

ASX / Media Release

AdAlta to present at 2019 Bioshares Biotech Summit

MELBOURNE, Australia, 26 July 2019: AdAlta Limited (ASX: 1AD), the biotechnology company focused on advancing its lead i-body candidate towards clinical development today announced Chief Executive Officer Sam Cobb will be presenting at and attending the forthcoming Bioshares Biotech Summit conference in New Zealand.

The Bioshares meeting will be held from July 26 to July 28, 2019, in Queenstown, New Zealand, and attendees will hear from 28 speakers, including analysts and biotech representatives who will discuss current biotech industry trends and the hottest areas of clinical development.

CEO Sam Cobb will present data on AdAlta's i-body platform and lead candidate, AD-214, for the treatment of fibrosis and explain what sets both the i-body technology and AD-214 apart from other drugs in market or being developed for the treatment of fibrosis.

Details of the presentation:

Session Title: Therapeutics for Chronic Diseases – Competitive Positioning

Session Details: The companies presenting in this session are exploiting their in-house drug discovery capabilities, to competitively position their businesses to treat a suite of chronic diseases. These start in orphan indications such as idiopathic pulmonary fibrosis and a rare kidney disease FSGS, and seeking to leverage those capabilities into major diseases such as NASH and chronic kidney disease through eventual global licensing deals.

Session Date/Time: July 26, 2017 from 4:00 PM to 5:00PM

A copy of the AdAlta presentation is attached with this cover note and will also be made available on the Company's website at www.adalta.com.au.

Notes to Editors

About AdAlta

AdAlta Limited is an Australian based drug development company headquartered in Melbourne. The Company is preparing for its phase 1 clinical studies for its lead compound AD-214. The clinical program is expected to commence early 2020 following the release of the current toxicity study data.

AdAlta's lead i-body candidate, AD-214 is 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. AdAlta is also in collaborative partnerships to advance the development of its i-body pipeline announcing an agreement with UK-based research organisation, Excellerate Bioscience on an undisclosed target of commercial interest.

AdAlta has a proprietary technology platform to generate i-bodies, a new class of protein therapeutics, with applications as therapeutic drugs to treat disease. Our technology 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, for use in treating serious diseases.

The Company also plans to continue further drug discovery and development directed towards other drug targets and diseases.

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

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AdAlta
next generation protein therapeutics

AdAlta Bioshares Presentation

July 2019

Sam Cobb, CEO and Managing Director

AdAlta Limited (ASX:1AD)

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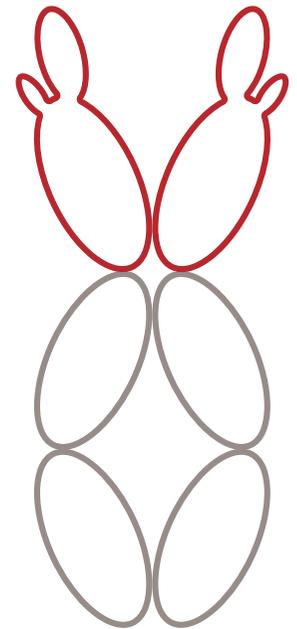
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1AD competitive positioning

- ▶ **i-body technology:** AdAlta's next-generation antibody platform technology
 - i-body platform technology for generating multiple products and collaborations for hard to treat diseases and difficult drug targets
 - Targeting 1-2 partnering deals with upfront payments (and future royalties and milestones) within the next 6-12 months
- ▶ **AD-214 lead therapeutic:** AdAlta's first i-body candidate for the treatment of fibrosis
 - Initial focus on Idiopathic Pulmonary Fibrosis (IPF) with US FDA Orphan Drug Designation and strong pre-clinical data
 - A disease with high unmet medical need and early transaction potential



AD-214

Treating 'undruggable' diseases

nature
REVIEWS

July 2015 volume 15 no. 7
www.nature.com/nrd

DRUG DISCOVERY
THE SCIENCE AND BUSINESS OF DRUG DISCOVERY AND DEVELOPMENT



Credit: Hemadil/Stock/Getty Images Plus

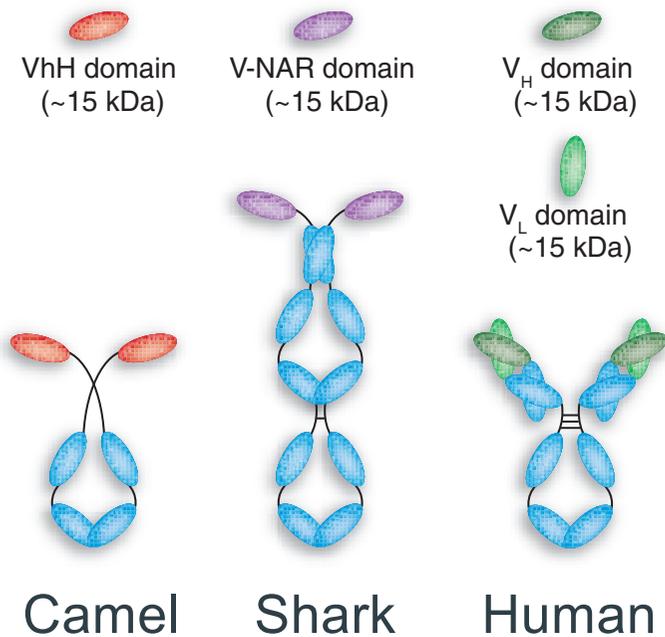
Nanobody approval gives domain antibodies a boost

The FDA has approved a first nanobody, lifting hopes for companies that are exploring innovative uses for domain antibodies.

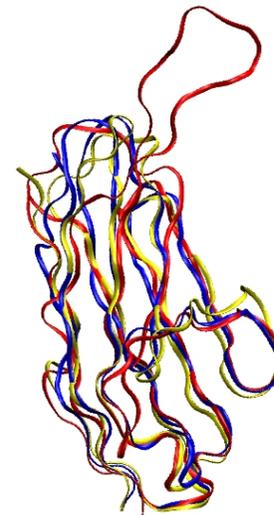
Where's the niche? If you keep that in mind there are many possibilities

AdAlta i-body technology

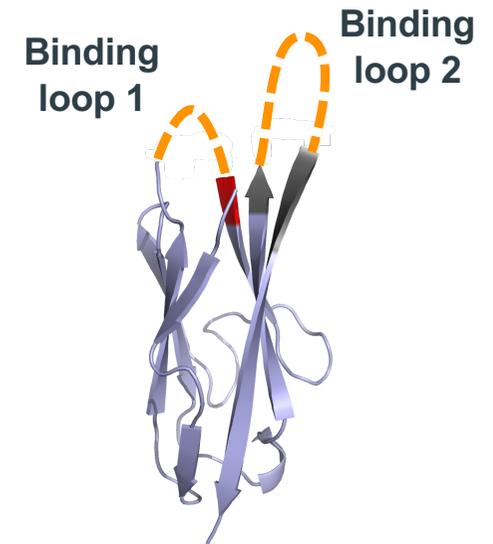
- ▶ Camels and sharks have a unique single domain antibody



- ▶ AdAlta's i-body technology based on the shape of the shark single domain



Overlay of shark (red) and human I-SET proteins (yellow/blue)



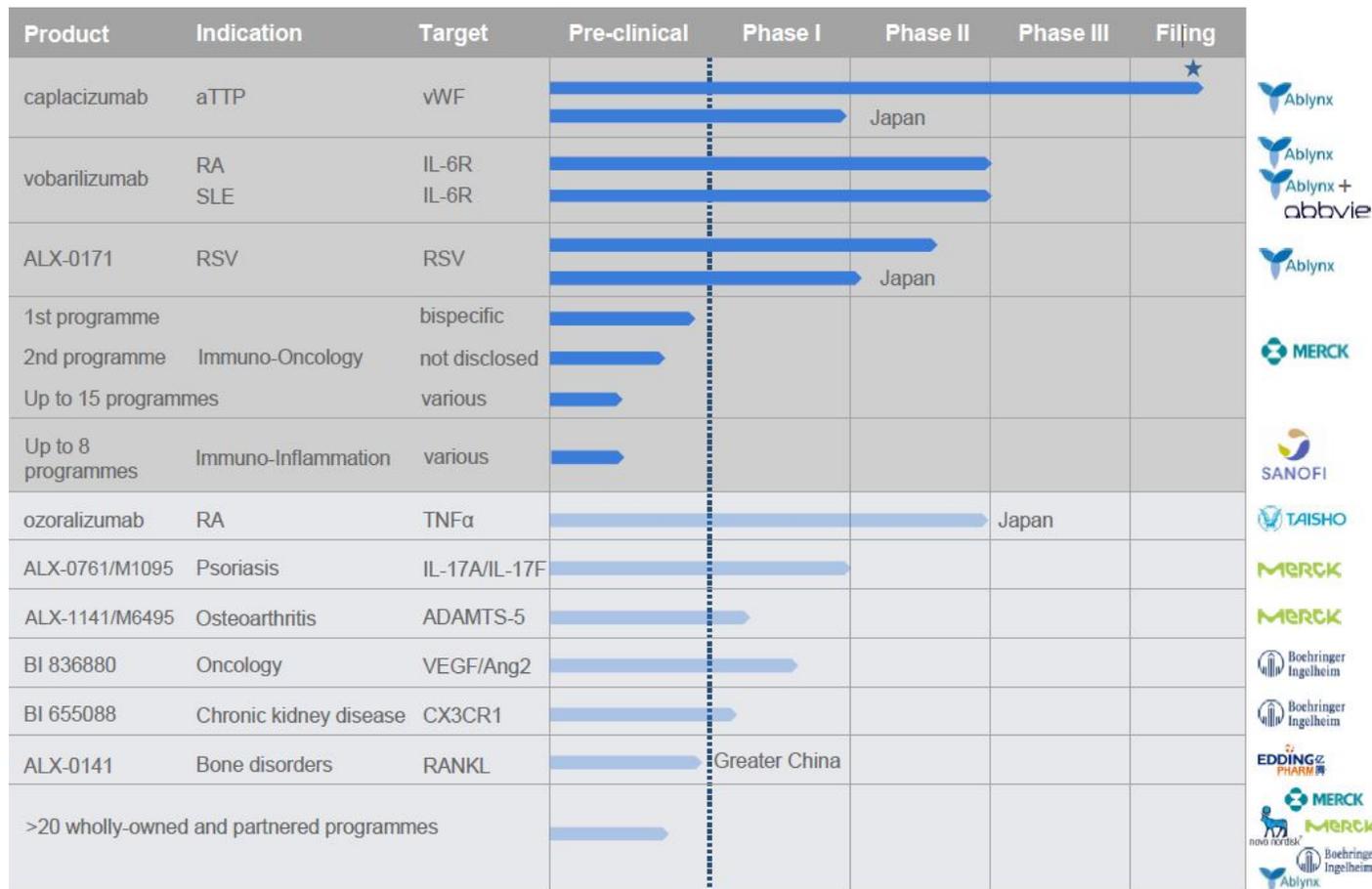
i-body: human i-set protein with synthetic loops

Advantages of the i-body

- ▶ **High affinity and specificity like monoclonal antibodies:** no off-target effects
- ▶ **Long loop:** potential to identify new epitopes, cavity binding and novel pharmacology
- ▶ **Extreme stability:** alternative routes of administration
- ▶ **Human framework:** less risk of immunogenicity

Drugging the undruggable: i-bodies can bind to targets like G protein-coupled receptors (GPCRs) and ion channels that have proved difficult to block with traditional antibodies

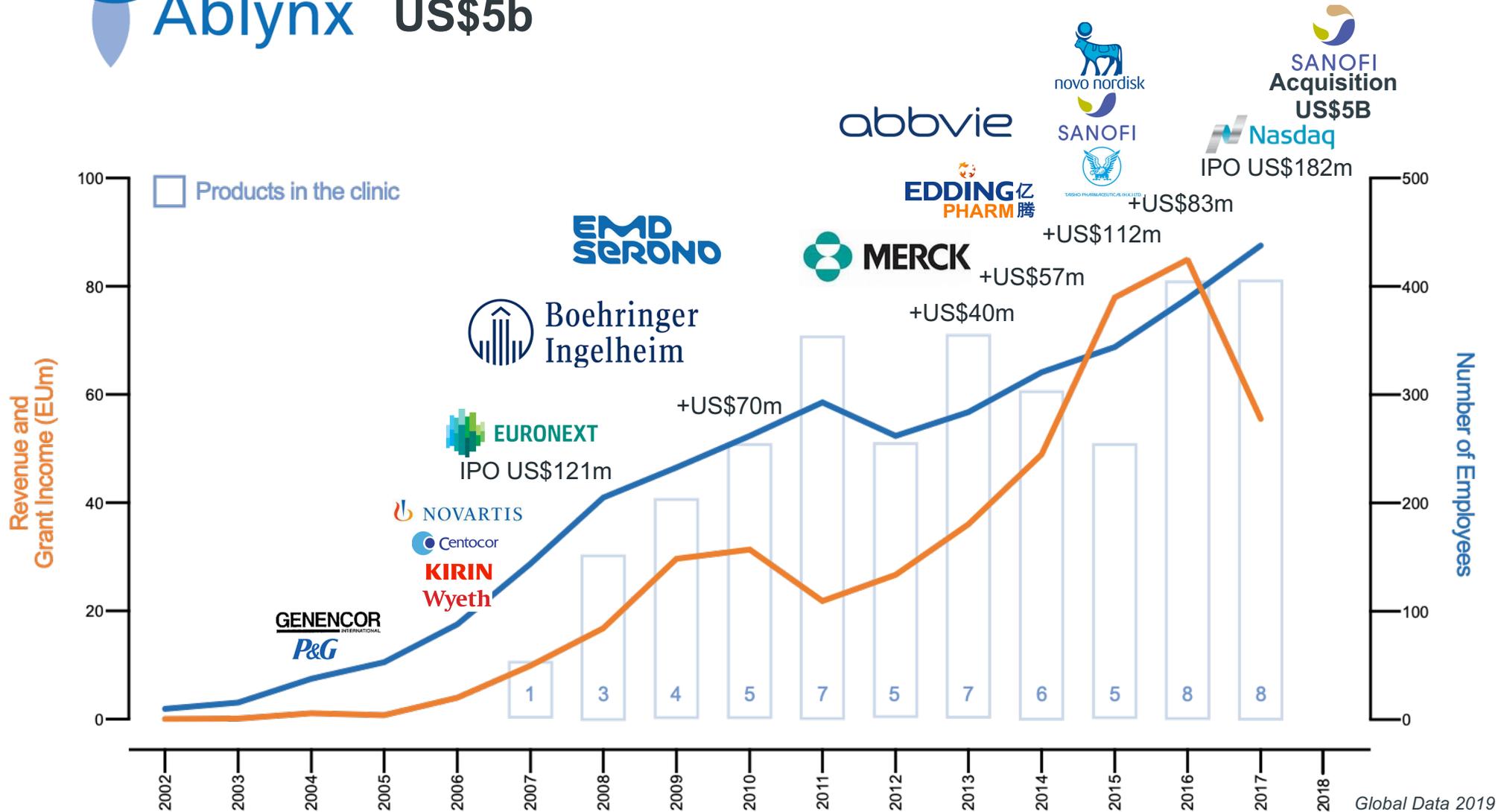
Building a multi-billion dollar antibody company: a case study



★ Filing in EU based on Phase II TITAN and Phase III HERCULES data



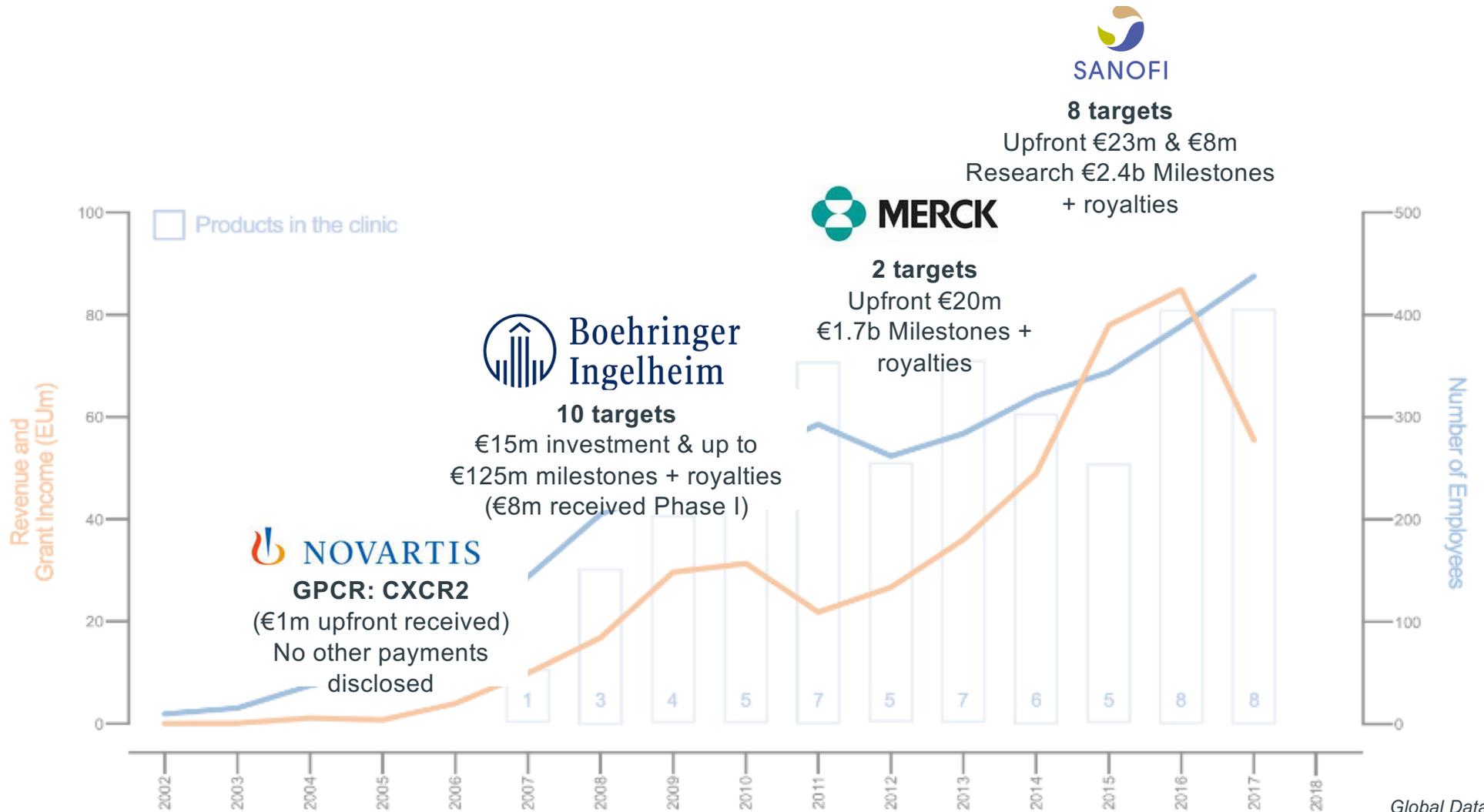
Single domain antibody company acquired for US\$5b



Global Data 2019



Ablynx Deal metrics changed as programs advanced



Global Data 2019

i-body platform: ability to build partnerships and pipeline

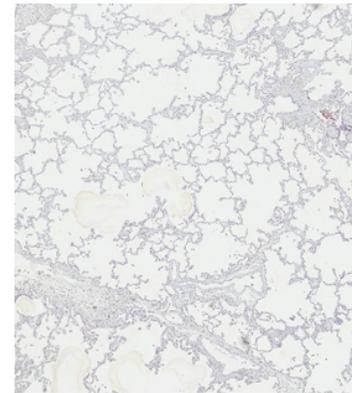
- ▶ AdAlta i-body platform technology providing potential for generating multiple products and collaborations
- ▶ Fibrosis focused lead program, AD-214, demonstrating advantages of the i-body platform
 - moving shortly into first in man trials
 - Targets CXCR4 – involved in fibrosis and many other disease areas
 - First in class / best in class treatment with US FDA orphan drug designation

AdAlta targeting 1-2 partnering deals with upfront payments (and future royalties and milestones) within the next 6-12 months

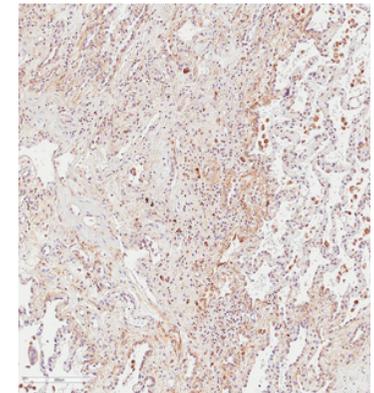
CXCR4 increased in disease

- ▶ CXCR4 expression increased in a number of human fibrotic diseased tissue (represented by brown staining)
- ▶ For example:
 - ▶ IPF diseased lung tissue in upper right panel compared with normal lung tissue
 - ▶ Diabetic diseased kidney tissue in lower right panel - compared with normal kidney tissue

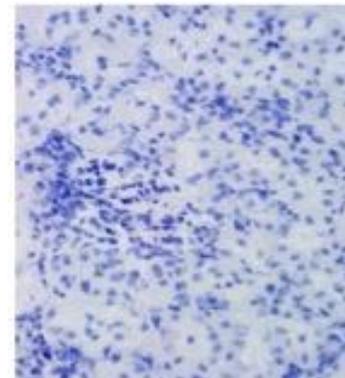
Normal human lung tissue



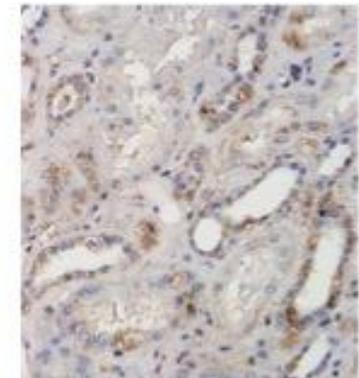
Diseased lung tissue



Normal human kidney tissue



Diseased kidney tissue



In each of the diseased tissue examples, CXCR4 is shown to be increased

CXCR4 a known target with approved drug

CXCR4 is important for maintaining stem cells in bone marrow, with Mozobil (AMD3100, pictured) approved for single use – in combination with G-CSF to prepare patients to receive cancer treatments

Mozobil is cardio-toxic if dosed more than once in humans; currently being evaluated for chronic treatment of WHIMs (CXCR4 mutation) at micro-doses

All other CXCR4 antagonists in development focused on mobilisation of stem cells



CXCR4 has more recently been recognised as a critical player in development of a number of areas of fibrosis including lung, kidney, heart, eye and skin

i-bodies have novel pharmacology

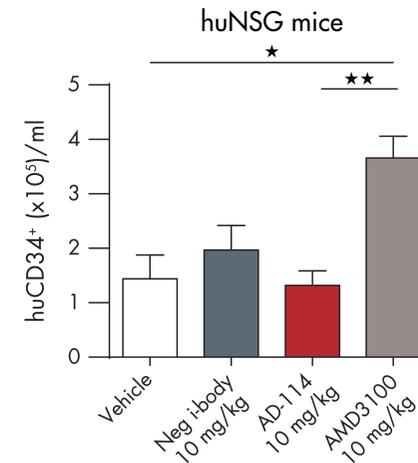
Activity with human tissue

- ▶ Anti-CXCR4 i-body inhibited migration of IPF fibroblasts only, no effect on normal fibroblasts
- ▶ This profile is unlike existing two IPF treatments and existing CXCR4 antagonist Mozobil (AMD3100)

| FIBROBLAST MIGRATION | No effect on normal fibroblasts | Inhibits IPF fibroblast migration |
|-----------------------------|---------------------------------|-----------------------------------|
| Anti-CXCR4 i-body | ✓ | ✓ |
| Nintedanib (Boehringer) | ✗ | ✓ |
| Pirfenidone (Roche) | ✓ | ✗ |
| Anti-CXCR4 AMD3100 (Sanofi) | ✓ | ✗ |

No stem cell mobilisation

- ▶ Anti-CXCR4 i-body did not mobilise stem cells in a humanised mouse model and NHP studies
- ▶ This profile is unlike other CXCR4 antagonists including small molecule drug Mozobil (AMD3100)



Current treatments for IPF

Pirfenidone (Esbriet)

- US Approval October 15th 2014 – previous rejection in 2010 (albeit positive advisory committee vote) with FDA requiring an additional study
 - 2018 sales of US\$1 billion
 - Sales continued to expand, driven by growth in the US (+19%) and Europe (+17%)

Nintedanib (Ofev)

- US Approval October 15th 2014
 - 2018 sales of US\$1.2 billion
 - 29% increase from 2017



Most advanced IPF trials



| | PBI-4050 | KD025 | PRM-151 | Pamrevlumab | GLPG-1690 |
|-------------------------------|---|--|--|--|--|
| Molecule Type | Small Molecule to CTGF | Small molecule to ROCK2 | Recombinant Protein, Serum Amyloid A | Monoclonal Antibody to CTGF | Small molecule to Autotaxin (LPA) |
| Phase II Trial Design | 41 patients 12 weeks Background of pirfenidone and nintedanib | 39 patients 24 weeks No background therapy | 116 patients 24 weeks Background of pirfenidone and nintedanib | 103 patients 48 weeks No background therapy | 23 patients 12 weeks No background therapy |
| Phase II Trial Results | Change in FVC PBI-4050: -12mL PBI + Nin: +2mL PBI + Perf: -102mL | Change in FVC KD025: -48mL SOC: -175mL | FVC %pred PRM-151: -2.5% Placebo: -4.8% | Change in FVC FG3019: -126mL Placebo: -308mL | Change in FVC GLPG: +8mL Placebo: -87mL |
| Phase III Progress | No details released | No details released | Aim to commence recruitment in 2019 | First patient dosed July 2019 | First patient dosed Dec 2018 |

A thin competitive landscape with more therapies critically required



■ Discovery
 ■ Preclinical
 ■ Phase I
 ■ Phase II
 ■ Phase III
 ■ Marketed

| | | | |
|--|---|---|---|
| <p>Biogen Inc</p> <ul style="list-style-type: none"> • Small Phase II trial for BG-00011 completed • Plans to initiate a second larger Phase II trial for AVB6 antagonist | <p>Galapagos</p> <ul style="list-style-type: none"> • Small Phase II trial for BG-00011 completed • Plans to initiate a second larger Phase II trial for AVB6 antagonist | <p>Bristol Myers Squibb</p> <ul style="list-style-type: none"> • Completing Phase II trial for RNAi compound licensed from Nitto BioPharma Inc. (BMS-986263) • BMS have exclusive rights to acquire PRM-151 following completion of Phase II trial | <p>Galecto Biotech</p> <ul style="list-style-type: none"> • Completed small Phase IIa for TD-139 that demonstrated safety but efficacy yet to be determined (Galectin3) |
| <p>Vicore Pharma</p> <ul style="list-style-type: none"> • Phase I trial completed and a Phase II trial planned for late 2019 with AT2R antagonist | <p>Indalo Therapeutics</p> <ul style="list-style-type: none"> • To commence Phase II with Integrin inhibitor 2019 IDL-2965 | <p>Other phase II companies</p> <ul style="list-style-type: none"> • MediciNova (tipelukast) • Celgene Corporation (CC-90001) • Merck & Co (gefapixant) • Novartis (ianalumab) • Taiho Pharmaceutical (TAS-115) | |

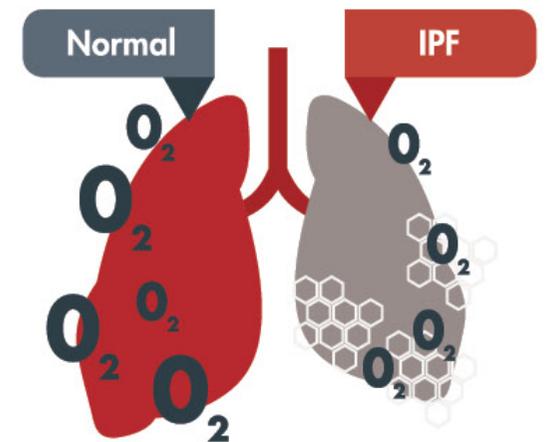
Global market interest in fibrosis treatments

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

| Date | Company | Product | Acquired by | Deal value (US\$) | Deal commentary |
|--------|------------------------|-----------------------|----------------------|--|---|
| Jul-19 | Bridge Biotherapeutics | BBT-877 | BI | \$50m upfront + \$1.2B in milestone payments | Phase I single dose completed with Phase I still in progress |
| Sep-18 | Samumed | SM04646 | United Therapeutics | \$10m upfront + \$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 |

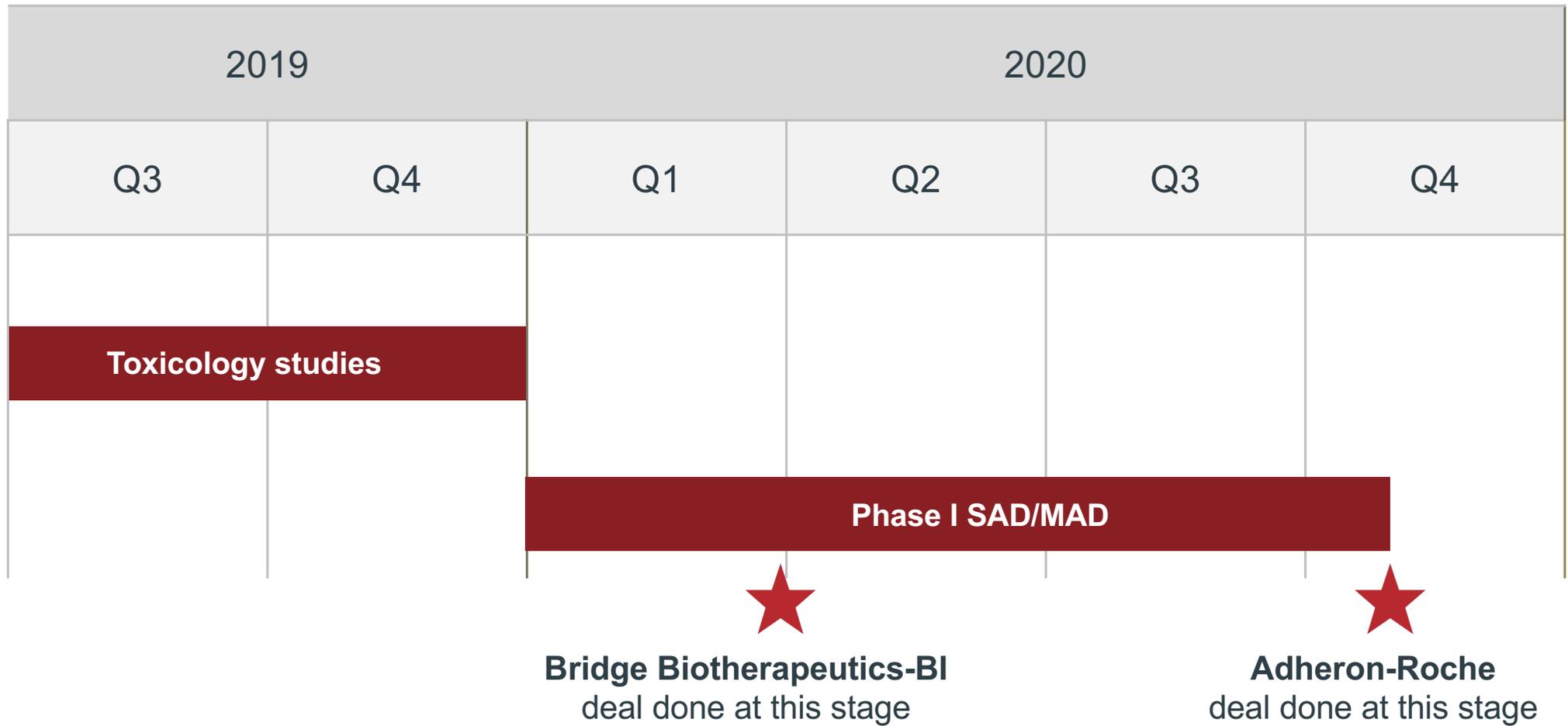
AdAlta's place in the IPF treatment landscape

- ▶ Landmark decade for treatments for IPF, approval of Pirfenidone and Nintedanib, which has led to greater confidence in the development of drugs for IPF
 - Neither are optimal therapies - the disease process is slowed, not reversed
- ▶ A number of products ahead of AdAlta:
 - Provide pathway for Phase II and III trials
 - Increased treatment options and probable survival benefit in IPF, will lead to an effective increase in prevalence, such that more patients will be seeking therapy
 - No IPF treatments under development targeting CXCR4
 - Existing approved CXCR4 small molecule antagonist Mozobil very different pharmacology to AD-214 and toxic when provided in chronic setting



High unmet medical need: there is a significant opportunity for multiple classes of drug to be clinically valuable and commercially successful for the management of IPF patients

AD-214 development: key milestones



AD-214 has broad application in treating fibrosis

AdAlta data suggests 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



Lung
IPF



Eye
Wet-AMD & PVR



Liver
NASH & CIRRHOSIS

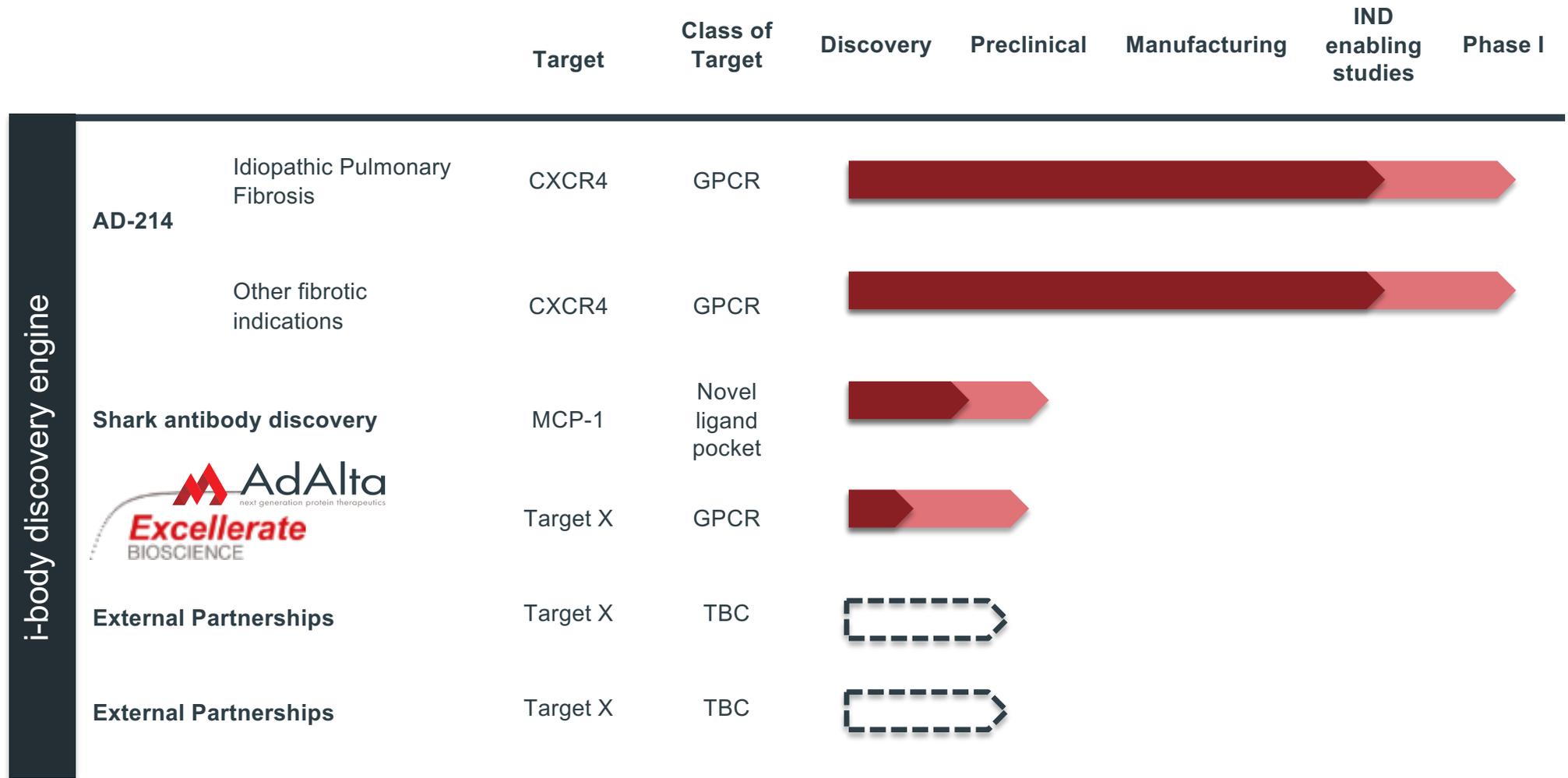


Kidney
RENAL FIBROSIS



Skin
SCLERODERMA

AdAlta pipeline 2020



AdAlta Limited (ASX:1AD) Summary

- ▶ AD-214 has significant pre-clinical validation demonstrating broad anti-fibrotic and anti-inflammatory effects as well as safety. Manufacturing on track with AD-214 set to be in clinic by Q1 2020
- ▶ Initial focus on treating Idiopathic Pulmonary Fibrosis (IPF) and other fibrotic diseases - high unmet clinical need. Market has history of early commercialisation transactions in fibrosis
- ▶ Platform technology for pipeline expansion and partnerships
- ▶ Targeting of 1-2 partnership transactions with upfront payments (and future milestone and royalty payments) within the next 6-12 months
- ▶ **Cash balance sufficient to fund the Company through pre-clinical and Phase 1 clinical studies for AD-214 and multiple value inflection points**

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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