AdAlta
next generation protein therapeutics

ASX Announcement

AdAlta on track with AD-214 manufacturing

MELBOURNE Australia, 15th October 2018, AdAlta Limited (ASX: 1AD), the biotechnology company advancing its lead i-body candidate toward clinical development, is pleased to announce that it is on track with the development of the manufacturing process for its lead fibrosis candidate AD-214. Initial results from the cell line development are in line with expectations just over 1 gram per litre (1g/L.)

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 first step in generating AD-214 product is developing a stable cell line and we are comfortable with the current cell line yields as provided by Selexis,” said AdAlta’s Chief Operating Officer Dallas Hartman. “The process for expression and purification will now be optimized at KBI and based on this initial readout, we believe that the yields are sufficient to meet our requirements moving forward. As we hoped they would, Selexis and KBI are working together in an integrated manner to develop a process for the manufacturing of AD-214.”

The appointments of Selexis and KBI follow the announcement earlier this 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.

“We are pleased with the progress Selexis has made to date and, based on our current timelines, we expect to complete the four-week non-human primate toxicology study 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 as previously reported are outlined in the presentation accompanying this announcement.

-ENDS-

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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.

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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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AdAlta Investor Presentation

October 2018

Sam Cobb, CEO and Managing Director

AdAlta Limited (ASX:1AD)

s.cobb@adalta.com.au

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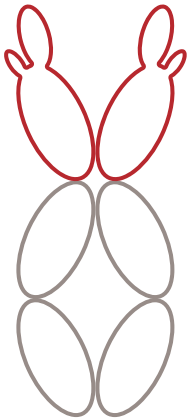
AdAlta (1AD) investment summary



AD-214

- A drug discovery and development company using its powerful technology platform to generate a promising new class of protein therapeutics, known as i-bodies, for treating a wide range of human diseases.

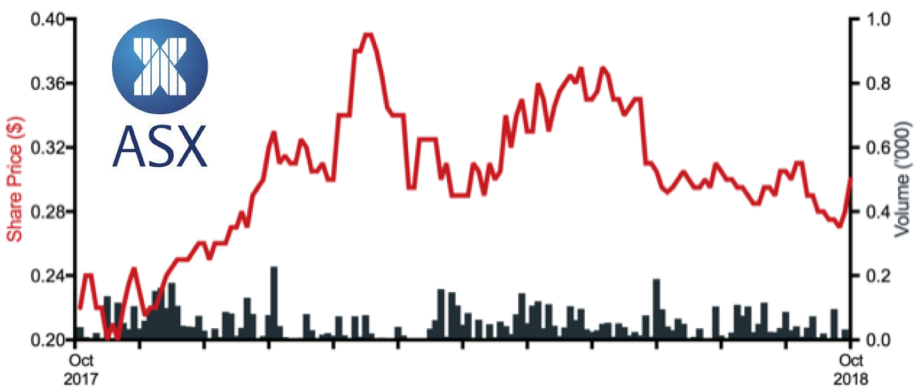
- **Investment highlights**
  - Initial focus on treating fibrosis – high unmet medical need
  - Advanced lead fibrosis drug candidate AD-214 with significant pre-clinical validation
  - Orphan drug designation for IPF granted with USA FDA
  - Early commercialisation potential
  - Developing i-body pipeline to further expand opportunities for partnering of novel i-body platform
  - Experienced team with strong track record of drug development and ability to deliver
  - Cash balance of AU$5.74m and strong support from institutional investors

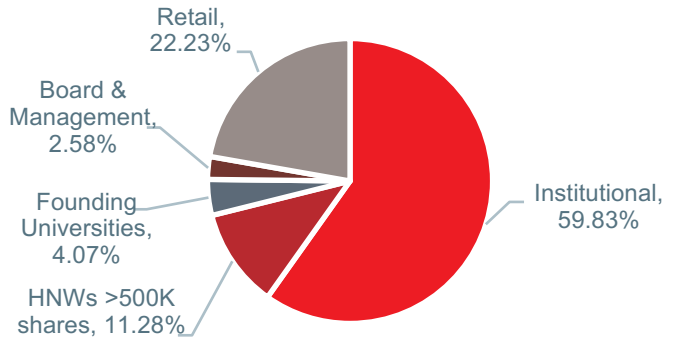
Financial position

Key financial details	
ASX code	1AD
Share price (10 October 2018)	AU$0.30
Market capitalisation	AU$35.12m
Shares on issue*	117,082,073
Options on issue	3,734,471
Current cash (30th September 2018)	AU$5.74m
Trading range (last 12 months)	AU$0.20 to $0.40
Average daily volume	32,700

Major shareholders	%
Yuuwa Capital LP	46.17
Platinum Asset Management	9.68
Citycastle Pty Ltd	4.58
National Nominees Limited	3.84
Meurs Holdings Pty Ltd	2.85
Other shareholders	32.88
Total	100%

Share performance (last 12 months)





*Excludes Director shares from Placement to be approved at AGM

AdAlta

Extensive support from institutional investors and HNWs

- Top 20 shareholders ~80%
- 60% institutional shareholders
- 11% HNWs with >500K shares each
- 4% founding academic institutions
- 2.6% Board, SAB and Management and 3,734,471 Options issued from $0.17-$1 under Employee Share Option Plan

YUUWA CAPITAL
reach for the sky

Australian based venture capital $40m fund

Platinum
ASSET MANAGEMENT

$27b under management, global equities investor

PPM
PRIVATE PORTFOLIO MANAGERS

Australian and international equities investor

AdAlta

Management and Board in place to deliver strategy



Sam Cobb: Founding CEO and Director

Extensive experience in raising equity, contract and grant funding

15 years of commercialisation and management experience



Dr Paul MacLeman: Chairman

Chairman of Myostin Therapeutics Ltd, Livac and Non-Executive Director of Sypharma Pty Limited
Founded biologics companies, experienced ASX listed executive



Dr Robert Peach

Founder and CSO of Receptos Inc, acquired by Celgene Corporation in 2015 for US$7.8bn

Deep experience in research and drug development



Dr John Chiplin: Independent Director

CEO of investment Company NewStar Ventures

Managing Director of acquired antibody company Arana Therapeutics (acquired by Cephalon Inc. for US$200 million)



Liddy McCall & Dr James Williams: Yuuwa Capital Directors

Founders and investment Directors of Yuuwa Capital

Founders of iCeutica Inc (acquired 2011) and Dimerix Limited

Directors of several Australian biotech and Agritech companies

Multiple FDA, CE Mark and TGA approvals



Scientific Advisory Board

Internationally recognised with proven track record of drug development



Dr Mick Foley, AdAlta CSO

Expert in phage display

NIH, NHMRC, ARC, Gates funding and over 70 scientific publications



Brian Richardson: drug discovery and development expert

Ex-Sandoz and Novartis (40+ years), including Head of Pre-clinical Research

Over 60 original peer reviewed research papers



Steve Felstead: clinical advisor

Ex-Pfizer (25 years), including Head of Clinical Research, Pharmatherapeutics Division

Developed Zithromax, Vfend, Celsentri, Viagra



John Westwick: pulmonary drug discovery and development

Over 14 years experience at Novartis, head of respiratory drug discovery

Five product launches and 13 positive proof of concepts in respiratory, including a number of antibodies which are now in phase III.



David McGibney: pre-clinical and clinical advisor

20 years with Pfizer, including Head of European R&D

Ex Pfizer Ltd board member

Developed Viagra, and 10+ blockbuster drugs

Market opportunity for IPF

Idiopathic Pulmonary Fibrosis (IPF) is an irreversible, unpredictable and incurable disease

THE STATISTICS

People living with IPF
300,000

People die from IPF every year
40,000

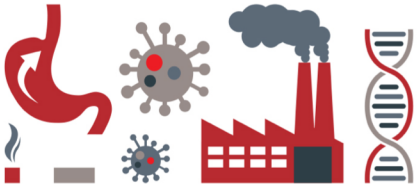
Median length of survival after IPF diagnosis
3.8 years

IPF incidence



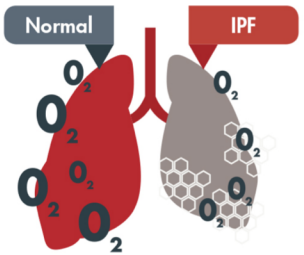


Causes



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



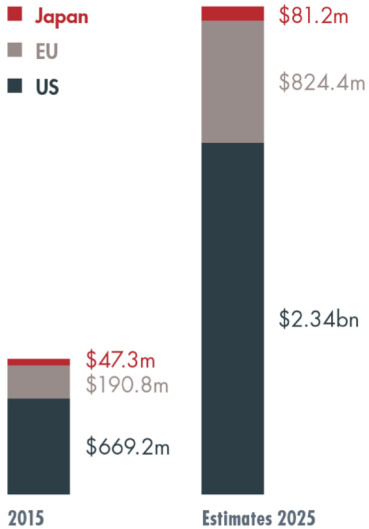
Resultant scarring/honeycombing in the lung restricts breathing and oxygen exchange.

Current IPF treatments

Pirfenidone — Roche

Nintedanib — Boehringer Ingelheim

IPF Therapy Sales (US$)



Source: GlobalData IPF Forecast 2016

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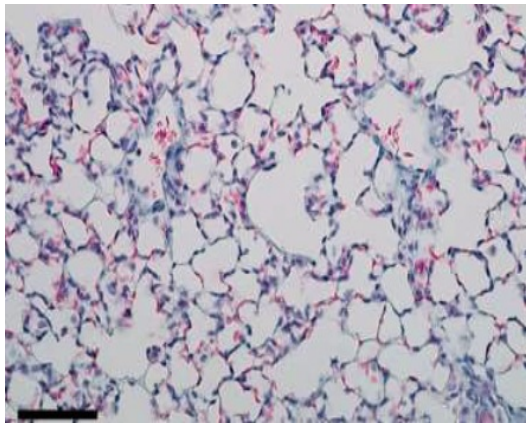
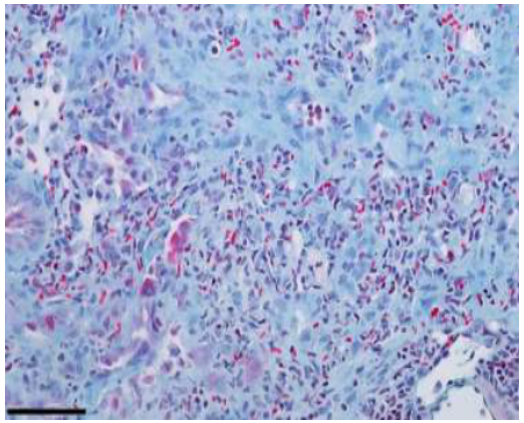
AD-214 novel treatment for fibrosis

AdAlta's lead i-body has demonstrated in vivo activity in the Bleomycin mouse model

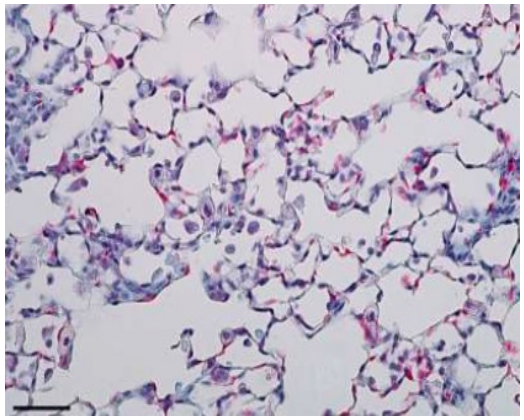
AdAlta's i-body reduces collagen content and inflammatory cell infiltration and demonstrates a similar architecture to that of the normal lung



Normal lung tissue



IPF lung tissue
(lung disease mouse model)



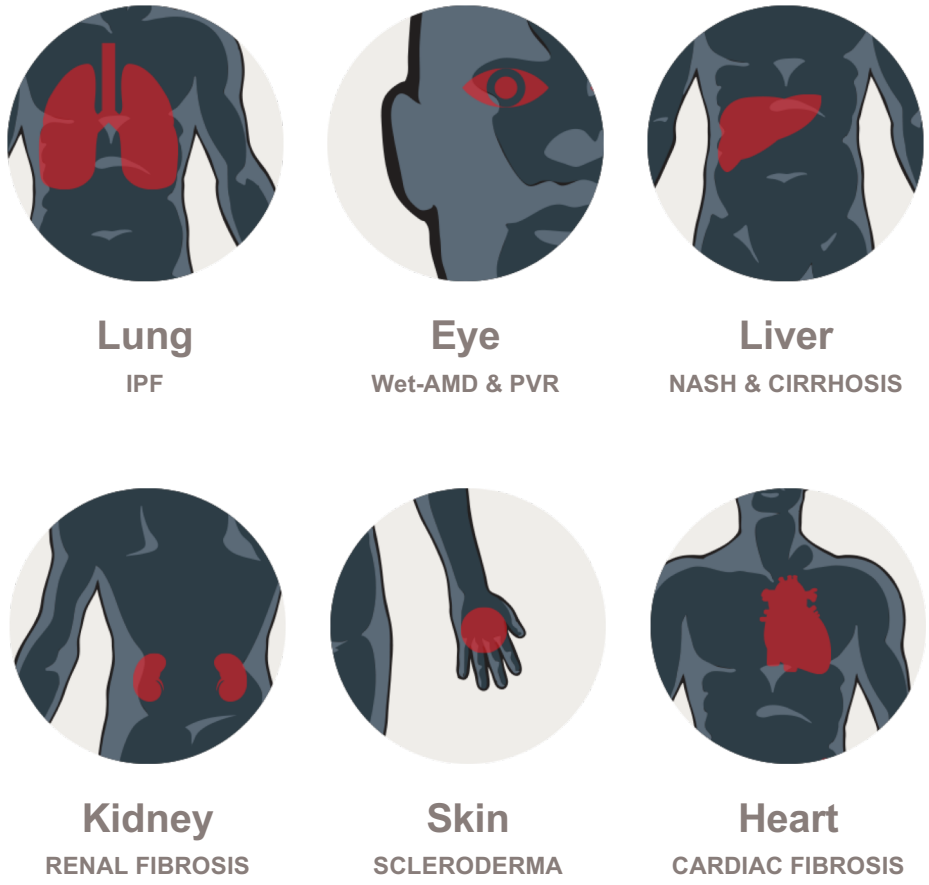
IPF lung tissue + AdAlta anti-CXCR4 i-body dosed for 21 days
(lung disease mouse model)

AD-214 has broad application in treating fibrosis

AdAlta data shows that AD-214 can improve fibrosis across a range of fibrotic diseases

- **LUNG:** Idiopathic Pulmonary Fibrosis
- **EYE:** Wet Age Related Macular Degeneration
- **LIVER:** NASH
- **SKIN:** Hypertrophic scar
- **KIDNEY:** Chronic Kidney Disease

AdAlta has demonstrated broad anti-fibrotic and anti-inflammatory effects in several animal models of disease and with human tissues with its lead i-body candidate.



Global market interest in fibrosis treatments

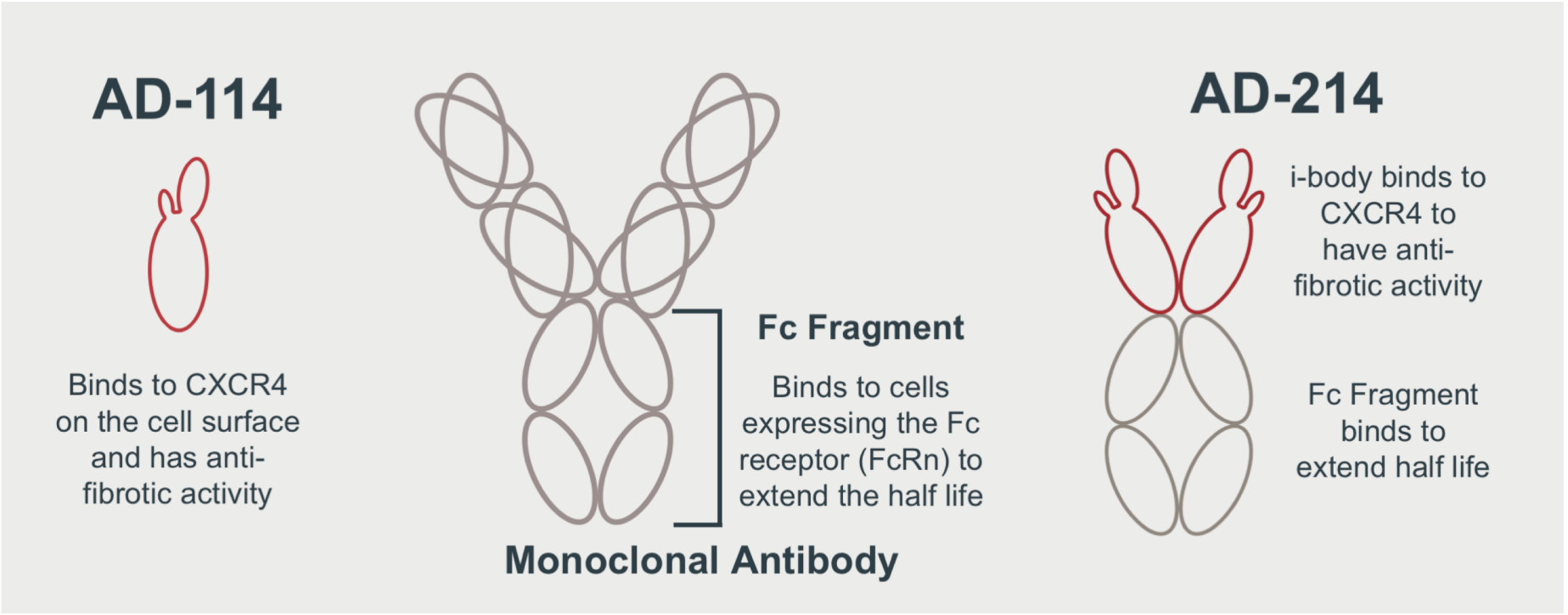
Fibrosis assets acquired at an early stage – typically based on Phase I results

Date	Company	Target	Acquired by	Deal value (US$)	Deal commentary
Sep-18	Samumed	SM04646	United Therapeutics	$10m upfront, plus $340m milestones	Undergoing Phase I, USA rights only
Sep-15	Adheron Therapeutics	SDP051	Roche	$105M upfront, plus $475M in milestones	SDP-51 at end of Phase I for IPF
Aug-15	Promedior	PRM-151	BMS	$150m upfront + $1.25B	Phase II IPF and myelofibrosis
Nov-14	Galecto Biotech AB	TD139	BMS	$444M	Option to acquire at end of clinical POC (no later than 60 days following Ph 1b for IPF completion)
Aug-14	Intermune	Esbriet / Pirfenidone	Roche	$8.3B	Approval in Europe / Japan, phase III in the US
Jun-13	MicroDose Therapeutx	MMI0100	Teva Pharmaceuticals	$40M upfront $125M milestones	MMI0100 was in pre-clinical development
Mar-12	Stromedix	STX100	Biogen Idec	$75M upfront $487.5M milestones	End of phase I for IPF
Jul-11	Amira / BMS	BMS-986020	BMS	$325M upfront $150M milestones	End of phase I for IPF

Source: GlobalData (all IPF deals since 2011)

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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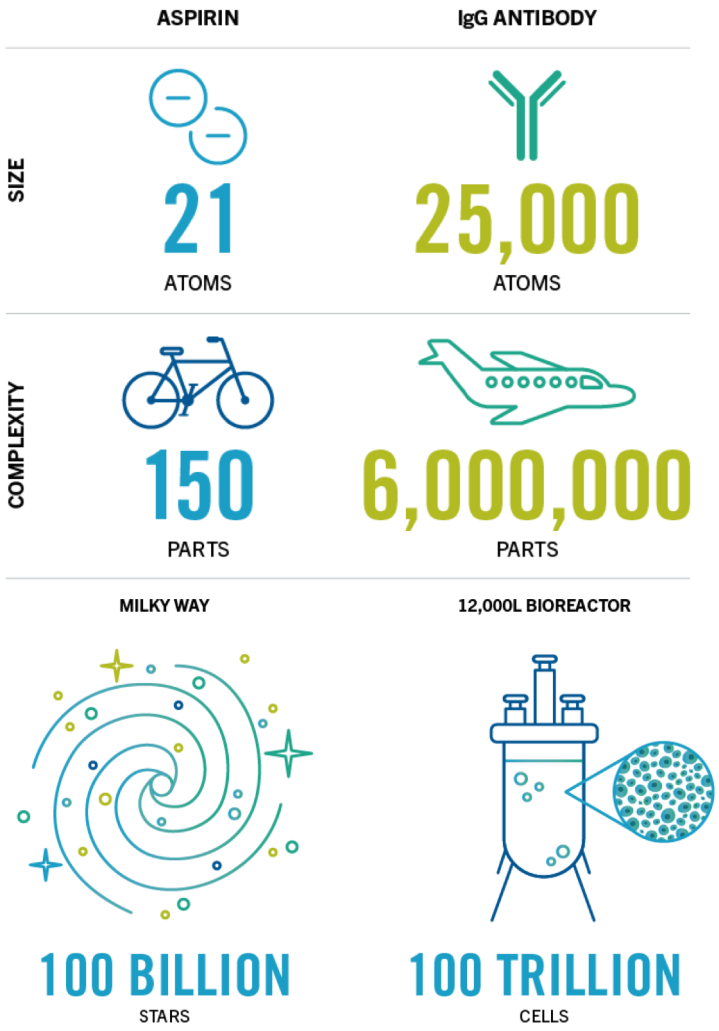
Manufacturing Fc-fusions

- The manufacturing process for a biologic protein is complex
- Biologics, such as Fc-fusions, are made in living cells and are thousands of times larger and more complex than relatively simple molecules like aspirin
- There are eleven Fc-Fusions on market and ~$20b in sales in 2017
  - Enbrel (TNFa) – rheumatoid arthritis $8.25b sales 2017
  - Eylea (VEGF) – wet-AMD, colorectal cancer $6.3b sales 2017
  - Orencia (CTLA4) – rheumatoid arthritis $2.6b sales 2017
  - Trulicity (Glucagon like peptide) – diabetes $2.2b sales 2017
- The development of an Fc-fusion is a well trodden path



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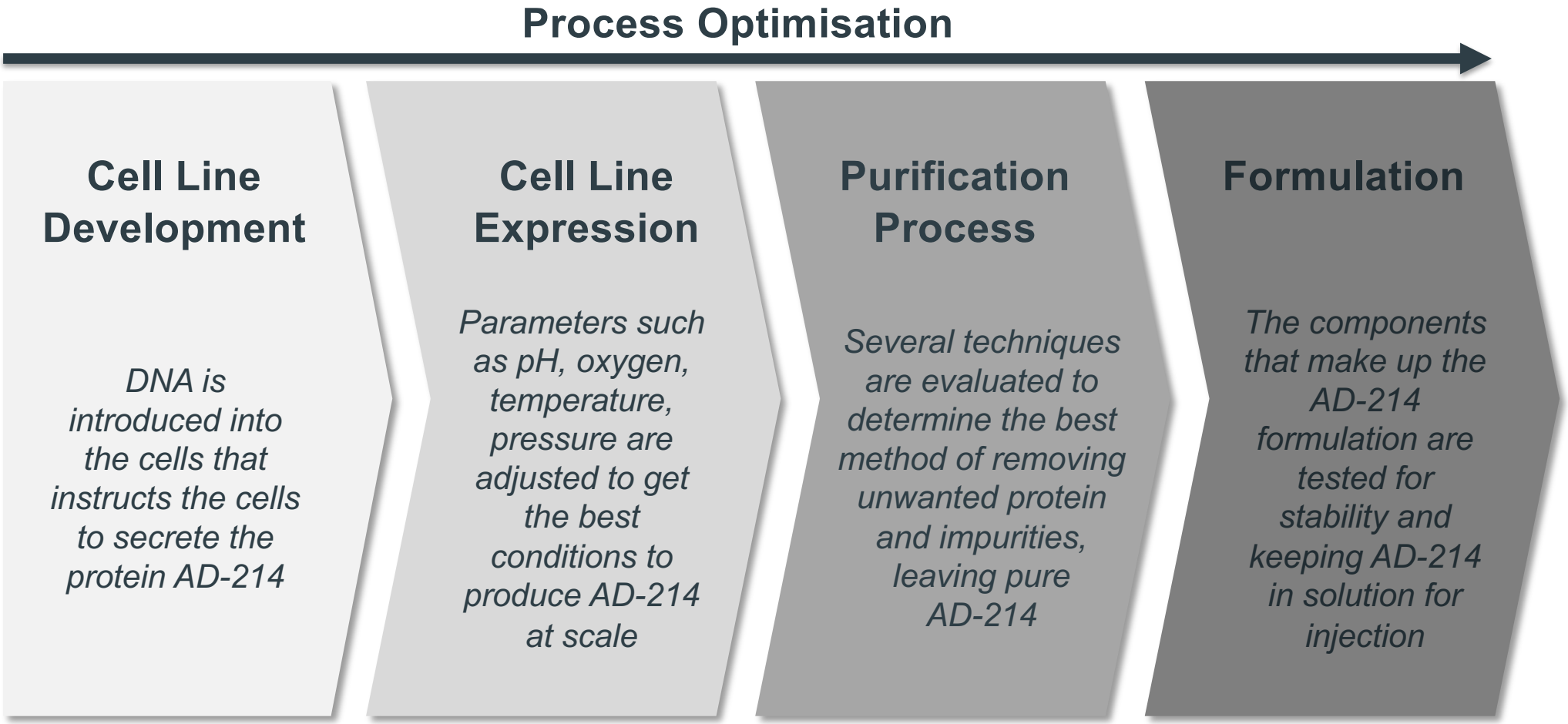
Developing the manufacturing process for AD-214



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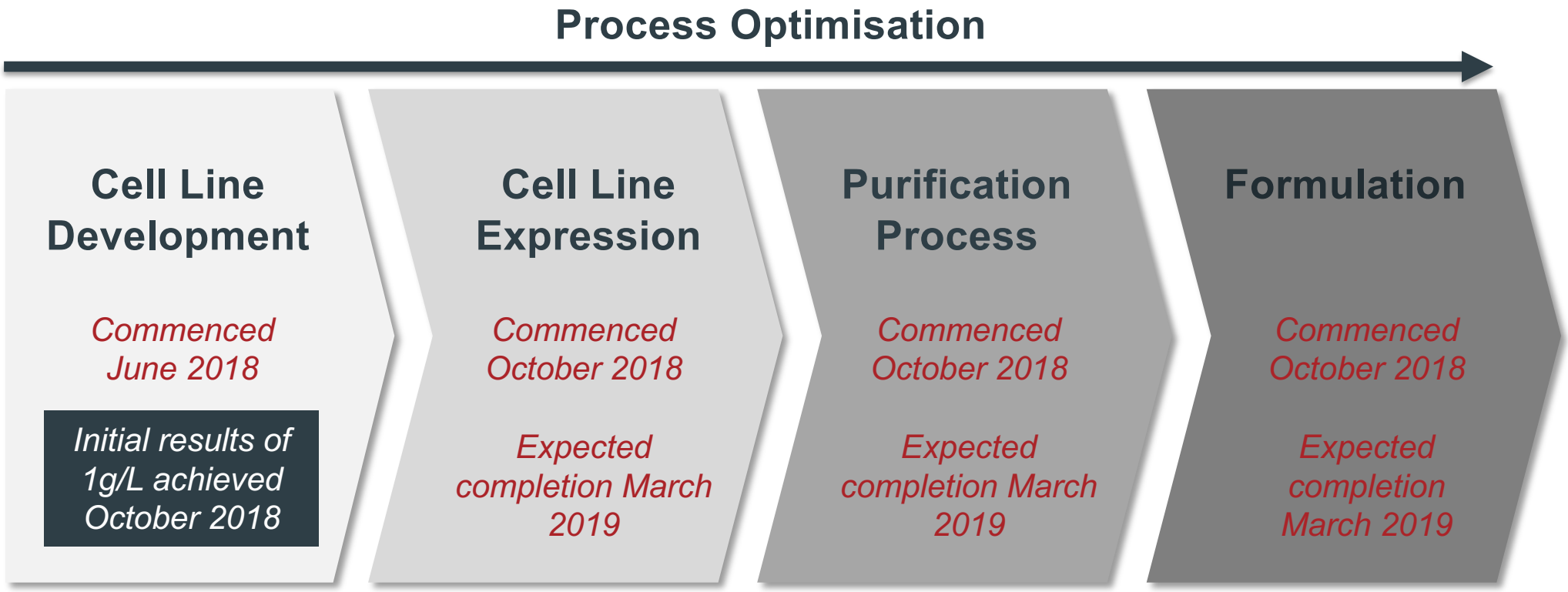
AD-214 manufacturing progress



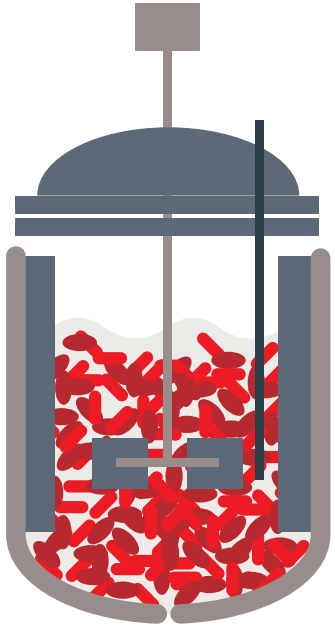
SELEXIS®

KBI BIOPHARMA

AdAlta

Manufacturing Milestones

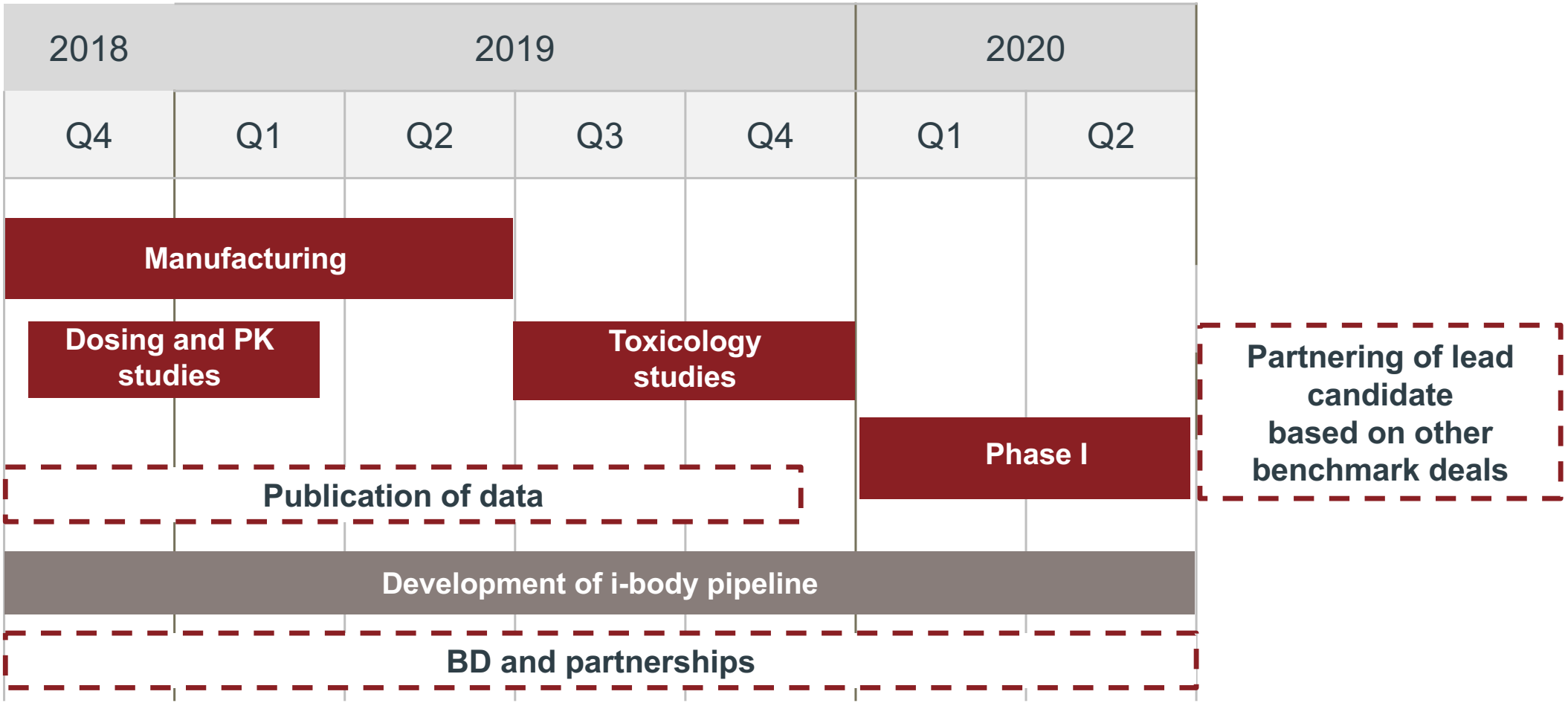
Milestone	Expected Date
Cell line development	October 2018 ✓ *Initial results just over 1g/L*
Optimisation of Process development	March 2019
AD-214 material available for toxicity studies	May 2019
AD-214 material available for Phase I clinical study	December 2019



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

AD-214 development: key milestones



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Significant achievements

- ✓ Orphan Drug Designation (US FDA) of AdAlta i-body for treatment of IPF
- ✓ Completion of additional pre-clinical animal models in diseases of the lung, kidney, skin; strengthening broad anti-fibrotic data package of anti-CXCR4 i-body
- ✓ Publication of key data in *Scientific Reports* (a *Nature* publication)
- ✓ Completion of several non human primate studies demonstrating safety of CXCR4 i-body but also safety of platform
- ✓ Key AU patent granted covering AD-214
- ✓ Successfully completed AD-214 cell-line development process



SCIENTIFIC REPORTS

OPEN

Anti-fibrotic Effects of CXCR4-Targeting i-body AD-114 in Preclinical Models of Pulmonary Fibrosis

Received: 8 November 2017
Accepted: 24 January 2018
Published online: 16 February 2018

K. Griffiths[1,2], D. M. Habiel[3], J. Jaffar[4], U. Binder[5], W. G. Darby[1,2], C. G. Hosking[1,2], A. Skerra[5], G. P. Westall[4], C. M. Hogaboam[3] & M. Foley[1,2]

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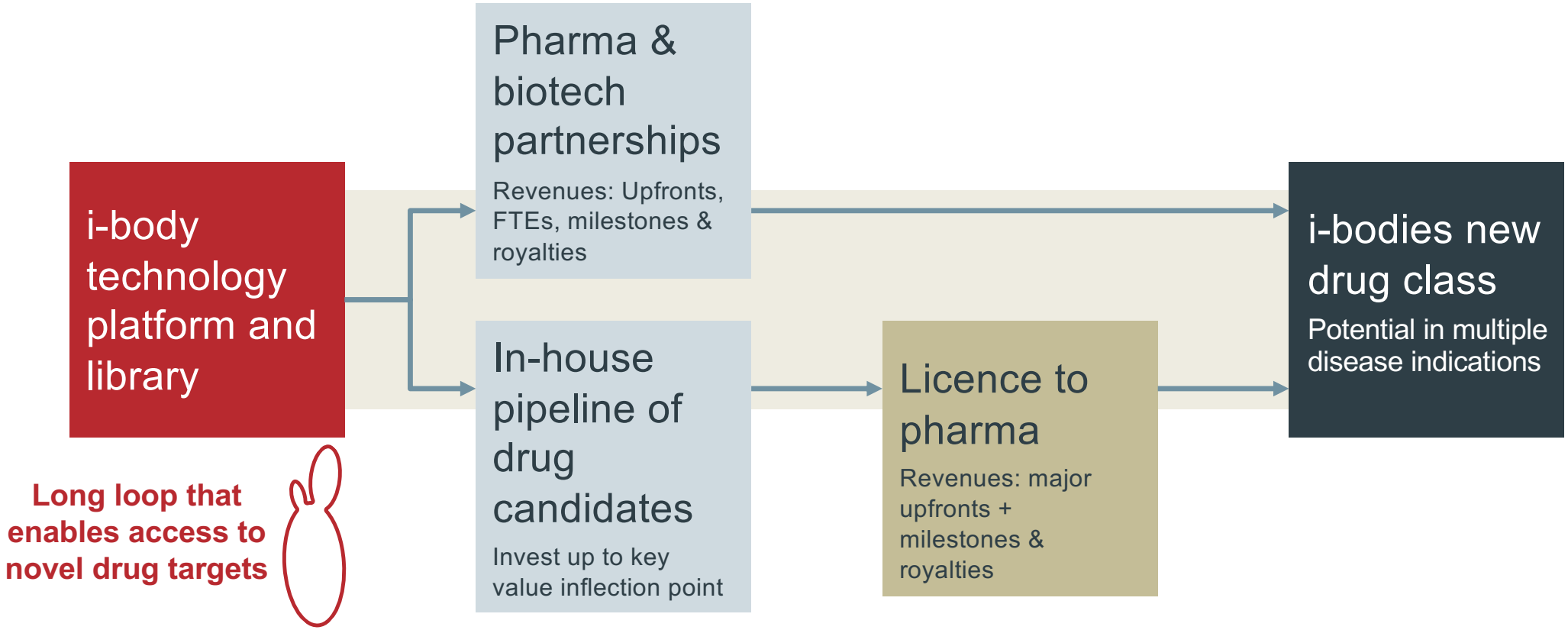
AdAlta business model – strategy to create value



Market benchmarks

Fibrosis lead AD-214	adheron THERAPEUTICS Sep-15 acquired by Roche $105m + $475m milestones phase I asset	Promedior Aug-15 acquired by BMS $150m + $1.25b milestones phase IIa asset	Galecto Biotech AB Nov-14 acquired by BMS $444m phase I asset
Next gen antibodies	arGEN-X April-16 with Abbvie $40m upfront + $645m milestones & royalties	pieris PHARMACEUTICALS May -17 with AZ $58m upfront + $2.1b milestones & royalties	Ablynx July-17 with Sanofi €31m upfront + €2.4b milestones & royalties
GPCRs	HEPTARES therapeutics Acquired Feb-15 by Sosei $400m Phase Ib asset + 7 pre-clinical leads	receptos Acquired by Celgene July-15 $8b Ph III, Ph II and GPCR platform	Ablynx April-16 with Boehringer €8m payment for Ph1 GPCR nanobody + €125m milestones & royalties

Expected news flow

H1 2018	✓	Publication of AD-114 data in *Scientific Reports* demonstrating i-body application of pulmonary fibrosis with human tissue and animal model data
	✓	Investor and analyst briefing detailing application of the i-body for the undruggable targets such as GPCRs and ion channels
	✓	Commence manufacturing of AD-214 with Selexis and KBI
H2 2018	✓	Manufacturing update on cell line development
	▶	Expected R&D tax return of ~$2m
	▶	Publish i-body ½ life and eye fibrosis data
	▶	Preliminary non-human primate data with AD-214
H1 2019	▶	Complete manufacturing including materials for tox program
	▶	Update on i-body pipeline development
H2 2019	▶	4 week NHP toxicology study
	▶	Regulatory discussions with US FDA
H1 2020	▶	Phase I SAD/MAD study with AD-214

AdAlta Limited (ASX: 1AD) summary

- Successfully raised $4.73m in Placement with institutional and high net worth investors and SPP with existing shareholders, completed post quarter's end, securing funding for AD-214 to end of manufacturing
- September cash position of $5.74m, with estimated ~$2m R&D tax incentive expected in Q2 FY 19
- Initial focus on treating Idiopathic Pulmonary Fibrosis (IPF) and other fibrotic diseases - high unmet clinical need
- AD-214 has significant pre-clinical validation demonstrating broad anti-fibrotic and anti-inflammatory effects as well as safety

Early commercialisation opportunity, with experienced management and Board to drive AD-214 development and secure technology platform partnerships / product licensing deals

AdAlta

next generation protein therapeutics

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