

# **APPENDIX 4D**

HALF YEAR REPORT GIVEN TO THE ASX UNDER LISTING RULE 4.2A

AMPLIA THERAPEUTICS LIMITED (formerly Innate Immunotherapuetics Limited)

ACN 165 160 841

HALF YEAR ENDED 30 SEPTEMBER 2018

# RESULTS FOR ANNOUNCEMENT TO THE MARKET (figures are in A\$'s)

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

Half Year Ended 30 September 2018 \$	Half Year Ended 30 September 2017 \$	Change \$	Change %
60,147	673,706	(613,559)	-91%
(717,802)	(2,495,289)	1,777,487	-71%
(717,802)	(2,495,289)	1,777,487	-71%
(1.9)	(11.1)	9.2	-83%

30 September 2018 Cents 31 March 2018 Cents 10.5

NET TANGIBLE ASSET BACKING PER SHARE

DIVIDENDS

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

2018 Final Dividend 2019 Interim Dividend

Record Date for determining entitlement to Dividend Payment date of Dividend

nil nil nil

n/a n/a

# Directors' Report

for the half year ended 30 September 2018

Your directors present their report on Amplia Therapeutics Limited (the "Company") and its wholly owned subsidiaries (the "Group") for the half year ended 30 September 2018.

# **DIRECTORS**

The names of directors in office at any time during or since the period are:

Warwick Tong – appointed 4 May 2018
Simon Wilkinson
Robert Peach
Christian Behrenbruch – appointed 4 May 2018
Christopher Burns – appointed 4 May 2018
Andrew Cooke – appointed 4 May 2018
Michael Quinn – resigned 4 May 2018
Elizabeth Hopkins – resigned 4 May 2018
Christopher Collins – resigned 4 May 2018
Andrew Sneddon – resigned 4 May 2018

# **REVIEW OF FINANCIAL RESULTS AND OPERATIONS**

The loss for the period before foreign currency translations was \$717,802.

Total current assets at the beginning of the period amounted to \$2,463,670 of which cash and cash equivalents totalled \$2,229,190. At 30 September, total current assets had decreased to \$1,924,256. Of this amount, \$1,693,857 was represented by cash and cash equivalents and \$218,538 was an accrual for the R&D tax incentive payment associated with qualifying R&D expenditure during the period 1 April 2017 to 31 March 2018. This incentive payment was received in October 2018.

Total liabilities at the beginning of the period amounted to \$279,422. This reduced to \$195,252 at the end of the period. The Group has no interest bearing or other term liabilities.

In April 2018 shareholders approved:

- 1. The 10 into 1 consolidation of the Company's shares resulting in a reduction of shares on issue to 22,562,995; and
- 2. The acquisition of Amplia Therapeutics Pty Ltd ("Amplia") through the issue of 18,460,308 new shares in the Company.

On completion of these events, the Company had 41,023,303 shares on issue.

Through the acquisition of Amplia, the Company acquired that company's Focal Adhesion Kinase (FAK) inhibiting drug candidates AMP945 and AMP886. FAK is emerging as a promising target in cancer combination therapy and is also a potential standalone treatment target in fibrotic disease. Amplia holds an exclusive world-wide licence to develop and commercialise AMP945 and AMP886.

At the Annual General Meeting, shareholders approved changing the name of the Company from Innate Immunotherapeutics Limited to Amplia Therapeutics

Limited. This occurred on 5 September 2018 and at the same time the Company's ASX stock code changed to "ATX".

The Company's core business has been, and continues to be, the clinical development of drugs to treat diseases where there is a significant unmet patient need. Following the acquisition of Amplia, the Company's principal activity has been the positioning of lead candidate AMP945 for the commencement of Australian based human clinical trials in 2019. To this end, a contract has been awarded to a global research organisation for the conduct of the required Phase I enabling preclinical toxicology and related studies.

On satisfactory completion of these animal safety studies, the Company plans to conduct a Phase I trial to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamic effects of AMP945 in healthy volunteers. Positive results from this study will inform the design of subsequent Phase II trials which would evaluate the efficacy of AMP945 in combination with approved immunotherapies, such as checkpoint inhibitors, in fibrotic cancers including pancreatic or ovarian cancer. The same results may also be used to inform the design of Phase II studies in a fibrotic disease such as idiopathic pulmonary fibrosis.

In parallel with the AMP945 clinical programme, the Company expects to commence the required preclinical positioning of AMP886 for human trials. In contrast to AMP945, which is highly selective for FAK alone, AMP886 is a multi-action molecule that hits two other important cancer pathways. This potentially makes AMP886 a strong candidate for combining with approved cancer chemotherapies for the treatment of cancers and/or patients that do not respond to the latest immuno-oncology treatments.

During the period the Company relinquished certain redundant MIS416 patents. Since the end of the period the Company has taken the decision to relinquish the patent relating to the anti-cancer use of MIS416. The Company currently retains the patents in relation to the use of MIS416 to treat radiation injury.

The financial statements for the six months ended 30 September 2018 have been prepared on a "going concern" basis. The going concern basis contemplates continuity of normal business activities and realisation of assets and settlements of liabilities in the normal course of business. The going concern of the Company is dependent on it maintaining sufficient funds for its operations and commitments. If sufficient funding is not obtained then the Company may not be able to realise the assets and liabilities at the values currently included in these financial statements.

The Company has entered into a Master Services Agreement ("MSA") with a global contract research organisation ("CRO") for the conduct of the required Phase I enabling preclinical toxicology and related studies for AMP945. The total estimated cost for completion of this project is \$1,100,000. The Company may cancel this project at any time in which case the Company is liable to pay the CRO for the services or costs incurred together with an administration fee.

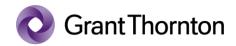
The Company anticipates that, subject to appropriate market conditions and investor appetite, it is likely that it will be able to raise additional capital in the short to medium term. In addition, the Company has the capacity to reduce/manage its operating costs if required. In these circumstances the Board considers that the Company is in a position to meet its liabilities as and when they fall due.

No other circumstances have arisen since the end of the financial period which would 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.

A copy of the Auditor's Independence Declaration as required under s307C of the Corporations Act 2001 follows and forms part of this Directors Report.

Signed in accordance with a resolution of the Directors.

Simon Wilkinson 28 November 2018



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# **Auditor's Independence Declaration**

# To the Directors of Amplia Therapeutics Limited

In accordance with the requirements of section 307C of the *Corporations Act 2001*, as lead auditor for the audit of Amplia Therapeutics Limited for the half year ended 30 September 2018, I declare that, to the best of my knowledge and belief, there have been:

- a no contraventions of the auditor independence requirements of the Corporations Act 2001 in relation to the review; and
- b no contraventions of any applicable code of professional conduct in relation to the review.

Grant Thornton Audit Pty Ltd Chartered Accountants

T S Jackman
Partner - Audit & Assurance

Melbourne, 28 November 2018

# CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

	Half Year Ended 30 September 2018 \$	Half Year Ended 30 September 2017 \$
OTHER INCOME Rent received Interest income R&D tax incentive	9,251 50,896	16,383 16,327 640,996
TOTAL OTHER INCOME	60,147	673,706
EXPENDITURE  Research & development expenses  Patents & associated expenses  Business development expenses  Administrative & general expenses  Depreciation & amortisation  Share based compensation (employee & non-employee)  TOTAL EXPENDITURE  LOSS BEFORE INCOME TAX EXPENSE  Income tax (expense)	(136,472) (76,906) - (466,682) (795) (97,094) (777,949)	(2,028,770) (80,227) (158,251) (815,111) (15,277) (71,359) (3,168,995)
LOSS AFTER INCOME TAX	(717,802)	(2,495,289)
OTHER COMPREHENSIVE INCOME Items that may be subsequently reclassified to profit or loss Foreign currency translation Income tax thereon		(61,916)
OTHER COMPREHENSIVE INCOME NET OF INCOME TAX	<u> </u>	(61,916)
TOTAL COMPREHENSIVE LOSS FOR THE HALF YEAR	(717,802)	(2,557,205)
EARNINGS PER SHARE Basic and diluted earnings per share - cents (weighted)	(1.9)	(11.1)

This consolidated statement of profit or loss and other comprehensive income should be read in conjunction with the accompanying notes to the financial statements.

# CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	30 September 2018 \$	31 March 2018 \$
Current Assets		
Cash & cash equivalents	1,693,857	2,229,190
Accounts receivable	-	244,363
R&D future tax incentive receivable	218,538	167,643
Other current assets	11,861	2,474
Total current assets	1,924,256	2,643,670
Non Current Assets		
Property, plant & equipment Intangible assets	2,393 7,937,932	<u>-</u>
Total non current assets	7,940,325	
Total Assets	9,864,581	2,643,670
Current Liabilities		
Accounts payable & accrued liabilities	195,252	279,422
Total current liabilities	195,252	279,422
Non Current Liabilities		
Total Liabilities	195,252	279,422
Net Assets	9,669,329	2,364,248
Equity		
Paid in capital	130,945,206	123,019,417
Foreign currency translation reserve	(1,818,617)	(1,818,617)
Share option reserve	372,990	1,468,304
Accumulated losses	(119,830,250)	(120,304,856)
Total Equity	9,669,329	2,364,248

This consolidated statement of financial position should be read in conjunction with the accompanying notes to the financial statements.

# CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

CONSOLIDATED ENTITY	Issued Capital \$	Accumulated Losses \$	Share Option Reserve \$	Foreign Currency Translation \$	Total Equity \$
At 1 April 2017	123.018.641	(116,779,039)	2,165,543	(1,776,189)	6,628,956
At 1 April 2017	123,010,041	(110,779,039)	2,100,043	(1,770,109)	0,020,930
(Loss) after income tax for the half year Other comprehensive income net of tax		(2,495,289)	-	- (61,916)	(2,495,289) (61,916)
Total comprehensive (loss) after tax		(2,495,289)	-	(61,916)	(2,557,205)
Transactions with owners in their capacity as owners Vesting of share options		<u> </u>	71,359	-	71,359
At 30 September 2017	123,018,641	(119,274,328)	2,236,902	(1,838,105)	4,143,110
At 1 April 2018	123,019,417	(120,304,856)	1,468,304	(1,818,617)	2,364,248
(Loss) after income tax for the half year Other comprehensive income net of tax		(717,802)	-	-	(717,802)
Total comprehensive (loss) after tax		(717,802)	-	-	(717,802)
Transactions with owners in their capacity as owners Issue of shares - acquistion of Amplia Therapeutics Cost of issuing shares Expired unexercised/lapsed options Vesting of share options	7,937,932 (12,143) -	- - 1,192,408 -	- (1,192,408) 97,094	:	7,937,932 (12,143) - 97,094
At 30 September 2018	130,945,206	(119,830,250)	372,990	(1,818,617)	9,669,329

This consolidated statement of changes in equity should be read in conjunction with the accompanying notes to the financial statements.

# CONSOLIDATED STATEMENT OF CASH FLOWS

	Half Year Ended 30 September 2018 \$	Half Year Ended 30 September 2017 \$
Cash flows related to operating activities Rent recieved Interest received Refund of MIS416 trial deposits R&D tax incentive received Payments to suppliers Payments to employees Net operating cash flows	8,830 226,260 - (401,700) (361,140) (527,750)	16,388 17,882 - 1,848,693 (2,540,438) (748,458) (1,405,933)
Cash flows related to investing activities Payment for purchases of property, plant and equipment Net investing cash flows	(3,188) ( <b>3,188</b> )	(4,419) (4,419)
Proceeds from issue of shares Capital raising costs Net financing cash flows	(12,143) (12,143)	(12,911) (12,911)
Net increase/(decrease) in cash held	(543,081)	(1,423,263)
Cash at beginning of period Foreign exchange effect on cash & cash equivalents balances	2,229,190 7,748	5,763,357 (4,887)
Cash at end of period	1,693,857	4,335,207
Reconciliation of cash Cash & cash equivalents in Statement of Financial Position	1,693,857	4,335,207

This consolidated statement of cash flows should be read in conjunction with the accompanying notes to the financial statements.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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

The half year financial report is a general purpose financial report prepared in accordance with the Corporations Act 2001 and AASB 134 Interim Financial Reporting. The half year financial report does not include notes of the type normally included in an Annual Report and should be read in conjunction with the most recent annual financial report.

The accounting policies applied in preparing the financial statements for the half year ended 30 September 2018 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 as at and for the year ended 31 March 2018.

EXPENSES	Half Year Ended 30 September 2018 <u>\$</u>	Half Year Ended 30 September 2017 \$
Loss before income tax has been determined after charging/crediting:		//
Write back of provision for restoration and make good costs	-	(18,396)
Depreciation - leashold improvements	-	977
- plant & equipment	705	11,711
- office furniture & equipment	795	2,589
Provison for impairment of assets	-	148,231
Rent & leasing expense	-	71,840
Employee benefits	269,513	873,588
Foreign exchange loss/(gain) Share based compensation - employees & directors	(7,744) 97,094	6 71,359
Share based compensation - employees & directors	97,094	71,339
DETAILS OF INVESTMENTS IN CONTROLLED ENTITIES	30 September 2018 Ownership Interest	31 March 2018 Ownership Interest
Innate Immunotherapeutics (NZ) Limited (incorporated in New Zealand)	100%	100%
- issued share capital of NZ\$100 is unpaid at 30 September 2018	100%	0%
ACN 612 556 948 Pty Ltd (formerly Amplia Therapeutics Pty Ltd) - issued capital \$10 is unpaid at 30 September 2018	100%	0%
EARNINGS PER SHARE (EPS)	30 September 2018	30 September 2017
Earnings used in the calculation of basic EPS	(717,802)	(2,495,289)
Earnings used in the calculation of diluted EPS	(717,802)	(2,495,289)
Weighted average number of shares outstanding during the half year	Number	Number
Basic EPS (post consolidation basis)	38,487,546	22,562,599
Diluted EPS (post consolidation basis)	38,487,546	22,562,599

On 26 April 2018 the Company consolidated it's shares on a 10 into 1 basis as approved by shareholders. Options were not included in the weighted average number of ordinary shares outstanding for the pupose 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.

	Half Year Ended 30 September 2018 Cents	Half Year Ended 30 September 2017 Cents
Basic EPS - cents (6 months) Diluted EPS - cents (6 months)	(1.9) (1.9)	(11.1) (11.1)
DIVIDENDS Interim Dividend Final Dividend	30 September 2018 Cents nil nil	31 March 2018 Cents nil nil

## CONSOLIDATED RETAINED PROFITS/(LOSSES)

Retained profits/(accumulated losses) at 1 April Net profit attributable to members

Transfer from share option reserve associated with expired unexercised/lapsed options Retained profits/accumulated losses at 30 September

30 September 2018 <u>\$</u>	30 September 2017 <u>\$</u>
(120,304,856)	(116,779,039)
(717,802)	(2,495,289)
1,192,408	<u>-</u>
(119,830,250)	(119,274,328)

30 September 2018

### **ORDINARY SHARES ON ISSUE**

Number of securities on issue at 1 April 2018

After consolidation 10 into 1 on 30 April 2018 Issued during the period for the acquisition of Amplia Therapeutics (post consolidation) Number of securities on issue at 30 September 2018

NUMBER	NUMBER
225,625,991	225,625,991
22,562,995	-
18,460,308	-
41.023.303	225,625,991

There were 3,595,000 (31 March 2018: 15,675,000 - pre consolidation) options outstanding at reporting date. During the period 960,000 options were issued to Non Execeitive Directors and 1,370,000 options were issued to the Chief Executive Officer. A further 750,000 options were issued to the Operations Manager. There were 515,000 options that are outstanding and were issued in prior periods that are yet to be exercised/lapsed 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 independent valuation of the two drug assets to test the deemed acquisition value for impairment prior to the signing of this report. This independent valuation of the licenses exceeded the deemed total acquisition value of \$7,937,932. Hence, the Company believes it appropriate to carry forward the value of the licenses at the deemed acquisition value i.e. \$7,937,932.

### 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 AMP866 by filling an IND or commencing a Phase I trial within three years. There are various milestone payments under the license agreement totalling 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

The Company has entered into a Master Services Agreement ("MSA") with a global contract research organisation ("CRO") for the conduct of the required Phase I enabling preclinical toxicology and related studies for AMP945. The total estimated cost for completion of this project is \$1,100,000. The Company may cancel this project at any time in which case the Company is liable to pay the CRO for the services or costs incurred together with an administration fee.

No other circumstances have arisen since the end of the financial period 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 six months of \$717,802 and the cash and cash equivalents balance of \$1,693,857. 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. On 4 May 2018 the Company completed the acquisition of ATP. The exploitation of the two licences will require further funding. These conditions indicate a material uncertainty exists in relation to "going concern". If sufficient funding is not obtained then then the Company may not be able to realise the assets and liabilities at the values currently included in these financial statements.

The Directors continue to monitor the ongoing funding requirements and are of the opinion that the financial statements have been appropriately prepared on a going concern basis.

## SEGMENT REPORTING

A segment is a component of the Consolidated Entity that engages in business activities to provide products or services within a particular environment. The Consolidated Entity operates in one operating segment, being the biopharmaceutical sector, and the majority of its activities are concentrated in researching and developing it's leading drug candidates (i.e. AMP945 & AMP866).

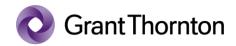
# **DIRECTORS' DECLARATION**

In the opinion of the Directors:

- 1. The financial statements and notes, of the Consolidated Entity, are in accordance with the Corporations Act 2001, including:
- a) giving a true and fair view of the consolidated entity's financial position as at 30 September 2018 and of its performance for the half year ended on that date:
- b) with Accounting Standard AASB134 Interim Financial Reporting and the Corporations Regulations 2001; and
- 2. There are reasonable grounds to believe that the Consolidated Entity will be able to pay its debts as and when they become due and payable.

This declaration is made in accordance with a resolution of the Board of Directors pursuant to Section 303(5) of the Corporations Act 2001.

Simon Wilkinson Date: 28 November 2018



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# **Independent Auditor's Review Report**

To the Members of Amplia Therapeutics Limited

Report on the review of the half year financial report

## Conclusion

We have reviewed the accompanying half year financial report of Amplia Therapeutics Limited (the Company) which comprises the statement of financial position as at 30 September 2018, and the statement of profit or loss and other comprehensive income, statement of changes in equity and statement of cash flows for the half year ended on that date, a description of accounting policies, other selected explanatory notes, and the directors' declaration.

Based on our review, which is not an audit, nothing has come to our attention that causes us to believe that the half year financial report of Amplia Therapeutics Limited does not give a true and fair view of the financial position of the Company as at 30 September 2018, and of its financial performance and its cash flows for the half year ended on that date, in accordance with the *Corporations Act 2001*, including complying with Accounting Standard AASB 134 *Interim Financial Reporting*.

# Material uncertainty related to going concern

We draw attention to the financial report, which indicates that the Company incurred a net loss of \$717,802 during the half year ended 30 September 2018 with a closing cash balance of \$1,693,857. As stated in Note 1, these events or conditions, along with other matters as set forth in the financial report, indicate that a material uncertainty exists that may cast significant doubt on the Company's ability to continue as a going concern. Our conclusion is not modified in respect of this matter.

# Directors' responsibility for the half year financial report

The Directors of the Company are responsible for the preparation of the half year financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* and for such internal control as the Directors determine is necessary to enable the preparation of the half year financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

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## Auditor's responsibility

Our responsibility is to express a conclusion on the half year financial report based on our review. We conducted our review in accordance with Auditing Standard on Review Engagements ASRE 2410 Review of a Financial Report Performed by the Independent Auditor of the Entity, in order to state whether, on the basis of the procedures described, we have become aware of any matter that makes us believe that the half year financial report is not in accordance with the Corporations Act 2001 including giving a true and fair view of the Company's financial position as at 30 September 2018 and its performance for the half year ended on that date, and complying with Accounting Standard AASB 134 Interim Financial Reporting and the Corporations Regulations 2001. As the auditor of Amplia Therapeutics Limited ASRE 2410 requires that we comply with the ethical requirements relevant to the audit of the annual financial report.

A review of a half year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

### Independence

In conducting our review, we have complied with the independence requirements of the Corporations Act 2001.

Grant Thornton Audit Pty Ltd Chartered Accountants

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T S Jackman

Partner - Audit & Assurance

Melbourne, 28 November 2018