

ASX RELEASE

28 April 2021

QUARTERLY ACTIVITIES AND CASH FLOW REPORTS

Melbourne, Australia: Amplia Therapeutics Limited (ASX: ATX), (“Amplia” or the “Company”), a company developing new approaches for the treatment for cancer and fibrosis, is pleased to announce further progress across its small molecule, FAK inhibitor program and the release of its Appendix 4C Cash Flow Report (attached) for the quarter ending 31 March 2021.

A Shareholder Update and Presentation is scheduled for **10:30am on Wednesday 28 April, 2021**.

Interested parties are requested to register using this link: <https://bit.ly/3n3knN0>

The Shareholder Update presentation is annexed to and forms part of this quarterly report.

Key Highlights from the Quarter

- Completed dosing in Amplia’s Phase 1 clinical trial of AMP945;
- Key collaboration with Garvan Institute established;
- Demonstrated that AMP886 and AMP945 reduce fibrosis in animal models of NASH;
- Clinical advisory groups established to support Phase 2 trials.

Amplia’s CEO and Managing Director, Dr John Lambert, commented that “This quarter has seen our Company consolidate its position in clinical development and lay solid foundations for our next stage of growth. During this quarter Amplia completed a successful Phase 1 trial of AMP945 in healthy volunteers on time and within budget. On the basis of the initial positive results from this trial, the Company has already commenced planning Phase 2 trials in both cancer and fibrosis patients.

Operations update

During the quarter, Amplia made significant progress with its Phase 1 clinical trial of AMP945 in healthy volunteers which resulted in the final participants being dosed in early April. Initial data from the trial has indicated that orally administered AMP945 appears to be safe and well tolerated. A clinical study report providing more detail on the single and multiple ascending dose safety and tolerability studies as well as the pharmacokinetics, pharmacodynamics and the effect of food on the absorption of the drug will be provided to the Company during this current quarter. However, based on an initial assessment of the available data, the Company has already commenced developing plans for its Phase 2 clinical development program of AMP945.

In March, Amplia announced that it had agreed terms for a collaboration with the Garvan Institute of Medical Research, Sydney. This collaboration will bring together Amplia’s clinical-stage FAK inhibitors with the Garvan’s unique insights into FAK biology and its clinical research network. In the first stage of the collaboration, the parties intend to translate new treatment regimens for use in the planned clinical trials of AMP945 in pancreatic cancer patients later this year. The second stage of the collaboration will bring together Amplia’s FAK inhibitors and the Garvan’s expertise in FAK biology to develop new therapeutic strategies for difficult-to-treat cancers using other combination regimens.

Data arising from the collaboration so-far has confirmed that AMP945 is a potent antifibrotic agent and, in animal models of pancreatic cancer, is able to enhance the activity of gemcitabine/Abraxane®

which is a standard of care for many patients with pancreatic cancer. A more detailed description of the data received so-far is provided in the attached Investor Presentation.

As has been communicated previously, Amplia is conducting a program of non-clinical studies to identify additional opportunities for its FAK inhibitors, either for partnering or for future development by the Company. During the quarter, Amplia tested both its FAK inhibitors in a mouse model of Non-Alcoholic Steatohepatitis (NASH). NASH is an inflammatory disease caused by an accumulation of fat in the liver. This inflammation eventually leads to the build-up of fibrotic scar tissue, leading to cirrhosis, and then primary liver cancer (HCC, or hepatocellular carcinoma). It is estimated that approximately 5% of adults in the United States have NASH. Despite this significant unmet need, attempts to develop an effective therapeutic for NASH have met with little success.

In the NASH model, treatment with both AMP886 and AMP945 significantly lowered the activity of fibroblasts, which are the cells responsible for laying down collagen, and this activity was associated with a reduction in both fibrosis and liver changes associated with NASH. These data support Amplia's view that FAK plays a central role in the underlying pathology of many fibrotic diseases. The Company has now demonstrated anti-fibrotic activity for its FAK inhibitors in animal models of lung fibrosis and NASH, and in a range of *in vitro* studies. On the basis of these recent results, further studies are now planned to evaluate the use of AMP886 and AMP945 as potential treatments for liver disease and other fibrotic conditions.

Financial update

Amplia finished the March 2021 quarter with cash of \$1,848,000. During the quarter, the Company used \$996,000 in operating activities, with \$666,000 being used for research and development that was primarily focused on completing the Phase 1 clinical trial of AMP945.

Having completed recruitment in the Phase 1 clinical trial, research and development expenditure is forecast to decrease in the coming quarter.

Payments to Related Entities

In Section 6.1 of the Appendix 4C lodged for this quarter, the Company discloses payments to related parties of \$106,000. This includes \$71,175 in payment to the CEO/Managing Director in line with Dr Lambert's employment contract as well as \$35,000 in Director fee payments.

Outlook and future activities

Amplia's primary focus will now move to preparing for Phase 2 clinical trials of AMP945 in both pancreatic cancer and pulmonary fibrosis. This will involve working with the Company's clinical advisors to further refine clinical study designs, fully scoping the studies and preparing for regulatory and ethics committee submissions required to allow initiation of Phase 2 studies. In addition, the Company will continue its parallel program of non-clinical studies for AMP945 and AMP886 in order to expand the Company's data set supporting the potential utility of AMP945 and AMP886 in other therapeutic areas of commercial potential.

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

- End -

For Further Information

Dr. John Lambert
CEO and Managing Director

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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).

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

Amplia Therapeutics Limited

ABN

16 165 160 841

Quarter ended ("current quarter")

31 March 2021

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	<666>	<2,419>
(b) product manufacturing and operating costs		
(c) advertising and marketing		
(d) leased assets		
(e) staff costs	<157>	<608>
(f) administration and corporate costs	<111>	<402>
1.3 Dividends received (see note 3)		
1.4 Interest received	-	2
1.5 Interest and other costs of finance paid		
1.6 Income taxes paid		
1.7 Government grants and tax incentives	-	568
1.8 Other (provide details if material)		
Intellectual property costs & licence fees	<34>	<64>
COVID cashflow boost	-	57
Miscellaneous	<28>	<50>
1.9 Net cash from / (used in) operating activities	<996>	<2,916>
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities		
(b) businesses		
(c) property, plant and equipment	<5>	<5>

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
(d) investments		
(e) intellectual property		
(f) other non-current assets		
2.2 Proceeds from disposal of:		
(a) entities		
(b) businesses		
(c) property, plant and equipment		
(d) investments		
(e) intellectual property		
(f) other non-current assets		
2.3 Cash flows from loans to other entities		
2.4 Dividends received (see note 3)		
2.5 Other (provide details if material)		
2.6 Net cash from / (used in) investing activities	<5>	<5>

3. Cash flows from financing activities		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	-	3,988
3.2 Proceeds from issue of convertible debt securities		
3.3 Proceeds from exercise of options	50	76
3.4 Transaction costs related to issues of equity securities or convertible debt securities	<4>	<401>
3.5 Proceeds from borrowings		
3.6 Repayment of borrowings		
3.7 Transaction costs related to loans and borrowings		
3.8 Dividends paid		
3.9 Other (provide details if material)		
3.10 Net cash from / (used in) financing activities	46	3,663

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	2,804	1,108
4.2	Net cash from / (used in) operating activities (item 1.9 above)	<996>	<2,916>
4.3	Net cash from / (used in) investing activities (item 2.6 above)	<5>	<5>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	46	3,663
4.5	Effect of movement in exchange rates on cash held	<1>	<2>
4.6	Cash and cash equivalents at end of period	1,848	1,848

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	103	460
5.2	Call deposits	1,745	2,344
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	1,848	2,804

6.	Payments to related parties of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	106
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.</i>		

Quarterly cash flow report for entities subject to Listing Rule 4.7B

7. Financing facilities	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
<i>Note: the term "facility" includes all forms of financing arrangements available to the entity. Add notes as necessary for an understanding of the sources of finance available to the entity.</i>		
7.1 Loan facilities		
7.2 Credit standby arrangements		
7.3 Other (please specify)		
7.4 Total financing facilities	-	-
7.5 Unused financing facilities available at quarter end		-
7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.		

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (item 1.9)	<996>
8.2 Cash and cash equivalents at quarter end (item 4.6)	1,848
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	1,848
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	1.86
<i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>	
8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?	
Answer: No. Due to completion of enrolment in the Company's Phase 1 clinical trial, Research and Development costs are expected to decrease in the coming quarter.	
8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?	
Answer: The Company is in continuous dialog with its corporate finance advisors and expects to raise further capital during the coming quarter.	
8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?	
Answer: Yes. Based on the Company's dialog with its corporate finance advisors the entity expects to be able to meet its business objectives.	
<i>Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.</i>	

Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 28 April 2021

Authorised by: The Audit Committee
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.

Amplia Therapeutics - Shareholder Update

April 2021

Amplia Therapeutics Limited



Disclaimer

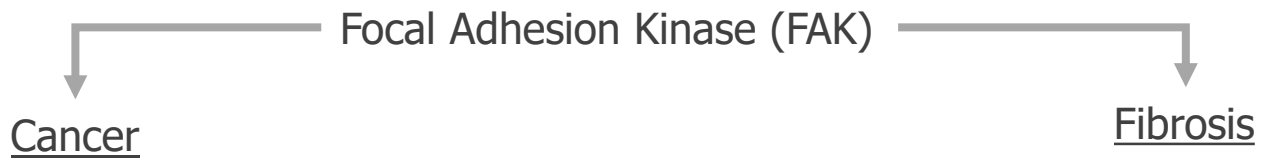
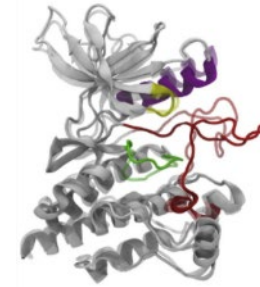


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This presentation contains forward-looking statements which can be identified by the use of words such as “may”, “should”, “will”, “expect”, “anticipate”, “believe”, “estimate”, “intend”, “scheduled” or “continue” or similar expressions. Any forward-looking 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.

Focal Adhesion Kinase – dual purpose drug target



Biology

- Cell migration and metastasis
- Collagen accumulation
- Local regulation of immune response

- Collagen accumulation
- Fibronectin production

Opportunity

Combination Therapy

- Pancreatic cancer
- Ovarian cancer

Monotherapy

- Lung fibrosis
- Liver fibrosis

Target Indications



Idiopathic Pulmonary Fibrosis (IPF)

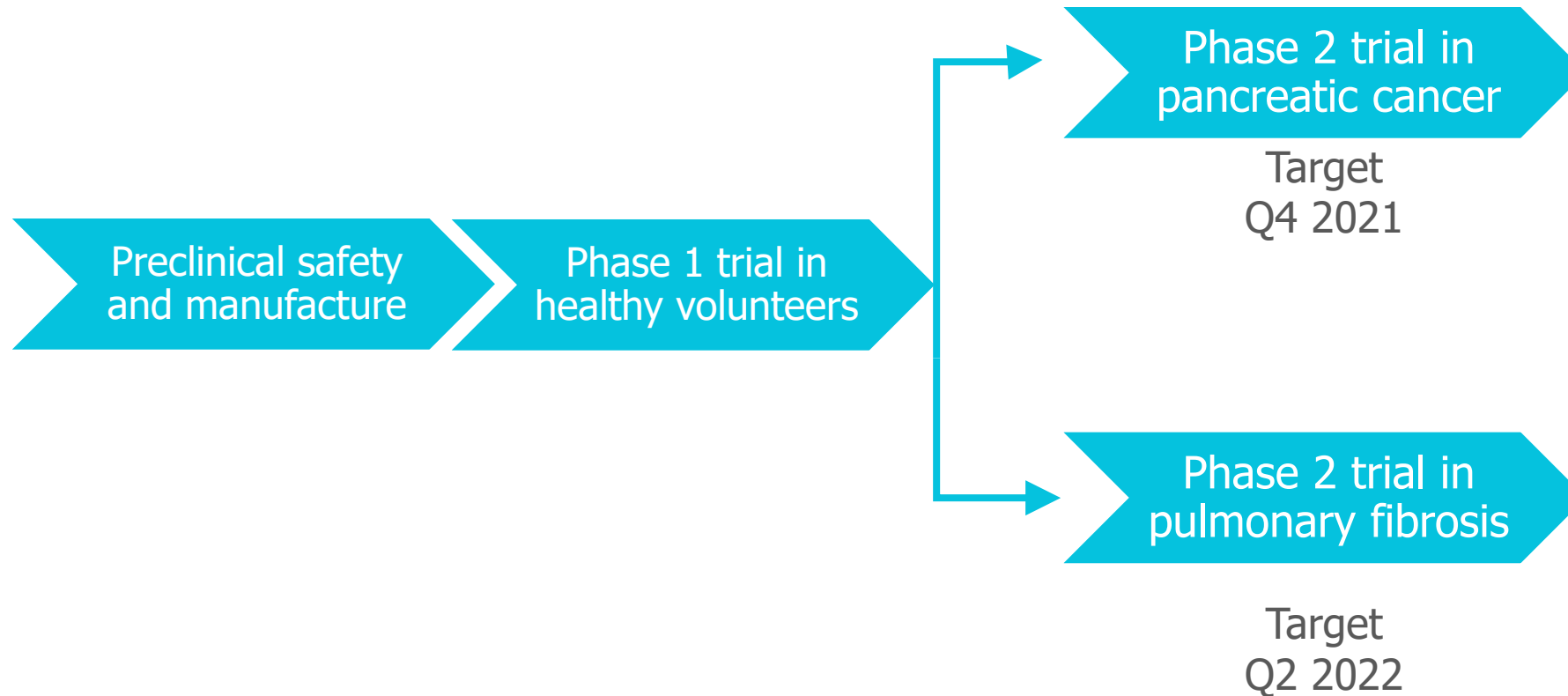
- A devastating, progressive disease caused by the build-up of fibrotic tissue in the lung
- Affects 3M people worldwide, including 130,000 in the US
- Untreated, median survival time is 2-3 years
- Available drugs slow the progression of the disease but are unable to prevent the eventual loss of lung function

Pancreatic Cancer

- Fibrotic and difficult-to-treat cancer
- Overall 5-year survival rate is ~10%
- Median survival time for metastatic disease is 6-8 months
- Highly unmet need in oncology



AMP945 parallel development paths



Phase 1 Clinical Trial

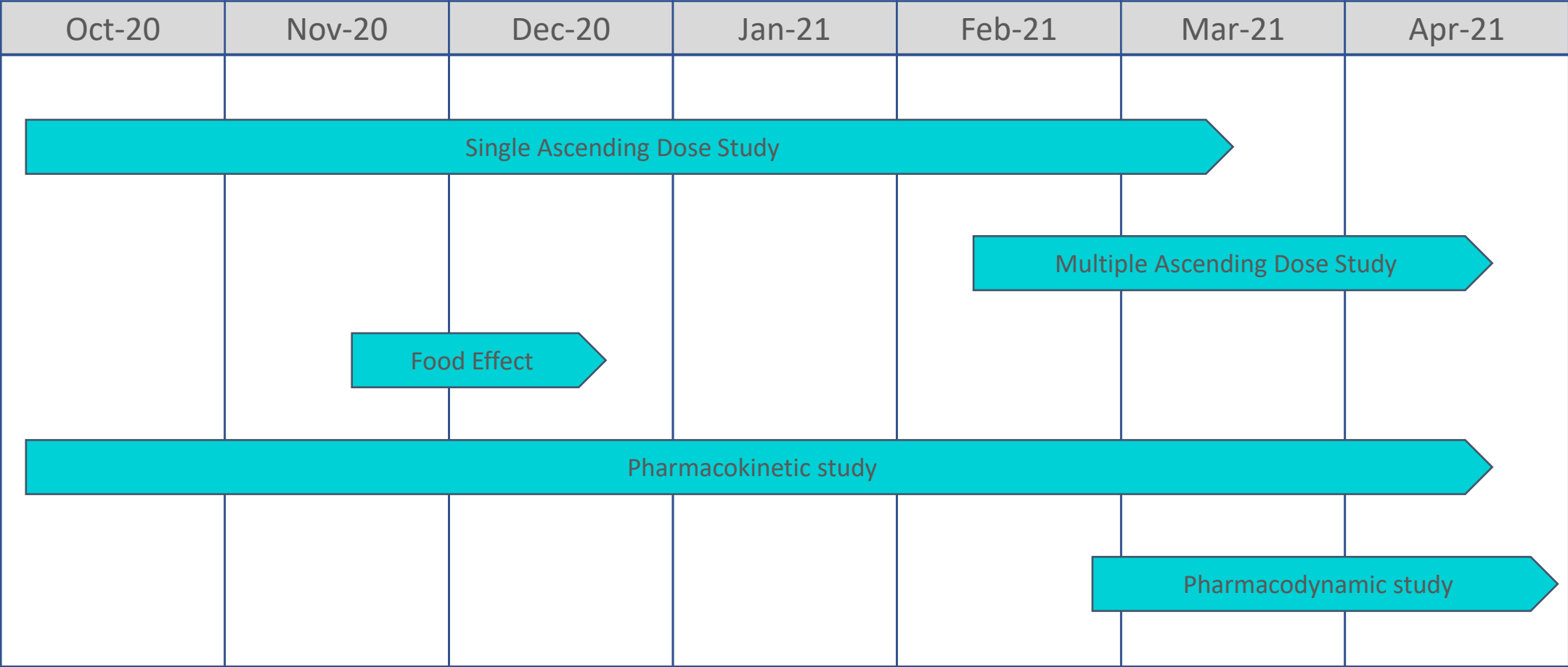
Phase 1 update



- Trial execution:
 - Commenced in October 2020 — completed dosing in April 2021
 - Conducted in healthy volunteers
 - Single site in Melbourne Australia, Nucleus Network
- Phase 1 trial components:
 - Single Ascending Doses
 - Multiple Ascending Doses
 - Food Effect
 - Pharmacokinetics
 - Pharmacodynamics
- Dosing was completed on time and on budget



Phase 1 trial of AMP945 – design and execution



Phase 1 – initial data



- Safe and well-tolerated at doses tested
- No evidence of food effect
- Pharmacokinetics support once-a-day oral dosing
- Supports advancing AMP945 into Phase 2 clinical trials
 - Planning for Phase 2 trial in pancreatic cancer and pulmonary fibrosis already commenced
 - On track to initiate first Phase 2 clinical trial in late 2021
 - Longer term animal toxicology studies to be conducted to support fibrosis indications
- Full study reported expected during this current quarter



Garvan Collaboration



Garvan collaboration



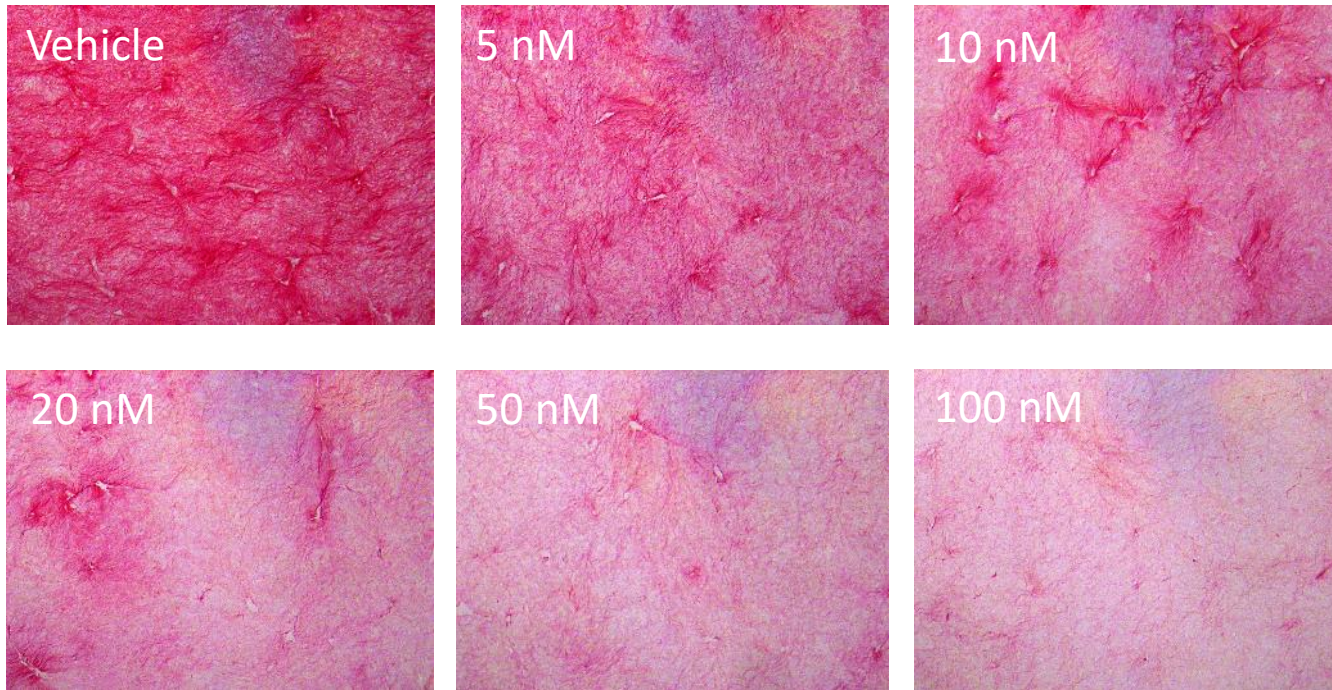
- Researchers in Prof. Paul Timpson's research group have been studying the role of FAK in pancreatic cancer models for >6 years
- Have shown that FAK inhibition
 - Improves efficacy of gemcitabine/Abraxane®
 - Extends survival
 - Reduces metastases
- Amplia has been collaborating with Timpson Lab for over 1 year
 - Confirmed that AMP945 exerts same effects as reference FAK inhibitors
 - Additional *in vitro* and *in vivo* studies further validate
 - Antifibrotic activity of AMP945
 - Potential application for use in pancreatic cancer
 - Garvan and Amplia agreed to formalise a collaboration in March 2021
 - Build on existing knowledge and IP and leverage clinical networks



AMP945 inhibits new collagen deposition *in vitro*

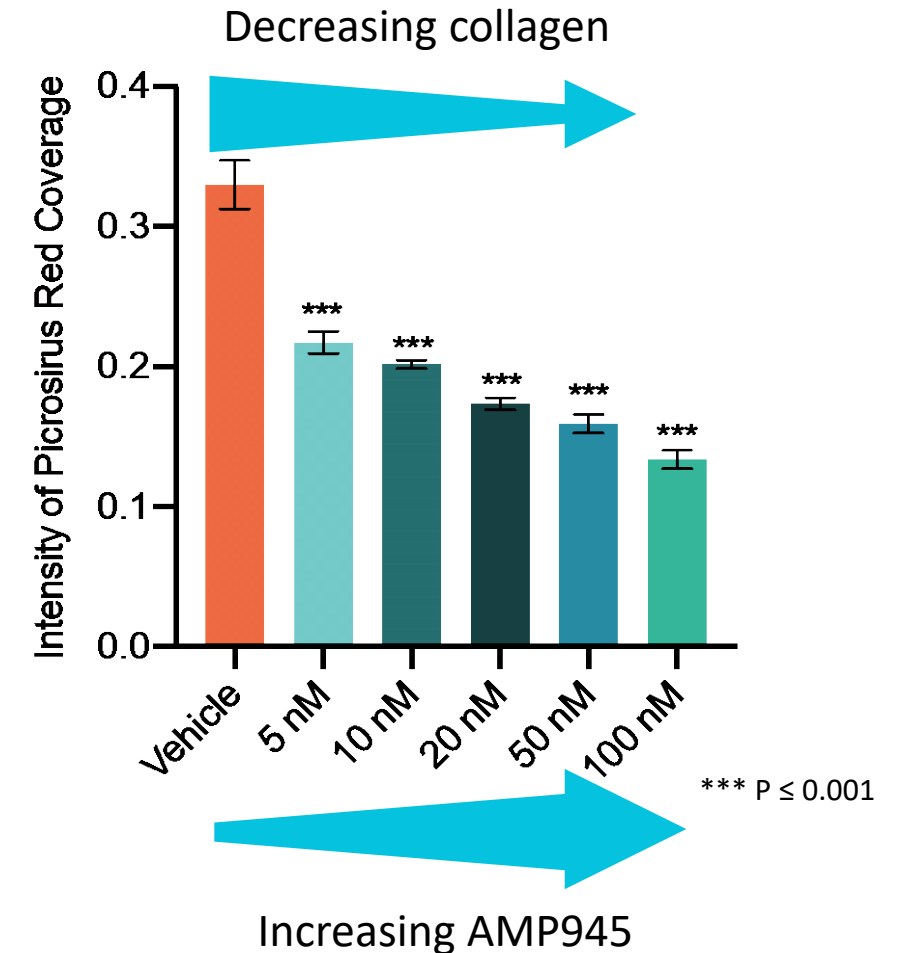


Picosirius red staining for total collagen



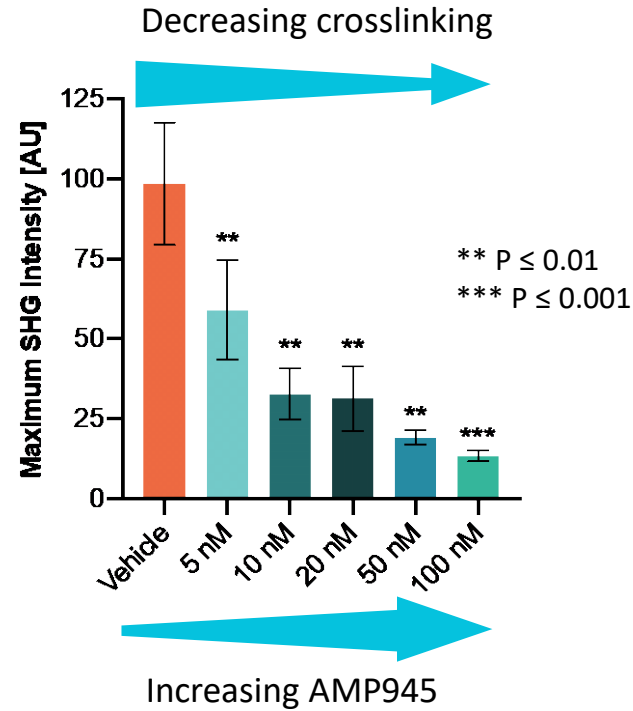
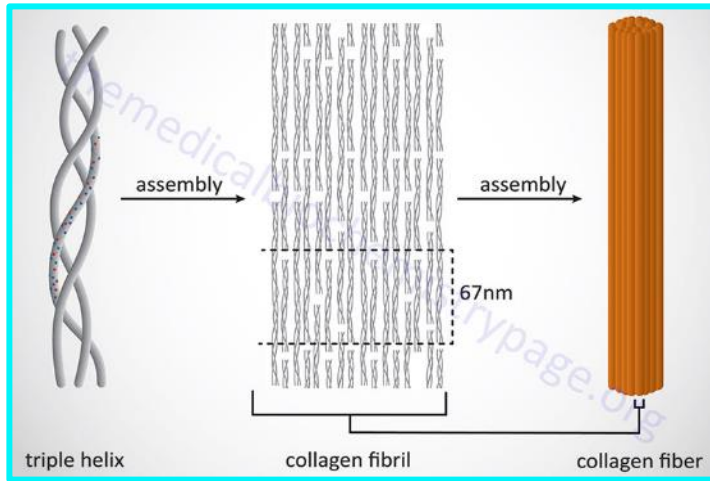
Take home messages:

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



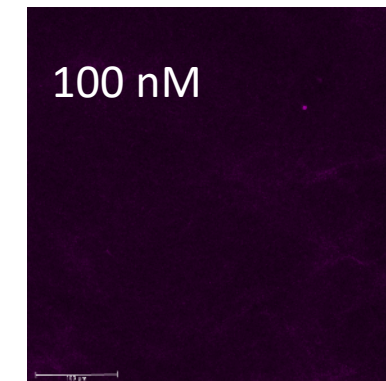
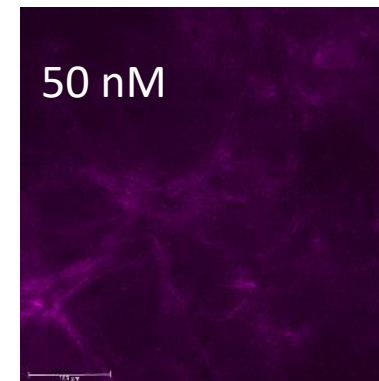
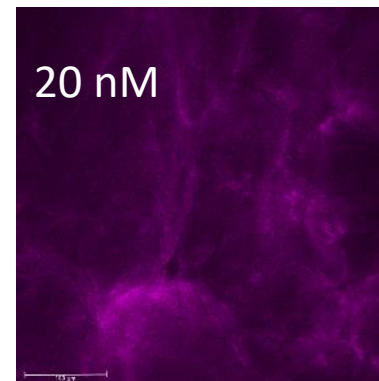
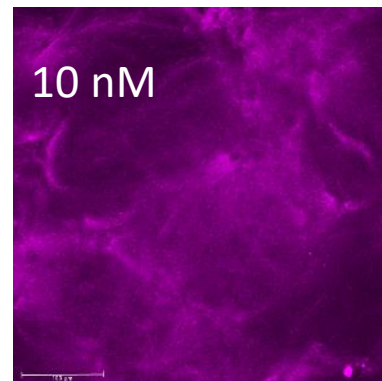
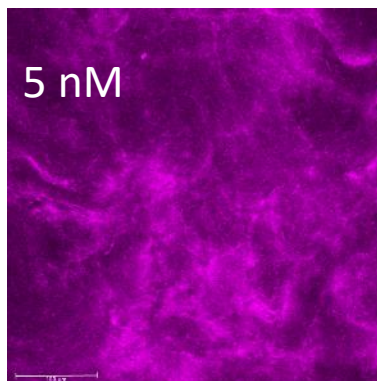
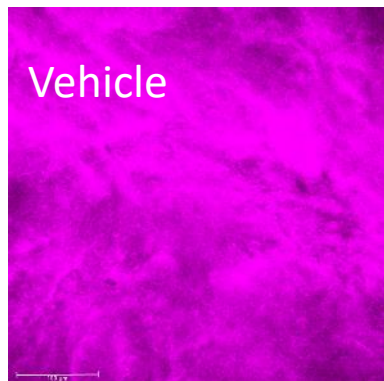
Data produced in the laboratory of Professor Paul Timpson (Garvan)

AMP945 inhibits collagen cross-linking *in vitro*

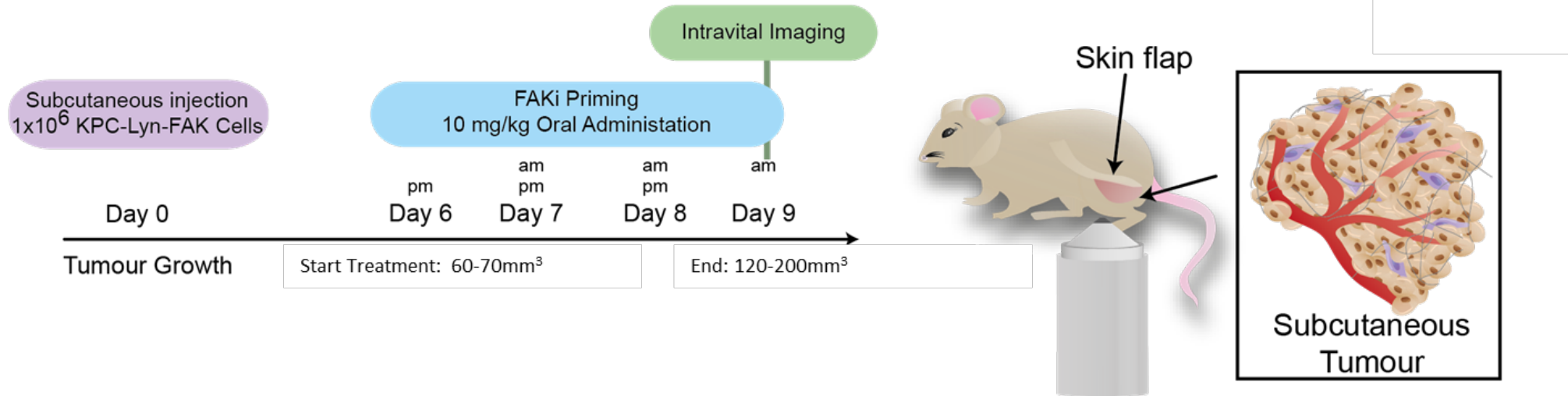


Take home messages:

- Crosslinked collagen is a key building block of fibrotic tissues
- AMP945 inhibits collagen cross-linking



In vivo study design

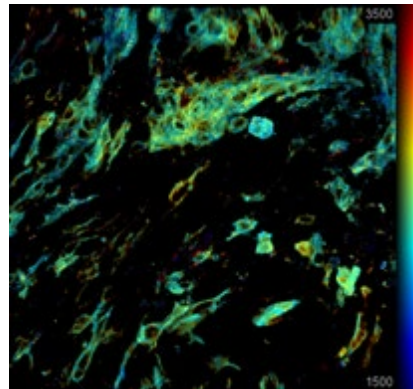


AMP945 inhibits p-FAK in the subcutaneous KPC mouse model of pancreatic cancer

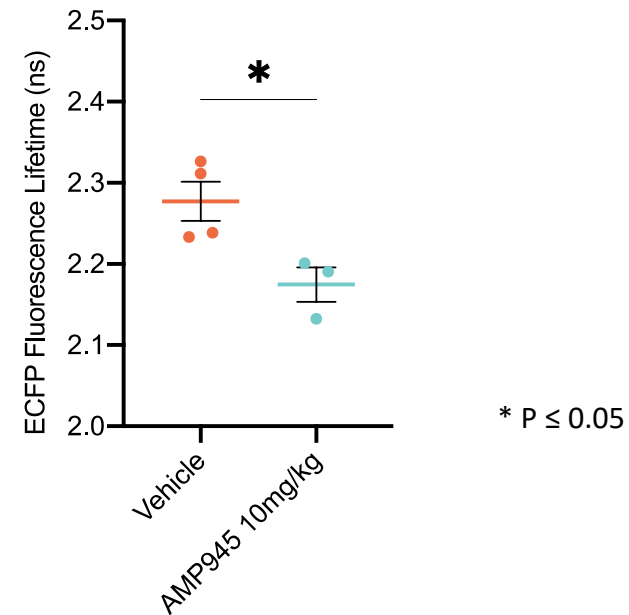
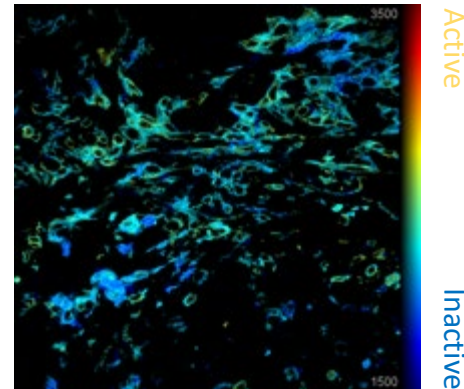


p397-FAK using FAK-Lyn biosensor

Vehicle



AMP945 10mg/kg



Data produced in the laboratory of Professor Paul Timpson (Garvan)

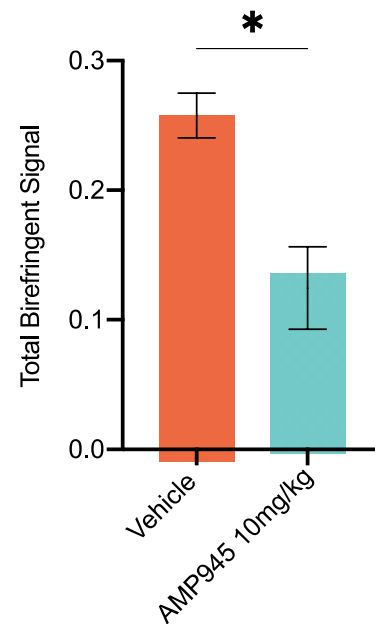
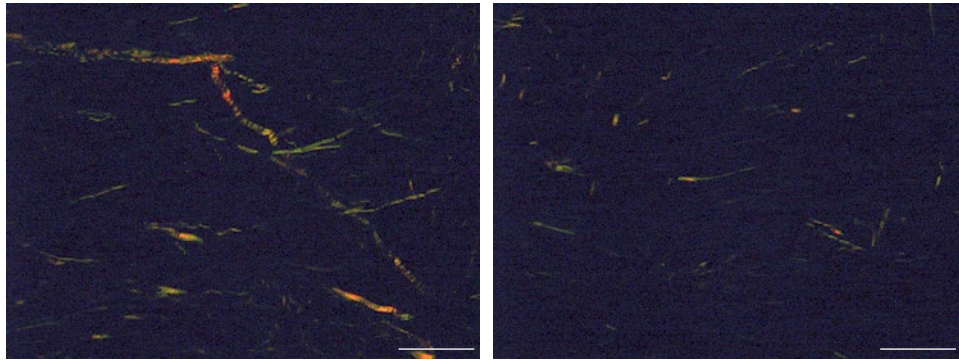
AMP945 inhibits collagen formation and cross-linking *in vivo*



Total collagen

Vehicle

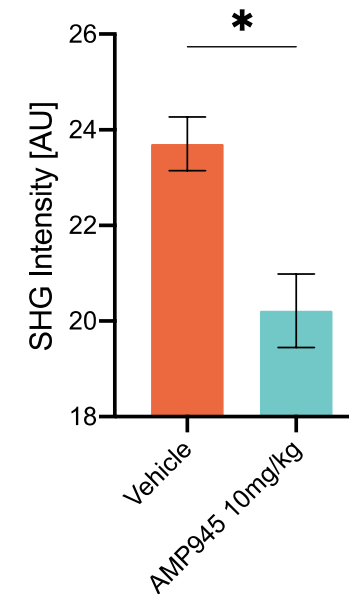
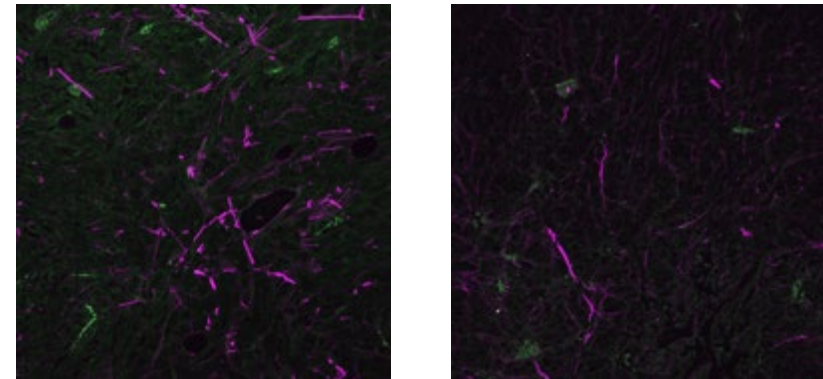
AMP945 10 mg/kg



Cross-linked collagen

Vehicle

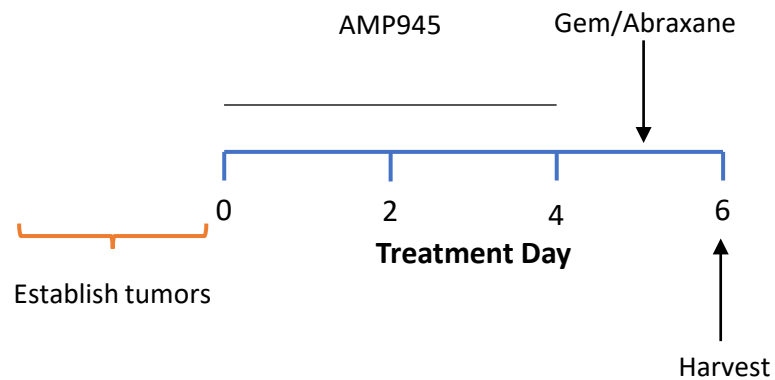
AMP945 10 mg/kg BID



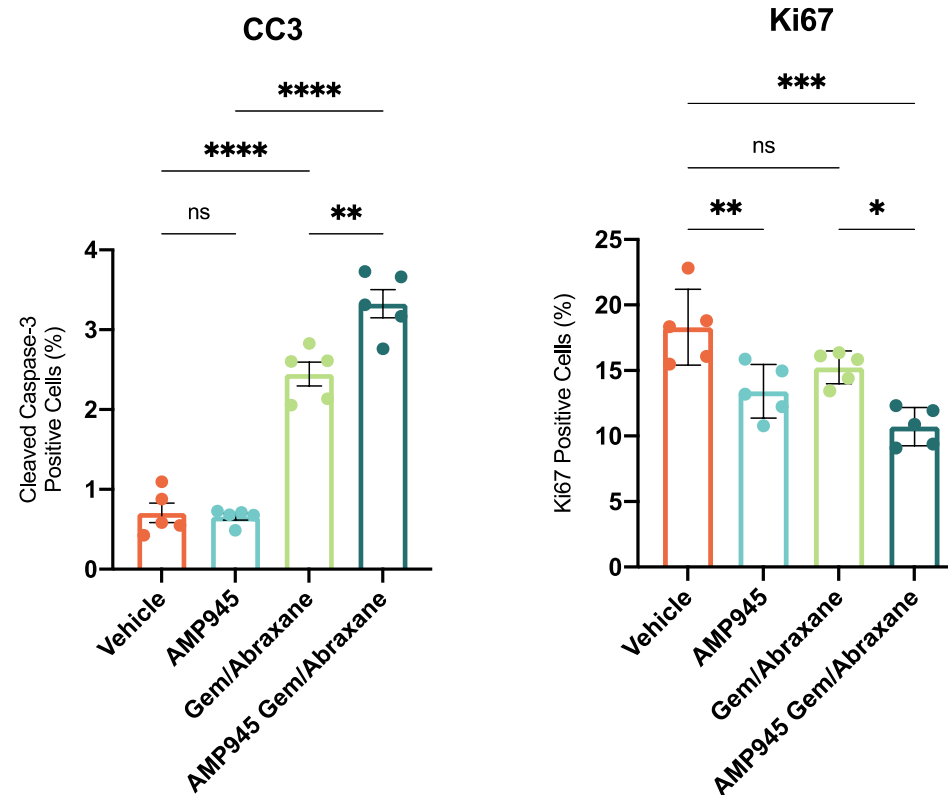
* P ≤ 0.05

Data produced in the laboratory of Professor Paul Timpson (Garvan)

AMP945 'priming' enhances response to Gemcitabine/Abraxane[®] *in vivo*



Tumors analysed 24 hrs post Gem/Abraxane administration



* P ≤ 0.05
 ** P ≤ 0.01
 *** P ≤ 0.001
 **** P ≤ 0.0001

CC3: Cleaved Caspase-3, a marker of cell death
 Ki67: a marker of cell proliferation

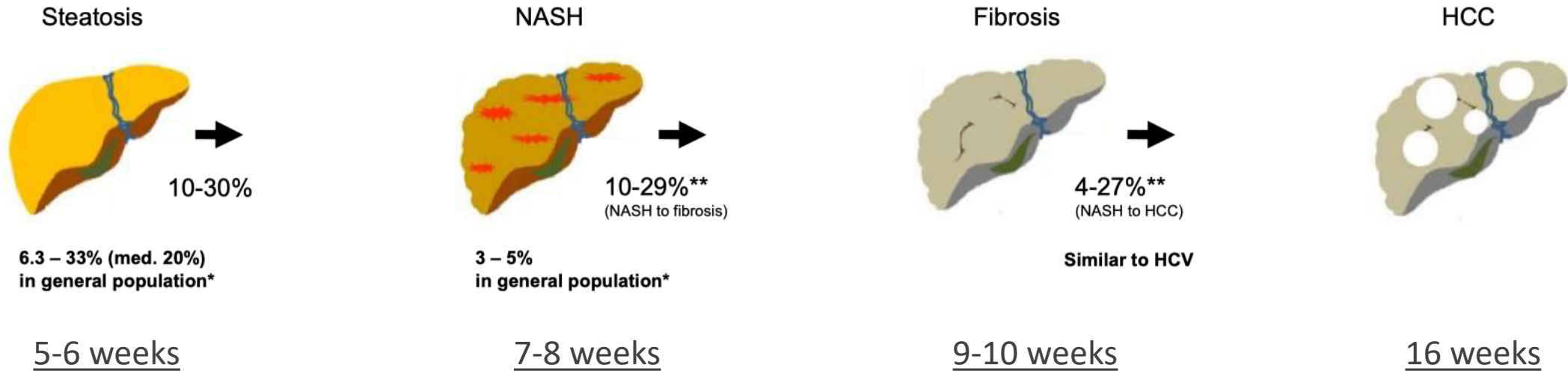
Take home messages from Garvan studies so-far



- AMP945 inhibits fibrosis markers both *in vitro* and *in vivo*
- Oral doses of AMP945 in mice inhibit p-FAK in tumors
- Priming with AMP945 enhances the effect of gemcitabine/Abraxane[®] as measured by impact on key markers of cell death and proliferation

NASH Preclinical Study

STAM™ - model of NASH¹



- 1st hit: Chemical – low dose of streptozotocin at birth
- 2nd hit: Diet – continuous high-fat diet

“An *in vivo* model which does appear to recapitulate most pathological attributes of NASH is the STAM™ mouse model.”

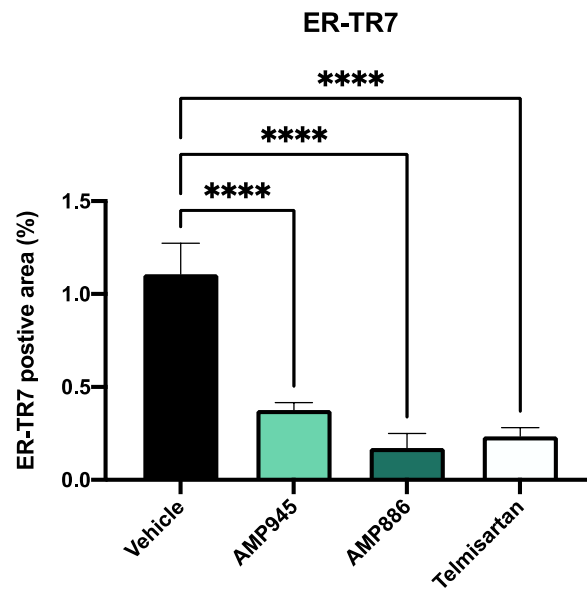
<https://insphero.com/blog/why-we-need-better-preclinical-models-for-nash-drug-discovery/>

¹NASH – Non-Alcoholic Steatohepatitis – fibrotic liver disease which affects approximately 5% of adults in the US

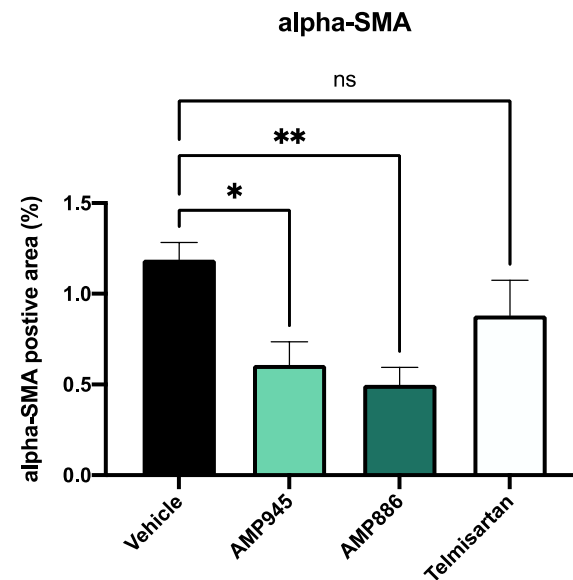
AMP945 effective in animal model of NASH



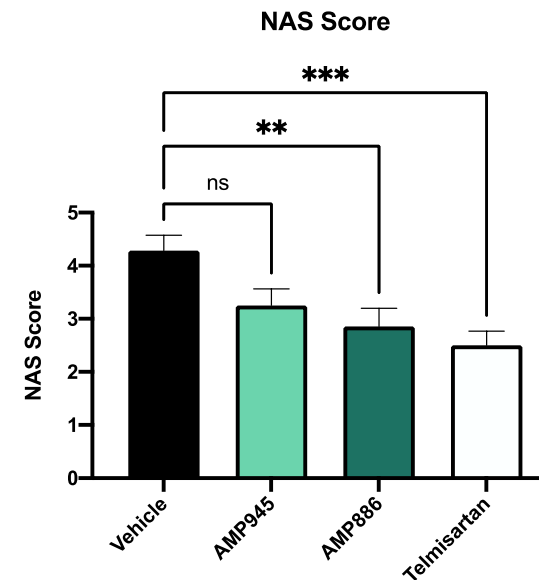
Fibroblast marker



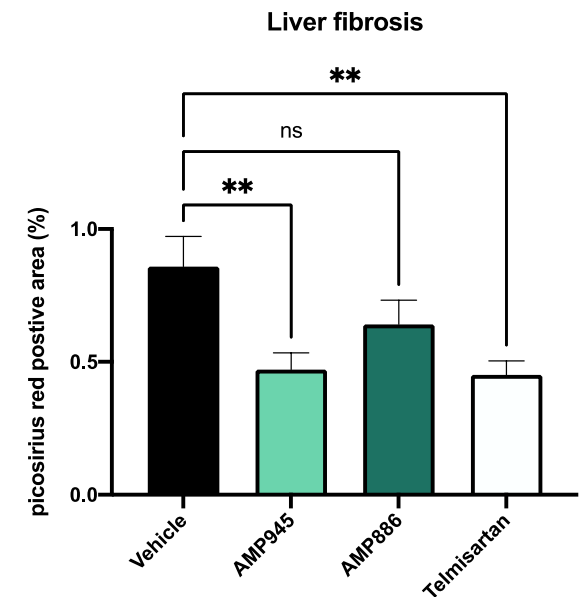
Fibroblast activation



NASH symptoms



Fibrosis



* P ≤ 0.05
** P ≤ 0.01
*** P ≤ 0.001
**** P ≤ 0.0001

Take home messages from NASH study



- AMP945 and AMP886 significantly inhibit fibroblasts and their activation in the liver
- These effects translate to inhibition of NASH and fibrosis in the liver
- The findings support utility of Amplia's FAK inhibitors in a variety of fibrotic diseases with unmet medical need

Summary



- Amplia has made excellent progress on development of its FAK inhibitor assets
 - Phase 1 trial on track
 - Exciting data from Garvan collaboration
 - Early signs of efficacy on NASH model
- Phase 2 studies well supported by a platform of clinical and pre-clinical data
- Further transformation and growth expected as the Company readies for Phase 2 clinical studies





ampliatx.com