

# ASX RELEASE 30<sup>th</sup> January 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 31 December 2023.

## **Key Highlights from the Quarter**

- The Phase 1b stage of the ACCENT trial was completed. Promising early signs of drug efficacy were observed.
- The Phase 2a stage of the ACCENT trial commenced with first patient dosing in January 2024.
- The Korean drug regulators approved the Company's application to conduct the ACCENT trial in Korea.
- Korean sites for the ACCENT trial are ready to recruit patients.
- An Investigational New Drug application was submitted to the US Food and Drug Administration (and clearance obtained in January 2024).
- A\$1.47m loan provided by Non-Executive Director to progress current initiatives.

#### **Operations Update**

#### **Clinical Development**

During the quarter the Company announced that the Phase 1b stage of the ACCENT clinical trial in advanced pancreatic cancer patients was complete. The Phase 1b stage consisted of identifying an optimal dose of the Company's best-in-class FAK inhibitor narmafotinib, when combined with the chemotherapy drugs gemcitabine and Abraxane®, in first-line patients with advanced pancreatic cancer. Specifically, a safe and well-tolerated dose of narmafotinib was identified that provides sufficient drug levels to significantly suppress FAK activity over the dosing period. Importantly, there were preliminary signs of efficacy from the 14 patients dosed in the Phase 1b trial.

With an optimal dose now identified, the Phase 2a stage of the ACCENT trial can proceed. In this stage of the trial, the efficacy of narmafotinib in combination with gemcitabine and Abraxane will be determined in a larger patient group. Ethics approvals to conduct the Phase 2a stage of the trial at our existing six sites in Australia were obtained in December. Importantly, we also received approval from the Korean regulator, the Korean Ministry of Food and Drug Safety (MFDS), to run the trial at five hospitals in South Korea. CEO Dr Chris Burns and Clinical Operations Manager Ms Nicole Kruger visited the trial sites in early December to meet with the Principal Investigators and clinical teams at each site. Final approvals from the individual trial sites have now been obtained and patient screening has begun.

In December the Company submitted an Investigational New Drug (IND) application to the US Food and Drug Administration (FDA) to conduct a clinical trial of narmafotinib, in combination with the chemotherapy regime known as FOLFIRINOX, in the USA. FOLFIRINOX, a combination of four chemotherapy drugs, is the preferred chemotherapy regime for the treatment of advanced pancreatic cancer in the USA. We have demonstrated, and previously disclosed, that narmafotinib enhances the activity of FOLFIRINOX in a mouse model of pancreatic cancer. In January 2024 we received a 'Study May Proceed' letter from the FDA indicating that the IND had been cleared.

#### **Non-clinical Development**

A poster presentation describing preclinical research demonstrating narmafotinib activity in mouse models of ovarian cancer was presented at the specialist *American Association of Cancer Research – Ovarian Cancer* conference in Boston. The data presented clearly demonstrated that narmafotinib is active in models of chemotherapy-resistant ovarian cancer with improved tumour growth inhibition and tolerability compared to the current standard-of-care agent for this chemotherapy-resistant patient population. Furthermore, narmafotinib was active when the standard-of-care drug was ineffective.

#### Non-Executive Director Loan for \$1.47 million in January 2024

The Company is pleased to announce it has entered into an unsecured loan agreement with Non-Executive Director, Dr Robert Peach.

Under the Loan Agreement, Dr Peach has agreed to advance A\$1.47 million to the Company, providing a non-dilutive extension to our cash runway on terms more favourable to the Company than other available loan facilities and delivers funding for Amplia to progress current initiatives.

The loan will be received within 5 days of this date, accruing 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.

The Company is extremely grateful for the ongoing support and confidence shown by Dr Peach in the Phase 2a ACCENT trial and the Company's future.

#### Financial update

Amplia finished the December 2023 quarter with cash of \$3.9 million (September 2023: \$5.7 million).

During the quarter, the Company had net cash inflows of \$0.4 million in relation to operating activities (September 2023: \$2.2 million outflow). Operating cashflows included:

- Outflow of \$0.7 million for staff and administration/corporate costs;
- Outflow of \$1.4 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 first stage of the Phase 1b/2a clinical trial for narmafotinib
  (AMP945); and
- Inflow of \$2.4 million for the FY23 Research and Development Tax Incentive refund

The Company received the FY23 Research and Development Tax Incentive refund of \$2,408,458 in October 2023 which it used to fully repay the \$2,100,000 Research and Development Tax Incentive loan that it held with Treasury Corporation of Victoria.

Research and development expenditure is forecast to increase in the coming quarters in line with the progression of Phase 1b/2a of the ACCENT clinical trial for narmafotinib.

#### **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 director fee payments to the Non-Executive Directors.

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

Over the coming quarter, the Company will report further progress in the ACCENT trial as the Phase 2a portion of the trial progresses. We anticipate interim analysis for the trial in mid 2024. Additional clinical opportunities for narmafotinib in ovarian cancer are also being actively explored.

Preclinical studies with narmafotinib and AMP886 are ongoing to expand the clinical potential and further enhance the partnering prospects for these agents. Selected studies already completed are being written up for publication in peer-reviewed scientific journals.

- 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 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

ABN

| AMPLIA THERAPEUTICS LIMITED |  |
|-----------------------------|--|
|                             |  |

Quarter ended ("current quarter")

16 165 160 841 30 December 2023

| Con | solidated statement of cash flows              | Current quarter<br>\$A'000 | Year to date<br>(9 months)<br>\$A'000 |
|-----|--|----------------------------|---------------------------------------|
| 1.  | Cash flows from operating activities           |                            |                                       |
| 1.1 | Receipts from customers                        | -                          | -                                     |
| 1.2 | Payments for                                   |                            |                                       |
|     | (a) research and development                   | (1,357)                    | (3,494)                               |
|     | (b) product manufacturing and operating costs  | -                          | -                                     |
|     | (c) advertising and marketing                  | -                          | -                                     |
|     | (d) leased assets                              | -                          | -                                     |
|     | (e) staff costs                                | (382)                      | (1,214)                               |
|     | (f) administration and corporate costs         | (329)                      | (916)                                 |
| 1.3 | Dividends received (see note 3)                | -                          | -                                     |
| 1.4 | Interest received                              | 46                         | 123                                   |
| 1.5 | Interest and other costs of finance paid       | (13)                       | (58)                                  |
| 1.6 | Income taxes paid                              | -                          | -                                     |
| 1.7 | Government grants and tax incentives           | 2,423                      | 2,423                                 |
| 1.8 | Other (provide details if material)            | 3                          | (61)                                  |
| 1.9 | Net cash from / (used in) operating activities | 391                        | (3,197)                               |

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

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| Con | solidated statement of cash flows              | Current quarter<br>\$A'000 | Year to date<br>(9 months)<br>\$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 | (2)                        | (2)                                   |

| 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   | -       | -       |
| 3.4  | Transaction costs related to issues of equity securities or convertible debt securities | -       | -       |
| 3.5  | Proceeds from borrowings  | -       | -       |
| 3.6  | Repayment of borrowings   | (2,100) | (2,100) |
| 3.7  | Transaction costs related to loans and borrowings                                       | -       | -       |
| 3.8  | Dividends paid  | -       | -       |
| 3.9  | Other (repayment of lease liability)  | (20)    | (60)    |
| 3.10 | Net cash from / (used in) financing activities  | (2,120) | (4,260) |

| 4.  | Net increase / (decrease) in cash and cash equivalents for the period |       |         |
|-----|---|-------|---------|
| 4.1 | Cash and cash equivalents at beginning of period                      | 5,657 | 9,257   |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above)       | 391   | (3,197) |
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above)       | (2)   | (2)     |

| Con | solidated statement of cash flows                                | Current quarter<br>\$A'000 | Year to date<br>(9 months)<br>\$A'000 |
|-----|--|----------------------------|---------------------------------------|
| 4.4 | Net cash from / (used in) financing activities (item 3.10 above) | (2,120)                    | (2,160)                               |
| 4.5 | Effect of movement in exchange rates on cash held                | (28)                       | -                                     |
| 4.6 | Cash and cash equivalents at end of period                       | 3,898                      | 3,898                                 |

| 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<br>\$A'000 | Previous quarter<br>\$A'000 |
|-----|---|----------------------------|-----------------------------|
| 5.1 | Bank balances   | 722                        | 962                         |
| 5.2 | Call deposits   | 3,176                      | 5,172                       |
| 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)   | 3,898                      | 5,657                       |

| 6.  | Payments to related parties of the entity and their associates                          | Current quarter<br>\$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 explanation for, such payments. |   | e a description 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<br>amount at quarter<br>end<br>\$A'000 | Amount drawn at<br>quarter end<br>\$A'000 |
|-----|--|---|---|
| 7.1 | Loan facilities  | -   | -   |
| 7.2 | Credit standby arrangements  | -   | -   |
| 7.3 | Other (please specify)   | -   | -   |
| 7.4 | Total financing facilities   | -   | -   |
| 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, interes 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. |   | itional financing                         |

| 8.  | Estimated cash available for future operating activities   | \$A'000                    |
|-----|--|----------------------------|
| 8.1 | Net cash from / (used in) operating activities (item 1.9)  | 391                        |
| 8.2 | Cash and cash equivalents at quarter end (item 4.6)  | 3,898                      |
| 8.3 | Unused finance facilities available at quarter end (item 7.5)  | -                          |
| 8.4 | Total available funding (item 8.2 + item 8.3)  | 3,898                      |
| 8.5 | Estimated quarters of funding available (item 8.4 divided by item 8.1)   | N/A                        |
|     | Note: if the entity has reported positive net operating cash flows in item 1.9, answer item figure for the estimated quarters of funding available must be included in item 8.5. | 8.5 as "N/A". Otherwise, a |

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**

- 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: 30 January 2024

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".
- 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.