

**ASX RELEASE**

**27 October 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, focal adhesion kinase (FAK) inhibitor program and the release of its Appendix 4C Cash Flow Report (attached) for the quarter ending 30 September 2021.

### **Key Highlights from the Quarter**

- Design of the Phase 2 clinical trial of AMP945 in first-line pancreatic cancer patients finalised;
- New preclinical data from the Garvan Institute shows pre-treatment with AMP945 results in improved responsiveness to standard pancreatic cancer chemotherapy;
- Manufacture of clinical grade AMP945 active pharmaceutical ingredient (API) for upcoming clinical trial and preclinical toxicology studies on track to complete by year end;
- Progress in planning and development of clinical program for AMP945 for fibrotic interstitial lung diseases (ILDs), with clinical trial scheduled to start in 2H 2022.

Amplia’s CEO and Managing Director, Dr John Lambert, commented that “Amplia has made great progress across the board this quarter in its preparations for initiating the Phase 2 clinical program for AMP945 early next year. We were pleased to announce this quarter that we will be conducting our first Phase 2 clinical trial of AMP945 in first line pancreatic cancer patients. This provides the greatest opportunity for AMP945 in this disease as we will be able to treat the largest number of patients alongside their standard chemotherapy treatment. We are also at an advanced stage in planning for a second Phase 2 clinical trial in patients with fibrotic Interstitial Lung Disease (ILD). Both of these indications represent significant unmet medical needs and major opportunities for Amplia.”

### **Operations update**

In September, Amplia announced the design of its Phase 2 clinical trial of AMP945 in pancreatic cancer patients. The trial will add AMP945 to chemotherapy with gemcitabine and Abraxane®, which is a standard of care currently used to treat the majority of newly diagnosed advanced pancreatic cancer patients. Conducting the Phase 2 trial in first-line patients is expected to expedite recruitment for the trial and provide the best opportunity to observe an efficacy signal. The ability to test AMP945 in a first-line setting is made possible by the excellent safety and tolerability profile demonstrated in Amplia’s recent Phase 1 clinical trial. The company plans to initiate patient recruitment at Australian sites in the first quarter of calendar 2022, and currently estimates that full recruitment will take 18-24 months.

Also in September, the Company announced that its collaborators at the Garvan Institute of Medical Research had published a paper in *Science Advances*, a high impact peer-reviewed journal, reporting that, in an animal model of human pancreatic cancer, pre-treatment with a FAK inhibitor resulted in

tumours being more responsive to gemcitabine/Abraxane® chemotherapy. Furthermore, the FAK-priming reduced tumour metastasis to secondary sites such as the liver. These findings are based on the same treatment regimen and rationale that has underpinned the design of Amplia's Phase 2 clinical trial in pancreatic cancer patients. While these are data from preclinical animal studies, they support the strategy the Company is taking and the fundamental biology underpinning this approach.

The Company is on track to receive a newly manufactured batch of the AMP945 active pharmaceutical ingredient (API) by the calendar year end. This will provide clinical-grade material for formulations used in the preclinical toxicology studies to support the ILD clinical trials and for use in the Phase 2 clinical trials.

Amplia has also initiated the process for securing a generic drug name for AMP945. This process involves the development and selection of a number of candidate names that simultaneously satisfy multiple naming conventions, an extensive search on their suitability for global use, and then an extensive review and registration process. This can take up to 24 months to complete but is an important part of developing a new drug for commercial use.

The Company has also significantly advanced its plans toward initiating a clinical trial of AMP945 in patients with fibrotic Interstitial Lung Diseases (ILDs). The clinical trial design is nearly ready for final clinician review and feedback while the company conducts the longer-term animal toxicology studies required to support the anticipated chronic use in these diseases. The Company expects to start the first clinical trial of AMP945 in patients with fibrotic lung disease in the second half of 2022.

In September, the Company announced that it has appointed Mr Hamish George of Melbourne-based Bio101 as the Company's Chief Financial Officer.

#### **Financial update**

Amplia finished the September 2021 quarter with cash of \$3.17 million.

During the quarter, the Company used \$0.90 million in operating activities, with \$0.48 million being used for research and development that was primarily focused on completing studies to support the Phase 1 clinical trial of AMP945.

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

Additionally, Amplia received an R&D Tax Incentive rebate for the 2020/2021 financial year of \$1.1 million after the quarter end, which is not reflected in the Appendix 4C Quarterly Cashflow.

#### **Payments to Related Entities**

In accordance with Listing Rule 4.7C, payments made to related parties and their associates included in item 6.1 of the Appendix 4C incorporates directors' fees, salaries and superannuation. Total payments made for the quarter equals \$126,945 and includes \$77,675 in payments to the CEO/Managing Director in line with Dr Lambert's employment contract as well as \$49,270 in Director fee payments.

#### **Outlook and future activities**

Amplia's primary focus for the coming quarter will be on preparing for the Phase 2 clinical trial of AMP945 in pancreatic cancer and the toxicology studies required before the Phase 2 trial in pulmonary fibrosis. This will include finalising and submitting 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.

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**For Further Information**

Dr. John Lambert

CEO and Managing Director

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**About Amplia Therapeutics Limited**

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

## 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")**

30 September 2021

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(484)	(1,477)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(179)	(428)
(f) administration and corporate costs	(304)	(409)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	-
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material)	66	69
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(901)</b>	<b>(2,245)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(3)	(7)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>(3)</b>	<b>(7)</b>
<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	3,814
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	39
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(6)	(278)
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 (repayment of lease liability)	-	-
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>(6)</b>	<b>3,575</b>
<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	4,081	1,848
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(901)	(2,245)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(3)	(7)

Appendix 4C  
Quarterly cash flow report for entities subject to Listing Rule 4.7B

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(6)	3,575
4.5	Effect of movement in exchange rates on cash held	-	-
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>3,171</b>	<b>3,171</b>

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	136	136
5.2	Call deposits	3,035	3,945
5.3	Bank overdrafts	-	-
5.4	Other (provide details)		
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>3,171</b>	<b>4,081</b>

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	127
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>		

The amount at 6.1 includes Director fees and salary (including superannuation) for the CEO and Managing Director and Non-Executive Directors.

<b>7. Financing facilities</b>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
<i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i>		
<i>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)	-	-
<b>7.4 Total financing facilities</b>	<b>-</b>	<b>-</b>
<b>7.5 Unused financing facilities available at quarter end</b>		<b>-</b>
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.		

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	(901)
8.2 Cash and cash equivalents at quarter end (item 4.6)	3,171
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	3,171
<b>8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<b>3.5</b>
<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: N/A	
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: N/A	
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: N/A	
<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: 27 October 2021  
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**Board of Directors**

Authorised by: .....  
(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.