

# Allergy solutions for life

IR roadshow presentation

September 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

# Q2: Strong commercial and strategic momentum

- **Best-ever Q2 revenue**
  - Underlying growth of 11%
  - 42% growth in tablet sales
  - ITULAZAX<sup>®</sup> approved in Europe
  - Further recovery of SCIT sales
  - Consolidation of Jext<sup>®</sup> sales and new AAI strategy for the USA
- **Full-year outlook upgraded**

## Group revenue



Growth rates are in local currencies

## Global tablet sales



## Avg. growth in tablet sales



# ALK key figures

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



Established in  
**1923**



Employees  
**2,379**



Markets  
**38**



Leader in AIT,  
treating patients  
**~1.7m**



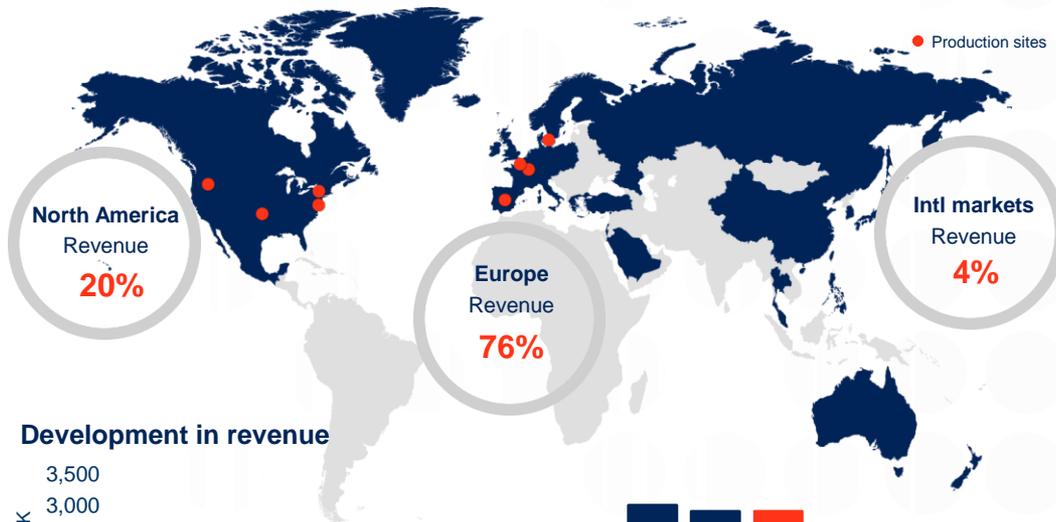
People with allergy  
covered by portfolio of  
new, standardised tablets  
**>80%**



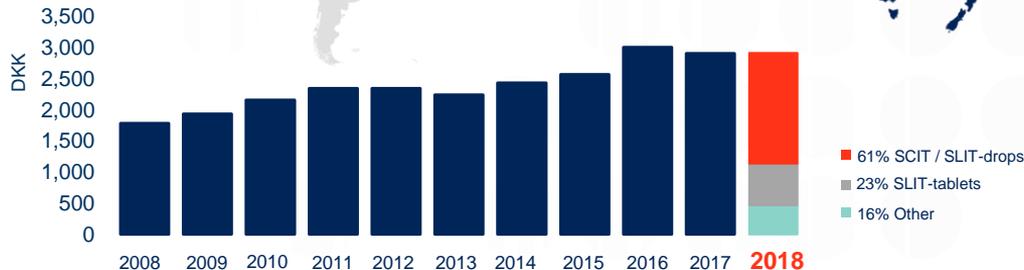
Exclusivity via  
biological  
manufacturing  
process

# Global presence

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

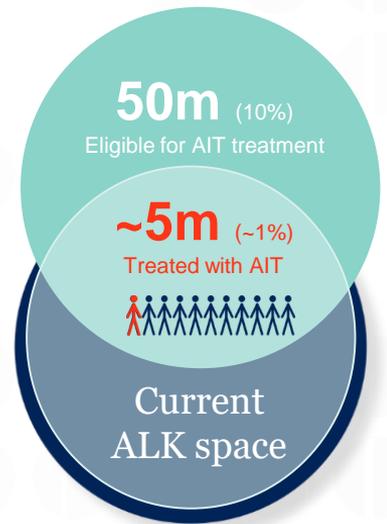
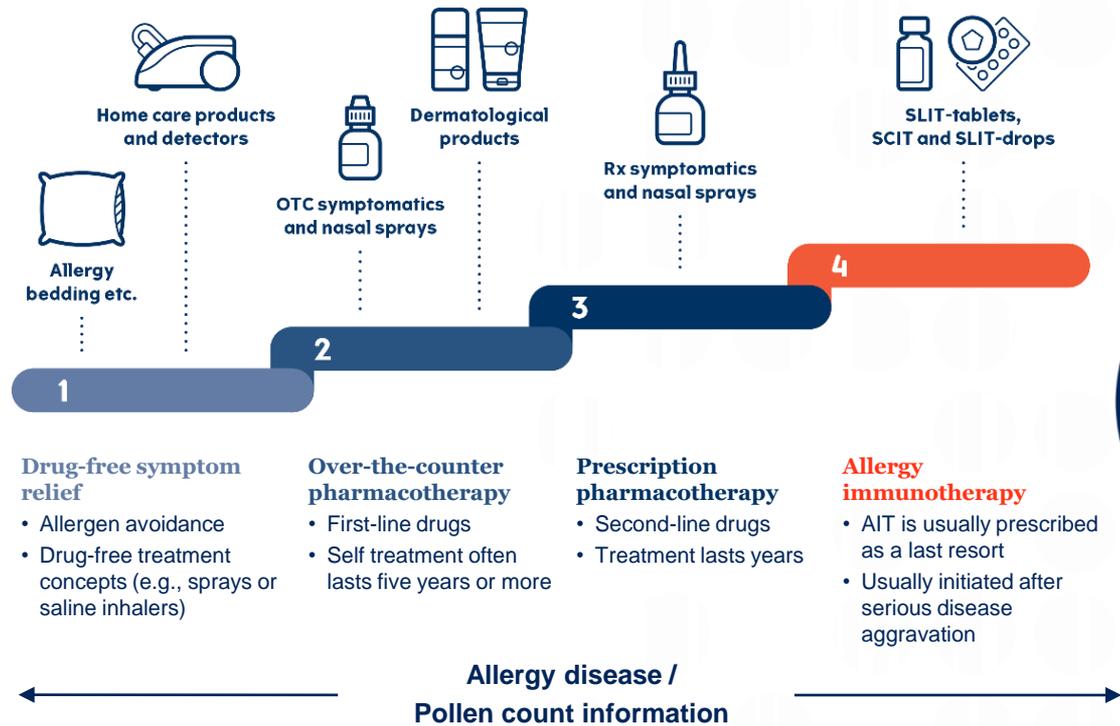
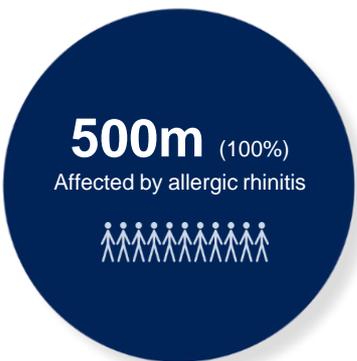


## Development in revenue



# 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



# Execution of strategy on track

*Three-year transformation 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  $\geq 10\%$  annually

Raise margins quickly to specialty pharma levels after 2020

# Succeed in North America

*Strategic priority No 1*

## Q2 highlights



ALK continues to target  $\geq 10\%$  growth across main product categories



Tablet sales up 19%



SCIT sales up 13%; unexpected decline in sales of non-allergy products



Penicillin Dx expansion awaiting FDA discussions

## SLIT-tablets

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

Improved uptake and Rx depth & breadth

Acceptance growing and on-track to double number of 'early adopters' in 2019

Enhancing sales force effectiveness by upgrading skills and replicating successes

# Complete and commercialise tablet portfolio for all relevant ages

*Strategic priority No 2*

## Imminent launch of tree tablet



European approval in 17 countries



Regulatory file submitted in Canada



First launches in 2H 2019 under brand name ITULAZAX®



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



## Strong commercial and clinical progress

Sales of ACARIZAX®/ODACTRA™ doubled

Double-digit growth in sales of pollen allergy tablets, incl. CEDARCURE™

ACARIZAX® / ODACTRA™ paediatric trials in Europe and North America

Pivotal trial with ACARIZAX® in China



# Patient engagement and adjacent business

*Strategic priority No 3*

## Engaging digitally with consumers at scale in German and UK launch markets

**klarify.me**  
by Allergan and AstraZeneca



**klara**



FY target

YTD status by end Q2



## Adjacent products and services

Partnership to launch next-generation epinephrine auto-injector pen in the USA

Ongoing business development of adjacent products and services



# Optimise and reallocate

*Strategic priority No 4*

## Wide-ranging efficiency programme



Production site strategy; focus on supply chain quality, robustness and scalability



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



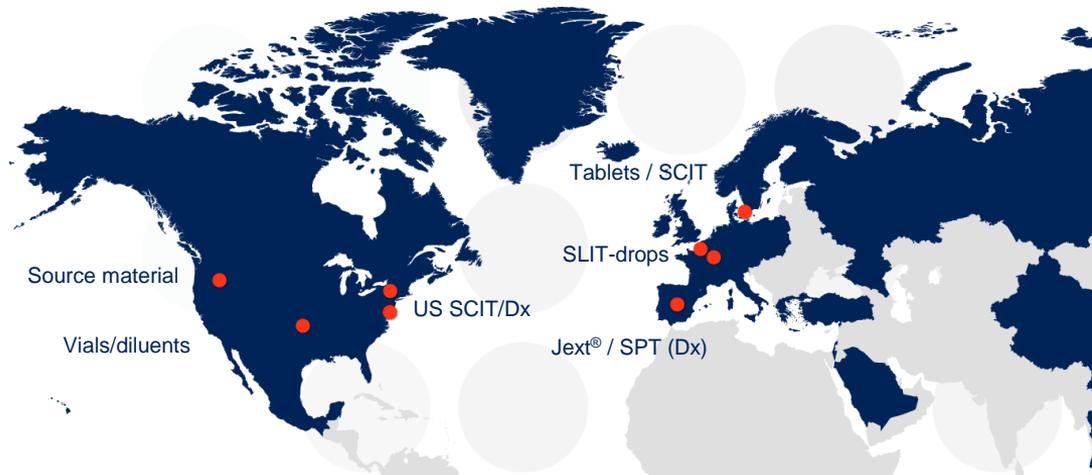
ANSM injunction lifted in France



Divestment of production line dedicated to formulation of tablets

## Manufacturing footprint

Centres of excellence



● Production sites

# Financial status

Q2 2019: Full-year outlook upgraded based on the year-to-date results and the forecast for the second half

DKK million	2015	2016	2017	2018	2019G
<b>Revenue</b>	<b>2,569</b>	<b>3,005</b>	<b>2,910</b>	<b>2,915</b>	<b>3,2-3,300</b>
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	
<b>EBITDA</b>	<b>451</b>	<b>642</b>	<b>253</b>	<b>136</b>	<b>150-250</b>
CAPEX	199	204	267	178	
Free cash flow	18	201	(745)	(264)	~ (300)
Cash and marketable sec.	608	840	711	396	

## 2019 revenue

- Growth across all sales regions
- Strong tablet growth

# Latest 2019 outlook

DKK	7 Feb. outlook	9 May outlook	13 Aug Outlook	Comments	2018 actuals
<b>Revenue</b>	3,100-3,300m	Tracking towards higher end of range	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
<b>EBITDA</b>	100-200m	Tracking towards higher end of range	DKK 150-250m	Incrementally higher gross margins, significantly higher R&D costs, increasing S&M costs. Immaterial currency impact.	136m
<b>Free cash flow</b>	~(400)m	(400)m or better	Approx. DKK (300)m	Subdued earnings and business investments incl. DKK 200m CAPEX to streamline production.	(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.

## Symptoms of respiratory allergies

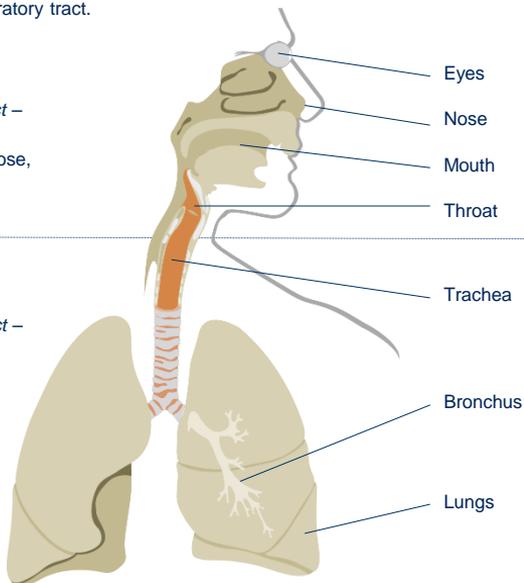
Respiratory allergies can affect both the upper and lower respiratory tract.

### Upper respiratory tract – allergic rhinitis

Running or blocked nose, itchy eyes, sneezing.

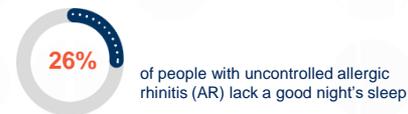
### Lower respiratory tract – allergic rhinitis

Shortness of breath, narrowed airways, coughing, wheezing.



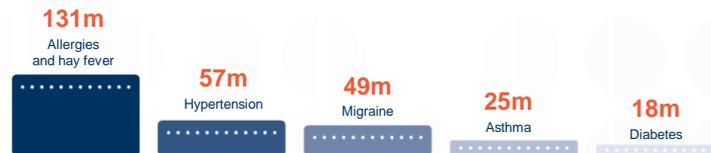
## Insufficient sleep

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

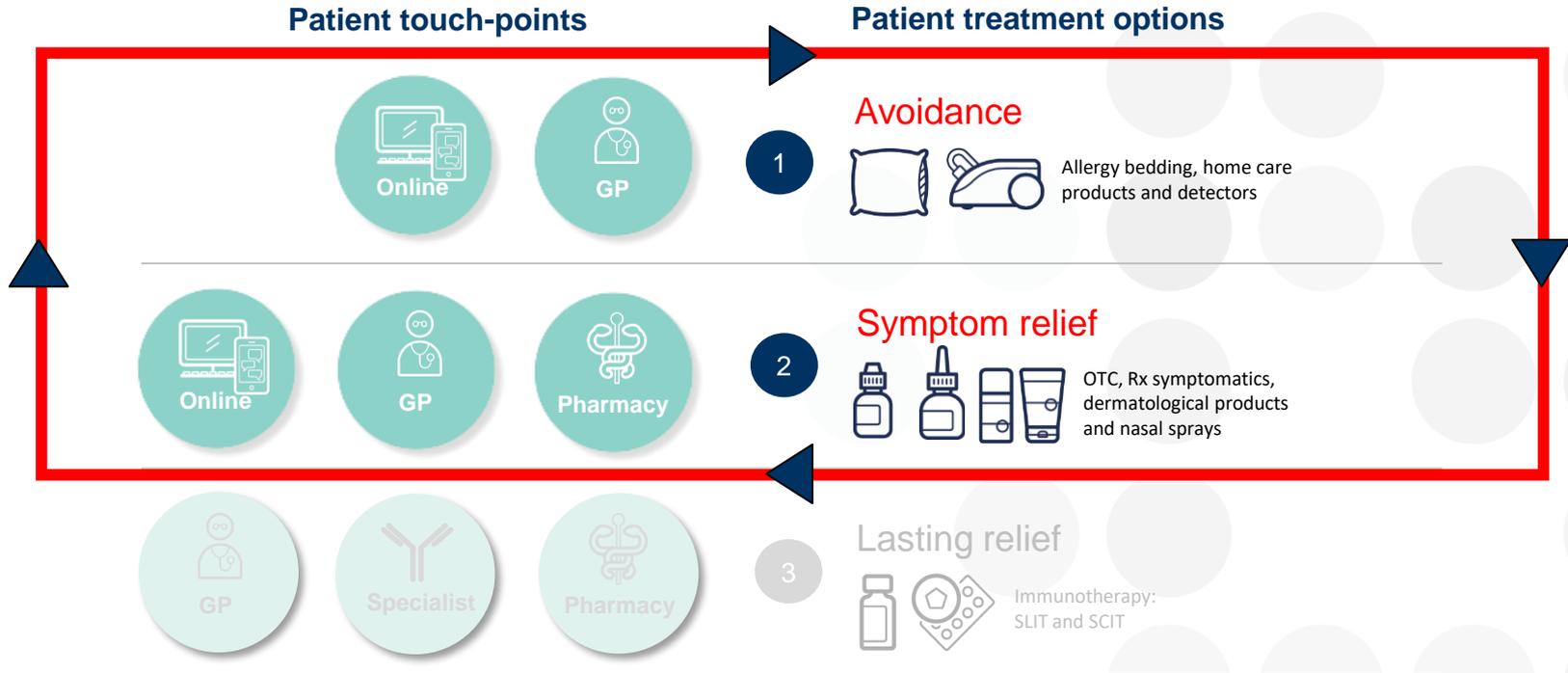
# Treatment strategies in allergy

## 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



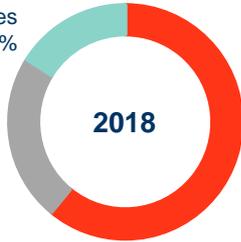
Immunotherapy:  
SLIT and SCIT

# ALK's current portfolio

## Revenue by product line

Other products and services 16%

SLIT-tablets 23%



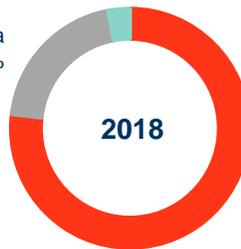
2018

SCIT/SLIT-drops 61%

## Revenue by geography

International markets 4%

North America 20%



2018

Europe 76%



# 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

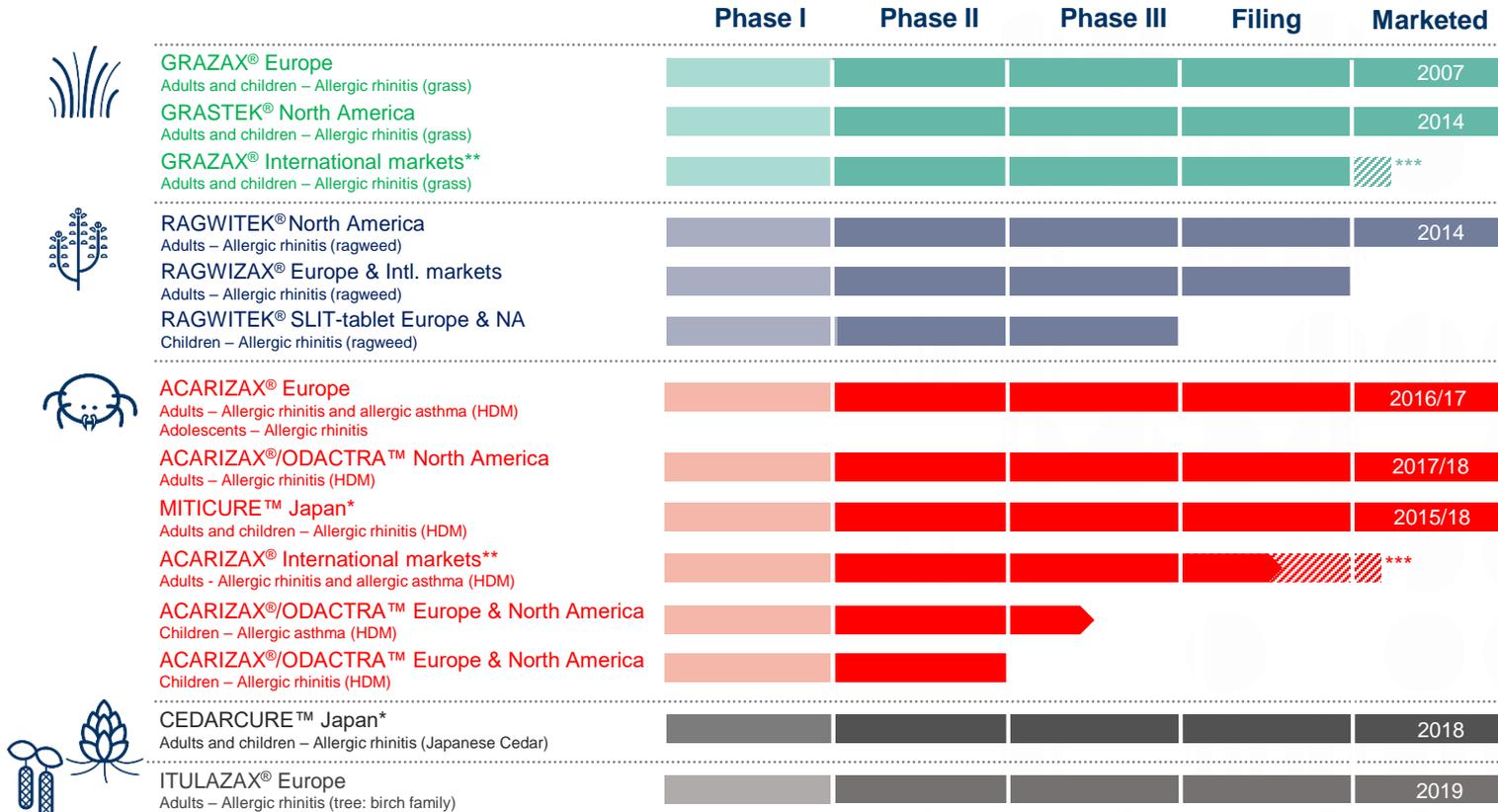
**Tablets:** SLIT-tablets are administered by the patient at home and are available for all the most important respiratory allergies. Tablet-based AIT is the most well-documented allergy treatment

## Manufacturing footprint

Centres of excellence



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



**~22,000**  
subjects included in clinical development, incl. 21 Phase III trials

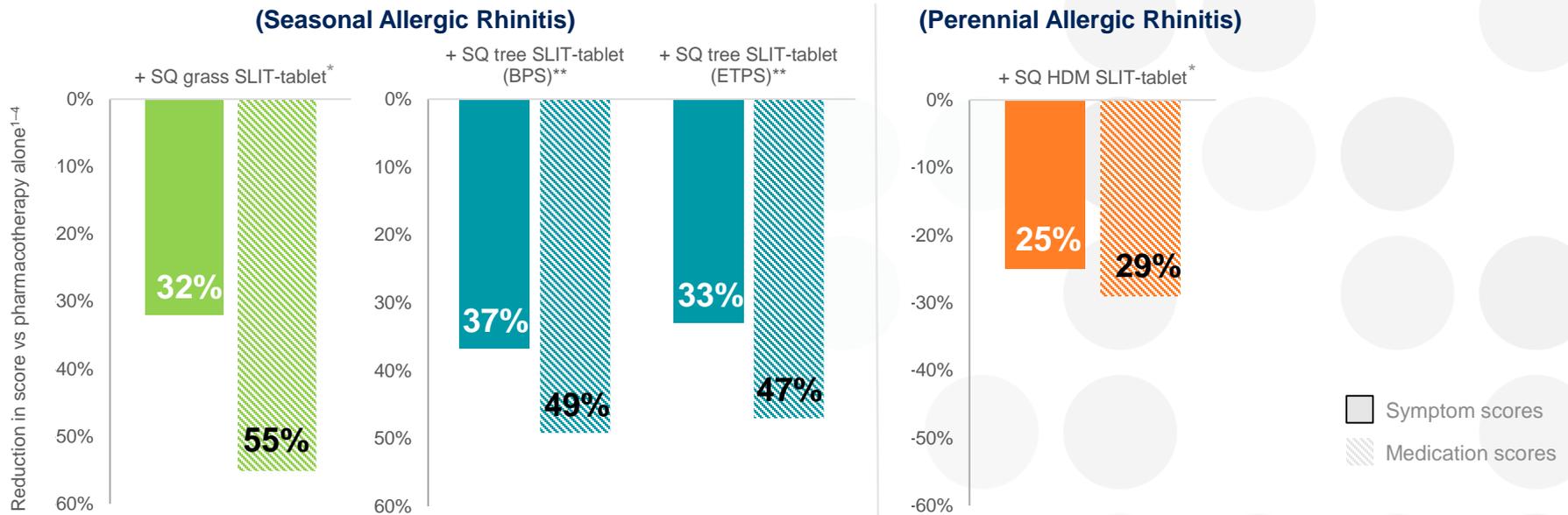
\*) Licensed to Torii for Japan    \*\*) Licensed Abbott for South-East Asia and Seqirus for Australia/New Zealand    \*\*\* Already marketed in selected markets

# SLIT-tablet characteristics

- 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

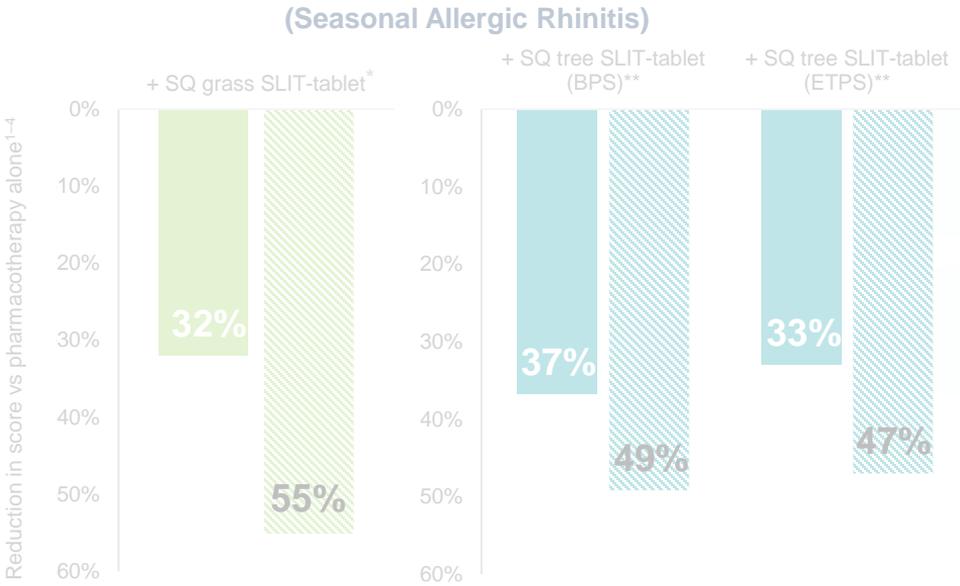


# Consistent improvement in allergy symptoms for **seasonal** and **perennial** allergies with SQ SLIT-tablets



\*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%**

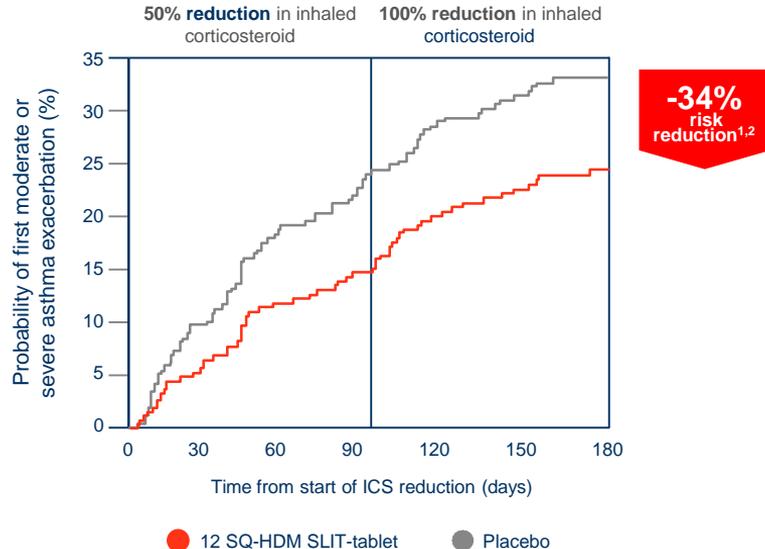
Improvement in combined symptom and medication score (TCS) vs. Placebo in **children** with ragweed AR<sup>1</sup>

□ 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>**

Adapted from Virchow JC et al. 2016.<sup>1</sup>

1. JAMA 2016;315(16):1715–25. 2. ACARIZAX® Summary of Product Characteristics.

# 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>

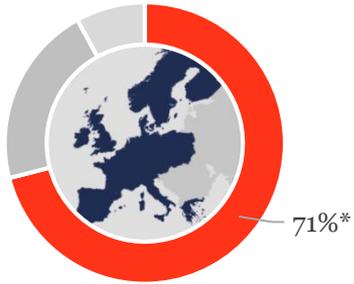
<sup>1</sup>Birch homologous group: *Betula verrucosa* (birch), *Alnus glutinosa* (alder), *Carpinus betulus* (hornbeam), *Corylus avellana* (hazel), *Quercus alba* (oak), *Fagus sylvatica* (beech). IgE, immunoglobulin, class E; SLIT, sublingual immunotherapy.



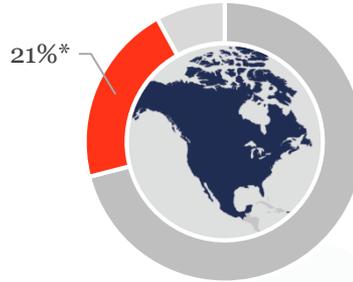
# Growth in all sales regions in Q2

## Revenue and growth

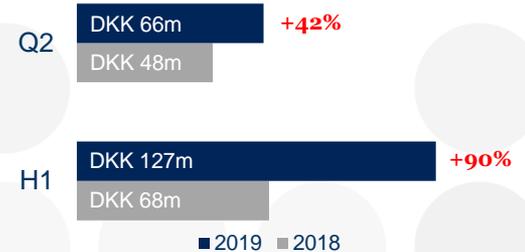
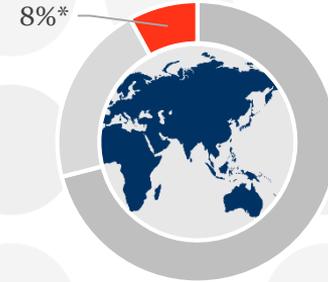
### Europe



### North America



### Int'l markets

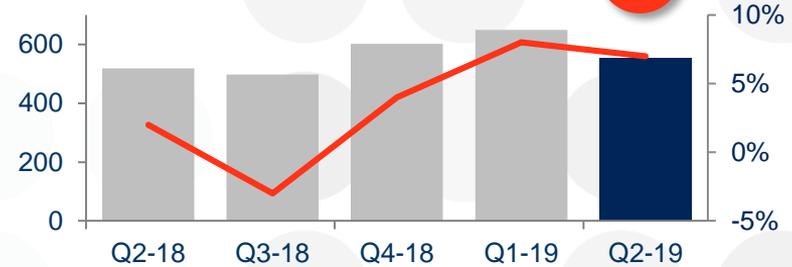


\*) Share of revenue Q2

# Europe: Double-digit tablet growth in most markets

- Strong uptake of ACARIZAX<sup>®</sup> and GRAZAX<sup>®</sup>
- Continued rebound for SCIT sales
- SLIT-drops sales normalising in France
- Sales of Jext<sup>®</sup> auto-injectors consolidated

Revenue in Europe  
DKKkm



Growth rates are in local currencies

SLIT-tablets  
**+36%**

SCIT/SLIT-drops  
**-6%**

0%  
adjusted

Other  
**-2%**

# H1 results better than expected

DKK million	H1 2018	H1 2019
Revenue	1,467	1,652
<b>Gross profit</b>	<b>826</b>	<b>931</b>
<i>Gross margin</i>	56%	56%
Capacity costs	816	917
<b>EBITDA</b>	<b>102</b>	<b>157</b>
<b>EBIT</b>	<b>10</b>	<b>14</b>
Net financials	(3)	(20)
Tax	0	1
<b>Net profit</b>	<b>7</b>	<b>(7)</b>
Free cash flow	(201)	(149)

58% excl.  
impairment

Business and  
transformation  
investments

Higher sales  
and  
efficiencies

Improved  
cash flow from  
operations

# The ALK Business Transformation

- ALK**
- Tablet portfolio
  - Consolidated legacy portfolio



# 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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