ABN 16 165 160 841

**ASX RELEASE** **17 December 2020**

**Shareholder Update / 2020 Review**

Amplia Therapeutics Limited (ASX: ATX) ("Amplia" or the "Company") is pleased to provide shareholders with an end-of-year review covering the key achievements the Company has made with respect to the development of its Focal Adhesion Kinase (FAK) drug candidates and the delivery of key corporate objectives.

There is little doubt that 2020 has been one of the most challenging years that many of us have faced. However, despite the enormous challenges posed by the coronavirus pandemic, Amplia has had an extremely successful and productive year.

One of the key goals for the Company was to initiate the first-in-human clinical trial of AMP945. This required the successful completion of preclinical toxicology studies, developing an appropriate trial design, obtaining approval from an independent Human Research Ethics Committee, planning and launching the trial, and securing the necessary capital to conduct the trial. In view of the complexities created by the coronavirus pandemic, this was a significant achievement in terms of both effort and co-ordination. To date, Amplia's timelines have not been materially impacted by the corona virus pandemic and we are extremely proud to have been able to deliver this significant milestone for our shareholders in the face of the challenges presented.

From a corporate perspective, we completed the planned restructure of our Board and also expanded the expertise available within the Company through the appointment of Mark Devlin as Chief Scientific Officer. We also were delighted to welcome institutional shareholders Platinum Asset Management and Blueflag Holdings onto our register through their participation in the capital raises the Company conducted during the year.

The value of our achievements in 2020 have been reflected in significant increases in the Company's share price, market capitalisation and average daily trading volumes. Furthermore, the significant achievements and progress delivered by the Company have been made through very efficient use of working capital.

The next 12 months are also expected to be significant for Amplia with results from its Phase 1 trial expected in 1H 2021, and plans to initiate at least one Phase 2 clinical trial before the end of 2021. The Company also expects to generate non-clinical data for its drugs in both cancer and fibrotic disease indications which will support the Company's clinical and licensing/partnership programs.

ATX's Board and Management would like to express their appreciation to shareholders for their support during 2020 and look forward to delivering another year of strong performance in 2021.

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

- End -

**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).

# 2020 – Amplia Year in Review

December 2020

**Amplia Therapeutics Limited**

Amplia
Exposing cancer. Enhancing treatment.

# Disclaimer

The information contained in the presentation is not intended to be an offer for subscription, invitation or recommendation with respect to shares of Amplia Therapeutics Limited ("Amplia") in any jurisdiction. No representation or warranty, express or implied, is made in relation to the accuracy or completeness of the information contained in this document or opinions expressed in the course of this presentation. The information contained in this presentation is subject to change without notification.

This presentation contains forward-looking statements which can be identified by the use of words such as "may", "should", "will", "expect", "anticipate", "believe", "estimate", "intend", "scheduled" or "continue" or similar expressions. Any forward-looking statements contained in this presentation are subject to significant risks, uncertainties, assumptions, contingencies and other factors (many of which are outside the control of, and unknown to Amplia, and its officers, employees, agents or associates), which may cause the actual results or performance to be materially different from any future result so performed, expressed or implied by such forward-looking statements.

There can be no assurance or guarantee that actual outcomes will not differ materially from these statements. The data and results pertaining to clinical subjects used in this presentation are illustrative of medical conditions and outcomes associated with potential applications of Amplia's acquired product pipeline. Actual results from clinical trials may vary from those shown.

# Company snapshot

| | |
|---|---|
| Shares | 107.6M |
| Market cap [1] | $24.7M |
| Options | 14.1M |
| Cash [2] | $3.6M |
| Last qtr burn [2] | ($0.5M) |
| Headquarters | Melbourne |
| Board | Warwick Tong (Chair)<br>John Lambert (MD)<br>Robert Peach (NED)<br>Chris Burns (NED) |
| Substantial institutional holders | Platinum – 16%<br>Blueflag Holdings – 7% |

[1] close of trade, 11 Dec 2020

[2] quarter ending 30 Sep 2020

ATX Price and Volume – 12 months


| | |
|---|---|
| price [1] | $0.23 |
| 12mth high - low | $0.37 - $0.04 |
| av. daily volume | 175,000 |

# Company highlights

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

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

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

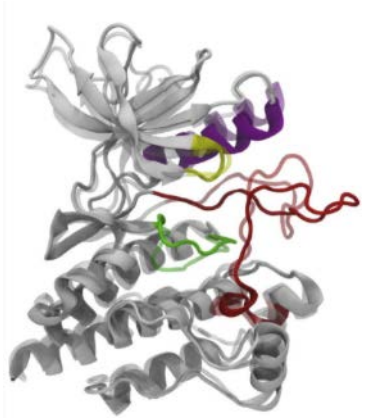
Range of commercial opportunities for partnering, licensing and co-development

First Phase 1 clinical trial initiated in October 2020, expected to complete in 2Q 2021

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

# Focal Adhesion Kinase – dual purpose drug target



Focal Adhesion Kinase (FAK)

## Cancer defence mechanisms

- cell migration and metastasis
- tumour microenvironment (TME)
- local regulation of immune response

## Fibrotic disease treatments

- central role in fibrosis
- collagen accumulation
- fibronectin production
- myofibroblast differentiation

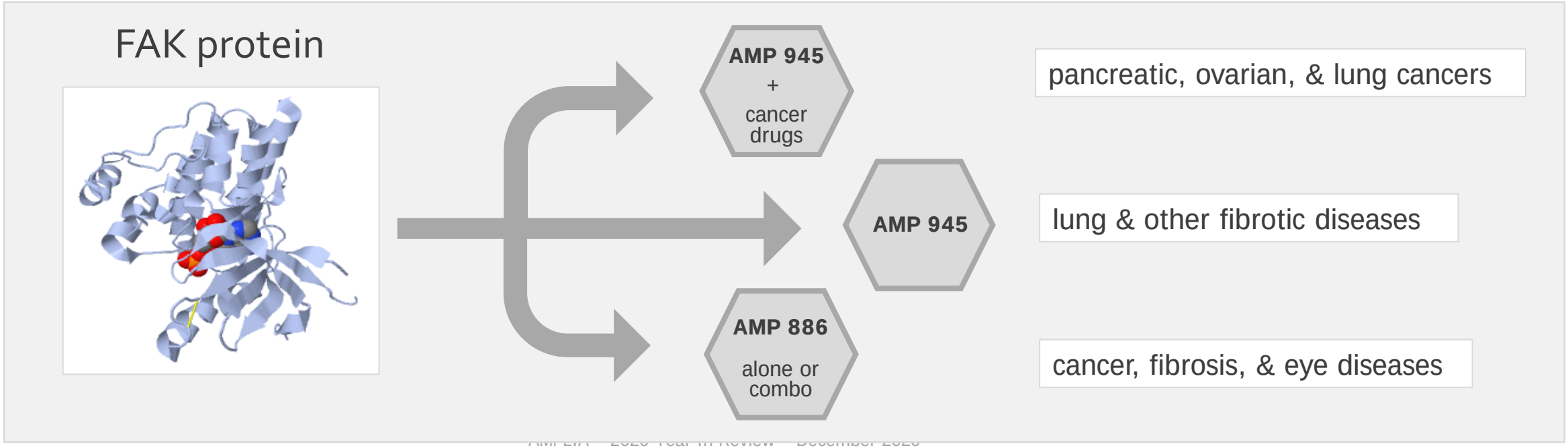
# Amplia is developing two FAK inhibitors (FAKi's)

Amplia has exclusive, worldwide licenses to two proprietary, FAK inhibitors:

- **AMP945** – highly potent, highly selective, orally bioavailable – only blocks the FAK protein
- **AMP886** – orally bioavailable, potent blocker of the FAK protein and other cancer drug targets

Both were developed by the Cancer Therapeutics CRC (CTx) – a collaboration of Australia's leading cancer researchers whose past commercial successes include:

- licensing a drug to Merck in 2016 (US$15M upfront, up to US$500M milestones + royalties)
- establishing a collaboration and license agreement with Pfizer in 2018 (US$14M upfront, up to $US460M milestones + royalties)



# Amplia's FAKi's provide a promising opportunity set

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

Amplia is taking three approaches realize these opportunities:

1. **take AMP945 into clinical development** for pancreatic cancer and idiopathic lung fibrosis (both granted Orphan Drug Designations by the FDA)

2. **explore** 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 cancer or fibrotic diseases

# Key announcements during 2020

| | |
|---|---|
| **Jan** | Placement raising $930,000 corner-stoned by Platinum |
| **Feb** | Restructure and streamlining of Board completed |
| **Feb** | Paul Timpson joins Scientific Advisory Board |
| **Mar** | Orphan Drug Designation secured for pancreatic cancer |
| **May** | Orphan Drug Designation secured for idiopathic pulmonary fibrosis |
| **Jun** | Toxicology studies required to support Phase 1 trial completed |
| **Jul** | Underwritten Entitlement Offer raising $4.0M – corner-stoned by Platinum and Blueflag |
| **Jul** | Nucleus Network appointed as Phase 1 clinical trial site |
| **Aug** | Mark Devlin appointed as Chief Scientific Officer |
| **Sep** | Ethics clearance for Phase 1 clinical trial in healthy volunteers |
| **Oct** | First patient dosed in Phase 1 healthy volunteer trial |
| **Dec** | Receives $530,000 R&D Tax Incentive |

# Finance – strong & growing support from the market

**Amplia completed two capital raisings during 2020 providing nearly $5M:**

- $0.93M Placement at $0.07/share in January
- $4.0M fully underwritten Entitlement Offer at $0.10/share in July

**Two significant institutional investors joined the Amplia register:**

- Platinum Asset Management: established an initial 8.6% holding in January, which increased to 16% through participation in the July Entitlement Offer
- Blueflag Holdings: established an 7% stake in Amplia through participation in the July Entitlement Offer

**Additional $0.53M received in Dec 2020 from R&D tax rebate scheme**

**Improved engagement and strong support in the market:**

- Share price: up 3-fold since 2 Jan 2020 ($0.230 v $0.068)
- Market cap: increased significantly to $25M from $4M on 2 Jan 2020
- Liquidity: average turnover increased from 40,000 to 175,000 shares per day

# Corporate – robust foundation for growth established

## Completed planned restructure of Board

- Founding and Innate Directors retire from Board: Christian Behrenbruch, Simon Wilkinson and Andrew Cooke (maintains ongoing role as Company Secretary) in February
- John Lambert: joins Board as Managing Director in February

## Scientific Advisory Board expanded

- Professor Paul Timpson: leading pancreatic cancer researcher at the Garvan Institute of Medical research joins Amplia's Scientific Advisory Board in February

## Executive Management team expanded

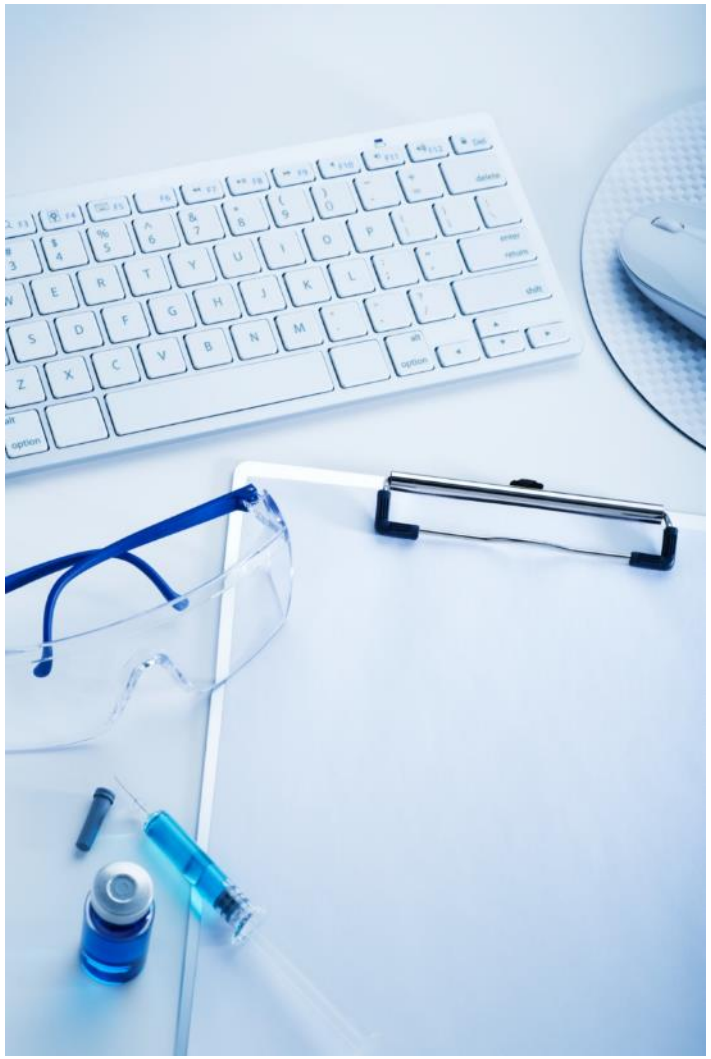
- Dr Mark Devlin: Group Leader from the Cancer Therapeutics CRC who was part of the team that discovered AMP945 and AMP886 and ex-CEO of CTxOne, appointed as Chief Scientific Officer in August

# Regulatory – orphan drug and trial clearances

**During 2020, Amplia secured Orphan Drug Designations (ODD) for the use of AMP945 to treat two indications:**

- Pancreatic Cancer: announced 25 March 2020
- Idiopathic Pulmonary Fibrosis (IPF): announced 19 May 2020

**Orphan Drug Designation** means that Amplia qualifies for waived FDA fees, clinical trial protocol assistance, and 7 years of market exclusivity in FDA-administered markets, if it is approved for either indication



## Ethics Clearance For Phase 1 Trial

Amplia received clearance from the Alfred Hospital Human Research Ethics Committee (HREC) to conduct a Phase 1 clinical trial in healthy volunteers in September:

- clearance based on preclinical safety, toxicology and scientific data generated to date for AMP945
- high safety bar, due trial to being conducted in healthy volunteers

# Clinical – first human trial of AMP945 started

**In October, Amplia commenced dosing subjects in the first human clinical trial of AMP945:**

- Supported by extensive preclinical data package
- Completion of toxicology studies announced in July
- Ethics clearance to conduct Phase 1 trial received in September

**Phase 1 clinical trial in healthy volunteers:**

- Started dosing subjects in October
- Approximately 64 healthy volunteers to be recruited
- Single ascending dose, multiple ascending dose, food-effect and pharmacodymamic studies

Trial expected to complete in Q2, with top-line data available in mid-2021

Clinical trial data from healthy volunteer study expected to support progression into Phase 2 trials for multiple indications (both cancer and fibrotic diseases)

# Media – Amplia in the news

**Amplia has started to attract the attention of both mainstream media and specialist, investor forums**


THE AUSTRALIAN ARTS | CULTURE

LIFE&TIMES

A CANCER GAME CHANGER

Food for fraught: advice for infants to eat meat sets the pot boiling

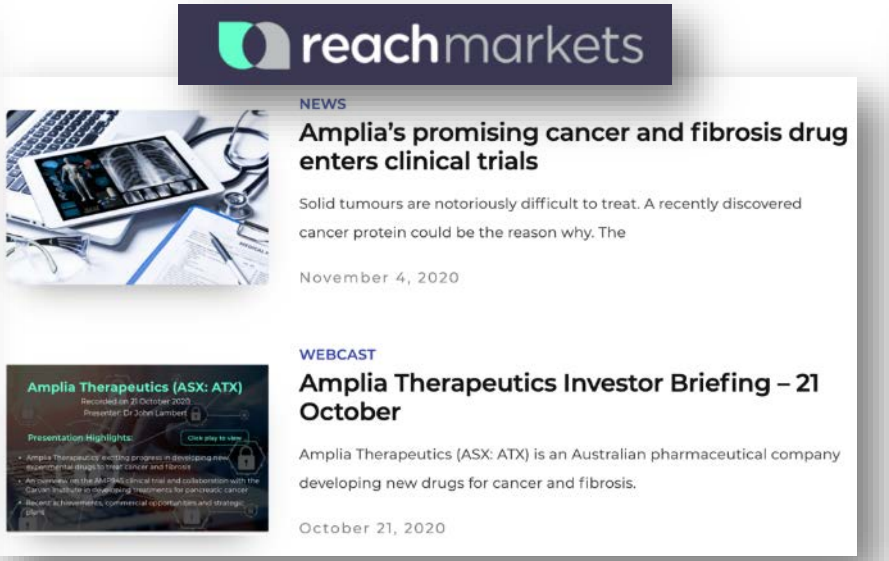

THE NATION

THE AUSTRALIAN, WEDNESDAY, OCTOBER 14, 2020 3

Aussie breakthrough aiming to tear down cancer 'shield'

EXCLUSIVE

NATASHA ROBINSON
HEALTH EDITOR


reachmarkets

NEWS

Amplia's promising cancer and fibrosis drug enters clinical trials

Solid tumours are notoriously difficult to treat. A recently discovered cancer protein could be the reason why. The

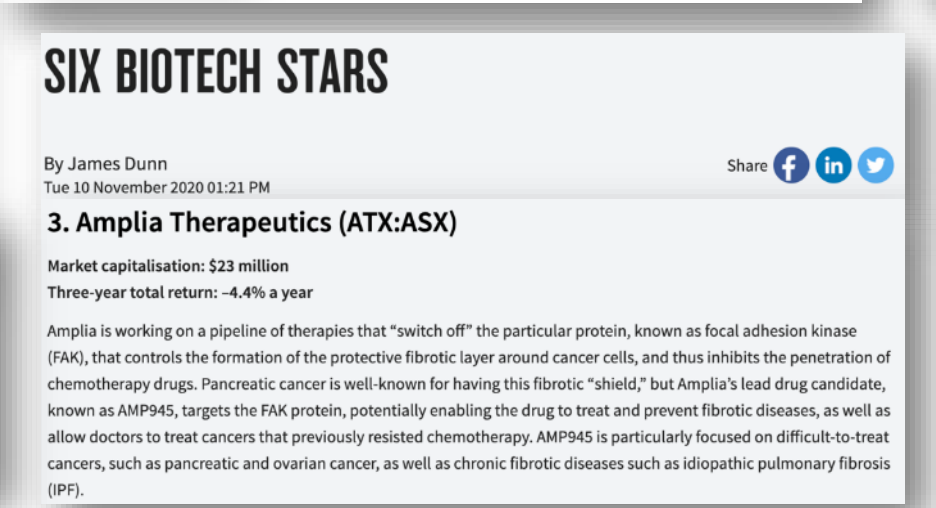
November 4, 2020

WEBCAST

Amplia Therapeutics Investor Briefing – 21 October

Amplia Therapeutics (ASX: ATX) is an Australian pharmaceutical company developing new drugs for cancer and fibrosis.

October 21, 2020


SIX BIOTECH STARS

By James Dunn
Tue 10 November 2020 01:21 PM

Share

3. Amplia Therapeutics (ATX:ASX)

**Market capitalisation: $23 million**
**Three-year total return: –4.4% a year**

Amplia is working on a pipeline of therapies that "switch off" the particular protein, known as focal adhesion kinase (FAK), that controls the formation of the protective fibrotic layer around cancer cells, and thus inhibits the penetration of chemotherapy drugs. Pancreatic cancer is well-known for having this fibrotic "shield," but Amplia's lead drug candidate, known as AMP945, targets the FAK protein, potentially enabling the drug to treat and prevent fibrotic diseases, as well as allow doctors to treat cancers that previously resisted chemotherapy. AMP945 is particularly focused on difficult-to-treat cancers, such as pancreatic and ovarian cancer, as well as chronic fibrotic diseases such as idiopathic pulmonary fibrosis (IPF).



Bioshares

18 May 2020
Edition 843

*Delivering independent investment research to investors on Australian biotech, pharma and healthcare companies*

***Amplia Therapeutics' AMP945 to Begin Clinical Trials in H2 2020***

Amplia Therapeutics (ATX: $0.083) is completing final toxicology studies of its FAK inhibitor, AMP945, before it moves into its first clinical trial in the second half of this year.

The company has a market capitalisation of only $6 million, but has several significant value creation points ahead over the next 18 months.

monotherapy (such as fibrotic lung diseases) and as a combination therapy in pancreatic or ovarian cancer.

**Verastem Paving the Path for FAK Inhibition**

The company leading the way in FAK inhibition drug development is Verastem. Oncology Based on preclinical data, Amplia's lead compound is competitive with Verastem's lead FAK inhibitor

# Company objectives for 2021

**Complete and report data from Phase 1 clinical trial of AMP945**

- Single ascending dose (SAD) – complete in Q1
- Multiple ascending dose (MAD) – complete in Q2
- Report top-line data – mid-2021

**Expand non-clinical data package (ongoing throughout 2021)**

- AMP945 in animal models of fibrotic diseases
- AMP945 in animal models of cancer
- *In vitro* studies on mechanism of action of AMP945
- Non-clinical exploratory studies evaluating potential applications for AMP886

**Preparatory work to support Phase 2 program (Q2/Q3)**

- Multi-kilogram manufacture of clinical grade AMP945
- Extended toxicology studies to support fibrosis clinical trials

**Initiate Phase 2 clinical trials of AMP945 for one or more indications**

- File Investigational New Drug (IND) application for AMP945 (Q3)
- Initiate first Phase 2 trial of AMP945 (Q4)

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