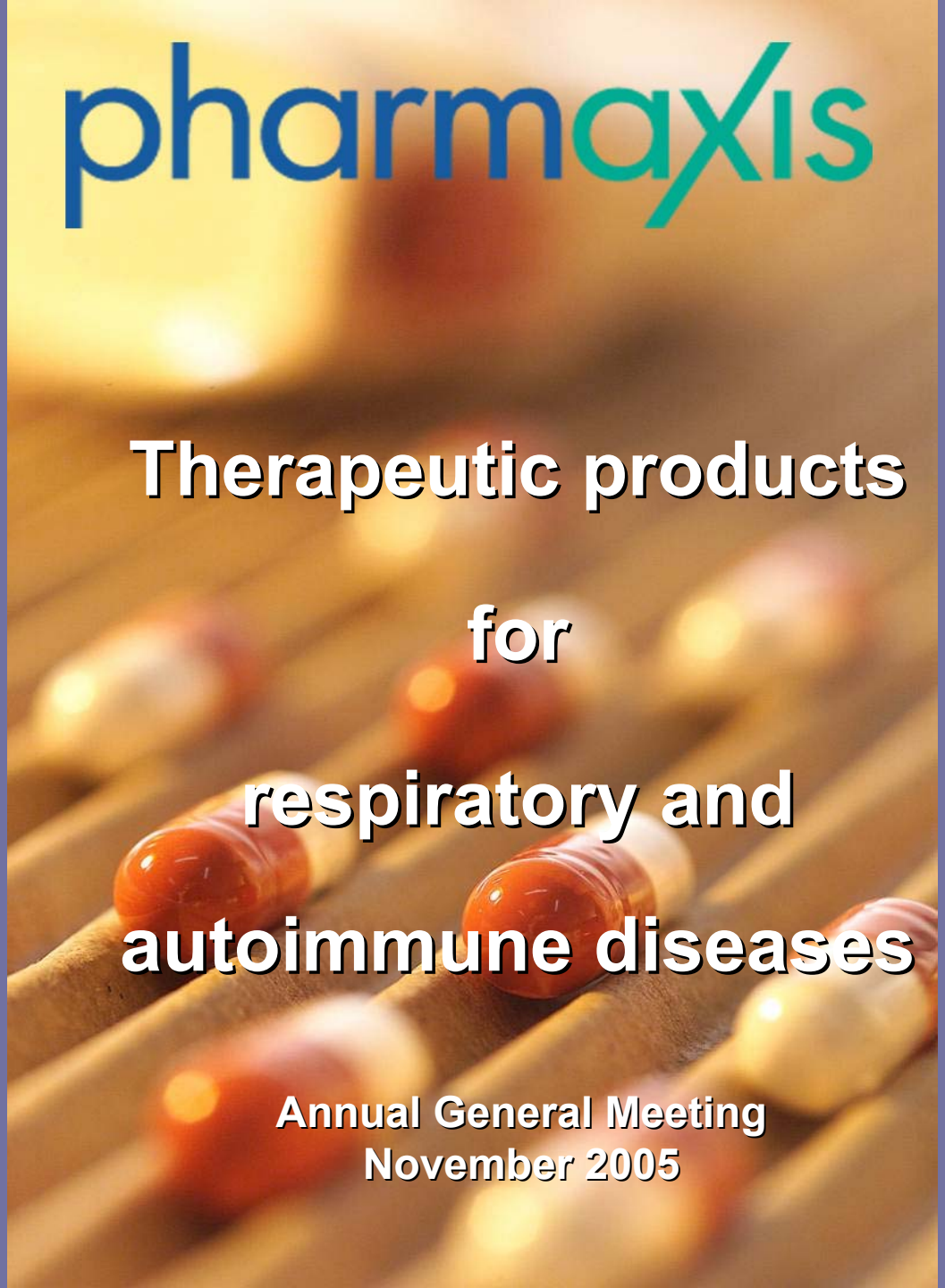
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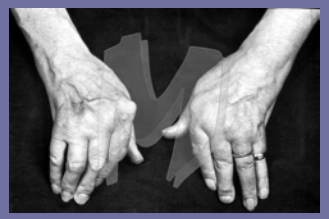
Therapeutic products
for
respiratory and
autoimmune diseases
Annual General Meeting
November 2005

# Highlights

**Bronchitol**

**Aridol**



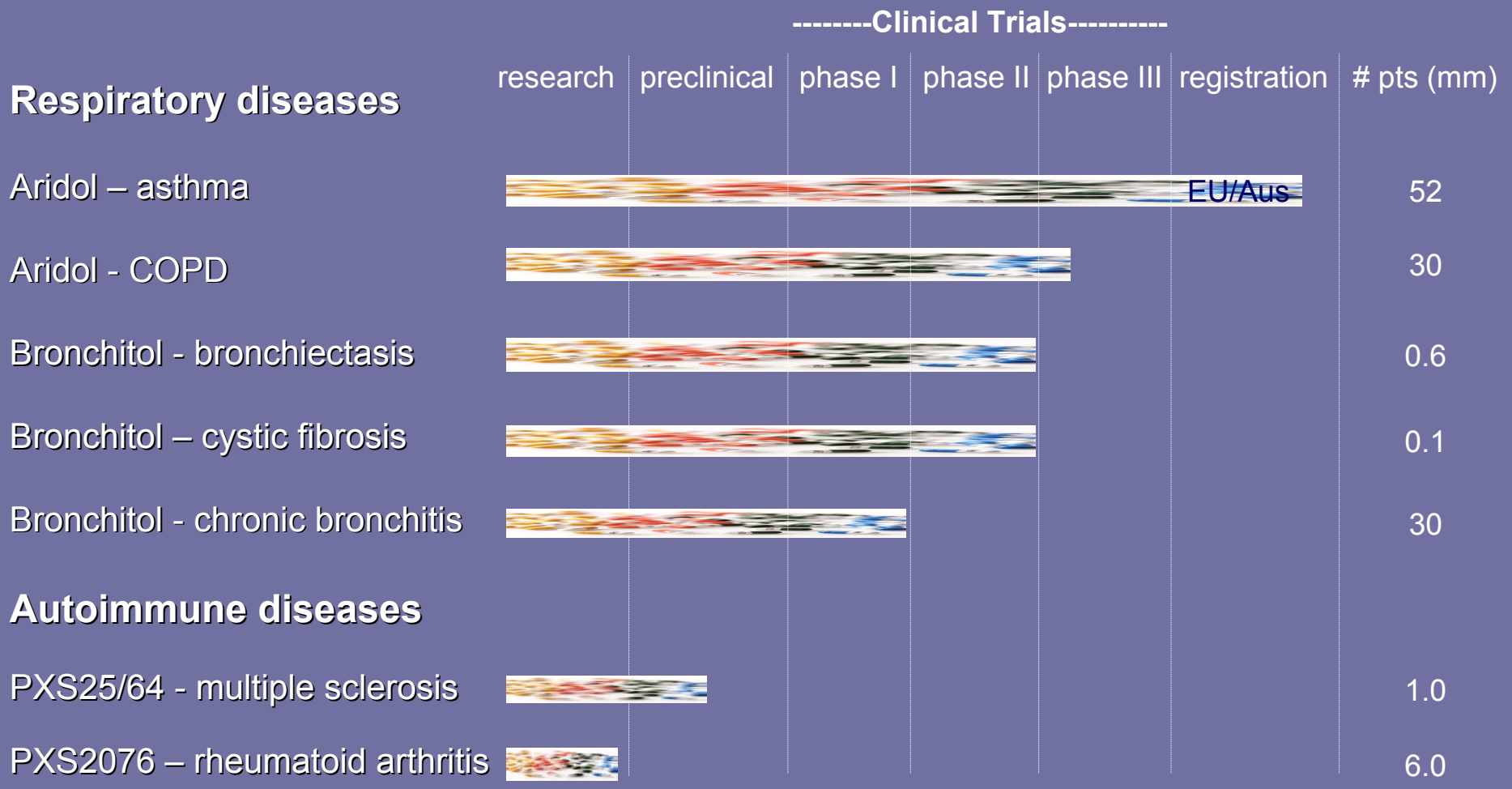
**Autoimmune disease**

**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



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# Management

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

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

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

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

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

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

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



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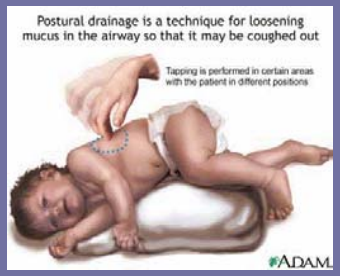
# Bronchitol

## 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



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# 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 $FEV_1$
- 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

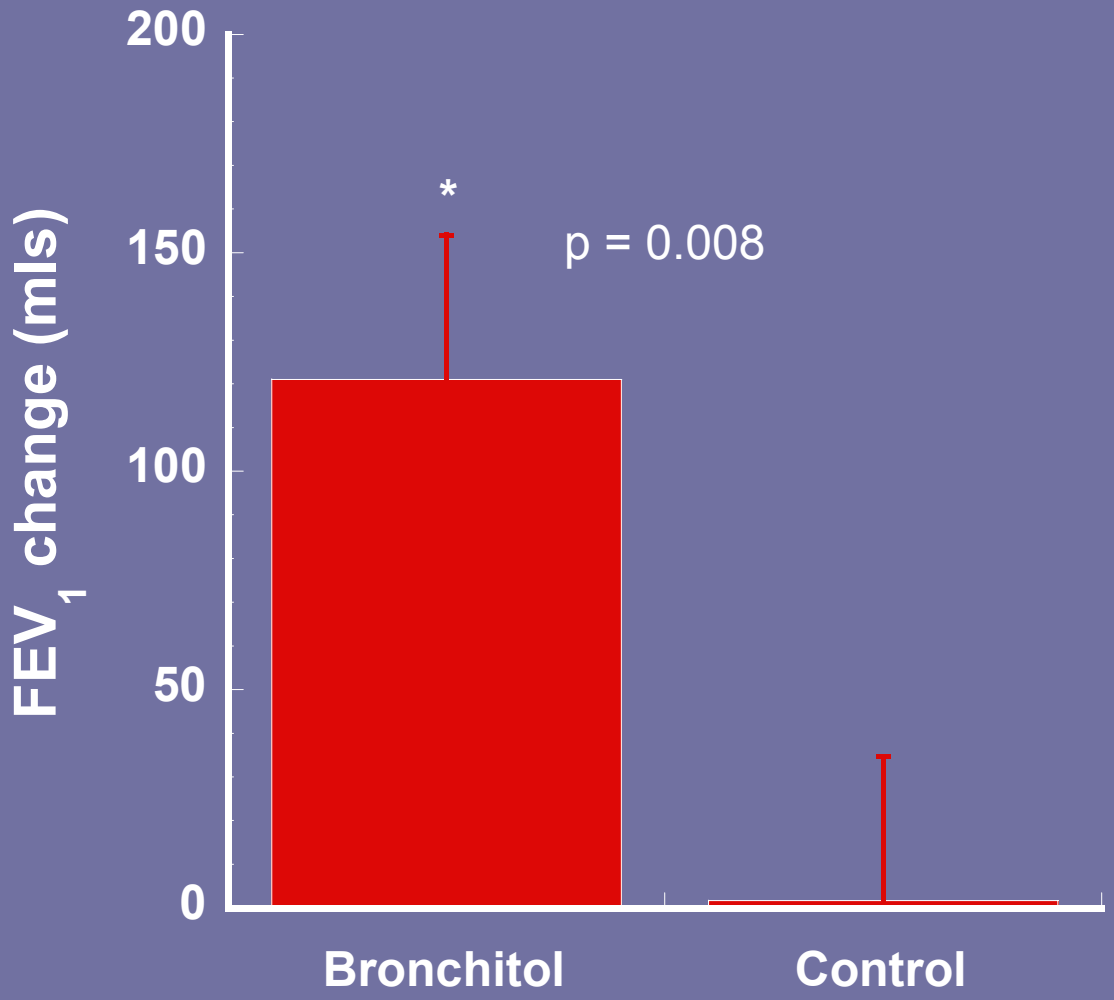
| | Bronchitol* | Control* | p value |
|---|---|---|---|
| Change in $FEV_1$ | 7 ± 2% | 0 ± 2% | 0.008 |
| Change in $FEF_{25-75}$ | 15.5 ± 5% | 0.6 ± 5% | < 0.01 |

*includes patients being treated with pulmozyme

**($FEF_{25-75}$ or MMEF is considered a measure of small airway function)**

# Bronchitol

## CF Phase II Results: $FEV_1$ Change



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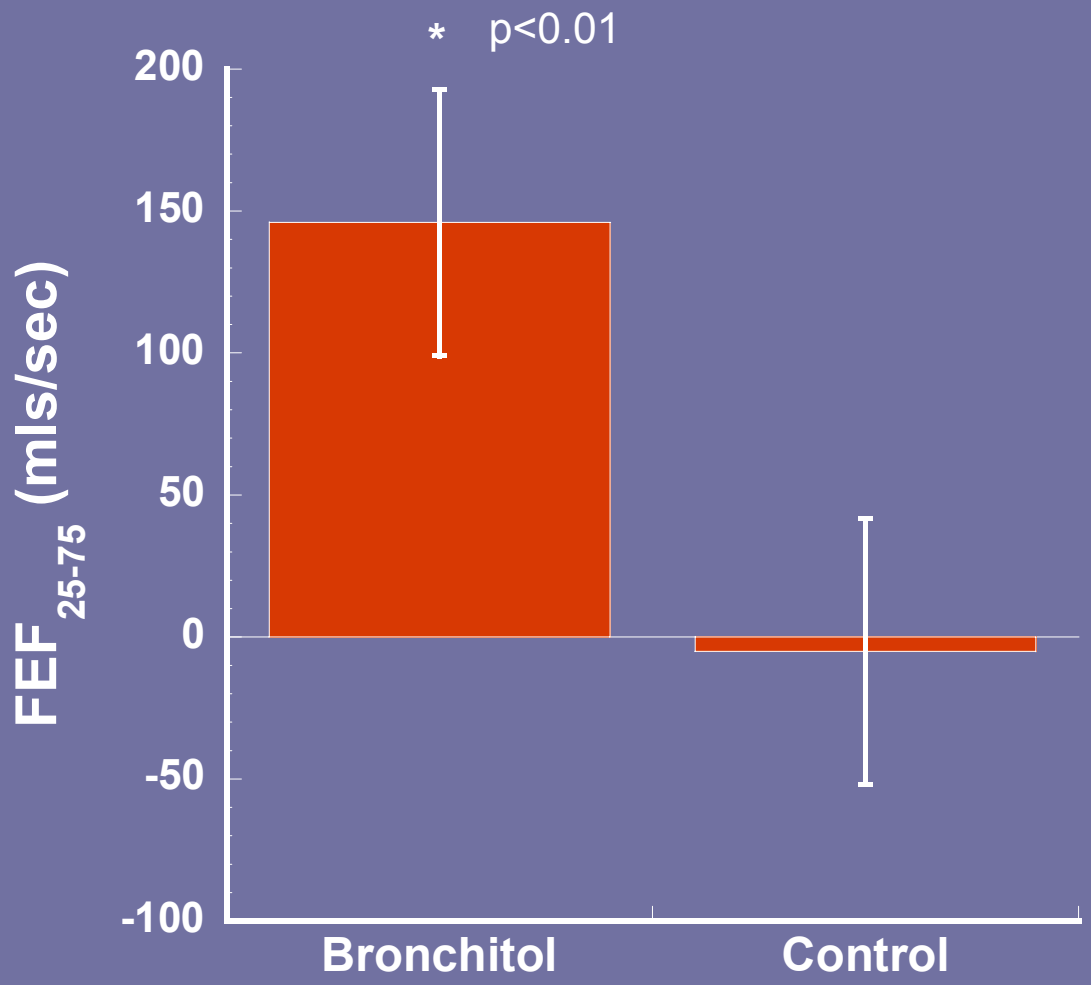
# Bronchitol

## CF Phase II Results: $FEF_{25-75}$ Change



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# Bronchitol

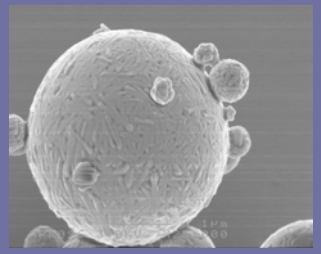
## cystic fibrosis registration strategy

- Phase III trial (EU & Aus):
  - Dosing to be finalized based on ongoing dose-ranging study
  - Commence 1H2006
  - Primary endpoint: Change in $FEV_1$
  - 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

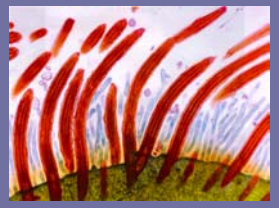
# Bronchitol

## 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.***

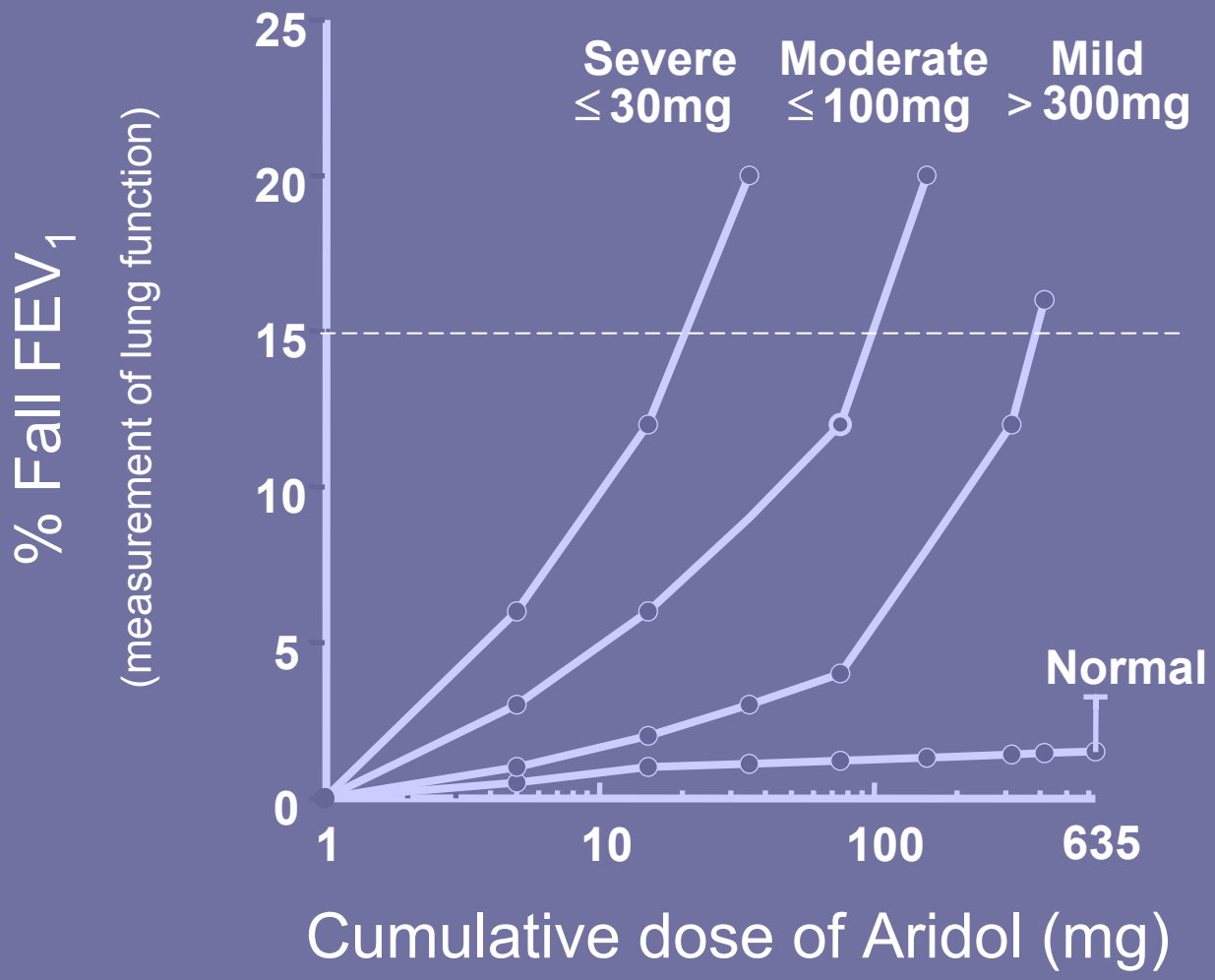
# Aridol

## 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



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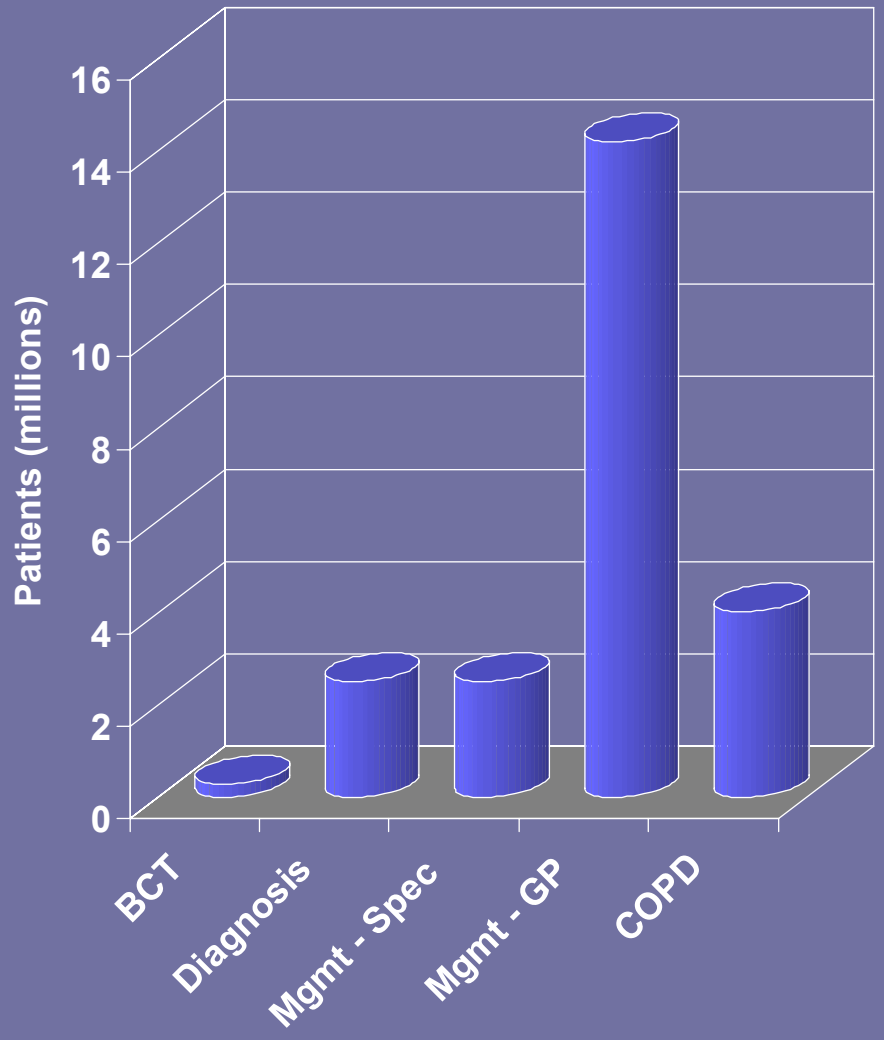
# Aridol

## 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)



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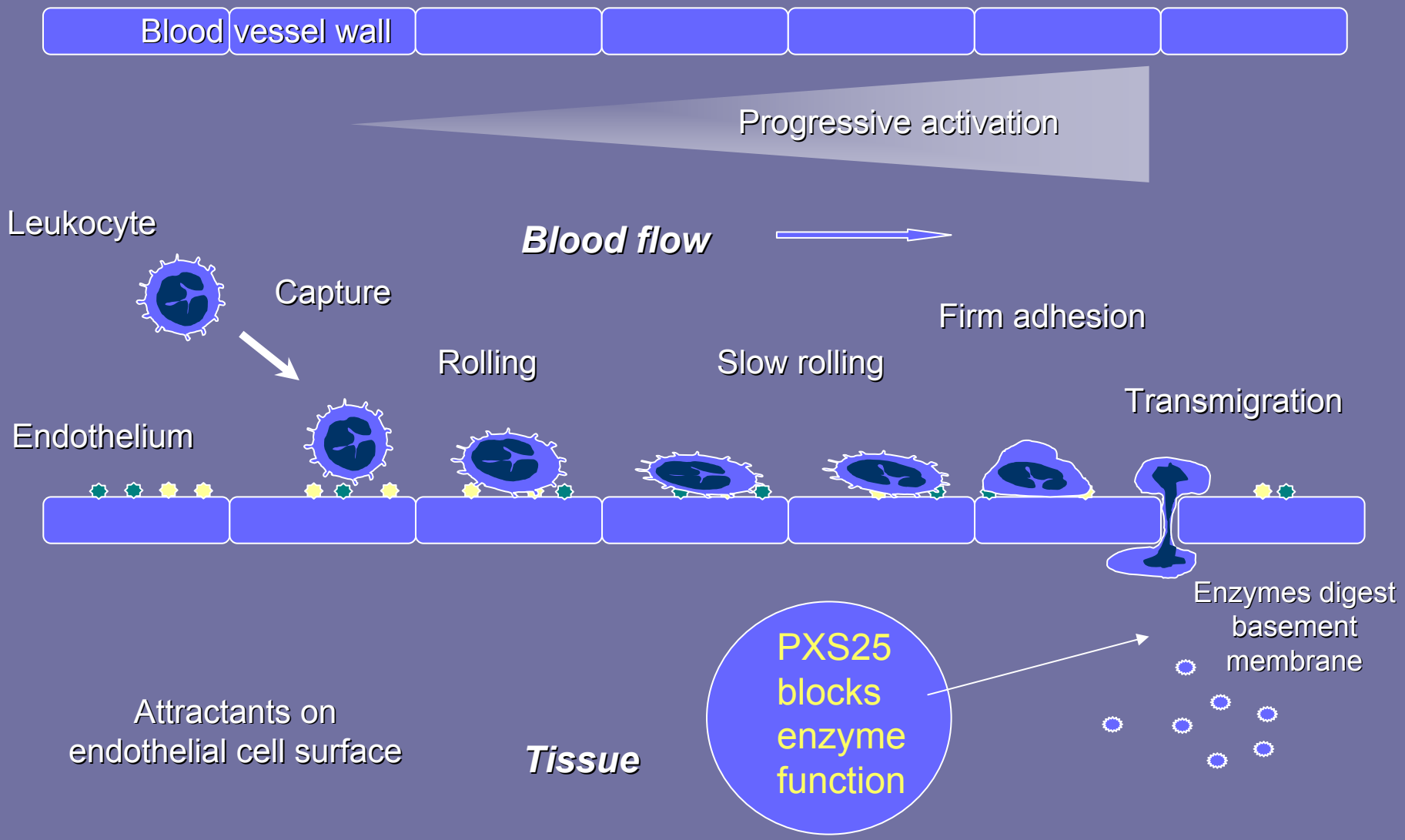
# Autoimmune diseases

multiple sclerosis

rheumatoid arthritis

# Autoimmune Disease

## Inflammation: the leukocyte activation cascade



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# Autoimmune Disease

## PXS64

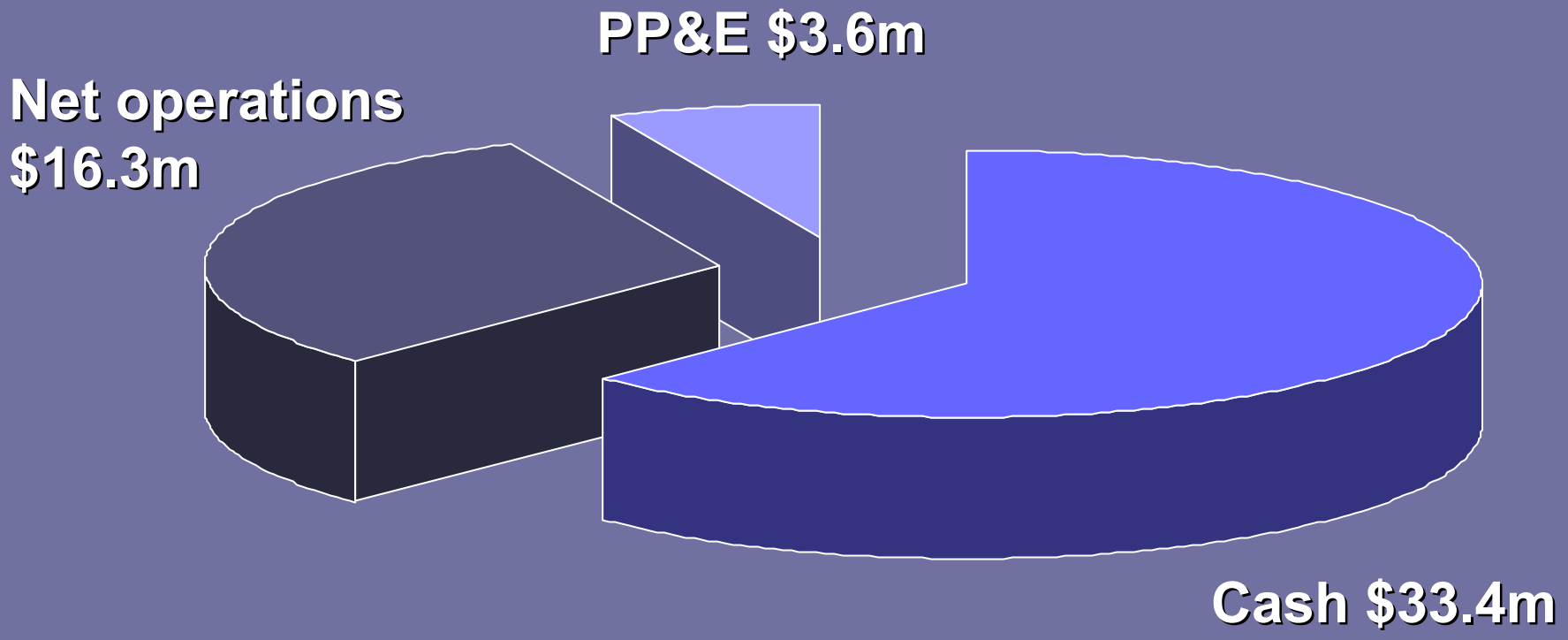
- Selective inhibitor of T cell migration
- Novel mechanism
- Effective in animal models of multiple sclerosis
- Oral prodrug of PXS25, both discovered by Pharmaxis
- Current status: preclinical development, start human Phase I clinical trials 1H06

# Financial Overview

| | Year ended 30 June, | | | |
|---|---|---|---|---|
| | 2005 $'000 | 2004 $'000 | 2003 $'000 | 2002 $'000 |
| **Financial Performance** | | | | |
| Revenue | | | | |
| Interest received | 1,702 | 1,075 | 284 | 43 |
| Research grants | 1,172 | 1,105 | 976 | 646 |
| Other | | 48 | 43 | |
| | 2,874 | 2,228 | 1,303 | 689 |
| Expenses | | | | |
| Research & development | (9,154) | (6,047) | (1,790) | (1,151) |
| Commercial | (847) | - | | |
| Administration | (3,105) | (2,182) | (981) | (140) |
| Total expenses | (13,106) | (8,229) | (2,771) | (1,291) |
| Net loss before and after tax | (10,232) | (6,001) | (1,468) | (602) |
| | | | | |
| Depreciation & amortisation | 626 | 410 | 256 | 130 |
| EBITDA | (11,308) | (6,666) | (1,496) | (515) |
| | | | | |
| **Cash Flows** | | | | |
| 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 | 8,172 | 17,833 | 6,633 | (399) |

| | 30 June, | |
|---|---|---|
| | 2005 | 2004 |
| | $'000 | $'000 |
| **Financial Position** | | |
| 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



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# Global Capital Raising

| Global Capital Raising<br>• Coordinated bookbuild in Australia and USA<br>• One of largest Australian biotech capital raisings - $86.7 million<br>• Common pricing of A$2.20<br>  ▪ 0.5% discount to 30 day VWAP at announcement<br>  ▪ 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 |

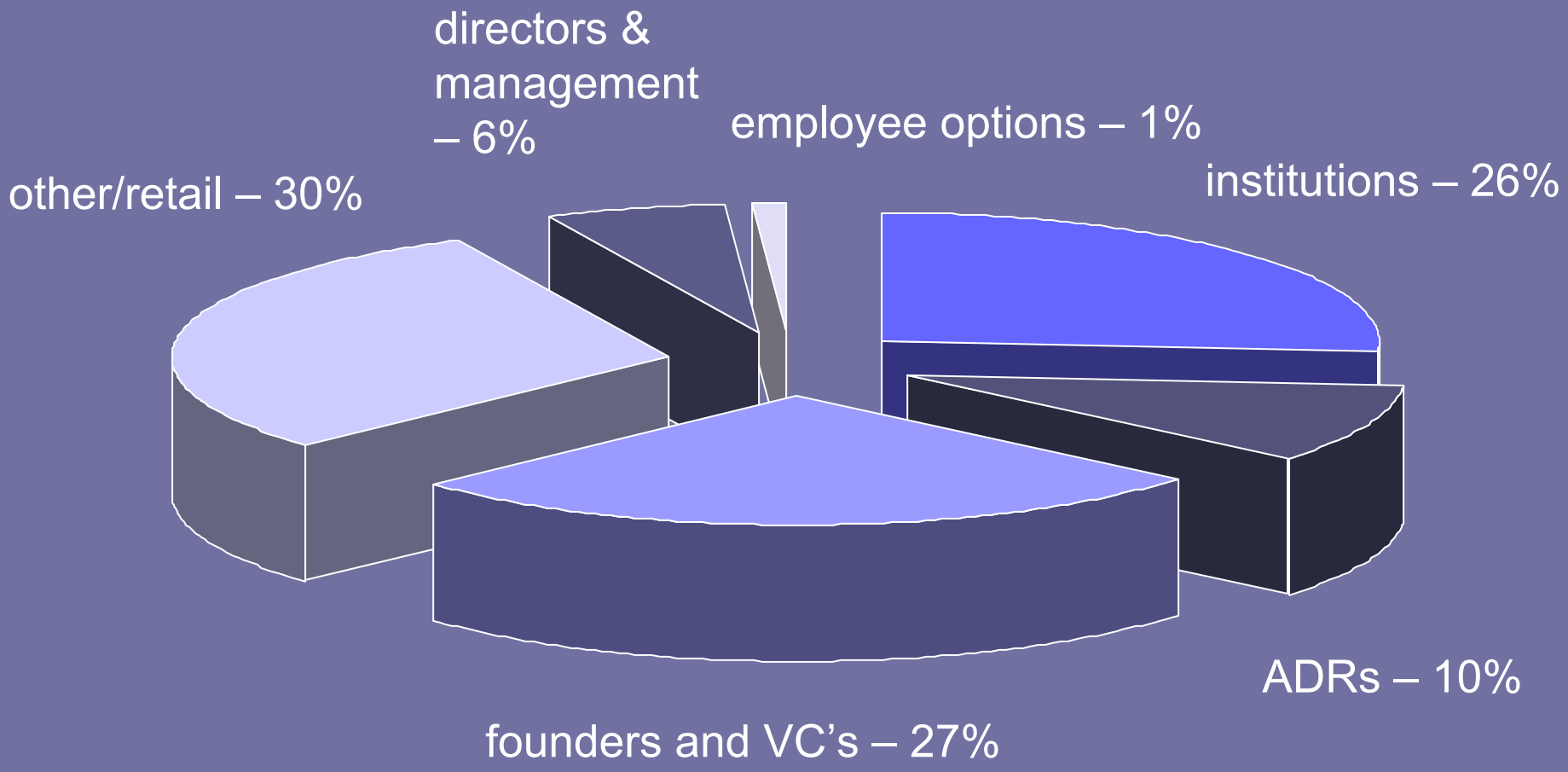
# Cash of A$110 million(1) - positioned to:

- 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

(1) Proforma 30 Sept

# Share Capital post Capital Raising

(including 11.4 million employee options)



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# 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