

ASX RELEASE

28 July 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 30 June 2022.

Key Highlights from the Quarter

- Positive pre-IND meeting feedback received from US FDA;
- First site opened for recruitment in ACCENT Phase 2 clinical trial of AMP945 in pancreatic cancer;
- Significant progress in manufacturing and toxicology studies of AMP945.

Operations Update

During the Quarter, Amplia received positive pre-IND (Type B) feedback from the US FDA on the Company’s proposed development plans for its investigational focal adhesion kinase inhibitor, AMP945, in people with pancreatic cancer. The Company also sought FDA’s specific feedback on the design of its ACCENT clinical trial of AMP945 in first-line patients with advanced pancreatic cancer.

The FDA agreed that the available and planned pre-clinical data appear to support both the trial and a future marketing application in the proposed indication. The FDA advised that the design of the ACCENT trial, including selection of the first-line patient population and the proposed dose-escalation followed by a Simon 2-stage design, is generally acceptable. FDA also confirmed Amplia’s understanding that dose selection for the Simon 2 stage expansion phase of the trial should be based on a combined view of safety, efficacy, pharmacokinetics and pharmacodynamics across a wide range of doses.

Additionally, during the Quarter, ethics committee approval was received to conduct the trial and the first site for recruitment of patients to the ACCENT trial was opened at Monash Health in Victoria, Australia. Three additional sites are scheduled to be activated in late July/early August. Previously the Company had forecast that the first patient would be recruited to the trial in the second calendar quarter of 2022 but this target was not met, primarily due to a longer than expected timeline to finalise contracts and governance arrangements with the various clinical sites. These matters have now been resolved allowing the ACCENT trial to recruit patients as planned. In order to recover any delays caused by slower than expected clinical trial start-up, the Company is assessing additional sites, increased patient outreach options and is planning an acceleration of South Korean site activation.

The Company has continued to make progress towards the initiation of a Phase 2 clinical study in Idiopathic Pulmonary Fibrosis patients with completion of dosing in the enabling 3-month toxicology studies of AMP945. Draft reports from these studies are expected in August 2022 and the Company will inform the market of any material outcomes.

Manufacture of AMP945 drug substance for use in non-clinical and clinical studies was also conducted with higher than expected yields of AMP945 being obtained, reflecting improved manufacture process understanding.

A manufacture process for AMP945 higher potency drug product capsules was also developed. By delivering doses with fewer capsules, patient convenience and adherence to clinical trial protocols will be enhanced. Ongoing stability studies of AMP945 drug substance and drug product also show that AMP945 remains within specification for extended periods of time, supporting a likely long product shelf-life.

In June, new data from preclinical studies was disclosed showing that AMP945 had comparable activity to OFEV[®], the current market leader in the treatment of idiopathic pulmonary fibrosis. The Company expects that this new information will encourage interest from both clinical investigators and patients.

After joining the Company in February 2021 as Director Operations, Dr Rhiannon Jones was promoted to Chief Operations Officer (COO) effective July 1, 2022. Dr Jones has been leading much of Amplia's manufacturing activities and her promotion to this broader role is a reflection of Amplia's growth into a more mature clinical-stage company.

Financial update

Amplia finished the June 2022 quarter with cash of \$12.7 million (March 2022: \$14.6 million).

During the quarter, the Company had net cash outflows of \$1.8 million in relation to operating activities (March 2022: \$2.3 million). Operating cashflows included outflows of:

- \$0.3 million for staff and administration/corporate costs; and
- \$1.2 million for research and development costs, which primarily related to toxicology studies, ACCENT trial clinical costs and manufacturing costs of AMP945 drug substance and product.

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 July-August 2022.

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 \$102,230 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 on recruitment progress in the ACCENT trial as well as updates on progression towards optimal dose selection. The Company also expects to receive draft study reports from 3-month toxicology studies and will report top-line outcomes from these studies.

Work on Amplia's second FAK inhibitor, AMP886, is ongoing and outcomes from preclinical and manufacturing development work will be provided when ongoing studies are completed.

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 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")

30 June 2022

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(1,246)	(1,246)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(317)	(317)
(f) administration and corporate costs	(284)	(284)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	1	1
1.5 Interest and other costs of finance paid	(2)	(2)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	41	41
1.8 Other (provide details if material)	(25)	(25)
1.9 Net cash from / (used in) operating activities	(1,832)	(1,832)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(7)	(7)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 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)	(53)	(53)
2.6	Net cash from / (used in) investing activities	(60)	(60)
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	22	22
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	22	22
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	14,609	14,609
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,832)	(1,832)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(60)	(60)

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 (3 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	22	22
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	12,739	12,739

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	2,115	3,985
5.2	Call deposits	10,624	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)	12,739	14,609

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	102
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.

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 1.515%). 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 June 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)	(1,832)
8.2 Cash and cash equivalents at quarter end (item 4.6)	12,739
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	12,739
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	7.0
<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 July 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.