

ASX RELEASE 31st July 2024

#### **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 2024.

# **Key Highlights from the Quarter**

- Updated data and analysis from the Phase 1b ACCENT trial in pancreatic cancer presented at the prestigious annual meetings of the American Association for Cancer Research (AACR) and the American Society of Clinical Oncology (ASCO).
- Recruitment in the ACCENT Phase 2a trial has progressed well and in early June we reported 24 of 26 patients had been recruited.
- The inaugural meeting of the Company's Clinical Advisory Board was held.

#### **Operations Update**

#### Clinical Development

The strategic priority for the company over the last quarter has been timely execution of the Phase 2a portion of the ACCENT trial in pancreatic cancer. The ACCENT clinical trial explores the safety, tolerability, and most importantly, efficacy of the Company's best-in-class FAK inhibitor narmafotinib, in combination with the chemotherapy drugs gemcitabine and Abraxane®, in newly diagnosed patients with advanced pancreatic cancer.

The Company reported dosing the first patient in the Phase 2a ACCENT trial in January this year using the dose identified from the Phase 1b trial. In March 2024, the Company reported that 11 patients had been dosed in the Phase 2a trial at that time, and in June we reported that 24 patients of the 26 required had been recruited to the trial.

The Phase 2a stage of the ACCENT trial is open at six sites in Australia - in Melbourne, Sydney and Brisbane - and at five hospitals in the Republic of Korea, in and around the capital Seoul. Korea was chosen as a second country in which to conduct the trial given the excellent medical and clinical trial facilities and capabilities in the country.

The Phase 2a trial is being conducted using Simon's Two-Stage Design, a commonly used method for Phase 2 clinical trials. The trial design was chosen as it can result in efficient determination of whether a new drug has sufficient promise to warrant further development. In the ACCENT trial, the first stage consists of efficacy assessment in a group of 26 patients where a confirmed complete or partial response in six (6) patients in considered sufficiently promising to warrant continuation of the trial. In the second stage of the trial an additional 24 patients will be enrolled, giving a total of 50 patients. The decision about the drug's efficacy is made based on the combined results of both stages.

It is important to note that the formal term 'confirmed partial response' means that there is at least a 30% reduction in the overall size of tumour lesions, sustained over a two-month period, with no new tumour lesions. Given that the ACCENT trial is focused on patients with advanced pancreatic cancer, a >30% reduction in tumour size represents a significant therapeutic response in this aggressive disease. In the Phase 1b stage of the ACCENT trial completed in October last year, we reported that six out of the fourteen patients on the trial recorded a partial response.

In April we presented a poster with updated analysis of data from the ACCENT Phase 1b trial at the world's foremost scientific meeting in cancer research, the annual meeting of the AACR. In addition to the excellent response rate observed for the fourteen patients on the trial, significantly higher than predicted from historical studies of gemcitabine and Abraxane treatment alone, we also presented data showing there was a clear dose-dependence in response, where four of the six partial responses observed were from the highest dosing cohort. This, combined with other data, strongly suggests that the responses observed are related to effects from the drug narmafotinib.

This data was subsequently published in the abstracts for the annual ASCO meeting in May. During the conference, the inaugural meeting of the Company's Clinical Advisory Board was also held to discuss the ACCENT trial progress, as well as strategy and plans for additional trials of narmafotinib in pancreatic cancer. The CAB consists of five world-class clinical oncologists, with expertise in pancreatic cancer from Australia, the US and Canada.

## **Financial update**

Amplia finished the June 2024 quarter with cash of \$4.8 million (March 2024: \$3.4 million).

During the quarter, the Company had net operating cash outflows of \$2.5 million in relation to operating activities (March 2024: \$2.0 million outflow). Operating cashflows included:

- Outflows of \$0.7 million for staff and administration/corporate costs; and
- Outflows of \$1.8 million for research and development costs, which primarily related to trial costs, Contract Research Organisation (CRO), manufacturing and other CMC related costs incurred in relation to the Phase 1b/2a clinical trial for narmafotinib (AMP945).

During the quarter the Company undertook a two for five, fully underwritten pro-rata non-renounceable Entitlement offer and raised \$4.27m (before costs) receiving significant support from new and existing institutional investors and the Company's Directors.

## **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 \$112,500 and relate to payments to the CEO/Managing Director in line with employment contracts and payments to the Non-Executive Directors.

# **Outlook and future activities**

The Company will continue to focus on timely execution of the Phase 2a portion of the ACCENT trial. Additional clinical opportunities for narmafotinib, including a potential clinical trial in ovarian cancer, are also being actively explored.

- End -

#### **For Further Information**

Dr. Christopher Burns CEO and Managing Director Chris@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 the field of cancer and Amplia has a particular development focus in fibrotic cancers such as pancreatic cancer. FAK also plays a significant role in a number of chronic diseases, such as idiopathic pulmonary fibrosis (IPF). For more information visit <a href="www.ampliatx.com">www.ampliatx.com</a> and follow Amplia on <a href="www.ampliatx">Twitter</a> (@ampliatx), <a href="mailto:Threads">Threads</a> (@ampliatx) and <a href="mailto:LinkedIn">LinkedIn</a>.

# **Appendix 4C**

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

# Name of entity

AMPLIA THERAPEUTICS LIMITED			
ABN Quarter ended ("current quarter")			
16 165 160 841 30 June 2024			

Con	solidated 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	(1,761)	(1,761)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(308)	(308)
	(f) administration and corporate costs	(400)	(400)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	26	26
1.5	Interest and other costs of finance paid	(1)	(1)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	(82)	(82)
1.9	Net cash from / (used in) operating activities	(2,526)	(2,526)

2.	Cash flows from investing activities	
2.1	Payments to acquire or for:	
	(a) entities	-
	(b) businesses	-
	(c) property, plant and equipment	-
	(d) investments	-
	(e) intellectual property	-
	(f) other non-current assets	-

ASX Listing Rules Appendix 4C (17/07/20)

Page 1

Con	solidated 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)	-	-
2.6	Net cash from / (used in) investing activities	-	-

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	4,268	4,268
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(292)	(292)
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)	(21)	(21)
3.10	Net cash from / (used in) financing activities	3,955	3,955

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	3,385	3,385
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,526)	(2,526)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

Cons	solidated 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)	3,955	3,955
4.5	Effect of movement in exchange rates on cash held	(1)	(1)
4.6	Cash and cash equivalents at end of period	4,813	4,813

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	181	379
5.2	Call deposits	4,632	3,006
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)	4,813	3,385

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	113
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.		cription of, and an

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

7.	Financing facilities  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.	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1	Loan facilities	1,528	1,528
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	Total financing facilities	1,528	1,528
7.5	Unused financing facilities available at qu	arter 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.

The Company entered into an unsecured loan agreement with Non-Executive Director, Dr Robert Peach for \$1,467,000. The loan will accrue interest at the simple (non-compounding) rate of 10.0% per annum on a pro rata basis, with a repayment date of the earlier of 31 December 2024 or the receipt of the FY24 R&D tax incentive refund.

Estimated cash available for future operating activities	\$A'000
Net cash from / (used in) operating activities (item 1.9)	(2,526)
Cash and cash equivalents at quarter end (item 4.6)	4,813
Unused finance facilities available at quarter end (item 7.5)	-
Total available funding (item 8.2 + item 8.3)	4,813
Estimated quarters of funding available (item 8.4 divided by item 8.1)	1.9
-	Net cash from / (used in) operating activities (item 1.9)  Cash and cash equivalents at quarter end (item 4.6)  Unused finance facilities available at quarter end (item 7.5)  Total available funding (item 8.2 + item 8.3)  Estimated quarters of funding available (item 8.4 divided by

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.

- 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:Yes – the Company expects that it will substantially continue to have the current level of operating cash outflows as it continues to fund the ongoing Phase 2a ACCENT trial and other trial activities. However, the Company expects to receive an operating inflow of \$3.17 million in the September 2024 quarter, in relation to its FY24 R&D tax incentive rebate. On receipt of the \$3.17 million the Company will fully repay the R&D funding loan (\$1.53 million as at 30 June 2024), leaving the Company with a proforma cash and cash equivalent at 30 June 2024 of \$6.46 million.

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: Yes, the Company does propose to take steps to raise further cash to fund its continuing operations beyond the Interim Analysis for the ongoing Phase 2a ACCENT trial and other trial activities. The Company anticipates that a further capital raising will be undertaken following the completion and release of the Interim Analysis. Following the recent Entitlement Offer extended to existing shareholders, the capital raise is likely to be a placement focussed on sophisticated and institutional investors from Australian and overseas markets where there has been increasing interest in the Company's progress. Assuming a successful Interim Analysis, the Company believes that the proposed capital raising is likely to be successful given the strength of its emerging operations and the increased prospectivity for development of the Company's lead compound narmafotinib (AMP945) as a best-in-class FAK inhibitor.

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: Yes – the Company does expect to be able to continue its operations and to meet its business objectives. With its existing cash reserves along with the proceeds expected from the FY24 R&D tax incentive (net paying off the FY24 R&D funding loan) the Company will continue to fund its operations and further progress its assets through to and beyond the Interim Analysis. Subject to a positive Interim Analysis and with additional capital raising, the Company expects that it will be able to fund the subsequent development of its lead compound narmafotinib (AMP945) through to the clinic as a best-in-class FAK inhibitor.

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**

- 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: 31 July 2024

Authorised by: The Board of Directors

(Name of body or officer authorising release - see note 4)

#### Notes

- 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.
- 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.