

A woman with blonde hair and glasses, wearing a white lab coat and purple nitrile gloves, is performing a skin test. She is using a small tool to apply a substance to a patient's arm. In the background, there is a white tray with several small vials and a blue container. The scene is set in a clinical or laboratory environment.

# Allergy solutions for life

IR roadshow presentation

August 2022



# Allergy solutions for life

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 global leader in allergy immunotherapy (AIT)*



Established

**1923**



Employees

**2,600**



Markets

**47**



Patients in treatment  
with ALK products\*

**2.1m**



Number of most common global  
respiratory allergies covered by  
ALK's tablet portfolio

**5**



Participated in clinical  
trials for the tablets

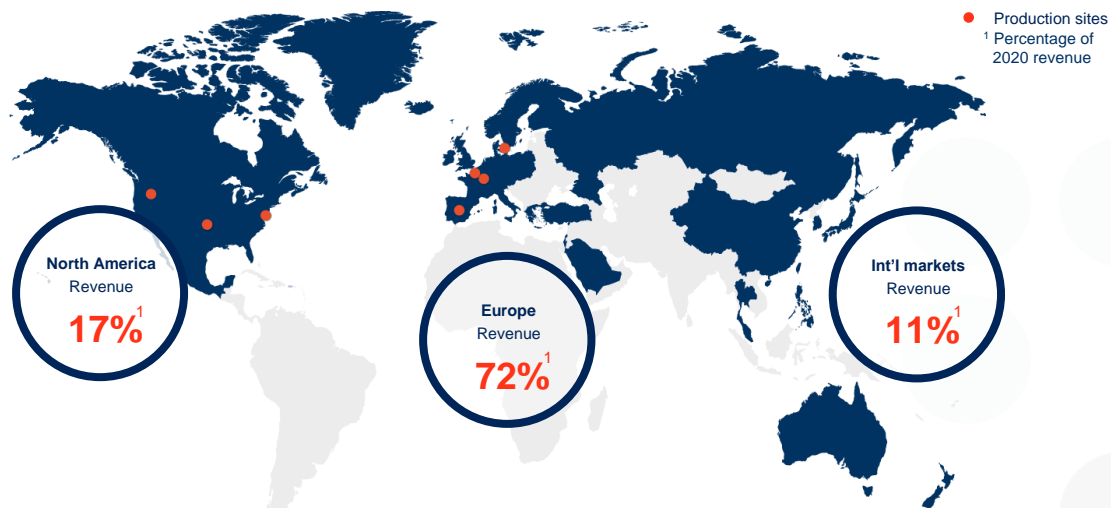
**>24,000**

\* Covering AIT and adrenaline

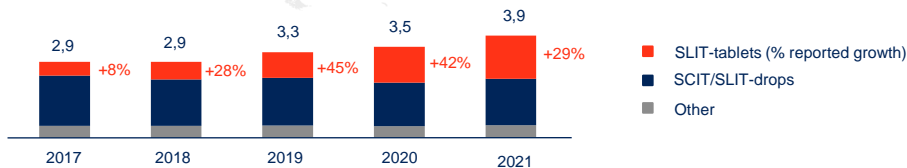


# ALK's global presence

*Allergy solutions for life*



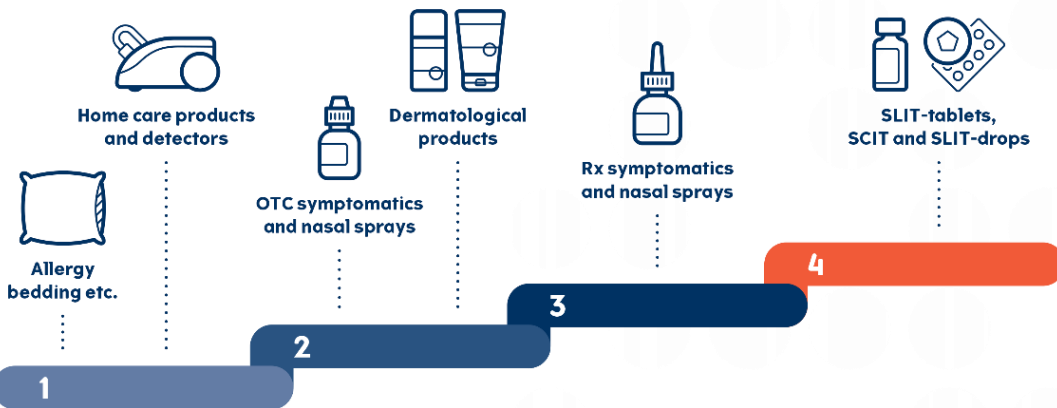
Development in revenue, DKK Bn



# Allergy Disease Management

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

**500m** (100%)  
Affected by allergic rhinitis



## Drug-free symptom relief

- Allergen avoidance
- Drug-free treatment concepts (e.g., sprays or saline inhalers)

## Over-the-counter pharmacotherapy

- First-line drugs
- Self treatment often lasts five years or more

## Prescription pharmacotherapy

- Second-line drugs
- Treatment lasts years

## Allergy immunotherapy

- AIT is usually prescribed as a last resort
- Usually initiated after serious disease aggravation

**50m** (10%)  
Eligible for AIT treatment

**<5m** (~1%)  
Treated with AIT



Current  
ALK space

← Allergy disease /  
Pollen count information →

# 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





# Key advances in long-term strategy

Q2 2022 strategic achievements



Succeed in  
North America



~10% growth

Tablet sales up 19%,  
equal growth in the USA  
and Canada

Long-established  
market barriers remain  
a challenge in the USA



Complete and commercialise  
the tablet portfolio



Growth &  
paediatric  
development

18% growth in tablet sales

Key paediatric trials with  
ACARIZAX® and  
ITULAZAX® on track for  
2023 completion

HDM tablet filing in China  
still expected late 2022



Consumer engagement  
and new horizons



Mobilise  
patients

Digital mobilisation of  
patients grew strongly  
with new launches in  
four countries



Innovation

Food AIT: Initiation of  
Phase I trial

US adrenaline: Projects  
on track for 2024 filing



Optimise for  
excellence



Production  
capacity

New agreement with  
Catalent, which  
secures long-term  
manufacturing capacity  
for ALK's SLIT-tablet  
portfolio



Portfolio  
rationalisation

Upgrades of  
documentation for  
legacy products



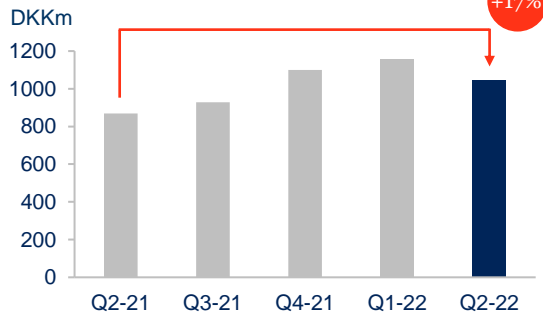
Lead the way – people and planet

# Strong financial performance in Q2

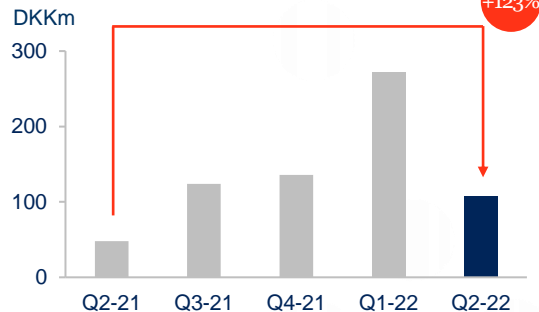
*2022 full-year outlook upgraded*

- 17% local currency growth; with double-digit growth in all regions
- Strong bounce back in Europe
- EBITDA up 123% in reported currency to DKK 107m on higher sales and better margins
- Launch of Phase I clinical trial for peanut SLIT-tablet

## Revenue



## EBITDA



# Key figures

DKKm	2022E*	2021	2020
Revenue	10 - 13%	3,916	3,491
Tablet sales growth	≥20%	29%	42%
Gross margin	+1-2 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 11 August 2022

# Appendix







**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)

# 6M: Revenue and segment information

	Europe		North America		International markets		Total	
Amounts in DKKm	6M 2022	6M 2021	6M 2022	6M 2021	6M 2022	6M 2021	6M 2022	6M 2021
SCIT/SLIT-drops	593	614	165	142	71	28	829	784
SLIT-tablets	784	662	78	58	201	147	1,063	867
Other products and services	127	98	160	121	21	19	308	238
<b>Total revenue</b>	<b>1,504</b>	<b>1,374</b>	<b>403</b>	<b>321</b>	<b>293</b>	<b>194</b>	<b>2,200</b>	<b>1,889</b>
Sale of goods							2,151	1,855
Royalties							42	34
Services							7	-
<b>Total revenue</b>							<b>2,200</b>	<b>1,889</b>

	Europe		North America		International markets		Total	
Growth, 6M 2022	Growth l.c.	Growth	Growth l.c.	Growth	Growth l.c.	Growth	Growth l.c.	Growth
SCIT/SLIT-drops	-4%	-3%	5%	16%	139%	154%	3%	6%
SLIT-tablets	18%	18%	22%	34%	36%	37%	21%	23%
Other products and services	28%	30%	20%	32%	3%	11%	22%	29%
<b>Total revenue</b>	<b>9%</b>	<b>9%</b>	<b>14%</b>	<b>26%</b>	<b>48%</b>	<b>51%</b>	<b>14%</b>	<b>16%</b>

Geographical markets (based on customer location):

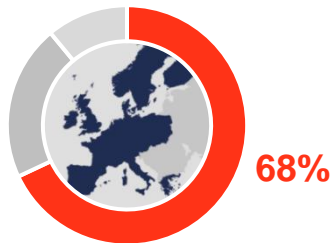
**Europe** comprises the EU, the UK, Norway and Switzerland — **North America** comprises the USA and Canada — **International markets** comprise Japan, China and all other countries

# Broad-based growth in all sales regions

*EU sales bounced back strongly, positive momentum elsewhere*

## Europe

Share of Q2 revenue



Q2

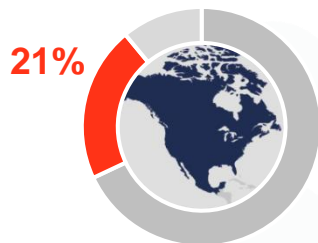
713m

621m

+14%

## North America

Share of Q2 revenue



Q2

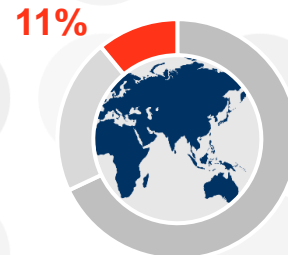
217m

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*

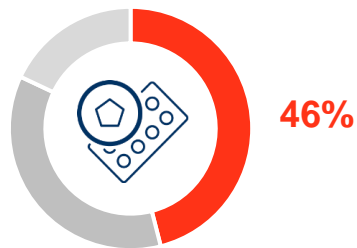


# Portfolio-wide growth led by tablets

*On track for FY tablet growth of 20% or more*

## Tablets

Share of Q2 revenue



Q2

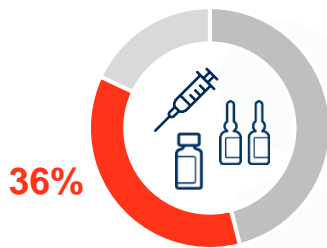
480m

401m

+18%

## SCIT/SLIT-drops

Share of Q2 revenue



Q2

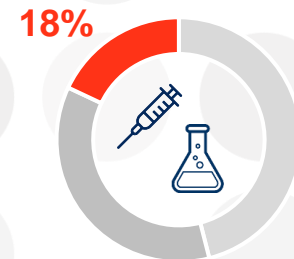
380m

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 upgraded

*Broad-based growth in all regions*

DKK	8 Feb 2022 outlook	4 Aug 2022 outlook	Comments	2021 actuals
<b>Revenue</b>	<b>8-12%</b> growth in local currencies	<b>10-13%</b> growth in local currencies	<ul style="list-style-type: none"> <li>• ≥20% growth in tablet sales, double-digits across regions</li> <li>• EU sales now expected at ~10%</li> <li>• Mid, single-digit growth from non-tablet portfolio</li> <li>• High-end: Continuous strong revenue growth, especially in Europe, with tablets leading the way, as well as improved sales of legacy products</li> <li>• Low-end: pricing pressures, particularly in selected markets in Europe, further negative effects from COVID, and/or impact from inability to meet market demand for certain legacy products in North America</li> </ul>	3,916m
<b>EBITDA</b>	<b>DKK 625-725m</b>	<b>DKK 675-750m</b>	<ul style="list-style-type: none"> <li>• Gross margin still to improve by 1-2 p.p.</li> <li>• R&amp;D costs unchanged at DKK 650-700m</li> <li>• S&amp;M ratio still to slightly improve, despite investments in growth, including China</li> </ul>	534m

*Assumptions: Current exchange rates. No revenue from acquisitions and/or partnerships. No sizeable payments for M&A/in-licensing. Negative free cash flow.*

# Key 2022 goals

*Towards '25 in 25'*



Succeed in  
North America



>10% growth

Increase prescriber depth among key specialists and pursue partnerships in digital health.

Grow legacy product sales

Obtain approval for ODACTRA®/ACARIZAX® in adolescents



Complete and commercialise the  
tablet portfolio



Growth &  
paediatric  
development

Grow tablet sales by ~20% with double-digit growth across all regions

Progress development for paediatric use and China



Consumer engagement  
and new horizons



Innovation

Food AIT: Initiate Phase I development of peanut tablet in H1



Innovation

Adrenaline: Prepare for planned 2024 regulatory submissions of AAI-projects



Optimise for  
excellence



Production  
efficiency

Further progress PASS programme

No quality-related major interruptions to supply

Improve gross margin 1-2 p.p.



**Lead the way – people and planet**

# 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

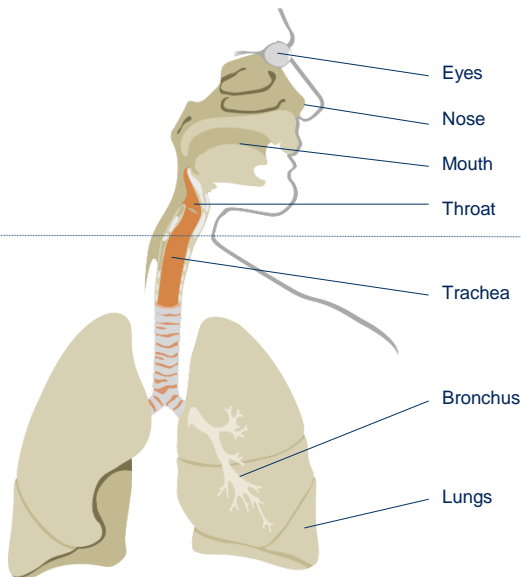
Respiratory allergies can affect both the upper and lower respiratory tract.

### Upper respiratory tract – allergic rhinitis

Running or blocked nose, itchy eyes, sneezing.

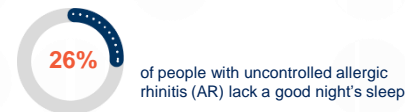
### Lower respiratory tract – allergic rhinitis

Shortness of breath, narrowed airways, coughing, wheezing.



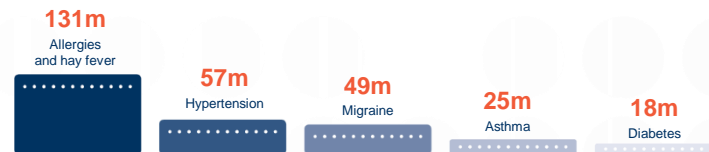
## Insufficient sleep

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



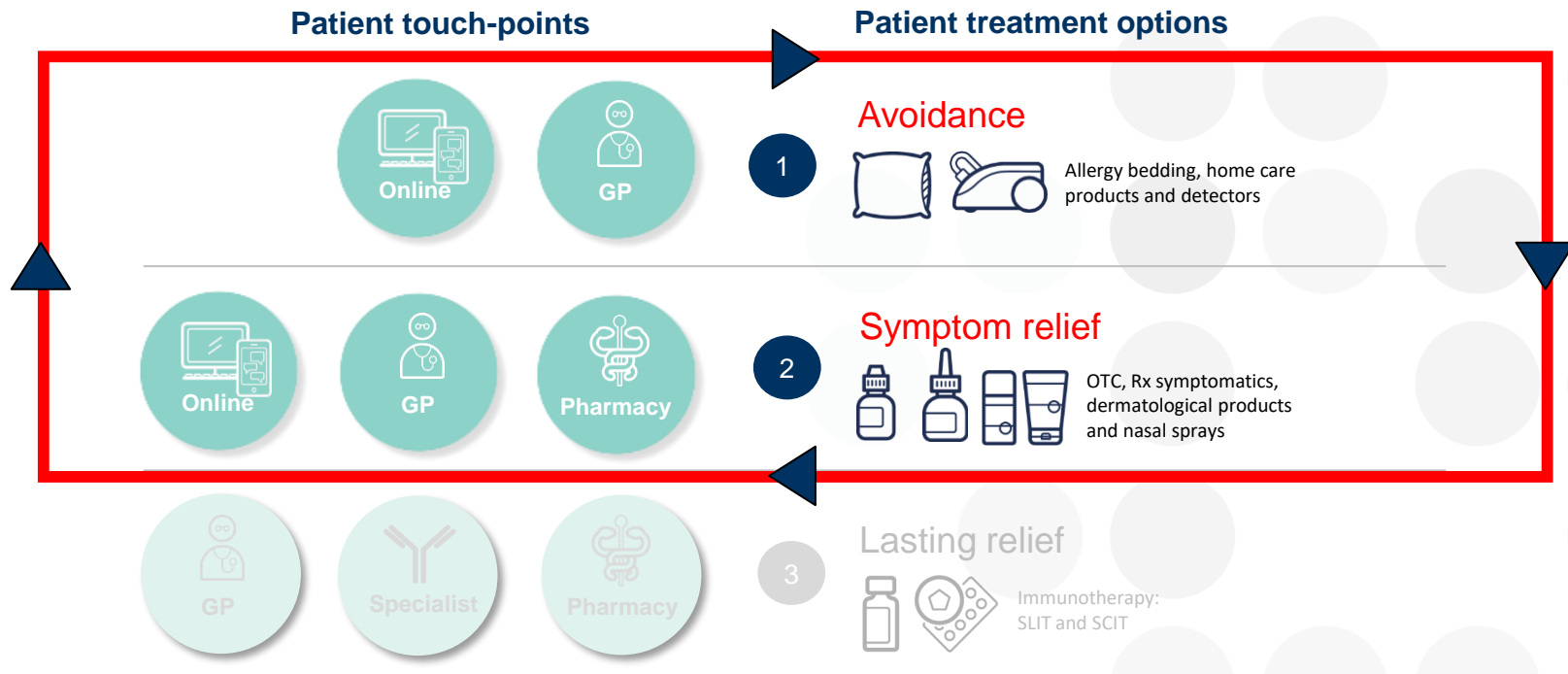
# Treatment strategies in allergy

## Patient touch-points

## Patient treatment options



# Patients caught in self-management circle



# Treatment strategies in allergy

- Low level of diagnosis
- Low level of patient disease understanding
- Low patient knowledge of treatment options
- Lack of HCP incentives & referral
- Perception of cost vs relief

**Only 1% on AIT**

**500m**

affected by allergic rhinitis

**50m**

eligible for AIT

**5m**

on AIT



3

**Lasting relief**



Immunotherapy:  
SLIT and SCIT

# 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

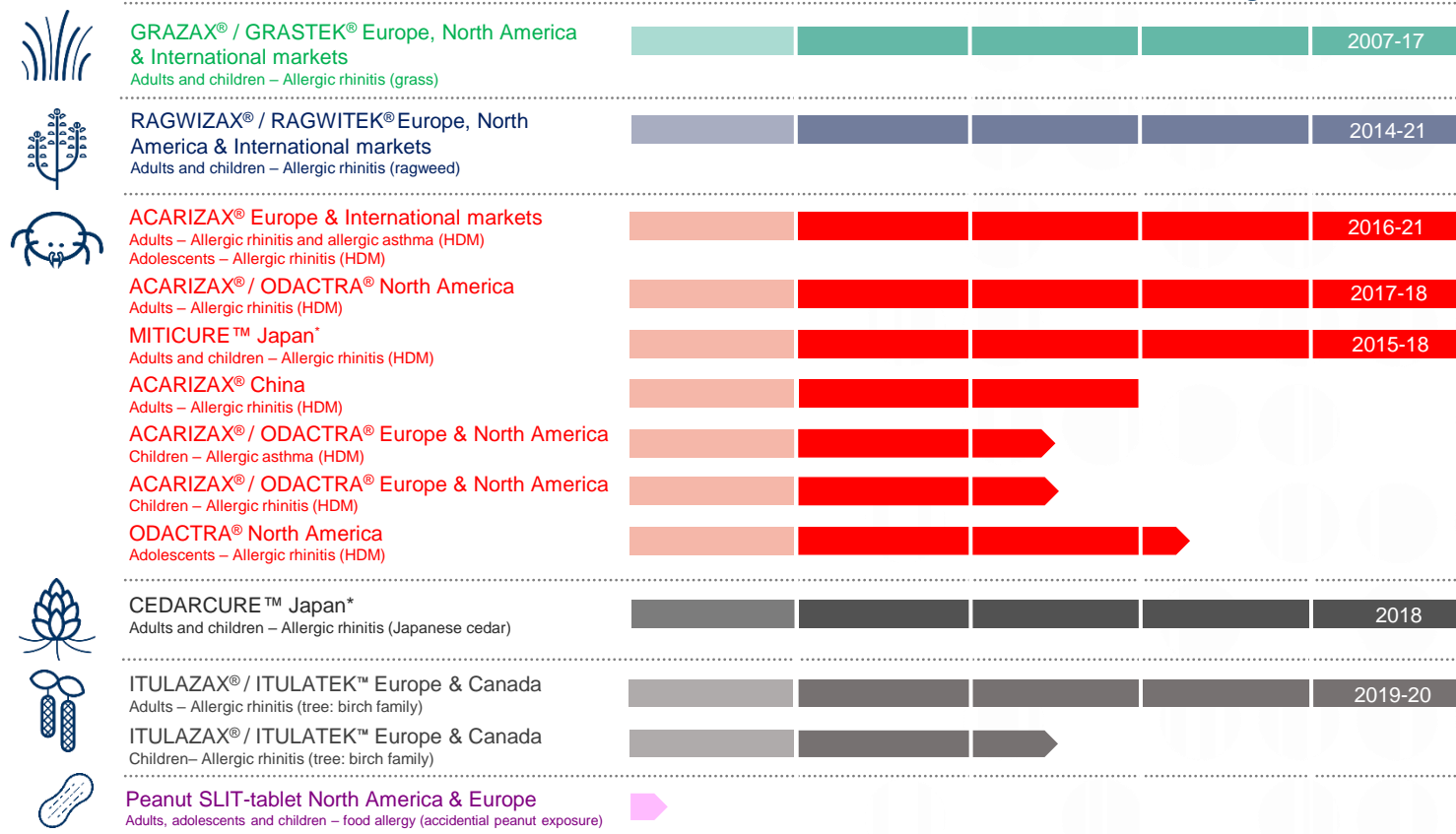
**Tablets:** SLIT-tablets are administered by the patient at home and are available for all the most important respiratory allergies. Tablet-based AIT is the most well-documented allergy treatment

## Manufacturing footprint

Centres of excellence



# R&D pipeline



## >24,000

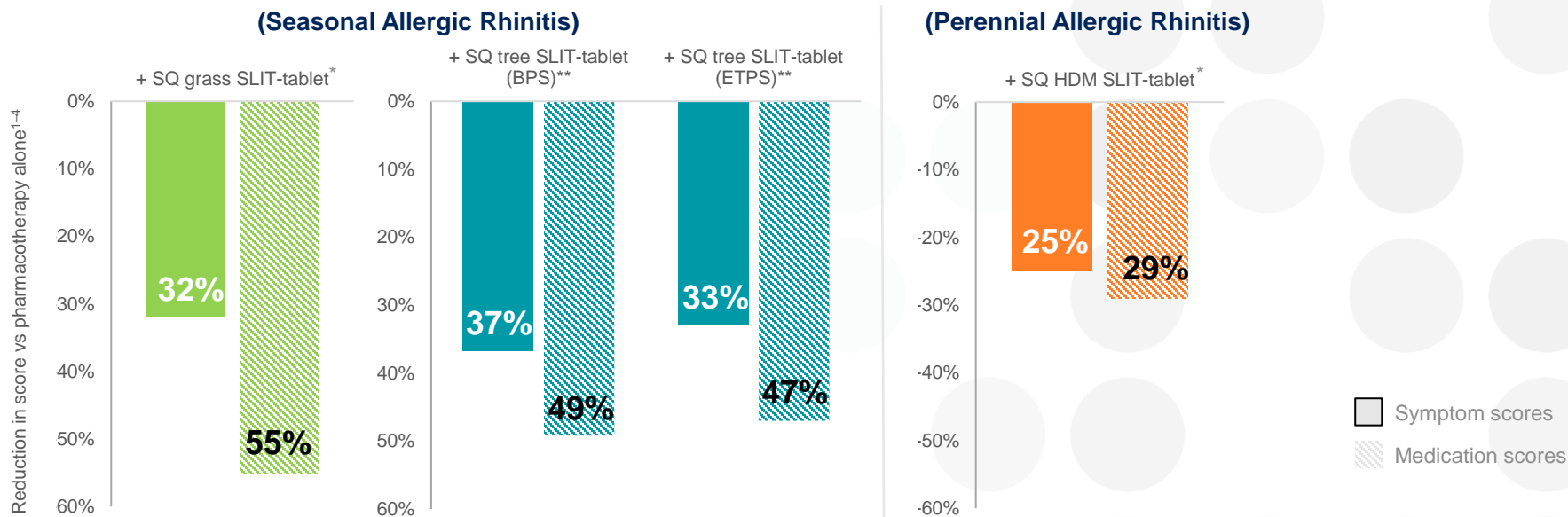
people participated in clinical development of the tablets which saw 21 Phase III trials

# 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



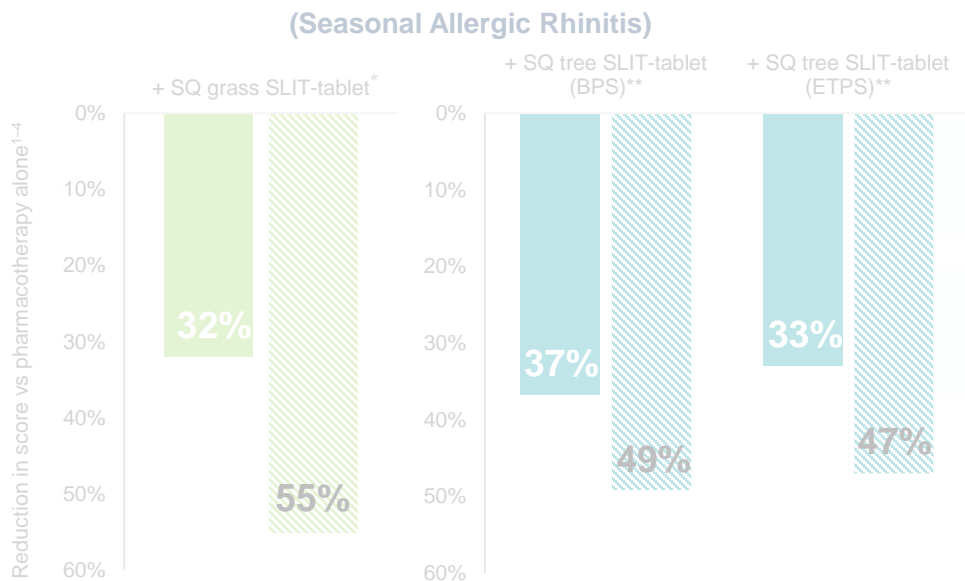
\*Median scores. \*\*Mean scores.

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%**

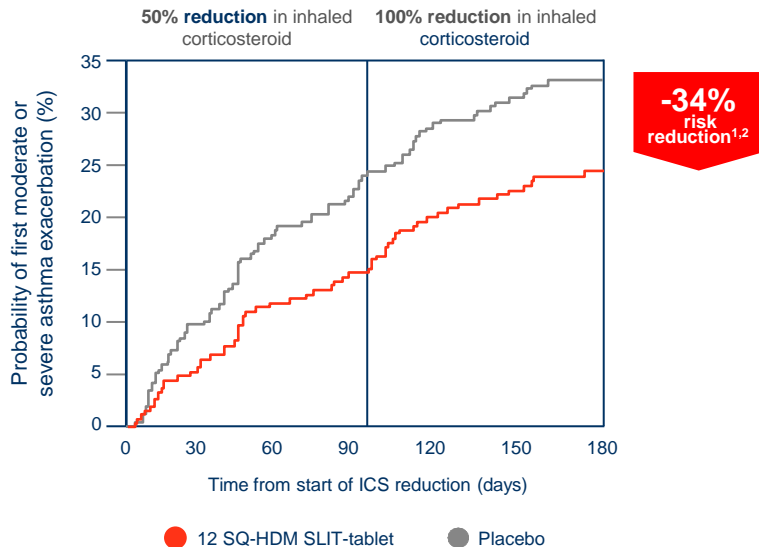
Improvement in combined symptom and medication score (TCS) vs. Placebo in **children** with ragweed AR<sup>1</sup>

□ 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® 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® in China, Macau and Taiwan
- Jext® 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® HDM and Soluprick SQ
- ACARIZAX® Phase III registration trial in China still paused due to COVID

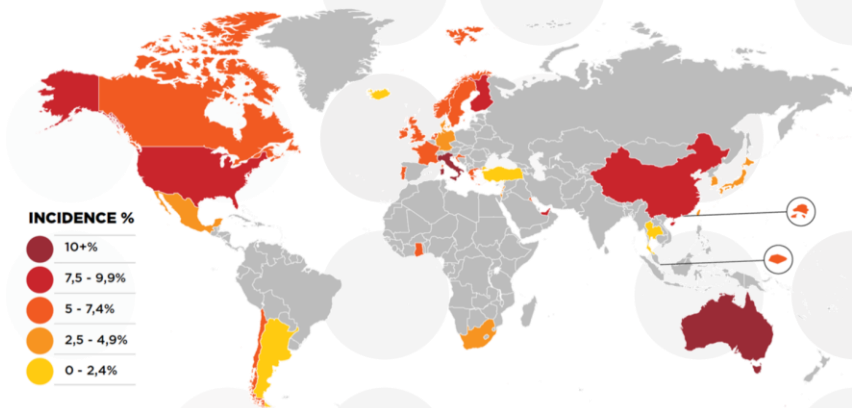


# Food allergies: A major unmet medical need

*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

## Investor Relations:

Per Plotnikof, Vice President, Head of Investor Relations

Phone: +45 4574 7576

E-mail: [ppidk@alk.net](mailto:ppidk@alk.net)

Read more: [www.alk.net](http://www.alk.net)

