Research Note

Invion Group Ltd

Full speed ahead

INVION

Targeting inflammation

Chief Research Analyst

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Name:	**Invion Group Ltd**
Country:	**Australia**
Price:	**AUD 0.022**
ISIN Code:	**AU000000IVX4**
Reuters Code:	**IVX.AX**
Market Cap (AUD m):	**18.1**
EV (AUD m):	**11.1**
Cash & cash eq. (AUD m):	**7.0 *)**
Shares outstanding (m):	**822.75**
Volume:	**2,382,160**
Free float:	**100%**
52-week Range:	**0.02-0.09**

) Including recent capital raising

AUD mln	2013A	2014A	2015E
Revenues	1.855	0.929	1.200
Net Loss/Profit	-5.302	-6.844	-7.000
Net loss per share (cents)	-0.96	-1.41	-0.85
R&D costs	1.529	1.850	4.200
Cash increase/(decrease)	-1.006	0.958	3.100
Cash and marketable sec.	3.050	3.952	7.000

Executive Summary

- Invion Group is an Australian based biotech company focused on the development of treatments for large indications in respiratory disease and autoimmune disease. The company has three drug assets in development, with three FDA-regulated, phase II clinical trials and two preclinical feasibility programs currently ongoing. Its lead compound is INV102 (nadolol): a beta blocker (beta adrenergic biased ligand) currently used to treat high blood pressure and migraine that is being repurposed to treat chronic inflammatory airway diseases (e.g. asthma and COPD).

- Invion currently has two phase II clinical trials underway for the development of oral nadolol, as well as feasibility studies for the development of an inhaled version of the drug. Earlier this year, the company announced positive interim data from its Phase II oral INV102 in smoking cessation. The blind-broken analysis shows clinically relevant changes in four biomarkers of inflammation in INV102 (nadolol) treated patients compared to placebo. Recruiting for the smoking cessation phase II trial has been completed with 136 patients enrolled. Recently, the company received a positive response in an important pre-IND meeting with the FDA, enabling further development of novel compound INV102 (nadolol) as a potential new inhaled therapy to treat chronic airway diseases like asthma.

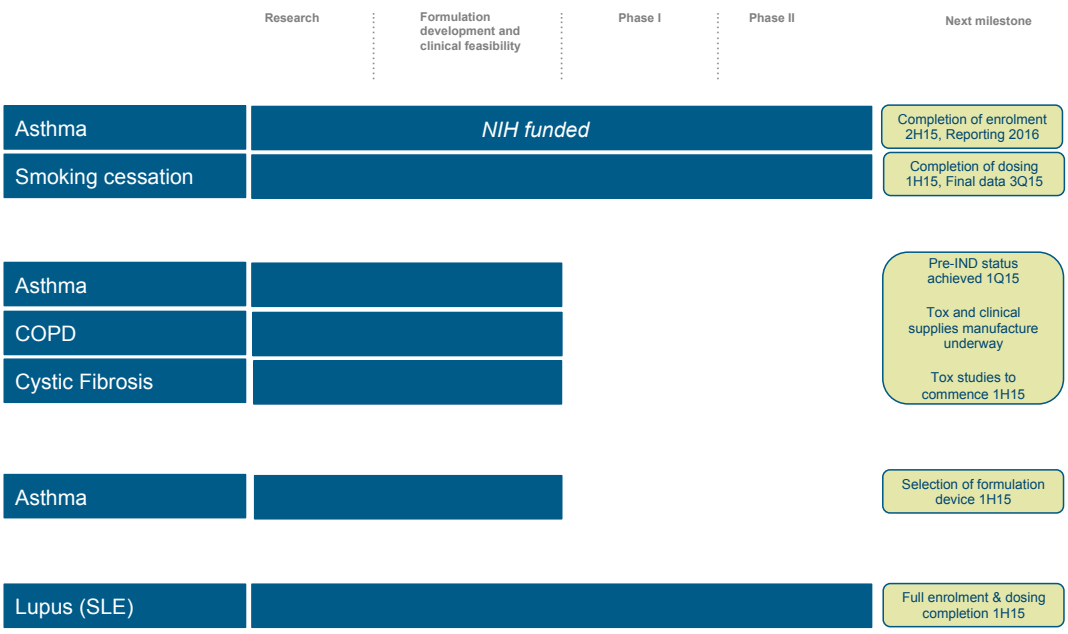
- There are a number of key milestones to focus on in the next 6-12 months which include: final data and reporting from Phase II oral INV102 in smoking cessation, progression to Phase I of inhaled INV102 and completion and final Phase II data of INV103 in lupus patients.

- At the end of March, the company had AUD 0.7 million in cash. Recently, the company was successful in raising in total AUD 6.3 million through a placement to professional and sophisticated investors and a 2 for 7 non-renounceable right issue entitlement offer to existing eligible shareholders.

- Based on sum-of-the-parts valuation, we believe **Invion** is substantially undervalued at the current share price of AUD 0.025. Using our valuation model, the Company's total value is AUD 100 million, or AUD 0.12 per share. This represents a substantial upside from the current share price.

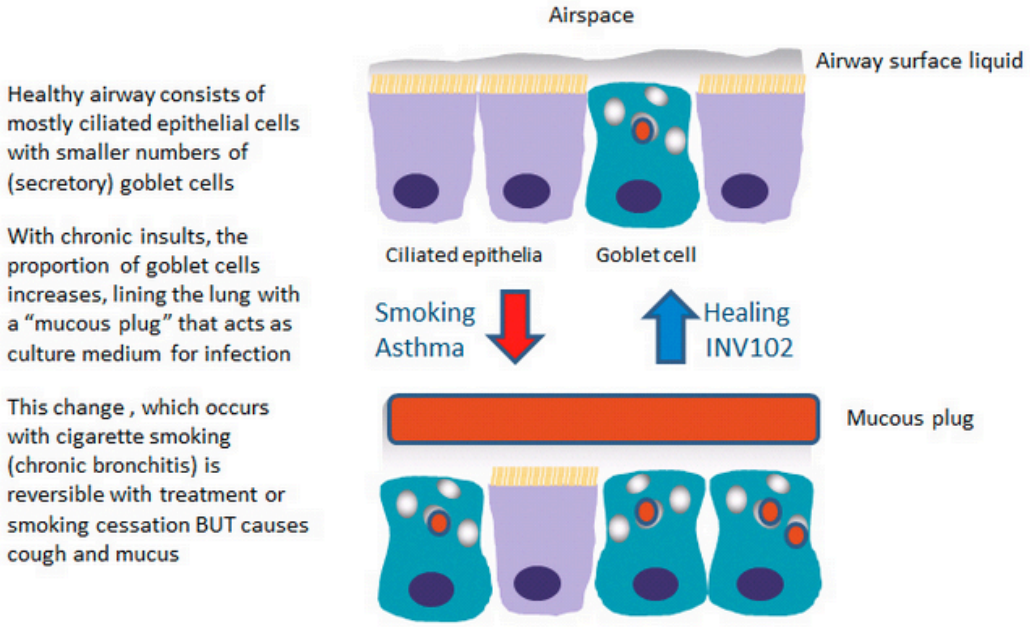
Pipeline Overview

Invion's pipeline is focused on the treatment of respiratory diseases, predominantly by repositioning proven therapeutics for new indications or innovative delivery options. Its lead compound is nadonol (INV102), a beta blocker that is on the market to treat high blood pressure an migraine. Invion repositioned it to treat chronic inflammatory airway diseases such as asthma and COPD. INV102 is in Phase II clinical trials for patients with chronic bronchitis that failed to quit smoking due to the failure to get rid of the smoker's cough. A second Phase II trial is currently used for patients with asthma – this trial is funded by the US National Institutes of Health. Invion's second compound is INV103, which is in a Phase II study for patients with mild Lupus. INV103 is a modified natural protein that is delivered intravenously. The company's third compound in development is INV104, an approved oral drug for patients with asthma. Invion plans to develop this drug as an inhaled version into the lungs. Invion has a collaboration with 3M which gave Invion access to 3M's metered dose inhalation technology.



Smoking Cessation (oral INV102)

The fastest path to market for Invion is the use of an oral version of INV102 (nadolol) to help patients quit smoking. Coughing is one of the main symptoms of smoking cessation and for many people it is the main reason for smokers not to quit. Many smokers develop a chronic cough, which is exacerbated initially after smoking cessation. It generally occurs within the first two weeks of quitting, an important period of productive cough. The symptoms of chronic cough are often so severe that many smokers return to smoking to suppress the cough symptoms.



INV102 can treat the underlying cause of chronic cough and mucus secretion. INV102 has been shown to down regulate IL-13 and the production of mucus in the lung. It is expected that INV102 will expedite healing of the airway in smokers and return to ciliated epithelium, leading to decreased cough and mucus production, which in turn leads to increased success rate in quitting.

A Phase II study was started in March last year. Recruitment for the smoking cessation phase II trial has been completed in January with 155 patients enrolled. In the beginning of this year, Invion announced positive interim data from about 30 patients. The data showed significant changes in 4 biomarkers of inflammation in patients treated with INV102 compared to those give placebo. The noted biomarker responses in patients are:

- IL-8, a powerful chemo attractant for inflammatory cells, was stable between visits 6 and 7, with a median decrease in IL-8 levels compared to placebo which showed a median increase in IL-8 levels;
- ERK2, a biomarker for the beta arrestin pathway, showed a greater median decrease than placebo-treated patients resulting in a lower median value at visit 7 (487 v 1,910 pg/mL);
- MUC 1, a glycoprotein that lines the surface of epithelial cells in the lung, showed a modest median decrease in patients receiving nadolol and placebo; and
- Neutrophils, the white blood cells that are the hallmark of inflammation of chronic bronchitis decreased 7% (mean) versus a mean increase of 1.4% in placebo patients.

Asthma: Oral INV102 (Nadolol)

In March last year Invion started a Phase II trial in patients with mild asthma using an oral version of INV102. That trial is officially due to be completed by mid 2015. The US National Institutes of Health (NIH) is funding the clinical trial with a non-dilutive funding contribution in excess of USD 4 million. The NIH was triggered to fund this Phase II trial as a result of the results after 9-10 weeks of treatment. These results showed a dose dependent decrease in airway hyper responsiveness that achieved clinically significant improvement. The study of approximately 60 patients is being conducted in partnership with Baylor University (Texas), Duke University (North

Carolina), and Washington University (St Louis), is expected to run until 2015. In March the company received a positive response in an important pre-IND meeting with the FDA. This enables further development of INV102 as a potential new inhaled therapy to treat chronic airway diseases like asthma. It demonstrates that the FDA now has approved the clinical strategy for inhaled nadolol as well as the associated drug delivery hardware. This is a proprietary pressurized metered dose inhalation technology developed by global manufacturing collaborator 3M Drug Delivery Systems. The FDA also has accepted the company's two Phase I study outlines and proposed toxicology program.

In summary, Nadolol (INV102) shows promise as a novel agent to promote airway healing, reduce inflammation and block the beta arrestin pathway, thereby establishing a "virtuous circle" to treat airway disease including smoker's cough, severe asthma, COPD and cystic fibrosis.

INV103 (ala-Cpn10)

On 18 July 2013, the Company commenced its phase II clinical trial of INV103 (ala-Cpn10) in patients with SLE/lupus. This trial, which aims to generate data on the safety, tolerability, and efficacy of INV103 as a potential new therapy in this disease area, is being conducted in collaboration with the University of Pennsylvania, Northwestern University, and Metroplex Clinical Research Centre (USA). The trial is expected to complete in the first half of 2015.

INV104 (zafirlukast)

Zafirlukast is a leukotriene receptor antagonist (LTRA) or anti-leukotriene that blocks the action of the cysteinyl leukotriene receptors to reduce inflammation, constriction of the airways, and the build-up of mucus in the lungs. The oral version of the drug, marketed as a generic and by Astra Zeneca as 'Accolate', is a first-in-class anti-leukotriene and treatment for asthma, which in clinical trials has shown an attractive safety and efficacy profile when delivered by inhalation at <1% of the oral dose. Invion has an exclusive, worldwide license to develop and commercialize all inhaled formulations and applications of zafirlukast. Feasibility for the development of an inhaled form of this drug is underway with formulation and device development anticipated to be announced in 1H 2015.

Upcoming Milestones

There are a number of key milestones to focus on in the next 6-12 months. The first two milestones for 1H2015 have already been achieved:

2015H1

- Phase I interim data from oral INV102 (nadolol) study in smoking cessation ☑
- Pre-IND status for inhaled INV102 as potential therapy for chronic airway diseases ☑
- Manufacture toxicology supplies and commencement of toxicology studies for inhaled INV102 (nadolol)
- Completion and final data from Phase II study of INV103 in lupus patients
- Selection of formulation and device for inhaled INV104 (zafirlukast)

2015H2

- Completion and final data from Phase II oral INV102 in smoking cessation
- Completion of enrolment of NIH funded Phase II study of INV102 in patients with asthma

Analyst: Marcel Wijma MSc

Marcel Wijma, Chief Research Officer and managing partner, has a longstanding history in financial biotech research. After selling Van Leeuwenhoeck Research (VLR) to SNS Securities in 2006, he established an award winning analyst team in biotech/life sciences at SNS Securities. In 2009, Marcel was awarded by Financial Times/Starmine as being one of the Top-3 biotech analysts in Europe. Later that year, Marcel purchased VLR from SNS Securities after which the company was reconstituted. At VLR, he leads the professional VLR research organisation, which is augmented by selected external financial researchers with a specialisation in Life Sciences. Mr. Wijma has a Masters degree in Financial Economics from Erasmus University in Rotterdam.