



ALK launches ambitious, transformational growth strategy

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ALK-Abelló
Inside information

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ALK ([ALKB:DC](#) / OMX: ALKB / AKABY / AKBLF):

- **Three-year investment plan to extend ALK's leadership in allergy immunotherapy and establish a wider global presence in allergy and allergic asthma.**
- **Four parts to strategy:**
- **Establish and succeed in North America. Over the three-year period, ALK will invest approximately DKK 1 billion to succeed in North America.**
- **Complete the tablet portfolio for all relevant ages.**
- **Develop patient engagement systems and adjacent business.**
- **Optimise and reallocate ALK's resources.**
- **During the transformation period in the next two-to-three years, ALK expects earnings to be subdued due to the investments needed to shape a new ALK:**
 - **2018 revenue is expected to be slightly below 2017 with strong growth in tablet sales to be offset by expected price reductions in Southern Europe, and the consequences of supply constraints following upgrades in the legacy business, as well as significant product rationalisations.**
 - **After 2018, ALK expects to deliver attractive organic revenue growth of 10% or more annually, and later on, also profitability at specialty pharma levels.**
 - **The growth forecast assumes a minimum viable sales uptake of tablets in North America and no income from new adjacent business opportunities.**
- **ALK is currently evaluating the most optimal way to finance its growth strategy, including the ability to raise debt and/or new equity. New financing together with existing credit facilities, is expected to cover a projected accumulated negative free cash flow of ~DKK 1 billion during the transformation period.**
- **In case of a capital increase, principal shareholder, Lundbeckfonden, will subscribe at least its proportional share.**
- **Webcast with Management today at 11.00 CET.**

ALK today announced that its Boards of Directors and Management have adopted a corporate strategy to redefine ALK's position in the global allergy market and stimulate a new era of growth for the company.

Today, ALK is the global leader in allergy immunotherapy (AIT), a unique and broadly approved, disease-modifying treatment which addresses the underlying cause of allergy as well as reducing patients' symptoms and their use of medications. ALK's product portfolio, protected via biological manufacturing and sourcing processes, currently helps around 1.5 million people suffering from severe respiratory allergies and asthma. However, this constitutes less than 1% of the total number of people affected by allergic rhinitis world-wide and ALK captures less than 2% of the overall spend in the global allergy and allergic asthma market.

The strategy aims to transform ALK into a broader-based allergy company, by expanding its core allergy immunotherapy (AIT) business – especially in North America – and using its expertise to grow especially the tablets franchise and introduce new, complementary products and services that reach even more allergy sufferers. At the same time, ALK will engage with these allergy sufferers earlier in their disease journey via digital platforms and other initiatives, smoothing their path to AIT treatment, and partnering more closely with prescribers to treat more patients.

The new ALK will support patients across a wider spectrum of allergic disease – from early intervention, through symptom treatment, specific diagnosis, AIT and anaphylaxis treatment.

Carsten Hellmann, ALK's President & CEO, says: *"The paradigm for ALK has changed from two years ago. In that time, we have significantly grown our European business, we have invested heavily in North America, and also in our legacy, non-tablet business. We believe that we can build further on these foundations to establish a bigger, more robust ALK, which is why we are evaluating, with support from our principal shareholder, how to strengthen our financial resources to sustain the required high investment levels, predominantly in the USA."*

He continues: *"We have successfully developed a new generation of oral allergy vaccines in tablet form, and we believe strongly that these products have the potential to make a major difference for people with severe allergies and related asthma. However, it is a fact that today the vast majority of people with allergies never receive AIT treatment while, for those who do, our products are typically a last resort after years of trying other solutions. In light of this, our goal is to build an effective future growth platform for these core products and to leverage our profound expertise more effectively, engaging with patients earlier in their disease so that we can service many more people than we do today."*

Lene Skole, CEO of principal shareholder Lundbeckfonden and Vice Chairman of ALK's Board of Directors, says: *"This new strategy marks the beginning of a new era of investment and growth for ALK under the leadership of CEO Carsten Hellmann and has the potential to transform ALK from a niche player, into one with a wider presence across an entire disease area. As the company's principal shareholder, we fully endorse this strategy and understand that the next two-to-three years will likely entail negative cash flows as additional investments fuel the company's transformation. Our clear expectations are that these additional investments will establish a new, long-term growth platform, raising ALK's revenue growth to attractive*

levels and lifting earnings in line with those of the wider specialty pharmaceutical industry."

The updated strategy – which builds upon ALK's successful European business and recent investments in North America – places succeeding with the tablet portfolio at its core, and has four key components:

1) Establish and succeed in North America

North America is the world's largest allergy market, with over 50 million allergy sufferers, and it offers ALK the greatest medium-term growth potential. For example, there are around 10 million AIT-eligible allergy sufferers in the USA alone, just one-third of whom actually receive AIT today.

Nevertheless, current industry dynamics offer ALK a unique window of opportunity. A trend towards allergy self-medication such as over-the-counter (OTC) symptom-suppressants, along with patent expiries for other important treatments, has resulted in large pharma companies choosing to de-prioritise partnering with allergists. However, ALK is perfectly positioned to fill this void via its newly formed commercial organisation and strong business to business (B2B) sales model in North America which has long fostered strong relationships with specialists.

Central to success will be using ALK's expertise and shared interests with allergists to drive better access and outcomes for all AIT-eligible patients, reaching out with support, disease information and treatment options via specialist sales representatives, digital platforms, and via referral systems that encourage them to consult an allergist. ODACTRA™/ACARIZAX® will play a pivotal role in this strategy.

During the past year, ALK has built a local pharma organisation in North America on top of its existing allergenic extracts business – almost quadrupling its field-force to 80 people – and has gained a deep understanding of the overall allergy and respiratory market and its structural barriers. Using a highly targeted, commercial approach building on an understanding of the businesses of the most relevant allergy specialists, ALK will demonstrate how the tablets can expand the number of patients who benefit from AIT, reinforcing and revitalising the role of allergy specialists.

Key initiatives:

- The ongoing launch of ODACTRA™/ACARIZAX® for house dust mite allergy, a treatment that allows patients to be initiated at any time for this perennial allergy. This product also opens up a whole new part of the Southern USA, with a population of close to 70 million people, and which is largely unaffected by grass or ragweed allergies.
- The inclusion of US patients in the multi-year clinical trial of ODACTRA™/ACARIZAX® in children with allergic asthma, which will support an important expansion of the label and aid the product's adoption in North America.
- A commercial approach, first focusing on high-frequency interactions with the ~2,000 most relevant allergy specialists, many of whom have experiences with GRASTEK® and RAGWITEK®, before expanding outreach to an additional ~4,000.
- Gain the best possible market access and establish partnerships with managed care organisations to demonstrate the health economic benefits of the tablets.
- Implementation of improved patient support programmes to ensure affordable treatment initiation and successful treatment adherence.
- Partnerships with patient and physician groups as well as key opinion leaders to build AIT awareness and advocacy, thereby laying the foundation for a scalable business model. For example, ALK has supported the American College of Allergy, Asthma and Immunology and the Allergy-Asthma Network with the creation of a shared decision-making tool to help patients to choose the most appropriate form of AIT. In addition, ALK is collaborating with selected allergy specialists to help improve allergy management in corporate healthcare plans.
- A digital engagement strategy that shares ALK's allergy expertise and offers a relevant portfolio of treatment options for allergy sufferers – either ALK-sourced or from partnerships – with content that encourages them to consult their allergist, where AIT will be available. (See section 3 for more details).
- A continued commitment to supplying allergy specialists with allergenic extracts which ALK anticipates will also benefit from the increased patient consultations.

Key metrics for initial success in North America are

- New patient initiations for all tablets – especially for ODACTRA™/ACARIZAX®.
- The number of allergists who offer the full spectrum of AIT options.
- The number of new patients engaging with specialists due to ALK's digital and partnership efforts.
- Improved AIT adherence at partnered allergy practices.

2) Complete the tablet portfolio for all relevant ages

ALK is committed to offering a full portfolio of tablets for all relevant ages, covering the five most common global respiratory allergies (>80%). ALK will invest to complete the remaining clinical development, secure registrations, build market access and gather evidence for the tablets' use in asthma, children and adolescents. In particular, ACARIZAX®/ODACTRA™ is key to expanding the use of AIT for allergy and asthma – something that is already happening in Europe.

Key initiatives:

- Clinical studies to complete the portfolio for all relevant ages, plus US post-approval commitments:
 - ACARIZAX®/ODACTRA™ trials to expand its label and geographical reach, including two paediatric trials in allergic asthma and rhinitis involving 1,600 children and adolescents (5-17 years) in Europe and North America, as well as clinical development in China.
 - An efficacy and safety trial for the tree tablet in children.
 - A paediatric safety trial in the USA for RAGWITEK® (in addition to former partner Merck's ongoing paediatric efficacy trial).
 - US post-marketing surveillance studies for GRASTEK®, RAGWITEK® and ODACTRA™.

Consequently, over the next five years, annual total R&D costs are expected to be in the range of DKK 400-600 million.

- Expanded tablet commercialisation:
 - Launches of ACARIZAX®/ODACTRA™ in additional markets in Europe and in further selected International markets. Launch in Japan for paediatric use, with other markets to follow.

- Further build sales of GRAZAX[®]/GRASTEK[®], leveraging the halo effect of ACARIZAX[®]/ODACTRA[™] as well as data from the GRAZAX[®] *Asthma Prevention* (GAP) trial.
- RAGWITEK[®] launches in selected new markets, plus paediatric approvals in North America.
- Launches of the tree tablet in Europe, Canada and possibly beyond.
- Partner launch of the Japanese cedar tablet in Japan, following the recent regulatory approval.

3) Patient engagement systems and adjacent business

ALK will establish a new commercial consumer care division to drive digital patient engagement with the ultimate aim of creating new value from ALK's expanded allergy presence. ALK already has more than 2.5 million unique users on its web-platforms and this audience will be expanded and leveraged to engage with patients earlier in their disease journey.

Market research shows that there is a clear trend towards self-medication for allergies, using over-the-counter remedies. Meanwhile, the internet has become the principal source of disease information for people with allergies, around 60% of whom rarely see a doctor. This makes it more relevant than ever for ALK to engage directly with patients, both to raise awareness of the full range of allergy treatment options, and to encourage consulting an allergist who can prescribe AIT.

As well as smoothing the path for more patients to initiate AIT treatment, ALK will help allergists to ensure a greater number of AIT patients complete their treatment by launching a new range of support tools. At the same time, ALK will position itself to penetrate the non-AIT market which today represents around 95% of allergy market revenue, worth more than DKK 120 billion with the aim of supporting allergy sufferers earlier in their disease journey. ALK will do this by looking at adjacent business opportunities, via partnerships, in-licensing or product acquisitions.

Key initiatives:

- Establish a new consumer care division to drive digital patient engagement.
- Use digital platforms to offer solutions for early allergy intervention, symptom alleviation and relief.
- Launch new tools to help improve treatment adherence.
- Explore expanding ALK's portfolio with respiratory prescription medicines.
- Expand the anaphylaxis franchise in Europe and launch in the USA and other markets.

4) Optimise and reallocate ALK's resources

ALK will improve efficiency by strengthening its competencies and structures as well as simplifying processes – particularly within Product Supply, which in future will work more closely with Sales & Marketing to support ALK's commercial objectives. The goal in Product Supply is to improve ALK's gross margin, while across the whole organisation, ALK will identify and free up resources which can be reallocated to better support the strategic growth initiatives.

Key initiatives:

- ALK will accelerate product rationalisation to focus on products that are both cost effective to produce and allow ALK to benefit from the regulation-led market consolidation. By reducing overall workloads, rationalisation will also improve the efficiency and robustness of ALK's product supply.
- ALK will maintain and invest in a slimmer range of SCIT and SLIT-drops to ensure allergy sufferers and prescribers have a comprehensive range of AIT treatment options available to them.
- Work to improve the robustness of product supply continues and, in the short term, ALK will continue to operate with temporary supply constraints while upgrades take place. Robust inventories will be gradually rebuilt during 2018.
- Reducing scrappage, increasing production yield – particularly for the house dust mite tablet – improving the efficiency of production processes and the overall manufacturing flow, as well as assessing the potential for increased automation.
- Continued de-prioritising of activities that fall outside ALK's strategic priorities and a streamlining of the organisation accordingly:
- R&D will focus on life-cycle management of the current pipeline as well as supporting the introduction of complementary products and services to optimise AIT outcomes for patients.
- Product Supply, working with Commercial Operations, will accelerate product rationalisation and improve the efficiency and robustness of ALK's supply operations.
- Work to streamline administrative processes and functions will continue.
- Efforts across the organisation will focus on ensuring functions are the right size, with the right competences, while any freed up resources will be reallocated in support of the long-term growth strategy.
- Transforming ALK's company culture into one that supports the ambition of being relevant to more patients by embracing change, agility, empowerment and decisive prioritisation.

Financial implications

This strategy aims to transform ALK, over a maximum period of three years, into a business capable of delivering sustainable, high revenue and earnings growth.

Revenue

2018 revenue is expected to be slightly below 2017 with strong growth in tablet sales which will be offset by expected price reductions in Southern Europe, and the consequences of supply constraints following needed upgrades to the legacy business, as well as significant product rationalisations.

Beyond 2018, and dependant upon tablet sales – particularly in North America – ALK expects to deliver attractive organic revenue growth of 10% or more annually from its existing business. These revenue expectations build on a base case that assumes a minimum viable sales uptake of tablets in North America.

In addition to the forecast growth for its current business, ALK aims to increase its relevance to patients and become the preferred partner for doctors, translating these relationships into income from new, adjacent, complementary products and services, starting in 2018. Due to timing uncertainties, any revenue from these adjacent products and services has not been included in the above stated growth expectations.

Earnings

During the transformation period, the strategy will require significant business investment to deliver the key priorities, predominantly for clinical trials as well as sales and marketing costs associated with the build-up in North America, where ALK expects to invest approximately DKK 1 billion over the next three years. These investments, along with upgrades for the legacy business and product rationalisations, are expected to subdue ALK's earnings over the next three years, although the impact will be offset to some extent by efficiencies.

Longer-term ambition for profitability

After the transformation period, ALK aims to raise earnings margins as quickly as possible to levels that are in line with the wider specialty pharmaceutical industry.

Cash flow

Free cash flow is expected to be negative during the transformation period because of subdued earnings and relatively high tax payments, working capital requirements and CAPEX investments. Based on the above-described plans – which include maintaining high production capacity for the tablets to facilitate long-term sales growth – ALK estimates that the accumulated negative free cash flow will be approximately DKK 1 billion over the transformation period, with the greatest effect in 2018-19. This estimate does not include any potential significant future downpayments in connection with the in-licensing of products or any M&A activity. Nor does it include earnings upsides from such activities or from other new complementary products and services.

Capital structure

ALK is currently evaluating the most optimal way to finance its growth strategy, including the ability to raise debt and/or new equity. New financing together with existing credit facilities, are expected to allow ALK to adequately fund the expected negative free cash flow during the transformation period. ALK's principal shareholder, Lundbeckfonden, holding 40% of the shares and 67% of shareholder votes, has informed ALK that, in case of a capital increase, it will subscribe at least its proportional share of the new equity. Danske Bank A/S is assisting ALK with evaluating its financing options.

In support of the strategy implementation, ALK is temporarily suspending dividend payments. The Board of Directors will revisit the dividend policy regularly during the transformation period.

ALK will provide annual updates on the progress of the strategy as well as its sales and earnings projections.

Unchanged financial guidance for 2017

The updated strategy does not change ALK's financial guidance for 2017. ALK continues to expect full-year revenue at around DKK 2.9 billion and an operating profit (EBITDA) of DKK 225-250 million following accelerated investments to consolidate European market share gains and to build up the organisation in North America. Free cash flow is still expected at approximately minus DKK 700 million. As a consequence of the updated strategy, ALK will discontinue certain non-strategic development projects as well as scrap some obsolete equipment, leading to a one-off write-down of assets worth approximately DKK 150 million. The write-down will be recognised in Q4 2017 and does not impact ALK's EBITDA guidance.

Risk factors

This announcement contains forward-looking statements, including forecasts of future revenue, operating profit and cash flow as well as expected business-related events. Such statements are naturally subject to risks and uncertainties as various factors, some of which are beyond the control of ALK, may cause actual results and performance to differ materially from the forecasts made in this announcement. Without being exhaustive, such factors include e.g., general economic and business-related conditions, including legal issues, uncertainty relating to demand, pricing, reimbursement rules, partners' plans and forecasts, fluctuations in exchange rates, competitive factors and reliance on suppliers. Additional factors include the risks associated with the sourcing and manufacturing of ALK's products as well as the potential for side effects from the use of ALK's existing and future products, as allergy immunotherapy may be associated with allergic reactions of differing extents, durations and severities.

ALK-Abelló A/S

For further information please contact:

Carsten Hellmann, President & CEO, tel +45 4574 7576

Investor Relations: Per Plotnikof, tel. +45 4574 7527, mobile +45 2261 2525

Media: Jeppe Ilkjær, tel. +45 7877 4532, mobile +45 3050 2014

Webcast

Today at 11.00 a.m. (CET), ALK will host a webcast for analysts and institutional investors, at which Management will review the strategy and answer any questions.

The meeting will be audio cast live on ALK's website at <http://ir.alk.net>, where the related presentation will be made available shortly before the meeting begins. Participants in the conference call are kindly requested to call in before 10.55 a.m. (CET). Danish participants should call in on tel. +45 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: 91052319#

About ALK

ALK is a research-driven, global pharmaceutical company focusing on allergy prevention, diagnosis and treatment. ALK is a world leader in allergy immunotherapy – a treatment of the underlying cause of allergy. The company has approximately 2,300 employees, with subsidiaries, production facilities and distributors worldwide. ALK has entered into partnership agreements with Torii, Abbott, and Seqirus to commercialise sublingual allergy immunotherapy tablets in Japan, Russia and South-East Asia, and Australia and New Zealand, respectively. The company is headquartered in Hørsholm, Denmark, and listed on Nasdaq Copenhagen. Find more information at www.alk.net.