# Allergy solutions for life

IR roadshow presentation

November 2019



# 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

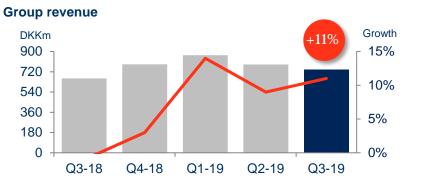


# Q3: On track for double-digit growth

### • Highest-ever Q3 revenue

- 11% overall growth
- o 35% growth in tablet sales
- Strong launch of ITULAZAX<sup>®</sup> in first markets
- Further recovery of SCIT sales
- Full-year outlook updated





#### Growth in tablet sales



Growth rates are in local currencies

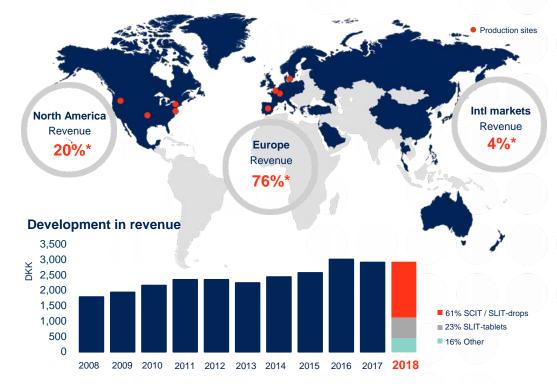


**ALK key figures** 

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

# **Global presence**

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



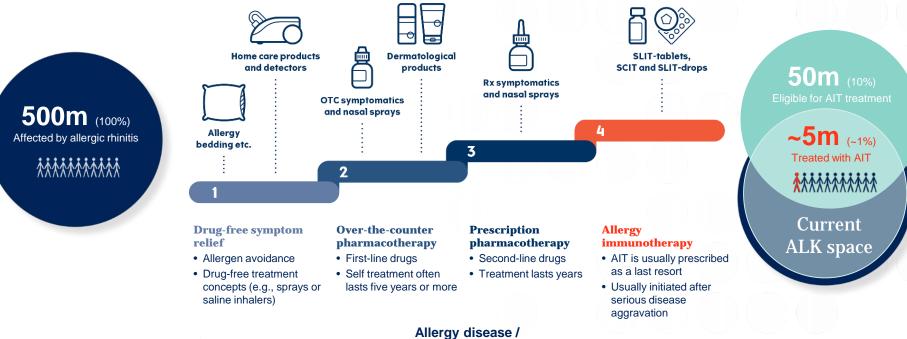


>80%

### ALK

# 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



Pollen count information



# Three year transformation strategy 2018-20

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 ≥10% annually Raise margins quickly to specialty pharma levels after 2020



### **Succeed in North America**

Strategic priority No 1

### Q3 highlights



ALK targets ~10% growth across main product categories

<sup>∧</sup> Tablet sales up 47%

SCIT sales up 2%; up 19% when adjusted for discontinuations



Other products up 29%; strong PRE-PEN<sup>®</sup> sales and improved sales of non-allergy products

### **SLIT-tablets**

Progress on key metrics critical to long-term success in the USA

Improved uptake and Rx depth & breadth

Acceptance growing and doubling number of 'early adopters' in 2019 still achievable

Enhancing sales force effectiveness by upgrading skills and replicating successes



### **Complete and commercialise tablet portfolio for all relevant ages** Strategic priority No 2

### Strong initial launch of tree tablet



ITULAZAX<sup>®</sup> approved in 17 EU markets



More than 4,000 patients initiated in first markets. Germany saw ALK's best ever tablet launch



Positive feedback from HCPs



Completion of tablet range to cover five of the most important respiratory allergies



### Strong commercial and clinical progress

9M sales growth of 44% in-line with full-year expectations

Pivotal trial with ACARIZAX<sup>®</sup> in China

ACARIZAX<sup>®</sup> / ODACTRA<sup>™</sup> paediatric trials in EU and North America

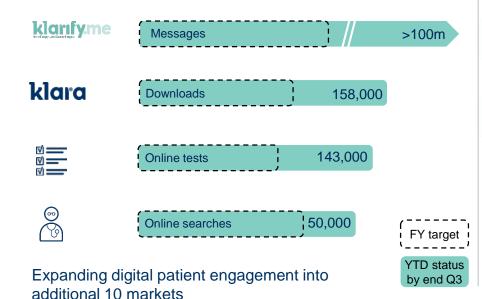
Paediatric filings for ragweed tablet being prepared for EU, USA and Canada



# Patient engagement and adjacent business

Strategic priority No 3

# Digital patient engagement exceeds expectations



### Adjacent products and services

Ongoing development work to launch next-generation epinephrine autoinjector pen in the USA

Ongoing business development of adjacent products and services







# **Optimise and reallocate**

Strategic priority No 4

### Wide-ranging efficiency programme



Ongoing investments in production site strategy; focus on supply chain quality, robustness and scalability



Accelerated portfolio rationalisation (~300 product variants phased out vs. 2016)



Upgraded ALUTARD® product approved and launched in Germany

### Manufacturing footprint Centres of excellence

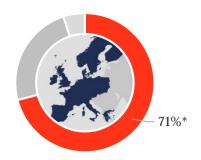




# Growth in all sales regions in Q3

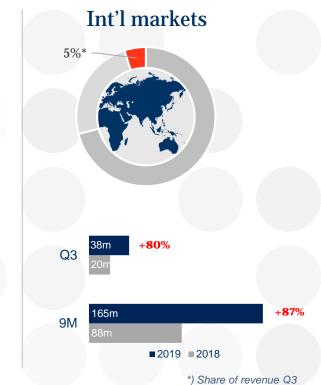
Revenue and growth

Europe





### North America 24%\* +17% 176m Q3 +11% 496m 9M ■2019 ■2018



Growth rates are in local currencies

#### IR roadshow presentation – November 2019



# Europe: Strong underlying tablet growth

- Very good early response to ITULAZAX<sup>®</sup> with ALK's best ever tablet launch in Germany
- Continued rebound for SCIT sales
- SLIT-drops sales normalising in France
- Sales of other products influenced by normalisation of Jext<sup>®</sup> sales and pruning

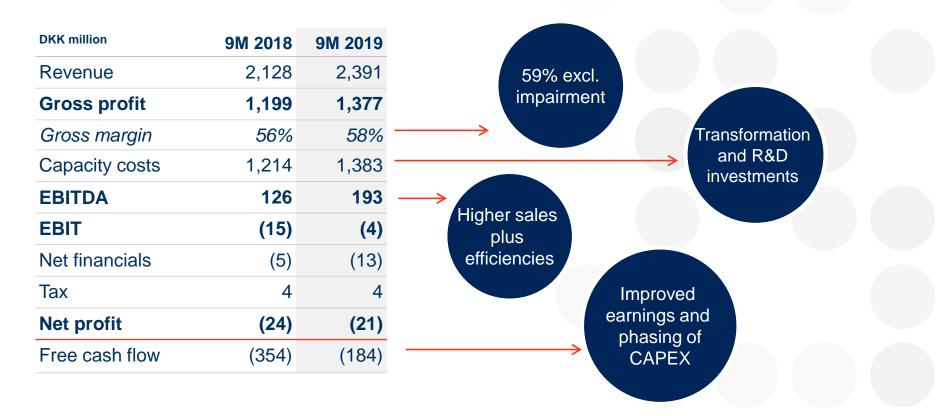








### 9M earnings and cash flow better than expected





# **Financial status**

Q3 2019: Full-year outlook upgraded based on the year-to-date results and the forecast for Q4

DKK million	2015	2016	2017	2018	2019G
Revenue	2,569	3,005	2,910	2,915	3,2-3,300
Gross margin	67%	67%	56%	56%	
R&D	407	385	426	392	
(% of revenue)	16%	13%	15%	13%	
Sales/Marketing & Adm.	1,033	1,140	1,298	1,364	
EBITDA	451	642	253	136	200-250
CAPEX	199	204	267	178	
Free cash flow	18	201	(745)	(264)	~ (200)
Cash and marketable sec.	608	840	711	396	

### 2019 revenue

- Growth across all sales regions
- Strong tablet growth

# 2019 outlook updated

DKK	7 Feb. outlook	9 May outlook	13 Aug Outlook	7 Nov Outlook	Comments	2018 actuals
Revenue	3,100- 3,300m	Tracking towards higher end of range	DKK 3,200- 3,300m	DKK 3,200- 3,300m	Broad-based growth across regions, particularly within tablets. Negative impact from portfolio pruning and SLIT-drops. Minor positive currency impact.	2,915m
EBITDA	100-200m	Tracking towards higher end of range	DKK 150- 250m	DKK 200- 250m	Incrementally higher gross margins, significantly higher R&D costs, increasing S&M costs. Immaterial currency impact.	136m
Free cash flow	~(400)m	(400)m or better	~DKK (300)m	~DKK (200)m	Improved, but still subdued earnings, phasing of CAPEX investments	(294)m

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



# Appendix



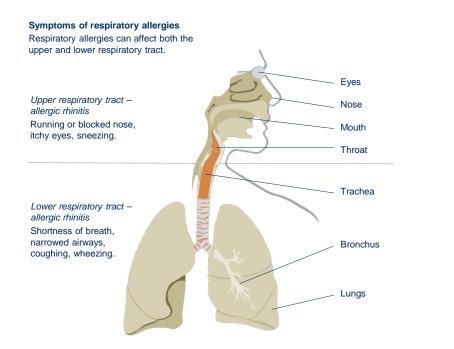


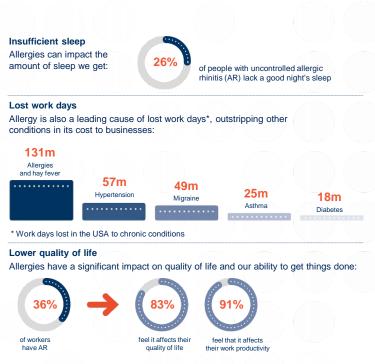
# Pioneer since 1923 – Prevention, Diagnosis & Treatment Leader in disease modifying allergy immunotherapy (AIT) World's 1<sup>st</sup> producer of sublingual AIT tablets (SLIT-tablets)



# 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.





### Allergic Rhinitis is more than a seasonal annoyance



Infections

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



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Disease progression
 & severity
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More likely to have poorly controlled asthma5\*

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

**Sleep disurbance** 



**Performance** 

Associated with reduced productivity and cognitive effects, impacting work and school performance7-9

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#### **Future vulnerability**

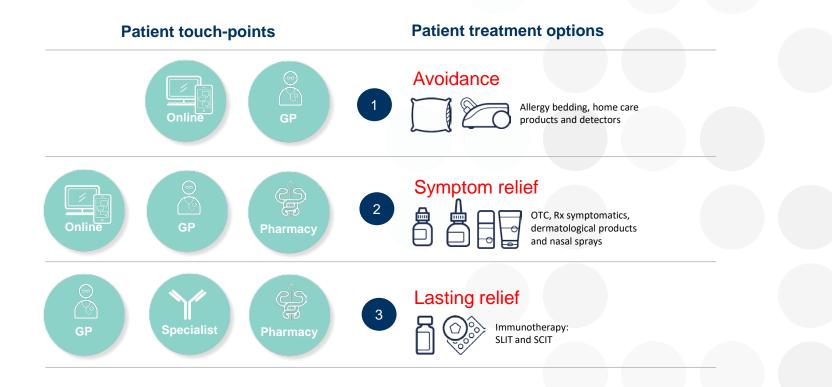
**ALK** 

Increased risk of developing asthma4,10 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

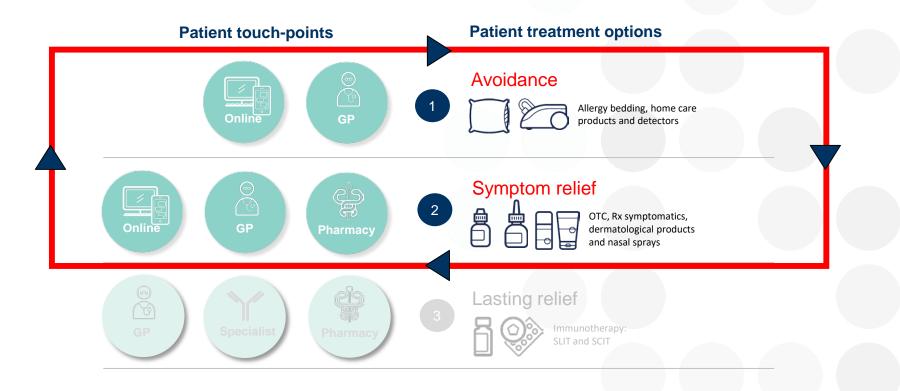


# Treatment strategies in allergy





# 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



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# ALK's current portfolio



# 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

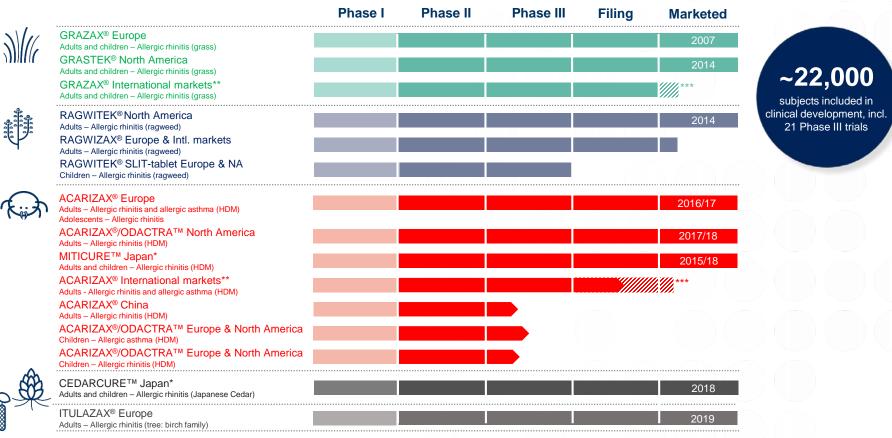
### Manufacturing footprint Centres of excellence





### ALK

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



\*) Licensed to Torii for Japan \*\*) Licensed Abbott for South-East Asia and Seqirus for Australia/New Zealand \*\*\* Already marketed in selected markets



# **SLIT-tablet characteristics**



Allergen extract sourced from native allergens (e.g. grass pollen, tree pollen, ragweed pollen, cedar pollen, house dust mites)



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Fast-dissolving freeze-dried tablet formulation utilising Zydis® technology

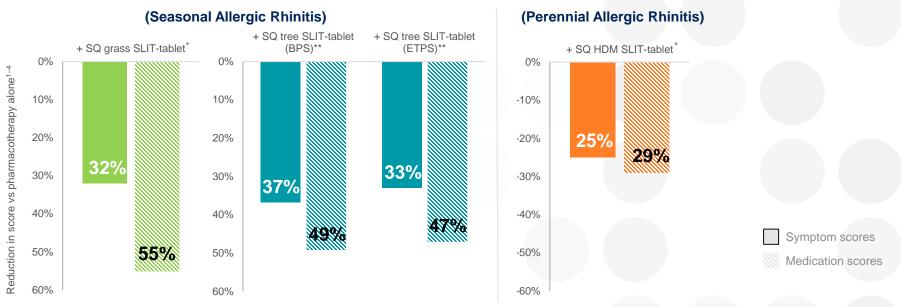




Once-daily home administration



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



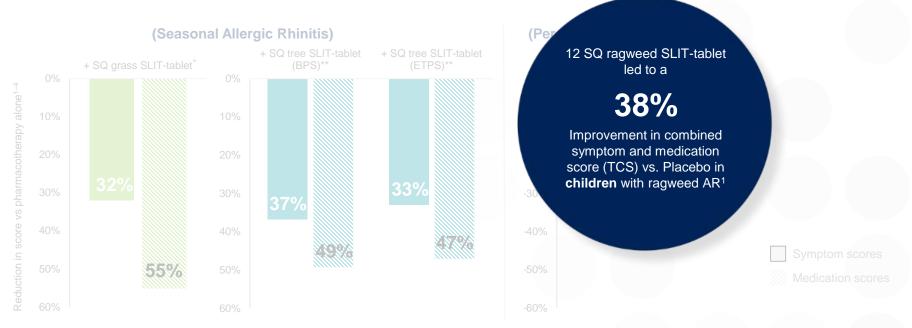
\*Median scores. \*\*Mean scores.

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

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



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

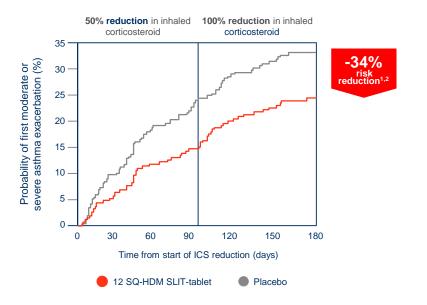




### Commitment to explore and confirm benefits of SQ SLITtablet treatment in asthma

### 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:





Adapted from Virchow JC et al. 2016.1



# 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 symptomrelieving 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 verucosa (birch), Alnus glutinosa (alder), Carpinus betulus (hornbeam), Corylus aveilana (hazel), Quercus alba (oak), Fagus sylvatica (beech). IgE, immunoglobulin, class E; SLIT, sublingual immunotherapy.







### **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.



# Thank you for your attention

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