AdAlta

Closing in on clinical and partnering milestones

AdAlta Limited (ASX:1AD)
A modern targeting system for next generation drugs
Investor Overview
8 March 2024

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AdAlta (ASX:1AD): a modern targeting system for next generation drugs

Purpose: i-body® targeting for next generation therapeutics

Going where antibodies can't to produce high-value, next generation protein and cell therapies for debilitating diseases

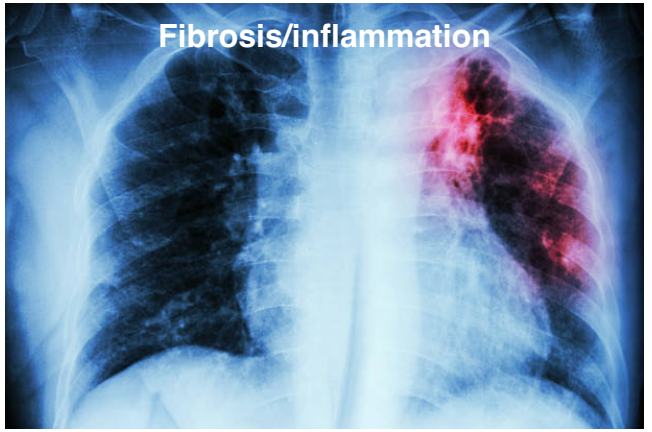
Discovery business

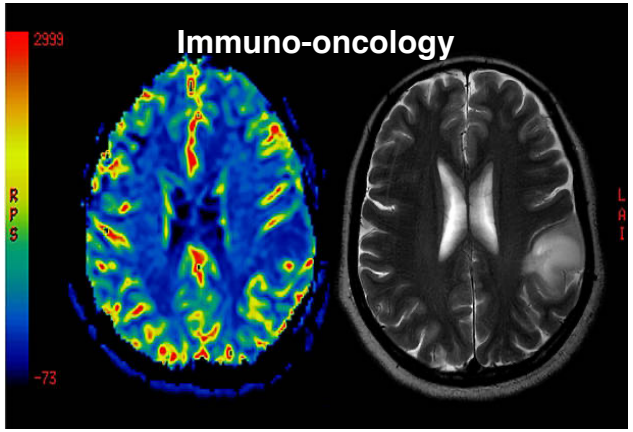
i-body® "inventory" of high value product candidates for development or licensing

i-body® platform + in-house discovery team

Product development business

Product candidates progressing through value-adding development milestones for out-licensing or co-development

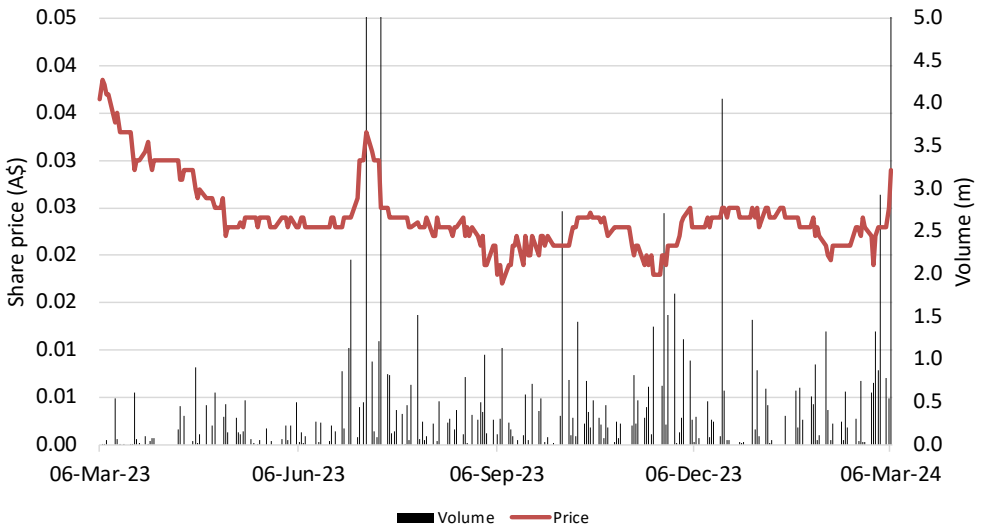




Experienced leaders, in-house protein engineering + cost effective Australian location

Near-term momentum and opportunities for shareholders

Share price performance (ASX:1AD) (12 months)



Largest shareholders (6 March 2024)**	%
Platinum International Healthcare Fund	18.1
Meurs Group	12.6
Sacavic Group	6.4
FMI Pty Ltd atf Commonwealth of Australia	5.1
Radiata Foundation	3.9
Other (~1,450 total holders)	*54.9*
Total	**100%**

Attractive current valuation and fundamentals

- Enterprise value ~A$11.6m* (Market capitalisation A$15.2m)
- Strong and supportive institutional register
- Differentiated technology and in-house R&D team

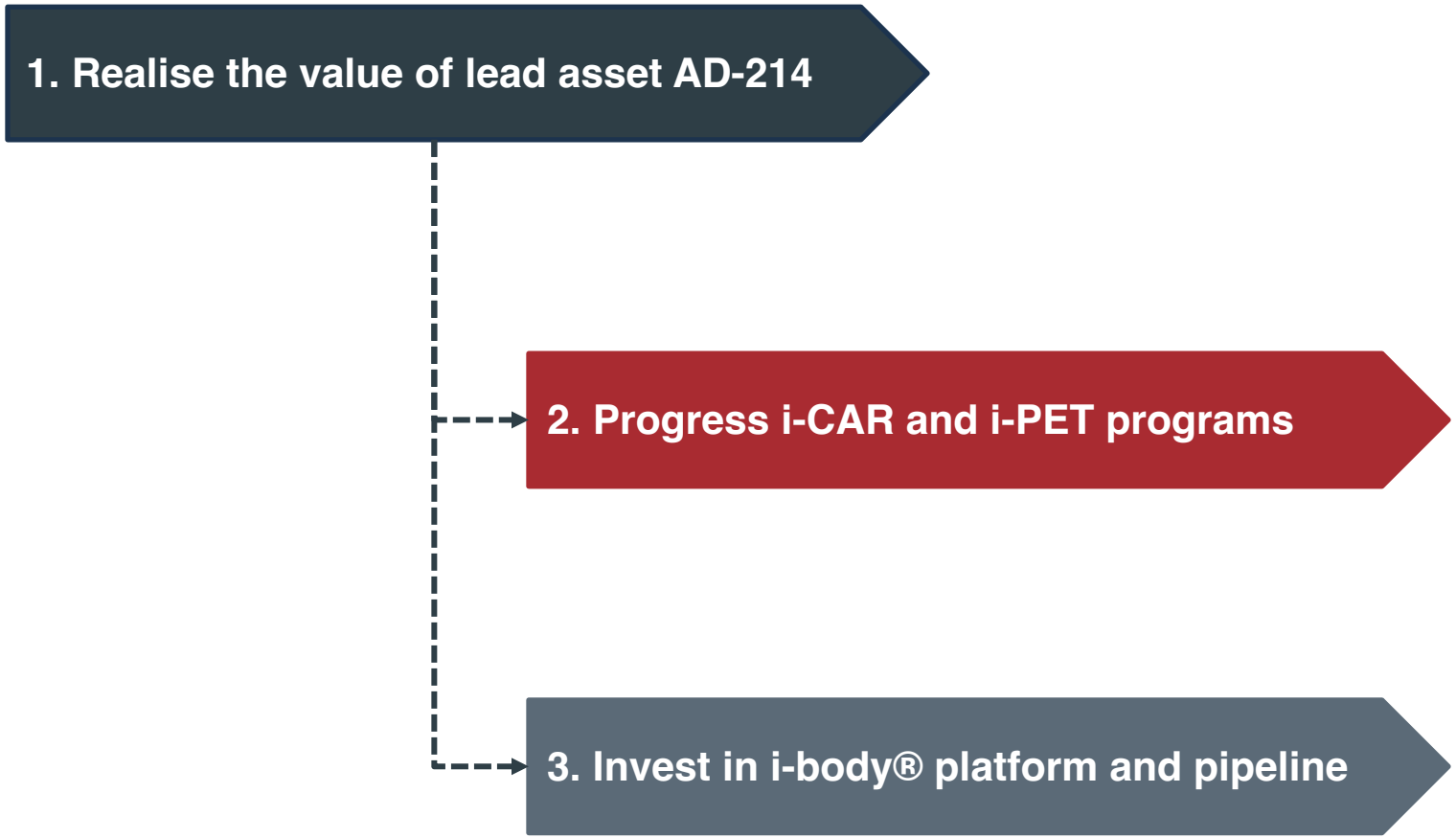
Momentum accelerating towards return on AD-214 investment

- **New Phase I extension study clinical data achieves critical milestone for partnering and Phase II readiness**
- Active partnering market: IPF assets commanding upfront license payments of more than US$45 million
- Multiple partnering strategies in play

Pipeline of other assets and opportunities developing well to follow on from AD-214

*Market capitalization A$15.2m at 6 March 2024 less 31 Dec 2023 cash $3.68m
**Based on 525.8m issued ordinary shares; does not include effect of 173.1m 1ADOA listed options and 13.8m unlisted options

Three core strategies, all with near term partnering potential



Near term partnering opportunities

- Out-licensing; or
- Co-development/asset financing

- Co-development collaborations in core i-body® application areas

- Sponsored research collaborations in non-core i-body® application areas
- Complimentary technology and product in-licensing

AD-214: new hope for fibrotic disease patients

Bill van Nierop: IPF survivor speaks to challenge of living with IPF

"… sadly I am one of a few who can actually relate to the lived experience with and without PF …"

"***You see our symptoms are basically an ongoing internal struggle to breathe freely*** … and it's invisible to all, including family, friends and the general community."

"I talked with a 60 something grandmother, who really enjoyed days looking after grandkids, but as disease progressed she found sometimes she needed to reduce the time a bit. You won't believe that her daughter in law suggested she would just bring them around less, 'you're always tired but you look really well', so I won't bother you as much. Shattering to the poor woman obviously, but again demonstrates the absolute lack of understanding of this debilitating disease. ***Looks well, so can't be too ill, except she's struggling to breathe and is on a journey with an inevitable end***."

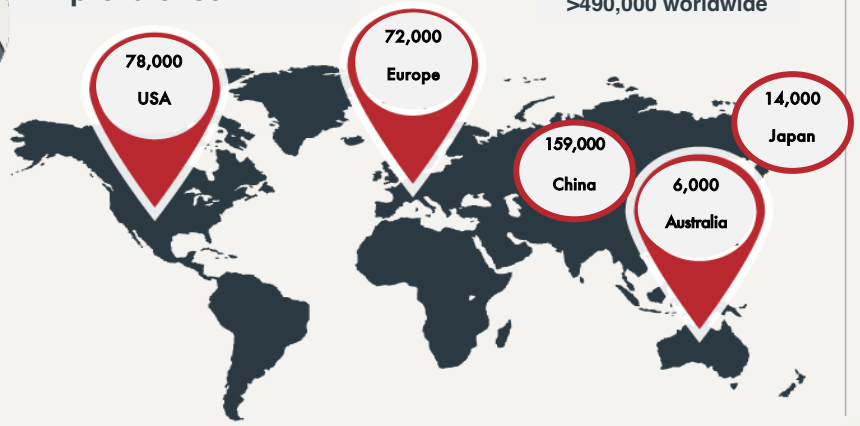
Source: Bill van Nierop, https://www.facebook.com/kayakforlungs 28 September 2023

https://www.lonagkayakforlungs.com.au/

The need: Better outcomes for Idiopathic Pulmonary Fibrosis (IPF) and other fibrotic diseases

IPF prevalence

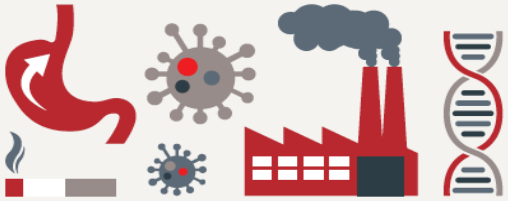
>490,000 worldwide



50% of sufferers die within 3-5 years following diagnosis

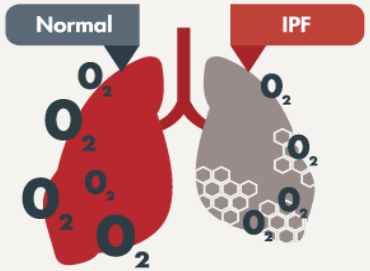
>100,000 pa

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.

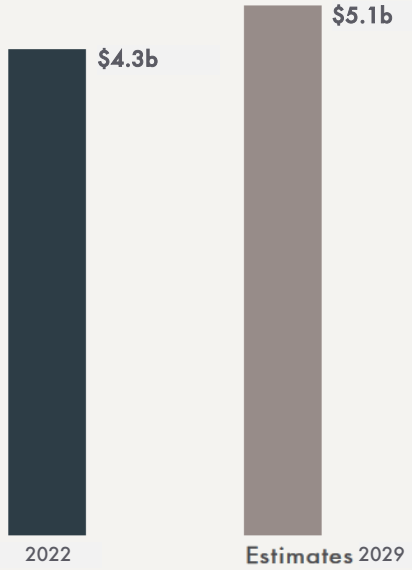
Current IPF treatments

Pirfenidone — Roche

Nintedanib — Boehringer Ingelheim

Slow, but do not halt progression. Serious side effects limit compliance, tolerability

IPF Therapy Sales (US$)



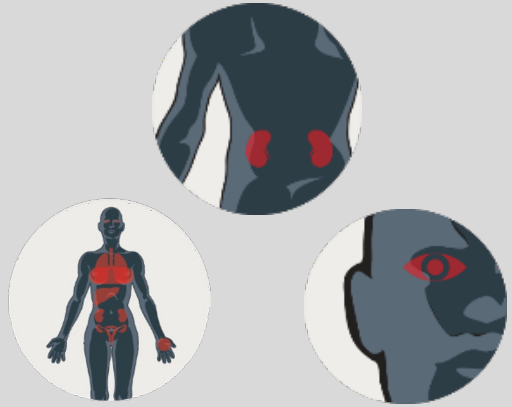
Source: GlobalData,[2] company financial reports, AdAlta analysis

45% of developed world deaths have a chronic fibrosis component

- Lung **(US$4b)**
- Kidney **(US$10b)**
- Eye **(US$15b)**
- Cancer **(US$1b each)**[3]

New drivers of incidence

- "Long COVID"[1]
- Re-emergence of silicosis



[1] PM George, et al, "Pulmonary fibrosis and COVID-19: the potential role for antifibrotic therapy", Lancet published online May 15, 2020.
[2] GlobalData, Idiopathic Pulmonary Fibrosis: Competitive Landscape, April 2023
[3] GlobaData, disease analysis reports

AdAlta's solution: AD-214 has a compelling value proposition

A$45m investment to date has built strong value proposition

First in class molecule targeting established mode of action in fibrotic disease

- ✓ Competitively positioned as only antibody-like therapeutic entering late-stage development pipeline

Pre-clinical efficacy in multiple animal models of fibrotic disease – derisks clinical studies

- ✓ Led by Idiopathic Pulmonary Fibrosis (IPF): TAM US$4.3b
- ✓ Multiple US$b indication potential: kidney, eye, cancer

Phase I successfully completed

- ✓ Well tolerated, evidence of target binding
- ✓ Addresses partner questions

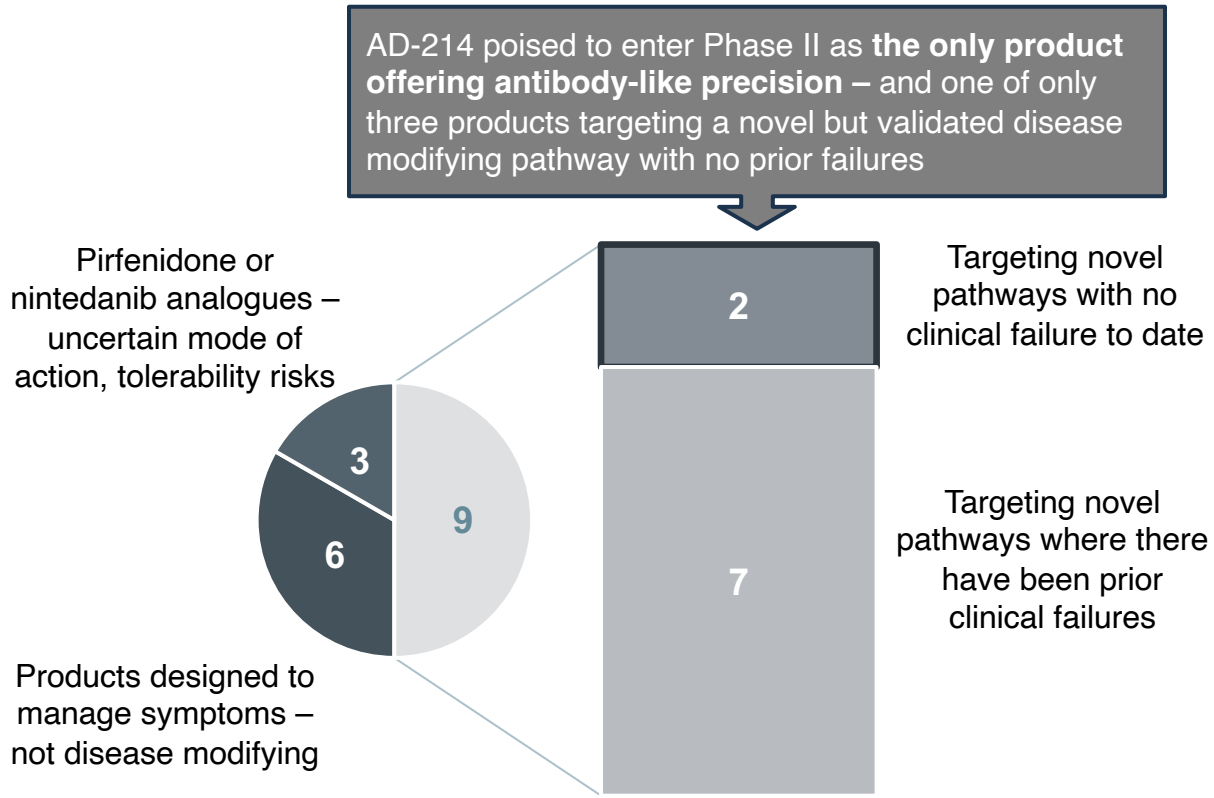
Target IV product profile verified; enhanced SC product profile identified – supports clinical adoption

- ✓ Intravenous (IV) every 2 weeks; subcutaneous (SC) every week

Strong intellectual property, regulatory position

- ✓ Patents protecting asset to 2036 and beyond
- ✓ US FDA Orphan Drug Designation for IPF
- ✓ 10-12 years market exclusivity (US, EU)

AD-214 is competitively well positioned in Phase II and beyond pipeline*



* As at October 2023; excludes 11 studies categorized as Phase I/II, institution led or with <25 patients per arm which are unlikely to be powered to show efficacy
Source: GlobalData, clinicaltrials.gov, company press releases, AdAlta analysis

AD-214 is now ready to move into Phase II clinical studies for IPF

Breaking: new data

Validated target	Novel mode of action, IP	GMP manufacturing	Pre-clinical efficacy	NHP GLP toxicology	Phase I clinical trials (IV)
• CXCR4 • Player in inflammatory, fibrotic processes • Biomarker, prognostic indicator	• Patented i-body® antagonist • Target found on diverse cell types • Inhibition of fibrotic cell migration, collagen deposition, fibrotic markers	• Fc-fusion format • CDMO: KBI Biopharma • IND-ready CMC package • IV, SC routes of administration likely feasible (inhaled and IVT also possible)	• Bleomycin mouse model of IPF • FA and UUO model of kidney fibrosis • Laser CNV model of eye fibrosis • Combination oncology pending	• Very clean tox profile • Half-life supports weekly+ dosing • Sustained receptor occupancy	• Very well tolerated in two studies • High, extended target engagement consistent across multiple doses • Dose simulations support efficacy of commercially feasible IV and SC regimens

Pre-IND meeting:
Panel of pre-clinical studies "generally sufficient" to support an Investigational New Drug application
The Phase I trial design is "reasonable"

Orphan Drug Designation: granted (US)

Phase 1 clinical studies completed in 58 participants covering planned Phase II doses

Phase 1, randomized, blinded and placebo controlled dose-escalating studies of the safety, tolerability, and pharmacokinetics of single and repeat doses of AD-214 when administered intravenously to healthy volunteers[1]

Phase 1 protocol in healthy volunteers

Part A (Completed)

Single ascending dose

- 42 participants in 7 cohorts (31 active: 11 placebo)
- AD-214 administered IV at 0.01-20 mg/kg

Part B (Completed)

Multiple dose

- 8 participants in 1 cohort (6 active: 2 placebo)
- AD-214 administered IV at 5 mg/kg IV (3 doses two weeks apart)

Extension – Aug '23-Feb'24 (Completed)

Multiple dose

- 8 participants in 1 cohort (6 active: 2 placebo)
- AD-214 administered IV at 10 mg/kg IV (3 doses two weeks apart and a fourth dose 12 weeks later at peak of antidrug antibodies)

Breaking: new data

Target Phase II dose is 10 mg/kg AD-214 IV every two weeks

Supported by *ex vivo* mode of action studies and PK/PD modelling

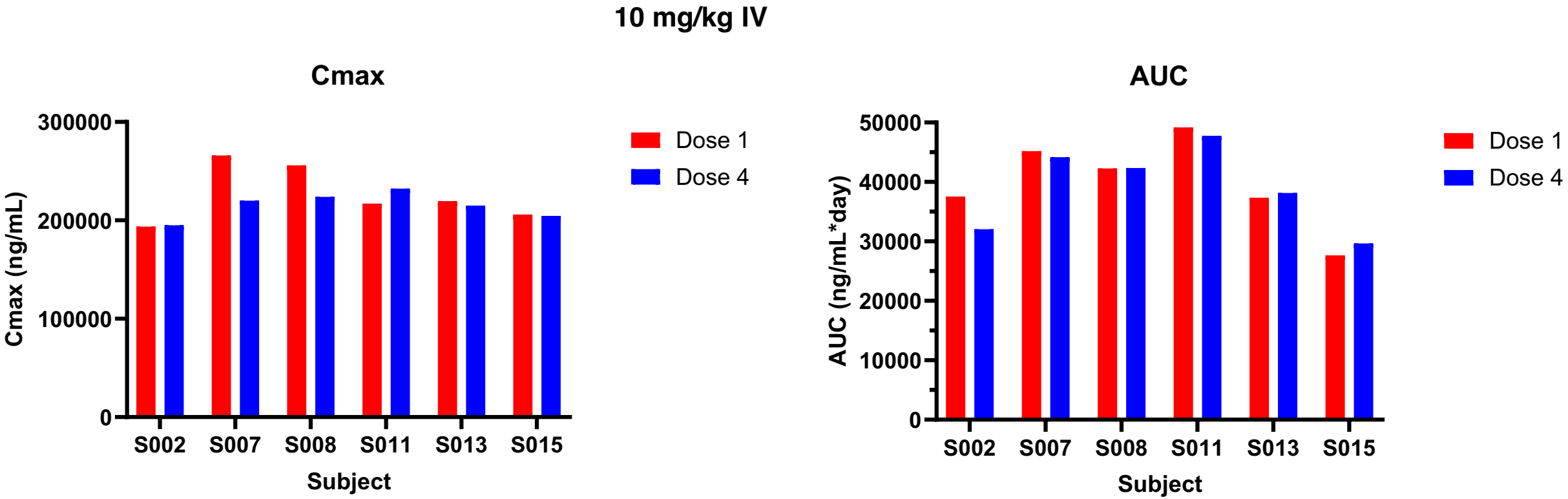
1. NCT04415671 and NCT05914909 on https://clinicaltrials.gov

Phase I extension study achieves critical partnering and Phase II readiness milestones

Phase I extension study finding	Significance
1. *Multiple doses of 10 mg/kg IV AD-214 are **well tolerated**, no dose limiting toxicity, only "mild" adverse events*	✓ **Establishes safety profile** necessary to advance this dose to Phase II
2. *PK (maximum and total exposure) and PD (white cell and receptor occupancy*) profiles are **consistent across multiple doses** and multiple patients; **in line with model predictions***	✓ **Supports potential efficacy** of selected Phase II dose
3. *Antidrug antibodies present at low levels only; **no evidence of effect** on PK and PD parameters*	✓ ADAs (or other immune responses) are **unlikely to detract from clinical safety or efficacy**
4. Larger biopharmaceutical licensing partners want to know that the target Phase II dose is **safe**, has **potential to be effective** and that any immune response will not detract from this	✓ *Results **comprehensively address** pharma company clinical questions received to date*

* RO profile after fourth dose remains under evaluation

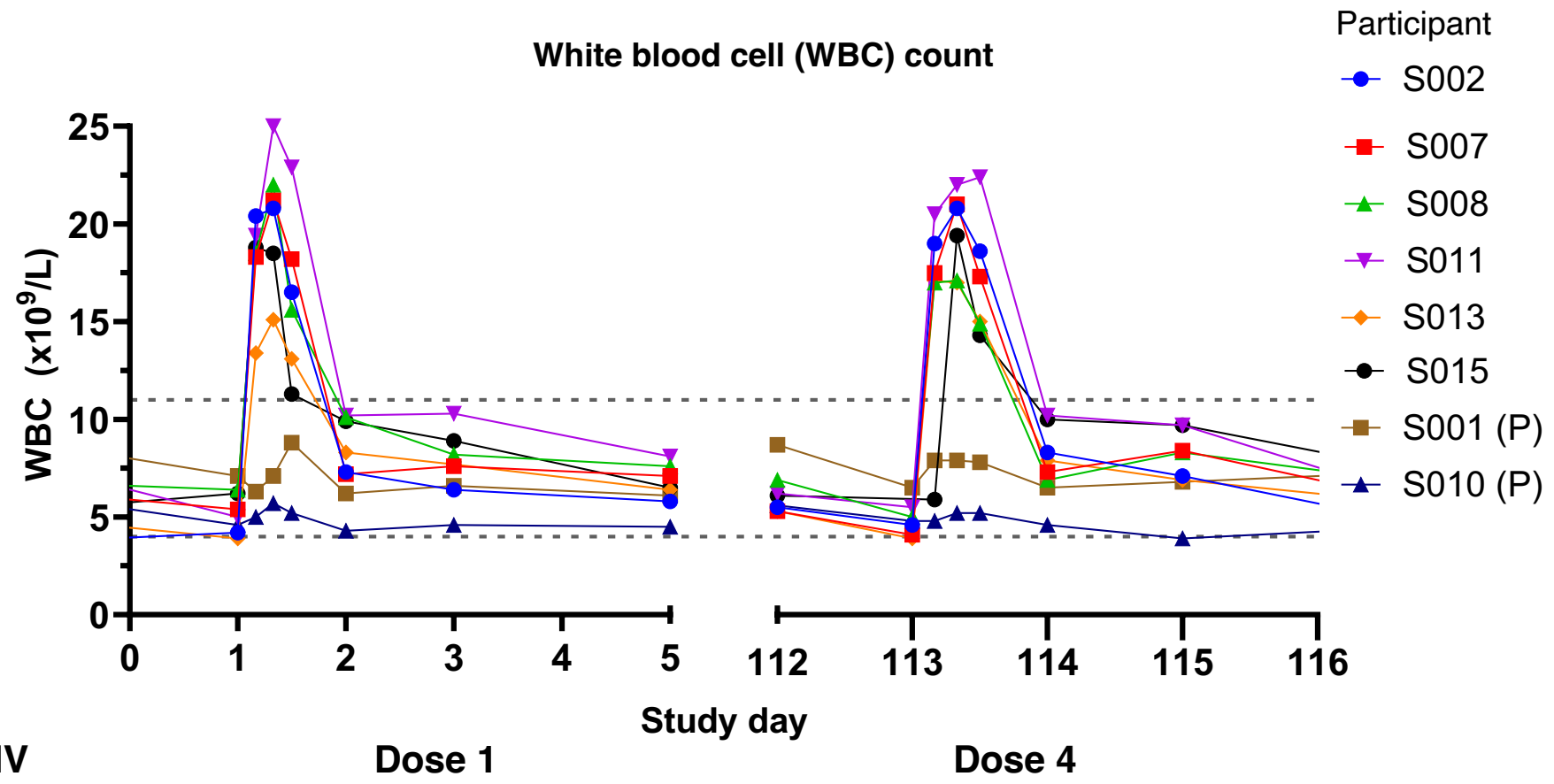
PK profile was consistent between dose 1 and dose 4 and independent of ADA response for all extension study participants*



PK was assessed by measuring the concentration of AD-214 in the blood over time. At dose four, every participant receiving AD-214 achieved the same maximum concentration of AD-214 (Cmax, left hand chart) and total exposure (concentration multiplied by time at that concentration or AUC, right hand chart) as at dose one, despite different levels of ADAs. Slight variations between doses for individual participants reflect experimental variability and were not correlated with ADA levels or any other measured parameter. Variations between participants are normal and expected. Placebo results not shown.

*Preliminary AdAlta PK analysis conducted using PKSolver

White blood cell counts (a PD marker) were consistent across all participants and all doses in extension study



PD was assessed by measuring the increase in white blood cells (WBC) circulating over time (chart above) and the level and duration of RO (data not shown). Every participant receiving AD-214 achieved the same maximum WBC count at dose four as at dose one, despite different levels of ADAs. No increase in WBC counts was observed in placebo recipients (marked P). Dotted lines show lower and upper limits of normal WBC levels in the absence of CXCR4 blocking.

*Preliminary AdAlta analysis of raw study results

The development plan

Phase II financing strategy

Either co-development in asset specific entity

- AD-214 licensed to AdAlta subsidiary
- Strategic or financial investors invest in subsidiary
- AdAlta leads Phase II
- AdAlta receives management fees, retains substantial equity ownership
- On completion of Phase II, AD-214 is on-licensed
- AdAlta benefits from value uplift of any Phase II success

Or out-licensing to larger biopharmaceutical company

- Global or regional company licenses global development and commercialization rights
- Partner responsible for funding, executing Phase II
- AdAlta receives upfront payment, development milestones and royalties on any future commercial sales
- AdAlta return is fixed now

Phase I extension study data being shared with short list of partners to enable them to complete their evaluation of AD-214

Objective is a near term transaction

Product development strategy

Target intravenous (IV) product profile

- IV administration in clinic
- Two weeks minimum between infusions: meets minimum product criteria for clinical adoption
- Fastest, cheapest to clinical proof of concept
- Progress to Phase II

Potential subcutaneous (SC) product profile

- Patient self administration at home (like diabetes, arthritis)
- Weekly or daily injections: maximum convenience, minimum costs
- Enhanced market share, reduced COGS
- Develop formulation, progress to Phase I

Choice of formulation to take through to Phase III

Based on relative success of each development

The value: Pharma companies are actively licensing IPF assets for significant value

Date	Licensor/target	Licensee/acquirer	Transaction	Upfront payment to licensor	Contingent milestones	Clinical Phase at transaction
Feb 23	Redx	Jounce Therapeutics	Acquisition#	**US$294m**	N/A	2
Jan 23	Daewoong	CSPC Pharmaceuticals (创新进中国)	China only license	**US$76m^**	US$336m	2
Aug-22	Kiniksa	Genentech, A Member of the Roche Group	License	**US$80m**	US$620m	2
Apr-20	Curzion Pharmaceuticals	Horizon	Acquisition*	**US$45m**	Not disclosed	2
Nov-19	Promedior	Roche	License	**US$390m**	US$1,000m	2
Nov-21	Blade Therapeutics	Biotech Acquisition Company	Acquisition#	**US$254m**	N/A	2 (Ready)
Nov-20	OncoArendi Therapeutics	Galápagos	License	**€25m**	€320m	2 (Ready)
Sep-21	Syndax	Icyte	License	**US$152m**	US$602m	2 (Ready)
Feb-21	泰德制药 Tide Pharmaceutical	Graviton Bioscience Corporation	License	**Not disclosed**	US$517.5m	1
Jul-19	bridgebio therapeutics	Boehringer Ingelheim	License	**€45m**	€1,100m	1
Oct-22	DJS antibodies	abbvie	Acquisition	**US$255m**	Not disclosed	Pre-clinical (+ platform)

AD-214 almost Phase II ready

Source: Company press releases; * Lead indication was diffuse cutaneous systemic sclerosis which usually evolves into IPF; # Did not complete; ^ Includes development milestones

Co-developed immuno-oncology programs: i-CAR-cell and other advanced therapies

The need: Multifunctional CAR-cell therapies

Therapy involves re-engineering patient's own immune cells to "see" cancer – **living drug, single dose, potentially curative**

6 FDA-approved CAR-T therapies since 2017 transforming outcomes:

Complete response rates: **83%** r/r pALL, **51-65%** r/r LBCL, **78%** r/r MM[4]

>US$2.6 billion earned in 2022[3]

US$20.3 billion CAR-T market forecast for 2028[1]

… but so far only for blood cancers

90% of cancers are solid tumours: harder to target, harder to access, immune suppressive … needs new multifunctional CAR cell therapies

>50% of CAR-T revenues from solid tumours by 2030[2]

1. Grandview Research, "T-cell Therapy Market Size, Share & Trends Analysis" Feb 2021
2. Polaris Market Research, "CAR-T Cell Therapy Market Share, Size Trends, Industry Analysis Report", June 2021
3. Company websites and financial filings
4. Kymriah, Yescarta and Carvytki prescribing information; r/r = relapsed/refractory; pAML – paediatric acute lymphoblastic leukemia, LBCL = large B cell lymphoma, MM = multiple myeloma

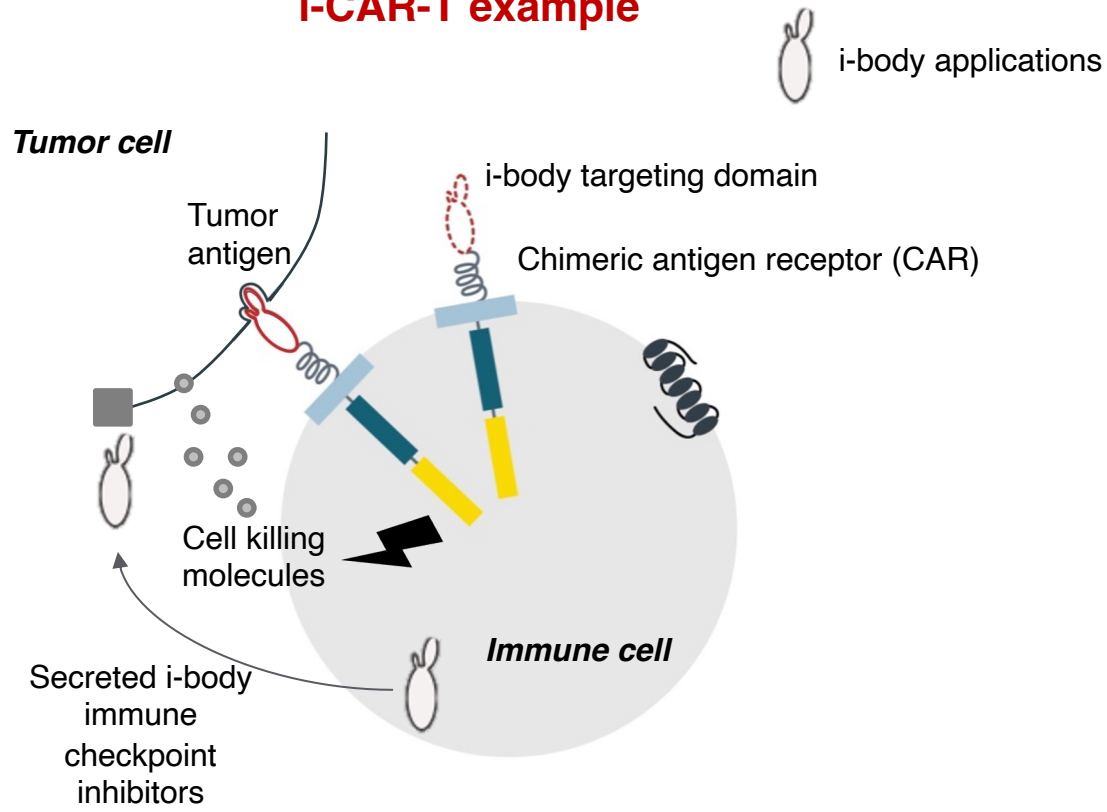
AdAlta's solution: i-bodies enable superior CAR constructs (i-CARs) and other advanced therapies when combined with partner platforms

TINY i-body® needs LESS room in inserted gene, enabling MORE engineered function

Produces superior, multifunctional advanced therapy products

- **Improved targeting**
  - Novel tumor antigens, dual and bi-specific CARs
- **Persistence and performance**
  - Overcome immune suppression "checkpoints", enhanced trafficking, reduced exhaustion
- **Payload**
  - Higher payload for vectorized antibody therapeutics (mRNA, *in vivo* CAR-T, etc)

i-CAR-T example



Significant industry interest from potential additional partners

Value could be realized at preclinical PoC

Three targets in development with Carina Biotech using repeatable partnering model

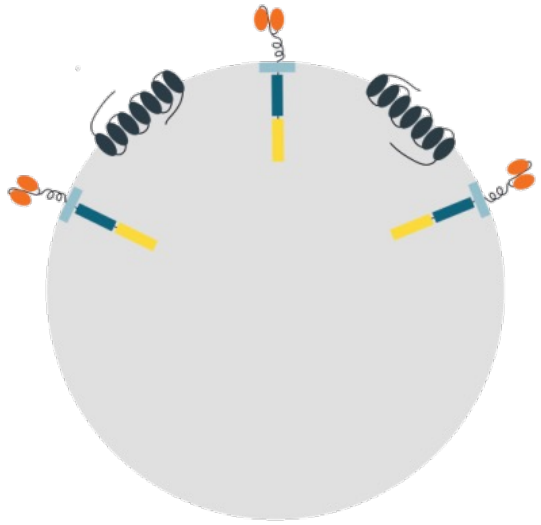
AdAlta
next generation protein therapeutics

i-body® platform

carina biotech

cell therapy platform

i-CAR-Ts for solid tumor patients



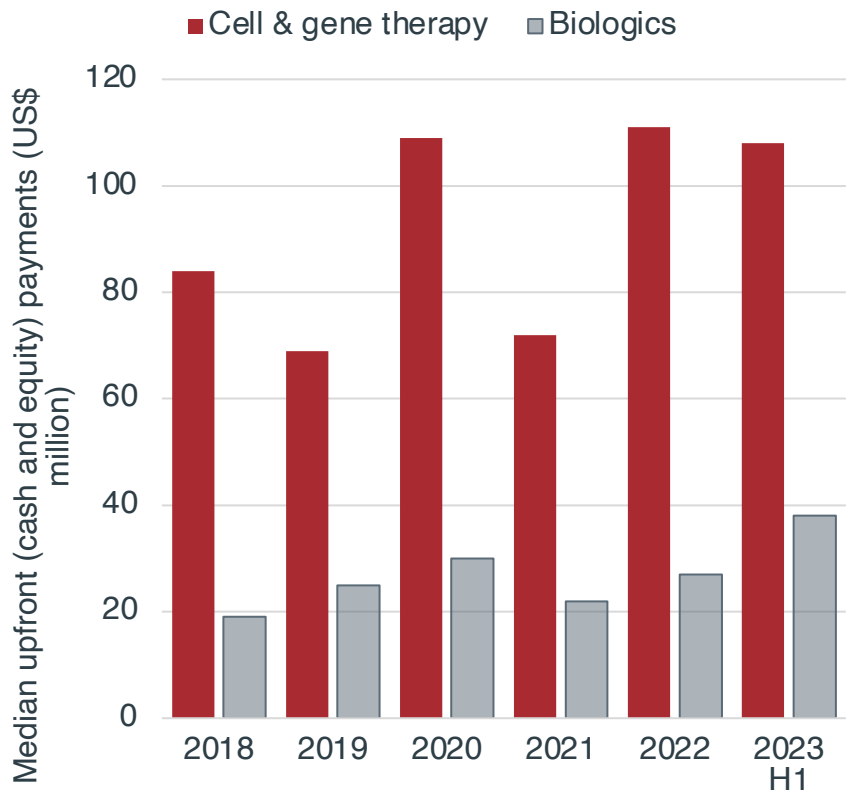
- ✓ i-body® enabled CAR-T (i-CAR-T) cells have successfully demonstrated *in vitro* cancer cell line killing (lysis)
- ✓ Target A: 3 A-i-CAR-T cells progressed to *in vivo* proof of concept
- ✓ Two targets (targets B and C): commenced i-body discovery in Q2 2023

Collaboration overview

- **AdAlta discovers and supplies i-bodies against solid tumor associated antigens (targets)**
- **Carina engineer into i-CAR-T cells and demonstrate in vitro cytotoxicity (cell killing)**
- **AdAlta and Carina jointly fund in vivo proof of concept studies in relevant tumor models**
- **AdAlta and Carina jointly (50:50) own resulting i-CAR-T products**

The value: Cell & gene therapy up front deal values 3.5x higher than other biologic drugs with potential to partner early

Asset in-licensing terms



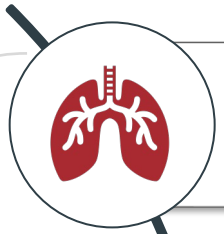
Pre-clinical proof of concept cell therapy transactions

Date	Licensee	Licensor	No. of assets	Upfront/ target (US$m)	Deal value/ target (US$m)
Jun-22	Bristol Myers Squibb	immatics	2	30	730
Jul-20	SANOFI	Kiadis pharma	1	20	988
Feb-20	GSK	immatics	2	25	300
Nov-19	Allogene	Notch Therapeutics	1	10	304
Oct-18	Roche	SQZ BIOTECH	1	45	1702
Median value				**25**	**730**

Source: JPMorgan, Q2 2023 Biopharma Licensing and Venture Report, July 2023 ("Biologics" includes biologics, mAbs, ADC, proteins, DNA, RNA, etc); GlobalData, company press releases, AdAlta analysis

Unlocking value in i-body pipeline

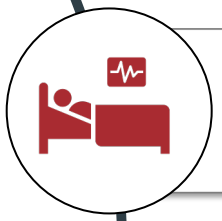
AdAlta's portfolio: High value therapeutics addressing challenging diseases in fibrosis and immuno-oncology and a platform grow further



Fibrosis: degenerative, progressive, fatal

AdAlta's AD-214 could meet a desperate need for new approaches for debilitating diseases of the lung (US$4.3b), kidney (US$10b) and eye (US$15b)

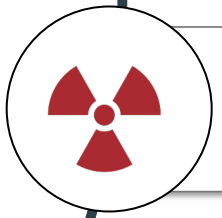
Comparator licensing transactions: >US$45m up front; US$320-1,000m milestones



CAR-T cell therapy providing new hope… for blood cancer patients so far

AdAlta and Carina's i-CAR-T cells could offer the same hope for solid tumour patients (US$20b by end of decade)

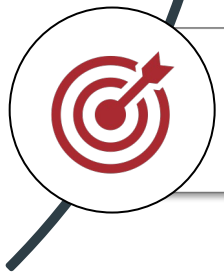
Comparator licensing transactions: >US$10m up front; >US$300m milestones



Immuno-oncology drugs revolutionising cancer treatment… for some

AdAlta and GE Healthcare's GZMB i-PET imaging agent could identify responders early (US$6b)

Comparator product revenue potential: >US$400m pa



Traditional antibodies can't do everything!

AdAlta's i-bodies are a differentiated drug discovery platform partners can leverage for difficult diseases

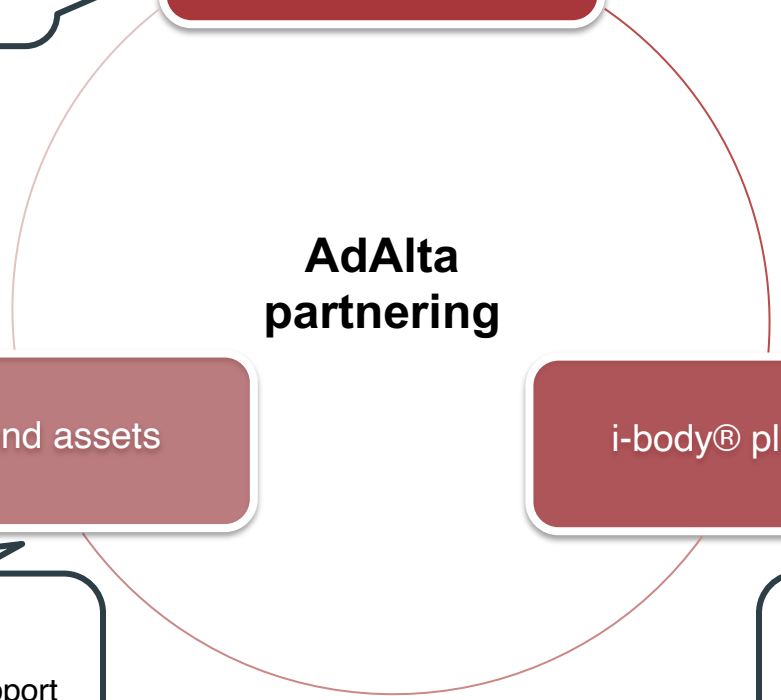
Partnering momentum increasing to unlock asset value and build pipeline

- Illustrative recent progress

Out-licensing or co-investment for Phase II development

Generating return on investment to date
- 21 active licensee evaluations post BIO2023
- One party testing AD-214 in own assays
- Fielding several co-investment enquiries

AD-214 Phase II



In-licensing/acquiring clinical stage assets with i-body® synergies

Co-discovery/sponsored research using i-body® platform and "inventory" of new targets

Potential clinical stage pipeline post AD-214
- Screening criteria: clinical inflection point achievable within two years, i-bodies can support next generation product
- Target: 4-5 assets under review

Adding to GEHC, Carina, GPCR Tx
- Focus on GPCRs and i-CAR cell therapy
- GPCR Target X: 2 inbound enquiries at BIO2023 + 6 requests for further information from outreach campaign

Upcoming milestones and objectives in 2024

1. Realise the value of AD-214

- ✓ **Complete Phase I extension study**
  - ✓ **Phase II dose well tolerated, PK/PD profile supportive of potential efficacy, no concerning immune response**
- ❖ GPCR Therapeutics (Korea) collaboration
  - Results of GPCR Tx evaluation of CXCR4 i-bodies
- ❖ Finance AD-214 pathway to Phase II clinical studies
  - Out-license or project finance
  - Unlock financing for other strategy pillars

2. Progress i-CAR and i-PET programs

- ❖ Progress Carina Biotech i-CAR-T cell therapy collaboration
  - A-i-CAR-T in vivo proof of concept: go/no go for further development
  - Complete i-body discovery on targets B and C: go/no go for *in vitro* cell cytotoxicity
- ❖ Continue GE Healthcare collaboration for GZMB-i-PET imaging agent
  - Milestones dependent on GE Healthcare

3. Invest in i-body® platform and pipeline

- ❖ i-body®2.0 program and i-body® “inventory” build
  - ✓ **World first discovery of high potency, pan-species inhibitor of malaria parasite invasion**
  - Commencing discovery on two new “catalogue” targets suitable for multiple i-CAR collaborations
  - Generate new know-how and IP demonstrating power of i-body platform
- ❖ Synergistic technology and product transaction opportunities
  - Careful evaluation of opportunities to expand clinical stage pipeline

Experienced in-house team

Executing from discovery through product development

BOARD

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INDEPENDENT DIRECTOR

Dr. David Fuller

INDEPENDENT DIRECTOR

EXECUTIVE

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Brian Richardson

DRUG DISCOVERY & DEVELOPMENT EXPERT

Steve Felstead

CLINICAL DEVELOPMENT

John Westwick

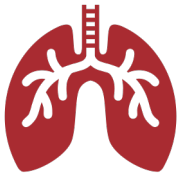
PULMONARY DRUG DISCOVERY & DEVELOPMENT

PARTNERS AND KEY CONTRACTORS

IN-HOUSE DISCOVERY & DEVELOPMENT TEAM

8 PhD/MSc Staff + La Trobe Uni location
Skills in protein chemistry, i-body discovery, product development, pre-clinical development

AdAlta's foundations in place for growth



Lead asset AD-214 heading to Phase II (US$4.3b IPF market plus other indications), substantially de-risked by Phase I extension study clinical readouts

AD-214 partnering window open with multiple options in play: active market with comparator valuations >US$45m upfront with US$0.3-1b milestones

Pipeline of other assets, partnerships and partnering opportunities, including emerging pipeline of high value CAR cell therapies

Experienced team and differentiated discovery platform enable clear potential for growth beyond AD-214

Strong and supportive institutional and large shareholder register

Attractive valuation relative to commercial potential of pipeline

AdAlta

A modern targeting system for next generation drugs

AdAlta Ltd (ASX:1AD)
Investor Presentation
October 2023

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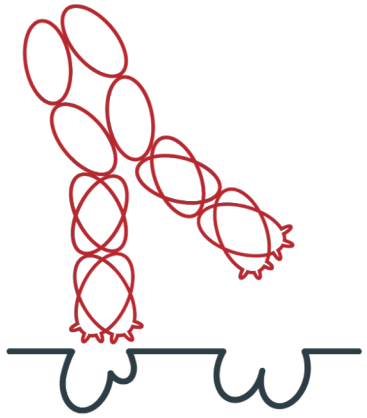
i-bodies are a powerful drug discovery tool to engage targets that traditional antibodies can't

Small Molecules

Avoid off-target issues of small molecules

Antibodies



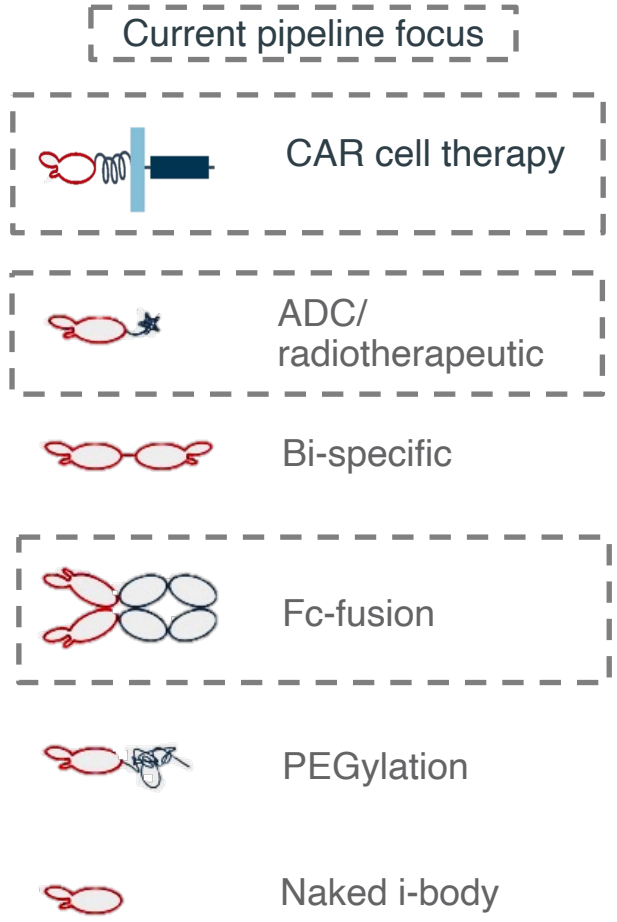
~10% the size of human antibodies

Enables access to novel targets and efficient payload delivery

i-bodies™

Unique binding capabilities drive unique pharmacology

Flexible, modular formats



AdAlta's pipeline so far: Five active assets plus growing i-body® inventory