



AdAlta  
next generation protein therapeutics

# Shareholder Update

DEC  
2018

## MESSAGE FROM THE CEO

AdAlta will celebrate 2018 as a year of advancement, where we made significant improvements to our lead i-body program that created a more commercially attractive product. We're developing our lead i-body, AD-214, as a potential treatment for fibrotic conditions, with a focus on the lung disease Idiopathic Pulmonary Fibrosis (IPF).

### Highlights for the year have included:

- **Publication of key lung fibrosis data in Scientific Reports, from the publisher of Nature;**
- **Announcement of AD-214, our superior lead candidate with improved benefits for patients and potential partners including an increase in both potency and half-life;**
- **Appointment of key partners Selexis and KBI Biopharma for the manufacture of AD-214, with the successful completion of cell line development by Selexis demonstrating commercially viable yields; and**
- **Completion of an AU\$4.73m capital raise, with support from institutional and sophisticated investors as well as existing shareholders via a private placement and share purchase plan.**

As outlined in the June 2018 Shareholder Update, AdAlta has progressed with an improved version of its CXCR4 i-body, now called AD-214. The i-body has now been formatted as an Fc-fusion protein that offers increased potency and will stay in the patient's body for longer, due to a longer half-life. This modification was well received by potential pharma partners during discussions at various partnering meetings including those which we recently had at BIO-Europe in November 2018.

Re-formatting of the i-body as an Fc-fusion required a new manufacturing process, and the appointment of Selexis and KBI Biopharma was announced in June. Our COO Dallas Hartman has been keeping a close eye on the process and we have been impressed with the depth of knowledge and expertise both companies have demonstrated. An interview with Dallas on page two includes more information about the manufacturing process and the progress to date.

AdAlta would like to thank shareholders for their support during the capital raise undertaken in July and August, which saw the placement of fully paid ordinary shares to sophisticated and institutional investors as well a Share Placement Plan for existing shareholders, for a combined total raise of \$4.73m. These funds will be used for manufacturing and pre-clinical studies of AD-214 as well as internal research and the development of new i-bodies.

AdAlta has had a busy end of the year attending BIO-Europe and Investival investment and partnering meetings, which were valuable opportunities to update potential pharma partners on the progress of AD-214. It was also great to meet with many shareholders during the briefing sessions that were held in capital cities around Australia in October.

AdAlta was excited to receive the MedTech and Pharma award in the Australian Technologies Competition in November. This award recognises the global potential of our i-body platform and its attractiveness to pharma companies as a drug discovery tool.

We look forward to completing the preclinical development of AD-214 through 2019 and keeping you up to date with our progress towards the clinic in 2020.

On behalf of the AdAlta team, I would like to wish all shareholders, friends and family of AdAlta a merry Christmas and a happy new year.



**Sam Cobb**  
CEO and  
Managing Director

# MANUFACTURING AD-214: THE PROCESS AND THE PROGRESS

Chief Operating Officer Dallas Hartman has been overseeing the development of a manufacturing process for AdAlta's lead candidate, AD-214, with partners Selexis and KBI Biopharma. Here Dallas describes the process of manufacturing AD-214 and the progress made during 2018.

## **AD-214 is structured as an Fc-fusion protein, what does this mean?**

AD-214 is an Fc-Fusion protein that contains two i-body molecules at the front end, that bind with high affinity to the human target, CXCR4. These have the anti-fibrotic and anti-inflammatory activity. At the back end of AD-214 is the Fc Fragment or tail region of a traditional monoclonal antibody that will extend the half-life or duration of time in which the i-body will stay in the body.

## **Is it difficult to manufacture Fc-fusion proteins?**

No, there are currently 11 marketed drugs that are Fc-fusion proteins. Standard processes have been established for the manufacture of Fc-fusion proteins.

## **What is involved in developing the manufacturing process for AD-214?**

Cell line development is the first step in the manufacturing process for biologics like AD-214. The gene of AD-214 is introduced into mammalian cells and grown under conditions that select only cells which have incorporated the DNA. The cell line expressing the highest level of AD-214 protein is identified and grown under different culture conditions to optimise expression levels for subsequent purification. The purification process removes unwanted contaminants from AD-214 in a manner that delivers optimum product yields. Finally, AD-214 is transferred into a formulation solution that is both stable and appropriate for human administration.

## **Where is AdAlta currently up to in developing the process?**

Selexis has completed cell line development, and initial cell culture ferments produced by KBI indicated titres above 1 gram per litre, that have already been improved upon. KBI is working toward a further increased titre by optimising culturing conditions, a process that has commenced and is expected to be completed in March 2019. Initial purification development at KBI has begun with encouraging results. *(See milestones on page four for further details.)*



Bill Van Nierop

## IPF PATIENT STORIES: BILL VAN NIEROP

Idiopathic Pulmonary Fibrosis, the focus of AdAlta's lead candidate, AD-214, is most noticeably characterised by a shortness of breath and decline in lung function that leaves many patients relying on supplemental oxygen 24 hours a day. IPF patient Bill Van Nierop, from Brisbane, was diagnosed with IPF in 2015 and has a current lung function of only 53%.

During IPF awareness month in September 2018, Bill took his active approach to dealing with IPF to a whole new level, tackling the challenge to paddle 2,200km down the Murray river. Bill's motivation was to raise awareness for pulmonary fibrosis, an often under-appreciated disease in Australia, and to raise much-needed funding to support pulmonary fibrosis research.

Throughout his 42-day journey Bill tackled cold weather, whitecaps and strong headwinds of up to 40km/hr, as well as the fatigue and side effects that come with IPF and current treatments. Bill said "it's really a mental challenge, which I find more tiring", but he persevered to complete the journey and raise over \$90,000 for Lung Foundation Australia. Through the process he also generated over 138 media mentions seen or heard by over 500,000 people including a segment on The Weekend Today Show.

AdAlta is very proud of Bill and what he has accomplished. It was a herculean effort to tackle this challenge while living everyday with IPF and Bill's story is a strong reminder of why we at AdAlta do what we do.

## ADALTA WINS MEDTECH AND PHARMA AWARD

The Australian Technologies Competition is more than just a competition – it's a development program that assesses, mentors, profiles and promotes innovative and emerging technologies with the greatest global potential.

In November, it was announced that AdAlta was the winner of the Medtech and Pharma category.

AdAlta was selected from 199 entrants as a semi-finalist, and invited to attend a workshop in Sydney in July to learn from an expert panel before submitting a comprehensive business plan.

Off the back of its submission, AdAlta was selected as one of 11 finalists. At the Finals Showcase, AdAlta Project Manager Ebony Fietz pitched to an audience of judges and invited investors and advisors. The global potential of AdAlta's technology was recognised through awarding of the MedTech and Pharma award.



*Project Manager Ebony Fietz with Alfredo Martinez-Coll from MTP Connect at the Australian Technologies Competition award presentation*

## INDUSTRY AND INVESTOR EVENTS

**Discovery on Target:** Chief Scientific Officer Mick Foley presented at Discovery on Target held in Boston, USA on Sept 25-28, highlighting the unique ability of the i-body to modulate activation of G-protein coupled receptors (GPCRs).

**Shareholder Briefings:** A series of shareholder information sessions were held in October in Perth, Sydney, Melbourne and Brisbane to provide an update on the manufacturing process for AD-214 currently being completed by Selexis and KBI Biopharma.

**AusBiotech:** CEO Sam Cobb attended the AusBiotech national conference in October 2018 speaking on panels about leadership diversity as well as GPCR drug targets, a focus of AdAlta's i-body technology

**BIO-Europe:** CEO Sam Cobb and Project Manager Ebony Fietz attended BIO-Europe which was held in Copenhagen from November 5-7. The meeting brought together over 2,200 companies, providing AdAlta with the opportunity to meet with potential pharmaceutical and biotechnology partners to discuss both AD-214 and the i-body platform.

**Inv€stival:** CEO Sam Cobb presented at the Biotech and Money Inv€stival Showcase on November 13, held in partnership with the Jefferies London Healthcare Conference.



*CEO Sam Cobb and Project Manager Ebony Fietz meeting with Selexis and KBI representatives at BIO-Europe.*

## Phage Display awarded the Nobel Prize

The two scientists that pioneered phage display, George Smith and Gregory Winter, were awarded the Nobel Prize in Chemistry in 2018 for their work in Phage Display.

Phage Display is the technology that AdAlta uses to screen the i-body library, with our Chief Scientific Officer Mick Foley

being one of the first to introduce the technique in Australia. "Phage display is a powerful technique for the identification of novel antibody drug treatments and in our case, for identifying novel i-body therapeutics" said Mick Foley.



### Fund Manager interviews and Analyst Reports

**PPM Insights:** AdAlta CEO Sam Cobb was interviewed by Hugh MacNally, Chairman and Founder of Private Portfolio Managers (PPM) for the August issue of the PPM Insights publication. Hugh MacNally will also be speaking at the AdAlta Special Investor/Analyst briefing to be held on January 31, 2019. The report is available on the PPM Funds website: <https://www.ppmfunds.com/life-science-inside-four-australian-and-new-zealand-companies-that-are-changing-the-biotech-landscape>

**Morgans:** In November, Morgans Financial initiated research coverage on AdAlta. The initiation research report provides comprehensive coverage of AdAlta's lead candidate, AD-214, and also outlines the early transaction potential in the fibrosis space, particularly for drugs that treat Idiopathic Pulmonary Fibrosis. Morgans initiated coverage with an ADD recommendation and a valuation range of A\$0.42 to A\$1.21, with a target price of A\$0.82 being the midpoint. The report is available on the AdAlta website with other analyst reports: <http://adalta.com.au/investors/analyst-reports>.

### Annual General Meeting

**AdAlta's Annual General Meeting** was held on November 28 with all resolutions being approved by shareholders. The presentation provided at the AGM by CEO Sam Cobb can be viewed here: [http://1ad.live.irmau.com/irm/PDF/1416\\_0/AGMPresentation](http://1ad.live.irmau.com/irm/PDF/1416_0/AGMPresentation)

### Upcoming investor events

**Special Investor/Analyst Briefing:** AdAlta will hold its third Special Investor/Analyst Briefing in Melbourne on January 31, 2019 focusing on the 'Pathway to the Clinic' and bringing together analysts, IPF clinicians and patients as well as drug development experts from AdAlta's Scientific Advisory Board. Any investors that would like to attend are encouraged to email [e.fietz@adalta.com.au](mailto:e.fietz@adalta.com.au).

### Upcoming news and milestones

Several non-human primate studies will be completed in late-2018 and early-2019 providing valuable dosing and safety information that will inform the AD-214 four-week toxicology study to be commenced mid-2019. The completion of these non-human primate studies, in parallel with the development of a manufacturing process for AD-214, will leave AdAlta ready to commence its first-in-man clinical trial in January 2020.

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## Key Milestones

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

Partnering of lead candidate based on other benchmark deals

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