

ASX RELEASE

29<sup>th</sup> May 2020

# APPENDIX 4E – PRELIMINARY FINAL REPORT YEAR ENDED 31 March 2020 COMMENTARY AND ANALYSIS

During the year ending 31 March 2020, Amplia Therapeutics made significant progress in the development of its key pharmaceutical asset AMP945, a molecule with promising potential for the treatment of both cancer and fibrotic diseases. The Company remains committed to the development of inhibitors of Focal Adhesion Kinase (FAK). Operational highlights reported during the year include:

- Expansion of Amplia's scientific and clinical advisory boards (March 2019 and February 2020)
- Promising preclinical efficacy data of AMP945 in a squamous cell cancer model (July 2019)
- Completion of GMP, scale manufacture of AMP945 to be used in Amplia's inaugural clinical trial of AMP945 (July 2019)
- Preliminary results from preclinical safety studies indicating no initial safety concerns (August 2019)
- Additional data showing AMP945's superior selectivity for FAK, relative to competitor molecules (August 2019)
- FDA awarding an Orphan Drug Designation for AMP945 in the treatment of pancreatic cancer (March 2020)

During the year, Amplia completed two successful rounds of capital raising. In July 2019, the Company raised a total of \$1.2m through a Rights Issue, Private Placement and Directors and Management Placement. An additional Placement to new and existing professional and sophisticated investors raised \$0.9m in January 2020. Platinum International Healthcare Fund participated in this round of funding taking a substantial shareholder position in Amplia. The proceeds from these capital raisings have been used to complete preclinical testing of Amplia's lead asset, AMP945, such that the drug is on-track for first clinical testing in human subjects later this year.

In June 2019, Dr John Lambert succeeded Mr Simon Wilkinson as CEO, and in February 2020, Amplia announced a several changes to the composition of its Board of Directors. These changes reflect the significant progress that has been made following the acquisition of the Amplia assets in 2018. With this transition complete, Dr Chris Behrenbruch, Mr Simon Wilkinson and Mr Andrew Cooke resigned as Directors and Dr John Lambert was appointed as Managing Director. Mr Andrew Cooke remains as Company Secretary.

The Group's loss after tax for the year ended 31 March 2020 was \$2,219k (2019: \$1,869k). This result included non-cash share based compensation of \$203k (2019: \$244k). Since 31 March 2019, the net assets of the Group decreased by \$59k to \$8,606k as of 31 March 2020.

Research and development expenses increased to \$1,072k (2019: \$736k). This substantially reflects the preclinical activities undertaken in respect of the Group's leading development candidate AMP945. The Group's General and Administration expenses were \$858k (2019: \$804k).

In May 2020, the Company was awarded a second Orphan Drug Designation by the US FDA for the use of AMP945 in the treatment of idiopathic pulmonary fibrosis. This second Orphan Drug Designation is in addition to and compliments the Orphan Drug Designation for AMP945 in the treatment of

Level 29, 55 Collins Street, Melbourne VIC 3000 Email info@ampliatx.com www.ampliatx.com pancreatic cancer awarded in March 2020. The company remains on track to initiate clinical development of AMP945, initially in a Phase 1 trial in healthy volunteers, in the second half of 2020.

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

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



## **APPENDIX 4E**

PRELIMINARY FINAL REPORT GIVEN TO THE ASX UNDER LISTING RULE 4.3A

AMPLIA THERAPEUTICS LIMITED

ACN 165 160 841

FINANCIAL YEAR ENDED 31 MARCH 2020

## HIGHLIGHTS OF RESULTS FOR ANNOUNCEMENT TO THE MARKET

(figures are in A\$000s)

OTHER INCOME
PROFIT/(LOSS) BEFORE INCOME TAX
PROFIT/(LOSS) AFTER INCOME TAX
WEIGHTED EARNINGS PER SHARE - CENTS

March 2020 \$000s	March 2019 \$000s	Change \$000s	Change %
38	71	(33)	-46%
(2,219)	(1,870)	(349)	19%
(2,219)	(1,870)	(349)	19%
(4.6)	(4.7)	0.1	-3%

	Current <u>Year</u>	Previous <u>Year</u>
Interim Dividend Final Dividend	nil il	nil nil
	nil	nil

The Directors have resolved that no dividend will be paid this year.

Record Date for determining entitlement to Dividend	n/a
Payment date of Dividend	n/a

The company's Annual General Meeting will be held 28 August 2020 at 2:00pm Venue: Level 22, Collins Square, Tower 5, 727 Collins Street, Docklands VIC 3008

## CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

	31 March 2020 \$000s	31 March 2019 \$000s
REVENUE	-	-
OTHER INCOME		
Rent received	-	-
Interest income R&D tax incentive	4 34	20 51
TOTAL OTHER INCOME	38	71
EXPENDITURE		
Research & development expenses	(1,072)	(736)
Patent and associated expenses	(123)	(155)
General and administration expenses	(858)	(804)
Depreciation & amortisation	(1)	(2)
Share based compensation (directors, employees & non-employees)	(203)	(244)
TOTAL EXPENDITURE	(2,257)	(1,941)
LOSS BEFORE INCOME TAX EXPENSE	(2,219)	(1,870)
Income tax (expense)	-	-
LOSS AFTER INCOME TAX	(2,219)	(1,870)
OTHER COMPREHENSIVE INCOME		
Foreign currency translation	-	-
Income tax thereon	-	-
OTHER COMPREHENSIVE INCOME/(LOSS) NET OF INCOME TAX	<u> </u>	<u> </u>
		,

Basic and diluted earnings per share (weighted) (4.6) cents

(4.7) cents

## CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	31 March 2020 \$000s	31 March 2019 \$000s
Current Assets		
Cash & cash equivalents	1,108	1,241
R&D incentive accrual	34	-
Other current assets	36	11
Total current assets	1,178	1,252
Non Current Assets		
Property, plant & equipment	1	2
Intangible assets	7,938	7,938
Total non current assets	7,939	7,940
Total Assets	9,117	9,192
Current Liabilities		
Accounts payable & accrued liabilities	511_	527
Total current liabilities	511	527
Non Current Liabilities		
Total Liabilities	511	527
Net Assets	8,606	8,665
Equity		
Paid in capital	132,903	130,946
Foreign currency translation reserve	(1,819)	(1,819)
Share option reserve	447	456
Accumulated losses	(122,925)	(120,918)
Total Equity	8,606	8,665

## CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

	Issued Capital \$000s	Accumulated Losses \$000s	Share Option Reserve \$000s	Foreign Currency Translation \$000s	Total Equity \$000s
CONSOLIDATED ENTITY At 1 April 2018	123,019	(120,305)	1,469	(1,819)	2,364
(Loss) after income tax for the year Other comprehensive income/(loss) net of tax	-	(1,870) -	-	-	(1,870)
Total comprehensive (loss) after tax		(1,870)	-	-	(1,870)
Transactions with owners in their capacity as owners					
Issue of shares Cost of issuing shares	7,938 (11)	-	-	-	7,938 (11)
Transfer due to expiry of options	(11)	- 1,257	- (1,257)	-	(11)
Amortisation of share options		-	244	-	244
	7,927	1,257	(1,013)	-	8,171
At 31 March 2019	130,946	(120,918)	456	(1,819)	8,665
(Loss) after income tax for the year	-	(2,219)	-	-	(2,219)
Other comprehensive income net of tax		-	-	-	-
Total comprehensive (loss) after tax		(2,219)	-	-	(2,219)
Transactions with owners in their capacity as owners					
Issue of shares	2,149	-	-	-	2,149
Cost of issuing shares	(192)	-	-	-	(192)
Transfer due to expiry of options Amortisation of share options	-	212	(212) 203	-	- 203
Amonisation of share options		-	203	-	203
	1,957	212	(9)	-	2,160
At 31 March 2020	132,903	(122,925)	447	(1,819)	8,606

## CONSOLIDATED STATEMENT OF CASH FLOWS

	Year Ended 31 March 2020 <u>\$000s</u>	Year Ended 31 March 2019 <u>\$000s</u>
Cash flows related to operating activities		
Interest received	3	20
R&D incentive received	-	218
Payments to suppliers	(1,568)	(611)
Payments to employees	(522)	(615)
Net Operating Cash Flows	(2,087)	(988)
Cash flows related to investing activities		
Payment for purchases of property, plant and equipment	-	(3)
Proceeds from disposal of property, plant and equipment	-	-
Net investing cash flows	-	(3)
Cash flows related to financing activities		
Issue of ordinary shares & exercise of options	2,149	-
Capital raising, listing & other costs	(192)	(11)
Net financing cash flows	1,957	(11)
Net increase/(decrease) in cash held	(130)	(1,002)
Cash at beginning of period	1,241	2,229
Foreign exchange effect on cash & cash equivalents balances	(3)	14
Cash at end of period	1,108	1,241
Reconciliation of cash		
Cash & cash equivalents in Statement of Financial Position	1,108	1,241

#### NOTES TO THE CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

## STATEMENT OF ACCOUNTING POLICIES - BASIS OF PREPARATION OF FINANCIAL REPORT

This financial report (unaudited) is a general purpose financial report prepared in accordance with the Corporations Act 2001. This financial report does not include notes of the type normally included in an Annual Report (audited) and should be read in conjunction with the most recent annual financial report (audited).

Intangible assets have been accounted for at cost. The carrying value of intangible assets is reviewed for impairment purposes. Any necessary adjustments are made in the period to which they relate. Intangible assets will be amortised over their life. However, as they are yet to be commercialised there is no definitive period for which to calculate the definitive life and are being carried at cost. During the period the intangible assets were the subject of an updated independent valuation. No impairment was considered necessary and are being carried forward at cost (refer note "Intangible Assets" below).

AASB 16 - Leases: The Consolidated Entity has adopted AASB 16 from 1 April 2019. AASB 16 replaces AASB 17 Leases and for lessees eliminates the classifications of operating leases and finance leases. As the Group does not have any leases the adoption of the standard has had no impact on the Group's accounting policies reported during the current or prior years.

The accounting policies applied in preparing the financial statements for the year ended 31 March 2020 are consistent with those applied in preparing the comparative information presented in these financial statements and are the same as those applied by the Consolidated Entity in its consolidated financial report (audited) as at and for the year ended 31 March 2019.

	31 March 2020 <u>\$000s</u>	31 March 2019 <u>\$000s</u>
Profit / (loss) before income		
tax has been determined after:		
Income		
R&D incentives	34	51
Expenses		
Depreciation - office furniture & equipment	1	2
Employee benefits	493	570
Foreign exchange gain/(loss)	(2)	14
Share based compensation - employees & directors	203	244
The remuneration of the auditors was:		
- audit services	45	46
- tax services	7	13
- other services	-	14

DETAILS OF INVESTMENTS IN CONTROLLED ENTITIES	31 March 2020			31 March 2019
	Ownership	Investment	Ownership	Investment
	Interest		Interest	
Amplia Therapeutics (UK) Limited	100%	\$180	100%	\$180
<ul> <li>issued share capital of GBP100 fully paid</li> </ul>				
ACN 612 556 948 Pty Ltd (formerly Amplia Therapeutics P/L)	100%	0%	100%	\$0

- issued capital \$10 is unpaid at 31 March 2020

Innate Immunotherapeutics (NZ) Limited (incorprated in New Zealand) was deregistered during the period.

### **EARNINGS PER SHARE (EPS)**

Details of basic and diluted EPS in accordance with paragraph 9 and 18 of AASB 133:

· - ·		
Earnings used in the calculation of basic EPS Earnings used in the calculation of diluted EPS	(2,219) (2,219)	(1,870) (1,870)
Weighted average number of shares outstanding during the year	Number	Number
Basic EPS	48,470,801	39,755,425
Diluted EPS	48,470,801	39,755,425
Options have not been included in the weighted average number of ordina	ary shares outstanding for the	

purpose of calculating the diluted EPS as they do not meet the requirements for inclusion under AASB 133. Options are non-dilutive as the Group result was a loss. Prior period comparatives have been updated in this consolidated financial statements.

	Cents	Cents
Basic EPS - cents	(4.6)	(4.7)
Diluted EPS - cents	(4.6)	(4.7)
NET TANGIBLE ASSET BACKING PER SHARE		
Net tangible asset backing per share - cents	1.0	1.8

## NOTES TO THE CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

	31 March 2019 <u>\$000s</u>	31 March 2019 <u>\$000s</u>
DIVIDENDS Interim Dividend Final Dividend	nil nil	nil nil nil
CONSOLIDATED ACCUMULATED LOSSES		
Accumulated losses at the beginning of the financial year Net profit attributable to members Transfer due to expiry of options Accumulated losses at the end of the financial year	(120,918) (2,219) 	(120,305) (1,870) <u>1,257</u> (120,918)
ORDINARY SHARES ON ISSUE	NUMBER	NUMBER
Number of shares on issue at 1 April 2019	41,023,303	225,625,991
After consolidation 10 into 1 on 30 April 2018 Issued during the period for the acquisition of	-	22,562,995
Amplia Therapeutics (post consolidation)	2 000 000	18,460,308
Placement of shares @ 10c per share 14 June 2019 Rights Issue @ 10c per share 31 July 2019	3,600,000 6,847,282	-
Placement of shares to Directors & Management @ 10c per share 31 August 2019 Placement of shares @ 7c per share 24 January 2020 Number of shares on issue 31 March 2020	1,700,000 <u>13,292,600</u> 66,462,185	41.022.202
Number of shares on issue 31 March 2020	66,463,185	41,023,303

#### OPTIONS

There were 10,353,688 (31 March 2019: 3,270,000) options outstanding at reporting date. During the period 6,073,688 options were issued as part of the placements @ 10c per share on 14 June, 31 July and 31 August 2019 and 1,200,000 options were issued to the Chief Executive Officer. No options were exercised during the period. 190,000 options expired unexercised.

## INTANGIBLE ASSETS

On 26 April 2018 the Company's shareholders approved the acquisition of Amplia Therapeutics Pty Ltd ("ATP") via the issue of 18,460,308 shares. The closing share price on that date was 43 cents. The deemed share consideration paid on acquisition was therefore \$7,937,932. The only asset of ATP at acquisition was an exclusive worldwide license to develop and commercialise the drug candidates AMP945 & AMP886. The Company commissioned an updated independent valuation of the two drug assets to test the deemed acquisition value for impairment prior to the signing of this report. This updated valuation of the licenses exceeded the deemed total acquisition value of \$7,937,932. Hence, the Company continues to believe that it is appropriate to carry forward the value of the licenses at the deemed acquisition value i.e. \$7,937,932.

### COVID-19

In March 2020, the World Health Organisation declared the outbreak of a novel coronavirus (COVID-19) as a pandemic, which continued to spread throughout Australia. The spread of COVID-19 has caused significant volatility in Australian and international markets. There is significant uncertainty around the breadth and duration of business disruptions related to COVID-19, as well as its impact on Australian and international economies and, as such, the Company is unable to determine if it will have a material impact to its operations.

### COMMITMENTS AND CONTINGENT LIABILITIES AND ASSETS

Under the above noted in-licence agreement, dated 15 March 2018, the Company must use commercially reasonable efforts to develop AMP945 by filing an Investigational New Drug ("IND") application or commence a Phase I trial within two years and AMP886 by filing an IND or commencing a Phase I trial within three years. In February 2020 the Cancer Research Technology Limited agreed to extend the timeframe, in which the Phase 1 trials be commenced, to the end of 2020. Under this agreement there is an annual maintenance fee of between US\$10,000 to US\$20,000 per annum. Additionally, under this agreement there are various milestone payments totaling US\$250,000 for the commencement of Phase I and US\$150,000 for the allowance of the two IND's. Further milestone payments would only become due and payable upon commencing Phase II & III studies, regulatory approvals and ultimately commercialisation.

#### POST REPORTING DATE EVENTS

At the date of this report, there are no matters or circumstances which have arisen since the end of the financial year which will significantly affect the operations of the economic entity, the results of those operations or the state of affairs of the economic entity in subsequent periods.

### **GOING CONCERN**

The financial statements have been prepared on a going concern basis after taking into consideration the net loss for the twelve months of \$2,219k and the cash and cash equivalents balance of \$1,108k. The going concern basis contemplates continuity of normal business activities and realisation of assets and settlement of liabilities in the ordinary course of business. The going concern of the Company is dependent on it maintaining sufficient funds for its operations and commitments. The Directors continue to monitor these ongoing funding requirements and are of the opinion that the financial statements have been appropriately prepared on a going concern basis.

## AUDIT STATUS

The full financial report and notes are currently in the process of being audited.