

# Six-month interim report (Q2) 2015 (unaudited)

# Company release No. 15/2015

# 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).

In Q2, ALK continued to deliver underlying growth in its base business in line with that of Q1. Overall financial performance was impacted by lower milestone payments compared to last year:

- ▶ Q2 revenue, including partner income, amounted to DKK 565 million (615).
- Q2 revenue in the base business grew by 1% in local currencies to DKK 546 million (516). Underlying growth was 4% when adjusted for last year's one-off upfront payment from ALK's collaboration partner for China.
- Q2 partner income from SLIT-tablets was DKK 19 million (99) due to lower milestone payments.
- ▶ Q2 EBITDA before special items was DKK 20 million (109). Excluding milestone payments and sales royalties, EBITDA before special items increased to DKK 19 million (10).
- ▶ H1 total revenue was DKK 1,215 million (1,299) and base business revenue growth was 3%. H1 EBITDA before special items was DKK 158 million (320). Excluding sales royalties and milestone payments, EBITDA before special items grew to DKK 151 million (140), reflecting improved underlying profitability in the base business.

#### Pipeline events

- ▶ Regulatory reviews of ALK's lead product candidate, the HDM SLIT-tablet, continue to progress in Europe and Japan. Subject to approval, first launches are expected to take place in 2016.
- ▶ MSD (known as Merck in the USA and Canada) will discuss its plans for submission of a Biologic License Application (BLA) for the HDM SLIT-tablet with the FDA at a pre-BLA meeting later this year.
- A regulatory filing for the HDM SLIT-tablet has been submitted in Australia by bioCSL.
- In August, Torii obtained positive results in a pivotal Phase II/III trial of the Japanese cedar SLIT-tablet.
- ▶ All other pipeline activities continue to advance as planned.

# 2015 financial guidance

The full-year guidance has been adjusted to reflect the year-to-date sales growth in the base business and postponed investments:

- ▶ ALK now expects to grow revenue in the base business by 3-5% in local currencies (previously 0-5%) based on low single-digit growth in Europe and high single-digit growth in non-European markets. Full-year revenue for the base business is expected to be DKK 2.3-2.35 billion (previously DKK 2.25-2.35 billion).
- The SLIT-tablet partnerships in North America and International markets are expected to generate additional revenue in the form of sales royalties, product supply, service fees and, potentially, milestone payments.
- Operating profit (EBITDA before special items), excluding sales royalties and milestone payments from partnerships, is expected to be in the range of DKK 250-300 million (previously DKK 225-300 million). Exchange rates are not expected to materially affect EBITDA.
- Free cash flow is projected to be negative in the range of DKK 50-150 million excluding sales royalties and milestone payments from partners (previously negative in the range of DKK 100-200).
- ▶ ALK has strengthened its financial position through an increase of mortgage loans of net DKK 330 million.

Hørsholm, 18 August 2015

# ALK-Abelló A/S

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Today, ALK hosts a conference call for analysts and investors at 2.00 p.m. (CEST) 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. (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: 25148308#.



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

	H1	H1	Full year
Amounts in DKKm	2015	2014	2014
Income statement			
Revenue	1,215	1,299	2,433
Operating profit before depreciation and amortisation (EBITDA)			
before special items	158	320	453
Operating profit before depreciation and amortisation (EBITDA)	139	294	404
Operating profit (EBIT) before special items	83	253	313
Operating profit (EBIT)	64	227	264
Net financial items	60	9	36
Profit before tax (EBT)	124	236	300
Net profit	143	139	181
Average number of employees	1,833	1,791	1,809
Balance sheet			
Total assets	3,909	3,318	3,419
Invested capital	2,354	2,178	2,214
Equity	2,485	2,298	2,354
Cash flow and investments			
Depreciation, amortisation and impairment	75	67	140
Cash flow from operating activities	(5)	179	320
Cash flow from investing activities	(96)	(98)	(219)
- of which investment in tangible assets	(65)	(41)	(202)
of which acquisitions of companies and operations	(12)	(24)	(24)
Free cash flow	(101)	81	101
Information on shares		404	404
Share capital	101	101	101
Shares in thousands of DKK 10 each	10,128	10,128	10,128
Share price, end of period – DKK	780	842	651
Net asset value per share – DKK	245	227	232
<b>Key figures</b> Gross margin – %	65	72	70
EBITDA margin before special items – %	13	25	19
EBITDA margin – %	11	23	17
Earnings per share (EPS) – DKK	14.8	14.4	19.0
Earnings per share (DEPS), diluted – DKK	14.5	14.0	18.0
Cash flow per share (CFPS) – DKK	(0.5)	18.5	33.0
Share price/Net asset value	3.2	3.7	2.8

Definitions: see last page

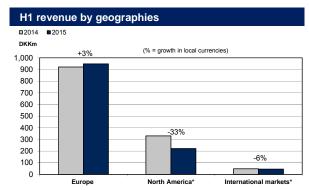


#### **INCOME STATEMENT**

	Q2		Q2			H1		H1	
	2014	%	2015	%	Amounts in DKKm	2015	%	2014	%
_									
	615	100	565	100	Revenue	1,215	100	1,299	100
	186	30	217	38	Cost of sales	427	35	365	28
	429	70	348	62	Gross profit	788	65	934	72
	97	16	101	18	Research and development expenses	192	16	190	15
	258	42	265	47	Sales, marketing and administrative expenses	513	42	491	38
	-	-	-	-	Other operating income and expenses	-	-	-	
	74	12	(18)	(3)	Operating profit/(loss) (EBIT) before special items	83	7	253	19
	(21)	(3)	(9)	(2)	Special items	(19)	(2)	(26)	(2)
	53	15	(27)	(5)	Operating profit/(loss) (EBIT)	64	5	227	21
	-	-	(8)	(1)	Net financial items	60	5	9	1
	53	15	(35)	(6)	Profit/(loss) before tax (EBT)	124	10	236	22
	22	4	(89)	(16)	Tax on profit	(19)	(2)	97	7
_	31	5	54	10	Net profit	143	12	139	15
					Operating profit before depreciation and				
	109	18	20	4	amortisation (EBITDA) before special items	158	13	320	25
					Operating profit before depreciation				
	88	14	11	2	and amortisation (EBITDA)	139	11	294	23

#### **BUSINESS REVIEW**

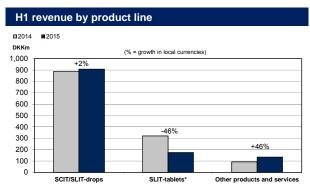
(Comparative figures for 2014 are shown in brackets / Revenue growth rates are stated as growth in local currencies, unless otherwise indicated)



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

# **Q2** highlights

Revenue growth in ALK's base business (i.e. total revenue excluding that related to the SLIT-tablet partnerships in North America and International markets) was 1% and within the 0-5% guidance range. Adjusted for last year's one-off upfront payment from ALK's collaboration partner for China, Eddingpharm, growth in the base business was 4%. Progress was mainly driven by SCIT products in the USA and the Nordic countries, SLIT-drops in France as well as GRAZAX® and Jext® across Europe.



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

As anticipated, partner income from SLIT-tablet partnerships was lower than last year, where ALK recognised DKK 81 million in milestone payments from MSD. Partner income from SLIT-tablets in Q2 2015 amounted to DKK 19 million (99).

Operating profit (EBITDA) before special items was DKK 20 million (109) yielding an EBITDA margin of 4% (18%). Excluding milestone payments and sales royalties, EBITDA before special items increased slightly to DKK 19 million (10). Exchange rates had a marginally positive effect on EBITDA.



# 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**

Q2 revenue in Europe increased by 1% to DKK 422 million (414). Europe accounted for 75% of total revenue (67%).

Performance was, to a great extent, impacted by the phasing-out of the local, unregistered SLIT-drops portfolio in the Netherlands. This phasing-out was effectively completed in Q2. Excluding the Dutch SLIT-drops sales, revenue in Europe grew by 4% in the quarter.

GRAZAX® sales developed positively while the Jext® adrenaline auto-injector was another source of growth. SCIT-sales were, by and large, stable, while SLIT-drops sales, as expected, continued to decline in most markets except France.

Solid performance was recorded in France, the UK, the Nordic countries and the minor eastern European markets. The Allergy Unlocked<sup>®</sup> initiative is deemed to have had a positive impact on sales in selected markets. Positive growth was also seen in Italy and Spain, indicating that these markets continue to stabilise.

The situation in the European markets remains largely unchanged, however, in Germany, new treatment guidelines for allergy immunotherapy, issued by the national allergy associations, impact German market dynamics. The guidelines stress the importance of prescribing registered and scientifically documented products and are believed to have had a generally negative impact on treatment initiations for non-registered, so-called named-patient products. ALK remains confident that there will be an increased demand for evidence-based medicine which will consequently benefit ALK's long-term strategy.

H1 revenue in Europe amounted to DKK 948 million (921) reflecting growth of 3%. Adjusted for the loss of Dutch SLIT-drops sales, H1 growth was 5%.

#### **North America**

Q2 revenue in North America declined by 44% to DKK 116 million (169). North America thus accounted for 21% (28%) of total revenue.

ALK increased sales of its allergen extracts and other products to specialists and clinics by 14% to DKK 104 million (75), sustaining the double-digit growth in North American product sales seen in recent quarters.

Income from the MSD partnership amounted to DKK 12 million, down from DKK 94 million last year where revenue included two milestone payments totalling DKK 81 million.

Publicly available prescription data from the US market continues to indicate a modest uptake of GRASTEK® and RAGWITEK® in 2015 during the first seasons in which doctors and patients could start the products at least 12 weeks ahead of the pollen season.

As previously communicated, ALK maintains a conservative view of the sales uptake during the first few years after launch, and the uptake witnessed so far supports this view. SLIT-tablets represent a new treatment class in North America, and ALK expects that it will take time and efforts to build and educate the market. However, a significant number of severe allergy sufferers remain in poor disease control despite the use of conventional allergy medications and ALK remains confident in the long-term potential for SLIT-tablets.

A wider adoption of the SLIT-tablets may occur, once the HDM SLIT-tablet treating house dust mite allergy reaches the North American markets, which – subject to the outcome of clinical trials and regulatory approval – is expected within the next few years. The HDM SLIT-tablet will also allow Merck to offer a complete portfolio of SLIT-tablets targeting the three major respiratory allergies in North America.

H1 revenue in North America was DKK 222 million (330). The 44% decline was related to last year's three milestone payments totalling DKK 162 million.

#### International markets

Q2 revenue in International markets was DKK 27 million (32), a 16% decrease. International markets accounted for 5% of total revenue (5%).

Product sales grew by double digits in China, largely due to re-stocking, and in Turkey. ALK also recognised marginally higher income from Torii, primarily related to R&D support. Excluding last year's upfront payment from Eddingpharm, growth was 61%.

H1 revenue in International markets amounted to DKK 45 million (48).

# Revenue by product line

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

In Q2, total revenue from SCIT and SLIT-drops declined by 2% to DKK 413 million (408). SCIT and SLIT-drops accounted for 73% (66%) of total revenue. Excluding last year's upfront payment from Eddingpharm, growth was 2%.



SCIT sales continued to develop positively in North America, International markets and most European markets with the exception of Germany. SLIT-drops sales continued to decline as a result of changes in reimbursement and documentation requirements with the ultimate aim of phasing out unregistered allergy immunotherapy products.

H1 revenue from SCIT and SLIT-drops was DKK 907 million (887). Growth was -1% and 1% in local currencies, respectively, disregarding the abovementioned upfront payment.

#### **SLIT-tablets**

Q2 revenue from SLIT-tablets decreased to DKK 78 million (155) due to lower milestone payments. SLIT-tablets accounted for 14% (25%) of total revenue.

In Europe, sales of GRAZAX<sup>®</sup> increased by 7% to DKK 59 million (56). Revenue from SLIT-tablets in North America and International markets amounted to DKK 19 million (99).

H1 revenue from SLIT-tablets was 174 million (320). The 49% decline resulted solely from lower milestone payments.

#### Other products and services

In Q2, revenue from other products and services (adrenaline auto-injectors, diagnostics, etc.) grew by 22% to DKK 74 million (52), accounting for 13% (9%) of total revenue. Growth was attributable to the adrenaline auto-injector Jext®.

H1 revenue from other products and services was DKK 134 million (92). The 28% growth was mainly due to Jext<sup>®</sup>.

# **R&D PIPELINE AND PARTNERSHIPS**

ALK's own pipeline activities and the pipeline activities under the partnerships with MSD, Torii, Abbott and bioCSL continue to advance.

# ALK's European R&D pipeline activities

The European health authorities are reviewing ALK's regulatory filing for the house dust mite (HDM) SLIT-tablet. The filing is supported by a comprehensive clinical development programme, including two pivotal clinical trials documenting the tablet's efficacy in both HDM-induced allergic asthma and allergic rhinitis. Subject to approval, the first launches of the tablet could take place in 2016.

ALK's other clinical development activities are progressing as planned: The multi-year pan-European *GRAZAX*® *Asthma Prevention* (GAP) trial is expected to complete at the turn of the year 2015/16 and to report top-line data in Q1 2016. Furthermore, ALK is planning the next steps in the

clinical development of the tree SLIT-tablet and conducting development activities for SCIT legacy products to further strengthen the product documentation.

#### 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 (HDM) allergies in the USA, Canada and Mexico.

In June 2015, MSD informed ALK of the top-line results from a Phase III clinical trial in the USA and Canada to investigate the safety and efficacy of the HDM SLIT-tablet in the treatment of allergic rhinitis. The trial, involving approximately 1,500 patients, demonstrated a statistically significant reduction in the Total Combined Rhinitis Score (the sum of average daily rhinitis symptoms and medication). The trial also showed that treatment was generally well tolerated.

MSD will discuss its plans for submission of a Biologic License Application (BLA) for the HDM SLIT-tablet with the FDA at a pre-BLA meeting later this year.

Following last year's approvals and launches of GRASTEK® and RAGWITEK®, MSD has 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. Preparations for a paediatric development programme for RAGWITEK® are also progressing.

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 August 2015, Torii reported positive results from a clinical Phase II/III trial into a SLIT-tablet for Japanese cedar pollen allergic rhinitis. The trial met



its primary efficacy endpoint providing statistically significant improvement in the 'Total Combined Rhinitis Score' (TCRS) compared with patients who received placebo, demonstrating that the SLITtablet reduced symptoms of Japanese cedar pollen allergic rhinitis. The trial also showed that the treatment was well tolerated and had a favourable safety profile. The trial included approximately 1,000 patients and was initiated in 2014 to investigate the safety and efficacy of the SLIT-tablet in patients with Japanese cedar tree pollen allergic rhinitis. Torii will now proceed with the preparations for a submission of a New Drug Application to the Japanese Ministry of Health, Labour and Welfare. Subject to approval, the Japanese cedar pollen tablet may reach the market by 2017.

Meanwhile, the Japanese Ministry of Health, Labour and Welfare is reviewing the registration application for the HDM SLIT-tablet, which Torii submitted in January 2015. Subject to approval, this tablet may reach the market in 2016. Upon receipt of market authorisation, ALK is entitled to a milestone payment.

Under the agreement with Torii, ALK may receive up to DKK 450 million (EUR 60 million) in upfront and development milestone payments, of which approximately DKK 340 million (EUR 45 million) has been recognised since 2011. 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.

The first registration trial has been successfully completed and is expected to lead to a regulatory filing of GRAZAX® by 2016. In 2015, ALK and Abbott will also initiate registration activities for the other SLIT-tablets. ALK estimates that the first launches under the partnership may take place in 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 market 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 programmes in Europe. Subject to approval, the HDM SLIT-tablet may reach the market by 2017.

bioCSL is also preparing a filing for GRAZAX<sup>®</sup> in Australia. This regulatory submission is expected in 2015/16.

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 H1 2015

(Comparative figures for H1 2014 are shown in brackets. / Revenue growth rates are stated as growth in local currencies, unless otherwise indicated)

**Revenue** in H1 decreased by 11% in local currencies to DKK 1,215 million (1,299). Exchange rate developments impacted reported growth positively by approximately 5 percentage points.

Revenue in ALK's base business increased by 3% to DKK 1,172 million (1,101). Excluding a one-off upfront payment in Q2 2014 from ALK's partner for China, Eddingpharm, ALK's base business recorded a growth of 4% in H1.

Income from the SLIT-tablet partnerships was down 82% to 43 million (198). Last year, ALK booked three milestone payments from MSD totalling DKK 162 million, whereas milestone payments in H1-2015 amounted to DKK 4 million.

Cost of sales increased 17% (12% in local currencies) to DKK 427 million (365) and gross profit was DKK 788 million (934), which corresponds to a gross margin of 65% (72%). Disregarding milestone payments, the normalised gross margin of 65% (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 705 million (681). Research and development expenses and administrative



expenses were, by and large, unchanged. The 5% increase (2% in local currencies) in sales and marketing expenses reflected a planned increase in activity ahead of the anticipated 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 158 million (320). Excluding milestones payments and sales royalties, EBITDA before special items improved to DKK 151 million (140) reflecting an improved underlying profitability in the base business despite expanded sales and marketing activities. In H1, 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 19 million (26), **reported EBITDA** was DKK 139 million (294). 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 60 million (9) due to unrealised exchange rate gains related to USD and CHF intercompany loans.

**Tax on profit** resulted in income of DKK 19 million (loss of 97). As previously reported, tax in Q2 was impacted by a one-off positive adjustment of DKK 73 million following the transfer of all adrenaline activities from ALK's Swiss subsidiary to the Danish parent company.

**Net profit** increased slightly to DKK 143 million (139).

**Cash flow** from operating activities had an outflow of DKK 5 million (inflow of 179). The decrease was due to significantly lower milestone payments.

Cash flow from investment activities had an outflow of DKK 96 million (98) which primarily related to the continued build-up of capacity for tablet production.

Free cash flow had an outflow of DKK 101 million (an inflow of 81). Cash flow from financing saw an inflow of DKK 269 million (outflow of 93). ALK has obtained a 20-year mortgage-backed loan of DKK 351 million (net) to strengthen its financial position. The interest rate and mortgage fee on the loan has been fixed for five years at 1.17% p.a. At the same time, ALK has paid back a loan of DKK 21 million, resulting in a total increased financial capacity of DKK 330 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 June, ALK held 441,126 of its own shares or 4.4% (4.6% at the end of 2014) of the share capital.

At the end of June, **cash and cash equivalents** totalled DKK 458 million vs. DKK 289 million at the end of 2014 and DKK 299 million at the end of June 2014.

**Equity** totalled DKK 2,485 million (2,298) at the end of the period, and the equity ratio was 64% (69%).

#### **OUTLOOK FOR 2015**

The full-year outlook for 2015 has been adjusted to reflect the sales growth in the base business and postponed investments:

ALK now expects to grow revenue in the base business by 3-5% in local currencies (previously 0-5%) based on low, single-digit growth in Europe and high single-digit growth in non-European markets. Growth initiatives are expected to outweigh the impact of European austerity measures. Revenue in the base business is expected at DKK 2.3-2.35 billion (previously DKK 2.25-2.35 billion).

The SLIT-tablet partnerships in North America and International markets are expected to generate additional revenue in the form of sales royalties, product supply, service fees and, potentially, milestone payments. During 2015 and 2016, ALK expects to recognise up to DKK 185 million in milestone payments relating to the registration progress of the house dust mite SLIT-tablet. Partner income is in particular subject to uncertainty and ALK is therefore unable to provide specific guidance on its exact level or timing.

Production and capacity costs are forecast to increase slightly 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 house dust mite 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), excluding sales royalties and milestone payments from partnerships, is expected to be in the range of DKK 250-300 million (previously DKK 225-300). Exchange rates are not expected to materially affect EBITDA.



Initiatives under the *Simplify* programme are expected to entail minor restructuring costs, which will be reported in a special items line. CAPEX is projected at approximately DKK 150-200 million (previously approximately DKK 200 million), while free cash flow is expected to be negative in the range of DKK 50-150 million excluding sales royalties and milestone payments from partners (previously negative in the range of DKK 100-200).

#### OTHER EVENTS IN Q2

As part of the ongoing efforts to facilitate growth in Turkey and Middle-Eastern markets, ALK has agreed to acquire the activities of its Turkish distributor Albio against a cash consideration of DKK 12 million. The activities will be integrated into ALK's newly established Turkish subsidiary. ALK markets a range of allergy immunotherapy products in Turkey, including GRAZAX®. The acquisition is currently awaiting final approval by the authorities.

ALK is evaluating further options for geographical expansion and discussions are ongoing to allow ALK to access other emerging markets.

# SUBSEQUENT EVENTS

Since Q2, ALK and its partners have made important clinical progress with regulatory filing in Australia (HDM SLIT-tablet) as well as positive Phase II/III results for the cedar pollen SLIT-tablet in Japan. Please refer to the Section 'R&D PIPELINE AND PARTNERSHIPS' for additional information.

# **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.

2015 Financial calendar Silent period Q3 report

15 October 2015 12 November 2015



# 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 June 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 June 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, 18 August 2015

# **Board of Management**

Jens Bager President and CEO Henrik Jacobi Executive Vice President Research & Development Søren Daniel Niegel Executive Vice President Commercial Operations

Flemming Pedersen

CFO & Executive Vice President

Helle Skov

**Executive Vice President** 

**Product Supply** 

#### **Board of Directors**

Steen Riisgaard Chairman 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
2014	2015	Amounts in DKKm	2015	2014
615	565	Revenue	1,215	1,299
186	217	Cost of sales	427	365
429	348	Gross profit	788	934
97	101	Research and development expenses	192	190
207	215	Sales and marketing expenses	414	393
51	50	Administrative expenses	99	98
	-	Other operating expenses	-	-
74	(18)	Operating profit/(loss) (EBIT) before special items	83	253
(21)	(9)	Special items	(19)	(26)
53	(27)	Operating profit/(loss) (EBIT)	64	227
	(8)	Net financial items	60	9
53	(35)	Profit/(loss) before tax (EBT)	124	236
22	(89)	Tax on profit	(19)	97
31	54	Net profit	143	139
3.21	5.58	Earnings per share (EPS) – DKK	14.78	14.39
3.13	5.44	Earnings per share (DEPS), diluted – DKK	14.47	14.04

# STATEMENT OF COMPREHENSIVE INCOME (unaudited)

Q2		H1	H1
2015	Amounts in DKKm	2015	2014
54	Net profit for the period	143	139
	·		
	Other comprehensive income		
	Items that will be reclassified subsequently to the Income statement, when		
	•		
(12)	•	45	3
` -	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)
7	Tax related to other comprehensive income	(4)	3
(5)		· , ,	(4)
(0)		• •	( - /
49	Total comprehensive income	184	135
	2015 54 (12) - - - 7 (5)	Net profit for the period  Other comprehensive income  Items that will be reclassified subsequently to the Income statement, when specific conditions are met:  (12) Foreign currency translation adjustment of foreign subsidiaries  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  Tax related to other comprehensive income  (5) Other comprehensive income	2015 Amounts in DKKm  2015  Net profit for the period  Other comprehensive income  Items that will be reclassified subsequently to the Income statement, when specific conditions are met:  (12) Foreign currency translation adjustment of foreign subsidiaries  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  Tax related to other comprehensive income  (4)  (5) Other comprehensive income



# CASH FLOW STATEMENT FOR THE ALK GROUP (unaudited)

	H1	H1
Amounts in DKKm	2015	2014
Not profit	143	139
Net profit	143	139
Adjustments:		
Tax on profit	(19)	97
Financial income and expenses	(60)	(9)
Share-based payments	8	6
Depreciation, amortisation and impairment	75	67
Change in provisions	(1)	6
Change in working capital	(73)	(64)
Net financial items, paid	(6)	13
Income taxes, paid	(72)	(76)
Cash flow from operating activities	(5)	179
	` ` `	
Acquisitions of companies and operations	(12)	(24)
Additions, intangible assets	(19)	(39)
Additions, tangible assets	(65)	(41)
Change in other financial assets	-	6
Cash flow from investing activities	(96)	(98)
	(404)	0.4
Free cash flow	(101)	81
Dividend paid to shareholders of the parent	(49)	(49)
Sale of treasury shares	7	(43)
Exercise of share options	(19)	_
Change in financial liabilities	330	(1)
Cash flow from financing activities	269	(93)
Cash now from financing activities	203	(55)
Net cash flow	168	(12)
Cash and cash equivalents at 1 January	289	312
Unrealised gain/(loss) on foreign currency and financial assets carried as		
cash and cash equivalents	1	(1)
Net cash flow	168	(12)
Cash and cash equivalents at 30 June	458	299

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 June	31 Dec.	30 June
Amounts in DKKm	30 June 2015	31 Dec. 2014	2014
Amounts in Dittill	2010	2014	2017
Non-current assets			
Intangible assets			
Goodwill	422	415	412
Other intangible assets	331	248	305
	753	663	717
Tangible assets			
Land and buildings	697	681	673
Plant and machinery	387	328	333
Other fixtures and equipment	59	59	61
Property, plant and equipment in progress	408	481	336
	1,551	1,549	1,403
Other non-current assets			
Securities and receivables	7	7	7
Deferred tax assets	321	168	140
	328	175	147
Total non-current assets	2,632	2,387	2,267
Current assets			
Inventories	461	408	359
Trade receivables	275	240	245
Receivables from affiliates	-	1	57
Income tax receivables	31	13	11
Other receivables	26	53	50
Prepayments	26	28	30
Cash and cash equivalents	458	289	299
Total current assets	1,277	1,032	1,051
Total assets	3,909	3,419	3,318



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

		21.5	
Assessed to DIVIV	30 June	31 Dec.	30 June
Amounts in DKKm	2015	2014	2014
Equity			
Share capital	101	101	101
Currency translation adjustment	60	16	(24)
Retained earnings	2,324	2,237	2,221
Total equity	2,485	2,354	2,298
Liabilities			
Non-current liabilities			
Mortgage debt	335	20	21
Bank loans and financial loans	299	299	300
Pensions and similar liabilities	196	190	153
Other provisions	4	4	8
Deferred tax liabilities	49	28	29
	883	541	511
Current liabilities			
Mortgage debt	18	2	2
Bank loans and financial loans	3	3	3
Trade payables	54	90	78
Income taxes	68	6	53
Other provisions	25	32	41
Other payables	373	391	332
	541	524	509
Total liabilities	1,424	1,065	1,020
Total a society and tick title .	0.000	2.440	2 240
Total equity and liabilities	3,909	3,419	3,318



# EQUITY FOR THE ALK GROUP (unaudited)

Amounts in DKKm	Share capital	Currency translation adjustment	Retained earnings	Total equity
Equity at 1 January 2015	101	16	2,237	2,354
Net profit	_	-	143	143
Other comprehensive income	-	45	(4)	41
Total comprehensive income	-	45	139	184
Share-based payments Share options settled	- -	- -	8 (19)	8 (19)
Purchase of treasury shares	_	-	-	-
Sale of treasury shares	-	-	7	7
Dividend paid	-	-	(51)	(51)
Dividends on treasury shares	-	-	2	2
Other transactions	-	-	(53)	(53)
Equity at 30 June 2015	101	61	2,323	2,485

Equity at 1 January 2014	101	(27)	2,175	2,249
Net profit	-	-	139	139
Other comprehensive income	-	3	(7)	(4)
Total comprehensive income	-	3	132	135
Share-based payments	-	-	6	6
Purchase of treasury shares	-	-	(43)	(43)
Dividend paid	-	-	(51)	(51)
Dividends on treasury shares	-	-	2	2
Other transactions	-	-	(86)	(86)
Equity at 30 June 2014	101	(24)	2,221	2.298



# NOTES (unaudited)

# 1 ACCOUNTING POLICIES

The interim report for the period 1 January to 30 June 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

			No	orth	Intern	ational		
	Eu	rope	Am	America		kets	Total	
Amounts in DKKm	H1 2015	H1 2014						
SCIT/SLIT-drops	749	755	129	93	29	39	907	887
SLIT-tablets	131	122	29	190	14	8	174	320
Other products and services	68	44	64	47	2	1	134	92
Total revenue	948	921	222	330	45	48	1,215	1,299
Sale of goods							1,172	1,085
Royalties							3	2
Milestone and upfront payments							4	178
Services							36	34
Total revenue							1,215	1,299

			North	า	Internat	ional		
	Europ	е	Ameri	ca	marke	ts	Total	
	Growth		Growth		Growth		Growth	
0 " 111 0045	local	0 "	local		local	0 "	local	
Growth, H1 2015	currencies	Growth	currencies	Growth	currencies	Growth	currencies	Growth
SCIT/SLIT-drops	-1%	-1%	16%	39%	-33%	-26%	-1%	2%
SLIT-tablets	8%	7%	-88%	-85%	111%	75%	-49%	-46%
Other products and services	44%	55%	12%	36%	127%	100%	28%	46%
Total revenue	3%	3%	-44%	-33%	-12%	-6%	-11%	-6%



# NOTES (unaudited)

# 2 REVENUE (CONTINUED)

	Europe			orth erica	International markets		Total		
Amounts in DKKm	Q2 2015	Q2 2014	Q2 2015	Q2 2014	Q2 2015	Q2 2014	Q2 2015	Q2 2014	
SCIT/SLIT-drops	326	332	68	50	19	26	413	408	
SLIT-tablets	59	56	12	94	7	5	78	155	
Other products and services	37	26	36	25	1	1	74	52	
Total revenue	422	414	116	169	27	32	565	615	
Sale of goods							545	498	
Royalties							1	2	
Milestone and upfront payments							-	97	
Services							19	18	
Total revenue		•	•	•		•	565	615	

	North International		ional						
	Europ	Europe		America		markets		Total	
	Growth local		Growth local		Growth local		Growth local		
Growth, Q2 2015	currencies	Growth	currencies	Growth	currencies	Growth	currencies	Growth	
SCIT/SLIT-drops	-2%	-2%	14%	36%	-34%	-27%	-2%	1%	
SLIT-tablets	7%	5%	-90%	-87%	125%	40%	-53%	-50%	
Other products and services	27%	42%	15%	44%	461%	0%	22%	42%	
Total revenue	1%	2%	-44%	-31%	-16%	-16%	-13%	-8%	

# 3 SPECIAL ITEMS

Q2	Q2		H1	H1
2014	2015	Amounts in DKKm	2015	2014
20	6	Severance pay etc.	14	24
1	3	Other restructuring expenses	5	2
21	9	Total	19	26

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



# NOTES (unaudited)

#### 4 KEY CURRENCIES AND CURRENCY SENSITIVITY

	H1	H1
Average exchange rates	2015	2014
USD	6.63	5.44
GBP	10.16	9.09

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 1,215 million for the first half 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

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

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

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