

# Nine-month interim report (Q3) 2015 (unaudited)

## Company release No. 20/2015

#### Performance for the period

(Comparative figures for 2014 are shown in brackets / revenue growth is measured in local currencies. Revenue from ALK's base business is defined as total revenue excluding revenues from the SLIT-tablet partnerships in North America and International markets).

Performance in Q3 was boosted by partner milestone payments:

- ▶ Q3 revenue including partner income grew by 24% to DKK 667 million (522).
- ▶ Q3 revenue in the base business grew by 1% in local currencies to DKK 534 million (515). Adjusted for the phasing out of non-registered SLIT-drop products in the Netherlands, growth was 3%.
- Q3 partner revenue from SLIT-tablets was DKK 133 million (7).
- ▶ Q3 EBITDA before special items was DKK 171 million (57). Excluding milestone payments and sales royalties, EBITDA before special items was DKK 57 million (57).
- ▶ 9M total revenue was DKK 1,882 million (1,821).
- ▶ 9M EBITDA before special items was DKK 329 million (377). Excluding milestones payments and sales royalties, it was DKK 208 million (197) reflecting an improved underlying profitability in the base business despite expanded sales and marketing activities.

#### Pipeline events

ALK made significant progress with its R&D pipeline:

- ▶ In Q3, ALK's lead product candidate, the HDM SLIT-tablet, was approved by the authorities in both Europe and Japan under the brand names ACARIZAX<sup>®</sup> and MITICURE™, respectively. Pricing and reimbursement talks have begun and the first market launches are expected in early 2016.
- ▶ MSD continues to progress in preparation for regulatory submissions in the USA and Canada for the HDM SLIT-tablet, while a regulatory review is ongoing in Australia, Switzerland and Turkey.
- ▶ GRAZAX<sup>®</sup> has been filed for approval in Russia. In Japan, a submission of a registration application for the SLIT-tablet against Japanese cedar pollen allergy is currently expected in 2015/16.

# 2015 financial guidance

The full-year guidance has been updated to include estimated income from ALK's SLIT-tablet partnerships, including a milestone payment from Torii recognised in September:

- ▶ Full-year revenue is now expected to be approximately DKK 2.5 billion (previously: DKK 2.3-2.35 billion excluding the milestone payment from Torii and other income from the SLIT-tablet partnerships). ALK expects to grow revenue in the base business by approximately 3% in local currencies (previously: 3-5%) when excluding a one-off milestone payment received last year.
- ▶ EBITDA before special items is expected to be approximately DKK 400 million (previously: DKK 350-400 million including the milestone payment from Torii, but excluding income from sales royalties and other milestone payments from the SLIT-tablet partnerships). Exchange rates are not expected to materially affect FBITDA
- Free cash flow is projected at around DKK 0 million (previously: negative in the range of DKK 50-100 million excluding sales royalties and milestone payments from the SLIT-tablet partnerships).

Hørsholm, 12 November 2015

#### ALK-Abelló A/S

Contact: Jens Bager, President and CEO, tel. +45 4574 7576

Today, ALK hosts a conference call for analysts and investors at 2.00 p.m. (CET) at which Management will review the financial results and the outlook. The conference call will be audio cast on <a href="www.alk-abello.com/investor">www.alk-abello.com/investor</a>, where the presentation will be available shortly before the call begins. Participants in the audio cast are kindly requested to call in before 1.55 p.m. (CET). Danish participants should call in on tel. 7022 3500 and international participants should call in on tel. +44 (0) 20 7572 1187 or +1 646 722 4972. Please use the following Participant Pin Code: 19234451#.



# FINANCIAL HIGHLIGHTS AND KEY RATIOS FOR THE ALK GROUP (unaudited)

	9M	9M	Full year
Amounts in DKKm	2015	2014	2014
Income statement			
Revenue	1,882	1,821	2,433
Operating profit before depreciation and amortisation (EBITDA)			
pefore special items	329	377	453
Operating profit before depreciation and amortisation (EBITDA)	303	347	404
Operating profit (EBIT) before special items	214	275	313
Operating profit (EBIT)	188	245	264
Net financial items	48	34	36
Profit before tax (EBT)	236	279	300
Net profit	205	165	181
Average number of employees	1,839	1,796	1,809
Balance sheet	4044	2.204	2.440
Total assets	4,014	3,364	3,419
nvested capital	2,462	2,282	2,214
Equity	2,546	2,345	2,354
Cash flow and investments			
Depreciation, amortisation and impairment	115	102	140
Cash flow from operating activities	(4)	163	320
Cash flow from investing activities	(145)	(137)	(219)
of which investment in tangible assets	(99)	(75)	(202)
of which acquisitions of companies and operations	(12)	(24)	(24)
Free cash flow	(149)	26	101
Information on shares	404	101	101
Share capital Shares in thousands of DKK 10 each	101	10,128	10,128
Share price, end of period — DKK	10,128 764	713	651
Net asset value per share – DKK	251	232	232
	251	232	232
<b>Key figures</b> Gross margin — %	66	70	70
EBITDA margin before special items – %	17	21	19
EBITDA margin – %	16	19	17
Earnings per share (EPS) – DKK	21.2	17.1	19.0
Earnings per share (DEPS), diluted – DKK	20.9	16.7	18.0
Cash flow per share (CFPS) – DKK	(0.4)	16.9	33.0
Share price/Net asset value	3.0	3.1	2.8

Definitions: see last page

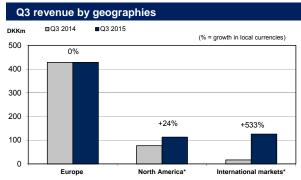


#### **INCOME STATEMENT**

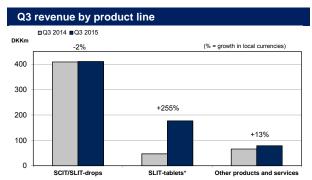
Q3		Q3			9M		9M	
2014	%	2015	%	Amounts in DKKm	2015	%	2014	%
 2014	/0	2010	70	Amounto in Bradii	2010	70	2014	
522	100	667	100	Revenue	1,882	100	1,821	100
184	35	206	31	Cost of sales	633	34	549	30
338	65	461	69	Gross profit	1,249	66	1,272	70
88	17	91	14	Research and development expenses	283	15	278	15
228	44	239	36	Sales, marketing and administrative expenses	752	40	719	39
_	-	_	-	Other operating income and expenses	-	-	-	-
22	4	131	20	Operating profit (EBIT) before special items	214	11	275	15
 (4)	(1)	(7)	(1)	Special items	(26)	(1)	(30)	(2)
 18	5	124	19	Operating profit (EBIT)	188	10	245	17
25	5	(12)	(2)	Net financial items	48	3	34	2
43	10	112	17	Profit before tax (EBT)	236	13	279	19
17	3	50	7	Tax on profit	31	2	114	6
26	5	62	9	Net profit	205	11	165	12
	-			Operating profit before depreciation and				
57	11	171	26	amortisation (EBITDA) before special items	329	17	377	21
53	10	164	25	Operating profit before depreciation	303	16	347	19
55	10	104	25	and amortisation (EBITDA)	303	10	347	19

# **BUSINESS REVIEW**

(Comparative figures for 2014 are shown in brackets. Revenue growth rates are stated as growth in local currencies, unless otherwise indicated)



<sup>\*</sup> Revenue from North America and International markets also includes income from partners, such as milestone payments, product supply, sales royalties, etc.



\* Revenue from SLIT-tablets also includes income from partners, such as milestone payments, product supply, sales royalties, etc.

#### Q3 financial highlights

Revenue growth in ALK's base business (i.e., total revenue excluding the SLIT-tablet partnerships in North America and International markets) was 1%. Progress was driven by SCIT products in North America and parts of Europe as well as by GRAZAX®, Jext® and diagnostics across Europe.

Partner income from the SLIT-tablet partnerships amounted to DKK 133 million (7). The increase was prompted by a milestone payment from Torii, while partner income from North America increased due to sales royalties and R&D service fees.

EBITDA before special items was DKK 171 million (57), yielding an EBITDA margin of 26% (11%). Excluding milestone payments and sales royalties, EBITDA before special items was DKK 57 million (57). EBITDA was negatively influenced by increasing costs in support of the European launch of the HDM SLIT-tablet, by changes in the base business sales mix, and the build-up of manufacturing capacity to supply partners with SLIT-tablets.



# Revenue by geographies

(Comparative figures for 2014 are shown in brackets. Revenue growth rates are stated as growth in local currencies unless otherwise indicated)

## **Europe**

Q3 revenue in Europe of DKK 428 million (428) was unchanged in local currencies. Europe accounted for 64% of total revenue (82%).

GRAZAX® sales advanced in most markets and the Jext® adrenaline auto-injector and diagnostics products were other sources of growth. SCIT-sales were largely unchanged, while SLIT-drops sales, as expected, continued to decline.

In Germany, new treatment guidelines have strengthened demand for evidence-based products such as GRAZAX<sup>®</sup>, while sales of non-registered, named-patient products are weakening. ALK's overall revenue grew in Germany.

Performance was impacted by the phasing-out of the local, unregistered SLIT-drops portfolio in the Netherlands. Excluding this change, revenue in Europe grew by 3%. The phase-out has been completed but will affect comparative figures to the end of year.

9M revenue in Europe amounted to DKK 1,376 million (1,349), reflecting growth of 2%. Adjusted for the phase-out of SLIT-drop sales in the Netherlands, 9M growth in Europe was 4%.

In France, authorities are conducting a general review of pharmaceutical prices. While no final outcome has been reached for ALK, a dialogue with the authorities has been initiated to determine whether there will be any implications for ALK's named-patient products.

# **North America**

Q3 revenue in North America grew by 24% to DKK 113 million (77). North America thus accounted for 17% (15%) of total revenue.

ALK increased sales of allergen extracts, diagnostics, veterinary and other products to specialists and clinics by 12 % to DKK 99 million (75).

Income from the MSD partnership amounted to DKK 14 million, up from DKK 2 million last year.

9M revenue in North America was DKK 335 million (407). The 32% decline was related to last year's three milestone payments totalling DKK 162 million.

#### International markets

Q3 revenue in International markets was DKK 126 million (17). International markets accounted for 19% of total revenue (3%).

ALK recognised a milestone payment from Torii upon approval of MITICURE™ (the HDM SLIT-tablet). Income from other markets – Asia-Pacific, Turkey and China – was down, predominantly due to a slow-down of growth in China.

The acquisition of the Turkish distributor Albio, announced in the six-month report, has been given final approval by authorities and the company's activities have been integrated with those of ALK's Turkish subsidiary.

9M revenue in International markets amounted to DKK 171 million (65) following 145% growth.

# Revenue by product line

#### **SCIT and SLIT-drops**

In Q3, revenue from SCIT and SLIT-drops declined by 2% in local currencies to DKK 411 million (409).

SCIT sales continued to grow in double digits in North America while sales in Europe were flat. SLIT-drops sales continued to decline as a result of changes in reimbursement and documentation requirements.

9M revenue from SCIT and SLIT-drops declined 1% in local currencies to DKK 1,318 million (1,296). Disregarding the phase-out of the Dutch SLIT-drops portfolio, as well as last year's upfront payment from ALK's partner for China, Eddingpharm, 9M revenue grew by 2%.

## **SLIT-tablets**

Q3 revenue from SLIT-tablets grew by 255% to DKK 177 million (47).

The majority of growth came from Japan where ALK recognised a milestone payment from Torii. Total revenue in International markets was DKK 119 million (5) in Q3.

In Europe, sales of GRAZAX® increased by 7% to DKK 44 million (40), with a strong contribution from double-digit growth in Germany. Revenue from SLIT-tablets in North America amounted to DKK 14 million (2).

9M revenue from SLIT-tablets was 351 million (367). The 11% decline was solely due to lower milestone payments versus 2014.



#### Other products and services

In Q3, revenue from other products and services (adrenaline auto-injectors, diagnostics, and other products) grew by 13% to DKK 79 million (66). Both the adrenaline auto-injector Jext<sup>®</sup>, and diagnostics and other products recorded double-digit growth.

9M revenue from other products and services grew by 22% to DKK 213 million (158), mainly due to Jext®, while other products recorded growth of 9%.

# **R&D PIPELINE AND PARTNERSHIPS**

ALK's own pipeline activities, and pipeline activities under the partnerships with MSD, Torii, Abbott and bioCSL made significant progress in Q3.

**ALK's European R&D pipeline activities**In August 2015, ALK successfully completed the registration procedure for ACARIZAX® in 11
European countries, including Europe's two largest AIT markets, Germany and France.

ACARIZAX<sup>®</sup> is indicated in adult patients (18-65 years) diagnosed by a clinical history and by a positive test for HDM sensitisation, with at least one of the following conditions:

- Persistent moderate to severe HDM allergic rhinitis despite the use of symptom-relieving medication.
- HDM allergic asthma not well controlled by inhaled corticosteroids and associated with mild to severe HDM allergic rhinitis.

First launches are expected in early 2016. Moreover, regulatory submissions have been made in Switzerland and Turkey where reviews are ongoing. In parallel, ALK is working to secure registrations in additional European countries.

ALK's other clinical development activities are progressing as planned: The multi-year *GRAZAX*® *Asthma Prevention* (GAP) trial is expected to report top-line data in Q1 2016. Furthermore, ALK is planning the next steps in the clinical development of the tree SLIT-tablet.

#### Partnership with MSD for North America

ALK's partnership with MSD (known as Merck in the USA and Canada) grants MSD exclusive rights to develop, register and commercialise SLIT-tablets against grass pollen, ragweed pollen and house dust mite allergies in the USA, Canada and Mexico.

MSD continues to progress in preparation for regulatory submissions in the USA and Canada for

the HDM SLIT-tablet. The submission will be based on a completed Phase III clinical trial that investigated the safety and efficacy of the HDM SLIT-tablet in the treatment of allergic rhinitis. MSD met with the US Food and Drug Administration in September 2015.

Earlier this year, MSD also completed a clinical trial to investigate the safety and tolerability of co-administering GRASTEK® and RAGWITEK®. The trial showed that co-administering the two products was generally well tolerated. A paediatric development programme for RAGWITEK® has also been initiated and the first patients have been recruited in a clinical trial.

Under the partnership with MSD, ALK may receive up to DKK 1.6 billion (USD 290 million) in milestone payments, of which DKK 500 million (USD 90 million) has been recognised since 2007. In addition, ALK is entitled to royalty payments on net sales as well as payments for product supply and R&D support. MSD incurs all costs of clinical development, registration, marketing and sales of the products. ALK is responsible for tablet production and supply.

#### Partnership with Torii for Japan

ALK and Torii have an exclusive license agreement to develop, register and commercialise ALK's AIT products for asthma and allergic rhinitis in Japan. The agreement grants Torii exclusive rights to develop, market and distribute SLIT-tablets against house dust mite (HDM) and Japanese cedar pollen allergy. The partnership also covers an HDM SCIT product and HDM diagnostic products.

In September 2015, the Japanese Ministry of Health, Labour and Welfare approved the HDM-SLIT tablet in Japan. The tablet, with the local brand name MITICURE™, could reach the market in early 2016. Torii will move ahead with its launch plan once a price for MITICURE™ has been set and reimbursement agreed under Japan's National Health Insurance System.

MITICURE™ is indicated in adults and adolescents (12-64 years) for the treatment of allergic rhinitis caused by house dust mites. Furthermore, Torii has initiated a new clinical Phase III trial to investigate the safety and efficacy of MITICURE™ in paediatric patients (5-11 years).

Meanwhile, Torii is continuing its preparations for the submission of a New Drug Application for a SLIT-tablet for treatment of Japanese cedar pollen allergic rhinitis. The submission is currently



expected in 2015 or 2016 and will be based on positive results from a clinical Phase II/III trial which reported data in August 2015. Subject to approval, this new SLIT-tablet could reach the market in 2017.

Under the partnership with Torii, ALK has now received all potential upfront and development milestone payments totalling DKK 450 million (EUR 60 million). In addition, ALK is entitled to royalty payments, sales milestones on the products' net sales, as well as payments for product supply and R&D support. Torii incurs all costs of clinical development, registration, marketing and sales of the products. ALK is responsible for production and supply.

## Partnership with Abbott for Russia

The partnership with Abbott covers the supply and marketing of ALK's SLIT-tablets in Russia. Abbott is granted exclusive rights to distribute and commercialise ALK's SLIT-tablet portfolio covering grass, ragweed, tree and HDM allergies. The partnership adds ALK's SLIT-tablets, which cover the most prevalent allergies, to Abbott's franchise of respiratory products.

In September 2015, the Abbott-ALK partnership filed for a regulatory approval of GRAZAX® in Russia based on a successfully completed registration trial. Subject to approval by authorities, ALK estimates that GRAZAX® may be launched in Russia during 2017.

Under the agreement, Abbott and ALK will share the revenue generated. Abbott will purchase the products from ALK at agreed prices and, in addition, pay royalties on net sales. ALK will be the marketing authorisation holder.

#### Partnership with bioCSL for Australia

ALK and bioCSL have a partnership for Australia and New Zealand. The agreement grants bioCSL exclusive rights to promote and sell ALK's SLIT-tablets for house dust mite (HDM) allergy and grass pollen allergy as well as ALK's adrenaline autoinjector Jext<sup>®</sup>.

In July 2015, bioCSL filed for regulatory approval of the HDM SLIT-tablet in Australia based on available clinical data from the development programme in Europe. Subject to approval, the HDM SLIT-tablet could reach the market in 2017.

Under the agreement, ALK will receive an undisclosed milestone payment upon approval of the HDM SLIT-tablet in Australia. ALK will be

responsible for product supply and will sell products to bioCSL at an agreed price structure ensuring a split of the final in-market revenues generated by bioCSL.

#### FINANCIAL REVIEW OF 9M 2015

(Comparative figures for 9M 2014 are shown in brackets. Revenue growth rates are stated as growth in local currencies, unless otherwise indicated)

**9M revenue** decreased by 1% in local currencies to DKK 1,882 million (1,821). Exchange rate developments impacted the reported growth positively by approximately 4 percentage points.

Revenue in ALK's base business increased by 3% to DKK 1,706 million when excluding last year's upfront payment from ALK's collaboration partner in China. The phasing-out of the products in the Netherlands reduced the growth in ALK's base business recorded by 2 pp.

Income from the SLIT-tablet partnerships was down 24% to 176 million (203). Last year, ALK booked three milestone payments from MSD totalling DKK 162 million, whereas milestone and upfront payments for the same period this year amounted to DKK 116 million.

Cost of sales increased 15% (10% in local currencies) to DKK 633 million (549) and gross profit was DKK 1,249 million (1,272), which corresponds to a gross margin of 66% (70%). Disregarding milestone payments, the normalised gross margin of 64% (67%) was, as expected, negatively influenced by changes in the base business' sales mix as well as the build-up of capacity to supply partners with SLIT-tablets.

Capacity costs increased 4% (1% in local currencies) to DKK 1,035 million (997). Research and development expenses and administrative expenses were, by and large, unchanged. The 6% increase (2% in local currencies) in sales and marketing expenses reflected a planned increase in activity ahead of the European launch of the HDM SLIT-tablet as well as activities to support ALK's geographical expansion plans.

**EBITDA** (operating profit before depreciation and amortisation) before special items was DKK 329 million (377). Excluding milestones payments and sales royalties, EBITDA before special items improved to DKK 208 million (197) reflecting an improved underlying profitability in the base business despite expanded sales and marketing activities. The improvement was driven by revenue growth and *Simplify* intiatives. Exchange rates only



had a minor positive effect on EBITDA since the positive effect on revenue was largely counterbalanced by the impact on production and capacity costs.

After special items of DKK 26 million (30), **reported EBITDA** was DKK 303 million (347). The special items mainly related to the restructuring of the Product Supply organisation in Q1 and of ALK's commercial organisation in the Netherlands.

**Net financials** saw a gain of DKK 48 million (34) due to unrealised exchange rate gains related to USD and CHF intercompany loans.

**Tax on profit** was DKK 31 million (114), corresponding to an effective tax rate of 13% (41%). As previously reported, tax in Q2 was impacted by a one-off positive adjustment of DKK 73 million following the transfer of activities from the Swiss subsidiary to the Danish parent company.

Net profit increased to DKK 205 million (165).

**Cash flow** from operating activities saw an outflow of DKK 4 million (inflow of 163). This was mainly due to lower milestone and upfront payments.

Cash flow from investment activities saw an outflow of DKK 145 million (137) which primarily related to the continued build-up of capacity for tablet production.

Free cash flow saw an outflow of DKK 149 million (an inflow of 26). Cash flow from financing saw an inflow of DKK 260 million (outflow of 100). As previously reported, ALK has obtained a 20-year mortgage-backed loan of DKK 351 million (net) to strengthen its financial position. At the same time, ALK has paid back a loan of DKK 21 million. Outflows related to the dividend payment of DKK 5 per share, which was declared at the Annual General Meeting in March, as well as net cash settlement of share options.

ALK's holding of its **own shares** was reduced following settlement of share option and conditional share programmes. At the end of September, ALK held 391,051 or 3.9% of its own shares (4.6% at the end of 2014 and 4.6% end-September 2014).

At the end of September, **cash and cash equivalents** totalled DKK 401 million versus DKK 289 million at the end of 2014 and DKK 238 million at the end of September 2014.

**Equity** totalled DKK 2,546 million (2,345) at the end of the period, and the equity ratio was 63% (70%).

## **OUTLOOK FOR 2015**

The full-year guidance has been updated to include estimated income from the SLIT-tablet partnerships, including a milestone payment from Torii recognised in September:

Full-year revenue is now expected to be approximately DKK 2.5 billion (previously: DKK 2.3-2.35 billion excluding the milestone payment from Torii and other income from the SLIT-tablet partnerships).

ALK expects to grow revenue in the base business by approximately 3% in local currencies (previously: 3-5%) based on low, single-digit growth in Europe and high single-digit growth in non-European markets and when excluding a one-off milestone payment received last year. Revenue in the base business is expected to be approximately DKK 2.3 billion (previously: 2.3-2.35 billion).

Full-year revenue from the SLIT-tablet partnerships in North America and International markets are expected to be approximately DKK 200 million.

Production and capacity costs are forecast to increase as ALK increasingly allocates funds in support of key elements of the long-term growth strategy. These include geographical expansion, market-building activities ahead of the launch of the HDM SLIT-tablet in Europe, as well as the scale-up of manufacturing capacity. These initiatives will be partly funded by operational efficiencies and cost savings created by the Simplify programme. Operating profit (EBITDA before special items) is expected to be approximately DKK 400 million (previously: DKK 350-400 million including the milestone payment from Torii, but excluding income from sales royalties and other milestone payments from the SLIT-tablet partnerships). Exchange rates are not expected to materially affect EBITDA.

Initiatives under the *Simplify* programme are expected to entail restructuring costs, which will be reported in a special items line.

CAPEX is projected at approximately DKK 150-200 million (unchanged), while free cash flow is projected at around DKK 0 million (previously: negative in the range of DKK 50-100 million excluding sale royalties and milestone payments from the SLIT-tablet partnerships).



## MID-CYCLE STRATEGY REVIEW

ALK has concluded its regular mid-cycle review of the company's strategy and reaffirmed the goal of transforming ALK from a largely European company focused on allergic rhinitis to a truly global company with a portfolio of standardised and evidence-based products which in addition to allergic rhinitis also treat, and potentially prevent, allergic asthma.

The successful roll out of the new HDM SLIT-tablet is crucial since this product also offers the opportunity to establish SLIT-tablets as a recognised and regularly prescribed treatment for allergic asthma patients.

In Germany, treatment guidelines have been updated to stress the importance of prescribing registered and scientifically documented allergy immunotherapy products, while, in Italy, ALK secured national reimbursement for GRAZAX® for the first time. These developments fit well with ALK's Allergy Unlocked® activities designed to help improve the way respiratory allergic disease is perceived and treated, with the goal of broadening access to AIT.

ALK continuously makes adjustments to the strategy to support value creation. Wherever possible, ALK will investigate opportunities to accelerate the ongoing rationalisation of the product portfolio to gradually focus sales efforts on more profitable, high volume, evidence-based products, i.e. the SLIT-tablets.

#### Preliminary revenue outlook for 2016

In line with the previously communicated mediumterm strategic growth outlook, ALK expects to grow revenue in the base business during 2016 by 0-5%.

In addition to base business growth, the SLIT-tablet partnerships are expected to contribute to overall revenue growth when disregarding milestone payments. While ALK continues to take a conservative view of the SLIT-tablets' sales uptake in the first few years, growth is expected to accelerate from 2017 provided that the HDM SLIT-

tablets is launched in Japan, North America and other markets.

In North America, the SLIT-tablets represent a new treatment class; the concept of pre-seasonal treatment initiation is new, and the practitioners have traditionally favoured multi-allergen compounded allergy shots. ALK remains confident in the long-term potential for SLIT-tablets in North America: A significant number of eligible patients have either refused allergy shots or have abandoned treatment. A wider adoption of the SLIT-tablets may occur, once the HDM SLIT-tablet reaches the North American markets as this tablet will allow MSD to offer a complete portfolio of SLIT-tablets targeting the three main respiratory allergies.

As usual, ALK will provide a detailed financial outlook for 2016 in its Annual Report for 2015 to be released on 9 February 2016.

# **RISK FACTORS**

This interim report contains forward-looking statements, including forecasts of future revenue and operating profit as well as expected businessrelated 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 interim report. Without being exhaustive, such factors include e.g., general economic and businessrelated 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. An additional factor is potential 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.

# 2016 Financial calendar

Silent period Annual report 2015 12 January 2016 9 February 2016



## STATEMENT BY MANAGEMENT

The Board of Directors and Board of Management today considered and approved the interim report of ALK-Abelló A/S for the period 1 January to 30 September 2015.

The interim report has been prepared in accordance with IAS 34 'Interim financial reporting' as adopted by the EU and additional Danish disclosure requirements for the interim reports of listed companies. As in previous years, the interim report has not been subject to audit or review.

In our opinion, the interim report gives a true and fair view of the Group's assets, equity and liabilities, financial position, results of operations and cash flow for the period 1 January to 30 September 2015. Moreover, in our opinion, the interim report gives a true and fair view of developments in the Group's activities and financial position and describes significant risk and uncertainty factors that may affect the Group.

# Hørsholm, 12 November 2015

## **Board of Management**

Jens Bager Henrik Jacobi
President and CEO Executive Vice Pres

Henrik Jacobi Søren Daniel Niegel
Executive Vice President Executive Vice President
Research & Development Commercial Operations

Flemming Pedersen

CFO & Executive Vice President

Helle Skov

**Executive Vice President** 

**Product Supply** 

#### **Board of Directors**

Steen Riisgaard Lene Skole Lars Holmqvist Vice Chairman

Andreas Slyngborg Holst Jacob Kastrup Anders Gersel Pedersen

Jakob Riis Katja Barnkob Thalund Per Valstorp



# INCOME STATEMENT FOR THE ALK GROUP (unaudited)

Q3	Q3		9M	9M
2014	2015	Amounts in DKKm	2015	2014
522	667	Revenue	1,882	1,821
184	206	Cost of sales	633	549
338	461	Gross profit	1,249	1,272
88	91	Research and development expenses	283	278
182	193	Sales and marketing expenses	607	575
46	46	Administrative expenses	145	144
	-	Other operating expenses	-	-
22	131	Operating profit (EBIT) before special items	214	275
(4)	(7)	Special items	(26)	(30)
18	124	Operating profit (EBIT)	188	245
25	(12)	Net financial items	48	34
43	112	Profit before tax (EBT)	236	279
17	50	Tax on profit	31	114
26	62	Net profit	205	165
2.69	6.40	Earnings per share (EPS) – DKK	21.17	17.08
2.63	6.32	Earnings per share (DEPS), diluted – DKK	20.86	16.68

# STATEMENT OF COMPREHENSIVE INCOME (unaudited)

Q3	Q3		9M	9M
2014	2015	Amounts in DKKm	2015	2014
26	62	Net profit for the period	205	165
		p p		
		Other comprehensive income		
		Other comprehensive income		
		Items that will be reclassified subsequently to the Income statement, when		
		specific conditions are met:		
28	(2)	Foreign currency translation adjustment of foreign subsidiaries	43	31
-	-	Net fair value adjustment of financial assets available for sale	-	-
-	-	Cash flow hedges, deferred gain/loss incurred during the period	-	-
-	-	Gain on sale of financial assets available for sale recognised in financial income	-	(10)
(4)	-	Tax related to other comprehensive income	(4)	(1)
24	(2)	Other comprehensive income	39	20
	. ,	•		
50	60	Total comprehensive income	244	185



# CASH FLOW STATEMENT FOR THE ALK GROUP (unaudited)

	9M	9M
Amounts in DKKm	2015	2014
Net profit	205	165
Adjustments:		
Tax on profit	30	114
Financial income and expenses	(48)	(34)
Share-based payments	12	9
Depreciation, amortisation and impairment	115	102
Change in provisions	(3)	1
Change in working capital	(204)	(93)
Net financial items, paid	(7)	11
Income taxes, paid	(104)	(112)
Cash flow from operating activities	(4)	163
Acquisitions of companies and operations	(12)	(24)
Additions, intangible assets	(32)	(44)
Additions, tangible assets	(99)	(75)
Change in other financial assets	(2)	6
Cash flow from investing activities	(145)	(137)
Free cash flow	(149)	26
Dividend noid to shougholders of the negati	(40)	(40)
Dividend paid to shareholders of the parent	(49) 19	(49)
Sale of treasury shares Exercise of share options		-
·	(34) 324	- (2)
Change in financial liabilities		(2)
Cash flow from financing activities	260	(100)
Net cash flow	111	(74)
Cash and cash equivalents at 1 January	289	312
Unrealised gain/(loss) on foreign currency and financial assets carried as	200	0.2
cash and cash equivalents	1	_
Net cash flow	111	(74)
Cash and cash equivalents at 30 September	401	238

The cash flow statement has been adjusted to the effect that exchange rate adjustments in foreign subsidiaries are not included in the statement. As a result, the individual figures in the cash flow statement cannot be reconciled directly to the income statement and balance sheet.



# BALANCE SHEET - ASSETS FOR THE ALK GROUP (unaudited)

	20 Sont	31 Dec.	20 Sont
Amounts in DKKm	30 Sept. 2015	2014	30 Sept. 2014
		<del>-</del>	
Non-current assets			
Intangible assets			
Goodwill	421	415	415
Other intangible assets	331	248	300
	752	663	715
Tangible assets			
Land and buildings	706	681	682
Plant and machinery	414	328	331
Other fixtures and equipment	57	59	59
Property, plant and equipment in progress	371	481	366
	1,548	1,549	1,438
Other non-current assets			
Securities and receivables	9	7	7
Deferred tax assets	323	168	142
	332	175	149
Total non-current assets	2,632	2,387	2,302
Current assets			
Inventories	466	408	379
Trade receivables	304	240	299
Receivables from affiliates	16	1	57
Income tax receivables	14	13	12
Other receivables	154	53	46
Prepayments	27	28	31
Cash and cash equivalents	401	289	238
Total current assets	1,382	1,032	1,062
Total assets	4,014	3,419	3,364



# BALANCE SHEET - EQUITY AND LIABILITIES FOR THE ALK GROUP (unaudited)

	30 Sept.	31 Dec.	30 Sept.
Amounts in DKKm	2015	2014	2014
Equity	404	404	404
Share capital	101	101	101
Currency translation adjustment	58	16	4
Retained earnings	2,387	2,237	2,240
Total equity	2,546	2,354	2,345
Liabilities			
Non-current liabilities			
Mortgage debt	331	20	20
Bank loans and financial loans	299	299	299
Pensions and similar liabilities	198	190	158
Other provisions	4	4	7
Deferred tax liabilities	61	28	29
	893	541	513
Current liabilities			
Mortgage debt	17	2	2
Bank loans and financial loans	2	3	3
Trade payables	60	90	63
Income taxes	75	6	40
Other provisions	21	32	32
Other payables	400	391	366
Cultivi payables	575	524	506
	J. <b>G</b>		200
Total liabilities	1,468	1,065	1,019
Total equity and liabilities	4,014	3,419	3,364



# EQUITY FOR THE ALK GROUP (unaudited)

	Share	Currency translation	Retained	Total
Amounts in DKKm	capital	adjustment	earnings	equity
Equity at 1 January 2015	101	16	2,237	2,354
			•	·
Net profit	-	-	205	205
Other comprehensive income	-	43	(4)	39
Total comprehensive income	-	43	201	244
Share-based payments	-	-	12	12
Share options settled	_	_	(34)	(34)
Purchase of treasury shares	_	_	-	-
Sale of treasury shares	_	_	19	19
Dividend paid			(51)	(51)
Dividends on treasury shares			(31)	(31)
Other transactions	-		(52)	(52)
Other transactions	-		(32)	(32)
Equity at 30 September 2015	101	59	2,386	2,546
Equity at 1 January 2014	101	(27)	2,175	2,249
Equity at 1 Junuary 2014	101	(21)	2,170	2,240
Net profit	_	_	165	165
Other comprehensive income	_	31	(11)	20
Total comprehensive income		31	154	185
Total comprehensive income			104	100
Share-based payments	-	-	9	9
Purchase of treasury shares	-	-	(49)	(49)
Dividend paid	-	-	(51)	(51)
Dividends on treasury shares	-	-	2	2
Other transactions	-	-	(89)	(89)
			` /	/
Equity at 30 September 2014	101	4	2,240	2,345



# NOTES (unaudited)

## 1 ACCOUNTING POLICIES

The interim report for the period 1 January to 30 September 2015 is presented in accordance with IAS 34 'Interim financial reporting' as adopted by the EU and additional Danish disclosure requirements for interim reports of listed companies. The additional Danish disclosure requirements are defined in the Danish Executive Order on Interim Reports issued under the Danish Financial Statements Act. The accounting policies are unchanged compared to the Annual Report 2014, except for all new, amended or revised accounting standards and interpretations effective from 1 January 2015. These have no material impact on the interim report. Please see the Annual Report 2014 for a more detailed description of the Group's accounting policies.

#### 2 REVENUE

			North		Intern	national		
	Europe		Am	erica	mar	kets	Tot	al
Amounts in DKKm	9M 2015	9M 2014	9M 2015	9M 2014	9M 2015	9M 2014	9M 2015	9M 2014
SCIT/SLIT-drops	1,087	1,103	195	143	36	50	1,318	1,296
SLIT-tablets	175	162	43	192	133	13	351	367
Other products and services	114	84	97	72	2	2	213	158
Total revenue	1,376	1,349	335	407	171	65	1,882	1,821
Sale of goods							1,708	1,598
Royalties							5	2
Milestone and upfront payments							116	178
Services							53	43
Total revenue							1,882	1,821
Rase husiness revenue (i.e. total re	evenue exclu	ding the SLIT-	tahlet nartne	rshins in Nortl	n America			
Base business revenue (i.e. total revenue excluding the SLIT-tablet partnerships in North America and International markets)						1,706	1,618	
Partner revenue							176	203
Total revenue							1,882	1,821

	Europ	Α	Norti Ameri		Internat marke		Total	
Growth, 9M 2015	Growth local currencies	Growth						
SCIT/SLIT-drops	-2%	-1%	15%	36%	-36%	-28%	-1%	2%
SLIT-tablets	8%	8%	-82%	-78%	930%	923%	-11%	-4%
Other products and services	33%	36%	11%	35%	15%	0%	22%	35%
Total revenue	2%	2%	-32%	-18%	145%	163%	-1%	3%



# NOTES (unaudited)

# 2 REVENUE (CONTINUED)

	Fu	Europe		North America		International markets		Total	
Amounts in DKKm	Q3 2015	Q3 2014	Q3 2015	Q3 2014	Q3 2015	Q3 2014	Q3 2015	Q3 2014	
SCIT/SLIT-drops	338	348	66	50	7	11	411	409	
SLIT-tablets	44	40	14	2	119	5	177	47	
Other products and services	46	40	33	25	-	1	79	66	
Total revenue	428	428	113	77	126	17	667	522	
Sale of goods Royalties Milestone and upfront payments Services							536 2 112 17	513 - - 9	
Total revenue							667	522	
Base business revenue (i.e. total and International markets)	revenue exclu	ding the SLIT-	tablet partne	rships in North	n America		534	515	
Partner revenue							133	7	
Total revenue							667	522	

	Europ	Α.	North Ameri		Interna marke		Total	
Growth, Q3 2015	Growth local currencies	Growth						
SCIT/SLIT-drops	-3%	-3%	14%	32%	-48%	-36%	-2%	0%
SLIT-tablets	7%	10%	510%	600%	1758%	2280%	255%	277%
Other products and services	20%	15%	7%	32%	-48%	-100%	13%	20%
Total revenue	0%	0%	24%	47%	533%	641%	24%	28%

# 3 SPECIAL ITEMS

Q3	Q3		9M	9M
2014	2015	Amounts in DKKm	2015	2014
4	6	Severance pay etc.	20	28
	1	Other restructuring expenses	6	2
4	7	Total	26	30

Special items represent one-off costs associated with the initiatives to streamline the business structure under the Simplify programme initiated in 2012.



# NOTES (unaudited)

#### 4 KEY CURRENCIES AND CURRENCY SENSITIVITY

	9M	9M
Average exchange rates	2015	2014
		_
USD	6.65	5.52
GBP	10.20	9.20

Sensitivity in the event of a 10% increase in exchange rates (full year effect)

Amounts in DKKm	Revenue	EBITDA
USD	approx. + 50	approx. + 20
GBP	approx. + 5	approx. 0

The sensitivities are estimated on the basis of current exchange rates.

#### 5 ACQUISITIONS OF COMPANIES AND OPERATIONS

In June 2015, ALK took over the allergy immunotherapy activities of its former distributor in Turkey, Albio Allerji Ürünleri Ith. Ve Tic. Ltd. Şti. (Albio) with a view to facilitating growth in the Turkish market. The acquisition was made through ALK's Turkish subsidiary.

The transaction was accounted for using the purchase method.

The total purchase value of DKK 12 million was settled in cash.

Intangible assets in the form of customer lists and distribution rights represented DKK 7 million. After recognition of identifiable assets and liabilities at fair value, goodwill related to the acquisition has been calculated at DKK 5 million. The balance represents the value of assets, the fair value of which cannot be measured reliably, future growth potential and the value of acquired employees.

The purchase price allocation is preliminary.

The purchase agreement included a contingent consideration corresponding to a minor part of the purchase price covering the period until 2017.

Out of the ALK Group's revenue of DKK 1,882 million for the first 9 months of 2015, DKK 0 million is attributable to sales generated by the acquired operations after the acquisition date.

Had the activities in Albio been consolidated from 1 January 2015, the contribution to revenue and profit would have been DKK 3 million and less than DKK 1 million respectively.



# **DEFINITIONS**

Invested capital Intangible assets, tangible assets, inventories and current receivables

reduced by liabilities except for mortgage debt, bank loans and financial loans

Gross margin - % Gross profit x 100 / Revenue

EBITDA margin - % Operating profit before depreciation and amortisation x 100 / Revenue

Net asset value per share Equity at end of period / Number of shares at end of period

Earnings per share (EPS) Net profit/(loss) for the period / Average number of outstanding shares

diluted

Earnings per share (DEPS), Net profit/(loss) for the period / Diluted average number of outstanding shares

Cash flow per share (CFPS) Cash flow from operating activities / Average number of outstanding shares

**Markets** Geographical markets (based on customer location):

> - Europe comprises the EU, Norway and Switzerland - North America comprises the USA and Canada

- International Markets comprise Japan, China and all other countries

**HDM** House dust mite

**SCIT** Subcutaneous immunotherapy

**SLIT** Sublingual immunotherapy

Named-patient products Products that are not registered pharmaceuticals, but are used under the

responsibility of the prescribing physician and produced and supplied directly

to a named patient

Key figures are calculated in accordance with 'Recommendations and Ratios 2015' issued by the Danish Society of Financial Analysts.