

ASX RELEASE

8 November 2021

### Amplia Entitlement Offer Investor Presentation

Amplia Therapeutics Limited (ASX: ATX) (“Amplia” or the “Company”) has today announced a capital raising consisting of:

- a Placement to institutional and sophisticated investors to raise \$5.4m; and
- a 1 for 4, fully underwritten pro-rata non-renounceable Entitlement Offer to raise \$7.0m

The New Shares issued under the Placement and the Entitlement Offer will be offered with free attaching options on the basis of 1 option for every 3 New Shares issued.

The attached Investor Presentation relates to this capital raising process.

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

- End -

#### For Further Information

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CEO and Managing Director  
[john@ampliatx.com](mailto:john@ampliatx.com)  
[www.ampliatx.com](http://www.ampliatx.com)

#### 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 Investor Slide Deck

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8 November 2021

Amplia Therapeutics Limited



# Disclaimer



This investor presentation (Presentation) has been prepared by Amplia Therapeutics Limited ACN 165 160 841 (**Amplia** or the **Company**) and is dated 8 November 2021. This Presentation has been prepared in relation to a 1 for 4 pro rata non-renounceable entitlement offer of new ordinary fully paid shares in Amplia (**Entitlement Offer**) and a placement of shares to professional and sophisticated investors (**Placement**). The Entitlement Offer and Placement are referred to as the **Capital Raising** or the Offer. For every three shares issued under the Offer, investors will be offered one free attaching option exercisable at \$0.28 and expiring on 31 December 2023 (**Options**). The Entitlement Offer and the offer of Options to Placement participants is being made under a prospectus issued under section 713 of the Corporations Act 2001 (Cth) (**Corporations Act**) to be dated the same date as this Presentation (**Prospectus**).

This Presentation contains summary information about Amplia and its activities as at the date of this Presentation. The information in this Presentation is of a general nature and does not purport to be complete or comprise all information which a shareholder or potential investor may require in order to determine whether to deal in Amplia shares or that would be required in a prospectus or product disclosure statement prepared in accordance with the requirements of the Corporations Act. It should be read in conjunction with Amplia's other periodic and continuous disclosure announcements lodged with the Australian Securities Exchange, which are available at [www.asx.com.au](http://www.asx.com.au).

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## **Past performance**

Past performance information, including past share price performance, should not be relied upon as an indication of future performance.

## **Investment risk**

An investment in Amplia shares is subject to investment and other known and unknown risks, some of which are beyond the control of the Company. Amplia does not guarantee any particular rate of return or the performance of its shares.

## **Future performance**

This Presentation contains certain references to forecasts, estimates, assumptions and other forward-looking statements and statements regarding the intent, belief or current expectations of Amplia. The words "likely", "expect", "aim", "should", "could", "may", "anticipate", "predict", "believe", "plan" and other similar expressions are intended to identify forward-looking statements.

Forward-looking statements, opinions and estimates provided in this Presentation are based on assumptions and contingencies which are subject to change without notice, as are statements about market and industry trends, which are based on interpretations of current market conditions. Forward-looking statements are provided as a general guide only and should not be relied upon as an indication or guarantee of future performance. This Presentation contains such statements, which are subject to risk factors associated with an investment in Amplia. The Company believes that these statements are reasonable, but they may be affected by a range of variables which could cause actual results or trends to differ materially.

Forward-looking statements involve known and unknown risks, uncertainties and assumptions and other important factors that could cause actual results, performance or achievements of Amplia to be materially different from future results, performances or achievements expressed or implied by such statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this Presentation.

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## **Financial data**

All references to dollars (\$) and cents are to Australian currency, unless otherwise stated.

## **Market and industry data**

This Presentation contains data relating to the industries, segments and markets in which the Company operates (**Industry Data**). Unless otherwise stated, this information has been prepared by Amplia using both publicly available data and its own internally generated data. Amplia's internally generated data is based on estimates and assumptions that the directors and management of the Company believe are reasonable. In addition to the Industry Data, the Presentation contains third party market data, estimates and projections. There is no assurance regarding the accuracy of such information and the third party information, and the Industry Data, has not been independently verified by Amplia.

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# Overview



# Investment highlights



- Two Focal Adhesion Kinase (FAK) inhibitors with activity profiles supporting multiple therapeutic opportunities
  - Origins in Cancer Therapeutics Cooperative Research Centre
  - Clear differentiation from other FAK inhibitors in development
- AMP945 has completed a Phase 1 trial in 56 volunteers and was shown to have an excellent safety and tolerability profile
- AMP886 is in preclinical development and the Company has recently secured an extension to the time allowed before it enters clinical trials
- For AMP945, Phase 2 clinical trials are planned in cancer and fibrosis
- Highly experienced management team, Board and clinical advisor network
- Solid track record in delivery against timelines and budgets
- Collaboration in place with world leading FAK-biology group at the Garvan Institute
- Funds raised from the Offer will support the conduct of a Phase 1b/2a clinical trial of AMP945 in patients with pancreatic cancer



# Board of Directors



## Warwick Tong

MB, ChB, MPP, GAICD  
Non-Executive

Independent Chairman

- GSK (NZ, London, Singapore)
- ex-CEO & Director of Cancer Therapeutics CRC (Melbourne)



## John Lambert

PhD, GAICD  
MD & CEO

- Biota Pharmaceuticals
- Medicines Development for Global Health
- University Melbourne, ANU, Harvard University



## Jane Bell

LLM, LLB, BEc  
Non-Executive  
Independent  
Director

- Deputy Chair, Monash Health
- Administrative Appeals Tribunal, Member
- NED UCA Funds Management 2014-2021



## Robert Peach

PhD  
Non-Executive  
Independent  
Director

- Co-founder Receptos (acquired by Celgene for \$7.8B in 2015)
- Apoptos, Biogen Idec, IDEC, Bristol Myers Squibb

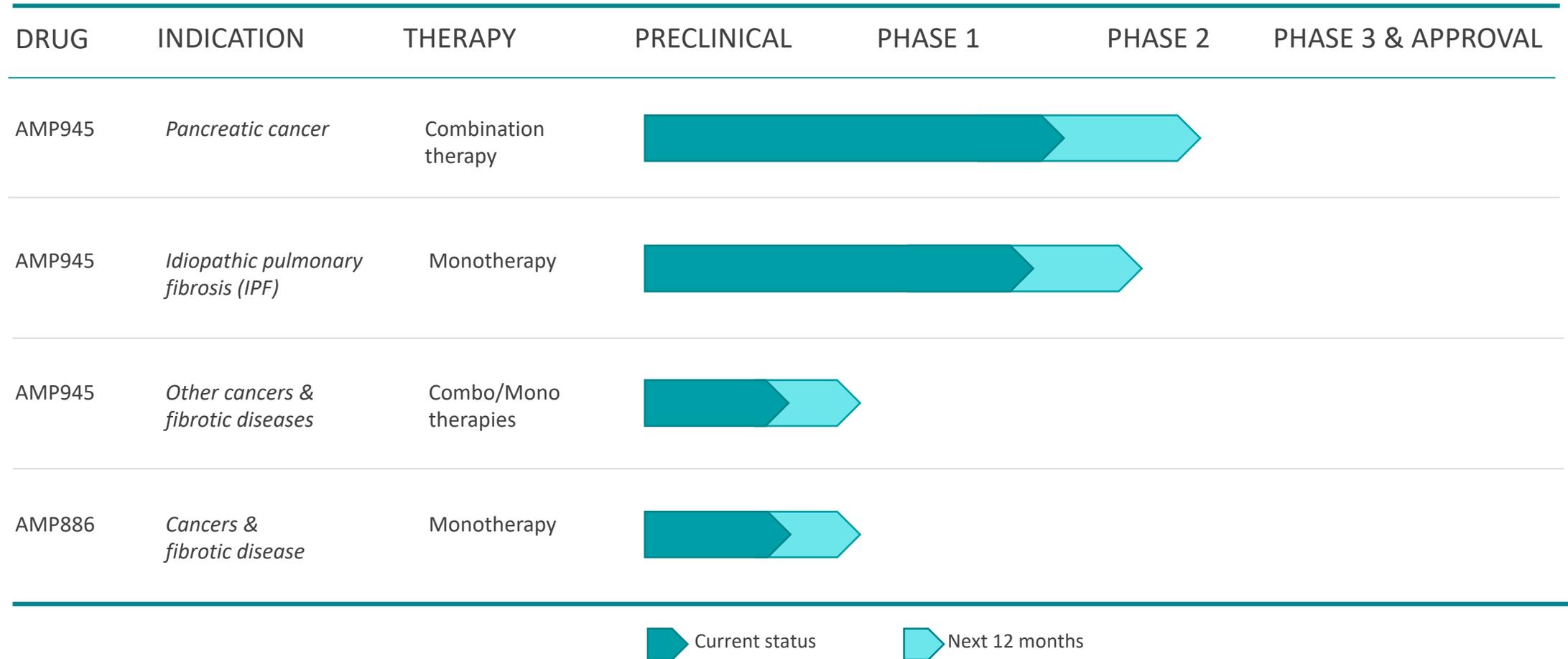


## Chris Burns

PhD, FRSC, GAICD  
Non-Executive  
Independent  
Director

- Pfizer (UK), Ambri (Head of Chemistry), University of Sydney
- Cytopia (Head Medicinal Chemistry, Research Director)

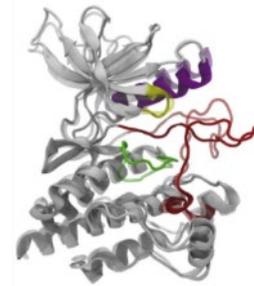
# Amplia's pipeline



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# About focal adhesion kinase (FAK)

# FAK: a drug target with multiple therapeutic opportunities



Focal Adhesion Kinase (FAK)

## Indication

**FIBROTIC DISEASES**

**SOLID CANCERS**

## Opportunities

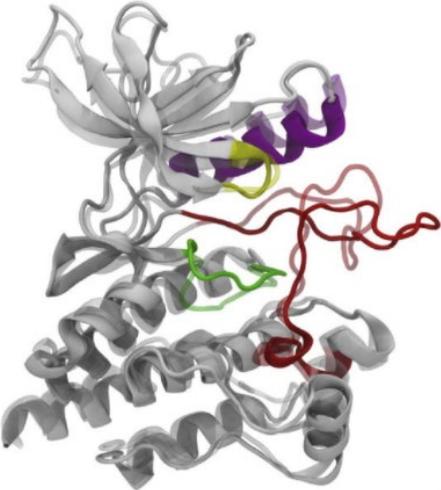
### Monotherapy

- Lung fibrosis
- Liver fibrosis (NASH)
- Renal fibrosis
- Wound healing

### Combination Therapy

- Pancreatic cancer
- Ovarian cancer
- Breast cancer
- Hepatocellular carcinoma
- Melanoma
- Gastric cancer
- Lung cancer

# Inhibiting FAK targets cancer's defence mechanisms



Focal Adhesion Kinase (FAK)

Fibrosis
FAK helps establish and maintain the dense, fibrotic tissue around cancers
Immune response
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)



FAK is involved in many cancer defence mechanisms that reduce the effectiveness of cancer drugs

Increased FAK activity is found in many, difficult-to-treat, solid cancers

Elevated levels of FAK in cancers are associated with poor outcomes



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.**

# Amplia's target indications



## Pancreatic Cancer

- 60,000 new diagnoses and 48,000 deaths from pancreatic cancer in the US each year\*
- Difficult-to-treat cancer that is often surrounded by a protective, fibrotic stromal layer
- Less than 20% of patients eligible for surgery – chemo main treatment
- Few new therapies approved and most patients treated with cytotoxic chemotherapy drugs

AMP945 was awarded Orphan Drug Designation by the US FDA for use in treating Pancreatic Cancer in March 2020

\* [American Cancer Society](#), 2021

## Idiopathic Pulmonary Fibrosis (IPF)

- Affects 130,000 in the US and ~3M people worldwide\*\*
- Devastating, progressive disease caused by the build up of fibrotic tissue in the lungs
- Only two drugs approved which slow progression but are unable to stop the disease
- With treatment, median survival time is 3-5 years

AMP945 was awarded Orphan Drug Designation by the US FDA for use in treating Idiopathic Lung Fibrosis in May 2020

\*\* [The American Journal of Managed Care](#), 2021

# Why target pancreatic cancer and pulmonary fibrosis?



Pancreatic Cancer	Pulmonary Fibrosis
Preclinical data provides rationale for clinical study in this disease	
AMP945 enhances the efficacy of standard of care in pancreatic cancer models	AMP945 reduces fibrosis in the bleomycin model of lung fibrosis
Gateway indication to other fibrotic cancers/fibrotic diseases	
Ovarian cancer; Breast cancer; Hepatocellular carcinoma; Melanoma; Gastric cancer; Lung cancer	Liver fibrosis (NASH); Renal fibrosis; Wound healing
Unmet need and partnering landscape	
Unmet need where incremental improvements to standard of care will be widely accepted	Unmet need with limited treatment options available
Treatments are expected to evolve with kinase inhibitors becoming a more significant drug class in this indication	Vibrant partnering landscape for fibrosis drugs

# Product differentiation



Company	FAKi	FAK Selectivity	Pancreatic Cancer		Fibrosis
			First Line	Combo with	
Amplia	AMP945	✓✓✓	✓	Gemcitabine/Abraxane®	✓
Verastem	defactinib	✓	✗	Pembrolizumab	✗
InxMed	IN10018	✓✓	✗	Pembrolizumab KN046	✗

**Amplia's AMP945 is differentiated from its competitors by**

1. Exquisite FAK selectivity
2. Pairing with first-line therapy
3. Combination with gemcitabine/Abraxane, an approved pancreatic cancer therapy
4. AMP945's clinical safety profile is consistent with development in fibrosis indications

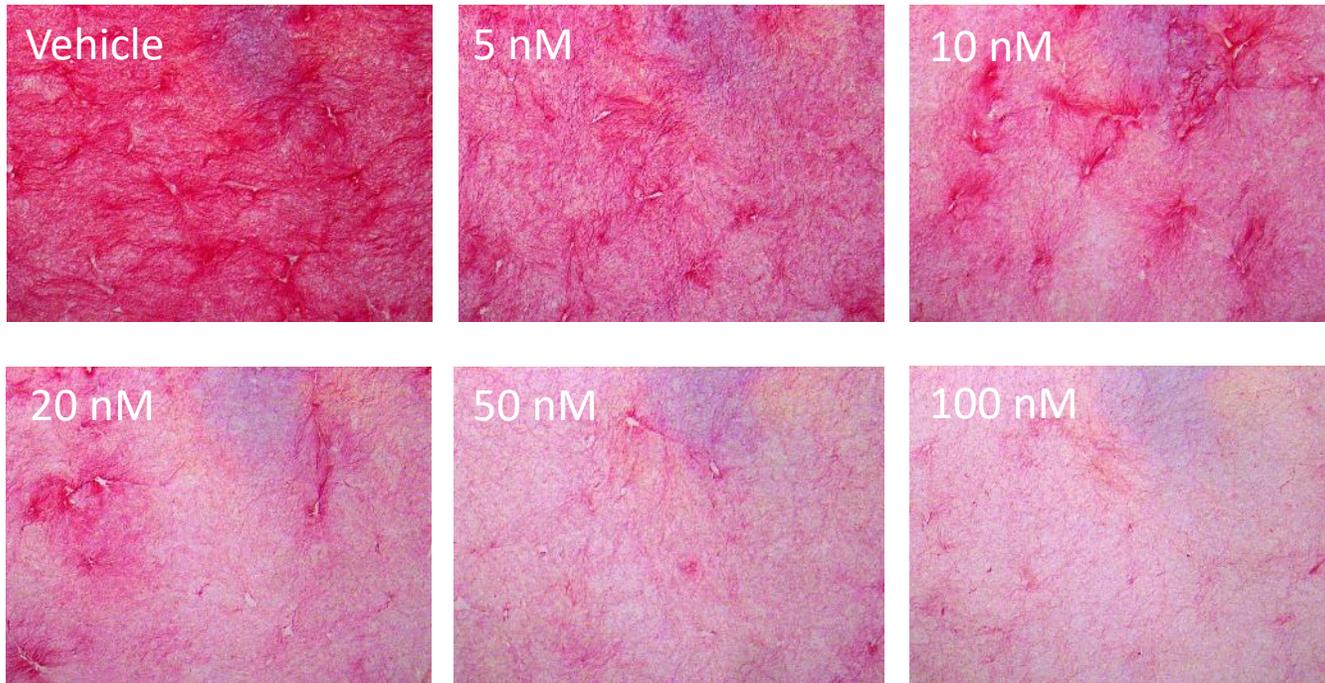
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# Rationale for Phase 2 clinical trials of AMP945

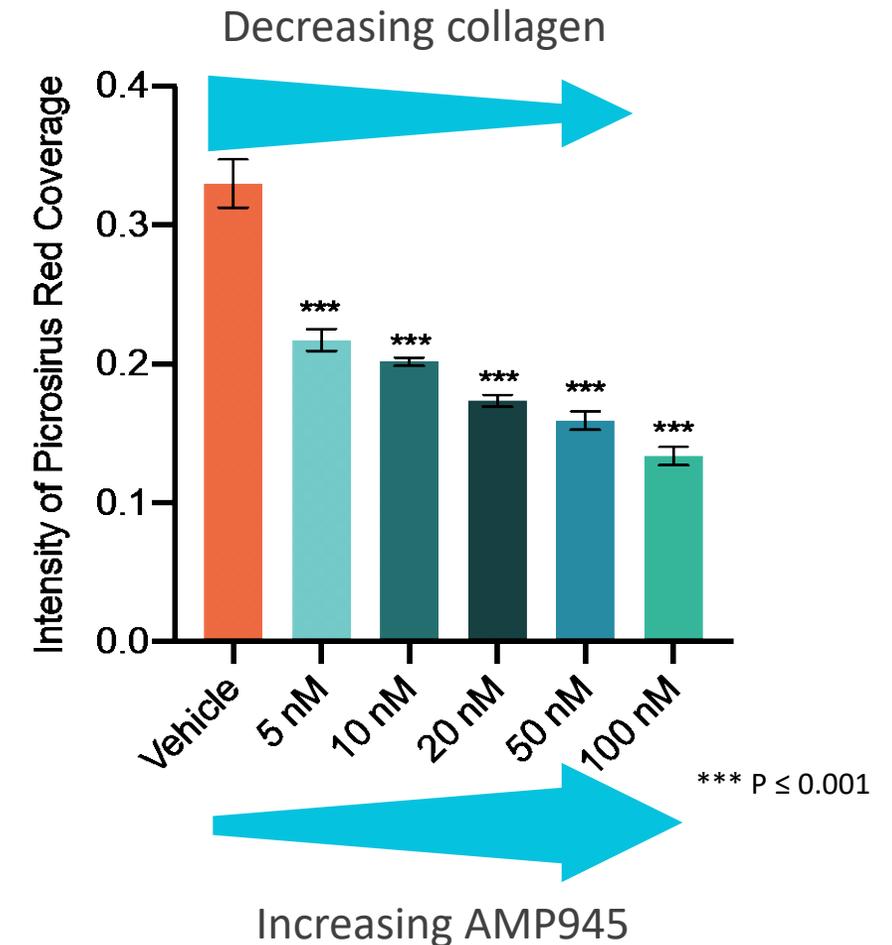
# AMP945 inhibits deposition of collagen *in vitro*



Picosirius red staining for total collagen

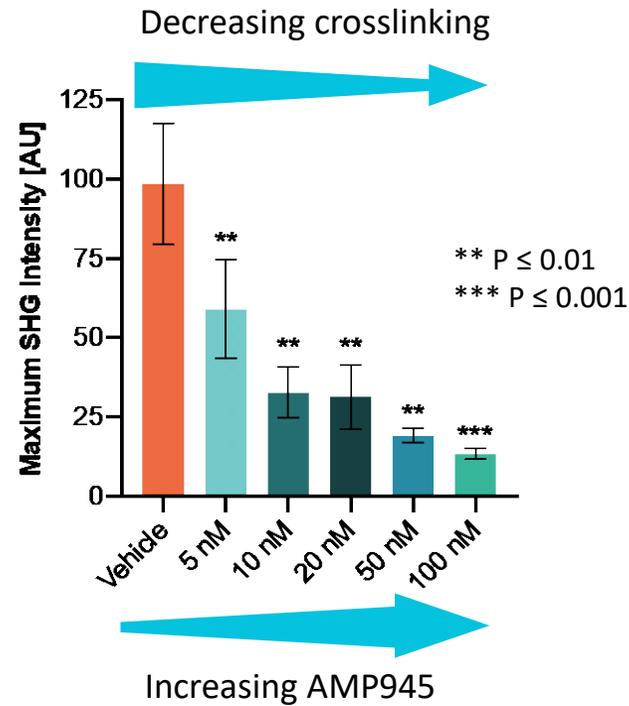
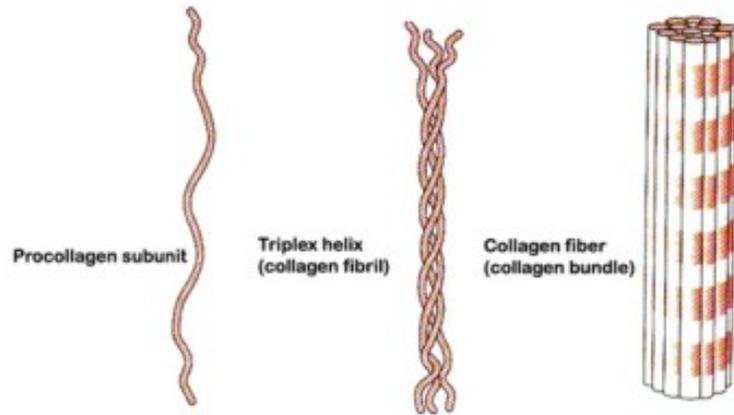


- Fibroblasts lay down new collagen
- Collagen is a key component of fibrotic tissue
- AMP945 inhibits fibroblasts, causing less new collagen to be deposited

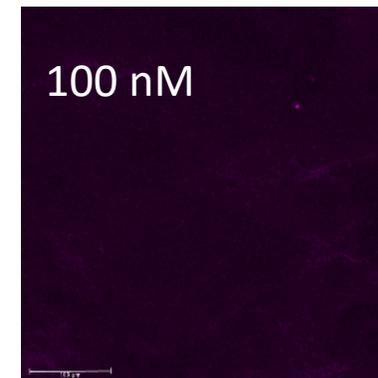
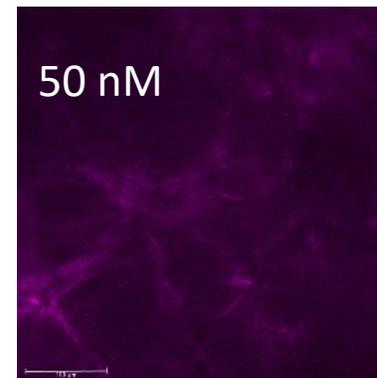
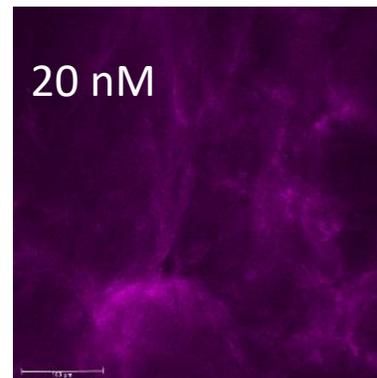
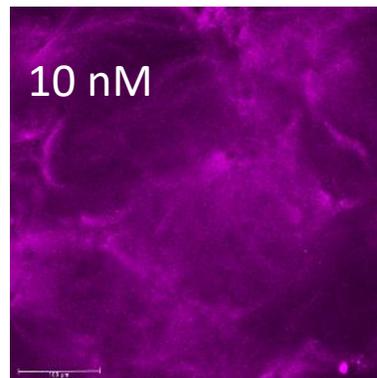
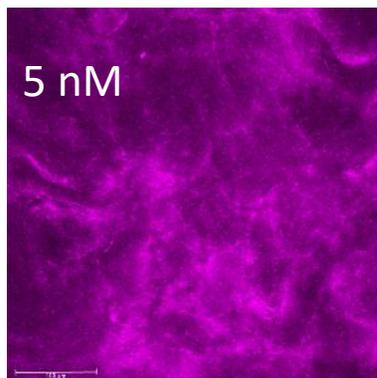


Studies conducted in the laboratory of Professor Paul Timpson (Garvan)

# AMP945 blocks collagen cross-linking *in vitro*



- Crosslinking of collagen is required for the formation of fibrotic tissues
- AMP945 inhibits collagen cross-linking in a dose-dependent manner



# AMP945 treats and prevents lung fibrosis



## Bleomycin animal model of lung fibrosis

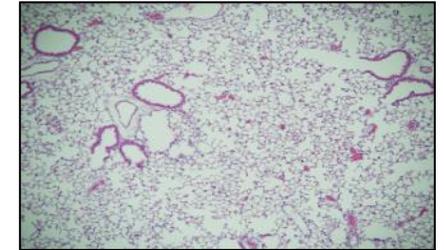
### PREVENTION

- AMP945 administered before onset of fibrosis
- Evaluating ability of AMP945 to prevent fibrosis from becoming established

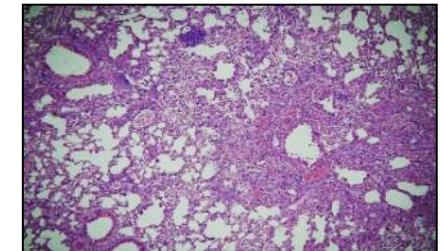
### TREATMENT

- AMP945 administered after onset of fibrosis
- Evaluating ability of AMP945 to treat established fibrosis

control – healthy lung



bleomycin – fibrotic lung



bleomycin + AMP945



- FAK has a pivotal role in the biochemical pathways regulating both the development and progression of fibrosis in the lungs
- AMP945 both prevents and reverses the fibrosis in the industry-standard disease model for lung fibrosis

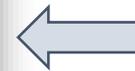
# Peer-reviewed preclinical rationale for Phase 2 trial



Murphy, Kendelle J., Reed, Daniel A., et al., *Science Advances*, 7 (2021), eabh0363.

- Recent publications highlight potential synergy of FAK inhibition with current standards of care

## Key findings



- Priming with FAK inhibitor before treatment with gemcitabine/Abraxane®
  - Increases survival in KPC pancreatic cancer model
  - Reduces metastasis
- FAK inhibition synergises with Abraxane®



Journal of Experimental & Clinical Cancer Research

**RESEARCH** **Open Access**

Focal adhesion kinase inhibition synergizes with nab-paclitaxel to target pancreatic ductal adenocarcinoma



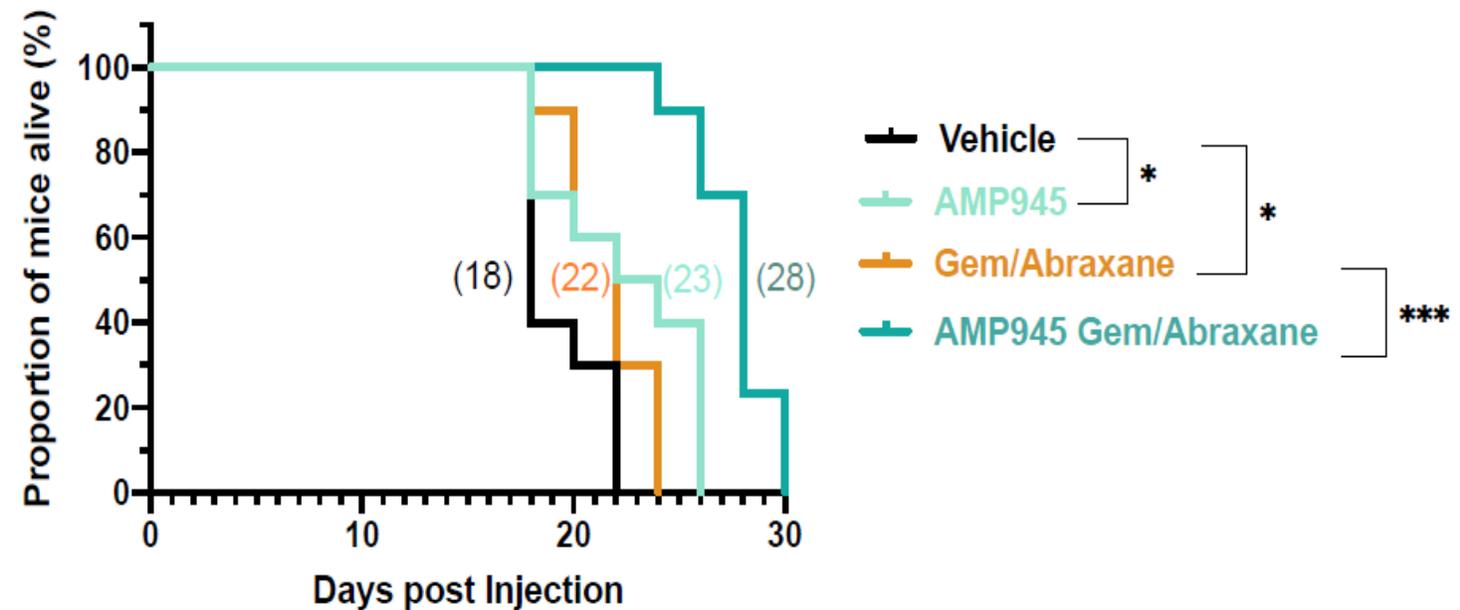
Le Large, T. Y. S., Bijlsma, M. F., et al., *Journal of Experimental & Clinical Cancer Research*, 40 (2021), 91.

# AMP945 improves survival in an aggressive pancreatic cancer model



## Survival in the KPC mouse model of pancreatic cancer

- 25% improvement in survival when added to standard of care ( $p \leq 0.001$ )
- KPC is a highly aggressive animal model of human pancreatic cancer
- Demonstrates pharmaceutical activity of AMP945 translates into survival benefit

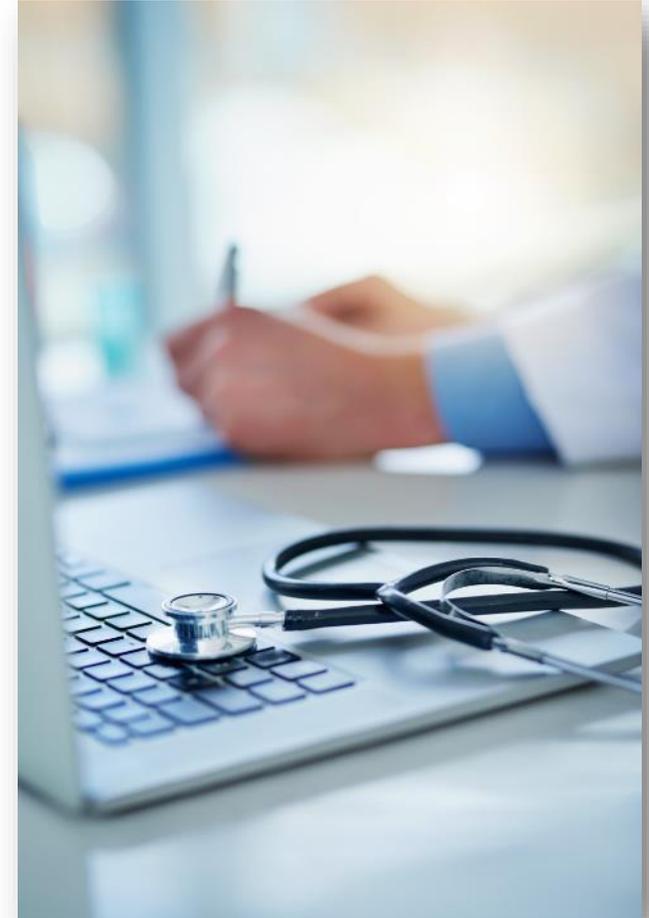


*"A 25% improvement in survival in this model is very impressive and a level of improvement that we rarely see"*

# Phase 1 trial of AMP945 completed in May 2021



- Trial execution:
  - Commenced in October 2020 - completed May 2021
  - Recruited in 56 healthy volunteers aged 18 - 65
  - Single site in Melbourne Australia
- Summary of Outcomes
  - Safe and well-tolerated at all doses tested
  - No serious adverse events (SAEs) or withdrawals and no identified safety trends
    - Single ascending doses up to 125mg
    - Multiple ascending dose (100mg QD for 7 days)
  - No food effect
  - Once-a-day oral dose supported by pharmacokinetics
    - Predictable dose/exposure relationship
  - Achieved blood levels of AMP945 expected to inhibit FAK
  - Low risk of interaction with other drugs in combination therapy



# AMP945's excellent clinical safety profile



## Summary of Treatment Emergent Adverse Events from Amplia's Phase 1 trial of AMP945

	Single Dose					Multiple Dose			
	Cohort 1 AMP945 15 mg (N=6)	Cohort 2 AMP945 30 mg (N=6)	Cohort 3 AMP945 60 mg (N=6)	Cohort 4 AMP945 125 mg (N=6)	Pooled Placebo (N = 8)	Cohort 1 AMP945 25 mg (N = 6)	Cohort 2 AMP945 50 mg (N=6)	Cohort 3 AMP945 100 mg (N = 6)	Pooled Placebo (N = 6)
Severity Rating	Number of Events					Number of Events			
Mild	1	1	5	1	3	7	6	4	5
Moderate	0	2	1	0	0	2	0	0	0
Severe	0	0	0	0	0	0	0	0	0

N = Number of volunteers per Cohort

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# Phase 2 Clinical Trial Overview

# Objectives of the Offer

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- The funds raised by the Offer will support the conduct of a Phase 1b/2a clinical trial of AMP945 in patients with pancreatic cancer
- The trial has been designed in two parts
  - Stage 1: Dose selection in approximately 12 pancreatic cancer patients and initial assessment of efficacy in a further 26 pancreatic cancer patients
  - Stage 2: Further efficacy assessment in approximately 24 pancreatic cancer patients
- Proceeds from this capital raise are forecast to fund Stage 1 of the trial as well as providing working capital, fund additional manufacturing work for AMP945 and support further ongoing non-clinical studies of AMP945 and AMP886

## **Questions the Phase 2 study aims to answer**

- Does AMP945 enhance the efficacy of gemcitabine and Abraxane<sup>®</sup> in patients with advanced pancreatic cancer?
- If AMP945 does enhance the efficacy of gemcitabine and Abraxane<sup>®</sup>, how does this manifest clinically?
- What is the optimal dose of AMP945 to maximise its effect on FAK?
- Which patients respond best to AMP945 combined with gemcitabine and Abraxane<sup>®</sup>?

# Phase 2 study of AMP945 in pancreatic cancer

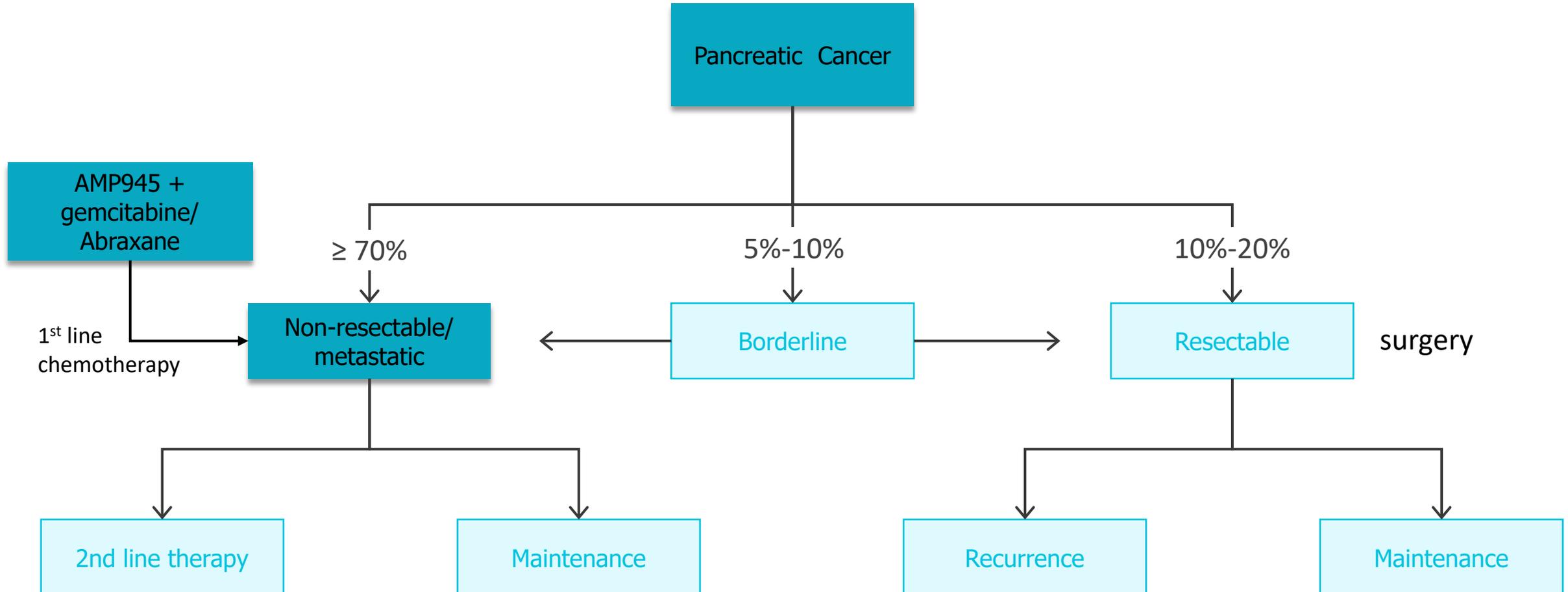
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## Key Trial Elements

- Patients with non-resectable or metastatic pancreatic cancer
- First-line therapy
  - Largest patient cohort
  - Healthier patients
  - Aims to position AMP945 as a first-line treatment option
- Intermittent dosing of AMP945 between normal chemotherapeutic doses of gemcitabine/Abraxane®
  - Designed to enhance standard of care
  - Mirrors design of preclinical efficacy studies

# AMP945 will be integrated into first-line therapy in the trial



# Phase 2 trial efficacy endpoints

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- Primary Endpoint – Objective Response Rate (ORR)
  - Widely used in single-arm trials
  - Able to support Accelerated Approvals
  - Sensitive endpoint
- Secondary Endpoints – Safety, DoR, PFS, OS, CR, Symptoms, Pharmacokinetics
  - Alternate measures of efficacy
  - Initial assessment of effect sizes
- Exploratory Endpoints – pFAK, CA19-9, fibrosis markers
  - Signals of response
  - Predictive biomarkers (e.g. MERLIN)

Endpoints are described in detail in [FDA Guidance for Industry](#)  
ORR: Objective response rate; DoR: Duration of Response; PFS: Progression free survival; OS: Overall survival; CR: Complete response; CA19-9: Carbohydrate antigen 19-9; MERLIN: Moesin-Ezrin-Radixin-Like Protein.

# Phase 2 trial design



## Stage 1

- Select the optimal dose of AMP945
  - Minimal dose giving maximum effect on pFAK
  - Safety and tissue sampling guides dose selection
- Initial test of efficacy of optimal dose combined with gemcitabine/Abiraxane standard of care
  - Assess efficacy across multiple endpoints
  - Check for predictive markers of response



## Stage 2

- Adapt trial based on Stage 1 results
- Recruit additional patients
- Increase confidence in efficacy results to support randomised trial

# Phase 2 trial summary



## Population

Patients with Stage III or IV pancreatic cancer  
First line therapy  
ECOG status  $\leq 1$   
Life expectancy of  $>3$  months

## Design

Phase 1b/2a open label, single arm study to evaluate safety, PK, PD and efficacy of AMP945 in combination with gemcitabine/Abraxane®

## Treatment

### Dose escalation

- Fixed doses of G/A, escalating doses of AMP945
- 4 cohorts of 3-6 pts. 1 month cycle

### Expansion

- Part 1: 26 pts, 5 months  
Interim Analysis

### Expansion

- Part 2: 24 pts, 9 months



## Endpoints

**Dose Escalation**  
Safety, PK, RP2D

### Expansion

- Primary: Objective response, duration of response
- Secondary: Overall survival, progression free survival
- Exploratory: Impact on/of biomarkers

Stage IV only in expansion phase

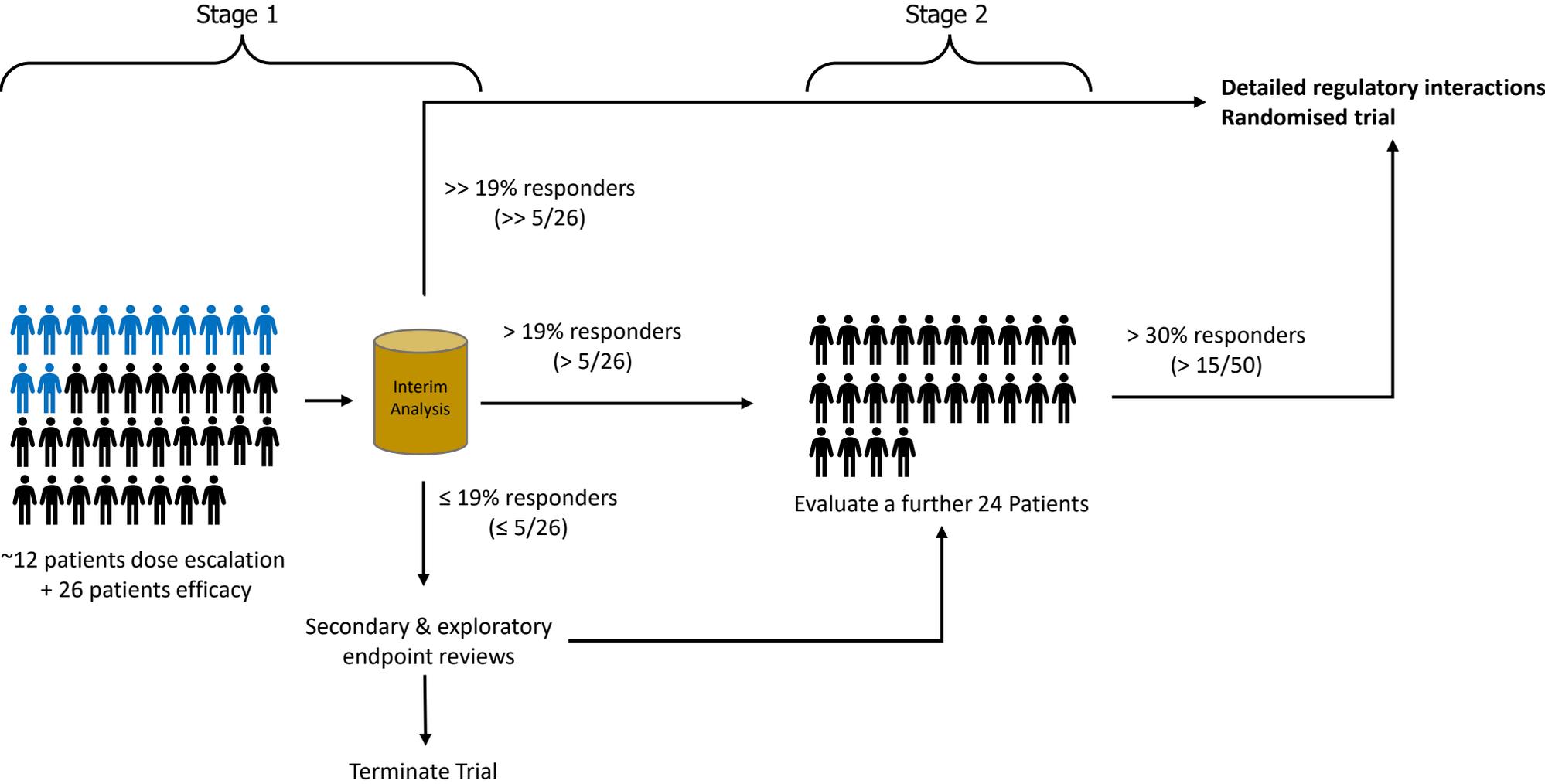
AMP945 + G/A safety run-in

Safety and tissue sampling guides dose selection

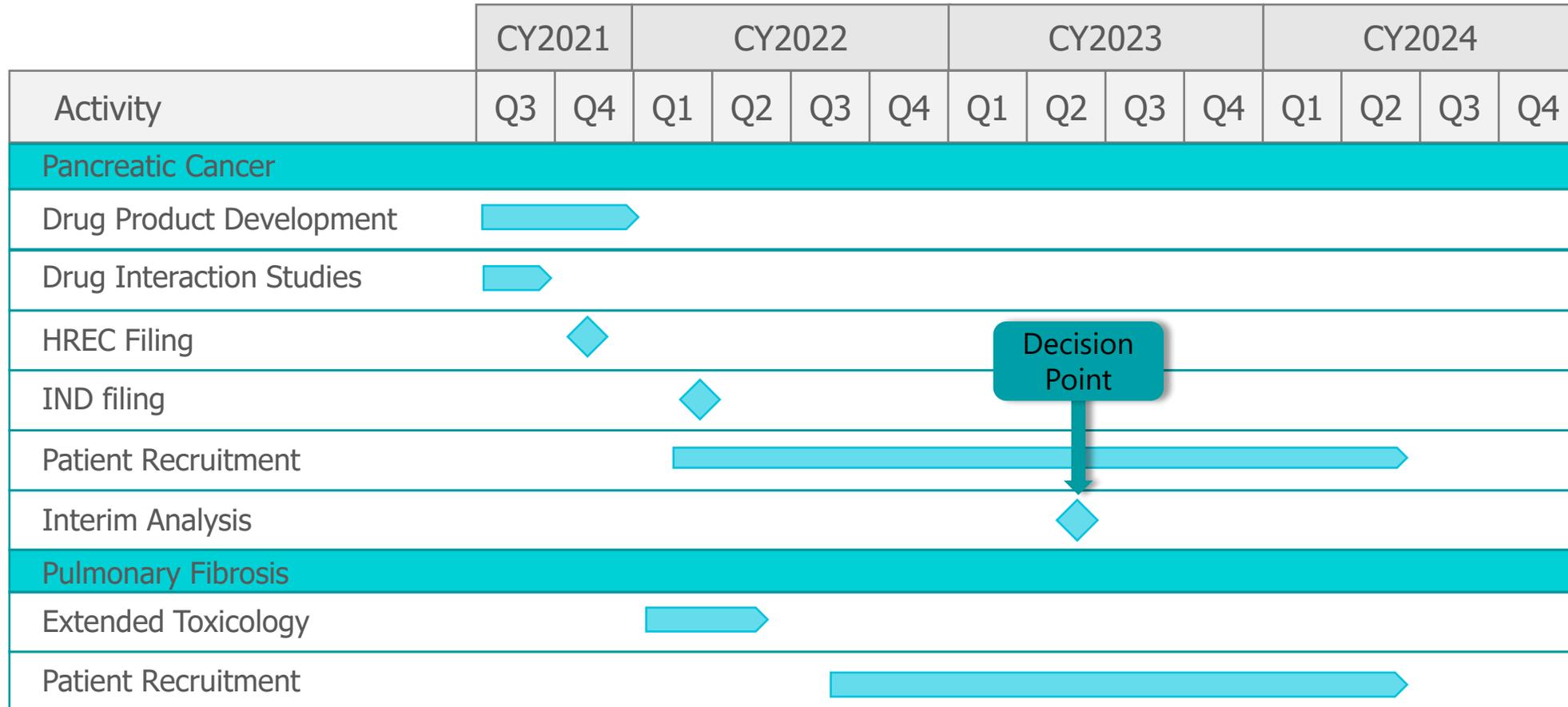
Select dose used in expansion phase

Recruitment due to commence Q1 2022

# Phase 2 trial overview and decision tree



# Amplia's planned clinical schedule



HREC: Human Research Ethics Committee  
 IND: Investigational New Drug

# Capital Raising Summary

# Key details of Capital Raising



<b>Structure and size</b>	<ul style="list-style-type: none"><li>• <b>Placement</b> to institutional investors to raise gross proceeds of approximately \$5.4m, via the issue of 30.1 million New Shares utilising the Company's existing placement capacity under ASX Listing Rule 7.1 and 7.1A. New Shares issued under the Placement will be eligible to participate in the Entitlement Offer.</li><li>• <b>Entitlement Offer:</b> 1 for 4, pro-rata, non-accelerated, non-renounceable entitlement offer to raise approximately \$7.0m via the issue of approximately 38.7 million New Shares to Eligible Investors in Australia and New Zealand on the Record Date.</li><li>• Total proceeds of the Capital Raising of approximately \$12.4m (before costs).</li></ul>
<b>Offer Price</b>	<ul style="list-style-type: none"><li>• <b>Offer Price</b> of \$0.18 per New Share, representing a discount of:<ul style="list-style-type: none"><li>• 7.7% to the closing price of Amplia shares of \$0.195 per share on Wednesday, 3 November 2021; and</li><li>• 12.2% to the volume weighted average price of Amplia shares for the 5 business days ending on 3 November 2021.</li></ul></li></ul>
<b>Attaching Options</b>	<ul style="list-style-type: none"><li>• New Shares issued under the Placement and Entitlement Offer will be offered with free attaching options on the basis of 1 option for every 3 New Shares issued (<b>Options</b>). The issue of Options under the Placement is conditional on shareholder approval.</li><li>• The Options will have an exercise price of \$0.28 and expire on 31 December 2023 and will be issued under the Prospectus. A total of 22.9 million Options are expected to be issued in connection with the Placement and Entitlement Offer.</li><li>• The Company will apply for quotation of the Options on ASX.</li></ul>
<b>Underwriting</b>	<ul style="list-style-type: none"><li>• The Capital Raising will be lead managed by Taylor Collison Limited (<b>Lead Manager</b>). The Entitlement Offer (but not the Placement) is expected to be fully underwritten by the Lead Manager.</li></ul>
<b>Prospectus</b>	<ul style="list-style-type: none"><li>• The Entitlement Offer and the offer of Options to Placement participants will be made under a transaction-specific prospectus dated 8 November 2021.</li></ul>
<b>Ranking</b>	<ul style="list-style-type: none"><li>• New Shares issued under the Capital Raising will rank pari passu with existing fully paid shares of the Company, other than their entitlement to free attaching Options.</li></ul>
<b>Extraordinary General Meeting</b>	<ul style="list-style-type: none"><li>• Extraordinary General Meeting to be held on 17 December 2021 to approve the issue of Options to Placement participants.</li></ul>

# Source and application of funds



Source	Amount	Application	Amount
Cash as at 30 September 2021	\$3.2m	AMP945 Phase 1b/2a clinical trial costs	\$7.0m
R&D rebate received	\$1.1m	AMP945 manufacturing costs	\$2.9m
Placement	\$5.4m	IPF Toxicology and non-clinical POC studies	\$1.25m
Entitlement Offer	\$7.0m	Patent and licence fees	\$0.65m
		General admin and working capital	\$4.03m
		Costs of the offers	\$0.88m
<b>TOTAL</b>	<b>\$16.7m</b>	<b>TOTAL</b>	<b>\$16.7m</b>

# Pro forma balance sheet



\$AUD	31 March 2021 (audited)	Jun. & Sept. Quarter Appendix 4C	Adj.	Placement & Entitlement Offer	Pro-forma Statement (unaudited)
<b>Current Assets</b>					
Cash and cash equivalents	1,848,408	1,322,573	1,140,352 <sup>(a)</sup>	12,387,210 <sup>(b)</sup>	16,698,543
Trade and other receivables	1,000,000	-	(1,000,000)	-	-
Other current assets	87,278	-	-	-	87,278
<b>Total Current Assets</b>	<b>2,935,686</b>	<b>1,322,573</b>	<b>140,352</b>	<b>12,387,210</b>	<b>16,785,821</b>
<b>Non-Current Assets</b>					
Intangibles	7,937,932	-	-	-	7,937,932
Plant and equipment	5,471	6,775	-	-	12,246
<b>Total Non-Current Assets</b>	<b>7,943,403</b>	<b>6,775</b>	<b>-</b>	<b>-</b>	<b>7,950,178</b>
<b>Total Assets</b>	<b>10,879,089</b>	<b>1,329,348</b>	<b>140,352</b>	<b>12,387,210</b>	<b>24,735,999</b>
<b>Current Liabilities</b>					
Trade and other payables	539,130	-	-	-	539,130
<b>Total Current Liabilities</b>	<b>539,130</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>539,130</b>
<b>Total Liabilities</b>	<b>539,130</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>539,130</b>
<b>Net Assets</b>	<b>10,339,959</b>	<b>1,329,348</b>	<b>140,352</b>	<b>12,387,210</b>	<b>24,196,869</b>
<b>Equity</b>					
Issued capital	136,554,307	3,575,806	-	12,387,210	152,517,324
Reserves	(1,007,113)	-	-	-	(1,007,113)
Retained earnings (accumulated losses)	(125,207,235)	(2,246,458)	140,352	-	(127,313,341)
<b>Total Equity</b>	<b>10,339,959</b>	<b>1,329,348</b>	<b>140,352</b>	<b>12,387,210</b>	<b>24,196,869</b>

**Note:** <sup>(a)</sup> Adjustment relates to R&D tax incentive rebate for the period ended 31 March 2021 received on 08 October 2021.

<sup>(b)</sup> Cash and cash equivalents received for Placement and Entitlement Offer excludes approximately \$876,117 in relation to the cost of the Placement and Offers.

# Offer Timetable



Event	Date (2021)
Trading halt lifted	Monday, 8 November
Capital Raising announced, Prospectus lodged, trading halt lifted	Monday, 8 November
Settlement of the Placement	Thursday, 11 November
Issue of New Shares under the Placement	Friday, 12 November
Record Date for Entitlement Offer (7.00pm)	Tuesday, 16 November
Entitlement Offer opens	Friday, 19 November
Entitlement Offer closes	Tuesday, 7 December
Announcement of results of Entitlement Offer	Friday, 10 December
Settlement of the Entitlement Offer	Monday, 13 December
Issue of New Shares and Options under the Entitlement Offer	Tuesday, 14 December
Trading of New Shares issued under the Entitlement Offer	Wednesday, 15 December
Despatch of holding statements for New Shares and Options issued under Entitlement Offer	Thursday, 16 December
Extraordinary General Meeting	Friday, 17 December
Issue of Options under the Placement	Monday, 20 December
Commencement of trading of Options on ASX	Wednesday, 22 December

\* The timetable is indicative and subject to change. Amplia reserves the right to vary these times and dates, by agreement with the Lead Manager and subject to the ASX Listing Rules. All times are Melbourne times.

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# Key risks

# Key risks



Risk	Description
<b>COVID-19 and global health risks</b>	<p>Global health risks or the potential for these events could have a negative impact on the Company. Since early 2020 the coronavirus pandemic, now known as COVID-19, has spread rapidly to many countries globally. The impact of COVID-19 has led to the adoption of extreme preventative measures by governments and other authorities, including the imposition of limits on public gatherings, restrictions on travel, the closure of borders, requirements for self-isolation, restriction of access to services and the closure of stores and businesses, including in Australia. Given the high degree of uncertainty surrounding the extent and duration of COVID-19 it is not possible to assess the impact of COVID-19 on the Company's business. These events have had and can be expected to continue to precipitate sudden significant changes and volatility in regional and global economic conditions and financial markets.</p> <p>If there is a significant increase in the number of COVID-19 cases, this may burden hospitals and healthcare institutions to the extent that all non-urgent medical procedures, including clinical trials, may be cancelled or postponed indefinitely. This may impact the ability of the Company to progress the phases of their clinical trials. As a result, the operations of the Company may be significantly adversely affected by such events.</p>
<b>Reliance of In-Licensed Assets</b>	<p>The Company's only current significant assets are its drug candidate assets (including AMP945). These assets are not owned outright by the Company. They have been in-licensed from Cancer Research Technology Limited, a wholly owned subsidiary of Cancer Research UK. The Licence contains terms and conditions including obligations to progress the development of the licensed assets and obligations to make certain milestone payments. Forthcoming license payments include annual license maintenance fees of USD15,000, a milestone fee for the opening of an IND for AMP945 of USD100,000 and a milestone fee for the initiation of the first Phase 2 clinical trial of AMP945 of USD250,000. Further development milestone payments are due upon the initiation and completion of a Phase 3 clinical trial and upon regulatory submission and approval of a product, should that occur.</p> <p>In the event that the Company breaches any of these obligations or any of the other Licence terms and conditions, and cannot rectify such a breach within a prescribed time period, there is a risk the Licence may be cancelled and the Company would lose control of its current drug product assets. This would create a fundamental uncertainty about the Company's ability to continue as a going concern.</p>
<b>Non-clinical development risk</b>	<p>Before the Company's drug candidates can be considered appropriate for human clinical trialling or regulatory approval, drug candidates must successfully satisfy a number of nonclinical requirements. These include the ability to manufacture sufficient amounts of drug of sufficient quality to be used in nonclinical studies, clinical trials and ultimately for commercial use. Candidate drugs must demonstrate acceptable safety and tolerability in rigorous toxicology studies commensurate with their intended therapeutic use. There is no guarantee that these requirements will be met, failing which the Company would be unable to develop its products.</p>
<b>Clinical development risk</b>	<p>The nature of clinical drug development is inherently risky, with many drug candidates failing to be successfully developed into marketable products. The Company is positioning its drug candidates for clinical trialling. Clinical trials have many associated risks which may impact commercial potential and therefore future profitability. Such trials may fail to recruit patients, be terminated for safety reasons, or fail to be completed within acceptable timeframes. The Company's clinical trials may require that other experimental drug candidates or approved products be tested in combination with the Company's own drug candidates. The supply of such combination therapeutics is beyond the Company's immediate control and lack of access to these may cause the Company to alter its plans or introduce delays in the Company's clinical development program. Clinical trialling may reveal drug candidates to be unsafe, poorly tolerated or non-effective. Any of these outcomes will likely have a significant adverse effect on the Company, the value of its securities and the future commercial development of its drug candidates including AMP945. Clinical trials might also potentially expose the Company to product liability claims in the event its products in development have unexpected effects on clinical subjects.</p>
<b>Regulatory approvals necessary for clinical trials</b>	<p>The Company may be unable to secure necessary approvals from regulatory agencies and institutional bodies (clinics and hospitals) to conduct its planned clinical trials. Using funds raised in the Offer, the Company plans to initiate a Phase 2 clinical trial in newly diagnosed patients with pancreatic cancer (first-line patients). There is no assurance that regulatory bodies and local ethics committees will approve the Company's plans to recruit first-line patients. There is also no assurance that drug candidates trialled by the Company will prove to be safe and efficacious in clinical trials, or that the regulatory approval to manufacture and market its products will be received.</p>
<b>Regulatory and reimbursement approvals</b>	<p>The research, development, manufacture, marketing and sale of products developed by the Company are subject to varying degrees of regulation by a number of government authorities in Australia and overseas. Pharmaceutical products under development, such as drug candidate AMP945, must undergo a comprehensive and highly regulated development and review process before receiving approval for marketing. The process includes the provision of clinical data relating to the quality, safety and efficacy of the products for their proposed use. There is no guarantee that such regulatory approvals will be granted.</p> <p>Products may also be submitted for cost reimbursement approval. The availability and timing of that reimbursement approval may have an impact upon the uptake and profitability of products in some jurisdictions. There is no guarantee that such approvals will be granted.</p>

# Key risks (cont.)



## Company risks

Risk	Description
<b>Commercialisation of products and potential market failure</b>	The Company has not yet commercialised any products and as yet has no revenues. The Company is also dependent on commercially attractive markets remaining available to it during the commercialisation phase and there is a risk that, once developed and ready for sale, commercial sales may not be achieved. Furthermore, any products developed by the Company may prove to be difficult or impossible to manufacture at commercial scale, uneconomical to manufacture on a large scale, uneconomical to market, compete with superior products marketed by third parties or not be as attractive as alternative treatments.
<b>Competition and regulation</b>	The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant change. A number of companies, both in Australia and abroad, may be pursuing the development of products that target the same markets and/or diseases that the Company is targeting. The Company's products may compete with existing products that are already available to customers. The Company may face competition from parties who have substantially greater resources than the Company. Competing products may be superior to the Company's products, which would adversely impact the commercial viability of the Company's products.
<b>Dependence upon key personnel</b>	The Company depends on the talent and experience of its personnel as an important asset. There may be a negative impact on the Company if any of its key personnel leave. It may be difficult to replace them, or to do so in a timely manner or at comparable expense. Additionally, any key personnel of the Company who leave to work for a competitor may adversely impact the Company. In summary, the Company's ability to attract and retain personnel will have a direct impact on its ability to deliver its project commitments. Additionally, increases in recruitment, wages and contractor costs may adversely impact upon the financial performance of the Company.
<b>Research &amp; Development (R&amp;D) Tax Rebate</b>	The Company is currently entitled to receive an R&D rebate on part of its expenditure in research and development. There is a risk that the Australian Government may make material changes to the rebate scheme, which may adversely impact the funding available to the Company to fund its operations. In order to obtain an R&D rebate on that part of its expenditure that is incurred out of Australia the Company must first gain approval for that expenditure from the Australian Government. Such an approval is called an Advanced Finding. The Company has received Advanced Findings for R&D work which is planned for its lead assets AMP945 and AMP886.
<b>Growth</b>	There is a risk that the Company may be unable to manage its future growth successfully. The ability to hire and retain skilled personnel as outlined above may be a significant obstacle to growth.
<b>Commercial partners</b>	The Company's growth strategy may be impacted if it is unable to find suitable commercialisation partners. The Company's due diligence processes may not be successful and a commercial partnership may not perform to the level expected.
<b>Intellectual property</b>	The Company's ability to commercialise any product depends upon its ability to protect its intellectual property and any improvements to it. The intellectual property may not be capable of being legally protected, it may be the subject of unauthorised disclosure or be unlawfully infringed, or the Company may incur substantial costs in asserting or defending its intellectual property rights.
<b>Revenues and profitability</b>	The Company does not currently generate revenue from product sales nor are revenues anticipated in the short to medium term. The Company's ability to achieve both revenues and profitability is dependent on a number of factors, including its ability to complete successful clinical trials, obtain regulatory approval for its products and successfully commercialise those products. There is no guarantee that the Company's products (including Drug candidate AMP945) will be commercially successful.

# Key risks (cont.)



## General risks

Risk	Description
<b>Economic</b>	General economic conditions, movements in interest and inflation rates and currency exchange rates may have an adverse effect on the Company's business and production activities, as well as on its ability to fund those activities.
<b>Market conditions</b>	<p>Share market conditions may affect the value of the Company's quoted shares (and options to acquire quoted shares) regardless of the Company's operating performance. Share market conditions are affected by many factors such as:</p> <ul style="list-style-type: none"> <li>a) general economic outlook;</li> <li>b) introduction of tax reform or other new legislation;</li> <li>c) interest rates and inflation rates;</li> <li>d) changes in investor sentiment toward particular market sectors;</li> <li>e) the demand for, and supply of, capital; and</li> <li>f) terrorism or other hostilities.</li> </ul> <p>The market price of securities can fall as well as rise and may be subject to varied and unpredictable influences on the market for equities in general and pharmaceutical stocks in particular. Neither the Company nor the Directors warrant the future performance of the Company or any return on an investment in the Company.</p>
<b>Litigation</b>	There is a risk that the Company may in future be the subject of or required to commence litigation. There is, however, no litigation, mediation, conciliation or administrative proceeding taking place, pending or threatened against the Company.
<b>Tax risks</b>	<p>Changes to the rate of taxes imposed on the Company (including in overseas jurisdictions in which the Company operates now or in the future) or tax legislation generally may affect the Company and its Shareholders. In addition, an interpretation of Australian tax laws by the Australian Taxation Office that differs to the Company's interpretation may lead to an increase in the Company's tax liabilities and a reduction in Shareholder returns.</p> <p>Personal tax liabilities are the responsibility of each individual investor. The Company is not responsible either for tax or tax penalties incurred by investors.</p>
<b>Additional requirements for capital</b>	The Company's capital requirements depend on numerous factors. Depending on the Company's ability to generate income from its operations, the Company may require further financing in addition to amounts raised under the Capital Raising. Any additional equity financing will dilute shareholdings, and debt financing, if available, may involve restrictions on financing and operating activities. If the Company is unable to obtain additional financing as needed, it may be required to reduce the scope of its operations, its production levels, or scale back its research and development and/or clinical trials as the case may be. There is however no guarantee that the Company will be able to secure any additional funding or be able to secure funding on terms favourable to the Company.
<b>Speculative investment</b>	<p>The above list of risk factors ought not to be taken as exhaustive of the risks faced by the Company or by investors in the Company. The above factors, and others not specifically referred to above, may in the future materially affect the financial performance of the Company and the value of the securities offered under the Offer. Therefore, the shares to be issued pursuant to the Offer carry no guarantee with respect to the payment of dividends, returns of capital or the market value of those securities.</p> <p>Potential investors should consider that an investment in the Company is speculative and should consult their professional advisers before deciding whether to apply for securities pursuant to the Offer.</p>



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