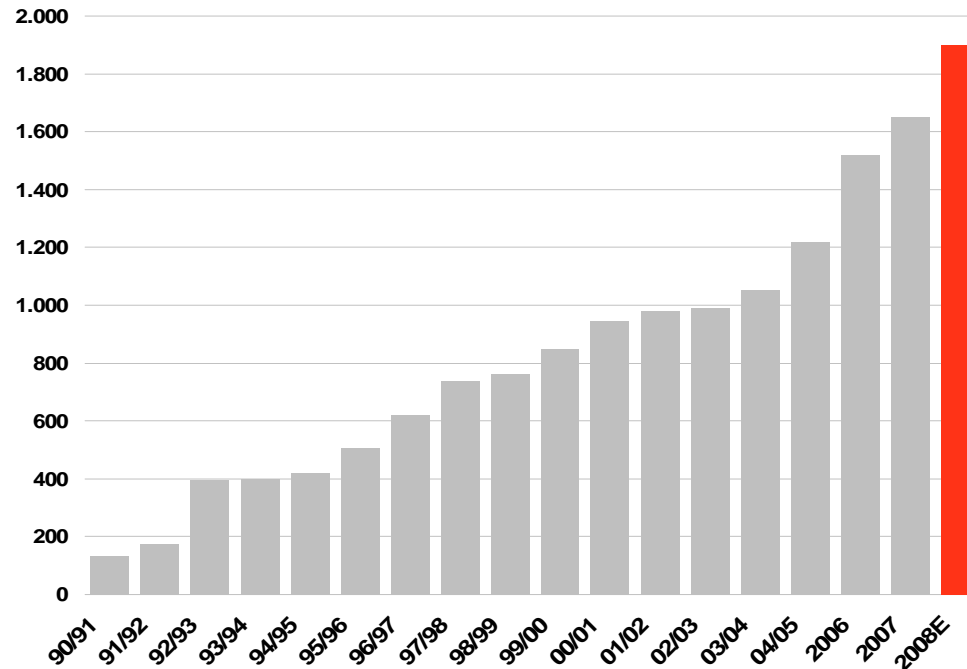


# General Investor Presentation

November 2008

# About ALK – quick facts

- **Global company with presence in Europe, the US and China**
- **Founded in 1923, today approximately 1,500 employees**



- **Trading codes: Reuters: ALKB\_CO / Bloomberg (ALKB DC)**
- **ISIN number DK0060027142**

# Forward-looking statements

*This presentation contains forward-looking statements, including forecasts of future revenue and operating profit as well as expected business-related events. Such statements are subject to risks and uncertainties because various factors, some of which are beyond the control of the ALK Group, may cause actual results and performance to differ materially from the forecasts made in this presentation. Without being exhaustive, such factors include, among others, general economic and business conditions, including legal issues, uncertainty relating to pricing, reimbursement rules and market penetration for GRAZAX<sup>®</sup>, fluctuations in currencies and demand, changes in competitive factors and reliance on suppliers, but also factors such as side effects from the use of the company's existing and future products since allergy vaccination may be associated with allergic reactions of differing extent, duration and severity.*

# Table of contents

- **Financial & business development** **slide 5**
- **Research & Development** **slide 16**
- **General introduction** **slide 26**

# Recent business highlights

- Continued revenue and earnings growth
- **GRAZAX®** obtains reimbursement in Spain
- **GRAZAX®** for children approved in Europe
- World-class long-term results with **GRAZAX®**
- Further development of house dust mite tablet programme under planning
- Investments in production to support growth progress as planned
- Partnership with Schering-Plough



# 2008: Continued revenue growth

- **Revenue in 9M up 11%\* to 1,308 DKKm**
  - Vaccine sales up 12%\*
  - Strong SLIT sales development
  - Negative currency effect of 3 pp
- **Full-year organic growth in vaccine sales expected at 12-15%**

## Long-term growth ambition

- **Grow sales of allergy vaccines with 15% on average per year**



\*) organic growth rate

# Satisfactory development in earnings

- **Cost development under control**
  - 9M 2008 gross margin at 70% (69)
  - Growth in capacity costs adjusted
- **9M 2008 EBIT of 78 DKKm (207)**
  - Includes payments from Schering-Plough
- **Full-year EBIT expected at 110-140 DKKm**
- **Strong balance sheet**



## Long-term ambition:

- To continue improve gross margins
- To expand earnings capacity

# Status on GRAZAX®

- **Approved for marketing in 28 European countries (Sept. '06)**
- **National reimbursement in**
  - Sweden, **Norway**, Finland, Germany, the Netherlands, Ireland, Austria, **Spain**, Switzerland and Greece
- **Regional reimbursement in Italy and the UK**
- **Patient individual reimbursement in Denmark**



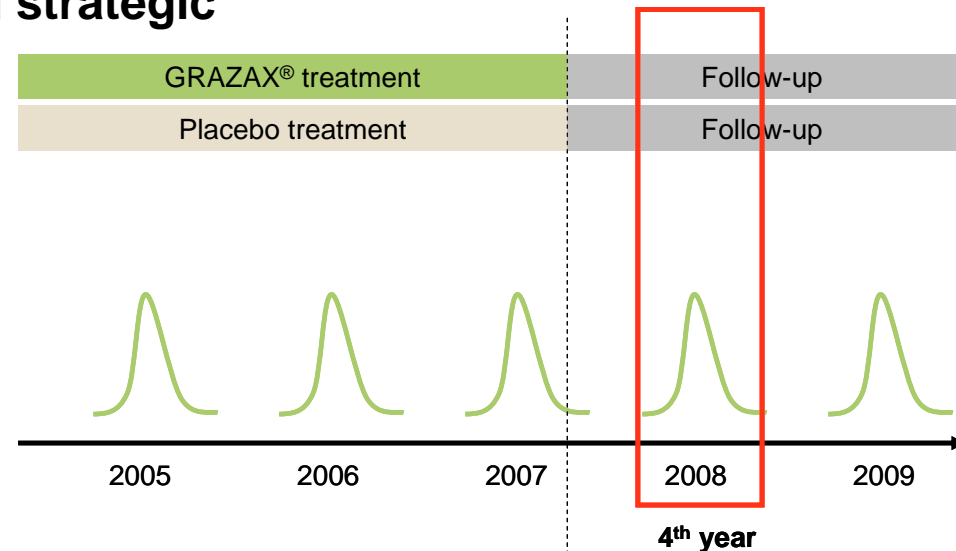
# Children indication with GRAZAX® secured

- **November 2008: GRAZAX® approved for children and adolescents in 27 European countries**
- **Approval opens an important patient segment for ALK**



# World-class results with GRAZAX®

- **First follow-up year: Persistent clinical effect**
  - Statistically significant results
  - Hay fever symptoms reduced by 31%
  - Use of symptom-relieving medication reduced by 52%
- **Major milestone providing a solid strategic foundation for ALK**
- **GRAZAX®: Only product to show consistent clinically relevant effect year after year**



# Proof of concept with dust mite tablet

- **Solid results from clinical trial with house dust mite vaccine (MT-02) in August 2008**
  - 50% reduction in steroid usage
  - Highly statistically significant results
  - Good safety profile
  
- **Further clinical development in planning**



# Investments continue as planned

- **New raw materials production unit in the US (Idaho) ready for production in 2009**
- **Expansion of the production capacity**
  - Extension of API facility in Denmark ready in 2009
  - Extension of tablet production facility in the UK (Swindon) ready for production in 2010
- **New HQ-facility**
  - Construction of a new facility initiated in Denmark (Hoersholm), ready in late 2009
- **Total investments of around 400 DKKm in 2008**
  - Outstanding investments in 2009-10 of around 200 DKKm



# Partnership with Schering-Plough



- **Partnership to develop and commercialise 3 tablet-based allergy vaccines in North America**
  - GRAZAX<sup>®</sup>, ragweed and house dust mite allergy
  - Deal based on milestone and royalty payments
- **Schering-Plough responsible for all clinical development, registration, marketing and sales of the products**
  - ALK responsible for production and supply
- **Schering-Plough currently conducts phase III clinical studies with GRAZAX<sup>®</sup> in the US**
  - Studies to be completed by end of 2009



# Ongoing progress and news flow

- Ongoing price and reimbursement conclusions in Europe
- Additional data from long-term study (GT-08)
- Data from grass tablet studies in the US (Schering-Plough)
- Further development of tablet programmes
  
- Financial calendar
- Annual report 2008 February 19, 2009
- Annual General Meeting March 27, 2009
- Three-month interim report (Q1) 2009 May 1, 2009
- Six-month interim report (Q2) 2009 August 18, 2009
- Nine-month interim report (Q3) 2009 November 19, 2009

## Risk factors

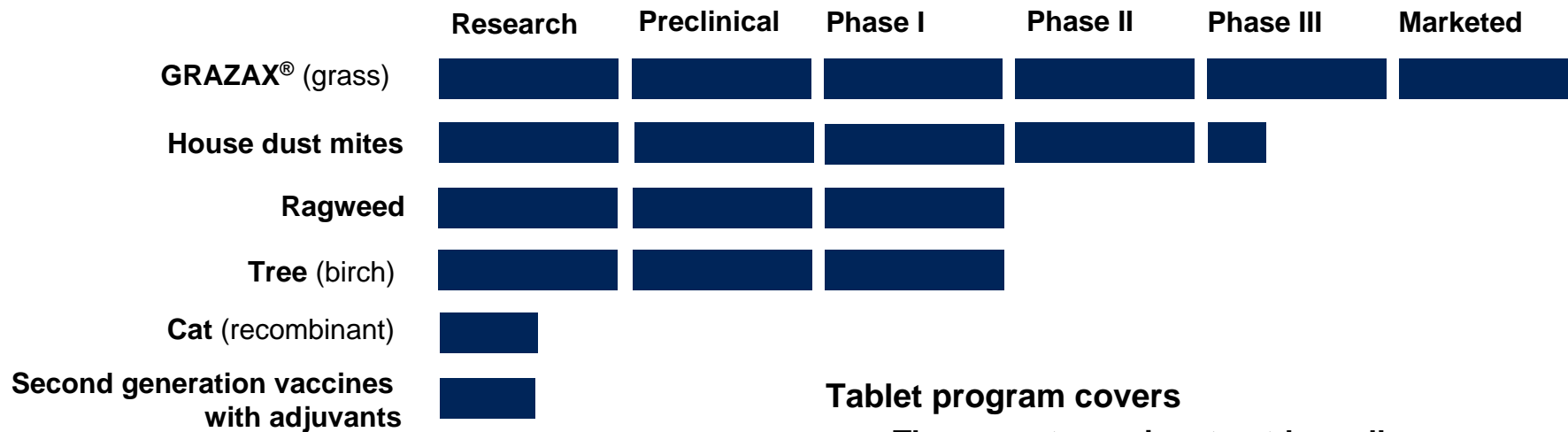
*Without being exhaustive, the following risks are of significance to ALK:*

### **Risks related to:**

- **development of new drugs**
- **regulation and price control**
- **commercialization**
- **dependence on third parties**
- **competition**
- **patents and IPR**
- **production and quality**
- **unexpected adverse treatment effects**
- **unexpected negative business impact of global economic development**

# Research & Development

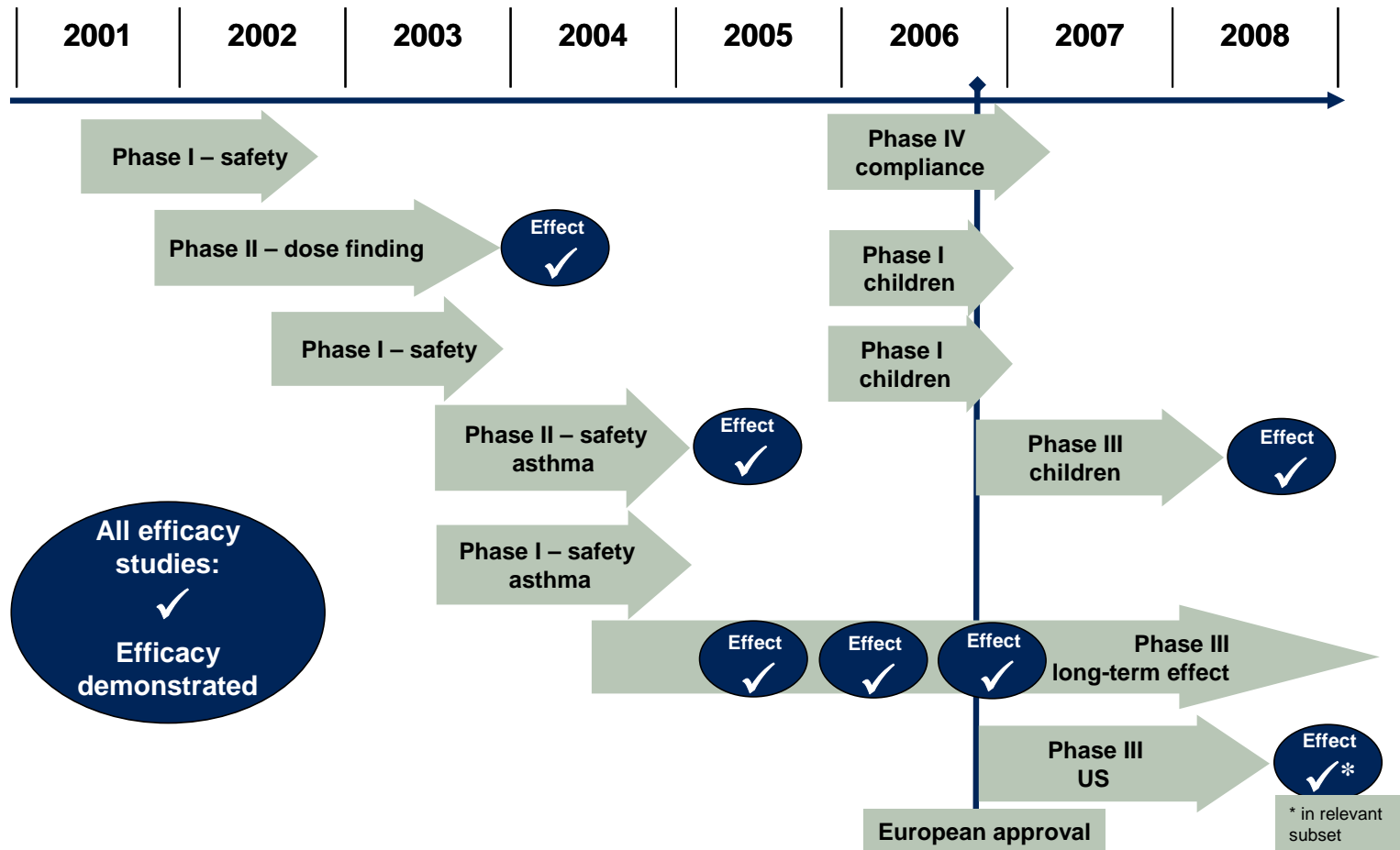
# Other tablet vaccines in ALK's pipeline



### Tablet program covers

- **Three most prominent outdoor allergens in Europe and the US**  
(grass, tree and ragweed pollen)
- **Two most prominent indoor allergen in the world** (house dust mites and cat)

# GRAZAX<sup>®</sup> clinical program



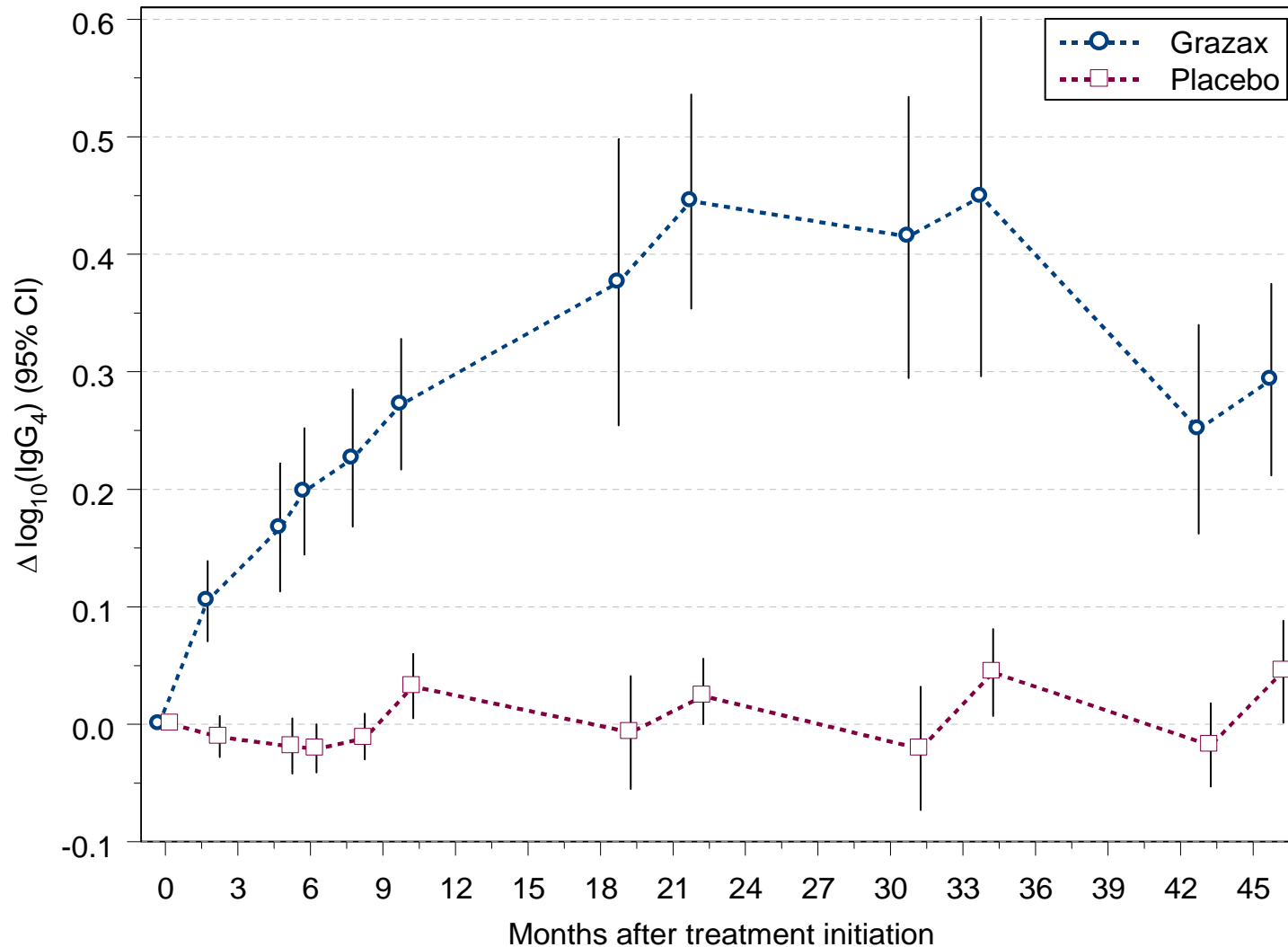
# Persistent clinical effect (GT-08)

- **First follow-up year in long-term study: Persistent clinical effect**
  - Statistically significant results
  - Hay fever symptoms reduced by 31%
  - Use of symptom-relieving medication reduced by 52%



GRAZAX® GT-08 Study	First season 2005	Second season 2006	Third season 2007	First follow-up year 2008
	Median	Median	Median	Median
Symptom score reduced: Entire season	34%	44%	37%	31%
Medication score reduced: Entire season	53%	73%	60%	52%

# Immunological effect (IgG<sub>4</sub>)



# 15 peer-reviewed scientific publications on GRAZAX®

“**Malling HJ, Lund L, Ipsen H, Poulsen L.** Safety and immunological changes during sublingual immunotherapy with Standardized Quality grass allergen tablets. *J Investig Allergol Clin Immunol* 2006; 16 (3): 162–168.”

“**Durham SR, Yang WH, Pedersen MR, et al.** Sublingual immunotherapy with once-daily grass allergen tablets: a randomized controlled trial in seasonal allergic rhinoconjunctivitis. *J Allergy Clin Immunol* 2006; 117: 802–809.”

“**Rak S, Yang WH, Pedersen MR, Durham SR.** Once-daily sublingual allergen specific immunotherapy improves quality of life in patients with grass pollen induced allergic rhinoconjunctivitis: a double-blind, randomised study. *Qual Life Res* 2007; 16 (2): 191–201.”

“**Kleine-Tebbe J, Ribel M, Herold DA.** Safety of a SQ-standardised grass allergen tablet for sublingual immunotherapy: a randomized, placebo-controlled trial. *Allergy* 2006; 61: 181–184.”

“**Calderon M, Essendrop M.** Specific immunotherapy with high dose SQ standardised grass allergen tablets was safe and well tolerated. *J Investig Allergol Clin Immunol* 2006; 16 (6): 338–344.”

“**Dahl R, Stender A, Rak S.** Specific immunotherapy with SQ standardized grass allergen tablets in asthmatics with rhinoconjunctivitis. *Allergy* 2006; 61: 185–190.”

“**Dahl R, Kapp A, Colombo G, et al.** Efficacy and safety of sublingual immunotherapy with grass allergen tablets for seasonal allergic rhinoconjunctivitis. *J Allergy Clin Immunol* 2006; 118: 434–440.”

“**Durham SR, Riis** Grass allergen tablet immunotherapy relieves individual seasonal eye and nasal symptoms, including blocked nasal blockage. Short communication in *Allergy* 2007”

“**Calderon et al.** Prolonged pre-seasonal treatment phase with GRAZAX sublingual immunotherapy increases clinical efficacy. Short communication in *Allergy* 2007”

**Ibañez et al.** Safety of Specific Sublingual Immunotherapy with SQ Standardised Grass Allergen Tablets in Children. *PAI* 2007”

“**Bachert C et al.,** Cost-effectiveness of grass allergen tablet (GRAZAX(R)) for the prevention of seasonal grass pollen induced rhinoconjunctivitis - a Northern European perspective. *Clinical and Experimental Allergy* 2007; 37(5): 772-779.”

“**Canonica G.W. et al.,** Cost-effectiveness of GRAZAX(R) for prevention of grass pollen induced rhinoconjunctivitis in Southern Europe. *Respiratory Medicine* 2007; 101(9), 1885-1894.”

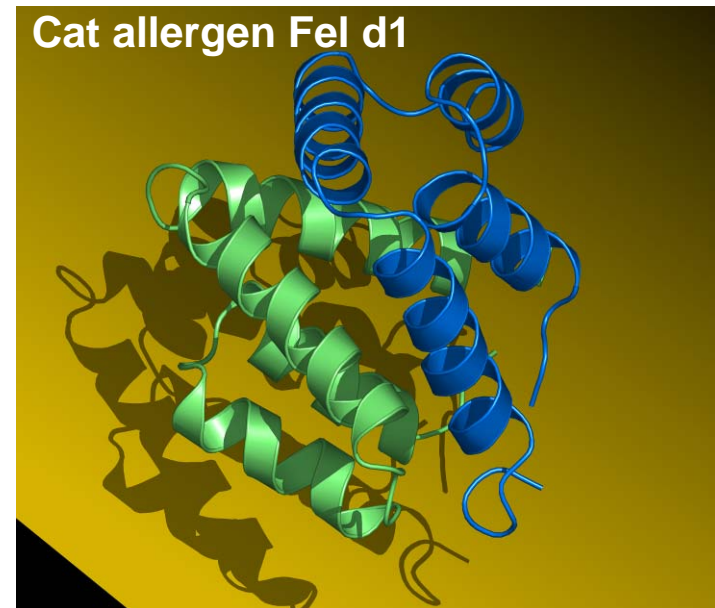
“**Bériot-Mathiot et al.,** Influence of time horizon and treatment patterns on cost-effectiveness measures: the case of allergen-specific immunotherapy with Grazax. *Journal of Medical Economics*, 2007; 10(3): 215-228”

“**Poulsen PB, Pedersen KM et al.,** [Economic evaluation of a tablet-based vaccination against hay fever in Denmark] (Danish), *Ugeskrift for læger*, 2008; 14;170(3):138-42.”

“**Dahl R, Kapp A, Colombo G, et al.** Sublingual grass allergen tablet immunotherapy provides sustained clinical benefit with progressive immunological changes over 2 years. *J Allergy Clin Immunol* (In Press).

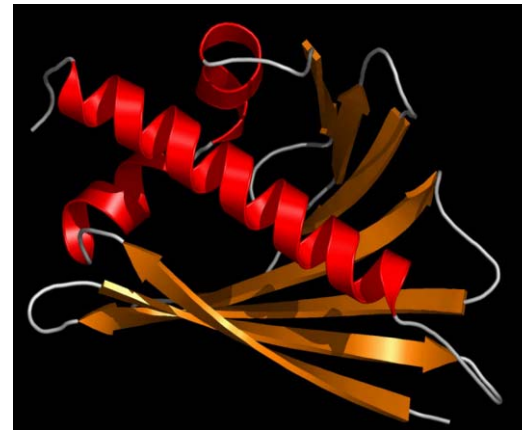
# Introducing the cat tablet

- **Recombinant allergens**
- **Research activities have been initiated**
- **First clinical trials expected in 2010/11**

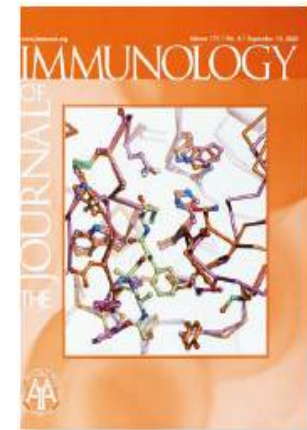


# Pioneering recombinant technology

- **ALK has over 20 years of experience in recombinant allergen technology**
- **ALK was the first to characterize 3D structure of major allergens**
- **Industrial production processes**
  - Long-term stable supply of active ingredients
  - Easy up-scaling
- **Clinical profile**
  - Theoretically comparable to vaccines based on natural allergens



Bet v1, birch allergen



3D allergen structure  
Cover article  
in 'Journal of Immunology'

# Next generation tablets with adjuvants

## Allergy vaccines with improved clinical profile

- **Faster onset of clinical efficacy**
- **Faster onset of long-term efficacy**
- **Further differentiation from symptomatic medicine**

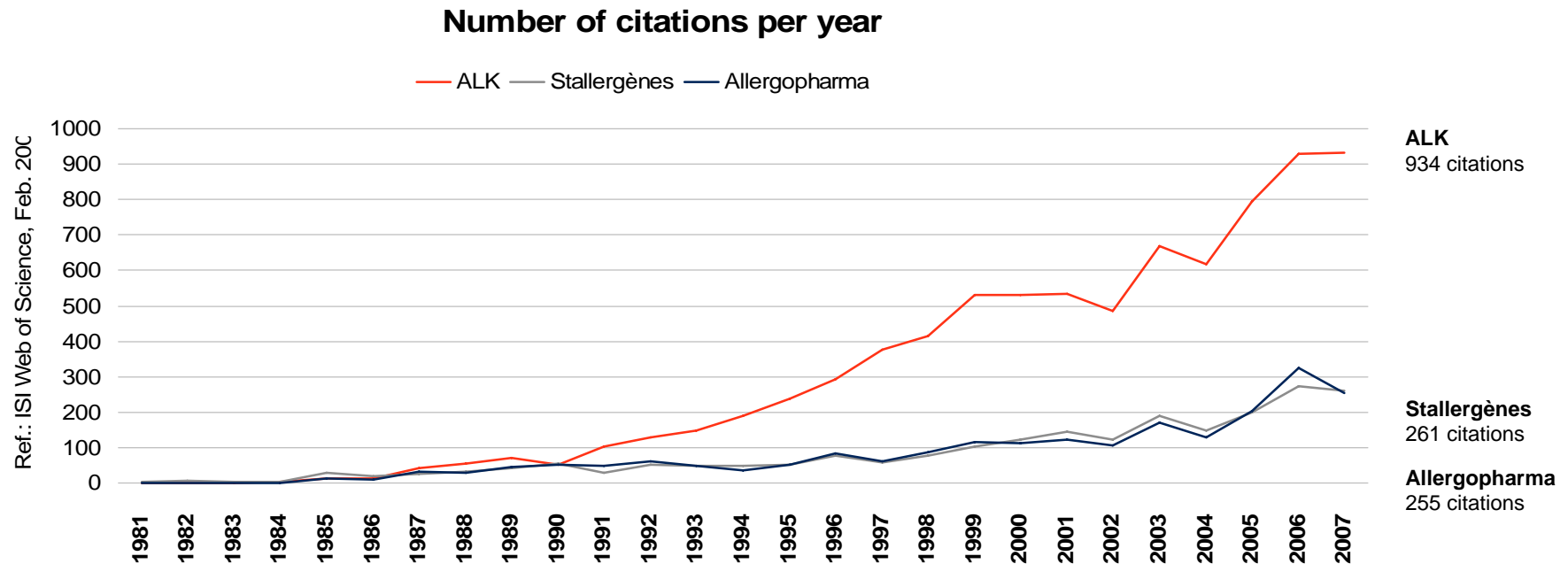
## Adjuvants

- **Further stimulation of the immune system**
- **Increases the response to the vaccine**

### Adjuvants in testing:

- Mineral salts
- Particulate delivery vehicles
- Microbial derivatives

# Number one in scientific impact



- **Exclusive IP rights securing freedom to operate**
- **97 patent families covering areas such as recombinant allergens, mutated allergens, expression systems & tablet technologies**

# General introduction

# Prevalence of allergic diseases

	USA	Europe
<b>Total population of allergic patients</b>	<b>65 million</b>	<b>87 million</b>
Grasses	56% of allergic population	52% of allergic population
House Dust Mites	45%	49%
Ragweed	49%	n.a.
Birch	23%	14%
Cat	39%	30%
Weed	n.a.	27%
Cedar, Japanese	10%	n.a.
Dog	19%	n.a.
Food	10%	11%
Venom	13%	13%

**Note: In average a patient is allergic to more than 2.3 sources. (Source: Arch Pediatr Adolesc med/vol 156, Oct. 2002)**

Sources: USA: Annals of Allergy, Asthma, & Immunology, Vol 81, September, 1998, Page 203 FF. Canada: Clinical and Experimental Allergy, 1997, Vol 27, Pages 52-59 Europe: Europ J All Clin Immun, P 239 and Prel res, J All Clin Immun, V 106, Number 2, P 247 ff, Linneberg et al. Allergy to Cats (ALK-publication) page 2 based on 5 worldwide studies. Venom: Insect Sting Allergy, Ulrich R. Muller, 1990. Food Allergy: USA: Curr Opin Allergy Clin Immunol 2002 Jun; 2(3): 257-61. Europe: Allerg Immunol (Paris 2002 Apr; 34(4): 135-40.

# Allergic Rhinitis: Impact on the individual

- **Nose blocked/runny**
- **Eyes itching**
- **Difficult to breathe**
- **Difficult to concentrate**
- **More sick-days**
- **Impaired work life**
- **Impaired social life**
- **Spring and summer unbearable**
- **Risk of development of asthma**
- **~ 70% of patients feel that allergy limits quality of life**



# Traditional allergy medicine

- **Tablets, sprays or eye/nose drops (anti-histamines and steroids)**
- **Treats the symptoms, but not the underlying disease**
- **After treatment the symptoms return (no long lasting effect)**
- **Treatment must be repeated every year**

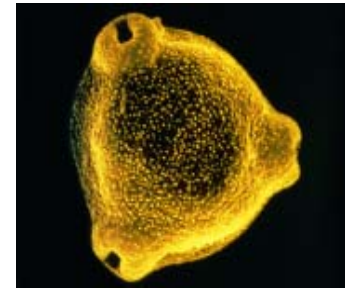
60-68% of patients:

Symptomatic medications are in the range of 'not at all effective' to 'moderately effective'

European Federation of Allergy and  
Airway Diseases Patients Associations (EFA)

# What is allergy?

- **An immunological overreaction against the molecules (allergens) that the patient is allergic to**
- **Allergic diseases in the airways**
  - Rhinitis (hay fever)
  - Allergic asthma
- **Other allergic diseases**
  - Contact eczema (dermatitis)
  - Insect sting allergy
  - Food allergy



Birch pollen



Birch allergen

# What is allergy vaccination?

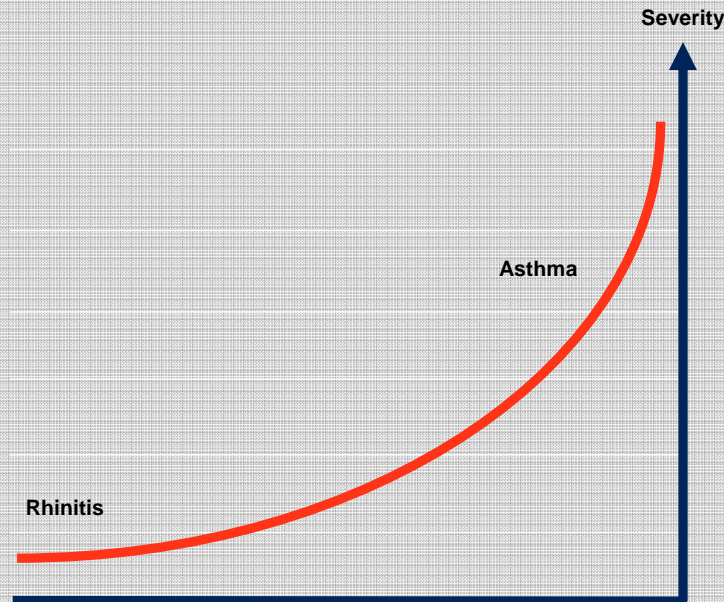
- **Treatment with controlled doses of purified and standardised allergens (proteins), extracted from natural allergen sources:**
  - Pollens (grass, trees etc.)
  - House dust mites
  - Animals
  - Insect venom
- **Immune system becomes tolerant to the allergens**
  - Immune system is desensitised, so that it does not overreact to the allergens



# Clinical platform of allergy vaccination

Clear need for effective and convenient medical treatments

## The Allergic March



Prevention of developing new allergies and allergic asthma

The only curative treatment

Three benefits of allergy vaccination  
(specific immunotherapy)

Symptom reduction

### References:

- WHO Position Paper, Allergy 1998, New England Journal of Medicine 1999
- WHO position paper, Allergy 1998, Journal of Allergy and Clinical Immunology 2002
- Journal of Allergy and Clinical Immunology 2001

# Immunotherapy – three ways of administration

- **Subcutaneous immunotherapy (SCIT)**
- Different species
- 30-40 injections through three years (up dosing and maintenance)
- Persuasive clinical documentation
- Dominate the markets in Northern Europe and the US
  
- **Sublingual immunotherapy (SLIT)**
- Different species and mixes
- Daily administration with a single-dose container
- Non-registered, sold on a 'named patient' basis
- Marketed in Central and Southern Europe
  
- **Tablets**
- GRAZAX® is the first once-daily tablet-based vaccine
- Persuasive clinical documentation
- Coming products: Tablets against house dust mite, ragweed and birch pollen allergy



# Products

## Subcutaneous immunotherapy (SCIT)

Injections under the skin  
~ 49% of the sales (2007)



## Sublingual Immunotherapy (SLIT)

Under the tongue  
~ 29% of the sales (2007)



## Tablet-based immunotherapy

Under the tongue  
~3% of the sales  
(launch in progress)



## Allergy Diagnosis & Emergency treatment for allergic shock (adrenaline pen)

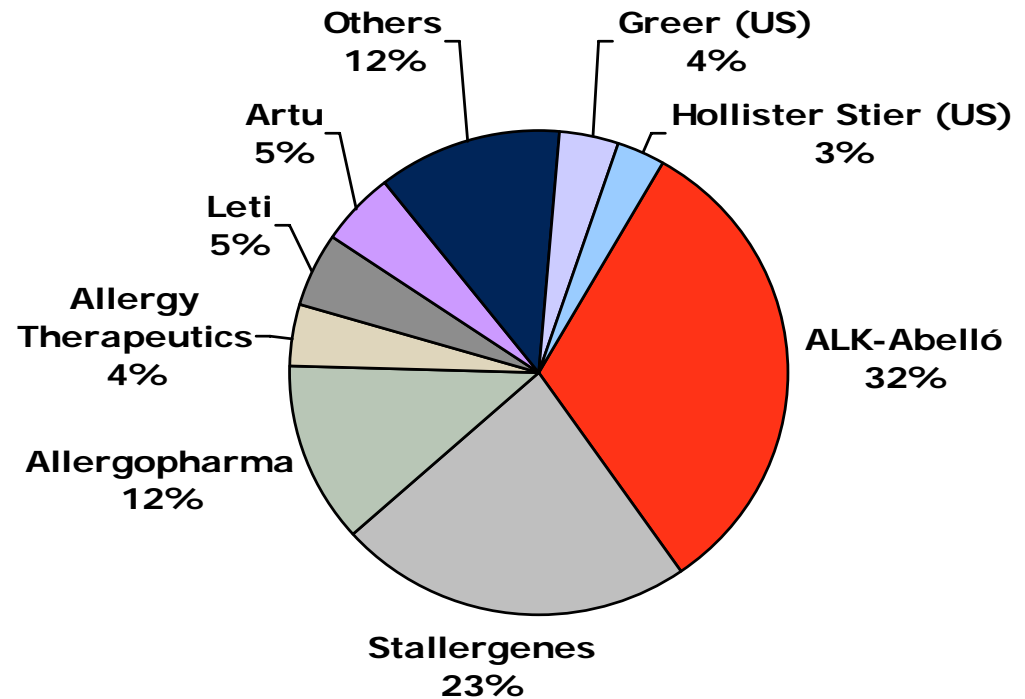
~ 19 % of the sales (2007)



# Well-established market leader

**Fragmented market with several small local companies**

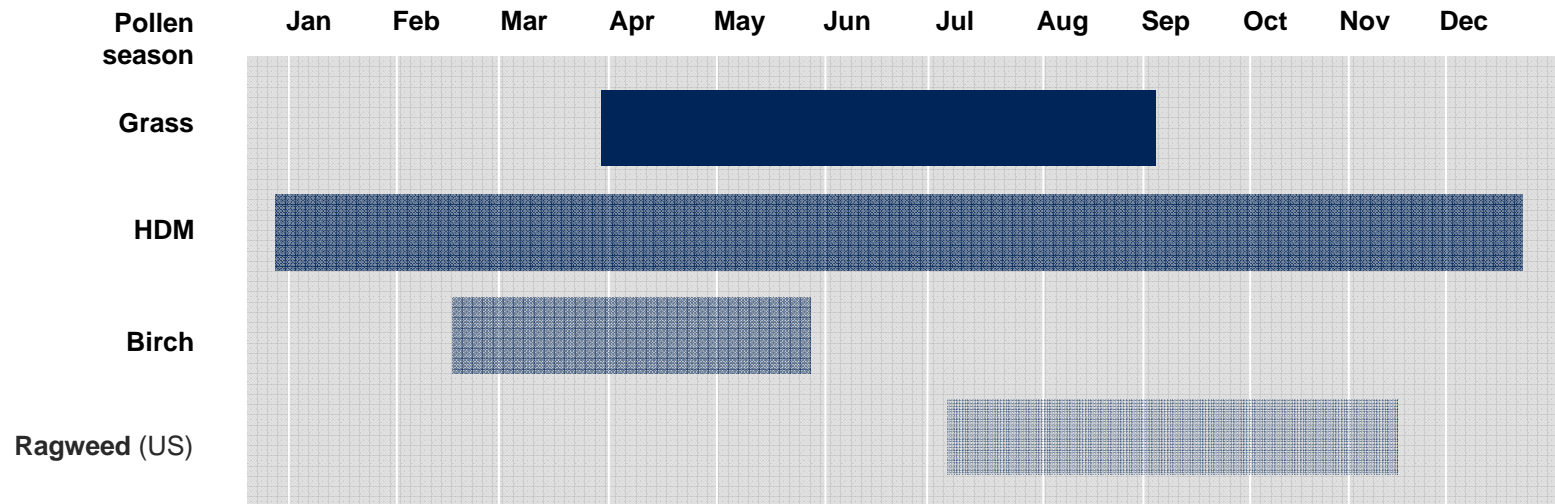
- **ALK is the only company serving both Europe and the US**
- **Total value of market approximately EUR 600**



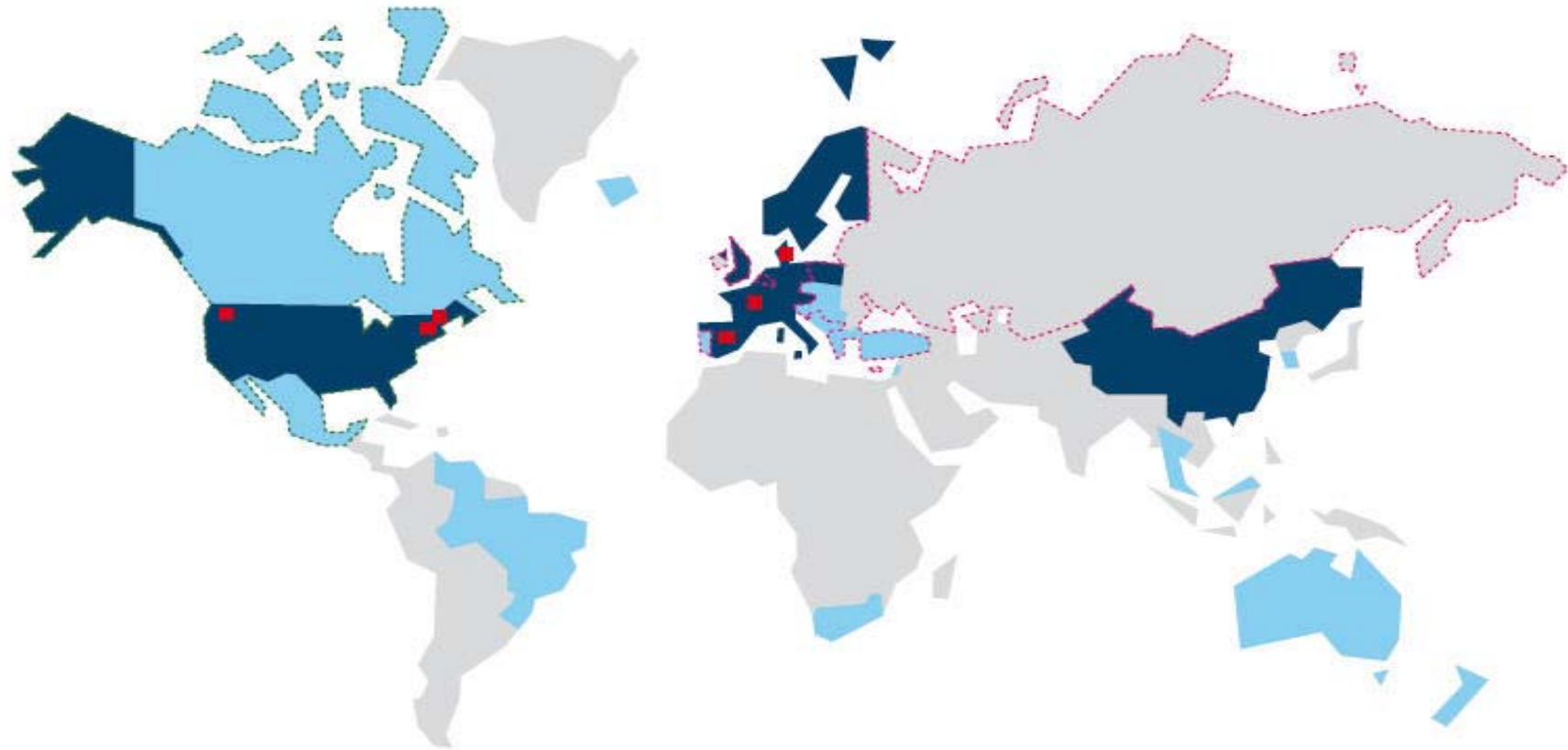
**Figure** is an internal estimate of market shares based on local reporting, surveys and other publicly available material

# Allergy calendar

**Grass and house dust mite (HDM) are the most important allergens**



# Global presence



- Production
- Distributors
- Subsidiaries in Austria, France, Germany, Italy, the Netherlands, Poland, Spain, Sweden (Nordic), Switzerland, UK and USA  
Sales offices in China, Denmark, Finland and Norway
- Partnership with Schering-Plough in Canada, Mexico and USA
- - - - Partnership with the Menarini Group in Belgium, Greece, Ireland, Luxembourg, Portugal, Turkey, UK and Eastern Europe

# Contact Investor Relations

**For further information, please visit:**

**[www.alk-abello.com](http://www.alk-abello.com)**

**or contact**

**Per Plotnikof**

**Head of Investor Relations**

**Phone: +45 4574 7527**

**E-mail: [ppidk@alk-abello.com](mailto:ppidk@alk-abello.com)**

**Fax: +45 4574 8607**