



**AdAlta**  
next generation protein therapeutics

# Shareholder Update

**JUNE  
2019**

## MESSAGE FROM THE CEO

AdAlta has had an exciting start to 2019, culminating in a \$5 million Placement to new and existing institutional and sophisticated investors and an Entitlement Offer to raise up to a further \$2 million. We are very grateful for the support of all new and existing shareholders.

This funding will see the Company through multiple data read-outs and value inflection points, including the phase I human trial in healthy human volunteers of our lead drug candidate, AD-214 as well as the advancement of our business development around potential partners for the i-body platform.

Importantly, this funding will be used to progress AD-214 to a major value inflection point: demonstrating the safety of AdAlta's potential new treatment for Idiopathic Pulmonary Fibrosis (IPF) through a phase I study in humans.

AdAlta has made significant progress in developing a manufacturing process for AD-214 over the last six months, culminating in a successful confirmation run in April. This is an important step in the development of AD-214 and one which demonstrated the full end-to-end manufacturing process. We are now looking ahead to generating the material which will be used for our 4-week toxicology study later this year and for our first in-human clinical trial early next year. These activities are discussed further on page two.

In February, we were also pleased to announce further development of the i-body pipeline through a collaboration with UK-based Excellerate Bioscience. AdAlta will screen the i-body library on a specified target and Excellerate Bioscience will profile the identified leads to assist with the selection of candidates with greatest therapeutic potential. Excellerate Bioscience has significant expertise in evaluating drugs which bind to G Protein-coupled Receptors (GPCRs), a class of difficult drug targets well suited to the unique structure of AdAlta's i-body. More information regarding the collaboration can be found on page three.

AdAlta has been featured regularly in the media this year. I have been honoured to add my voice to the ongoing conversation around bringing more women into leadership positions. I was also able to share my story with Life Science Leader in an article which including lessons learned during my time as CEO of AdAlta. Dr Boreham's Crucible covered our Investor Symposium held in January in his characteristically witty manner, and we were newly featured in publications such as nabtrade and the Switzer report.

The second half of 2019 will be very exciting for AdAlta with the delivery of our AD-214 material for completion of the 4-week toxicology study and continued expansion of the i-body pipeline through collaboration. I thank all our shareholders for their continued support and look forward to keeping you updated on our progress throughout the year.



**Sam Cobb**  
CEO and  
Managing Director

# AD-214: PROGRESS TO THE CLINIC

## Manufacturing Update

In 2019 one of AdAlta's key achievements has been the generation of a manufacturing process for our lead i-body candidate, AD-214. The ability to develop a robust manufacturing process that meets regulatory requirements is necessary to commence the first-in-human clinical trial as the drug substance that will be administered to patients needs to be manufactured to align with the principles of Good Manufacturing Practice (GMP).

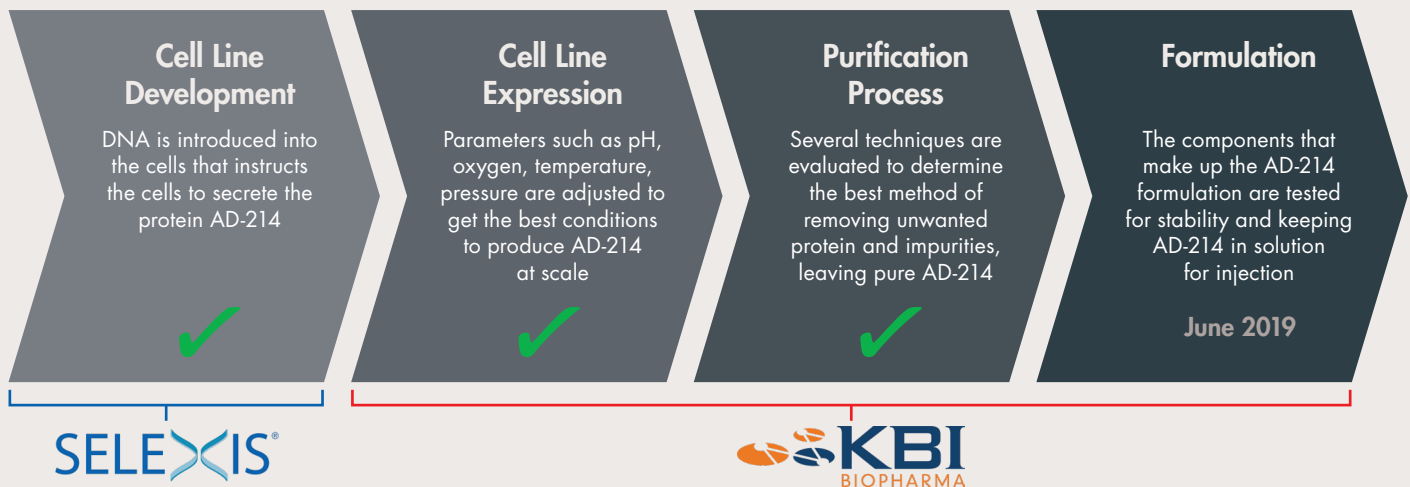
AdAlta has worked with Selexis to develop a cell line that expresses AD-214 and KBI Biopharma to optimise the processes that expresses and purifies AD-214. This has involved introducing the DNA for AD-214 into a mammalian cell line and optimising the parameters to instruct the cells to produce the highest amount of AD-214 protein. A process has then been developed to remove the unwanted impurities and proteins, testing several techniques to determine the best method. The completion of these development activities culminated in the successful execution of what is termed a confirmation run in April 2019. The confirmation run was the first time that the cell expression (upstream) and purification

(downstream) processes were combined at scale. This activity proved that AD-214 could be successfully produced using the established process and at the scale required.

The final step in the development of our manufacturing process is to confirm the formulation for AD-214. This will confirm the chemical components that are combined with AD-214 to form the solution that will be administered to patients. It is expected that this activity will be completed in June 2019 as outlined below.

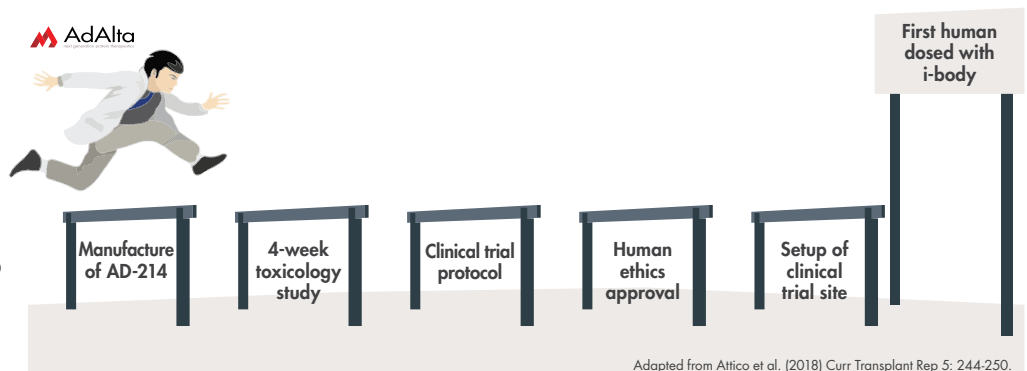
AdAlta will subsequently have a method for generating AD-214 that will supply both the 4-week toxicology study (discussed further below) as well as the first-in-human clinical trial, for which material will adhere to Good Manufacturing Process (GMP) standards as required by regulatory agencies.

Our Chief Operating Officer, Dallas Hartman has managed the development of the manufacturing process for AD-214, working with both Selexis and KBI Biopharma. Dallas provided an overview of developing a manufacturing process during AdAlta's Investor Briefing in January ([click here to watch](#)) as well as an update on the progress of AD-214 ([click here to watch](#)) stating that "we are still on track from a timeline perspective and a budgetary perspective".



## THE PATHWAY TO A HUMAN CLINICAL TRIAL

Clinical dosing of the first human in our upcoming phase 1 trial will be a significant milestone for not only AdAlta's lead candidate AD-214 but also for the i-body platform. This will be the first time the i-body has been administered to humans. A summary of the hurdles to be cleared during 2019 prior to the commencement of a human phase I clinical trial in early 2020 are outlined here.



# EXPANDING THE I-BODY PIPELINE

## Excellerate Bioscience Collaboration

AdAlta announced in February 2019 a collaboration with UK-based research organisation Excellerate Bioscience.

### Who is Excellerate Bioscience?

Excellerate Bioscience is a research organisation that was founded by leaders in the fields of molecular and cellular pharmacology. Excellerate Bioscience aims to use its expertise in pharmacology of G protein-coupled receptors (GPCRs) to improve and streamline the drug discovery process. In simpler terms, the organisation has a wealth of knowledge around the different relationships that drugs can have with their cell targets and how this relationship influences the development potential of the drug. Gathering this information at an early stage can help to identify better future drugs quicker.

### Why collaborate with Excellerate Bioscience?

AdAlta has demonstrated that the structure of the i-body is advantageous in binding to difficult-to-reach drug targets. One such class of these are GPCRs which have a current market size of US\$82 billion, although 80% of GPCRs remain unexploited by therapeutics. AdAlta's interest in GPCRs is an excellent fit with the expertise of Excellerate Bioscience, whose Chief Scientific Officer, Steven Charlton is "one of the world's foremost experts in GPCR pharmacology" according to AdAlta Scientific Advisory Board member, John Westwick.

### How will the collaboration work?

AdAlta and Excellerate Bioscience have together chosen a GPCR target of commercial interest and AdAlta will subsequently screen its i-body library to identify i-bodies that bind to the target. The profiles of the i-body binders identified through this collaboration will be characterised by Excellerate Bioscience. The profiles of the novel i-bodies, along with Excellerate Bioscience's considerable expertise in GPCR pharmacology, will enable the selection of binders with the greatest therapeutic potential at an early stage of development.

## SIEF Fellowship Review: Dr Chris Hosking



AdAlta post-doctoral scientist Dr Chris Hosking is nearing the conclusion of his Science and Industry

Endowment Fund (SIEF) Business Fellowship that was awarded in July 2017. We caught up with Chris to hear how the fellowship has supported his work with AdAlta.

### What was the outcome of your SIEF Business Fellowship?

My project has entailed screening the i-body library against difficult drug targets. This has included two classes of receptors: a G-protein coupled receptor (GPCR) and an ion channel (these are further explored in the i-body fact sheet here). These types of targets have traditionally been very difficult to identify new and specific drugs for. Following the identification of lead i-bodies to these new drug targets, we then generate i-body materials for further evaluation.

### How do you believe the outcomes of your fellowship will influence AdAlta's activities?

Through my project I have completed valuable optimisation of AdAlta's screening, lead generation and optimisation processes. The knowledge from my project can be applied to other projects that will grow AdAlta's pipeline of i-body molecules against classes of drug targets that have previously proven difficult to find effective therapeutics for.

### What opportunities have you been given through the SIEF Business Fellowship?

It has been beneficial to come together with other fellows and update the progress of projects and see what other work is being achieved. It has also been great to gain insights and skills on how to pitch projects to other people both within and outside of my particular area of research and even to people outside of science.

### AdAlta in the media

**Life Science Leader:** A profile of CEO Sam Cobb was included in the April issue of the US publication documenting the “rollercoaster ride” of her 11-year tenure as CEO.

**Stockhead:** CEO Sam Cobb was featured by Stockhead as part of their “Women in Leadership” series in February, sharing her views on how far we’ve come and how far we have to go in seeing females in leadership positions.

**Nabtrade:** AdAlta was featured by nabtrade in March as one of “Four biotechs that could give your portfolio a dose of growth”.

**Dr Boreham’s Crucible:** AdAlta was featured in Dr Boreham’s Crucible in February providing a re-cap on our lead program and Investor Symposium.

**Bioshares:** AdAlta’s \$5 million placement and achievement of manufacturing milestones was covered in Bioshares Edition 793, released in May.

### Upcoming Investor Events

**Gold Coast Investment Showcase:** CEO Sam Cobb will be presenting at the Gold Coast Investment Showcase to be held on June 25th and 26th.

**Bioshares:** AdAlta CEO Sam Cobb will be speaking at the Bioshares Biotech Summit to be held in Queenstown, NZ on July 26th and 27th.

**Bio Connections Australia:** CEO Sam Cobb will present at Bio Connections Australia, an event designed to foster the growth of early phase clinical research in Australia to be held on August 19th and 20th in Melbourne.

### AD-214 Milestones

Key value inflection points for AdAlta’s lead i-body AD-214 for the treatment of Idiopathic Pulmonary Fibrosis (IPF).

2019				2020			
Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Manufacturing							
Dosing and PK studies		Toxicology studies					
				Phase I Human Clinical Trials			

### Building out the Pipeline

AdAlta is working on expanding its i-body pipeline with internal programs as well as targeting at least 1–2 external partnership agreements with upfront payments (and future milestones and royalties) within the next 12 months.

	Target	Class of Target	Discovery	Preclinical	Manufacturing	IND enabling studies	Phase I
AD-214	Idiopathic Pulmonary Fibrosis	CXCR4	GPCR	▶			
	Other fibrotic indications	CXCR4	GPCR	▶			
Shark antibody discovery	MCP-1	Novel ligand pocket	▶				
i-body discovery	TRPV4	Ion Channel	▶				
AdAlta Excellerate Bioscience	Target X	GPCR	▶				
External Partnerships	Target X	TBC	▶				

**Discovery on Target:** CEO Sam Cobb has been invited to speak at Discovery on Target to be held in Boston, USA on September 18–19.

**Australian Microcap Investment Conference:** CEO Sam Cobb will speak at the 10th Annual Australian Microcap Investment Conference being held in Melbourne on 22nd and 23rd October.

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