19 July 2021

ASX Announcement

WEBINAR TO DISCUSS AD-214 RESULTS AND STRATEGY

MELBOURNE Australia, 19 July 2021: AdAlta Limited (ASX:1AD), the clinical stage biotechnology company developing novel therapeutic products from its i-body platform will hold a webinar to discuss the results of Phase I trials of AD-214 and plans to develop an inhaled version of its first in class anti-fibrotic, AD-214, for Idiopathic Pulmonary Fibrosis (IPF) and other Interstitial Lung Diseases (ILDs) that were announced today.

The webinar is open to all, however pre-registration is required.

Details of the webinar are:

Date: Monday, 19 July 2021

Time: 2pm Australian Eastern Standard Time

Registration:

https://us02web.zoom.us/webinar/register/WN_CnMpEkOQT3qLSFRPKIa1Cg

The webinar will be recorded and be made available on AdAlta's website within a week of the event. The presentation that will be discussed is attached to this announcement.

Authorised for lodgement by:

Tim Oldham
CEO and Managing Director
July 2021

AdAlta Limited
15/2 Park Drive
Bundoora VIC 3083 Australia

T +61 3 9479 5159
E enquiries@adalta.com.au
ABN 92 120 332 925

adalta.com.au

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 has advanced its lead i-body candidate, AD-214, into clinical studies. 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 co-develop i-bodies as diagnostic imaging agents against Granzyme B, a biomarker of response to immuno-oncology drugs, a program now in preclinical development.

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:

Investors

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

Media

IR Department
Tel: +61 411 117 774
E: jane.lowe@irdepartment.com.au

AdAlta
next generation protein therapeutics

AD-214 strategy update

AdAlta Investor Presentation, 19 July 2021

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.

Key points: AdAlta to progress inhaled version of AD-214 into efficacy studies for IPF

Invaluable findings from AD-214 clinical study and separate radiolabelled AD-214 preclinical studies map a pathway to conducting next clinical trials in patients with a preferred inhaled formulation

- Intravenous (iv) AD-214 successfully completes Phase I multidose cohort at 5 mg/kg, received HREC approval to progress to 10 mg/kg
- Preclinical development of radiolabelled AD-214 complete; informs dosing, supports early transition to direct lung delivery
- Totality of results to date provide clear pathway to future development of AD-214 for IPF via inhalation: more targeted, convenient and cost effective
- Timelines to efficacy data in IPF patients largely unchanged; imaging to continue to inform dosing and distribution
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AD-214 Phase 1 clinical program

The Phase 1 program is evaluating safety and distribution of AD-214 in healthy volunteers and patients

Phase 1 protocol in healthy volunteers

Part A

Single dose, healthy volunteers (HV SAD)

42 participants in 7 cohorts

0.01-20 mg/kg dose

Completed

Part B

Multiple ascending dose, healthy volunteers (HV MAD)

Up to 24 participants in 3 cohorts

3 x 5-15 mg/kg every 2 weeks

5mg/kg completed

Objectives of Phase 1 Part A and B:

- Top-line safety data
- Explore optimal dosing intervals
- Support FDA IND applications for further studies in all CXCR4 indications

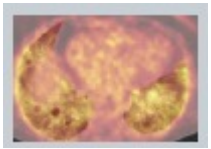
Phase 1b protocol in IPF and ILD (and other fibrotic disease) patients* (planned H2 2021)

Arm 1

PET screening of fibrotic diseases

Open label with standard of care**

~12 patients (~6 IPF/ILD) + PET



Arm 2

Multi-dose in IPF/ILD

Open label with standard of care**

~6 patients, max 6 doses over 18 weeks +/- PET imaging

Pre-clinical development of RL-AD-214 for PET imaging complete

Objectives of Phase 1b:

- Effect of elevated lung CXCR4 on distribution of AD-214 in IPF/ILD patients
- Safety of AD-214 in combination with standard of care**
- Explore CXCR4 expression over time as potential biomarker

* Supported by a Biomedical Translational Bridge grant from Medical Research Future Fund and MTPConnect

** Includes pirfenidone, nintedanib or non-pharmacologic intervention.

AD-214 Phase I healthy volunteer results to date

AD-214 has an excellent safety profile in single doses to 20 mg/kg and multiple doses to 5 mg/kg*

AD-214 molecule has an excellent safety profile in single and multiple doses (see Appendix for more detail)*

- No dose limiting toxicities or adverse events of clinical concern in single doses to 20 mg/kg
- Moderate infusion related reactions (IRRs) in 3 participants (2 drug, 1 placebo) receiving multiple 5mg/kg doses
  - Rapidly resolved at end of infusion
  - *Appear formulation related*
- No concerning clinical laboratory results, no adverse liver or other organ function detected
- *HREC approved progressing to 10 mg/kg*

AD-214 clearly engages the target CXCR4 receptor *in vivo**

- Dose dependent changes in biomarkers of CXCR4 engagement observed
- High and extended duration of receptor occupancy on circulating T cells
- *Biomarker response consistent across multiple doses at 5 mg/kg – no evidence of tolerance*

AD-214 pharmacokinetics are dose proportionate*

- Peak and total AD-214 exposure increases in a dose proportionate or more manner to 20 mg/kg, consistent across multiple doses at 5 mg/kg
- Elimination half-life 44±15 hours at 20 mg/kg
- *No evidence of tolerance or drug induced clearance*
- *Rapid distribution from plasma observed at all doses, consistent with rapid increase/saturation of receptor occupancy and preclinical imaging*

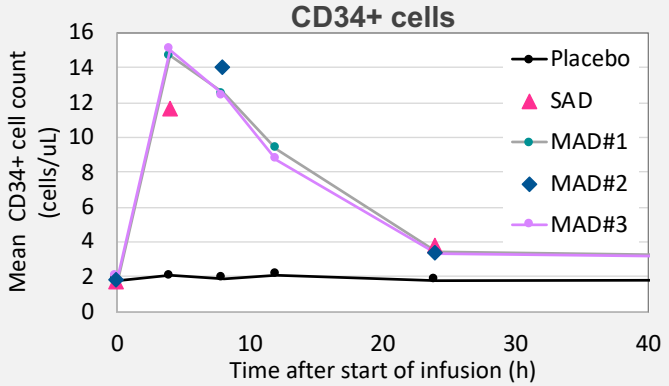
* Multiple dose data subject to database lock and full statistical analysis; receptor occupancy data only available to 4 hours after end of third infusion; antidrug antibody data only available to 14 days after second infusion (pre third infusion)

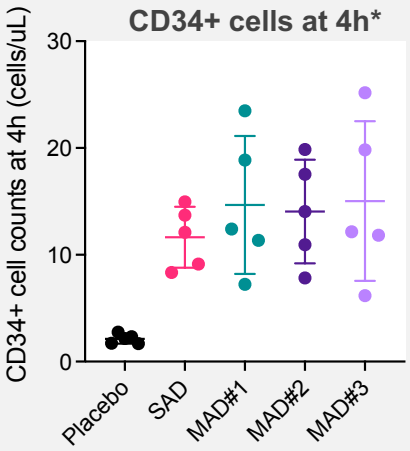
Biomarkers of CXCR4 receptor engagement at 5 mg/kg

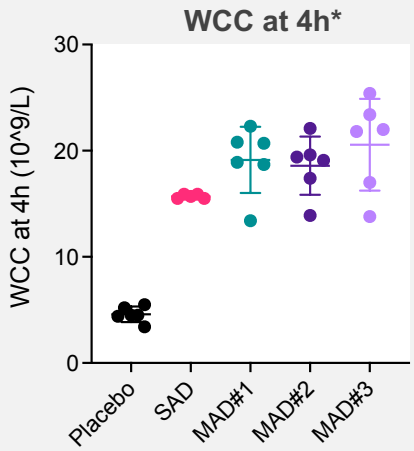
Transient increases in blood biomarkers demonstrate consistent engagement of the target receptor, CXCR4 across multiple AD-214 doses

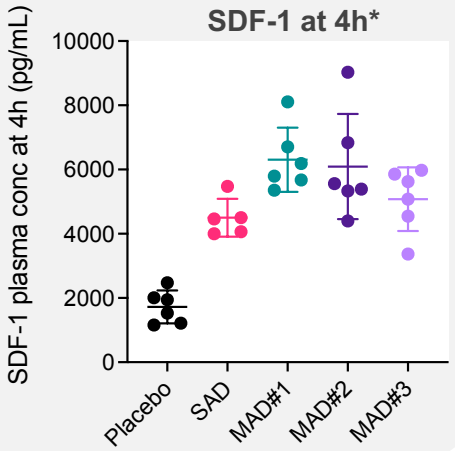
Biomarker data confirm single dose findings, consistent across multiple doses: no drug induced tolerance or accumulation

- White blood cell counts (WCC), haematopoietic stem cell (CD34+) counts and concentration of SDF-1 are biomarkers of CXCR4 engagement by AD-214
- Profile of biomarkers is consistent across multiple doses at 5 mg/kg*
- 100% T cell CXCR4 receptor occupancy achieved for at least 24h (data not shown, maximum duration analysis pending)







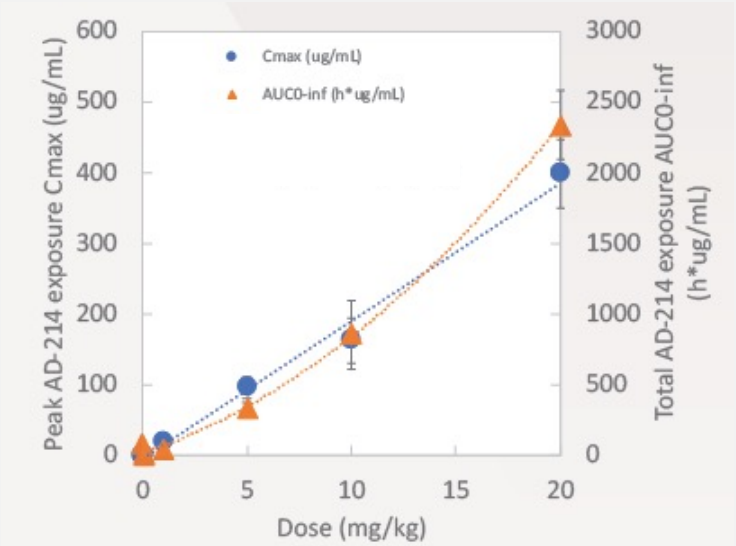


* SAD = single ascending dose at 5mg/kg; MAD#1/MAD#2/MAD#3 are first, second and third multiple doses at 5 mg/kg; CD34+ and WCC data is shown at 8h for MAD#2

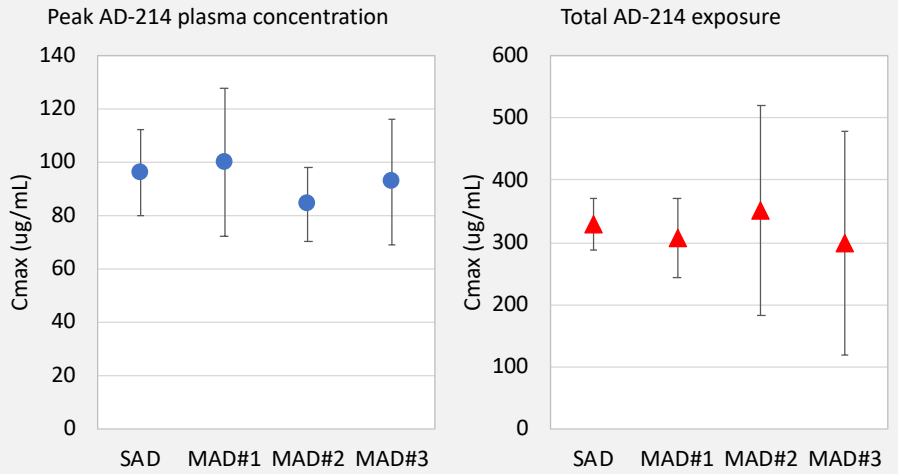
AD-214 pharmacokinetics

Maximum exposure, Cmax, and total exposure, AUC0-inf, increase in a dose proportionate manner and are consistent across multiple doses of AD-214 at 5 mg/kg, supporting absence of drug induced tolerance or clearance

Maximum and total plasma exposure - SAD



Maximum and total plasma exposure – 5 mg/kg



Pharmacokinetic profile

- Rapid distribution from plasma (consistent with rapid and high CXCR4 receptor occupancy and PET imaging distribution studies)
- Elimination half-life 44±15 h at 20 mg/kg

* SAD = single ascending dose at 5mg/kg; MAD#1/MAD#2/MAD#3 are first, second and third multiple doses at 5 mg/kg

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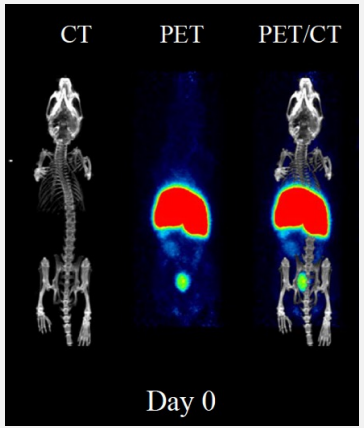
AD-214 distribution by PET imaging

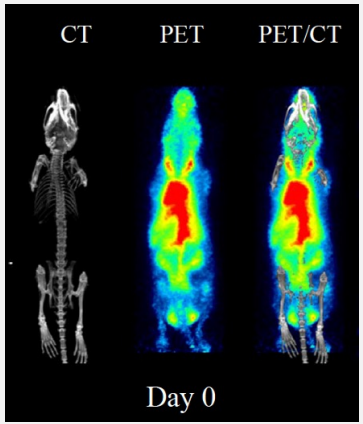
Pre-clinical PET imaging shows that while AD-214 distributes to tissues containing CXCR4 expressing cells, more than half the administered dose rapidly distributes to, or is cleared via, the liver. This is not seen with other i-bodies

PET/CT images in healthy mice

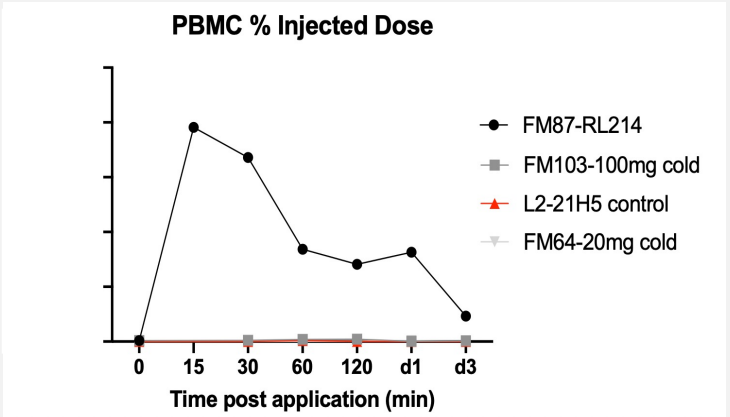
^{89}Zr-AD-214



^{89}Zr-ADLP-16-Fc



Radiation count from i-bodies bound to non-human primate (NHP) white blood cells



Radiolabelled AD-214 successfully developed

- Conjugated with DFOSq (Telix Pharma) and labelled with ^{89}Zr
- Imaging in healthy mice, NHPs

AD-214 substantially and rapidly distributes to liver (left)

Other i-bodies studied distribute more generally (right)

^{89}Zr-AD-214 still able to be detected on white blood cells and in tissues with resident immune cells eg spleen, bone marrow

- High doses of unlabelled AD-214 block the signal in these tissues, confirming specific binding via CXCR4

ADLP16-Fc is an Fc-fusion i-body against a GPCR other than CXCR4. The Fc domains were point mutated to remove effector function. Both were conjugated with DFOSq (Telix Pharma), radiolabelled with ^{89}Zr, and formulated in AD-214 formulation buffer

PET imaging studies inform dosing and route of administration

PET imaging with radiolabelled AD-214 supports early transition to inhaled route of administration

Rapid liver distribution and clearance reduces bioavailability

- Consistent with pharmacokinetic profile and a first pass clearance mechanism
- More than half administered dose not available to target site of action

CXCR4 binding capability retained, supportive of potential efficacy

- Consistent with observed biomarker, receptor occupancy and bleomycin mouse efficacy data

Liver distribution does not appear to affect safety profile

- No localization in hepatocytes (responsible for metabolic activity in liver)
- Consistent with lack of observed changes in liver function or toxicity in toxicology and clinical studies

Direct lung delivery of AD-214 could achieve a therapeutic dose at lower levels than intravenous delivery

Radiolabelled AD-214 will continue to be a useful development tool

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Benefits of inhalation

Delivery of AD-214 by inhalation has potential to improve bioavailability, be more convenient for patients, be more cost effective, and improve partnering flexibility

Improved bioavailability	• AD-214 delivered direct to fibrotic areas • First pass liver clearance avoided • Dosing schedule flexibility to optimise receptor coverage
Greater patient convenience	• Self administration (no scheduled clinic visits; freedom of movement) • Less invasive
Enhanced cost effectiveness	• Lower drug dose means lower cost of goods • Lower healthcare costs for administration
Diversified partnering options	• Potential to partner AD-214 by indication using different routes of administration - broadens potential long term options

Inhalation in IPF

Numerous drugs have been formulated for inhalation in IPF and respiratory disease, a substantial number of biologics are in development for inhalation and off-the-shelf devices are available for rapid translation from intravenous route

Inhalation used regularly in IPF and other respiratory diseases

4 inhaled IPF therapeutics in development

United Therapeutics (Phase III) Galecto (Phase IIb)

Avalyn (Phase I/II) pieris (Pre-clinical, biologic)

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

Substantial number of biologics in development for inhalation*

- 2 marketed inhaled biologics
- 19 clinical stage inhaled biologics including
  - Several fragment antibodies
  - 1 single domain antibody (nanobody)
- Majority sized between 15-80 kDa (AD-214 73 kDa, single i-bodies 15 kDa)
- Majority via solution for inhalation

Off-the-shelf devices for nebulization of liquid formulations

OMRON PHILIPS PARI VECTURA

- Smart mesh nebulisers assist compliance, accuracy, drug efficiency
- Low shear forces designed for biologics
- Liquid formulations: potential to utilize AD-214 intravenous formulation with minimal modification




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

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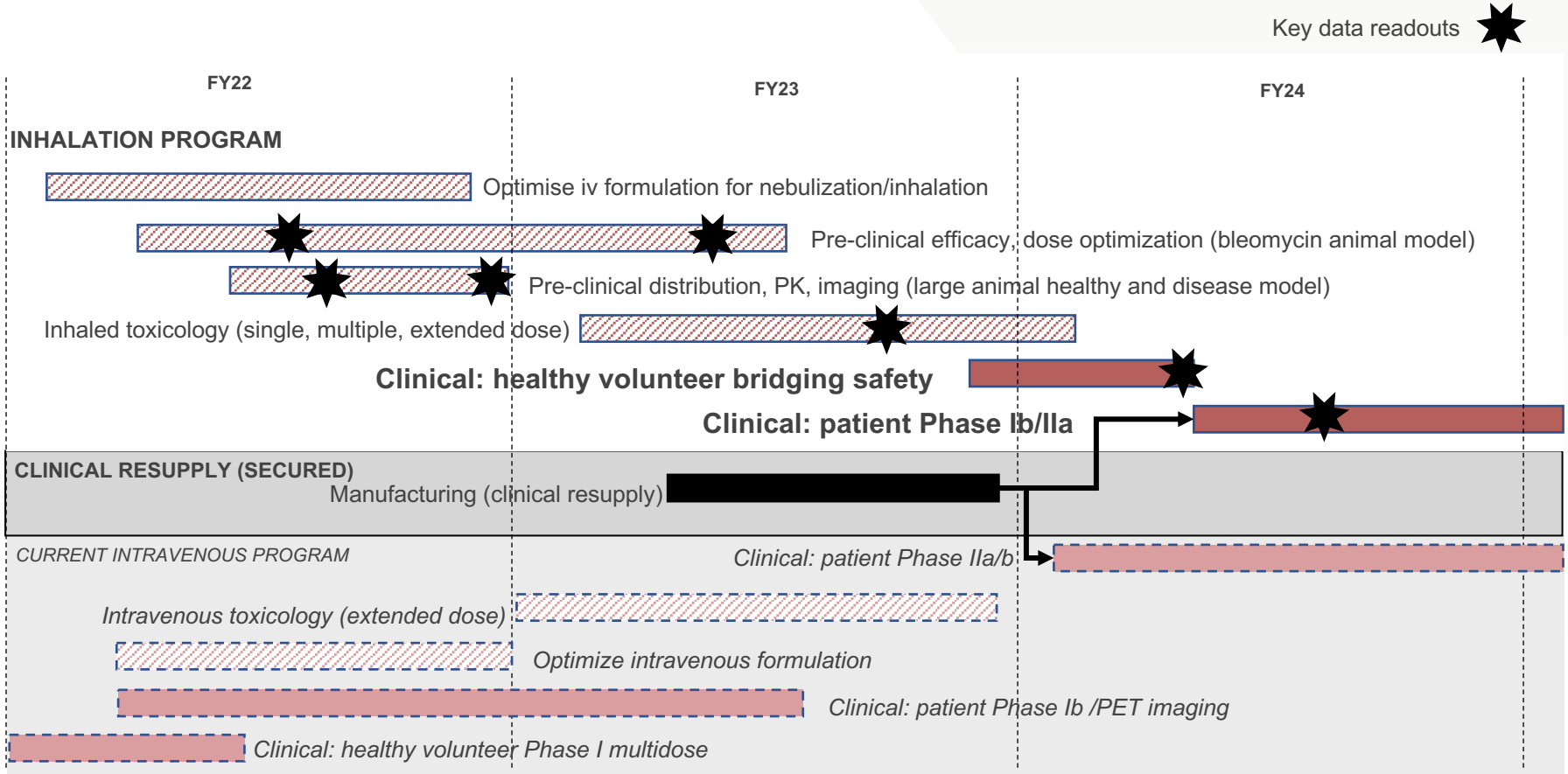
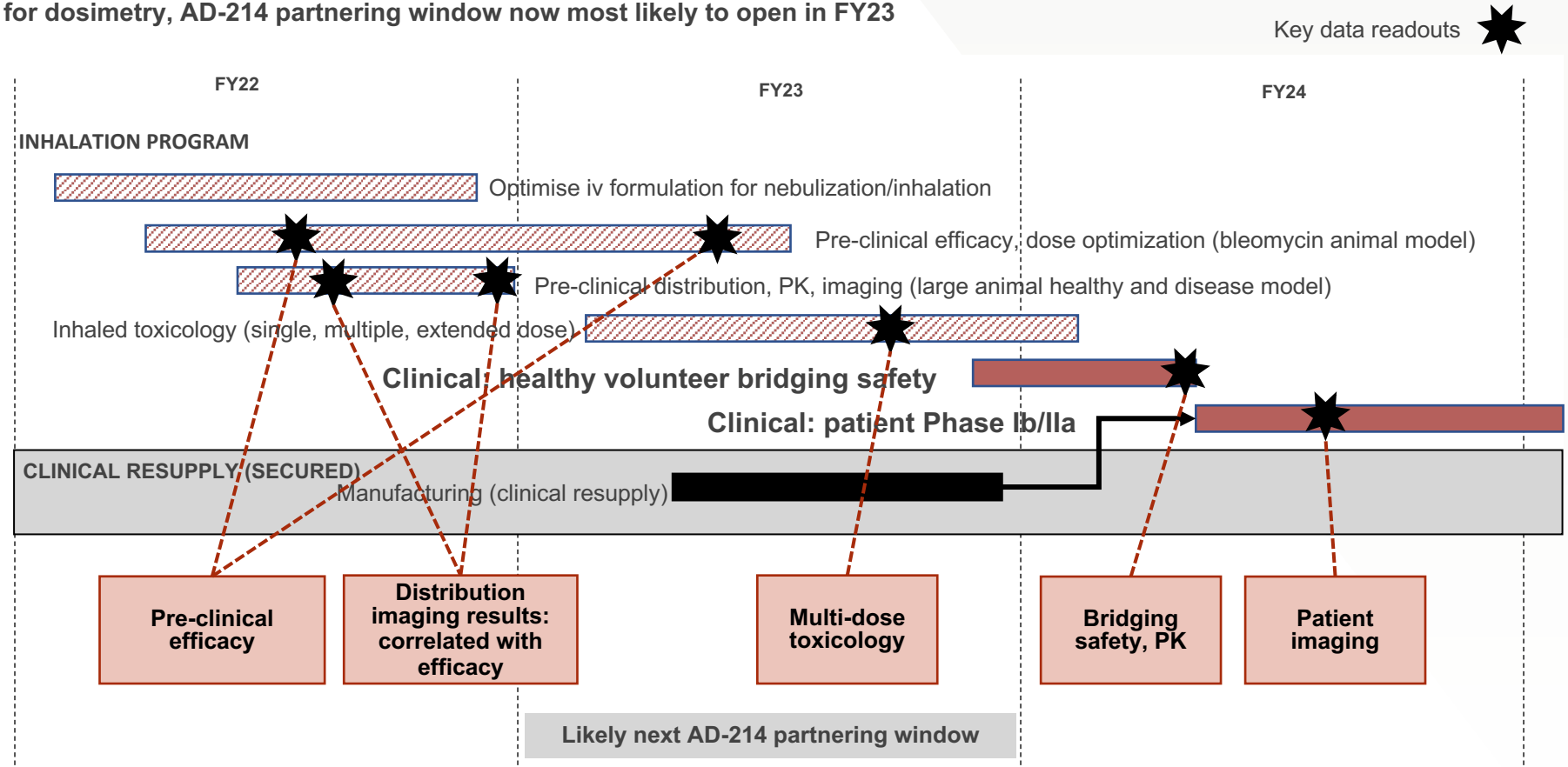
Pathway to clinical studies in patients

Timeline to clinical efficacy in IPF patients largely unchanged; imaging remains a key development tool



Key milestones

Numerous new milestones to demonstrate progress, pre-clinical imaging more comprehensive that patient imaging and key for dosimetry, AD-214 partnering window now most likely to open in FY23



Idiopathic Pulmonary Fibrosis (IPF)

AD-214 remains a first in class opportunity in a $3b market for a degenerative, fatal disease in dire need of improved treatment options

In IPF, scarring and stiffening of the lungs **progressively and irreversibly reduces lung function**

Despite being poorly tolerated and having difficult side effects, the two current therapies sell

$3b per year

3.8 years
median survival after diagnosis

>300,000
people living with IPF,
It is irreversible

40,000
people die from IPF every year

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

"Long COVID" is a developing issue – potentially further increasing the need for better anti-fibrotic drugs.

* PM George, et al, "Pulmonary fibrosis and COVID-19: the potential role for antifibrotic therapy", Lancet published online May 15, 2020.

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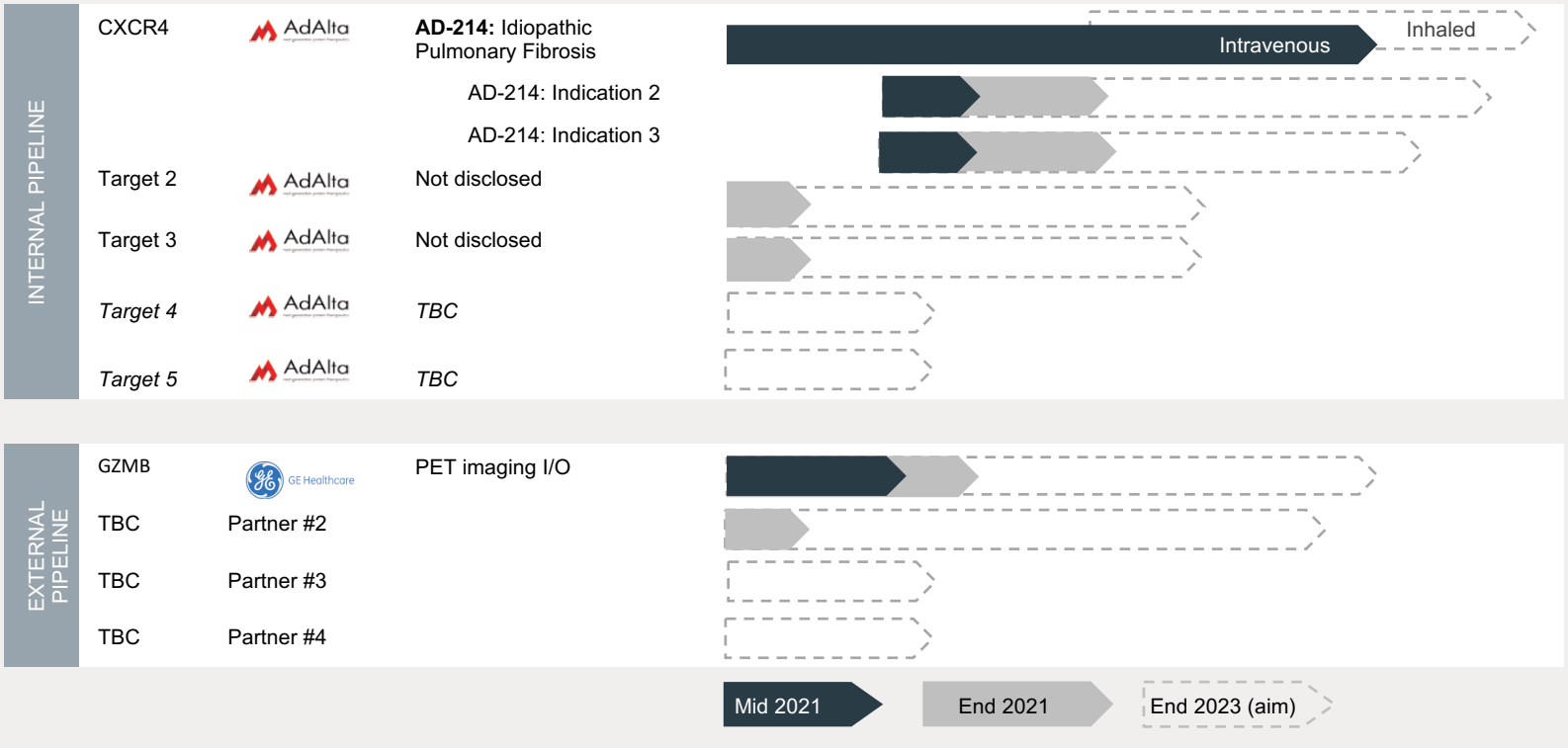
Milestones for remainder of FY2022

Milestones extended through end of FY2022

	AD-214	Other Assets
H1 2021	✓ Orphan Drug Designation for AD-214 in IPF ✓ Results of Phase I single dose studies in healthy volunteers ✓ Phase I multi-dose studies in healthy volunteers commence ✓ *PET tracer pre-clinical development results*	✓ Progressing the GE Healthcare collaboration from discovery to pre-clinical development
H2 2021	✓ *Top line results of multi-dose studies in healthy volunteers* • Additional indications pre-clinical data	• Entering a second collaboration agreement • Commencing development of two new i-body enabled internal pipeline assets
H1 2022	• Initial efficacy of inhaled AD-214 in IPF animal model • First inhalation PET images to visualise distribution of AD-214 in the lungs of healthy and fibrotic disease model animals	• New i-body 2.0 IP filed • GE Healthcare preclinical update

An expanding pipeline of i-body enabled products



Corporate snapshot

Key financial details (16 Jul 2021)

ASX code	1AD
Market capitalisation	**A$33.1m**
Share price (12 month range)	A$0.135 ($0.091 - 0.265)
12 month return	43%
Ordinary Shares (daily volume)	245,179,578 (603,321)
Unlisted Options	7,514,067
Cash (31 Mar 2021)	**A$6.05m**

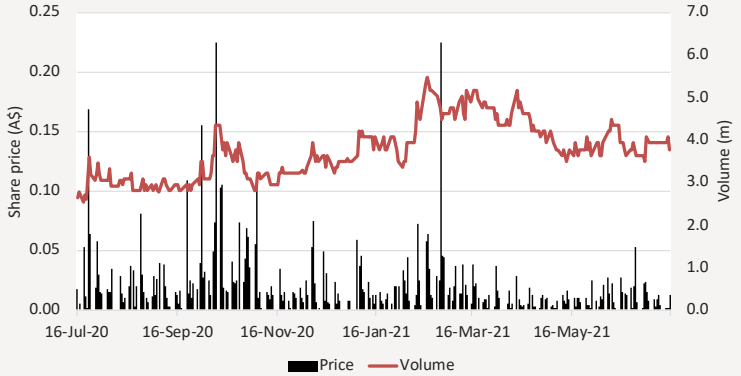
Major shareholders (16 Jul 2021) %

Yuuwa Capital LP	22.0
Platinum Asset Management	11.6
Meurs Holdings Pty Ltd	7.3
Radiata Super Pty Ltd	3.1
Sacavic Pty Ltd	1.8
Other (1,537 total holders)	*54.2*
Total	**100%**

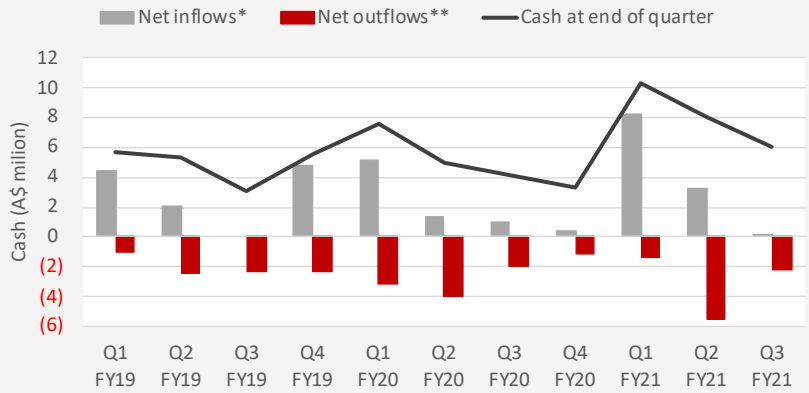
Analyst Coverage

Edison
Pitt Street Research
Securities Vault
BioShares

Share price performance (last 12 months)



Quarterly cash flows (A$ million)



Investment proposition

Platform to create value

Patented, validated i-body platform for asset creation: designed for “difficult” targets

Lead asset has multiple indications

AD-214: first-in-class asset for multiple fibrotic indications and cancer
Phase I – clear path to Phase II

>$3b market potential in first indication

GZMB asset: GEHC partnership

Solving the challenge of identifying I/O drug responders
Preclinical

PET imaging agent market worth US$6.4b

Clear vision for growth

Build on existing clinical and commercial validation of platform to add internal programs, expand collaborations

Leading expertise

Experienced drug development team in place

Several near-term growth catalysts

AdAlta substantially undervalued relative to peers, with near term and mid-term value drivers.

AdAlta
next generation protein therapeutics

Contact:

Tim Oldham, CEO and Managing Director
enquiries@adalta.com.au
www.adalta.com.au

AD-214 Phase I healthy volunteer study: safety findings

Single doses to 20 mg/kg (42 participants)

- ***No dose limiting adverse events***
- ***No serious adverse events***
- ***No concerning clinical laboratory results***
- ***Dose escalation steps completed without concern***
- ***Adverse events (AEs) were non-concerning***
  - Predominantly mild
  - Three Grade 2 (moderate) AEs

Multiple doses 5 mg/kg (8 participants)

- ***No dose limiting adverse events***
  - Safety Management Committee and Human Research Ethics Committee approved progression to 10 mg/kg
- ***No serious adverse events***
- ***No concerning clinical laboratory results***
- ***Adverse events (AEs) profile supports safety of AD-214 molecule***
  - Predominantly mild
  - Three Grade 2 (moderate) treatment related AEs
  - Infusion related reactions (IRRs) reported in three participants – resolved rapidly when infusion ended
- ***IRRs linked to formulation***
  - Observed in participants receiving both AD-214 (2) and placebo (1)
  - Trended to increasing intensity and frequency with subsequent doses
  - Not associated with changes in vital signs, clinical, physical or cytokines
  - Protocol amended to include standard antihistamine and corticosteroid treatment options

AD-214 Phase I healthy volunteer study: immune response findings

Single doses to 20 mg/kg (42 participants)

- ***Isolated instances of minor cytokine elevation***
  - Transient and primarily low level of elevation of IL-6 and IL-8 in some participants (including placebos)
- ***No clinically significant cytokine release***
- ***Antidrug antibodies: detected in 11 participants***
  - Predominantly low titre
  - Characterisation pending
- ***No clinical symptoms related to immune response observed***

Multiple doses 5 mg/kg (8 participants)

- ***Sporadic and primarily low level elevation of cytokines IL-6 and IL-8, sporadic increases in TNF-a and IFN-g***
  - No clear association with IRRs or antidrug antibodies
  - Low level increases in IL-6 in many participants 24-48h post infusion
- ***No clinically significant cytokine response and no link to IRRs or ADAs***
- ***Antidrug antibodies: detected in three participants after second dose***
  - All low titre
  - One also reported IRR (association unlikely)
  - Characterisation pending
  - Third dose data pending