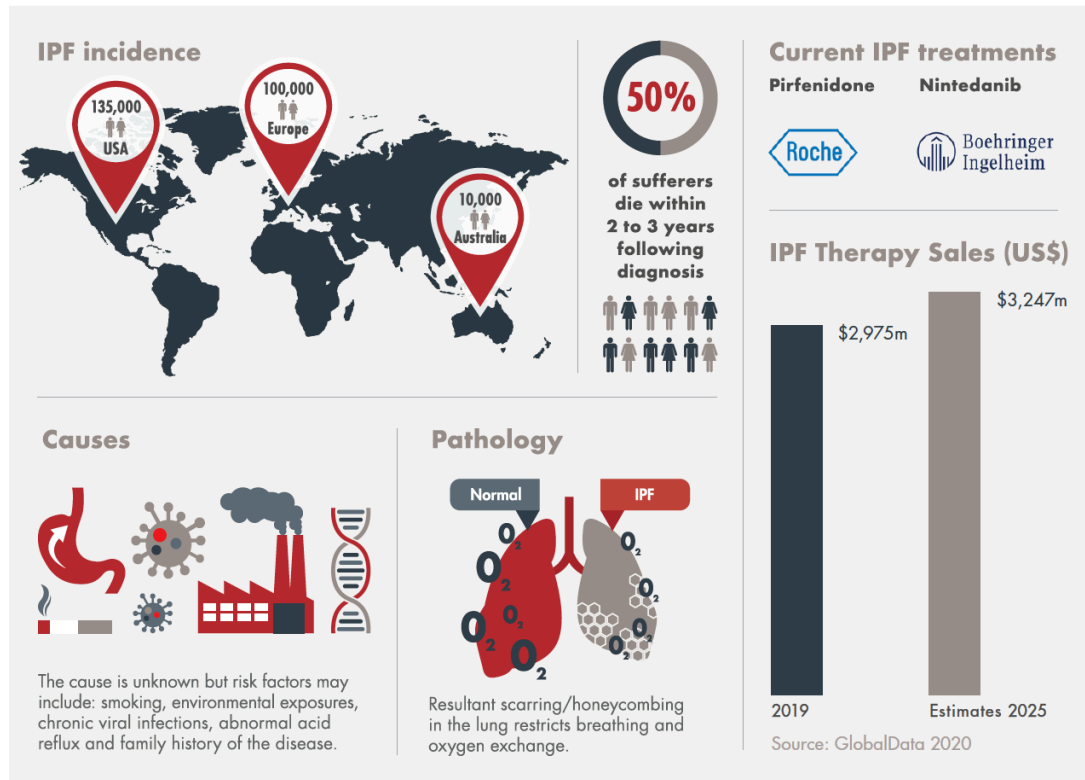
Idiopathic Pulmonary Fibrosis (IPF) is irreversible, unpredictable, incurable

**>300,000**  
people living with IPF

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

**3.8 years**  
median survival after diagnosis

**Current treatments come with safety, efficacy limitations**



**Burden of fibrotic lung disease following COVID-19 likely to be high**

*"Antifibrotic therapies could have value preventing severe COVID-19 in IPF patients and preventing fibrosis after SARS-CoV-2 infection"\**

# Current Phase I clinical trial update



## Pre-IND meeting

- Pre-clinical studies “generally sufficient” to support an IND application
- Phase I trial design is “reasonable”

## Part A (Results early 2021)

Single dose,  
healthy  
volunteers  
(HV SAD)

• ~44 subjects

## Part B (early 2021 to late 2021)

Single dose,  
ILD/IPF patients  
(Pax SAD)

• ~15-30 subjects

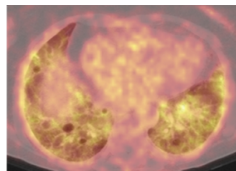
## Part C (late 2021 to mid-2022)

Multiple dose,  
ILD/IPF patients  
(Pax MAD)

• ~12-24 subjects

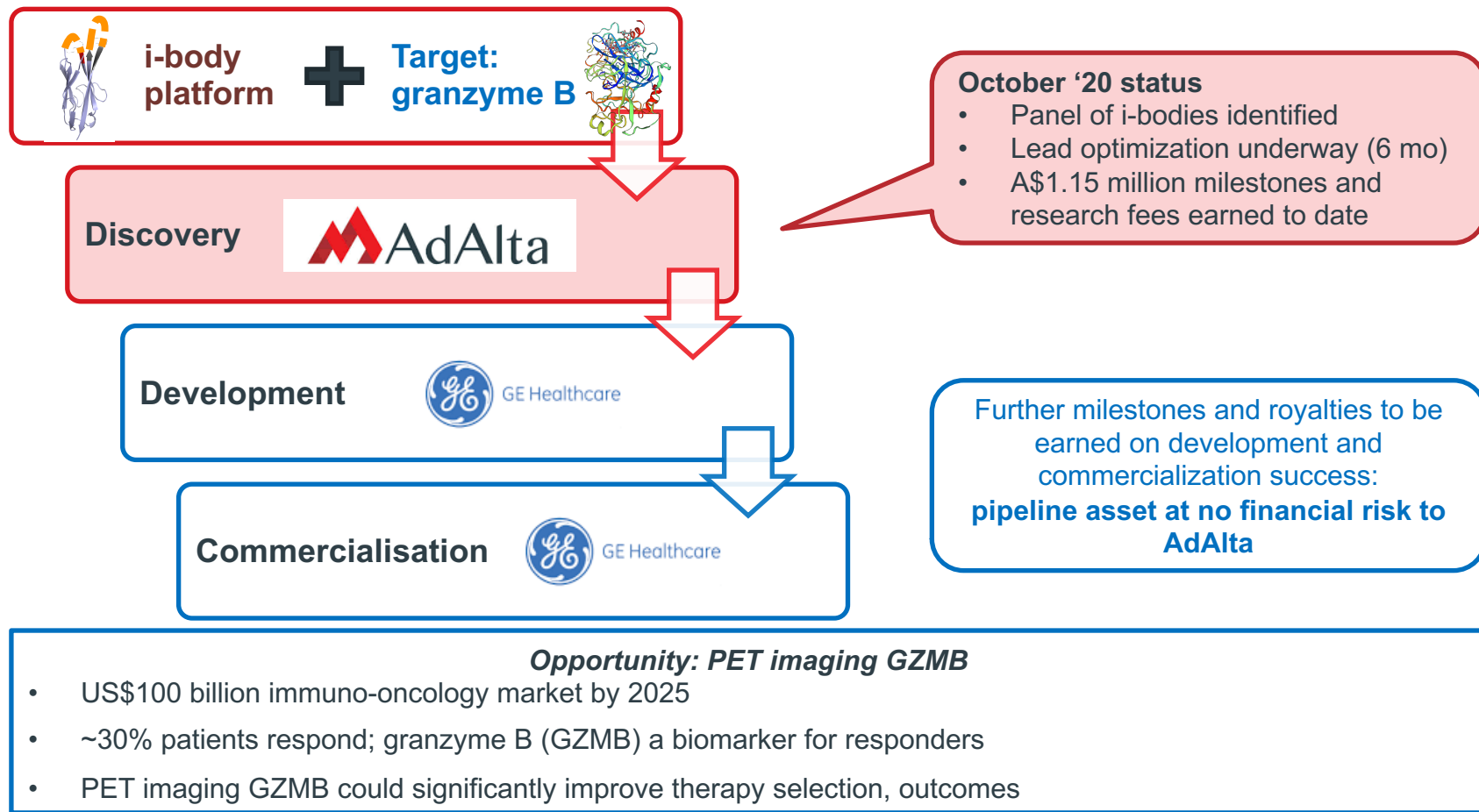
## October '20 status

- 21 participants received AD-214 or placebo (~3:1)
- 4 cohorts complete from 0.01-1 mg/kg
- No safety findings of clinical concern
- First participants in 5 mg/kg cohort treated
- No dose limiting adverse events observed to date

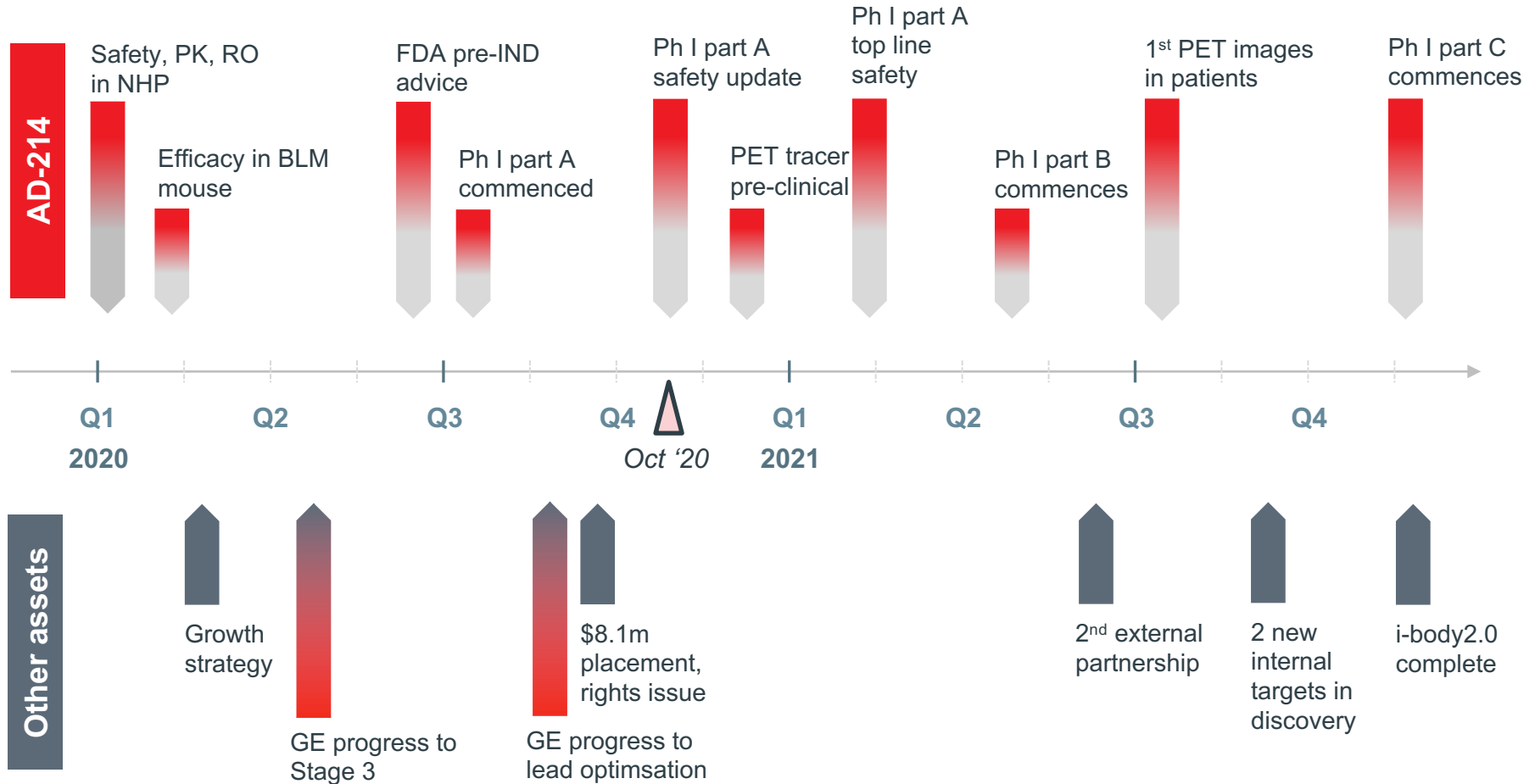


AD-214 PET tracer to show distribution and receptor occupancy: development on track  
A\$1m BTB grant funding

# External pipeline: multi-national GE Healthcare



# Key execution milestones



# Industry experienced leadership and advisors

## Board



**Dr Paul MacLeman**  
Chair



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



**Liddy McCall**  
(alt: Dr James Williams)  
Director



**Dr Robert Peach**  
Independent Director



**Dr David Fuller**  
Independent Director



## Scientific Advisory Board



**Brian Richardson**  
Drug discovery and  
development expert



**Steve Felstead**  
Clinical development



**John Westwick**  
Pulmonary drug discovery  
and development



## Executive



**Dallas Hartman, PhD**  
Chief Operating Officer



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



**Mick Foley, PhD**  
Chief Scientific Officer



**Kevin Lynch, MD**  
Consultant Medical Expert



# Financial position

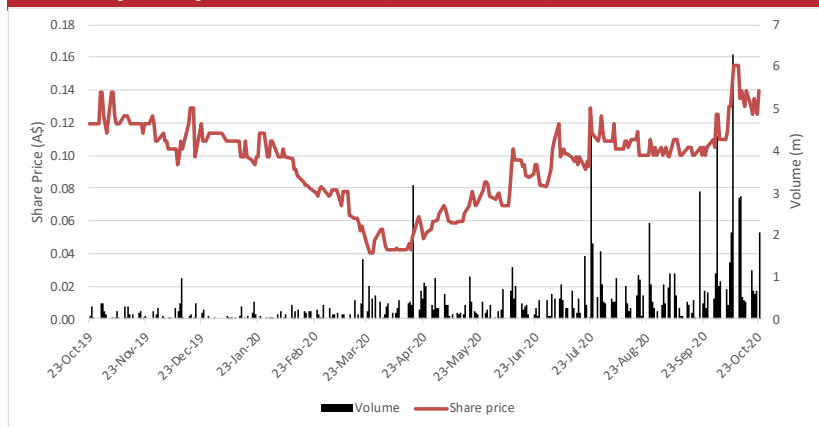
## Key financial details (23 Oct)

ASX code	1AD
<b>Market capitalisation</b>	<b>A\$34.32m</b>
Share price (12 month range)	A\$0.14 (\$0.04-0.18)
Ordinary Shares (daily volume)	245,175,853 (423,180)
Listed Options	23,348,803
Unlisted Options	7,514,067
<b>Cash (30 Sep 2020)</b>	<b>A\$10.03m</b>

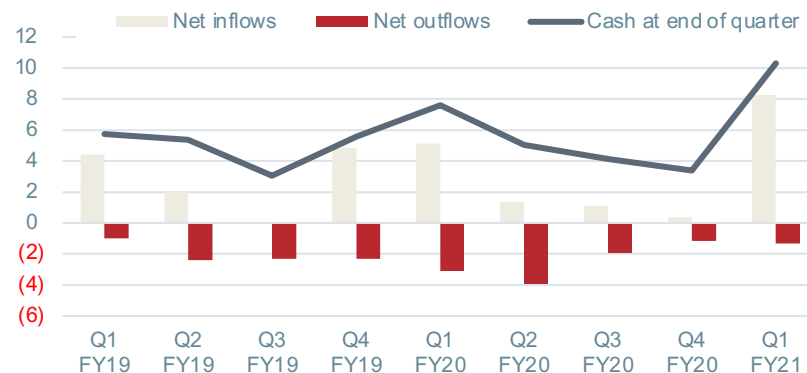
## Major shareholders (23 Oct)

	%
Yuuwa Capital LP	22.0
Platinum Asset Management	11.6
Meurs Holdings Pty Ltd	7.3
CS Third Nominees Pty Ltd	3.1
Radiata Super Pty Ltd	1.9
Other	54.1
<b>Total</b>	<b>100%</b>

## Share price performance (last 12 months)



## Quarterly cash flows (A\$ million)



# AdAlta (ASX:1AD) Investment proposition

- ▶ **Patented i-body platform for asset creation: designed for “difficult” targets**
  - Unique structure, properties addresses targets that challenge traditional antibodies
- ▶ **AD-214: clinical stage first-in-class asset for fibrosis**
  - Phase I trial underway in US\$3 billion orphan disease idiopathic pulmonary fibrosis (IPF)
  - Part A top line safety data + Part B PET images H1 2021
  - Partnering window opening towards end of 2021
  - Pre-clinical data available, emerging in multiple fibrotic indications and cancer
- ▶ **GE Healthcare: commercial validation of platform**
  - Partner funded discovery program; progressed to lead optimisation
- ▶ **Clear vision for growing existing assets and adding more; A\$10m cash balance**
  - AD-214: Phase I patient data, expand indications, partner
  - Internal pipeline: GPCRs in fibrotic, inflammatory disease and cancer (2-3 new assets by end 2021)
  - External pipeline: partner selected and funded targets: 2<sup>nd</sup> partnership by mid-2021
  - Platform leadership: continuous improvements to i-body platform, formulation and manufacturing
- ▶ **Experienced drug development team driving strategic focus**
- ▶ **Unique investment opportunity: validated platform, cash runway, ready to realize expansion potential**





## **Contacts for more information:**

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