Initiating Coverage Report

Invion Group

Full speed ahead

INVION

Targeting inflammation

Chief Research Analyst

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Name:	**Invion Group Ltd**
Country:	**Australia**
Price:	**AUD 0.026**
ISIN Code:	**AU000000IVX4**
Reuters Code:	**IVX.AX**
Market Cap (AUD m):	**19.8**
EV (AUD m):	**12.7**
Cash & cash eq. (AUD m):	**7.100**
Shares outstanding (m):	**822.75**
Volume:	**2,668,090**
Free float:	**100%**
52-week Range (AUD):	**0.01-0.09**

AUD million (ending 30/6)	2014A	2015E	2016E
Total Income	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

Contents

Executive Summary

- Invion Group (ASX:IVX) 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 across four clinical development programs underway including three FDA-regulated, phase II clinical trials and two preclinical feasibility studies currently ongoing. Its lead compound is INV102 (nadolol): is a 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, COPD and cystic fibrosis).

- Invion currently has two phase II programs 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. The company completed dosing in this trial and expects the release of topline data in 2015Q3. 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.

- **MILESTONES IMMINENT: Invion reported that it is announcing 3 major milestones – including data from 2 separate phase II clinical trials – in the current quarter.** There are a number of key milestones to focus on in the next several months which include: data from the Phase II oral INV102 in patients undergoing smoking cessation, data from a Phase II trial of INV103 in lupus patients and completion of

enrolment of the NIH-funded Phase II trial of INV102 in asthma patients. Recently Invion signed a partnership with Hovione to develop and manufacture inhaled INV104 using Hovione's proprietary inhaler. The first clinical studies are expected to commence 2016Q2.

- At the end of June, the company had AUD 7 million in cash. Earlier this year, 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 0.026. 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.

Company Profile

Invion Group (ASX:IVX) is an Australia based biotechnology company that is targeting chronic inflammatory airway diseases like Asthma, COPD and Cystic Fibrosis. Its lead compound is nadolol (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 quite smoking due to the failure to get rid of the smoker's cough.

The company's strategy is focused on the ongoing development of its pipeline to treat respiratory diseases and repositioning proven therapeutics for new indications via inhaled administration. The reasoning behind this focus is twofold:

- Addressing a medical unmet need
- Commercially large markets for indications that exist globally

The current three compounds in development are: INV102 (nadolol), INV103 (ala-Cpn10) and INV104 (zafirlukast). Business development is geared towards maximizing the potential commercial opportunities arising from these drug development programs. For that the company is looking for strategic partnerships, both for the clinical and commercial development.

For INV102 it has an agreement with the US the US National Institute of Allergy and Infectious Diseases (NIAID), part of he US National Institutes of Health (NIH), which are the primary agency of the United States government responsible for biomedical and health-related research. The NIAID is funding the **"NIMA"** trial via a cooperative agreement grant to Baylor University College of Medicine of approximately USD 4.4 million.

For INV 102 Invion has a commercial collaboration with 3M for the development of its inhaled respiratory drug franchise. Invion's agreement with 3M is assessing the feasibility of inhaled versions of INV102 (nadolol) and INV104 (zafirlukast) using 3M's proprietary pressurized metered dose inhalation (pMDI) technology. It will also enable manufacture for toxicology, and subsequently phase I studies, under an Invion-sponsored Investigational New Drug application, with the US Food and Drug Administration. The companies intend to develop both drug candidates through to commercialisation, if they prove – through pre-clinical, phase I and phase II clinical development stages - to be safe and effective when delivered by an inhaler.

Market for Chronic Respiratory Illnesses

Over half a billion people worldwide suffer from inflammatory airways disorders, such as asthma and chronic obstructive pulmonary disease (COPD). In addition to the individual suffering, these diseases place a great burden on healthcare systems and generate enormous costs for society. Although inflammation underlies many of these conditions, until recently it has not been possible to take routine measurements of airway inflammation. Continuous monitoring of airways inflammation is a potentially enormous application, and has parallels with the monitoring of blood-glucose levels in insulin-dependent diabetics, a market worth USD 650 billion.

Asthma

Despite remarkable advances in diagnosis and long-term management, asthma remains a serious public health concern. Asthma, like chronic bronchitis, is a chronic inflammatory disease of the air passageways of the lungs. Asthma causes the bronchial tubes to be overly sensitive, or "hyper-responsive", to many different stimuli, causing them to swell and produce mucus and making it difficult for air to pass freely in and out of the lungs. For many people with asthma symptoms come and go, but their susceptibility to developing bronchial narrowing persists. A major goal of modern asthma treatment is reducing bronchial sensitivity to as close to normal as possible.

The modern age of asthma treatment began more than 50 years ago with the introduction of the first pressurized metered-dose inhaler (pMDI) in 1956. The pMDI provided convenient delivery of effective bronchodilator therapy. Patients with asthma used the rapidly acting nonselective beta-agonists (isoprenaline and epinephrine) through the mid 1960s, when the number of asthma-related deaths skyrocketed. The increased death rate was attributed to a decreased response to nonselective β-agonists that prompted patients to overuse their inhalers. Reduced sensitivity to bronchodilators became recognized as a harbinger of severe, life-threatening asthma attacks. Subsequent warnings from regulatory agencies markedly reduced the use of the nonselective beta-agonists. The selective short-acting β_2-adrenergic agonist (SABA) salbutamol, called

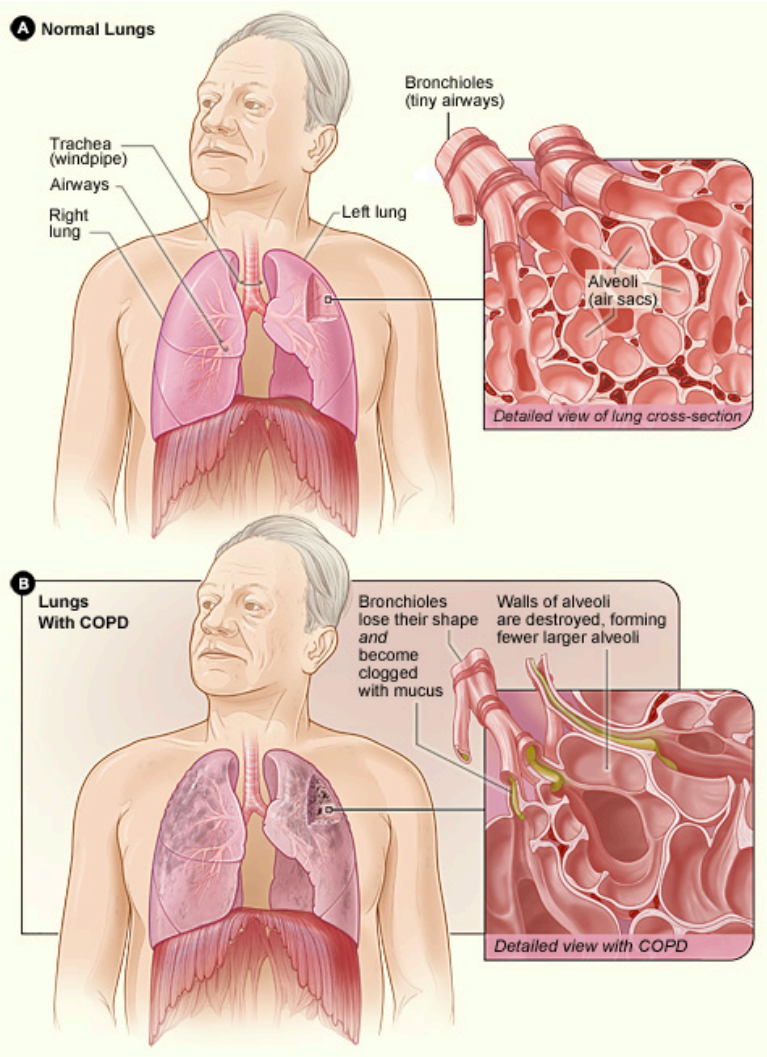
albuterol in the US, replaced the nonselective agents and has been demonstrated to be a safe and effective bronchodilator. During this time, the goal of asthma treatment shifted from managing bronchospasm to preventing inflammation. Systemic corticosteroids, long recognized as an effective anti-inflammatory treatment for asthma, were associated with serious systemic adverse events when used long term. Delivery of inhaled corticosteroids (ICSs) via a pMDI in the early 1970s ushered in a new era of asthma management. By the late 1980s and 1990s, the efficacy of anti-inflammatory therapy using ICSs was realized, and ICSs became established as first-line therapy for patients with asthma. However, clinical response to ICS therapy can vary among patients with asthma, and the dose-response curve for ICS treatment plateaus for many efficacy measures at low to medium doses thus, a need for new therapies became evident. A novel class of asthma therapies was introduced in the 1990s that targeted the synthesis or activity of the leukotriene family of inflammatory mediators in the pathogenesis of asthma. Leukotriene modifiers (LTMs) generally have been shown to be less effective than ICSs, possibly because they target only the leukotriene pathway of inflammation, whereas ICSs have a broader anti-inflammatory effect.

Bronchodilator medicines (SABAs and LABAs) help to relax the muscles around the airways in the lungs, however studies have shown that treatment with LABAs may exacerbate underlying disease severity. Even though LABAs decrease the frequency of asthma episodes, these medicines may make asthma episodes more severe when they occur, potentially leading to death, and LABAs now contain "black box" warnings from the FDA.

COPD

COPD, or chronic obstructive pulmonary disease, is a progressive disease that makes it hard to breathe. COPD can cause coughing that produces large amounts of mucus (a slimy substance), wheezing, shortness of breath, chest tightness, and other symptoms. Cigarette smoking is the

leading cause of COPD. Most people who have COPD smoke or used to smoke. Emphysema and chronic bronchitis are the two most common conditions that make up COPD. Chronic bronchitis is an inflammation of the lining of your bronchial tubes, which carry air to and from your lungs. Emphysema occurs when the air sacs (alveoli) at the end of the smallest air passages (bronchioles) in the lungs are gradually destroyed.



The Centers for Disease Control (CDC) report that COPD affects up to 24 million Americans, and according to the American Lung Association, is the fourth leading cause of death in the United States. COPD patients typically die from complications, such as severe lung infections, heart problems, or lung cancers.

The main risk factor for COPD is smoking. Researchers estimate that smoking causes 80-90% of COPD deaths. According to the American Lung Association, female smokers are nearly 13 times more likely to die from COPD than females who have never smoked. Male smokers are nearly 12 times more likely to die from COPD than males who have never smoked. Therefore, Patients are encouraged to stop smoking. Nicotine replacement products, including the patch (Habitrol®, Nicoderm CQ®, Nicotrol®), chewing gum (Nicorette®), lozenges (Commit®), inhalers (Nicotrol Inhaler®), nasal sprays (Nicotrol NS®), and the antidepressant bupropion (Zyban®), may help patients quit smoking. These drugs work in part by continuing to release low levels of a brain chemical called dopamine. In this way, these smoking cessation medications decrease the craving for nicotine and reduce the signs and symptoms of withdrawal.

Varenicline (Chantix®) is a newer drug that works in a similar way. Chantix® stimulates the release of low levels of dopamine in the brain to help reduce the signs and symptoms of withdrawal. In addition, Chantix® blocks nicotine receptors in the brain. The U.S. Food and Drug Administration (FDA) has approved the course of Chantix® treatment for 12 weeks. Individuals who successfully quit smoking during Chantix® treatment may continue to use Chantix® for an additional 12 weeks to further increase the likelihood of long-term smoking cessation. However, all of the products mentioned above do not treat the underlying cause of chronic caugh and mucus secretion which is a major obstacle to quite smoking and an important cause of perioperative complications in patients with COPD. There is a substantial untapped market for a therapy that can work to heal lungs in concert with efforts to break nicotine addiction.

There is currently no cure for COPD. Instead treatment focuses on reducing the symptoms and complications of the disease. Treatment varies, depending on the specific condition. It can range from medication and oxygen supplementation to transplant surgery. Bronchodilators are commonly used to relax the bronchi muscles in the lungs that can cause bronchospasms and restrict the airways.

$47.1 billion by 2017

The global market for respiratory drugs is estimated to be **$47.1 billion by 2017**.

Nadolol is targeted to be used in conjunction with existing therapies to make them safer and more effective representing a niche in an existing large and growing market.

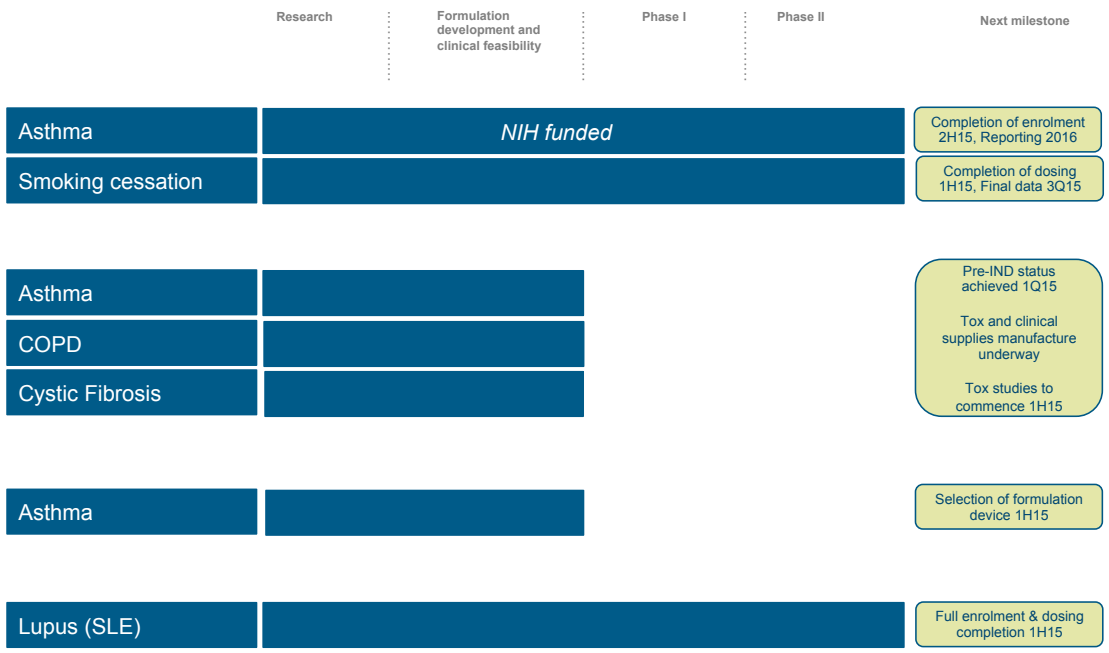
$3.8 billion by 2017

The smoking cessation drug market is predicted to be **$3.8 billion by 2016.**

Nicotine-focussed therapies comprise the bulk of the existing market, but they do not address lung healing. **Nadolol** represents an opportunity to add-on and expand an existing market.

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 nadolol (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 quite 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. 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 for patients with asthma, which was inlicensed from Accolade Pharma. 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.



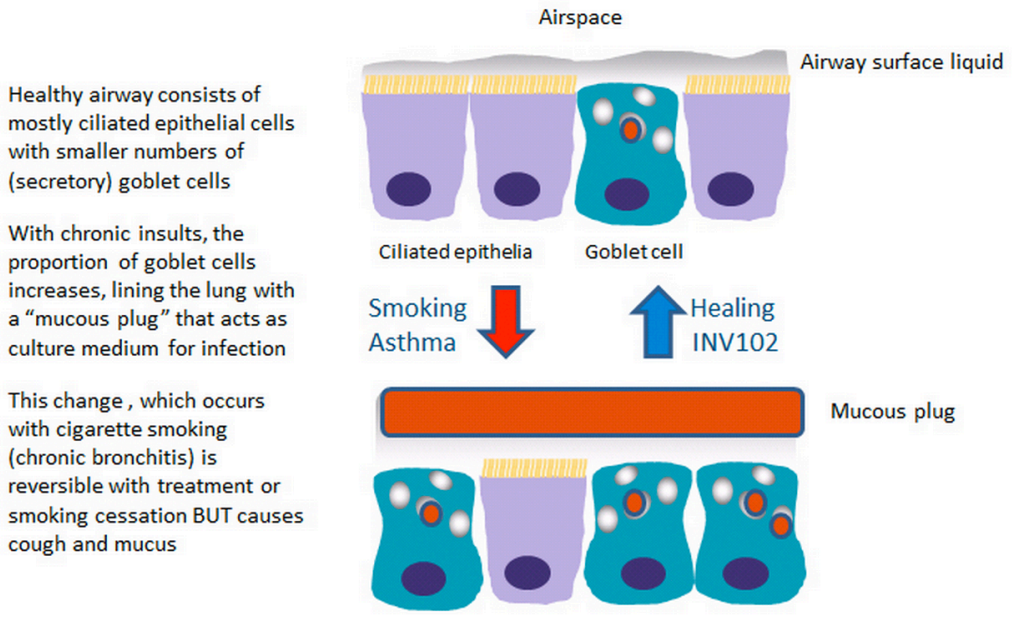
Smoking Cessation (oral INV102)

Nadolol (INV102) is a non-selective beta-blocker used for the treatment of high blood pressure, migraine headaches and chest pain, and has been safely taken by more than 8 million patients.

Beta blockers fall into two categories: antagonists, and β-adrenergic inverse agonists. Most beta-blockers that are on the market are antagonists: they block agonist stimulation of the receptor but do not inactivate spontaneously active receptors. INV102 is one of the three beta-adrenergic inverse agonists. This subset of beta blockers block agonist stimulation of the receptor and also inactivate intracellular inflammatory events that are stimulated spontaneously or by β-agonists. Long-term exposure to β-adrenergic inverse agonists, either by the oral or inhaled route, block cellular changes induced by beta-agonists, thereby inactivating the production of inflammatory cytokines and decreasing sensitization to airway challenges. Of the three beta-adrenergic inverse agonists, nadolol demonstrates the best inverse agonist activity in the airways.

It was specifically contraindicated for patients who also suffered asthma, as it was found that this drug would promote this condition (bronchoconstriction). However, researchers, showed that by dosing only small amounts of this beta blocker and slowly increasing that dose, airway hyper-responsiveness is decreased, as well as having an anti-inflammatory effect, therefore being a potential new treatment for asthma. This is the core discovery behind Invion's INV102 program.

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.

Recently, Invion announced that it has completed dosing in the Phase IIb trial in smoking cessation. This trial is being performed in the United States under an Invion-sponsored Investigational New Drug (IND) application.

This is an important milestone ahead of the release of headline study data, expected in 2015Q3.

The trial is designed to provide further testing of three hypotheses concerning the effects of INV102 (nadolol) on the airway epithelium:

- the impact of nadolol on biomarkers of airway inflammation, β-arrestin pathway activation and abnormal mucus production;
- the safety and efficacy of nadolol as an aid to smoking cessation in patients with increased cough and sputum (phlegm) production who have repeatedly failed to quit;
- the correlation of biomarkers of airway healing with cigarette smoking reduction or cessation, in order to optimise the nadolol regimen and patient selection for planned phase III clinical trials.

Results from this trial could pave the way for an entirely new approach to the treatment of chronic respiratory diseases like COPD, cystic fibrosis and severe asthma and could provide novel intellectual property if correlations provide insights to safety or efficacy linking nadolol usage to specific profiles of biomarkers.

Invion's Chief Medical Officer Dr Mitchell Glass said that completion of dosing was an important milestone. "This means that safety and tolerability of titration has been established in this vulnerable population – there is no indication that patients who received nadolol versus placebo were adversely affected. All existing data from previous nadolol studies have validated Invion's novel approach to treating the airway epithelium, even in the face of ongoing insult like cigarette smoking."

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): Lupus

Chaperonin 10 (Cpn10) is a naturally occurring protein present in all cells that, in conjunction with chaperonin 60, performs the essential housekeeping role of protein folding, i.e. it helps proteins develop into exactly the right shape required for them to work effectively. Cpn10 is thought to function as a natural regulator of the innate immune system. It is released locally by activated or damaged cells in response to "danger" signals, and down-regulates inflammatory immune responses. It is hypothesized that in disease states, levels of Cpn10 may not be high enough to control inflammation; however, administration of pharmacological levels of the molecule may overcome ongoing inflammatory signals and result in therapeutic benefit.

Invion's asset INV103 (Cpn10) is a minimally modified version of the naturally occurring chaperonin 10, and, in clinical trials conducted to date, has been demonstrated to also have an immunomodulatory function. In 2012, independent analyses were conducted on the INV103 (Cpn10) clinical and preclinical database, intellectual property and hypothesised mechanism of action. Based on these findings, and on a clear regulatory pathway and commercial potential, the most promising development target for INV103 (Cpn10) has been identified as systemic lupus erythematosus ("lupus"). Lupus is a multisystem autoimmune disease that occurs when the immune system attacks the body's cells and tissues leading to chronic inflammation, antibody production, and immune complex deposition resulting in tissue damage. Symptoms can be vague and vary from person to person, and consequently diagnosis can be difficult.

Lupus increases a woman's risk of other health problems and can also cause heart diseases, osteoporosis and kidney disease to occur earlier in life. There is no known cure for lupus, and the goals of treatment are to prevent flares, treat symptoms when they occur and reduce organ damage. Medication plays an important role in treating lupus, and therapies can involve NSAIDs, corticosteroids, antimalarial drugs or immunosuppressant/chemotherapeutic medication.

Lupus is currently the focus of intense research. Studies are currently looking at the genes that play a role in the disease and in the immune system, ways to change the immune system in people with lupus, lupus in different ethnic groups, environmental causes or triggers of lupus, the role of hormones and treatments for lupus.

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- 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.

Recently, the company announced that it has signed a partnership for inhaled zafirlukast with Hovione. Hovion has extensive experience in the development and manufacture of Active Pharmaceutical Ingredients and Drug Product Intermediates. 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. Zafirlukast is differentiated from other products being re-purposed for inhalation, given the extensive clinical database illustrating both its safety and efficacy. The collaboration has overcome the major impediment to reformulation and development of INV104 by producing a formulation devoid of banned propellants. Invion has received agreement from the FDA to proceed in an accelerated development of the formulation and device.

SWOT Analysis

Strengths

Strong management with extensive commercial and clinical development expertise

Vast expertise in respiratory diseases

Reduced risk profile due to proven safety record of the reformulated drugs

Weaknesses

Operating losses cumulating year-on-year

Delay pipeline development

Opportunities

Profitable Partnerships and license agreements with large pharmaceuticals

High unmet medical need

Large potential markets

Threats

Uncertainty about the outcome of clinical trial of the products

Higher level of expenditure than budgeted

Patent Position

Core Patent Overview INV102 (nadolol)

FAMILY 1: Methods of treating airways diseases with beta-adrenergic agonists

Status	Description	Patent	Expiry date
Granted	Cover methods of treating asthma with nadolol, involving administration of an initial low dosage of nadolol and increasing the dosagenbased on the response of the patients	US7528175	11 Feb 2025
Pending	Claims describing a method for treating a respiratory disease or chronic obstructive pulmonary disease (COPD) in a patient	US12/436051	8 Oct 2024
Pending	Application directed to more general methods for treatment of pulmonary airway disease by use of beta adrenergic inverse agonists. Various routes of administration cited	US10/574677	8 Oct 2024
FAMILY 2	*USE OF BETA ADRENERGIC INVERSE AGONISTS FOR SMOKING CESSATION*		
	Claims directed to use of beta adrenergic inverse agonists for mucus hypersecretion, particularly with respect to patients quitting or attempting to quite smolking. Various routes of administration including transdermal patch and chewing gum claimed. Claims also include inverse agonists used together with agents to promote smoking cessation. The USPTO acting as PCT International Preliminary Examining authority has recently issued a notice that all claims meet PCT requirements for industrial applicability, novelty and inventive step		9 Jan 2032

Core Patent Overview INV103 (ala-Cpn10)

Status	Description	Patent	Expiry date
Granted **(US, EP, AU, JP)**	Immunosuppression This is the corner stone patent. The key Composition of Matter claim for a modified form of ala-Cpn10 resides in this family		2026

Financials

For the half year ended 31 December 2014, Invion reported a net loss of AUD 5.5 million compared to a net loss of AUD 2.9 million in the same period last year. During this period, gross R&D expenditures totalled AUD 3.8 million (31 Dec 2013 AUD 0.9 million). Full year figures are expected end of August.

Total cash at the end of June 2015 is expected to amount to AUD 7 million.

Financial Summary (AUD mln)

Profit & Loss Statement For half year ended 31 Dec	**Dec 31 2014A (6 months)**	**Dec 31 2013A (6 months)**
Revenues	*0.210*	0.249
Expenses		
R&D Costs	*(3.802)*	(0.883)
General & administrative expenses	*(1.034)*	(0.824)
Finance costs	*(0.484)*	-
Income (loss) before income taxes	*(5.715)*	(3.286)
Tax Credits	*0.239*	0.380
Net Loss (Income)	*(5.475)*	(2.904)

Consolidated statement of cash flows

	Dec 31 2014A (6 months)	Dec 31 2013A (6 months)
Cashflow from operating activities	**(3.515)**	**(1.395)**
Cash flow from investing activities	**(0.208)**	**0.059**
Cash flow from financing activities	**1.695**	**0.106**
Cash and cash equivalents at beginning of the period	3.952	3.050
Net change in cash and cash equivalents	(2.027)	(1.230)
Cash and cash equivalents at the end of the period	**1.910**	**1.865**

Management Capabilities

Invion is being built by seasoned biotechnology innovators. The company is led by an experienced Board and management team, which has been responsible for the rapid development of the business and has a successful track record of developing, protecting and commercializing innovative scientific products and processes. In the past several years, Invion has been investing in developing a team of experts that have a focus on patient outcomes and can deliver results. Its board and senior management team are highly experienced in the development and early stage commercialization of therapeutics in respiratory illnesses.

Management Team

Dr Greg Collier, Chief Executive Officer

Dr Collier has more than 20 years experience spanning operational, clinical and scientific aspects of pharmaceutical research, development and commercialization. He has led the planning and execution of multiple commercial transactions including in and out licensing deals and major M&A activities, and he has successfully taken a drug from discovery through to regulatory approval. Notably, Dr Collier steered ChemGenex Pharmaceuticals from a research-based company with a market capitalization of AUD 10M to a company with completed clinical trials and regulatory dossiers submitted to the FDA and EMA. In 2011, ChemGenex was sold to Cephalon for AUD 230 million. Prior to his commercial pharmaceutical career, Dr Collier had an outstanding academic career resulting in over 150 peer reviewed publications, and senior authorship on 33 patents. Dr Collier was the inaugural Alfred Deakin Professor at Deakin University, and also held positions at Melbourne University, Monash University and the University of Toronto. In 2010, Dr Collier was awarded the Roche Award of Excellence for his contribution to the biotechnology industry.

Dr Mitchell Glass, Executive Vice President R&D, Chief Medical Officer

Dr Mitchell Glass is a 27 year veteran of the pharmaceutical industry. His experience is broad, ranging from senior positions in top ten pharmaceutical companies, to investment in and management of start-ups and biotechs. After seven years of research, teaching and patient care at the University of Pennsylvania, Dr Glass joined ICI Pharmaceuticals in 1988 where he established the pulmonary therapeutics group and led the development and submission of the antileukotriene ACCOLATE®. From 1995-6, Dr Glass was VP and Director at SmithKline Beecham where he was responsible for cardiovascular, respiratory, renal and metabolic drug development and commercialisation, including submission of the NDA/MAA for COREG®. From 1998 to 2003, Dr Glass was Chief Medical Officer and VP of Clinical Development and Regulatory Affairs of AtheroGenics, Inc. (AGIX), where he led product development from IND to initiation of Phase 3 for AGI 1067 and was a member of the IPO team. Dr Glass joined AQUMEN Biopharmaceuticals KK and NA as CEO of AQUMEN NA and a Main Board Director. Since 2008, Dr Glass has been a Director of OrphageniX Inc. (gene editing) and AVATAR Biotechnologies (biosimilars) and a consultant in R&D and fundraising to early stage therapeutics companies. Dr Glass graduated from the University of Chicago and is board certified in internal medicine, pulmonary and critical care medicine.

Melanie Farris, Head of Operations & Company Secretary

Ms Farris is an experienced operations, communications and governance professional with a strong track record in the planning, management and delivery of a range of corporate projects across industries including life sciences, investment and not-for-profit. Ms Farris specialities include corporate affairs, compliance, financial management and reporting, policy development, investor and public relations, stakeholder engagement, human resources, M&A due diligence

and integration. She has had previous roles with HRH The Prince of Wales's Office, Global Asset Management (GAM), Imperial Cancer Research Fund and The Prince's Foundation; and has volunteered in a professional capacity for groups including NAPCAN and Sands Queensland. An Associate of the Governance Institute of Australia, Ms Farris is also appointed Secretary to the Group's subsidiary, Invion, Inc.

Seth Yakatan Vice President, Business Development

Mr Yakatan brings more than 24 years of experience as a life sciences business development and corporate finance professional, actively supporting small cap and major companies in achieving corporate, financing and asset monetization objectives through the successful structuring and management of strategic transactions and investments totaling more than several billion dollars in value. As a co-founder of Katan Associates, Mr Yakatan has successfully structured and managed strategic alliances and deals, based on his insight and expertise in the US and Global Life Science sector, including numerous buy- and sell-side M&A transactions. Mr Yakatan has authored several publications and lectured and guest lectured at corporate workshop and universities on valuation theory and real-world practice and case studies, and consulted to several state and provincial governments worldwide on commercialisation and capital access initiatives. Mr Yakatan holds an MBA in Finance from the University of California, Irvine and a BA in History and Public Affairs from the University of Denver.

Valuation

We value Invion at AUD 100 million using a risk-adjusted NPV valuation. This is valuing the potential of the clinical programs in smoking cessation, asthma and lupus.

We estimate that INV102 in smoking cessation could be launched in 2019 and generate peak sales of USD 150 million. This assumes that the therapy confers a medically meaningful benefit in smoking cessation and is priced at USD 250 per course of treatment and gains 10% market penetration. Other assumptions are:

- number of smokers (US): 42 million, of which 70% wants to quit smoking (source CDC)
- 10% of that number succeeds to quit smoking, 90% fails due to a number of reasons
- Invion can target that group of people, with an expected market share of 5-10%

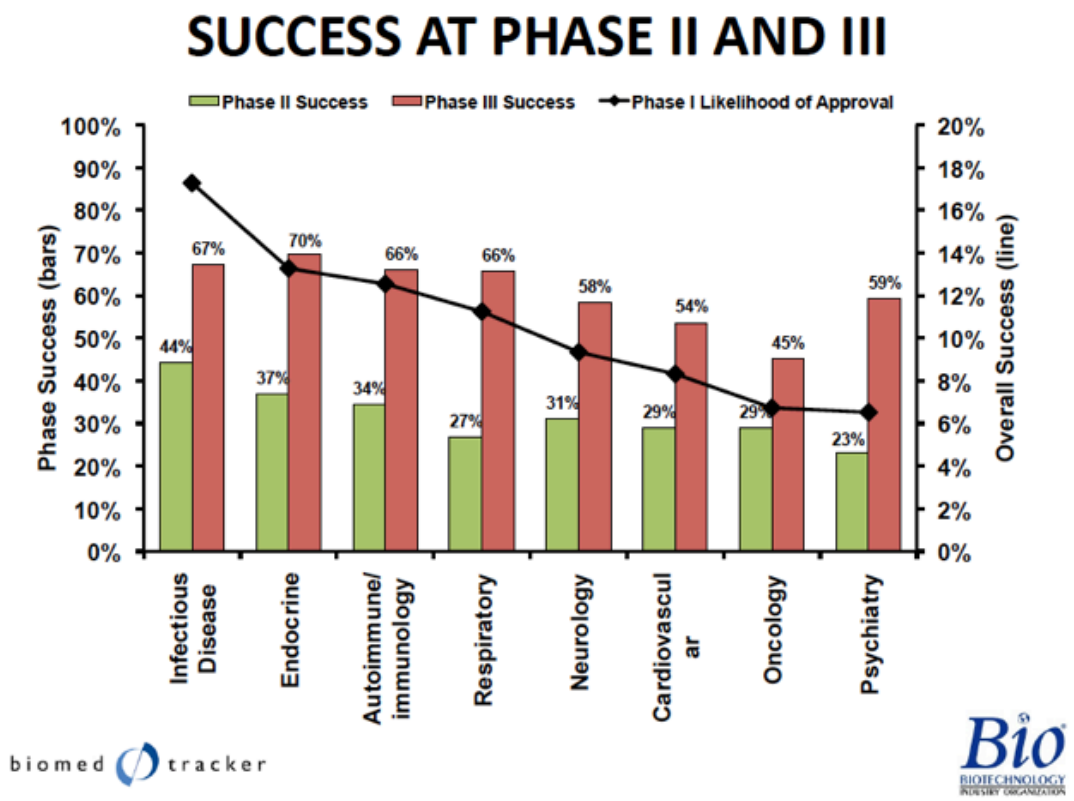
This is based on the number of smokers that cannot continue smoking cessation due to the side effects. On a similar basis with 10% market penetration and pricing of USD xx, we estimate that INV102 could achieve peak sales of USD 250 million in asthma after being launched in 2020. We value the programs INV103 and INV104 at a considerable lower level because we feel that it will take longer for these therapies to be marketed.

Product	*Discount Rate*	*NPV Value (AUD mln)*	*Probability of succes*	*Adj NPV (AUD mln)*	*Per Share*
INV102 smoking cessation	*20%*	*100*	*50%*	*50*	*0.05*
INV102 Asthma	*20%*	*80*	*40%*	*32*	*0.034*
INV103 Lupus	*20%*	*60*	*25%*	*15*	*0.015*
INV104 Asthma	*20%*	*20*	*15%*	3	0.001
Total				***100***	***0.10***

Source: Van Leeuwenhoeck Inc

With INV102 in Phase II clinical trials we estimate a probability of success of 50% till market launch. This is based on an independent survey executed by BioMedTracker and BIO in 2012[1]. See also the graph below. We have increased the potential of success because of the proven track record of the underlying compounds. In our view, that makes it more likely that the products will actually be approved.

1 Clinical Development Success Rates for Investigational Drugs, Pharma CI2012


SUCCESS AT PHASE II AND III
Phase II Success
Phase III Success
Phase I Likelihood of Approval
Phase Success (bars)
Overall Success (line)
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
20%
18%
16%
14%
12%
10%
8%
6%
4%
2%
0%
44%
67%
37%
70%
34%
66%
27%
66%
31%
58%
29%
54%
29%
45%
23%
59%
Infectious Disease
Endocrine
Autoimmune/ immunology
Respiratory
Neurology
Cardiovascular
Oncology
Psychiatry
biomed tracker
Bio
BIOTECHNOLOGY

Upcoming Milestones

There are a number of key milestones to focus on in the next few months. The first milestones for 2015H1 have already been achieved:

2015H1

Oral INV102 (nadolol)

- Blind-broken interim data from phase II smoking cessation trial ☑
- Completion of enrolment in phase II smoking cessation trial ☑
- Completion of dosing in phase II smoking cessation trial ☑

Inhaled INV102 (nadolol)

- Pre-IND status for inhaled nadolol as a potential therapy for asthma, COPD & cystic fibrosis ☑
- Manufacture of toxicology and clinical supplies ☑
- Commencement of toxicology studies ☑

Milestones anticipated by mid-Q3 2015

- Data from phase II oral INV102 (nadolol) study in patients undergoing smoking cessation
- Data from phase II clinical trial of INV013 (ala-Cpn10) in lupus patients (revised from 2015H1 further to enrolment delay in the final cohort of patients)
- Selection of formulation and device for inhaled INV104 (zafirlukast) (revised from 1H15)

Milestones anticipated 2H 2015

- Completion of enrolment of NIH-funded phase II study of INV102 (nadolol) in asthma patients

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.