

Due Diligence and Valuation Report

Arrowhead Code:	69-14-01
Coverage reinitiated:	February 23, 2024
This document:	February 23, 2024
Fair share value bracket	AUD 0.17 – AUD 0.30
Share price (February 23, 2024):	AUD 0.075 ⁱ

Analysts

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Market Dataⁱⁱ

52-Week Range:	AUD 0.062 – AUD 0.115
Average Daily Volume (3M Avg.):	40,259
Market Cap (February 23, 2024):	AUD 14.55 million (mn)

Company Overview: Amplia Therapeutics Limited (ATX or Amplia) is an Australian clinical-stage drug development company focused on developing small molecule inhibitors of Focal Adhesion Kinase (FAK) for the treatment of cancer and fibrotic diseases. The company is currently developing two proprietary, orally available, small molecule FAK inhibitors as candidate drugs – narmafotinib (AMP945) and AMP886. These two drugs inhibit FAK an enzyme which is believed to play a critical role in certain cancers and fibrotic diseases. Amplia was established to advance these potential drugs through clinical trials and eventually launch and commercialize them in the market.

Amplia’s lead drug – AMP945 – which is also known as narmafotinib, is a potent and selective FAK inhibitor. The company is evaluating the efficacy of using the drug in the treatment of pancreatic cancer and Idiopathic Pulmonary Fibrosis (IPF). The company completed a safety and tolerability study in healthy volunteers in 2021 and recently completed a Phase 1B clinical trial of narmafotinib in combination with standard-of-care treatment for pancreatic cancer.

The Phase 1B ACCENT trial, which was completed in 4Q23, indicated that the drug is safe and well-tolerated in patients when co-dosed with gemcitabine and Abraxane. The company has begun the Phase 2A trial of this combination and is recruiting patients across six sites in Australia and five sites in Korea.

The company’s second pipeline drug, AMP886, inhibits FAK and two other validated oncology targets (VEGFR3 and FLT3). This drug is currently being evaluated in preclinical models of cancer and fibrotic disease to identify future development, partnering, and licensing opportunities.

Amplia is listed on the Australian Securities Exchange (ASX) under the ticker “ATX”.



Company:	Amplia Therapeutics Limited
Ticker:	ASX: ATX
Headquarters:	Melbourne, Victoria
Non-Executive Chair:	Warwick Tong
CEO & MD:	Christopher Burns
COO:	Rhiannon Jones
Website:	www.ampliatx.com



Key Highlights: (1) Amplia’s core drug, narmafotinib, is undergoing Phase 2A clinical trials to test its efficacy when used in combination with gemcitabine and Abraxane, the current standard-of-care regimens used to treat pancreatic cancer; (2) ATX has begun the Phase 2A trial across six sites in Australia and five sites in South Korea; the recruitment process for patients is underway; (3) In January 2024, the company received the US Food and Drug Administration (FDA) clearance for its Investigational New Drug (IND) application that will support clinical trials for narmafotinib in combination with FOLFIRINOX, a standard-of-care treatment for pancreatic cancer used in the US and Europe; (4) Amplia, in partnership with the Stupack Lab at UCSD, is conducting preclinical studies to determine the potential of narmafotinib in ovarian cancer; the initial results demonstrate better tolerance and tumor reduction compared to PARP inhibitor (Niraparib) in a mouse model of maintenance therapy; (5) Amplia has received grant funding to support its research collaboration with the Commonwealth Scientific and Industrial Research Organization (CSIRO) to develop novel topical formulations of narmafotinib to reduce scarring and aid in the healing of wounds and burns; (6) AMP886 inhibits Acute Myeloid Leukemia (AML) in an established disease model, where it can enhance the efficacy of venetoclax therapy; (7) Narmafotinib has shown effectiveness in decelerating the advancements of fibrosis in the lungs, similar to nintedanib, which is the current standard-of-care medicine for IPF; (8) Amplia has received separate Orphan Drug Designation from the US FDA for narmafotinib in the treatment of pancreatic cancer and IPF.

Key Risks: (a) Unfavorable readouts in future clinical phases and pre-clinical studies; (b) Inability to secure funding for conducting trials for applications in pancreatic cancer and ovarian cancer.

Valuation and Assumptions: Based on the due diligence and valuation estimates, Arrowhead believes that Amplia Therapeutics’ fair market value per share is AUD 0.17 to AUD 0.30, derived using a Relative Valuation (RV) methodology.

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1. Investment Thesis

Arrowhead is initiating its coverage on Amplia Therapeutics Limited (ASX: ATX) with a fair value of AUD 0.17 per share in the low-bracket scenario and AUD 0.30 per share in the high-bracket scenario, derived using Relative Valuation methodology.

ATX is a clinical-stage drug development company currently developing two candidate drugs – AMP945 (narmafotinib) and AMP886 – that will deliver improved treatment outcomes for patients. These drugs are orally bioavailable inhibitors of FAK that are being tested for their use in the treatment of pancreatic cancer and fibrotic diseases. Further, the company is exploring application of the drugs in other diseases such as ovarian cancer, IPF and to reduce wounds and scars.

Successful completion of Phase 1B trials and commencement of Phase 2A trials for pancreatic cancer

Narmafotinib, the company’s lead drug, has completed the Phase 1B ACCENT trial, where it was administered along with gemcitabine and Abraxane – the current standard-of-care treatment for pancreatic cancer. In October 2023, the company announced encouraging results from these trials, which demonstrated narmafotinib to be safe and well-tolerated when used in combination with gemcitabine and Abraxane. While the trial was not powered for efficacy readouts, the preliminary efficacy data was encouraging when compared to historical data in the same patient population for the gemcitabine and Abraxane combination alone. The safety review committee examined the clinical trial data and endorsed the chosen dosage for the dose-expansion Phase 2a study. The company has received the necessary approvals to progress to Phase 2A trials at the existing sites in Australia and five new sites in Korea.

US FDA clearance for IND application of narmafotinib along with FOLFIRINOX

Amplia has been conducting pre-clinical studies to test the efficacy of narmafotinib when administered with FOLFIRINOX, a four-drug regimen, which is the standard-of-care treatment for pancreatic cancer in the US. Preliminary data has shown improved survival in mouse models of pancreatic cancer for mice treated with narmafotinib and FOLFIRINOX compared to those treated with FOLFIRINOX alone. This provides a strong rationale for clinical testing of this novel treatment combination. Earlier this month, Amplia received the US FDA’s clearance for its IND application for a clinical trial of narmafotinib in combination with FOLFIRINOX in advanced pancreatic cancer patients in the US. This combination trial will be crucial for Amplia to position its narmafotinib as the preferred drug to enhance the efficacy of existing chemotherapy combinations in pancreatic cancer.

Better performance compared to its peers

Narmafotinib displays significant advantages over its peer drugs such as defactinib, ifebemtinib and GSK2256098. The lead drug has showcased better selectivity and improved pharmacokinetics (PK) profile with minimal drug-drug interaction (DDI) liabilities. The PK profile refers to the absorption, distribution, metabolism, and excretion of drugs in the body. The DDI determines the influence of a second drug on exposure of the study drug and, conversely, the influence of the study drug on exposure of a second drug. Given that narmafotinib has been providing results in Phase 1B trials and has now moved into Phase 2A trials, its prospects look promising.

Partnership with Australian National Science Agency CSIRO for scar and wound treatment

Amplia has partnered with Australia’s national science agency, CSIRO, under a government sponsored granting scheme. The collaboration focuses on formulating narmafotinib for topical applications, particularly for wounds and burns, to aid in healing and minimize scarring. With the global wound healing market surpassing USD 20 bn, this initiative is poised to bolster ATX’s future growth.

Exhibit 1: Superior performance of narmafotinib vs peersⁱⁱⁱ

	Selectivity	Good PK profile	Good DDI profile	Clinical Notes	Stage of development
Narmafotinib	✓✓	✓	✓	Safe and well tolerated	Phase 1b/2a (pancreatic cancer)
Defactinib	✗	✗	?	Recent success in Phase 2 LGSOC	Phase 2 pancreatic & ovarian cancer trials in combination with PD1 or RAF/MEK inhibitors
Ifebemtinib	✓	✓	?	Drug related, off-target adverse events noted	Phase 2 (ovarian cancer) Phase 1b/2 in KRAS mutant solid tumours
GSK2256098	✓	✗	✗	First generation FAKI issues with DDI and MTD lower than effective dose	DISCONTINUED

Potential upside from other opportunities

While Amplia's primary focus is to deliver innovative outcomes in the treatment of pancreatic cancer, it has been working towards developing additional applications for narmafotinib. The company has been able to show effectiveness in decelerating the advancements of fibrosis in the lungs, similar to nintedanib, which is the standard-of-care treatment for IPF. Despite being poorly tolerated by IPF patients, nintedanib's annual sales exceed USD 2 bn. Given that narmafotinib is better tolerated in laboratory animals and clinically, management has initiated IND-enabling studies with narmafotinib in IPF.

...but certain risks could impede future growth

Unfavorable readouts in future clinical phases and pre-clinical studies

In the Phase 1B ACCENT trial of narmafotinib in combination with gemcitabine/Abraxane in pancreatic cancer, the drug was tested for safety and tolerability at increasing doses, but was not powered for efficacy readouts. While the preliminary data is positive, it is possible that the drug might not yield favorable results in the next phases of testing, which could be a huge setback for the company.

Inability to secure funding for future clinical trials

Amplia is currently well-funded to conduct the Phase 2A ACCENT trial. It has also recently received funding, in the form of grants, for narmafotinib's topical application for wounds and burns. However, the company's plans to conduct trials for applications in pancreatic cancer (combination with FOLFIRINOX) and ovarian cancer are completely dependent on its ability to raise further funding. The inability to raise appropriate funding at the right time may hamper its growth prospects.

2. Business Overview

2.1 Introduction^{iv}

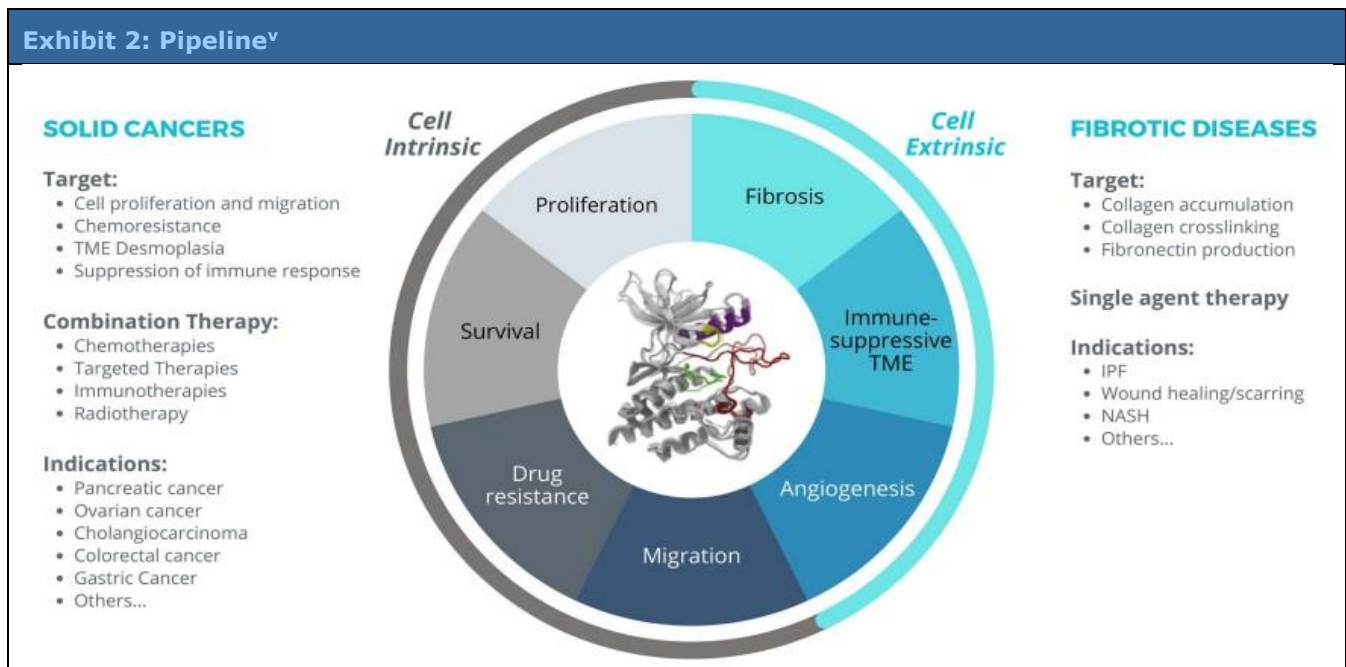
Amplia Therapeutics Limited is an Australian clinical-stage drug development company focused on the development of two orally available inhibitors of FAK – AMP945, or narmafotinib, and AMP886 – for the treatment of cancer and fibrotic diseases. The company was formed in 2016 and was reverse-listed onto the ASX in May 2018, when Innate Immunotherapeutics Limited (Innate), a listed entity, acquired Amplia Therapeutics Pty Limited (ATPL) by issuing stock as consideration. Through the transaction, Innate acquired ATPL’s FAK cancer program. In September 2018, Innate changed its name to Amplia Therapeutics Limited as part of a wider branding refresh.

The drugs in Amplia's current pipeline were discovered at the Melbourne-based Cancer Therapeutics Cooperative Research Centre, a partnership involving prominent cancer and drug discovery researchers from leading medical research institutes in Australia. Amplia was founded with the goal of progressing these promising drug candidates through clinical development and eventual commercialization.

Amplia’s first drug – AMP945, or narmafotinib – is a selective and potent FAK inhibitor and is in the clinical development stage for pancreatic cancer and advanced pre-clinical development for IPF. In 4Q 2023, Amplia completed the Phase 1B ACCENT trial of narmafotinib in combination with gemcitabine/Abraxane (current standard-of-care treatment for pancreatic cancer). The ACCENT safety review committee reviewed clinical trial data and endorsed the chosen dosage for the dose-expansion phase of the trial. They have advocated progressing to the Phase 2A segment of the trial, which is currently underway at the six existing trial sites in Australia at sites in Melbourne, Sydney, and Brisbane. In addition, the company has received approval from the South Korean regulator to conduct Phase 2A ACCENT clinical trials at the five selected clinical trial sites in South Korea.

The company’s second pipeline drug, AMP886, inhibits FAK and two key disease drug targets (VEGFR3 and FLT3). This drug is currently being evaluated in pre-clinical models of cancer.

ATX is the parent company with one wholly-owned subsidiary – ACN 612 556 948 Pty Ltd (formerly Amplia Therapeutics Pty Ltd). This subsidiary is the license holding company.



2.2 Pipeline drugs

Amplia’s pipeline consists of two proprietary small molecule FAK inhibitors – narmafotinib, or AMP945, and AMP886 – which are being tested for use in the treatment of cancer and a range of fibrotic diseases, in combination with the existing treatment regimens. Its lead candidate drug, narmafotinib, has successfully completed Phase 1B ACCENT trials

in pancreatic cancer and has commenced a Phase 2A trial to test its efficacy in conjunction with the current standard-of-care treatment for pancreatic cancer.



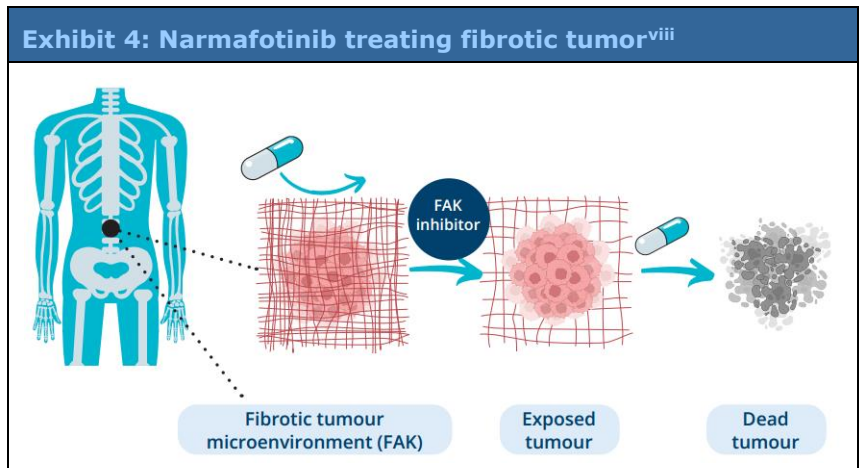
2.2.1 Narmafotinib or AMP945^{vii}

An inhibitor is a substance that slows down or prevents a particular chemical reaction/process or reduces the activity of a particular reactant, catalyst, or enzyme. Since inhibitors can be used to interfere with the activity of a specific enzyme, protein, or biological process in the body, they are increasingly used to treat various medical conditions, including but not limited to cancer, infectious diseases, and metabolic disorders. "Orally available inhibitors" refer to drugs or compounds that can be taken orally (through the mouth) and function as regular inhibitors.

FAK (focal adhesion kinase) is a non-receptor tyrosine kinase, an enzyme that acts as a primary regulator of focal adhesion signaling to regulate cell proliferation, growth, survival, and migration.

For this reason, FAK has been increasingly targeted in the treatment of cancer, particularly in cancers that generate a protective fibrotic tissue, and a micro-environment that suppresses the immune response (immuno-suppressive) around the tumor cells. By targeting FAK, there is potential to disrupt these fibrotic and immuno-suppressive pathways and slow the progression of cancer.

Narmafotinib is a highly potent and selective FAK inhibitor that was discovered through a structure-guided drug discovery program. It is an ATP (adenosine triphosphate) competitive, orally bioavailable, small molecule inhibitor of FAK that is used to block FAK activity in cancer cells and surrounding tissue, thereby blocking survival/proliferation signals, as well as inhibiting fibrosis and cell migration, making these cancers more vulnerable and responsive to the standard-of-care treatment regimens being used globally.



2.2.1.1 Narmafotinib’s application in the treatment of pancreatic cancer

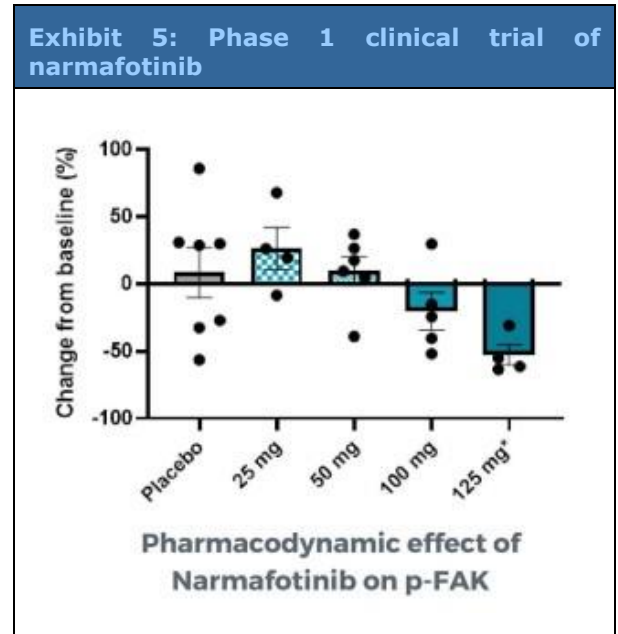
Pancreatic cancer or pancreatic ductal adenocarcinoma (PDAC) is a malignant tumor in the pancreas. PDAC progression is accompanied by a fibrotic response in the stroma, involving the elevated deposition and remodeling of extracellular matrix (ECM), promoting tissue stiffness, driving tumor progression and causing a poor chemotherapeutic response. The current standard-of-care chemotherapy treatments/regimens for pancreatic cancer are limited to gemcitabine in combination with Abraxane (nab-paclitaxel) or a FOLFIRINOX regimen consisting of oxaliplatin, irinotecan, leucovorin and 5-fluorouracil. However, the efficacy of these treatments is low, with a poor 5-year survival rate of 12%.

To enhance the existing survival rate in pancreatic cancer patients, Amplia has been testing its candidate drug, narmafotinib, under various conditions to improve the efficacy of the existing standard-of-care cancer treatments.

2.2.1.2 Phase 1 clinical trial (ACTRN12620000894998)

Phase 1 clinical trial of narmafotinib – a randomized, double-blind, placebo-controlled study of the safety, tolerability and pharmacokinetics of single and repeat doses of narmafotinib administered orally to 56 healthy adult volunteers. Amplia successfully completed these trials in 2021, with the drug exhibiting excellent safety, tolerability, and pharmacokinetic properties on daily oral doses of the drug. The key highlights of the trial included:

- The single ascending dose study showed that narmafotinib could be detected in the plasma over 24 hours following administration at various dosages as low as 15 mg and up to 125 mg.
- Dose and exposure-response in skin punch biopsies following a single treatment with narmafotinib showed drug target engagement through reduction of pTyr-397-FAK levels, with a clear dose linear relationship demonstrated by a significant change in FAK activity from baseline.
- No serious or severe treatment-emergent adverse events (TEAE)s, nor any TEAEs leading to study withdrawal were observed and the majority of TEAEs reported were mild.



On the back of positive data from this trial, Amplia moved to a Phase 1B/2A clinical trial of narmafotinib in patients with pancreatic cancer.

2.2.1.3 ACCENT trial (NCT05355298) – Narmafotinib (AMP945) in combination with Gemcitabine and Abraxane

The ACCENT clinical trial is a single-arm, open-label study to test the activity of Amplia’s FAK inhibitor narmafotinib in combination with standard-of-care chemotherapy for pancreatic cancer. The protocol for the ACCENT trial is entitled “A Phase 1b/2a, Multicentre, Open Label Study of the Pharmacokinetics, Safety and Efficacy of AMP945 in Combination with Abraxane and gemcitabine in Pancreatic Cancer Patients”. The trial includes two phases:

- **Phase 1B** – This is a dose-escalation phase with an aim to identify an optimal dose of narmafotinib that is safe and tolerable.
- **Phase 2A** – This is a dose-expansion phase where activity of the optimal dose is determined in a larger patient group to assess the efficacy of narmafotinib in combination with gemcitabine and Abraxane.

Phase 1B

The Phase 1B trials involved an intermittent dosing regimen of narmafotinib in combination with gemcitabine and Abraxane in first-line chemotherapy for patients with unresectable or metastatic pancreatic cancer. Patients received a one-week priming dosage of narmafotinib (once-daily oral capsule), after which gemcitabine and Abraxane were given according to standard-of-care chemotherapy. Patients were given intermittent dosing of narmafotinib for four days prior to weekly chemotherapy. Dosing of the third cohort of patients in the Phase 1B stage of the trial began in April 2023.

However, in August 2023, the company reported a dose-limiting toxicity event, and three new patients were added to the cohort, consistent with the trial protocol.

Phase 1B of the ACCENT trial of narmafotinib was successfully completed in October 2023, with the data identifying a dose of narmafotinib was safe and well tolerated. While the trial was not powered for efficacy readouts, the preliminary efficacy data was encouraging when compared to historical data in the patient population for the gemcitabine and Abraxane combination.

The ACCENT Safety Review Committee examined the clinical trial data and endorsed the chosen dosage. They have advocated progressing to the Phase 2A segment of the trial, which has now started.

Phase 2A

Given the excellent clinical trial capabilities and world-class cancer hospitals and physicians in South Korea, Amplia has moved to include the country in the trial to speed up recruitment of patients for the Phase 2A. In December 2023, Amplia received approvals from the South Korean Ministry of Food & Drug Safety (MFDS) for conducting Phase 2A ACCENT clinical trial. The enrolments are beginning at the five selected clinical trial sites in South Korea. Amplia is working closely with the selected sites to expedite the screening and recruitment process.

The trial will initially enroll 26 patients over the coming months and an interim analysis of efficacy will then be conducted in mid-2024. An efficacy assessment showing six or more partial or complete responses out of the 26 patients will indicate that the drug has sufficient efficacy to continue the trial. An additional 24 patients will then be enrolled to give a total of 50 patients for this trial.

The primary endpoints are Objective Response Rate (ORR) and Duration of Response (DOR), with secondary endpoints being Progression Free Survival (PFS) and Overall Survival (OS). Safety and tolerability will continue to be assessed.

An additional batch of drug capsules for the ongoing ACCENT trial has been prepared by Amplia’s US-based world-class drug product manufacturer under Good Manufacturing Practice guidelines. In January 2024, the Phase 2A ACCENT trial commenced.

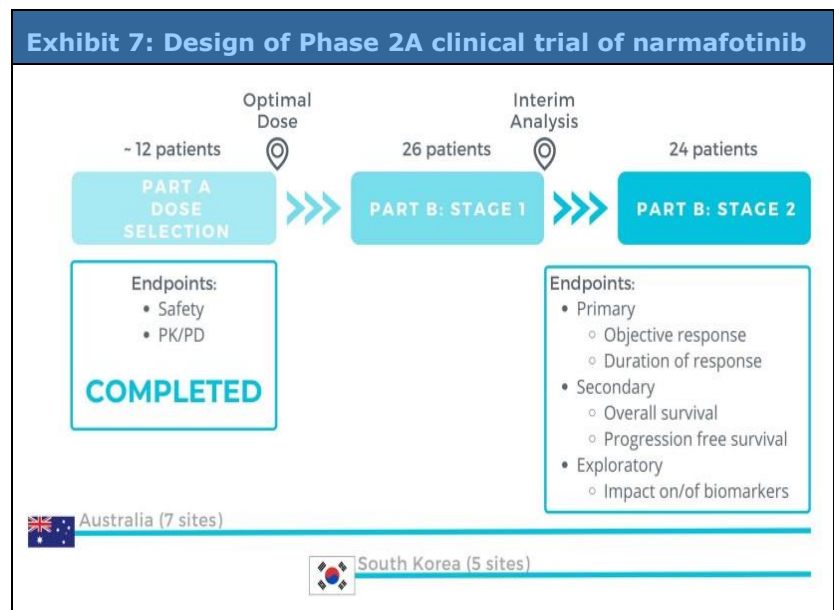
2.2.1.4 Clinical trials – Narmafotinib in combination with FOLFIRINOX

FOLFIRINOX, a standard-of-care treatment, is a combination of four chemotherapy drug regimens used for treating pancreatic cancer in many countries, such as the US and Europe. While it has shown some success in treating the deadly cancer, the median overall survival with this therapy is merely 11.1 months. Consequently, to improve the effectiveness of the treatment, Amplia has been conducting pre-clinical studies at Garvan Institute of Medical Research, Australia, to determine whether the efficacy of FOLFIRINOX can be improved when dosed in combination with narmafotinib. Preliminary data in mouse models of pancreatic cancer indicated up to ~35% improved survival for animals treated with

Exhibit 6: Phase 1B indications vs. historical response to Gemcitabine and Abraxane Combination ^{ix}

Classification	ACCENT Best Overall Response* n=14	Historical Best Overall Response** (n=431)
Complete Response (CR)	0 (0%)	<1%
Partial Response (PR)	5 (36%)	23%
Stable Disease (SD)	8 (57%)	27%
Disease Control Rate (PR + SD)	13 (93%)	50%
Progressive Disease (PD)	0 (0%)	20%
Not evaluable	1 (7%)	30%

* Investigator reviewed, not 100% Source Document Verified
** Independent review as part of MPACT trial (New England Journal of Medicine (2013) 369: 1691 – 703.)



narmafotinib and FOLFIRINOX compared to those treated with FOLFIRINOX alone. This provides a strong rationale for clinical testing of this novel treatment combination.

In 4Q23, Amplia filed the IND application to be reviewed by the US FDA to support the use of narmafotinib in combination with FOLFIRINOX for the treatment of pancreatic cancer. The IND submission included a comprehensive dossier with all the pre-clinical and clinical findings accumulated for narmafotinib so far, including comprehensive chemistry, manufacturing and controls information. The final document, with more than 10,000 pages, was the culmination of several months of work by the company.

In January 2024, Amplia received US FDA clearance for its IND application for a clinical trial of narmafotinib in combination with FOLFIRINOX in advanced pancreatic cancer patients in the US, which will expand the clinical opportunities for its FAK inhibitor. Given that FOLFIRINOX is the preferred treatment for pancreatic cancer patients in the US and most of Europe, this combination trial will be crucial for Amplia to position narmafotinib as the preferred drug to enhance the effectiveness of existing chemotherapy combinations in pancreatic cancer.

2.2.1.5 Additional clinical opportunities

1. **IPF** – IPF is a chronic, or long-term condition that affects the tissue surrounding the air sacs, or alveoli, in the lungs, making the lung tissue thick and stiff for unknown reasons. If the condition is prolonged, it can cause permanent scarring in the lungs, called fibrosis, which can make it progressively more difficult to breathe.

- In the industry standard mouse model of IPF, where the drug bleomycin is administered to induce lung injury and fibrosis in laboratory animals, narmafotinib has displayed similar activity when compared to the standard of care – nintedanib. Nintedanib and pirfenidone are the standard medicines that have demonstrated effectiveness in halting progression of fibrosis in the lungs.
- The desperation of the patients is such that they are willing to take the drug despite poor tolerance. Given that narmafotinib was better tolerated in the lab, management has initiated IND-enabling studies with narmafotinib in IPF.
- Ongoing reviews of scientific literature are conducted by the company to identify FAK's role in diseases, exploring the potential of a FAK inhibitor as a treatment option. Preliminary laboratory studies with narmafotinib have commenced in FY 2023, which are yet to be completed.

2. **Ovarian cancer** – Ovarian cancer is the presence of cancer cells in the ovary, fallopian tube, or peritoneum that grow out of control, forming a tumor. It is one of the deadliest cancers in females and it is estimated in the US alone, that over 13,000 patients died of ovarian cancer in 2023.

- Amplia has been working in partnership with Stupack Lab at UC San Diego, to conduct pre-clinical studies to determine the impact of narmafotinib in maintenance therapy for ovarian cancer. Currently, Poly (ADP-ribose) polymerases (PARP) inhibitors are used in maintenance treatment of high-grade serous ovarian cancer (HGSOC).
- In the studies at UCSD, narmafotinib demonstrated superior efficacy compared to PARP inhibitors in a mouse model of ovarian cancer, whilst also showing improved tolerability. Furthermore, narmafotinib showed promising activity in a model where the standard-of-care therapy was ineffective.
- In other studies from UCSD, results show that the activity of the FAK enzyme is upregulated in chemotherapy-resistant ovarian cancer and that FAK inhibition sensitizes the cancer to standard-of-care chemotherapy and immunotherapy as well, supporting a broad potential for narmafotinib in this disease.

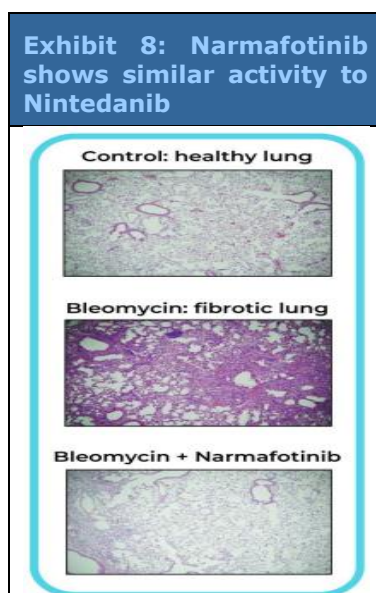
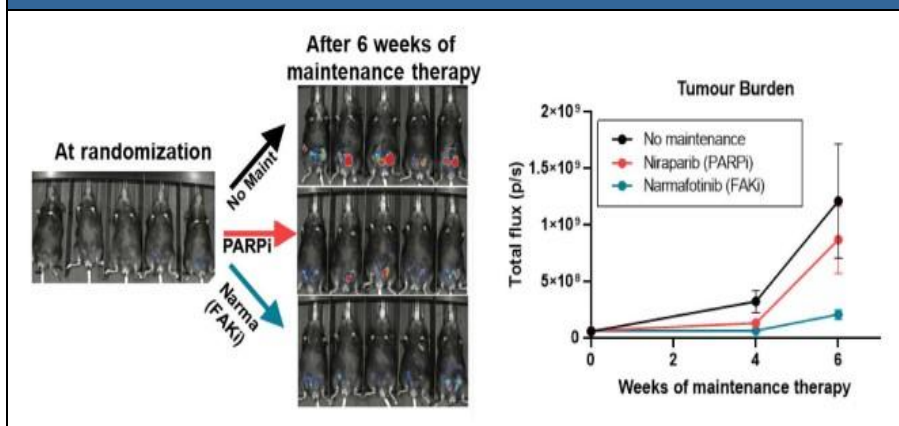


Exhibit 9: Narmafotinib acts as maintenance therapy in ovarian cancer treatment



2.2.1.6 Other key achievements

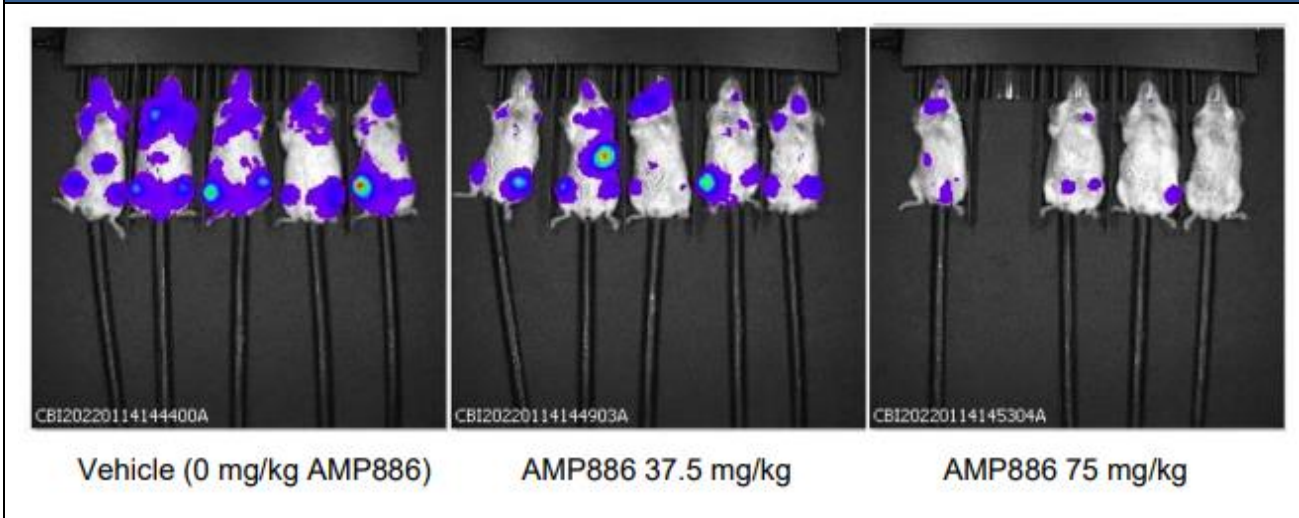
- The US FDA has granted orphan drug designations for two indications – pancreatic cancer and IPF – to Amplia’s narmafotinib. According to the US FDA, an orphan drug designation is a special status granted to drugs and biologics intended to treat rare diseases or conditions that affect fewer than 200,000 individuals in the US. Companies that obtain this designation may be eligible for various incentives, including tax credits for qualified clinical testing expenses, exemption from the FDA application user fee, and seven years of market exclusivity upon FDA approval. The FDA will not approve another drug with the same active ingredient for the same rare disease, except under certain circumstances.
- In June 2023, the World Health Organization (WHO) approved ‘narmafotinib’ as the International Non-proprietary Name (INN) for AMP945. This is an important milestone, as it signals the company’s intention to enter into commercial development of the drug.
- In May 2023, Amplia announced its collaboration with CSIRO, Australia’s national science agency, through grant funding, to develop formulations of narmafotinib for topical applications. Amplia will work with researchers at CSIRO to develop formulations of the drug that could be applied topically to wounds and burns and may aid healing and reduce scarring.

2.2.2 AMP886*

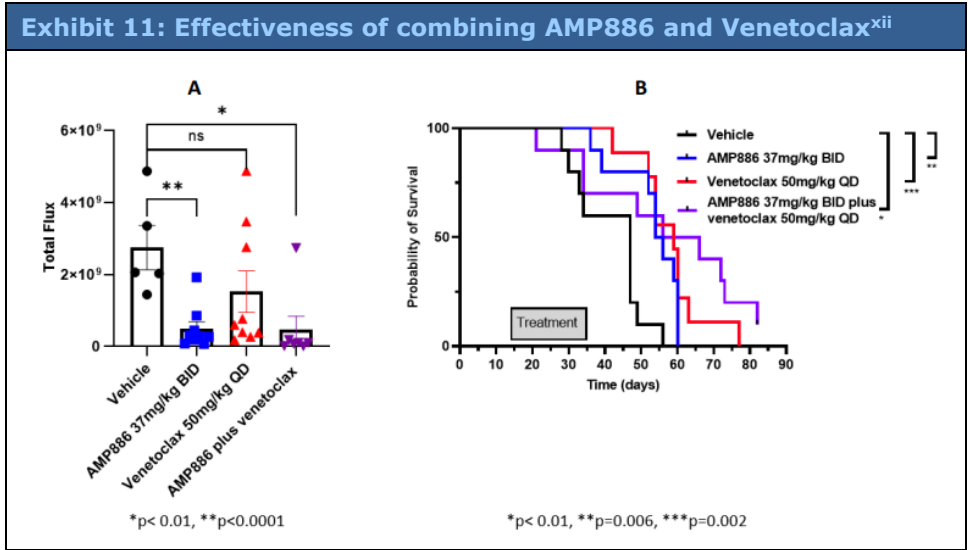
AMP886, another potent FAK inhibitor, targets two other validated disease targets (VEGFR3 and FLT3). Findings from pre-clinical studies indicate that AMP886 holds clinical promise for treating acute myeloid leukemia (AML) and specific types of solid tumors.

AMP886 inhibits AML in an established preclinical disease model, where it has been shown to enhance the efficacy of venetoclax therapy. This new opportunity expands the company’s pipeline into AML. Roughly 1% of all cancer diagnoses are AML – a heterogeneous cluster of cancers that affect blood and bone marrow. The most effective treatment for AML varies based on the patient but requires chemotherapy that can be toxic. Among the older patients, there is a lower response rate, and AML sees a high rate of relapse after treatment. Combining inhibition of FLT3 and FAK to overcome disease rebound following FLT3 monotherapy is an approach that may have a beneficial impact on AML patients.

Exhibit 10: Dose-dependent reduction in tumor growth measured via bioluminescence of AML MV4-11 cells following treatment with AMP886^{xi}



In a separate study, Amplia assessed the effectiveness of combining AMP886 with venetoclax, an approved drug for various blood cancers, in a mouse model of AML. The decision to add AMP886 to venetoclax was arrived at after reports suggested that a combination of FLT3 inhibitors and venetoclax could hold clinical promise for patients with relapsed or refractory AML. The data presented in Part A demonstrates that the combination of AMP886 and venetoclax is more proficient at reducing AML cell growth than venetoclax alone. In Part B, it is observed that while both AMP886 and venetoclax enhance survival in the MV4-11 model of AML, the combination of the two drugs tends to further improve survival.



2.4 Strategy and outlook^{xiii}

Amplia continues to scout for fresh avenues for collaboration, innovation, and the delivery of transformative outcomes for patients worldwide. As a company driven by values, Amplia pushes to shape a brighter future for its team, collaborative stakeholders, and the broader community. Its primary focus remains on advancing its leading asset, narmafotinib, through the ACCENT trial in pancreatic cancer. There are explicit plans to optimize the potential of the FAK inhibitor development program in various cancers and fibrotic diseases.

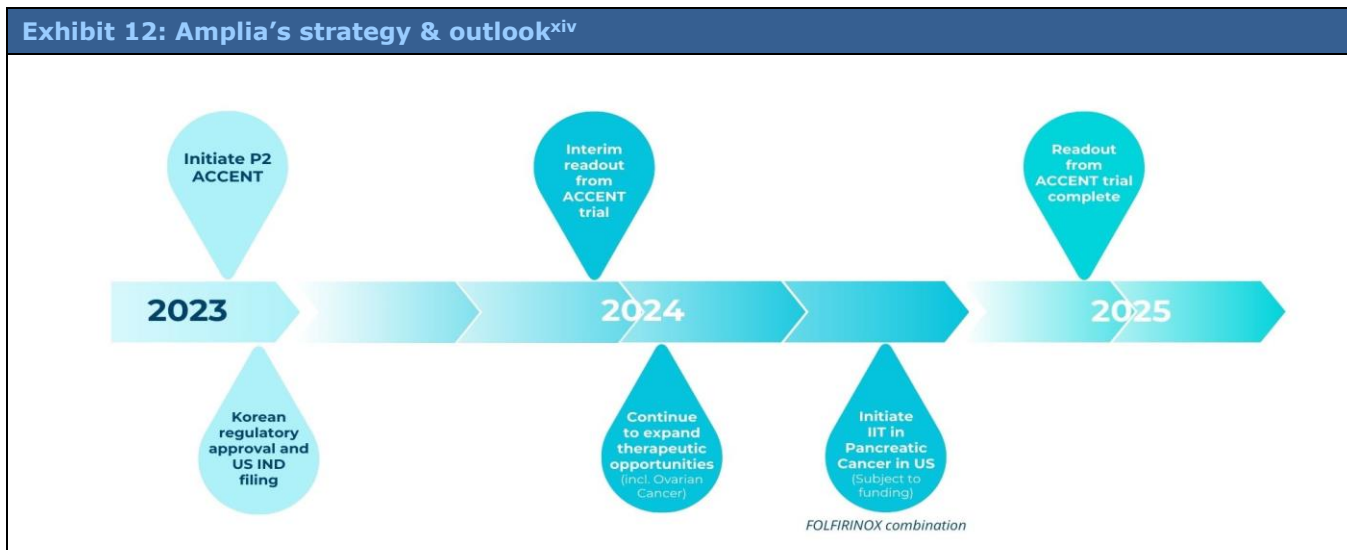
It is Amplia’s objective to position itself as a sophisticated and scalable company for the future. Guided by a highly qualified Board, the company is rooted in a culture of innovation and excellence, where planning and preparation are fundamental to its success.

Over the next 12 months, the company plans to advance its initiatives in drug discovery. The ACCENT trial has received approvals to conduct Phase 2A trial at the sites in Korea and Australia, and patients in Australia have already begun dosing, and the company expects to recruit patients in Korea very soon. While the Phase 1 trial was not powered for an efficacy readout, it still produced encouraging signs of efficacy, including a disease control rate of 93%, which compares to 50%-62% in prior trials of gemcitabine/Abraxane chemotherapy in similar patient populations.

The potential for the drug in ovarian cancer is significant, based on literature reports and data from their studies with UCSD. It is expected that the company will be able to initiate Phase 2 trials for this application over the next 12 months with discussions with clinicians already underway. Regarding applications of IPF, the company has completed its pre-clinical phase and expects to close IND-enablement by December 2024.

While the application of narmafotinib and AMP886 in other solid tumors is in pre-clinical stages, it is expected that the company will be able to progress narmafotinib in other applications soon.

The company has received the intellectual property (IP) for the composition of matter for narmafotinib and has filed for the salt form as well as method of use patents. The company also has an ongoing process of additional filings to extend the life of the IP.



2.5 Company strengths

- a) Large addressable market with strong growth potential:** Amplia’s targeted applications have a large market and are showcasing strong growth potential. The global pancreatic cancer market was estimated at over USD 6 bn in 2023 and is expected to surpass USD 36 bn by 2036. The increase in the number of pancreatic cancer patients is driven by changing lifestyle habits, adoption of alcohol and the increasing prevalence of obesity. The global ovarian cancer market was estimated at USD 1.5 bn in 2021 and is expected to reach USD 19.9 bn by 2031. A study on the economic burden of IPF found the average yearly total direct expenses per individual with IPF amounted to USD 31,655. When extrapolated from prevalence estimates, the overall annual expenditure in Australia was predicted to reach USD 299 mn. Nintedanib, which is the current standard of care for IPF patients and poorly tolerated, has annual sales of USD 2 bn.
- b) Significant advances in clinical trials process:** The company has made significant strides in completing its pre-clinical studies, IND enablement and clinical trials for its drugs and their respective applications. After the recent Phase 1B completion of narmafotinib’s application in pancreatic cancer, the company has already received all approvals and commenced Phase 2A trial. Continuous advances are being made to complete the IND enablement for narmafotinib’s ovarian cancer and IPF applications and preclinical studies for the use of narmafotinib and AMP886 to treat other solid tumors.

- c) Partnership with reputed institutions:** The company has partnered with institutions such as the Garvan Institute of Medical Research and Australia’s national science agency, CSIRO. They have helped the company proceed further in its studies and research into narmafotinib’s applications, along with FOLFIRINOX and topical applications of narmafotinib for wound and scar healing. The partnership with CSIRO also brought with it funding for the scar and wound application studies.
- d) Narmafotinib’s competitive advantage over its peers:** Having completed only Phase 1 of the clinical trials, narmafotinib has displayed some significant advantages over its peer drugs such as Defactinib, Ifebemtinib and GSK2256098. The lead drug has showcased better selectivity, pharmacokinetics profile and drug-drug interaction.

2.6 Company risks

- a) Unfavorable readouts in future clinical phases:** Future trials for the company’s core drugs may not meet the right efficacy requirements or obtain clearance from the regulatory authorities to get through to the stage at which the drug can be prescribed by doctors. Any setbacks in this phase can push the company back to pre-clinical studies where it might need to tweak its formulations and start again.
- b) Inability to secure funding:** The company would need to secure sufficient funding to bear all the R&D expenses for the clinical trials and completion of drug discovery. In its half-yearly report ended 30 September 2023, the company disclosed that it had sufficient funds to conduct its R&D work for the next 12 months.

2.7 Milestones

Exhibit 13: Company Milestones	
Year/Period	Events
2018	<ul style="list-style-type: none"> Reverse listing into Innate Immunotherapeutics by acquisition of Amplia Therapeutics Pty Limited. Innate’s board composition changed with the appointment of Andrew Cooke, Chris Behrenbruch, Chris Burns and Warwick Tong. Announced the change in the company name to Amplia Therapeutics Limited (ASX: ATX).
2019	<ul style="list-style-type: none"> Appointed Professor Lara Lipton and Professor Phil Hansbro to the scientific advisory board (SAB). Patent protection granted for the drug candidate AMP945. Appointed Dr. John Lambert as the CEO. Raised capital of AUD 2.7 mn for clinical enabling studies.
2020	<ul style="list-style-type: none"> Raised AUD 0.93 mn, including investment from Platinum International Healthcare. Board restructured with the appointment of Dr. John Lambert as Managing Director (MD) and Professor Paul Timpson to SAB and the exit of Dr. Chris Behrenbruch, Andrew Cooke and Simon Wilkinson from the company’s board. Received FDA orphan drug designation for pancreatic cancer and IDF. Announced capital raising of AUD 4 mn. Appointed Dr. Mark Devlin as Chief Scientific Officer (CSO) of the company.
2021	<ul style="list-style-type: none"> Appointed Jane Bell as an independent director. Collaboration agreement was signed with Garvan Institute of Medical Research. AMP945 progressed into later stages of clinical development in both cancer and fibrosis. Appointed José Iglesias as clinical advisor. Raised AUD 16.2 mn in new capital by share placement of AUD 3.8 mn and share placement & underwritten entitlement of AUD 12.4 mn.
2022	<ul style="list-style-type: none"> Phase 2 clinical trial of AMP945 in advanced pancreatic cancer patients approved by the Human Research Ethics Committee (HREC). Efficacy shown for AMP945 in a model of lung fibrosis. Dr. John Lambert resigned as CEO and MD. Appointed Dr. Christopher Burns as CEO and MD.
2023	<ul style="list-style-type: none"> Identified safe and tolerated dose of narmafotnib in Phase 1B portion of ACCENT clinical trials. Appointed Mr. Tim Luscombe as Chief Financial Officer (CFO). Phase 2 ACCENT trial in advanced pancreatic patients approved by the South Korean regulator. US FDA clearance received for IND application for clinical trial of narmafotinib in the US.

2.8 Shareholding pattern^{xv}

The company had 194,006,395 shares of common stock issued and outstanding on February 23, 2024. The shareholding pattern is as follows:

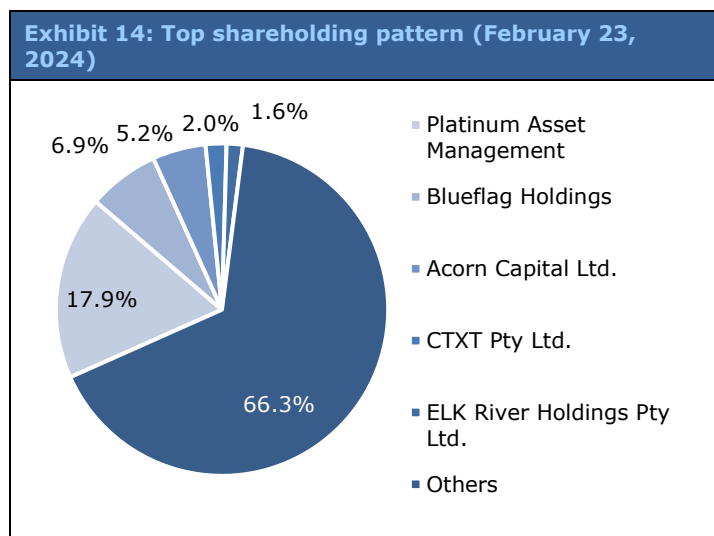


Exhibit 15: Top shareholding pattern (February 23, 2024)

Shareholders	Shares outstanding
Platinum Asset Management	34,813,002
Blueflag Holdings	13,472,500
Acorn Capital Ltd.	10,071,620
CTXT Pty Ltd.	3,940,579
ELK River Holdings Pty Ltd.	3,067,142
Others	128,641,552
Total	194,006,395

2.9 Listing and contact details

Amplia Therapeutics Limited is publicly listed on the Australian Securities Exchange and is traded under the ticker ATX.

Company Contacts

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Website: <http://www.ampliatx.com>

Email Id: info@ampliatx.com

3. News^{xvi}

- **Non-Executive Director loan for AUD 1.47 mn:** In January 2024, Amplia announced that it had entered into an unsecured loan agreement with Non-Executive Director, Dr Robert Peach. Under the agreement, Dr Peach had agreed to advance AUD 1.47 mn to Amplia, providing a non-dilutive extension to the company's cash runway at favourable terms for its current initiatives. The interest on the loan will accrue at 10% per annum on a pro rata basis and the repayment date will be earlier of 31 December 2024 or the receipt of FY 2024 R&D tax incentive refund.
- **US FDA clearance of Amplia's IND for pancreatic cancer trial in the US:** On January 18, 2024, Amplia announced that the US FDA cleared its IND application for a clinical trial of narmafotinib in the US. The proposed trial would explore the combination of narmafotinib and FOLFIRINOX in advanced pancreatic cancer patients in the US.
- **First patient dosing in Phase 2A ACCENT trial:** On January 17, 2024, ATX announced that the Phase 2A ACCENT trial in patients has commenced with the first patient being dosed with narmafotinib. The trial is being conducted at six trial sites open in Melbourne, Sydney and Brisbane and five additional sites which have been opened in South Korea. The trial will initially enroll 26 patients over the coming months and an interim analysis of efficacy will then be conducted in mid-2024.
- **Approval from Korean Regulator for Phase 2 of ACCENT trial:** On December 4, 2023, the company announced that it had received approval from the South Korean Ministry of Food and Drug Safety (MFDS) to test narmafotinib in combination with gemcitabine and Abraxane, in advanced pancreatic cancer patients in South Korea. With the approval, five preselected clinical trial sites could be opened to commence the enrolment of patients.
- **Positive results from clinical data of Phase 1B of the ACCENT trial:** On October 30, 2023, the company announced the completion of Phase 1B of the ACCENT trial. Dose escalation identified a dose of narmafotinib to provide sufficient drug levels to block the activity of the FAK enzyme. Phase 2A of the ACCENT trial would start immediately in seven trial sites in Melbourne, Sydney and Brisbane. Additionally, this dose was shown to be uniformly safe and well-tolerated across the cohorts of patients.
- **AUD 2.4 mn received in Research & Development (R&D) tax refund:** On October 19, 2023, the company announced that it had received AUD 2.4 mn in R&D tax refund. The refund was related to the company's expenditure in R&D for its FAK inhibitors, AMP945 and AMP886. After receipt of the refund, the company would repay the Victorian Government R&D cash flow initiative loan of AUD 2.4 mn.
- **Appointment of new CFO:** On September 25, 2023, the company announced the appointment of Mr. Tim Luscombe as the new CFO. Mr. Luscombe would replace Mr. Hamish George as CFO. He was the director of bio101 financial advisory and had been working with Amplia for the previous two years in a senior accounting capacity.
- **Approval of International Non-proprietary Name for AMP945:** On June 21, 2023, the company announced that its investigational FAK inhibitor, AMP945, was provided with the international non-proprietary name "narmafotinib." The company was allowed to use the name "narmafotinib" for AMP945, its leading FAK inhibitor.
- **AMP945 in combination with FOLFIRINOX enhanced treatment effect in Pancreatic Cancer Model:** On May 29, 2023, the company announced the enhancement of efficacy of AMP945, an investigational FAK inhibitor, in a pre-clinical model of pancreatic cancer when used in combination with FOLFIRINOX. Data from pre-clinical studies conducted at the Garvan Institute of Medical Research indicated improved survival for mice treated with AMP945 and FOLFIRINOX compared to those treated with FOLFIRINOX alone.
- **Grant funding to collaborate with Commonwealth Scientific and Industrial Research Organisation (CSIRO):** On May 22, 2023, the company announced that it had received grant funding for a research collaboration with Australia's national science agency CSIRO to develop topical formulations of the company's FAK inhibitors. It, along with CSIRO researchers, would develop a topical formulation of its small FAK inhibitors that could be applied to wounds and burns to help healing and reduce scarring. The global wounds and scars markets were estimated to be greater than USD 20 bn each.
- **Recruitment of second cohort for ACCENT trial completed:** On February 28, 2023, the company announced the completion of recruitment of the second cohort of the ACCENT trial in patients with pancreatic cancer. Following the results of Phase 1 of the ACCENT trial, the company's safety review committee, on January 11, 2023, approved the dose escalation of AMP945 for the second phase of the ACCENT trial.
- **Dose escalation and recruitment of cohort approved for ACCENT trial:** On January 11, 2023, the company announced that its clinical trial's safety review committee, following a review of safety data collected, approved dose escalation of AMP945 and recruitment of the second cohort. Dose escalation would continue until either a dose-limiting safety signal was achieved or the pharmacodynamic effect of AMP945 added no further efficacy.

- **First cohort of patients completed for ACCENT trial:** On November 29, 2022, the company announced it had completed enrolment of the first cohort of patients for the ACCENT trial. The first stage of the ACCENT trial was designed to test ascending doses of AMP945 administered in combination with standard gemcitabine/Abraxane chemotherapy in patients with advanced pancreatic cancer.
- **Appointment of Dr. Christopher Burns as CEO and MD:** On November 7, 2022, the company announced the appointment of Dr. Christopher Burns as CEO and MD starting December 5, 2022. Dr. Burns had over 25 years of experience in various roles in pharma, biotech and academia and had served as a non-executive member of the board.
- **Potential of AMP886 in the treatment of Acute Myeloid Leukemia (AML):** On October 3, 2022, the company announced that AMP886 inhibited AML in an industry-standard MV4-11 disease model, which also included Fms-like tyrosine kinase (FLT3) mutation. AMP886 inhibits both FAK and FLT3. In the second experiment, the company tested the efficacy of AMP886 with venetoclax, an inhibitor approved as a part of combination therapy, and it was shown that using AMP886 along with venetoclax improves survival in the MV4-11 model.
- **Dr. John Lambert Resigned as CEO and MD:** On September 12, 2022, the company announced that its CEO & MD, Dr. John Lambert, had resigned. Dr Lambert would leave the company in November 2022, and the search for a new CEO would commence immediately.
- **AUD 1.8 mn R&D tax incentive received:** On August 31, 2022, the company announced that it had received AUD 1.8 mn in an R&D tax incentive refund. The refund pertained to expenditure incurred in R&D associated with the company's FAK inhibitors, AMP945 and AMP886. These costs were associated with the company's phase 1B/2A ACCENT trials of AMP945, manufacturing development work and toxicology studies supporting longer-term dosing of AMP945.
- **First patient recruited for ACCENT trial:** On August 2, 2022, the company announced that the first patient had been dosed in the Phase 1B/2A ACCENT clinical trial of FAK inhibitor AMP945. Patients in the trial would receive AMP945 in addition to the standard treatment of gemcitabine/Abraxane. The use of AMP945 in the ACCENT trial was to enhance the efficacy of the standard treatment of gemcitabine/Abraxane chemotherapy for advanced pancreatic cancer.
- **AMP945 showed efficacy for lung fibrosis:** On June 2, 2022, the company announced that its FAK inhibitor, AMP945, had shown efficacy in a pre-clinical model of IPF. In the industry-standard bleomycin challenge mouse model of IPF, AMP945 had the same activity as OFEV (nintedanib), a market leader with net sales of EUR 2.5 bn.
- **Second ethics clearance for clinical trials of AMP945:** On May 13, 2022, the company announced that it had received HREC approval for Phase 2 clinical trials covering sites in Victoria, Australia. The approval allowed the company to accelerate recruitment and focus on the execution phase of the trial.
- **Pre-IND meeting with FDA:** On May 9, 2022, the company announced that the pre-IND meeting with the FDA's division of Oncologic Disease had been completed. The purpose of the meeting was to discuss Amplia's development plans for AMP945 and seek feedback on the design of the planned clinical study of AMP945. FDA recommended a more thorough interrogation of patient exposures to AMP945, gemcitabine and Abraxane by some further pharmacokinetic sampling.
- **Ethics clearance for the clinical trial of FAK inhibitor AMP945:** On April 6, 2022, the company announced the approval of a Phase 2 clinical trial in pancreatic cancer patients by HREC. The trial had two parts: in the first part, the optimal dose of AMP945 would be determined in approximately 12 patients and in the second part, 26 patients would be treated with an optimized dose of AMP945, along with clinically established doses of standard-of-care combination therapy consisting of gemcitabine and Abraxane.
- **AMP945 improved the effectiveness of Gemcitabine in the Human Pancreatic Cancer Model:** On February 17, 2022, the company announced that researchers at Garvan Institute in Sydney, Australia, had shown in an experiment conducted on mice that AMP945, when used in conjunction with gemcitabine, increased the survival rate by 33% compared to gemcitabine alone. In the experiment, the median survival time of untreated mice was 68 days as compared to the median survival time of 122 days for mice treated with gemcitabine only and the median survival time of 168 days for mice treated with AMP945 and gemcitabine.
- **Manufacturing of AMP945 for planned trials completed:** On January 13, 2022, the company announced that the manufacturing run of AMP945, a clinical-stage drug candidate, had been completed. This run provided additional drug supplies for support to toxicology studies and Phase 2 clinical trials in pancreatic cancer and lung fibrosis, scheduled to start in the first quarter of 2022.

4. Management and governance^{xvii}

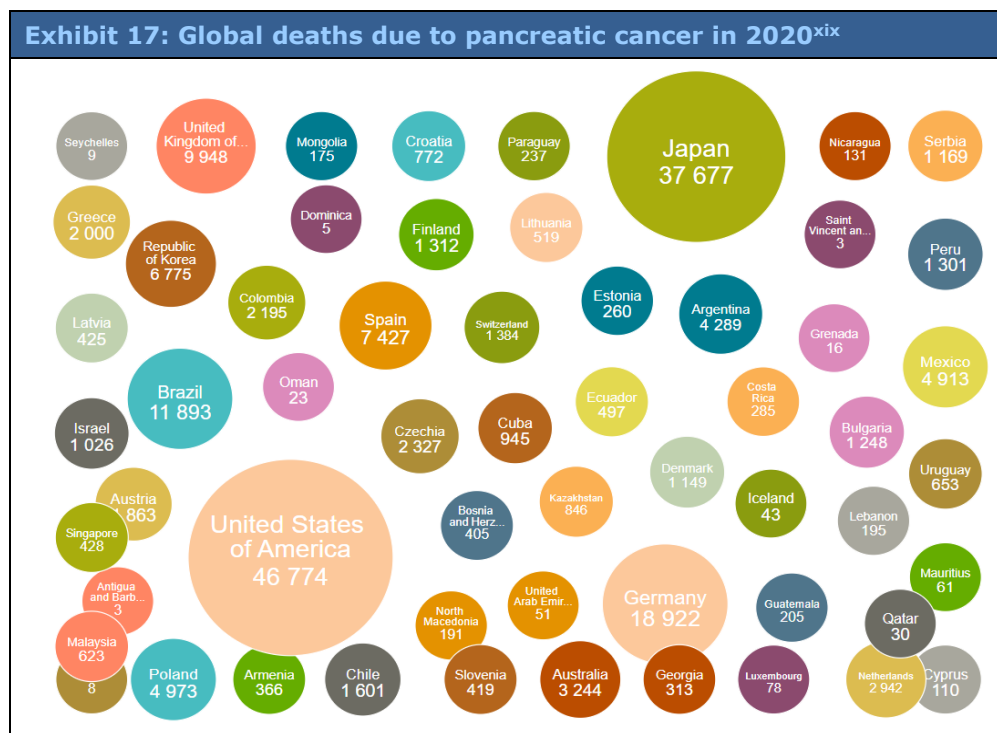
Exhibit 16: Management and governance		
Name	Position	Experience
Christopher Burns	Chief Executive Officer and Managing Director	<ul style="list-style-type: none"> Over 25 years of experience in various roles in pharma, biotech and academia. Held senior positions at various Australian biotechs including Cytopia, Certa Therapeutics and MycRx; and academic roles at the Walter and Eliza Hall Institute of Medical Research (WEHI) and University of Sydney. Inventor of over 30 patents and co-author of over 60 scientific publications. Fellow of Royal Society of Chemistry (UK) and Royal Australian Chemical Institute.
Rhiannon Jones	Chief Operating Officer	<ul style="list-style-type: none"> Over 10 years of experience in medical research and the biotechnology sector. Held senior roles at Cancer Therapeutics (CRC), WEHI and Monash University. Qualifications include PhD (chemistry), BSc (Honors) from the University of Adelaide and Certificate in Governance Practice from the Governance Institute of Australia.
Tim Luscombe	Chief Financial Officer (CFO)	<ul style="list-style-type: none"> Works as a CFO and company secretary (CS) for ASX-listed healthcare, private university spin-out companies and venture capital investee companies. Qualifications include a Bachelor of Commerce degree and Chartered Accountant qualification.
Warwick Tong	Non-Executive Chairman of the Board	<ul style="list-style-type: none"> Over 25 years of experience in pharmaceutical and biotechnology industries. Held senior roles in Glaxo, GlaxoWellcome, GSK, Surface Logix and Cancer Therapeutics CRC. Serves on SAB at Maurice Wilkins Centre, Cortex Health, University of Melbourne, and CSIRO Manufacturing.
Robert Peach	Independent Non-Executive Director	<ul style="list-style-type: none"> Over 25 years of experience in the pharmaceutical and biotechnology industries. Held senior scientific roles in Apoptos, Biogen Idec, IDEC and Bristol-Myers Squibb. Inventor and co-author of 17 patents and 70 scientific publications.
Jane Bell	Independent Non-Executive Director	<ul style="list-style-type: none"> More than 30 years of experience in financial services, law firms and corporate treasury. Serves as deputy chair at Monash Health, director at Mesoblast Limited (ASX: MSB) (Nasdaq: MESO) and at Jessie McPherson Private Hospital.
Andrew J. Cooke	Company Secretary	<ul style="list-style-type: none"> Over 30 years of experience in boardroom, law, corporate finance, governance and compliance. Worked as a consultant for public and private companies in the biotech, resources, property, mining services and technology sectors.

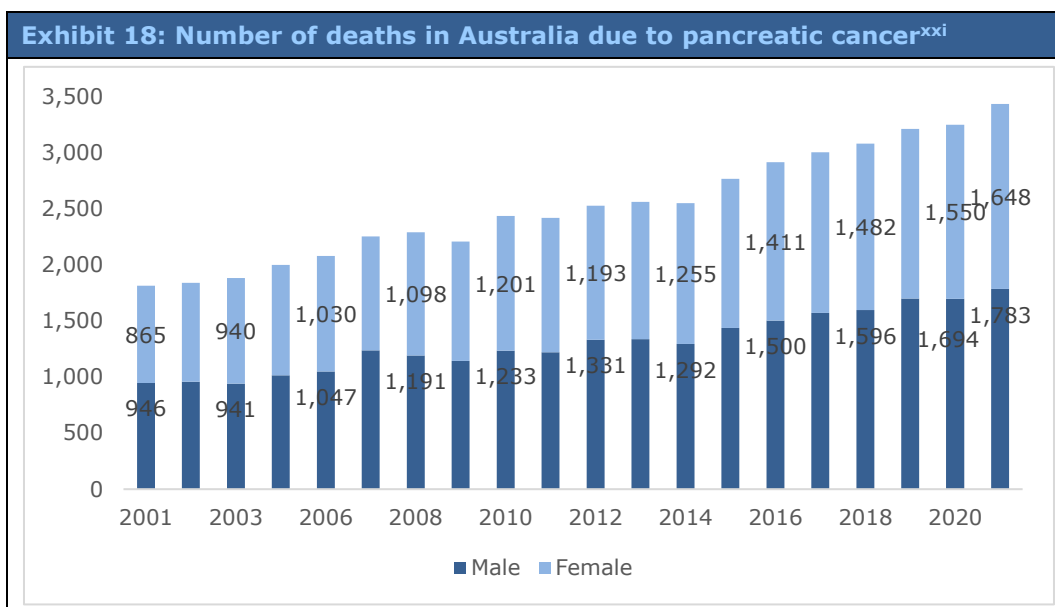
5. Industry overview

Amplia operates in the pharmaceutical industry and is engaged in the drug development of two oral inhibitors of FAK for treatment of cancer and fibrotic diseases. Its lead drug, Narmafotinib, has completed Phase 1 trials for pancreatic cancer application along with gemcitabine/Abraxane. Plans are underway to also trial the drug in combination with FOLFIRINOX, a standard-of-care treatment for pancreatic cancer. Its other applications include IPF, ovarian cancer, and topical applications for wounds and burns.

5.1 Pancreatic cancer^{xviii}

Pancreatic cancer is a state where the normal functioning of the pancreas has been disrupted. Healthy cells in this vital organ start growing uncontrollably, forming a mass known as a tumor. This tumor is malignant, and has the potential to grow and invade other parts of the body. As the tumor grows, it can impair pancreatic function, infiltrate nearby blood vessels and organs, and eventually spread to distant sites through a process called metastasis.





Pancreatic cancer, among all upper gastrointestinal cancers (occurring in organs of the upper digestive system such as the pancreas, liver, stomach, esophagus, and biliary system), exhibits one of the lowest survival rates beyond a five-year period at 12%. Projections indicate that by 2030, it is expected to become the second leading cause of cancer-related deaths. Unfortunately, two-thirds of pancreatic cancer patients succumb within the first year of diagnosis, and the survival rates for this type of cancer have shown minimal improvement over the past 40 years. Consequently, there is an urgent need for improvement in the current treatment for the disease.

5.1.2 Risk, symptoms and treatment ^{xxii}

Referred to as a "silent disease," pancreatic cancer is often diagnosed in advanced stages of growth. This is attributed to the pancreas being situated behind the stomach, allowing the cancer to go unnoticed until it reaches a size that impacts nearby organs. There are numerous factors that increase the risk of developing pancreatic cancer, and having one or more risk factors does not necessarily mean that one will develop pancreatic cancer. The factors that increase the risk of pancreatic cancer include:

- Smoking
- Overweight or obesity
- Exposure to chemicals and heavy metals found in pesticides and dyes
- Increasing age (most cases occur in adults over 60)
- Having a personal / family history of chronic pancreatitis, pancreatic cancer, ovarian cancer or colon cancer
- Diabetes (especially type 2 diabetes) and long-term use of diabetes medicines
- Excessive alcohol consumption and liver cirrhosis

There are two types of pancreatic cancers – endocrine and exocrine – both with different symptoms. These symptoms may include jaundice, pain in abdomen, weight loss / loss of appetite, indigestion / heartburn / feeling full, pale & greasy stools, nausea, fatigue, blurred vision, passing urine often, reflux etc. Numerous tests can be performed to investigate the symptoms and confirm the diagnosis of the type of pancreatic cancer. The commonly performed tests include physical examination, imaging tests, CT scan, MRI scan, ultrasound tests (including endoscopic ultrasound), somatostatin receptor scintigraphy, PET scans, angiography X-rays, surgery to examine organs or biopsy of pancreatic tissue.

The treatment of pancreatic cancer may differ based on the type of cancer, stage of disease, location, severity, general health, and choice of the patient. The current treatment regimens include:

- **Surgery:** Curative surgery aims to completely remove detectable cancer, while palliative surgery addresses advanced cases to alleviate symptoms. Endocrine cancers are more successfully treated with surgery, especially

those in the pancreatic head, often diagnosed early due to jaundice. However, most pancreatic cancers are diagnosed at an advanced stage, limiting surgical options. Staging laparoscopy assesses the cancer's extent and potential for resection, involving keyhole surgery and a biopsy of abnormal areas.

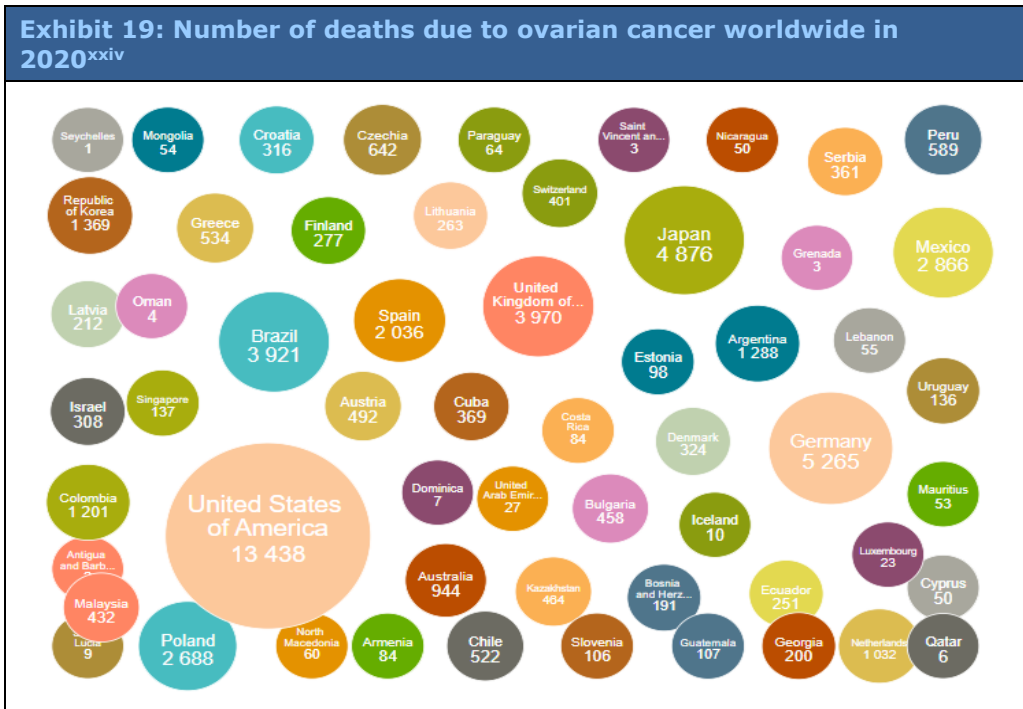
- **Ablation and embolization:** Ablation and embolization are not typically curative for pancreatic cancer; their primary purpose is symptom relief. Ablation employs heat (radiowaves or microwaves) or cold (cold gases) delivered through thin probes to destroy tumors. In contrast, embolization entails injecting a substance into an artery to block blood flow to the cancer tissue, inducing its death.
- **Radiation therapy:** In addition to surgery, patients may undergo radiation therapy for pancreatic cancer, which is typically administered externally using a machine. It is more effective for exocrine pancreatic cancer than for endocrine cancers, as the latter often exhibits poor responses to standard radiation. For treating endocrine cancers, a distinct form of radiation therapy called "peptide receptor radionuclide" therapy may be employed. This specialized treatment involves injection by a specialist, such as a nuclear physician.
- **Chemotherapy:** Paired with surgery, patients might be recommended to undergo chemotherapy. Prior to surgery, termed neoadjuvant therapy, chemotherapy can reduce tumor size, facilitating more successful removal. Post-surgery, adjuvant treatment may be prescribed to minimize the risk of cancer resurgence after resection.
- **Targeted therapy:** Targeted therapy involves the use of medications crafted to selectively target cancer cells while sparing normal ones. These drugs influence the growth, division, repair, or interactions of cancer cells. Individuals with advanced endocrine cancers may receive targeted therapy drugs such as sunitinib and everolimus.

While Amplia's drug narmafotinib is not a standalone treatment for pancreatic cancer, it is currently being tested in combination with the existing standard-of-care treatment for the disease to enhance the effectiveness of these regimens. Narmafotinib has commenced Phase 2 clinical trial for application in pancreatic cancer, whereby it is being administered along with chemotherapy drugs, gemcitabine and Abraxane. While Phase 1 was not powered for efficacy, the drug displayed high disease control rates. In pre-clinical models, narmafotinib has showcased improved survival when dosed in combination with gemcitabine / Abraxane (standard-of-care in Australia) and Folfirinox (standard-of-care in the US & France).

5.2 Ovarian cancer^{xxiii}

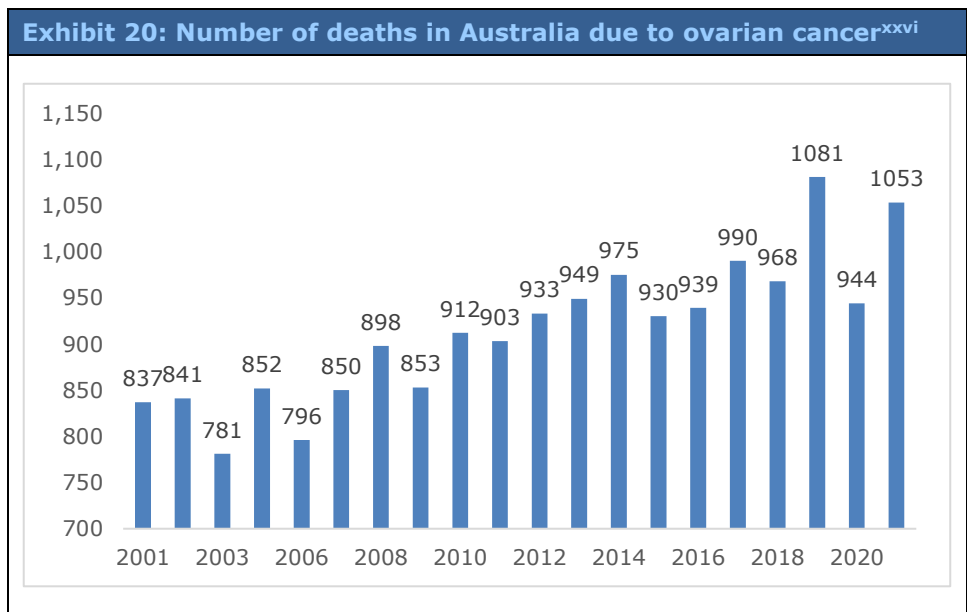
Ovarian cancer is a term often used to describe the presence of cancer cells in the ovary, fallopian tube, or peritoneum. These types of cancer begin when healthy cells in these areas change and grow out of control, forming a tumor. High-grade serous ovarian cancer remains the most lethal of the gynecologic malignancies, because of the high incidence of recalcitrant and rapidly recurring disease. Disease recurrence is now better controlled due to maintenance therapy with PARP inhibitors, particularly in homologous repair deficient tumors.

The global ovarian cancer market was worth USD 1.5 bn in 2021 and is expected to grow at a 23.8% CAGR between 2022 and 2031, to reach USD 19.9 bn. According to the American Cancer Society, ovarian cancer is the fifth leading cause of cancer death in women in the US, with more deaths than any other cancer of the reproductive system.



5.2.1 Ovarian cancer in Australia^{xxv}

In 2022, approximately 1,815 women were diagnosed with ovarian cancer, representing 2.5% of all new female cancers. During the same period, 1,016 women succumbed to the disease, accounting for 4.6% of all female deaths in the country. The five-year survival rate for ovarian cancer stands at 49%, and an estimated 5,035 women were alive with the disease in 2017 (diagnosed between 2013 and 2017). It is estimated that a woman has a 1.2% (1 in 84) chance of developing ovarian cancer by the age of 85 in the country.



With around 1,000 lives being claimed by ovarian cancer each year in Australia, it is projected that within the next decade, approximately 10,000 Australian women and girls may lose their lives to this disease. Despite the existence of early detection tests for ovarian cancer, the elusive nature of symptoms and the absence of a reliable screening method

result in the cause remaining unknown in the majority of cases. While a small percentage can be linked to genetic predisposition, about 70% of cases are diagnosed in the advanced stages, where the cancer has already spread to other areas of the body.

5.2.2 Risk, symptoms and treatment ^{xxvii}

While numerous factors may increase the risk of developing ovarian cancer, possessing one or more risk factors does not translate into certainty of developing it. The factors that increase the risk of ovarian cancer include:

- Family history of ovarian cancer
- Mutation in one of several known genes
- Genetic conditions like Lynch syndrome
- Increasing age – ovarian cancer is more common in women over 50
- Medical conditions such as endometriosis
- Use of hormone replacement therapy
- Excessive smoking and/or consumption of tobacco
- Obesity

The symptoms of ovarian cancer include abdominal bloating or increased abdominal size, abdominal or pelvic pain, appetite loss, feeling full quickly or indigestion, needing to urinate more often or urgently, changes in bowel habits, constipation or diarrhea, unexplained weight loss or weight gain and unexplained fatigue. The common tests include physical examination of abdomen and pelvis, ultrasounds, CT scan, MRI scan, PET scan, chest X-ray, blood tests to check for tumor markers, colonoscopy, surgery for biopsy and molecular and genetic testing to look for any inherited mutations.

The treatment of ovarian cancer differs based on each case and is dependent upon the stage of disease, location, severity and general health and choice of the patient. The current treatment regimens include:

- **Surgery:** The extent of the surgical intervention depends on the cancer's stage, with options ranging from the removal of a single ovary and its attached fallopian tube to the extraction of both ovaries and fallopian tubes, the uterus, the omentum, and/or lymph nodes. In cases where the cancer has advanced, the objective of surgery is to minimize the size of the tumors, ensuring no visible cancer remains — a procedure known as maximal tumor resection or cytoreductive/debulking surgery. The prognosis and survival outcomes are more favorable for women when the surgery successfully eliminates visible cancer, and chemotherapy follows the procedure. If the cancer has extended to other organs, it is likely that surgical removal of additional organs will be necessary. These may encompass the intestines, stomach, bladder, diaphragm, liver, spleen, gall bladder, appendix, pancreas, and peritoneum. In cases of highly advanced cancer, achieving maximal resection may not be feasible. Concurrently, other factors like pre-existing heart, lung, or additional medical conditions may render anesthesia and surgery impractical. In such instances, chemotherapy may be necessary to reduce the size of the tumors.
- **Chemotherapy:** Most women diagnosed with ovarian cancer undergo post-operative (adjuvant) chemotherapy to eradicate any residual cancer following surgery. In certain cases, particularly for women with stage III or IV ovarian cancer, neoadjuvant chemotherapy may be employed before surgery to reduce tumor size, facilitating a successful resection. A medical oncologist typically prescribes chemotherapy, and it is commonly administered intravenously. In instances of advanced or stage IV ovarian cancer, chemotherapy serves as the primary treatment to impede cancer growth and enhance overall survival.
- **Radiation therapy:** Along with surgery, some people may receive radiation therapy. This treatment is not commonly used to treat ovarian cancer, but it can be used to help relieve symptoms caused by the cancer or when it has come back after treatment (recurred).
- **Targeted therapy:** Targeted therapy involves the use of medications specifically crafted to target cancer cells while sparing normal cells from harm. In the case of advanced ovarian cancer, certain individuals may be presented with the option of receiving treatments like bevacizumab, as well as PARP inhibitors such as olaparib and Niraparib.
- **Hormone therapy:** Hormone therapy, employing hormones or medications that inhibit hormone action, is more commonly employed for ovarian stromal tumors than for epithelial ovarian cancer. Hormone therapies for ovarian cancer encompass luteinizing hormone-releasing hormone (LHRH) agonists, tamoxifen, and aromatase inhibitors. These treatments function to hinder estrogen's ability to stimulate the growth of cancer cells either by diminishing estrogen levels or acting as anti-estrogens.

Amplia has been testing its drug narmafotinib, along with Stupack Labs at UCSD, for applications in the treatment of ovarian cancer. In a mouse model of maintenance therapy, where the tumor was introduced in the vehicle and consequently removed, narmafotinib trended towards tumor reduction when compared to PARP inhibitors (Niraparib, i.e. targeted therapy). Narmafotinib was better tolerated than PARP inhibitors.

5.3 Idiopathic pulmonary fibrosis^{xxviii}

IPF is a condition where the scarring of the lungs leads to progressively challenging breathing. Broken down phonetically, pulmonary fibrosis translates to scarring in the lungs. Pulmonary fibrosis can be caused by several exposures – asbestos, coal dust, silica, etc. Certain medicines like amiodarone, bleomycin and nitrofurantoin list pulmonary fibrosis as a side-effect. It can also be caused by autoimmune conditions or can be hereditary. Evidently, there are many cases of pulmonary fibrosis in which a cause cannot be identified and are therefore called "idiopathic" pulmonary fibrosis.

Although the cause remains unclear, it typically impacts individuals aged 70 to 75 and is uncommon in those under 50. While various treatments can slow the progression of IPF, there is presently no remedy to halt or reverse the lung scarring. Consequently, IPF is classified as an uncommon and sporadic ailment. Globally, IPF impacts 13 to 20 individuals out of every 100,000 and approximately 30,000 to 40,000 new cases are identified globally every year. The National Institutes of Health (NIH) reports that around 100,000 individuals in the US are affected by IPF.

5.3.1 IPF in Australia^{xxix}

The study "Incidence, prevalence and mortality of idiopathic pulmonary fibrosis in Australia" was conducted by Ingrid A Cox, Petr Otahal et al, and published in December 2021. Some noteworthy findings of the study are summarized below:

- Age standardized mortality (deaths) for IPF was 6.3 per 100,000 population
- Age standardized new cases (incidence) were 11.2 per 100,000 population
- Age standardized total cases (prevalence) were 35.1 per 100,000 population
- Mortality, incidence and prevalence increased over the study period (1997-2015); however, it demonstrated a decreasing trend over the projected period (till 2025)
- Persons over the age of 70 years constituted 9% of the population but accounted for approximately 82-83% of all deaths, incidence and prevalent cases
- Estimates were higher in males than in females

In October 2022, another study titled "The economic burden of idiopathic pulmonary fibrosis in Australia: a cost of illness study" authored by Ingrid A Cox, Petr Otahal, et al was released. The study revealed that the average annual total direct expenses per individual with IPF amounted to USD 31,655. When extrapolated from prevalence estimates, the overall annual expenditure in Australia was predicted to reach USD 299 mn. These expenses were primarily influenced by antifibrotic medication, hospital admissions, and medications for associated health conditions. The utilization of resources and costs were found to vary based on disease severity, comorbidities, and the use of antifibrotic medication.

5.3.2 Diagnosis and treatment^{xxx}

There exist over 200 types of pulmonary fibrosis (PF), emphasizing the importance of healthcare teams in identifying the specific PF type for effective treatment. Thorough evaluation by a specialist is essential, and diagnostic tests may include:

- Physical examination: Specialist doctors listen to the patient's chest for fine crackles resembling velcro, providing valuable early diagnostic clues.
- Blood tests: Primarily conducted to rule out known causes of lung scarring.
- Lung function test: Measures lung performance and is crucial for monitoring disease progression over time.
- Chest X-ray: Utilized to detect early signs of PF, although it may not always reveal the disease.
- High-resolution computed tomography (HRCT) chest scan: This advanced CT scan enhances image quality, offering detailed pictures of the lungs.
- Lung biopsy: Involves analyzing lung tissue obtained through non-invasive surgery.

Following the test results, a multidisciplinary team (MDT) comprising various healthcare professionals (specialized doctor, general physician, lung function testing team, respiratory nurses, and physiotherapists) may convene to establish the definitive diagnosis. This collaborative group ensures a comprehensive and accurate assessment of the

patient's condition. Although there is no cure for PF, multiple treatment and management options exist to arrest or slow its progression and alleviate symptoms. Individuals with PF often benefit from the care of the MDT that becomes familiar with the patient.

Pulmonary rehabilitation, overseen by a physiotherapist, involves collaboration with various allied health specialists such as dietitians, occupational therapists, rheumatologists, and others, aiming to support the patient comprehensively. Additionally, radiologists and pathologists work behind the scenes, actively contributing to the initial diagnosis and ongoing progress monitoring. The treatment options that may be suggested include:

- **Antifibrotics** – In Australia, there are presently two antifibrotic medications accessible for its treatment. For individuals diagnosed with mild to moderate IPF, as determined by lung function tests, both pirfenidone and nintedanib have demonstrated effectiveness in decelerating the advancement of fibrosis in the lungs. These medications are subsidized by the Australian government for eligible IPF patients meeting specific criteria.
- **Immunosuppression** – Certain types of PF result from inflammation in lung tissue, frequently associated with autoimmune disorders like rheumatoid arthritis, scleroderma, Sjögren's syndrome, dermatomyositis, and anti-synthetase syndrome. Immunosuppressive medications such as prednisolone, mycophenolate mofetil, and azathioprine are commonly employed to manage these inflammatory conditions. Depending on the specific inflammatory-related PF the patient has, the specialist doctor customizes the medications to provide maximum benefit to the patient from the treatment.
- **Oxygen therapy** – If the patient experiences reduced oxygen levels in the blood, the healthcare provider may recommend the use of oxygen. The necessity for oxygen usage can vary, with some patients only requiring it during night-time sleep or exercise, while others may be advised to use it consistently throughout the day.
- **Pulmonary rehabilitation** – Pulmonary rehabilitation is a program led by trained healthcare professionals, incorporating both exercise and education. It equips patients with the necessary skills to effectively manage breathlessness and maintain overall well-being, reducing the likelihood of hospitalization.
- **Lung transplantation** – For certain PF patients, lung transplantation might be a viable treatment, though it may not be suitable for everyone. The success of transplantation is contingent upon factors such as age, other health conditions, and the severity of PF. The specialist doctor may offer counsel on whether transplantation is viable and refer the patient to a lung transplant unit.
- **Clinical trials in pulmonary fibrosis** – Clinical trials become especially significant when treatment choices are restricted. A clinical trial is a research study designed to determine the effectiveness of a treatment. Participants in clinical trials gain early access to new treatments during the testing phase. Success is not guaranteed, but involvement may include more frequent monitoring and increased interaction with the medical team.
- **Palliative care** – There is a misconception that palliative care is only relevant in the final stages of life, which is inaccurate. Palliative care focuses on symptom management and enhancing the quality of life for patients. An experienced palliative care team can offer valuable support at all stages of PF. Studies indicate that patients who engage with a palliative care team early in their condition experience improved symptom management throughout their journey.

Amplia disclosed that its year-long studies involving narmafotinib for IPF have revealed promising results. In a preclinical model of the disease, narmafotinib demonstrated comparable efficacy to the current standard-of-care drug, nintedanib. This was significant considering nintedanib's annual sales exceeding USD 2 bn, while it is poorly tolerated by patients. Accordingly, the company has initiated IND-enabling studies with narmafotinib in IPF.

5.4 Wound and scar management^{xxxii}

The formation of scars following injuries poses a significant financial burden on the healthcare system annually. FAKI has been identified as a crucial factor in the development of scars during wound healing. Previous studies have demonstrated the efficacy of small molecule FAKI in reducing scars, particularly in hypertrophic scars.

However, the clinical application of FAKI therapy faces challenges, primarily due to the absence of an efficient drug delivery system for extensive injuries such as burns, blasts, and large excisions. Based on a study, "Controlled Delivery of a Focal Adhesion Kinase Inhibitor Results in Accelerated Wound Closure with Decreased Scar Formation" by Kun Ma et al, a pullulan collagen-based hydrogel was developed to facilitate the delivery of FAKI to both excisional and burn wounds in murine models. Two variants of drug-laden hydrogels were created, allowing for either rapid or sustained release of FAKI for the treatment of burn and excisional wounds, respectively. The controlled delivery of FAKI via pullulan collagen hydrogels resulted in accelerated wound healing, decreased collagen deposition, and inhibited the activation of scar-forming myofibroblasts in both wound models.

In 2023, the estimated global market size for scar treatment reached USD 28.5 billion, with an anticipated CAGR of 9.8% from 2024 to 2030. The market is projected to expand due to factors such as heightened aesthetic concerns, a rise in road accidents and burn injuries, and technological advancements leading to the introduction of new devices.

The wound care market is expected to surpass USD 58 billion by the close of 2035, a CAGR of approximately 8.4% during the forecast period (2023-2035). By 2022, the industry size had already exceeded USD 22 billion. This growth is attributed to the increasing prevalence of slow-healing diseases like anemia, cancer, and diabetes globally. Stubborn wounds and injuries associated with autoimmune diseases, chronic ailments, and lifestyle-related conditions contribute significantly to the demand for wound care.

6. Valuation

The fair market value for Amplia's shares stood between AUD 32.3 mn and AUD 58.1 mn on February 23, 2024. The fair market value for the company's publicly traded shares stood between AUD 0.17 and AUD 0.30 on February 23, 2024. The valuation approach followed is the RV method.

6.1 Relative Valuation Method

Company Name	Exchange: Ticker	Market Capitalization (AUD mn)	Total Enterprise Value (AUD mn)	EV/Revenue	EV/Total Assets
AdAlta Limited	ASX:1AD	12.1	11.3	3.2	1.5
Chimeric Therapeutics Limited	ASX:CHM	21.9	19.5	NM	0.9
Immutep Limited	ASX:IMM	410.1	288.0	NM	2.0
Imugene Limited	ASX:IMU	841.6	689.0	NM	3.5
Invion Limited	ASX:IVX	32.1	28.0	6.8	1.5
Noxopharm Limited	ASX:NOX	22.5	19.5	NM	1.9
Vectus Biosystems Limited	ASX:VBS	16.0	12.8	21.3	2.8
Verastem, Inc.	NasdaqCM:VSTM	463.8	304.2	NM	2.2
Prescient Therapeutics Limited	ASX:PTX	37.0	15.1	50.3	0.8
RedX Pharma	AIM:REDX	139.0	138.3	18.0	2.8
Median				17.96	1.94
Average				19.93	1.98

Summary	Units	High Case	Low Case
Median EV/Total Assets		1.94	1.94
Arrowhead Premium/(Discount)		60.0%	0.0%
Amplia's Total Assets	AUD	18.7	18.7
Amplia's EV	AUD mn	58.1	32.3
Amplia's EV/share	AUD	0.30	0.17
Upside	%	299%	122%

Sensitivity Table - Amplia's Enterprise Value						
Median EV/ Total Assets (Comparable)	Total Assets (in AUD mn)					
	58.1	8.7	13.7	18.7	23.7	28.7
	1.73	15.0	23.7	32.3	40.9	49.6
	2.11	18.3	28.9	39.4	49.9	60.5
	3.11	27.0	42.6	58.1	73.6	89.2
	3.36	29.2	46.0	62.8	79.6	96.3
	3.61	31.4	49.4	67.4	85.5	103.5
	3.86	33.6	52.8	72.1	91.4	110.7

Important information on Arrowhead methodology

The principles of the valuation methodology employed by Arrowhead BID are variable to a certain extent depending on the subsectors in which the research is conducted, but all Arrowhead valuation research possesses an underlying set of common principles and a generally common quantitative process.

With Arrowhead Commercial and Technical Due Diligence, Arrowhead extensively researches the fundamentals, assets and liabilities of a Company, and builds solid estimates for revenue and expenditure over a coherently determined forecast period.

Elements of past performance, such as price/earnings ratios, indicated as applicable, are present mainly for reference purposes. Still, elements of real-world past performance enter the valuation through their impact on the commercial and technical due diligence.

Elements of comparison, such as multiple analyses may be to some limited extent integrated in the valuation on a project-by-project or asset-by-asset basis. In the case of this Amplia Therapeutics Limited report, there are no multiple analyses integrated in the valuation.

Arrowhead BID fair market value bracket

The Arrowhead Fair Market Value is given as a bracket. This is based on quantitative key variable analysis, such as key price analysis for revenue and cost drivers or analysis and discounts on revenue estimates for projects, especially relevant to those projects estimated to provide revenue near the end of the chosen forecast period. Low and high estimates for key variables are produced as a tool for valuation. The high-bracket NPV valuation is derived from the high-bracket key variables, while the low-bracket NPV valuation is based on the low-bracket key variables.

In principle, an investor who is comfortable with the high-brackets of our key variable analysis will align with the high-bracket in the Arrowhead Fair Value Bracket, and likewise in terms of low estimates. The investor will also take into account the Company intangibles – as presented in the first few pages of this document in the analysis of strengths and weaknesses and other essential Company information. These intangibles serve as supplementary decision factors for adding or subtracting a premium in the investor's own analysis. The bracket should be understood as a tool provided by Arrowhead BID for the reader of this report and the reader should not solely rely on this information to make his decision on any particular security. The reader must also understand that on one hand, global capital markets contain inefficiencies, especially in terms of information, and that on the other hand, corporations and their commercial and technical positions evolve rapidly: this present edition of the Arrowhead valuation is for a short to medium-term alignment analysis (one to twelve months). The reader should refer to important disclosures on page 28 of this report.

7. Analyst Certifications

I, Sumit Wadhwa, certify that all the views expressed in this research report accurately reflect my personal views about the subject security and the subject Company, based on the collection and analysis of public information and public Company disclosures.

I, Ayushi Saraswat, certify that all the views expressed in this research report accurately reflect my personal views about the subject security and the subject Company, based on the collection and analysis of public information and public Company disclosures.

Important disclosures

Arrowhead Business and Investment Decisions, LLC has received fees in 2024 and will receive further fees in 2024 from Amplia Therapeutics Limited for researching and drafting this report and for a series of other services to Amplia Therapeutics Limited, including distribution of this report and networking services. Neither Arrowhead BID nor any of its principals or employees own any long or short positions in Amplia Therapeutics Limited. Arrowhead BID's principals intend to seek a mandate for investment banking services from Amplia Therapeutics Limited in 2024 or beyond and intend to receive compensation for investment banking activities from Amplia Therapeutics Limited in 2024 or beyond.

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Any opinions expressed in this report are statements of Arrowhead BID's judgment to this date and are subject to change without notice.

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8. Notes and References

- ⁱ Source: Bloomberg as on February 23, 2024
- ⁱⁱ Source: Bloomberg as on February 23, 2024
- ⁱⁱⁱ Source: Company Presentation
- ^{iv} Source: [Company Website](#), Capital IQ, [Company Announcement dated 5 September 2018](#), [Company Announcement dated 30 October 2023](#), [Company Announcement dated 4 December 2023](#), Annual Report 2023, [Company Announcement dated 28 June 2021](#)
- ^v Source: Company Presentation
- ^{vi} Source: Company Presentation
- ^{vii} Source: [Company Website](#), Desktop Research, Annual Report 2023, [Company Announcement dated 2 August 2022](#), [Company Announcement dated 30 October 2023](#), [Company Announcement dated 4 December 2023](#)
- ^{viii} Source: Management of the Company
- ^{ix} Source: [Amplia's Cancer Program](#)
- ^x Source: Annual Report 2023, [Company Announcement dated 3 October 2022](#)
- ^{xi} Source: [Company Announcement dated 3 October 2022](#)
- ^{xii} Source: [Company Announcement dated 3 October 2022](#)
- ^{xiii} Source: Annual Report 2023
- ^{xiv} Source: [Company Announcement dated 3 October 2022](#)
- ^{xv} Source: Bloomberg as on January 28, 2024
- ^{xvi} Source: [Historical announcements \(asx.com.au\)](#)
- ^{xvii} Source: Annual Report 2021, Company Website
- ^{xviii} Source: <https://www.cancer.net/cancer-types/pancreatic-cancer/introduction> ; [Research Nester](#)
- ^{xix} Source: [World Health Organization](#)
- ^{xx} Source: [Cancer Australia – Australian Government](#), [Pancare Foundation](#)
- ^{xxi} Source: [World Health Organization](#)
- ^{xxii} Source: [Cancer Australia – Australian Government](#), [Garvan Institute of Medical Research](#), [Obesity Evidence Hub](#)
- ^{xxiii} Source: <https://www.cancer.net/cancer-types/ovarian-fallopian-tube-and-peritoneal-cancer/introduction>, [Straits Research](#)
- ^{xxiv} Source: [World Health Organization](#)
- ^{xxv} Source: [Cancer Australia – Australian Government](#), [Ovarian Cancer Research Foundation](#)
- ^{xxvi} Source: [World Health Organization](#)
- ^{xxvii} Source: [Cancer Australia – Australian Government](#)
- ^{xxviii} Source: [NHS \(UK\) Website](#); [Healthline](#), [American Lung Association](#)
- ^{xxix} Source: [National Center for Biotechnology Information – National Library of Medicine – Incidence, prevalence and mortality study](#), [National Center for Biotechnology Information – National Library of Medicine – Economic burden of IPF](#)
- ^{xxx} Source: [Lung Foundation Australia](#)
- ^{xxxi} Source: [Controlled Delivery of a Focal Adhesion Kinase Inhibitor Results in Accelerated Wound Closure with Decreased Scar Formation](#), [Amplia receives grant to collaborate with CSIRO – Supplementary Announcement](#)