Therapeutic products for respiratory diseases

pharmaxis

July 2009

Forward Looking Statements

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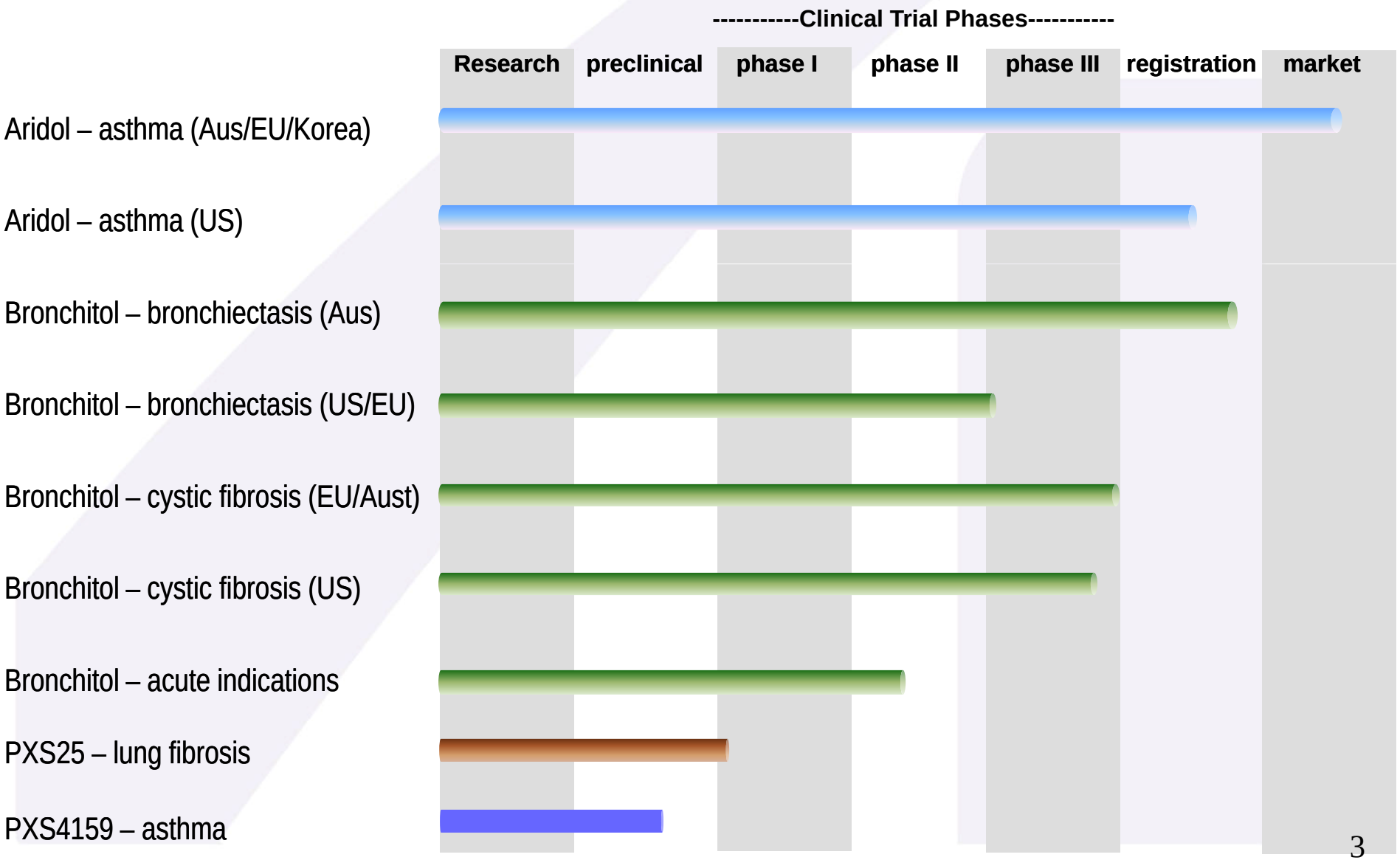
Development Pipeline



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.

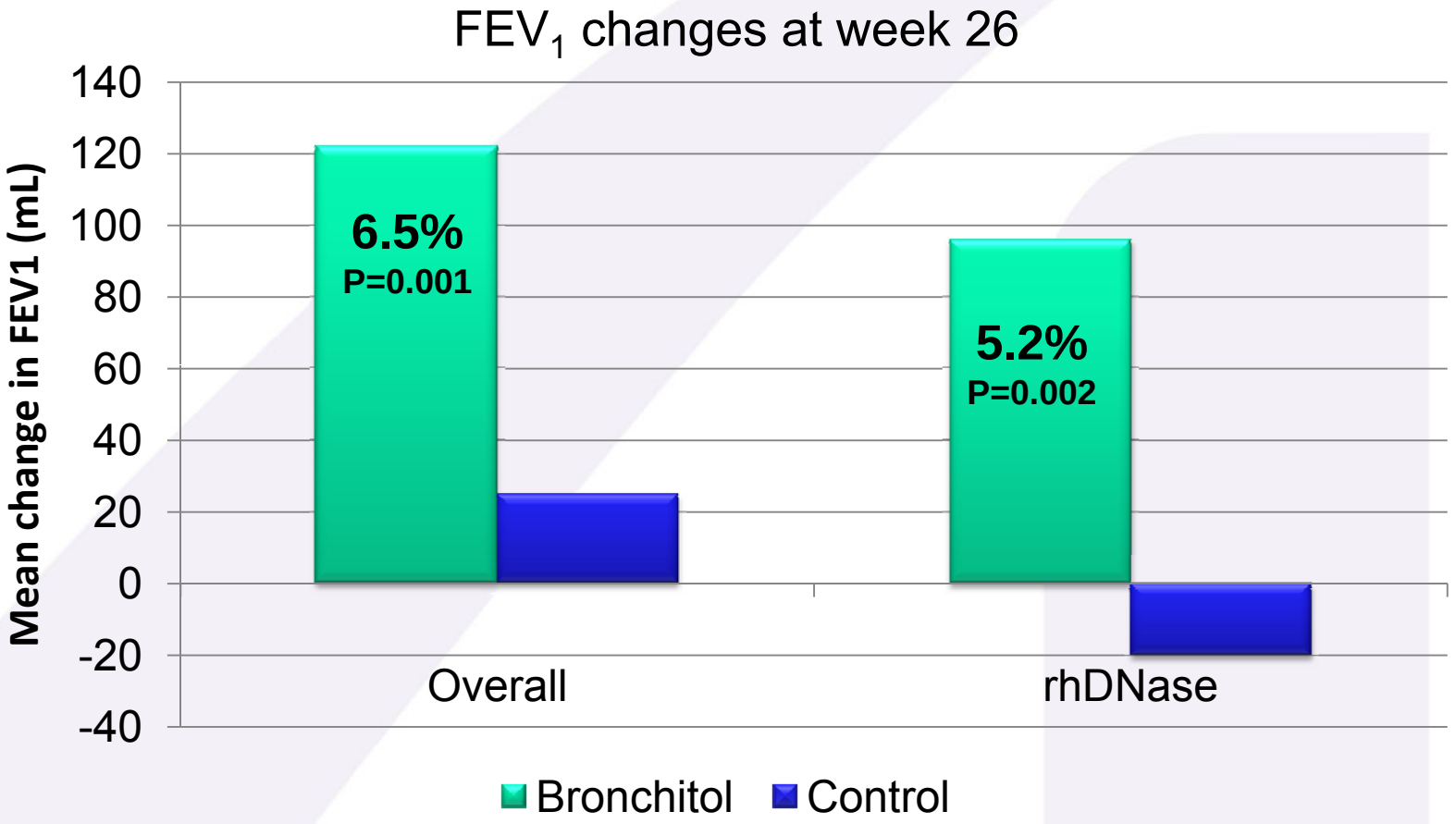
- Meetings with European regulators outlined regulatory review path
- Aridol New Drug Application accepted for review by FDA

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

Bronchitol for Cystic Fibrosis

Not an approved pack – for illustration purposes only

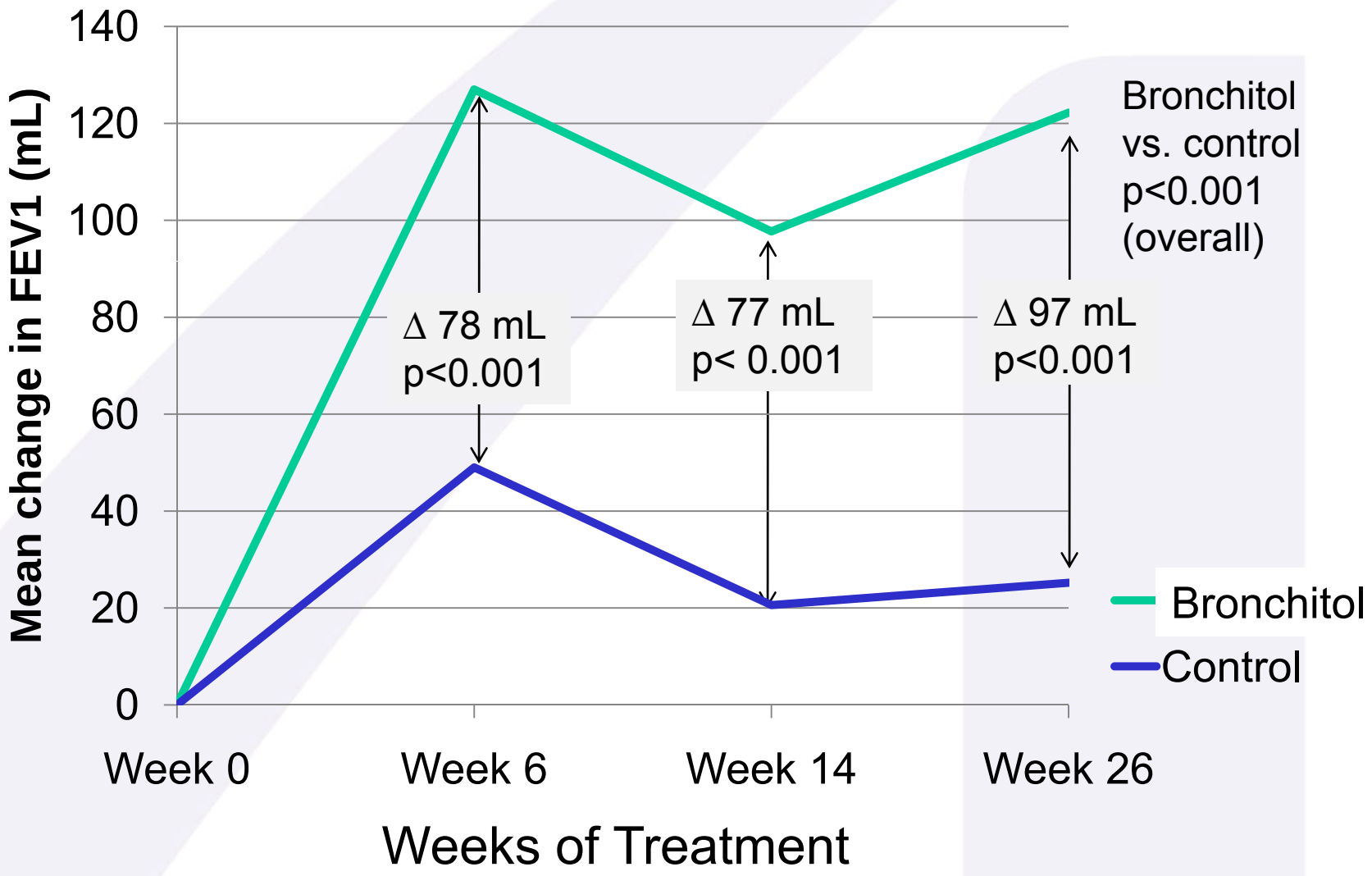
Primary and key secondary endpoint – CF 301



Safety:

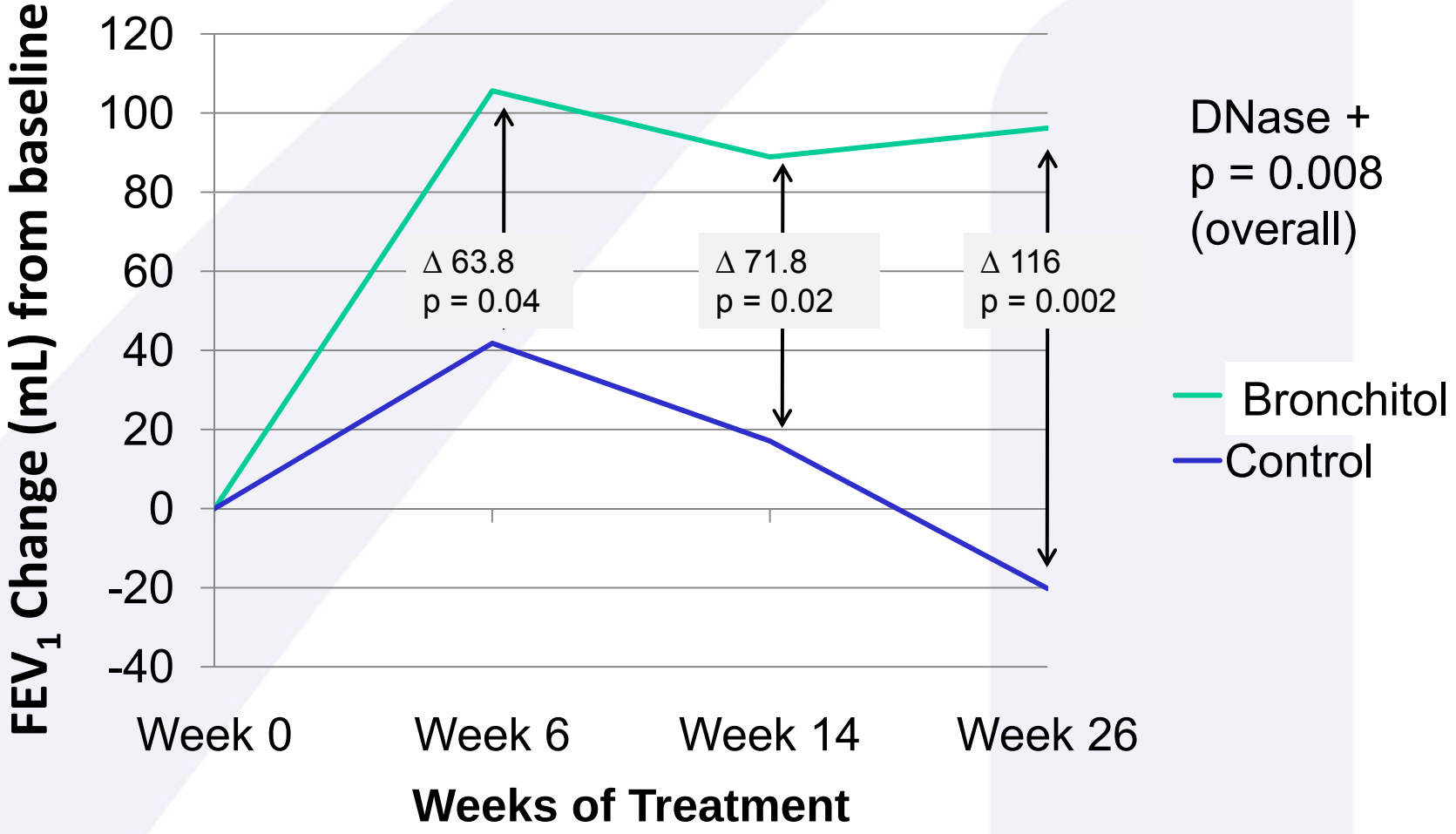
- Bronchitol well tolerated
- Favorable safety profile
- Adverse events – consistent between treatment groups

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



CF301 – Key Secondary Endpoint

Absolute (ml) change from baseline in FEV1 over time for rhDNase+ subjects



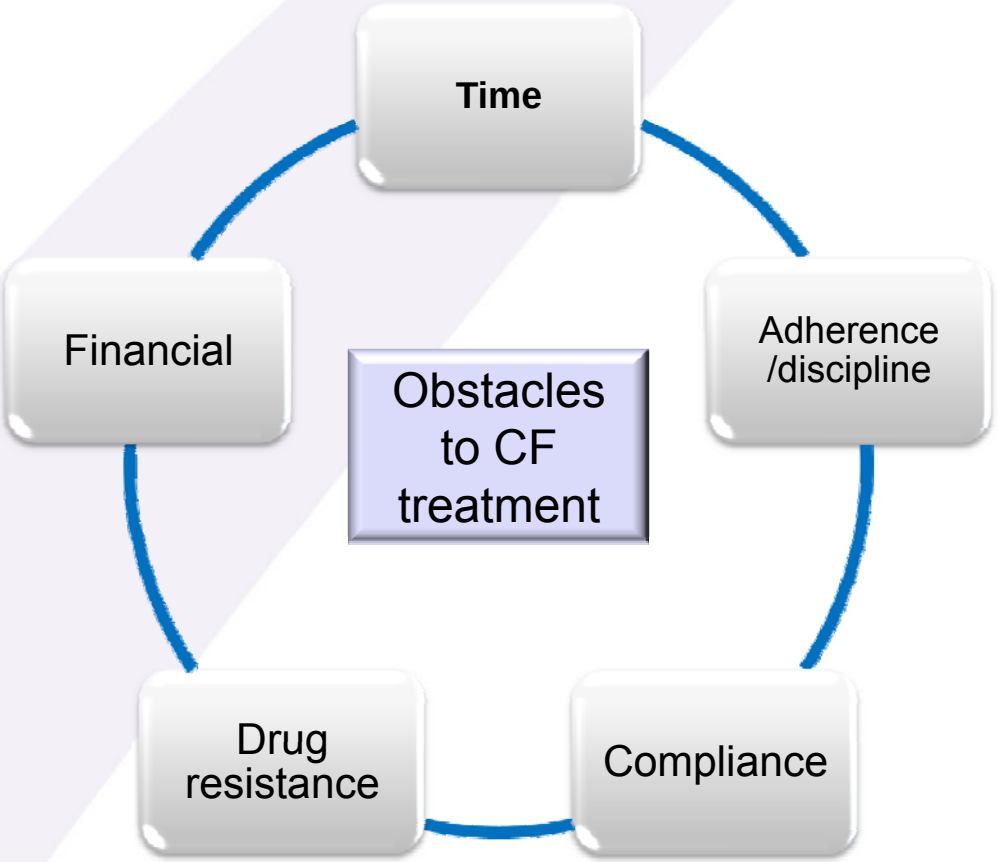
Positioning Bronchitol in CF Treatment

Grade of recommendation	Mild	Moderate/Severe
A Benefit is substantial	• None	• 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 β2 agonists	• Hypertonic saline • Azithromycin (if p.a. present) • Ibuprofen (FEV1>60%) • Inhaled β2 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)	

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

Source: Willowdale market research

Positioning Bronchitol in CF Treatment

Mucus Alteration / Liquid Restoration CF Products

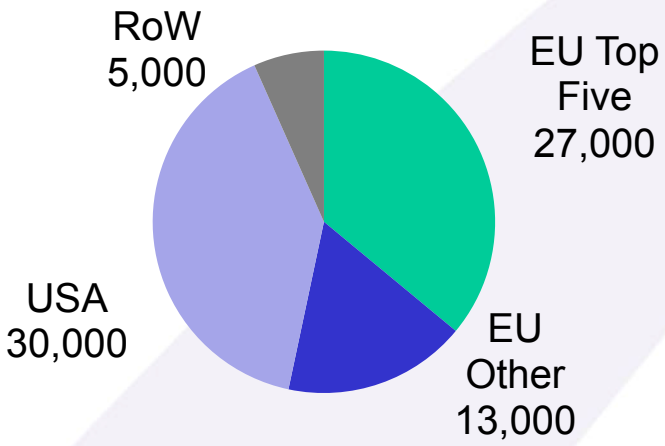
	Pulmozyme	Hypertonic Saline	Bronchitol	Denufosol	Moli1901
Company	Genentech	n/a	Pharmaxis	Inspire	AOP
Status	Market	Not registered	Phase III	Phase III	Phase II
Administration	Nebulizer	Nebulizer	Dry powder inhaler	Nebulizer	Nebulizer
Dosing	1x daily	2-3x daily	2x daily	3x daily	1x daily
Administration Time (per dose)	20 minutes	20 minutes	3-5 minutes	20 minutes	20 minutes
FEV_1 Benefit	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)

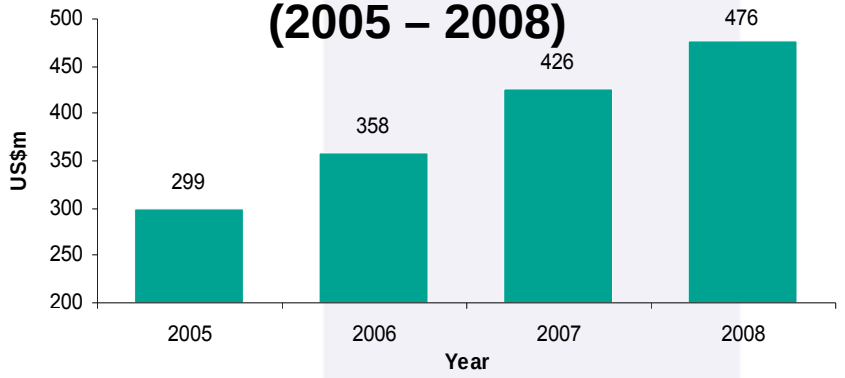


CF Market	US	EU (T5)
Existing use of rhDNase	62%	52%
Annual cost	US$22k	US$13k
CF Centres	110	350
Required Field Force	~15	~25

Worldwide sales of rhDNase US$476m (2008)

Source: 2008 Roche and Genentech annual reports

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
Bronchitol – cystic fibrosis				
P III trial (CF301) Additional data available				
File MAA in EU (centralised)				
P III trial (CF302) fully enrolled				
P III trial (CF302) data available				
Bronchitol – bronchiectasis				
MAA decision (Aus)				
Start 2nd P III trial enrollment				
Complete 2nd PIII enrollment				
Aridol				
U.S. NDA complete response				
Facilities				
New factory validation complete				
PXS25				
Commence Phase 1 program				

END

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