Therapeutic products for respiratory diseases

pharmaxis

October 2009

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.

Factors that could cause or contribute to such differences include, but are not limited to, factors discussed in the "Risk Factors and Other Uncertainties" section of our Form 20-F filed with the US Securities and Exchange Commission

We are not under any duty to update forward-looking statements unless required by law.

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

Pharmaxis Global Operations 2009

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Luton
-8 clinical
-8 marketing

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Pennsylvania
-4 commercial
-4 clinical/reg

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Shanghai
-2 commercial

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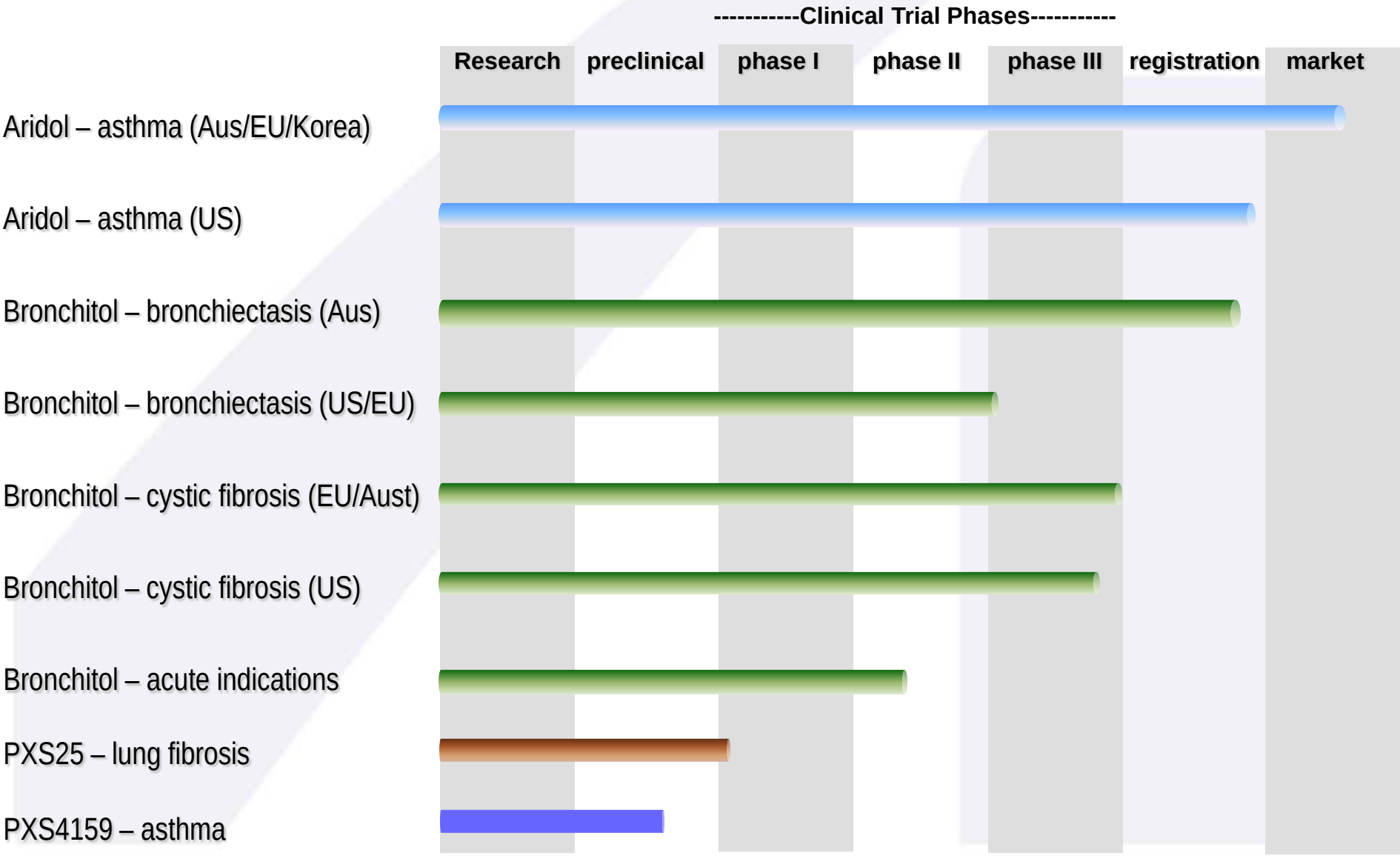
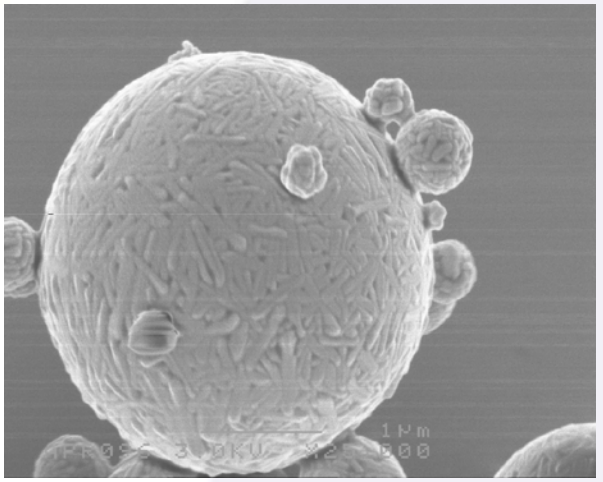
Frenchs Forest
- 88 employees

Development Pipeline



Bronchitol

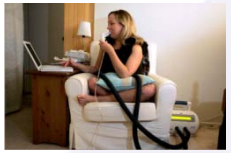


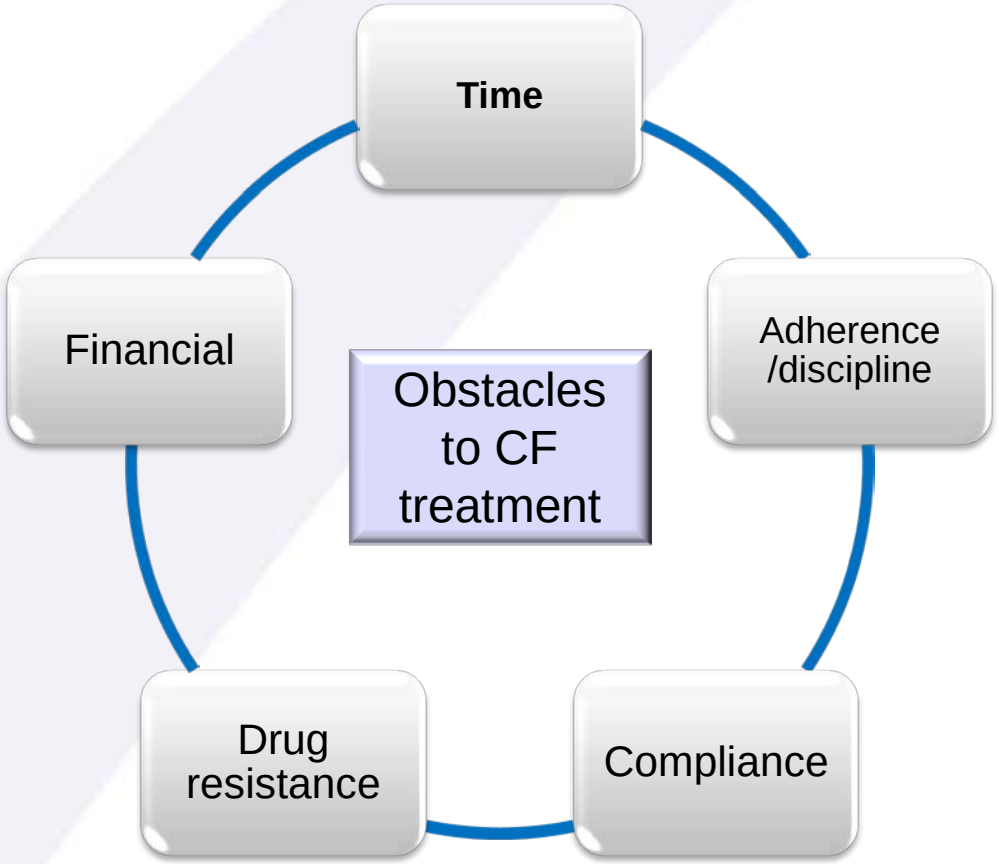
Mucus clearance:

Cystic fibrosis
Chronic Obstructive Pulmonary Disease
Bronchiectasis

Cystic Fibrosis market research

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



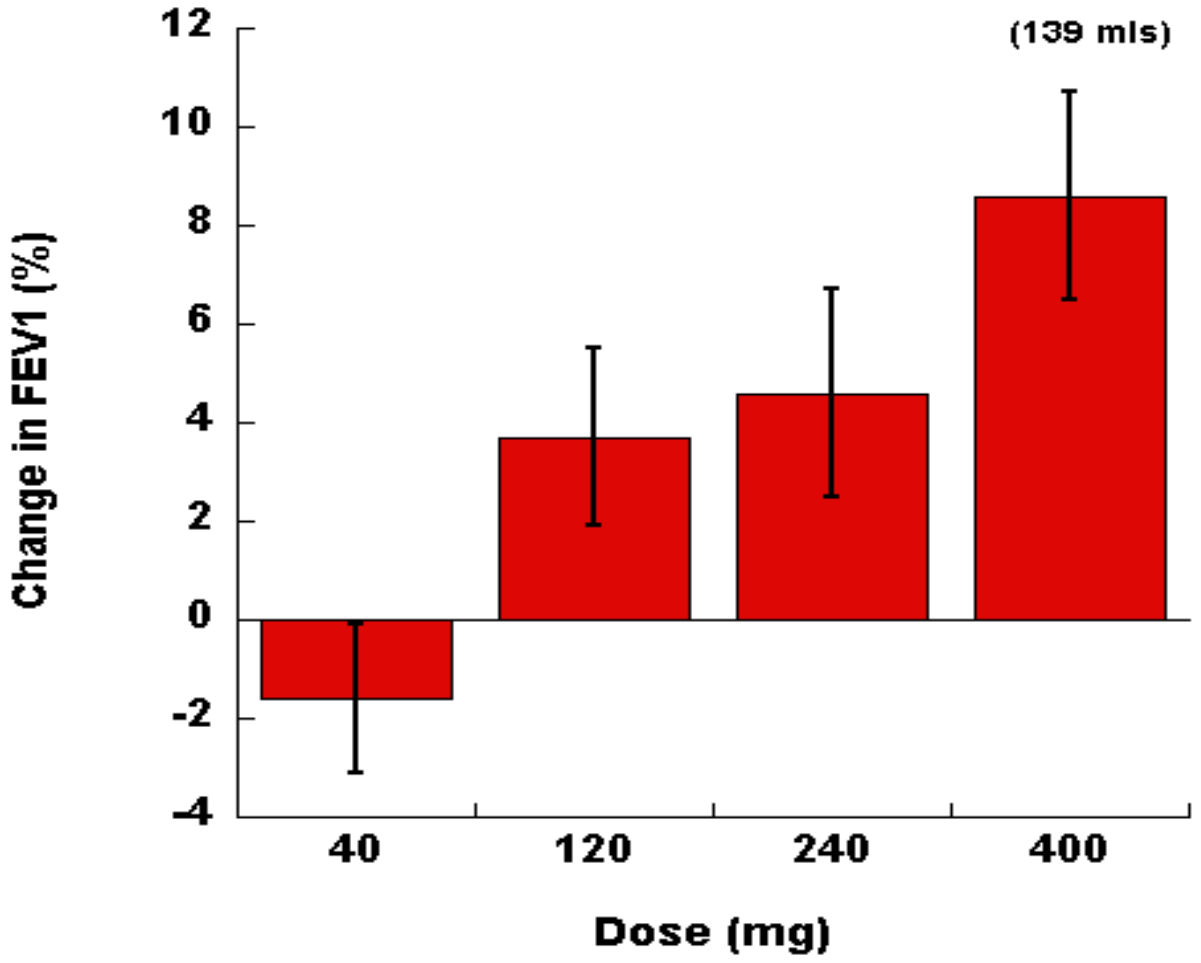


- Time requirements and adherence to therapy are pervasive challenges
  - *"the treatments take time. Although the payback is longevity and QOL, at the moment the treatments can take up a large part of the day."*
  - *"patients feel very pressed for time."*
  - *"Because of the time requirement, you 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

Bronchitol – the first CF specific dry powder

CF-202 Dose Response 400 mg Selected

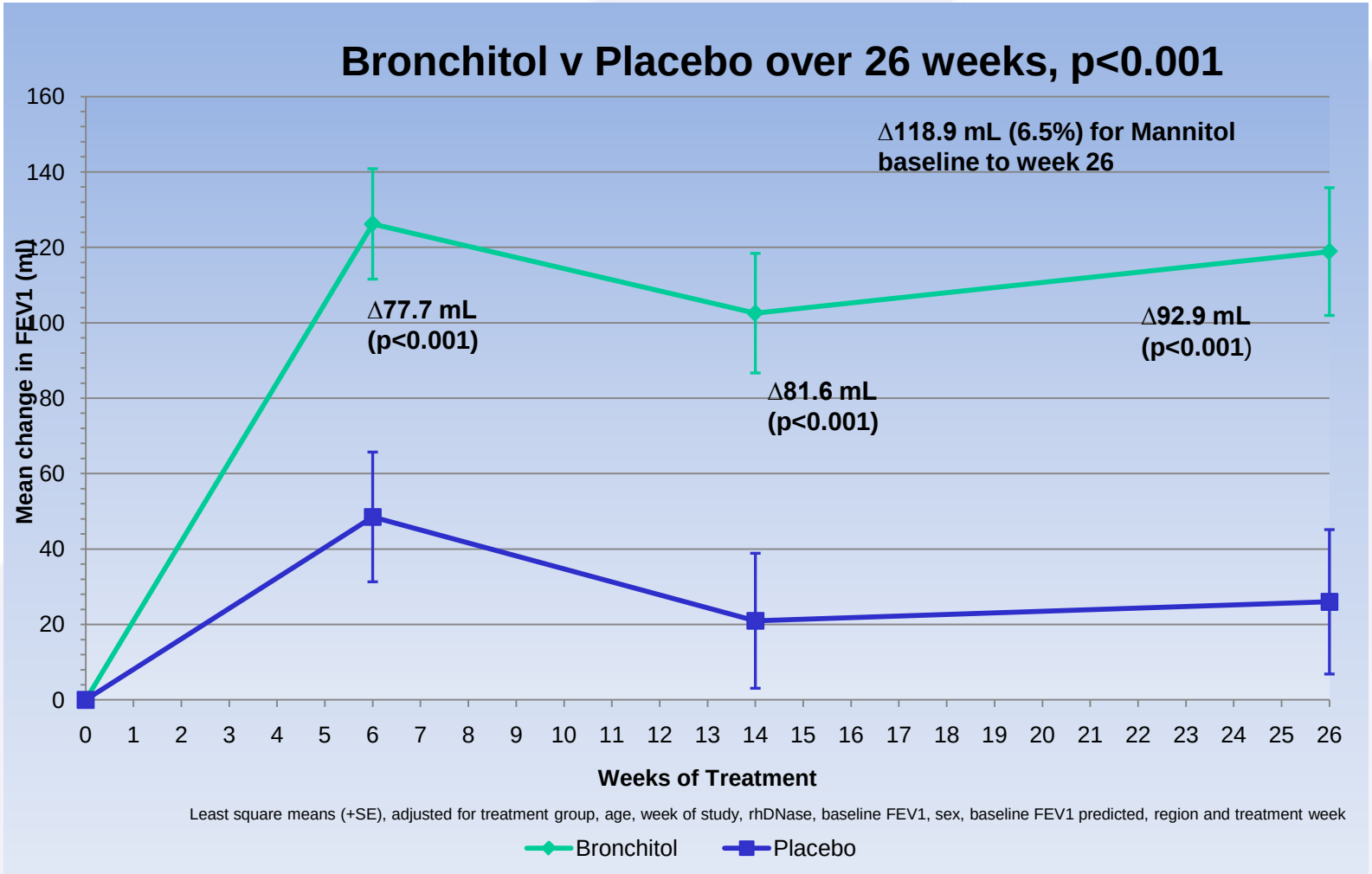


- 48 subjects
- Open label multidose study
- 400mg twice a day, then 40, 120, 240mg twice a day for 14 days in a random order
- Washout between doses

DPM-CF-202

Pharmaxis –Data on File [DPM-CF-202]

CF-301 Absolute mean change (mL) in FEV_1



DPM-CF-301

Pharmaxis –Data on File [DPM-CF-301]

Bronchitol; TPP → Commercial reality in CF

Bronchitol:

- An easy, quick, portable dry powder inhaled drug that won't interrupt cystic fibrosis patient's daily schedules.
- Suitable for all ages and stages of cystic fibrosis
- Acts quickly to help clear mucus, producing a lasting benefit to lung function, reducing exacerbations and improving quality of life.

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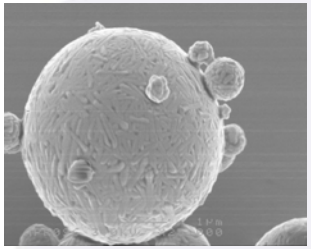
Market access Milestones:

- Phase 3 delivers Target Product Profile – May 2009
  - Presentation of clinical trial results
    - Oral presentation at EU CF meeting
    - Oral presentation at Au CF meeting
    - Oral presentation at European Respiratory Society meeting
    - Oral presentation at North American CF meeting (October)
  - EMEA submission
    - Request for accelerated review submitted – September 2009
    - Marketing application submission – October 2009

Bronchitol – cystic fibrosis registration

- **2nd Pivotal Phase III trial**
  - Two pivotal trials required by the FDA
  - Protocol review through Special Protocol Assessment (FDA)
  - Double blind, placebo controlled
  - 319 subject 6 years and older
  - 400mg, twice per day for 6 months
  - 1º endpoint - lung function by spirometry (FEV1)
  - 2º endpoints – antibiotic use, exacerbations, lung function, QoL
- **Enrolment closed at 319 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

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

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- First marketing application filed (Aus) in Sep 2008

Bronchitol – bronchiectasis registration (II)….

- **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 FDA
  - Orphan Drug designation USA
  - Commencement October 2009
  - Data 2011

Aridol™

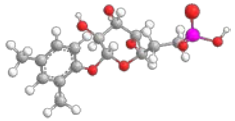
- Identifies airway reactivity (active airway **inflammation**) which helps physicians in the diagnosis and management of **asthma**

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

International regulatory status - Aridol

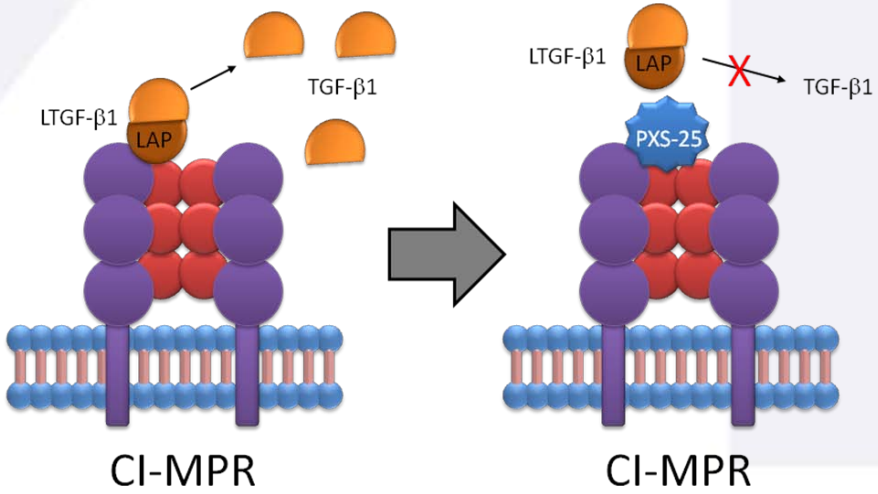
- **Australia**
  - First market to launch
  - 50% penetration in 2 years — June 2006
- **Europe**
  - Approved European Union (MRP) — May 2007
  - Regional marketing partners appointed
  - Launches underway
- **South East Asia**
  - Approved for marketing – Korea — Jan 2008
    - Pricing approval completed mid-2009
- **USA**
  - NDA submitted. Complete response expected — Dec 2009

R&D - Status (PXS-25)



- Inhibits cleavage of latent TGFβ to active TGFβ
  - anti-fibrotic agent with anti-inflammatory properties
    - small molecule with robust pharmaceutical profile
    - clinical target is pulmonary fibrosis
      - *500,000 cases and no approved drugs*

- Phase 1 trial commenced October 2009
  - data due end 2009



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 - Q3 2009
  - 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	
	30-Sep-09	30-Sep-08
	A$	A$
Revenue from sale of goods	183	106
Cost of sales	(47)	(29)
Gross profit	136	77
Interest	952	2,076
Other income	88	3
Expenses		
Research & development	(8,111)	(5,960)
Commercial	(1,251)	(1,371)
Administration	(1,721)	(1,283)
Finance expenses	(286)	-
Total expenses	(11,369)	(8,614)
Loss before income tax	(10,193)	(6,458)
Income tax expense	(11)	(6)
Loss for the period	(10,204)	(6,464)
Basic and diluted earnings (loss) per share - $	(0.047)	(0.033)
Depreciation & amortisation	505	252
Fair value of options issued under employee plan	604	611

Financial Statements

Balance Sheet Data	As at	
	30-Sep-09	30-Jun-09
	A$	A$
Cash and cash equivalents	113,438	124,993
Property, plant & equipment	32,559	32,698
Intangible assets	1,189	1,193
Total assets	151,822	163,997
Total liabilities	(23,508)	(26,306)
Net assets	128,314	137,691
Cash Flow Data	**Three months ended**	
	30-Sep-09	30-Sep-08
	A$	A$
Cash flows from operating activities	(10,025)	(4,877)
Cash flows from investing activities	(1,276)	(1,430)
Cash flows from financing activities	(189)	11
Net increase (decrease) in cash held	(11,537)	(6,296)

END

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