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next generation protein therapeutics

# **i-bodies** – a new class of protein therapeutics to treat human disease

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# Corporate and investment summary

- A drug discovery and development company focused on using its proprietary technology platform to generate a 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-114 with significant pre-clinical validation
  - Fully funded for phase 1 development of lead fibrosis drug and i-body pipeline
  - Early commercialisation potential
  - Experienced team with strong track record of drug development and ability to deliver

| Capital structure | |
|---|---|
| ASX code | 1AD |
| Shares on issue* | 100m |
| Share price (14 Oct) | 22 cents |
| Market capitalisation | $22m |
| Current cash | $10m |
| **Total** | **100%** |

* 50.3m shares escrowed for 6-24 months

| Major Shareholders | % |
|---|---|
| Yuuwa Capital LP | 54.06 |
| Platinum Asset Management | 8.00 |
| Citycastle Pty Ltd | 5.31 |
| La Trobe University | 3.04 |
| Robin Beaumont | 1.84 |
| Other shareholders | 27.75 |
| Total | 100% |



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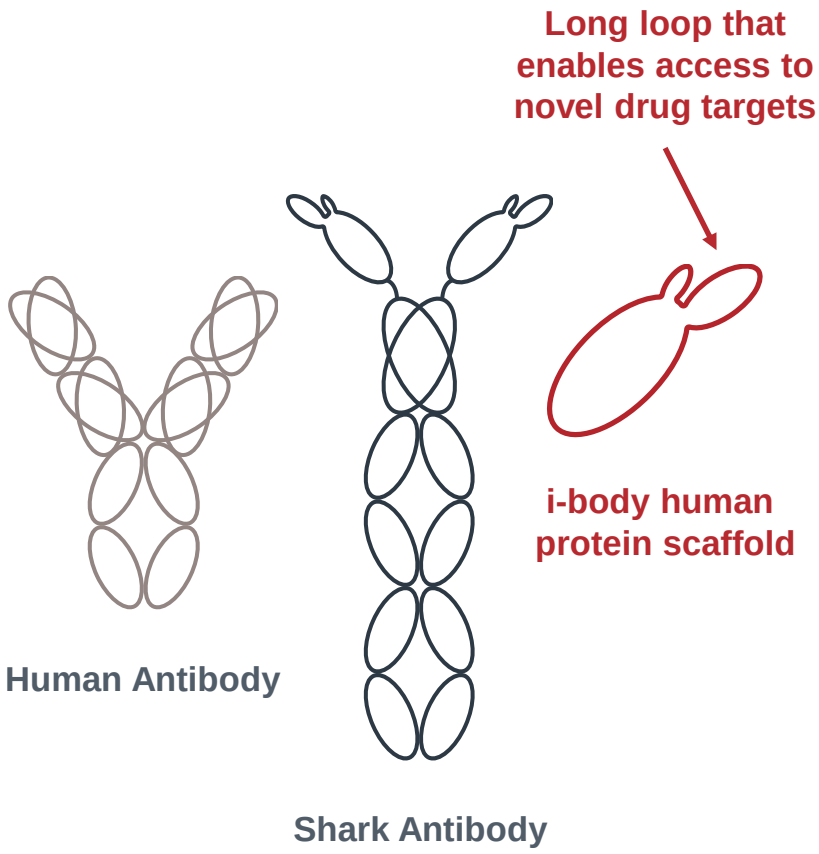
# i-body technology

AdAlta is developing a new technology platform that produces unique proteins known as i-bodies, that mimic the shape of shark antibody binding domain and engineers their key stability features into a human protein, for therapeutic intervention in disease.

The single domain antigen binding region of shark antibodies is extremely stable and has a long binding loop not present in either human or next generation antibodies.

## Advantages of i-bodies

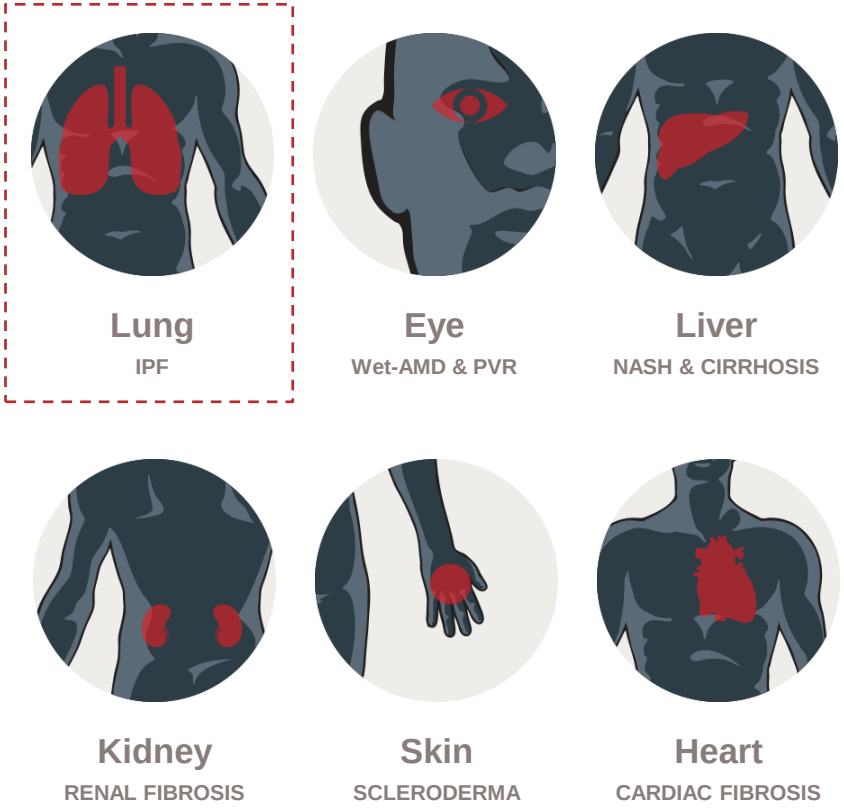
- High target specificity and high affinity for their target
- Small proteins; 10% the size of a typical human antibody
- Highly stable to proteases, high temperatures and low pH
- Long loop that can bind to a diverse range of therapeutically relevant targets including those that are difficult for current antibody therapies
- **Human protein** – reduced risk of immune response



# Fibrosis: unmet medical need with multiple indications

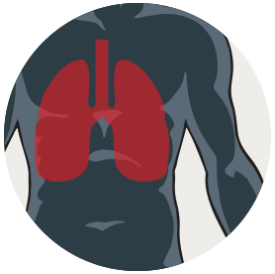
- Developing i-bodies as improved therapies for the treatment of fibrosis
  - a condition that is prevalent in 45-50% of all diseases
- Fibrosis can occur in many tissues of the body as a result of inflammation or damage
  - it can result in scarring of vital organs causing irreparable damage and eventual organ failure
- AdAlta's initial focus is on lung fibrosis

**Collectively fibrosis represents a large unmet clinical need**



# AD-114 lead program in Idiopathic Pulmonary Fibrosis (IPF)

- AD-114 is lead i-body candidate in pre-clinical development
  - Demonstrates both anti-fibrotic and anti-inflammatory activity in the lung
  - Important for arresting and modifying the disease and tackling the treatment of idiopathic pulmonary fibrosis (IPF); this is the primary indication



**Lung**

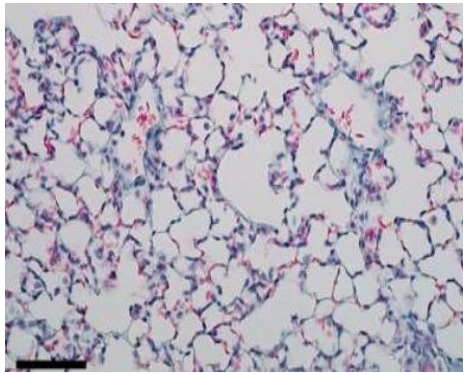
**IPF**

**Idiopathic Pulmonary Fibrosis**
A chronic, highly lethal and rare disease.
50-70% mortality rate
>135,000 people in US alone
World wide sales ~$4.2B  by 2020

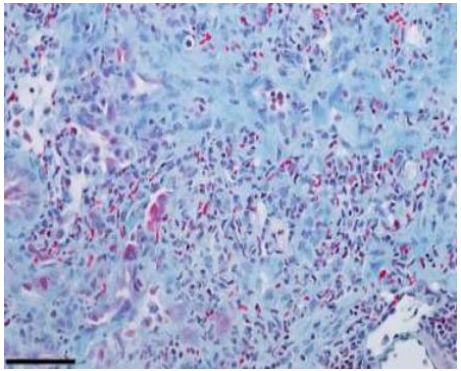
*Source: Evaluate Pharma, Orphan Drug Report 2015*

# AD-114 prevents lung fibrosis in disease models

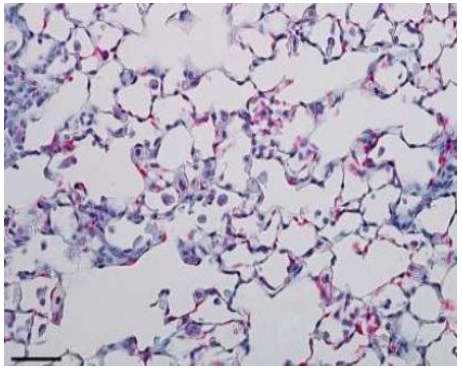
Extensive pre-clinical AD-114 studies have demonstrated positive *in vitro* (in the lab) and *in vivo* (in animals) data



**Normal lung tissue**



**IPF lung tissue**
(lung disease mouse model)



**IPF lung tissue + AD-114 dosed for 21 days**
(lung disease mouse model)

AD-114 reduces collagen content and inflammatory cell infiltration and demonstrates a similar architecture to that of the normal lung in the Bleomycin mouse model



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# AD-114 key advantages compared to existing IPF treatments

| Human tissue *In vitro* activity | No effect on normal tissue | Effect on diseased / IPF tissue |
|---|---|---|
| i-body AD-114 | ✔ | ✔ |
| Nintedanib (Boehringer) | ✗ | ✔ |
| Pirfenidone (Roche) | ✔ | ✗ |
| Other CXCR4 drug (Sanofi) | ✔ | ✗ |

- AD-114 has greater *in vitro* efficacy compared to the only approved therapies Nintedanib and Pirfenidone for IPF treatment
  - Existing IPF treatments have limited efficacy; either no effect or slow down disease progression i.e. no cure
- Novel mechanism of action compared to other drugs targeting CXCR4
- Very specific for diseased tissue and no effects on normal tissue
- AD-114 has both anti-fibrotic and anti-inflammatory effects

Novel mechanism of action for fibrosis treatment enabling a “first in class” therapy

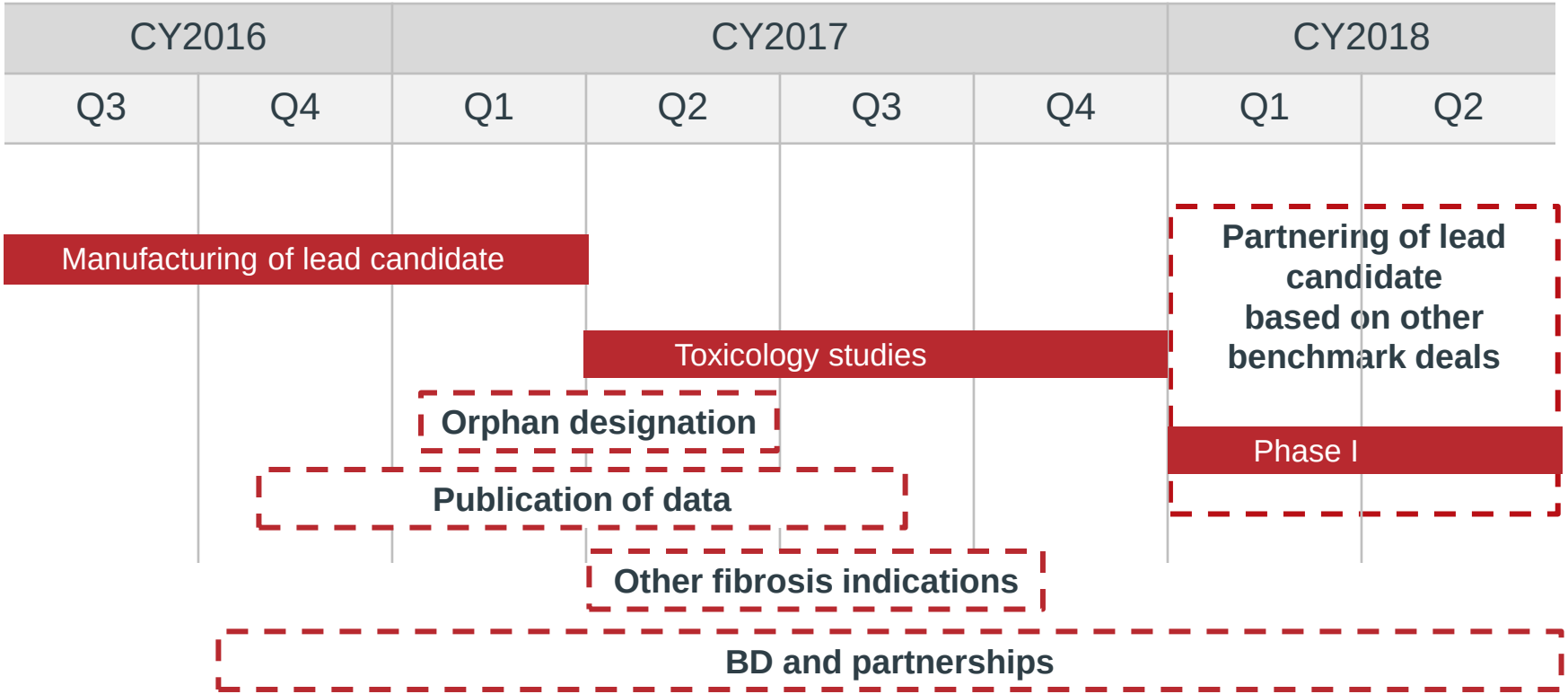
# Global market interest in fibrosis treatments

Recent transactions confirm that big pharma are actively acquiring fibrosis assets at an early stage – typically based on Phase I results

| Date | Company | Target | Acquired by | Deal value (US$) | Deal commentary |
|---|---|---|---|---|---|
| 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: Medtrack Pharma Intelligence, Informa (all IPF deals since 2011)*

# AD-114 development: key milestones



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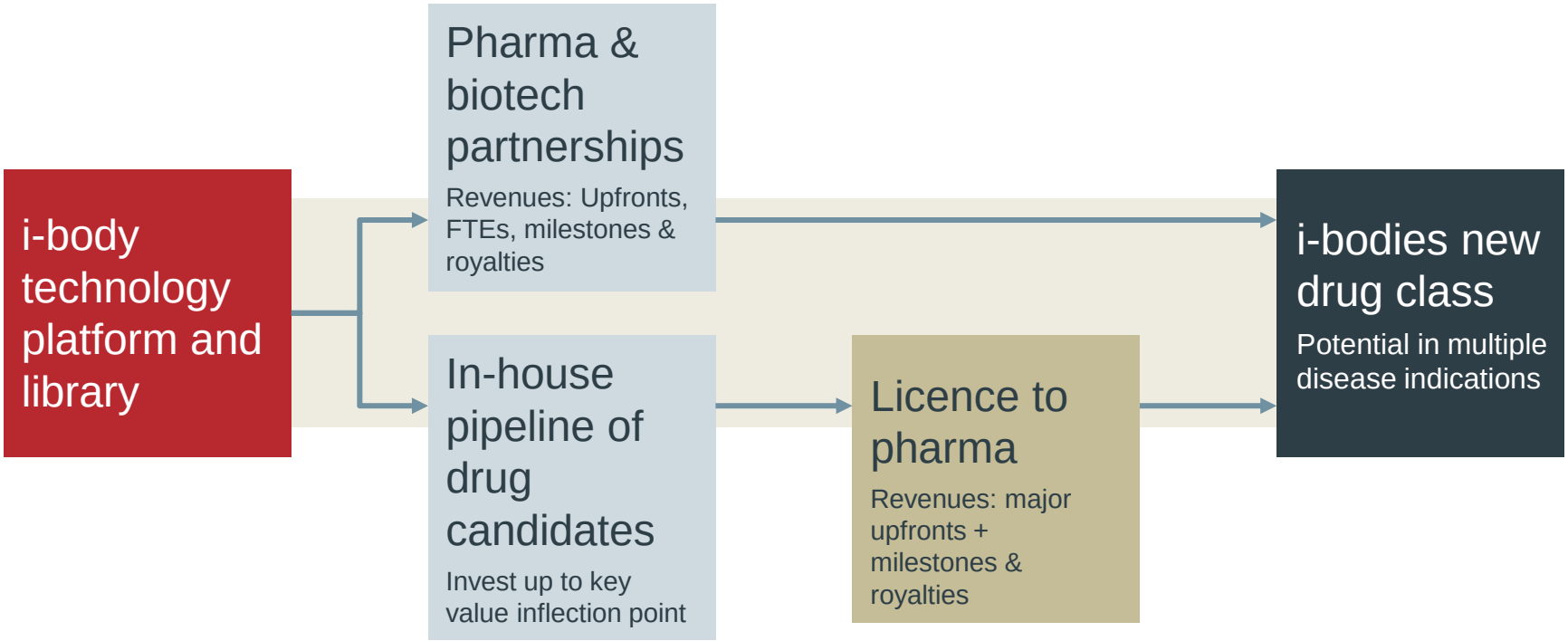
# Expected newsflow next 12 months

| | | |
|---|---|---|
| Q3 2016 | ✓ | Commence manufacturing of material for toxicology testing with FujiFilm Diosynth Biotechnologies |
| Q4 2016 | ▶ | Additional AD-114 IPF fibrosis data |
| | ▶ | Hypertrophic scarring animal results for AD-114 |
| | ▶ | Completion of evaluation of AD-114 with IPF clinicians Alfred Hospital |
| H1 2017 | ▶ | Orphan Drug Designation (US FDA) |
| | ▶ | Presentation at Biotech Showcase, San Francisco |
| | ▶ | Data available from AD-114 NASH animal studies |
| | ▶ | Manufactured material for toxicology testing available |
| H2 2017 | ▶ | Eye fibrosis additional data, funded by NHMRC development grant |
| | ▶ | Completion of other pre-clinical study animal models of AD-114 |
| | ▶ | Initial Kidney/Heart data available for AD-114 |
| | ▶ | AD-114 toxicology results |

# AdAlta business model – strategy to create value



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# Market benchmarks

| | | | |
|---|---|---|---|
| **Fibrosis lead AD-114** | adheron THERAPEUTICS<br>Sep-15 acquired by Roche<br>$105m + $475m milestones<br>phase I asset | Promedior<br>Aug-15 acquired by BMS<br>$150m + $1.25b milestones<br>phase IIa asset | Galecto Biotech AB<br>Nov-14 acquired by BMS<br>$444m<br>phase I asset |
| **Next gen antibodies** | arGEN-X<br>April-16 with Abbvie<br>$40m upfront + $645m milestones & royalties | pieris PHARMACEUTICALS<br>Dec -15 with Roche<br>$6.4m upfront + $410m milestones & royalties | Ablynx<br>Nov-15 with Novo-Nordisk<br>€9m upfront + €182m milestones & royalties) |
| **GPCRs** | HEPTARES therapeutics<br>Acquired Feb-15 by Sosei<br>$400m Phase Ib asset + 7 pre-clinical leads | receptos<br>Acquired by Celgene July-15<br>$8b Ph III, Ph II and GPCR platform | Ablynx<br>April-16 with Boehringer<br>€8m payment for Ph1 GPCR nanobody (€125m milestones & royalties) |



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# Management and Board in place to deliver strategy

**Sam Cobb: Founding CEO and Director**

Extensive experience in raising equity and commercialisation of technology

**Dr Mick Foley: Founding CSO**

Expert in phage display for screening of the i-body library

**Dr Paul MacLeman: Chairman**

Managing Director of a ASX listed IDT Australia Ltd

Founded biologics companies, experienced ASX listed executive

**Dr John Chiplin: Independent Director**

Managing Director of acquired antibody company Arana Therapeutics

**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

## Internationally recognised SAB with proven track record of drug development

**David McGibney: pre-clinical and clinical advisor**

20 years with Pfizer, including Head of European R&D, developed 10+ blockbuster drugs

**Brian Richardson: drug discovery and development expert**

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

**John Westwick: pulmonary drug discovery and development**

Over 14 years experience at Novartis, head of respiratory drug discovery, with five product launches and 13 products currently in the clinic



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# AdAlta investment summary

- Powerful proprietary technology platform to develop a pipeline of i-bodies for the treatment of a wide range of human diseases
- Initial focus on treating Idiopathic Pulmonary Fibrosis and other fibrotic diseases - high unmet clinical need
- Advanced lead candidate with significant pre-clinical validation of AD-114 demonstrating anti-fibrotic and anti-inflammatory effects
- Early commercialisation opportunity
- Experienced management and Board to drive AD-114 development and secure technology platform partnerships and product licensing deals
- IPO August 2016 raised $10M to meet major milestones: clinical trials of AD-114 in fibrosis and development of i-body pipeline