ASX Announcement

AD-214 manufacturing results ahead of expectations

MELBOURNE Australia, 29th January 2019, AdAlta Limited (ASX: 1AD), the biotechnology company advancing its lead i-body candidate toward clinical development, is pleased to announce improved cell line development results for its lead fibrosis candidate, AD-214.

Results are now above previously reported expression levels, at 3 grams per litre (3g/L), up from the 1g/L reported in October 2018.

Importantly, the improved results mean the Company remains on track with the development of the manufacturing process for AD-214. It is on target to deliver Good Laboratory Practice (GLP) material for its four-week non-human primate toxicology study, which is expected to commence in July 2019 and be completed in second half of 2019. AdAlta is also on track to deliver Good Manufacturing Practice (GMP) material for its Phase 1 human study which is expected to commence in January 2020.

“The improved yield is very much in line with our expectations and means we remain on track with our clinical program. The yield is also within the normal range and is a commercially scalable level,” said AdAlta’s Chief Operating Officer Dallas Hartman.

“Developing a stable cell line remains the key priority and we remain comfortable with the current cell line yields that Selexis has provided. KBI Biopharma will continue to optimise the process for expression and purification yields continue to be sufficient to meet our requirements.”

In June 2018, AdAlta commenced development of the AD-214 cell line with Selexis SA. KBI Biopharma, Inc. was also appointed for the manufacturing process development, analytical development, formulation development, and clinical manufacturing services.

The appointments of Selexis and KBI follow the announcement mid-last year that AdAlta would take forward an improved version of its lead therapeutic program for the treatment of Idiopathic Pulmonary Disease (IPF). This new version AD-214, is expected to deliver significantly improved half-life (duration of time the drug remains in the body), enhanced activity, and be applicable across a broader range of fibrotic disease areas, making it more attractive to patients and pharmaceutical partners.

“Having results that are commercially scalable are important as we continue the development of our lead fibrosis candidate, AD-214. We expect to complete the four-week non-human primate toxicology study for AD-214 in the second half of 2019, which will then lead us into the clinic in early 2020,” said AdAlta’s Chief Executive Officer, Sam Cobb.

Timelines and manufacturing milestones as previously reported are outlined in the presentation accompanying this announcement which will be presented by COO, Dallas Hartman at AdAlta’s investor day this Thursday.

-ENDS-

Notes to Editors

About AdAlta

AdAlta Limited is an Australian based drug development company headquartered in Melbourne. The Company is focused on using its proprietary technology platform to generate i-bodies, a new class of protein therapeutics, with applications as therapeutic drugs to treat disease.

I-bodies are a promising, novel class of drugs that offer a new and more effective approach to treating a wide range of human diseases. They are identified and developed using our proprietary technology platform.

We have pioneered a technology that mimics the shape and stability of a crucial antigen-binding domain, that was discovered initially in sharks and then developed as a human protein. The result is a range of unique compounds, now known as i-bodies, for use in treating serious diseases.

AdAlta is developing its lead i-body candidate, AD-214, for the treatment of idiopathic pulmonary fibrosis (IPF) and other human fibrotic diseases, for which current therapies are sub-optimal and there is a high-unmet medical need.

AD-214 is an Fc-fusion protein that contains two i-body molecules that bind with high affinity to the human target CXCR4. At the back end of AD-214 is the Fc fragment, or tail region, of a traditional monoclonal antibody that will extend the drug's half-life. As AD-214 is made using Fc-fusion technology, it requires an alternate manufacturing process to the original drug, AD-114.

The Company also plans to continue further drug discovery and development directed towards other drug targets and diseases with its i-body technology platform.

Further information can be found at: www.adalta.com.au.

For more information, please contact:

AdAlta Limited
Sam Cobb, CEO
Tel: +61 (0)3 9479 5159
E: s.cobb@adalta.com.au

About KBI Biopharma, Inc.

KBI Biopharma is a biopharmaceutical contract development & manufacturing organization driven to accelerate the development of innovative discoveries into life-changing biological products and expand global access of medicines to patients in need.

From early-stage biotech to academic/non-profit organizations to many of the world's largest pharmaceutical companies, KBI has served 250+ clients globally to accelerate and optimize their drug development programs.

KBI's extensive track record of successful programs is a result of its unique approach: applying the insight gained from our advanced biophysical and analytical protein characterization techniques towards the development of robust and scalable processes. KBI delivers accelerated and integrated process development and cGMP manufacturing programs for a wide range of recombinant protein Active Pharmaceutical Ingredients (API) and cell therapies for our clients.

KBI was founded in 1996 and operates facilities in Durham and Research Triangle Park (NC), Boulder (CO), The Woodlands (TX), and San Diego (CA).

www.kbibiopharma.com

About Selexis SA

Selexis SA is a pioneering life sciences company and a global leader in mammalian (suspension-adapted CHO-K1) cell line generation, providing unparalleled proprietary technology and the highly-specialized expertise that is necessary to translate scientific innovation into life-saving medicines for patients. Selexis' *SUREtechnology* Platform™ facilitates the rapid, stable, and cost-effective production of virtually any recombinant protein and provides seamless integration of the bioproduction continuum, spanning discovery to commercialization.

With more than 100 partners worldwide, more than 100 drug products in clinical development and three commercial products utilizing Selexis-generated cell lines, the Company has a history of empowering scientists and biopharmaceutical companies around the world to realize the full potential of their research. More information is available at www.selexis.com.

About the KBI BioPharma and Selexis expedited and integrated approach towards cell line and process development

Selexis and KBI Biopharma have joined forces to offer integrated development leading to cGMP manufacture of recombinant proteins in an expedited timeframe.

Cell line development activities at Selexis and process development activities at KBI are performed in parallel and in a highly coordinated and efficient manner. KBI has successfully performed development and cGMP manufacturing with more than twenty Selexis cell lines.

The integrated development workflow takes advantage of Selexis' CHO-M system with its high expression and associated media and feeds, KBI's well-established platform approach towards upstream and downstream process development for a wide variety of antibody related proteins (e.g. antibodies, Fc- proteins, bispecifics, and related proteins), KBI's technical expertise and broad experience in upstream and downstream development for a wide variety of recombinant proteins (e.g. (glycoproteins, enzymes, bispecifics with unique scaffolds, etc.), as well as KBI's industry leading analytical and formulation technical expertise.

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next generation protein therapeutics

Manufacturing of AD-214

January 2019

Dallas Hartman

AdAlta Chief Operating Officer

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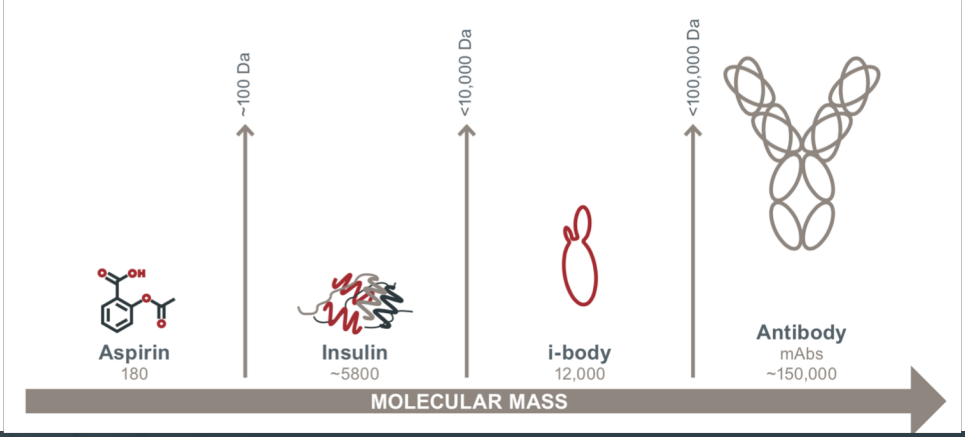
Why is manufacturing so important?

- Regulatory
  - Materials that are going to be given to humans as potential treatments need to meet certain standards set by government regulatory agencies
  - The process for manufacturing biologics defines the final product
  - The pathway for the development of biologics manufacturing takes 12-18 months – sometimes longer
- Safety
  - A defined process is required to produce biologics materials in order to begin clinical trials in humans
- Creating a commercial product
  - Investing time in manufacturing is critical for the success of a biologics program
  - The manufacturing process forms an integral part of a due diligence package for the potential partnering of a biologics product

Manufacturing biologics

Small Molecules	Biologics
Produced by chemical synthesis	Produced by living host cells
Low molecular weight	High molecular weight
Single molecular entity	Heterogeneous mix of similar molecules
Well defined modifications	Many modifications possible
Stable	Sensitive to many conditions
Purification relatively easy	Relatively complex purification process
Low specificity; off-target effect	High specificity



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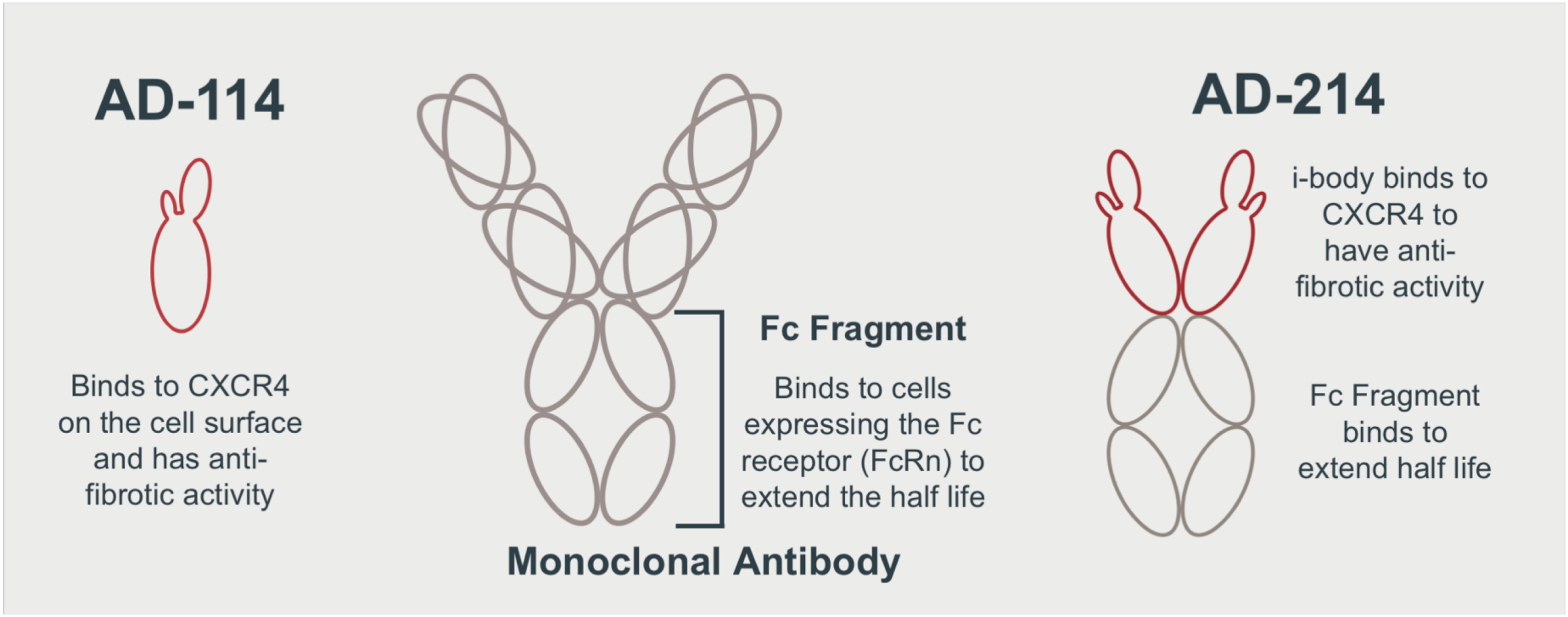
What is an Fc-Fusion?

AdAlta's lead i-body AD-214 is an Fc-Fusion



AD-214 is a superior drug candidate

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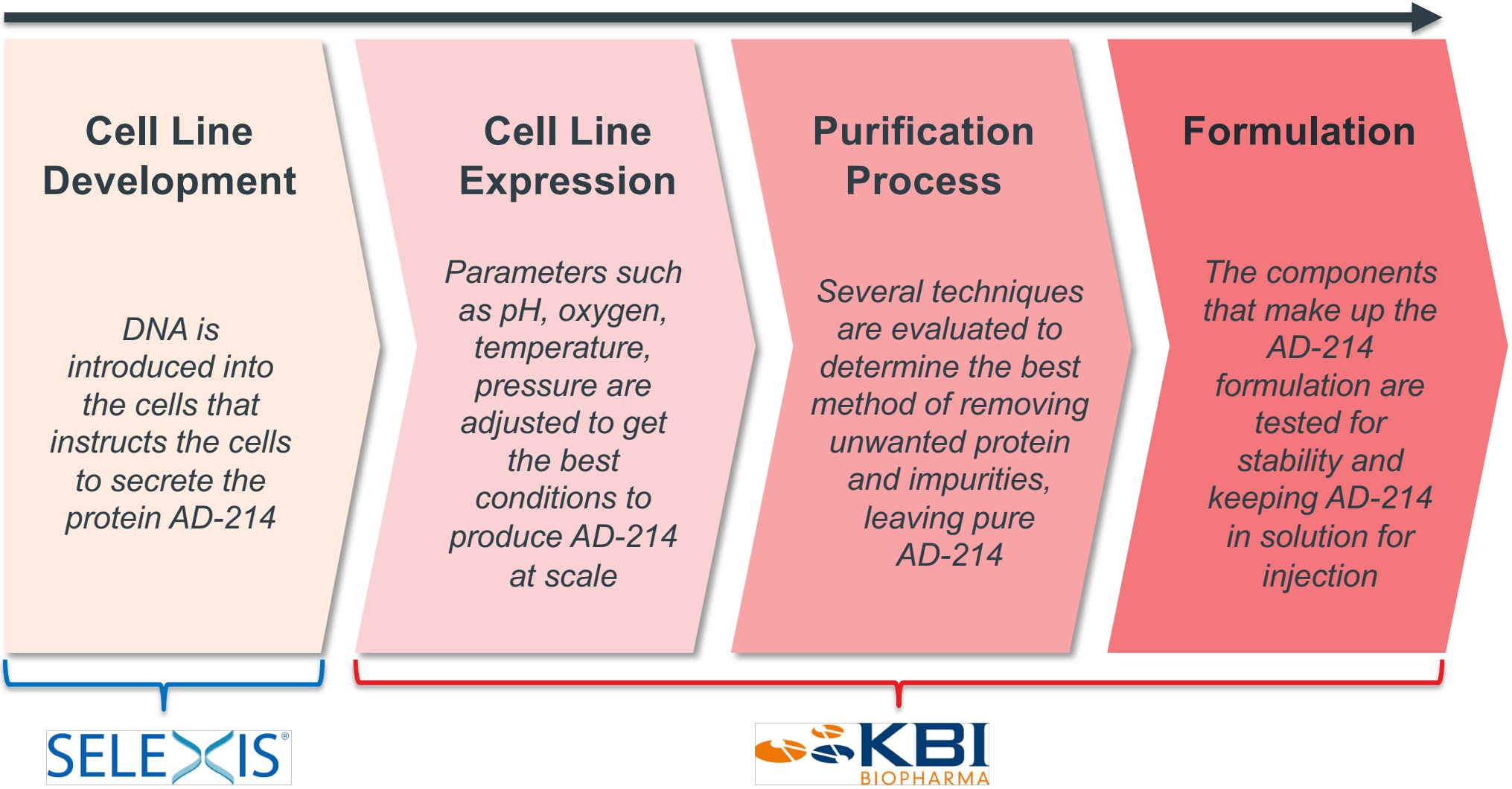
Developing AD-214 manufacturing process



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Why Selexis?

R&D & Clinical Pipeline Based on the SURE*technology*TM Platform

	PRECLINICAL	IND FILING	PHASE I	PHASE II	PHASE III	MARKET
AUTOIMMUNE/INFLAMMATORY DISEASES	23			1	3	2
BLOOD DISORDERS		1	3		1	
CANCER	20	1	15	8	1	1
METABOLIC/INFLAMMATORY DISORDERS	2	1	1	1		
DERMATOLOGY/EYE DISORDERS	1			1		
UNDISCLOSED	7					

94 CLINICAL DRUG CANDIDATES

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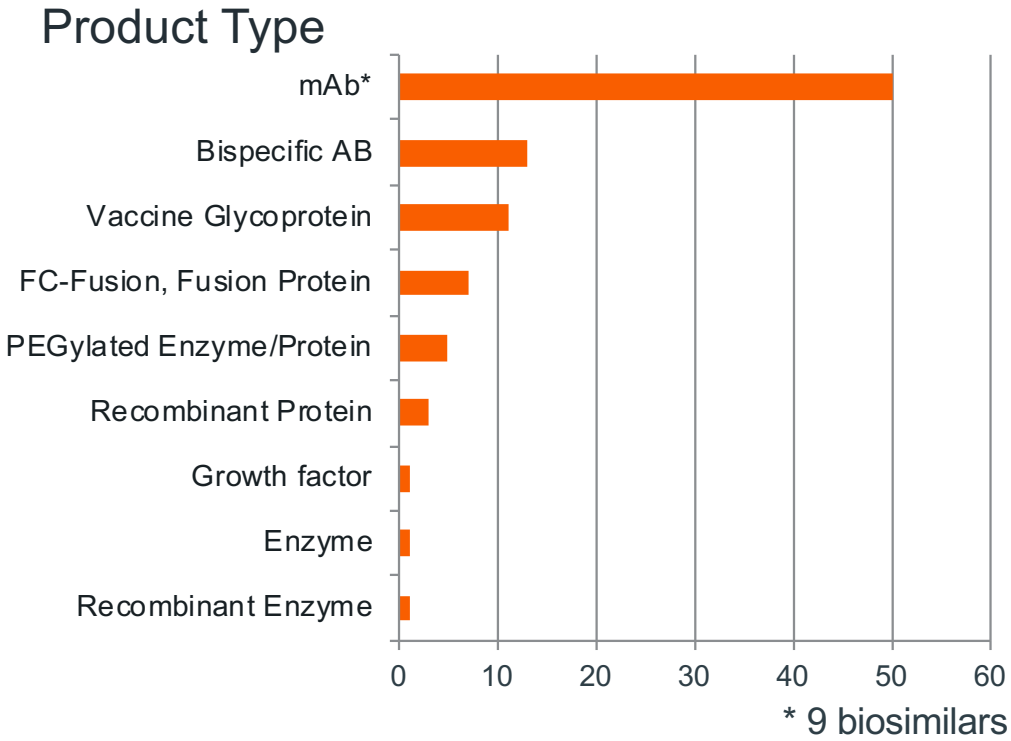
Why KBI?

Mammalian Process Development: >90 Projects



50+ programs & 12 client INDs supported per year

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Selexis & KBI together

KBI has performed Process and Analytical Development using over 20 Selexis cell lines

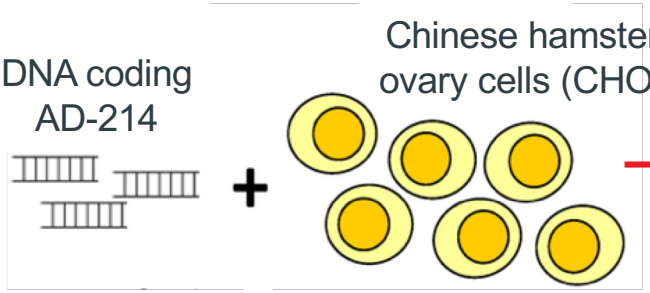
Project	Type of Molecule	Clone stage	Titer Range (g/L)
A	mAb	Final clone	4.5 - 8.5*
B	Bispecific mAb	Final clone	3.5 - 4.5
C	Fusion protein	Lead clones	2.2 - 2.8
D	Bispecific mAb	Lead clones	2.1 - 2.7
E	Bispecific mAb	Lead clones	2.0 - 2.4
F	Bispecific mAb	Lead clones	4.2 - 4.8
AdAlta	Fc- Fusion	Lead clones	2.7 - 3.3

* Example of titer improvement from first-in-human to commercial production

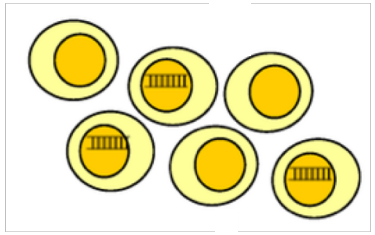
What is a clone?

DNA coding AD-214

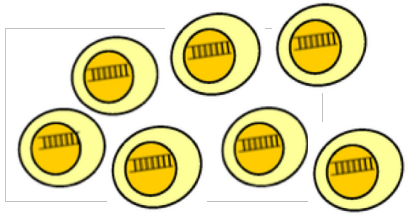
Chinese hamster ovary cells (CHO)



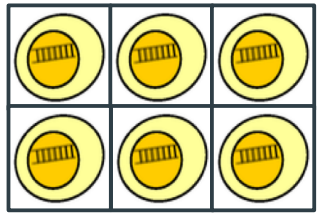
Introduce AD-214 DNA into cells



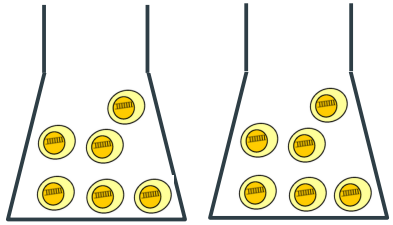
Only some cells integrate the DNA from AD-214
The cells with integrated AD-214 DNA are individual clones



Clones with only AD-214 are then selected and further evaluated



Separate individual clones are tested for production levels of AD-214



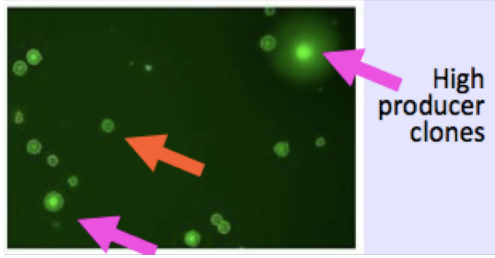
Grow highest producers at larger scale and test with more conditions

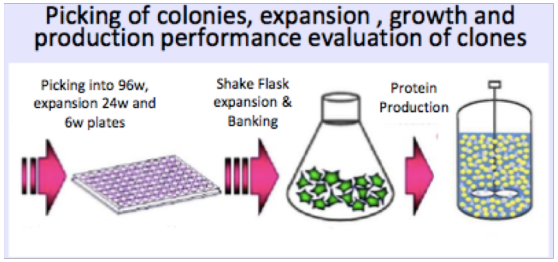
Lead clones
- Check that they are stable
- Check they are isolated from a single cell

Cell line for GMP production

Cell line development (Selexis)

- Selexis completed the following cell line development activities:
  - Generated research cell banks (RCB) for the four lead AD-214 clones
  - Confirmed sequences of all lead clones
  - Determined copy number for all lead clones
  - Demonstrated monoclonality for all lead clones
- Cell line stability is ongoing; completion due late February
- ICH complaint documentation near complete





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Cell line expression (KBI)

- Performed for clone selection and process optimization
- Process optimization focused on product levels and quality
- Process optimization performed in scalable mini bioreactors
- Examine nutrient, media feed strategies, temperature shifts, pH, oxygen content and metabolite levels
- All four lead clones produce approximately 3g/L

Small-scale bioreactor

Lead clones

	ProA Titer (g/L)						
Days	R1	R2	R3	R4	R5	R6	R7
6	0.7	0.8	0.8	0.8	0.8	0.8	0.9
8	1.3	1.4	1.3	1.3	1.3	1.3	1.5
10	2.1	2.3	2.0	2.0	2.0	2.0	2.0
12	2.4	2.7	2.6	2.5	2.4	2.5	2.6
14	2.7	2.7	3.0	3.0	3.0	3.1	3.2
Harvest	2.4	2.5	2.9	3.0	3.0	3.1	3.1
	Clone 1		Clone 2		Clone 3		Clone 4

Different conditions for Clone 1

	ProA Titer (g/L)						
Days	R13	R14	R20	R21	R22	R23	R24
6	0.7	0.8	0.8	0.6	0.7	0.7	0.7
8	1.3	1.4	1.5	1.0	1.1	1.4	1.4
10	2.1	2.3	2.4	1.8	2.0	2.4	1.9
12	2.4	2.7	3.0	2.5	2.5	2.6	1.6
14	2.7	2.7	3.3	2.8	2.6	3.0	1.6
Harvest	2.4	2.5	2.9	2.5	2.4	2.7	1.5

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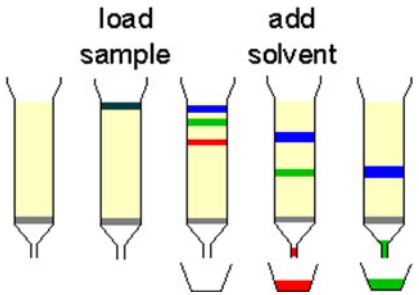
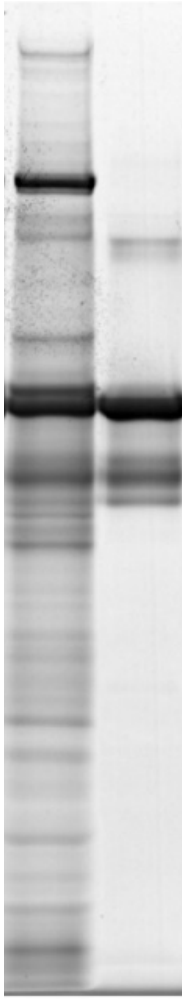
Product purification (KBI)

- Cell culture media contains the product plus contaminants that need to be removed
- Product is purified by chromatography

Add cell culture media which includes i- body AD-214, host cell proteins and other contaminants



Collect purified i- body AD-214



- A standard 3-step purification is being developed by KBI
  - Capture
  - Intermediate polishing
  - Final polishing
- A chromatography resin for each step has shown promising results and will be incorporated into a complete process

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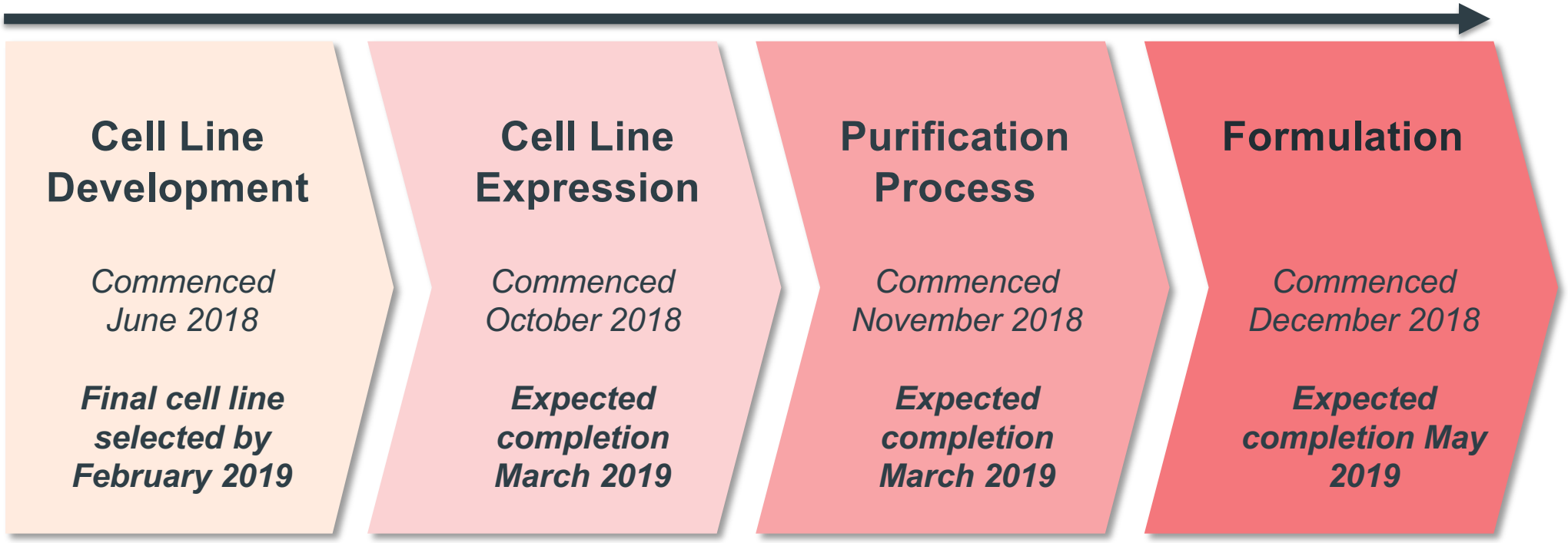
Product formulation (KBI)

- Proteins can be very sensitive to their environment
- AD-214 need to be in a solution that keeps it stable and active over long periods of time
- Screen different additives (excipients) to determine most appropriate formulation solution
- Early screening of additives has been completed

AD-214 manufacturing progress



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KBI BIOPHARMA

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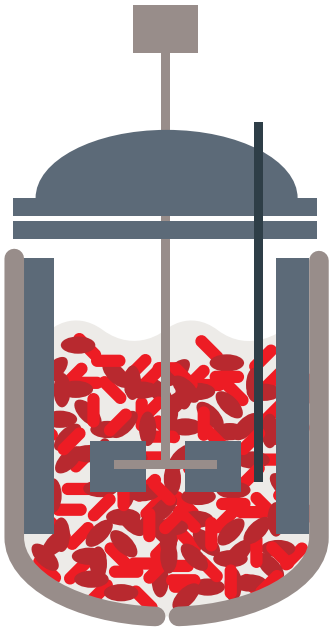
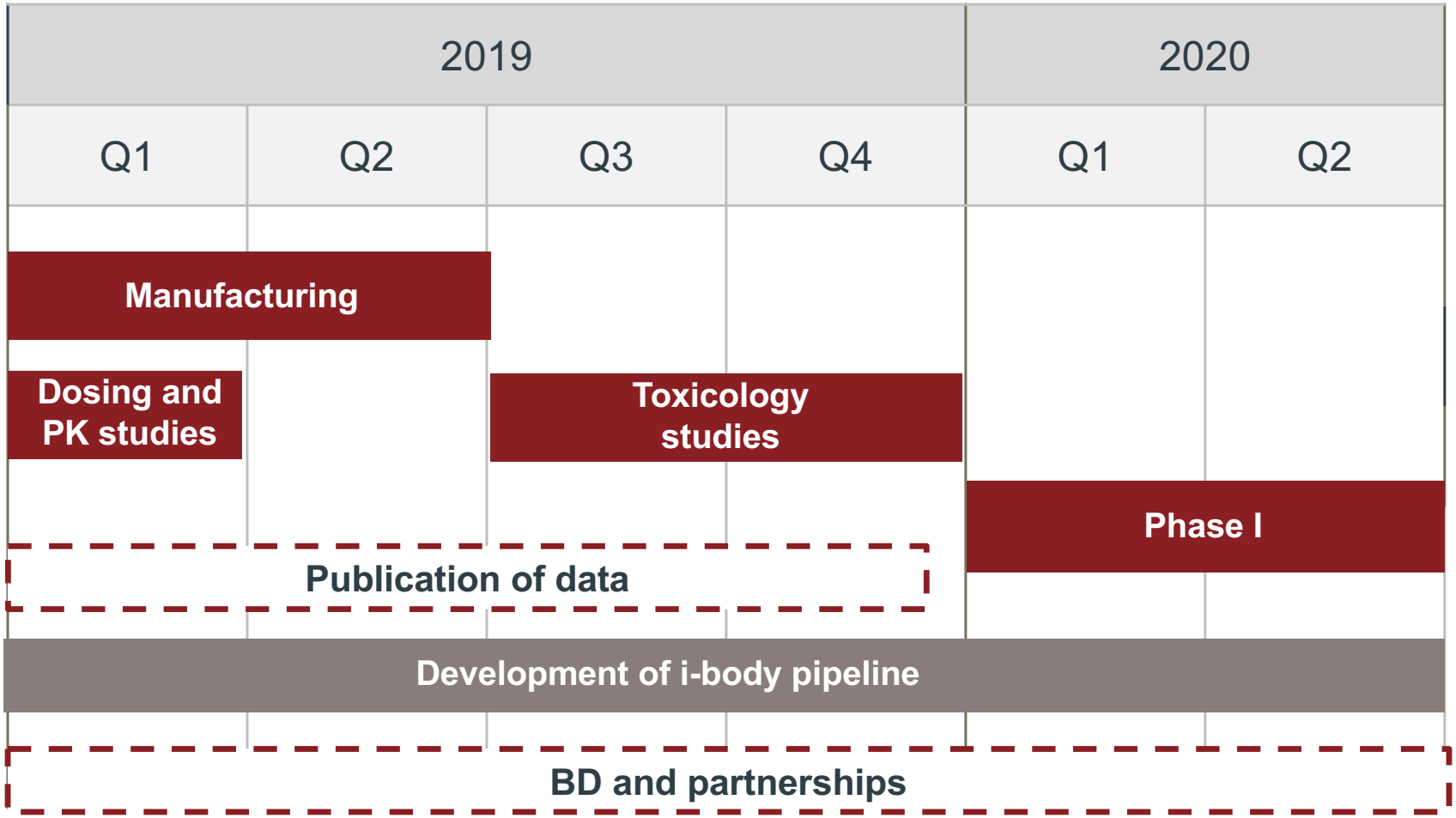
Manufacturing Milestones

Milestone	Expected Date
Cell line development	February 2019 ✓
Optimisation of process development and formulation	March 2019
AD-214 material available for toxicity studies	June 2019
AD-214 material available for Phase I clinical study	December 2019



AD-214 development: key milestones



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AD-214 manufacturing summary

- AD-214 has significant pre-clinical validation demonstrating broad anti-fibrotic and anti-inflammatory effects as well as safety
- Cell line development results are now ahead of expectations at 3 grams per litre (3g/L), up from the 1g/L reported in October 2018
- On track to deliver non-Good Manufacturing Practice (non-GMP) material for its four-week non-human primate toxicology study to commence in July 2019
- On track to deliver Good Manufacturing Practice (GMP) material for its Phase 1 human study which is expected to commence in January 2020

AdAlta working successfully with Selexis and KBI to provide materials for progression of AD-214 to the clinic

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next generation protein therapeutics

AdAlta Limited

ASX: 1AD

Dallas Hartman, COO

d.hartman@adalta.com.au

www.adalta.com.au