

ASX RELEASE

24 January 2022

## 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 31 December 2021.

### Key Highlights from the Quarter

- Supplementary data from Phase 1 clinical trial confirmed that orally administered AMP945 is able to inhibit its intended target, FAK, in the tissues of human subjects;
- Completed GMP manufacture of a 2 kg batch of AMP945 for use in upcoming Phase 2 clinical trials and preclinical studies;
- Dr José Iglesias, a pharmaceutical industry leader with extensive experience in developing treatments for pancreatic cancer, appointed as Clinical Advisor; and
- Balance sheet strengthened to support Phase 2 clinical trials planned for 2022 through a \$12.4M capital raise and access to an additional \$3.2M arising from the R&D tax incentive program.

Amplia’s CEO and Managing Director, Dr John Lambert, commented that “While 2021 was a challenging year for everyone, I am extremely proud of what our team at Amplia has been able to achieve. In the last quarter of 2021, we put in place all the elements to make 2022 a watershed year for the Company. We have a robust package of data supporting our strategy as we initiate the first Phase 2 trials for AMP945 and we have successfully completed a 2 kilogram GMP manufacturing run of AMP945 which provides sufficient drug material to complete two 3-month animal toxicology studies as well as take us deep into two Phase 2 clinical trials. And finally, through the much-appreciated support of our shareholders we have raised the capital to support these important activities.”

### Operations update

In November, Amplia provided additional data from its Phase 1 clinical trial demonstrating that oral dosing of AMP945 in healthy volunteers resulted in a reduction of the activity of FAK, the drug’s intended target. The inhibition of FAK, which was measured in skin biopsies taken from participating subjects, indicates that after oral administration of AMP945, the drug is absorbed and distributed to tissues where it achieves the desired biological effect in human subjects.

A key focus for Amplia during the December quarter was preparation for the Phase 2 clinical trials of AMP945 in patients with pancreatic cancer and fibrotic lung disease. Significant progress has been made in the design and development of Amplia’s trial of AMP945 in patients with fibrotic lung disease that is currently scheduled to start in 2H CY2022.

Critical to these preparations was the manufacture of AMP945 drug substance. Work conducted at Amplia’s Contract Manufacturing Organisation (CMO) during the December quarter culminated in early January with the successful production of a 2 kilogram GMP (Good Manufacturing Practice) batch

of AMP945. As part of this scale-up production, improvements were made to the manufacturing process that are expected to further support the future clinical and commercial development of AMP945. In addition to the planned Phase 2 clinical trials, this drug material will enable Amplia to supply two longer duration (3-month) animal toxicology studies required to support clinical trials in patients with fibrotic lung disease.

Furthermore, during the December quarter the Company made significant progress on the development of new manufacturing processes for AMP945 drug product capsules. This manufacturing development work is intended to underpin GMP manufacture of the commercial product through the introduction automated capsule filling, bottling and confirmation of product shelf-life. The Company expects to report on the outcome of these studies in the near future.

In October, Amplia announced it had appointed Dr José Iglesias as a Clinical Advisor. Dr Iglesias is an experienced pharmaceutical executive who has held senior roles at Eli Lilly, AMGEN, Abraxis and Celgene during the course of his 30-year career. Dr Iglesias was responsible for the Phase 3 clinical development of Abraxane® which has been incorporated into the worldwide standard-of-care for the treatment of patients with advanced pancreatic cancer. In October, Amplia also appointed Mr Hamish George of Melbourne-based Bio101 to provide Chief Financial Officer services to the Company.

In November, Amplia announced that it had successfully negotiated an amendment to its Licence Agreement with Cancer Research UK (CRUK) for its second FAK inhibitor AMP886. Under the renegotiated agreement, Amplia has until 31 December 2023 to file an Investigational New Drug (IND) application or initiate a Phase 1 clinical trial of AMP886. Amplia is actively exploring a number of cancer and fibrotic disease areas where AMP886 may have clinical utility based on its particular activity profile.

During the quarter, Amplia significantly strengthened its balance sheet to support the additional development activities and the initiation of two Phase 2 clinical trials. In November 2021, the Company announced a Placement and a fully underwritten 1-for-4 Entitlement Offer to raise a total of \$12.4 million. The capital raise was successfully completed in December 2021.

#### **Financial update**

Amplia finished the December 2021 quarter with cash of \$16.2 million (September 2021: \$3.2 million).

The increase in cash was driven by:

- The Company successfully raising \$12.4 million (fees excluded) through a Placement and Underwritten Entitlement Offer (as announced to the ASX on 8 November 2021);
- Receipt of the FY21 R&D Tax Incentive refund of \$1.1 million (as announced to the ASX on 14 October 2021); and
- Receipt of Tranche 1 of the FY22 R&D Funding Loan of \$1.3 million administered by Treasury Corporation of Victoria and Invest Victoria (as announced to the ASX on 2 December 2021).

During the quarter, the Company had net cash inflows of \$0.18 million in relation to operating activities (September 2021: outflows \$2.1 million). The net inflow was driven by the receipt of \$1.1 million FY21 R&D Tax Incentive. Other operating cashflows included outflows of:

- \$0.48 million for staff and administration/corporate costs; and
- \$0.46 million for research and development, which was primarily focused on completing the Phase 1 clinical trial for AMP945 and preparing for the first stage of the Phase 2 clinical trial for AMP945.

Having now raised sufficient funds to undertake the first stage of the Phase 2 clinical trial for AMP945, research and development expenditure is forecast to increase in the coming quarters.

#### **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 \$65,000 and solely relate to payments to the CEO/Managing Director in line with Dr Lambert's employment contract.

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

Amplia's primary focus for 2022 will be on initiating Phase 2 clinical trials in pancreatic cancer and, in the second half of the year, lung fibrosis. The Company is required to apply for Human Research Ethics Committee (HREC) clearance to conduct these Phase 2 clinical trials. While all the preparations by the Company for the clinical trial of AMP945 in pancreatic cancer remain on track, the current Omicron outbreak is having a significant impact on the resources and focus of the healthcare system. In view of this, Amplia believes that it is likely that the initiation of recruitment for this trial may be delayed until early in the June quarter.

The Company is continuing to refine the design of the Phase 2 clinical trial of AMP945 in lung fibrosis and, during the March quarter, the Company will initiate two longer term (3-month) animal toxicology studies to support the extended dosing of AMP945 that will be used in this clinical trial. The Company is also undertaking further non-clinical studies evaluating clinical opportunities for AMP886, Amplia's second FAK inhibitor.

At this stage, other than the initiation of recruitment in its Phase 2 clinical trial of AMP945 for pancreatic cancer, the Company is not aware of any impact that the current Omicron outbreak may have on the timing of its other operational objectives.

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

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#### **For Further Information**

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#### **About Amplia Therapeutics Limited**

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

## Appendix 4C

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

**Name of entity**

AMPLIA THERAPEUTICS LIMITED

**ABN**

16 165 160 841

**Quarter ended ("current quarter")**

31 December 2021

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(462)	(1,939)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(142)	(570)
(f) administration and corporate costs	(340)	(749)
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	1,140	1,140
1.8 Other (provide details if material)	(13)	56
<b>1.9 Net cash from / (used in) operating activities</b>	<b>183</b>	<b>(2,062)</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	-	(7)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 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>-</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)	12,387	16,201
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	30	69
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(866)	(1,144)
3.5	Proceeds from borrowings	1,260	1,260
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>12,811</b>	<b>16,386</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	3,171	1,848
4.2	Net cash from / (used in) operating activities (item 1.9 above)	183	(2,062)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(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 (9 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	12,811	16,386
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>16,165</b>	<b>16,165</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	6,380	136
5.2	Call deposits	9,785	3,035
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>16,165</b>	<b>3,171</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	65
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

*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.*

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. Add notes as necessary for an understanding of the sources of finance available to the entity.</i>		
7.1 Loan facilities	1,260	1,260
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
<b>7.4 Total financing facilities</b>	<b>1,260</b>	<b>1,260</b>
<b>7.5 Unused financing facilities available at quarter end</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.	<p>The Loan facility is a non-dilutive funding facility of up to \$2.1million with Treasury Corporation of Victoria (TCV) as part of the Victorian Government's R&amp;D Cash Flow Loan Initiative. The Facility will be received in two tranches: the first of \$1.26 million was received in December 2021; and the second of up to \$0.84 million is expected to be received in the quarter ending 31 March 2022. The amount of the second tranche funding will be capped so as not to exceed a total Facility draw down of 80% of the Company's forecast R&amp;D Tax Incentive (RDTI) rebate for FY2022. Interest on Facility advances is variable at the "TCV 11am" loan interest rate (currently 0.265%). Repayment of the Facility is timed to coincide with receipt of the Company's FY2023 RDTI refund, expected by 31 October 2023, but may be repaid earlier. The Facility is secured by the FY2022 and FY2023 RDTI refunds. As at 31 December 2021 the total loan facility was \$1.26 million, being fully drawn.</p>	

<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)	183
8.2 Cash and cash equivalents at quarter end (item 4.6)	16,165
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	16,165
<b>8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<b>N/A</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

*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.*

## 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: 24 January 2022  
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Authorised by: The Board  
.....  
(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.