

# A world leader in allergy immunotherapy

Q1 2016 results & FY outlook  
Teleconference,  
4 May 2016



# Today's agenda

## Q1 2016

- Highlights
- Market trends
- Financials

## 2016

- ACARIZAX<sup>®</sup> roll-out
- Pipeline and news flow
- European market dynamics
- Outlook

## Q&A session



**EVP, Commercial Operations**  
Søren Niegel



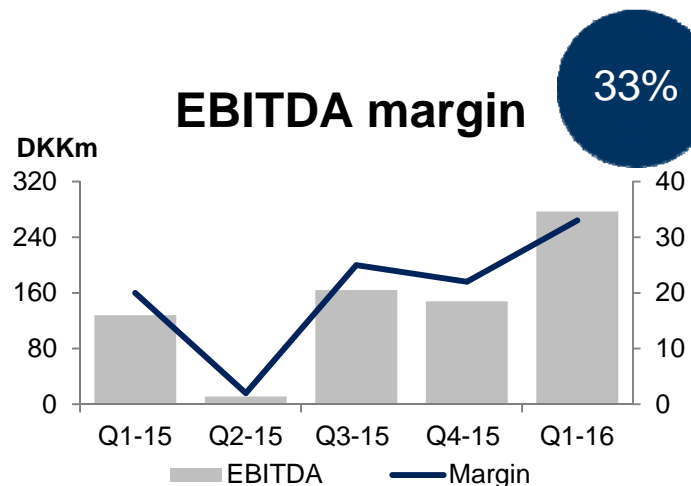
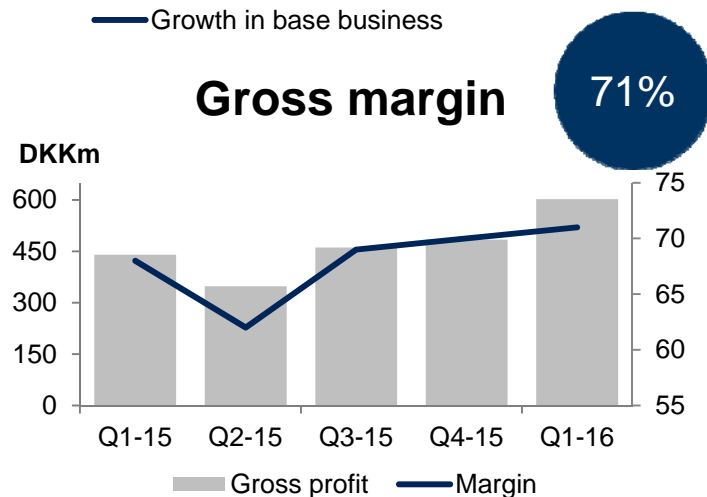
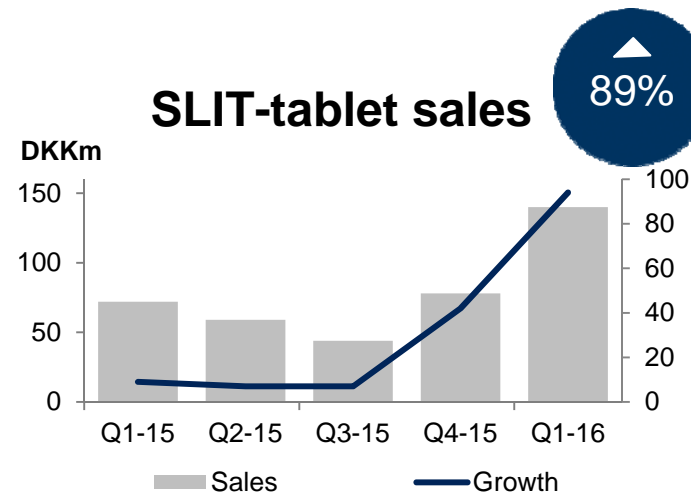
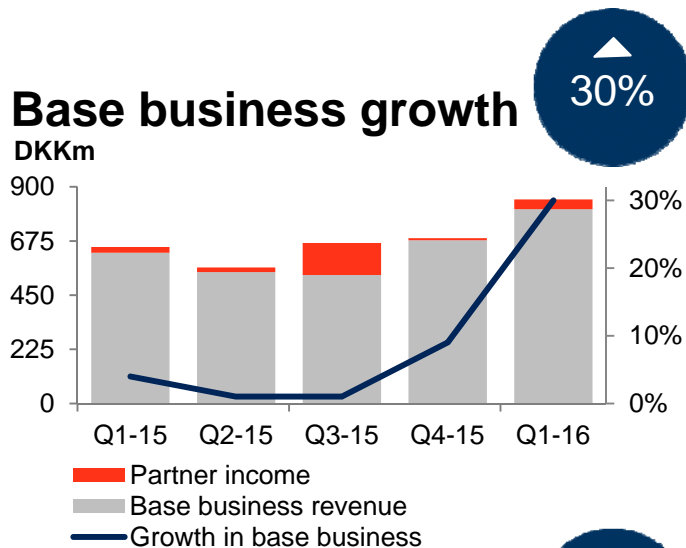
**EVP, Group CFO**  
Flemming Pedersen



**VP, Head of IR**  
Per Plotnikof

# Q1 highlights

Growth rates are stated as organic growth rates in local currencies



# Europe: Double-digit growth

*Growth rates are stated in local currencies*

**31% organic growth → DKK 681m revenue**

- Positive impact from market disruptions

**94% growth in SLIT-tablet sales**

- High number of patient initiations

**19% growth in sales of other products**

- SLIT-drops sales grew by 46%

**Capacity expansion progresses as planned**

- Doubling of SLIT-drops capacity end Q2



# North America: Double-digit growth

*Growth rates are stated in local currencies*

37% growth → Revenue of DKK 151 million

DKK 112 million sales of legacy products (+22%)

- Allergen extracts (SCIT), diagnostics, etc.

DKK 39 million income from MSD (+129%)

- Milestone payment, royalties for GRASTEK<sup>®</sup> and RAGWITEK<sup>®</sup>



# International markets: Underlying growth

*Growth rates are stated in local currencies*

4% decline → Revenue of DKK 16 million

- 26% growth adjusted for last year's upfront payment from Seqirus

32% growth in base business

- Turkey and China

MITICURE™ launched in Japan

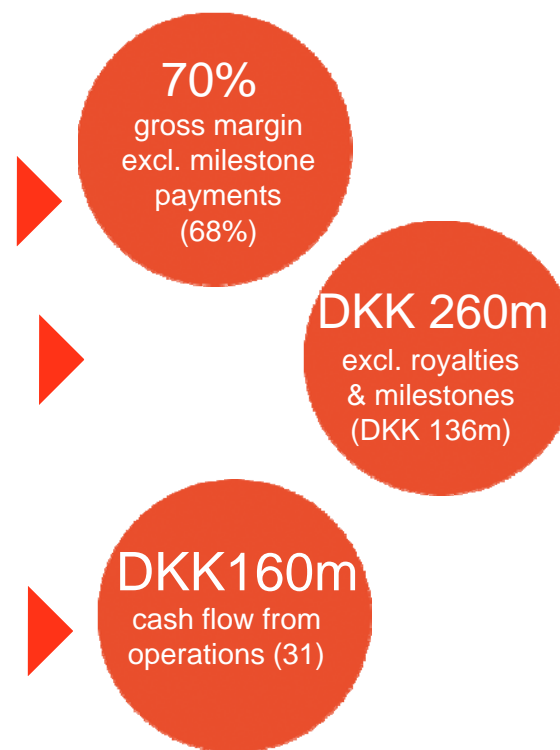
- Minor sales royalties and R&D services

Early-access for ACARIZAX® in Australia



# Better than expected performance

DKK million	Q1 2016	Q1 2015
Base business	807	626
SLIT-tablet partnerships	41	24
Revenue	848	650
Gross profit	602	440
Capacity costs	353	339
EBITDA before special items	296	138
EBITDA	277	128
Net profit	123	89
Free cash flow	155	(3)



# Forward-looking statements

**This presentation contains forward-looking statements, including forecasts of future revenue and operating profit, as well as expected business-related events. Such statements are subject to risks and uncertainties as various factors, some of which are beyond ALK's control, may cause actual results and performance to differ materially from the forecasts made in this presentation.**

**Without being exhaustive, such factors include general economic and business-related conditions including legal issues, uncertainty relating to demand, pricing, reimbursement rules, partners' plans and forecasts, fluctuations in exchange rates, reliance on suppliers, as well as changes to market structures. An additional factor would be the consequences of potential side effects from the use of ALK's products, as allergy immunotherapy may be associated with allergic reactions of differing extents, duration and severity.**

# ACARIZAX<sup>®</sup> European roll-out

## Market authorisation in 12 EU countries

- Launched in Germany and Denmark
- Regulatory approval in Spain in April 2016
- Ongoing discussions on pricing and reimbursement in other countries
- Preparation for additional registrations
- Efforts focused on gaining acceptance and support among key opinion leaders
- Publication in *The Journal of the American Medical Association (JAMA)*



## >5,000 patients so far

- Launched in Germany and Denmark in January - satisfactory sales
- 2016 goal of achieving significant share of 20-30,000 annual HDM initiations



# Major pipeline events in 2016/17

*Pivotal news-flow concerning all five SLIT-tablets*

Events	Exp. timing	
Europe	Next launches of ACARIZAX <sup>®</sup> in EU-12	2016
	Registration of ACARIZAX <sup>®</sup> in additional countries	2016 ▶
	Paediatric development of ACARIZAX <sup>®</sup>	2016 ▶
	<b>GRAZAX<sup>®</sup> Asthma Prevention trial</b>	2016 ✓
	<b>Initiation of Phase III trial with tree SLIT-tablet</b>	2016 ✓
USA	<b>Submission of BLA for ACARIZAX<sup>®</sup></b>	2016 ✓
Canada	Submission of NDA for ACARIZAX <sup>®</sup>	2016
Japan	Phase III trial with MITICURE <sup>™</sup> in paediatric patients	2016/17
	Approval of SLIT-tablet for Japanese cedar pollen	2016/17
Russia	Approvals of GRAZAX <sup>®</sup> and ragweed SLIT-tablet	2016/17
	Regulatory filing of ACARIZAX <sup>®</sup>	2016
Australia	Approvals of ACARIZAX <sup>®</sup> and GRAZAX <sup>®</sup>	2016/17
Rest of World	Turkey: Approval of ACARIZAX <sup>®</sup>	2016/17

# European market dynamics

## Growth enablers

Increasing trend towards evidence-based products

Record-high number of patient initiations

Increased sales and marketing efforts – ACARIZAX®

Expansion of production capacity

## Uncertainties

Speed of main competitors' re-introduction

Response by authorities, practitioners and patients

- Full-year ALK sales now projected to grow by double digits
- Slightly clearer view of market dynamics

# Revised 2016 outlook

Outlook for 2016	Comments	2015
~DKK 2.75bn base business revenue (previously: DKK 2.6bn)	<ul style="list-style-type: none"> <li>• ~15% organic growth</li> <li>• Double-digit growth in all major geographies</li> </ul>	2.38bn
Additional revenue from SLIT-tablet partnerships	<ul style="list-style-type: none"> <li>• No guidance on sales royalties, product supply, services and milestone payments</li> <li>• DKK 40m in additional milestones 2016-17</li> </ul>	185m
~DKK 575m EBITDA before special items, additional sales royalties & milestones (previously: DKK 450m)	<ul style="list-style-type: none"> <li>• New guidance include February milestone</li> <li>• Slightly declining gross margin</li> <li>• Operational efficiencies and cost savings</li> </ul>	331m
DKK 50m special items (previously: DKK 30m)		
~DKK 200m CAPEX (unchanged)	<ul style="list-style-type: none"> <li>• SLIT-tablet capacity, tree AIT, Jext<sup>®</sup></li> </ul>	199m
Free cash flow better than in 2015 (previously: largely on level with 2015)		+18m

# Q&A session



# Thank you for your attention

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

## Upcoming events:

9 May: Copenhagen roadshow

10 May: London roadshow

11 May: Paris roadshow

12 May: Milan roadshow

13 May: Frankfurt roadshow

18 May: SEB/Commerzbank: German & Nordic Market Day, Boston

19 May: SEB NASDAQ Nordic Market Day, New York

10 June: Jefferies Global Healthcare Conference, New York

## Investor Relations:

Per Plotnikof

Head of Investor Relations

Phone: +45 4574 7576

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

