AdAlta

next generation protein therapeutics

i-bodies – a new class of protein therapeutics to treat human disease

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Corporate and investment summary

- A drug discovery and development company focused on using its proprietary technology platform to generate a new class of protein therapeutics, known as i-bodies, for treating a wide range of human diseases
- **Investment highlights**
  - Initial focus on treating fibrosis – high unmet medical need
  - Advanced lead fibrosis drug candidate AD-114 with significant pre-clinical validation
  - Fully funded for phase 1 development of lead fibrosis drug and i-body pipeline
  - Early commercialisation potential
  - Experienced team with strong track record of drug development and ability to deliver

Capital structure	
ASX code	1AD
Shares on issue*	101,037,617
Share price (4 January)	AU$0.185
Market capitalisation	AU$18.7m
Current cash	$9m
Trading Range	AU$0.31 to $0.165

* 50.9m shares escrowed for 6-24 months from listing

Major Shareholders	%
Yuuwa Capital LP	53.5
Platinum Asset Management	7.97
Citycastle Pty Ltd	5.26
La Trobe University	3.01
Robin Beaumont	1.82
Other shareholders	28.44
Total	100%

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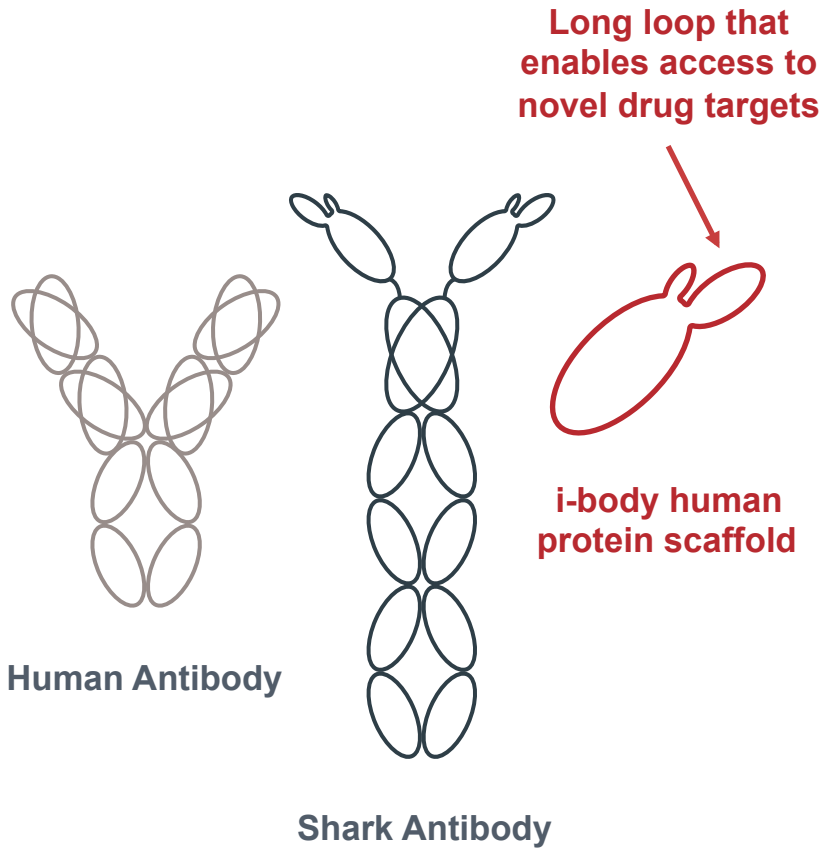
i-body technology

AdAlta is developing a new technology platform that produces unique proteins known as i-bodies, that mimic the shape of shark antibody binding domain and engineers their key stability features into a human protein, for therapeutic intervention in disease.

The single domain antigen binding region of shark antibodies is extremely stable and has a long binding loop not present in either human or next generation antibodies.

Advantages of i-bodies

- High target specificity and high affinity for their target
- Small proteins; 10% the size of a typical human antibody
- Highly stable to proteases, high temperatures and low pH
- Long loop that can bind to a diverse range of therapeutically relevant targets including those that are difficult for current antibody therapies
- **Human protein** – reduced risk of immune response



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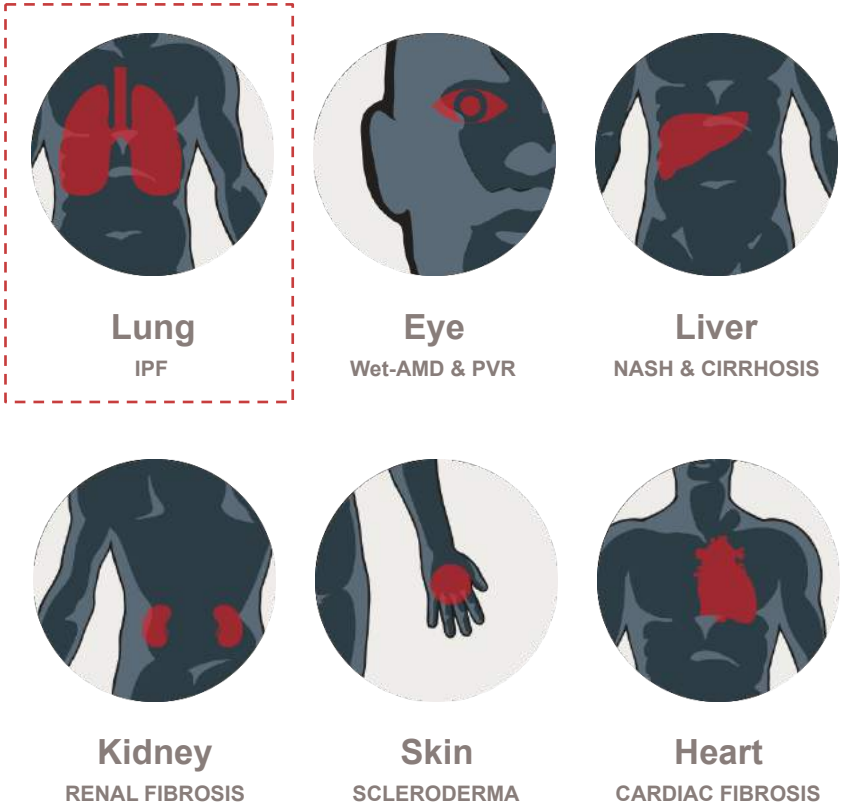
Fibrosis: unmet medical need with multiple indications

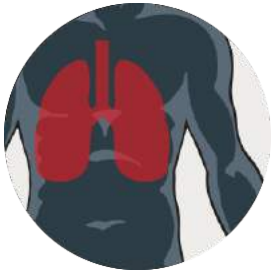
- Developing i-bodies as improved therapies for the treatment of fibrosis
  - a condition that is prevalent in 45-50% of all diseases
- Fibrosis can occur in many tissues of the body as a result of inflammation or damage
  - it can result in scarring of vital organs causing irreparable damage and eventual organ failure
- AdAlta's initial focus is on lung fibrosis

Collectively fibrosis represents a large unmet clinical need



AD-114 lead program in Idiopathic Pulmonary Fibrosis (IPF)

- AD-114 is lead i-body candidate in pre-clinical development
  - Demonstrates both anti-fibrotic and anti-inflammatory activity in the lung
  - Important for arresting and modifying the disease and tackling the treatment of idiopathic pulmonary fibrosis (IPF); this is the primary indication



Lung

IPF

Idiopathic Pulmonary Fibrosis
A chronic, highly lethal and rare disease.
50-70% mortality rate
>135,000 people in US alone
World wide sales ~$4.2B by 2020

Source: Evaluate Pharma, Orphan Drug Report 2015

CXCR4 and idiopathic pulmonary fibrosis (IPF)

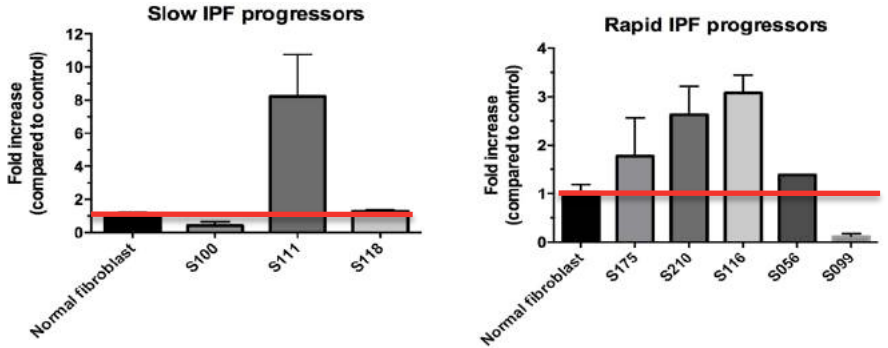
Patients that rapidly progress express more CXCR4 compared to slow IPF progressors

CXCR4 +ve cells (fibrocytes) significantly elevated in stable IPF patients, and further increased during acute exacerbations

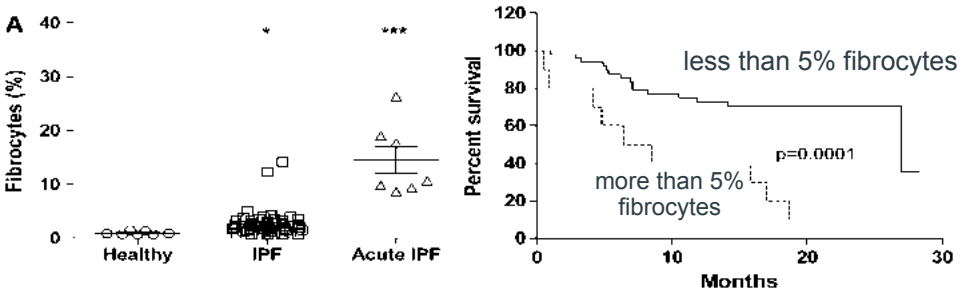
Fibrocytes not correlated with lung function but an independent predictor of early mortality

- 7.5 months with more than 5% fibrocytes
- 27 months with less than 5% fibrocytes

CXCR4 expression increased in fast progressing IPF patient tissue



Fibrocyte numbers predict mortality



REF: Moeller, et al. Am J Respir Crit Care Med Vol 179. pp 588–594, 2009

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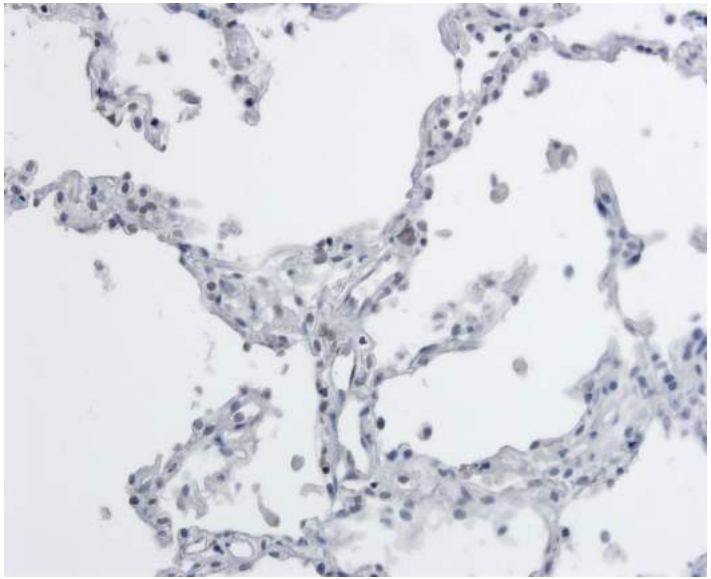
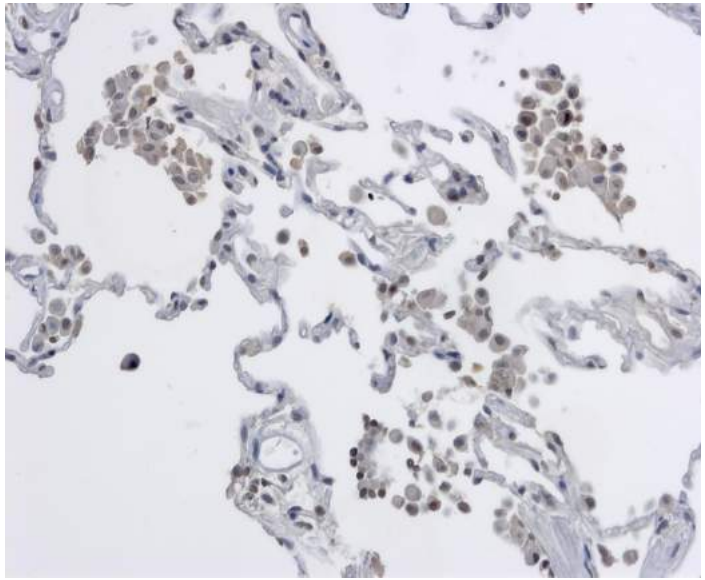
AD-114 binds to lung tissue from patients with fibrosis

AD-114 was used for Immunohistochemical (IHC) staining of normal and diseased lung tissues to verify expression of CXCR4 *in situ*



AD-114 does not bind lung tissue from normal lungs



AD-114 binds to lung tissue from lungs with fibrosis

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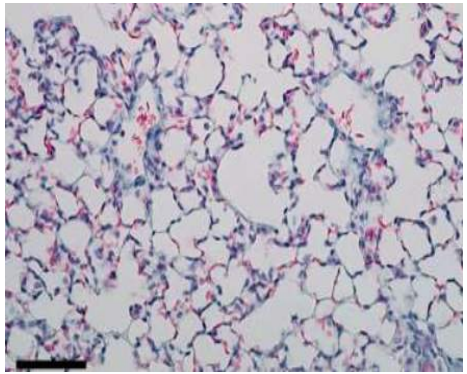
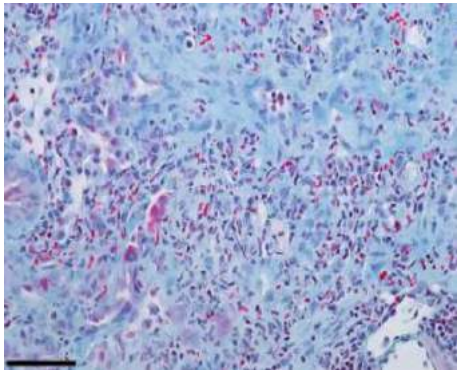
AD-114 prevents lung fibrosis in disease models

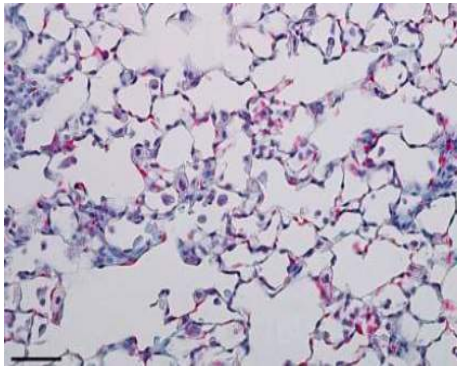
Extensive pre-clinical AD-114 studies have demonstrated positive *in vitro* (in the lab) and *in vivo* (in animals) data



Normal lung tissue



IPF lung tissue
(lung disease mouse model)

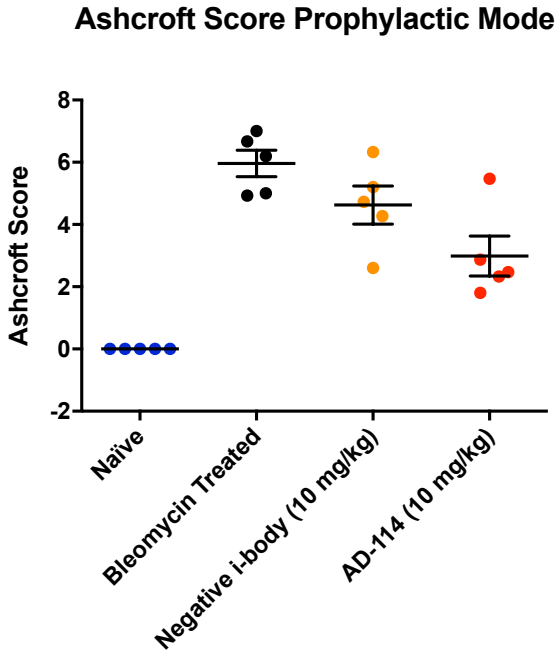


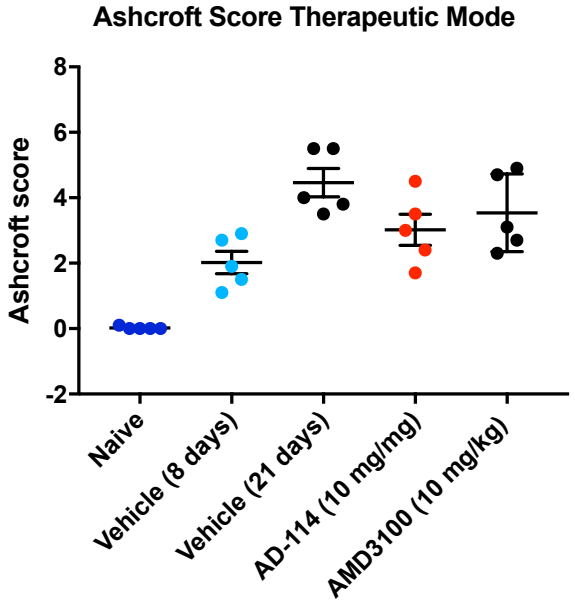
IPF lung tissue + AD-114 dosed for 21 days
(lung disease mouse model)

AD-114 reduces collagen content and inflammatory cell infiltration and demonstrates a similar architecture to that of the normal lung in the Bleomycin mouse model

AD-114 prevents lung fibrosis in disease models

AD-114 significantly reduces Ashcroft scores in both prophylactic and therapeutic modes of the Bleomycin mouse model of fibrosis





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AD-114 key advantages compared to existing IPF treatments

Human tissue *In vitro* activity	No effect on normal tissue	Effect on diseased / IPF tissue
i-body AD-114	✔	✔
Nintedanib (Boehringer)	✗	✔
Pirfenidone (Roche)	✔	✗
Other CXCR4 drug (Sanofi)	✔	✗

- AD-114 has greater *in vitro* efficacy compared to the only approved therapies Nintedanib and Pirfenidone for IPF treatment
  - Existing IPF treatments have limited efficacy; either no effect or slow down disease progression i.e. no cure
- Novel mechanism of action compared to other drugs targeting CXCR4
- Very specific for diseased tissue and no effects on normal tissue
- AD-114 has both anti-fibrotic and anti-inflammatory effects

Novel mechanism of action for fibrosis treatment enabling a “first in class” therapy

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Global market interest in fibrosis treatments

Recent transactions confirm that big pharma are actively acquiring fibrosis assets at an early stage – typically based on Phase I results

Date	Company	Target	Acquired by	Deal value (US$)	Deal commentary
Sep-15	Adheron Therapeutics	SDP051	Roche	$105M upfront, plus $475M in milestones	SDP-51 at end of Phase I for IPF
Aug-15	Promedior	PRM-151	BMS	$150m upfront + $1.25B	Phase II IPF and myelofibrosis
Nov-14	Galecto Biotech AB	TD139	BMS	$444M	Option to acquire at end of clinical POC (no later than 60 days following Ph 1b for IPF completion)
Aug-14	Intermune	Esbriet / Pirfenidone	Roche	$8.3B	Approval in Europe / Japan, phase III in the US
Jun-13	MicroDose Therapeutx	MMI0100	Teva Pharmaceuticals	$40M upfront $125M milestones	MMI0100 was in pre-clinical development
Mar-12	Stromedix	STX100	Biogen Idec	$75M upfront $487.5M milestones	End of phase I for IPF
Jul-11	Amira / BMS	BMS-986020	BMS	$325M upfront $150M milestones	End of phase I for IPF

Source: Medtrack Pharma Intelligence, Informa (all IPF deals since 2011)

AD-114 and non-alcoholic steatohepatitis (NASH)

- Non-alcoholic steatohepatitis (NASH) is a pandemic, metabolic disease which has both inflammatory and fibrotic components
- AD-114 is lead i-body candidate in pre-clinical development
  - Demonstrates both anti-fibrotic and anti-inflammatory activity in the liver
  - Important for arresting and modifying the disease and tackling the treatment of NASH

Liver

NASH & CIRRHOSIS

NASH

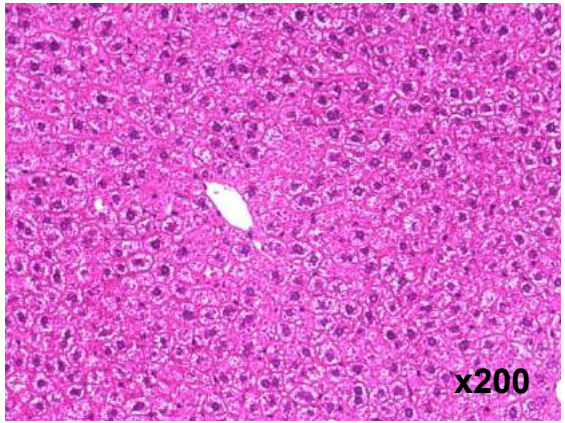
A chronic disease with high levels of morbidity and mortality

About 3-5% of adults in the United States have NASH

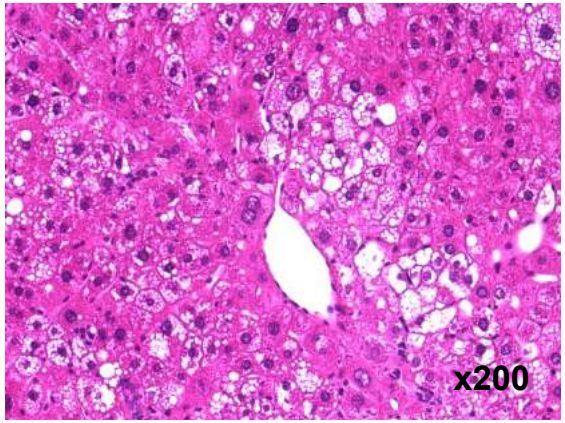
Sales of drugs for the treatment of fibrosis caused by NASH are estimated to be US$1.6 billion by 2020.

AD-114 prevents fibrosis in a mouse model of liver fibrosis

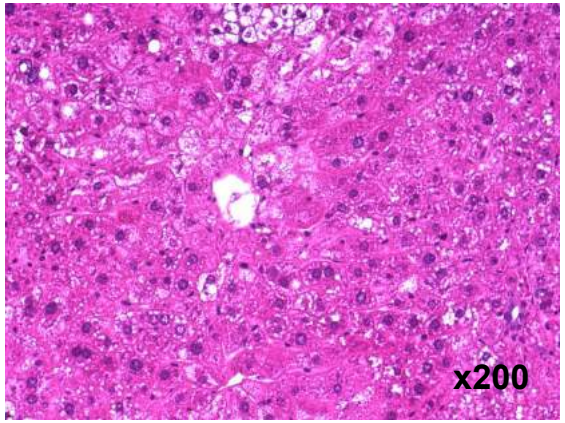
Therapeutic setting



Normal liver tissue



NASH liver tissue
(liver disease mouse model)



NASH liver tissue + AD-114 dosed for 21 days
(liver disease mouse model)

AD-114 significantly reduces hepatocellular ballooning, a key feature required for the diagnosis of NASH

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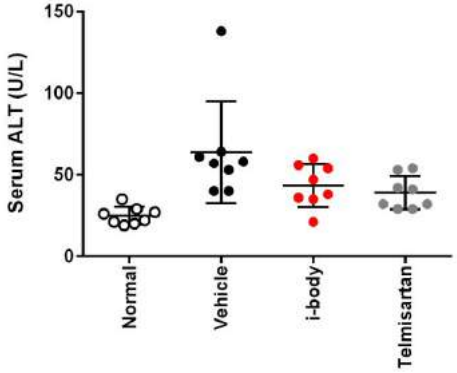
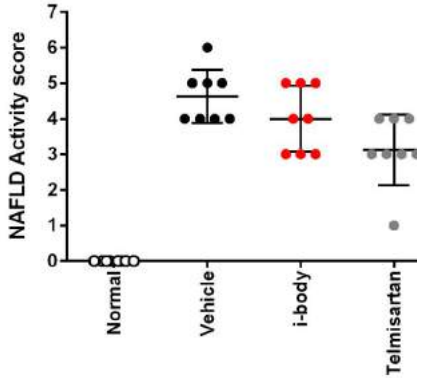
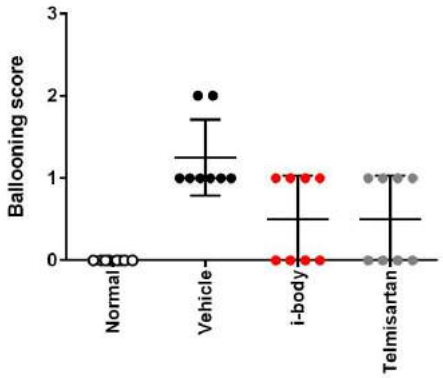
AD-114 prevents fibrosis in a mouse model of liver fibrosis

- AD-114 decreased serum ALT levels and non-alcoholic fatty liver disease (NAFLD) score compared with the vehicle or disease model group
- The improvement in serum ALT levels suggests that i-body ameliorated hepatocellular injury and inflammation preventing progression of disease
- Hepatocyte ballooning was significantly decreased compared with the vehicle or diseased group
- AD-114 possess hepatoprotective and anti-NASH effects







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AD-114 and eye fibrosis

- Infections or inflammation in the eye result in impairment of visual function and can ultimately lead to fibrosis. Complications from common eye diseases that can result in fibrosis occur in age related macular degeneration (AMD) and diabetic retinopathy.
- AD-114 is lead i-body candidate in pre-clinical development
  - Demonstrates both anti-fibrotic and anti-leakage activity in the eye
  - Important for arresting and modifying the disease and tackling the treatment of eye fibrosis

Eye

Wet-AMD & PVR

Eye Fibrosis

AMD is the commonest cause of severe visual impairment in people over the age of 50 years in the developed world

>1m in AU and 2m in USA with AMD

Market research estimates that the market size for AMD will be over US$10 billion by 2023 while the market size for diabetic retinopathy will be US$10 billion in 2022.

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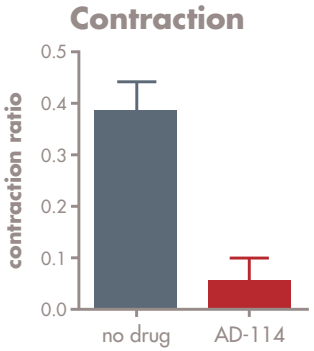
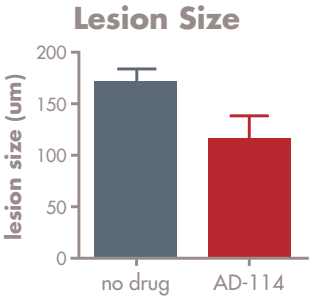
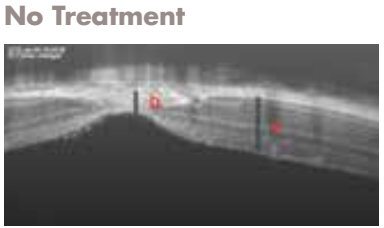
AD-114 prevents eye fibrosis

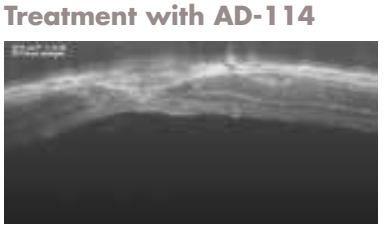
- Mouse chorodial neo-vascularization model(CNV): laser burn to the retina
  - Induces subretinal haemorrhage
  - Contraction of retinal tissue
  - Alteration in microglia and glial response
  - Alteration in gene expression
- IVT injection of single dose of i-body
  - Improves retinal retraction and reduces lesion size
  - Fibrosis gene expression reduced

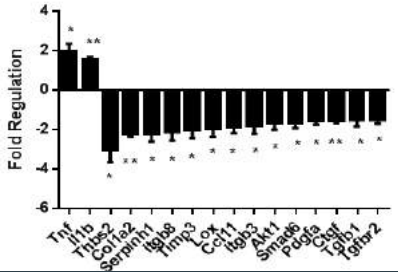
AD-114 reduces contraction and lesion size in eye fibrosis mouse model











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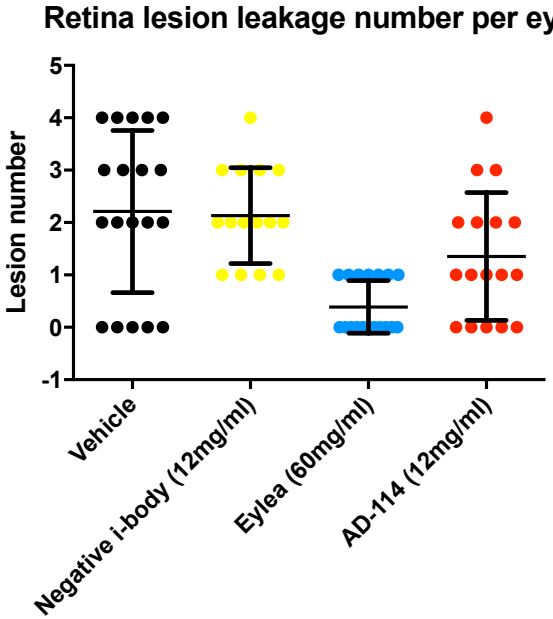
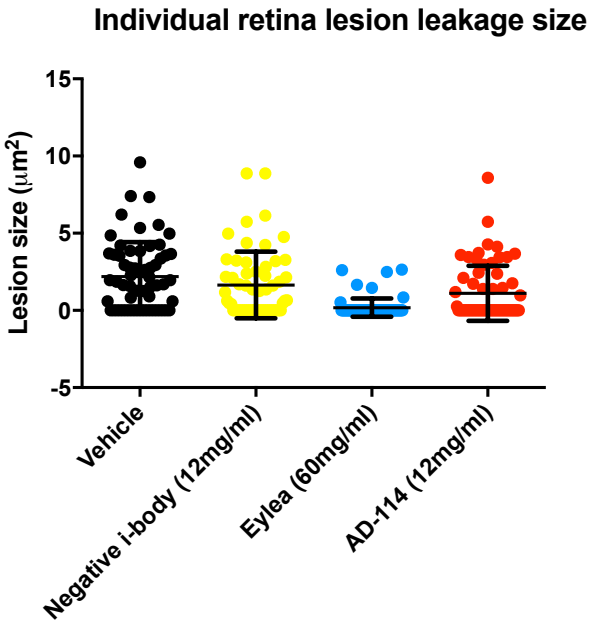
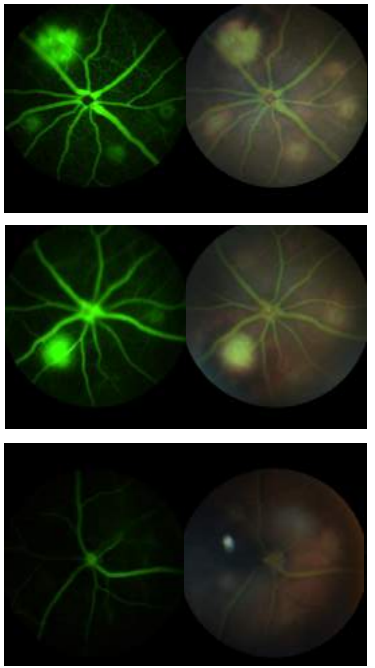
AD-114 reduces lesion size and number

- AD-114 is able to reduce the number and size of the lesion in both preventative and therapeutic models of CNV
- Eylea was also able to reduce lesion number and size in these models







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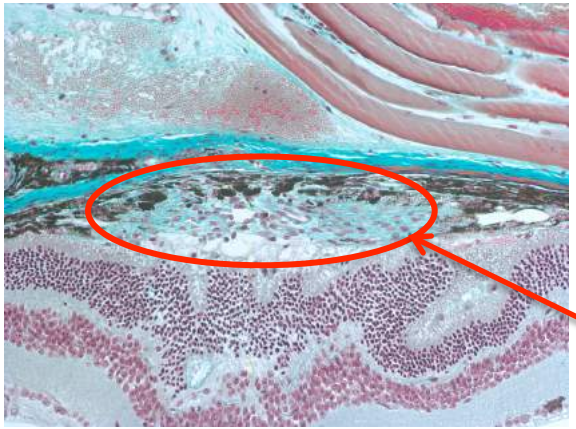
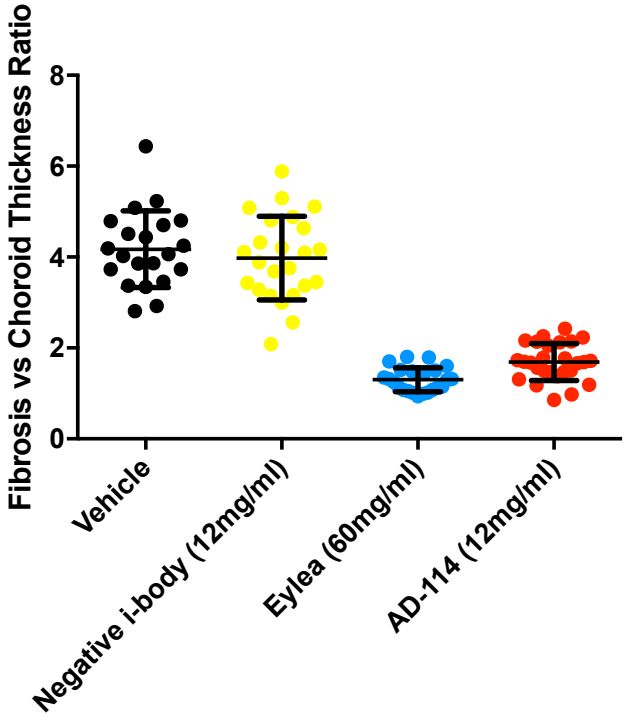
AD-114 reduces fibrosis

- AD-114 is able to significantly reduce fibrosis as measured by trichrome staining in both preventative and therapeutic models of CNV
- Eylea was also able to reduce fibrosis in these models



Fibrosis as measured by trichrome staining for collagen



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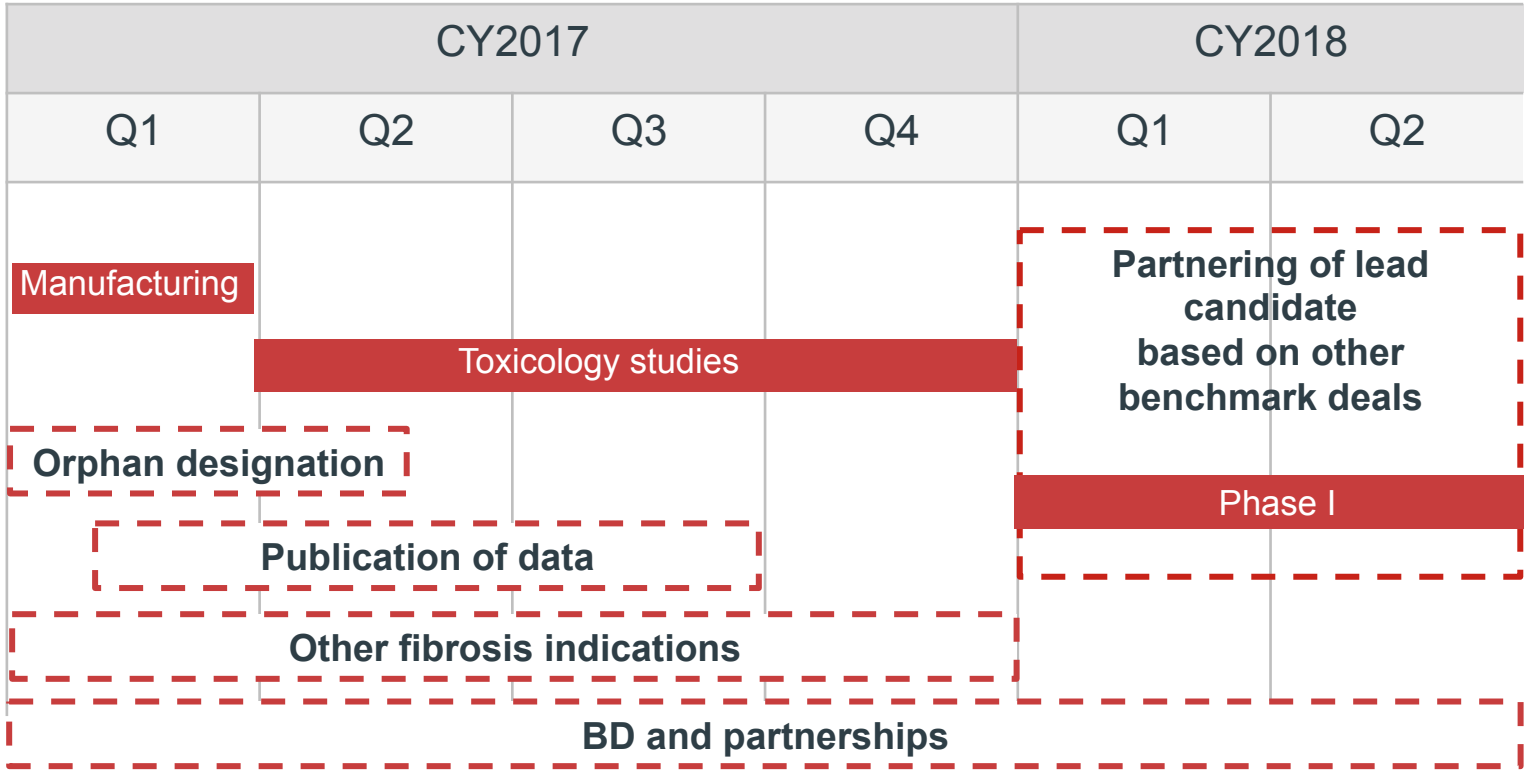
AD-114 development: key milestones



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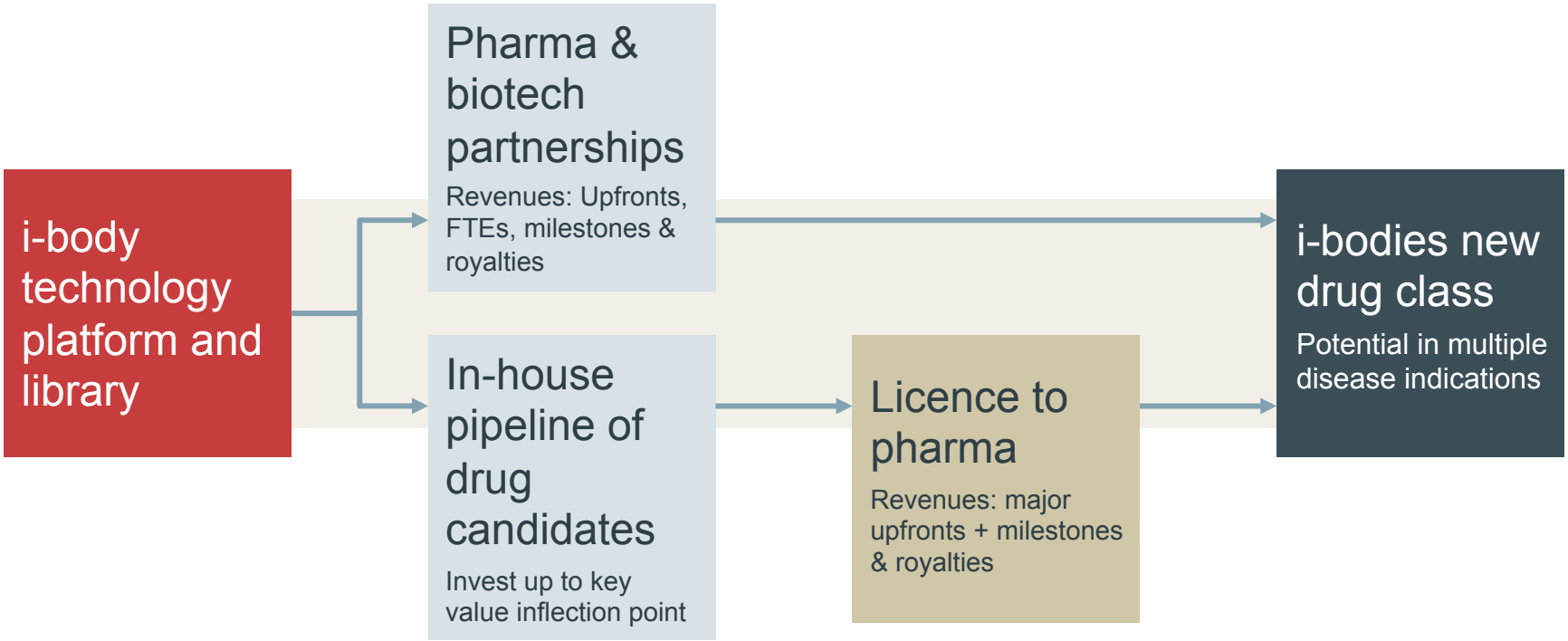
Expected news flow next 12 months

Q3 & Q4 2016	✓	Commence manufacturing of material for toxicology testing with FujiFilm Diosynth Biotechnologies
	✓	Additional AD-114 IPF fibrosis data
	✓	Completion of evaluation of AD-114 with IPF clinicians Alfred Hospital
	✓	Completion of AD-114 NASH animal study
H1 2017	▶	Hypertrophic scarring animal results for AD-114
	▶	Orphan Drug Designation (US FDA)
	▶	Manufactured material for toxicology testing available
H2 2017	▶	Eye fibrosis additional data, funded by NHMRC development grant
	▶	Completion of other pre-clinical study animal models of AD-114
	▶	AD-114 toxicology results

AdAlta business model – strategy to create value



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Market benchmarks

Fibrosis lead AD-114	adheron THERAPEUTICS Sep-15 acquired by Roche $105m + $475m milestones phase I asset	Promedior Aug-15 acquired by BMS $150m + $1.25b milestones phase IIa asset	Galecto Biotech AB Nov-14 acquired by BMS $444m phase I asset
Next gen antibodies	arGEN-X April-16 with Abbvie $40m upfront + $645m milestones & royalties	pieris PHARMACEUTICALS Dec -15 with Roche $6.4m upfront + $410m milestones & royalties	Ablynx Nov-15 with Novo-Nordisk €9m upfront + €182m milestones & royalties)
GPCRs	HEPTARES therapeutics Acquired Feb-15 by Sosei $400m Phase Ib asset + 7 pre-clinical leads	receptos Acquired by Celgene July-15 $8b Ph III, Ph II and GPCR platform	Ablynx April-16 with Boehringer €8m payment for Ph1 GPCR nanobody (€125m milestones & royalties)

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Management and Board in place to deliver strategy

Sam Cobb: Founding CEO and Director

Extensive experience in raising equity, contract and grant funding

15 years of commercialisation and management experience

Dr Paul MacLeman: Chairman

Managing Director of a ASX listed IDT Australia Ltd

Founded biologics companies, experienced ASX listed executive

Dr Robert Peach

Founder and CSO of Receptos Inc, acquired by Celgene Corporation in 2015 for US$7.8bn

Deep experience in research and drug development

Dr John Chiplin: Independent Director

CEO of investment Company NewStar Ventures

Managing Director of acquired antibody company Arana Therapeutics

Liddy McCall & Dr James Williams: Yuuwa Capital Directors

Founders and investment Directors of Yuuwa Capital

Founders of iCeutica Inc (acquired 2011) and Dimerix Limited

Directors of several Australian biotech and Agritech companies

Multiple FDA, CE Mark and TGA approvals

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Scientific Advisory Board

Internationally recognised with proven track record of drug development

David McGibney: pre-clinical and clinical advisor

20 years with Pfizer, including Head of European R&D

Ex Pfizer Ltd board member

Developed Viagra, and 10+ blockbuster drugs

Brian Richardson: drug discovery and development expert

Ex-Sandoz and Novartis (40+ years), including Head of Pre-clinical Research

Over 60 original peer reviewed research papers

John Westwick: pulmonary drug discovery and development

Over 14 years experience at Novartis, head of respiratory drug discovery

Five product launches and 13 positive proof of concepts in respiratory, including a number of antibodies which are now in phase III.

Dr Mick Foley, AdAlta CSO

Expert in phage display

NIH, NHMRC, ARC, Gates funding and over 70 scientific publications

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AdAlta investment summary

- Powerful proprietary technology platform to develop a pipeline of i-bodies for the treatment of a wide range of human diseases
- Initial focus on treating Idiopathic Pulmonary Fibrosis and other fibrotic diseases - high unmet clinical need
- Advanced lead candidate with significant pre-clinical validation of AD-114 demonstrating anti-fibrotic and anti-inflammatory effects
- Early commercialisation opportunity
- Experienced management and Board to drive AD-114 development and secure technology platform partnerships and product licensing deals
- IPO August 2016 raised $10M to meet major milestones: clinical trials of AD-114 in lung fibrosis and development of i-body pipeline