

pharmaxis

A close-up photograph of a person's hand holding a blue and white inhaler device. The hand is positioned centrally, with the fingers gripping the device. The background is a plain, light-colored wall.

**Therapeutic products
for
chronic respiratory
and autoimmune
diseases**

March 2005

The Business.....



Manufacture

- Fund product development through to registration
- Launch products in accessible markets
- Retain full product rights



Aridol

- Diagnosis and management of asthma and chronic obstructive pulmonary disease



Bronchitol

- Treatment of cystic fibrosis and chronic obstructive pulmonary disease

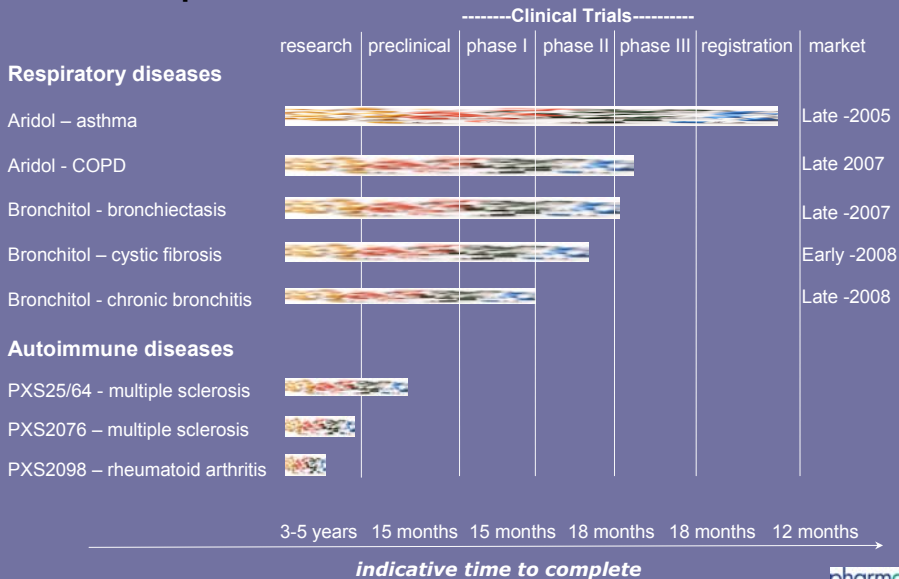


Autoimmune disease

- Research into new treatments for multiple sclerosis and rheumatoid arthritis



The Pipeline....





The Economic Opportunity.....

Product	Target Application	Patient Population (million)	Market Size (A\$ million)	First Revenue
Aridol	Management of asthma	52	\$1,600	2005
Aridol	Management of COPD	30	\$400	2006
Bronchitol	Bronchiectasis	0.6	\$1,500	2007
Bronchitol	Chronic Bronchitis	30	\$4,000	2008
Bronchitol	Cystic Fibrosis	0.1	\$1,000	2008
PXS25/64	Multiple sclerosis	1	\$3,500	n.a.
PXS2076	Rheumatoid arthritis	6	\$3,600	n.a.



The People.....



● Alan Robertson PhD CEO Inventor/developer of Zomig



● David McGarvey CA CFO/Secretary CFO at Memtec



● Brett Charlton PhD CMO Clinical research at Stanford



● Gary Phillips MBA Commercial CEO at Novartis Australia



● John Crapper MBA COO Managing Director of Memcor



● William Cowden PhD CSO Co-inventor of TNF antibodies



● Ian McDonald CTO VP Chemistry, Merck Laboratories



The Progress.....

- Aridol
 - Completed Phase III trial (Aus/EU)
 - IND accepted by US FDA
 - US study designed
 - Marketing application lodged - Australia
 - Marketing application assembled – Europe
- Bronchitol - Bronchiectasis
 - Completed Phase II trial
 - FDA Orphan Drug status granted
- Bronchitol – Cystic Fibrosis
 - Phase II trial in process
 - Approval granted for 3 month trial versus Pulmozyme
- New oral version of PXS25 discovered
- Manufacturing
 - TGA approved GMP facility completed
 - Production capacity tripled
- Staff numbers doubled (36)
- Placement and SPP raised \$19 million
- P3 grant awarded



The future

2005

Q1

Q2

Q3

Q4

2006

Cystic fibrosis study results available

Lodge Aridol marketing application for Europe

Commence cystic fibrosis study versus pulmozyme

Commence cystic fibrosis dosing study

PXS25/64 clinical studies

Australian Aridol launch

Commence bronchiectasis Phase III study

Complete US Aridol study

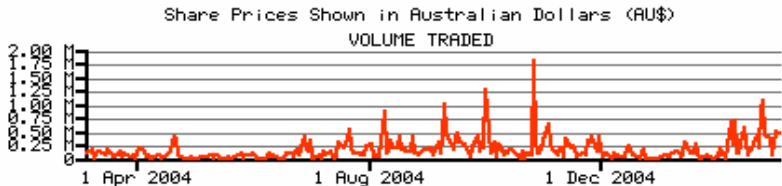
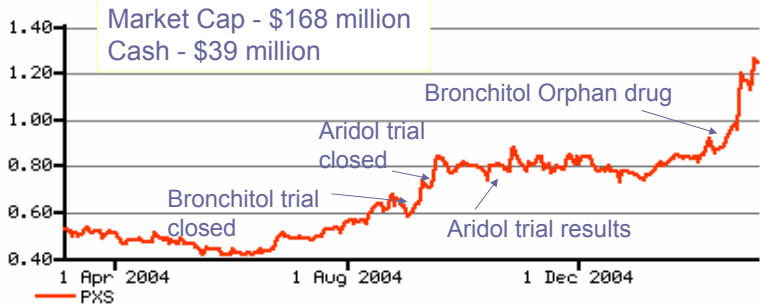
European Aridol launch

Lodge Aridol marketing application for USA

Complete bronchiectasis Phase III study

The Market.....

Pharmaxis has hit all Major Milestones since Listing





Aridol

asthma

asthma management

chronic obstructive pulmonary disease

Aridol™

- ◆ Aus/European clinical program completed
- ◆ New product for the diagnosis and management of Asthma and COPD
- ◆ Phase III completed
- ◆ Dossier filed with TGA (Aus)
- ◆ EU submission assembled
- ◆ Accurately determines airway inflammation
- ◆ Quick and easy to use – ideal for general practice
- ◆ Supported by international opinion leaders in respiratory medicine





Positive Phase III trial results...

- Accurately identifies asthma
- Effective at identifying clinical mis-diagnosis (7%)
 - ⇒ 140,000 Australians
- 20% of subjects over treated and over diagnosed
 - ⇒ 400,000 people in Australia
- 25% of subjects not well controlled
 - ⇒ 500,000 Australian asthmatics
- Outcome - marketing approval submission



Worldwide development of Aridol

In Progress
Planned

Total ~ 18 studies
3,500 patients

Sweden
Asthma x 1

Norway
Asthma x 1
Asthma x 1

Denmark
Asthma x 1
Asthma x 2

USA
Asthma x 1

UK
Asthma x 2
Asthma x 1

Greece
COPD x 1

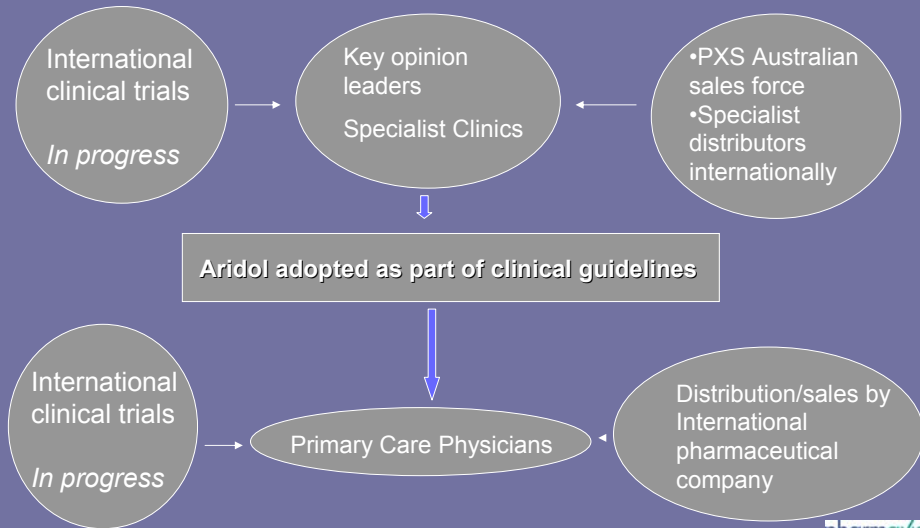
Switzerland
Asthma x 2
COPD x 1
Asthma x 2

Australia
Asthma x 2
COPD x 1
Asthma x 1
COPD x 1

Multi National Studies x 2
- Asthma (GPs) in 7 countries
- COPD in 3 countries



Route to market for Aridol™





Independent Aridol Market Research from two largest markets

US target audience

Generalists	Internists	10
	FP's / GP's	10
Specialists	Allergists	15
	Pulmonologists	15

European target audience

Generalists	12
Specialists	18

Research performed by:

- Puretech Development (USA)
- Datamonitor (Europe)

Areas Probed in Questionnaire

- Detailed MD office demographics
- Current Asthma & COPD practices
- Qualitative reactions to Aridol™
- Projected Aridol™ utilization

Overall Aridol™ Feedback

"Absolutely yes I would try this test . . . It especially sounds like it will help my patients"

- Allergist

"This ought to be a quite useful test, especially in COPD'ers. Therapeutic trial is not preferred"

- Insurance Medical Director

"I see this replacing methacholine in my practice . . . I would absolutely give this test a try"

- Pulmonologist

"About 50% of my patients I am looking to optimize dosing . . . I am very concerned with overdosing on steroids"

- Internist

"This sounds like it will be very easy to do. I like that everything comes pre-packed for me"

- Respiratory Lab Tech

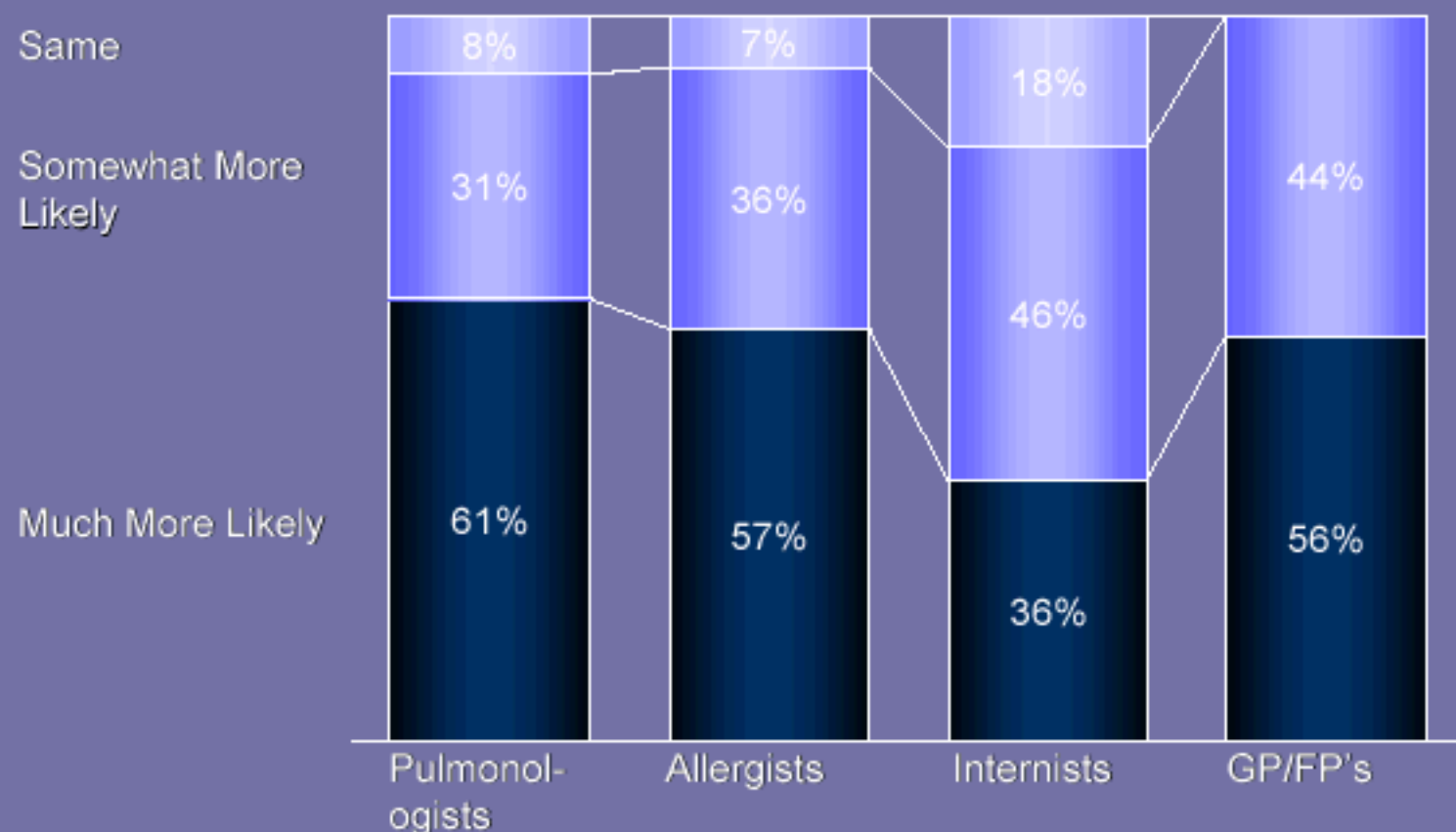
"I can't see myself implementing this test . . . It's time-consuming and I don't trust spirometry in general"

- Internist



Physicians Responded Very Favorably to Aridol™

Are you more or less likely to use Aridol™ than you currently use challenge tests?*

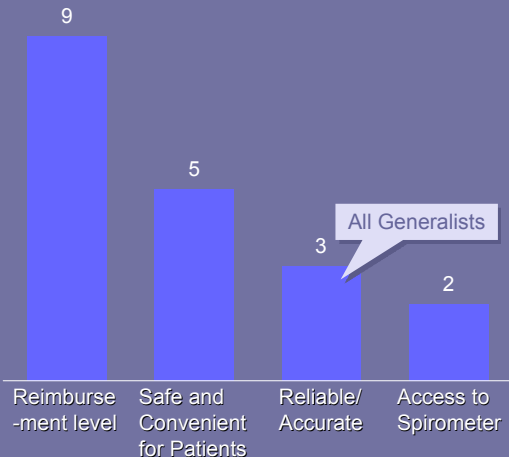


*No respondents chose "Much less likely" or "Somewhat less likely"
Source: PureTech Asthma / COPD Market Survey



Reimbursement and safety / reliability perceptions are the key challenges

Number of Physicians Who Mentioned* This Concern About Aridol™



- US consultant's key finding is that no new procedure codes or modifications to procedure codes are necessary for reimbursement of Aridol
- Completed Aridol phase 3 study designed to answer safety and reliability questions.

* Sum of prompted and unprompted responses
Source: Physician Interviews; PTD analysis



Aridol International Launch

Australia

- Anticipated to be Q4 2005
- Sales force to be appointed Q2/Q3 2005
- Experienced marketer appointed Dec 2004
- Profile being raised at major scientific meetings

Europe

- In discussion with distributors
- Key Opinion Leader relationships developed
- Dossier submission – mutual recognition procedure
- Clinical work in progress
- Stability data being collected



Bronchitol

cystic fibrosis

bronchiectasis

chronic obstructive pulmonary disease



Bronchitol™

Cystic fibrosis, bronchiectasis and chronic bronchitis



● Bronchiectasis

- Phase II completed
- Pivotal pre-registration clinical trials scheduled to commence H2 2005
- Orphan Drug status granted



● Cystic fibrosis

- Phase II trial in progress
- Additional trials in progress
- Pre-registration studies to commence H1 2006



● Chronic bronchitis

- Label extension following bronchiectasis approval



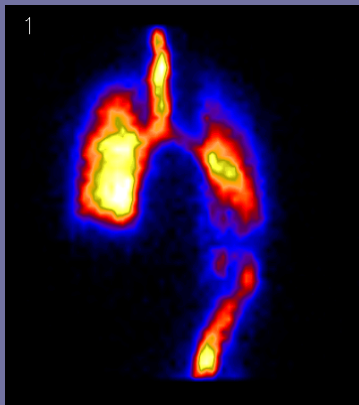
How Bronchitol works.....





Bronchitol in the clinic.....TM

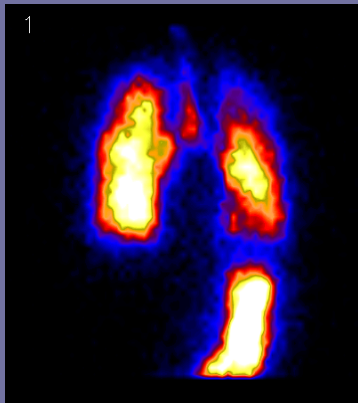
chronic bronchitis - without BronchitolTM





Bronchitol in the clinic.....

chronic bronchitis - with Bronchitol - 400mg





Phase II bronchiectasis trial positive.....

Objective

Quality of life

Symptoms

Results

Statistically significant improvement

Statistically significant improvement

Clinical improvement target

All patients

Severe patients (43/60)

>4.0

4.8

6.8

Adverse events

None serious



Trial participants' responses.....

- “It has been some weeks since my part of the trial finished and to be honest I have not felt as well as when I was on the Bronchitol.”
Trial participant 1
- “Thank you for any help that you can give and I wish you well with the Bronchitol project as it has made such a difference to my health.”
Trial participant 2
- “This patient has been on the Phase II clinical trial of Bronchitol for bronchiectasis. This has revolutionised her life, she would benefit and would be greatly relieved of her daily symptoms if she could continue this treatment.”
Physician
- “Healthy people take the ability to breathe very much for granted..... To have something to make our declining years a lot more comfortable is something we could only dream about previously.”
Trial participant 3



Bronchitol route to market

Bronchiectasis

- ✓ Preclinical
- ✓ Pilot studies
- ✓ Phase II proof of concept
- ✓ Manufacturing scale up
- ✓ Phase II proof of effectiveness
- Phase III(1) registration - 2005
- Phase III(2) registration - 2005
- Marketing application - 2007
- Product launch - 2007

Cystic Fibrosis

- ✓ Preclinical
- ✓ Pilot studies
- ✓ Phase II proof of concept
- ✓ Manufacturing scale up
- Phase II proof of effectiveness
- Phase III registration - 2006
- Market application - 2007
- Product launch - 2008

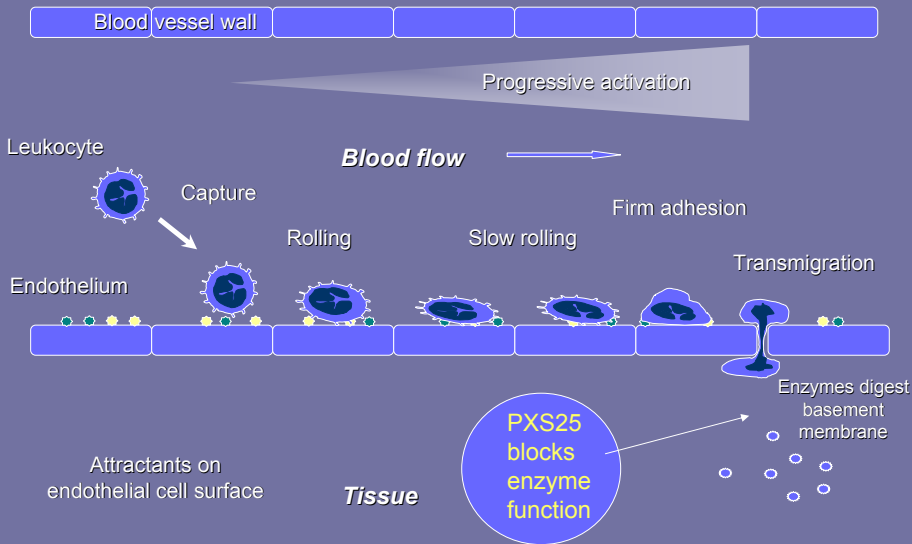


Autoimmune diseases

multiple sclerosis
rheumatoid arthritis

Autoimmune Disease

Inflammation: the leukocyte activation cascade





Autoimmune Disease

● PXS25/64

- Selective inhibitor of T cell migration
- Novel mechanism of action
- Effective in models of multiple sclerosis
- Being evaluated in models of Ulcerative Colitis
- Complementary with existing treatments

● Competitive Edge

- Delivery by the oral route
- Approach clinically validated

● Status

- Preclinical development
- Human studies 2005

Very large market opportunities



Financials



Financials

(\$A'000)	Quarter ended 31 Dec		Half-year ended 31 Dec		Year ended
	<u>2004</u>	<u>2003</u>	<u>2004</u>	<u>2003</u>	30 June <u>2004</u>
<u>Income Statement</u>					
Revenues					
Grants	390	274	711	354	1,105
Interest	143	153	466	587	1,075
Research & development	(1,869)	(1,208)	(4,246)	(2,186)	(6,047)
Commercial	(120)	-	(320)	-	-
Administration	(633)	(425)	(1,536)	(852)	(2,182)
Net loss before and after tax	(2,622)	(1,633)	(6,102)	(3,038)	(8,229)
Depreciation & amortisation	137	119	275	236	490
EBITDA	(2,342)	(1,343)	(5,361)	(2,181)	(6,586)
<u>Capital Expenditures</u>	(310)	(118)	(561)	(118)	(360)



Financials

(\$A'000)

31-Dec-04

30-Jun-04

Financial Position

Cash and bank accepted commercial bills	38,860	25,217
Plant & equipment	1,805	1,474
Intangible assets	1,144	1,162
Shareholders' equity	40,870	26,780

Grants outstanding: \$6m 2005 to 2008

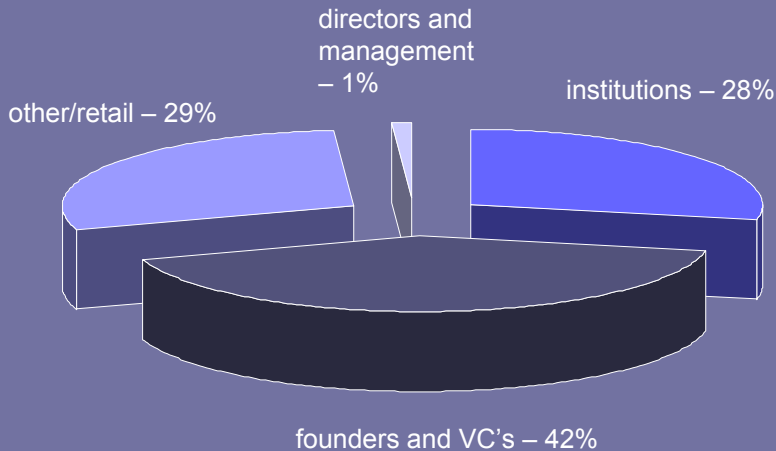


Share Capital

	<u>31 Dec 04</u>	<u>30 Jun 04</u>
Share Capital ('000)		
Shares on Issue	134,750	108,016
Escrowed to 10 November 2005	24,964	24,964
Options ('000)		
Options on Issue	10,364	10,751
Vested Options	7,727	7,207
Escrowed to 10 November 2005	6,720	6,720



Share Capital



31 December 2004



Summary

- Well resourced to execute Business Plan
- Bronchitol Orphan drug 2005
- Aridol asthma launch 2005
 - ✓ Annual revenue potential >\$250 million
- Integrated business
 - ✓ All marketing rights retained
- Bronchitol in Phase III for bronchiectasis
 - ✓ Market launch expected 2007
 - ✓ Very large market potential
- Bronchitol in Phase II for cystic fibrosis
- Pipeline of earlier stage products
 - ✓ Targeting large market potential