

# Allergy solutions for life

IR roadshow  
presentation

August 2021

Collection of catkins  
from ALK's birch tree  
orchard in Post Falls,  
Idaho. Allergenic  
source materials are  
the main ingredients of  
ALK's allergy  
immunotherapy  
products

The ALK logo consists of a stylized globe icon made of a grid of dots, followed by the letters 'ALK' in a bold, white, sans-serif font.

# 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 key figures

(Nasdaq Copenhagen: ALK.B / ALKB.CO)



Established:

**1923**



Employees:

**~2,500**



Markets:

**41**



Patients in treatment  
with ALK products\*:

**~2m**



The number of the most  
common global respiratory  
allergies covered by ALK's  
tablet portfolio:

**5**

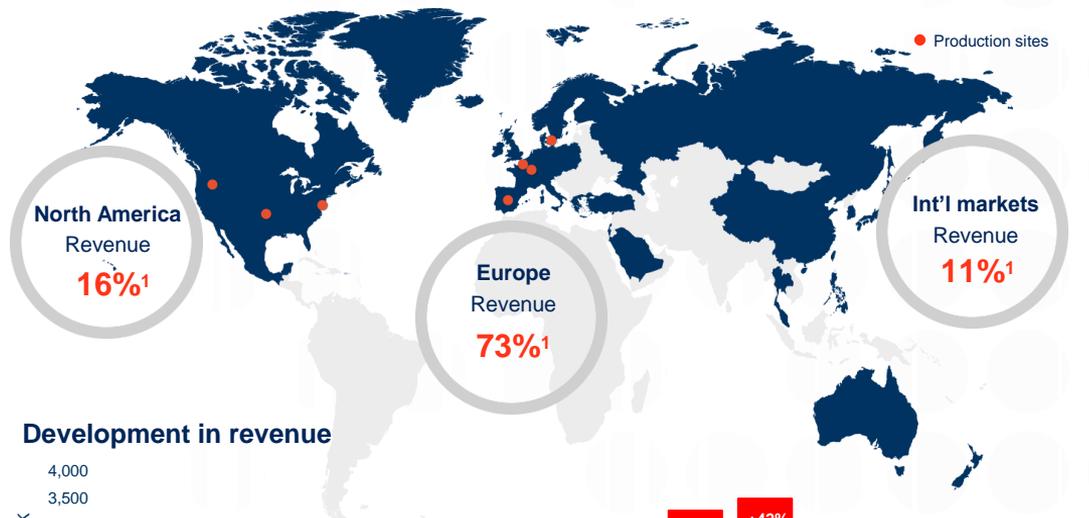


Participated in clinical  
trials for the tablets

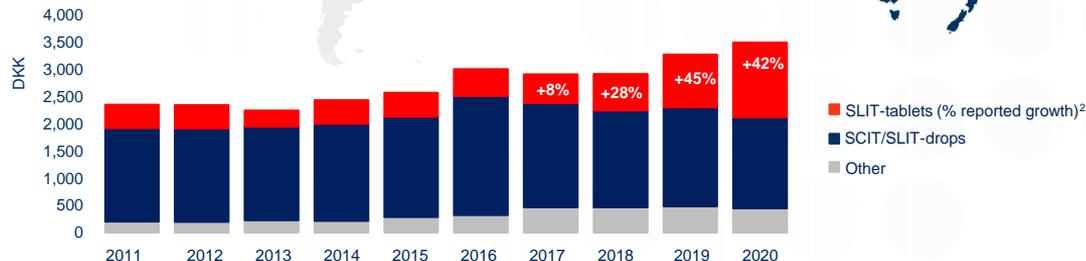
**>23,000**

\* Covering AIT and anaphylaxis

# Global presence



## Development in revenue

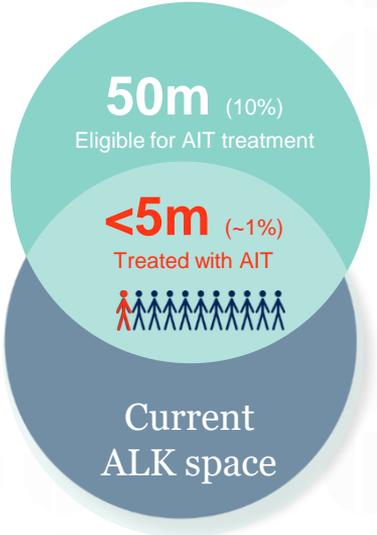
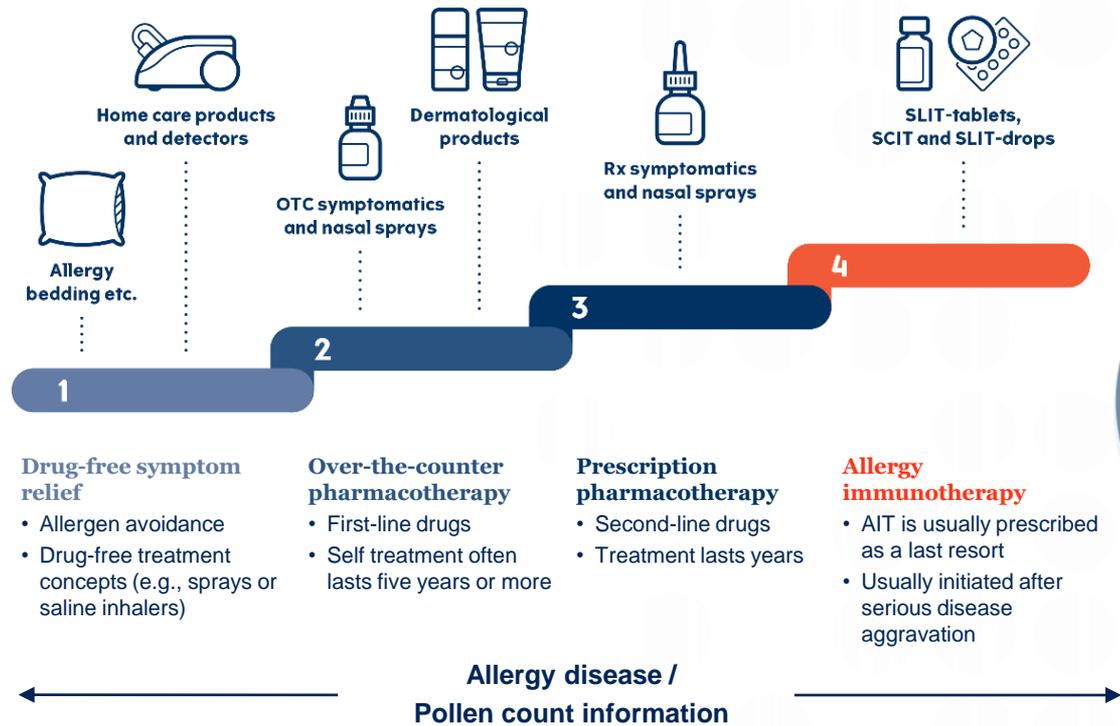
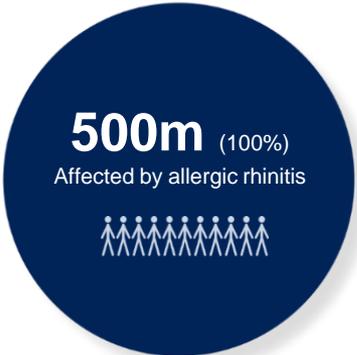


<sup>2</sup> includes certain milestone payments from partnerships in the period 2011 to 2016

<sup>1</sup> Percentage of 2020 revenue

# Allergy Disease Management

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



# Becoming the ‘go-to’ allergy company

*Transformation successfully completed, now towards '25 in 25'*

**2018-20**

## Transformation & growth

- 37% avg. tablet growth (CAGR)
- Cumulative earnings DKK 800m ahead of plan
- Past issues cleaned up
- Strong growth foundations

**2021-23**

## Growth & profitability

- $\geq 10\%$  organic growth p.a. driven by tablets
- Increase profitability (EBIT)
- Expand respiratory allergy leadership
- Fast-track tomorrow's opportunities, e.g. food

**2025**

## EBIT margin

**~25%**

# Important progress on strategy execution

## Sustain high growth

Continue tablet-fuelled growth momentum

Expand global leadership in respiratory AIT

Become relevant for many more allergy sufferers

Accelerate long-term growth:

Enter food allergy  
Expand in anaphylaxis

## Become profitable

Succeed in North America

Complete and commercialise tablet portfolio

Consumer engagement and new horizons

Optimise for excellence



Lead the way – people and planet

### Financial ambitions until 2025

An ALK capable of delivering sustainable, high revenue and earnings growth  
Revenue growth of  $\geq 10\%$  annually  
Continuously raise EBIT margin to  $\sim 25\%$  in 2025

# Strong sales and clinical progress for tablets

## Succeed in North America

### Targets



>10% growth

Tablet sales up 59%, legacy and non-AIT grow following easing of COVID restrictions



Digital engagement

Telehealth partnership expanded to new regions, klarify engagement platform launched in Canada



Business development

OTIPRIO<sup>®</sup>, a treatment for swimmer's ear, acquired from Otonomy

## Complete and commercialise tablet portfolio for all relevant ages

### Targets



>20% growth

ITULAZAX<sup>®</sup> continues to lead the way for tablet sales growth



New approvals

A further 22 approvals secured for tablets



Paediatric & adolescent development

ACARIZAX<sup>®</sup>/ODACTRA<sup>®</sup>: US adolescent trial completed ahead of application for expanded use. Other trials progressing to plan

# Accelerated business innovations to sustain growth

## Consumer engagement and new horizons

### Targets



~160,000 consumers mobilised via digital channels across all markets

Mobilise 250k patients



Business development

Licensing agreement with Grandpharma to register and commercialise Jext<sup>®</sup> in China



Innovation

Food AIT: Agreement with Catalent on use of tablet formulation technology



## Optimise for excellence

### Targets



Portfolio rationalisation

Year-to-date: >1,000 regulatory changes submitted to 36 regulatory authorities



Engagement

Focus on employee engagement and retention, with employee survey results showing engagement levels above pharma benchmark



# 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
- Initial launch in southern China under special licence
- 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



# Focus on new food allergy solutions

*Funded internal development programme now included in strategy*

## Sublingual, disruptive solutions

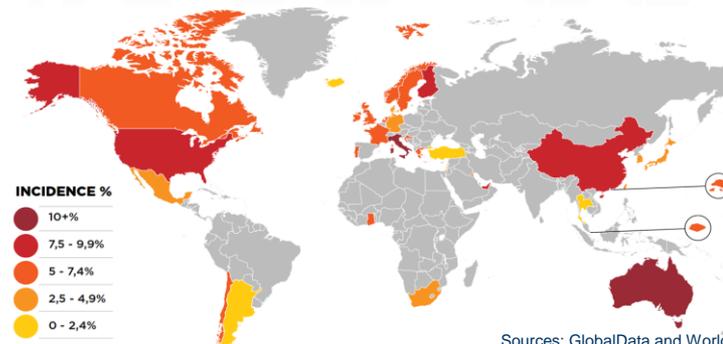
- Focus on allergies with the highest unmet need in children: Initially peanut, then tree nuts
- Sublingual, prescription-based treatments, building on ALK core competencies
- Aspire to deliver solution with high efficacy and benign safety



## Significant market potential

- Food allergies affect ~2.5% of global population
- Life-threatening condition
- Peanut, tree nuts, milk and egg account for most food allergy reactions in pre-school children
- Many peanut & tree nut cases persist into adulthood

### Prevalence of food allergies



Sources: GlobalData and Worldallergy.org

# Q2 revenue up 13%, 2021 full-year outlook upgraded

- Tablet sales up 23% and recovery of legacy sales.
- EBITDA of DKK 48m better than expected.
- FY outlook upgraded on improved sales outlook and increasing earnings.
- Significant strategy progress: China partnership, tablet approvals, clinical progress and more...

## Group revenue and growth

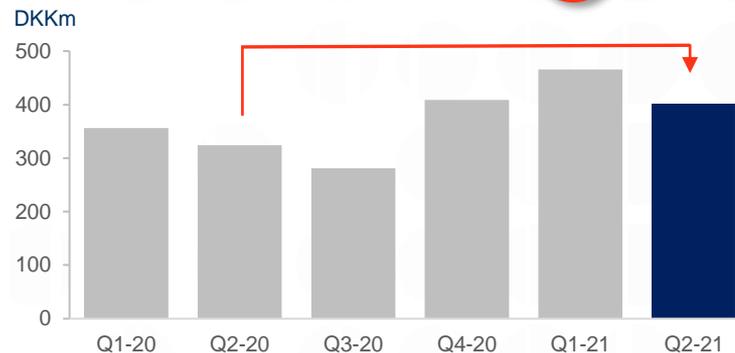
+13%



*Sales growth rates are in local currencies*

## Global tablet sales and growth

+23%



## Q2: Improved growth outlook for 2021

DKK million	2019	2020	2021E*
<b>Revenue</b>	3,274	3,491	<b>10-12%</b>
Tablet sales growth	45%	42%	<b>~25% or slightly above</b>
Gross margin	58%	58%	<b>59-60%</b>
R&D	466	515	<b>Slightly lower than 650</b>
Sales/Marketing & Adm.	1,456	1,362	
<b>EBITDA</b>	241	395	<b>450-500</b>
CAPEX	167	222	<b>250-300</b>
Free cash flow	(25)	56	<b>Minus ~100</b>
Cash and marketable sec.**	316	298	

\*) based on the 2021 guidance issued on 9 August 2021

\*\*) Additional, unused credit facility of DKK 600 million in place

# 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)

# Full-year financial outlook upgraded

	5 Feb 2021 Outlook	5 May 2021 outlook	9 Aug 2021 outlook	Comments	2020 actuals
<b>Revenue</b>	+8-12% (l.c.)	+9-12% (l.c.)	+10-12% (l.c.)	<ul style="list-style-type: none"> <li>• FY tablet growth now at to 25% or slightly above (previously ~25%)</li> <li>• Improved SCIT/SLIT-drops sales outlook</li> <li>• ~1 p.p. negative impact from currencies</li> </ul>	3,491m
<b>EBITDA</b>	DKK 325- 425m	DKK 375- 425m	DKK 450- 500m	<ul style="list-style-type: none"> <li>• Gross margin still to increase by 1-2 p.p.</li> <li>• General cost savings</li> <li>• R&amp;D now slightly below DKK 650m</li> <li>• Sales and marketing costs to normalise gradually</li> </ul>	395m
<b>Free cash flow</b>	DKK -200- 300m	Approx. DKK -200m	Approx. DKK -100m	<ul style="list-style-type: none"> <li>• Improved earnings, upfront payment</li> <li>• DKK 250-300m CAPEX (previously ~300m)</li> <li>• ~DKK 175m in payments of accrued rebates</li> </ul>	56m

Assumptions: Current exchange rates. No new revenue from acquisitions and/or partnerships. No new sizeable payments for M&A/in-licensing.

# H1: Revenue and segment information

	Europe		North America		International markets		Total	
Amounts in DKKm	H1 2021	H1 2020	H1 2021	H1 2020	H1 2021	H1 2020	H1 2021	H1 2020
SCIT/SLIT-drops	614	649	142	132	28	48	784	829
SLIT-tablets	662	507	58	46	147	127	867	680
Other products and services	98	104	121	102	19	13	238	219
<b>Total revenue</b>	<b>1,374</b>	<b>1,260</b>	<b>321</b>	<b>280</b>	<b>194</b>	<b>188</b>	<b>1,889</b>	<b>1,728</b>
Sale of goods							1,855	1,701
Royalties							34	27
<b>Total revenue</b>							<b>1,889</b>	<b>1,728</b>

	Europe		North America		International markets		Total	
Growth, H1 2021	Growth l.c.	Growth	Growth l.c.	Growth	Growth l.c.	Growth	Growth l.c.	Growth
SCIT/SLIT-drops	-5%	-5%	17%	8%	-40%	-42%	-4%	-5%
SLIT-tablets	30%	31%	33%	26%	16%	16%	28%	28%
Other products and services	-5%	-6%	29%	19%	57%	46%	14%	9%
<b>Total revenue</b>	<b>9%</b>	<b>9%</b>	<b>24%</b>	<b>15%</b>	<b>5%</b>	<b>3%</b>	<b>11%</b>	<b>9%</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

# Profitability better than expected

DKK million	6M 2020	6M 2021
Revenue	1,728	1,889
Gross profit	1,021	1,136
<b>Gross margin</b>	<b>59%</b>	<b>60%</b>
Capacity costs	868	979
<b>EBITDA</b>	<b>273</b>	<b>274</b>
EBIT	153	158
<b>Free cash flow</b>	<b>27</b>	<b>128</b>
<b>Cash/credit facilities</b>	<b>892</b>	<b>1,403</b>

Positive impact  
of continued  
tablet growth

R&D spend  
increased as  
planned by  
DKK 89m

Underlying  
improvement  
excluding  
R&D

Unused  
credit facilities  
of DKK 1.2bn

# 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

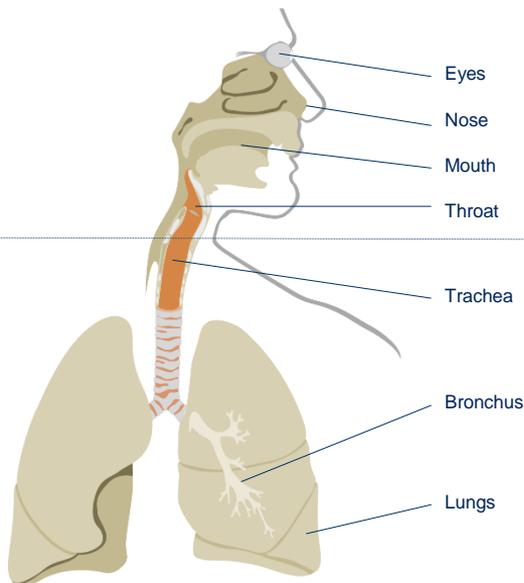
Respiratory allergies can affect both the upper and lower respiratory tract.

### Upper respiratory tract – allergic rhinitis

Running or blocked nose, itchy eyes, sneezing.

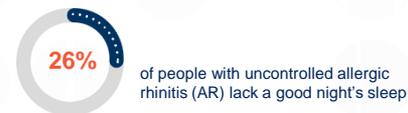
### Lower respiratory tract – allergic rhinitis

Shortness of breath, narrowed airways, coughing, wheezing.



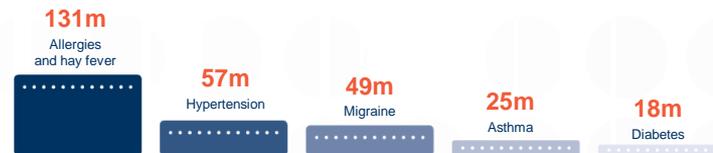
## Insufficient sleep

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

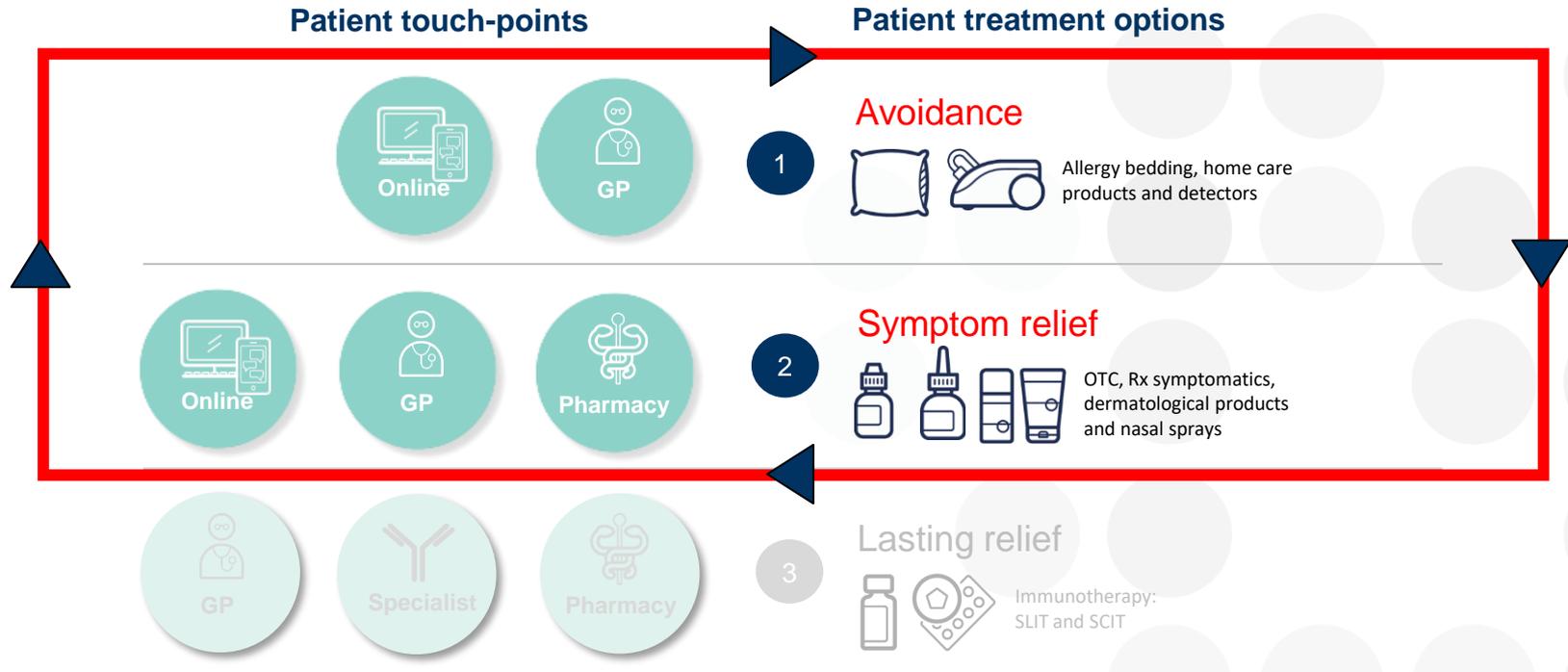
# Treatment strategies in allergy

## Patient touch-points

## Patient treatment options

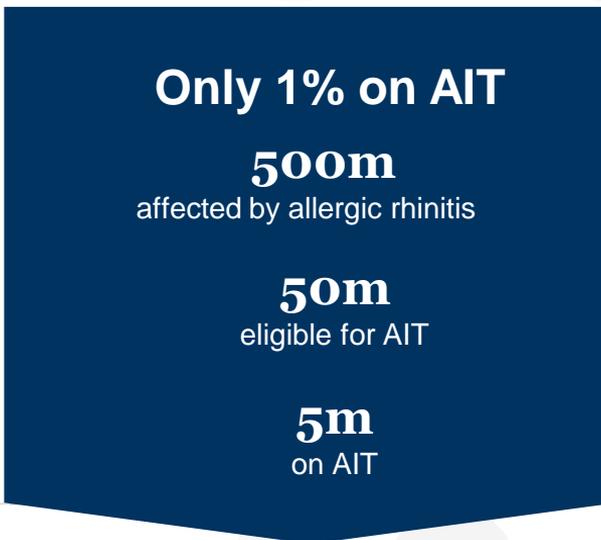


# Patients caught in self-management circle



# 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



3

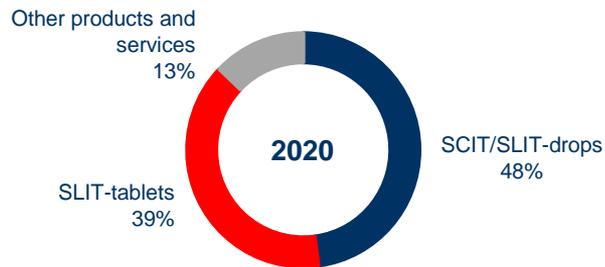
## Lasting relief



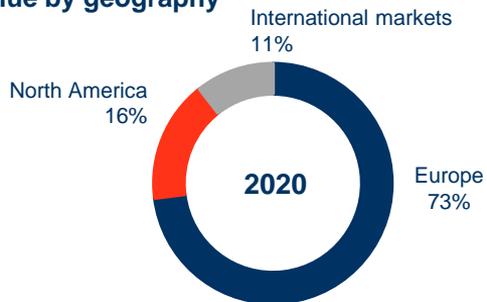
Immunotherapy:  
SLIT and SCIT

# ALK's current portfolio

## Revenue by product line



## Revenue by geography



# 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

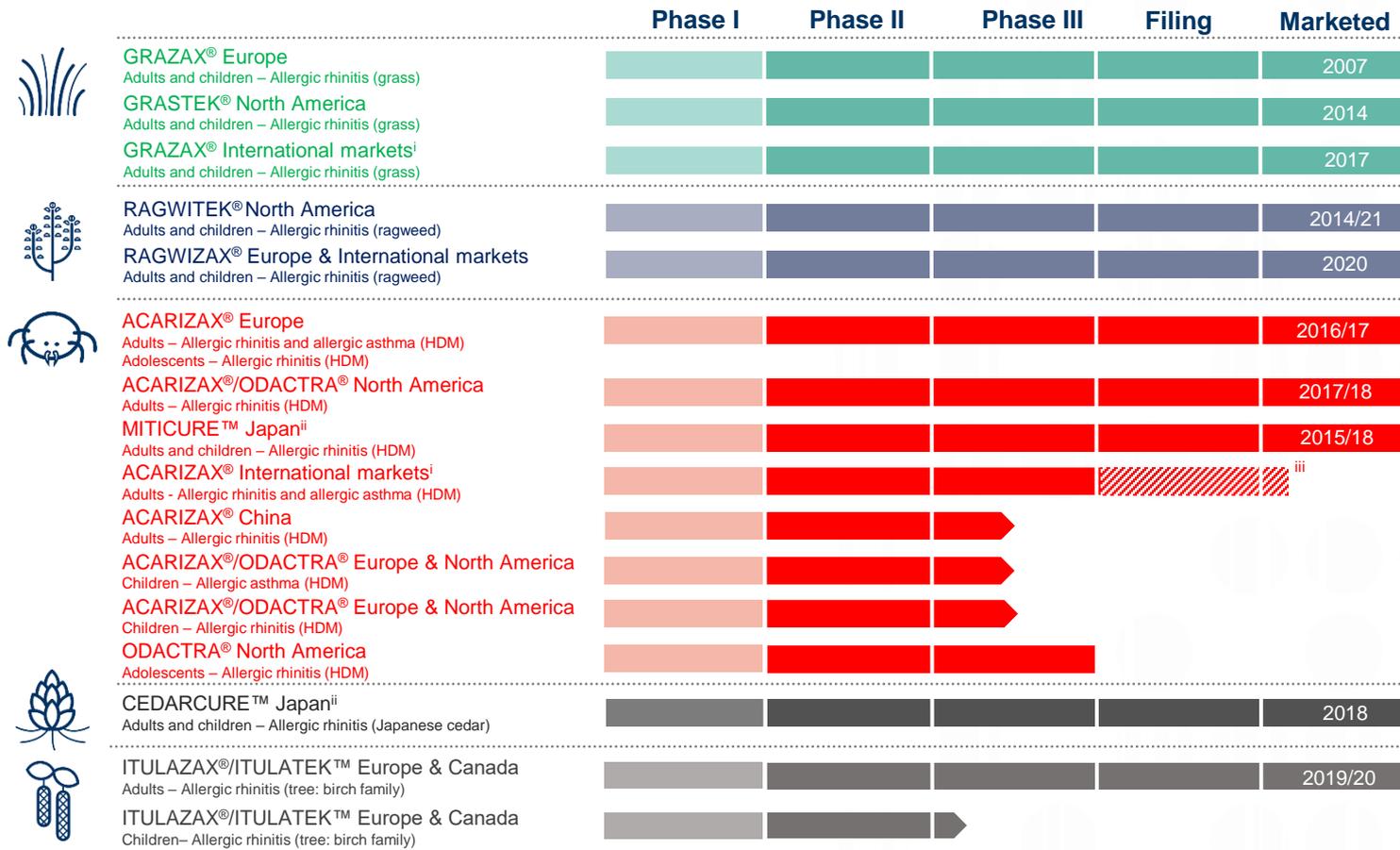
**Tablets:** SLIT-tablets are administered by the patient at home and are available for all the most important respiratory allergies. Tablet-based AIT is the most well-documented allergy treatment

## Manufacturing footprint

Centres of excellence



# SLIT-tablet portfolio covers >80% of respiratory allergies



~23,000

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

i. Licensed to Abbott for south-east Asia and Seqirus for Australia/New Zealand

ii. Licensed to Torii for Japan

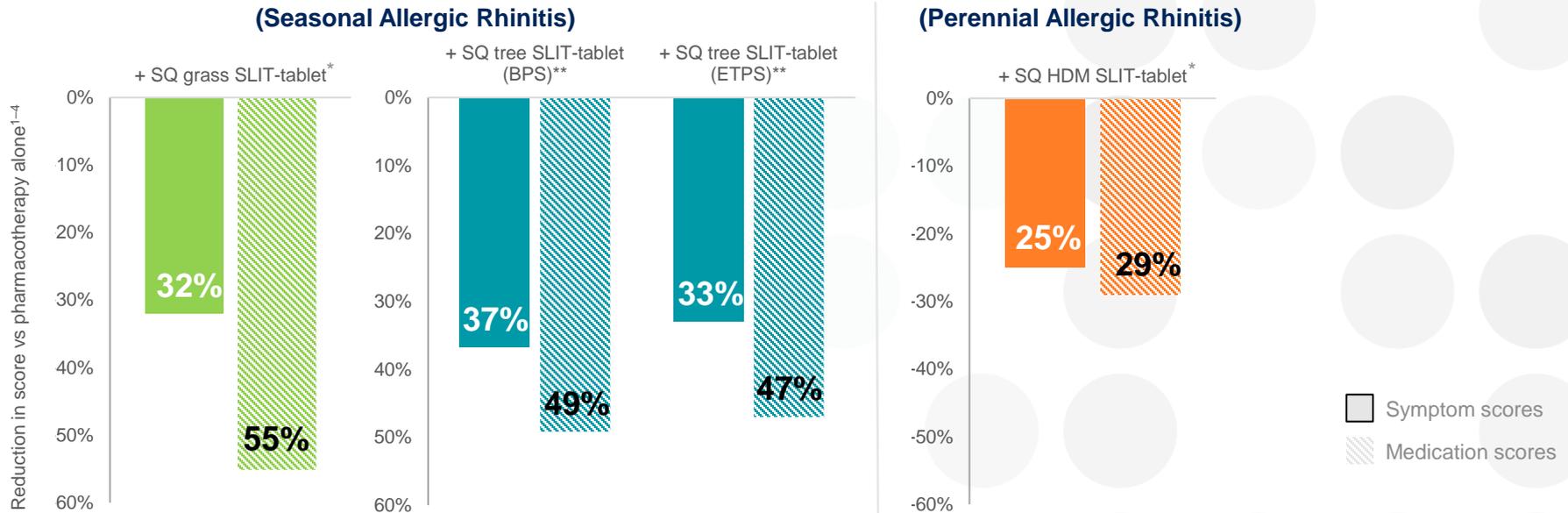
iii. Already marketed in selected markets

# 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

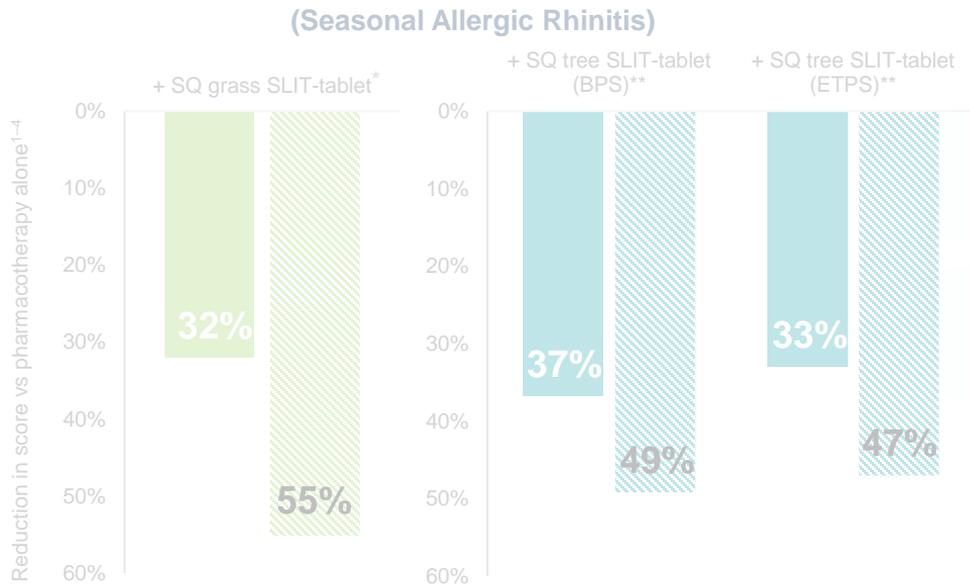


\*Median scores. \*\*Mean scores.

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%**

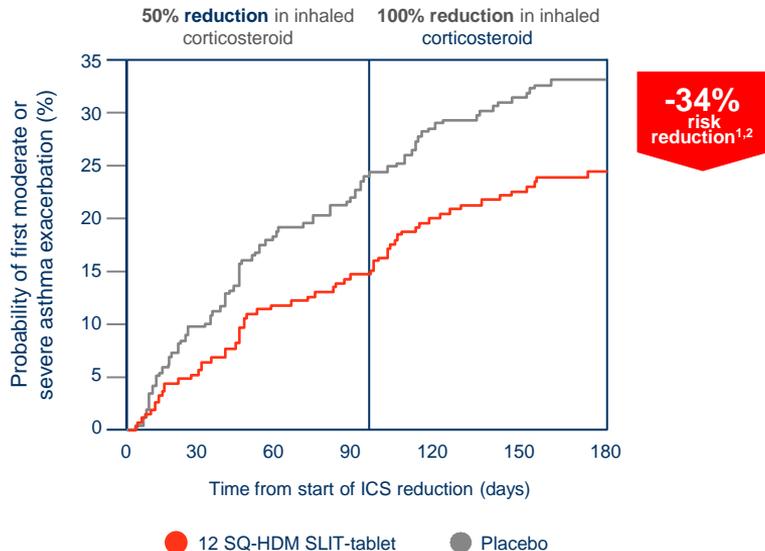
Improvement in combined symptom and medication score (TCS) vs. Placebo in **children** with ragweed AR<sup>1</sup>

□ 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>**

# ITULAZAX<sup>®</sup> patient profile

*Patients with AR can spend years trying different medications and suffering with allergic symptoms that can negatively impact their daily lives<sup>1</sup>*

## Indication

### Adult patients

**Moderate-to-severe allergic rhinitis** and/or **conjunctivitis** induced by pollen from the **birch homologous group<sup>1</sup>**

Clinical history of **symptoms** despite use of symptom-relieving medication

**Diagnosed** with a positive skin prick test and/or specific IgE test to a member of the birch homologous group<sup>1</sup>

<sup>1</sup>Birch homologous group: *Betula verrucosa* (birch), *Alnus glutinosa* (alder), *Carpinus betulus* (hornbeam), *Corylus avellana* (hazel), *Quercus alba* (oak), *Fagus sylvatica* (beech). IgE, immunoglobulin, class E; SLIT, sublingual immunotherapy.



# 2018-20: three years of overperformance

## Succeed in North America

Infrastructure & initial prescriber base established, ODACTRA® launched

Commercial strategy challenged by financial disincentives for allergists

Growth in value of bulk business pre-COVID

## Complete and commercialise tablet portfolio

Tablets launched for all five major respiratory allergies

37% average sales growth (3-year CAGR)

Clinical programme on track pre-COVID

## Patient engagement and adjacencies

Clarify digital engagement with hundreds of thousands of users

US adrenaline strategy in place

Consumer division and drug discovery partnerships

## Optimise and reallocate

Quality and robustness upgrades – site specialisation rolled-out

>300 products phased out, 3,500 regulatory updates of portfolio

Cultural transformation, efficiencies and savings

## Accumulated 3-year results

### Revenue

> **DKK 700m**

better than expected

### EBITDA

~ **DKK 800m**

better than expected

### Free cash flow

> **DKK 700m**

better than expected

# Succeed in North America



## Key priorities

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**Grow tablet** sales

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**Leverage digital platforms**  
to mobilise patients

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**Establish broader**, scalable  
sales channels for tablets



## 2021 objectives

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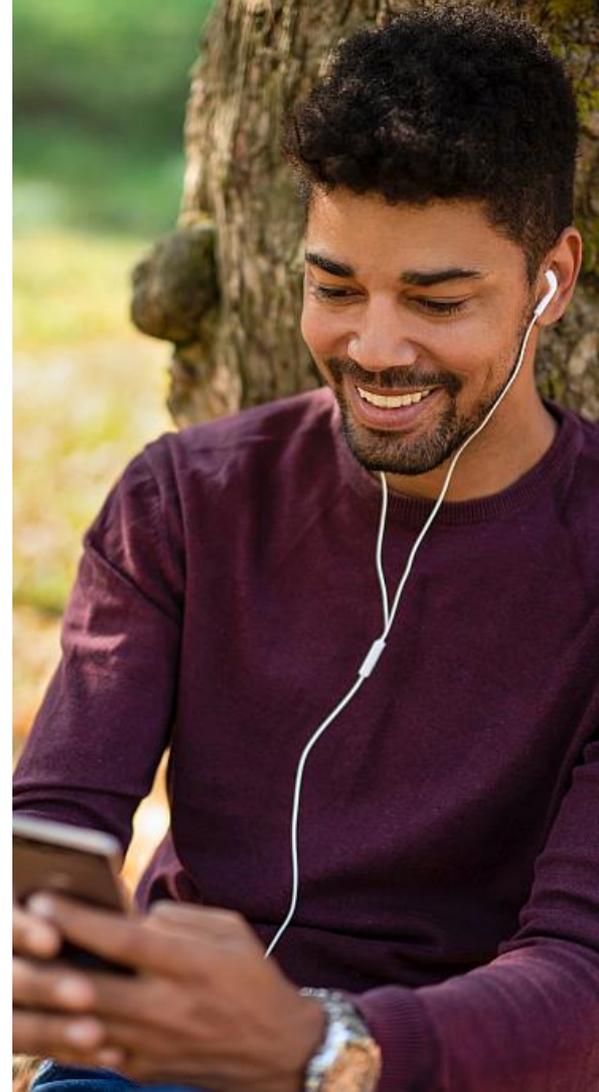
Increase total sales  
**by 10% or more**

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**Mobilise 20,000 US consumers**  
via digital engagement

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Secure paediatric indication for  
**RAGWITEK® in the USA**  
and adolescents for  
**ACARIZAX® in Canada**



# Complete and commercialise tablet portfolio



## Key priorities

Continue to  
**expand tablet franchise**

**Complete clinical development**  
for paediatrics, China and leverage  
data for new markets

Prepare launches in  
**younger patient groups**  
**and new markets**



## 2021 objectives

**Global tablet sales up >20%**  
maximising halo from ITULAZAX®

Progress clinical development for  
**paediatric use and new markets**

Trial	Exp. completion	Comments
HDM SLIT-tablet Registration trial China	<b>2022</b> (2021)	Expected to restart in mid- 2021
HDM SLIT-tablet Paediatric AR Europe/North America	<b>2023</b> (2022)	Patient recruitment extended with additional cohort
HDM SLIT-tablet Paediatric AA Europe/North America	<b>2022</b>	Ongoing
Tree SLIT-tablet Paediatric AR Europe/Canada	<b>2023</b>	To be initiated in 2021

# Consumer engagement and new horizons



## Key priorities

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**From OTC consumers to AIT patients** – develop and leverage digital ecosystem

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**Expand anaphylaxis franchise** and prepare next generation global adrenaline solution

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Develop innovative **new treatments for high impact allergic conditions**



## 2021 objectives

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**Mobilise 250,000 consumers** globally to take action on their allergies

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Food allergy: **prepare peanut project** for clinical development

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**Progress US development** for anaphylaxis



# Optimise for excellence



## Key priorities

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**Maintain quality excellence**  
and IT robustness

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Complete  
**portfolio rationalisation**  
and **site specialisation**

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**Maintain and upgrade**  
core legacy products

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**Leverage sales platforms**  
to drive economies of scale



## 2021 objectives

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**Contribute to 1-2 p.p.** gross  
margin improvement through  
portfolio pruning and efficiencies

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**Upgrade product** documentation  
and facilities to support  
core legacy portfolio

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**Zero quality-related** major  
interruptions to supply



# Financial ambitions until 2025

An ALK capable of delivering sustainable revenue growth and improved profitability

Revenue growth

**≥10%**

annually

EBIT margin

**~25%**

2025

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## Assumptions

- Gradually improving gross margin
- Significant R&D spend 2021-22; spend to decrease relative to revenue w. completion of large-scale development for respiratory tablets
- Costs for food allergy and new research included
- Leverage of sales and marketing platform will further decrease sales and marketing costs relative to revenue
- Annual CAPEX of ~DKK 300 million
- Not included: significant M&As, partnerships or in-licensing

# 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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