

ASX RELEASE

21<sup>st</sup> October 2020

**Amplia Presents at Reach Market Services “Meet the CEO”**

Amplia Therapeutics Limited (ASX: ATX) (“Amplia” or the “Company”) is pleased to provide the CEO’s Presentation which will be made today at 12 p.m. AEDT via a live webinar hosted by Reach Markets.

To participate, please register at: [www.reachmarkets.com.au/meet-the-ceos](http://www.reachmarkets.com.au/meet-the-ceos)

This ASX announcement was approved and authorised for release by the Board of Amplia Therapeutics.

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**For Further Information**

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**About Amplia Therapeutics Limited**

Amplia Therapeutics Limited is an Australian pharmaceutical company advancing a pipeline of Focal Adhesion Kinase (FAK) inhibitors for cancer and fibrosis. FAK is an increasingly important target in the field of cancer immunology and Amplia has a particular development focus in pancreatic and ovarian cancer. FAK also plays a significant role in a number of chronic diseases, such as idiopathic pulmonary fibrosis (IPF).

# Amplia Therapeutics

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October 2020

Amplia Therapeutics Limited



# Disclaimer

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# Company highlights



Developing small molecule drugs for two, significant disease areas:

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

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

First Phase 1 clinical trial started 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's FAKi's provide a promising opportunity set

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Amplia is developing Amplia's experimental drug candidates offer several commercial opportunities

Amplia is taking three approaches to realize these opportunities:

- 1. 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 including other cancer combination therapies, fibrotic diseases, uveal melanoma



# Company snapshot<sup>1</sup>



Shares 107.4M  
 Market cap \$29.0M  
 Options 14.1M  
 Cash <sup>2</sup> \$4.0M  
 Last qtr burn <sup>3</sup> (\$0.4M)

Listed May 2018

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 19 Oct 2020

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

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



price \$0.27  
 12mth high - low \$0.27 - \$0.05  
 av. daily volume 255,000

# Achievements to date in 2020

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- **Jan 2020** – Placement raising \$930K at \$0.07/share corner-stoned by Platinum
- **Jan 2020** – Completed restructure and streamlining of Board
- **Feb 2020** – Paul Timpson joins Scientific Advisory Board
- **Mar 2020** – Orphan Drug Designation awarded for pancreatic cancer
- **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** – Mark Devlin appointed as Chief Scientific Officer
- **Sep 2020** – Receives ethics clearance to conduct Phase 1 trial in healthy volunteers
- **Oct 2020** – First volunteers dosed in Phase 1 trial



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# Cancer Treatments

# Why cancer drugs often do not work

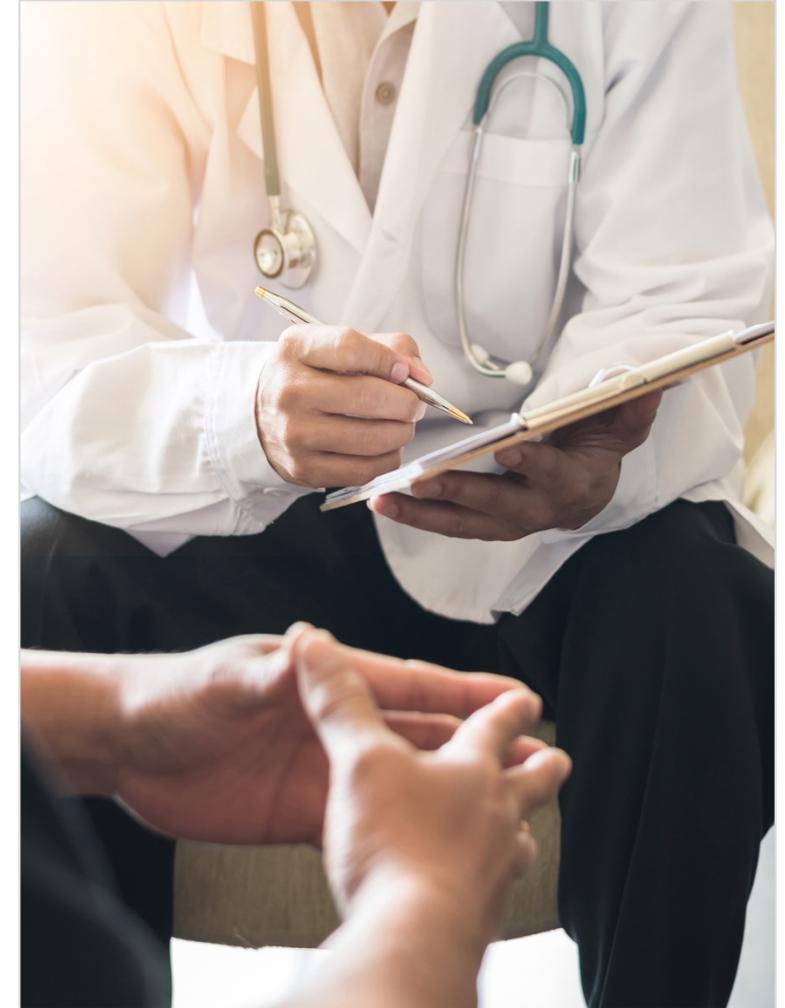


Pharmaceutical strategies to treat cancer:

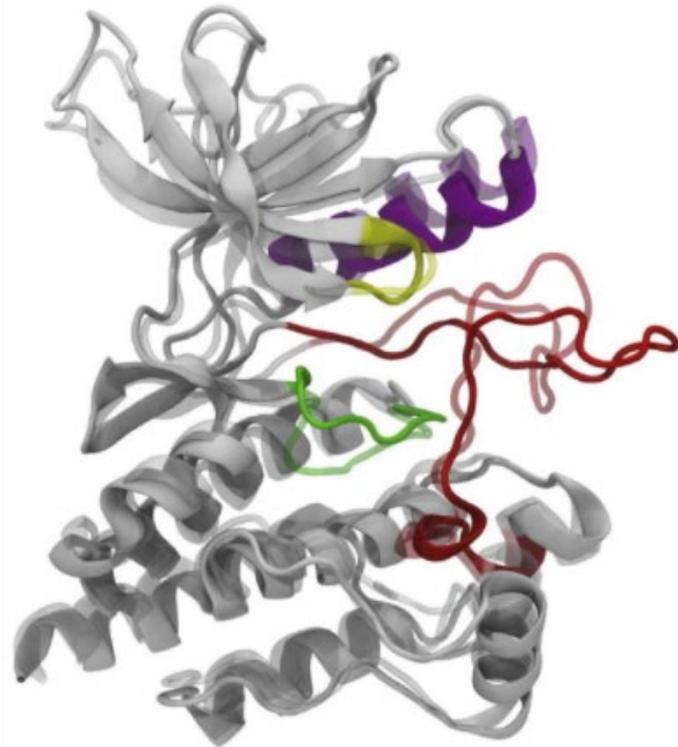
1. **cytotoxic drugs:** target rapidly dividing cancer cells
2. **targeted drugs:** block specific proteins elevated in cancer cells
3. **anti-angiogenic drugs:** block new blood vessels which feed the cancer
4. **immuno-oncology (I-O) drugs:** activate the immune system to attack the cancer

The effectiveness of these drugs limited by tumour 'defence' mechanisms which:

- allow cancers to migrate spread to other sites in the body
- generate resistant cancer cells
- physically shield the cancer from the immune system
- dampen the immune system's response against the cancer



# Amplia's drugs target cancer defence mechanisms



Focal Adhesion Kinase (FAK)

Fibrosis
FAK helps establish and maintain the dense, fibrotic tissue around cancers
Immune activity
FAK triggers the release of signaling molecules (cytokines) which suppress the immune system
Cell migration
FAK regulates cell migration that is involved in the formation of secondary cancers (metastases)

- elevated levels of FAK in cancers are associated with poor outcomes
- increased FAK activity is found in many difficult-to-treat, solid cancers
- FAK is involved in many cancer defence mechanisms that reduce the effectiveness of cancer drugs
- Amplia is investigating the use of FAK inhibitors (FAKi's) to disrupt cancer defence mechanisms, making them more responsive to cancer drugs

**Remove the shield. Deliver the blow.**

# AMP945 – treatment of solid cancers

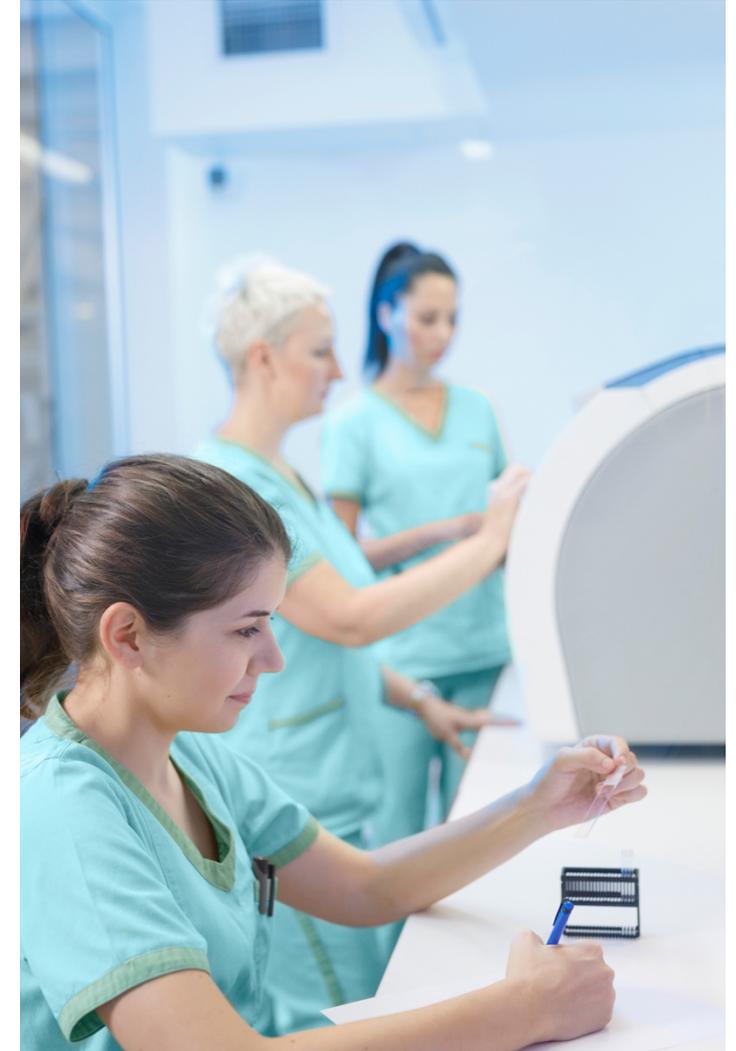


## Pancreatic cancer

- 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 combination therapies for pancreatic cancer
- These studies will help guide future clinical trials in patients with pancreatic cancer

## Other cancers

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



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# Fibrosis Treatments



# 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
- Current drugs increase median life expectancy by 2½ years

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

**Industry standard nonclinical disease model shows that AMP945 both treats and prevents lung fibrosis**

- Awarded Orphan Drug Designation by US FDA May 2020



# Potential for anti-fibrotic therapy beyond IPF



## **Microbial respiratory infections**

Many bacterial and viral infections damage lung tissue or induce an inflammatory responses that results in scarring and fibrosis which can have long term impacts on respiratory function

## **Silicosis**

Silicosis is an industrial lung disease in which dust particles from sand, rock and minerals containing silica are inhaled and cause extensive scarring in the lungs making it hard to breathe

## **Non-alcoholic steatohepatitis (NASH)**

Scarring of the liver caused by long-term inflammation and the build up of fatty tissues and is the most common chronic liver condition in Western populations (12% prevalence in the US)



# Status and Outlook

# Phase 1 Trial of AMP945



**First clinical trial of AMP945 commenced dosing in October 2020**

**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:**

- Assessment of the clinical safety and absorption of AMP945
- Platform for future clinical studies in cancer and fibrosis patients



# Upcoming targeted milestones

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- **Nov 2020** – Significant research collaboration
- **Dec 2020** – Start dosing of multi-dose 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 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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