



pharmaxis

Therapeutic products

for

respiratory and

autoimmune diseases

**Annual General Meeting
November 2005**

Highlights



Bronchitol



Aridol



**Autoimmune
disease**

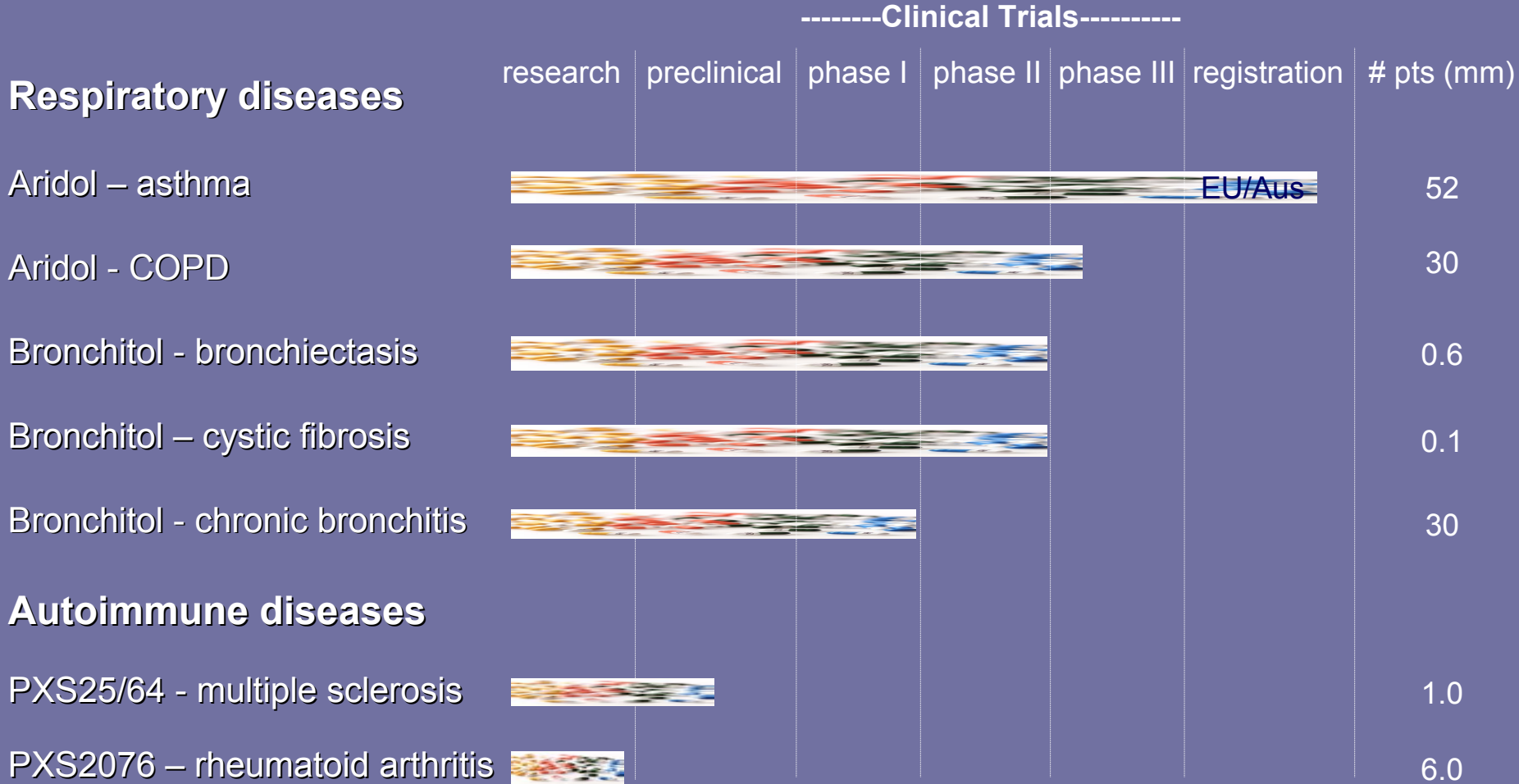
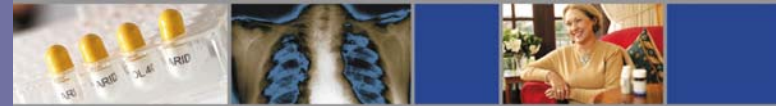


Manufacturing

- **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

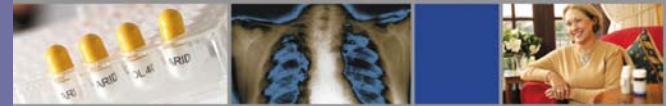


- **Ian McDonald, PhD**
VP Discovery, SIBIA (Merck); VP Discovery, SGX

CTO

Bronchitol

cystic fibrosis

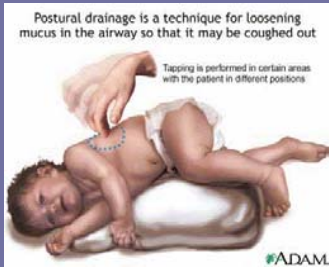


● Background

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

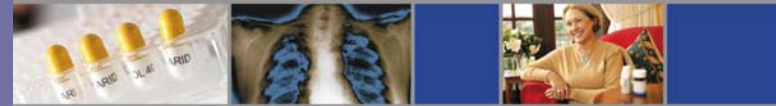
● Current treatments: rhDNase and tobramycin

- 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 FEV₁
- 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

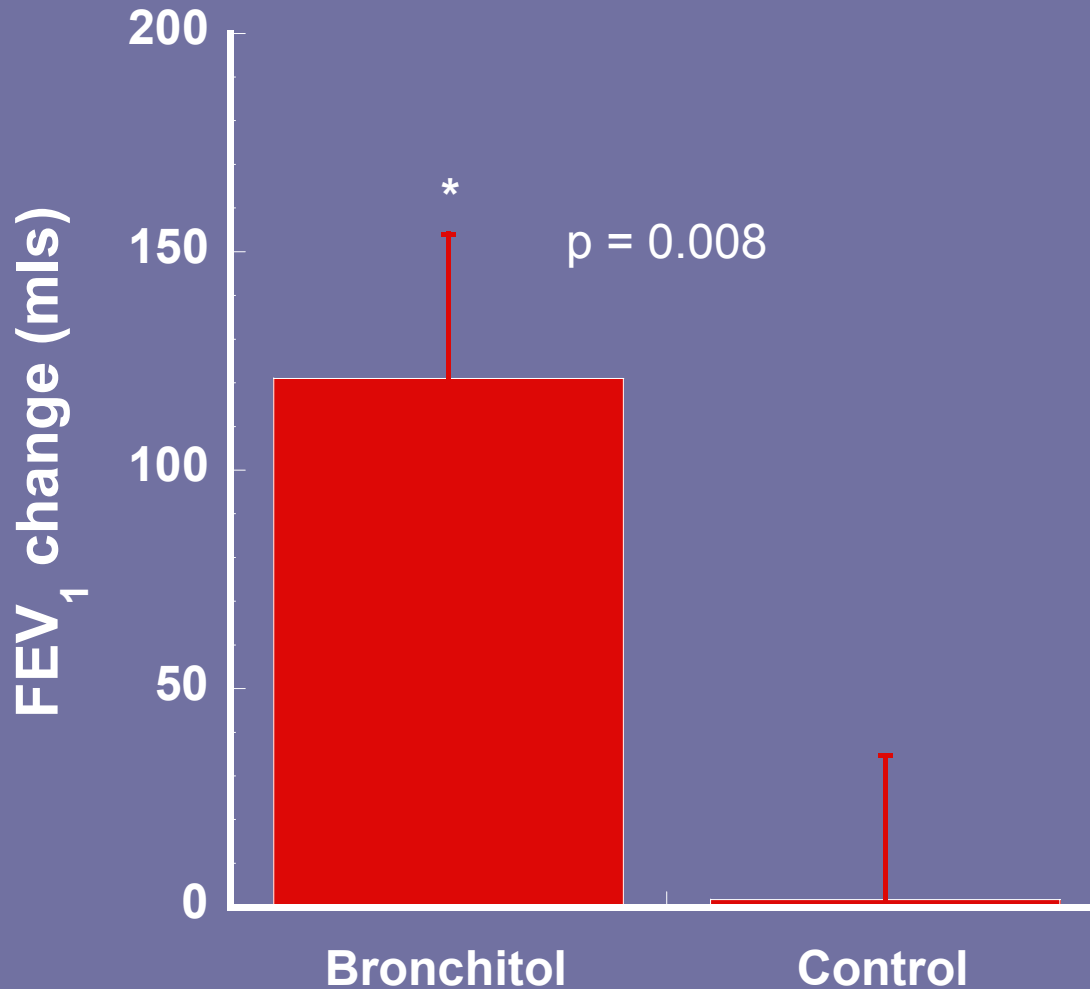
*includes patients being treated with pulmozyme

(FEF₂₅₋₇₅ or MMEF is considered a measure of small airway function)

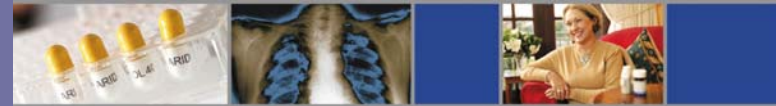
Bronchitol



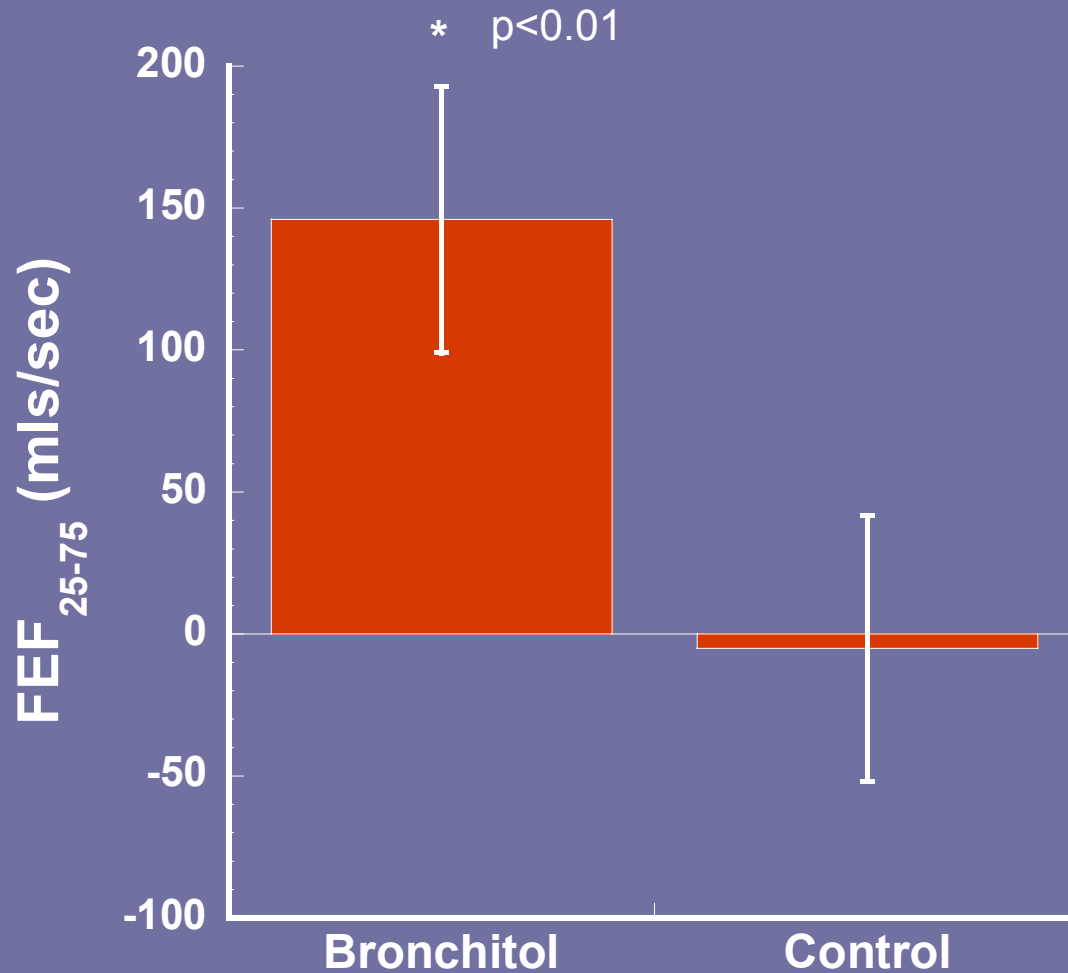
CF Phase II Results: FEV₁ Change



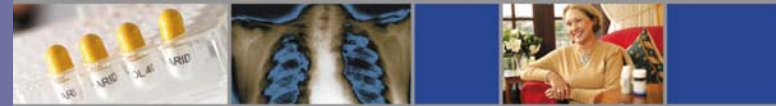
Bronchitol



CF Phase II Results: FEF₂₅₋₇₅ 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 FEV₁
- Placebo-controlled, 6 month dosing, finalising design with EMEA



● Phase III trial (US) to commence 2006

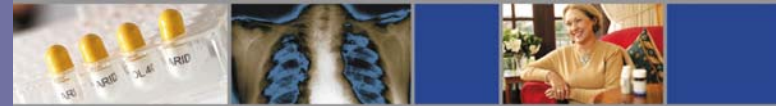
- Similar size, design to EU/Aus trial



● Orphan drug designation – EU and USA

Bronchitol

bronchiectasis



● Background

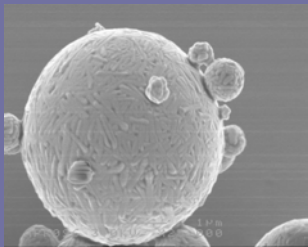


- Abnormal, irreversible dilation of the lower airways
- Daily mucus production, constant coughing, breathlessness: major quality of life impact
- Normal lung clearance impaired
- 100,000 affected in the U.S.



● 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

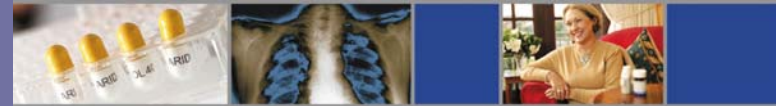
● Phase III Trials

- 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

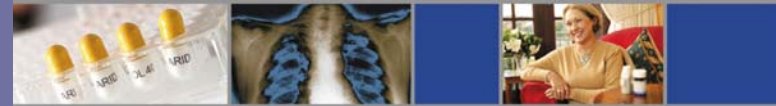


Aridol™



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

Aridol



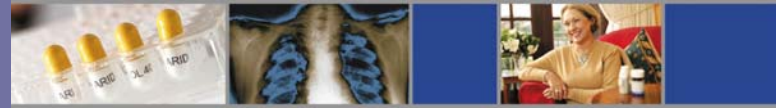
Asthma and COPD Opportunity

● 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

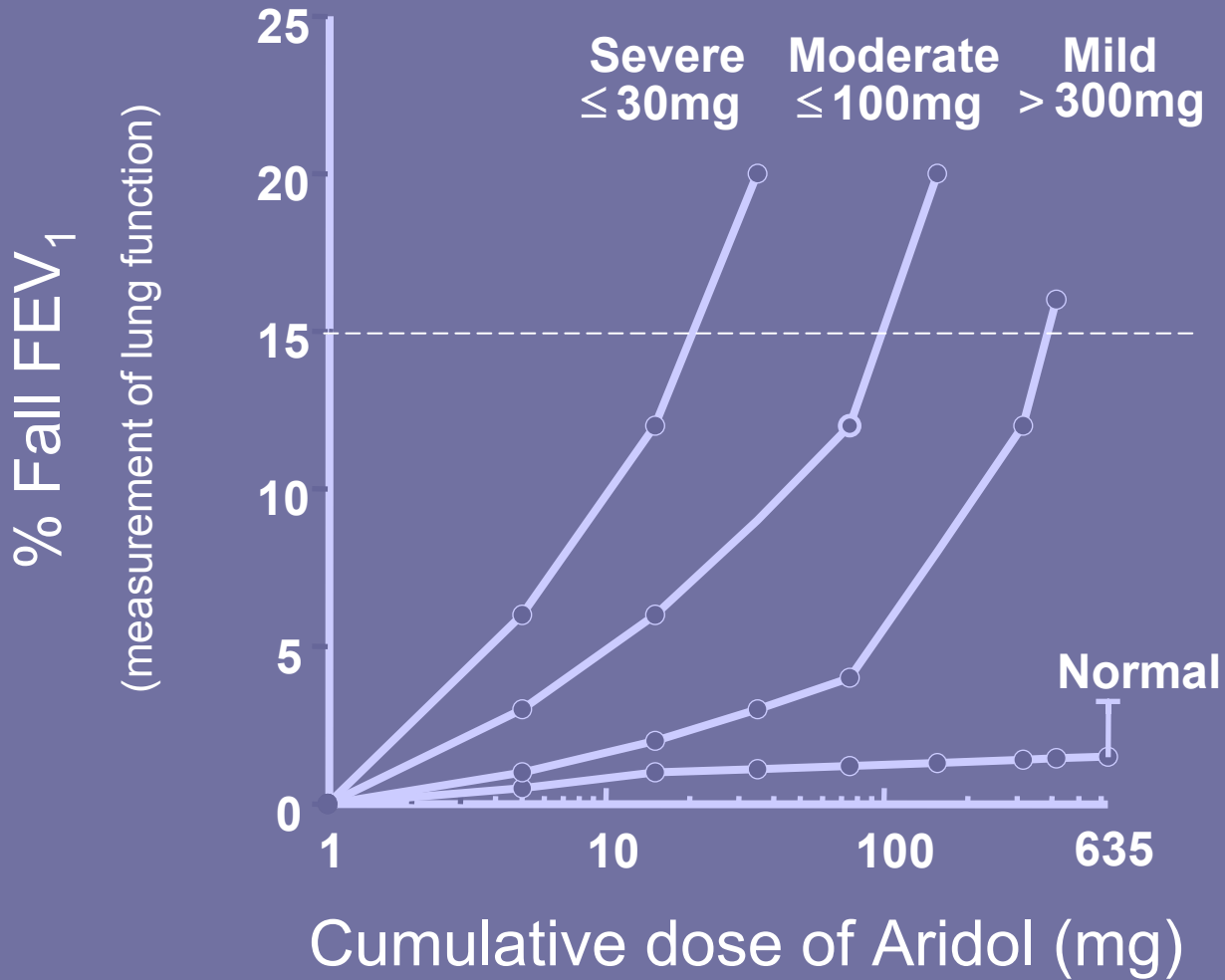
● COPD

- 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

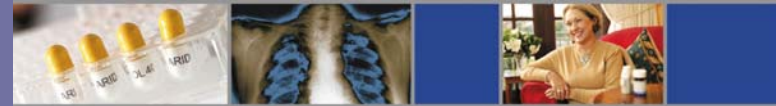


Aridol

quantitation of airway hyperresponsiveness



Aridol

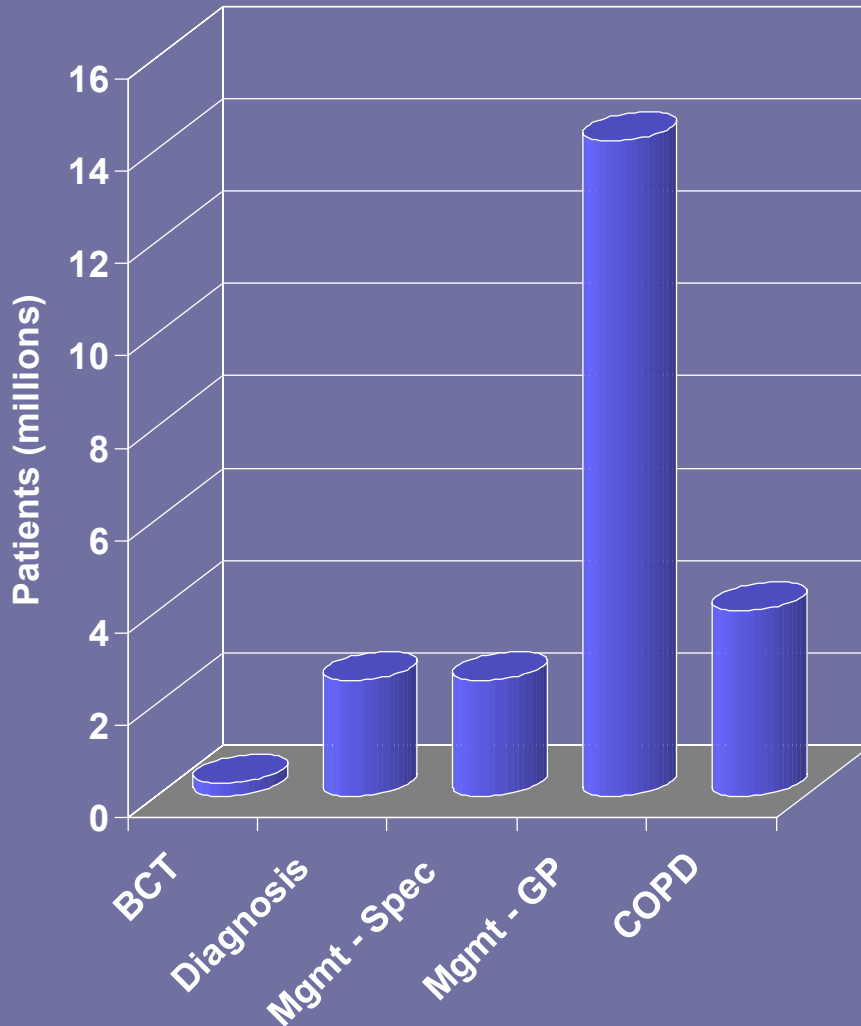
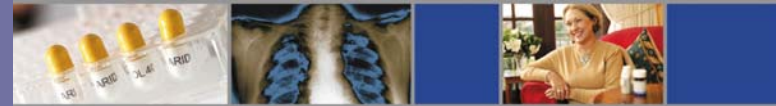


current status

- 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)

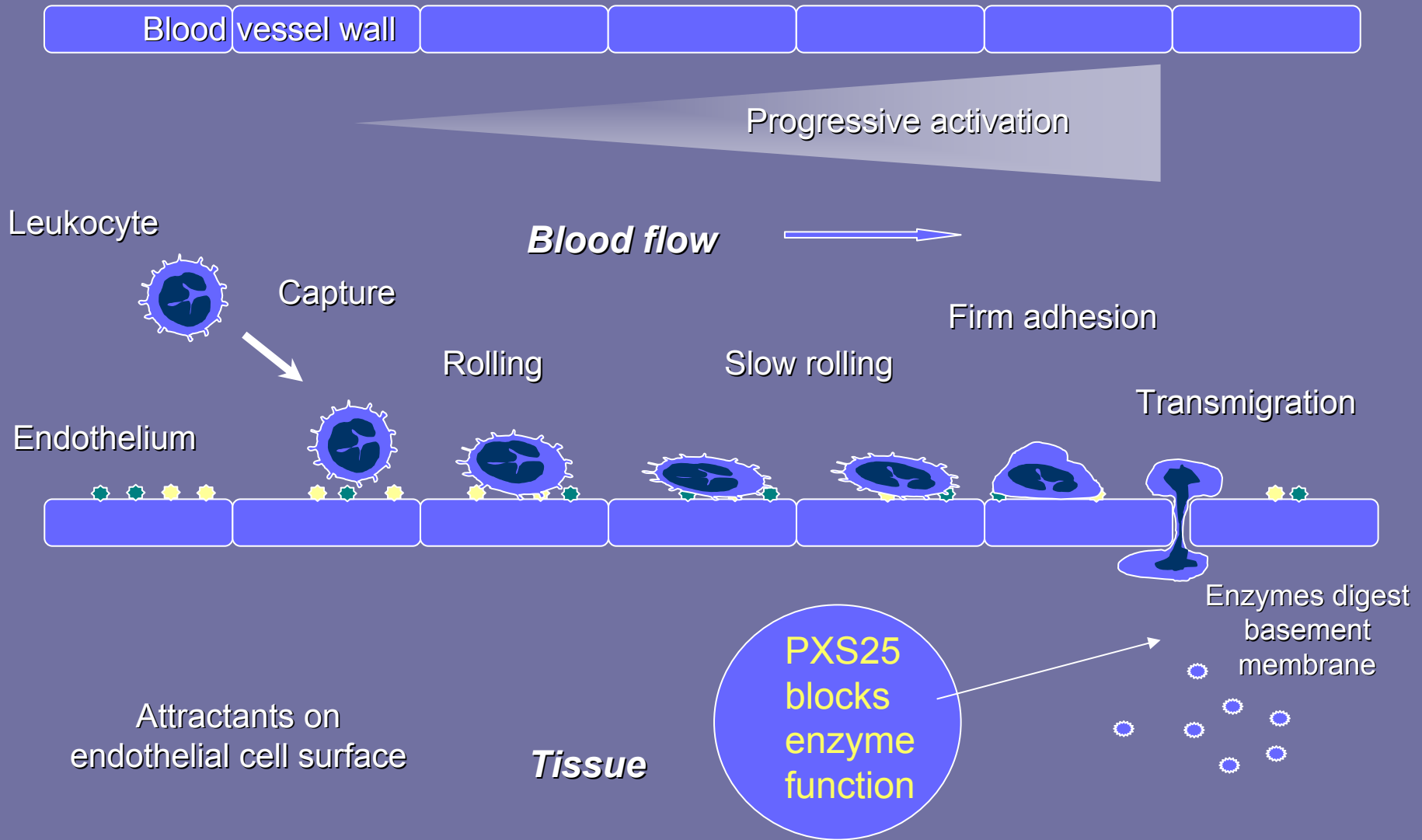
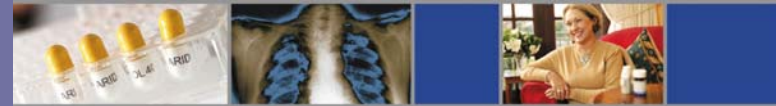


Autoimmune diseases

multiple sclerosis
rheumatoid arthritis

Autoimmune Disease

Inflammation: the leukocyte activation cascade





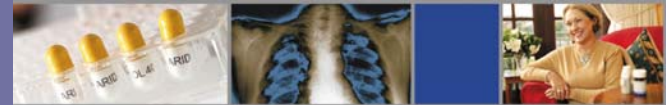
Autoimmune Disease

PXS64

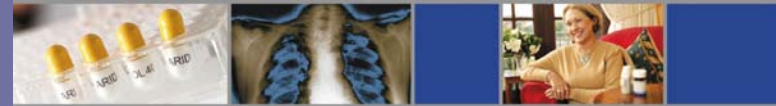
- Selective inhibitor of T cell migration
- Novel mechanism
- Effective in animal models of multiple sclerosis
- Oral prodrug of PXS25, both discovered by Pharmaxis
- Current status: preclinical development, start human Phase I clinical trials 1H06



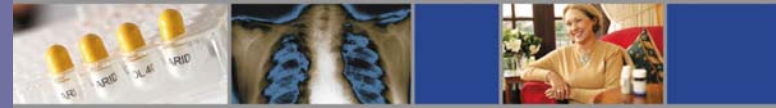
Financial Overview



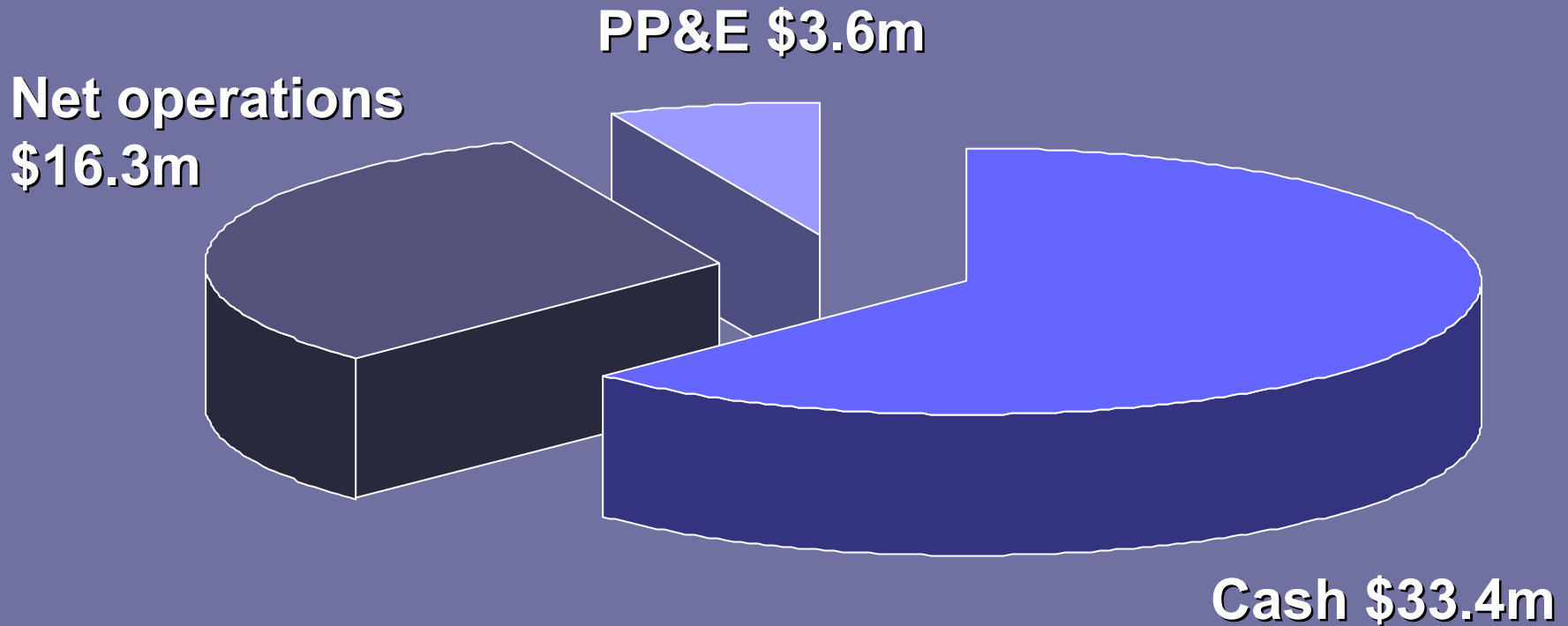
	Year ended 30 June,			
	2005 \$'000	2004 \$'000	2003 \$'000	2002 \$'000
Financial Performance				
Revenue				
Interest received	1,702	1,075	284	43
Research grants	1,172	1,105	976	646
Other		48	43	
	<u>2,874</u>	<u>2,228</u>	<u>1,303</u>	<u>689</u>
Expenses				
Research & development	(9,154)	(6,047)	(1,790)	(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)
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	<u>8,172</u>	<u>17,833</u>	<u>6,633</u>	<u>(399)</u>

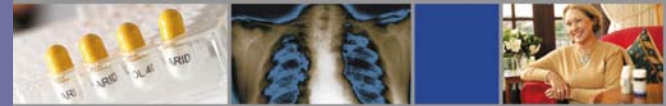


	30 June,	
	2005	2004
	\$'000	\$'000
Financial Position		
Cash and bank accepted commercial bills	33,389	25,217
Plant & equipment	2,477	1,474
Intangible assets	1,106	1,162
Total assets	37,937	28,261
Total liabilities	2,369	1,481
Total shareholders' equity	35,569	26,780



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



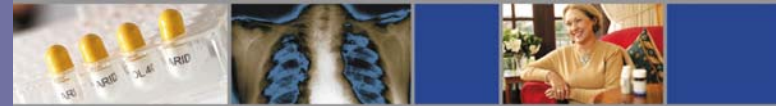


Global Capital Raising

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



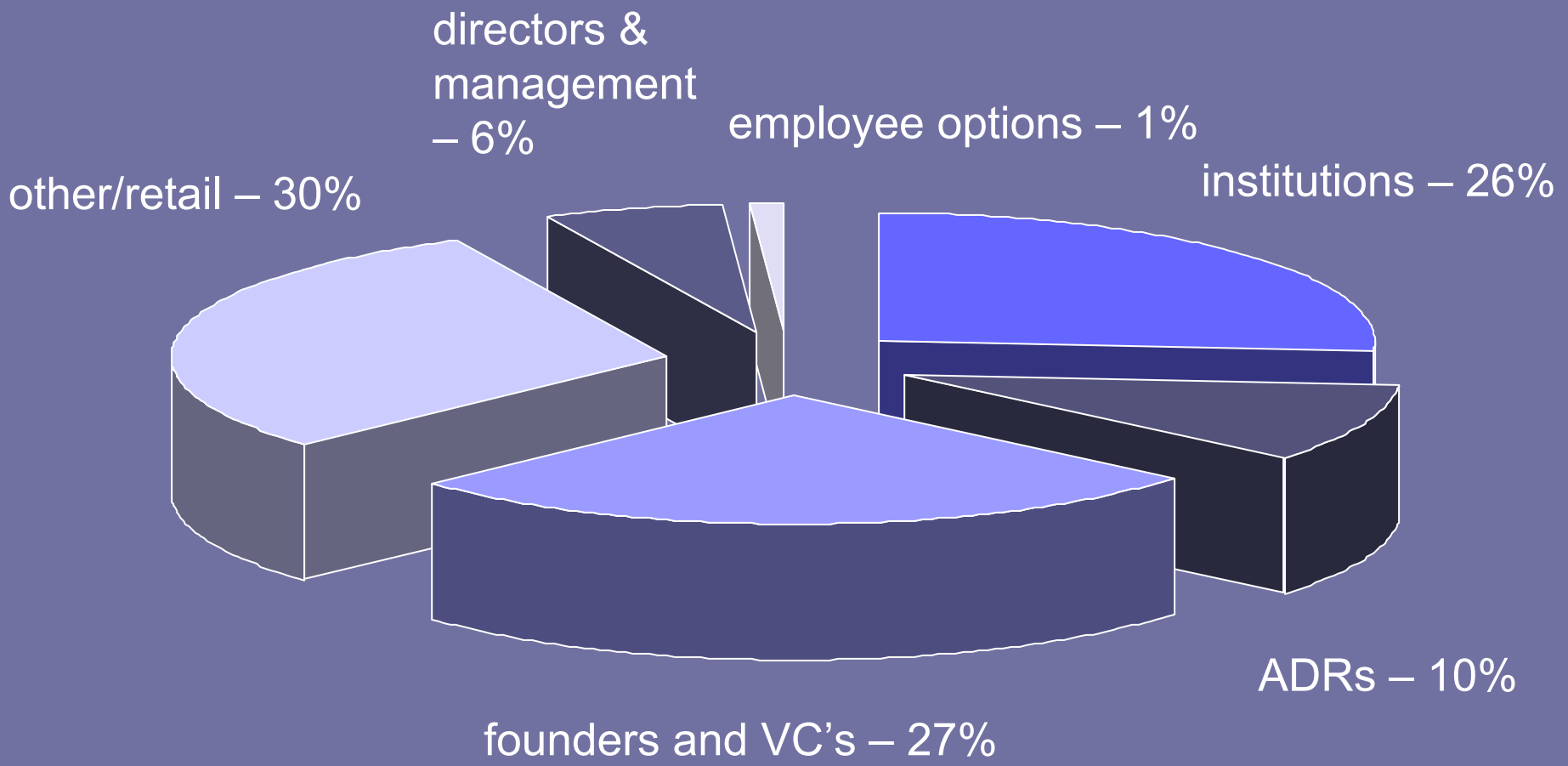
Cash of A\$110 million⁽¹⁾ - positioned to:

- 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

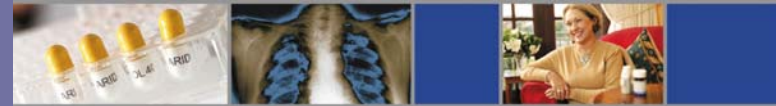


Share Capital post Capital Raising

(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