

AGM Presentation
November | 2016

Invion Limited (ASX:IVX)

Respiratory drug technologies targeting chronic airway disease

01

Asset 1: Nadolol

- Beta adrenergic biased ligand targeted to reverse mucous metaplasia in the airway epithelium
- Currently contraindicated, represents major shift in medical and scientific thinking around treatment of chronic airway disease
- Phase 2 Data from 155-patient P2 study in chronic bronchitis (smoking cessation) was reported to American Thoracic Society in May 2016. Good safety demonstrated, treated patients were more likely to stop smoking completely or dramatically reduce the number of cigarettes smoked; significant reduction of MUC5AC
- P2 study of nadolol in mild asthma reports 2H16, interim data shows good safety, no increased need for rescue medication
- Feasibility for inhaled nadolol to treat COPD, asthma and cystic fibrosis is well-progressed with 3M Drug Delivery Systems. Tox and clinical supplies manufactured, toxicological studies have commenced. Inhaled delivery will target airway directly, with less dosage.

02

Asset 2: Zafirlukast

- Leukotriene receptor antagonist (LTRA) that reduces inflammation, constriction of the airways and the build-up of mucus in the lungs
- FDA-approved oral therapy being reformulated as proprietary dry powder formulation through a joint development and licensing agreement with Hovione Scientia Limited

Platform development position: summary

Nadolol : capitalise on existing extensive research, strong data package and current medical and consumer sentiment for better, more effective therapies

- Oral: build on existing current strong research and data package via completion of POC study in asthma, COPD, cystic fibrosis
- Inhaled: utilise oral data package via completion of toxicology and P2 study in in COPD, asthma and cystic fibrosis

24 month target:


- Proof of concept for oral nadolol as a therapy for treatment of chronic airway disease
- P2 data for inhaled nadolol as a therapy for COPD, asthma and cystic fibrosis

Zafirlukast: capitalise on existing approved successful oral therapy and medical and consumer sentiment seeking safer therapies with fewer detrimental side effects

- FDA approved oral therapy. build on existing package through completion of toxicology studies and P2 clinical trials

24 month target:

- P2 data for inhaled zafirlukast as a therapy for asthma and exercise induced bronchospasm (EIB)

A hand holding a pen points towards a molecular model. The model consists of white, yellow, and orange spheres connected by rods, representing atoms and bonds. The background is a blurred laboratory setting with a chalkboard showing a chemical structure of a benzene ring with a methyl group (CH₃) attached. A green semi-transparent box is overlaid on the left side of the image, containing text.

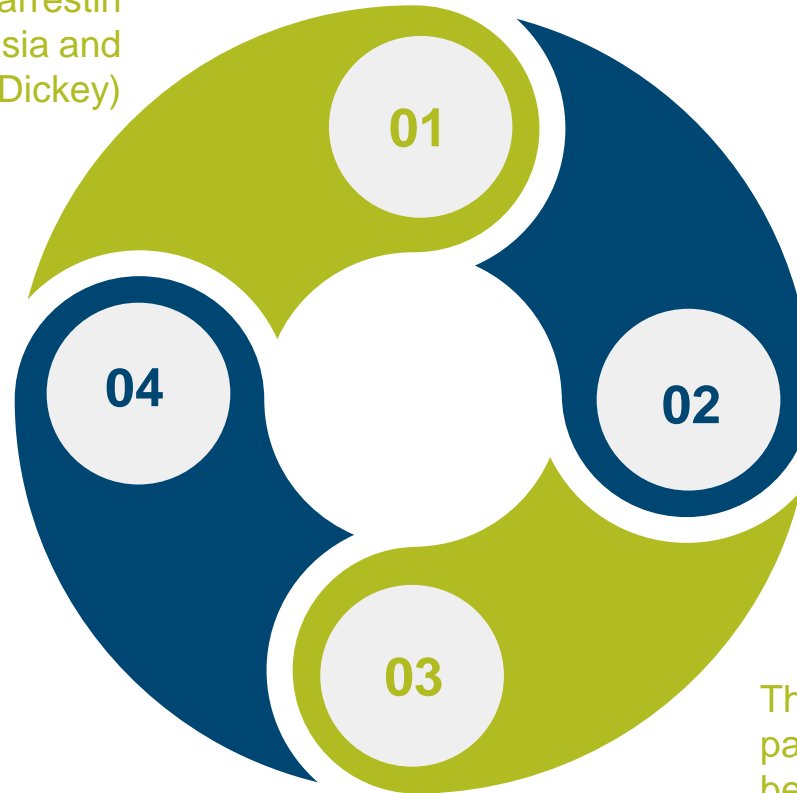
Nadolol Target: treatment of signs and symptoms of chronic airway disease via reduction of mucous production and airway healing

Nadolol directly targets pathway necessary for mucous metaplasia

External research shows

The necessary and sufficient role of the beta arrestin pathway in the development of mucous metaplasia and the chronic bronchitis phenotype (Bond, Dickey)

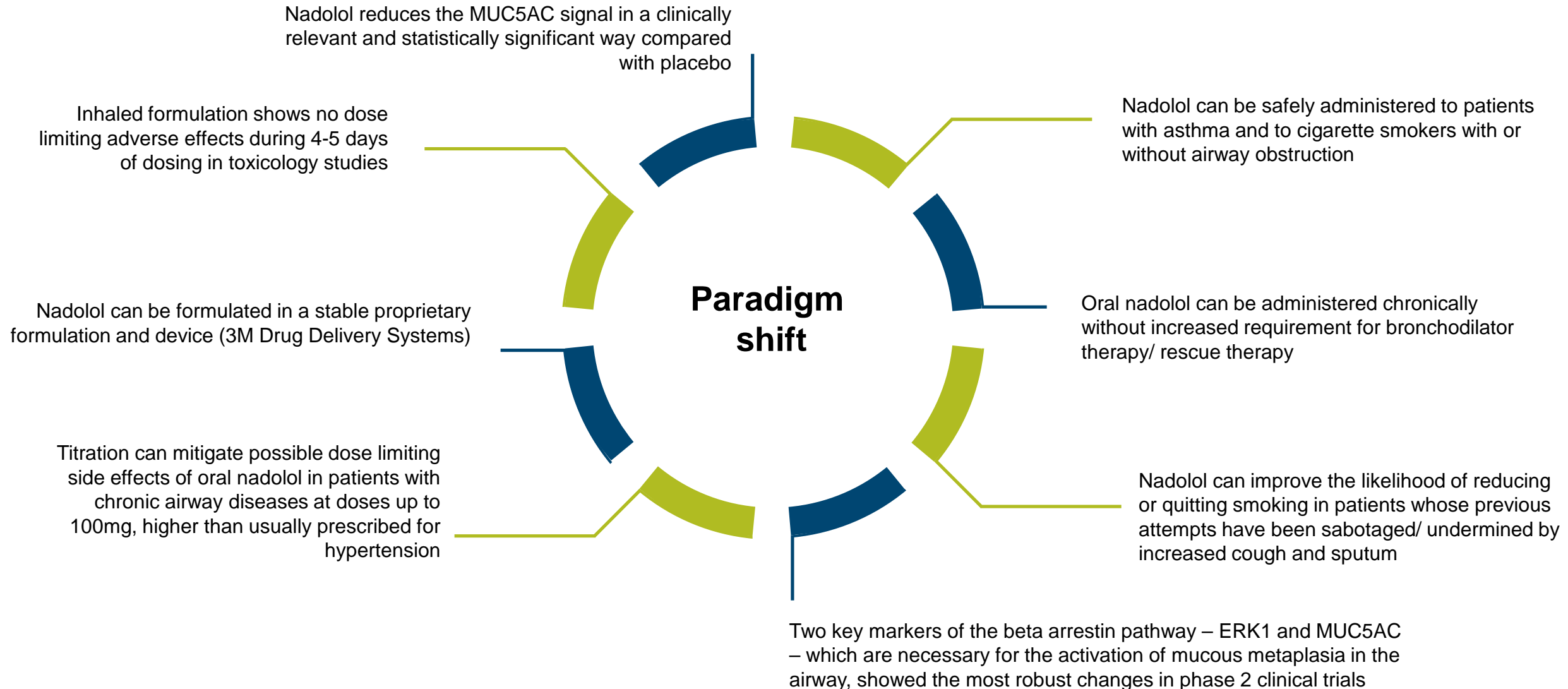
That propranolol an inverse agonist without biased ligand activity was ineffective in treating asthma (Short et al)



The role of biased ligand activity at the beta 2 receptor, which further separates nadolol from all other beta blockers (Lefkowitz: Nobel Prize in Chemistry 2012)

The unique chemistry of nadolol in blocking this pathway, i.e. that there are no other drugs with beta 2 receptor inverse agonism and biased ligand activity (Bond, Penn)

Invion research has demonstrated



Partnering opportunity: near term value inflection

Current asset status

FY 2016 – FY 2018

By mid calendar year 2019

Oral Nadolol

2 x POC studies in mild asthma (Hanania); Completed P2 in mild asthma (data 2H16)

P2 data in chronic bronchitis (smoking cessation) reported Q3 2015 – significant effect on MUC5AC

P2 (proof of concept) study: reduction of signs and symptoms of chronic airway disease
(\$1M over 2 years)


Proof of concept data for oral nadolol as a therapy for treatment of chronic airway disease

Inhaled Nadolol

Pre-IND status; toxicology and clinical supplies manufactured (3M Drug Delivery Systems); toxicology studies commenced (Charles River Laboratories)

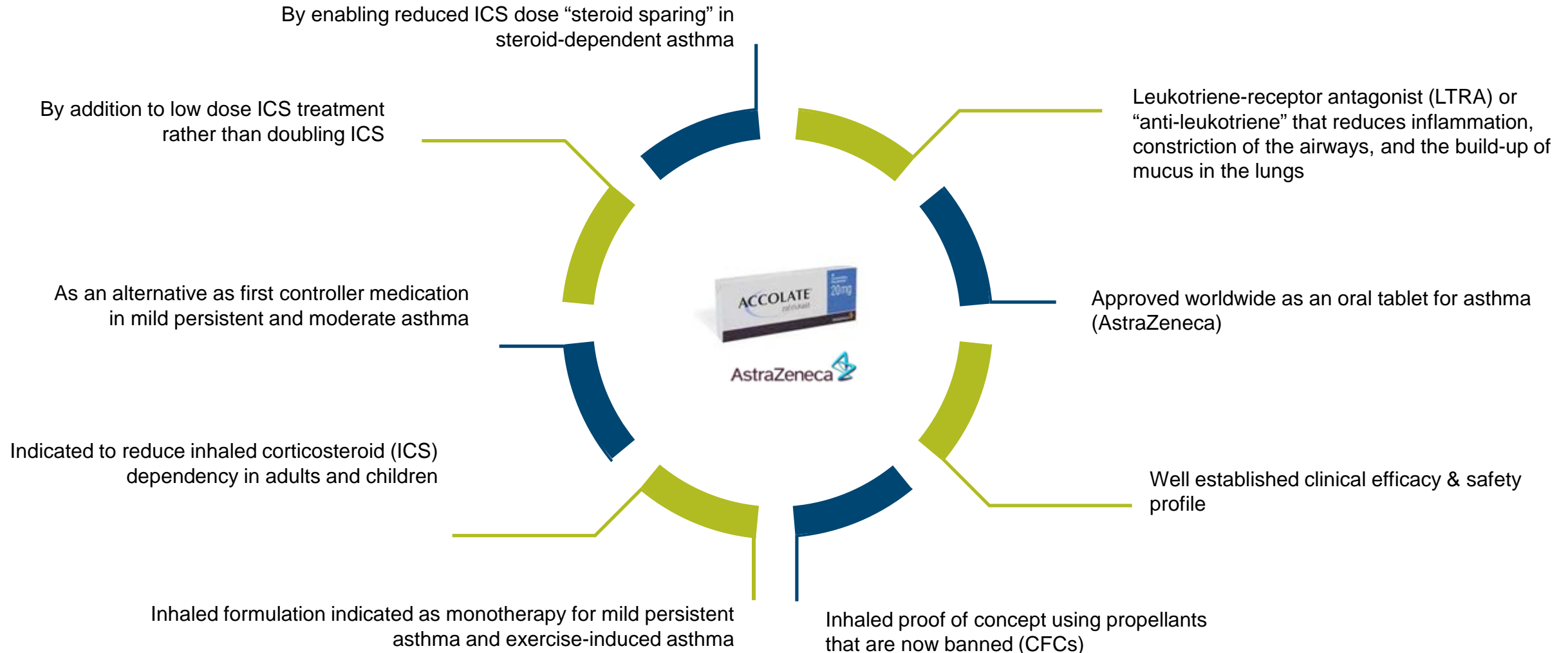
Completion of toxicology
P2 study: treatment of COPD, asthma and cystic fibrosis
(\$3.2M over 3 years)

P2 data for inhaled nadolol as a therapy for COPD, asthma and cystic fibrosis



Zafirlukast Target: inhaled non-steroidal anti-inflammatory treatment for asthma with delivery method that reduces/ eliminates systemic side effects

Inhaled reformulation of a successful oral therapeutic for asthma



Inhaled zafirlukast to address major unmet medical need

01 Current therapies linked to depression and psychotic episodes in children

02 Emerging consumer awareness and activism for better education and more detailed explanation of side effects

03 FDA Black box warnings exist

04 Inhaled zafirlukast can be delivered at 1/100th of oral dose thereby reducing systemic side effects

Framework for reformulation of zafirlukast

Agreement reached with FDA on:

- Chemistry manufacturing and controls (GMP)
- active pharmaceutical ingredient (API) with drug master file (DMF)
- formulation: dry powder inhaler (DPI) approved for development

Toxicology and bioanalytical Assay (GLP) to support 4 weeks' dosing

- 2 species for 28 days: naso-pulmonary exposure
- 1 species for 6 months

IND submission and clinical program

- Phase 1: single rising dose study for safety (paradoxical bronchoconstriction) & PK
- Phase 1: multiple dose safety study for safety & PK
- Phase 2: cold air, exercise and allergen [cat and ragweed]; steady state dosing for signs and symptoms of asthma [diary card] and attenuation of response to exercise and/or allergen

- Cash reserves of \$0.664 million at the end of September 2016
- Operating cash outflows have been reduced reflecting lower capital-intensive activity following the completion of major R&D program milestones
- Cash outflows during the September quarter were \$0.232 million
- The Company is driven to realise value from its assets via a commercial transaction following the successful completion of its major R&D milestones. Activities remain directed towards business development, and the partnering (via sale or out-licence) of one or all of its assets.

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