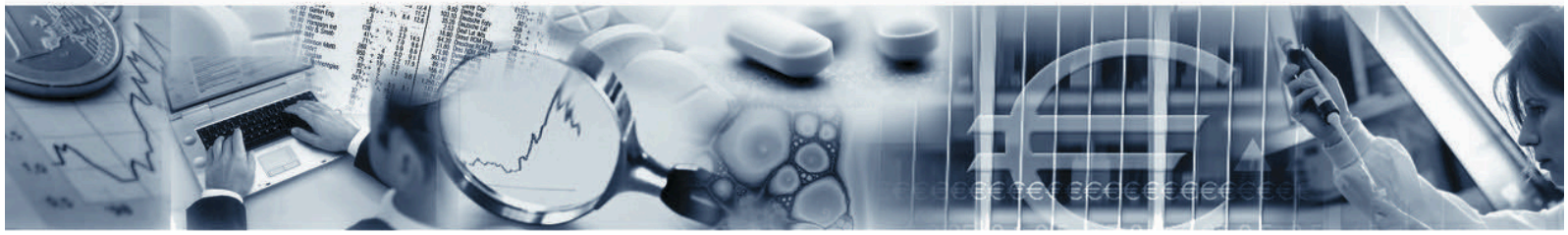

Update Report

Invion Group

Into higher gear

INVION

Targeting inflammation

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Date: 14 March 2016

Name:	**Invion Group Ltd**
Country:	**Australia**
Price:	**AUD 0.006**
ISIN Code:	**AU000000IVX4**
Reuters Code:	**IVX.AX**
Market Cap (AUD m):	**7.4**
EV (AUD m):	**5.3**
Cash & cash eq. (AUD m):	**2.1**
Shares outstanding (m):	**1,198**
Volume:	**1,618,130**
Free float:	**100%**
52-week Range (AUD):	**0.005-0.05**

AUD million (ending 30/6)	2014A	2015A	2016E
Total Income	0.929	2.610	2.500
Net (Loss)/Profit	(6.844)	(11.084)	(6.000)
Net loss per share (cents)	(1.27)	(2.15)	(0.70)
R&D costs	1.850	8.689	4.000
Cash increase/(decrease)	0.958	0.958	3.100
Cash and marketable sec.	3.952	2.285	5.385

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).

- In October 2015 Invion concluded its phase II program with oral INV102 in smoking cessation. The data showed that INV102 treated smokers were more likely to stop smoking completely or dramatically reduce the number of cigarettes smoked. It also demonstrated that INV102 is a safe and effective treatment for patients with chronic bronchitis enrolled in smoking cessation programs. The company expects an end of Phase II meeting with the FDA in the next few weeks to move INV102 into Phase III. The smoking cessation drug market is predicted to be USD 3.8 billion by 2016. While nicotine focused therapies comprise the bulk of the existing market, they do not address lung healing. INV102 represents an opportunity to add-on and expand an existing market.

- Invion also concluded a Phase II trial with its program INV103 in lupus patients. Three sets of data were reviewed from subjects who received twice-weekly doses of 10, 30 or 100mg of ala-Cpn10, or placebo. The adverse events and clinical chemistry profiles showed that increasing the dose 10-fold over levels used previously in the development of the drug asset could be achieved safely. The company is currently in partnering discussion with several pharmaceutical companies.

- At the end of December, the company had AUD 2.1 million in cash. In 2015, the company was successful in raising in total AUD 7.4 million through placements 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 0.006. With the positive phase II data of INV102 and INV103, we have increased our valuation for the company from AUD 100 million to AUD 116 million, or AUD 9.7c per share. This represents a substantial upside from the current share price.

Company Profile

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 drug assets in development, and three phase II clinical trials, regulated by the FDA, currently underway in the United States. INV102 (nadolol), a beta blocker (beta adrenergic biased ligand) currently used to treat high blood pressure and migraine, is being repurposed to treat chronic inflammatory airway diseases, including asthma and chronic obstructive pulmonary disease (COPD). INV104 (zafirlukast) is a leukotriene receptor antagonist (LTRA) that reduces inflammation, constriction of the airways and the build-up of mucus in the lungs. INV103 (ala-Cpn10) is a modified, naturally occurring human protein which has been proposed as a founding member of the Resolution Associated Molecular Pattern (RAMPs) family hypothesized to maintain and restore immune homeostasis.

INV102 successfully completed a Phase II clinical trial for patients with chronic bronchitis that failed to quit smoking due to the acute worsening of cough upon attempted cessation. The data demonstrated that treated smokers were more likely to stop smoking completely. These data mitigate the risk of INV102 development across the spectrum of airway diseases.
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 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 has shown the feasibility of a proprietary inhaled version of INV102 (nadolol) 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 company intends to develop inhaled INV102 through to partnering for commercialisation, if it proves – through pre-clinical, phase I and phase II clinical development stages - to be safe and effective when delivered by an inhaler.

Additionally, Invion is collaborating with Hovione Scientia (Lisbon Portugal, Princeton NJ) to develop a proprietary formulation and device for inhaled zafirlukast (INV104). As with INV102, the program is designed to complete nonclinical development through phase I and II to partnering for commercialization, including in fixed combination with inhaled corticosteroids (ICS).

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

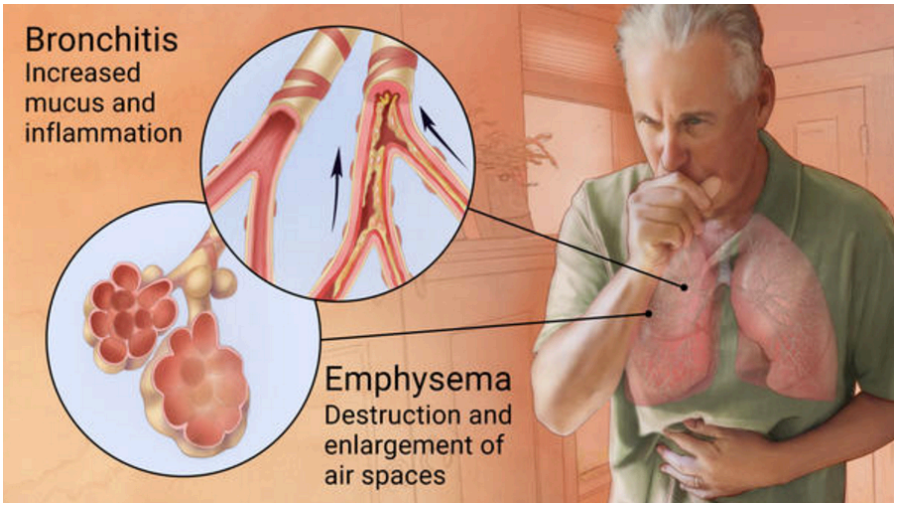
albuterol in the US, replaced the nonselective agents and has been demonstrated to be a safe and effective bronchodilator. During this time, the goal of asthma treatment shifted from managing bronchospasm to preventing inflammation. Systemic corticosteroids, long recognized as an effective anti-inflammatory 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, but are complementary to ICS, and have been indicated both in lieu of increasing ICS dose, or as "steroid sparing" agents. .

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, 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 the bronchial tubes, which carry air to and from the 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.

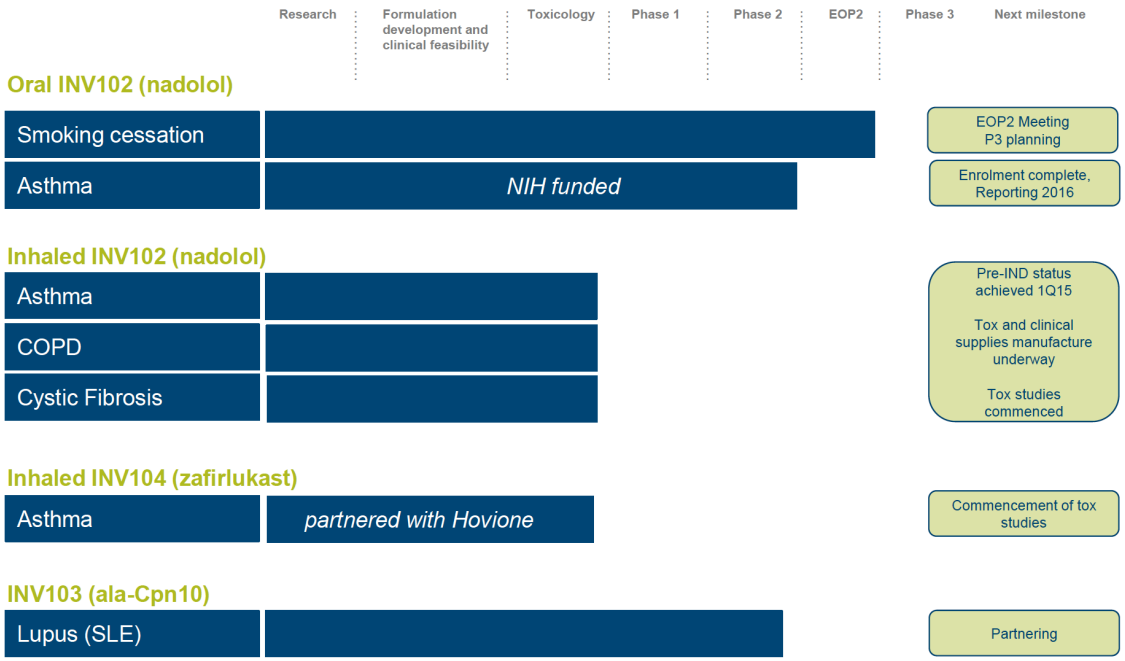
The main risk factor for COPD is smoking. Researchers estimate that smoking causes 80-90% of COPD deaths. According to the American Lung Association, female smokers are nearly 13 times more likely to die from COPD than females who have never smoked. Male smokers are nearly 12 times more likely to die 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 cough and mucus secretion which is a major obstacle to quite smoking and an important cause of complications in patients with COPD, and which creates a particular risk in the perioperative setting. 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.

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 and migraine. Invion repositioned it to treat chronic inflammatory airway diseases such as asthma and COPD.



Source: Invion Group Ltd

In October 2015, the company completed a Phase II clinical trial with INV102 for patients with chronic bronchitis that failed to quit smoking due to the failure to get rid of the smoker's cough. The data demonstrated that treated smokers were more likely to stop smoking completely. 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 had a collaboration with 3M which gave Invion access to 3M's metered dose inhalation technology and is presently developing this product in collaboration with Hovione Scientia.

Smoking Cessation (oral INV102)

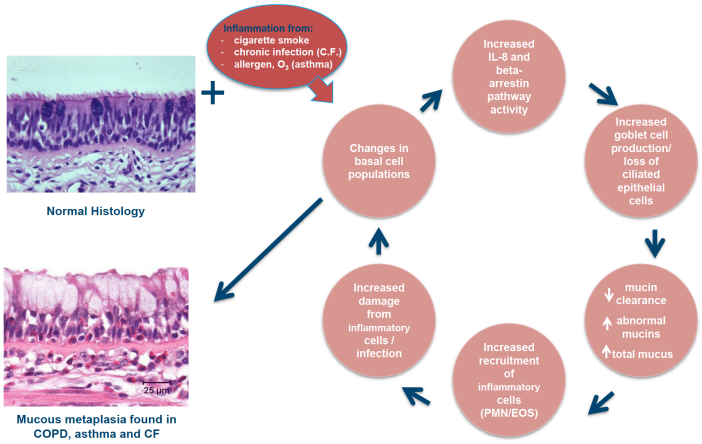
Nadolol (INV102) is a non-selective beta-blocker used for the treatment of high blood pressure, migraine headaches and chest pain, and has been safely taken by more than 8 million patients.

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, now understood to be, in part, its unique profile as both an inverse agonist and biased ligand.

Nadolol 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, full dosing could be achieved safely and 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.

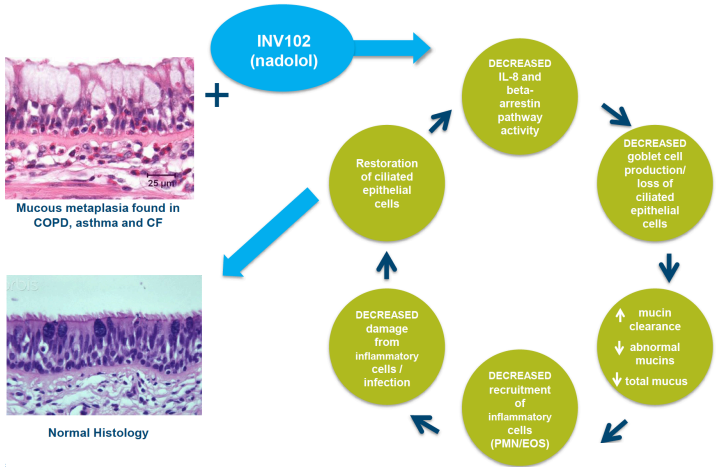
The fastest path to market for Invion is the use of an oral version of INV102 (nadolol) to help patients quit smoking. Coughing is one of the main symptoms of smoking cessation and for many people it is the main reason for smokers not to quit. Many smokers develop a chronic cough, which is exacerbated 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.



Source: Invion Group Ltd

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.



Source: Invion Group Ltd

A Phase II study was started in March 2014. Recruitment for the smoking cessation phase II trial has been completed in January 2015 with 155 patients enrolled. In October 2015, Invion successfully completed the trial.

The data from the randomised, double blinded, placebo controlled study showed smokers administered INV102 were more likely to stop smoking completely, or dramatically reduce the number of cigarettes smoked. In addition, INV102 reduced key biomarkers MUC5AC and ERK1 in collected sputum samples – supporting the company's hypothesis that INV102 has a novel mechanism of action directly targeting epithelial cells lining the airway.

We believe that these data are strong confirmation of the development strategy for both oral and inhaled INV102 for the treatment of airway disease.

Data from the study showed:

- INV102 was safe and well tolerated, and Invion's proprietary titration scheme enabled patients to reach efficacious doses
- Trial subjects treated with INV102 were more likely to achieve abstinence at the conclusion of dosing (12/62, 19.3%) compared to those administered placebo (7/59, 11%)
- More patients treated with INV102 achieved a >70% reduction in cigarettes smoked compared with placebo treated patients (38/62 on INV102 and 21/59 or 36% on placebo)
- Two key markers of the beta arrestin pathway – ERK1 and MUC5AC – which are necessary for the activation of mucous metaplasia in the airway, showed the most robust changes. MUC5AC levels were reduced by 82% in INV102 treated patients, compared to 54% in placebo subjects. ERK1 levels were reduced by 47% for INV102 compared with 27% for placebo.

There will be ongoing analysis of the clinical data generated from this trial to examine which patients responded to INV102 therapy and if this correlated with any of the several biomarkers measured in the sputum samples collected.

The aim of the further analysis will be to determine if the company can generate further IP around predicting patient response to INV102, and also determining the best patient groups to be selected for Phase III trials.

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

Summary Phase II data INV102 in smoke cessation

Invion Hypothesis		Demonstrated
Proprietary titration scheme safe and enables subjects to reach efficacious doses of drug – no need for rescue medication	√	Trial subjects treated with INV102 were more likely to achieve abstinence at the conclusion of dosing (12 out of 62 patients or 19.3%) compared to those administered placebo (7 out of 59 patients or 11%)
INV102 therapy will lead to reduction in cigarettes smoked	√	More patients treated with INV102 achieved a greater than 79% reduction in cigarettes smoked compared with placebo treated patients (38 out of 62 patients or 61% on INV102 and 21 out of 59 patients on placebo)
INV102 therapy will lead to complete abstinence in some patients	√	
INV 102 inhibits the beta arrestin pathway: a cellular pathway necessary for the activation of mucous metaplasia in the airway	√	MUC5AC levels were reduced by 82% in INV102 treated patients, compared to 54% in placebo subjects. ERK1 levels were reduced by 47% for INV102 compared with 27% for placebo

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.

Asthma: Oral INV102 (Nadolol)

In March 2014 the NIAID and Invion started a Phase II trial in patients with mild asthma using an oral version of INV102. In November 2015 the trial was fully enrolled. 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 66 patients is being conducted in partnership with Baylor College of Medicine (Texas), Duke University (North Carolina) and Washington University (Missouri). In March 2015 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 hypothesized 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.

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. Invion is progressing regulatory requirements to investigate INV103 (Cpn10) as a treatment for lupus. In 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, was completed in August 2015.

Three sets of data were reviewed from subjects who received twice-weekly doses of 10, 30 or 100mg of ala-Cpn10, or placebo. The adverse events and clinical chemistry profiles showed that increasing the dose 10-fold over levels used previously in the development of the drug asset could be achieved safely. The next step is to scale up INV103 and to get longer term toxicology in larger groups of patients. Invion intends to partner this program subsequently.

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.

In July 2015, the company signed a partnership for inhaled zafirlukast with Hovione Scientia,

an international pharmaceutical company expert in inhalation development and manufacturing. 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.

Source: Hovione Ltd

SWOT Analysis

Strengths	Weaknesses
Strong management with extensive relevant technical, commercial and financial expertise	Operating losses cumulating year-on-year
Vast expertise in respiratory diseases	Delay pipeline development
Reduced risk profile due to proven safety record of the reformulated drugs	
Opportunities	**Threats**
Profitable partnerships and license agreements with large pharmaceuticals	Uncertainty about the outcome of clinical trials
High unmet medical need	Higher level of expenditure than budgeted
Large potential markets	

Patent Position

Core Patent Overview INV102 (nadolol)

Status	Description	Patent	Expiry date
FAMILY 1	*METHODS OF TREATING AIRWAYS DISEASES WITH BETA-ADRENERGIC AGONISTS*		
Granted	Cover methods of treating asthma with nadolol, involving administration of an initial low dosage of nadolol and increasing the dosage based 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 smoking. 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

In March, Invion received notification of allowance on the patent right for the use of beta-adrenergic inverse agonists for smoking cessation, from the State Intellectual Property Office of the People's Republic of China. The use of beta-adrenergic inverse agonists for smoking cessation is the second family of core patents for oral INV102 (nadolol). Claims in this patent family are directed to the use of beta-adrenergic inverse agonists for prevention of mucus hyper secretion, particularly with respect to patients quitting or attempting to quit smoking.

Financials

For the half year ended 31 December 2015, Invion reported a net loss of AUD 3.0 million compared to a net loss of AUD 5.5 million in the same period last year. During this period, gross R&D expenditures totaled AUD 1.1 million (31 December 2014: AUD 3.8 million). The lower costs are related to a decrease of clinical trial costs (AUD 0.7 million instead of AUD 2.6 million) and feasibility studies (inhaled programs in total of AUD 0.3 million).
Total cash at the end 2015 amounted to AUD 2.1 million.

In the past year, Invion was successful in raising capital with existing share holders. On 1 September 2015 the Company announced an agreement to issue securities to an institutional investor in the United States in a private placement for gross proceeds of AUD 1,001,000. 71,500,000 fully-paid ordinary shares were issued at an issue price of AUD 1.4c per share, which was a 25% discount to the 15 day VWAP of AUD 1.8c, to 27 August, the last trading day prior to the agreement to issue. In addition, 51,500,000 share options were issued with an exercise price of AUD 1.4c and an expiry date of 3 September 2016.

Profit & Loss Statement

AUD million	2014A	2015A	2016H1A	2016E
Revenues	0.300	0.211	0.139	0.500
Other Income	0.629	2.400	0.742	2.000
R&D Costs	(1.851)	(8.639)	(1.111)	(3.000)
Other	(4.887)	(5.430)	(2.028)	(4.000)
SG&A	(1.837)	(2.009)	(0.986)	(2.100)
Operating Profit/(Loss)	(7.647)	(13.517)	(3.248)	(6.500)
Income tax benefit	0.763	0.476	0.255	0.500
Net Profit/(Loss)	(6.884)	(13.041)	(2.993)	(6.000)

Consolidated statement of cash flows

AUD million	Dec 31st 2014A (6 months)	Dec 31st 2015A (6 months)	June 30th 2016E (12 months)
Cashflow from operating activities	(3.515)	(2.150)	(4.500)
Cash flow from investing activities	(0.207)	-	(0.300)
Cash flow from financing activities	1.696	1.913	5.000
Cash and cash equivalents at beginning of the period	3.953	2.284	2.285
Net change in cash and cash equivalents	(2.027)	(0.237)	2.500

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 116 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 2020 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%

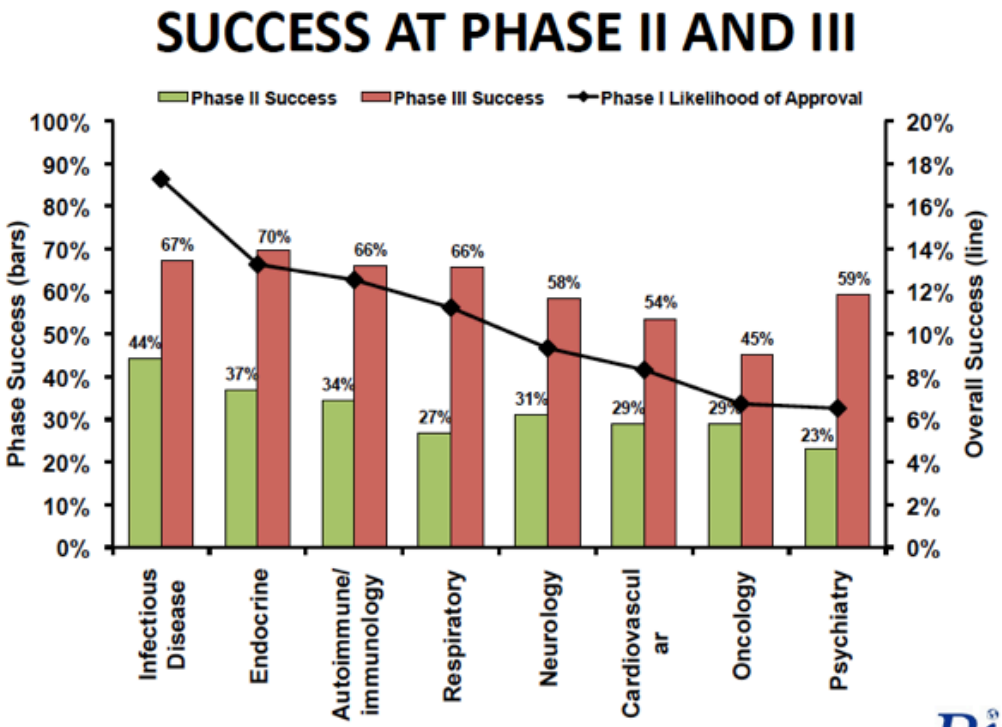
This is based on the number of smokers that cannot continue smoking cessation due to the side effects. On a similar basis with 10% market penetration and pricing of USD xx, we estimate that INV102 could achieve peak sales of USD 250 million in asthma after being launched in 2020. We value the programs 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*	*60%*	*60*	*0.05*
INV102 Asthma	*20%*	*80*	*40%*	*32*	*0.034*
INV103 Lupus	*20%*	*60*	*35%*	*21*	*0.015*
INV104 Asthma	*20%*	*20*	*15%*	3	0.001

Total	*116*	*0.10*

Source: Van Leeuwenhoeck Inc

With INV102 successfully concluded Phase II clinical trials we have increased the probability of success to 60% from 50% till market launch. Also for INV103 we have increased the probability of success to 35% from 25% 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 biomed tracker

Bio BIOTECHNOLOGY INDUSTRY ORGANIZATION

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.

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