

ASX RELEASE

19 April 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 March 2022.

### Key Highlights from the Quarter

- Received Human Research Ethics Committees (HREC) approval to conduct a Phase 2 clinical trial in first-line patients with pancreatic cancer.
- Rationale for Phase 2 trial further underpinned by new data from pancreatic cancer animal model;
- US FDA granted pre-IND meeting request to discuss development plans for AMP945;
- Commenced extended toxicology studies of AMP945 to support Phase 2 clinical trial in lung fibrosis patients and later-stage development;
- Completed GMP manufacture of a 2 kg batch of AMP945 active pharmaceutical ingredient (API) and generated capsules suitable for use in Amplia’s upcoming Phase 2 clinical trial;
- Balance sheet strengthened through receipt of \$0.84 million relating to the second and final drawdown of the Research and Development funding facility (Facility). Total proceeds received from the Facility were \$2.1 million.

Amplia’s CEO and Managing Director, Dr John Lambert, commented that “This has been another successful quarter for Amplia during which we lodged HREC applications for our planned Phase 2 clinical trial of AMP945 in first line pancreatic cancer patients. The first of these approvals was recently granted and we now have the green light to proceed with the trial. We are also pleased to see the Australian Federal Government recently announcing a commitment to provide significant resources to support improved outcomes for people with this devastating disease.

“In addition to the progress made on the clinical trial, our team also continued to deliver outcomes on the manufacturing, pre-clinical and regulatory fronts, all of which contribute significantly to the growth of our Company.”

### Operations update

A key focus for Amplia during the quarter ending 31 March 2022 was operational implementation of a Phase 2 clinical trial of AMP945 in first line pancreatic cancer patients. The Company prepared and submitted applications to the relevant Human Research Ethics Committees (HRECs) for the trial with the first approval to initiate the trial being received on 6 April 2022. In January 2022, Amplia reported the successful completion of a 2 kg production run of GMP grade AMP945 active pharmaceutical ingredient (API). AMP945 API has also been formulated into capsules that are ready for use in the upcoming clinical trial.

In February, Amplia announced that a conference abstract describing the results of its Phase 1 clinical trial of AMP945 had been accepted for presentation at the American Association for Cancer Research (AACR) meeting being held in April 2022. AACR is a high-profile and prestigious international conference attended by the world's leading pharmaceutical and academic cancer drug developers. Amplia's presentation, given on 8 April, described the results from Amplia's Phase 1 clinical trial of AMP945 in healthy volunteers that was completed in 2021.

Furthermore, in February, Amplia also reported that researchers at the Garvan Institute had shown that AMP945 is able to improve the efficacy of standard-of-care chemotherapy in a model of human pancreatic cancer. This builds on previously reported preclinical studies in which AMP945 was tested in the aggressive KPC mouse model of pancreatic cancer. In the recent study, conducted in the human-derived TKCC-10-LO orthotopic mouse model of pancreatic cancer, treatment with AMP945 prior to dosing with gemcitabine/nab-paclitaxel resulted in a statistically significant, 33% increase in survival compared with animals who were treated with only gemcitabine/nab-paclitaxel. The result further underpins the rationale for the Company's clinical trial in people with pancreatic cancer.

During the quarter, Amplia was granted a pre-IND (Type B) meeting with the US FDA. The meeting will allow the Company to present its development plans for AMP945 in people with pancreatic cancer and receive FDA's input and feedback on those plans. Through this engagement with the FDA, the Company is seeking to understand and address the FDA's requirements for regulatory approval early in development. FDA feedback will also support an IND application for AMP945 that the Company plans to submit later this year. The FDA has advised that it expects to provide a response to Amplia's pre-IND questions in May 2022.

Amplia has initiated extended toxicology studies in two different animal species. These studies are designed to support the Phase 2 clinical trial of AMP945 in people with lung fibrosis that is planned for the second half of CY2022. The animals in these studies will be dosed with AMP945 for a total of 13 weeks in order to identify any potential toxicities that may be associated with extended exposure to AMP945. The Company expects to receive results from these studies in the middle of CY2022.

### **Financial update**

Amplia finished the March 2022 quarter with cash of \$14.6 million (December 2021: \$16.2 million).

During the quarter, the Company had net cash outflows of \$2.3 million in relation to operating activities (December 2021: inflows of \$0.18 million). Operating cashflows included outflows of:

- \$0.5 million for staff and administration/corporate costs; and
- \$1.8 million for research and development costs, which primarily related to manufacturing and other CMC related costs incurred in relation to the first stage of the Phase 2 clinical trial for AMP945.

Research and development expenditure is forecast to increase in the coming quarters in line with the commencement of the Phase 2 clinical trial for AMP945, which is expected to commence recruitment in the coming weeks with the first patient expected to be dosed in April-May 2022.

During the quarter, the company also drew down a second and final tranche of \$0.84 million from a facility under the Victorian Government R&D Tax Cash Flow Incentive scheme (Facility), bringing total proceeds of the Facility to \$2.1 million. The Facility is repayable from the proceeds of the FY22 and FY23 R&D Tax Incentive Rebates, expected by 31 October 2023.

### **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 \$168,956 and relate to payments to the CEO/Managing Director in line with Dr Lambert's employment contract and payments to the Non-Executive Directors.

### **Outlook and future activities**

Amplia's focus is now on the timely and efficient execution of the Phase 2 clinical trial of AMP945 in pancreatic cancer. The first part of the trial will involve selection of the optimal dose before expansion of the trial to recruit more patients who will be dosed with the selected optimal dose.

The Company is also in advanced stages of planning for a second Phase 2 trial of AMP945 in idiopathic pulmonary fibrosis. Around the middle of 2022, the Company expects to report the results of 3-month toxicology studies of AMP945, the results of which are required prior to extended dosing in pulmonary fibrosis. The Company has issued requests for proposals from clinical trial vendors and expects to select a vendor in the coming quarter.

Further manufacturing work for AMP945 drug substance and drug product is ongoing as the Company builds supplies of material to support future clinical trial activities.

Non-clinical studies evaluating clinical opportunities for AMP945 and Amplia's second FAK inhibitor, AMP886, are ongoing and results of these studies will be disclosed when the studies are complete, currently forecast for C Q2 2022.

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  
[john@ampliatx.com](mailto:john@ampliatx.com)  
[www.ampliatx.com](http://www.ampliatx.com)

### **Glossary**

- CMC:** Chemistry Manufacture and Controls. The procedures whereby the manufacturing process is controlled including facilities, release testing, specifications and stability.
- HREC:** Human Research Ethics Committee. An independent committee of experts whose role is to review research proposals that involve human participants to ensure that they meet ethical standards and guidelines.
- GMP:** Good Manufacturing Practice: A set of principles guiding the manufacture of pharmaceuticals so that product quality is assured.
- IND:** Investigational New Drug. The regulatory framework under which new drugs are developed for approval in the United States, under the auspices of the Food and Drug Administration (FDA).

### **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 cancer and Amplia has a particular development focus in fibrotic tumours such as pancreatic and ovarian cancers. FAK also plays a significant role in a number of chronic diseases, such as idiopathic pulmonary fibrosis (IPF).

## Appendix 4C

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

**Name of entity**

AMPLIA THERAPEUTICS LIMITED

**ABN**

16 165 160 841

**Quarter ended (“current quarter”)**

31 March 2022

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (12 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	(1,811)	(3,750)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(222)	(792)
(f) administration and corporate costs	(306)	(1,055)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	-
1.5 Interest and other costs of finance paid	(1)	(1)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	1,140
1.8 Other (provide details if material)	13	69
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(2,327)</b>	<b>(4,389)</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	(8)	(15)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 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)	(12)	(12)
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>(20)</b>	<b>(27)</b>
<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	16,201
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	69
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(49)	(1,193)
3.5	Proceeds from borrowings	840	2,100
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>791</b>	<b>17,177</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	16,165	1,848
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,327)	(4,389)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(20)	(27)

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 (12 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	791	17,177
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>14,609</b>	<b>14,609</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	3,985	6,380
5.2	Call deposits	10,624	9,785
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>14,609</b>	<b>16,165</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	169
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 and bonuses) 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	2,100	2,100
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
<b>7.4 Total financing facilities</b>	<b>2,100</b>	<b>2,100</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 was received in two tranches: the first of \$1.26 million was received in December 2021; and the second of \$0.84 million was received in February 2022. The amount of the second tranche funding was 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 March 2022 the total loan facility was \$2.10 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)	(2,327)
8.2 Cash and cash equivalents at quarter end (item 4.6)	14,609
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	14,609
<b>8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<b>6.3</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: 19 April 2022

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

## Notes

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