

# 2020 Annual General Meeting CEO Presentation

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18 September 2020

Amplia Therapeutics Limited



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# Company Highlights



Developing small molecule drugs against Focal Adhesion Kinase (FAK) for two, significant disease areas:

- **cancer** – combination therapy in hard-to-treat solid tumours
- **fibrosis** – prevention and treatment

Orphan Drug Designations (ODDs) for both pancreatic cancer and idiopathic pulmonary fibrosis

Range of commercial opportunities for partnering, licensing and co-development

First Phase 1 clinical trial starting in October 2020

Data from Phase 1 will be relevant for multiple cancer and fibrotic disease indications

Investigational New Drug (IND) designation and Phase 2 clinical trial program targeted in 2021



# Amplia FAKi's provide a broad opportunity set

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**AMP945** and **AMP886** provide Amplia with several commercial opportunities

Amplia is taking three approaches realise these opportunities:

- 1. take AMP945 into clinical development** for pancreatic cancer and idiopathic lung fibrosis (both granted Orphan Drug Designations by the FDA)
- 2. license, partner or co-develop** other applications for AMP945 including other cancer combination therapies, fibrotic diseases, uveal melanoma
- 3. seek partners** for co-development or licensing of AMP886 to treat wet AMD, cancer or fibrotic diseases



# Company snapshot<sup>1</sup>



Shares	106.3M
Market cap	\$16.0M
Options	14.1M
Cash <sup>2</sup>	\$4.0M
Last qtr burn <sup>3</sup>	(\$0.4M)

Listed May 2018 (RTO)

Headquarters Melbourne

Board  
 Warwick Tong (Chair)  
 John Lambert (MD)  
 Robert Peach (NED)  
 Chris Burns (NED)

Substantial institutional holders  
 Platinum – 16.2%  
 Blueflag Holdings – 7.1%

<sup>1</sup> as at 15 Sep 2020

<sup>2</sup> cash held at 31 Aug 2020

<sup>3</sup> quarter ending 30 Jun 2020



price	\$0.15
12mth high - low	\$0.22 - \$0.04
av. daily volume	260,000

# Achievements in FY2020

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**Apr 2019** – European patent covering AMP945 until 2034 granted

**Jun 2019** – Preliminary dose-finding animal toxicology studies completed

**Jun 2019** – Dr John Lambert appointed as CEO

**Jul 2019** – Preclinical data on use of AMP945 to treat squamous cell carcinoma reported

**Jul 2019** – Placement and rights issue raising \$1.2M at \$0.10/share

**Aug 2019** – Positive data demonstrating high level of selectivity of AMP945 for FAK target

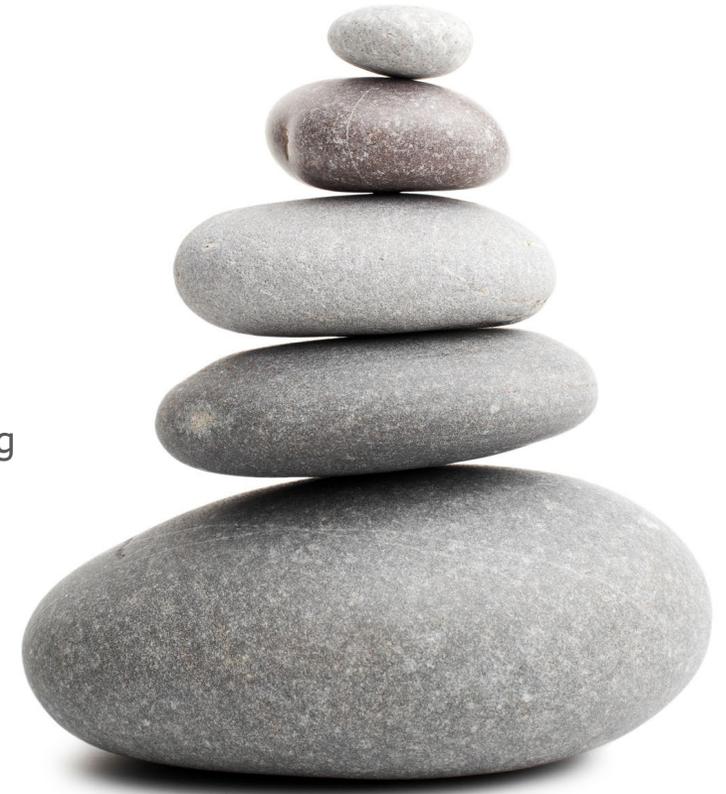
**Sep 2019** – Kilogram-scale batch of clinical grade AMP945 released for use in clinical testing

**Jan 2020** – Placement raising \$930K at \$0.07/share corner-stoned by Platinum

**Jan 2020** – Restructure and streamlining of Board completed

**Feb 2020** – Prof. Paul Timpson joins Scientific Advisory Board

**Mar 2020** – Orphan Drug Designation awarded for pancreatic cancer



# Achievements since 30 Mar 2020



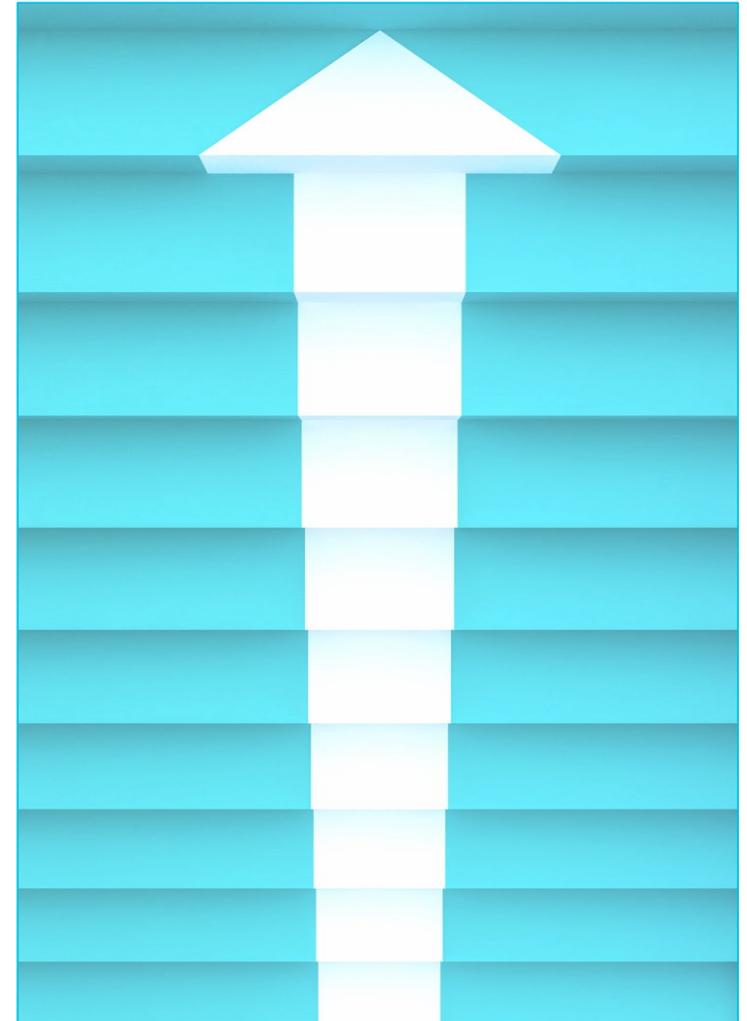
**May 2020** – Orphan Drug Designation awarded for idiopathic pulmonary fibrosis

**Jun 2020** – Completed toxicology studies required to support Phase 1 clinical trial

**Jul 2020** – Rights Issue raising \$4.0M at \$0.10/share

**Aug 2020** – Dr Mark Devlin appointed as Chief Scientific Officer

**Sep 2020** – Received ethics clearance to conduct Phase 1 trial in healthy volunteers



# Phase 1 Trial of AMP945



## First clinical trial of AMP945 will commence dosing in October 2020:

- GMP clinical manufacture complete (kg scale)
- Preclinical toxicology studies complete
- Nucleus Network selected to manage trial being conducted at the Alfred Hospital
- Clearance received from Human Research Ethics Committee (HREC)

## Phase 1 safety trial of orally administered AMP945 in healthy volunteers:

- Single Australian site
- 64 volunteers, cost of ~\$2M
- Single ascending dose (SAD) and multiple ascending dose (MAD)
- Forecast 6-9 months to complete

## Purpose of the trial:

- Initial assessment of the clinical safety and pharmacokinetics of AMP945
- Platform for future clinical studies in cancer and fibrosis patients



# AMP945 – treatment of solid tumours

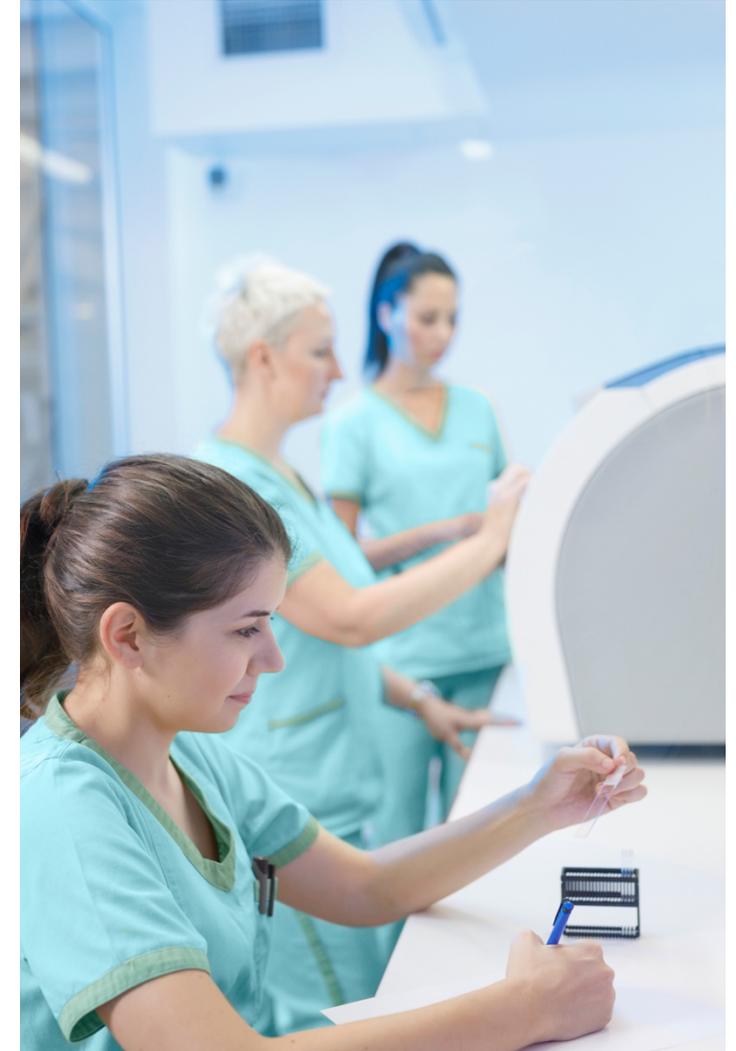


## Pancreatic cancer

- FDA Orphan Drug Designation for AMP945 in the treatment of pancreatic cancer received in March 2020
- Collaboration with Prof. Paul Timpson at the Garvan Institute to assess novel dosing regimes and combination therapies for pancreatic cancer
- These studies will help guide future clinical trials in patients with pancreatic cancer

## Other cancers

- Amplia plans to perform preclinical studies to evaluate combining AMP945 with other cancer drugs including MEK inhibitors
- These studies will inform the structure and design on Amplia's Phase 2 clinical program



# FAK in Idiopathic Pulmonary Fibrosis



Idiopathic Pulmonary Fibrosis (IPF) is a devastating, progressive disease caused by the build-up of fibrotic tissue in the lung which affects 3M people worldwide, including 130,000 in the US

Left untreated, the median survival time is 2-3 years, with lung transplantation the only treatment option currently available that improves outcomes

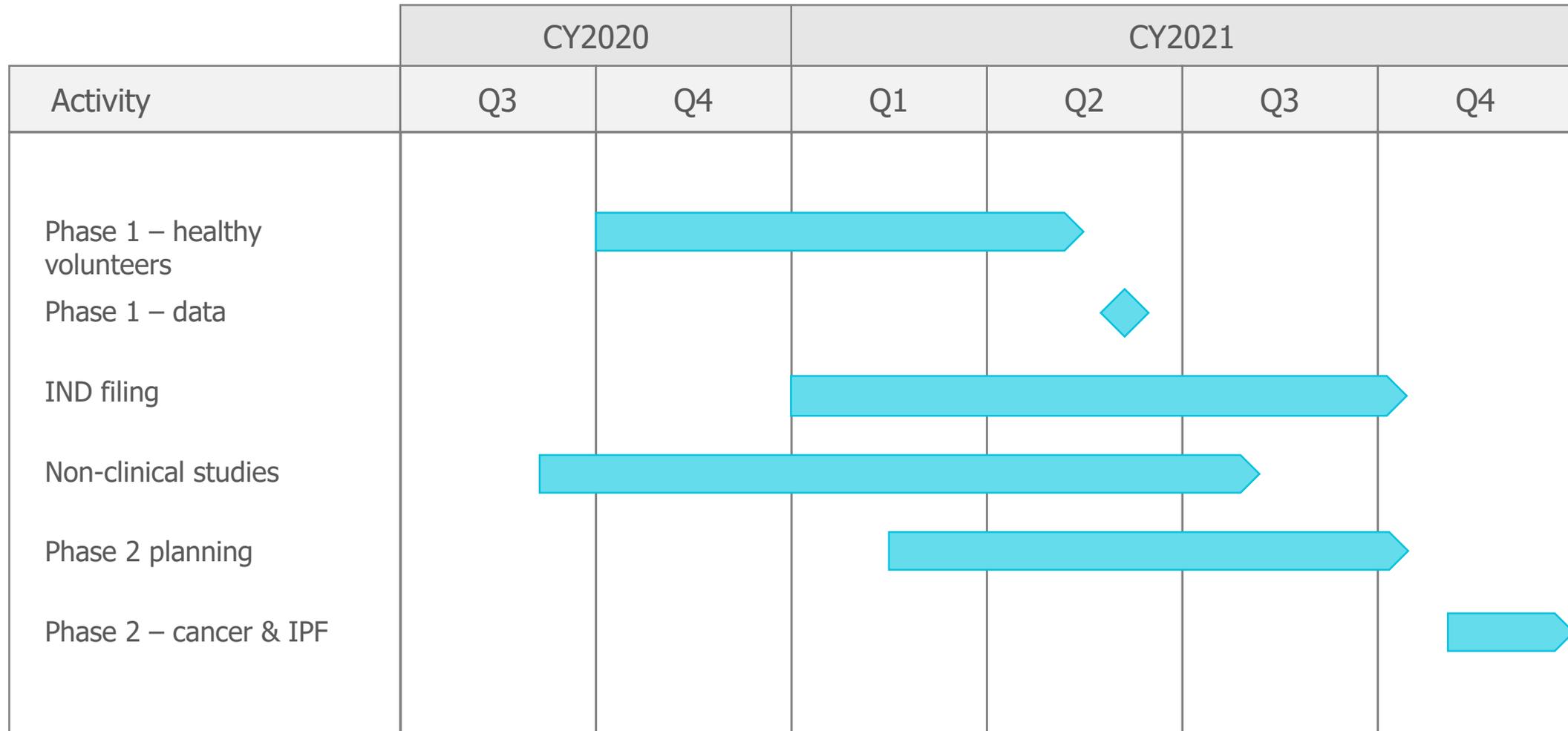
Approved antifibrotic drugs (pirfenidone and nintedanib) slow the progression of the disease by ~50%, but are unable to prevent the eventual loss of lung function:

- increase median life expectancy by 2½ years
- quality of life for end-stage disease remains very poor

FAK has a pivotal role in the biochemical pathways regulating the development and progression of fibrosis in the lungs



# AMP945 – 18-month development plan



# Upcoming targeted milestones

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- **Oct 2020** - Initiate dosing for SAD arm of Phase 1 clinical trial
- **Dec 2020** - Initiate dosing for MAD arm of Phase 1 clinical trial
- **Q2 2021** - Selection of first indication for Phase 2 based on preclinical combo studies
- **Q2 2021** - Headline data from both SAD and MAD arms of Phase 1 clinical study
- **Q3 2021** - File Investigational New Drug (IND) Application for AMP945 with FDA
- **Q4 2021** - Receive IND designation for AMP945
- **H2 2021** - Initiate Phase 2 program for AMP945 in cancer and IPF





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