

ASX RELEASE

28 October 2022

QUARTERLY ACTIVITIES AND CASH FLOW REPORTS

Melbourne, Australia: Amplia Therapeutics Limited (ASX: ATX), (“Amplia” or the “Company”), a company developing new drug candidates 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 2022.

Key Highlights from the Quarter

- Recruitment of first patient into ACCENT Phase 2 clinical trial of AMP945 in pancreatic cancer;
- Completion of 3-month toxicology studies of AMP945 with no new toxicities noted;
- New data for AMP886 showing efficacy in acute myeloid leukemia;
- Manufacturing improvements for AMP945 and additional clinical trial supply batches completed; and
- \$1.8m R&D Tax refund received.

Operations Update

Clinical Development

During the Quarter, Amplia announced that the first patient had been dosed in the Company’s Phase 1b/2a ACCENT clinical trial of focal adhesion kinase inhibitor AMP945. The trial will test whether AMP945 enhances the efficacy of gemcitabine/nab-paclitaxel standard of care chemotherapy in frontline patients with advanced pancreatic cancer. The ACCENT trial uses a novel pulsed-dosing treatment regimen which the Company expects will enhance efficacy and minimise the risk of adverse events.

There are currently three sites recruiting patients in Melbourne and Sydney with additional sites expected to open in Sydney, Melbourne and Brisbane in the very near future. Awareness of the ACCENT trial has been enhanced by the Company’s outreach through the media, patient advocacy groups and the clinical oncology community. Amplia will also attend and sponsor The Australasian Gastro-Intestinal Trials Group (AGITG) Annual Scientific Meeting to be held in Melbourne in November (<https://asm.gicancer.org.au/>). The Company generated significant interest when it presented the design and rationale for its ACCENT clinical trial at the American Association for Cancer Research (AACR) Special Conference on Pancreatic Cancer, in Boston, MA.

Non-clinical Development

As forecast, the Company received data from its 3-month toxicology studies of AMP945 which were conducted to support extended dosing of AMP945 in patients with pulmonary fibrosis and later development of AMP945. The Company is pleased to advise that these longer-term dosing studies have not identified any toxicities that would limit the clinical development of AMP945. As a supplementary analysis, samples collected during the 91-day toxicology studies were tested for metabolites of AMP945 and compared to human samples collected during the Phase 1 clinical trial of AMP945 in healthy volunteers which was completed in 2021. These tests have identified a metabolite of AMP945 which, while produced in both toxicology species and humans, appears to be present at higher levels in humans than in either toxicology species. Whilst these findings do not impact the current ACCENT clinical trial in pancreatic cancer, the Company is undertaking further analyses to

profile this metabolite and determine whether these findings impact planned non-oncology development activities. Importantly, preliminary *in vitro* screens have raised no safety concerns.

Given the growing interest in the potential of FAK inhibitors in a wide range of oncology and fibrotic indications, during the quarter Amplia entered into a new collaboration with leading FAK researchers at the University of California, San Diego. The research group, led by Professor Dwayne Stupack has published extensively on the role of FAK in ovarian cancer and experiments with AMP945 are underway to determine whether there is a rationale for a clinical trial of AMP945 in this indication. Results from these studies will be reported in due course.

Studies completed during the Quarter also showed that AMP886, Amplia's second FAK inhibitor, may have utility in the treatment of acute myeloid leukemia (AML). With the intent of building a clinical rationale for AMP886 in AML, further studies are underway to confirm and further understand the original findings.

Manufacturing Development

During the Quarter, Amplia's contract manufacturing organisation made significant improvements to the method of manufacture of AMP945 drug substance. The improvements included reduction of the number of manufacturing steps and removal of the need for a costly metal catalyst at one stage of the manufacture process. These improvements are expected to contribute to a more efficient and cost-effective manufacture process for AMP945.

The Company also conducted three successful manufacturing campaigns for AMP945 and placebo capsules. These clinical trial supply materials have all been released for use in Amplia's clinical studies of AMP945.

Amplia's CEO and Managing Director, Dr John Lambert commented that "With the recruitment of the first patient into the ACCENT trial, exciting new preclinical data and improvements in our method and scale of manufacture for AMP945, we have again made excellent progress this Quarter. With the opening of new sites in ACCENT we expect the trial to build even more momentum while at the same time we are seeking to expand our pipeline and build the dataset for AMP945 which will be required for future regulatory submissions."

Financial Update

Amplia finished the September 2022 quarter with cash of \$11.7 million (June 2022: \$12.7 million).

During the quarter, the Company had net cash outflows of \$1.1 million in relation to operating activities (June 2022: \$1.8 million). Operating cashflows included outflows and inflows of:

- \$0.6 million for staff and administration/corporate costs;
- \$2.3 million for research and development costs which primarily related to:
 - A start-up cost to the Company's clinical Contract Research Organisation (CRO) for establishment of the ACCENT trial's safety reporting systems and preparations for site openings in South Korea; and
 - Building stocks of clinical trial supplies by manufacturing new batches of AMP945 drug product capsules.
- \$1.8 million of Research and Development Tax Incentive refund.

With the payment of the CRO start-up costs and manufacturing work completed, R&D expenditure is forecast to reduce in future quarters and track patient recruitment in the ACCENT trial.

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 \$140,431 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

In the coming quarter, the Company expects to report further progress in the ACCENT trial including updates on progression towards optimal dose selection. Recruitment is expected to accelerate as further sites are opened in Australia. During the coming Quarter, a regulatory submission will be prepared which, if approved, will allow sites to be opened in South Korea.

The properties of AMP945's novel metabolite will be analysed so that any impacts or opportunities can be assessed.

Non-clinical studies of Amplia's second FAK inhibitor, AMP886, are ongoing as well as other studies on new opportunities for AMP945. Data generated from these studies will be communicated as they are received.

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

- End -

For Further Information

Dr. John Lambert
CEO and Managing Director
john@ampliatx.com
www.ampliatx.com

About Amplia Therapeutics Limited

Amplia Therapeutics Limited is an Australian pharmaceutical company advancing a pipeline of Focal Adhesion Kinase (FAK) inhibitors for cancer and fibrosis. FAK is an increasingly important target in 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) and the Company is also developing its FAK inhibitors in these indications.

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 2022

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(2,321)	(3,567)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(268)	(585)
(f) administration and corporate costs	(324)	(608)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	12	13
1.5 Interest and other costs of finance paid	(8)	(10)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	1,843	1,884
1.8 Other (provide details if material)	(76)	(101)
1.9 Net cash from / (used in) operating activities	(1,142)	(2,974)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(6)	(13)
(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)	12	(41)
2.6	Net cash from / (used in) investing activities	6	(54)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	(1)	21
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
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)	-	-
3.10	Net cash from / (used in) financing activities	(1)	21

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	12,739	14,609
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,142)	(2,974)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	6	(54)

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)	(1)	21
4.5	Effect of movement in exchange rates on cash held	78	78
4.6	Cash and cash equivalents at end of period	11,680	11,680

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	1,668	2,115
5.2	Call deposits	10,012	10,624
5.3	Bank overdrafts	-	-
5.4	Other (provide details)		
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	11,680	12,739

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	140
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.

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

7. Financing facilities	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
<i>Note: the term "facility" includes all forms of financing arrangements available to the entity. Add notes as necessary for an understanding of the sources of finance available to the entity.</i>		
7.1 Loan facilities	2,100	2,100
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 Total financing facilities	2,100	2,100
7.5 Unused financing facilities available at quarter end		-
7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.		
<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&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&D Tax Incentive (RDTI) rebate for FY2022. Interest on Facility advances is variable at the "TCV 11am" loan interest rate (currently 2.7650%). 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 30 September 2022 the total loan facility was \$2.10 million, being fully drawn.</p>		

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(1,142)
8.2 Cash and cash equivalents at quarter end (item 4.6)	11,680
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	11,680
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	10.2
<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: 28 October 2022

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.