pharmaxis

Therapeutic products for respiratory diseases

January 2010

Forward Looking Statements

This presentation may contain forward-looking statements that are based on management's current expectations and beliefs and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. The forward-looking statements contained in this presentation include statements about future financial and operating results, results of our clinical trials, status of our regulatory submissions, possible or assumed future growth opportunities and risks and uncertainties that could affect Pharmaxis' product and products under development. These statements are not guarantees of future performance, involve certain risks, uncertainties and assumptions that are difficult to predict, and are based upon assumptions as to future events that may not prove accurate. Therefore, actual outcomes and results may differ materially from what is expressed herein. In any forward-looking statement in which Pharmaxis expresses an expectation or belief as to future results, such expectation or belief is expressed in good faith and believed to have a reasonable basis, but there can be no assurance that the statement or expectation or belief will result or be achieved or accomplished.

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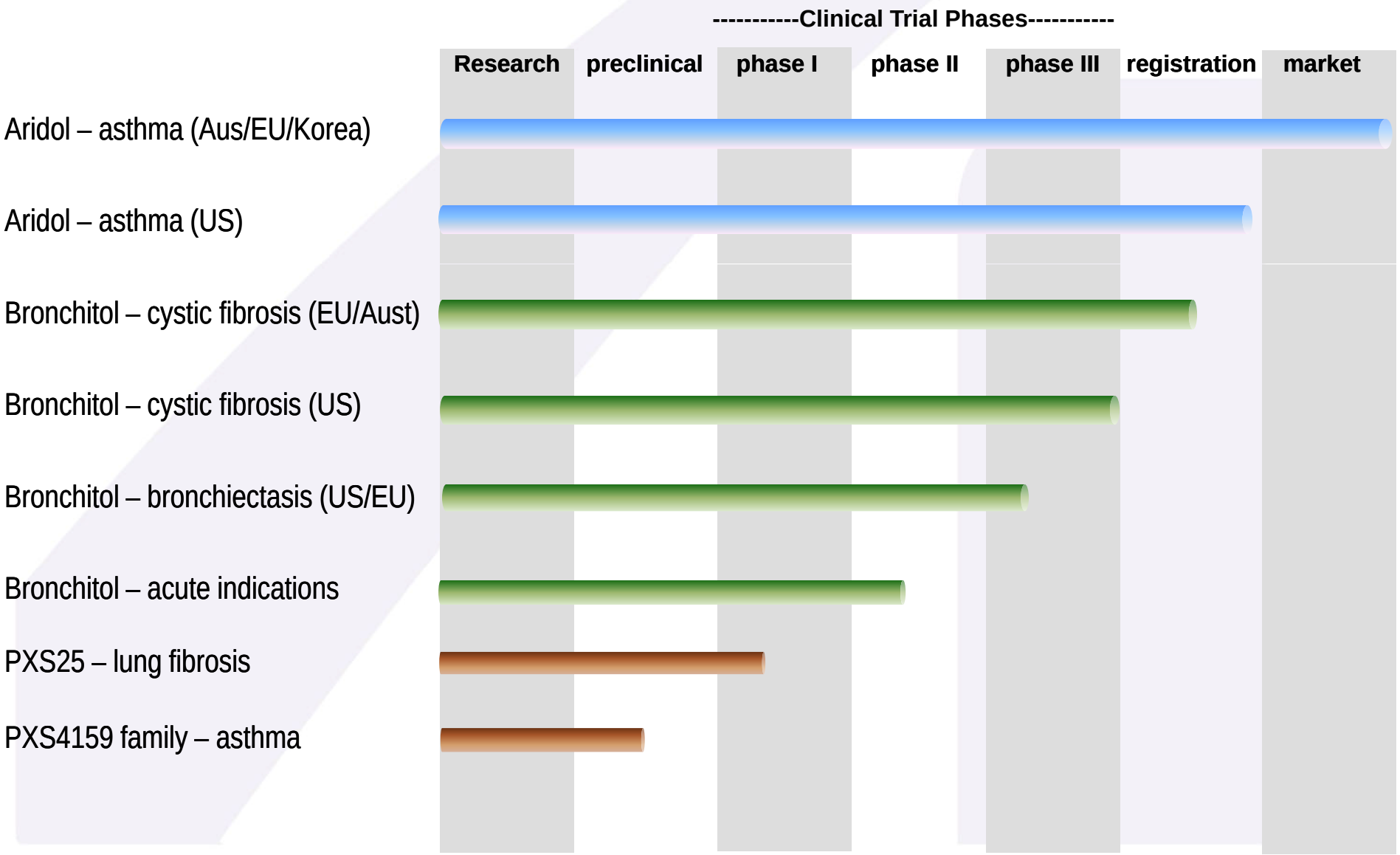
This investor presentation is not an offer of the sale of securities.

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
Discovery	PXS25 (M6P receptor blocker). PXS4159 (VAP1 inhibitor)
Listing	ASX (Nov 2003): PXS
Locations	Sydney, NSW, Australia // Exton, PA, USA // Luton, UK
Facility	GMP Manufacture of lead products
Employees	108
Cash (31/12/09)	A$102 million
Shares outstanding Options outstanding	219m 13m
Key patents	Aridol & Bronchitol granted in USA, Australia, Asia, Canada, Japan; pending in EU, Japan.
Analyst coverage	Wilson HTM, Credit Suisse, RBS Morgans, BBY, Shaw Stockbroking

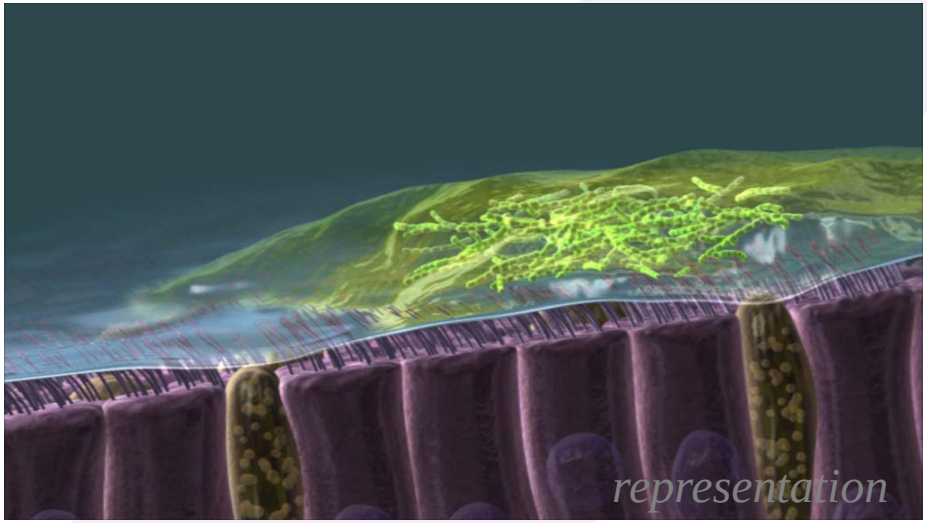
Development Pipeline



Bronchitol for Cystic Fibrosis

Osmotic clearance of abnormal mucus

Before treatment

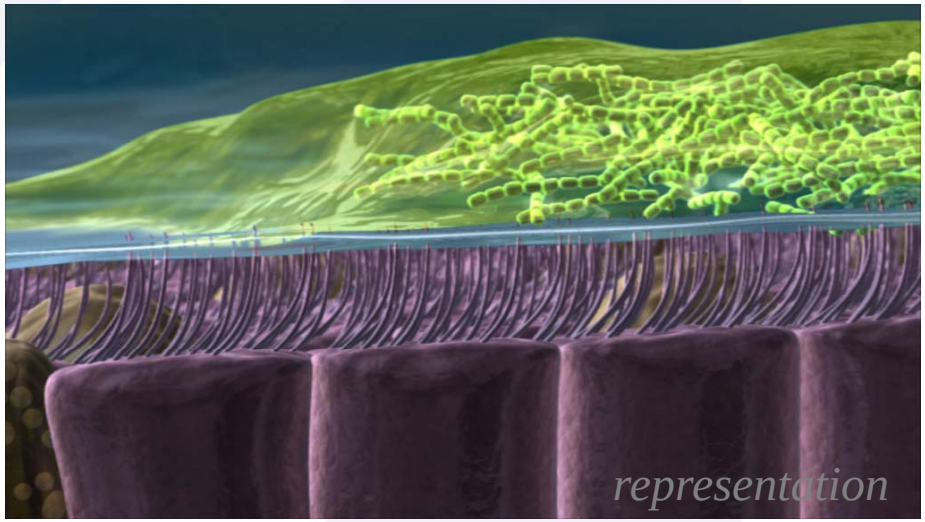


Lung surface dehydrated

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

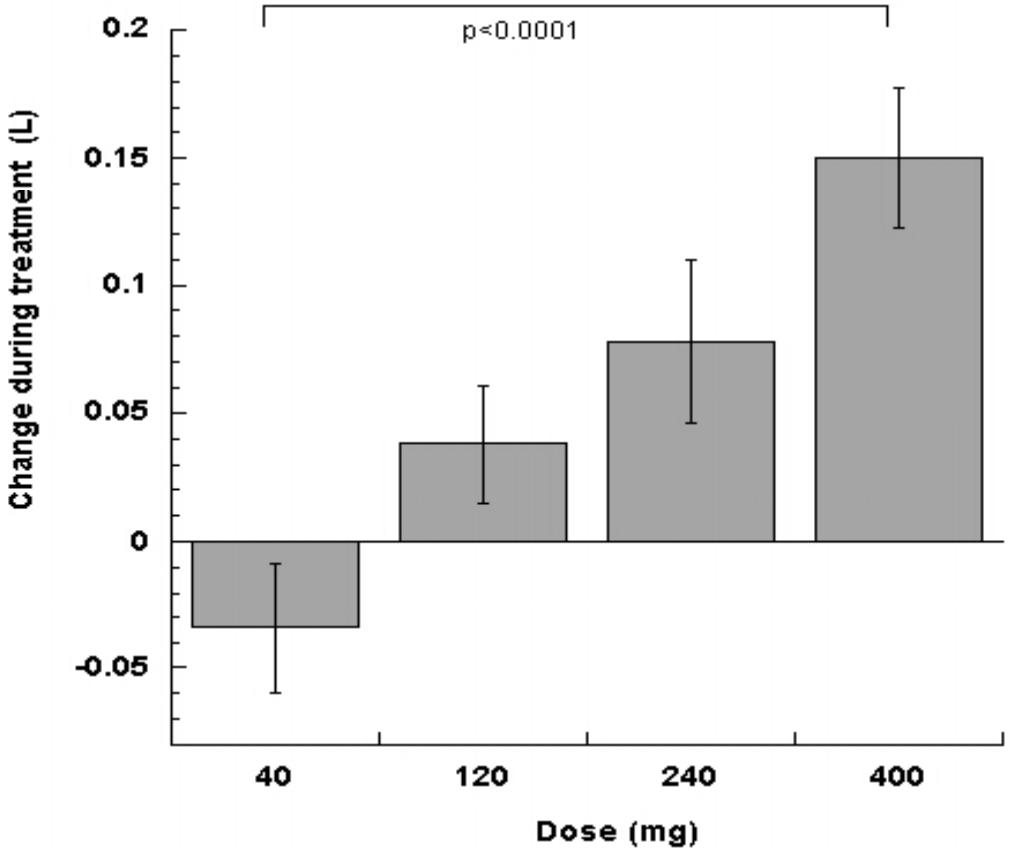
- **Background**
  - Genetic disorder affecting 75,000 worldwide (30,000 in US)
  - Poorly hydrated, tenacious, thick mucus
  - Current life expectancy is 37 years (US)
- **Current treatments: rhDNase and tobramycin**
  - Delivered by nebulizer (preparation, sterilization)
  - rhDNase (pulmozyme): global sales US$440mm (2007)
  - Tobramycin: global sales US$233mm (2007)

Treatment Progression – CFF Guidelines

Grade of recommendation	Mild	Moderate/Severe
A Benefit is substantial	-	rhDNase Tobi (if p.a. present)
B Benefit is moderate	rhDNase Tobi (if p.a. present) Azithromycin (if p.a. present) Hypertonic Saline Ibuprofen (FEV1>60%) Inhaled B2 agonists	Hypertonic Saline Azithromycin (if p.a. present) Ibuprofen (FEV1>60%) Inhaled B2 agonists
Insufficient evidence	Other inhaled antibiotics Oral corticosteroids (18+ yr olds) Leukotriene inhibitors / cromolyn sodium. Anticholinergic bronchodilators N-acetylcysteine	
Against	Inhaled corticosteroids (if asthma / ABPA absent) Oral corticosteroids (6-18 yr olds)	

There remains a lack of quality long term studies evaluating existing treatments used in CF

CF-202 Dose Response 400 mg Selected



- 48 subjects
- Open label multidose study
- 400mg twice a day, then 40, 120, 240mg twice a day for 14 days in a random order
- Washout between doses

DPM-CF-202

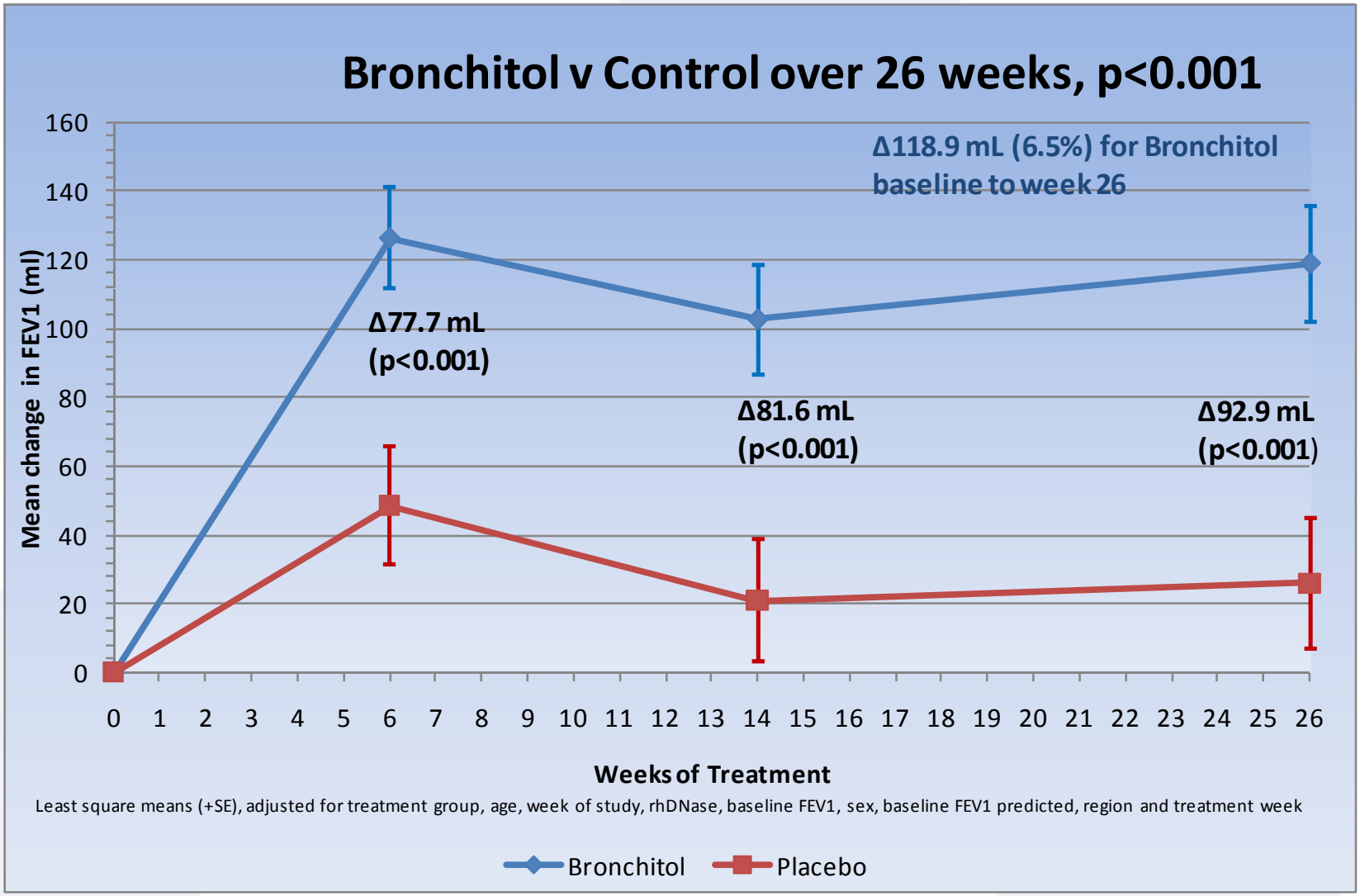
Bronchitol – cystic fibrosis registration

- **1st Pivotal Phase III trial**
  - Multicentre, double blind, placebo controlled
  - 325 subjects greater than 6 years old
  - 6 month treatment, 400mg twice per day followed by 6 month open
  - Primary endpoint:
    - lung function (FEV1)
  - Key secondary endpoint:
    - Lung function (FEV1) in patients on rhDNase
  - Other endpoints
    - exacerbations
    - antibiotic use
    - QOL and safety

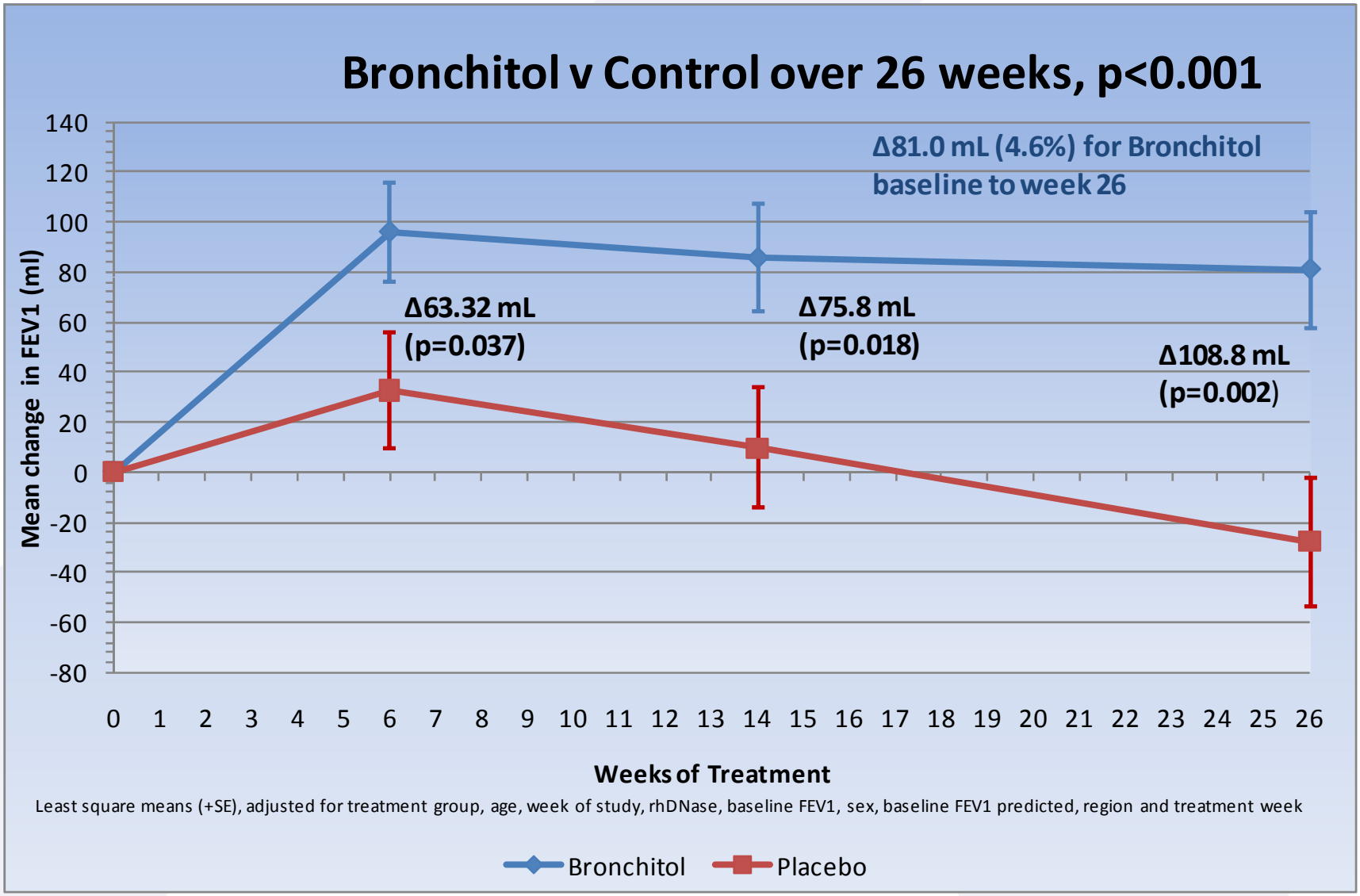
First Phase 3 -Key demographics at baseline

	Bronchitol n = 177	Placebo n = 118
Mean age (years) 6 – 11 years 12 – 17 years >18 years	23.1 15% 19% 64%	22.8 14% 21% 64%
Gender: Female	40.1%	51.7%
BMI; mean (SD) kg/m^2	21.1 (4.0)	20.4 (3.6)
FEV1; mean (range) L % of predicted	 2.07 (0.71, 4.92) 62.4% (26, 93)	 1.95 (0.78, 3.75) 61.4% (30,94)
Regular medication RhDNase; n (%) Antibiotics B_2 agonists	 96 (54.2%) 94.8% 83.9%	 67 (56.8%) 90.2% 87.1%

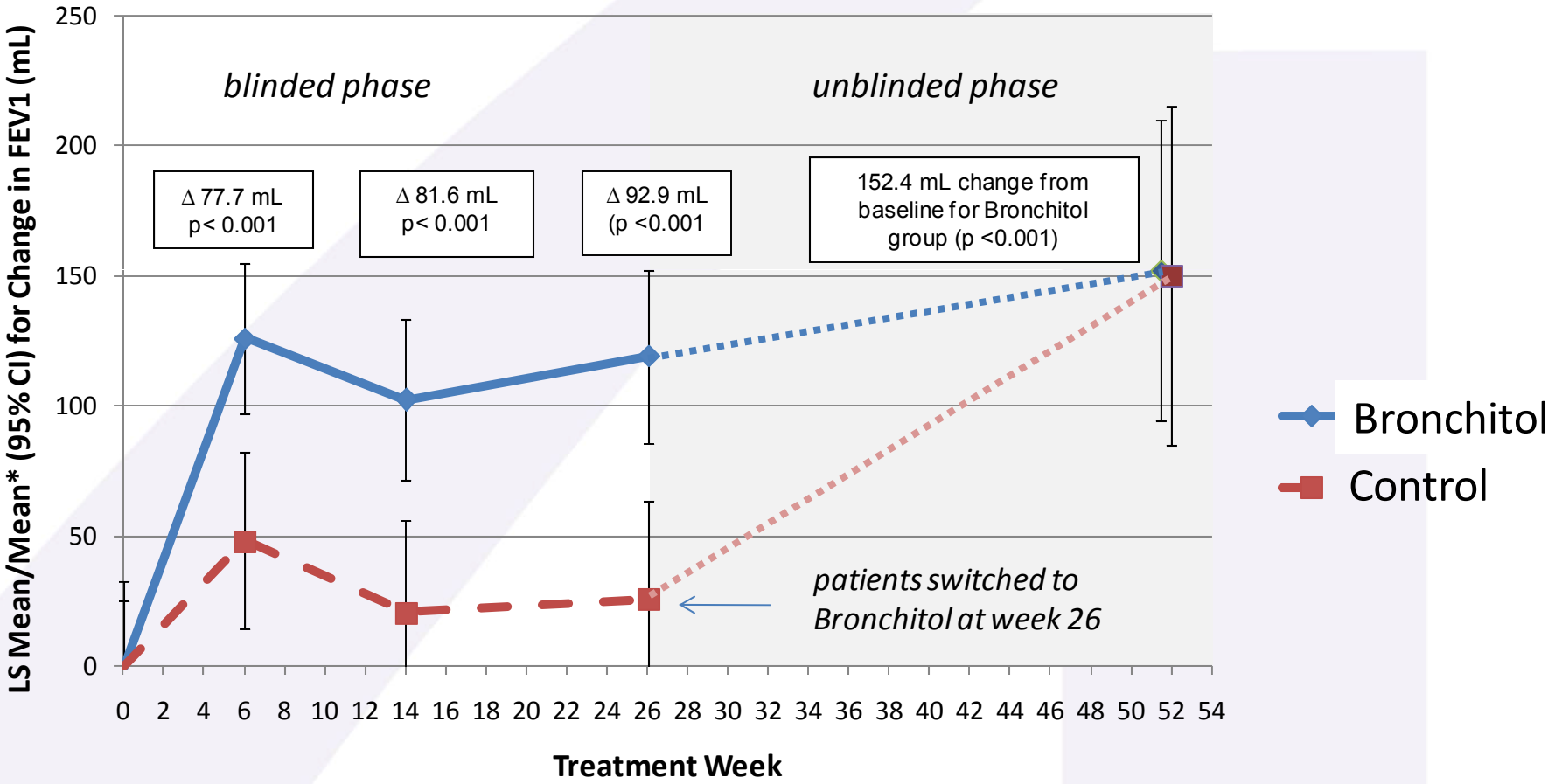
CF-301 Absolute mean change (mL) in FEV_1



CF301 Absolute mean change (mL) in FEV_1 (rhDNase users)

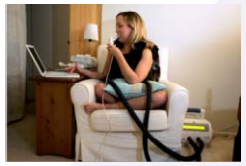


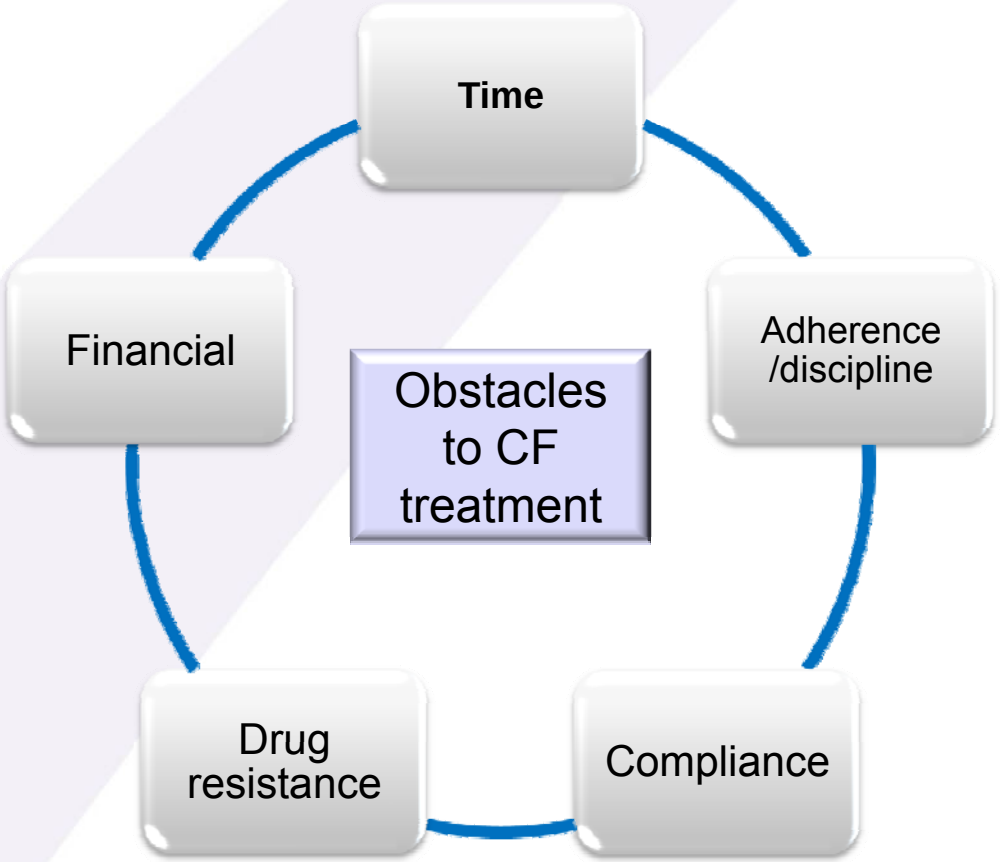
CF301 – lung function changes at 12 months



Cystic Fibrosis market research

The time commitment to treatment is the biggest challenge to physicians and patients





- Time requirements and adherence to therapy are pervasive challenges
  - *"the treatments take time. Although the payback is longevity and QOL, at the moment the treatments can take up a large part of the day."*
  - *"patients feel very pressed for time."*
  - *"Because of the time requirement, you have to prioritise meds sometimes. Do the biggest bang for the commitment buck."*
  - *"The time element is the key to adherence."*
  - *"Therapy gets in the way of daily activities – 50 minutes two times a day!"*
- Treating resistance to antibiotics is another challenge for physicians

Source: Willowdale market research

Positioning Bronchitol in CF Treatment

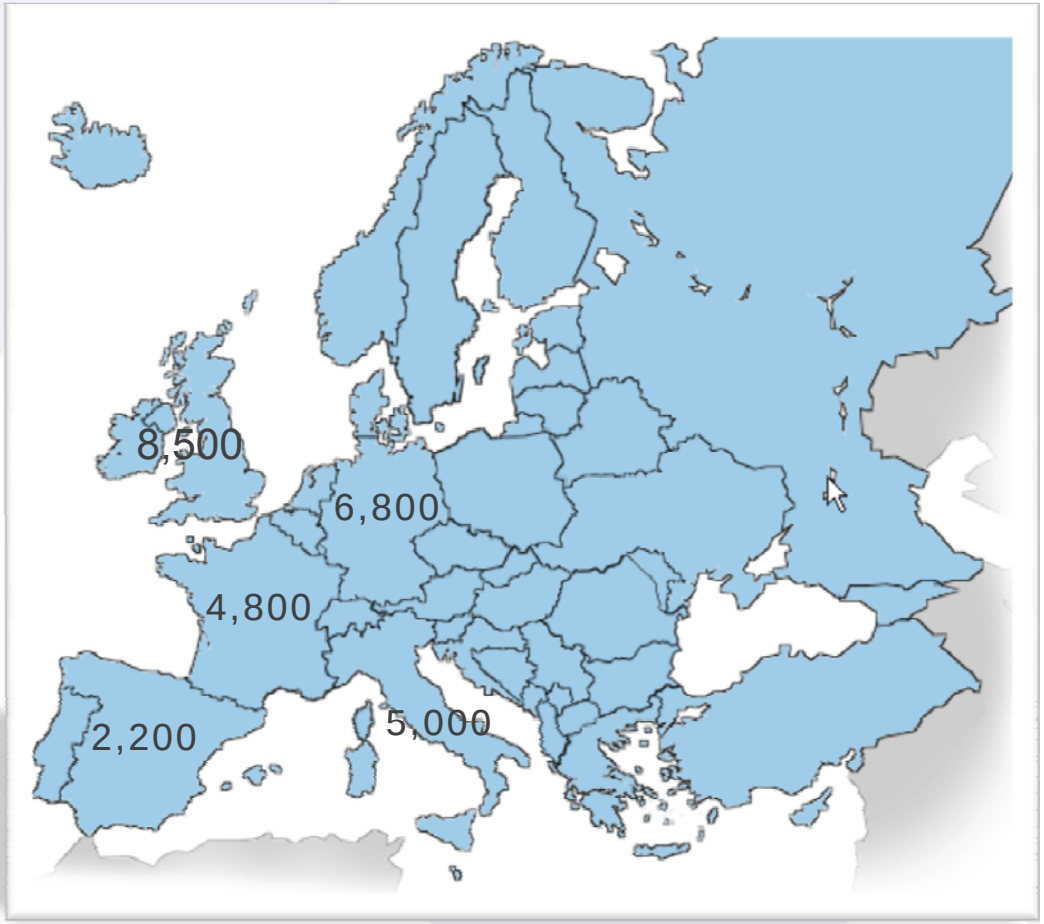
Mucus Alteration / Liquid Restoration CF Products

	Pulmozyme	Hypertonic Saline	Bronchitol	Denufosol	Moli1901
Company	Genentech	n/a	Pharmaxis	Inspire	AOP
Status	Market	Not registered	Phase III	Phase III	Phase II
Administration	Nebulizer	Nebulizer	Dry inhaler	Nebulizer	Nebulizer
Dosing	1x daily	2-3x daily	2x daily	3x daily	1x daily
Administration Time (per total dose)	20 minutes	20 minutes	<5 minutes	20 minutes	20 minutes
FEV(1) Benefit	6%	1%	7%	1-2%	2%

All products complimentary to anti-infective & anti-inflammatory therapies

Bronchitol – commercialisation in EU

- **European marketing application via centralised procedure**
  - Filed October 2009
- **Earliest approval 2H 2010**
- **Orphan drug – up to 12 years exclusivity**
- **Promotion by PXS augmented by EU partner**
- **Centralised approach to pricing**

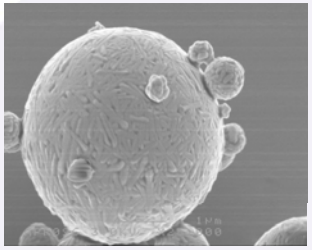


27,000 people with CF in top 5 EU countries

Bronchitol – cystic fibrosis registration

- **2nd Pivotal Phase III trial**
  - Protocol review through Special Protocol Assessment (FDA)
  - Double blind, placebo controlled, 40 centre
  - 300 subjects: 6 years and older
  - 400mg, twice per day for 6 months
  - 1o endpoint - lung function by spirometry (FEV1)
  - 2o endpoints – include antibiotic use, exacerbations, lung function
- **Enrolment closed at 320 subjects** **Sep 2009**
- **Headline data** **H1 2010**
- **Orphan drug designation – U.S.**
- **Fast track designation – U.S.**

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

1: Clin Pulm Med 2005;12:205

Number of bronchiectasis patients seeking treatment

	EU	Australia	USA	Asia	Total
% of patients with bronchiectasis (resp. specialists)	14%	9%	N/A	5%	
Trend	stable or increasing	stable	increasing	stable or decreasing	
Mod/Severe	55%	70%	55%	75%	
Patients seeking treatment	210,000	18,000	110,000	250,000 ++	600,000+

Prevalence: Much higher. Bronchiectasis is often missed but has been measured as >10% of COPD patients in a US patient cohort ~ 800k

Note: US Data comes from Datamonitor research, other data from Frost & Sullivan research

Bronchitol – bronchiectasis registration (I)…

- 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 — ↑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 Pivotal Phase III trial**
  - 350 patient, placebo controlled, double blind, randomised, 52 week treatment
  - 400mg twice a day
- **Primary endpoint**
  - Reduction in number of exacerbations
  - Quality of life
- **Secondary endpoints**
  - Exercise, mucus clearance, antibiotic use
- **Status**
  - Special Protocol Assessment concluded with U.S. FDA
  - Orphan Drug designation USA
  - First patient enrollment October 2009
  - Data 2011

Aridol™

- Identifies airway reactivity (active airway **inflammation**) which helps physicians in the diagnosis and management of **asthma**

- An **easy-to-use test kit** provides rapid results and doesn't require specialized equipment

International regulatory status - Aridol

- **Australia**
  - First market to launch
  - 50% penetration in 2 years — June 2006

- **Europe**
  - Approved European Union (MRP) — May 2007
  - Regional marketing partners appointed outside U.K.
  - Hospital Formulary App
- **South Korea**
  - Approved for marketing — Jan 2008
    - Pricing approval completed (Sep 09)
    - Launched (Oct 09)

- **USA**
  - NDA under review
  - Complete Response Letter received — Dec 2009
  - Process expected to conclude — 1H 2010

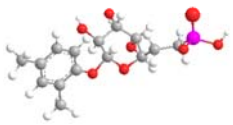
Aridol – growth markets

	USA	KOREA	GERMANY
Existing Market size	200,000 tests p.a.	120,000 tests p.a.	660,000 tests p.a.
Pricing	+++	+	++
Market drivers	Physician reimbursement	Physician reimbursement	Physician reimbursement
	Private physician market.		Private physician market
Entry route	Pharmaxis	Distributor	Distributor

Steroid Management

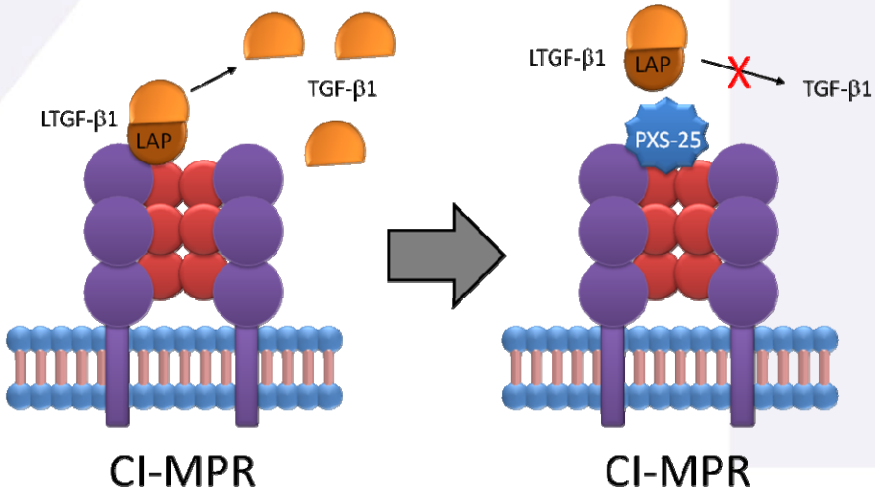
TRIAL	Data
ACRN 'BASALT' study	Q1 2009, Q1 2010
EU steroid response	Q1 2010
EU steroid titration	Q4 2010

PXS 25 for fibrosis



- Inhibits cleavage of latent TGFβ to active TGFβ
  - anti-fibrotic agent with anti-inflammatory properties
    - Small molecule with robust pharmaceutical profile
    - Clinical focus is pulmonary fibrosis

- Phase I trial completed
  - Safety, pharmacokinetics in healthy subjects



Manufacturing Capacity

- Current GMP facility
  - Manufactures Aridol for sale in EU, Asia & Australia
  - Manufacture Bronchitol for clinical trials
- New facility
  - Relocated May 2009
  - Equipment installation & validation complete
  - Complete process validation – Q2 2010
  - Capacity
    - Initial capacity - 1 spray drier: 40,000 patients p.a.
    - Expanded capacity – 2nd spray drier: 80,000 patients p.a.

Financial Statements

Income Statement Data	Three months ended		Six months ended	
	31-Dec-09	31-Dec-08	31-Dec-09	31-Dec-08
	A$	A$	A$	A$
Revenue from sale of goods	171	203	354	309
Cost of sales	(60)	(48)	(107)	(77)
Gross profit	111	155	247	232
Interest	978	1,581	1,930	3,657
Other income	77	141	165	144
Expenses				
Research & development	(9,184)	(7,629)	(17,295)	(13,587)
Commercial	(1,213)	(1,519)	(2,465)	(2,890)
Administration	(1,813)	(1,639)	(3,534)	(2,922)
Finance expenses	(222)	-	(508)	-
Total expenses	(12,432)	(10,784)	(23,802)	(19,399)
Loss before income tax	(11,266)	(8,907)	(21,460)	(15,366)
Income tax expense	(32)	(22)	(43)	(28)
Loss for the period	(11,298)	(8,929)	(21,503)	(15,394)
Basic and diluted earnings (loss) per share - $	(0.052)	(0.046)	(0.099)	(0.079)
Depreciation & amortisation	641	265	1,147	518
Fair value of options issued under employee plan	549	539	1,154	1,151

Financial Statements

Balance Sheet Data	As at	
	31-Dec-09	30-Jun-09
	A$	A$
Cash and cash equivalents	102,081	124,993
Property, plant & equipment	32,801	32,698
Intangible assets	1,144	1,193
Total assets	140,634	163,997
Total liabilities	(22,906)	(26,306)
Net assets	117,728	137,691

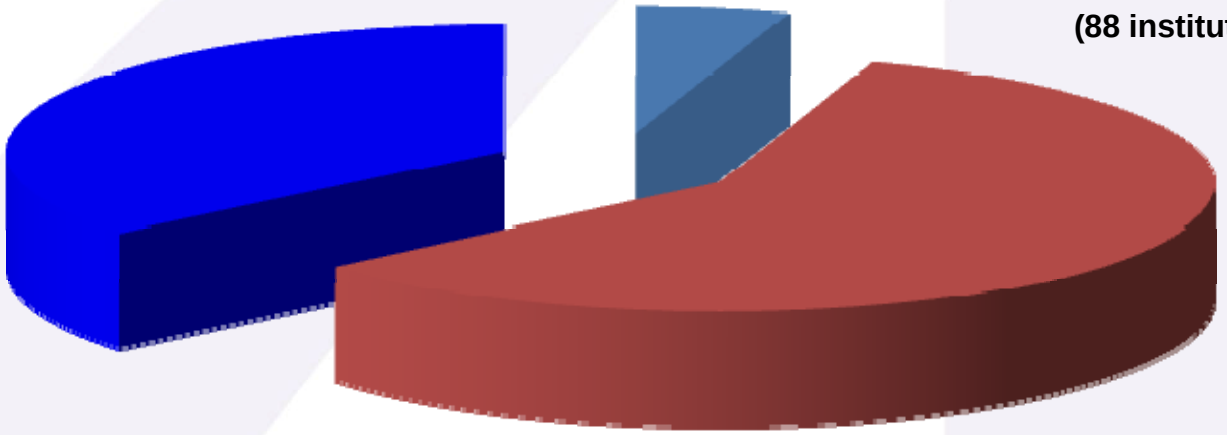
Cash Flow Data	Three months ended		Six months ended	
	31-Dec-09	31-Dec-08	31-Dec-09	31-Dec-08
	A$	A$	A$	A$
Cash flows from operating activities	(10,320)	(6,951)	(20,344)	(11,827)
Cash flows from investing activities	(909)	(4,657)	(2,233)	(6,087)
Cash flows from financing activities	(122)	-	(311)	11
Net increase (decrease) in cash held	(11,351)	(11,608)	(22,888)	(17,903)

Share Capital
(including options)

Management – 5%

Other/retail – 36%

Institutions – 59%
(88 institutions)



31 December 2009: 219.1m shares; 13.5m options

END

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