Therapeutic products for respiratory and autoimmune diseases

pharmaxis

July 2006

Forward Looking Statements

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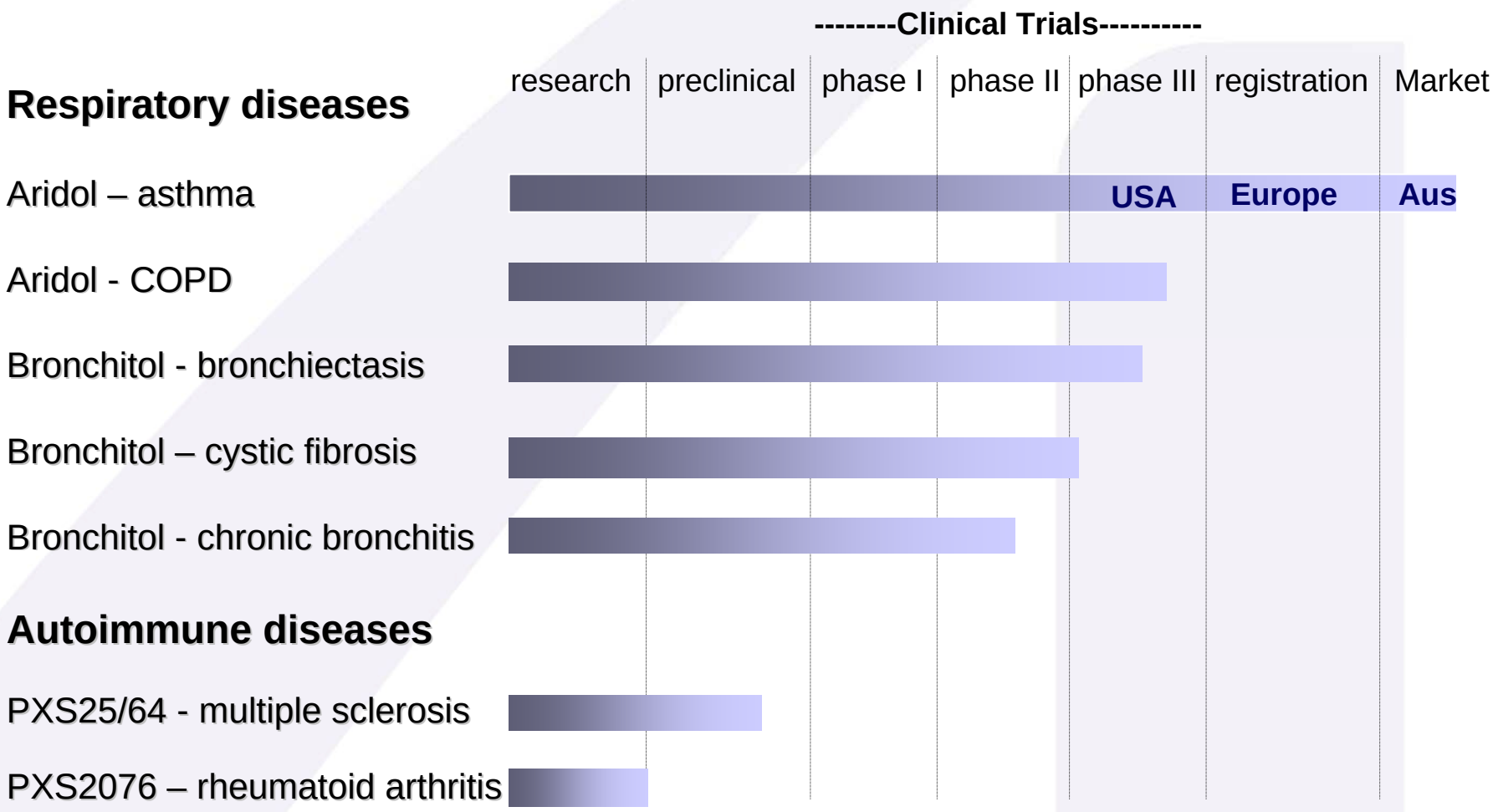
Summary

Objective	To research, develop and bring to market innovative therapeutic products for the treatment and management of respiratory and autoimmune diseases
Lead products	Aridol: management of asthma and COPD Bronchitol: therapeutic for cystic fibrosis and COPD
Discovery	PXS64 - multiple sclerosis
Listings	ASX (Nov 2003): PXS; NASDAQ (Aug 2005): PXSL
Location	Sydney, NSW, Australia
Facility	GMP Manufacture of lead products
Employees (28/2/06)	50
Cash (31/3/06)	A$103 m
Shares outstanding Options outstanding	176.9m (11.8m ADS) 9.7m
Key patents	Aridol & Bronchitol granted in USA, Australia, Asia; pending in EU and Canada
Analyst coverage	Wilson HTM INVESTMENT GROUP; CIBC World Markets; J | M | P SECURITIES

Pipeline

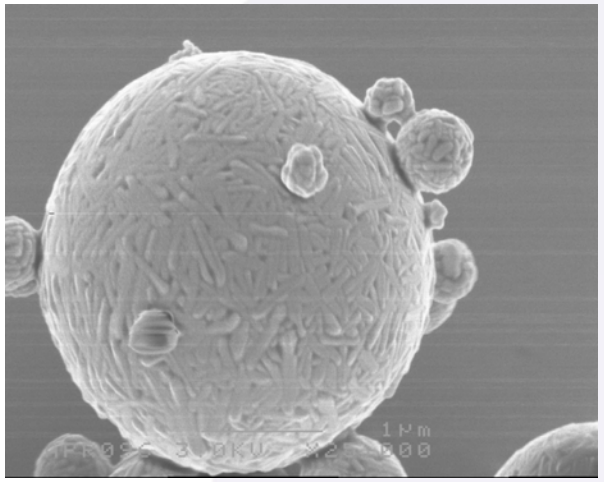
Pulmonary and Autoimmune Focus



Recent Highlights….

- **Aridol**
  - Completed Phase III - asthma (Aus and EU)
  - Approved for marketing in Australia (March 2006)
  - Market application lodged in EU (April 2005)
  - US Phase III study in progress - completion July 2006
  - Two marketing/distribution partners appointed in Europe
- **Bronchitol**
  - Commenced Phase III study in Europe
    - bronchiectasis
  - Completed Phase II trials
    - cystic fibrosis
  - Orphan Drug designation for CF, bronchiectasis (U.S.)
  - Orphan Drug designation for CF (Europe)

Bronchitol

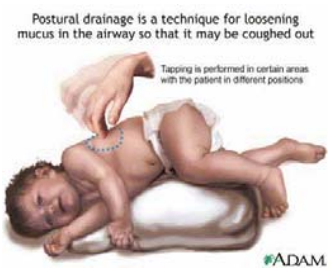


Mucus clearance:

Cystic fibrosis
Chronic Obstructive Pulmonary Disease
Bronchiectasis

Bronchitol

cystic fibrosis

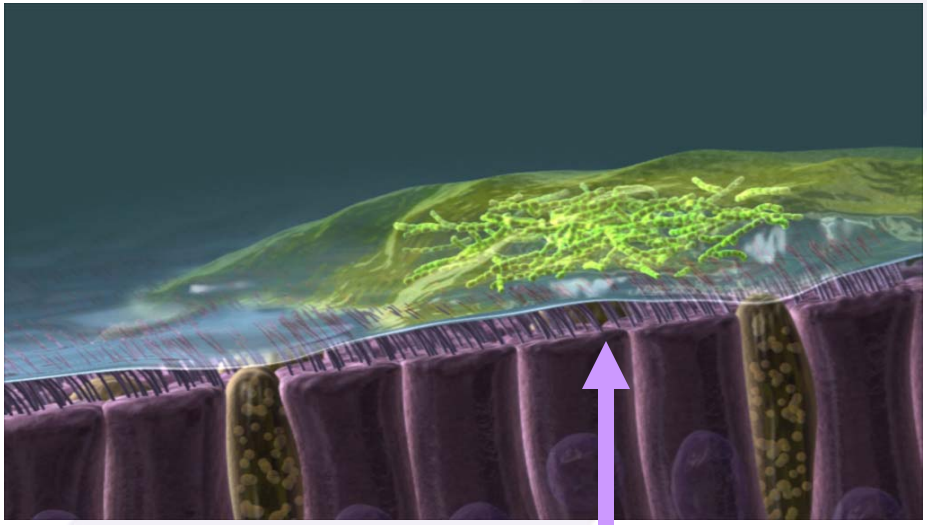


- Background
  - Genetic disorder affecting 75,000 worldwide (30,000 in U.S.)
  - Poorly hydrated, tenacious, thick mucus
  - Current life expectancy is 31 years
- Current treatments: rhDNase and tobramycin
  - Delivered by nebulizer (preparation, sterilization)
  - rhDNase (pulmozyme): US$265mm @ ~30% penetration
  - Tobramycin: US$233mm

How Bronchitol works……

Osmotic clearance of abnormal mucus

Before treatment

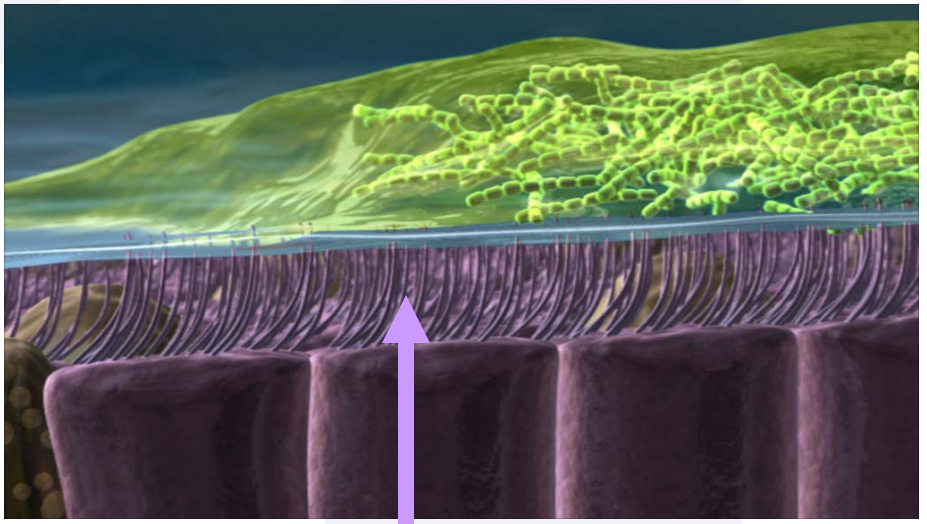


Lung surface dehydrated

Airway surface fluid layer impaired

Lung defense and hygiene compromised

After Bronchitol administration



Lung rehydrated

Airway surface liquid restored

Normal lung clearance

Bronchitol

Phase II cystic fibrosis trial

- Crossover, 8 site study in 39 CF patients
- Randomised two week treatment periods
- Double-blind, placebo controlled

- Primary Endpoint:
  - Change in FEV_1
- Secondary Endpoints:
  - Effect on other lung function measures
  - Effect on symptoms/signs
  - Effect on QoL
  - Safety (including microbiology)

Bronchitol

CF Phase II Results: Change in Lung Function

	Bronchitol*	Control*	p value
Change in FEV_1	7 ± 2%	0 ± 2%	0.008
Change in FEF_{25-75}	15.5 ± 5%	0.6 ± 5%	< 0.01

Includes patients being treated with pulmozyme

FEF_{25-75} is a measure of small airway function

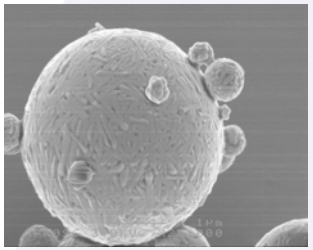
Bronchitol

cystic fibrosis registration strategy

- Phase III trial (EU & Aus):
  - Commence Q3 2006
  - Primary endpoint: same as Phase II (FEV_1)
  - Placebo-controlled, 6 month dosing
  - Scheduled completion end 2007
- Phase III trial (US) to commence early 2007
  - Similar size, design to EU/Aus trial
  - Scheduled completion beginning 2008
- Orphan drug designation – EU and USA

Bronchitol

bronchiectasis



- Background
  - Abnormal, irreversible dilation of the lower airways
  - Daily mucus production, constant coughing, breathlessness: major quality of life impact
  - Normal lung clearance impaired
  - 500,000 affected worldwide (110,000 in the U.S.)[1]
- Current treatments: bronchodilators, antibiotics
  - No drugs effective to clear mucus

1: Clin Pulm Med 2005;12:205

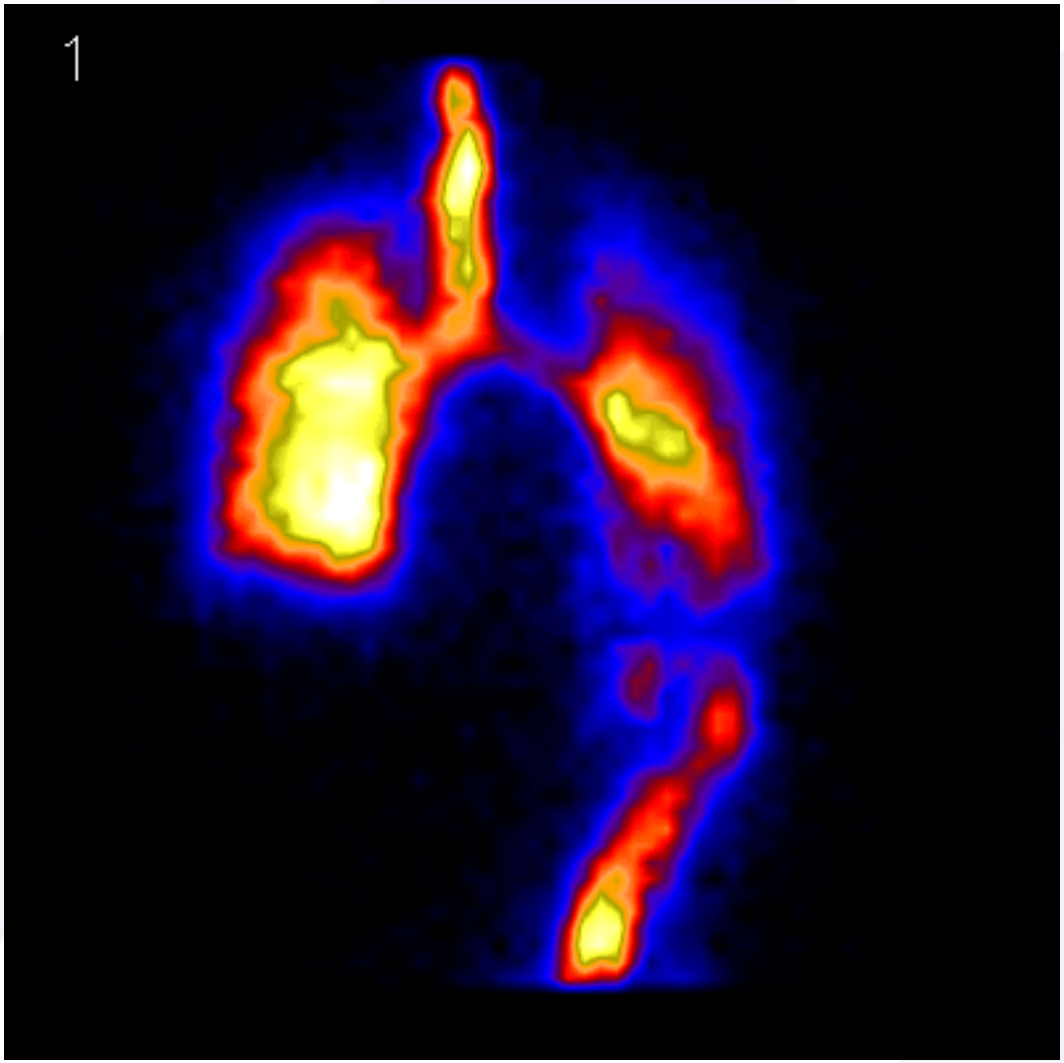
Bronchitol

bronchiectasis

- Phase II Trial results
  - Safe, effective, clinically significant improvements in health
- Phase III Trials
  - Commenced enrolment in Australia and the UK
    - Target patient recruitment of 350
    - Scheduled close of recruitment - end 2006
    - Data - mid 2007
  - US trial to commence early 2007
- Supplied on individual compassionate-use basis

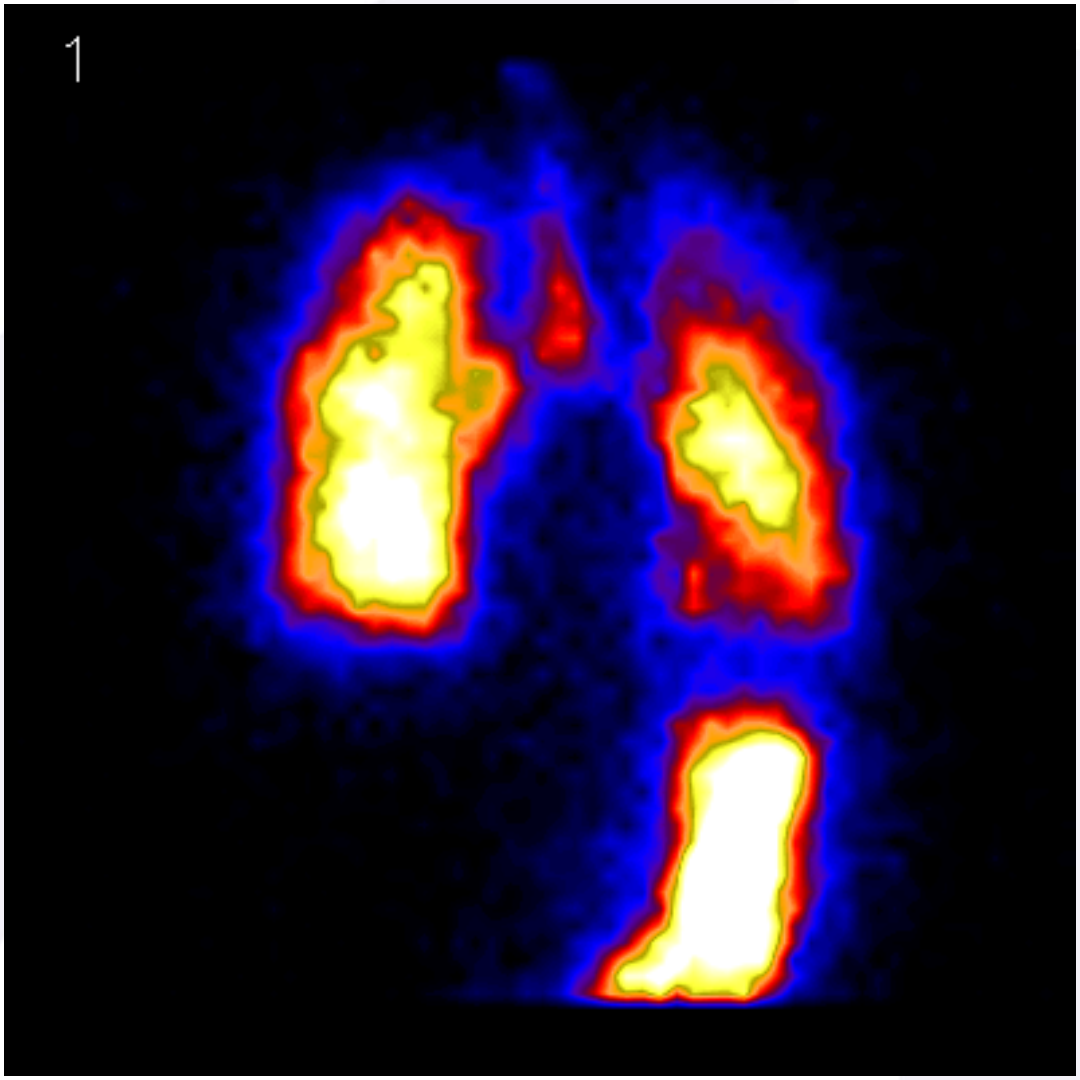
Bronchitol in the clinic.....

Chronic bronchitis – without Bronchitol



Bronchitol in the clinic.....

Chronic bronchitis – with 400 mg Bronchitol



Bronchitol

Chronic Obstructive Pulmonary Disease

- Clearance of retained lung secretions
- Proof of concept demonstrated with ICU patients
  - Currently supplied on request to patients with life threatening condition
- Clinical conditions include:
  - asthma, COPD, cystic fibrosis, secondary respiratory disease, neurogenic disorder
- Complete acute care pilot study (safety) Q4 2006
- Complete pivotal Phase III study Q4 2007
- 30 million COPD exacerbations per year in the U.S.[1]
- 1 million U.S. emergency room visits per year

1: ATS San Diego 2006

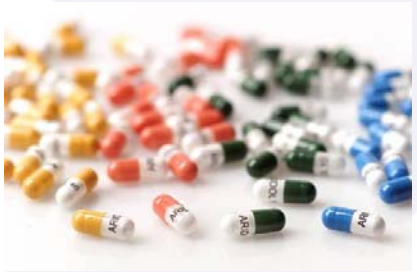
Aridol™

A rapid and simple test for airways inflammation that facilitates diagnosis and management of asthma and COPD patients.

Aridol

Asthma and COPD Opportunity

- **<u>Asthma</u>**
  - 51mm patients in 7 major markets
  - No ***simple*** test
  - ~34% of people diagnosed with asthma do not have the disease
  - Ongoing patient management difficult



- **<u>Chronic Obstructive Pulmonary Disease</u>**
  - 30 million people affected in 7 major pharmaceutical markets
  - Cost to US healthcare - US$30 billion pa
  - 20-25% respond to inhaled steroids but no test to identify them

Current best practice

Current guidelines for diagnosis:

- symptoms: wheeze, breathlessness, chest tightness, cough and nocturnal wakening,
- airflow limitation
- increase in airway hyperresponsiveness.

Current tests are not specific and / or not 'point of care'

The burden of asthma

Europe

Patients reporting daytime symptoms	Patients needing urgent care p.a.	Patients with disturbed sleep
46%	25%	30%

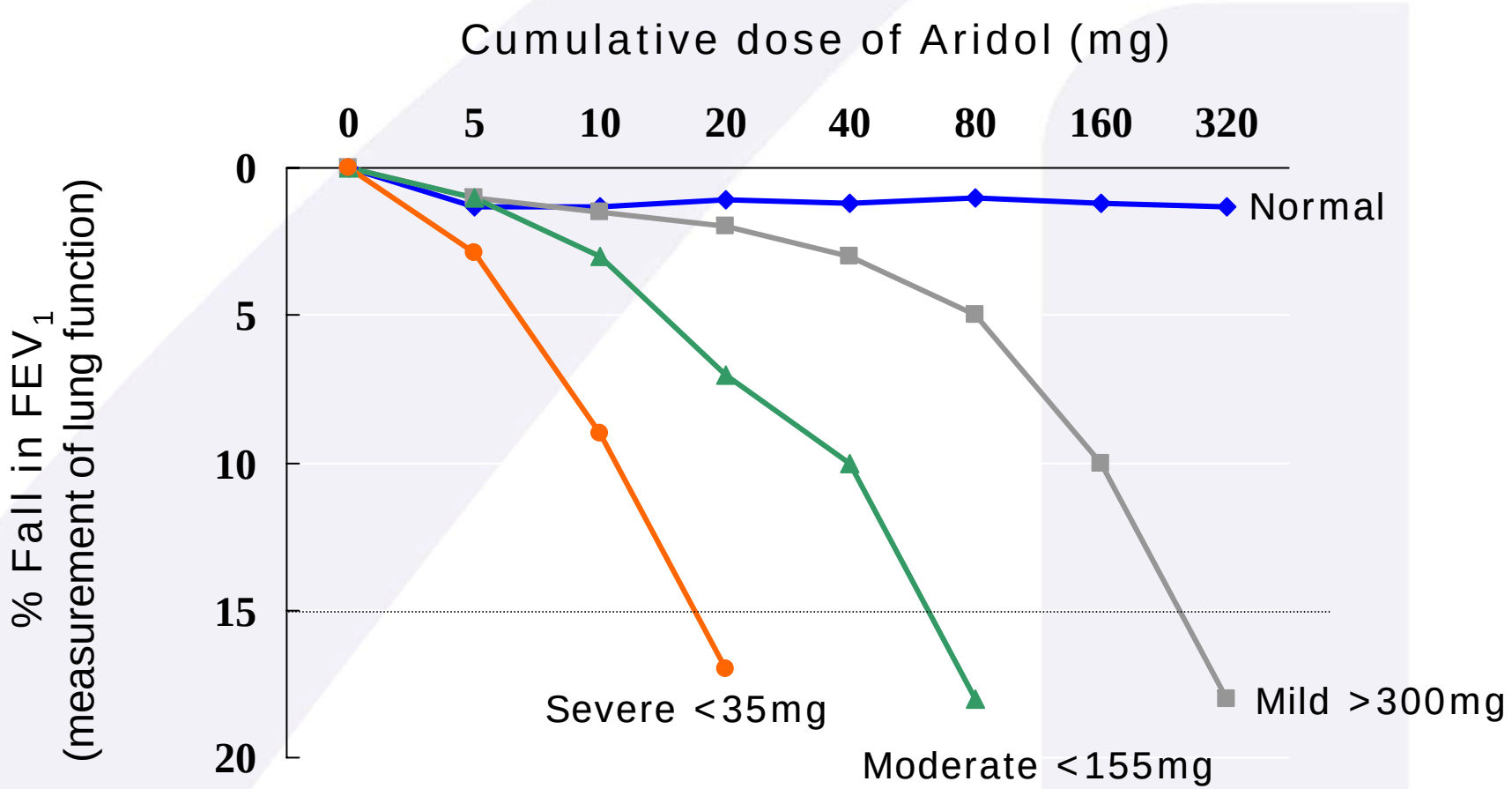
USA

Americans whose activities are restricted by asthma	US Annual hospitalisations due to asthma	Annual days of restricted activity due to asthma
64%	470,000	100 m

There exists a significant unmet medical need to improve the diagnosis and control of asthma

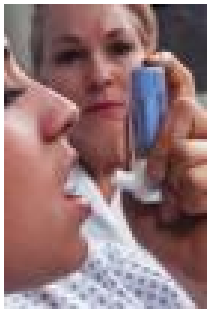
Aridol

Measurement of airway hyper-responsiveness



Aridol

Current status



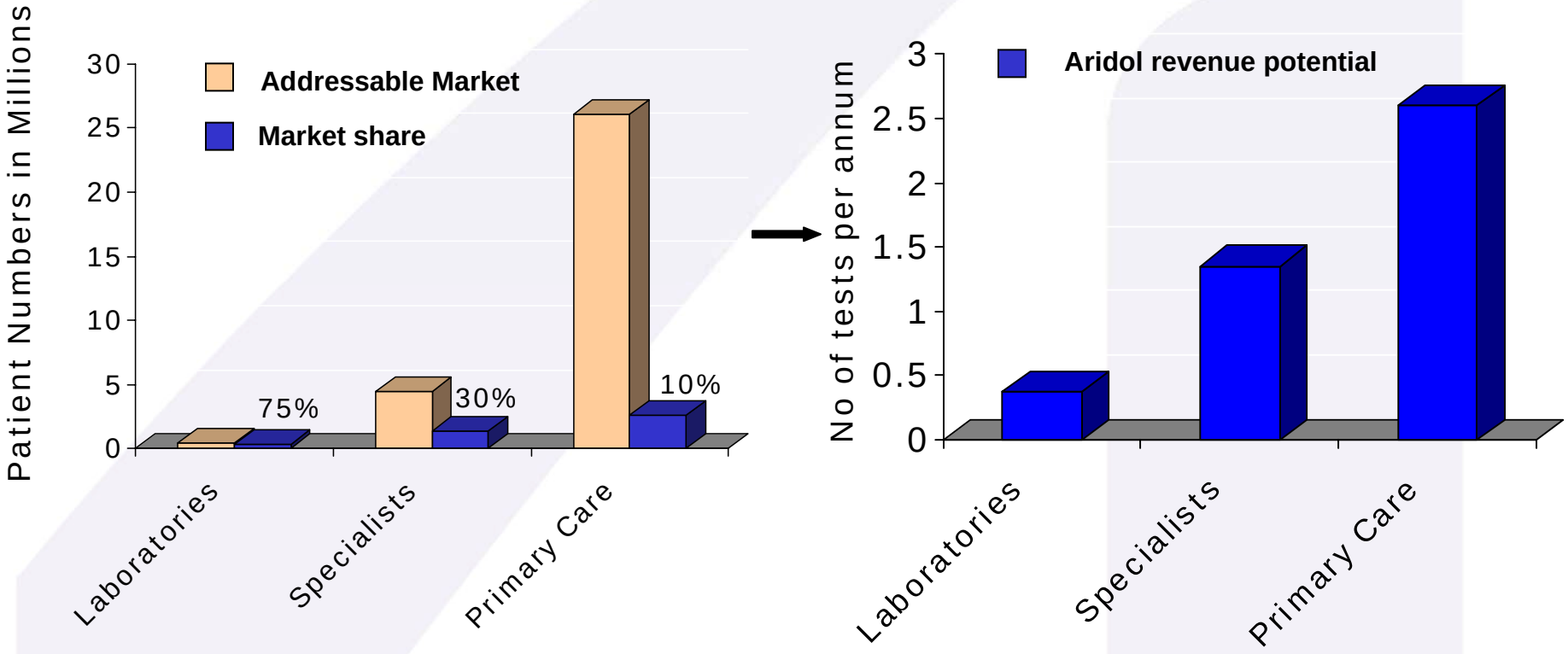
- **Phase III results (646 patient study)**
  - Effective at identifying clinical mis-diagnosis (7%)
  - 20% of subjects over treated and over diagnosed
  - 25% of subjects not well controlled
- **European marketing authorization submitted**
  - Anticipated approval – 3Q 2006
- **Approved for marketing - Australia**
  - Product launched - March 2006
- **US Phase III trial commenced**
  - Scheduled completion mid – 2006
  - Subjects enrolled at June 30: 297/280 (revised target-350)

Aridol

Marketing - Australia

- **Marketing and sales force recruited (Australia)**
- **Marketing partners appointed (Europe)**
- **Promotional materials prepared**
- **Market Introduction**
  1. Respiratory laboratories
  2. Respiratory specialists
     - Hospital formulary
     - Clinical trial use
  3. Primary Care Physicians
- **Reimbursement available under existing treatment code**

Aridol opportunity by market segment

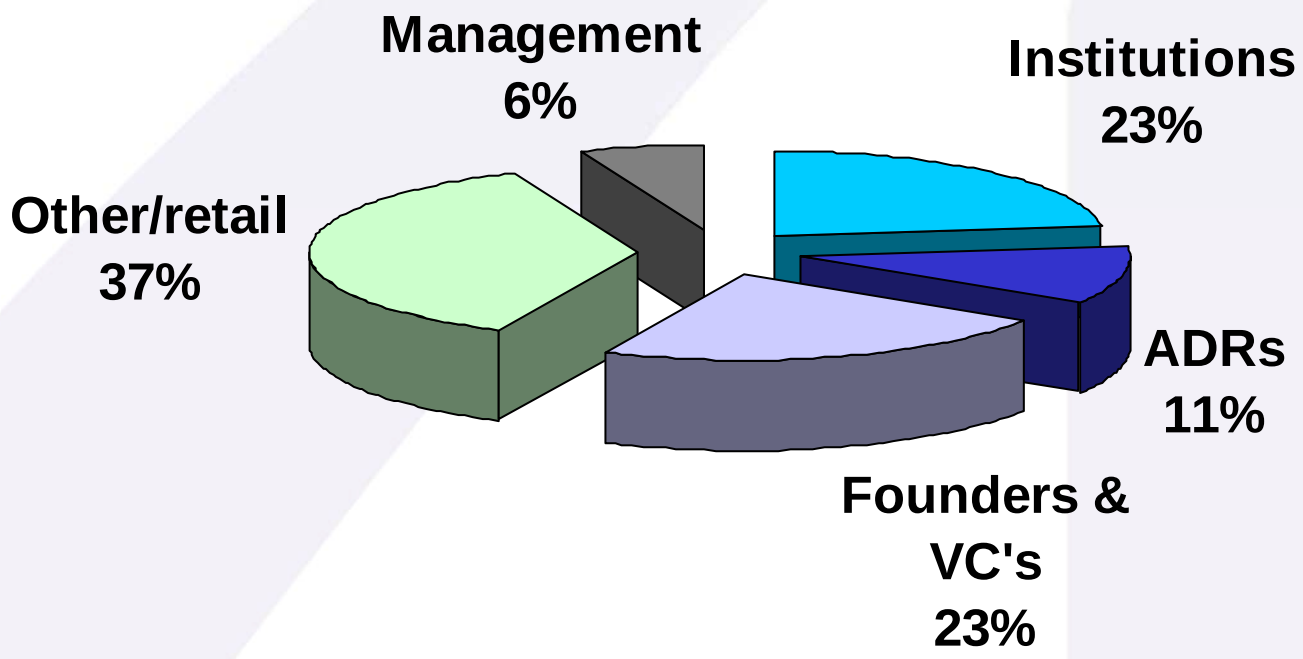


- **Replace old tests**
- **Increase referrals**
- **New indications**
- **Create 'practice' test market**

Total Opportunity = $210m+

Share Capital

(including options)



9 June 2006: 176.9m shares; 9.7m options

Financial Statements

Unaudited - A$'000 (except per share data)

Balance Sheet	As at	
	31-Mar-06	30-Jun-05
	A$	A$
Cash and cash equivalents	102,609	33,389
Plant & equipment	3,069	2,477
Intangible assets	1,174	1,106
Total assets	108,379	37,937
Total liabilities	2,999	2,470
Total shareholders' equity	105,380	35,467

Income Statement	Three months ended		Year-to-date	
	31-Mar-06	31-Mar-05	31-Mar-06	31-Mar-05
	A$	A$	A$	A$
Revenue				
Interest	1,418	498	2,854	1,209
Other income				
Grant income	468	357	898	847
Other	-	1	-	1
	1,886	856	3,752	2,057
Expenses				
Research & development	(4,404)	(2,083)	(10,050)	(6,363)
Commercial	(497)	(345)	(1,100)	(665)
Administration	(981)	(533)	(3,163)	(2,128)
Total expenses	(5,882)	(2,961)	(14,313)	(9,156)
Net loss before and after tax	(3,996)	(2,105)	(10,561)	(7,099)
Basic and diluted earnings (loss) per share	(0.023)	(0.016)	(0.068)	(0.059)
Depreciation & amortisation	174	146	706	421
Fair value of options issued under employee plan	408	69	812	163

Significant Milestones ahead

Milestone	3Q-06	4Q-06	1Q-07	2Q-07
Aridol				
Approval – Sweden				
Launch - Sweden				
COPD clinical data				
Ph III US clinical data available				
Bronchitol – cystic fibrosis				
PII dosing study data				
Commence PIII trial (EU)				
Combination trial enrolled				
Bronchitol – bronchiectasis				
PIII trial enrolment complete				
PIII data available				
File EU marketing application				
Bronchitol – COPD				
Commence PII pilot trial				
Data available				
PXS64				
Complete preclinical studies				