Invion Limited (ASX:IVX)

Clinical-stage life sciences company targeting chronic inflammation

Investor Presentation
March | 2015

Overview

1. **Revised strategy**
   - To position company for near term strategic partnership or trade sale
2. **New funding arrangements**
   - Conclusion of facility with The Australian Special Opportunity Fund
   - New R&D Tax rebate debt facility with Metamor Capital Partners
   - Further support with unsecured loans from Invion directors
3. **Capital raising**
   - Placement and non-renounceable entitlement offer
   - Underwritten by Morgans Corporate Limited and Patersons Securities Limited
4. **Next milestones**

Strategy update

Strategic streamlining of operations

- Refocus on core activities required to achieve key near to mid-term milestones and value-drivers.

- These include:
  - completion of enrolment and dosing and receipt of data in the phase II clinical trial of INV103 (ala-Cpn10) in lupus patients;
  - completion of dosing and receipt of data in the phase II clinical trial of oral INV102 (nadolol) in smoking cessation;
  - completion of feasibility, production of tox and phase I clinical supplies, and pre-IND status for inhaled INV102 (nadolol); and
  - selection of formulation and device for inhaled INV104 (zafirlukast) and partnering the program

Position company for strategic investment or trade sale

- Invion is currently completing its INV103 (ala-Cpn10) and INV102 (nadolol) programs, with pivotal data anticipated within 3-4 months. Based on recent transactions in the industry it is anticipated that this data will enable the Company to negotiate a strategic investment by a recognised biotech fund, or provide a platform for the sale of the Company or its assets within 6 months.

Funding arrangements

Share Purchase & Convertible Security agreement (SPCSA) with The Australian Special Opportunity Fund (ASOF)

- As part of the update to strategy, the Company has mutually agreed to conclude the SPCSA with ASOF, effective on 24 March 2015. The existing convertible security and all other outstanding liabilities will be repaid.

- As compensation for the conclusion of the SPCSA, ASOF will retain existing shares and options, and receive a new convertible note to the value of $250,000. This Note cannot be converted until after 15 December 2015, with some minor exceptions (e.g. change of control, share price >5c).

Funding from directors

- Additional unsecured (non-equity related) debt funding provided by Invion directors for working capital and for repayment of outstanding liabilities under the SPSCA.

R&D tax offset funding

- Agreement with Metamor Capital Partners to access capital ahead of the anticipated receipt of its R&D Tax incentive rebate. This funding facility provides Invion with a valuable capital management tool as it moves towards completion of current R&D activities and continues its partnering plans.

- This non-dilutive (non-equity related) secured facility has a limit of A$1.56M and is due for repayment in full by 30 October 2016 from the proceeds of the Company's anticipated R&D Tax incentive refund for the 2015 financial year.

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Capital raising overview

Placement and underwritten non-renounceable entitlement offer

Offer overview

Offer Details

- A Placement to institutional and sophisticated investors of approximately 35.8 million shares at an Offer Price of 2.5 cents per new ordinary share to raise approximately $895,000 to be followed by Entitlement Offer to existing shareholders targeted to raise approximately $4.1 million.

Pricing

- The Offer Price of 2.5 cents represents a 36% discount to the closing price on 11 March 2015 of 3.9 cents.

Use of funds

- These funds are budgeted to last until the end of Q3 2015 which will be following the expected release of pivotal clinical data relating to the INV103 (ala-Cpn10) and INV102 (nadolol) programs (anticipated within 3-4 months). It is expected that positive clinical data from one or both of these trials will position the company to negotiate a strategic investment in the company by a recognised biotech fund or provide a platform for a trade sale of the company or its assets.

Other

- New securities issued pursuant to the Placement will rank equally with Invion's existing securities.
- Morgans Corporate Limited and Patersons Securities Limited are underwriters and Joint Lead Managers to the Offer.

Estimated use of funds

$000's	Mar-Aug 2015
Opening cash	1.009
Capital raising *	4.976
R&D Tax Rebate funding facility	1.489
Other income	0.405
Total funds available	**7.880**
Outflows	
Program spend in INV103 (ala-Cpn10) **	0.628
Program spend in INV102 (nadolol) **	2.625
Program spend on inhaled respiratory franchise **	1.941
Operating expenditure	
-- Australian corporate salaries and director fees	0.122
-- US R&D salaries and director fees	0.573
-- Compliance (ASX, audit, share registry) , consultants (accounting, tax, legal, commercial) and other operating expenses	0.799
Settling of liabilities to SPCSA ***	0.430
Capital raising costs (including costs of R&D tax rebate facility)	0.558
Total outflow	**7.678**

** It is expected that this capital raising will fund the Company to the point of obtaining significant data that will position the Company to negotiate a strategic investment in the Company by a recognised biotech fund, or provide a platform for the sale of the Company or the assets of the Company.*

*** These amounts include current trade creditors for these programs*

**** As part of the update to strategy, the Company has concluded the Share Purchase and Convertible Security Agreement with The Australian Special Opportunity Fund, effective on 24 March 2015, with the existing convertible security and all other outstanding liabilities to be repaid.*

Timetable

Activity	Date
Announcement of the Placement and Entitlement Offer	20 March 2015
Mailing of the Entitlement Offer details	23 March 2015
Ex-date	24 March 2015
Record Date for Entitlement Offer (7.00pm (Sydney time))	26 March 2015
Information Booklet and Entitlement & Acceptance Form despatched	30 March 2015
Entitlement Offer opens	30 March 2015
Closing date for acceptances under Entitlement Offer (5.00pm (Sydney time))	17 April 2015
New Shares quoted on deferred settlement basis	20 April 2015
Company notifies ASX of under subscriptions	22 April 2015
Allotment of New Shares under the Entitlement Offer	24 April 2015
Despatch of holding statements for New Shares issued under the Entitlement Offer	27 April 2015
Normal ASX trading for New Shares issued under the Entitlement Offer commences	27 April 2015

This timetable is indicative only and subject to change. The Directors may vary these dates, in consultation with the Joint Lead Managers, subject to the Listing Rules. The last date to extend the closing date is 14 April 2015. An extension of the Closing Date will delay the anticipated date for issue of the New Shares. The Directors also reserve the right not to proceed with the whole or part of the Entitlement Offer any time prior to issue of the New Shares. In that event, the relevant Application Monies (without interest) will be returned in full to Applicants.

Pro forma Balance Sheet

	31-Dec-14 Historical	Placement	Entitlement Offer	31-Dec-14 Pro forma Historical
	$	$	$	$
Current Assets				
Cash and cash equivalents	1,909,903	830,088[a]	3,781,200[b]	6,521,191
Trade and other receivables	1,328,358	-	-	1,328,358
Other current assets	84,938	-	-	84,938
Total Current Assets	**3,323,199**	**830,088**	**3,781,200**	**7,934,487**
Non-Current Assets				
Trade and other receivables	73,705	-	-	73,705
Property, plant and equipment	31,300	-	-	31,300
Intangible assets	11,535,284	-	-	11,535,284
Total Non-Current Assets	**11,640,289**			**11,640,289**
Total Assets	**14,963,488**	**830,088**	**3,781,200**	**19,574,776**
Current Liabilities				
Trade and other payables	2,172,144	-	-	2,172,144
Financial liabilities	1,508,954	-	-	1,508,954
Short-term provisions	79,499	-	-	79,499
Total Current Liabilities	**3,760,597**	**-**	**-**	**3,760,597**
Non-Current Liabilities				
Deferred tax liabilities	4,437,299			4,437,299
Long-term provisions	16,957	-	-	16,957
Total Non-Current Liabilities	**4,454,256**	**-**	**-**	**4,454,256**
Total Liabilities	**8,214,853**	-	**-**	**8,214,853**
Net Assets	**6,748,635**	**830,088**	**3,781,200**	**11,359,923**
Equity				
Issued capital	113,466,852	830,088	3,781,200	118,078,140
Reserves	22,203,929	-	-	22,203,929
Accumulated losses	(128,922,146)	-	-	(128,922,146)
Total Equity	**6,748,635**	**830,088**	**3,781,200**	**11,359,923**

Notes to the Pro Forma Balance Sheet:

Pro Forma Adjustments
The Pro Forma Historical Financial Information has been derived from the Historical Financial Information and has been prepared on the basis that the following significant transactions occurred as at 31 December 2014:

Material transactions since 31 December 2014:

a) The issue of 35,826,290 New Shares under the Placement, raising gross proceeds of $895,757 less expenses of $65,669.

The Entitlement Offer:

b) The issue of 163,213,389 New Shares under the Entitlement Offer, expected to raise gross proceeds of $4,080,335 less estimated Offer Costs of $299,135.

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Company overview and key milestones

Invion: targeting inflammation

Invion: targeting inflammation

- Global life sciences group in pharmaceutical drug development
- Expertise and assets target chronic inflammation in two key areas of human health:
  - inflammatory airways disease (respiratory disease)
  - inflammation caused by autoimmune disease
- Executive Directors with proven track record
  - Dr Greg Collier, MD & CEO: former MD & CEO ChemGenex Pharmaceuticals (sold to Cephalon $230M); 150+ peer reviewed publications; Roche Award for Excellence
  - Dr Mitchell Glass, EVP R&D & CMO: 5 FDA-approved drugs, senior executive roles at AZ & GSK, Board certified pulmonary and critical care specialist
- Growing a broad pipeline of drug assets that target improved patient outcomes and major commercial opportunities
- Operations: Brisbane, Australia; Delaware, USA

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Invion's assets

Respiratory

- **INV102 (nadolol)**: a beta blocker (beta adrenergic biased ligand) currently used to treat high blood pressure, coronary chest pain (angina) and migraine, is being repurposed to treat chronic inflammatory airway diseases (e.g. asthma and COPD).

- **INV104 (zafirlukast**): a leukotriene receptor antagonist (LTRA) that reduces inflammation, constriction of the airways and the build-up of mucus in the lungs, is being developed as an inhaled therapy to treat asthma in adults and children.

    - INV102 & INV104 are the foundations of Invion's inhaled respiratory drug franchise

Autoimmune

- **INV103 (ala-Cpn10)**: a modified naturally occurring human protein and member of the Resolution Associated Molecular Pattern (RAMPs) family, hypothesised to maintain and restore immune homeostasis, is being developed to treat systemic lupus erythematosus (lupus or SLE).

    - Early partnering opportunity

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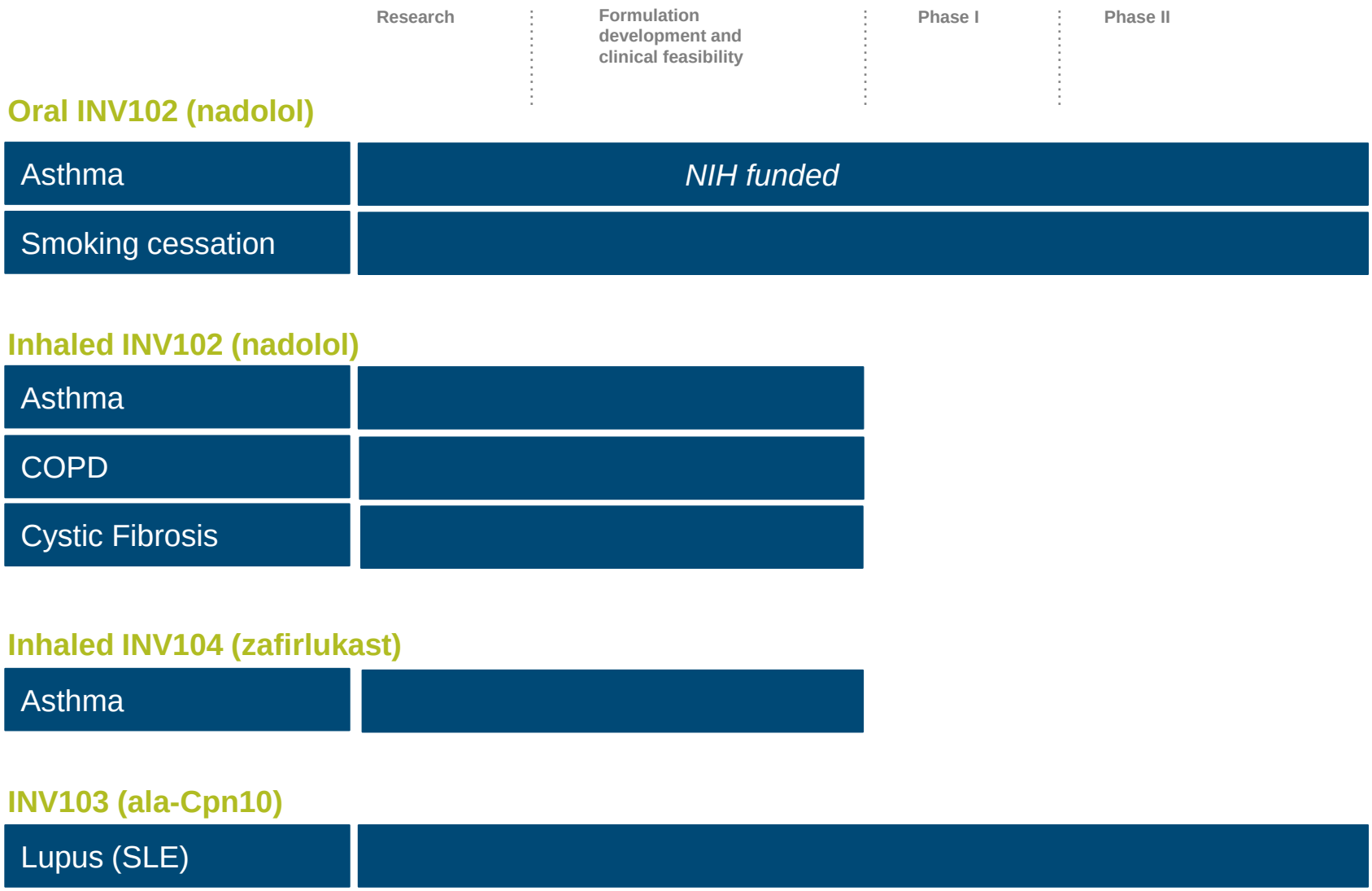
Pipeline


Research
Formulation development and clinical feasibility
Phase I
Phase II
Oral INV102 (nadolol)
Asthma
NIH funded
Smoking cessation
Inhaled INV102 (nadolol)
Asthma
COPD
Cystic Fibrosis
Inhaled INV104 (zafirlukast)
Asthma
INV103 (ala-Cpn10)
Lupus (SLE)

Recent INV102 (nadolol) milestones and clinical data

- Phase II smoking cessation trial blind-broken interim data released Jan 15. Clinically relevant changes in four biomarkers of inflammation demonstrated:
  - **IL-8**, a powerful chemoattractant 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.
- Full trial enrolment announced 2 Feb 15

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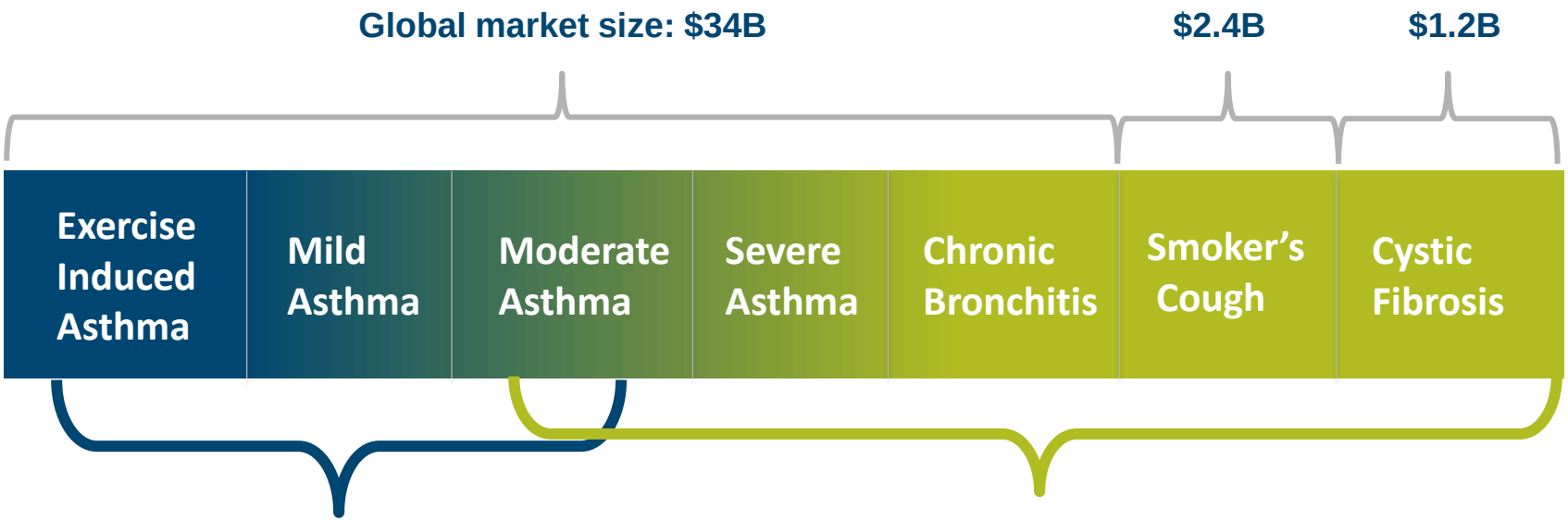
Targeting chronic inflammatory airway disease

INV102 (nadolol)

INV104 (zafirlukast)

Spectrum of airway disease and opportunities



INV104 (zafirlukast)
Monotherapy + combinations

INV102 (nadolol)
Monotherapy + combinations

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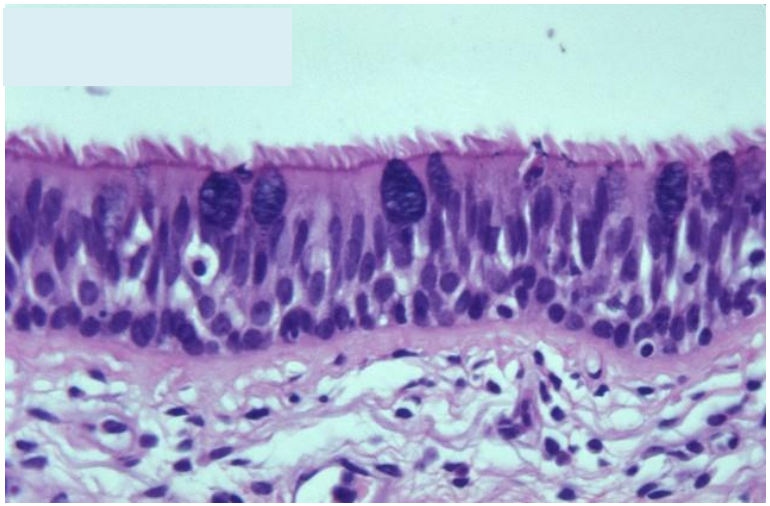
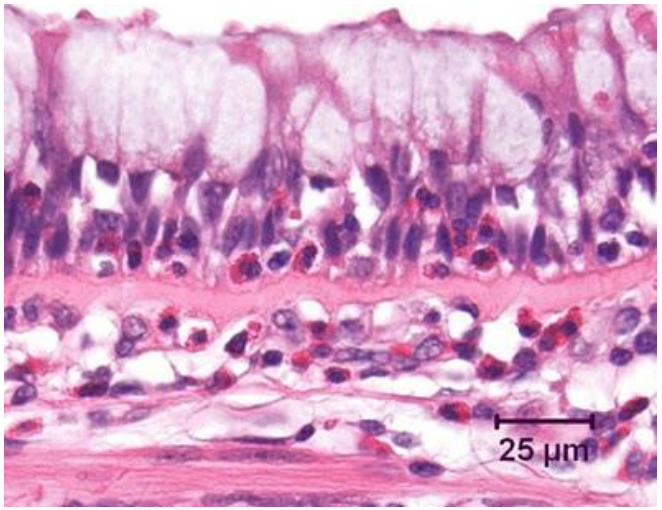
The critical role of the epithelium in severe airway disease

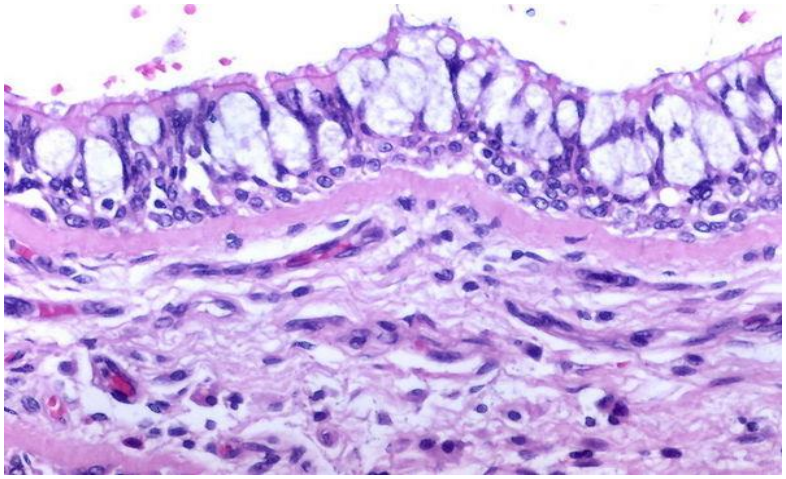
Normal respiratory epithelium



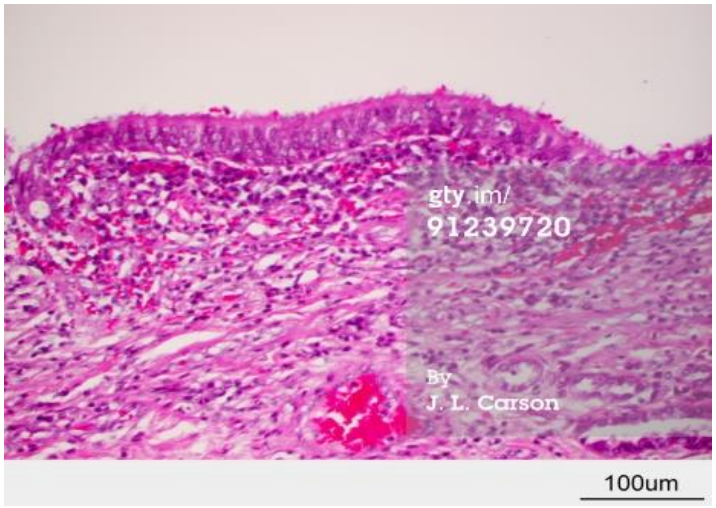
Severe asthma



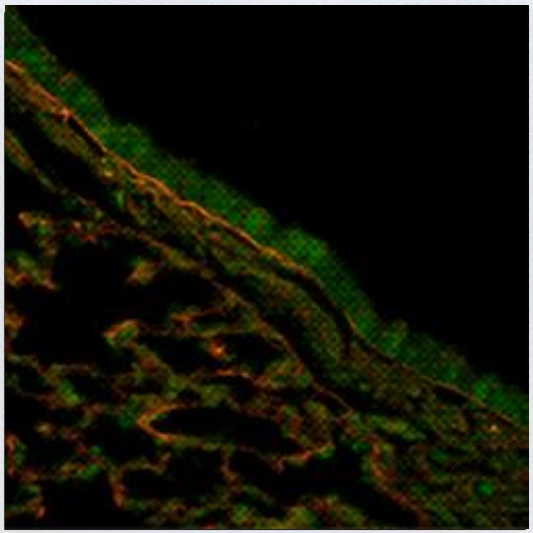
Chronic bronchitis



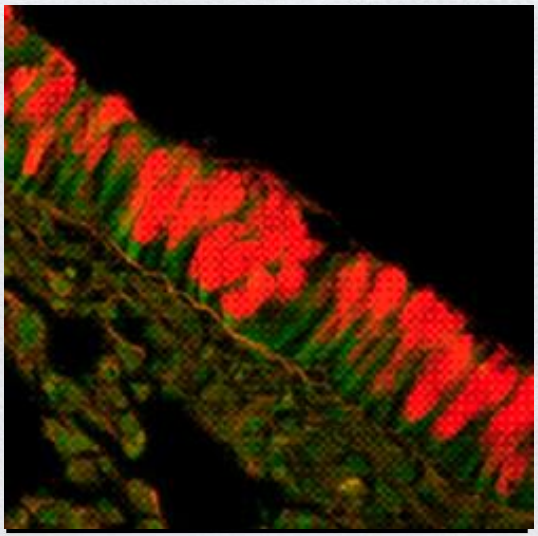
Cystic fibrosis



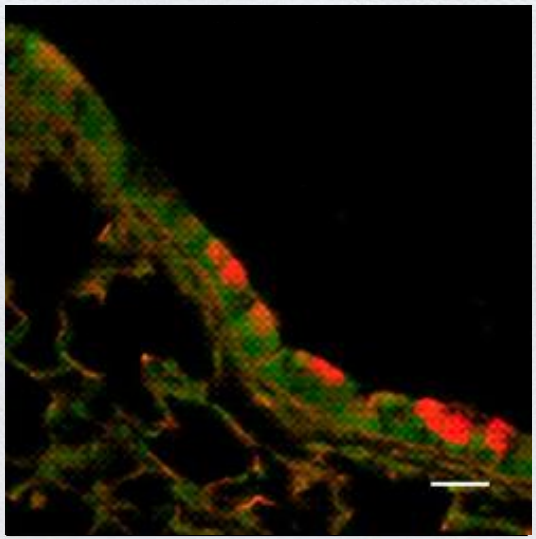
INV102 reverses epithelial changes in pre-clinical studies



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**

Reference: Nguyen LP., et.al., 2011. Complementary anti-inflammatory effects of a β-blocker and a corticosteroid in an asthma model. Arch Pharmacol. 2011: Oct 2.

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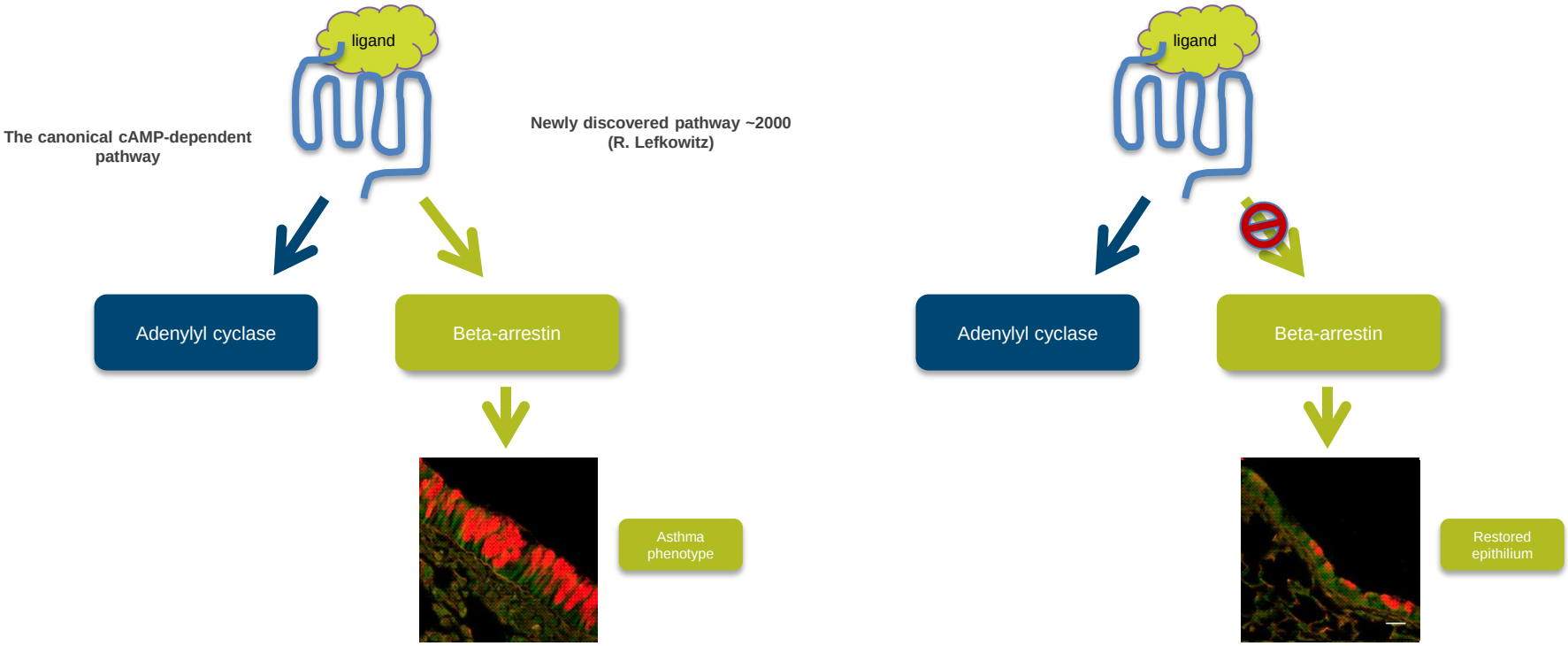
INV102 reverses epithelial changes via inhibition of the beta-arrestin pathway

- INV102 development is based on the science of Richard A. Bond PhD, Professor of Pharmacology, U Houston. In collaboration with nobel-prize winning Robert Lefkowitz, Dr Bond undertook studies on the spontaneous activity of G-protein-coupled receptors and compounds functioning as inverse agonists. Dr Bond's research has demonstrated that INV102 has been shown to inhibit the beta-arrestin signalling pathway.



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Respiratory therapeutics: oral program

INV102 (nadolol)

Oral INV102: emerging phase II clinical data

Phase II asthma trial (NIMA): interim analysis

- Randomised, placebo-controlled, 60 patient clinical trial in patients with mild asthma
- High % of patients (> 90%) tolerated titration to maximum possible dose without severe adverse events
- No pattern of cardiovascular or respiratory effects in patients during the four hours of observation required after each titration dose
- Patients demonstrated no requirement to increase rescue medication usage – provided either as a short-acting beta-agonist (SABA) or as an anti-muscarinic agent
- Next milestone: completion of enrolment anticipated 2H 2015 per NIAID

Phase II smoking cessation trial: status

- Randomised, placebo-controlled, 136 patient clinical trial in patients with chronic cough due to smoking who have failed to quit multiple times previously
- Q1 2015 sputum sample analysis showed positive effects of Nadolol versus placebo on airway inflammation and blockade of beta arrestin pathway
- Sputum data supports ongoing development of inhaled INV102
- Enrolment completed Jan 2015
- Data package to support partnering discussions EOPII meeting targeted for 2H2015
- Next milestones: completion of dosing anticipated 1H2015

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Respiratory therapeutics: inhaled program

INV102 (nadolol) in asthma, COPD & cystic fibrosis

INV104 (zafirlukast) in asthma

Inhaled INV102: program status

- Collaboration with 3M Drug Delivery systems
- Target outcome: proprietary formulation and device using 3M's proprietary pressurised metered dose inhalation (pMDI) technology
- Collaboration encompasses manufacture for toxicology and phase I studies
- Formulation and device selected
- Toxicology supplies manufactured
- Clinical supply manufacturing underway

Inhaled INV104: program status

- First inhaled non-steroidal anti-inflammatory drug for asthma
- Ongoing collaboration to develop proprietary formulation and device
- Largely risk mitigated development based on chemistry, inhaled toxicology and inhaled proof of concept studies conducted by ICI/ Zeneca under Mitchell Glass
- 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

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Targeting chronic inflammation caused by autoimmune disease

INV103 (ala-Cpn10)

INV103 phase II lupus trial: interim blinded data

- Double-blind, randomised, placebo-controlled clinical trial in lupus patients. Up to 40 subjects in up to 5 cohorts (8 patients per cohort), increasing dose and increasing disease severity. Doses 10mg, 30mg, 100mg, 300mg
- Data analysed from lower dose cohorts - 10mg and 30mg twice weekly dosing
- Good safety demonstrated – no pattern of adverse events
- Safety profile now supportive of concurrent testing of:
    1. higher doses – 100mg twice-weekly is a tenfold increase over previously tested highest doses; and
    2. patients with more severe disease – i.e. showing signs of renal impairment

- Business development and partnering activities geared towards maximising potential commercial opportunities from emerging data

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Invion: key milestones next 6-8 months

1H 2015

- ✓ Blind-broken interim data from phase II smoking cessation trial
- ✓ Completion of enrolment of INV102 oral (nadolol) in smoking cessation
- > Pre-IND status for inhaled INV102 (nadolol) as a potential therapy for asthma, COPD & cystic fibrosis
- > Manufacture toxicology supplies and commencement of toxicology studies for inhaled INV102 (nadolol)
- > Full enrolment and completion of dosing in phase II study of INV103 (ala-Cpn10) in lupus patients
- > Selection of formulation and device for inhaled INV104 (zafirlukast)

2H 2015

- > Completion and final data from phase II oral INV102 (nadolol) study in patients undergoing smoking cessation
- > Completion of enrolment of NIH-funded phase II study of INV102 (nadolol) in asthma patients

*The information above (and where reflected elsewhere in this presentation) sets out indicative timeframes and assumes:

1. Invion will continue to obtain the full benefit of the available R&D tax incentive for its eligible R&D activities and clinical trials.
2. The studies will proceed based on budgeted costs, assuming normal patient recruitment and clinical trial timelines, and with no material regulatory hurdles.
3. Ordinary R&D expenditure will continue broadly at the same levels as for past financial years.

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Key risks for investors

- **Funding risk** – the development of the respiratory franchise which includes progress to phase III clinical trials for oral INV102 (nadolol) in smoking cessation; plus the development of two inhaled drugs (INV102 & INV104) are the primary drivers of cash requirements in the coming 2 to 3 years. It is estimated $10 to $20 million will be required to complete phase III oral INV102, and reach phase II in the inhaled INV102 and inhaled INV104 programs. The funds raised under the Equity Raising are budgeted to last until the end of Q3 2015. To the extent the Company does not find an appropriate partner for its programs or an appropriate opportunity for the sale of the Company or the Company's assets, it may need to raise further funds, which may not be available when required or only available on unfavourable terms.

- **Clinical trial risk** - Invion's ability to obtain regulatory approval for its products and profitably commercialise its products is dependent upon its ability to conduct successful clinical trials which are inherently risky, depend upon the availability of patients and regulatory approvals, and have no guarantee of returning efficacious results or proving practical or cost effective.

- **Partnering risk** - successful partnering will rely on the independent interpretation of our clinical trial results and a decision that the product candidate will be approvable and profitable in the portfolio of the licensee.

- **Regulatory and reimbursement approval risk** – Invion's ability to research, develop, manufacture and sell its products is dependent upon regulatory approvals in target markets, for which there is no guarantee of securing such approvals in a timely and cost effective manner. While submissions may be made for reimbursement in certain jurisdictions, there is no guarantee that Invion will be reimbursed for any costs associated with developing its products, which may adversely impact its financial position.

Key risks for investors

- **Toxicology** – in parallel with clinical trials, Invion will continue to test its product candidates in animal species under controlled conditions governed by Good Laboratory Practices (GLP) and its equivalent regulations under the International Committee on Harmonisation (ICH). These studies could generate results that identify previously unknown safety concerns, limit the use of product candidates to certain patient populations, or limit the doses that may be used below the doses needed to achieve efficacy.

- **Delay risk** – the potential for delay of any of the key milestones, presents a number of risks, including the ability to secure a commercial partner, receive regulatory classification and achieve revenues within estimated timeframes.

- **Manufacturing and distribution capability risk** – Invion's ultimate success is dependent upon its ability, or that of its commercial partners, to scale up and maintain production within the estimated time frame, and in accordance with regulatory standards.

- **Competition** – Invion is aware that there are a number of products in development or recently approved for the treatment of autoimmune diseases, including lupus, as well as airway diseases including asthma and chronic bronchitis. One or more of these competitor products or product candidates may be sufficiently safe and effective so as to minimize the real or perceived value of Invion product candidates, thereby negatively affecting the value placed upon our products for licensing or partnering.

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 (11-Mar-15)	$0.039 (3.9 cents)
Shares on issue * (11-Mar-15)	~571.25M
Options on issue	~60M
Market cap (11-Mar-15)	~$22.2M
Cash at bank (31-Dec-14)	$1.9M

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Investor Presentation

March | 2015