

# **Invion Limited**

ABN 76 094 730 417

# **Appendix 4D**

# Half Year Report for the six months ended 31 December 2015 (current period) and the previous corresponding period, the six months to 31 December 2014

# Results for announcement to the market

				\$
Revenue from continuing operations	Down	34%	to	139,335
Total Income	Down	53%	to	881,945
(Loss) from ordinary activities after tax attributable to members:	Down	45%	to	(2,992,623)
Net (Loss) for the period attributable to members:	Down	45%	to	(2,992,623)
	Curre peri	_	corr	Previous esponding period
Net tangible asset backing per ordinary share	(0.35)	cents	(0.	86) cents

No dividend is proposed to be paid. The Company has not gained or lost control over any entity in the period.

This information should be read in conjunction with the most recent Annual Financial Report (30 June 2015). Full financial details of the Company are available in the attached audit reviewed Financial Report for the half-year ended 31 December 2015.

An explanation of the results of the current period is set out in the Directors' Report.

This report is based on the interim consolidated financial statements for the half year ended 31 December 2015 of Invion Limited and its controlled entities, which have been reviewed by Ernst & Young (EY). The Independent Auditor's Report provided by EY is included in the consolidated financial statements. EY have issued a review report that has been issued with a material uncertainty regarding continuation as a going concern.

# Invion Limited Financial report For half-year ended 31 December 2015





# Company Directory

#### Directors

Dr Greg Collier, Interim Executive Chair & MD Mitchell Glass, M.D., Executive VP R&D and CMO Dr James Campbell, Non-executive Director Mr Warren Brown, Non-executive Director Mr Gregory Brown (Alternate Director)

#### Company Secretary

Ms Melanie Farris

#### Registered Office

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#### Australian Business Number

76 094 730 417

# Securities Exchange Listing

Australian Securities Exchange ASX Code: IVX

#### **Auditors**

Ernst & Young Brisbane Australia

# Share Registry

Link Market Services Limited Locked Bag A14 Sydney South NSW 1235 Australia

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# **Directors' Report**

Your directors submit their report for the half-year ended 31 December 2015.

#### Directors

The names of the Company's directors in office during the half-year and until the date of this report are set out below. Directors were in office for this entire period unless otherwise stated.

Mr Brett Heading, Chairman (retired 31 January 2016)
Dr Greg Collier, MD and CEO (appointed Interim Executive Chair, 1 February 2016)
Mitchell Glass, M.D., Executive VP R&D and Chief Medical Officer
Dr James Campbell, Non-executive Director
Mr Warren Brown, Non-executive Director
Mr Gregory Brown (Alternate Director)

#### **Review and Results of operations**

The Invion Group consists of Invion Limited and its wholly owned subsidiary Invion, Inc. The Group has operations in Brisbane, Australia and Delaware, USA. The main activity of Invion during the period was the clinical and regulatory development of its assets: INV102 (nadolol), INV103 (ala-Cpn10), and INV104 (zafirlukast). The loss attributable to the owners of the parent for the period ended 31 December 2015 was \$2,992,623 (2014: \$5,475,387 loss). No dividend was proposed or paid during the period.

# **Asset Development**

In the period under review, the Company completed major milestones in the development programs for its three drug assets.

In July 2015, the Company secured a commitment from Hovione Scientia Limited, an international pharmaceutical company expert in inhalation development and manufacturing, to progress development of inhaled INV104 (zafirlukast) as a potential new treatment for asthma. Invion and Hovione will collaborate to develop the proprietary novel technology – a dry powder formulation of the compound INV104 (zafirlukast) delivered by Hovione's inhaler.

Under the terms of the agreement, Hovione will provide expertise on chemistry, particle engineering, formulation, device and GMP manufacturing to develop and manufacture Zafirlukast Dry Powder Inhaler (DPI), which will be delivered using its proprietary device.

The collaboration extends from fully integrated scale-up and manufacture of phase appropriate cGMP Zafirlukast Dry Powder Inhaler for non-clinical and clinical studies to further secure for Hovione the exclusive rights to manufacture commercial supplies of Zafirlukast DPI. Invion will oversee all non-clinical and clinical development and is moreover responsible for regulatory submissions. As consideration for Hovione's licensing and supply the finished drug product, Invion will pay an annual royalty to Hovione on total net sales of Zafirlukast DPI.

# Directors' Report (continued)

In August, The Company completed its phase II clinical trial entitled "Double-blinded, randomised, placebo-controlled study to investigate the safety, tolerability, pharmacokinetics, and biochemical activity of intravenous Cpn10 administration in subjects with SLE". The Company's decision to complete the trial was based on the review of safety and biochemical markers of effect in 28 subjects across four cohorts, which show that the study had met its objectives and supports the continued development of INV103 (ala-Cpn10) in longer and larger trials in patients with autoimmune diseases.

Three sets of data were reviewed from subjects who received twice-weekly doses of 10, 30 or 100mg of ala-Cpn10, or placebo. The adverse events and clinical chemistry profiles showed that increasing the dose 10-fold over levels used previously in the development of the drug asset could be achieved safely. Serum biomarkers of vascular inflammation were too variable in all cohorts to draw absolute conclusions about biological effect.

In October, the Company announced data from its phase II clinical trial of INV102 (nadolol) in patients trying to quit smoking. Data demonstrated that smokers administered INV102 were more likely to stop smoking completely, or dramatically reduce the number of cigarettes smoked. In addition, INV102 reduced two key markers of the beta arrestin pathway - ERK1 and MUC5AC – which are necessary for the activation of mucous metaplasia in the airway. These results support Invion's hypothesis that INV102 has a novel mechanism of action directly targeting epithelial cells lining the airway. INV102 was safe and well tolerated, and Invion's proprietary titration scheme enabled patients to reach efficacious doses.

The study was conducted on 155 patients at multiple US trial sites, including Washington University. All patients had tried to quit smoking multiple times but were defeated by chronic "smoker's cough" resulting from the build-up of mucus in the lungs following the last cigarette. The trial was designed to evaluate the efficacy of INV102 in improving rates of smoking cessation over a 10-12 week treatment period.

INV102 is hypothesised to work via the inhibition of a cellular pathway (the beta arrestin pathway) that causes cells lining the lungs to change from normal to mucus-producing cells. This mechanism is completely different from drugs presently approved and indicated either for smoking cessation or the treatment of chronic respiratory disease. In November, additional data analysed demonstrated that treatment with INV102 shows that MUC5AC, which is one of the major biomarkers reflecting mucous metaplasia in airways, was statistically significantly decreased from baseline to the end of maintenance at visit 8 in an analysis of all subjects who completed titration.

The Company subsequently submitted an abstract to the 2016 American Thoracic Society (ATS) annual meeting, and a request to the US Food and Drug Administration (FDA) for an End of Phase II (EOP2) meeting, to facilitate the commencement of the phase III program for oral INV102. The EOP2 meeting is scheduled to be held by the end of March 2016.

In November, the Company advised completion of enrolment in its phase II clinical trial of INV102 (nadolol) in patients with mild asthma (NIMA). The NIMA trial, which has been funded by the US National Institutes of Health (NIH), completed enrolment with 66 subjects.

# Directors' Report (continued)

The last dose will be administered by the end of April 2016, followed by reporting of safety and efficacy, which will be assessed by impact on non-specific airway hyper-responsiveness (NSAHR) after six months' therapy. NIMA had previously provided important interim safety data in mild asthma patients with baseline NSAHR who are not on inhaled corticosteroids (ICS).

## **Business Development**

Following the successful completion of major milestones across its four drug development programs during 2015, in October 2015, the Board appointed Ferghana Partners Group (New York, London, Boston) to progress various potential opportunities under review. Ferghana's expertise is in acquisitions, divestitures, corporate partnering and financial transactions in the global healthcare sector.

#### Loan funding

#### Loans from Directors

In March 2015, the Company entered into loan agreements with Directors subsequent to which unsecured (non-equity related) debt funding was provided to the Company for working capital and for the repayment of outstanding liabilities. In August 2015, a variation of the original loan agreement was effected. The key terms of the loan are:

- Each director/ related party loaned the Company \$200,000, for a total loan to the Company of \$1,200,000.
- Termination Date means the earlier of 14 July 2016; the date which is 5 Business Days after the Company completes a Successful Capital Raising (\$5 million (before offer costs)); or, the date on which the Lender demands payment of the Money Owing following the occurrence of an Event of Default.
- Interest rate is 10% per annum. Interest accrues daily and is payable at termination.

#### R&D tax incentive advance loan

In October, the Company received an R&D tax incentive cash rebate of approximately \$2.4 million against local and overseas R&D activities carried out in the financial year ending 30 June 2015. Earlier in 2015, Invion had entered into an agreement with Metamor Capital Partners to access capital ahead of the receipt of its R&D tax incentive rebate. This funding facility provided Invion with a valuable capital management tool as it progressed R&D activities in Q2 and Q3 2015. The non-dilutive (non-equity related) secured facility had a limit of \$1.56M and was drawn to \$1.04M at the time of repayment. The facility was repaid in full from the proceeds of the 2015 R&D tax incentive rebate and remains available for redraw to fund future R&D expenditure of the Company.

## Changes to issued capital

- 1) September Placement: On 1 September 2015 the Company announced an agreement to issue securities to an institutional investor in the United States in a private placement for gross proceeds of \$1,001,000. 71,500,000 fully-paid ordinary shares were issued at an issue price of \$0.014 per share. In addition 51,500,000 share options were issued with an exercise price of \$0.014 and an expiry date of 3 September 2016. On 17 December 2015, following shareholder resolution at the AGM held 18 November, 5,005,000 share options with an exercise price of \$0.0175 and an expiry date of 18 November 2020 were issued to the placement agent as part of their fee for this placement.
- 2) December Share Purchase Plan and Placement: On 10 December 2015, the Company announced the completion and issue and allotment of fully paid ordinary shares under a Share Purchase Plan (SPP) and private placement to sophisticated and professional investors. The issue price per share for both the SPP and Placement was \$0.0073. \$1,606,293 was raised under the SPP, and 220,039,961 shares were issued to existing shareholders. \$522,200 was raised under the private placement and 71,534,244 shares were issued to sophisticated and professional investors, who were existing shareholders. The issue price under both the SPP and Placement was \$0.0073 per share.
- 3) Convertible Security on issue to Australian Special Opportunity Fund: On 17 December 2015, the Company issued 12,500,000 fully paid ordinary shares at a deemed issue price of \$0.006 following the receipt of a conversion notice (value \$75,000) in relation to the \$250,000 convertible security on issue to the Australian Special Opportunity Fund (ASOF). At 31 December 2015, the remaining face value of the convertible security was \$175,000.
- 4) Lapse of unlisted share options: On 17 December 2015, a total of 1,826,177 share options issued under the Employee Share Option Plan (ESOP) lapsed unexercised.
- 5) Changes to issued capital subsequent to the reporting period: On 7 January 2016, the Company issued 20,000,000 fully paid ordinary shares at a deemed issue price of \$0.005 following the receipt of a conversion notice (value \$100,000) in relation to the convertible security on issue to ASOF. On 27 January 2016, the Company issued 18,750,000 fully paid ordinary shares at a deemed issue price of \$0.004 following the receipt of a conversion notice (value \$75,000). Having fully converted, at the date of this report, the face value of the convertible security on issue to ASOF is zero (\$0.00).

#### Total number of shares and options on issue

At 31 December 2015, the number of total ordinary shares of Invion Limited on issue was 1,198,321,273, and the total number of share options on issue was 118,193,458.

At the date of this report, the number of total ordinary shares of Invion Limited on issue is 1,237,071,273, and the total number of share options on issue is 118,193,458.

# Directors' Report (continued)

## Litigation

On 4 November 2015, the Company advised that the High Court of Australia process instituted by the appellants in the litigation matter had been dismissed without the need for a hearing.

On 2 July 2014, the Company advised that the defendants (appellants) had lodged a notice of appeal against the decision of former Chief Justice de Jersey, delivered in the Supreme Court of Queensland on 4 June 2014, for Invion Limited (formerly CBio Limited) in its case against former officers of the Company. The appeal was heard by the Queensland Court of Appeal on 23 February 2015, and was dismissed with costs on 12 June 2015.

The proceedings related to the resignations in October 2011 of the Company's then executive chairman, chief executive officer and chief financial officer; and payments made to these officers. Invion sought orders requiring the repayment of termination payments that were made to the defendants. Invion alleged that the termination payments were in breach of the defendant's fiduciary duties to the Company, and contravened the statutory duties imposed on them by sections 180, 181 and 182 of the Corporations Act 2001 (Cth).

The Supreme Court of Queensland determined that the defendants be required to repay the sum of \$1,071,482. The Court also dismissed the counterclaim by the defendants in which they sought damages from Invion for allegedly breaching an agreement pursuant to which bonus payments should have been paid after their resignations. A subsequent judgment was delivered on 20 June 2014 in relation to interest and costs, pursuant to which the Company is to receive \$1,306,283, in aggregate, for the original judgment and accumulated interest (to that date), plus costs of the action on an indemnity basis. The Company intends to use all avenues available to it to recover the judgment debt, however no financial asset is recorded in these Financial Statements.

#### Events after the reporting period

On 1 February 2016, the Company announced that, following his appointment as a Partner of the international law firm, Jones Day, Mr Brett Heading had resigned from the Board of Directors, and that Dr Greg Collier had been appointed as Interim Executive Chair of the Board.

#### Auditor's Independence Declaration

We have obtained the independence declaration on page 8 from our auditors, Ernst & Young.

Signed in accordance with a resolution of the directors.

Dr Greg Collier

Interim Executive Chair and Managing Director

Brisbane, 26 February 2016



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# **Auditor's Independence Declaration to the Directors of Invion Limited**

As lead auditor for the review of Invion Limited for the half-year ended 31 December 2015, I declare 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.

This declaration is in respect of Invion Limited and the entities it controlled during the financial period.

Ernst & Young

Ric Roach Partner

26 February 2016

# Interim consolidated statement comprehensive income

	Notes	31 December 2015	31 December 2014 \$
Grant received	-	139,100	185,355
Interest revenue		235	24,825
Total revenue	-	139,335	210,180
Other income	4	742,610	1,663,082
Employee and employee benefits expense		(748,150)	(785,107)
Depreciation and amortisation expenses		(671,846)	(739,644)
Finance costs		(183,859)	(483,688)
Administration & corporate expenses		(986,129)	(1,034,484)
Rent and occupancy expense		(33,078)	(32,617)
Share-based payment expense	13	(193,703)	(335,742)
Research & development costs	5	(1,111,397)	(3,802,772)
Patent costs		(126,397)	(225,072)
Business development		(75,364)	(149,099)
Loss before income tax expense	-	(3,247,978)	(5,714,963)
Income tax benefit	6	255,355	239,576
Loss for the period attributable to owners of the parent	- -	(2,992,623)	(5,475,387)
Other comprehensive loss Items may be reclassified subsequently to profit or loss:			
Unrealised exchange differences on translation of foreign subsidiary	-	289,838	1,076,290
Total comprehensive loss attributable to owners of the parent	-	(2,702,785)	(4,399,097)
Earnings per share for profit / (loss) from continuing operations attributable to the ordinary equity holders of the parent			
Basic and dilutive earnings (cents)		(0.33)	(0.79)

The interim consolidated statement of comprehensive income should be read in conjunction with the notes to the Financial Statements.

# Interim consolidated statement of financial position

	•	31 December 2015	30 June 2015
Current assets	Notes	\$	\$
Cash and cash equivalents	7	2,106,847	2,284,513
Trade and other receivables	8	281,747	1,918,212
Other current assets	Ü	57,892	133,819
Total current assets	-	2,446,486	4,336,544
Non-Current Assets	-	2,440,400	
Trade and other receivables	8	55,640	52,083
Property, plant and equipment	O	19,862	26,723
Intangible assets	9	11,592,203	11,683,939
Total Non-Current Assets	,	11,667,705	11,762,745
Total Assets	-	14,114,191	16,099,289
Current Liabilities			
Trade and other payables	10	653,065	2,054,258
Financial liabilities	11	1,523,365	2,578,744
Short-term provisions		92,951	81,260
Total current liabilities	-	2,269,381	4,714,262
Non-Current Liabilities			
Deferred tax liabilities		4,480,067	4,506,761
Long-term provisions		-	18,095
Total Non-Current Liabilities	-	4,480,067	4,524,856
Total Liabilities	•	6,749,448	9,239,118
Net Assets	-	7,364,743	6,860,171
		7,364,743	0,000,171
Equity		100 000 505	110 004 050
Issued Capital	12	122,898,505	119,884,852
Reserves	12	23,946,855	23,463,314
Accumulated losses	-	(139,480,617)	(136,487,995)
Total Equity		7,364,743	6,860,171

The interim consolidated statement of financial position should be read in conjunction with the notes to the Financial Statements.

# Interim consolidated statement of changes in equity

	Note	Issued capital \$	Options reserve \$	Foreign currency translation reserve \$	Convertible note reserve \$	Accumulated losses \$	Total equity \$
As at 1 July 2015		119,884,852	19,107,884	1,868,716	2,486,714	(136,487,994)	6,860,172
Loss for the period						(2,992,623)	(2,992,623)
Other comprehensive income / (loss)	_			289,838			289,838
Total comprehensive income / (loss)				289,838		(2,992,623)	(2,702,785)
Issue of share capital	12	3,211,993					3,211,993
Transaction costs	12	(198,340)					(198,340)
Share option expense	12		193,703				193,703
As at 31 December 2015		122,898,505	19,301,587	2,158,554	2,486,714	(139,480,617)	7,364,743

	Note	Issued capital \$	Options reserve \$	Foreign currency translation reserve \$	Convertible note reserve \$	Accumulated losses \$	Total equity \$
As at 1 July 2014		112,941,342	18,266,301	(88,518)	2,486,714	(123,446,759)	10,159,080
Loss for the period		-	-	-	-	(5,475,387)	(5,475,387)
Other comprehensive income / (loss)		-	-	1,076,290	-	-	1,076,290
Total comprehensive income / (loss)	·	-	-	1,076,290	-	(5,475,387)	(4,399,097)
Issue of share capital		530,000	-	-	-	-	530,000
Collateral shares	12	-	-	-	-	-	-
Transaction costs		(4,490)	-	-	-	-	(4,490)
Share option expense		-	463,142	-	-	-	463,142
As at 31 December 2014	_	113,466,852	18,729,443	987,772	2,486,714	(128,922,146)	6,748,635

The interim consolidated statement of changes in equity should be read in conjunction with the notes to the Financial Statements.

# Interim consolidated statement of cash flows

	Notes	31 December 2015 \$	31 December 2014 \$
Cash flows from (used in) operating activities	140103	<del>`</del>	<u> </u>
Payments to suppliers and employees		(4,655,714)	(4,343,205)
Cash received in the course of operations		139,514	8,411
R&D Tax Rebate		2,408,166	788,519
Interest paid on borrowings		(42,394)	-
Interest received		235	31,238
Net cash used in operating activities		(2,150,193)	(3,515,037)
Cash flows from (used in) investing activities			
Purchase of plant and equipment		-	(3,613)
Payment for intellectual property		-	(197,914)
Purchase of bank guarantee		-	(6,305)
Net cash provided by (used in) investing activities			(207,832)
Cash flows from (used in) financing activities			
Proceeds from issue of shares		3,085,493	-
Proceeds from borrowings under SPCSA		-	700,000
Proceeds from issue of convertible note		-	1,000,000
Cost of capital raising		(198,340)	(4,490)
Repayment of borrowings		(974,213)	-
Net cash provided by in financing activities		1,912,940	1,695,510
Net increase (decrease) in cash held		(237,253)	(2,027,359)
Net foreign exchange differences		59,587	(15,276)
Cash and cash equivalents at beginning of period		2,284,513	3,952,538
Cash and cash equivalents at end of period	7	2,106,847	1,909,903

The interim consolidated statement of cash flows should be read in conjunction with the notes to the Financial Statements.

#### Notes to the consolidated financial statements

# 1. Corporate information

Invion Limited is a Company limited by shares incorporated in Australia whose shares have been publicly traded on the Australian Securities Exchange since its listing on 15 February 2011 (ASX:IVX). Invion Limited is a clinical-stage life sciences (drug development) company. The Company is focused on the development of treatments for major market opportunities in inflammatory diseases including asthma, chronic bronchitis and lupus. Invion has three therapeutic candidates: INV102 (nadolol) – a repurposed beta adrenergic biased ligand; INV103 (ala-Cpn10) – a modified naturally occurring human protein; and INV104 (zafirlukast) - a leukotriene receptor antagonist (LTRA) or anti leukotriene.

The Invion Group ("the Group") consists of Invion Limited ("Invion" or "the Company") and its wholly owned subsidiary Invion, Inc. The Group has operations in Brisbane (Australia) and Delaware (USA).

#### 2. Basis of preparation and changes to the Company's accounting policies

The interim consolidated financial statements for the six months ended 31 December 2015 have been prepared in accordance with AASB 134 Interim Financial Reporting. The interim consolidated financial statements do not include all the information and disclosures required in the annual financial statements, and should be read in conjunction with the Company's annual financial statements as at 30 June 2015 and to announcements issued to the ASX.

#### 2a. Going concern

This financial report for the six months ended 31 December 2015 has been prepared on a going concern basis. The Company incurred an operating loss after income tax of \$2,992,623 (2014: \$5,475,387 loss) for the half-year. At 31 December 2015 the Company had net assets of \$7,364,743 (30 June 2015: \$6,860,171). In common with other companies in the biotechnology sector, the Company's operations are subject to risks and uncertainty due primarily to the nature of the drug development and commercialisation. Following the successful completion of major milestones across its four drug development programs during 2015, in October 2015, the Board appointed Ferghana Partners Group (New York, London, Boston) to progress various potential opportunities under review. Ferghana's expertise is in acquisitions, divestitures, corporate partnering and financial transactions in the global healthcare sector. That said, to allow the Company to execute its near term and longer term plans, the Board intends to continue to raise capital sufficient enough to meet operational needs until such time that a transaction is completed. These conditions of uncertainty and the need to raise further capital give rise to significant uncertainty as to whether the Company will be able to continue as a going concern and be able to pay its debts as and when they fall due. In the event that such arrangements are not entered into or are not successful, there is uncertainty whether the Company will continue as a going concern and the Company may be required to realise assets

# Going concern (continued)

and extinguish liabilities other than in the normal course of business and at amounts different from those stated in the financial report. This report does not include any adjustments relating to the recoverability or classification of recorded asset amounts or to the amounts or classification of liabilities that might be necessary should the Company not be able to continue as a going concern.

#### 2b. New standards, interpretations and amendments thereof, adopted by the Company

This half-year consolidated financial report has been prepared by adopting accounting policies that are consistent with those adopted in the annual financial statements for the year ended 30 June 2015. New standards and amendments to standards mandatory for the first time for the financial year beginning 1 July 2015 have been adopted. The adoption of these standards will not have a material financial effect on the current period or any prior period and is not likely to affect future periods. The Group has not elected to early adopt any other new standards or amendments that are issued but not yet effective. The future impacts of the above are being assessed by the Group.

#### 2c. Convertible Notes

The component of the convertible note that exhibits characteristics of a liability is recognised as a liability in the statement of financial position, net of transaction costs. On issuance of the convertible notes, the fair value of the embedded derivative and convertible note is determined and the residual (being the conversion option) is recorded as a separate component of equity. The net balance of the convertible note is recorded as an interest bearing liability. The liability is increased over the term of the liability using the effective interest rate implicit in the note. Any increase recorded is recognised as interest expense. Certain convertible notes contain a feature which allows options over ordinary shares to be issued. This option feature is recorded as an embedded derivative liability on issuance of the convertible note at the fair value of the embedded derivative. At each Balance Date while the convertible note is outstanding the embedded derivative liability is re-measured to fair value through the profit and loss.

#### 2d. Fair value hierarchy

The following table provides the fair value measurement hierarchy of the Group's liabilities which are measured at fair value after initial recognition.

		Fair value measurement using				
	Date of valuation	Total	Quoted prices in active markets (Level one)	Significant observable inputs (Level two)	Significant unobservable inputs (Level three)	
Financial liabilities measure	ed at fair value					
Convertible Note	31 December 2015	(302,500)	-		- (302,500)	
		(302,500)	-		- (302,500)	

For assets and liabilities that are recognised in the financial statements on a recurring basis, the Group determines whether transfers have occurred between Levels in the hierarchy by reassessing categorisation (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each reporting period.

Valuation Technique: In determining Fair Value, consideration is given to the price that would be paid to transfer the liability in an orderly transaction between market participants at the measurement date. Determination of the fair value of the convertible note has thus taken into the contractual obligations of the Company, expectations regarding the timing of conversion, the conversion price/actual share price and the probability of any other events occurring that would result in an increase to the face value of the convertible note as set out in the contract with the counterparty. Disclosure of quantitative unobservable inputs has not been made as they are not expected to materially impact the amount recorded.

## Reconciliation of recurring Level 3 fair value movements

Convertible Note	31 December 2015 \$	31 December 2014 \$
Balance at 1 July	385,000	-
Additions in period		1,090,666
Less conversion in period	(82,500)	-
Balance at 31 December	302,500	1,090,666

#### 3. Segment Information

The Invion Group operates as a clinical-stage life sciences (drug development) group with operations in Australia and the United States. The Group does not currently consider that the risks and returns of the Group are affected by differences in either the products or services it provides, nor the geographical areas in which the Group operates. As such the Group operates as one segment. Group performance is evaluated based on operating profit or loss and is measured consistently with profit or loss in the consolidated financial statements. Group financing (including finance costs and finance income) and income taxes are managed on a Group basis.

#### 4. Other income

	31 December 2015 \$	31 December 2014 \$
Other income		
Unrealised foreign exchange gain (loss)	14,444	385,327
R&D tax rebate (i)	728,166	1,272,075
Other income	-	5,680
	742,610	1,663,082

<sup>(</sup>i) The anticipated R&D tax rebate is lower than prior periods due to the completion of major clinical development activities.

# 5. Research and Development costs

	31 December 2015 \$	31 December 2014 \$
R&D costs		
Clinical trial costs	661,446	2,586,637
Drug production and supply	166,604	388,469
Feasibility for inhaled respiratory drug franchise	283,347	827,631
Other R&D costs	-	35
	1,111,397	3,802,772

#### 6. Income tax benefit

The company has recorded a tax benefit of \$255,355 for the period ended 31 December 2015 (2014: \$239,576). The tax benefit arises from the amortisation of the deferred tax liability recorded on acquisition of Inverseon, Inc. in August 2012, and will not be included in the carried forward losses of the company.

# 7. Cash and cash equivalents

For the purpose of the interim consolidated statement of cash flows, cash and cash equivalents are comprised of the following:

	31 December 2015 \$	30 June 2015 \$
Cash at bank and in hand	2,106,847	2,281,909
Petty cash advance	-	2,604
Total cash and cash equivalents	2,106,847	2,284,513

8. Trade and other receivables	31 December 2015 \$	30 June 2015 \$
Trade and other receivables		
Current (i)		
Trade debtors	7,671	8,085
R&D tax incentive rebate	200,000	1,880,000
Goods and services tax refundable	4,231	4,339
Bank guarantee deposit	24,936	24,936
Other – unsecured	44,909	852
Total trade and other receivables	281,747	1,918,212
Non-current		
Bank guarantee deposit	55,640	52,083
	55,640	52,083

<sup>(</sup>ii) The carrying value of trade debtors and other receivables approximate the fair value at balance date.

9. Intangible assets	31 December 2015 \$	30 June 2015 \$
Intangible Assets		
Intellectual property (at cost)	19,950,311	19,204,000
Less: impairment	(4,125,000)	(4,125,000)
Less: accumulated amortisation	(4,233,108)	(3,395,061)
Net carrying value	11,592,203	11,683,939
Reconciliation of intellectual property (at cost)		
Balance at 1 July	11,683,939	9,723,286
Foreign currency translation gain (loss)	571,650	3,090,921
Amortisation charge	(663,386)	(1,130,268)
Closing carrying value at 31 December	11,592,203	11,683,939

10. Trade and other payables	31 December 2015 \$	30 June 2015 \$
Trade and other payables		
Current (i)		
Trade creditors	440,017	1,705,068
Accrued expenses	107,884	245,888
Director related accruals (ii)	92,548	32,548
Director related payables (ii)	12,616	70,754
	653,065	2,054,258

- (i) The carrying value of trade creditors and other payables approximate the fair value at balance date. Trade creditors are non-interest bearing and are normally settled on 30-day terms.
- (ii) Director related accruals and payables reflect accrued fees and expense reimbursements due to directors as at 31 December 2015, accrued interest on Director loans (see Note 15, Related Party Transactions) and the balance of fees outstanding to McCullough Robertson Lawyers (see Note 16, Other Transactions).

December J 2015 2 \$	015 \$
Financial liabilities	
Current	
Promissory notes payable (from acquisition) (i) 20,865	531
Convertible Security (ii) 302,500 385,	000
Loans from directors and related parties (ii) 1,200,000 1,200,000	000
Other secured loan (R&D tax offset funding) - 974,	213
1,523,365 2,578,	744

- (i) Promissory notes payable relates to Notes assumed in the acquisition of Inverseon Inc. Notes are recorded at approximately fair value at balance date.
- (ii) The Convertible Security is on issue to the Australian Special Opportunities Funds (ASOF), as compensation for the March 2015 conclusion of the Share Purchase and Convertible Security Agreement (SPCSA) dated November 2014. The settlement deed also provides for an increase to the face value of the note to \$350,000 upon occurrence of events, including certain capital raisings, as set out in the agreement.
- (iii) In March 2015, the Company entered into loan agreements with Directors subsequent to which unsecured (non-equity related) debt funding was provided to the Company for working capital and for the repayment of outstanding liabilities. In August 2015, a variation of the original loan agreement was effected. The key terms of the loan are:
  - a. Each director/ related party loaned the Company \$200,000, for a total loan to the Company of \$1,200,000.

- b. Termination Date means the earlier of 14 July 2016; the date which is 5 Business Days after the Company completes a Successful Capital Raising (\$5 million (before offer costs)); or, the date on which the Lender demands payment of the Money Owing following the occurrence of an Event of Default.
- c. Interest rate is 10% per annum. Interest accrues daily and is payable at termination.

## 12. Issued Capital

	31 December 2015 Number	31 December 2015 \$
Issued Capital		<u> </u>
Ordinary shares issued and fully paid	1,198,321,273	122,898,505
Movements in ordinary shares on issue		
Ordinary shares on issue at 1 July	822,747,068	119,884,852
Shares issued in Placement (i)(ii)	143,034,244	1,523,200
Shares issued in Share Purchase Plan (ii)	220,039,961	1,606,293
Shares issued pursuant to Convertible Security Agreement (iii)	12,500,000	82,500
Transaction costs		(198,340)
Ordinary shares on issue at 31 December	1,198,321,273	122,898,505
Movements in reserves		
Balance at 1 July	63,514,635	23,463,314
Share option expense	56,505,000	193,703
Options lapsed	1,826,177	-
Other comprehensive income (translation of subsidiary)	-	289,838
Balance at 31 December	118,193,458	23,946,855

(i) On 1 September 2015 the Company announced an agreement to issue securities to an institutional investor in the United States in a private placement for gross proceeds of \$1,001,000. 71,500,000 fully-paid ordinary shares were issued at an issue price of \$0.014 per share. In addition 51,500,000 share options were issued with an exercise price of \$0.014 and an expiry date of 3 September 2016. On 17 December 2015, following shareholder resolution at the AGM held 18 November, 5,005,000 share options with an exercise price of \$0.0175 and an expiry date of 18 November 2020 were issued to the placement agent as part of their fee for this placement.

(ii) On 10 December 2015, the Company announced the completion and issue and allotment of fully paid ordinary shares under a Share Purchase Plan (SPP) and private placement to sophisticated and professional investors. The issue price per share for both the SPP and Placement was \$0.0073. \$1,606,293 was raised under the SPP, and 220,039,961 shares were issued to existing shareholders. \$522,200 was raised under the private placement and 71,534,244 shares were issued to sophisticated and professional investors, who were existing shareholders. The issue price under both the SPP and Placement was \$0.0073 per share.

(iii) On 17 December 2015, the Company issued 12,500,000 fully paid ordinary shares at a deemed issue price of \$0.006 following the receipt of a conversion notice (value \$75,000) in relation to the \$250,000 convertible security on issue to the Australian Special Opportunity Fund (ASOF). At 31 December 2015, the remaining face value of the convertible security was \$175,000.

# Share Purchase Agreement with Numoda Capital Innovations

In December 2014, the Group engaged the services of Numoda Corporation for the provision of clinical trial management services for the INV102 and INV103 phase II clinical trials. At the same time, the Group entered into a Share Purchase Agreement (SPA) with Numoda Capital Innovations (NCI). At the date of this report, NCI has invested approximately \$40,000 via open market purchase, and \$65,000 via private placement for a total investment of approximately \$105,000. The Company does not anticipate any further investment by NCI under the SPA.

# 13. Share-based payment

On 1 September 2015 the Company announced an agreement to issue securities to an institutional investor in the United States in a private placement for gross proceeds of \$1,001,000. 71,500,000 fully-paid ordinary shares were issued at an issue price of \$0.014 per share, which was a 25% discount to the 15 day VWAP of \$0.018, to 27 August, the last trading day prior to the agreement to issue. In addition, 51,500,000 share options were issued with an exercise price of \$0.014 and an expiry date of 3 September 2016. On 17 December 2015, following shareholder resolution at the AGM held 18 November, 5,005,000 share options with an exercise price of \$0.0175 and an expiry date of 18 November 2020 were issued to the placement agent as part of their fee for this placement.

The fair value of options granted during the six months ended 31 December 2015 was estimated on the date of grant using the Black-Scholes option pricing model applying the following assumptions:

Weighted average fair values at the measurement date	\$0.0032 / \$0.0023
Dividend yield (%)	0.00
Expected volatility (%)	80
Average risk-free interest rate over life (%)	2.555
Expected life (months)	6 / 30
Weighted average share price on 1 September 2015	\$0.014 / \$0.008

For the six months ended 31 December 2015, the Group has recognised \$193,703 of share-based payment transactions expense in the interim consolidated statement of comprehensive income (31 December 2014: \$335,742).

# 14. Commitments and contingencies

In May 2012 the Company entered into a four-year lease for new premises. In March 2014 the Company assigned its lease to a third party and subsequently entered into a sub-lease. The sublease expires in April 2016. Sub-lease payments are approximately \$24,000 per annum. In October 2013, Invion, Inc. (subsidiary company) entered into a lease for premises. The lease expires on 31 May 2016. Lease payments are approximately \$25,500 per annum. The Company has leasing commitments in connection with telephone, broadband and photocopying/printing totalling approximately \$10,000 over the coming 12 months.

At the Balance Date, the Company had contractual commitments relating to R&D development activities totalling approximately \$0.3 million (30 June 2015: \$0.73 million).

	Within one year	After one but within five years
	\$	, cuis \$
Operating leases	<u> </u>	
Premises	21,619	-
Telephone, broadband, photocopying, printing	1,734	-
	23,353	-
R&D Commitments		_
Drug manufacturing & clinical trial costs	272,944	-
	272,944	-
	-	

On 30 March 2001, the Company entered into a Royalty Agreement with CSL Limited (CSL). This agreement was entered into contemporaneously with the Deed of Assignment, an agreement which assigned CSL's rights to its Research Agreement with Uniquest Pty Ltd to CSL for payment of \$125,000. The Royalty Agreements stipulates that Invion is to pay royalties to CSL after commercialisation of products developed under the Research Agreement.

#### Contingencies related to litigation

As detailed in the Directors' report covering these Financial Statements, judgment was delivered on 20 June 2014 in relation to interest and costs, pursuant to which the Company is to receive \$1,306,283, in aggregate, for the original judgment and accumulated interest, plus costs of the action on an indemnity basis. The Company intends to use all avenues available to it to recover the judgment debt, however no financial asset is recorded in these Financial Statements.

## 15. Related party transactions

#### Loans from Directors

In March 2015, the Company entered into loan agreements with Directors subsequent to which unsecured (non-equity related) debt funding was provided to the Company for working capital and for the repayment of outstanding liabilities. In August 2015, a variation of the original loan agreement was effected. The key terms of the loan are:

- Each director/ related party loaned the Company \$200,000, for a total loan to the Company of \$1,200,000.
- Termination Date means the earlier of 14 July 2016; the date which is 5 Business Days after the Company completes a Successful Capital Raising (\$5 million (before offer costs)); or, the date on which the Lender demands payment of the Money Owing following the occurrence of an Event of Default.
- Interest rate is 10% per annum. Interest accrues daily and is payable at termination.

#### Transactions with the subsidiary

Invion Limited is the parent entity in the Group. Details of the Group's subsidiary are set out below. During the period the parent transacted with the subsidiary. All transactions were on an arm's length basis and have been eliminated on consolidation.

		% equity interest		
Name	Country of incorporation	31 Dec 2015	31 Dec 2014	
Invion Inc.	USA	100%	100%	

#### 16. Other transactions

McCullough Robertson Lawyers provided legal advisory services to the Company since 2004. Mr Brett Heading, who was appointed to the Board on 26 February 2012, was a Partner at McCullough Robertson. In the reporting period fees of \$66,445 were paid or were payable to McCullough Robertson Lawyers in connection with the provision of legal advisory services to the Company and disbursements including Court fees and fees payable to Counsel engaged on the Company's behalf.

#### 17. Events after the reporting period

Changes to issued capital subsequent to the reporting period: On 7 January 2016, the Company issued 20,000,000 fully paid ordinary shares at a deemed issue price of \$0.005 following the receipt of a conversion notice (value \$100,000) in relation to the convertible security on issue to ASOF. On 27 January 2016, the Company issued 18,750,000 fully paid ordinary shares at a deemed issue price of \$0.004 following the receipt of a conversion notice (value \$75,000). Having fully converted, at the date of this report, the face value of the convertible security on issue to ASOF is zero (\$0.00).

<u>Change to Board composition</u>: On 1 February 2016, the Company announced that, following his appointment as a Partner of the international law firm, Jones Day, Mr Brett Heading had resigned from the Board of Directors, and that Dr Greg Collier had been appointed as Interim Executive Chair of the Board.

# In accordance with a resolution of the directors of Invion Limited, I state that:

In the opinion of the directors:

- (a) the financial statements and notes of the company are in accordance with the Corporations Act 2001, including:
  - i. giving a true and fair view of the financial position as at 31 December 2015 and the performance for the half-year ended on that date; and
  - ii. complying with Accounting Standard AASB 134 Interim Financial Reporting and the Corporations Regulations 2001; and
- (b) subject to the inherent uncertainty regarding the continuation as a going concern as expressed in Note 2a, that is, the ability of the company to pay its debts as and when they fall due, the Board is of the opinion that there are reasonable grounds to believe the company will be able to pay its debts as and when they become due and payable.

On behalf of the Board

Dr Greg Collier

Interim Executive Chair and Managing Director 26 February 2016



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# Independent review report to the members of Invion Limited

# Report on the half-year financial report

We have reviewed the accompanying half-year financial report of Invion Limited, which comprises the interim consolidated statement of financial position as at 31 December 2015, the interim consolidated statement of comprehensive income, the interim consolidated statement of changes in equity and the interim consolidated statement of cash flows for the half-year then ended, notes comprising a summary of significant accounting policies and other explanatory information, and the directors' declaration of the consolidated entity comprising the company and the entities it controlled at the half-year end or from time to time during the half-year.

# Directors' responsibility for the half-year financial report

The directors of the consolidated entity 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 controls as the directors determine are necessary to enable the preparation of the financial report that is free from material misstatement, whether due to fraud or error.

# **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 financial report is not in accordance with the *Corporations Act 2001* including: giving a true and fair view of the consolidated entity's financial position as at 31 December 2015 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 Invion Limited and the entities it controlled during the period, 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. We have given to the directors of the consolidated entity a written Auditor's Independence Declaration, a copy of which is included in the directors' report.



## Conclusion

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the half-year financial report of Invion Limited is not in accordance with the Corporations Act 2001, including:

- a) giving a true and fair view of the consolidated entity's financial position as at 31 December 2015 and of its performance for the half-year ended on that date; and
- b) complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

# Material Uncertainty Regarding Continuation as a Going Concern

Without qualifying our review conclusion above, we draw attention to Note 2a in the financial report which indicates that the consolidated entity incurred a loss from continuing operations after income tax of \$2,992,623 in the half-year ended 31 December 2015 (2014: \$5,475,387 loss) and is dependent on the raising of additional funds to continue activities. As a result of this matter there is significant uncertainty whether the consolidated entity will continue as a going concern, and therefore whether it will realise its assets and extinguish its liabilities in the normal course of business and at the amounts stated in the financial report. The financial report does not include any adjustments relating to the recoverability and classification of recorded asset amounts or to the amounts and classification of liabilities that might be necessary should the consolidated entity not continue as a going concern.

Ernst & Young

Ric Roach Partner Brisbane

26 February 2016