

The logo for Pharmaxis, featuring the word "pharmaxis" in a white, lowercase, sans-serif font. The background of the slide is a dark blue gradient with a large, curved, light blue shape on the right side.






Chief Executive Officer

Dr Alan Robertson

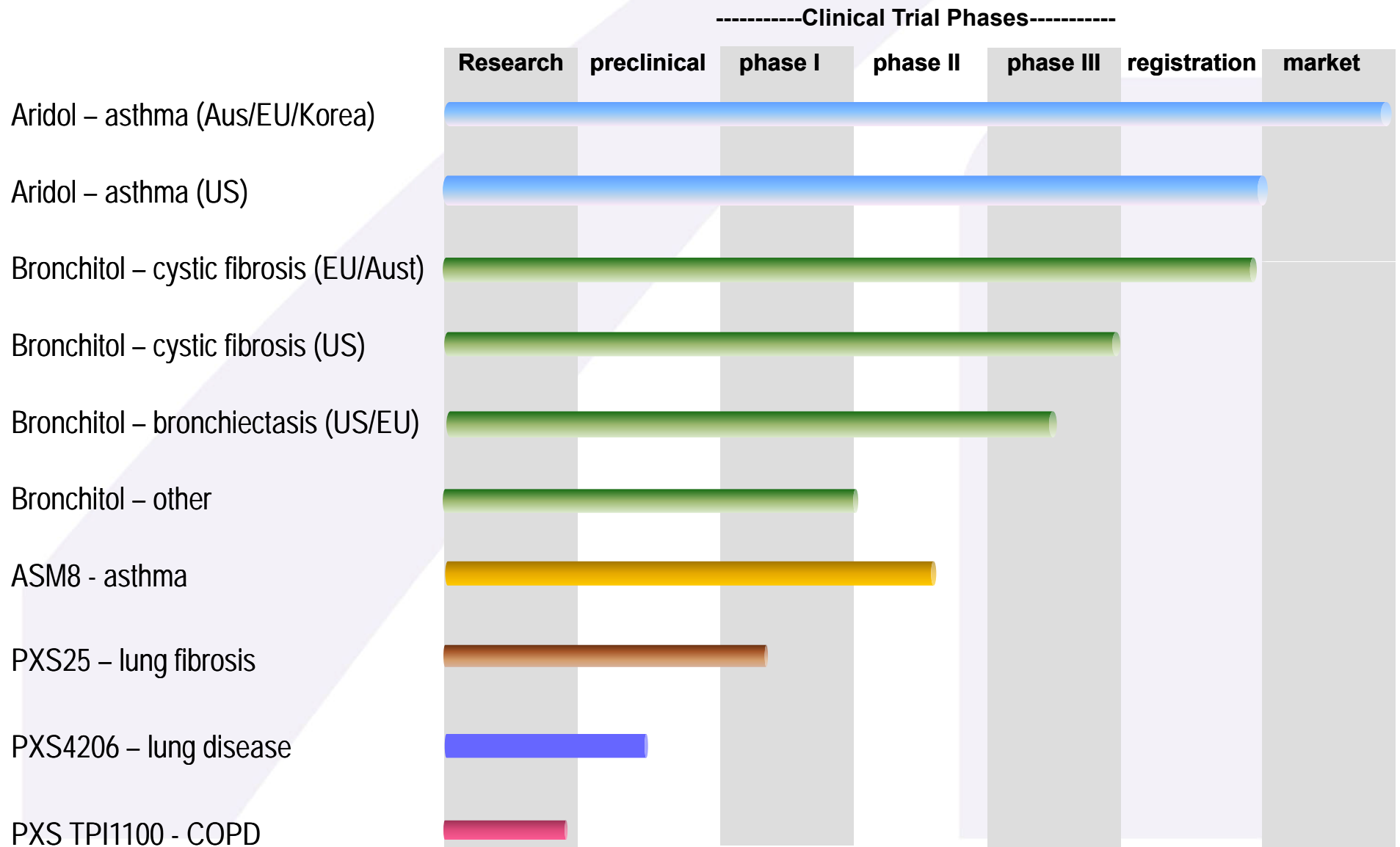
Annual General Meeting

October 2010

Company Overview

Objective	The development of products for respiratory and inflammatory diseases
Lead products	Aridol: management of asthma and COPD Bronchitol: therapeutic for cystic fibrosis and COPD ASM8: therapeutic for asthma
Discovery	PXS25 (M6P receptor blocker); PXS4206 (VAP1 inhibitor)
Listing	ASX (Nov 2003): PXS
Locations	Sydney, Australia • Exton, USA • Slough, UK • Montreal, Canada
Facility	GMP Manufacture of Aridol & Bronchitol
Employees	137
Cash (30/9/10)	A\$76 million
Shares & Options	Shares outstanding: 226m; Options outstanding: 13m
Key patents	Bronchitol & Aridol: granted in USA, Australia, Asia, Canada & Europe. Aridol: granted in Japan PXS25 and ASM8: base patents granted US and Europe +
Analyst coverage	    

Development Pipeline



Pharmaxis Global Operations 2010



Year in review - milestones passed



1. European and Australian filing of marketing applications for Bronchitol to treat cystic fibrosis



2. Bronchitol data shows sustained benefit for cystic fibrosis patients following 12 months of treatment

3. Acquisition of ASM8 and ASM1100 (Topigen)



4. ASM8 successful results in Phase II trial of asthma patients

5. PXS25 successfully completes Phase 1 clinical trial

6. CF302 result confirms efficacy and safety of Bronchitol in cystic fibrosis



7. New facility receives initial accreditation by TGA

Bronchitol

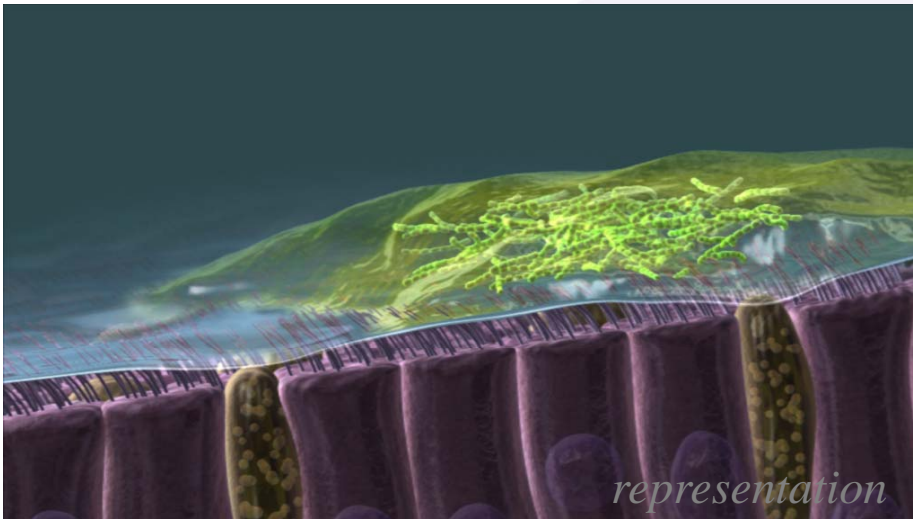


Mucus clearance:

***Cystic fibrosis
Chronic Obstructive Pulmonary Disease
Bronchiectasis***

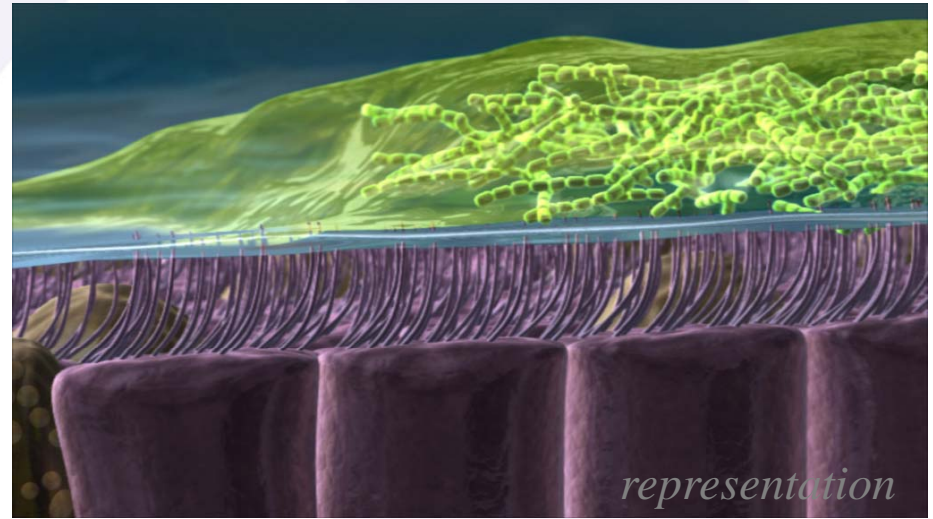
Osmotic clearance of abnormal mucus

Before treatment



Lung surface dehydrated
Airway surface fluid layer impaired
Lung defense and hygiene compromised

After Bronchitol administration



Lung hydrated
Airway surface liquid restored
Normal lung clearance

Bronchitol – cystic fibrosis

- **Background**



- Genetic disorder affecting 75,000 worldwide (30,000 in US)
- Poorly hydrated, tenacious, thick mucus
- Life expectancy is 37 years (US)

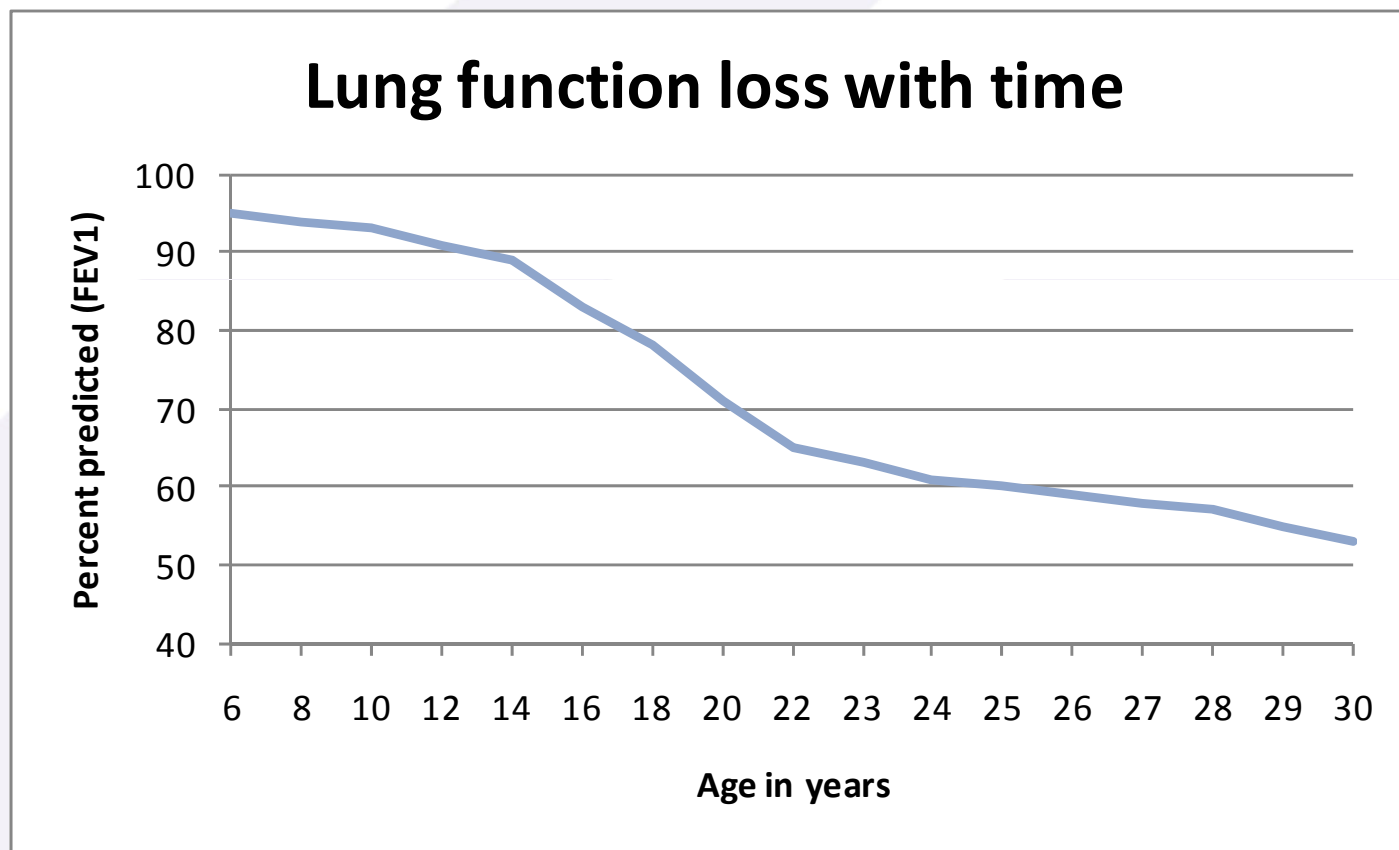
- **Current treatments**



- Delivered by nebulizer (preparation, sterilization)
- rhDNase (Pulmozyme®): global sales US\$460mm (2009)
- Tobramycin (Tobi®): global sales US\$233mm (2007)
- Aztreonam (Cayston®): approved EU: 9/09; US: 02/10



Average lung function decline in CF patients



Source: Cystic Fibrosis Foundation Patient registry, 2004

Bronchitol – cystic fibrosis clinical program

Two Pivotal Phase III trials – same design



- Multicentre, double blind, placebo controlled
- Approx 300 subjects greater than 6 years old per trial
- 6 month treatment, 400mg twice per day followed by 6 month open
- Primary endpoint:
 - lung function (FEV₁)
- Secondary endpoints:
 - Other lung function measures
 - Lung function (FEV₁) in patients on rhDNase
 - exacerbations
 - antibiotic use
 - QOL and safety
- CF301: 40 centres in UK, Ireland, Australia & New Zealand
- CF302: 53 centres in US, Canada, Argentina, Germany, France, Belgium & Netherlands
- Subjects remain on existing background therapies

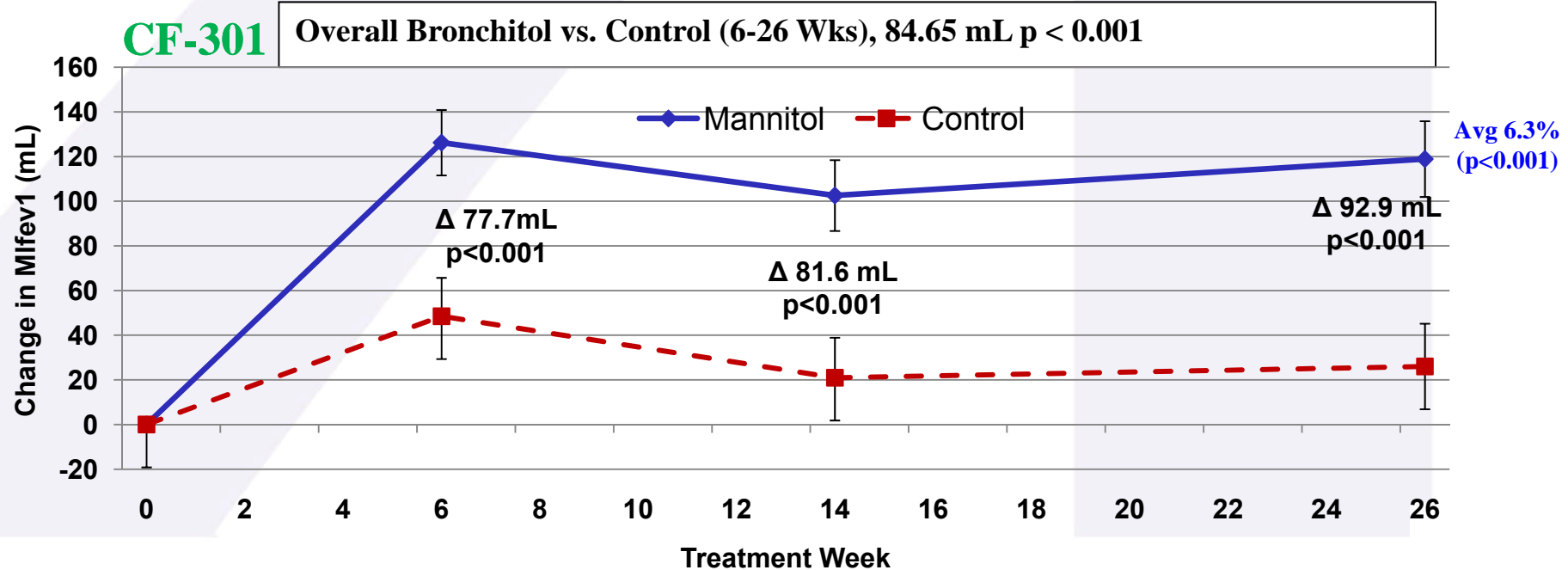
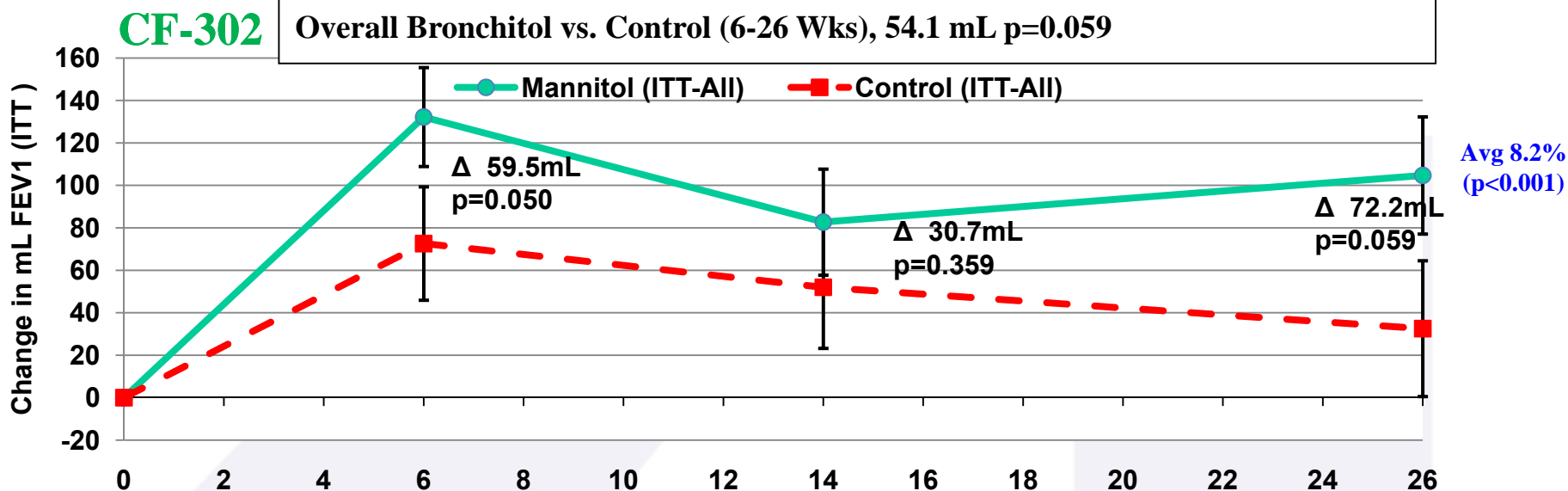
Cystic Fibrosis Trial Demographics



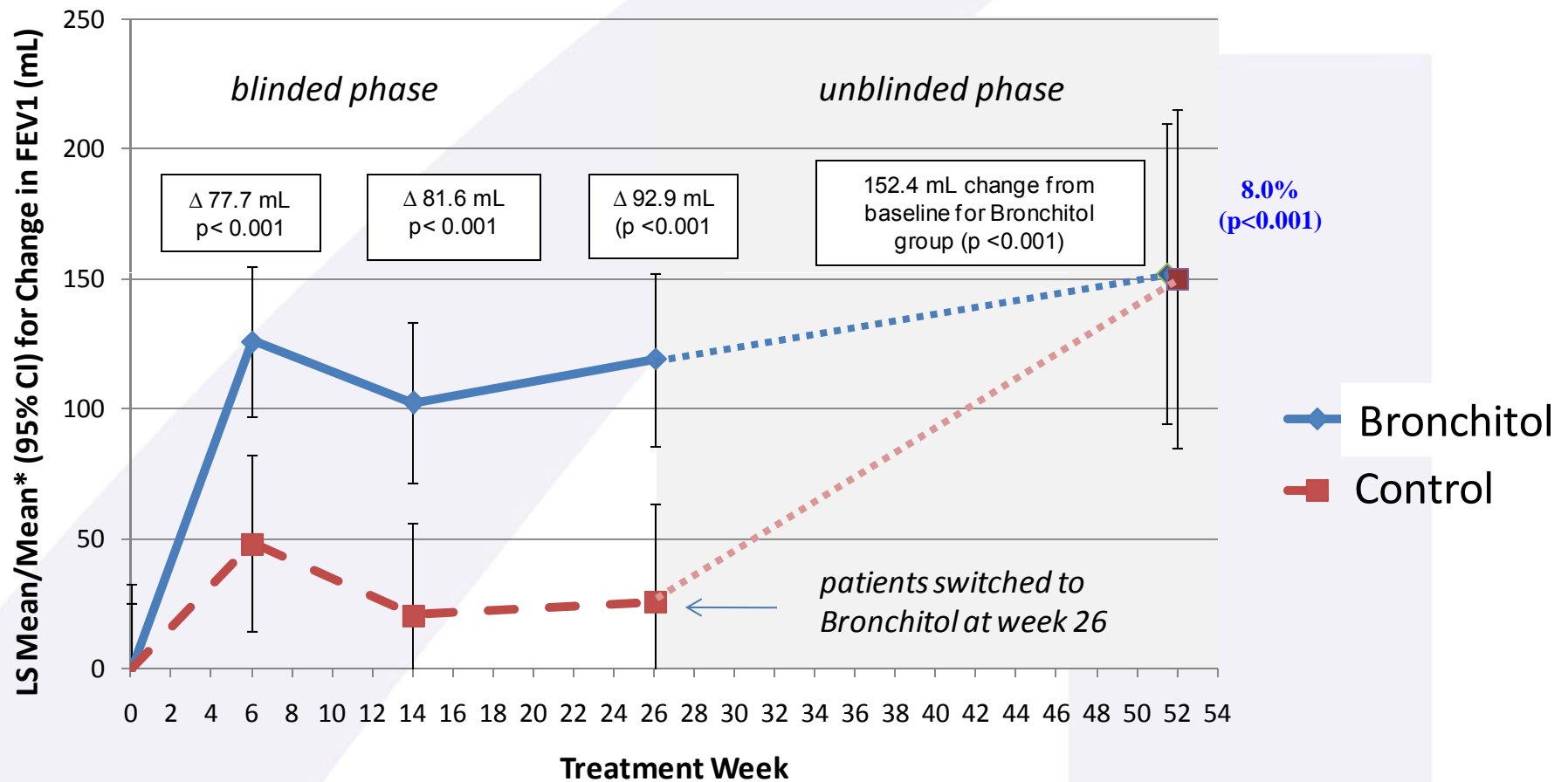
Criteria	CF301	CF302
Patients failing mannitol tolerance test	7%	7%
Patients randomised	324	318
Received treatment	295	305
Withdrawal rate	33%	14.8%
Average age	23	20
Age range	6 - 56	6 - 53
Mean predicted FEV ₁ on entry	62%	65%
Predicted FEV ₁ range	26% - 94%	34% - 96%
% patients on dornase alfa	55%	75.1%

CF-302 and CF-301 Mean change (mL) in FEV₁

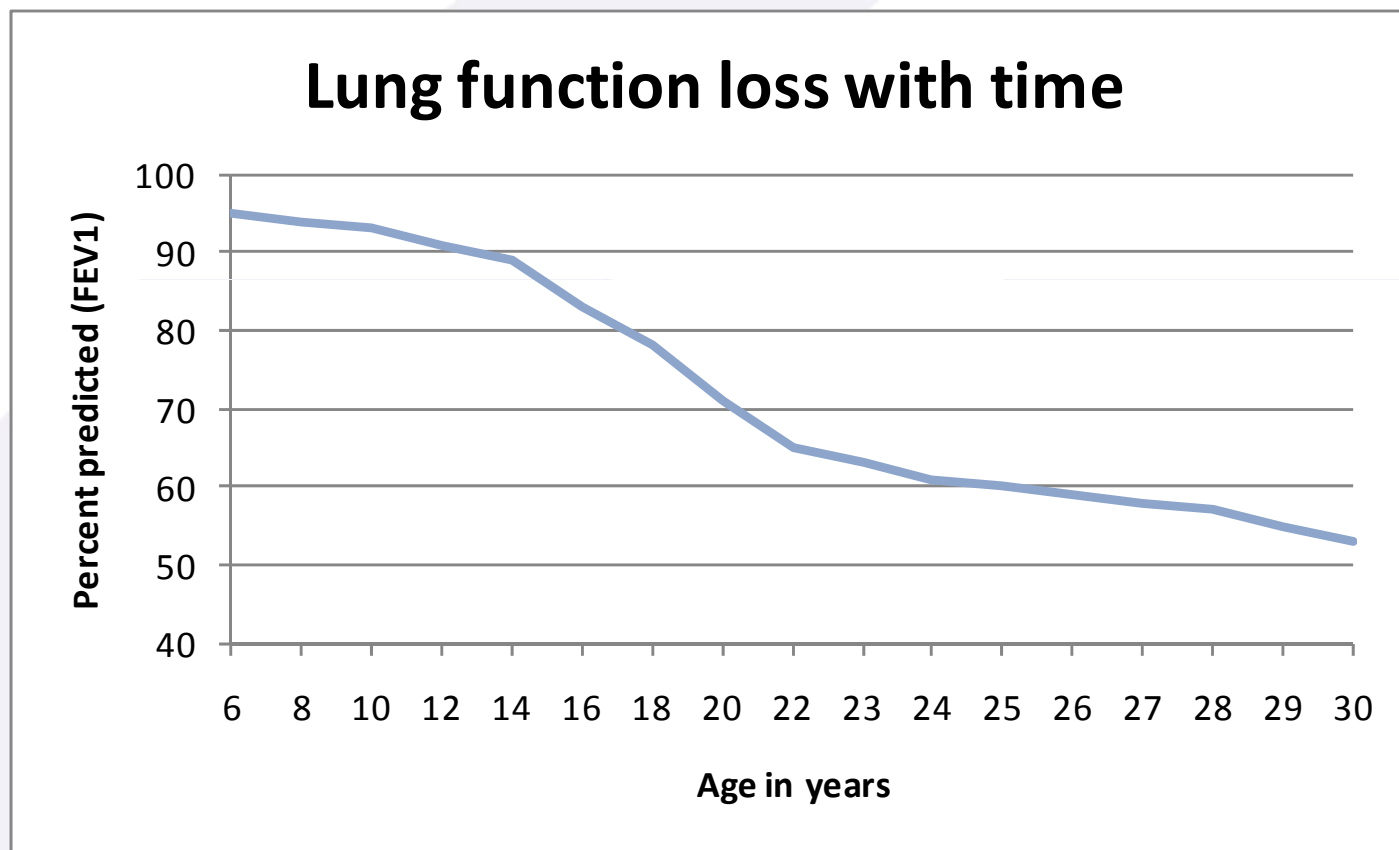
Similar pattern of Improvement



CF301 – lung function changes at 12 months



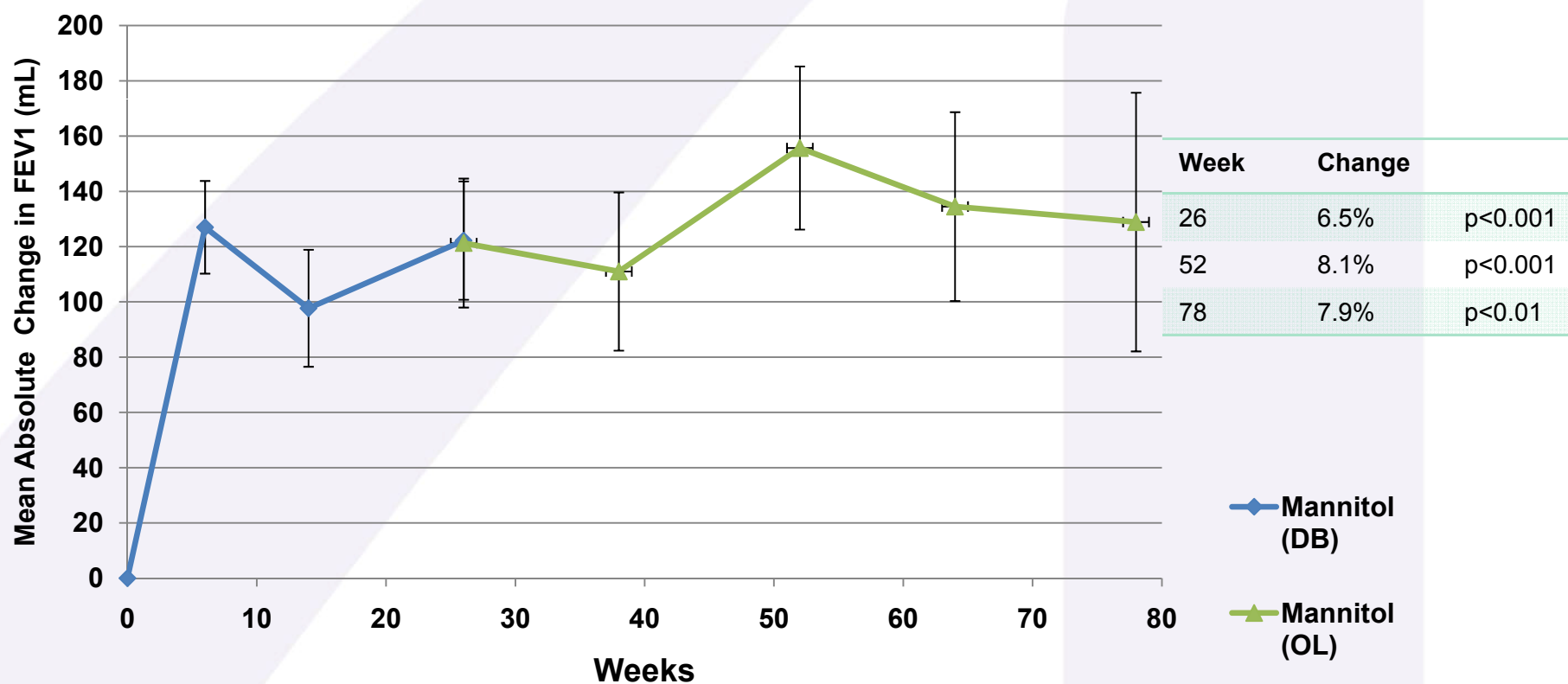
Average lung function decline in CF patients



Source: Cystic Fibrosis Foundation Patient registry, 2004

CF301 Bronchitol Arm (DB and OL for 18 months)

CF301 Change in FEV1 Summary Statistics for Bronchitol
(DB patients only) over 18 months



Clinical Summary



- Trials conducted across the CF world in subjects receiving best standard of care
- Two confirmatory pivotal Phase III studies
- Lung function improvement of over baseline of 6.3% (CF301) and 8.2% (CF302)



- Early and sustained lung function improvement over baseline
- Well-tolerated and safe
- Secondary endpoints analysis of pooled data underway



- Compelling body of evidence
- North American Cystic Fibrosis Meeting (Oct 2010)

Bronchitol – the first CF specific dry powder



- **Increased efficacy without fuss**
- **Treatment burden a significant issue to patients with CF**
- **2 - 5 minutes delivery time**
- **Convenient and portable**
- **No power source**
- **No cleaning / maintenance/ sterilisation**

Bronchitol – cystic fibrosis registration

Europe

- Orphan drug designation
- EMA submission
- EMA response anticipated
- First sales

Oct 2009

Q4 2010

1H 2011

USA

- Orphan drug designation
- Headline data
- NDA submission
- FDA response anticipated

June 2010

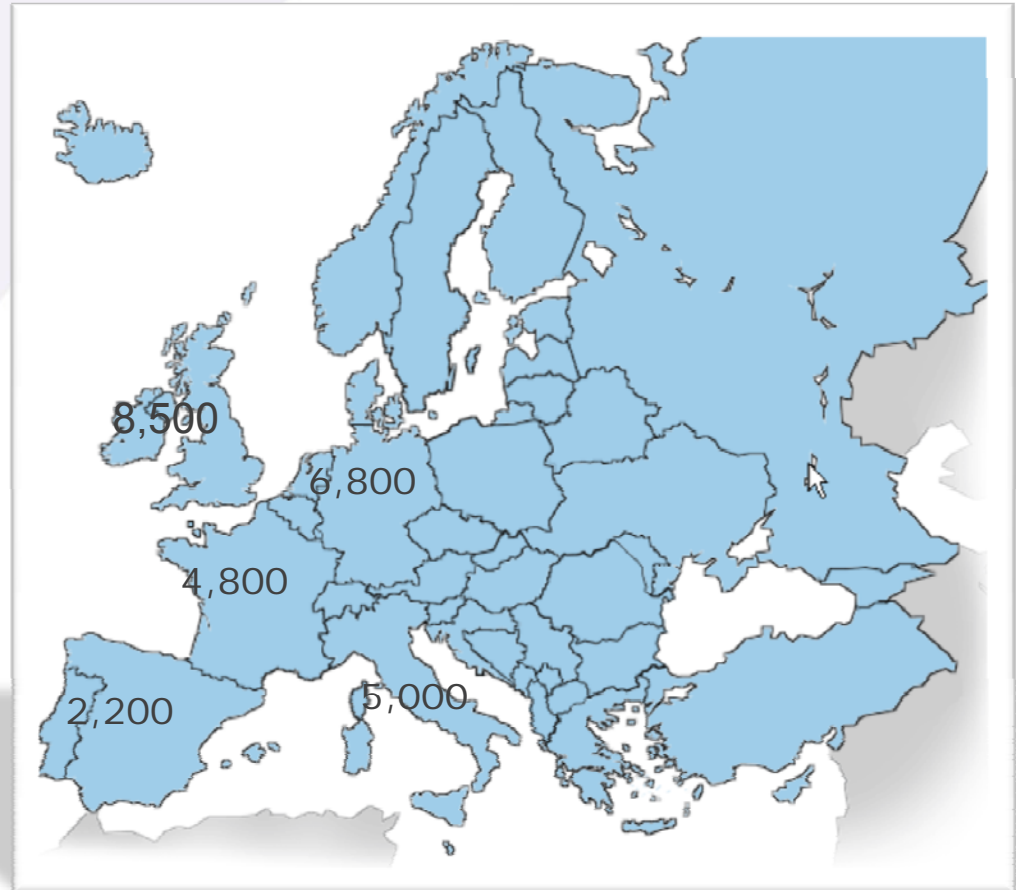
1H 2011

1H 2012



Bronchitol – commercialisation in EU

- Orphan drug – up to 12 years exclusivity
- Promotion by Pharmaxis in Western Europe (14 countries)
- Distributor for Central / Eastern Europe
- Launch Top 5 – 2011
- First launch UK / Germany
 - Q1 2011
 - Immediate launch – national pricing approval not required



40,000 people in EU with CF, 70% in top 5 countries

Bronchitol – European commercial infrastructure



- UK - Pharmaxis UK subsidiary and sales force in place (currently promoting Aridol)
- Remainder Western Europe (13 countries) - Quintiles:
 - Recruit and manage dedicated Pharmaxis sales force
 - Local market knowledge to speed access
 - Full back office support
 - Satellite model leveraging Top 5 management structure
- European CF market support – Pharmaxis UK subsidiary
 - Marketing
 - Pricing
 - Medical information, regulatory and pharmacovigilance
- Build to ~40 people

Bronchitol – commercialisation in the U.S.

Clinical....

- Two pivotal Phase 3 trials completed
 - data consistent between the two trials

Regulatory....

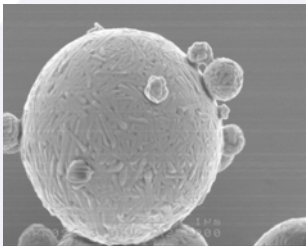
- trial design agreed with FDA
- NDA to be submitted as soon as possible
- opportunity for priority review
- response from FDA on NDA expected mid 2012
- orphan drug provides 7 years market exclusivity

Marketing....

- promotion by PXS out of existing Philadelphia office
- unified approach to pricing and reimbursement
- 150 CF centres requires 15 person field force
- 30,000 people in the US with CF
- addressable market >\$400 million



Bronchitol - bronchiectasis



- Abnormal, irreversible dilation of the lower airways
- Daily mucus production, constant coughing, breathlessness, recurrent acute bronchitis with infective exacerbations : low quality of life
- In 30-50% of cases, the cause is unknown
- Normal lung clearance impaired
- Current treatments: bronchodilators, antibiotics
- No drugs proven effective to clear mucus
- Affects 600,000 people worldwide

Bronchitol – bronchiectasis registration

- **1st Pivotal Phase III trial**



- 363 patient, placebo controlled, double blind, randomised 12 week treatment (twice per day) + 12 month open label extension

- **Primary endpoints**

- quality of life – validated Patient Reported Outcome
- mucus clearance – 24hr sputum volume



- **Primary Analysis**

- quality of Life SGRQ, $p < 0.001$ versus baseline
SGRQ, $p < 0.05$ versus placebo
- mucus clearance $\uparrow 30\%$, $p < 0.001$ versus placebo
- antibiotic use reduction $p < 0.05$ versus placebo
- adverse events (52 wks) cough 9%, sore throat 5%
no SAE attributed to treatment



Bronchitol – bronchiectasis registration



- **2nd Phase III trial**

- 475 patient, placebo controlled, double blind, randomised, 52 week treatment, 89 sites in US, Europe, South America

- 400mg twice a day

- **Primary endpoint**

- Reduction in number of exacerbations

- **Secondary endpoints**

- Exercise, mucus clearance, antibiotic use
- Quality of life

- **Status**

- Special Protocol Assessment concluded with U.S. FDA

- Orphan Drug designation

- First patient enrolment

- Complete recruitment

- Data

USA

October 2009

H1 2011

2012

Aridol™

- Identifies airway hyperresponsiveness which helps physicians in the overall assessment of **asthma**
- An **easy-to-use test kit** provides rapid results and doesn't require specialized equipment



Aridol – commercialisation status

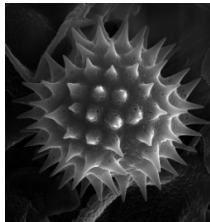


			2008	2009	2010
Sales (A\$'000)					
Australia	Launched 2006	Direct	216	232	268
Europe	Staggered launch from 2007	Distributors (7); UK – direct;	137	267	398
Korea	Launched Oct 09	Distributor	-	32	162
Clinical trials		Direct	174	64	-
US ⁽¹⁾	Approved Oct 2010	Direct	-	-	-
			527	595	828

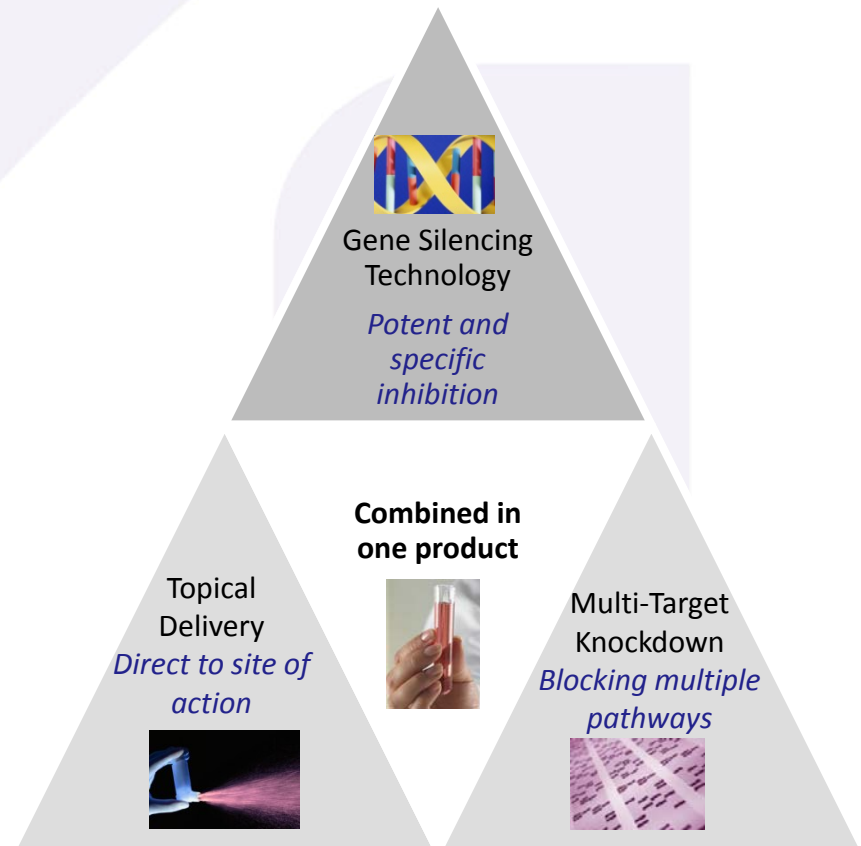
Marketing via education, key opinion leaders:

- Investigator initiated studies, > 70 peer reviewed articles
- US ACRN study: Aridol utility in asthma management - report H1 2011
- UK investigator : steroid management in asthma – report Q4 2011
- Swiss investigator: steroid management in COPD – report H1 2011

ASM8 : A new approach for uncontrolled asthma



- Targeting severe asthma
 - affects ~6 million people
 - major cause of ER visits
 - limited treatment options
 - Current treatment - Xolair
- Once daily by inhalation
- Improved side effect profile
 - Low systemic exposure
- Improved effectiveness
 - Targets multiple inflammatory proteins
- Inhibits protein synthesis

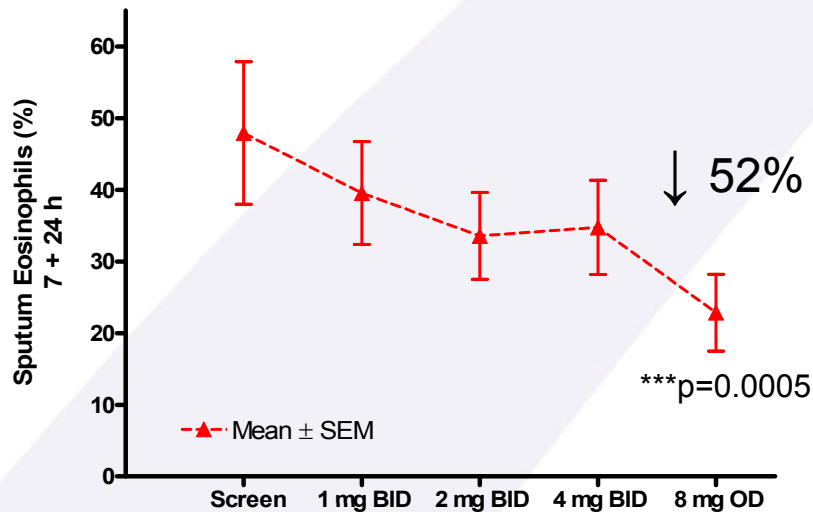


There exists an unmet medical need in patients with severe asthma

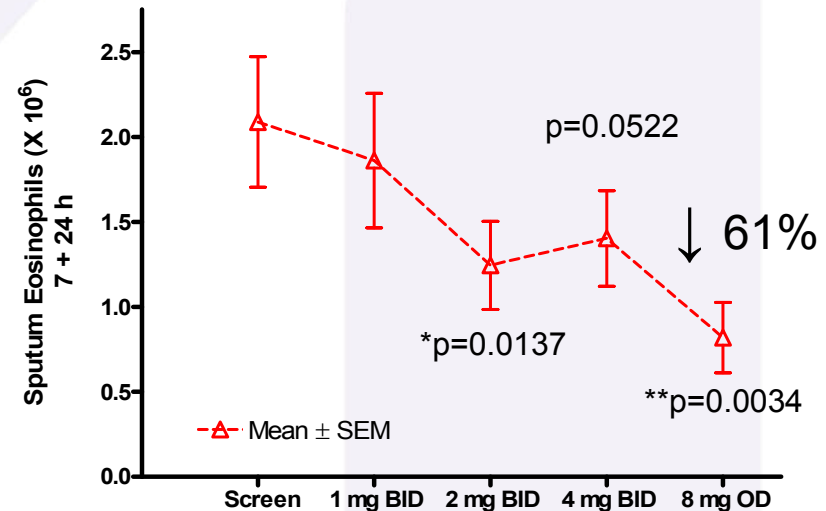
ASM8: Results of Phase 2a dose profiling study

(Sputum Eosinophils (sum of 7h and 24h))

% Eosinophils



Absolute # Eosinophils

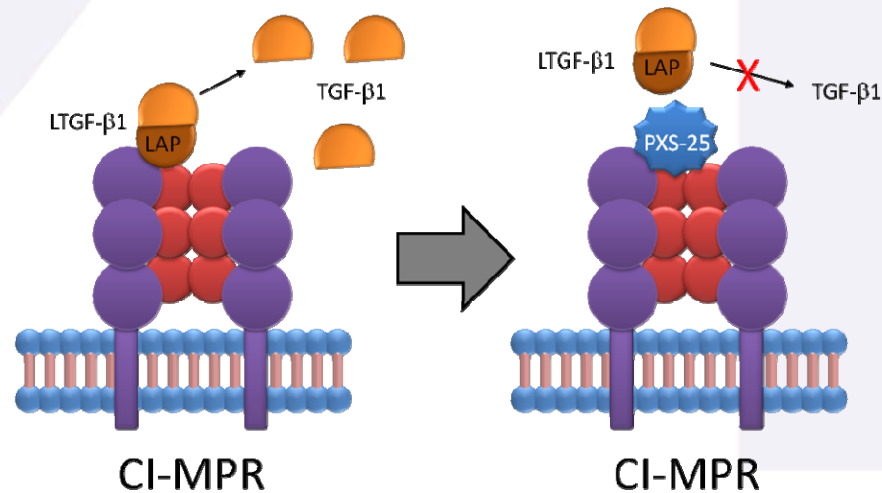
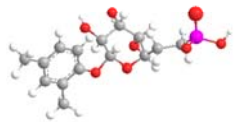


- 4 day treatment – sequential escalating dose
- 12 subjects – mild allergic asthma
- Primary endpoints – sputum eosinophils & safety
- Secondary endpoints – LAR, EAR, Target mRNA

- Next study
 - 14 day allergen challenge
 - commence Q4 2010

PXS25 for fibrosis

- ❑ Inhibits cleavage of latent TGF β to active TGF β
 - Targeting Idiopathic Pulmonary Fibrosis
 - Affects >500,000 people worldwide
 - Small molecule with robust pharmaceutical profile
- ❑ Phase I trial completed
 - Safety, pharmacokinetics in healthy subjects



Manufacturing Capacity



- Facility No 1 – Frenchs Forest Australia
 - GMP manufacture of Aridol for sale in EU, Asia & Australia
 - Manufacture of Bronchitol for clinical trials and compassionate use
 - Inspected by FDA in review of Aridol NDA
- Facility No 2 - Frenchs Forest Australia
 - Construction completed May 2009
 - TGA licence for clinical trials and compassionate use
 - Equipment installation & validation complete
 - Complete process validation – 2010
 - Capacity
 - Initial capacity - 1 spray drier: 40,000 patients p.a.
 - Expanded capacity – 2nd spray drier: 80,000 patients p.a.

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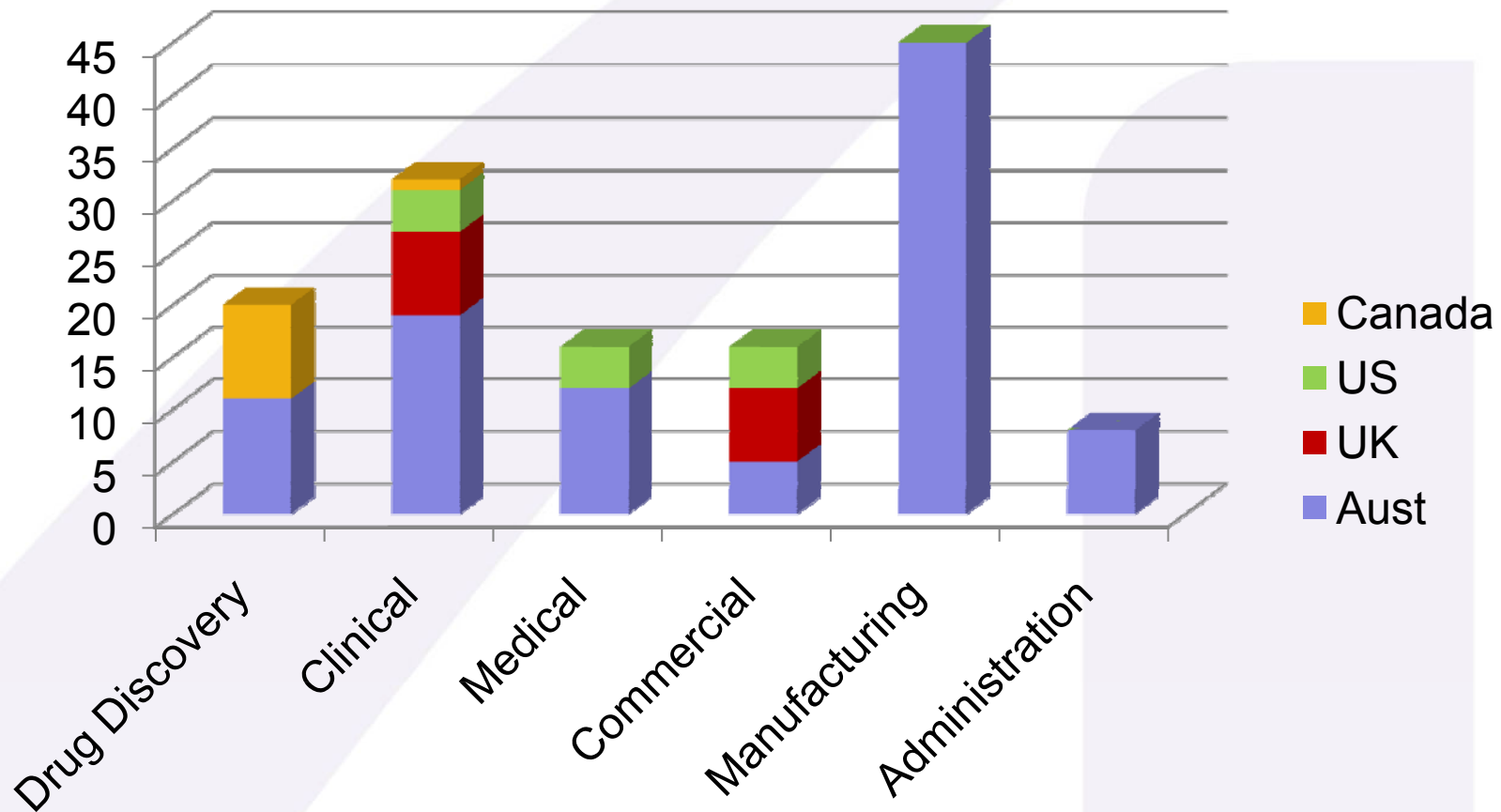
Chief Financial Officer

David McGarvey

Annual General Meeting

October 2010

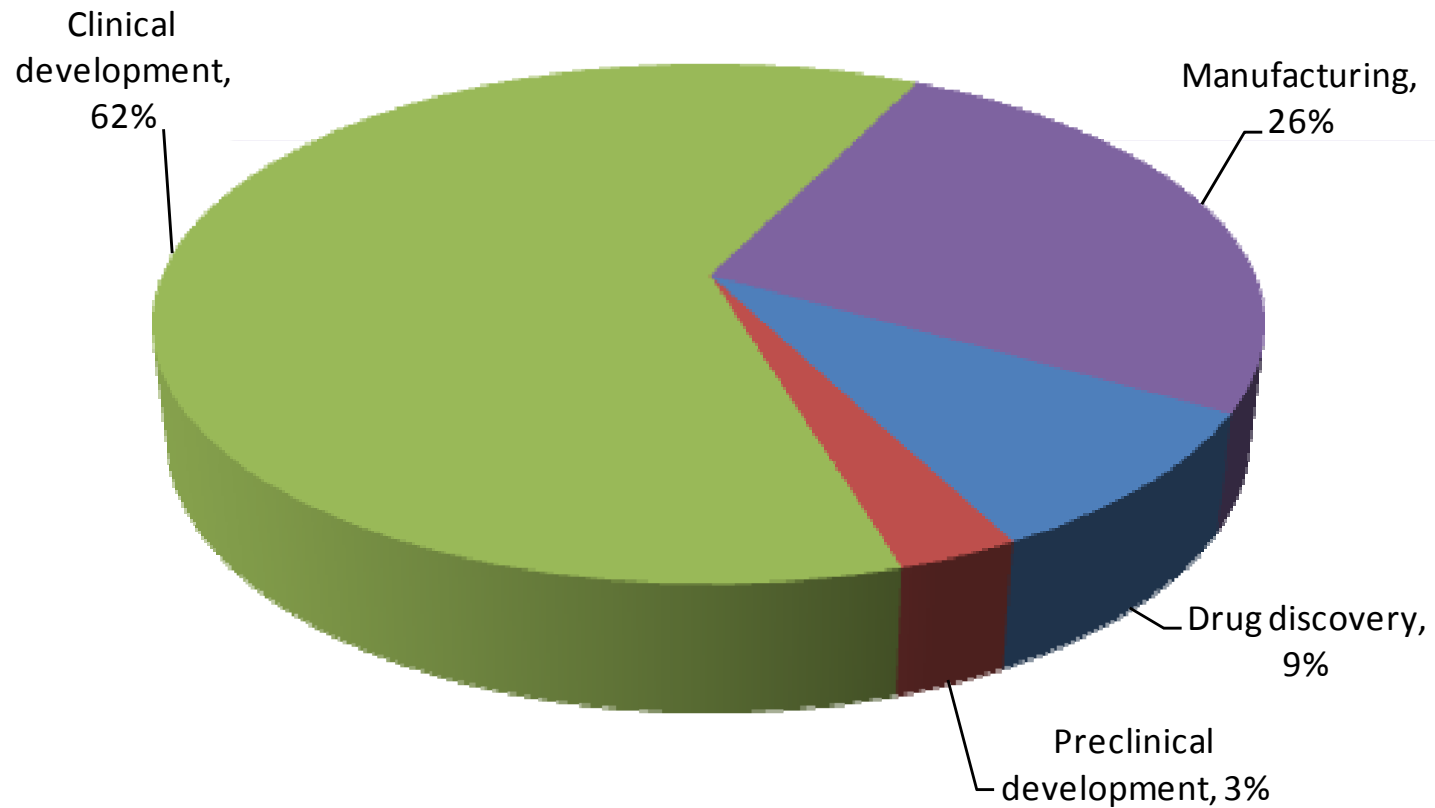
Employee Headcount at September 2010



Australia	UK	USA	Canada	China	Total
99	15	12	10	1	137

Research & Development 2010 - \$35m

Research & Development



Financial Statements

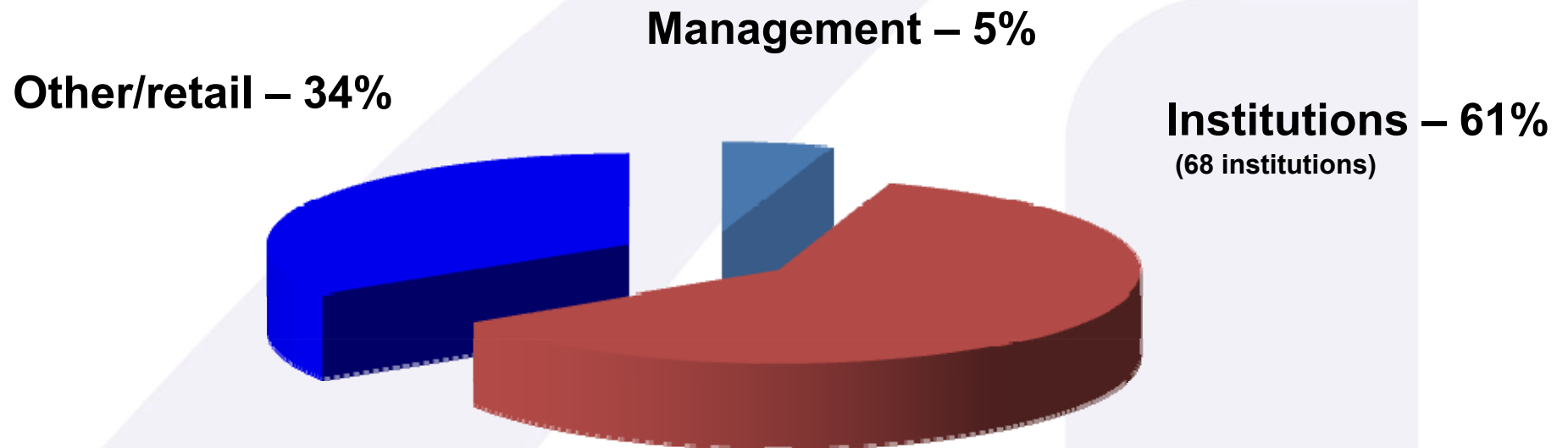
Year ended 30 June	<u>2010</u>	<u>2009</u>	<u>2008</u>	<u>2007</u>	<u>2006</u>
	A\$	A\$	A\$	A\$	A\$
Income Statements					
Revenue from sale of goods	828	595	527	205	8
Gross profit	521	442	398	156	6
Interest	3,935	5,347	7,402	5,278	4,282
Other income	616	523	1,576	2,152	1,299
Expenses					
Research & development	(35,140)	(29,308)	(19,996)	(23,840)	(16,978)
Commercial	(5,657)	(6,202)	(4,557)	(3,240)	(1,946)
Administration	(9,715)	(5,800)	(5,231)	(4,666)	(4,391)
Finance expenses	(854)	(122)	-	-	-
Total expenses	(51,366)	(41,432)	(29,784)	(31,746)	(23,315)
Loss before income tax	(46,294)	(35,120)	(20,408)	(24,160)	(17,728)
Income tax expense	(51)	(51)	(32)	(19)	(5)
Loss for the year	(46,345)	(35,171)	(20,440)	(24,179)	(17,733)

Financial Statements

As at 30 June	<u>2010</u>	<u>2009</u>	<u>2008</u>	<u>2007</u>	<u>2006</u>
Balance Sheet Data					
Cash and cash equivalents	85,787	124,993	111,842	76,182	97,840
Plant & equipment	32,537	32,698	3,668	3,521	3,205
Total assets	140,767	163,997	125,049	82,648	104,267
Total liabilities	(25,751)	(26,306)	(5,928)	(6,089)	(5,379)
Total shareholders' equity	115,016	137,691	119,121	76,559	98,888
Share Data					
Ordinary shares on issue	225,410	217,659	194,515	177,949	176,904
Options over ordinary shares on issue	13,155	15,075	11,536	9,836	9,692

Share Capital

(including options)



Institutions – 61%
(68 institutions)

30 September 2010: 226m shares; 13m options