

# **Invion Limited**

ABN 76 094 730 417

# **Appendix 4D**

# Half Year Report for the six months ended 31 December 2014 (current period) and the previous corresponding period, the six months to 31 December 2013

# Results for announcement to the market

				\$
Revenue from continuing operations	Down	16%	to	210,180
Total Income	Up	220%	to	1,873,262
(Loss) from ordinary activities after tax attributable to members:	Down	88%	to	(5,475,387)
Net (Loss) for the period attributable to members:	Down	88%	to	(5,475,387)
	Curr peri	_	corr	Previous esponding period
Net tangible asset backing per ordinary share	(0.86)	cents	0.	05 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 2014). Full financial details of the Company are available in the attached audit reviewed Financial Report for the half-year ended 31 December 2014.

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 2014 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 2014





# Company Directory

#### **Directors**

Dr Ralph Craven, Chairman
Dr Greg Collier, Managing Director & CEO
Mitchell Glass, M.D., Executive VP R&D and CMO
Dr James Campbell, Non-executive Director
Mr Brett Heading, 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

## Lawyers

McCullough Robertson Lawyers 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 2014.

#### 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.

Dr Ralph Craven, Chairman
Dr Greg Collier, Managing Director and Chief Executive Officer
Mitchell Glass, M.D., Executive VP R&D and Chief Medical Officer
Dr James Campbell, Non-executive Director
Mr Brett Heading, 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 2014 was \$5,475,387 (2013: \$2,904,760). No dividend was proposed or paid during the period.

In the period under review, the Company provided the market with updates on two of its three current phase II clinical programs, an update on feasibility studies in the Company's inhaled respiratory drug franchise, and announced the execution of a convertible security and share purchase agreement which provides a funding commitment of up to \$17,400,000 over 24 months.

In September 2014, the Company announced interim data from its phase II clinical trial of INV103 (ala-Cpn10) in lupus patients. Based upon the safety profile generated from the analysed data, the trial advanced to dosing patients with mild lupus at 100mg iv twice-weekly, which represents a 10-fold increase over the highest dose used in previous clinical trials of ala-Cpn10. This trial is due to complete prior to 30 June 2015.

Also in September 2014, the Company provided an update on blinded interim data from the US National Institute of Allergy and Infectious Diseases (NIAID) and National Institutes of Health (NIH) funded phase II clinical trial of oral INV102 (nadolol) in patients with mild asthma (NIMA trial). Evaluation of blinded data revealed important information relating to the trial's titration program designed to minimise bronchoconstriction and other negative effects of beta-blocker use in patients with airway hyper-responsiveness.

Also in September 2014, the Company announced the successful completion of Stage 1 feasibility studies in its collaboration with 3M Drug Delivery Systems for the development of

inhaled INV102 (nadolol). Invion's agreement with 3M is assessing the feasibility of inhaled versions of INV102 delivered using 3M's proprietary pressurized metered dose inhalation (pMDI) technology. The Company has moved steadily through feasibility for this project and has submitted an Investigational New Drug (IND) application with the US Food and Drug Administration (FDA).

In November 2014, the Company announced it had entered into an agreement with The Australian Special Opportunity Fund, LP, an institutional investor managed by The Lind Partners, LLC, for a funding commitment of up to AU\$17.4 million. Detailed information on this agreement is recorded under "Changes to issued capital", in this report.

Also in November 2014, the Company advised that it had satisfied the requisite criteria under AusIndustry's R&D Tax Incentive Scheme and that it had received a cash rebate of approximately \$0.79 million, with respect to certain local and overseas R&D activities carried out in the financial year ended 30 June 2014. The Company further advised that it had lodged an application with AusIndustry which sought to expand the programs eligible for 'advance finding' under the R&D Tax Incentive Scheme. This application was successful, and subsequent to the end of the reporting period, a further approximately \$0.390 million R&D tax rebate was received, bringing the total rebate received for activities in the 2014 financial year to approximately \$1.2 million.

#### Changes to issued capital

In November 2014, the Company announced it had entered into a Share Purchase and Convertible Security Agreement (SPCSA) with The Australian Special Opportunity Fund, LP, an institutional investor managed by The Lind Partners, LLC, for a funding commitment of up to AU\$17.4 million. The agreement provides Invion access to funds through a flexible convertible instrument, and the ability to secure additional funding in stages to meet interim financing needs, through the issue of shares at prices that are linked to market prices at the time of issue.

#### The agreement constitutes:

- i. a zero interest rate convertible security in the amount of between AU\$500,000 to AU\$1,000,000 (with a maximum face value of AU\$1,060,000), to be called on at the Company's discretion within the first six months following execution of the agreement;
- ii. equity purchases of up to AU\$700,000 per month through the issue of ordinary fully paid shares at an issue price of 90% of the volume weighted average price of the company's shares during a predetermined pricing period. For one monthly tranche only, the share price may be equal to 130% of the average of the daily volume weighted average price of the company's shares for the 20 trading days prior to the execution. Further, the Company will retain the ability to refuse to issue shares in a particular month if the share price falls below the floor price protection level of AU\$0.04;
- iii. the amounts funded under the agreement will bear no interest and will be unsecured against the Company's assets except for 3,000,000 shares, which will be issued as a security;

# **Directors' Report (continued)**

- iv. a commitment fee of AU\$100,000 each, in shares, at execution and on the date that the Company elects to receive the funding;
- v. 7,000,000 unlisted options, which will be issued as follows:
  - a. 3,500,000 options, issued on execution and exercisable at 120% of the average of the daily VWAPs for the 20 trading days immediately prior to the date of the execution
  - b. 3,500,000 options, issued on date of first funding and exercisable at 120% of the average of the daily VWAPs for the 20 trading days immediately prior to the date of the funding

In the period under review the Company has issued the following shares under the SPCSA:

Date	Description	Shares issued	Options issued	Deemed price per share	Option terms
10-Nov-14	First commitment shares and options	1,663,894	3,500,000	\$0.0601	Unlisted share options, exercise price \$0.0721, expiry date 11-Nov-17.
21-Nov-14	Second commitment shares and options, and collateral shares	4,663,894	3,500,000	\$0.0601	Unlisted share options, exercise price \$0.0721, expiry date 22-Nov-17.
21-Nov-14	One convertible security with a face value of AU\$1,060,000.	-	-	-	
18-Dec-14	First tranche funds	6,521,739	-	\$0.046	
	Total	12,849,527	7,000,000		

#### Subsequent to the Balance Date.

Date	Description	Shares issued	Options issued	Deemed price per share	Option terms
21-Jan-15	Second tranche funds	10,000,000	-	\$0.040	
11-Feb-15	Conversion of convertible security	1,219,512	-	\$0.041	
17-Feb-15	Conversion of convertible security	5,952,381	-	\$0.042	
	Total	30,021,420	7,000,000		

## Directors' Report (continued)

On 21 November 2014, the Annual General Meeting of Shareholders approved the issue of Share Options to Executive Vice President R&D and Chief Medical Officer, Dr Mitchell Glass. On 24 November 2014, a total of 8,812,500 options were issued with an exercise price of \$0.12 (12c) and an expiry date of 9 November 2018. Options will vest in accordance with predetermined clinical milestones.

At 31 December 2014, the number of total ordinary shares of Invion Limited on issue was 554,074,967, and the total number of share options on issue was 59,900,000.

At the date of this report, the number of total ordinary shares of Invion Limited on issue is 571,246,860, and the total number of share options on issue is 59,900,000.

## Litigation

In February 2012 legal proceedings were commenced against four former officers of the Company. The proceedings relate to the resignations on or about 12 October 2011 of the Company's then executive chairman, chief executive officer, chief financial officer and company secretary; and gross payments made to these officers. Invion alleged that the termination payments were in breach of the defendants' fiduciary duties to the Company, and contravened the statutory duties imposed on them by sections 180, 181 and 182 Corporations Act 2001 (Cth).

On 21 May 2013 the Company announced that it had reached a confidential settlement with one of the Defendants to the litigation, pursuant to which the Defendant has agreed, with no admission as to liability, to repay the purported Termination Payment to the Company together with a sum representing interest and costs.

On 4 June 2014, the Company advised that the Supreme Court of Queensland delivered judgment for the Company in its case against the remaining defendants. Invion sought orders requiring the repayment of termination payments that were made to the defendants. The Court 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.

On 23 June 2014, the Company advised that subsequent judgement had been delivered in relation to interest and costs, which were awarded to the Company on an indemnity basis. On 2 July 2014, the Company advised that the defendants had lodged a notice of appeal. The Company appeared as a party before the Court of Appeal on 23 February 2015, in relation to an appeal from the decision of the former Chief Justice de Jersey delivered on 4 June 2014. The Court of Appeal decision was reserved.

The Directors consider that the risk of a liability arising out of the litigation is remote. As such there is no contingent liability recorded in these Financial Statements.

# **Directors' Report (continued)**

# Events after the reporting period

On 19 January 2015, the Company announced positive interim data from its phase II double-blind placebo-controlled randomised clinical trial of oral INV102 (nadolol) in patients with chronic cough or established COPD who are trying to quit smoking but have failed multiple times previously. The blind-broken analysis shows clinically relevant changes in four biomarkers of inflammation – IL-8, ERK2, MUC 1 and neutrophils - in INV102 (nadolol) treated patients compared to placebo.

On 2 February 2015, the Company announced full enrolment in this phase II trial of oral INV102 (nadolol) in smoking cessation. Patient treatment and follow-up is expected to be completed early in the third calendar quarter of 2015, at which time intensive analysis of data will commence.

#### 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 Ralph Craven Chairman

Brisbane, 26 February 2015



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

In relation to our review of the financial report of Invion Limited for the half-year ended 31 December 2014, to the best of my knowledge and belief, there have been no contraventions of the auditor independence requirements of the *Corporations Act 2001* or any applicable code of professional conduct.

Ernst & Young

Ric Roach Partner Brisbane

26 February 2015

# Interim consolidated statement of comprehensive income

	Notes	31 December 2014 \$	31 December 2013 S
Grant received	_	185,355	207,337
Interest revenue		24,825	42,397
Total revenue	-	210,180	249,734
Other income	4	1,663,082	334,930
Employee and employee benefits expense		(785,107)	(697,958)
Depreciation and amortisation expenses		(739,644)	(960,374)
Finance costs		(483,688)	-
Administration & corporate expenses		(1,034,484)	(824,598)
Rent and occupancy expense		(32,617)	(19,986)
Share-based payment expense	13	(335,742)	(182,768)
Research & development costs	5	(3,802,772)	(883,865)
Patent costs		(225,072)	(176,564)
Business development		(149,099)	(124,156)
Loss before income tax expense	_	(5,714,963)	(3,285,605)
Income tax benefit	6	239,576	380,845
Loss for the period attributable to owners of the parent	<del>-</del>	(5,475,387)	(2,904,760)
Other comprehensive loss Items may be reclassified subsequently to profit or loss:			
Unrealised exchange differences on translation of foreign subsidiary	-	1,076,290	(38,978)
Total comprehensive loss attributable to owners of the parent	-	(4,399,097)	(2,943,738)
Earnings per share for profit / (loss) from continuing operations attributable to the ordinary equity holders of the parent			
Basic and dilutive earnings (cents)		(0.79)	(0.63)

# Interim consolidated statement of financial position

		31 December 2014	30 June 2014
Current assets	Notes _	\$	\$\$_
Cash and cash equivalents	7	1,909,903	3,952,538
Trade and other receivables	8	1,328,358	662,249
Other current assets	o o	84,938	141,774
Total current assets	-	3,323,199	4,756,561
Non-Current Assets	-	0,020,177	1,, 00,001
Trade and other receivables	8	73,705	67,400
Property, plant and equipment	O	31,300	28,971
Intangible assets	9	11,535,284	9,877,686
Total Non-Current Assets	-	11,640,289	9,974,057
Total Assets	-	14,963,488	14,730,618
Total Assets	-	14,700,400	14,730,010
Current Liabilities			
Trade and other payables	10	2,172,144	668,745
Financial liabilities	11	1,508,954	15,923
Short-term provisions		79,499	107,520
Total current liabilities	-	3,760,597	792,188
Non-Current Liabilities	-		
Deferred tax liabilities		4,437,299	3,764,259
Long-term provisions		16,957	15,091
Total Non-Current Liabilities	<del>-</del>	4,454,256	3,779,350
Total Liabilities	-	8,214,853	4,571,538
Net Assets	-	6,748,635	10,159,080
	-		
Equity			
Issued Capital	12	113,466,852	112,941,342
Reserves	12	22,203,929	20,664,497
Accumulated losses	_	(128,922,146)	(123,446,759)
Total Equity	_	6,748,635	10,159,080

# 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 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

_	Issued capital \$	Options reserve \$	Foreign currency translation reserve \$	Convertible note reserve \$	Accumulated losses \$	Total equity \$
As at 1 July 2013	107,407,805	17,831,956	(128,068)	2,486,714	(116,562,825)	11,035,582
Loss for the period	-	-	-	-	(2,904,760)	(2,904,760)
Other comprehensive income / (loss)	-	-	(38,978)	-	-	(38,978)
Total comprehensive income / (loss)	-	-	(38,978)	-	(2,904,760)	(2,943,738)
Shares issued to directors and related parties	114,280	-	-	-	-	114,280
Transaction costs	(8,772)	-	-	-	-	(8,772)
Share option expense	-	182,768	-	-	-	182,768
As at 31 December 2013	107,513,313	18,014,724	(167,046)	2,486,714	(119,467,585)	8,380,120

# Interim consolidated statement of cash flows

	Notes	31 December 2014 \$	31 December 2013 \$
Cash flows from (used in) operating activities	110103	<del>Y</del> _	<del></del>
Payments to suppliers and employees		(4,343,205)	(2,897,613)
Cash received in the course of operations		8,411	12,381
R&D Tax Rebate		788,519	1,447,985
Interest received		31,238	42,396
Net cash used in operating activities		(3,515,037)	(1,394,851)
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)	(44,960)
Proceeds from bank guarantee		-	104,603
Net cash provided by (used in) investing activities		(207,832)	59,643
Cash flows from (used in) financing activities			
Proceeds from issue of shares		-	114,280
Proceeds from borrowings under SPCSA		700,000	-
Proceeds from issue of convertible note		1,000,000	-
Cost of capital raising		(4,490)	(8,772)
Net cash provided by in financing activities		1,695,510	105,508
Net increase (decrease) in cash held		(2,027,359)	(1,229,700)
Net foreign exchange differences		(15,276)	43,813
Cash and cash equivalents at beginning of period		3,952,538	3,050,948
Cash and cash equivalents at end of period	7	1,909,903	1,865,061

#### 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 2014 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 2014 and to announcements issued to the ASX.

#### 2a. Going concern

This financial report for the six months ended 31 December 2014 has been prepared on a going concern basis. The Company incurred an operating loss after income tax of \$5,475,387 (2013: \$2,904,760 loss) for the half-year. At 31 December 2014 the Company had net assets of \$6,748,635 (30 June 2014: \$10,159,080). 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. To allow the Company to execute its near term and longer term plans, the Board intends to raise capital sufficient enough to meet operational and program development needs, and on 10 November 2014, the Company announced it had entered into an agreement with The Australian Special Opportunity Fund, LP, an institutional investor managed by The Lind Partners, LLC, for a funding commitment of up to AU\$17.4 million (detailed information on this agreement is recorded in the Directors' Report). The Directors also expect to announce another capital raising initiative prior to the end of the March 2015 quarter. 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 2014. New standards and amendments to standards mandatory for the first time for the financial year beginning 1 July 2014 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. Certain new accounting standards and interpretations have been published that are not mandatory for 31 December 2014 reporting periods and have not yet been applied in the financial report. The Directors believe that these new or amended Standards and Interpretations will not have any material financial effect on the financial statements presented.

#### 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.

#### 3. Licence Agreement - intangible asset

On 28 October 2013, the Company announced the execution of an exclusive, worldwide licence agreement with US-based Accolade Pharma LLC, for intellectual property to develop inhaled formulations of zafirlukast for the treatment of asthma and other respiratory conditions. A licence fee of \$500,000 was payable by the Company to Accolade Pharma LLC in equal installments over a 12 month period commencing January 2014. The amount owing at 31 December 2014 is recorded in payables in the interim consolidated statement of financial position. The in-licenced intellectual property is reflected as an intangible asset.

#### 4. Other income

	31 December 2014 \$	31 December 2013 \$
Other income		
Unrealised foreign exchange gain (loss)	385,327	5,665
R&D tax rebate	1,272,075	327,806
Other income	5,680	1,459
	1,663,082	334,930

## 5. Research and Development costs

	31 December 2014 \$	31 December 2013 \$
R&D costs		
Clinical trial costs	2,586,637	591,214
Drug production and supply	388,469	284,790
Feasibility for inhaled respiratory drug franchise	827,631	-
Other R&D costs	35	7,861
	3,802,772	883,865

## 6. Income tax benefit

The company has recorded a tax benefit of \$239,576 for the period ended 31 December 2014 (2013: \$380,845). 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 2014 S	30 June 2014 S
Cash at bank and in hand	1,906,245	951,477
Petty cash advance	3,658	1,061
Term deposit	-	3,000,000
Total cash and cash equivalents	1,909,903	3,952,538
8. Trade and other receivables	31 December 2014 S	30 June 2014 \$
Trade and other receivables	<del>_</del>	<u> </u>
Current (i)		
Trade debtors	414	-
R&D tax incentive rebate	1,111,362	626,486
Goods and services tax refundable	15,573	9,231
Interest receivable	-	7,733
Other – unsecured	201,009	18,799
Total trade and other receivables	1,328,358	662,249
Non-current	<b>-0</b> -0 -	. <del></del>
Bank guarantee deposit	73,705	67,400
	73,705	67,400

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

9. Intangible assets	31 December 2014 \$	30 June 2014 \$
Intangible Assets		<u> </u>
Intellectual property (at cost)	18,276,149	15,494,500
Less: impairment	(4,125,000)	(4,125,000)
Less: accumulated amortisation	(2,615,865)	(1,646,214)
Net carrying value	11,535,284	9,723,286
Funding right (at cost)	2,526,897	2,012,000
Less: Accumulated amortisation	(2,526,897)	(1,857,600)
Net carrying value	<del></del>	154,400
	11,535,284	9,877,686
Reconciliation of intellectual property (at cost) Balance at 1 July	9,723,286	10,145,330
In-licence INV104 (zafirlukast)	-	500,000
Foreign currency translation gain (loss)	2,388,701	-
Amortisation charge	(576,703)	(922,044)
Closing carrying value at 31 December	11,535,284	9,723,286
Reconciliation of funding right (at cost)		
Balance at 1 July	154,400	1,178,144
Foreign currency translation gain (loss)	-	-
Amortisation charge	(154,400)	(1,023,744)
Closing carrying value at 31 December	-	154,400
10. Trade and other payables	31 December 2014 \$	30 June 2014 \$
Trade and other payables	<del>_</del>	<del>V</del> _
Current (i)		
Trade creditors	1,742,626	527,425
Accrued expenses	425,799	110,880
Director related payables	3,719	30,440
	2,172,144	668,745

(i) The carrying value of trade creditors and other payables approximate the fair value at balance date.

11. Financial Liabilities	31 December 2014 \$	30 June 2014 \$
Financial liabilities		
Current		
Promissory notes payable (from acquisition) (i)	18,288	15,923
Interest accrued on promissory notes	-	-
Convertible Note (ii)	1,090,666	-
Financial liability – SPCSA (ii)	400,000	_
	1,508,954	15,923

- (i) Promissory notes payable are recorded at approximately fair value at balance date.
- (ii) The Share Purchase and Convertible Security Agreement (SPCSA) agreement constitutes:
  - i. a zero interest rate convertible security in the amount of between AU\$500,000 to AU\$1,000,000 (with a maximum face value of AU\$1,060,000), to be called on at the Company's discretion within the first six months following execution of the agreement;
  - ii. equity purchases of up to AU\$700,000 per month through the issue of ordinary fully paid shares at an issue price of 90% of the volume weighted average price of the company's shares during a predetermined pricing period. For one monthly tranche only, the share price may be equal to 130% of the average of the daily volume weighted average price of the company's shares for the 20 trading days prior to the execution. Further, the Company will retain the ability to refuse to issue shares in a particular month if the share price falls below the floor price protection level of AU\$0.04;
  - iii. the amounts funded under the agreement will bear no interest and will be unsecured against the Company's assets except for 3,000,000 shares, which will be issued as a security;
  - iv. a commitment fee of AU\$100,000 each, in shares, at execution and on the date that the Company elects to receive the funding;
  - v. 7,000,000 unlisted options, which will be issued as follows:
    - a. 3,500,000 options, issued on execution and exercisable at 120% of the average of the daily VWAPs for the 20 trading days immediately prior to the date of the execution;
    - a,500,000 options, issued on date of first funding and exercisable at 120% of the average of the daily VWAPs for the 20 trading days immediately prior to the date of the funding

The fair value of the options granted was estimated on the respective dates of execution funding using the Black-Scholes option pricing model. The fair value of \$127,400 has been included within Finance costs in the interim consolidated statement of comprehensive income.

## 12. Issued Capital

	31 December 2014 Number	31 December 2014 \$
Issued Capital	Nonbei	<del>,</del>
Ordinary shares issued and fully paid	554,074,967	113,466,852
Movements in ordinary shares on issue		
Ordinary shares on issue at 1 July	541,225,440	112,941,342
Shares issued pursuant to Share Purchase and Convertible Security Agreement (SPCSA) (i)	9,849,527	530,000
Collateral shares issued pursuant to SPCSA (ii).	3,000,000	-
Transaction costs	-	(4,490)
Ordinary shares on issue at 31 December	554,074,967	113,466,852
Movements in reserves		
Balance at 1 July	44,837,500	20,664,497
Share option expense	-	463,142
Options issued under ESOP (iii).	8,812,500	-
Options issued under SPCSA (iv).	7,000,000	-
Options exercised	-	-
Options lapsed	(750,000)	-
Other comprehensive income (translation of subsidiary)	-	1,076,290
Balance at 31 December	59,900,000	22,203,929

<sup>(</sup>i) On 10 November 2014, the Company entered into a Share Purchase and Convertible Security Agreement (SPCSA) with The Australian Special Opportunity Fund, LP, an institutional investor managed by The Lind Partners, LLC, for a funding commitment of up to AU\$17.4 million. The total number of shares issued under this Agreement until 31 December 2014 was 12,849,527.

<sup>(</sup>ii) Amounts funded under the SPCSA bear no interest and are unsecured against the Company's assets except for 3,000,000 shares, which have been issued as a security.

<sup>(</sup>iii) On 21 November 2014, the Annual General Meeting of Shareholders approved the issue of Share Options to Executive Vice President R&D and Chief Medical Officer, Dr Mitchell Glass. On 24 November

2014, a total of 8,812,500 options were issued with an exercise price of \$0.12 (12c) and an expiry date of 9 November 2018. Options will vest in accordance with predetermined clinical milestones.

(iv) On 10 November 2014, the Company entered into a Share Purchase and Convertible Security Agreement (SPCSA) with The Australian Special Opportunity Fund, LP, an institutional investor managed by The Lind Partners, LLC, for a funding commitment of up to AU\$17.4 million. The total number of options issued under this Agreement until 31 December 2014 was 7,000,000. The exercise price for each option is \$0.0601. 3,500,000 options expire on 11 November 2017. 3,500,000 options expire on 22 November 2017.

#### Share Purchase Agreement with Numoda Capital Innovations

In December 2013, 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). Under the share purchase agreement, NCI committed to acquire Invion shares via private placement and open market transactions whilst INV102 and INV103 clinical trials are ongoing. NCI's total commitment under the agreement is for an investment of up to \$2 million to occur across current and future clinical trials. The Board of Invion estimates the value of shares to be purchased and placed relative to the two clinical trials currently underway will be in the order of \$250,000. At the date of this report, NCI had invested approximately \$40,000 via open market purchase, and \$65,000 via private placement for a total investment of approximately \$105,000. It is anticipated a further approximately \$145,000 will be invested under this SPA prior to 30 June 2015.

#### 13. Share-based payment

On 21 November 2014, the Annual General Meeting of Shareholders approved the issue of Share Options to Executive Vice President R&D and Chief Medical Officer, Dr Mitchell Glass. On 24 November 2014, a total of 8,812,500 options were issued with an exercise price of \$0.12 (12c) and an expiry date of 9 November 2018. Options will vest in accordance with predetermined clinical milestones.

The fair value of options granted during the six months ended 31 December 2014 was estimated on the date of grant using the Black-Scholes option pricing model applying the following assumptions:

Dividend yield (%)	0.00
Expected volatility (%)	90
Average risk-free interest rate over life (%)	3.250
Expected life (months)	43
Weighted average share price (\$)	\$0.048

For the six months ended 31 December 2014, the Group has recognised \$335,742 of share-based payment transactions expense in the interim consolidated statement of comprehensive income (31 December 2013: \$182,768).

## 14. Commitments and contingencies

In May 2012 the Company entered into a four-year lease for new premises. In March 2013 the Company assigned its lease to a third party and subsequently entered into a sub-lease. The sublease expires in April 2016. Current sub-lease payments are approximately \$24,000 per annum. Further to the Assignment of the primary lease, the Company no longer has a "make good" obligation at the expiration of the lease term. In October 2013, Invion, Inc. (subsidiary company) entered into a 12 month lease for premises. In October 2014, this lease was extended for a further 12 months. 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 \$3.48 million (30 June 2014: \$2 million).

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.

The Directors consider that the risk of a liability arising out of the litigation (as noted in the Directors' Report) is remote. As such there is no contingent liability recorded in these Financial Statements.

	Within one year	After one but within five
	\$	years \$
Operating leases		
Premises	49,501	8,400
Telephone, broadband, photocopying, printing	10,206	-
	59,707	8,400
R&D Commitments		
Drug manufacturing & clinical trial costs	3,393,106	82,500
	3,393,106	82,500
	-	

#### 15. Related party transactions

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.

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Name	Country of incorporation	31 Dec 2014	31 Dec 2013
Invion Inc.	USA	100%	100%

#### 16. Other transactions

McCullough Robertson Lawyers has provided legal advisory services to the Company since 2004. Mr Brett Heading, who was appointed to the Board on 26 February 2012, is a Partner at McCullough Robertson. In the reporting period fees of \$128,639 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.

On 28 October 2013, Invion announced it had entered a licence agreement with Accolade Pharma LLC for an exclusive, worldwide licence to develop and commercialise all inhaled formulations and applications of zafirlukast. A licence fee of \$500,000 was payable by Invion to Accolade Pharma LLC over a 12 month period commencing January 2014. Dr Mitchell Glass, Invion's Executive Vice President of R&D and Chief Medical Officer, led the development and submission of Accolate for Zeneca (now AstraZeneca) to its FDA approval letter in 1998, and is a substantial shareholder of Accolade Pharma LLC.

#### 17. Segment Note

The Invion Group operates as a clinical-stage pharmaceutical drug development company with operations in Australia and the United States. The Company does not currently consider that the risks and returns of the Company 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 does not report segment information.

#### 18. Subsequent events

On 19 January 2015, the Company announced positive interim data from its phase II double-blind placebo-controlled randomised clinical trial of oral INV102 (nadolol) in patients with chronic cough or established COPD who are trying to quit smoking but have failed multiple times previously. The blind-broken analysis shows clinically relevant changes in four biomarkers of inflammation – IL-8, ERK2, MUC 1 and neutrophils - in INV102 (nadolol) treated patients compared to placebo.

On 2 February 2015, the Company announced full enrolment in this phase II trial of oral INV102 (nadolol) in smoking cessation. Patient treatment and follow-up should is expected to be completed early in the third calendar quarter of 2015, at which time intensive analysis of data will commence.

On 4 June 2014, the Company advised that the Supreme Court of Queensland delivered judgment for the Company in its case against former officers of the Company. The Court determined that the defendants be required to repay to the Company 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.

On 23 February 2015, the Company appeared as a party before the Court of Appeal, in relation to an appeal from the decision of the former Chief Justice de Jersey delivered on 4 June 2014. The Court of Appeal decision was reserved.

## 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 2014 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 Ralph Craven Chairman

26 February 2015



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# Independent review report to 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 2014, 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 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 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 2014 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 company 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 2014 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 company incurred a loss from continuing operations after income tax of \$5,475,387 in the half-year ended 31 December 2014 (2013: \$2,904,760 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 2015