

**Pharmaxis Ltd**  
**2005 Annual General Meeting**  
**Chairman's Address**

My fellow shareholders, 2005 has again been a year of great achievement for Pharmaxis.

As I reported in last years address the risk reward equation for you as our shareholders in this early stage of your company's development is directly proportional to the reduction of the risks associated with commercialising our inventions.

**ARIDOL**

With Aridol we have completed our clinical registration study and filed for approval to market in Europe and Australia to identify and help manage Asthma. Thus the risk for this product only remains with registration and marketing. Technical risk has been removed.

An additional Aridol study for the US market is now planned and expected to begin this year. Your company is confident of success with this study, as it relates more to clinical practice in the USA than it does the ability of Aridol to do what it has proven to do in many previous studies.

We have also commenced phase 2 studies to demonstrate that with Aridol it is possible to identify which patients with COPD (a large 30 million potential patient base) would benefit from inhaled steroids. Indications that this can be achieved have come from independent third party medical studies in Europe and so again your company has high expectations that the clinical work will be successful for this new and large purpose.

**BRONCHITOL**

Last year your company conducted a successful Phase 2 clinical trial for our second product, Bronchitol.

This trial prepared the way for a global Phase 3 clinical trial, which is designed to lead to registration of this compound for clinical use in the treatment of bronchiectasis on a world wide basis.

This year, we have followed this up with a successful Phase 2 clinical trial demonstrating that Bronchitol is beneficial to patients with Cystic Fibrosis. This work has paved the way for a global Phase 3 clinical trial designed to lead to the registration of Bronchitol for Cystic Fibrosis on a world wide basis.

From the work your company has completed on both of these classes of patients, I believe that eventually Bronchitol will be shown to be beneficial for most patients with bronchial congestion which would potentially see 30 million patients benefit from the product.

2006 should see our first approvals to market Aridol.

In general then we have come a long way in reducing the technical risks associated with our lead products, Aridol and Bronchitol and our share price movements have reflected our achievements.

There still remains the business risk associated with the marketing of the product. This will determine how much value your company can return to you, its investors, for their investment but - there will no longer be any risk that the product is of no value.

To fund this new projected clinical work, your company has just completed successfully a global capital raising involving a public issue in the United States and a placement of shares with Australian institutional shareholders.

This global capital raising funds the required clinical work that I have described before. In that sense it takes away another level of risk. We now have the resources to complete our clinical work.

We have now come a long way from our early research beginnings. We have excellent people with a track record of delivery. We have excellent products that change peoples lives and we have the financial resource to progress our work.

I am personally confident that our company will continue to achieve its milestones and so help many patients whose quality of life is not what it might be. At the same time I am also confident that this good work will deliver appreciating value to you our investors.

I believe we have the potential to be a truly significant Pharmaceutical business.

Your Managing Director, Dr Alan Robertson in his presentation will be providing a brief review of where we find ourselves at this point in time and some insight into the scope of the opportunity in front of us.

Your CFO, Mr. David McGarvey will give an overview of the company's financial position.

On your behalf, I want to thank your Board for their oversight and strategic Direction of our company. Also on your behalf, I would also like to thank your Management and staff for delivering the success we are enjoying.

Denis M Hanley

15 November, 2005

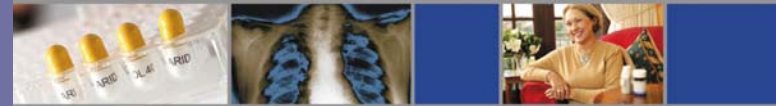


pharmaxis

**Therapeutic products  
for  
respiratory and  
autoimmune diseases**

**Annual General Meeting  
November 2005**

# Highlights



**Bronchitol**



**Aridol**



**Autoimmune  
disease**

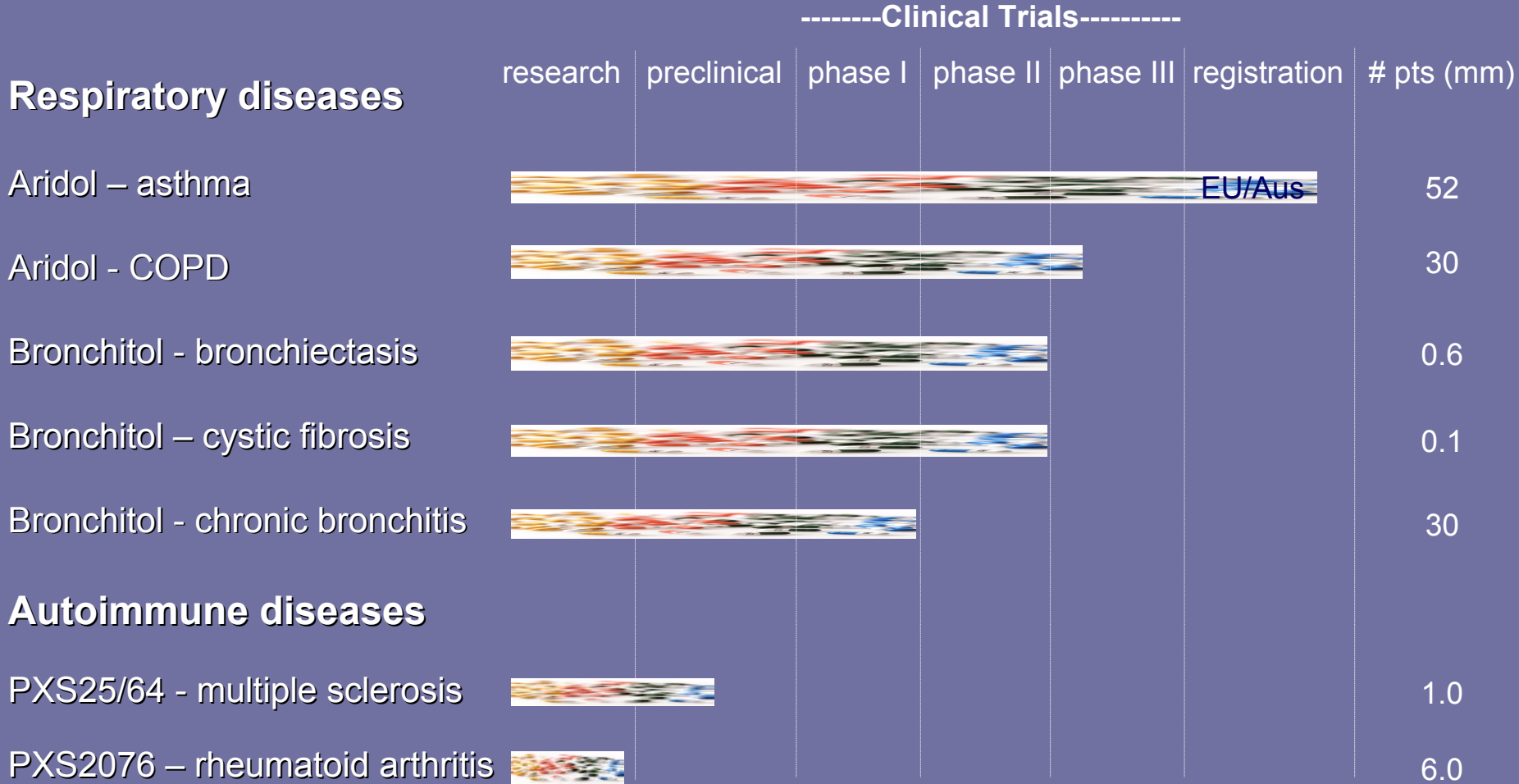
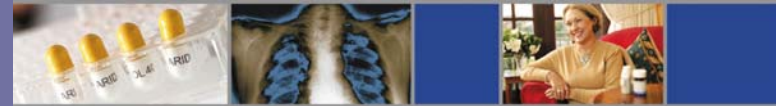


**Manufacturing**

- **Bronchitol: Entering Phase III**
  - Successful Phase II trial in cystic fibrosis
  - Successful Phase II trial in bronchiectasis
  - Orphan drug designation – Europe and USA
- **Aridol: Management of airway inflammation**
  - European Phase III completed (asthma)
  - US Phase III to start late 2005 (asthma)
  - Market authorization filed in EU, Australia (target 2006 launch)
  - COPD clinical study commenced
- **Retained marketing rights for all programs**
- **Experienced management**
- **Extensive patent portfolio**
- **Near term value enhancing milestones**

# Pipeline

## Pulmonary and Autoimmune Focus



# Management



- **Alan Robertson PhD**  
*Wellcome (GSK); Faulding; Amrad; Inventor of Zomig*

**CEO**



- **David McGarvey CA**  
*CFO, Memtec (NYSE); CFO, US Filter Filtration Group*

**CFO**



- **Brett Charlton, PhD**  
*Stanford; ANU*

**CMO**



- **Gary Phillips, MBA**  
*CEO, Novartis Australia*

**Commercial**



- **John Crapper, MBA**  
*Managing Director, Memcor; Syntex (Roche)*

**COO**



- **William Cowden, PhD**  
*ANU; Co-inventor of TNF mAb's*

**CSO**

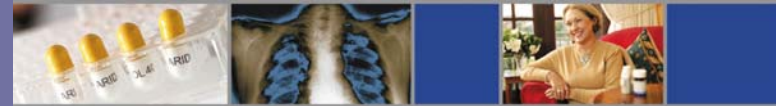


- **Ian McDonald, PhD**  
*VP Discovery, SIBIA (Merck); VP Discovery, SGX*

**CTO**

# Bronchitol

## cystic fibrosis

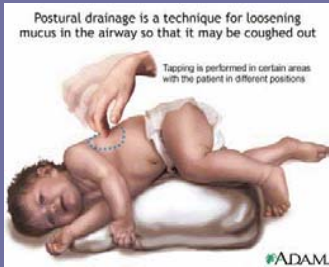


### ● Background

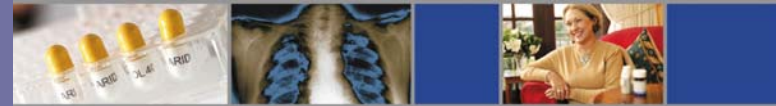
- Genetic disorder affecting 30,000 in U.S.
- Poorly hydrated, tenacious, thick mucus
- Current life expectancy is 31 years

### ● Current treatments: rhDNase and tobramycin

- Delivered by nebulizer (preparation, sterilization)
- rhDNase (pulmozyme): \$265mm @ ~30% penetration



# Bronchitol



## Phase II CF trial

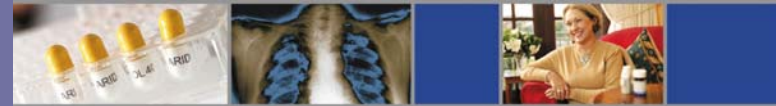


- Crossover, 8 site study in 39 CF patients
- Randomised two week treatment periods
- Double-blind, placebo controlled
- Primary Endpoint:
  - Change in FEV<sub>1</sub>
- Secondary Endpoints:
  - Effect on other lung function measures
  - Effect on symptoms/signs
  - Effect on QoL
  - Safety (including microbiology)





# Bronchitol



## CF Phase II Results: Change in Lung Function

	Bronchitol*	Control*	p value
Change in FEV <sub>1</sub>	7 ± 2%	0 ± 2%	0.008
Change in FEF <sub>25-75</sub>	15.5 ± 5%	0.6 ± 5%	< 0.01

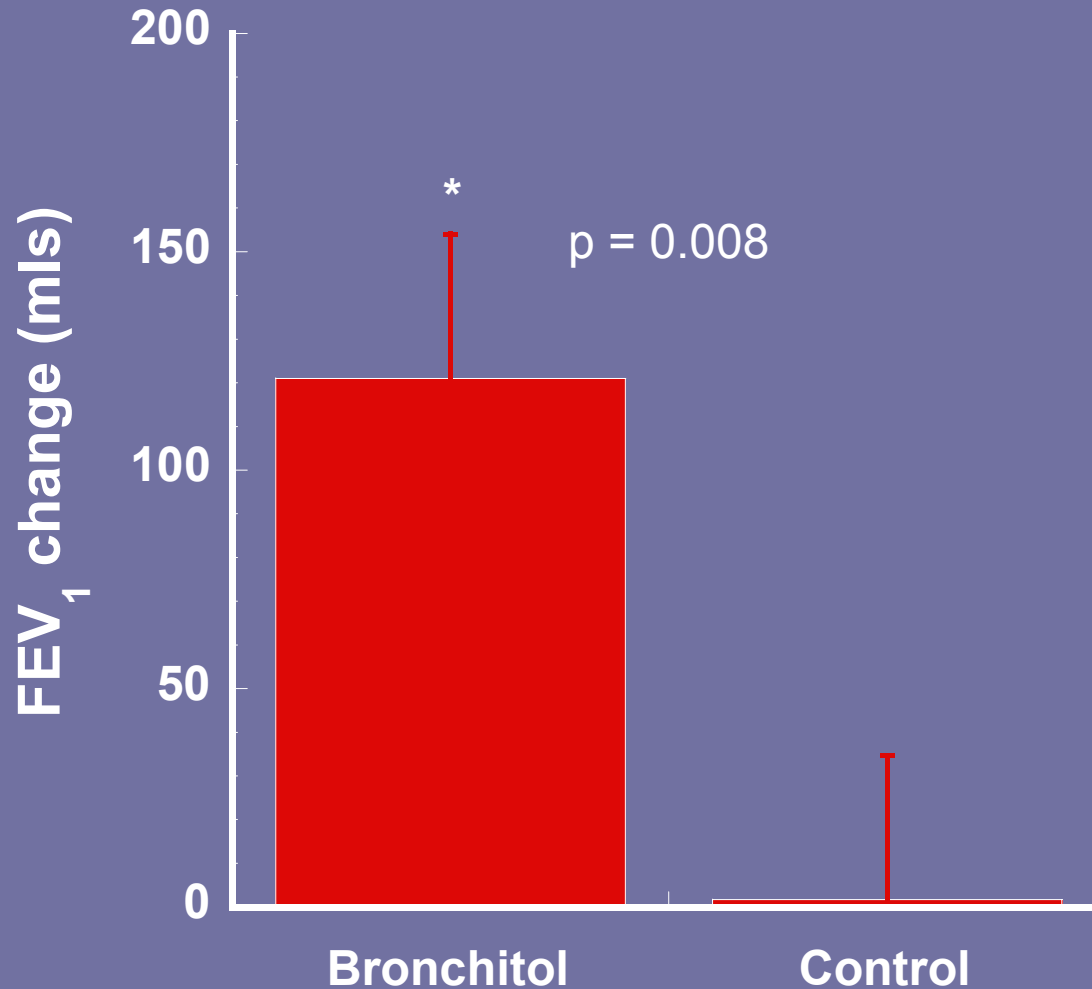
\*includes patients being treated with pulmozyme

**(FEF<sub>25-75</sub> or MMEF is considered a measure of small airway function)**

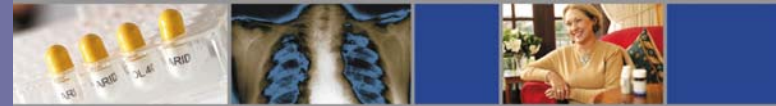
# Bronchitol



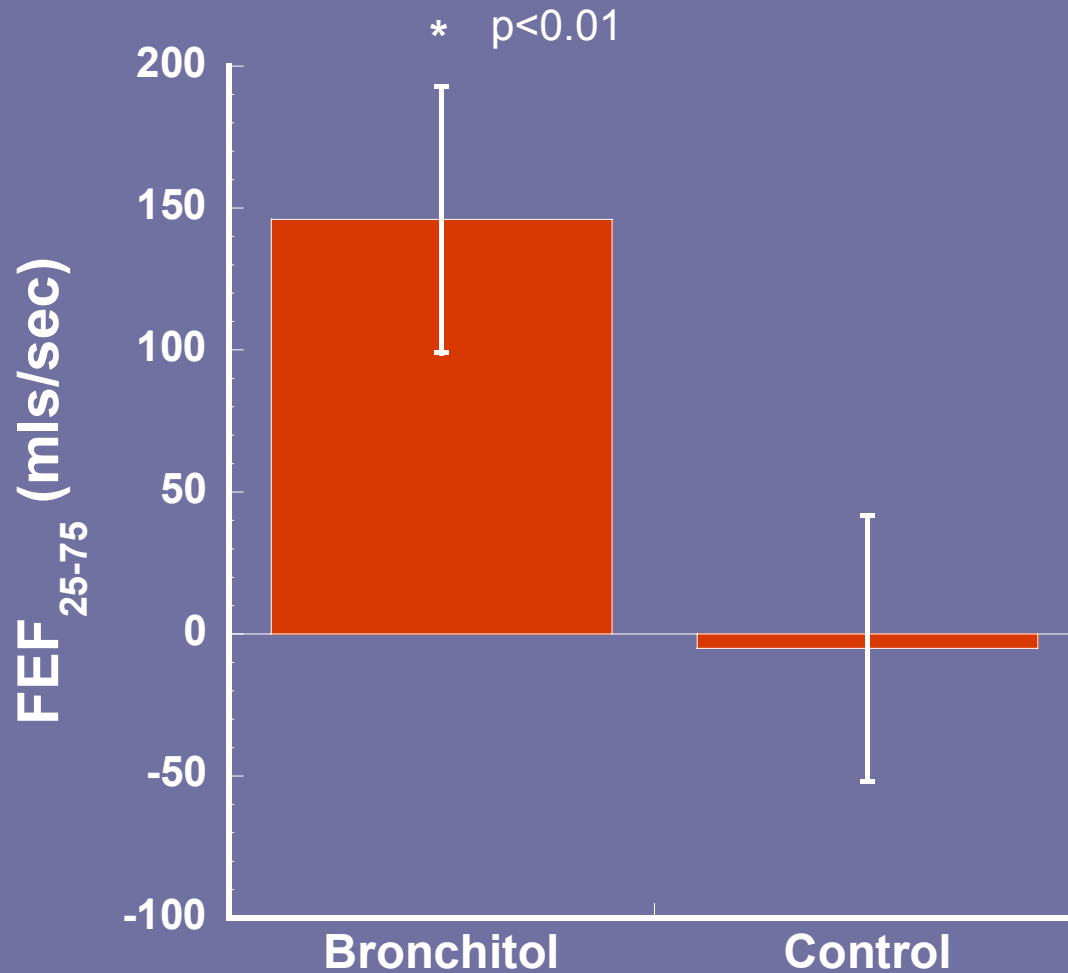
## CF Phase II Results: FEV<sub>1</sub> Change



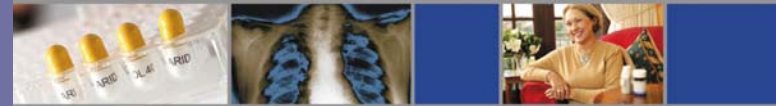
# Bronchitol



## CF Phase II Results: FEF<sub>25-75</sub> Change



# Bronchitol



## cystic fibrosis registration strategy



### ● Phase III trial (EU & Aus):

- Dosing to be finalized based on ongoing dose-ranging study
- Commence 1H2006
- Primary endpoint: Change in FEV<sub>1</sub>
- Placebo-controlled, 6 month dosing, finalising design with EMEA



### ● Phase III trial (US) to commence 2006

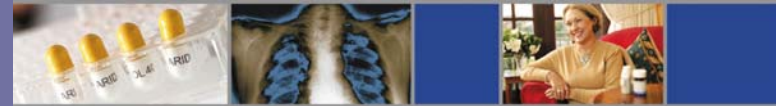
- Similar size, design to EU/Aus trial



### ● Orphan drug designation – EU and USA

# Bronchitol

## bronchiectasis



### ● Background

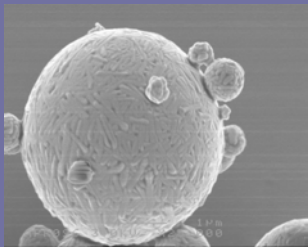


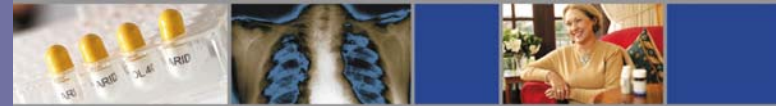
- Abnormal, irreversible dilation of the lower airways
- Daily mucus production, constant coughing, breathlessness: major quality of life impact
- Normal lung clearance impaired
- 100,000 affected in the U.S.



### ● Current treatments: bronchodilators, antibiotics

- No drugs effective to clear mucus





# Bronchitol

## bronchiectasis

### ● Phase II Trial results

- 60 patient, double-blind, crossover, placebo-controlled
- Promising results in QoL, symptom scores ( $p < 0.05$  versus placebo)
- For all patients – 4.5 unit improvement in St. George's impact score
- For the 75% of patients with unclear chests – 6.9 unit improvement in St George's impact score
- Well tolerated, no adverse events

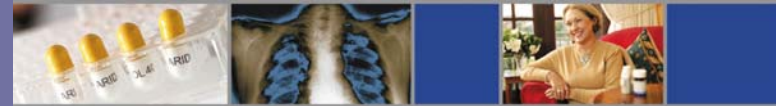
### ● Phase III Trials

- Plan to commence 4Q05/1Q06 in Australia, EU
- Finalising protocol following FDA meeting
- Initiate US pivotal trial mid-2006

### ● Supplied on compassionate-use basis in Australia

# Bronchitol

## chronic bronchitis



### ● Background



- Chronic cough, breathlessness, tenacious sputum
- >30 million people affected in 7 major pharma markets
- No therapy halts disease progression
- Current treatments aimed at symptom relief / bronchodilation



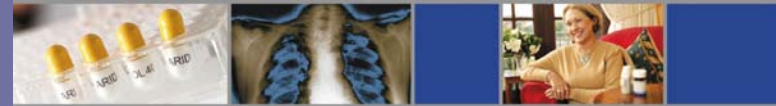
### ● Acute pilot studies completed

### ● Phase II clinical protocol in development

- Quality of Life
- Reduction in exacerbation period



### ● Study to commence 2006



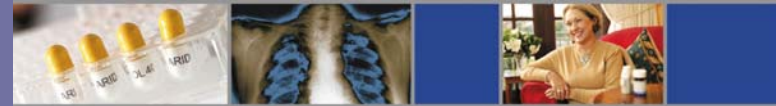
# Aridol™



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



# Aridol



## Asthma and COPD Opportunity

### ● Asthma

- 51mm patients in 7 major markets
- No simple test, many not diagnosed
- ~34% of people diagnosed with asthma do not have the disease
- Ongoing patient management difficult

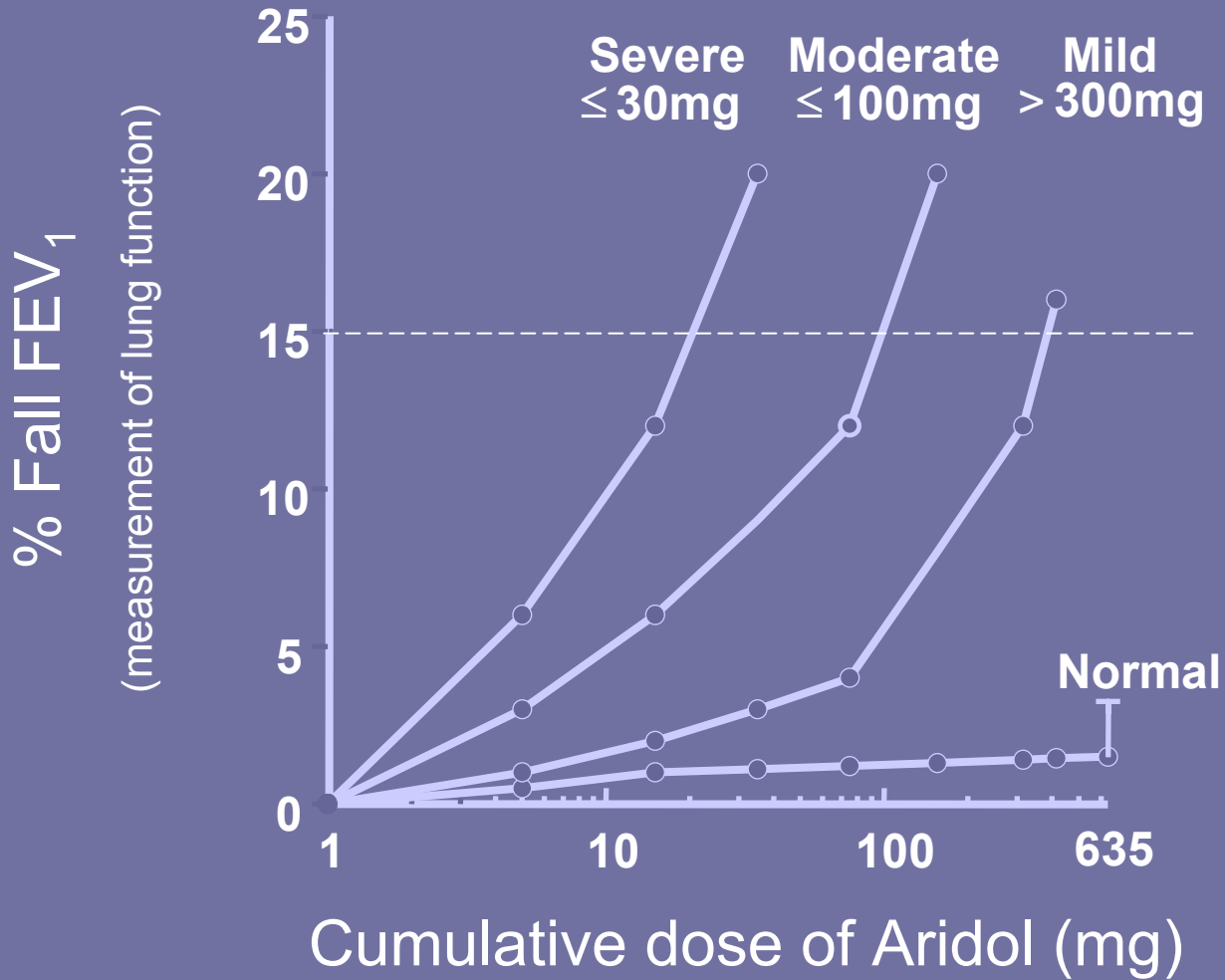
### ● COPD

- 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

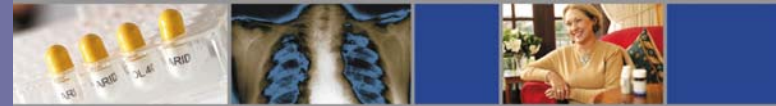


# Aridol

quantitation of airway hyperresponsiveness



# Aridol



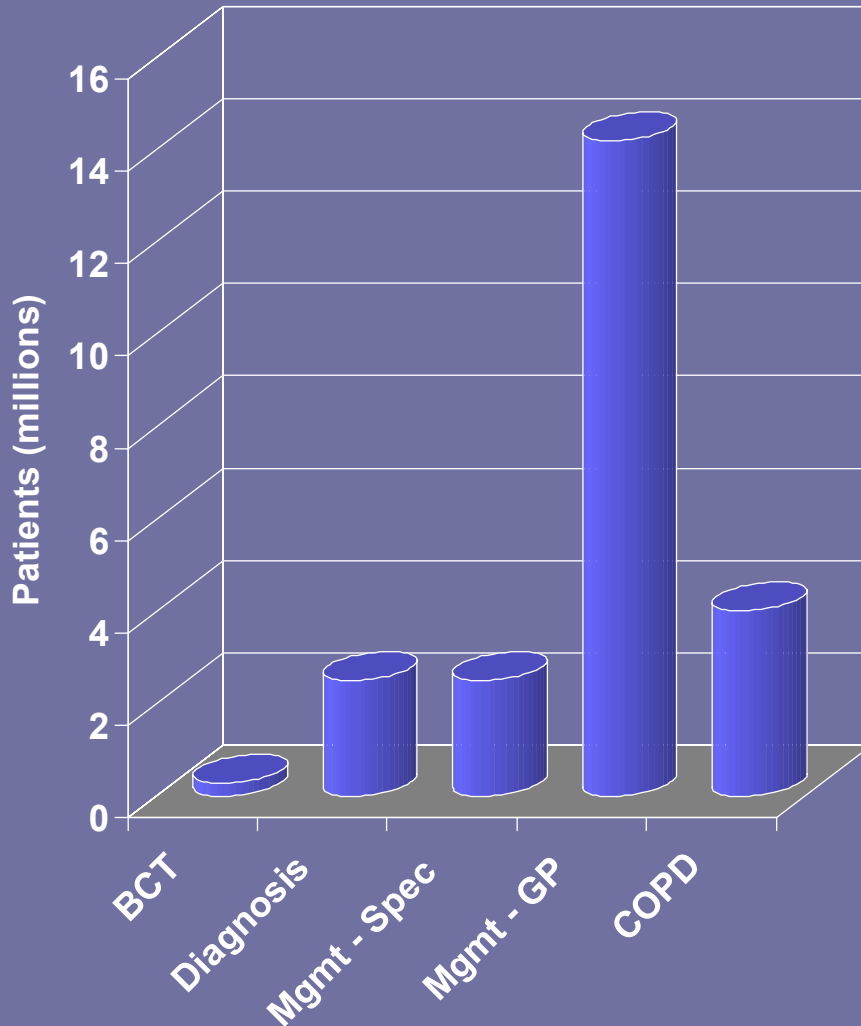
## current status

- Phase III results (646 patient study)
  - Good agreement with hypertonic saline ( $p < 0.01$ )
  - Effective at identifying clinical mis-diagnosis (7%)
  - 20% of subjects over treated and over diagnosed
  - 25% of subjects not well controlled
- European and Australian marketing authorization submitted
  - Potential 2006 launch
- US Phase III trial to commence Q42005
  - Scheduled completion H2 2006



# Aridol

## addressable market



- Multiple trials in progress with key US/EU opinion leaders
- Reimbursable under existing codes in US
- Marketing partner for GP audience
- Publication of clinical results for ICH acceptance
- First revenue 2006 (subject to approval)



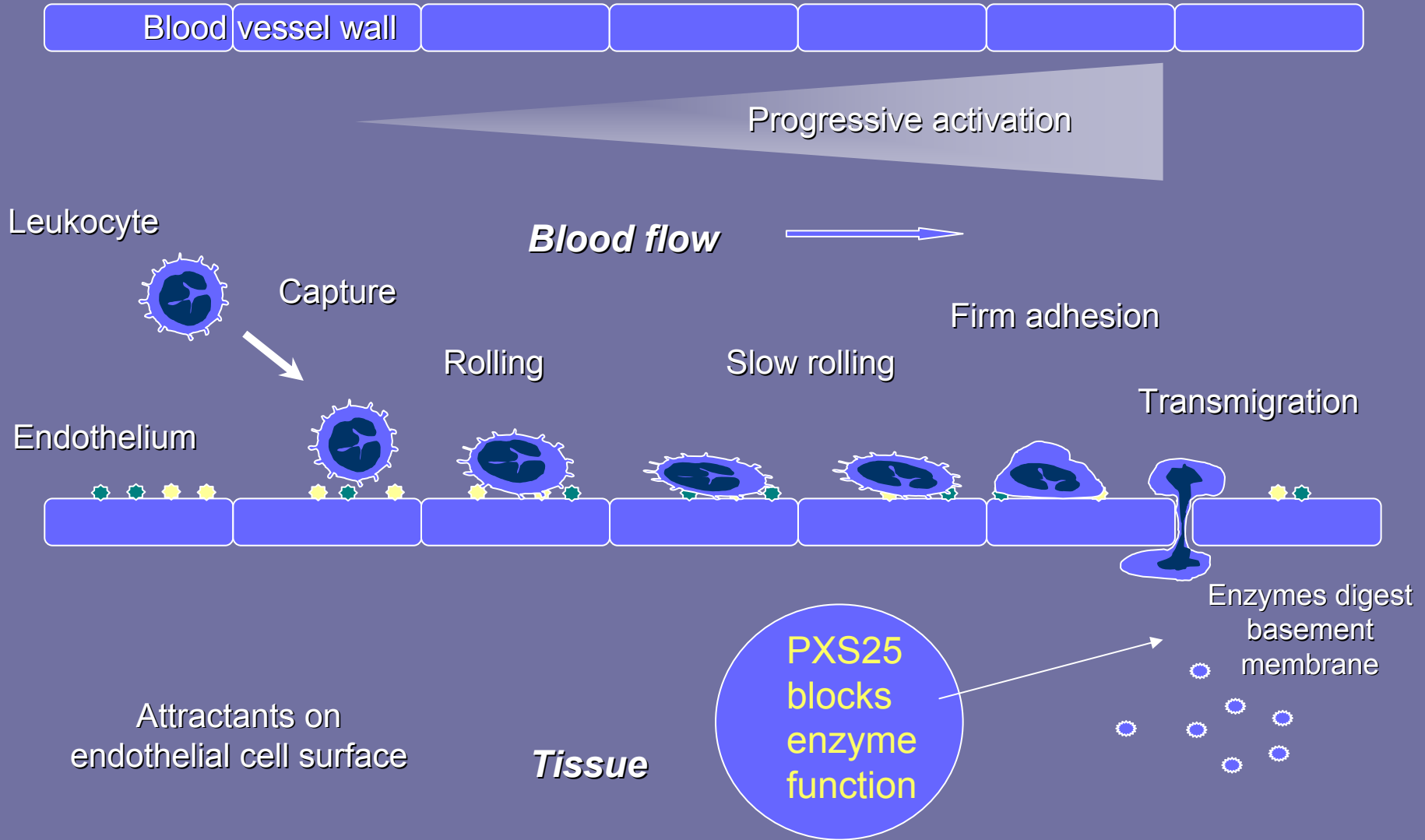
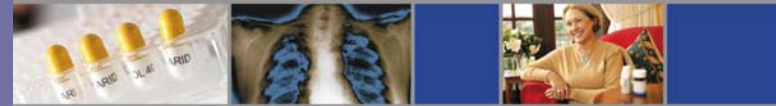
# Autoimmune diseases

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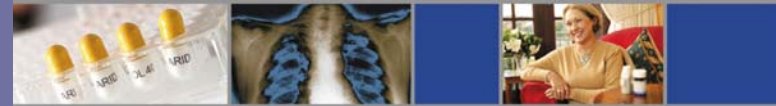
multiple sclerosis  
rheumatoid arthritis

# Autoimmune Disease

## Inflammation: the leukocyte activation cascade



# Autoimmune Disease



## PXS64

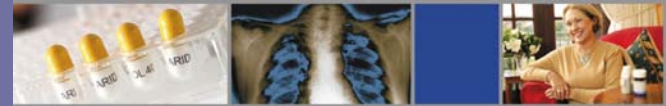
- Selective inhibitor of T cell migration
- Novel mechanism
- Effective in animal models of multiple sclerosis
- Oral prodrug of PXS25, both discovered by Pharmaxis
- Current status: preclinical development, start human Phase I clinical trials 1H06



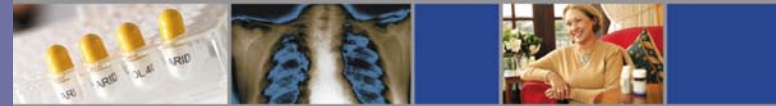
# Financial Overview

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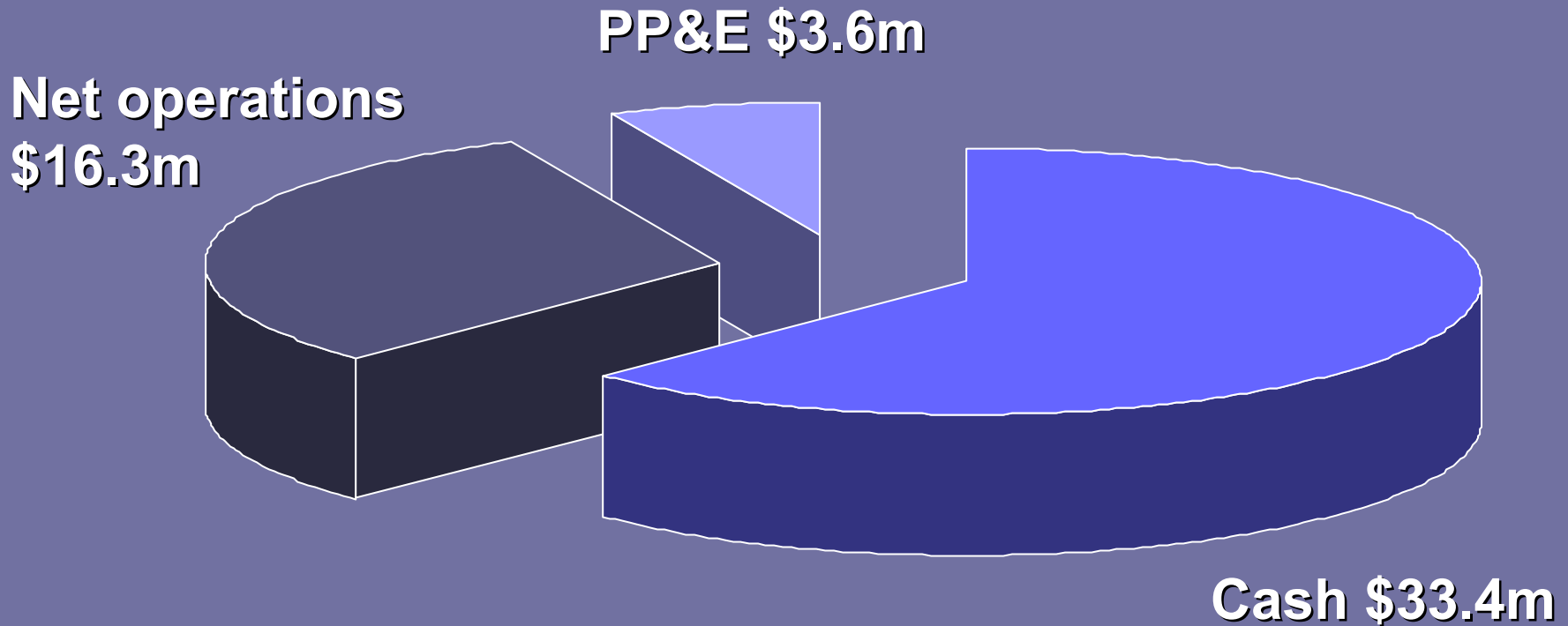
	Year ended 30 June,			
	2005 \$'000	2004 \$'000	2003 \$'000	2002 \$'000
<b>Financial Performance</b>				
Revenue				
Interest received	1,702	1,075	284	43
Research grants	1,172	1,105	976	646
Other		48	43	
	<u>2,874</u>	<u>2,228</u>	<u>1,303</u>	<u>689</u>
Expenses				
Research & development	(9,154)	(6,047)	(1,790)	(1,151)
Commercial	(847)	-		
Administration	(3,105)	(2,182)	(981)	(140)
Total expenses	<u>(13,106)</u>	<u>(8,229)</u>	<u>(2,771)</u>	<u>(1,291)</u>
Net loss before and after tax	<u>(10,232)</u>	<u>(6,001)</u>	<u>(1,468)</u>	<u>(602)</u>
Depreciation & amortisation	626	410	256	130
EBITDA	(11,308)	(6,666)	(1,496)	(515)
<b>Cash Flows</b>				
Cash flows from operating activities	(9,274)	(4,652)	(1,168)	(363)
Cash flows from investing activities	(1,575)	(406)	(1,652)	(36)
Cash flows from financing activities	19,021	22,891	9,453	-
Net increase (decrease) in cash held	<u>8,172</u>	<u>17,833</u>	<u>6,633</u>	<u>(399)</u>

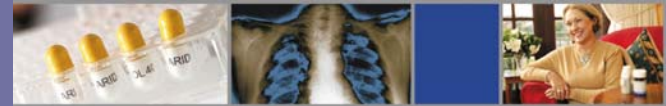


	30 June,	
	2005	2004
	\$'000	\$'000
<b>Financial Position</b>		
Cash and bank accepted commercial bills	33,389	25,217
Plant & equipment	2,477	1,474
Intangible assets	1,106	1,162
Total assets	37,937	28,261
Total liabilities	2,369	1,481
Total shareholders' equity	35,569	26,780



# Total Capital Raised to 30 June 2005 A\$53.3m



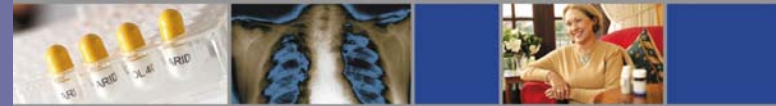


# Global Capital Raising

## Global Capital Raising

- **Coordinated bookbuild in Australia and USA**
- **One of largest Australian biotech capital raisings - \$86.7 million**
- **Common pricing of A\$2.20**
  - 0.5% discount to 30 day VWAP at announcement
  - 10% discount to 5 day VWAP at closing

Australia (ASX)	Private placement of 19.9 million shares, 60% institutions (>20)
USA (Nasdaq)	Public offering of 19.5 million shares/1.3 million ADS, >90% institutions (~10)
Total	39.4 million shares; 6% +/- US to Australia
Total shares on issue	174,398,092



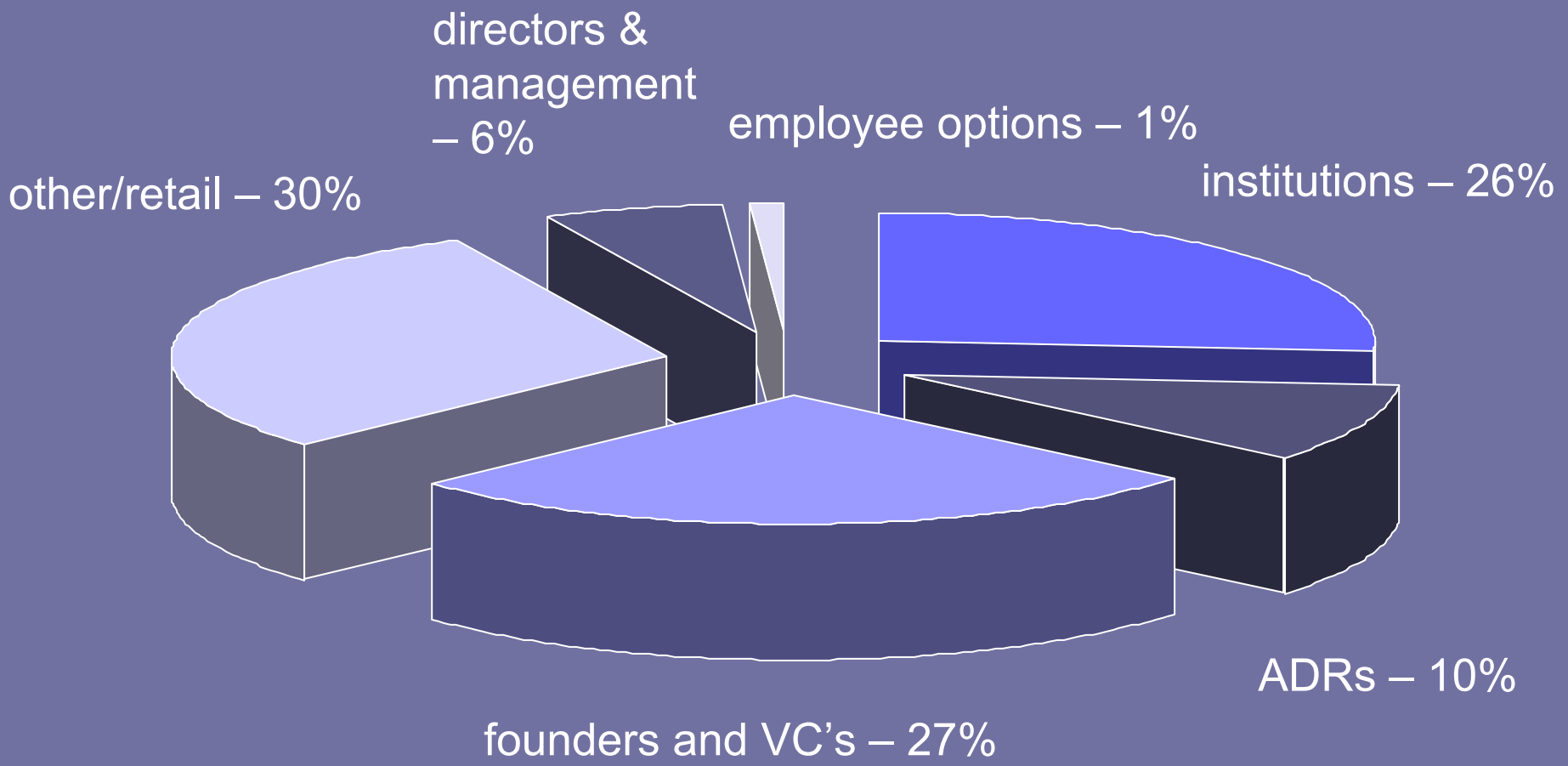
# Cash of A\$110 million<sup>(1)</sup> - positioned to:

- Complete clinical development of Bronchitol for cystic fibrosis
- Complete clinical development of Bronchitol for bronchiectasis
- Complete US clinical development of Aridol
- International launch of Aridol
- International launch of Bronchitol for cystic fibrosis and bronchiectasis
- Broaden the commercial opportunity for Aridol
- Additional clinical opportunities for Bronchitol – eg chronic bronchitis
- Expansion of manufacturing/company facilities
- Further development of preclinical pipeline

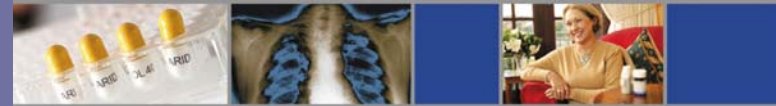


# Share Capital post Capital Raising

(including 11.4 million employee options)



# Recent Milestones

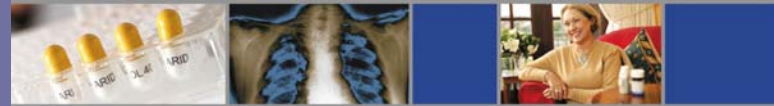


## ● Aridol

- Completed Phase III Aridol trial in asthma
- Filed for Aridol approval in Australia, EU

## ● Bronchitol

- Positive Phase II CF results
  - Positive Phase II bronchiectasis results
  - Orphan Drug designation for CF, bronchiectasis (U.S.)
  - Orphan Drug designation for CF (Europe)
- Discovered PXS64 for MS - improved oral form of PXS25
  - Tripled manufacturing capacity
  - A\$6 million Aus P3 government grant awarded
  - Global Capital raising completed - \$87 million



# Upcoming Milestones

## ● Aridol

- Potential Aridol approval in Australia & EU: 1H06
- Data from Phase II COPD trial: 2H06

## ● Bronchitol

- Initiate bronchiectasis pivotal trial: 4Q05/1Q06
- Initiate US bronchiectasis pivotal trials: mid-06
- Initiate CF pivotal trials: 2006
- Data from CF dosing study 1H06

## ● Pipeline

- US IND for PXS64 for multiple sclerosis: 1H06
- Nominate IND candidate for PXS2076 for RA: 2006