

22 November 2013

**INVION LIMITED AGM
CHAIRMAN'S ADDRESS & CEO PRESENTATION**

Invion Limited (ASX: IVX) is pleased to provide the Chairman's Address and CEO presentation for the 2013 Annual General Meeting of Shareholders being held this morning at 10.00am (AEST) at the offices of McCullough Robertson Lawyers, Level 11, 66 Eagle Street Brisbane.

Address to Shareholders by Dr Ralph Craven, Chairman.

I am very pleased to have the opportunity to speak with you again today, and feel privileged to say that this is my 3rd AGM addressing you as Chairman of this company.

We have come a long way from small beginnings to where we are today, a company for which I feel great positivity and enthusiasm. Our journey has been hard fought on a number of fronts; biotechnology is a highly regulated and complex sector to navigate successfully, but we are now positioned as a reputable company that has strong sector and investment presence and networks, and new, interested parties seeking to be a part of our growth.

This progression and our current standing are good for the company, and good for shareholders.

In addition to working to ensure good governance and strong oversight, your Board is focused on continuously adding value to Invion, and this has resulted during the year in movements both in management, and in strategic focus.

We are very fortunate to have secured a CEO of Greg Collier's standing and experience, as are we fortunate to have a Chief Medical Officer with the vast drug development and regulatory experience of Mitchell Glass. I thank them both for the progress they made this year.

In the last 12 months your company has initiated three phase II FDA-regulated clinical trials, and licenced a new compound for development.

Dr Collier will speak to these programs in more detail in his presentation, however I am pleased to stand before you and report that having three assets in development has de-risked our future growth prospects to a considerable extent.

We have made great strides in our autoimmune program with INV103, or Cpn10. Since we last met in this forum, an IND has been opened with the FDA, and a phase II trial in lupus patients is now well underway.

In our respiratory program, our phase II asthma trial of INV102 (nadolo) which is funded by the National Institutes of Health, has progressed well, and we look forward to interim information emerging in coming months.

Our smoking cessation program is enhanced, with data from this trial targeted to underpin our inhaled programs in COPD and cystic fibrosis.

We expect that in 2014 we shall significantly advance the preclinical inhaled programs of our respiratory franchise towards clinical status. This shall include the progression of INV104 (zafirlukast) which is targeted to be developed as the first inhaled, non-steroidal, anti-inflammatory treatment for asthma.

ASX ANNOUNCEMENT

It is appropriate that in this address I acknowledge the legal proceedings commenced in February 2012. As was last reported to you, the company has continued to meet all requirements and obligations to progress the matter expeditiously. There have, however, been a number of interlocutory hearings in recent months, which have caused delays to the process that are outside the company's control. Trial dates are now set down for May 2014, and the Board stands firm in its commitment to bringing the case to resolution as swiftly as possible.

Before closing, I take this opportunity to thank my colleagues on the Board, for their skill, enthusiasm and commitment to Invion. I thank the management and the staff of Invion, and I again thank you, our shareholders, for your continued interest and support.

About Invion Limited

Invion is a life sciences company focussed on the development of treatments for major opportunities in respiratory disease and autoimmune disease. The Group has three drug assets in development, and three phase II clinical trials, regulated by the Food & Drug Administration (FDA), currently underway in the United States. **INV102 (nadolol)** a beta blocker (*beta adrenergic inverse agonist*) 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) or *anti-leukotriene* 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 hypothesised to maintain and restore immune homeostasis. Invion is an ASX listed company (ASX:IVX), with its clinical headquarters in Delaware, USA.

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Invion Limited (ASX:IVX)

Clinical-stage life sciences company targeting chronic inflammation



Targeting inflammation

Disclaimer

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Invion: targeting inflammation

- > 3 drug candidates in development
 - > Developing two new respiratory franchises
 - > INV102 (nadolol): *beta blocker* being repurposed to treat inflammatory airway diseases asthma, COPD, cystic fibrosis and smoking cessation failures
 - > INV104 (zafirlukast): inhaled *anti-leukotriene* that reduces inflammation, constriction of the airways, and the build-up of mucus in the lungs
 - > An early partnering opportunity
 - > INV103 (ala-Cpn10): modified, *naturally occurring human protein* hypothesised to reduce inflammatory markers to maintain and restore immune homeostasis
- > 3 FDA-regulated phase II clinical trials currently underway

Management team with proven track record

Invion's management and board have significant experience repurposing drugs for new markets and guiding drugs through FDA regulatory and approval processes.

Greg Collier, PhD., Managing Director and Chief Executive Officer

- > 20 year career in pharma research, development and commercialisation
- > CEO ChemGenex Pharmaceuticals (sold to Cephalon \$230M)
- > 150 peer reviewed publications, 33 patents
- > Roche Award for Excellence

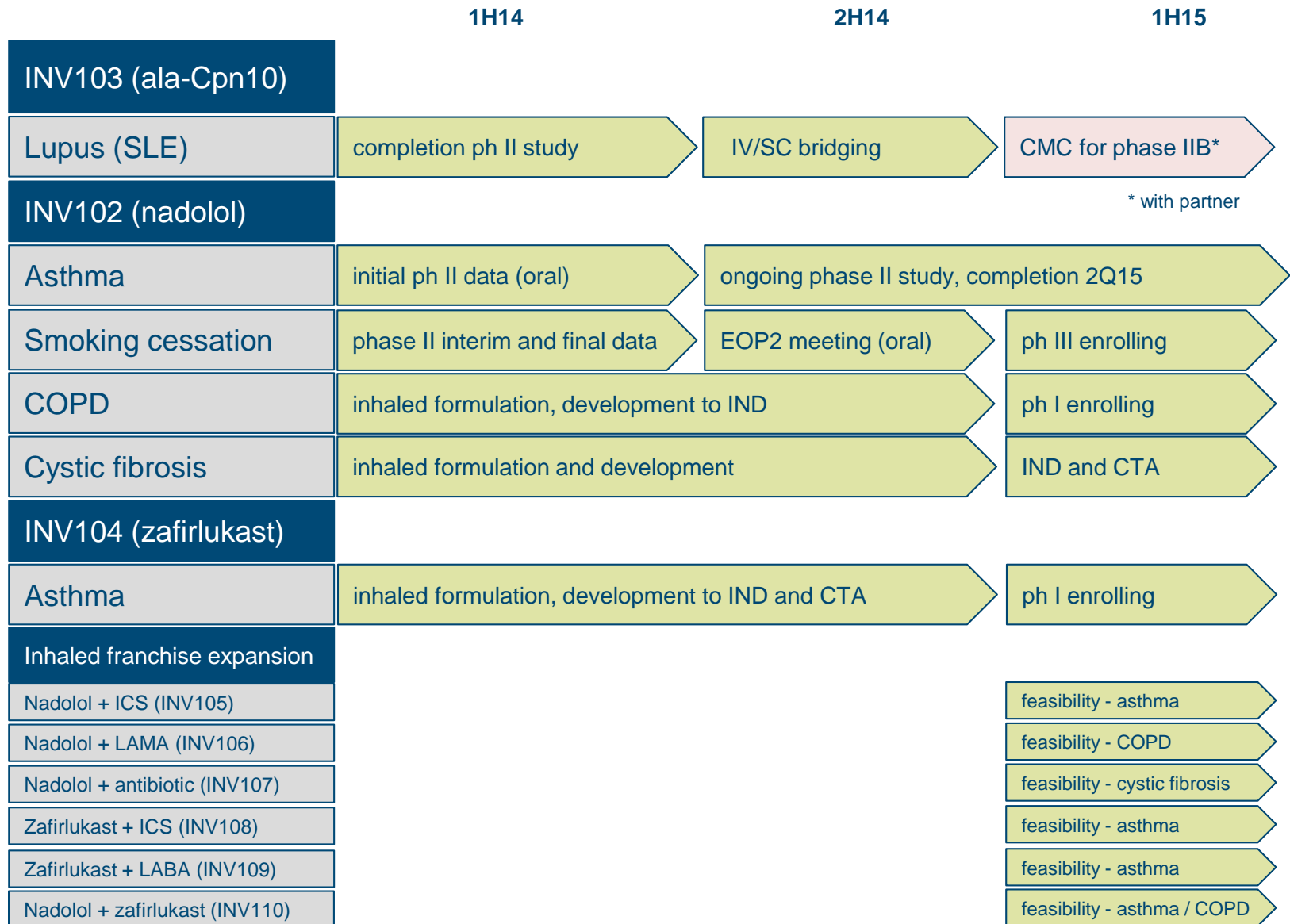
Mitchell Glass, M.D., Executive VP R&D and Chief Medical Officer

- > 5 FDA approved drugs
- > Managed more than 40 drug developments including "first in class"
 - > Led development of beta blocker carvedilol (Coreg)
 - > Led development phases I - III of oral zafirlukast (Accolate)
- > Board certified pulmonary and critical care specialist
- > 25 year veteran of Pharma (AZ, GSK) and Biotech (AGIX)

Current pipeline: three phase II underway

| | preclinical | phase I | phase II |
|-----------------------------|-------------|--|----------|
| INV103 (ala-Cpn10) | | | |
| Lupus (SLE) | | PK, safety and IL-6 reduction; for partnering | |
| INV102 (nadolol) | | | |
| Asthma | | NIH funded, US\$4m non-dilutive (oral program) | |
| Smoking cessation | | in patients with established COPD (oral program) | |
| COPD | | inhaled delivery | |
| Cystic fibrosis | | inhaled delivery | |
| INV104 (zafirlukast) | | | |
| Asthma | | inhaled delivery | |

18 month pipeline



INVION

Targeting inflammation

Targeting autoimmune disease

INV103 (ala-Cpn10): modified natural human protein

INV103 (ala-Cpn10): background and rationale

- > Minimally modified form of naturally occurring protein
- > Maintains heptameric structure and function
- > Intracellular function: prevent protein misfolding
- > Extracellular function: Cpn10 proposed as a founding member of the Resolution Associated Molecular Pattern (RAMPs) family (Shields et al, Clin Exp Immunol, 2011, 165: 292-300)
 - > Hypothesis: Maintain and restore homeostasis
 - > Critical component of prevention of autoimmunity
 - > Area of intense interest in immunology
- > Significant clinical data base > 250 patients
 - > demonstrated anti-inflammatory and immunoregulatory activity in multiple indications including RA, psoriasis
- > Strong pre-clinical data in lupus animal model (3 studies)
 - > reduced renal and circulating levels of key pro-inflammatory mediators (TNF- α , IL-6 and MCP-1) reduced CD4+ T cells and auto-reactive T cells and increased the number of activated DC (critical in the establishment of self tolerance)
- > Toxicology support through 3 months' dosing
- > Intellectual Property position: composition of matter protection in all major markets (US 2026)

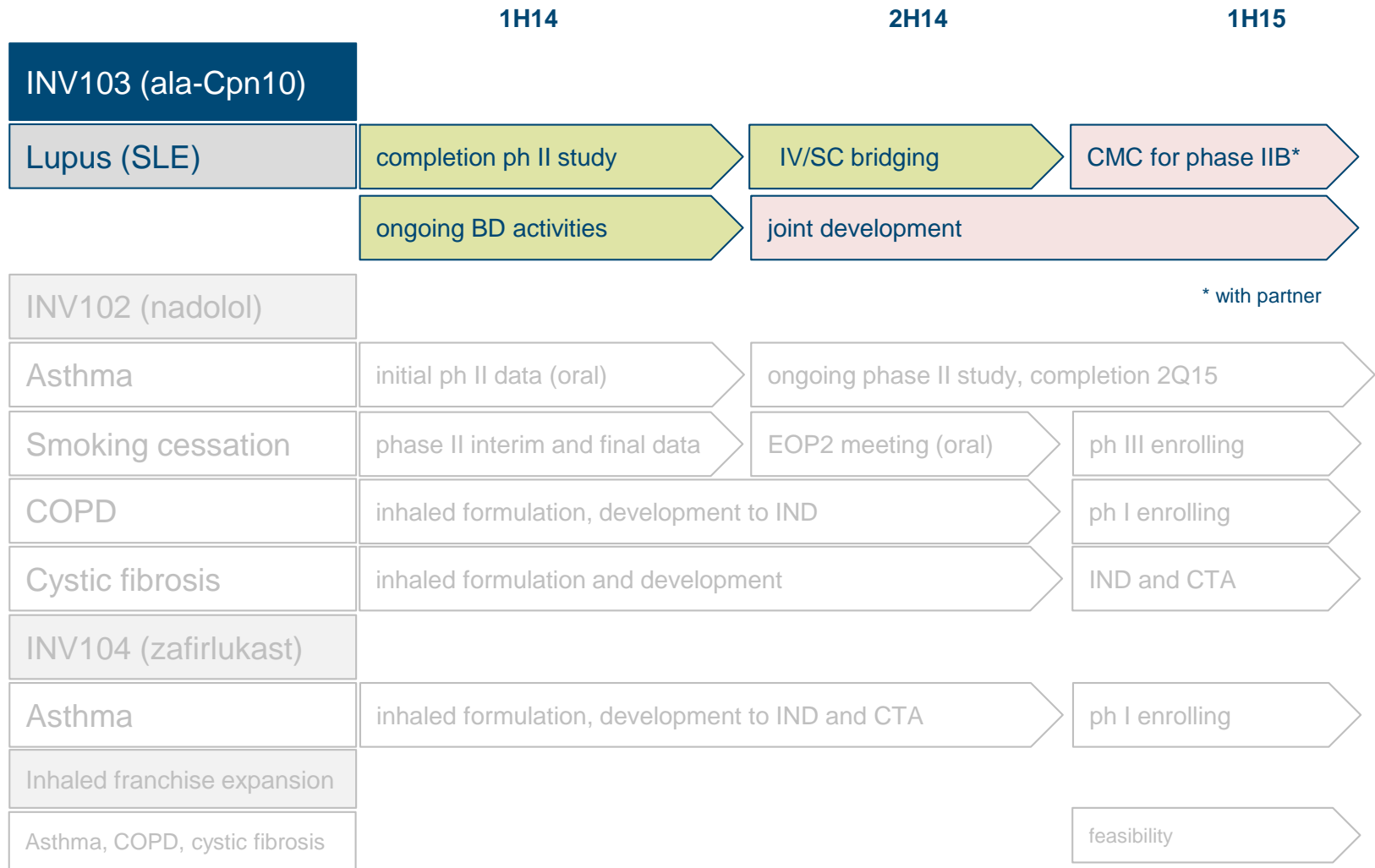
INV103: completed clinical trials

| Phase | Indication | Route | Total patients | INV103 patients | Doses |
|-------|----------------------|-------|----------------|-----------------|---------------------------------|
| 1a | Healthy volunteers | IV/SC | 19 | 14 | 1.2, 5.5, 10mg IV 5mg SC |
| 1b | Multiple Sclerosis | IV | 12 | 9 | 2.5 or 5mg, 5 doses |
| 2a | Multiple Sclerosis | IV | 50 | 39 | Placebo, 5mg |
| 2 | Ulcerative Colitis | IV | 8 | 8 | 5mg 2x weekly |
| 2a | Plaque Psoriasis | IV | 24 | 24 | 5, 7.5 or 10mg 2x weekly |
| 2a | Rheumatoid Arthritis | IV | 23 | 23 | 5, 7.5 or 10mg 2x weekly |
| 1a | Healthy volunteers | SC | 24 | 16 | 10,30,60,100mg sc |
| 1a | Healthy volunteers | SC | 22 | 17 | 30, 30x2, 60, 60x2, 80mg/weekly |
| 2a | Rheumatoid Arthritis | SC | 155 | 105 | Placebo, 25mg, 75mg 2x weekly |

INV103: phase II trial design – lupus

| | |
|------------------------|--|
| Trial name | INV103 (ala-Cpn10) in mildly active Systemic Lupus Erythematosus (lupus) |
| Trial design | Double-blinded, randomized, placebo-controlled, intravenous dosing |
| Patients | 32 subjects (8 subjects per dose cohort, 4 cohorts) |
| Timing | Commenced Q3 2013 Initial data Q4 2013 |
| Inclusion criteria | Mild lupus without clinical kidney disease |
| Principal Investigator | Alan Kivitz, M.D., Stanley Cohen, M.D. |
| Sites | Altoona, Pennsylvania; Dallas, Texas |
| Doses | 10 mg - 300mg twice weekly |
| Primary endpoint | Reduction from baseline serum IL-6 levels |
| Safety endpoints | Safety and toxicity; pharmacokinetics; assessment of anti-drug antibodies |
| Exploratory endpoints | SELENA-SLEDAI score (disease activity index); pharmacodynamics; markers of systemic inflammation and vascular damage |
| Comment | Clinical program under US IND |
| Regulatory Status | www.clinicaltrials.gov ID: NCT01838694 |

INV103: milestones



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Targeting inflammation

Targeting respiratory disease

Two proprietary and unique respiratory franchises

INVION

Targeting inflammation

Respiratory therapeutics: oral program

INV102 in asthma and COPD (smoking cessation)

INV102 (nadolol)

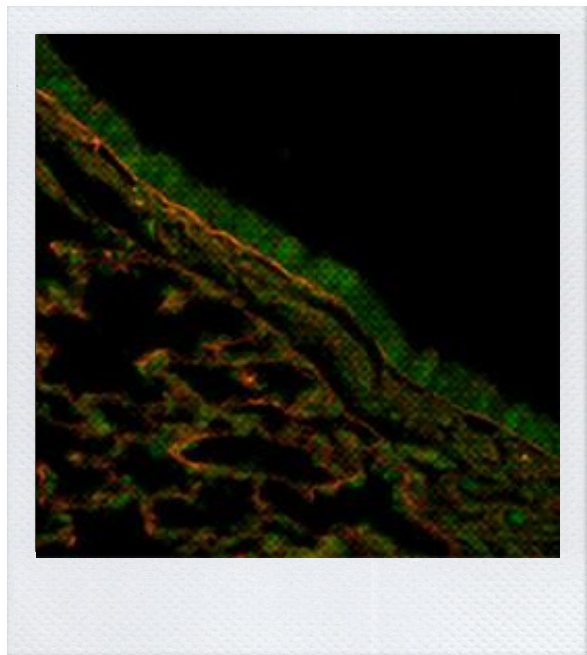
- > Generic drug being repurposed for a new target
- > Suite of patents granted and in prosecution
- > Aim to develop an inhaled drug for the treatment of respiratory diseases including asthma and COPD
- > Short term path to commercialisation with oral treatment

- > Nadolol is uniquely an inverse β -agonist in the airway
 - > inactivates intracellular inflammatory events that are stimulated
 - > spontaneously or
 - > by β agonists

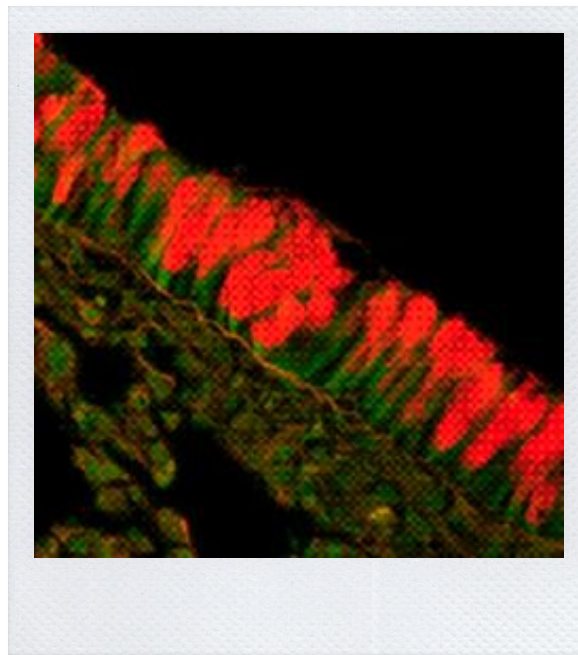
- > Clinical data to date
 - > Two phase II clinical trials completed
 - > Safety profile enhanced by titration starting at very low doses
 - > Dose-related reduction of airway hyper-responsiveness

- > Goals of oral INV102 (nadolol) program
 - > Asthma program (phases II and III) is NIH funded
 - > Invion utilises this program to provide data support for its inhaled program
 - > Smoking cessation program is a 'speed to market' strategy with primary goal of providing data to support the inhaled program

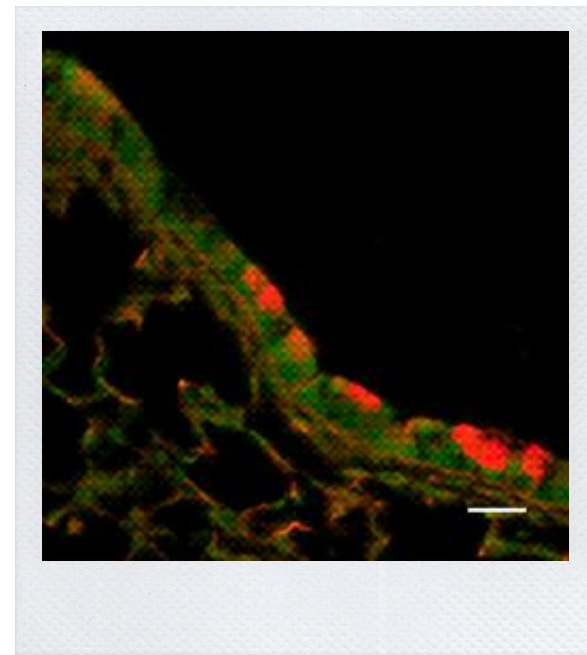
Preclinical studies demonstrate airway healing



Control lung tissue



Lung tissue of 'asthmatic' mice: epithelial cells have been converted to mucus-producing goblet cells. No effect of alprenolol.



Lung tissue of 'asthmatic' mice **treated with INV102 (nadolol)** for 28 days: **restored epithelium**

Proof of concept has been achieved in pre-clinical studies with inhaled INV102

Medical, regulatory and commercial precedent

Precedent: Chronic Heart Failure (CHF)

FROM

CONTRAINDICATED

Warning against use of beta blockers in CHF for > 25 years.
Carvedilol annual sales (1998) \$40m



TO

STANDARD OF CARE

After careful titration, beta blocker **Carvedilol** reduced mortality in all classes of CHF
First in class: Carvedilol peak annual sales \$1.5 BILLION (2010)

Invion target: Chronic Obstructive Pulmonary Disease (COPD)

FROM

CONTRAINDICATED

Warning against use of beta blockers in COPD for > 25 years.
Nadolol current sales: \$ nominal (generic)



TO

STANDARD OF CARE

After careful titration, beta blocker **INV102 (nadolol)** targeted to reduce airflow obstruction due to damaged airways.
Target: First in class

NOTE: The effect of INV102 (nadolol) on airways cells is unique among β blockers. β_1 success in the heart (CHF) mitigates the risk of β_2 success in the lung (COPD)

Completed two phase II clinical trials: POC

- > **Objective:** Proof-of-concept to evaluate safety and effects on airway with escalating doses administered to 19 subjects with mild asthma
- > **Primary endpoint:** Objective measure of airway hyper-responsiveness (PC20 MeChFEV1), the diagnostic hallmark of asthma
- > **Key Findings:**
 - > Safety: well tolerated in doses up to 40mg
 - > Efficacy: airway hyper-responsiveness:
 - > dose response with ineffective dose at 10mg/day
 - > 9 -10 weeks of treatment produced a dose-dependent decrease in airway hyper-responsiveness that achieved clinically significant improvement
 - > Lung function:
 - > attenuation of first dose decrease in FEV1 by titration
 - > same benefit and commercial strategy as Coreg in CHF
 - > Findings led US NIH to fund larger phase II study in asthma patients

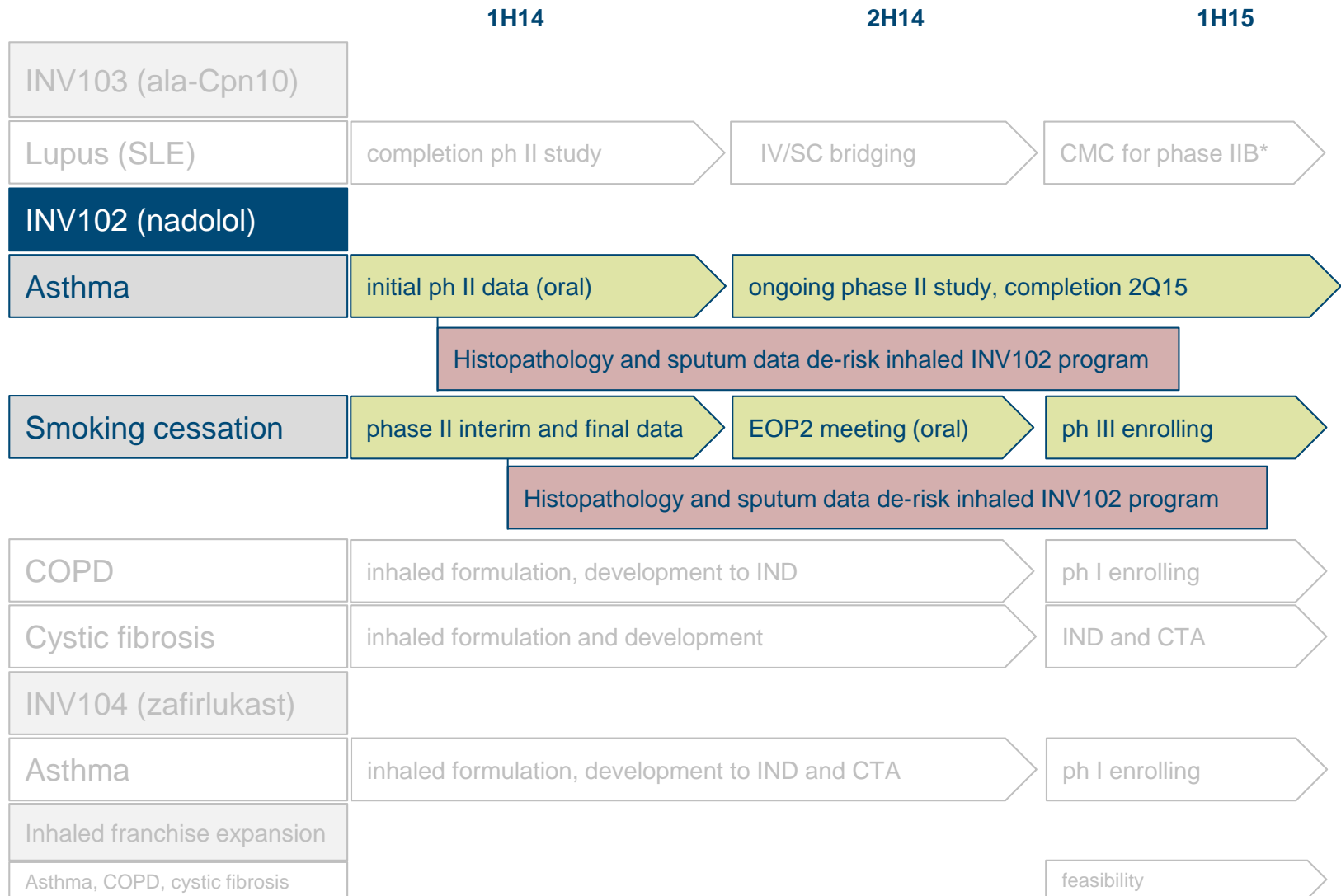
INV102: phase II trial design – smoking cessation

| | |
|------------------------|---|
| Trial name | INV102 (nadolo) in smoking cessation of patients with pre-existing COPD |
| Trial design | Double-blinded, randomised, placebo-controlled |
| Patients | 130 (65 per arm: 54 needed for analysis) |
| Timing | Commenced Q3 2013 Initial data 1H 2014 |
| Inclusion criteria | Previously failed to quit, have COPD and chronic cough |
| Principal Investigator | Prof Mario Castro |
| Sites | Washington University (St Louis) |
| Doses | 2.5mg, 5mg, 10mg, 25mg, 50mg (dose titration) |
| Primary endpoints | Abstinence from smoking in last 2 weeks of trial |
| Secondary endpoints | Number of cigarette-free days; clinical COPD questionnaire; MMRC Dyspnea Scale; markers of COPD; sputum markers of COPD |
| Safety endpoints | Change in FEV1; requirement for rescue medication; COPD exacerbation rate |
| Comment | Data will support broader oral and inhaled development program |
| Regulatory Status | www.clinicaltrials.gov ID: NCT01825122 |

INV102: phase II trial design – mild asthma

| | |
|------------------------|--|
| Trial name | INV102 (nadolol) in mild asthma (NIMA) |
| Trial design | Double-blinded, randomised, placebo-controlled, multi-centre |
| Patients | 60 subjects (30 subjects in each of two treatment arms) |
| Timing | Commenced Q1 2013 Expected completion 2015 |
| Inclusion criteria | Mild asthma: only β agonists as needed |
| Principal Investigator | Nicola A. Hanania, M.D., M.S., Baylor College of Medicine |
| Sites | Baylor, Washington University, Duke University |
| Doses | 1.25mg, 2.5mg, 5mg, 10mg, 25mg, 50mg (dose titration) |
| Primary endpoints | Improved airway hyper-responsiveness via change in methacholine PC20 (based on FEV1) |
| Safety endpoints | Safety of titration and 6 months' dosing |
| Exploratory endpoints | Reduced airway inflammation and mucous metaplasia; increased β 2AR density, affinity and signaling in airway epithelial cells; change in exhaled (eNO) |
| Comment | Clinical program under US IND (submitted Feb '07) |
| Regulatory Status | www.clinicaltrials.gov ID: NCT01804218 |

Oral program: milestones



INVION

Targeting inflammation

Respiratory therapeutics: inhaled program

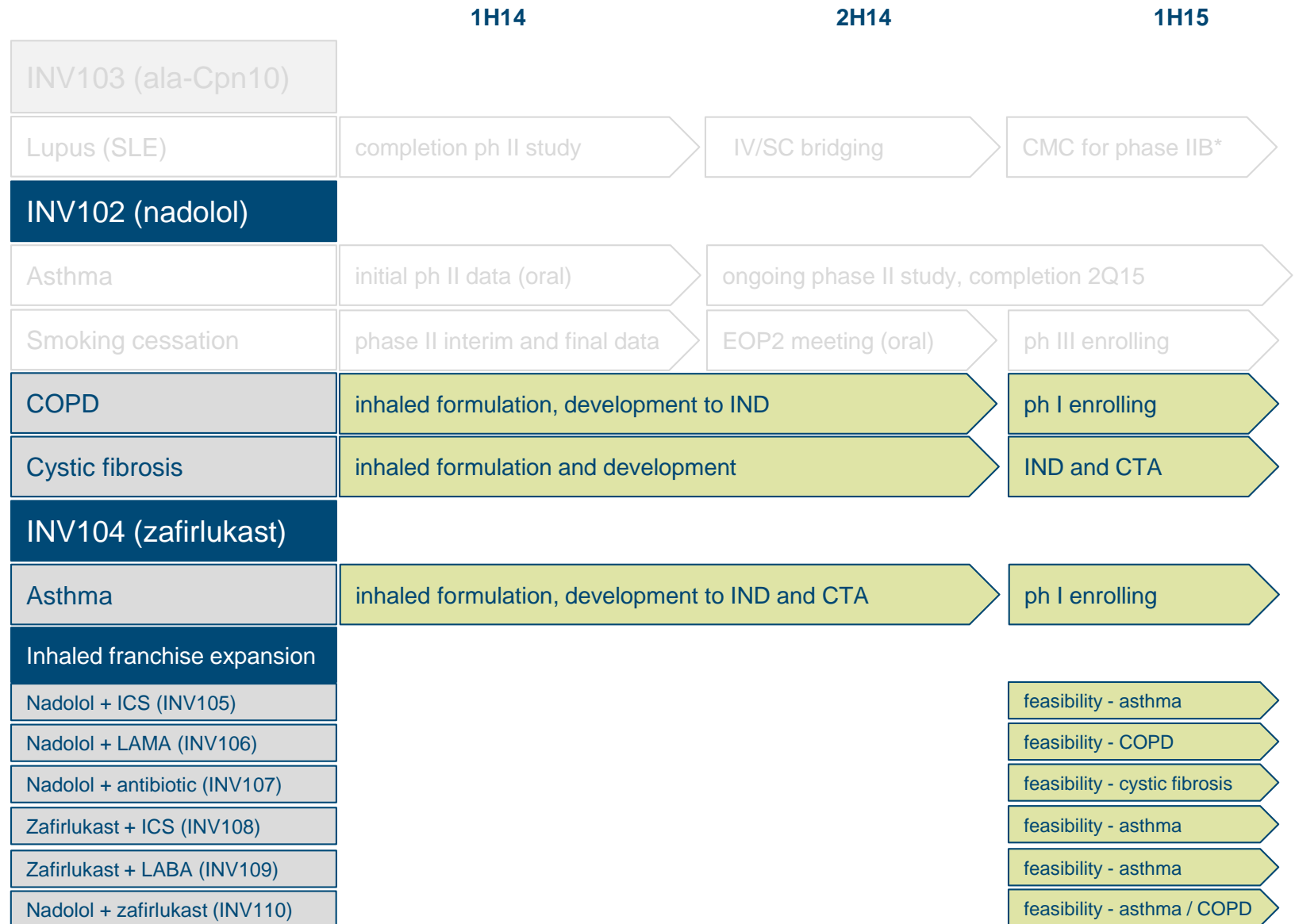
INV102 (nadolol) in COPD & cystic fibrosis

INV104 (zafirlukast) in asthma

INV102: inhaled development targets

- > Develop franchise across broad range of respiratory inflammation
 - > realize full value of franchise
- > **INV102 monotherapy**
 - > COPD (chronic bronchitis): signs and symptoms followed by reduction of exacerbations
 - > Cystic fibrosis (EU)
- > **INV102 combination therapy**
 - > Nadolol + ICS (INV105): severe asthma
 - > Nadolol + LAMA (INV106): COPD
 - > Nadolol + antibiotics (INV107): cystic fibrosis

Inhaled program: development plan



INV104 (zafirlukast)

- > *Leukotriene Receptor Antagonist (LTRA) or anti-leukotriene*
- > Targeted as first inhaled non-steroidal anti-inflammatory treatment for asthma
- > Established activity by inhalation route with excellent flow and deposition (MDI and DPI)
- > Large market potential with mitigated risk of a reformulated drug

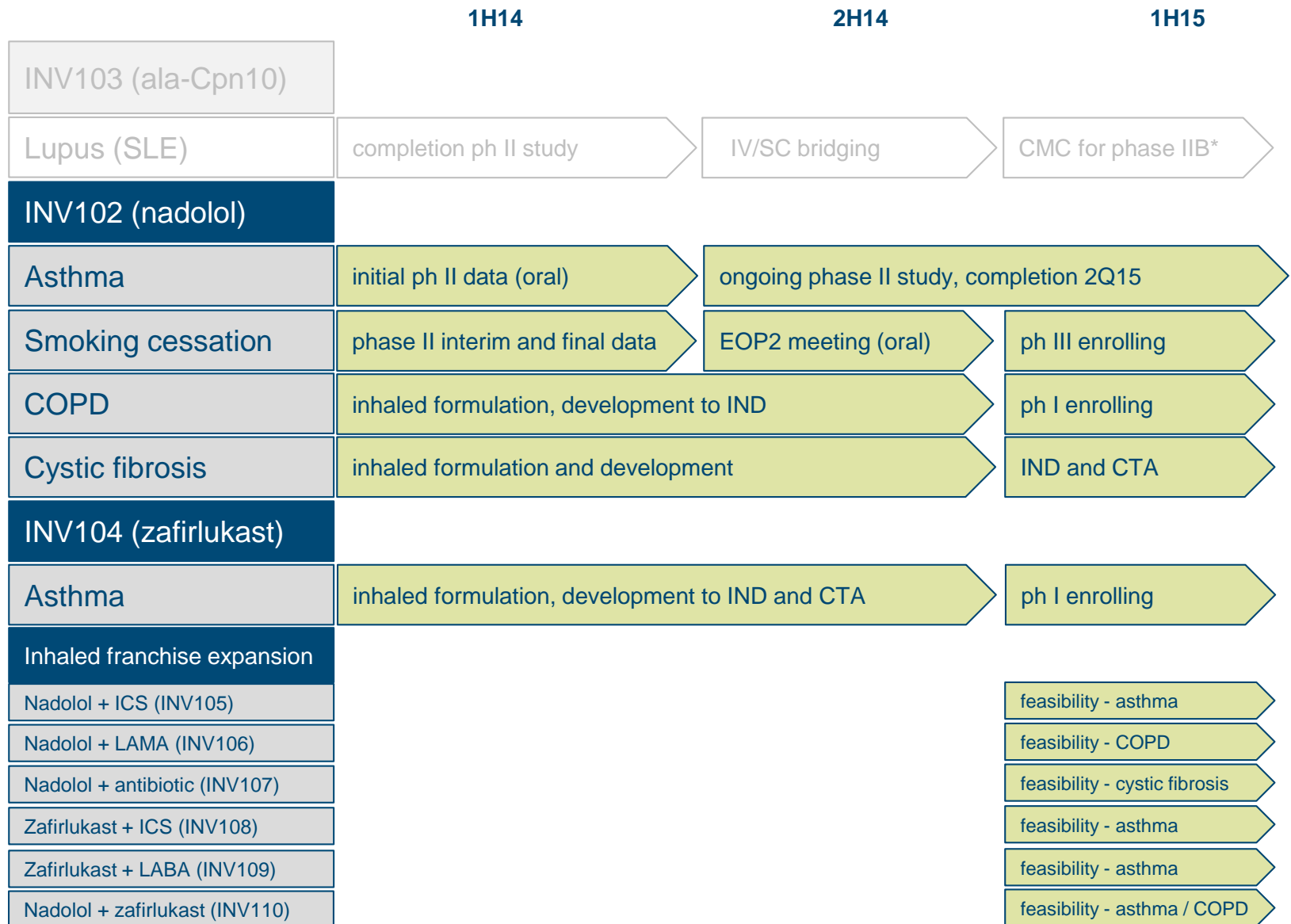
- > Data to date
 - > Well defined CMC/TOX/ADME and safety profile: > 4M patients as oral Accolate (AZ)
 - > 7 studies showed excellent prevention of asthma, cold air and exercise induced bronchospasm (EIB) without detectable drug blood levels
 - > FDA response to pre-IND meeting requires limited toxicology package
 - > 2 species x 28 days + 6 months, 1 species

- > Intellectual Property position
 - > Expired zafirlukast patents (public domain)
 - > New patent protection from combination, delivery, and linked diagnostic filings

INV104: inhaled development targets

- > Develop non-steroidal anti-inflammatory therapeutics franchise across broad range of respiratory inflammation targets
- > **INV104 monotherapy**
 - > Inhaled zafirlukast for mild to moderate asthma marked by atopy
 - > Inhaled zafirlukast for exercise-induced bronchospasm
 - > Inhaled zafirlukast leukotriene-driven asthma (e.g. triad asthma)
- > **INV104 combination therapy**
 - > Zafirlukast + ICS (INV108): moderate asthma (pure anti-inflammatory combination)
 - > Zafirlukast + LABA (INV109): pediatric asthma
 - > Zafirlukast + nadolol (INV110): asthma/ COPD

Respiratory franchise: oral & inhaled programs



Invion is developing a robust respiratory franchise

- > Two drugs: INV102 (nadolol) and INV104 (zafirlukast)
- > Multiple opportunities for new patents
- > Proprietary doses and formulations
- > Synergies in development expertise and know how
 - > GMP requirements: Chemistry and Manufacturing
 - > GLP requirements: Toxicology and pharmacokinetics (including NO blood levels)
 - > Clinical studies
 - > KOLs
- > Integrated plan for next 18 months

INVION

Targeting inflammation

Summary

- ✓ 3 drug assets with multiple paths to market
- ✓ early partnering opportunity for INV103 (ala-Cpn10)
- ✓ two de-risked novel and proprietary inhaled respiratory franchises
- ✓ 3 FDA-regulated phase II clinical trials
- ✓ experienced management team
- ✓ significant valuation drivers: 12-18 months

Corporate snapshot

| Sector | Life Sciences (Biotechnology) |
|-------------------------------------|--|
| Principal activities | Clinical-stage pharmaceutical drug development |
| Pipeline | 3 drug assets, multiple clinical and pre-clinical programs |
| Operations | Australia & USA |
| ASX code | IVX |
| Share price (12-Nov-13) | \$0.12 (12 cents) |
| Shares on issue | ~463M |
| Options on issue | ~31M |
| Market cap (12-Nov-13) | \$55M |
| Cash at bank (30-Jun-13) | \$3.03M |
| Anticipated R&D tax credit inflow | \$1.46M |
| Cash burn (12 months to 30-June-13) | ~\$6M |



Targeting inflammation

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CEO presentation
2013 AGM