

# Allergy solutions for life

IR roadshow presentation

November 2020



# 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.

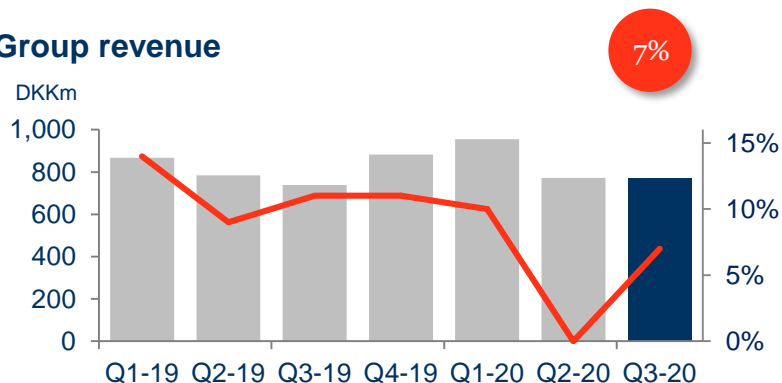
By collecting information and the latest and most trusted solutions together in one place, we want to make allergy surprisingly simple to manage. With 100 years of experience, nobody knows allergy like us, and we continuously apply our scientific knowledge and expertise to help people take control of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

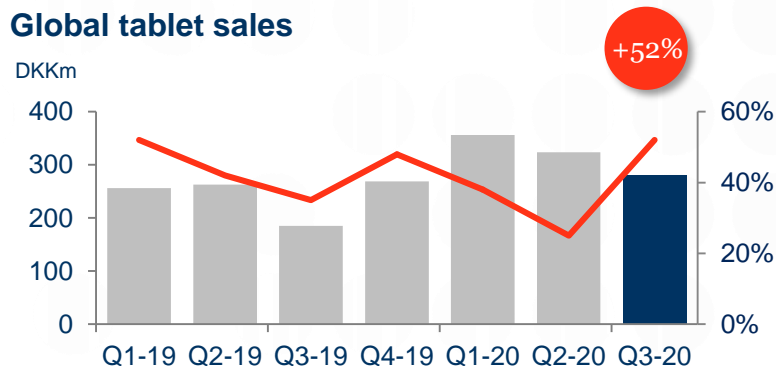
# Tablets fuel growth in Q3 despite COVID-19, guidance adjusted

- Revenue up 7% organically. Negative 2 p.p. impact from currencies
- Tablet sales up 52% on strong performances in Europe and International markets
- Negative 4 p.p. from planned product discontinuations
- EBITDA up 61% at DKK 58m on savings and delayed R&D expenditure
- FY earnings and cash flow outlook upgraded

## Group revenue



## Global tablet sales



# COVID-19 update

*Return to growth in Q3, ahead of high-season. USA and legacy products remain under pressure as expected*

## Focus is on continued supply of products

- Although patients returned to allergy clinics for treatment in Q3, access remains constrained
- Sales of home-based tablet treatments remain resilient and were boosted in some markets
- Sales of legacy products remains under pressure, missed US sales to exceed DKK 100 million in 2020
- Delays to clinical activities, patient recruitment impacted
- Ongoing regulatory reviews on track

## No major interruptions to production

*Contingency measures in place, inventories robust*



# ALK key figures

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



Established in  
**1923**



Employees  
**~2,400**



Markets  
**41**



Leader in AIT,  
treating  
**~1.9m**



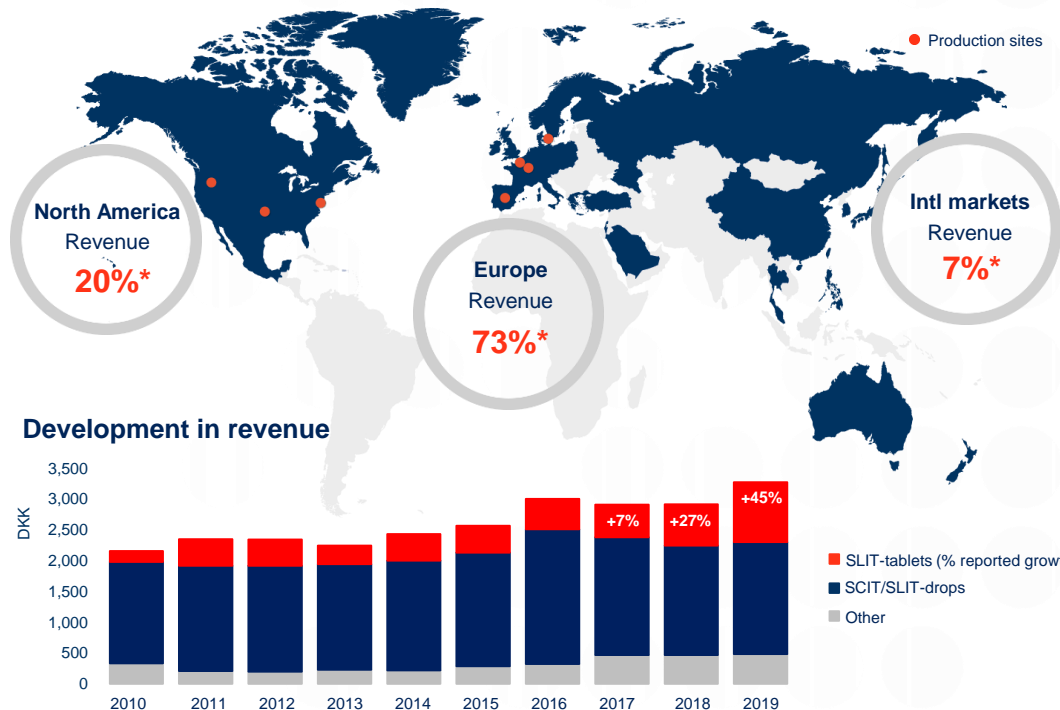
People with allergy  
covered by portfolio of  
new, standardised tablets  
**>80%**



Participants in clinical  
trials for the tablets  
**>22,000**

# Global presence

*Transformation in progress to accelerate growth and build broader presence in allergy*



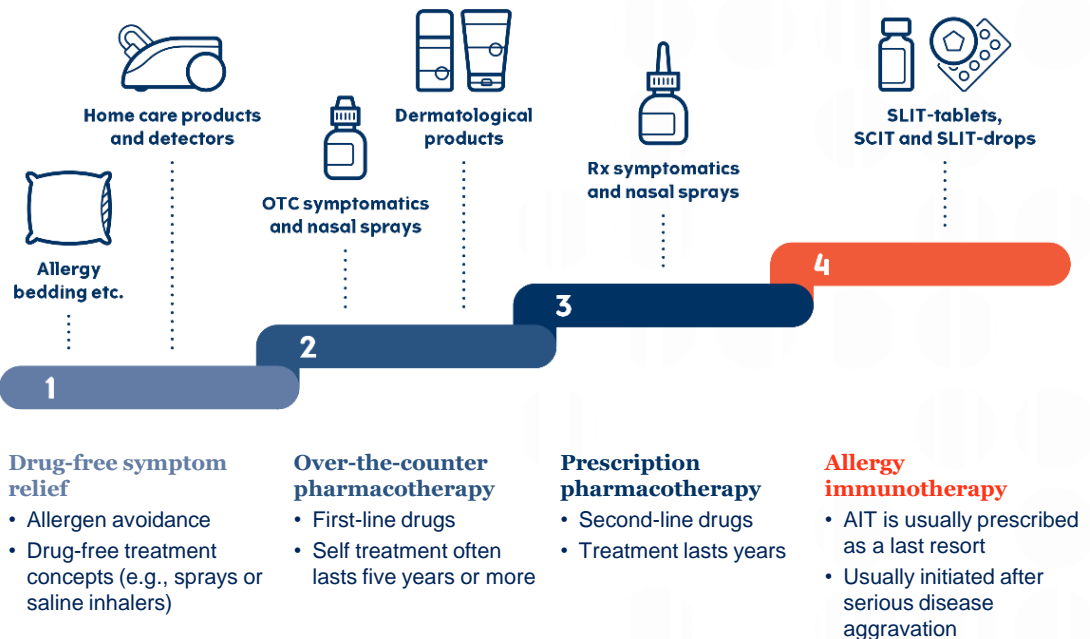
\*\* includes certain milestone payments from partnerships in the period 2010 to 2016

\* Percentage of 2019 revenue

# Allergy Disease Management > 120 bn DKK market

*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



← Allergy disease /  
Pollen count information →

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

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



Current  
ALK space

# Three-year transformation nears completion (I)

Succeed in  
North  
America

Complete and  
commercialise  
tablet  
portfolio

Patient  
engagement  
and  
adjacencies

Optimise and  
reallocate  
resources

## **Financial ambitions**

An ALK capable of delivering sustainable, high revenue and earnings growth

Revenue growth of  $\geq 10\%$  annually

Raise margins quickly to specialty pharma levels after 2020

# Three-year transformation nears completion (II)

## Succeed in North America

*COVID-19 means missed sales of DKK >100 million in 2020*

### Targets



10% growth

Growth severely impacted by COVID-19. Patient visits to clinics significantly lower than normal.



Rx depth

Tablet sales volumes increased while revenue fell as a result of discounting.



ITULATEK™  
in Canada

Launch of ITULAZAX® in Canada.



Digital  
engagement

~150,000 downloads of klarify app. Introduction of new website features: find a doctor and request remote consultations.

## Complete and commercialise tablet portfolio for all relevant ages

*Strong growth trajectory maintained*

### Targets



>30% growth

Global tablet sales up 52% with ACARIZAX® and ITULAZAX® leading the way



ITULAZAX®  
in Europe

ITULAZAX® roll-out remains on track with six recent launches: Germany and the Nordics continue strong performance



Evidence-based  
medicine

Further changes in Germany: All non-registered ALK products discontinued; HCP-fees updated



Clinical  
development

Delays to clinical activities, patient recruitment impacted



# Three-year transformation nears completion (III)

## Patient engagement and adjacent business

*Digital strategy continues to surpass expectations*

### Targets



Mobilise 100k patients

>475,000 two-way consumer relationships to date,  
>140,000 people mobilised to take action on their allergies



Digital engagement

New options added to US and German web resources: speak to a doctor



Innovation

Partnership with PharmaDoctor: Pharmacy-based, allergy test 'n treat service in the UK

## Optimise and reallocate

*Manufacturing robustness proven during COVID-19*

### Targets



Portfolio rationalisation

Work to consolidate the number of active pharmaceutical ingredients (APIs) continued



Production efficiency

Site specialisation, optimisation efforts and investments in quality continued with the aim of improving long-term efficiency



# Building a sustainable growth platform

*Subdued earnings during 2018-20 due to business and growth investments*

DKK million	Transformation period		
	2018	2019	2020E*
<b>Revenue</b>	2,915	3,274	~+8%
Tablet sales growth	27%	45%	>30%
Gross margin	56%	58%	~58%
R&D	392	466	500-525
Sales/Marketing & Adm.	1,364	1,210	
<b>EBITDA</b>	136	241	350-400
CAPEX	178	167	
Free cash flow	(264)	(25)	~0
Cash and marketable sec.**	396	316	

\*) based on the 2020 guidance issued on 11 November 2020

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

# 2020 earnings and cash flow outlook upgraded

DKK	9 May outlook	12 August outlook	5 November Outlook	Comments	2019 actuals
<b>Revenue</b>	+8-12 organic	Lower end of +8-12% organic	<b>~ +8% organic</b>	<ul style="list-style-type: none"> <li>-3 p.p. FY impact from portfolio pruning</li> <li>+30% FY tablet growth</li> <li>Assumes patients can/will visit doctors at current level for remainder of 2020</li> </ul>	3,274m
<b>EBITDA</b>	200-300m	300-350m	<b>350-400m</b>	<ul style="list-style-type: none"> <li>Gross margin on par with 2019</li> <li>Lower capacity costs due to COVID-19 and operational leverage</li> </ul>	241m
<b>Free cash flow</b>	~(300)m	~(200)m	<b>~0m</b>	<ul style="list-style-type: none"> <li>Higher earnings</li> <li>Repayment of accrued rebates now expected in 2021; DK-employee tax payments also in 2021</li> <li>DKK 250 million CAPEX</li> </ul>	(25)m

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

# 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)

# 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

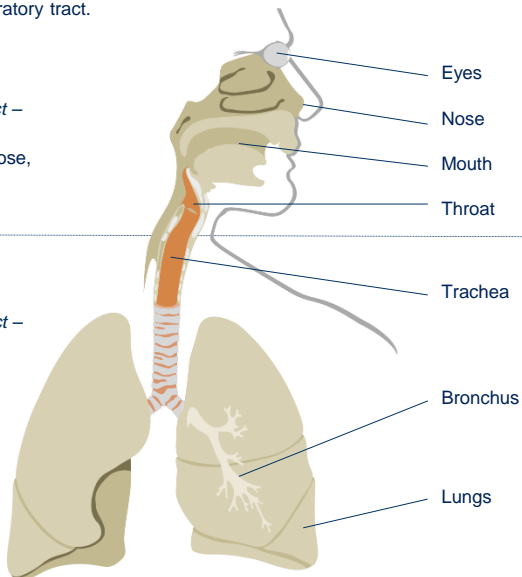
Respiratory allergies can affect both the upper and lower respiratory tract.

### Upper respiratory tract – allergic rhinitis

Running or blocked nose, itchy eyes, sneezing.

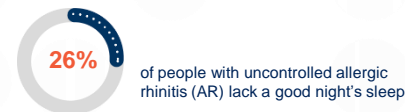
### Lower respiratory tract – allergic rhinitis

Shortness of breath, narrowed airways, coughing, wheezing.



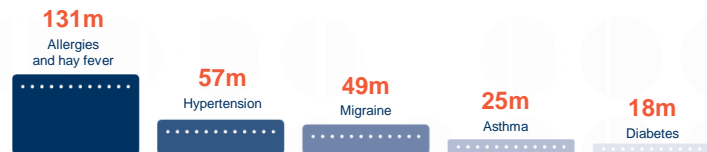
## Insufficient sleep

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

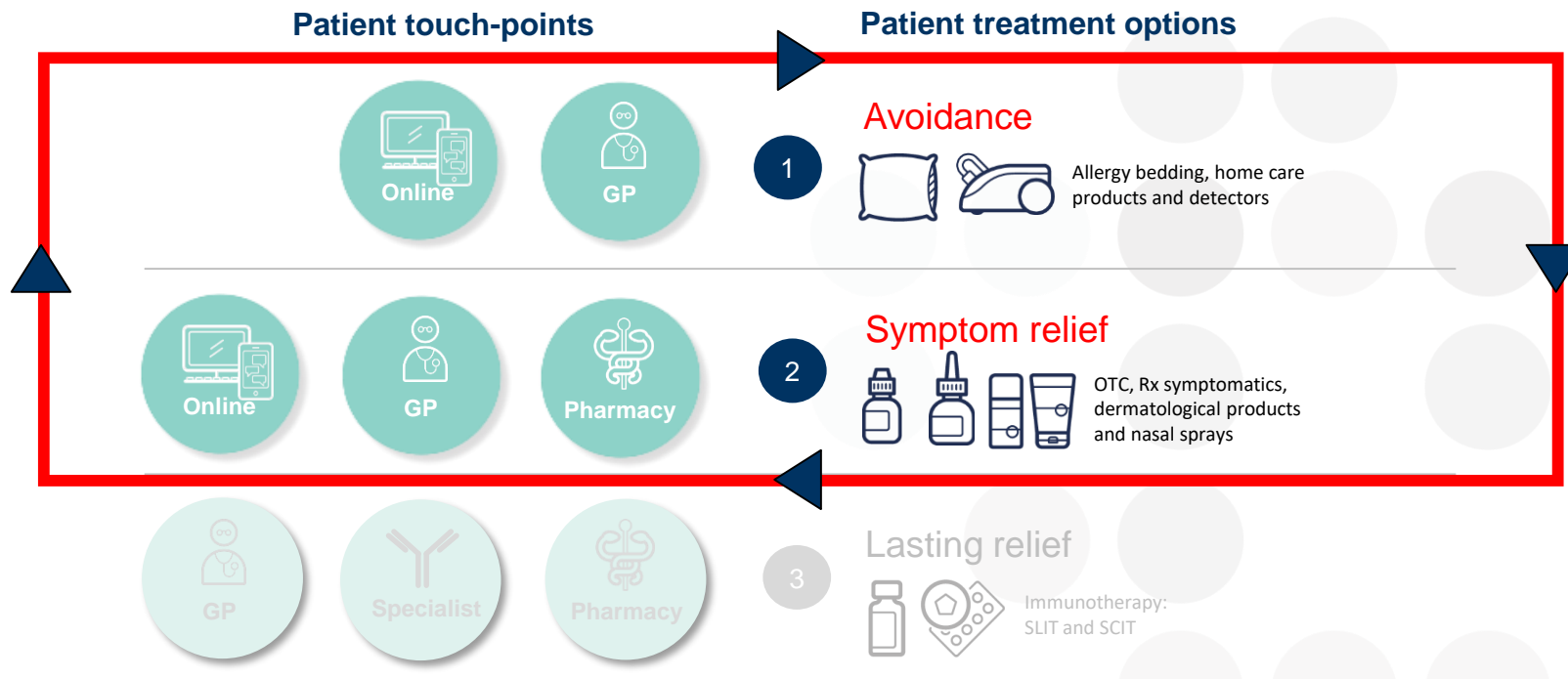
## Patient touch-points

## 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

## Revenue by product line



# 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



## GRAZAX® Europe

Adults and children – Allergic rhinitis (grass)

## GRASTEK® North America

Adults and children – Allergic rhinitis (grass)

## GRAZAX® International markets<sup>i</sup>

Adults and children – Allergic rhinitis (grass)



## RAGWITEK® North America

Adults – Allergic rhinitis (ragweed)

## RAGWIZAX® Europe & Intl. markets

Adults – Allergic rhinitis (ragweed)

## RAGWIZAX®/RAGWITEK® Europe & NA

Children – Allergic rhinitis (ragweed)



## ACARIZAX® Europe

Adults – Allergic rhinitis and allergic asthma (HDM)

Adolescents – Allergic rhinitis (HDM)

## ACARIZAX®/ODACTRA® North America

Adults – Allergic rhinitis (HDM)

## MITICURE™ Japan<sup>ii</sup>

Adults and children – Allergic rhinitis (HDM)

## ACARIZAX® International markets<sup>i</sup>

Adults – Allergic rhinitis and allergic asthma (HDM)

## ACARIZAX® China

Adults – Allergic rhinitis (HDM)

## ACARIZAX®/ODACTRA® Europe & North America

Children – Allergic asthma (HDM)

## ACARIZAX®/ODACTRA® Europe & North America

Children – Allergic rhinitis (HDM)

## ODACTRA® North America

Adolescents – Allergic rhinitis (HDM)



## CEDARCURE™ Japan<sup>ii</sup>

Adults and children – Allergic rhinitis (Japanese Cedar)

## ITULAZAX® Europe

Adults – Allergic rhinitis (tree: birch family)

## ITULATEK™ Canada

Adults – Allergic rhinitis (tree: birch family)

Phase I

Phase II

Phase III

Filing

Marketed

2007

2014

2014

2020

iii

2016/17

2017/18

2015/18

iv

2018

2019

2020

# ~22,000

patients included in  
clinical development, incl.  
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. Approved in Europe

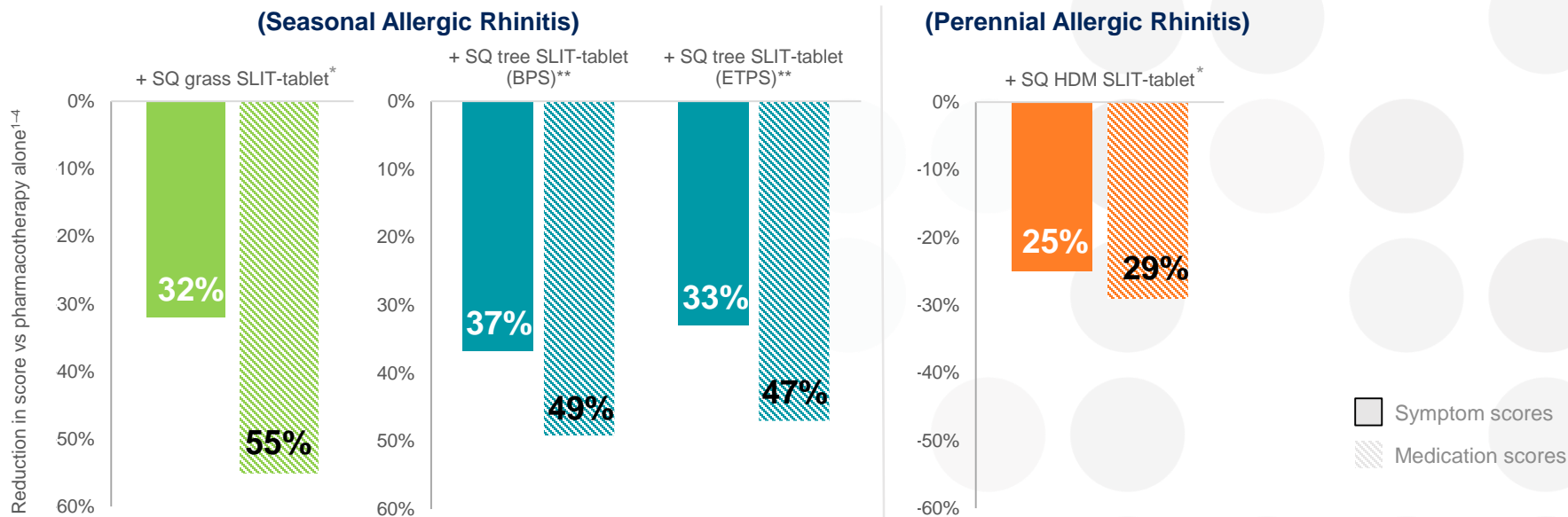
iv. Already marketed in selected markets

# 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

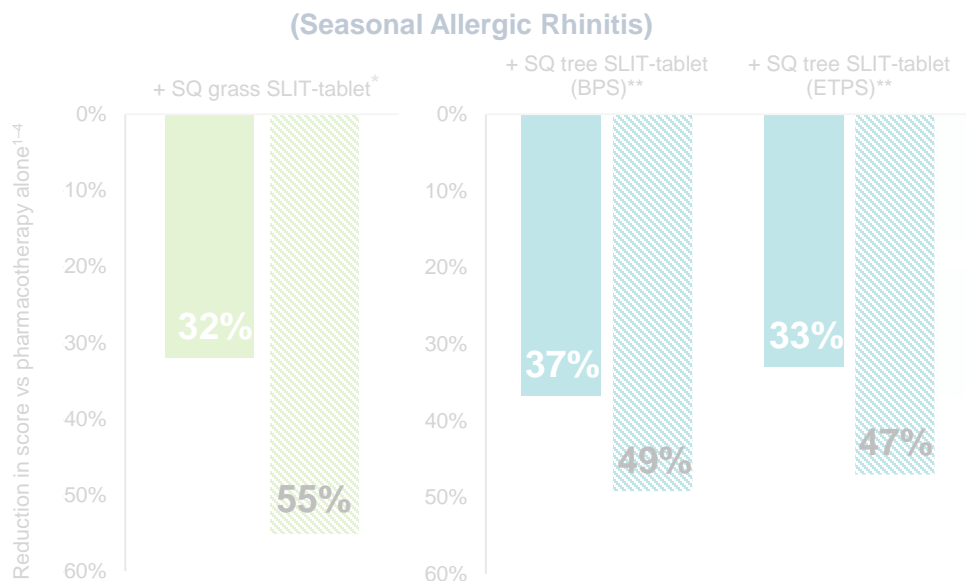


\*Median scores. \*\*Mean scores.

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

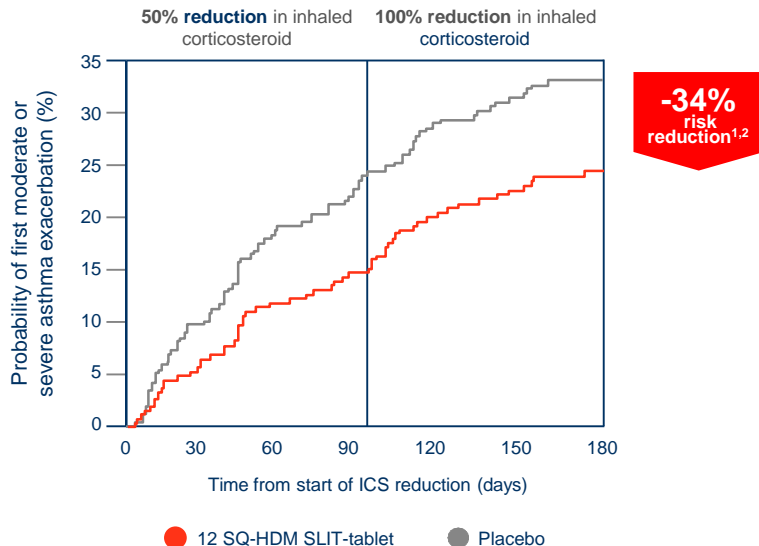
\*Average TCS - combined symptom and medication score. Full analysis set: Placebo (n=487), RAGWIZAX® (n=460). PRPS: Peak ragweed pollen season. RAGWIZAX® is 12 SQ-Amb of standardised allergen extract from short ragweed (*Ambrosia artemisiifolia*).

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.

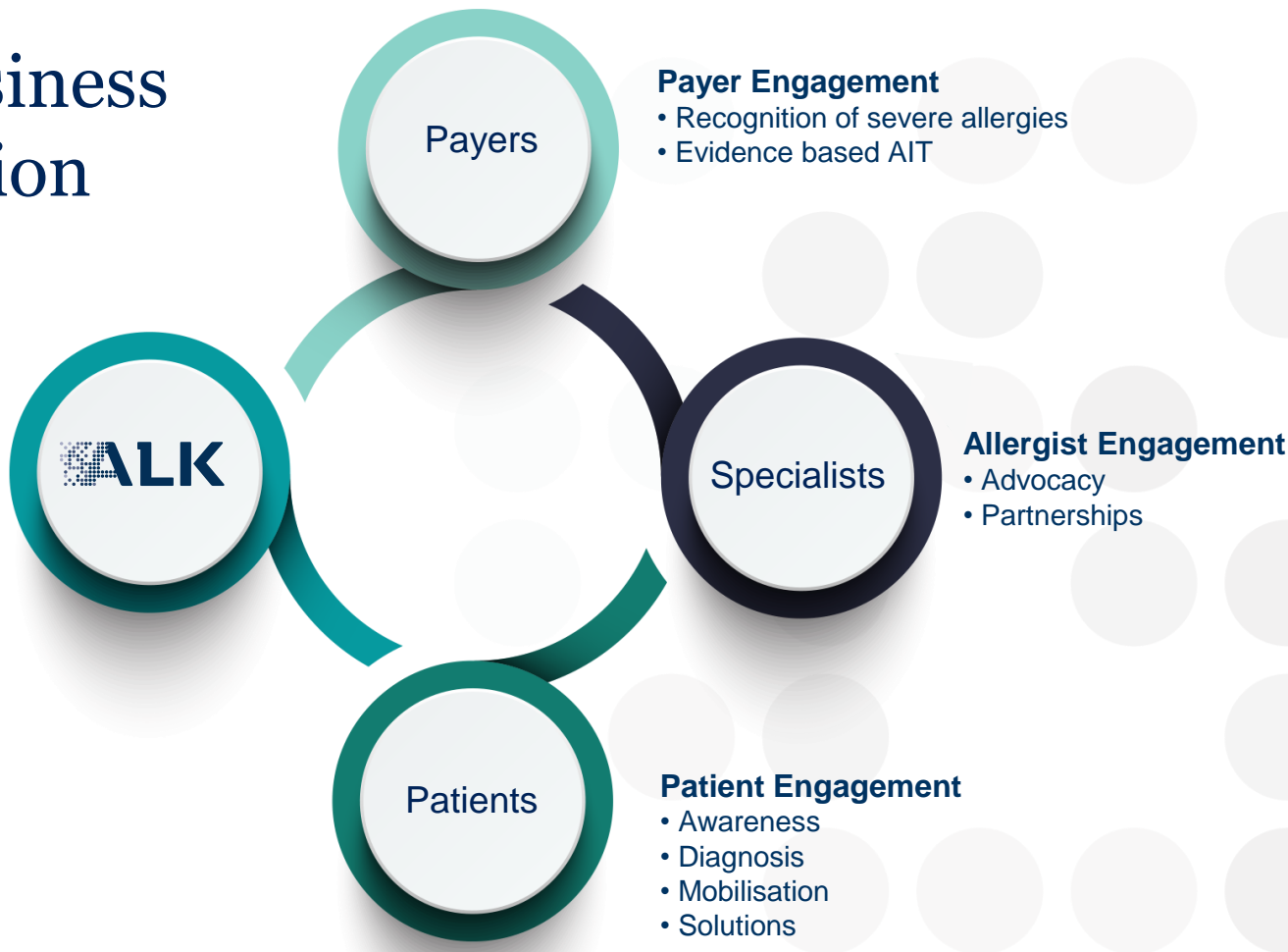


I've been on antihistamines and sprays for several seasons. Isn't there anything more you can do for me?

# The ALK Business Transformation

## ALK

- Tablet portfolio
- Consolidated legacy portfolio



# Resilient sales in Europe and International markets

## Europe



**Q3**

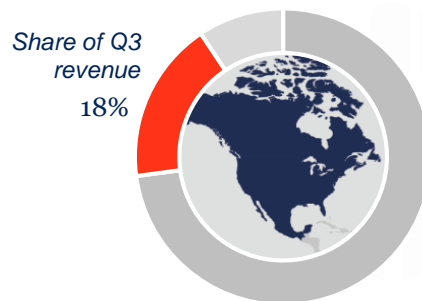


+6%\*

■ 2019 ■ 2020

\*Planned product discontinuations reduced growth by 5 percentage points

## North America



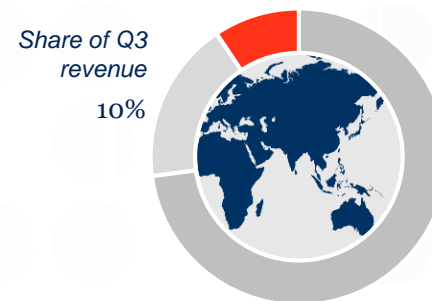
**Q3**



-14%

■ 2019 ■ 2020

## International markets



**Q3**



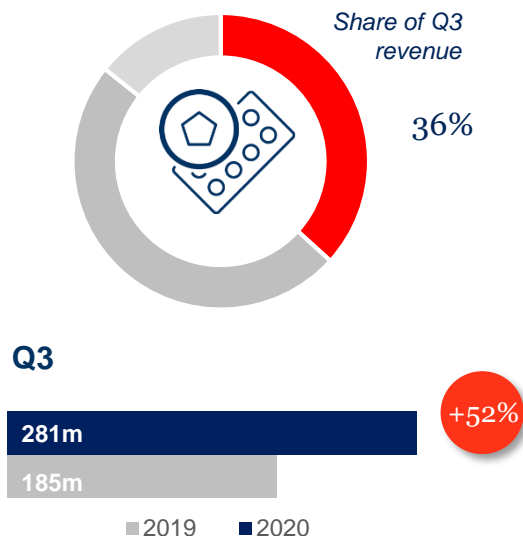
+110%

■ 2019 ■ 2020

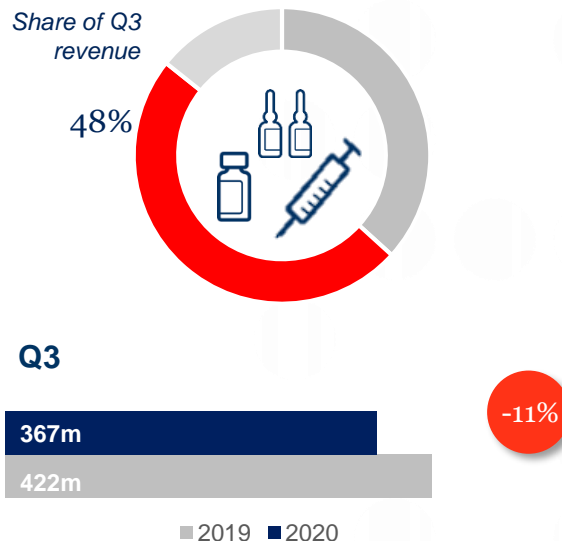
Sales in all markets expressed in DKK  
Growth rates are organic and in local currencies

# Strong, high growth in tablet sales

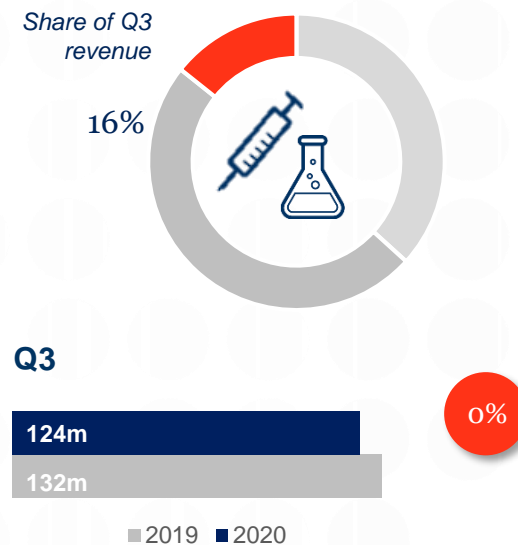
## Tablets



## SCIT/SLIT-drops



## Other products



Sales in all markets expressed in DKK  
Growth rates are organic and in local currencies

# Improved financial robustness

*EBITDA up 72%*

DKK million	9M 2019	9M 2020
Revenue	2,391	2,500
Gross profit	1,377	1,449
<b>Gross margin</b>	<b>58%</b>	<b>58%</b>
Capacity costs	1,383	1,289
<b>EBITDA</b>	<b>193</b>	<b>331</b>
EBIT	(4)	159
<b>Free cash flow</b>	<b>(184)</b>	<b>(67)</b>
<b>Cash/credit facilities</b>	<b>767</b>	<b>780</b>

Change in  
product mix

R&D up 7%  
S&M down 11%

Efficiencies,  
savings and  
delayed R&D  
costs due to  
COVID-19

Higher  
earnings,  
timing of  
payments

# 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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