



# AdAlta

next generation protein therapeutics

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# MESSAGE FROM THE CEO

AdAlta has had a solid year of execution in 2017, as we tick the various boxes required to take AD-114 into the clinic.

Key highlights for the year have included:

- ✓ The US Food and Drug Administration granting AdAlta's lead drug development program, AD-114, orphan drug status;
- ✓ AD-114 demonstrating application as a broad anti-fibrotic therapy in the following areas: lung, eye, kidney, liver and skin;
- ✓ The safe dosing of non-human primates with AD-114 in a number of toxicology studies;
- ✓ Granting of the key patent for AD-114 in Australia with international applications pending; and
- ✓ Continued pipeline development of potential drug candidates using AdAlta's i-body platform.

AdAlta's goal is to expedite AD-114 into the clinic. AD-114 has demonstrated anti-fibrotic activity, leading to potential clinical applications in fibrotic diseases, notably idiopathic pulmonary fibrosis (IPF), for which current therapies have limited efficacy and there is a high-unmet medical need.

The initiation of human trials using AD-114 trials requires, among other things, a package of data demonstrating safety and tolerability in non-human primates across several routes of administration and doses.

We have now completed three non-human primate studies, demonstrating the safety of AD-114 including:

- single dose, study of the plasma half-life;
- ascending dose study; and
- ascending, repeat dose study for a period of seven days.

Our last hurdle prior to entering the clinic is a four-week safety study in non-human primates across a range of doses. We expect completion of this study in the first half of 2018.

Beyond pre-clinical data, AdAlta is putting together a package of information critical for pharmaceutical partnering. One key piece of this package was the granting of orphan drug status for AD-114 by the US Food & Drug Administration (FDA) earlier this year. Orphan drug status allows for R&D tax credits, new drug application fee waivers and a seven-year period of market exclusivity from the US FDA following approval. In addition, the Australian patent has

been granted for AD-114. A commercial agreement has also been put in place with XL-protein GmbH, granting exclusive rights to the PASylation® technology, which extends the activity of AD-114 in the human body.

On behalf of the entire AdAlta team, I would like to wish all shareholders a Merry Christmas and a happy new year. We look forward to achieving a number of value-creating milestones throughout 2018, keeping you up to date with our progress along the way.

All the best for 2018,

**Sam Cobb**

CEO and Managing Director



## AD-114: pieces of puzzle coming together



# WHAT IS AN I-BODY?

AdAlta is pioneering a novel next generation antibody platform technology called the 'i-body'.

The i-body is built on the scaffold of a human protein, which mimics the shape of an antibody from the shark. The long loop of the i-body gives it an advantage over typical and existing antibody therapies, enabling it to access the deep grooves and bind to a diverse range of therapeutically-relevant targets.

We have a library of over 20 billion of these unique human i-body compounds, and we're in the process of exploring their therapeutic potential. We are utilising the power of our i-body technology to create a pipeline of new drugs, with an initial focus on treating fibrotic diseases.

## What is an i-body?

1



Shark antibody binding domain with unique long loop.

2



A human protein that is the same shape as the shark antibody is the backbone or scaffold protein of the i-body.

Two long loops called "CDR" regions are engineered onto the human protein. These enable tight binding to the drug target and have a therapeutic effect.

3

Each unique i-body has different binding loops or "CDR" regions. The i-body library has 20 billion unique i-bodies.



 **AdAlta's i-body,**  
next generation protein therapeutics

Is the combination of a human protein that mimics the shape of the shark antibody with unique long loop binding sites.

# AD-114, ONE STEP CLOSER TO TREATING IPF

Idiopathic pulmonary fibrosis (IPF) is a rare and serious fibrotic lung condition that causes persistent and progressive scarring of the tiny air sacs (alveoli) in the lungs, with symptoms including shortness of breath and coughing.

The Lung Foundation Australia estimates that there are around 2,300 new cases diagnosed in Australia every year. The prognosis of IPF is very poor, with a median survival of only three to five years following diagnosis.

IPF and fibrotic diseases in general, have a high unmet patient need and are extremely difficult to treat. With just two IPF drugs on the market, and the prognosis of IPF being very poor, there is a great need for new therapies in this space.

AD-114 differs from existing treatment options and others currently in clinical development due to its unique mode of action that targets the chemokine receptor CXCR4. The target CXCR4

is expressed at low levels or absent in healthy tissue and is increased and at high levels in tissues affected by a number of disease states, including fibrosis. AD-114 is the only anti-CXCR4 drug candidate being developed for the treatment of fibrosis. AD-114 has demonstrated both anti-inflammatory and anti-fibrotic activity, two elements critical to the success of an IPF therapy.

World-leading lung disease researcher Professor Cory Hogaboam, from Cedars Sinai Medical Centre, has described our data to date and his own experience with AD-114 as "impressive" and providing a "compelling case for treating IPF".

"Quite simply, I am very impressed with the specificity of AdAlta's anti-CXCR4 i-bodies in these assays.

We had previously used CXCR4 antagonist Mozobil/AMD3100 and Pirfenidone, and saw little effect with these drugs on human IPF fibroblasts.

In contrast, the AdAlta CXCR4 i-bodies were able to inhibit the activation of fibroblasts from various patients with IPF.

Equally of note, the AdAlta i-bodies to CXCR4 appear to hit the sweet spot for a potential therapy for IPF, inhibiting fibroblast activation of IPF fibroblasts but importantly not normal fibroblasts unlike the existing drug Nintedanib which effects the migration of all fibroblasts regardless of source."

**Professor Cory Hogaboam,**  
Cedars Sinai Medical Centre

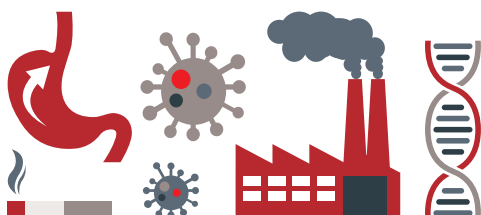
## IPF incidence



of sufferers die within 2 to 3 years following diagnosis

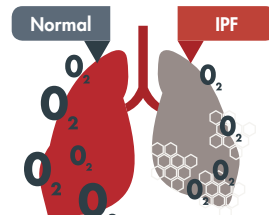


## Causes



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

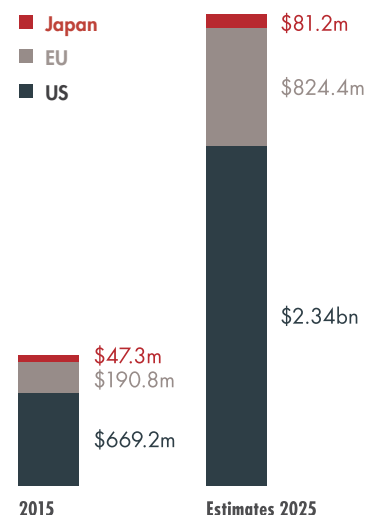


Nintedanib



Boehringer Ingelheim

## IPF Therapy Sales (US\$)



Source: GlobalData IPF Forecast 2016

# GRANTS FURTHER SUPPORT ADALTA'S RESEARCH



## AdAlta awarded SIEF funding

On July 24 2017, AdAlta announced that a \$427,000 Science and Industry Endowment Fund (SIEF) Business Fellowship had been awarded to support work to screen our i-body library to identify and develop new i-body candidates against difficult to access drug targets. The SIEF grant was awarded to Dr Chris Hosking, who has particular expertise with antibody phage display. The funding enables expansion of the i-body pipeline and is expected to generate considerable new intellectual property and commercial opportunities for AdAlta.



## University of Sydney awarded NHMRC grant

On 7 December 2017, Carol Pollock at the University of Sydney was awarded a four year NHMRC grant of \$768,000 to support the evaluation of AD-114 for the treatment of Chronic Kidney Disease. This work will demonstrate the additional clinical application of AD-114 for the treatment of kidney fibrosis (CKD) using a different mechanism of action to currently-approved therapies. CKD currently affects an estimated 1.7million Australians.

## 60 days in report from COO, Dallas Hartman

Dallas Hartman joined the AdAlta team early October, as Chief Operating Officer, making quick work of getting up to speed and commenting "he has never had such short lunches". He is looking forward to the long term impact this will have on his waist line. Dallas is focused on the manufacturing of AD-114 to ensure materials are available for the final non-human primate study as well as the initiation of AdAlta's first clinical study in 2018.



### See Dallas' bio here:

<http://adalta.com.au/about-us/management>

## Annual Report and Annual General Meeting

AdAlta's 2017 Annual Report was released 7th September 2017 and can be accessed at [www.adalta.com.au](http://www.adalta.com.au)

We thank those shareholders who were able to attend AdAlta's Annual General Meeting on 14 November. At the meeting, CEO, Sam Cobb explored the key activities completed throughout the year and looked ahead to 2018. A copy of Sam's presentation can be accessed via the following [link](#).

All resolutions were passed by shareholders at the meeting. To view a copy of the results, please visit [link](#).

## Latest Analyst Reports

**Bioshares:** Sam Cobb CEO spoke at the Bioshares Investment Summit in July 2017, as part of the "Insights into Fibrosis Drug Development" session.

**Patersons:** The research report released by Patersons Securities Limited follows the significant drug development milestones achieved as AD-114 by AD-114 progresses towards the clinic for the treatment of Idiopathic Pulmonary Fibrosis.

These reports along with additional analyst commentary can be found at <http://adalta.com.au/investors/analyst-reports/>.



# INDUSTRY AND INVESTOR EVENTS

Our lead candidate AD-114 and our i-body platform continue to attract interest from a range of parties both domestically and offshore.



**Lung** – in August, CEO Sam Cobb spoke at the IPF Summit in Boston (USA) on novel therapeutic approaches to treating IPF and CSO Mick Foley presented a poster on AD-114 data. AdAlta was the only Australian company invited to speak at the IPF Summit, among a number of internationally recognised pharma and biotech companies.

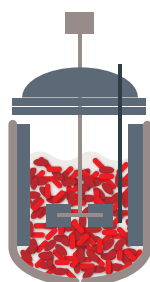


**Eye** – in May, CSO Mick Foley and our collaborator at the University of Melbourne, Professor Erica Fletcher attended and presented at the annual Association for Research in Vision & Ophthalmology (ARVO) meeting in Baltimore (USA) the recent anti-fibrotic data of AD-114 for the treatment of the eye disease Age Related Macular Degeneration (AMD).



**Kidney** – in October and November, a number of poster presentations were made by Professor Carol Pollock of the University of Sydney and her team both in Australia and the USA at the Australia NZ Society of Nephrology's and the American Society of Nephrology's annual meetings.

**Fibrosis** – in November, CSO Mick Foley presented to international pharma and biotech companies at the Anti-Fibrotic Drug Development Summit in Boston (USA) about the broad anti-fibrotic application of AD-114.



**Protein Expression** – contract manufacturer Lonza presented i-body expression data in yeast at the 9th Conference on Recombinant Protein Production in Dubrovnik, Croatia, April 2017.

## Investors

AdAlta has been busy updating investors and potential investors on our progress towards the clinic, with recent investor presentations including the Biotech Showcase 2017, Bioshares 2017, Ausbiotech Broker meets Biotech and Biotech Invest meetings in San Francisco, Brisbane, Adelaide, Perth and Melbourne respectively.

In February 2017, AdAlta's inaugural fibrosis investment R&D briefing saw key opinion leaders, investors, analysts and clinicians discuss fibrosis drug development and the opportunity. Our second symposium in February 2018 will focus on "drugging the undruggable targets", and opportunities and advantages the AdAlta i-body may have.

## Upcoming presentations

San Francisco, USA: 8–10th January 2018, Biotech Showcase Investor presentation and various investor and partnering meetings.

Melbourne: 2nd February 2018, AdAlta Investor/Analyst Briefing. Please contact AdAlta if you are interested in attending [enquiries@adalta.com.au](mailto:enquiries@adalta.com.au).

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