



# Allergy solutions for life

IR roadshow presentation

November 2022



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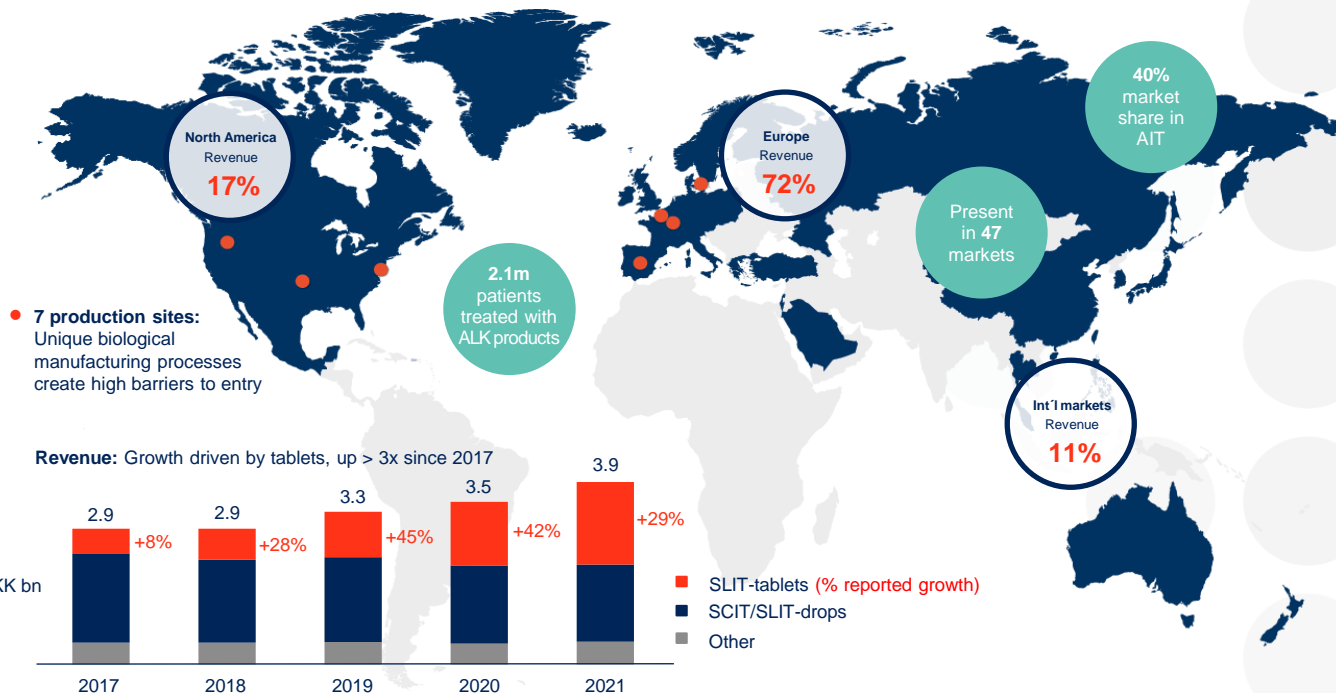
More than 500 million people worldwide have allergies. Many of them suffer in silence because the way ahead is too confusing.

By collecting information and the latest and most trusted solutions together in one place, we want to make allergy surprisingly simple to manage. With 100 years of experience, nobody knows allergy like us, and we continuously apply our scientific knowledge and expertise to help people take control of their allergy and their life.

We want to make a difference by offering solutions for everyone who is touched by allergy – through a comprehensive range of products, services and resources that offer a fast-track to a more balanced life

# ALK at a glance

*The leader in allergy immunotherapy (AIT): Delivering short-term symptom relief and long-term disease control*



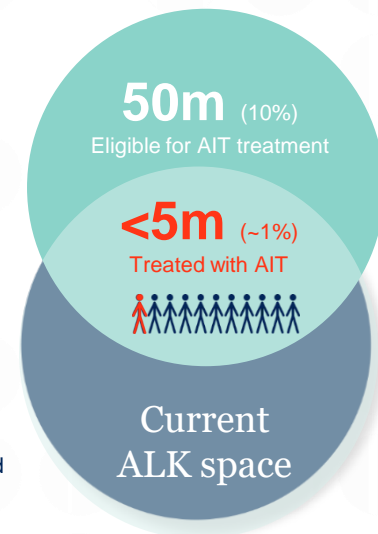
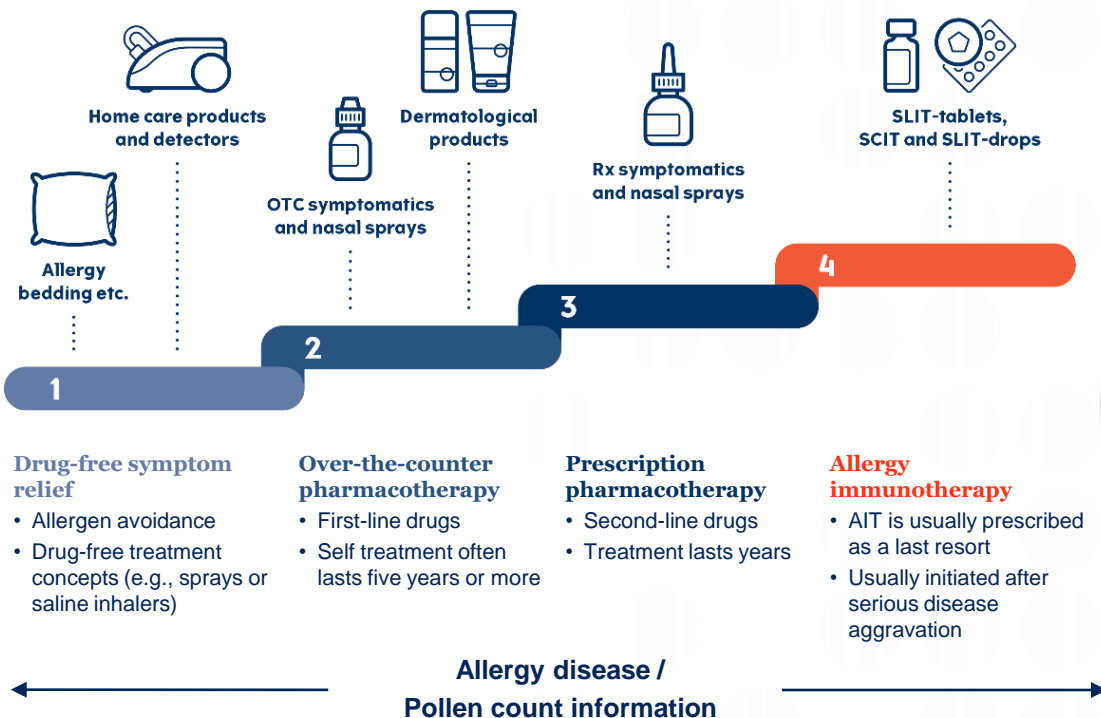
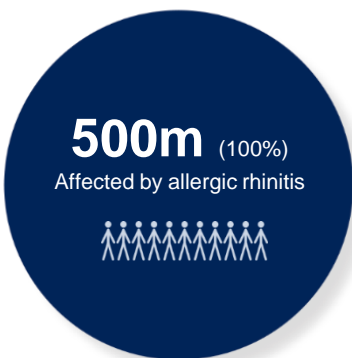
- **Applying modern science to allergy/AIT:** Over 20+ years, ALK has developed the industry's most comprehensive clinical data set and insights into patient behaviour
- **85% of adults** with respiratory allergy requiring AIT covered by the ALK SLIT-tablet portfolio. Working towards full paediatric coverage



Listed on Nasdaq CPH (ALK B / ALKB.DC)

# Allergy Disease Management

Majority of people with allergy rarely see a doctor and patients often endure a decade or more before turning to AIT



# Being the most relevant company for people with allergy

*Expanding the core AIT business and developing new markets*



## People with allergy

- How to become relevant for 100% to identify the 10%?
- How to build a broader presence in the allergy field?
- What is relevance to allergic patients?

## Current AIT market

- 50m people may benefit from AIT
- How to guide potential AIT patients to treatment?

## Current AIT market

- DKK 9bn / 5 million people
- ALK market share: ~40%
- Tablets: 45% of revenue

# Towards '25 in 25' and growth beyond

*Relentless focus on strategy execution and on initiatives to safeguard/accelerate growth*



**2018-21**

**Build trust**

**35% avg. annual tablet growth**

**Past issues fixed  
and efficiency improved**



**Present**

**8-12% growth driven by tablets**

**Continue to increase efficiency**

**Complete investments in  
paediatric development of  
respiratory tablets**

**Invest to hedge/accelerate growth:  
China, peanut AIT, next-gen. AAI**



**Future**

**≥10% organic growth annually**

**~25% EBIT margin in 2025**


**Further expand respiratory leadership  
through completion of paediatric  
coverage**


**Further expand in China and in  
anaphylaxis**


**Commercialise food AIT**

# Becoming the ‘go-to’ allergy company

## Sustain high growth, improve profitability

 Expand global leadership in respiratory AIT

 Become relevant for many more allergy sufferers

 Enter food allergy  
Expand in anaphylaxis

## Long-term strategy

Succeed in North America

Complete and commercialise tablet portfolio

Consumer engagement and new horizons

Optimise for excellence

 Lead the way – people and planet

# ALK continues to execute long-term strategy

Q3 2022 strategic achievements



## Succeed in North America



~10% growth

Long-established market barriers slowing tablet progress in USA

Focus on prescriber & consumer engagement, assessing new business models

## Complete and commercialise the tablet portfolio



Growth & paediatric development

Key paediatric trials with ACARIZAX® and ITULAZAX® on track with few patient dropouts

HDM tablet filing in China still expected late 2022

## Consumer engagement and new horizons



Innovation

Food AIT: Phase I peanut trial recruited first participants

US adrenaline: Projects on track for 2024 filing



Mobilise patients

Digital engagement activities continue to mobilise patients towards treatment

## Optimise for excellence



Organisational excellence

Employee engagement among top 5% of benchmark companies



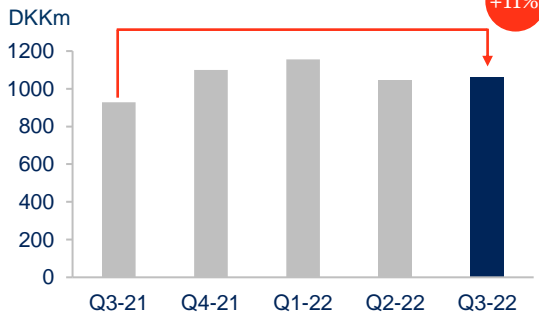
Lead the way – people and planet

# Q3 revenue up 11%, outlook updated

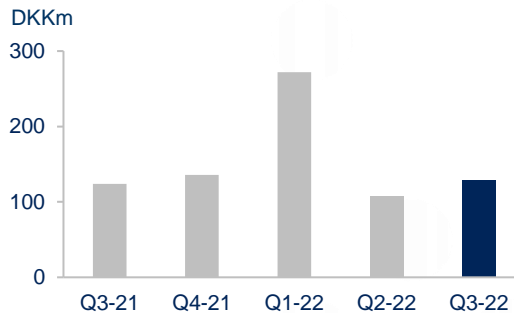
9M organic growth: 13%

- Growth in all regions, driven by tablet portfolio and Jext<sup>®</sup>
- Tablet sales up 13% in Q3, and 19% for the first 9 months
- EBITDA up slightly in Q3 and up 27% for the year-to-date
- Further progress on strategic priorities

## Revenue



## 9M EBITDA up 27%



Growth rates are in local currencies



# Key figures

DKKm	2022E*	2021	2020
Revenue	11 - 13%	3,916	3,491
Tablet sales growth	<20%	29%	42%
Gross margin	~1 p.p.	61%	58%
R&D	650-700	631	515
Sales/Marketing and Adm.	-	1,474	1,362
EBITDA	675-750	534	395
CAPEX	<400	263	222
Free cash flow	>0	+202	+56

\* based on the 2022 guidance issued on 10 November 2022

# Appendix

The background image shows a close-up of a hand wearing a grey, textured work glove. The hand is holding a large, tangled mass of yellowish-brown, fibrous material, likely seaweed or algae. The material is dripping with a liquid, possibly water or a processing fluid, which is creating a misty or steamy atmosphere. The hand is positioned at the top of the frame, and the material is being held over a large pile of the same material that fills the bottom and middle of the frame. The lighting is dramatic, highlighting the texture of the glove and the wet, fibrous nature of the material.



**Pioneer since 1923** – Prevention, Diagnosis & Treatment

**Leader** in disease modifying allergy immunotherapy (AIT)

**World's 1<sup>st</sup>** producer of sublingual AIT tablets (SLIT-tablets)

# 9M: Revenue and segment information

	Europe		North America		International markets		Total	
Amounts in DKKm	9M 2022	9M 2021	9M 2022	9M 2021	9M 2022	9M 2021	9M 2022	9M 2021
SCIT/SLIT-drops	872	907	256	216	108	49	1,236	1,172
SLIT-tablets	1,098	940	114	87	309	238	1,521	1,265
Other products and services	217	167	261	187	27	26	505	380
<b>Total revenue</b>	<b>2,187</b>	2,014	<b>631</b>	490	<b>444</b>	313	<b>3,262</b>	2,817
Sale of goods							3,191	2,762
Royalties							64	55
Services							7	-
<b>Total revenue</b>							<b>3,262</b>	2,817

	Europe		North America		International markets		Total	
Growth, 9M 2022	Growth l.c.	Growth	Growth l.c.	Growth	Growth l.c.	Growth	Growth l.c.	Growth
SCIT/SLIT-drops	-4%	-4%	5%	19%	107%	120%	2%	5%
SLIT-tablets	16%	17%	18%	31%	30%	30%	19%	20%
Other products and services	29%	30%	24%	40%	0%	4%	24%	33%
<b>Total revenue</b>	<b>8%</b>	<b>9%</b>	<b>14%</b>	<b>29%</b>	<b>40%</b>	<b>42%</b>	<b>13%</b>	<b>16%</b>

Geographical markets (based on customer location):

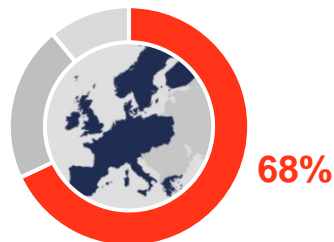
**Europe** comprises the EU, the UK, Norway and Switzerland — **North America** comprises the USA and Canada — **International markets** comprise Japan, China and all other countries

# Broad-based growth in all sales regions

*EU sales bounced back strongly, positive momentum elsewhere*

## Europe

Share of Q2 revenue



Q2

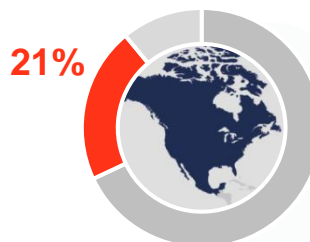
713m

621m

+14%

## North America

Share of Q2 revenue



Q2

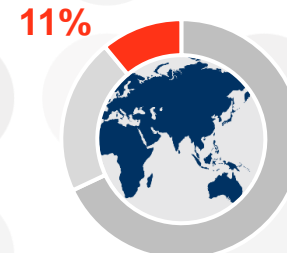
217m

161m

+19%

## International markets

Share of Q2 revenue



Q2

115m

86m

+30%

■ 2022 ■ 2021

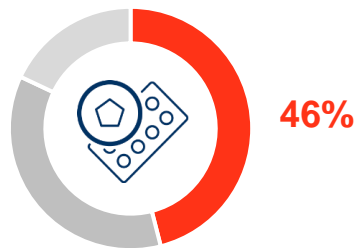
*Sales in all markets expressed in DKK - Growth rates are in local currencies*

# Portfolio-wide growth led by tablets

On track for FY tablet growth of 20% or more

## Tablets

Share of Q2 revenue



Q2

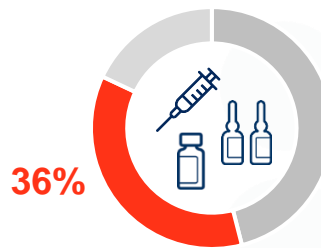
480m

401m

+18%

## SCIT/SLIT-drops

Share of Q2 revenue



Q2

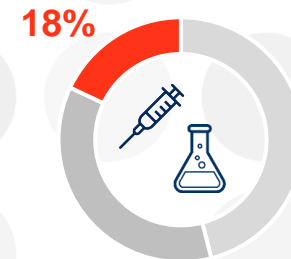
380m

351m

+4%

## Other products

Share of Q2 revenue



Q2

185m

116m

+50%

■ 2022 ■ 2021

Sales in all markets expressed in DKK - Growth rates are in local currencies

# 2022 outlook updated

DKK	8 Feb 2022 outlook	4 Aug 2022 outlook	10 Nov 2022 outlook	Comments	2021 actuals
<b>Revenue</b>	8-12% growth in local currencies	10-13% growth in local currencies	11-13% growth in local currencies	<ul style="list-style-type: none"> <li>• Tablet sales growth now expected below 20%</li> <li>• &gt;5% growth from non-tablet portfolio</li> <li>• High-end: Continuous strong revenue growth, with improved sales of legacy products and/or tablets</li> <li>• Low-end: Further destocking, negative effects from COVID, and/or impact from lower demand against weak pollen season</li> </ul>	3,916m
<b>EBITDA</b>	DKK 625-725m	DKK 675-750m	DKK 675-750	<ul style="list-style-type: none"> <li>• Gross margin to improve by 1 p.p.</li> <li>• R&amp;D costs unchanged at DKK 650-700m</li> <li>• S&amp;M ratio still to slightly improve</li> </ul>	534m

# Key 2022 goals

Towards '25 in 25'



## Succeed in North America

- Increase prescriber depth among key specialists and pursue partnerships in digital health.   
 >10% growth
- Grow legacy product sales
- Obtain approval for ODACTRA®/ ACARIZAX® in adolescents

## Complete and commercialise the tablet portfolio

- Grow tablet sales by double-digits with growth across all regions
- Progress development for paediatric use and China

## Consumer engagement and new horizons

- Food AIT: Initiate Phase I development of peanut tablet in H1
- Adrenaline: Prepare for planned 2024 regulatory submissions of AAI-projects

## Optimise for excellence

- Further progress PASS programme
- No quality-related major interruptions to supply
- Improve gross margin 1 p.p.

# Our sustainability journey

*Our aim is to make ALK products more universally accessible, while ensuring sustainable growth*



Securing access to allergy care for all remains our greatest opportunity to positively influence our business and society in general.

Additionally, we are focusing on creating positive impact on the environment and climate, diversity and inclusion, and responsible business practices.

# Key results in 2021

*Good progress on our sustainability initiatives and ESG reporting*



- + 100.000 new patients
- Entry in Saudi Arabia and Uzbekistan
- Children/adolescent indication in 10 new countries
- 3,800 healthcare professionals educated



- Osiris packaging recyclable
- 42% reduced CO<sub>2</sub> emissions\*
- 50% waste reused or recycled
- Energy use remains stable
- Water use challenged



- 1 accident with lost time across all sites
- 49% women in management in general up from 46%
- 29% women in VP and senior director positions up from 26%
  
- 33% women on the Board of Directors
- 97% board meeting attendance rate
- CEO pay ratio remains a 34%

\* Compared to 2019 baseline of emissions from non-renewable sources

# Allergy at a glance

*Allergies occur when the body's immune system overreacts to substances that are usually considered harmless, such as various types of pollen, house dust mites, moulds and animal fur.*

## Symptoms of respiratory allergies

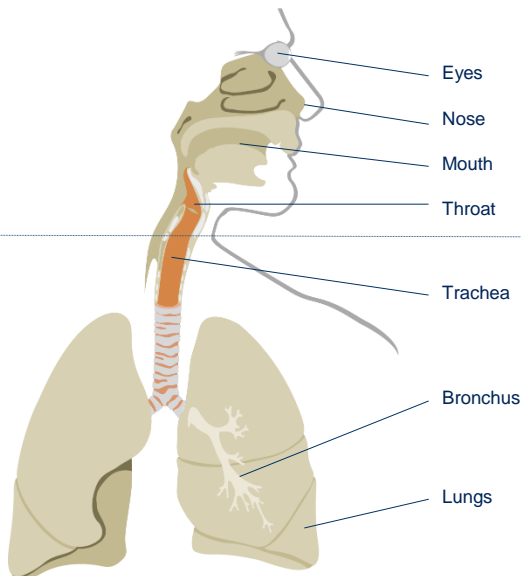
Respiratory allergies can affect both the upper and lower respiratory tract.

### Upper respiratory tract – allergic rhinitis

Running or blocked nose, itchy eyes, sneezing.

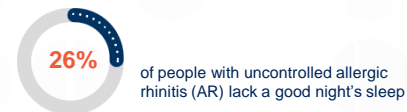
### Lower respiratory tract – allergic rhinitis

Shortness of breath, narrowed airways, coughing, wheezing.



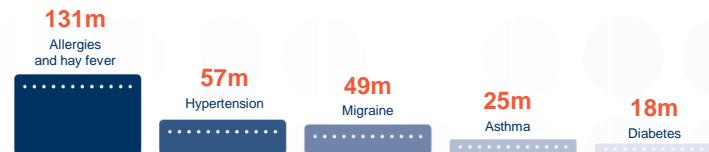
## Insufficient sleep

Allergies can impact the amount of sleep we get:



## Lost work days

Allergy is also a leading cause of lost work days\*, outstripping other conditions in its cost to businesses:



\* Work days lost in the USA to chronic conditions

## Lower quality of life

Allergies have a significant impact on quality of life and our ability to get things done:



# Allergic Rhinitis is more than a seasonal annoyance



## Infections

Increased risk of **respiratory infections** and antibiotics use<sup>3</sup>



## Disease progression & severity

More likely to have **poorly controlled asthma**<sup>5\*</sup>



## Sleep disturbance

Nocturnal symptoms impacting sleep, which is linked to **poorer QoL**<sup>6</sup>



## Performance

Associated with **reduced productivity** and cognitive effects, impacting work and school performance<sup>7-9</sup>



## Future vulnerability

Increased **risk of developing asthma**<sup>4,10</sup> and other upper airway disease (e.g. rhinosinusitis)<sup>4</sup>

1. *Clin Trans Allergy* 2015;5:39. 2. *Allergy* 2007;62:17–25. 3. *Ann Allergy Asthma Immunol* 2018;120:169-76. 4. *J Fam Pract* 2012;61:S11-S15. 5. *Prim Care Respir J* 2012;21:222-8. 6. *J Allergy Clin Immunol* 94:182–8. 7. *Am J Rhinol Allergy* 2012; 26:390-94. 8. *J Clin Epidemiol* 2001;54:610–18 9. *Allergy Clin Immunol* 2007;120:381-7 10. *J Allergy Clin Immunol* 2007;120:863-95

# ALK's core products

*Market exclusivity secured via biological manufacturing processes and know-how*

ALK offers products, services and resources covering a wide range of allergies. The company also has products in related areas, including early allergy intervention, diagnosis and emergency treatment

**ALK's AIT products come in three different forms:**

**Injections:** Subcutaneous immunotherapy (SCIT) is given as regular injections under the skin. The treatment is administered by a doctor

**Sublingual drops:** sublingual immunotherapy (SLIT) is taken in the form of drops administered under the tongue. Patients administer the drops themselves, avoiding the need for regular visits to the doctor

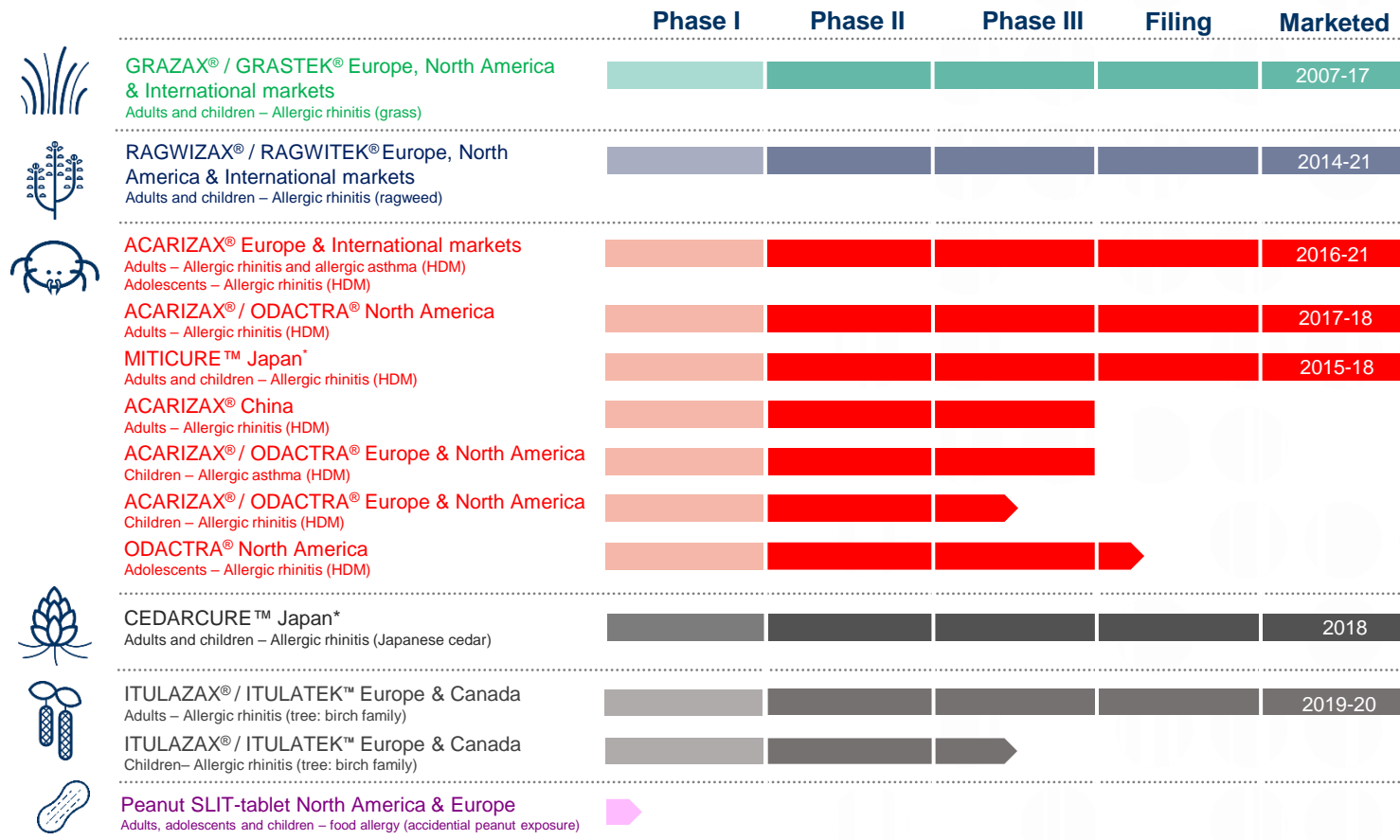
**Tablets:** SLIT-tablets are administered by the patient at home and are available for all the most important respiratory allergies. Tablet-based AIT is the most well-documented allergy treatment

## Manufacturing footprint

Centres of excellence



# R&D pipeline



>24,000

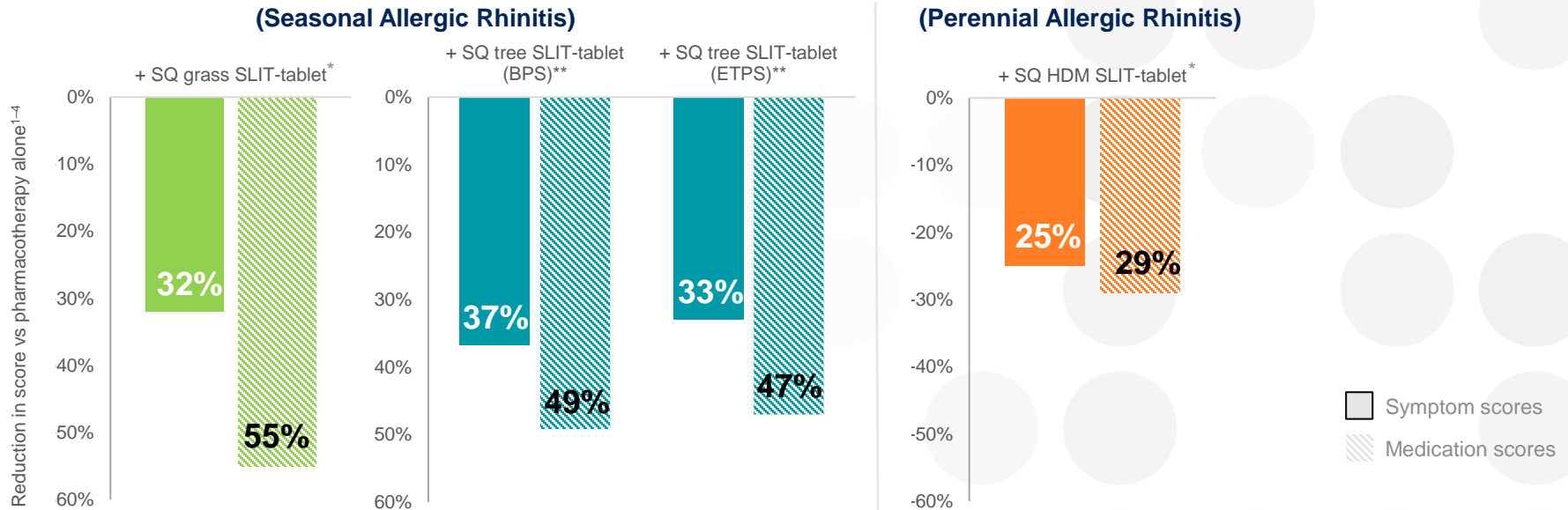
people participated in clinical development of the tablets which saw 21 Phase III trials

# SLIT-tablet characteristics

- 1 Allergen extract sourced from native allergens (e.g. grass pollen, tree pollen, ragweed pollen, cedar pollen, house dust mites)
- 2 Fast-dissolving freeze-dried tablet formulation utilising Zydis® technology
- 3 Consistent quality ensured by the highly standardised production process
- 4 Once-daily home administration



# Consistent improvement in allergy symptoms for **seasonal** and **perennial** allergies with SQ SLIT-tablets

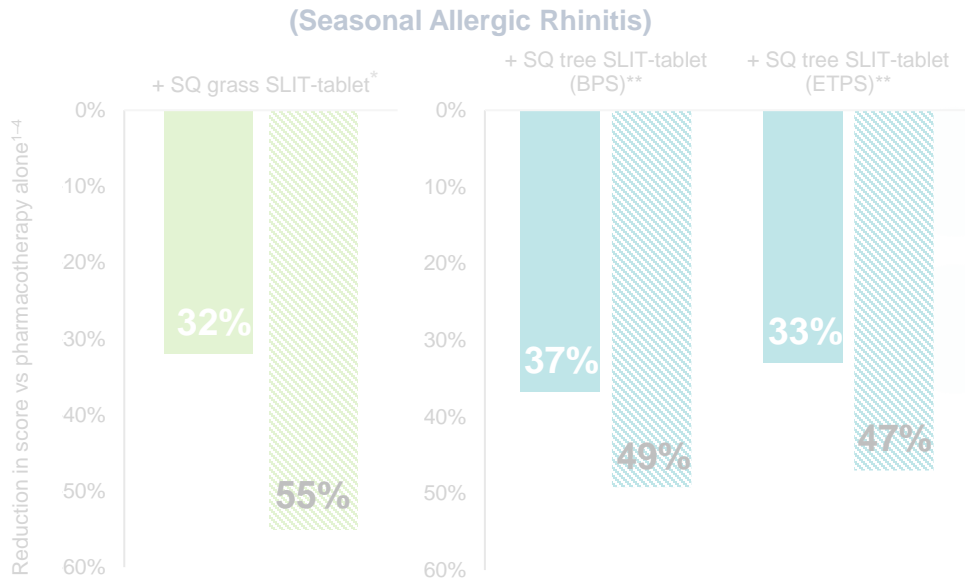


\*Median scores. \*\*Mean scores.

ETPS, extended tree pollen season; BPS, birch pollen season.

1. *J Allergy Clin Immunol* 2012;129:717-25. 2. GRAZAX® Summary of Product Characteristics 3. *J Allergy Clin Immunol* 2018;143:1058-66. 4. ACARIZAX® Summary of Product Characteristics.

# Consistent improvement in allergy symptoms for **adults** and **children** with SQ SLIT-tablets



(Per

12 SQ ragweed SLIT-tablet led to a

**38%**

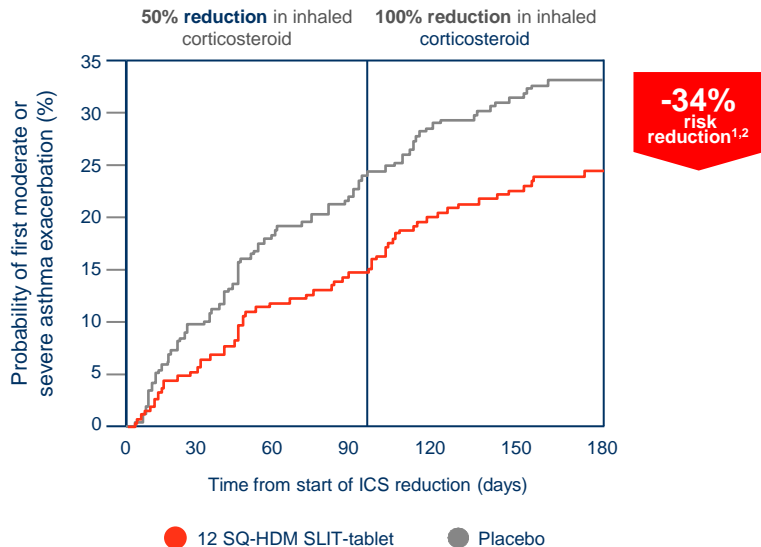
Improvement in combined symptom and medication score (TCS) vs. Placebo in **children** with ragweed AR<sup>1</sup>

□ Symptom scores  
 ▨ Medication scores

\*Average TCS - combined symptom and medication score. Full analysis set: Placebo (n=487), RAGWIZAX® (n=460). PRPS: Peak ragweed pollen season. RAGWIZAX® is 12 SQ-Amb of standardised allergen extract from short ragweed (*Ambrosia artemisiifolia*).  
 1. ALK-Abelló A/S. Press Release No 3/2019, Jan 15 2019. Last accessed May 2019

# Commitment to explore and confirm benefits of SQ SLIT-tablet treatment in asthma

**12 SQ HDM SLIT-tablet demonstrated a 34% reduction in risk of asthma exacerbations during ICS reduction (p=0.017)<sup>1,2</sup>**



**Analyses of secondary endpoints:**



**36% risk reduction for nocturnal awakening or increase in daily symptoms (p=0.031)<sup>1,2</sup>**



**42% risk reduction of deterioration in lung function (p=0.022)<sup>1,2</sup>**



**51% risk reduction of severe asthma exacerbation (p=0.076)<sup>1,2</sup>**



**48% risk reduction of increased SABA use (p=0.029)<sup>1,2</sup>**

# Jext<sup>®</sup> to be launched as first autoinjector in China

*Partnership with leading Chinese supplier of adrenaline, Grandpharma*

## Agreement to accelerate long-term growth

- Grandpharma to register and sell Jext<sup>®</sup> in China, Macau and Taiwan
- Jext<sup>®</sup> would be first AAI to market in China
- Upfront and registration milestone payments totalling ~DKK 90 million
- ALK will receive revenue from the supply of products to Grandpharma



## Growing Chinese allergy market

- China is the second largest HDM AIT market in the world
- +50 ALK employees in four sales offices, upgraded organisation
- ALK products: Alutard<sup>®</sup> HDM and Soluprick SQ
- ACARIZAX<sup>®</sup> Phase III registration trial in China still paused due to COVID

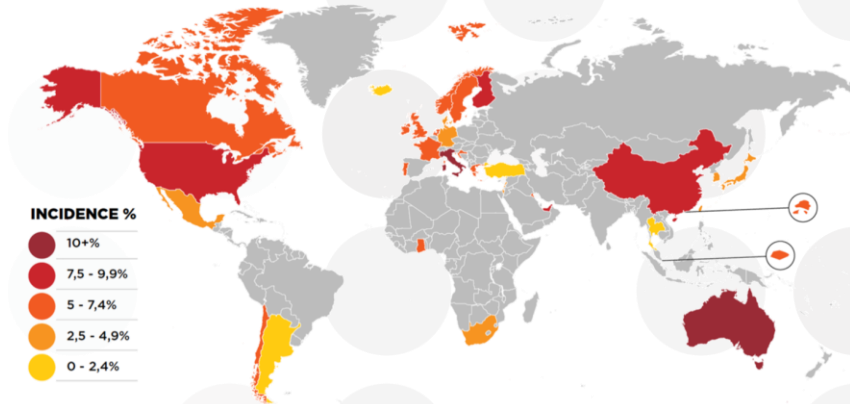


# Food allergies: A major unmet medical need

*A life-threatening condition*

- Food allergy affects approximately 2.5% of people and can be a life-threatening condition
- In pre-school children, peanut, tree nuts, milk and egg, cause 80% of food allergy reactions
- For the vast majority, peanut and tree nut allergies persist into adulthood
- Peanut allergy affects up to 1 million children in Europe, and 1.5 million in the USA
- Even exposure to trace amounts can cause life-threatening reactions
- Emergency care is the current standard clinical intervention

## Prevalence of food allergies



Sources: GlobalData and <https://www.worldallergy.org/education-and-programs/education/allergic-disease-resource-center/professionals/food-allergy>

# ALK's Phase I peanut trial

*Results due in 2023*

- A Phase I trial to assess tolerability and safety of a once-daily peanut sublingual immunotherapy (SLIT)-tablet
- Includes approximately 100 adults, adolescents, and children with peanut allergy at 15 centres in North America
- An open label trial of various doses to identify an optimal starting dose for treatment, an up-dosing regimen and maintenance dose
- Builds on ALK's existing capabilities and 20+ years' experience from developing portfolio of respiratory allergy tablets



## Part 1 (determination of starting dose)

Cohort 1: Adults  
n=8

Dose 1

SR



Cohort 2: Adults  
n=8

Dose 2

SR



Cohort 8: Adults  
n=8

Dose 3

SR



Cohort 9: Adults  
n=8

Dose 4

SR



Cohort 10: Adults  
n=8

Dose 5

## Part 2 (determination of up-dosing and maintenance dose)

Cohort 6: Adults  
n=10

Dose x



Dose 9

Cohort 7: Adolescents  
n=10

Dose x



Dose 9

Cohort 8: Children  
n=10

Dose x



Dose 9

Cohort 9: Highly sensitive adults/adolescents  
n=TBD

Dose x



Dose 9

Cohort 10: Highly sensitive children  
n=TBD

Dose x



Dose 9

# Forward-looking statements

*This presentation contains forward-looking statements, including forecasts of future revenue, operating profit and cash flow as well as expected business-related events. Such statements are naturally subject to risks and uncertainties as various factors, some of which are beyond the control of ALK, may cause actual results and performance to differ materially from the forecasts made in this announcement. Without being exhaustive, such factors include e.g., general economic and business-related conditions, including legal issues, uncertainty relating to demand, pricing, reimbursement rules, partners' plans and forecasts, fluctuations in exchange rates, competitive factors and reliance on suppliers. Additional factors include the risks associated with the sourcing and manufacturing of ALK's products as well as the potential for side effects from the use of ALK's existing and future products, as allergy immunotherapy may be associated with allergic reactions of differing extents, durations and severities. The emergence of the coronavirus pandemic, and the extent and duration of countermeasures against the virus, represent an additional uncertainty that may also affect forward-looking statements.*

# Thank you for your attention



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