

pharmaxis

# Therapeutic products for respiratory diseases

July 2009

# Forward Looking Statements

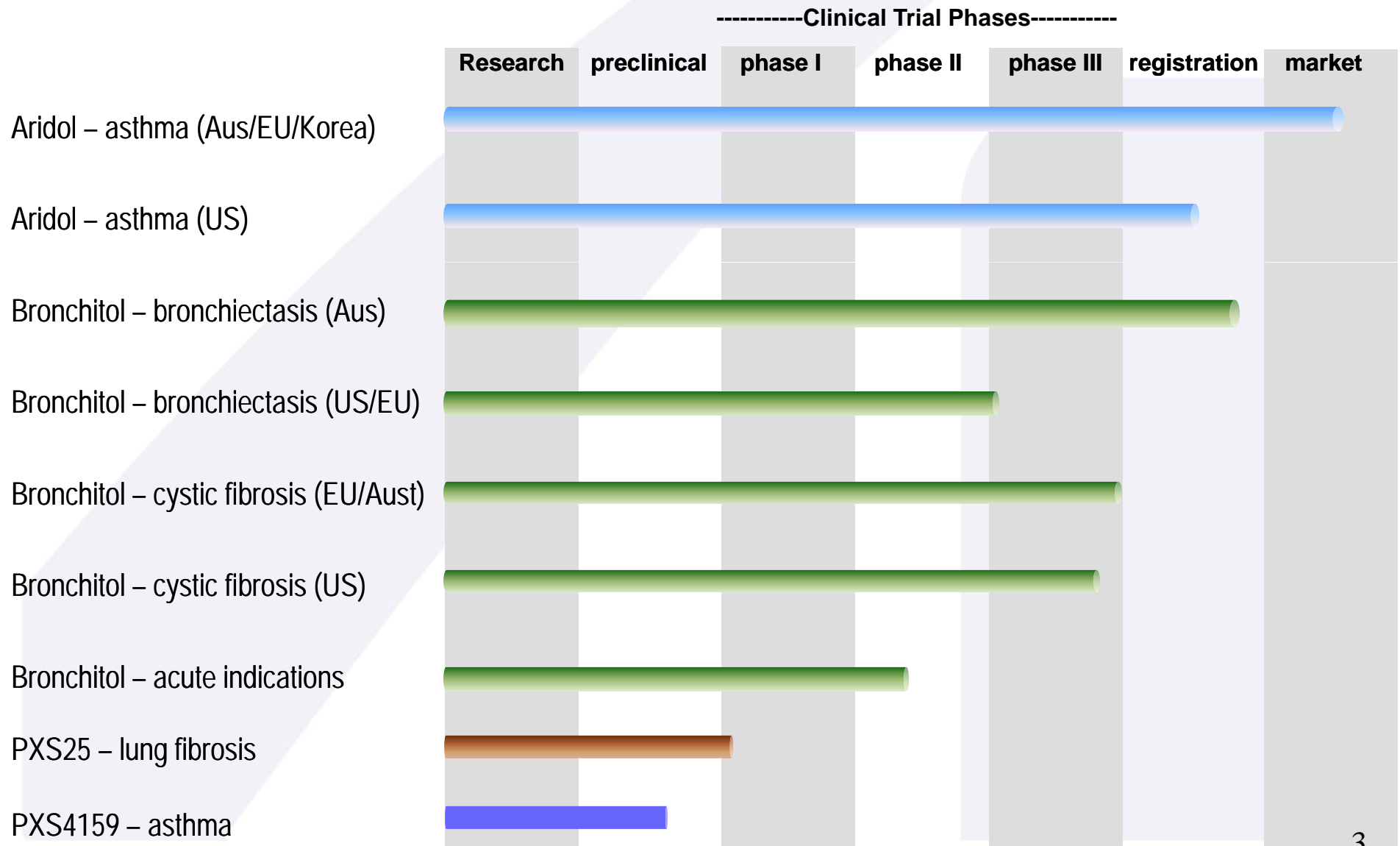
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This investor presentation is not an offer of the sale of securities.

# Development Pipeline



# Operational Highlights of Quarter 2, 2009



- Phase 3 trial with Bronchitol in CF returns positive result
- Oral presentation at the European annual cystic fibrosis scientific meeting.



- Meetings with European regulators outlined regulatory review path
- Aridol New Drug Application accepted for review by FDA



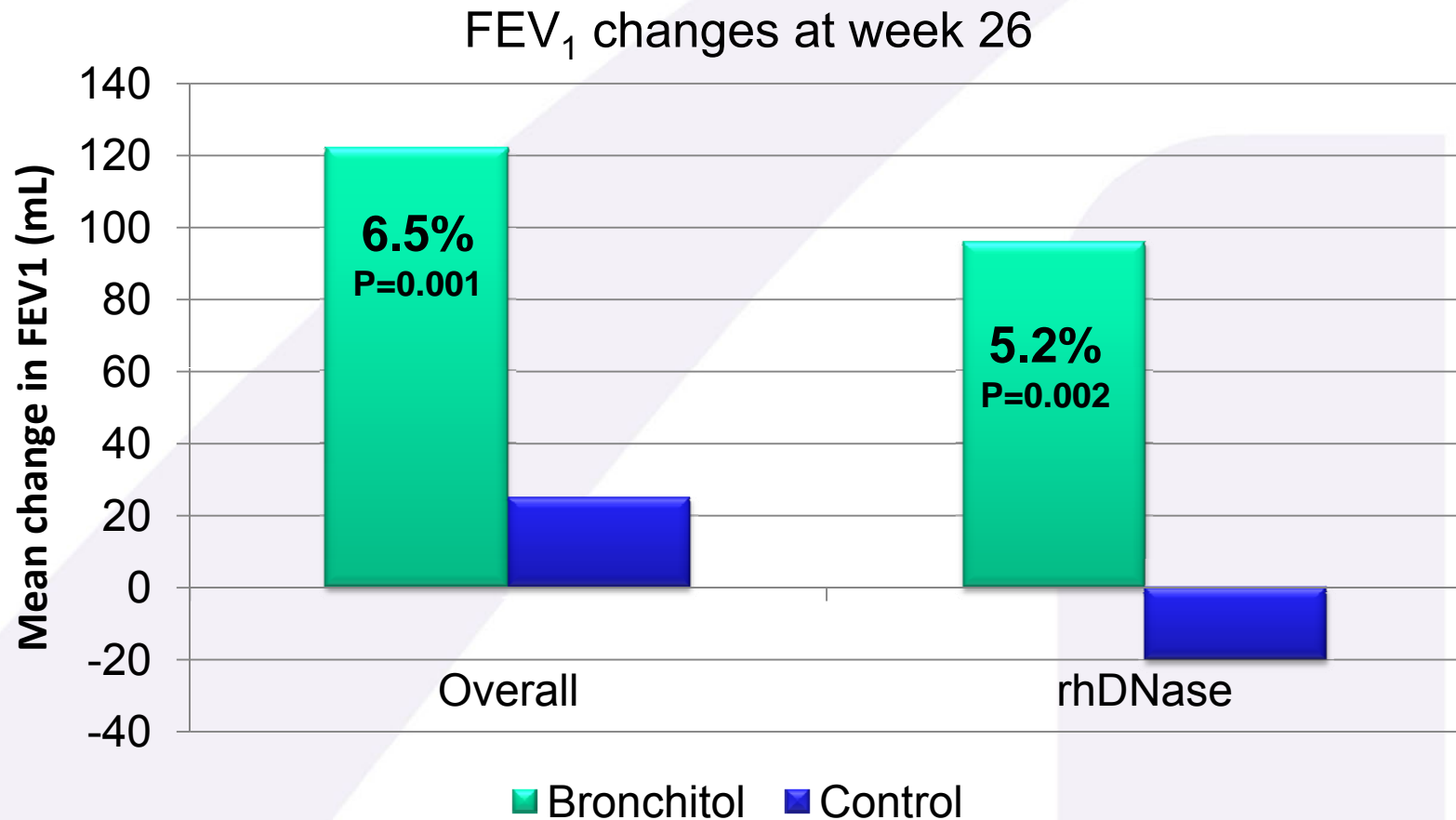
- PXS25 presented at the 2009 American Thoracic Society meeting in San Diego

# Bronchitol for Cystic Fibrosis



Not an approved pack – for illustration purposes only

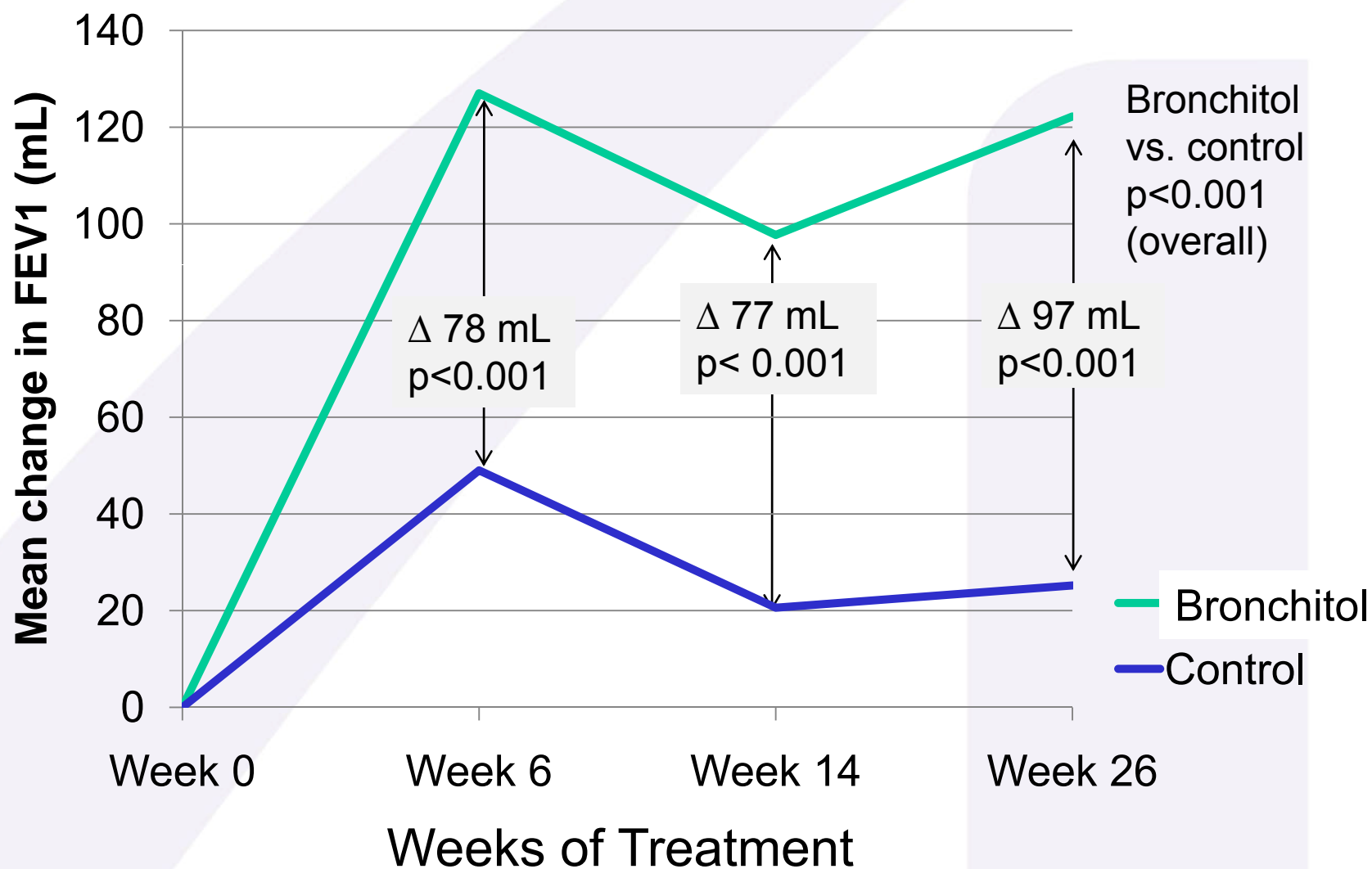
# Primary and key secondary endpoint – CF 301



## Safety:

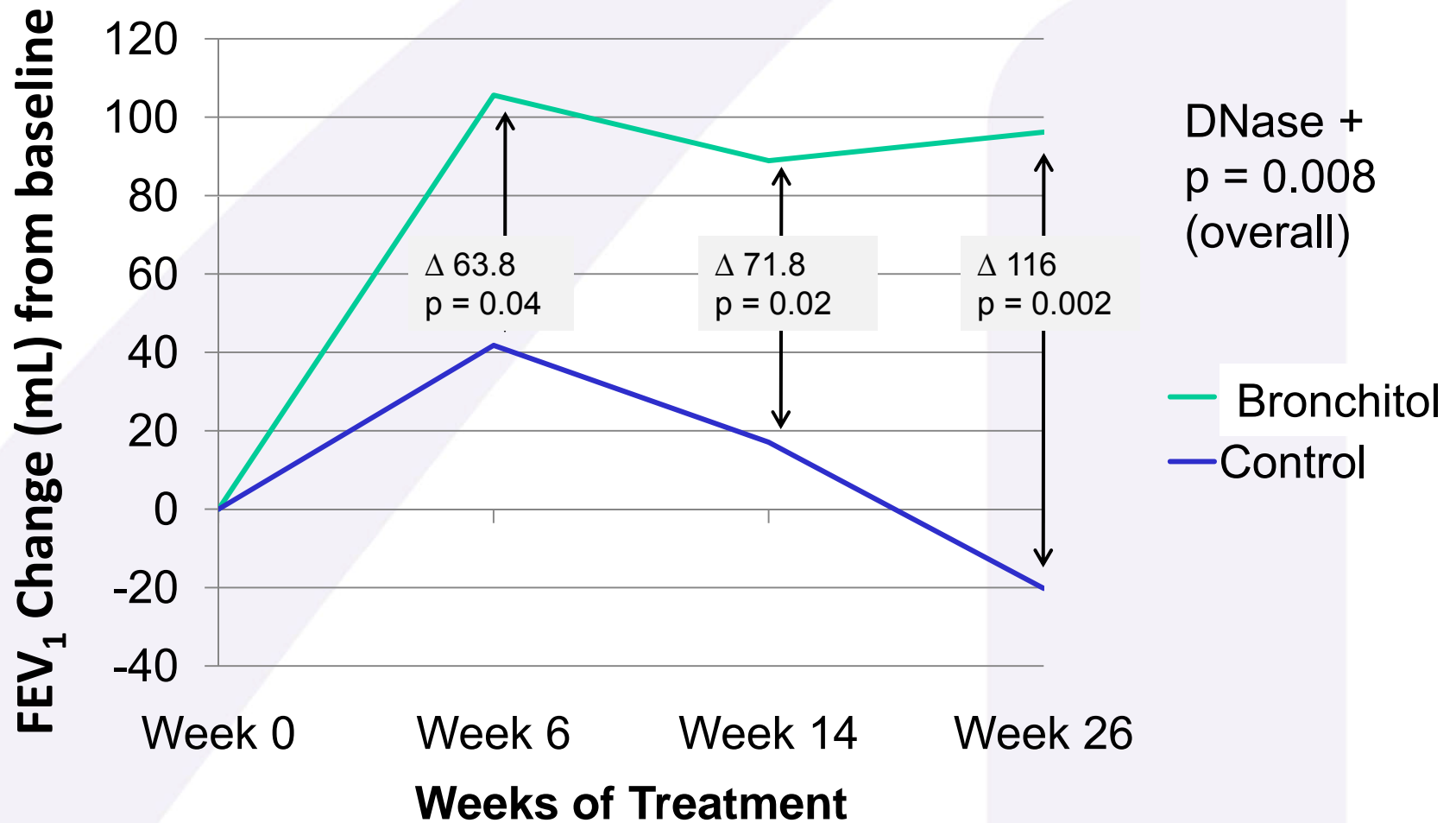
- Bronchitol well tolerated
- Favorable safety profile
- Adverse events – consistent between treatment groups

# CF 301 – Mean change (ml) in FEV1 over time



# CF301 – Key Secondary Endpoint

Absolute (ml) change from baseline in FEV<sub>1</sub> over time for rhDNase+ subjects





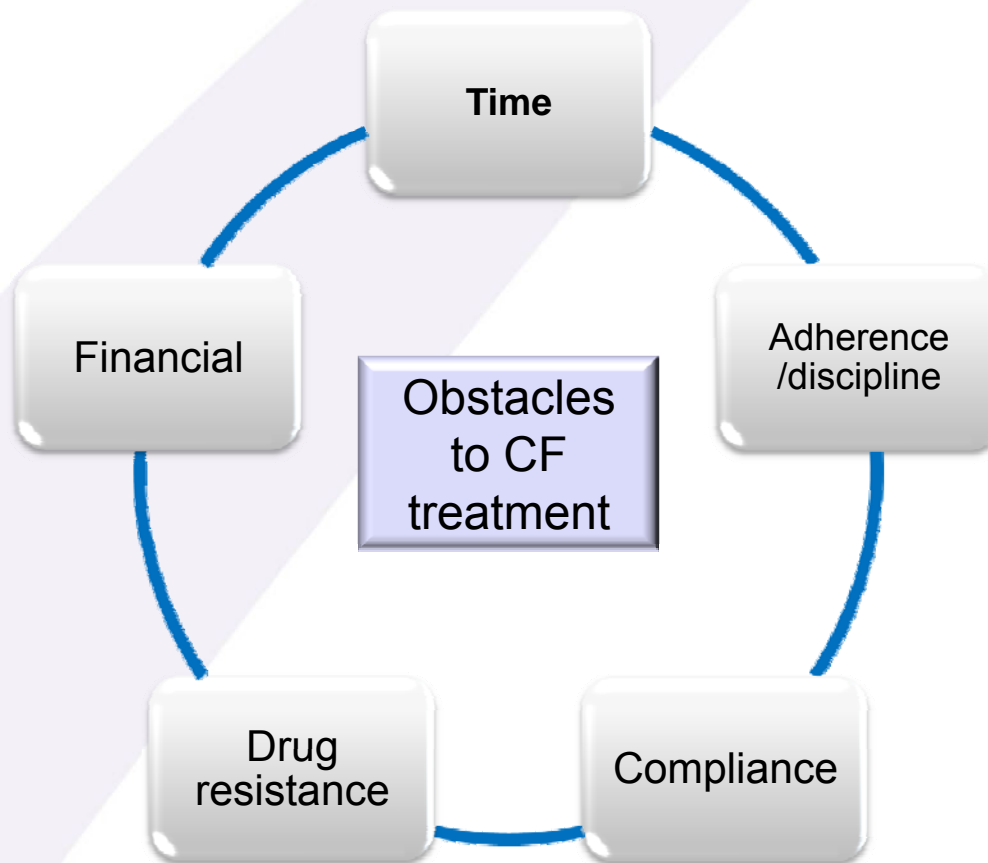
# Positioning Bronchitol in CF Treatment

Grade of recommendation	Mild	Moderate/Severe
A Benefit is substantial	<ul style="list-style-type: none"> <li>• None</li> </ul>	<ul style="list-style-type: none"> <li>• rhDNase</li> <li>• Tobi (if p.a. present)</li> </ul>
B Benefit is moderate	<ul style="list-style-type: none"> <li>• rhDNase</li> <li>• Tobi (if p.a. present)</li> <li>• Azithromycin (if p.a. present)</li> <li>• Hypertonic saline</li> <li>• Ibuprofen (FEV1&gt;60%)</li> <li>• Inhaled <math>\beta</math>2 agonists</li> </ul>	<ul style="list-style-type: none"> <li>• Hypertonic saline</li> <li>• Azithromycin (if p.a. present)</li> <li>• Ibuprofen (FEV1&gt;60%)</li> <li>• Inhaled <math>\beta</math>2 agonists</li> </ul>
Insufficient evidence	<ul style="list-style-type: none"> <li>• Other inhaled antibiotics</li> <li>• Oral corticosteroids (18+ yr olds)</li> <li>• Leukotriene inhibitors / cromolyn sodium</li> <li>• Anticholinergic bronchodilators</li> <li>• N-acetylcysteine</li> </ul>	
Against	<ul style="list-style-type: none"> <li>• Inhaled corticosteroids (if asthma / ABPA absent)</li> <li>• Oral corticosteroids (6 -18 yr olds)</li> </ul>	

Source: Treatment Progression – CFF Guidelines

# 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

# Positioning Bronchitol in CF Treatment

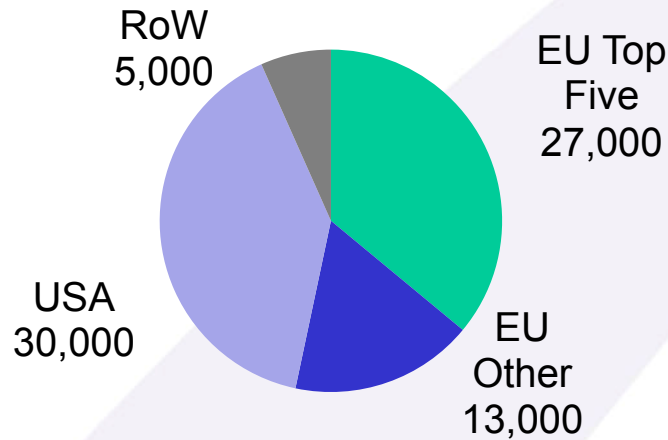
Mucus Alteration / Liquid Restoration CF Products

	Pulmozyme	Hypertonic Saline	Bronchitol	Denufosol	Moli1901
<b>Company</b>	Genentech	n/a	Pharmaxis	Inspire	AOP
<b>Status</b>	Market	Not registered	Phase III	Phase III	Phase II
<b>Administration</b>	Nebulizer	Nebulizer	Dry powder inhaler	Nebulizer	Nebulizer
<b>Dosing</b>	1x daily	2-3x daily	2x daily	3x daily	1x daily
<b>Administration Time (per dose)</b>	20 minutes	20 minutes	3-5 minutes	20 minutes	20 minutes
<b>FEV<sub>1</sub> Benefit</b>	5.6%	3.2%(n.s.)	6.5%	1-2%	2%

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

# Sizing the CF Market Opportunity

**Patients  
(75,000)**



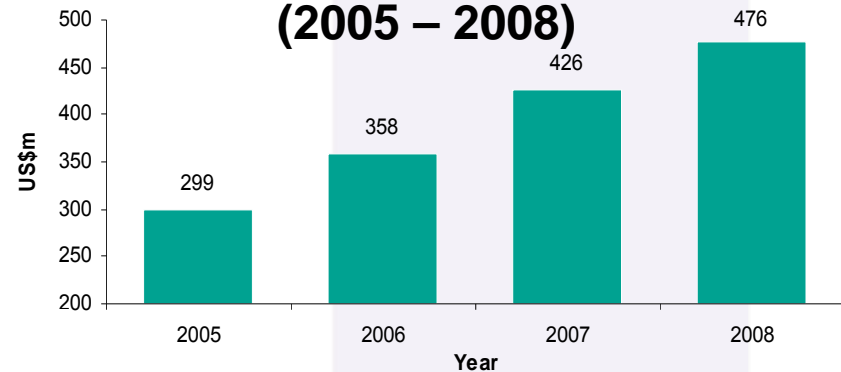
**Worldwide sales of rhDNase US\$476m  
(2008)**



Source: 2008 Roche and Genentech annual reports

CF Market	US	EU (T5)
Existing use of rhDNase	62%	52%
Annual cost	US\$22k	US\$13k
CF Centres	110	350
Required Field Force	~15	~25

**Worldwide sales of rhDNase  
(2005 – 2008)**



Source: 2005 – 2008 Roche annual reports

Note: Sales are converted from CHF to USD using the exchange rate on the last day of each financial year

# Commercialisation Timetable - CF

	Europe	USA
H2 2009	File MAA in EU (centralised)	Close Recruitment Second Phase III Trial (CF302)
H1 2010		Second Phase III Trial Reports
H2 2010	Earliest Anticipated Approval	File NDA
H1 2011	Target sales	Earliest Anticipated Approval
H2 2011		Target sales

# 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.



# 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



# Major near term catalysts ahead

Milestone	3Q-09	4Q-09	1Q-10	2Q-10
<b>Bronchitol – cystic fibrosis</b> P III trial (CF301) Additional data available File MAA in EU (centralised) P III trial (CF302) fully enrolled P III trial (CF302) data available				
<b>Bronchitol – bronchiectasis</b> MAA decision (Aus) Start 2 <sup>nd</sup> P III trial enrollment Complete 2 <sup>nd</sup> PIII enrollment				
<b>Aridol</b> U.S. NDA complete response				
<b>Facilities</b> New factory validation complete				
<b>PXS25</b> Commence Phase 1 program				



**END**

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