

# Six-month interim report (Q2) 2016 (Unaudited)

#### Performance for the period

(Comparative figures for 2015 are shown in brackets / revenue growth is measured in local currencies. Revenue from ALK's base business is defined as total revenue excluding income from the SLIT-tablet partnerships in North America and International markets).

ALK continued to record high double-digit sales growth in Europe and North America in Q2. Sales in Europe benefited from continued increase of new orders in France and other markets which were affected by the temporary suspension of production at ALK's main competitor. ALK sales also benefited from an accelerated shift in favour of registered products.

- Q2 total revenue, including partner income, grew organically by 41% to DKK 773 million (565).
- Q2 revenue in the base business grew organically by 43% to DKK 762 million (545).
- European sales of SLIT-tablets doubled, thanks to strong growth in GRAZAX<sup>®</sup> sales, while ACARIZAX<sup>®</sup> continued to progress ahead of plans in its introductory phase, and has already become the most prescribed product for new AIT initiations in adult patients with house dust mite allergy in Denmark and Germany.
- Operating profit (EBITDA) in Q2 was DKK 159 million (11), and the EBITDA margin was 21% (2%). EBITDA before special items was DKK 167 million (20).
- ► H1 total revenue was DKK 1,621 million (1,215) and base business revenue was DKK 1,569 million, following 36% organic growth. H1 EBITDA before special items was DKK 463 million (158).
- Free cash flow was an inflow of DKK 218 million (an outflow of 101) in H1.

#### **Pipeline update**

- Strong clinical progress for ACARIZAX<sup>®</sup>: Approval in Australia, first regulatory submissions in South-East Asia, submission of clinical trial application in China, regulatory submission in Canada and new launches in Europe where the Netherlands became the 13<sup>th</sup> country to issue a marketing authorisation.
- Controlled phase-out of North American partnership with MSD, ref. to company announcement No 22/2016.

#### Updated 2016 financial guidance

The updated guidance reflects H1 2016 performance and a higher than expected order intake in Europe.

- Total full-year revenue is now projected to exceed DKK 2.9 billion, including income from partnerships (previous guidance only reflected base business revenue).
- ▶ Full-year revenue in the base business is now expected to grow organically by approximately 20% (previously: 15%).
- Guidance assumes 5-10% organic growth in the base business in H2 2016 and a minor contribution from partnerships. In H2 2015, income from partnerships included a DKK 112 million milestone payment.
- Full-year EBITDA is now expected to exceed DKK 600 million before special items (previously: approximately DKK 575 million before additional sales royalties and milestone payments).
- Free cash flow is now expected at DKK 50-100 million (previously better than in 2015 (DKK 18 million)).

The markets in Europe have not yet normalised following a temporary halt in production by ALK's main competitor, and ALK expects to have a clearer view on the sustained impact on its market share gains during autumn where many new patients typically are initiated on AIT treatment.

Hørsholm, 16 August 2016

#### ALK-Abelló A/S

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Today, ALK is hosting a conference call for analysts and investors at 1.30 p.m. (CEST) at which Management will review the financial results and the outlook. The conference call will be audio cast on <u>www.alk-abello.com/investor</u>. Participants in the audio cast are kindly requested to call in before 1.25 p.m. (CEST). 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: 96524073#. The conference call will also be webcast live on our website, where the related presentation will be made available shortly before the call begins.



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

	H1	H1	Full year
Amounts in DKKm	2016	2015	2015
Income statement			
Revenue	1,621	1,215	2,569
Operating profit before depreciation and amortisation (EBITDA)			
before special items	463	158	452
Operating profit before depreciation and amortisation (EBITDA)	436	139	451
Operating profit (EBIT) before special items	382	83	293
Operating profit (EBIT)	355	64	292
Net financial items	(1)	60	108
Profit before tax (EBT)	354	124	400
Net profit	195	143	344
Average number of employees	1,959	1,833	1,854
Balance sheet			
Total assets	4,503	3,909	4,252
Invested capital	2,336	2,354	2,434
Equity	2,842	2,485	2,697
Cash flow and investments			
Depreciation, amortisation and impairment	81	75	159
Cash flow from operating activities	270	(5)	183
Cash flow from investing activities	(52)	(96)	(165)
<ul> <li>of which investment in tangible and intangible assets</li> </ul>	(71)	(65)	(199)
<ul> <li>of which acquisitions of companies and operations</li> </ul>	-	(12)	(12)
Free cash flow	218	(101)	18
Information on shares			
Share capital	101	101	101
Shares in thousands of DKK 10 each	10,128	10,128	10,128
Share price, end of period – DKK	1,169	780	876
Net asset value per share – DKK	281	245	266
Key figures			
Gross margin – %	68	65	67
EBITDA margin before special items – %	29	13	18
EBITDA margin – %	27	11	18
Earnings per share (EPS) – DKK	20	15	35
Earnings per share (DEPS), diluted – DKK	20	14	35
Cash flow per share (CFPS) – DKK	28	(1)	19
Share price/Net asset value	4.2	3.2	3.3

Definitions: see last page

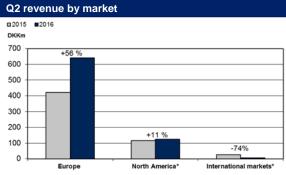


#### INCOME STATEMENT

1 5 % 100 35 65 16 42
100 35 65 16
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## **BUSINESS REVIEW**

(Comparative figures for 2015 are shown in brackets / Revenue growth rates are stated as organic growth in local currencies, unless otherwise indicated)

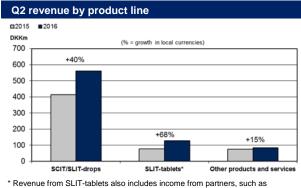


\* Revenue from North America and International markets also includes income from partners, such as milestone payments, product supply, sales royalties, etc.

#### Highlights

Revenue in ALK's base business (i.e., total revenue excluding income from SLIT-tablet partnerships) grew by 43% in Q2. Double-digit growth was recorded across all product segments as well as in Europe and North America.

Sales in Europe continued to be influenced by the temporary suspension of production at ALK's main competitor earlier in the year. Although the competitor was permitted to resume manufacturing in March, the consequences of the shutdown have continued, resulting in a sustained increase in orders for ALK. Meanwhile, an increase in capacity at ALK's production plants meant that a greater proportion of new orders could be fulfilled. Sales



milestone payments, product supply, sales royalties, etc.

also benefited from an accelerated shift to registered products.

Operating profit (EBITDA) was DKK 159 million (11) and EBITDA before special items was DKK 167 million (20). H1 total revenue was DKK 1,621 million (1,215) and EBITDA before special items was DKK 463 million (158). Earnings were driven by top-line growth and disciplined cost control.



#### Revenue by geography

(Comparative figures for 2015 are shown in brackets / Revenue growth rates are stated as organic growth in local currencies, unless otherwise indicated)

#### Europe

Q2 revenue in Europe grew organically by 56%, adjusted for last year's divestment of the European veterinary business and hence exceeding the growth of 31% seen in Q1. Q2 benefited from a carry-over effect from orders placed in Q1 but invoiced in Q2. Revenue totalled DKK 641 million (422) and the region accounted for 83% of total revenue in the quarter (75%).

Performance was positively influenced by the extraordinarily high number of patient initiations with ALK products in France, currently Europe's second largest AIT market, and other markets affected by supply shortages. These disruptions were prompted by the authorities' December 2015 decision to suspend production at ALK's main competitor and to order the recall of a number of its products. Although the competitor was permitted to resume manufacturing and distribution in March 2016, the consequences continue to be felt into Q2, with patients who switched from out-of-stock AIT products to ALK products in Q1 continued on ALK treatments when renewing their prescriptions.

To meet increased demand and make substitute products available for medical practitioners and patients, ALK doubled SLIT-drops production capacity at its facility in France during H1. This ramp-up, resulting in the hiring and training of 130 new employees, was completed as planned by the end of Q2, when normal delivery times were reestablished. Furthermore, ALK increased the output of its highly automated tablet production process.

The capacity increases allowed ALK to meet a higher proportion of demand in countries affected by supply shortages during Q2. As a result, doubleor triple-digit sales growth was recorded in a number of European countries. Moreover, doubledigit growth was also seen in Germany, Europe's largest AIT market, where the launch of ACARIZAX<sup>®</sup> and new treatment guidelines continue to strengthen demand for registered AIT products while simultaneously weakening sales of unregistered named-patient products. This shift towards evidence-based medicine accelerated in Q2.

H1 revenue in Europe amounted to DKK 1,322 million (948) following 42% organic growth.

#### North America

Q2 revenue in North America increased by 11% to DKK 126 million (116). North America thus accounted for 16% (21%) of total revenue.

ALK increased its sales of allergen extracts, diagnostics and other products to specialists and clinics in the USA and Canada by 12% to DKK 116 million (104), sustaining the strong sales momentum seen in North America with double-digit growth in nine consecutive quarters.

Income from the MSD partnership amounted to DKK 10 million (12). Sales royalties from GRASTEK<sup>®</sup> and RAGWITEK<sup>®</sup> remained modest.

H1 revenue in North America was DKK 277 million (222). The 24% growth was driven by ALK product sales and the milestone payment from MSD in Q1.

#### International markets

Q2 revenue in International markets was DKK 6 million (27), a 74% decrease. International markets accounted for less than 1% of total revenue (5%).

Base business revenue contracted by 69% due to de-stocking in the largest market, China, and suffered from comparison with Q2 2015 when ALK's partner was building its stock. Growth was seen in Turkey and Australia.

Income from SLIT-tablet partnerships in the region decreased 78%. Income included sales royalties related to MITICURE<sup>™</sup> in Japan while Q2 2015 income also included R&D reimbursements. Sales of MITICURE<sup>™</sup> in Japan have been steadily increasing since the end of the Japanese cedar pollen season, as prescriber focus switches to the year-round problem of HDM allergy.

H1 revenue in International markets amounted to DKK 22 million (45).

## Revenue by product line

#### SCIT and SLIT-drops

Total revenue from SCIT and SLIT-drops grew by 40% in Q2 to DKK 561 million (413). These product lines accounted for 73% (73%) of total revenue.

SCIT sales developed positively in Europe and North America, yielding an overall organic growth of 11%, while sales in International Markets declined.

Demand for SLIT-drops in France and a few other European markets, affected by the abovementioned supply shortages, was so strong that overall SLIT-drops sales grew by 101%. This reverses a trend seen over recent years, where sales of SLIT-drops in most countries, except



France, had been decreasing due to changes in reimbursement and documentation requirements aimed at phasing out unregistered AIT products.

H1 revenue from SCIT and SLIT-drops was DKK 1,155 million (907) resulting in growth of 30%.

#### SLIT-tablets

Q2 revenue from SLIT-tablets grew by 68% to DKK 128 million (78) and accounted for 17% (14%) of total revenue.

European sales of SLIT-tablets doubled to DKK 117 million (59). GRAZAX<sup>®</sup> sales benefited from the record-high number of patient initiations in Q1 when grass allergy patients across Southern and Eastern Europe switched from unregistered and out-of-stock AIT products to GRAZAX<sup>®</sup> tablets. Sales were further boosted by the ongoing launch of ACARIZAX<sup>®</sup>.

ACARIZAX<sup>®</sup> sales continued to progress satisfactorily. As of 30 June 2016, ACARIZAX<sup>®</sup> was the most prescribed product for new initiations of AIT in adult house dust mite allergy patients in Denmark and Germany, well in line with ALK's stated ambition of achieving a significant capture rate among the 20-30,000 normal patient initiations in these markets.

Revenue from the SLIT-tablet partnerships in North America and International markets amounted to DKK 11 million (19) due to lower reimbursements for R&D services.

H1 revenue from SLIT-tablets was DKK 309 million (174). Growth of 79% was predominantly due to strong European tablet sales.

#### Other products and services

Q2 revenue from other products and services (adrenaline auto-injectors, diagnostics, etc.) grew by 15% to DKK 84 million (74), accounting for 11% (13) of total revenue. Growth was attributable to diagnostics, whereas sales of Jext<sup>®</sup> continue to be below expectations. Work to improve the robustness of the supply chain continues in collaboration with sub-suppliers.

H1 revenue from other products and services was DKK 157 million (134). The 20% growth was mainly driven by North American diagnostics sales.

## **R&D PIPELINE AND PARTNERSHIPS**

ALK's own pipeline activities, as well as the pipeline activities under the partnerships with Merck, Torii, Abbott and Seqirus, continue to advance.

#### ALK's R&D pipeline activities

ALK aims to complete clinical development of the SLIT-tablet portfolio as quickly as possible.

Recruitment of patients to a pivotal Phase III clinical trial of the tree SLIT-tablet is progressing in Europe. The trial is expected to complete in 2017. In support of the subsequent regulatory submission, ALK has recently completed a Phase II trial in an environmental exposure chamber with the product. The trial included 219 patients and involved exposure to both birch and oak pollen. The trial showed that the tree SLIT-tablet significantly reduced the patients' symptoms in response to both birch and oak pollen exposure compared to placebo. Oak pollen allergy is very common in North America, while birch pollen allergy is the most prevalent tree pollen allergy in Europe.

In June, at the European Academy of Allergy and Clinical Immunology's (EAACI) annual congress in Vienna, ALK presented the comprehensive results from the multi-year, pan-European GRAZAX® Asthma Prevention (GAP) trial. This trial demonstrated that GRAZAX® nearly halved children's risk of experiencing asthma symptoms two years after treatment, and that GRAZAX<sup>®</sup> also reduced the proportion of patients experiencing asthma symptoms during the entire five year trial. Moreover, immunological findings supported the disease-modifying nature of GRAZAX® along with its sustained relief from grass allergy symptoms. Results provide the strongest evidence to date for the early use of GRAZAX® in children who suffer from moderate-to-severe grass allergy and are at risk of developing asthma.

Meanwhile, ALK continues its efforts to launch ACARIZAX<sup>®</sup> – first in the 11 European countries covered by the last year's regulatory approval, and then to obtain approval in additional countries. In EU, besides Denmark and Germany, ACARIZAX<sup>®</sup> has now been launched with reimbursement in Sweden, Slovakia and Finland. In addition, ACARIZAX<sup>®</sup> has been approved by authorities in Spain and the Netherlands.

Preparations to investigate the safety and efficacy of ACARIZAX<sup>®</sup> in children are underway. ALK is currently designing a European paediatric trial which is expected to start in 2017.

Finally, ALK has submitted a Clinical Trial Application for ACARIZAX<sup>®</sup> in China and a Phase I trial is being designed.

Partnership with MSD for North America In May 2016, MSD submitted a New Drug Application for ACARIZAX<sup>®</sup> in Canada, based on



results from the clinical programmes in Europe and North America. The Canadian application targets both allergic rhinitis and allergic asthma.

The US Food and Drug Administration (FDA) continues to review the Biologics License Application for ACARIZAX<sup>®</sup>, submitted by MSD in February 2016. The US application targets allergic rhinitis. Subject to approval by the authorities, ACARIZAX<sup>®</sup> would complete the portfolio of SLITtablets so that it covers all three major respiratory allergies in North America.

As previously communicated (company announcement No 22/2016), the partnership agreement with MSD has been terminated and will be phased out over a six month period and all rights to GRASTEK<sup>®</sup>, RAGWITEK<sup>®</sup> and ACARIZAX<sup>®</sup> will revert to ALK by early 2017. The registration processes for ACARIZAX<sup>®</sup> continue with increasing involvement from ALK. Moreover, MSD will also complete an ongoing paediatric clinical trial with RAGWITEK<sup>®</sup>.

ALK is allocating resources from its North American operations and the Danish headquarters to ensure a smooth transition. ALK has also initiated a full strategic review to determine which new strategy for the North American tablet franchise will best deliver long-term value creation for ALK. The review includes an assessment of potential partnerships and synergies with ALK's North American subsidiary. Given the disappointing sales performance for GRASTEK<sup>®</sup> and RAGWITEK<sup>®</sup> over the past two years, first priority will be ensuring that the right blend of marketing skills and focus are applied to overcome the current market barriers.

#### Partnership with Torii for Japan

In December 2015, Torii launched ACARIZAX<sup>®</sup> in Japan under the brand name MITICURE<sup>™</sup>. MITICURE<sup>™</sup> is indicated for use in adolescents and adult patients but Torii is conducting an additional clinical trial to investigate the safety and efficacy of MITICURE<sup>™</sup> in paediatric patients (5-11 years).

In December 2015, Torii submitted a New Drug Application for the SLIT-tablet against Japanese cedar-induced allergic rhinitis. The authorities' review of this application is ongoing. Subject to approval by the Ministry of Health Labour and Welfare, this tablet could reach the market in 2017.

#### Partnership with Abbott for Russia

Preparations for the registration of ACARIZAX<sup>®</sup> are advancing. In the meantime, authorities are reviewing the registration applications for GRAZAX<sup>®</sup> (submitted in September 2015) and the ragweed

SLIT-tablet (submitted in December 2015). ALK continues to estimate that first launches, subject to approval by the authorities, could take place in 2017.

#### Partnership with Abbott for South-East Asia

Regulatory submissions for ACARIZAX<sup>®</sup> have been made in August 2016 in Taiwan and Hong Kong. Abbott expects to file in additional of the seven markets covered by the partnership before yearend. Based on ALK's European data package, all submissions target a label covering both allergic rhinitis and allergic asthma. First launches are expected from 2017.

## Partnership with Seqirus for Australia and New Zealand

In Q1 2016, ACARIZAX<sup>®</sup> was made available to Australian patients under an 'early access' programme. The authorities informed Seqirus that a permanent marketing authorisation for ACARIZAX<sup>®</sup> was granted on 21 July 2016, covering both allergic rhinitis and allergic asthma. This triggers a minor milestone payment to ALK, which will be reported in Q3. Seqirus also filed for approval of GRAZAX<sup>®</sup> in December 2015. As with ACARIZAX<sup>®</sup>, the GRAZAX<sup>®</sup> application is based on data from ALK's European development programme.

Further details on the SLIT-tablet partnerships can be seen on page 9.

#### **FINANCIAL REVIEW OF H1 2016**

(Comparative figures for H1 2015 are shown in brackets. / Revenue growth rates are stated as organic growth in local currencies, unless otherwise indicated)

**Revenue** in H1 increased 33% in DKK and 36% in local currencies to DKK 1,621 million (1,215). Revenue in the base business grew organically by 36% to DKK 1,569 million (1,172) while income from the SLIT-tablet partnerships increased 24% to DKK 52 million (43).

**Cost of sales in H1** increased 20% (organically 21% in local currencies) to DKK 513 million (427), and the DKK 1,108 million gross profit (788) yielded a gross margin of 68% (65%). Disregarding milestone payments, the normalised gross margin of 68% (65%) was positively influenced by higher sales volumes and economies of scale, offsetting the cost of building up production capacity to meet the product supply needs as well as changes in the base business' sales mix. ALK is also increasingly adding costs in support of its production compliance programmes.

**Capacity costs** increased 4% (organically 5% in local currencies) to DKK 732 million (705). R&D



expenses increased by 3% (organically 2% in local currencies), while administrative expenses were unchanged. The increase of 5% (organically 8% in local currencies) in sales and marketing expenses reflected the higher activity levels, including the ongoing launch of ACARIZAX<sup>®</sup>.

**Reported EBITDA (operating profit before depreciation and amortisation)** was DKK 436 million (139) and EBITDA before special items was DKK 463 million (158). The improvement was prompted by top-line growth, economies of scale in production and cost control. Exchange rates did not have a significant effect on EBITDA.

Special items of DKK 27 million (19) mainly related to severance pay to the former CEO in Q1 and *Simplify* projects in Q2. Disregarding the severance pay to the former CEO, *Simplify* items remained unchanged compared to H1 2015.

**Net financials** were a loss of DKK 1 million (gain of 60).

**Tax on the profit** was an expense of DKK 159 million versus an income of DKK 19 million last year where tax was impacted by a one-off positive adjustment in Q2 2015 of DKK 73 million following the transfer of all adrenaline activities from the Swiss subsidiary to the Danish parent. The high effective tax rate of 45% in H1 2016 was the result of the geographical distribution of income.

Net profit increased to DKK 195 million (143).

**Cash flow** from operating activities was an inflow of DKK 270 million (an outflow of 5). The increase was primarily due to higher profitability in the base business.

Cash flow from investment activities was an outflow of DKK 52 million (96) which primarily related to the build-up of capacity for tablet production, partly offset by the divestment of a facility in the USA.

Free cash flow was an inflow of DKK 218 million (an outflow of 101 million). Cash flow from financing was an outflow of DKK 49 million (an inflow of 269). 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. In direct comparison, H1 2015 was impacted by ALK obtaining a mortgage-backed loan of DKK 351 million (net).

ALK's holding of its **own shares** was reduced following the settlement of share options and conditional shares. At the end of June, ALK held 296,844 of its own shares or 2.9% of the share capital (3.6% at the end of 2015).

At the end of June, **cash and marketable securities** totalled DKK 771 million vs. DKK 608 million at the end of 2015 and DKK 458 million at the end of June 2015.

**Equity** totalled DKK 2,842 million (2,485) at the end of the period, and the equity ratio was 63% (64%).

## **UPDATED OUTLOOK FOR 2016**

ALK is updating its guidance to reflect H1 2016 performance and a higher than expected order intake in Europe. Moreover, the guidance now includes revenue from partnerships whereas ALK previously only provided guidance for its base business.

Base business revenue is now expected to grow organically by approximately 20% in local currencies (previously: 15% growth and revenue of approximately DKK 2.75 billion). Double-digit growth is anticipated in all main geographies.

Partnerships are also contributing to ALK's revenue with sales royalties, product supply income and service fees. Including this contribution from partnerships, ALK's total revenue is expected to exceed DKK 2.9 billion (previously ALK did not provide guidance for total revenue).

The new guidance assumes 5-10% organic growth in the base business in H2 2016 and a minor contribution from partnerships in H2 2016. The decline in partner income is as expected because H2 2015 included a one-off milestone payment of DKK 112 million.

The markets in Europe have not yet normalised following a temporary halt in production by ALK's main competitor, and ALK expects to have a clearer view on the sustained impact on its market share gains during autumn where many new patients typically are initiated on AIT treatment.

Gross margins will be negatively impacted by increased production and production compliance costs as well as depreciations and lower milestone payments than in 2015. Hence, the reported gross margin is still expected to decline slightly.

R&D and administrative expenses are expected to remain largely unchanged compared to 2015, whereas sales and marketing expenses are projected to increase modestly in support of strategic growth initiatives.



EBITDA is now expected to exceed DKK 600 million before special items (previously: approximately DKK 575 million before special items, additional royalties and milestone payments). The EBITDA upgrade reflects higher underlying profitability in the base business.

Initiatives under the *Simplify* programme are expected to entail restructuring costs along with costs related to the change in Management. Special items are still projected at around DKK 50 million.

CAPEX is still projected at approximately DKK 200 million, while free cash flow is now expected at approximately DKK 50-100 million (previously: better than the inflow of DKK 18 million in 2015).

The outlook is based on current exchange rates.

## **OTHER EVENTS**

The Board of Directors has appointed Carsten Hellmann as new President and CEO of ALK. Carsten Hellmann has held executive positions in various global healthcare and biopharmaceutical companies and has a strong track record of creating visible commercial results. He replaces Jens Bager who left ALK in February 2016.

Carsten Hellmann is currently CEO of Merial and Executive Vice President and member of the Executive Committee of Sanofi (NYSE:SNY). He will be joining ALK no later than 1 January 2017. The Chairman of ALK's Board, Steen Riisgaard, will continue his extended operational responsibilities until Carsten Hellmann's contractual obligations to Sanofi are complete.

In July 2016, ALK received an Untitled Letter from the FDA regarding an inspection of ALK's production facilities in Denmark which took place in March 2016. ALK is in dialogue with the FDA to resolve the issue.

## **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 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.

#### 2016 Financial calendar

Silent period

Q3 report

13 October 2016 10 November 2016



## FACTS ON ALK'S SLIT-TABLET PARTNERSHIPS

#### Partnership with MSD for North America

In 2007, ALK entered into a partnership with MSD (then Schering Plough) – known as Merck in the USA and Canada – to develop and commercialise ALK's SLIT-tablets against grass pollen (GRASTEK<sup>®</sup>), ragweed pollen (RAGWITEK<sup>®</sup>) and house dust mite (ACARIZAX<sup>®</sup> in Europe) allergies in the USA, Canada and Mexico.

Under the agreement with MSD, ALK was entitled to certain upfront and milestone payments, royalties on net sales as well as payments for product supply and R&D support. ALK has received approximately DKK 700 million in total payments. MSD has been responsible for all costs of clinical development and commercialisation, while ALK has been responsible for tablet production and supply of drug substance.

The partnership has been terminated by MSD and will be phased out over a six month period and all rights to the three products will revert to ALK by early 2017. MSD will complete the ongoing clinical trial with RAGWITEK<sup>®</sup> in children and the ongoing registration processes for ACARIZAX<sup>®</sup> will continue, with increased involvement from ALK.

#### Partnership with Torii for Japan

The 2011 partnership agreement grants Torii exclusive rights to develop, register and commercialise ALK's AIT products for allergic rhinitis and asthma in Japan. The agreement covers SLIT-tablets against house dust mite (branded MITICURE<sup>TM</sup> in Japan) and Japanese cedar pollen allergy, as well as a house dust mite SCIT product and a house dust mite diagnostic product.

ALK has received all potential upfront and development milestone payments totalling DKK 450 million (EUR 60 million) from Torii. 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, established in 2014, covers the supply and marketing of ALK's SLIT-tablets in Russia. Abbott has exclusive rights to distribute and commercialise ALK's SLIT-tablet portfolio mirroring the country's most common allergies: grass (GRAZAX<sup>®</sup>), ragweed, tree and house dust mite (ACARIZAX<sup>®</sup>), adding the products to its own respiratory range.

Abbott and ALK will share the revenue generated by the partnership. Abbott will purchase the products from ALK at agreed prices and, in addition, pay royalties on net sales.

#### Partnership with Abbott for South-East Asia

In January 2016, the partnership with Abbott was expanded to cover seven South-East Asian markets: Hong Kong, Malaysia, the Philippines, Singapore, South Korea and Thailand. In these markets, Abbott has exclusive rights to register and sell ACARIZAX<sup>®</sup>, which is a strong fit with Abbott's existing ENT and paediatrics portfolio.

ALK and Abbott will share the revenue generated in the territories. ALK will be responsible for product supply to Abbott.

#### Partnership with Seqirus for Australia

The partnership, established in 2015, grants Seqirus exclusive rights to promote and sell ACARIZAX<sup>®</sup> and GRAZAX<sup>®</sup> in Australia and New Zealand.

ALK receives an undisclosed milestone payment upon approval of ACARIZAX<sup>®</sup> in Australia (21 July 2016). ALK will be responsible for product supply and will sell products to Seqirus at an agreed price structure ensuring a split of the final in-market revenue generated by Seqirus.



## STATEMENT BY THE 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 June 2016.

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 June 2016. 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, 16 August 2016

#### **Board of Management**

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

Flemming Pedersen	Helle Skov
CFO & Executive Vice President	Executive Vice President
	Product Supply

#### **Board of Directors**

Steen Riisgaard Chairman and acting CEO with extended operational responsibilities	Lene Skole Vice Chairman	Lars Holmqvist
Andreas Slyngborg Holst	Jacob Kastrup	Anders Gersel Pedersen

Jakob Riis

Katja Barnkob Thalund

Per Valstorp



#### INCOME STATEMENT FOR THE ALK GROUP (unaudited)

Q2	Q2		H1	H1
2015	2016	Amounts in DKKm	2016	2015
565	773	Revenue	1,621	1,215
217	267	Cost of sales	513	427
348	506	Gross profit	1,108	788
101	97	Research and development expenses	197	192
215	232	Sales and marketing expenses	435	414
50	50	Administrative expenses	100	99
-	-	Other operating income	6	-
(18)	127	Operating profit (EBIT) before special items	382	83
(9)	(8)	Special items	(27)	(19)
(27)	119	Operating profit (EBIT)	355	64
(8)	12	Net financial items	(1)	60
(35)	131	Profit before tax (EBT)	354	124
(89)	59	Tax on profit	159	(19)
54	72	Net profit	195	143
6	7	Earnings per share (EPS) – DKK	20	15
5	7	Earnings per share (DEPS), diluted – DKK	20	14

#### STATEMENT OF COMPREHENSIVE INCOME (unaudited)

Q2	Q2		H1	H1
2015	2016	Amounts in DKKm	2016	2015
54	72	Net profit for the period	195	143
		Other comprehensive income		
		Items that will be reclassified subsequently to the Income statement, when specific conditions are met:		
(12)	5	Foreign currency translation adjustment of foreign subsidiaries	(17)	45
7	(1)	Tax related to other comprehensive income	1	(4)
(5)	4	Other comprehensive income	(16)	41
49	76	Total comprehensive income	179	184



## CASH FLOW STATEMENT FOR THE ALK GROUP (unaudited)

	H1	H1
Amounts in DKKm	2016	2015
Net profit	195	143
Adjustments for non-cash items	249	3
Change in working capital	(84)	(73)
Net financial items, paid	3	(6)
Income taxes, paid	(93)	(72)
Cash flow from operating activities	270	(5)
Acquisitions of companies and operations	-	(12)
Additions, intangible assets	(20)	(19)
Additions, tangible assets	(51)	(65)
Sales of assets	19	(00)
Cash flow from investing activities	(52)	(96)
	()	()
Free cash flow	218	(101)
Dividend paid to shareholders of the parent	(49)	(49)
Sale of treasury shares	49	7
Exercise of share options	(39)	(19)
Proceeds from borrowings	-	351
Repayment of borrowings	(10)	(21)
Cash flow from financing activities	(49)	269
Net cash flow	169	168
Cook et 1. Jonuary	176	81
Cash at 1 January Marketable securities at 1 January	432	208
Cash and marketable securities at 1 January	608	208
	000	203
Unrealised gain/(loss) on foreign currency and financial assets carried as		
cash and marketable securities	(6)	1
Net cash flow	169	168
Cash at 30 June	229	324
Marketable securities at 30 June	542	134
Cash and marketable securities at 30 June	771	458
		-50

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)

	30 Jun.	31 Dec.	30 Jun.
Amounts in DKKm	2016	2015	2015
		2010	2010
Non-current assets			
Intangible assets			
Goodwill	423	423	422
Other intangible assets	334	336	331
	757	759	753
Tangible assets			
Land and buildings	732	771	697
Plant and machinery	393	419	387
Other fixtures and equipment	56	59	59
Property, plant and equipment in progress	358	322	408
	1,539	1,571	1,551
Other non-current assets			
Securities and receivables	8	8	7
Deferred tax assets	362	378	321
	370	386	328
Total non-current assets	2,666	2,716	2,632
Current assets			
Inventories	559	520	461
Trade receivables	331	273	275
Receivables from affiliates	30	30	-
Income tax receivables	80	14	31
Other receivables	41	65	26
Prepayments	25	26	26
Marketable securities	542	432	134
Cash	229	176	324
Total current assets	1,837	1,536	1,277
Total assets	4,503	4,252	3,909



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

		04 B	00 I
	30 Jun.	31 Dec.	30 Jun.
Amounts in DKKm	2016	2015	2015
Equity			
Share capital	101	101	101
Currency translation adjustment	(3)	14	60
Retained earnings	2,744	2,582	2,324
Total equity	2,842	2,697	2,485
Liabilities			
Non-current liabilities			
Mortgage debt	319	327	335
Bank loans and financial loans	-	1	299
Pensions and similar liabilities	206	202	196
Other provisions	5	6	4
Deferred tax liabilities	90	100	49
	620	636	883
Current liabilities			
Mortgage debt	17	17	18
Bank loans and financial loans	299	300	3
Trade payables	72	81	54
Income taxes	199	73	68
Other provisions	28	22	25
Other payables	426	426	373
	1,041	919	541
Total liabilities	1,661	1,555	1,424
Total equity and liabilities	4,503	4,252	3,909



#### EQUITY FOR THE ALK GROUP (unaudited)

Total comprehensive income

Share-based payments

Sale of treasury shares

Dividends on treasury shares

Share options settled

Other transactions

Equity at 30 June 2015

Dividend paid

Amounts in DKKm	Share capital	Currency translation adjustment	Retained earnings	Total equity
Equity at 1 January 2016	101	14	2,582	2,697
N = 4			405	405
Net profit Other comprehensive income	-	- (17)	195	195 (16)
Total comprehensive income		(17)	196	179
		(17)	130	175
Share-based payments	-	-	4	4
Share options settled	-	-	(38)	(38)
Purchase of treasury shares	-	-	-	-
Sale of treasury shares	-	-	49	49
Dividend paid	-	-	(51)	(51)
Dividends on treasury shares	-	-	2	2
Other transactions	-	-	(34)	(34)
Equity at 30 June 2016	101	(3)	2,744	2,842
Equity at 1 January 2015	101	16	2,237	2,354
Net profit	<u>_</u>		143	143
Other comprehensive income		45	(4)	41
	-	40	(4)	41

-

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(51)

(19)

139

8

(19)

7

(51)

2

(53)

2,323



## NOTES (unaudited)

#### **1 ACCOUNTING POLICIES**

The interim report for the period 1 January to 30 June 2016 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 2015, except for all new, amended or revised accounting standards and interpretations effective from 1 January 2016. These have no material impact on the interim report. Please see the Annual Report 2015 for a more detailed description of the Group's accounting policies.

#### 2 REVENUE

	_			orth		ational	_	
		rope		nerica		kets		otal
Amounts in DKKm	H1 2016	H1 2015	H1 2016	H1 2015	H1 2016	H1 2015	H1 2016	H1 2015
SCIT/SLIT-drops	996	749	143	129	16	29	1,155	907
SLIT-tablets	257	131	49	29	3	14	309	174
Other products and services	69	68	85	64	3	2	157	134
Total revenue	1,322	948	277	222	22	45	1,621	1,215
Sale of goods Royalties						1,569 4	1,172 3	
Milestone and upfront payments							34	4
Services							14	36
Total revenue							1,621	1,215
Base business revenue (i.e. total rev	enue excludino	the SLIT-tabl	et partnershi	os in North Am	nerica and Int	ernational		
Markets)							1,569	1,172
Partner revenue					52	43		
Total revenue							1,621	1,215

			North	1	Internat	ional		
	Europ	е	Amerio	ca	marke	ts	Total	
	Organic growth local		Organic growth local		Organic growth local		Organic growth local	
Organic growth, H1 2016	currencies	Growth	currencies	Growth	currencies	Growth	currencies	Growth
SCIT/SLIT-drops	36%	33%	10%	11%	-43%	-45%	30%	27%
SLIT-tablets	97%	96%	68%	69%	-71%	-79%	79%	78%
Other products and services	6%	1%	31%	33%	100%	50%	20%	17%
Total revenue	42%	39%	24%	25%	-46%	-51%	36%	33%



#### NOTES (unaudited)

#### 2 REVENUE (CONTINUED)

	E.,	rope		orth erica		ational kets	To	tal
Amounts in DKKm	Q2 2016	Q2 2015	Q2 2016	Q2 2015	Q2 2016	Q2 2015	Q2 2016	Q2 2015
SCIT/SLIT-drops	487	326	71	68	3	19	561	413
SLIT-tablets	117	59	10	12	1	7	128	78
Other products and services	37	37	45	36	2	1	84	74
Total revenue	641	422	126	116	6	27	773	565
Sale of goods							762	545
Royalties					1	1		
Milestone and upfront payments					-	-		
Services							10	19
Total revenue							773	565
Base business revenue (i.e. total rev Markets)	enue excluding	the SLIT-table	et partnershi	ps in North Am	erica and Int	ernational	762	545
Partner revenue							11	20
Total revenue							773	565

	Europe		North America		International markets		Total	
Organic growth, Q2 2016	Growth local currencies	Growth	Growth local currencies	Growth	Growth local currencies	Growth	Growth Iocal currencies	Growth
SCIT/SLIT-drops	55%	49%	5%	4%	-84%	-84%	40%	36%
SLIT-tablets	100%	98%	-8%	-17%	-78%	-86%	<b>68%</b>	64%
Other products and services	-2%	0%	27%	25%	100%	100%	15%	14%
Total revenue	56%	52%	11%	<b>9</b> %	-74%	-78%	41%	37%

#### 3 SPECIAL ITEMS

Q2	Q2		H1	H1
2015	2016	Amounts in DKKm	2016	2015
6	4	Severance pay etc.	22	14
3	4	Other restructuring expenses	5	5
9	8	Total	27	19

Severance and other restructuring expenses represent one-off costs from 2012 to 2016 associated with the initiatives to streamline the business structure under the *Simplify* programme.



#### NOTES (unaudited)

## 4 KEY CURRENCIES AND CURRENCY SENSITIVITY

	H1	H1
Average exchange rates	2016	2015
USD	6.69	6.63
GBP	9.50	10.16

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

Amounts in DKKm	Revenue	EBITDA
	approx. + 50 approx. + 5	approx. +5 approx. 0

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

## 5 ADJUSTMENTS FOR NON-CASH ITEMS

	H1	H1
Amounts in DKKm	2016	2015
Tax on profit	159	(19)
Financial income and expenses	1	(60)
Share-based payments	4	8
Reversal of accounting gain on sale of non-current assets	(6)	-
Depreciation, amortisation and impairment	81	75
Other adjustments	10	(1)
Total	249	3



## 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	Net asset value / Number of shares end of period
Equity ratio	Equity / Total assets
Earnings per share (EPS)	Net profit/(loss) for the period / Average number of outstanding shares
Earnings per share (EPS), diluted	Net profit/(loss) for the period / Average number of outstanding shares diluted
Cash flow per share (CFPS)	Cash flow from operating activities / Average number of outstanding shares diluted
Markets	Geographical markets (based on customer location): o Europe comprises the EU, Norway and Switzerland o North America comprises the USA and Canada o International Markets comprise Japan, China and all other countries

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