



AdAlta  
next generation protein therapeutics

# Shareholder Update

JUNE  
2018

## MESSAGE FROM THE CEO

We're just six months in and 2018 has already been a very exciting year for AdAlta. In April we announced the move to our improved lead candidate, AD-214. The new Fc-fusion version of our lead i-body drug has significantly enhanced its propensity to bind to its target, CXCR4, and by incorporating an Fc fragment, we've been able to extensively lengthen the half life. These improvements build on our achievements with AD-114 and see us working with a superior candidate for both patients and potential partners. You can learn more about the detailed structure and characteristics of AD-214 overleaf.

We have further progressed our AD-214 development plans with the recent announcement of Selexis and KBI Biopharma as the cell line development and manufacturing partners for AD-214, respectively. Both Selexis and KBI Biopharma have considerable experience and expertise in the development of manufacturing processes for biological compounds, together having developed four Fc-fusions. We look forward to initiating the development process for AD-214, led by our Chief Operating Officer Dallas Hartman, who has over 20 years' experience in product development.

We are leveraging the pre-clinical work completed to date in the development of AD-214. We have already demonstrated that the i-body is safe in a series of non-human primate studies, allowing a somewhat expedited preclinical schedule for AD-214. It is our intention to progress the development of AD-214 through preclinical studies in 2018 in order to initiate the pivotal four-week safety study in 2019 before moving into a first-in-man clinical trial.

AD-214 is expected to be more attractive to pharma partners due to its increased binding and longer half-life, with these characteristics also allowing AD-214 to target a wider range of fibrotic diseases beyond Idiopathic Pulmonary Fibrosis (IPF). The improved lead candidate will also have increased appeal for IPF patients due the potential for less frequent dosing.

As we pivot to AD-214, AdAlta will retain its FDA orphan drug designation and strong patent position as these certifications are based on the active moiety of the drug, the i-body at the front end, which has not been altered in the generation of AD-214.

We have been heartened by the response we have received to the announcement of AD-214, including two recent updates from Bioshares, updated research coverage by Patersons and further articles in Rare Disease Report, Check Orphan and Pulmonary Fibrosis News. The i-body has also recently featured in scientific publications, with preclinical data published in *Scientific Reports* a journal from the publisher of *Nature*, and an overview of the i-body as a next-generation antibody in *Australasian Biotechnology*.

It was great to meet with many shareholders during the briefing sessions held in April in major capital cities. We look forward to keeping you updated as we continue our preclinical and clinical development of AD-214, a lead candidate we believe to have both improved therapeutic and commercial potential. The Company anticipates the need to secure further sources of funding to complete this development and further expand the pipeline.

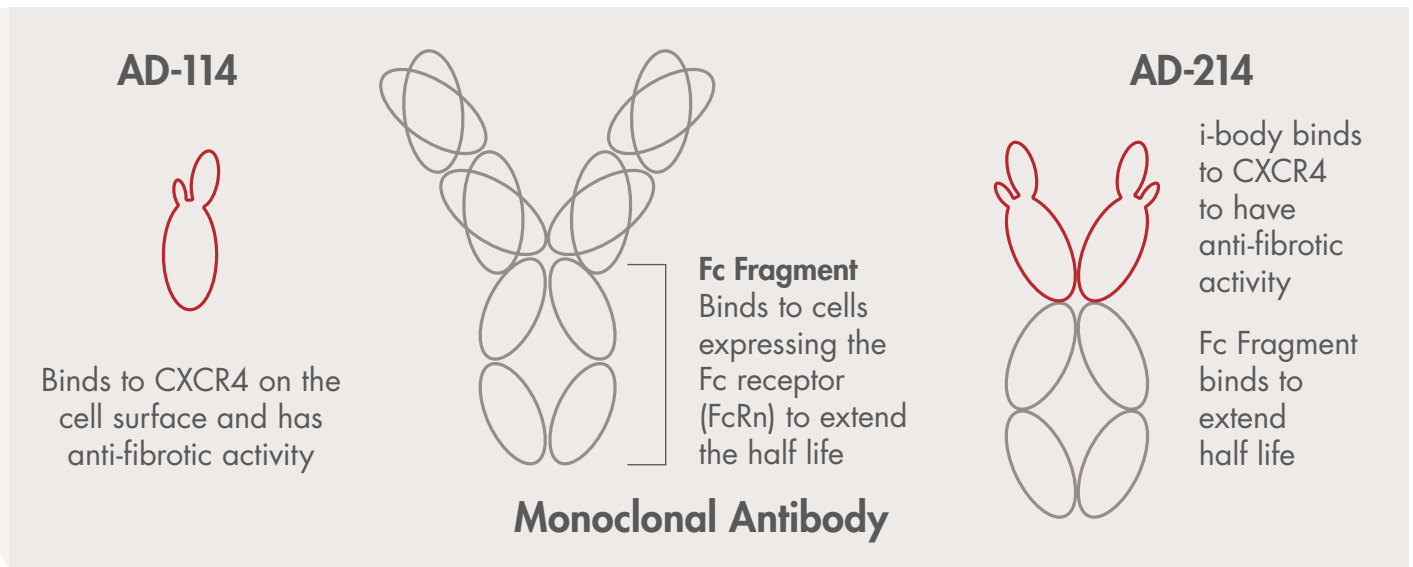




**Sam Cobb**  
CEO and  
Managing Director

# AD-214: AN IMPROVED DRUG FOR TREATING IPF

AdAlta recently announced improvements to its lead therapeutic program, introducing a second-generation lead candidate called AD-214. The improved lead candidate is an Fc-fusion protein containing two AD-114 i-body molecules at the front end that bind with

high affinity to the human target CXCR4, to treat Idiopathic Pulmonary Fibrosis (IPF). At the back end of AD-214 is the Fc fragment, or tail region, of a traditional monoclonal antibody that extends the i-body's half-life, the duration of time which the i-body will stay in the body.



	<b>AD-114</b> 	<b>AD-214</b> 
<b>High affinity binding to CXCR4</b>	✓	✓✓✓
<b>Specificity to CXCR4</b>	✓	✓
<b>Unique pharmacology compared to other CXCR4 antagonists</b>	✓ No stem cell mobilisation	✓ No stem cell mobilisation
<b>Half-life</b>	24hrs in non human primates	Significantly improved from AD-114 (Approved Fc-fusions half life in humans range from 4-25 days)
<b>Dosing</b>	Daily, subcutaneously	Less frequent IV or subcutaneous dosing required due to more potent and improved half life
<b>Partnering</b>	Suited to IPF	Suited to a range of fibrotic diseases, including IPF, NASH & wet AMD

AdAlta will proceed to the clinic with AD-214, which retains the unique therapeutic benefits of AD-114 while delivering enhanced activity and significantly improved half-life. AdAlta will leverage all efforts to date; the orphan drug designation obtained from the FDA for AD-114 can also be applied to the development of AD-214, making AdAlta eligible for drug application fee waivers and fast track to market.

Improved binding due to the presence of two i-body molecules, as well as increased half-life provides the potential for less frequent dosing and means AD-214 can be applied to a broader range of fibrotic diseases. As a result, AD-214 is expected to be more attractive to patients and potential pharma partners.

## An Update from CSO Mick Foley

Together with his team at La Trobe University, Chief Scientific Officer, Associate Professor Mick Foley has been working to expand the AdAlta pipeline through the initiation and further development of several projects panning the i-body library against targets deemed difficult to access with current technologies. Mick and his team have also been improving the methodological framework that is used to complete panning projects, identifying opportunities to streamline the process and applying these improvements to the current projects in the pipeline.

Mick has also had the opportunity to gain further recognition for the i-body as a next generation antibody through contribution to a recent article in Science magazine and publications as below. Mick will present at international conference Discovery on Target in Boston later this year.

## 9 Months In: COO Dallas Hartman

AdAlta Chief Operating Officer Dr Dallas Hartman is now focused on ensuring AD-214 makes swift progress to the clinic with the recent announcement of our cell line development and manufacturing partners Selexis and KBI Biopharma. Having recently returned from the USA, Dallas is looking forward to working with Selexis and KBI to deliver results. KBI has considerable expertise and experience, having previously developed more than four Fc-fusion products together. Dallas has over 20 years industry experience manufacturing and characterising Fc-fusion products at both CSL and Nexvet.

## 12 months in: SIEF Fellow Chris Hosking

Dr Chris Hosking is approaching the 12-month mark in his Science and Industry Endowment Fund (SIEF) Business Fellowship, awarded July 2017. Chris has been undertaking several projects that involve screening AdAlta's i-body library to identify unique binders to targets previously proven difficult to access. Chris is currently using his expertise with antibody phage display to pan for binders to an ion channel and a GPCR, both classes of drug targets whose commercial value was highlighted during the Investor Symposium in February this year.

# LATEST PUBLICATIONS



**Scientific Reports:** Data was published demonstrating anti-fibrotic effects of the AdAlta lead candidate. AdAlta's CXCR4 i-body showed superior activity in samples from Idiopathic Pulmonary Fibrosis (IPF) patients and no effects in samples from healthy donors.



**Australasian Biotechnology:** an overview of the i-body platform as a next-generation antibody and its ability to access difficult targets was included in the April Issue. AdAlta CEO, Sam Cobb, was also profiled as a leading woman in Biotech.



**Journal of Biological Chemistry:** the seminal paper describing AD-114 was selected to appear in a special issue of JBC highlighting exciting advances coming out of Australia and New Zealand.

# KEEPING UP TO DATE

## Upcoming presentations

CEO Sam Cobb will be presenting at the 121 Tech Investment event to be held in Hong Kong, June 13 and 14.

CEO Sam Cobb will be presenting at the Gold Coast Investment Showcase hosted by Morgans and Stockhead to be held on the Gold Coast, June 20-21. Please contact us via [enquiries@adalta.com.au](mailto:enquiries@adalta.com.au) if you are interested in attending this event.

AdAlta Chief Scientific Officer Mick Foley will be presenting in the GPCR targets session of Discovery on Target to be held in Boston, September 25-28, discussing the advantages of the i-body platform to an international biotech and pharma audience.

## Latest analyst reports

**Bioshares:** The announcement of AD-214 was comprehensively covered in Bioshares Editions 740 and 741.

**Patersons:** the research note that was published in April following the announcement of AD-214 covers the

significantly increased therapeutic and commercial potential of the second-generation lead candidate and suggests the pivot to AD-214 should be positive for AdAlta in the long run.

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

## Industry and investor events

**Annual investor and analyst briefing day:** AdAlta hosted its second special investor and analyst briefing in Melbourne in February 2018. Along with AdAlta representatives, the presenters came from both financial and drug development backgrounds, while attendees were predominantly analysts and shareholders. Topics included next generation antibodies and their role in drug discovery, with particular application to ion channels and GPCRs. Material presented during the investor briefing and videos from the day can be viewed on the AdAlta website, via this link: <http://adalta.com.au/commercial-potential-targeting-complex-proteins-gpcrs-ion-channels>.

## Shareholder briefings:

A round of shareholder update sessions were held in Melbourne, Sydney, Brisbane and Perth in April 2018. Shareholders had the opportunity to speak with CEO Sam Cobb and meet COO Dr Dallas Hartman. The focus was providing shareholders with an update on the progress of AD-214.

## Biotech Showcase and BIO-Europe:

CEO Sam Cobb presented at the Biotech Showcase in San Francisco in January 2018 and had several meetings with potential pharma partners at the BIO-Europe meeting in Amsterdam in March 2018.

## BioMelbourne Network Connecting Women Lunch:

CEO Sam Cobb was recently part of the 'On the Couch' segment at the 10th year anniversary BioMelbourne Network's "Connecting Women" Lunch, speaking in front of 600 biotech, medtech and pharma professionals. Sam discussed both her journey and AdAlta's over the last 10 years.

## Key Milestones

2018		2019				2020	
Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
Manufacturing							
				Toxicology studies			
Publication of data						Phase I	
Development of i-body pipeline							
BD and partnerships							

## Upcoming news and milestones

AdAlta has recently announced the appointment of Selexis and KBI Biopharma as the manufacturing partner for AD-214. The remainder of 2018 will be focused on the development of a manufacturing process for AD-214. These materials will then be used for the non-human primate four week toxicology study in the second half of 2019 and for the first-in-man clinical trials in the first half of 2020. AdAlta will continue to expand its pipeline of i-bodies and engage in further discussion with potential partners for AD-214 and the platform.

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