



INVION

Targeting inflammation



INVION LIMITED (ASX:IVX) INVESTOR UPDATE

November / December 2015

STOP PRESS: Phase 2 data

- ✓ **Patients receiving INV102 (nadolol) were more likely to stop smoking completely or dramatically reduce the number of cigarettes smoked**
- ✓ **INV102 (nadolol) significantly decreases key mucous metaplasia biomarker MUC5AC**
- ✓ **Invion requests FDA End of Phase 2 meeting and submits abstract to 2016 American Thoracic Society (ATS) annual meeting**

SHARE PURCHASE PLAN

Closing date (extended):
5pm, Monday 7 December 2015.

Use of funds:

Funds will be used for general working capital and applied to costs associated with ongoing analysis of data from the completed phase 2 clinical trial of INV102 (nadolol) in smoking cessation, preparation for an End of Phase 2 meeting with the US FDA, ongoing business development and partnering discussions for the Company's three drug assets, and maintenance of Invion's intellectual property portfolio.

For more information:

Please contact the offer information line on
1300 131 543.

Dear Shareholder,

You may be aware that Invion has launched a Share Purchase Plan to support the next stage of the Company's development following the successful completion of major milestones across four drug development programs during 2015.

In particular, we are keen to complete partnering discussions to maximise the speed of progress with our lead drug candidate INV102 (nadolol) following recently announced positive results in a Phase 2 study in smokers attempting to quit the habit.

Under the SPP offer, eligible shareholders can subscribe for up to \$15,000 worth of new shares at a 10% discount to the volume weighted average price (VWAP) of Company shares traded on the ASX in the five days prior to the issue date.

I encourage shareholders to take part in this opportunity, which follows the report of successful trial results and provides a new chance to invest in prevailing market conditions and at a critical stage of development.

At this time, we are focused and committed to securing a strategic investment and/or sale of the Company and /or its assets.

We believe there is potential for investor upside in the short to medium term with either route.

Assisting our endeavour is leading specialist healthcare group Ferghana Partners. Based in New York, this group specialises in corporate partnerships and financing transactions. Our advisors are now carefully examining various potential opportunities.

Recent Data

Invion's development agenda is buoyed by the recent release of positive Phase 2 trial results from a study of INV102 (nadolol) as new treatment to assist smoking cessation.

While the drug has historically been used to treat migraine and high blood pressure, we know it also blocks a key pathway known as the beta arrestin pathway, which is strongly implicated in phenotype of chronic airway disease.

Our study demonstrated good safety – which is a critical and positive outcome for a drug that has to date been contraindicated in airway disease - and had paved the way for a novel therapy that will complement existing drugs potentially making them safer and more effective.

Smokers on QUIT programs who were administered INV102 were likely to stop smoking completely or dramatically reduce the number of cigarettes smoked due to a reduction in the chronic 'smoker's cough' which typically develops as a result of excessive mucus production following a final cigarette.

While smoking cessation is our *short path to market* strategy for oral INV102, these results underpin our broader agenda to see INV102 developed as a first in class treatment for other chronic airway conditions like COPD, asthma and cystic fibrosis.

Each of these diseases have a substantial unmet medical need, as well as great commercial opportunity. The smoking cessation drug market is predicted to be \$3.8 billion by 2017. While nicotine-focused therapies comprise the bulk of the existing market, these do not address lung healing. All data to date suggests our hypothesis is sound – that we are on the right track.

INV102 (nadolol) in mild asthma

In a separate study, we are currently examining INV102 in patients with mild asthma. This Phase 2 investigation completed enrolment in November with 66 patients enrolled at three US sites.

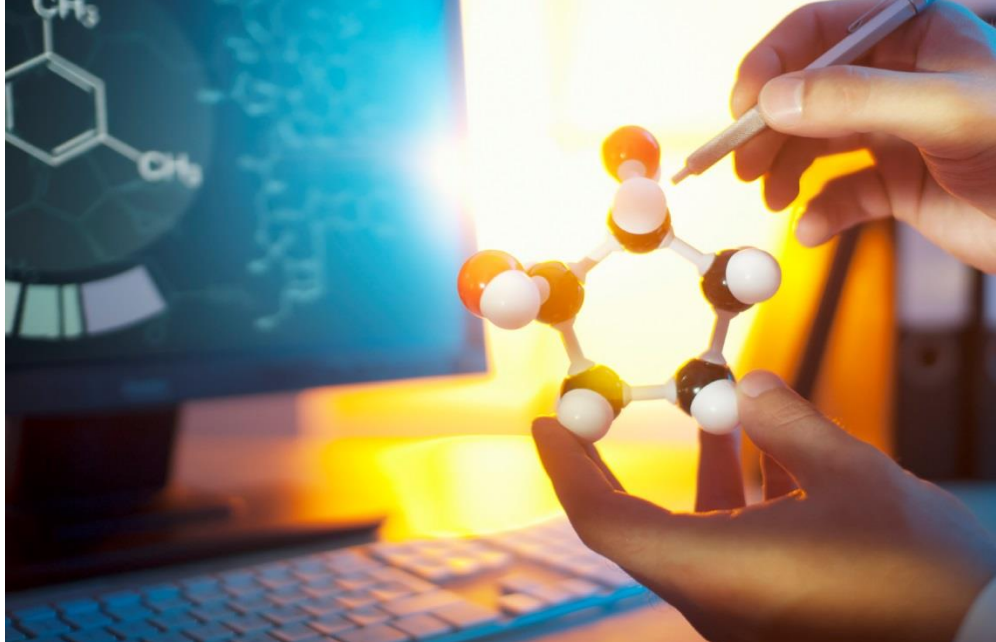
The study, like the smoking cessation study, is being conducted under IND (Investigational New Drug application). This means it has been carefully examined and approved by the US Food and Drug Administration for patient trial.

This trial is being funded by the US National Institutes of Health (NIH) (non-dilutive). Patient dosing is expected to be completed in the 1H 2016.

While mild asthma is not ultimately a commercial target for Invion, demonstrating the drug's safety and efficacy in this patient population will further pave the way for INV102 to be introduced as a new treatment for a wide range of airway diseases.

INV104 (zafirlukast)

Investors should also note the Company recently secured a commitment from international pharmaceutical company Hovione Scientia Limited to progress development of inhaled INV104 (zafirlukast) as a potential new treatment for asthma.



An oral version of this drug is already approved and has been administered to more than 4 million people to treat respiratory conditions.

This Hovione collaboration is designed to bring the first inhaled, dry powder version of zafirlukast to market using Hovione's proprietary inhalation hardware technology.

We expect that delivery of this non-steroidal drug in this way will provide superior benefit and bypass any problems currently associated with systemic delivery. This is a very attractive commercial proposition, with the global market for asthma therapeutics already in excess of \$22 billion per year.

Invion has received agreement from the FDA to accelerate development of our novel formulation and device.

We have made excellent progress along the formulation and manufacturing path, and at this time remain on track with our plan for clinical development towards approval – and potentially the ultimate approval and commercialisation of this drug.

Third Asset - INV103 (ala-Cpn10)

As shareholders will know, we are continuing partnering discussions for our third asset, INV103.

This naturally occurring human protein was recently the focus of a Phase 2 study in patients with the autoimmune disease, lupus.

Extensive analysis of trial results has shown relevant target cell activity and these findings are now included in a comprehensive data package that has been provided to potential pharmaceutical partners.

Finally

Finally, we again encourage investors to take part in this SPP opportunity. The offer will close on **7 December**, with new shares to be allotted on **10 December**.

Drug development and commercialisation is a laborious and complicated process, but we are encouraged by strong clinical results and remain confident in the science underpinning our lead programs.

From this basis, we look forward to delivering shareholder returns as we achieve next milestones or strike a partnership arrangement.

Thank you for your ongoing support,

A stylized, handwritten signature in blue ink, consisting of several loops and a long horizontal stroke at the end.

Dr Greg Collier
Managing Director and
Chief Executive Officer

Invin in the News

In the past two months there have been a number of articles released on Invin particularly following the announcement of positive data from the Phase 2 clinical trial of INV102 (nadolol) in patients trying to quit smoking

"Hoping the big pharma outfits will cough up"

Tim Boreham
The Australian
6 October 2015

"Drug trials show new 'quit' strategy"

The Australian
6 October 2015

"Invin eyes success with quit smoking drug"

Prashant Mehra
The Australian
The Sydney Morning Herald
NT News
Perth Now
The West Australian
6 October 2015

"Drug breathes life into asthma cure"

Courier Mail
6 October 2015

"Invin eyes success with quit smoking drug"

SBS News
6 October 2015

"INV102 phase II results"

Sky Business News
Broadcast Clip
6 October 2015

"Invin's kicking smoker's cough"

John Dagge
Herald Sun
6 October 2015

"Lung drug hope"

Grant McArthur
Herald Sun
6 October 2015

"The anti-smoking drug INV102 targets the damage to the smokers lungs. It is hoped it could be used for asthma and cystic fibrosis..."

3AW Broadcast clip
6 October 2015

Quit smoking drug 'treats respiratory illnesses as well'

Grant McArthur
Adelaide Advertiser
6 October 2015

"Quit smoking drug hopes"

Border Mail (Albury Wodonga)
Burnie Advocate
6 October 2015

"Invin eyes success with quit smoking drug"

Fiveaa Radio Adelaide
5 October 2015

"The Aussie drug that could really kick butt"

Geelong Advertiser
6 October 2015

"Invin smokin' hot"

Prashant Mehra
Gold Coast Bulletin
6 October 2015

"Quit smoking drug hopes"

Illawarra Mercury
Launceston Examiner
6 October 2015

"Invin completes Phase 2 study of Smoking Cessation Product"

M2 Pharma
5 October 2015

"Quitting success"

Hobart Mercury
6 October 2015

"Invin pushes to develop respiratory drug"

MSN
6 October 2015

"Invin Trial successful"

Newcastle Herald
6 October 2015

"Invin successfully completes phase 2 study of INV102 (nadolol) to aid smoking cessation"

Noodles
6 October 2015

"Phase 2 data show effectiveness of Invin's inhaled nadolol for smoking cessation"

OINDP News
6 October 2015

"Invin says Phase II trial of airway disease successful, pushes for further study"

The Pharma Letter
5 October 2015

"Invin Successfully Completes Phase 2 Study of INV102 (nadolol) To Aid Smoking Cessation"

The Street
6 October 2015

"Hope for Smokers"

Townsville Bulletin
6 October 2015

"Invin pushes to develop respiratory drug"

Trading Room
6 October 2015

"Invin-successfully completes phase 2 study of INV102 (nadolol) to aid smoking cessation"

4-traders
6 October 2015

"Invin trial successful"

Esperance Express
30 October 2015

"Invin trial successful"

Northern Daily Leader
31 October 2015

"New Drug to aid quitting"

Retail Pharmacy
6 November 2015

Invin is a life sciences company focussed on the development of treatments for major opportunities in respiratory and autoimmune disease.

Invin has three drug assets in development across four development programs:

INV102 (nadolol) is a beta adrenergic biased ligand targeted to reverse mucous metaplasia in the airway epithelium treat chronic inflammatory airway diseases. In Q4 2015, Invin reported that data from a 155 patient phase 2 study of oral INV102 in smoking cessation demonstrated good safety and that treated patients were more likely to stop smoking completely or dramatically reduce the number of cigarettes smoked. Feasibility for an inhaled version of the drug to potentially treat COPD and cystic fibrosis is well-progressed with 3M Drug Delivery Systems, and toxicological studies have commenced. In addition, a phase 2 study of oral INV102 in mild asthma patients funded by the US NIH is fully recruited and will complete dosing in 1H 2016.

INV104 (zafirlukast) is a leukotriene receptor antagonist (LTRA) that reduces inflammation, constriction of the airways, and the build-up of mucus in the lungs. An FDA-approved oral therapy, Invin is, through a joint development and licensing agreement with Hovione Scientia Limited, developing a proprietary dry powder formulation of the drug for the development of INV104 (zafirlukast) as a potential inhaled therapy for asthma.

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 hypothesised to maintain and restore immune homeostasis. Invin reported final data from its phase 2 clinical trial in lupus patients in Q3 2015. 30mg and 100mg iv twice weekly showed reduced response to stimulation by LPS after 1 month of dosing. These data, which reflect relevant activity at the target cell type in patients with a target (autoimmune) disease, has formed the foundation of partnering discussions for this program.

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With three drug assets in three phase 2 clinical trials across four development programs, Invin has achieved the following milestones in 2015 and is now in a good position to seek to realise value from its assets:

- ✓ Blind-broken interim data from phase 2 smoking cessation trial of INV102 (nadolol)
- ✓ Pre-IND status for inhaled INV102 (nadolol) as a potential therapy for asthma, COPD & cystic fibrosis
- ✓ Manufacture of toxicology and clinical supplies and commencement of toxicology studies for inhaled INV102 (nadolol)
- ✓ Data from phase 2 clinical trial of INV013 (ala-Cpn10) in lupus patients
- ✓ Selection of formulation and device for inhaled INV104 (zafirlukast)
- ✓ Commencement of manufacture of toxicology and clinical supplies for INV104 (zafirlukast)
- ✓ Completion of dosing in phase 2 smoking cessation trial of INV102 (nadolol)
- ✓ Positive safety and efficacy data from phase 2 oral INV102 (nadolol) study in patients undergoing smoking cessation
- ✓ Completion of enrolment of NIH-funded phase 2 study of INV102 (nadolol) in asthma patients

Analyst Research

In 2015, the following research has been published on Invin

Morgans Research Flash on Phase 2 results

Morgans Research, 5 October 2015

"Smoking is the Key"

Morgans Research, 4 September 2015

Van Leeuwenhoeck Research (US) Inc. initiates coverage on Invin

Van Leeuwenhoeck Research, 30 July 2015

"Smoking Hot"

Morgans Research, 4 February 2015

All research is available at <http://inviongroup.com/category/analyst-coverage>

