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The opportunity in the US is substantial, but success will ultimately come down to execution

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The United States sits at a turning point in allergy care, shaped by decades of legacy practice and a growing demand for disease-modifying solutions. In this conversation, Peter Halling outlines how ALK navigates structural complexity, builds local scale, and prepares its next wave of innovation across immunotherapy and anaphylaxis. The discussion brings together strategy, execution and leadership at a moment when the US allergy market is beginning to open up in new ways.

How has the US market historically fitted into ALKâ??s global profile, and how did you evaluate its long-term potential when you became CEO?

In our sector, it is common to see European specialty companies generate 30 to 50 percent of their revenues in the US. That has never been our profile. Today, North America accounts for closer to one fifth of ALKâ??s revenues, with the US itself representing a smaller share than in many peer organisations. The underlying reason is structural. The US allergy market developed around an allergist-driven model, where physicians compound personalised allergen extracts in their own clinics and administer injections on site. Many of these products have been used for decades and were never approved under modern FDA standards. They continue to be used under specific regulatory exemptions, while any new product must go through full clinical development and regulatory review. That framework has limited the pace of innovation and made the market harder to scale in a systematic way.

As a result, the market has relied heavily on older products and complex reimbursement structures, even as the number of patients with allergic disease has continued to rise. The constraint has not been demand, but the way the system itself evolved. What has changed more recently is that innovation is now beginning to reach the US allergy space. Our sublingual immunotherapy tablets (SLIT) are part of that shift, including use in paediatric patients. We have also expanded into anaphylaxis through an epinephrine nasal spray from ARS Pharmaceuticals, through an international licence and a US co-promotion arrangement. At the same time, new food allergy treatments, including programmes in peanut allergy, are progressing and helping to broaden the market.

The US also remains significantly underpenetrated. Many patients do not complete allergen immunotherapy (AIT) programmes, and a large proportion remain on symptomatic treatment alone despite being suitable candidates for disease-modifying therapy. Awareness, referral patterns, access, and the practical burden of multi-year treatment all contribute to that gap. Taken together, this combination of unmet need and emerging innovation defines the long-term opportunity we see in the US market.

How does North America fit into ALKâ??s Allergy+ strategy, and what makes the region distinct in supporting its growth ambitions?

Our Allergy+ strategy is anchored in a clear ambition: to more than double our global patient reach to five million per year by 2030 by expanding access to allergen immunotherapy and broadening our innovation beyond respiratory allergy. North America, and the US in particular, plays an important role in achieving that goal, not only as a growth market but also as a core part of our operating model. The regionâ??s importance goes beyond commercial potential. We have built a substantial footprint in the US, with manufacturing in Port Washington, New York, source materials processing in Post Falls, Idaho, and additional capabilities developed through acquisitions in Oklahoma, alongside commercial and corporate functions in states such as Texas and New Jersey. A significant share of the source materials used across our global portfolio is produced in the US, which is why we continue to view it as a long-term investment hub rather than simply a sales market.

Strategically, the US stands out for its complexity. Market entry is not defined solely by approval from the FDA, but also by the ability to navigate a fragmented access environment involving private and public insurance systems, pharmacy benefit managers (PBMs), and meaningful variation at state level. As a result, building awareness, securing reimbursement, and ensuring sustained patient access are as critical as development itself. That makes the market demanding to operate in, but also highly attractive once those pathways are established.

Canada is structurally different and operates in a more centralised system that, in many respects, resembles Europe, which is why we always consider it separately within North America. More broadly, complexity is not unique to the US. Europe, despite a common regulatory framework, remains fragmented across its member states, each with its own access dynamics. What distinguishes the US is its scale and the level of unmet need. Once access is in place, the opportunity to grow is significant. From that perspective, North America is not simply a contributor to our Allergy+ ambitions, but a region where disciplined execution can materially accelerate our progress.

How do you assess the current state of allergen immunotherapy adoption in the US, and where do you see the greatest opportunity to expand access and impact?

The US allergen immunotherapy market remains relatively conservative, despite clear long-term growth drivers. Historically, treatment has been concentrated within the allergist community, which is highly specialised and very strong clinically, but limited in size and capacity. That naturally constrains adoption unless access to care can be broadened. One way we address this is by working beyond allergists and engaging more closely with paediatricians and ENT specialists. The approval of our SLIT tablets for children as young as five has been an important step, as it enables earlier intervention and allows a wider group of physicians to manage these patients. Tablet-based therapy also reduces the practical burden compared with injection-based treatment, as it can be administered at home, which benefits both patients, their caregiver and healthcare professionals.

At the same time, we continue to work closely with allergists. Sublingual tablets offer more flexible and efficient treatment pathways for the right patients, and we are seeing increasing uptake where they fit well within clinical practice. The objective is not to replace existing approaches, but to complement them and expand overall treatment capacity. Education and awareness are equally important. We engage across the allergy ecosystem, including prescribers, payers and patient organisations, to clarify the distinction between symptomatic treatment and disease-modifying AIT, and to ensure that available options are well understood. This includes training new prescribers, working with key opinion leaders and professional societies, and supporting patient advocacy efforts.

Market access is the final, critical element. Patients need reliable coverage once treatment is initiated if persistence and long-term benefit are to be achieved. That requires close coordination across medical affairs, market access and research activities, including scientific exchange at congresses and the publication of clinical data in relevant journals. Overall, expanding adoption in the US is not about a single initiative, but about building understanding, confidence and access across the entire allergy community.

How does the partnership with ARS Pharmaceuticals illustrate ALKâ??s approach to innovation in the US, and what role does your local footprint play in enabling that strategy?

It is important to be clear that this was not an acquisition. We entered into a strategic licence and co-promotion agreement with ARS Pharmaceuticals, a US-listed biotech. We paid approximately USD 145 million upfront for the rights to its epinephrine nasal spray, in most markets outside the US, while in the US we co-promote the product, primarily in the paediatric setting, with ARS retaining overall commercial responsibility.

We chose ARS because the product represents meaningful innovation in an area of clear unmet need. It addresses anaphylaxis, a potentially life-threatening emergency, through a needle-free nasal spray that can reduce hesitation and enable faster treatment when time is critical. That combination of clinical relevance and practical simplicity made it a strong fit for us, both strategically and culturally. The partnership allows us to expand our reach outside the US while also strengthening our position within it through the co-promotion model.

More broadly, it reflects how we view the US as an innovation ecosystem. The depth of research, the strength of intellectual property protection, and the availability of talent continue to make the US highly attractive for biotech and pharmaceutical innovation. While hubs such as Boston and the San Francisco Bay Area are well known, there are strong centres elsewhere as well. In our case, we engaged with ARS in San Diego, which is a well-established biotech cluster in its own right. Success in the US creates the conditions to reinvest and accelerate further innovation.

That strategic focus is reinforced by our long-standing operational presence in the US. We have manufacturing in Port Washington, New York, source-materials operations in Post Falls, Idaho, and

additional sites for sourcing and processing raw allergen materials in states including Oklahoma, Illinois and Washington. Our main US office is in Round Rock, Texas, supported by pharmaceutical operations in Bedminster, New Jersey, and a presence in Connecticut. This footprint allows us to produce locally, export globally, and stay closely connected to the market.

Importantly, this is not a recent shift. We established this presence more than twenty years ago, well ahead of current discussions around onshoring and supply chain resilience. Being embedded in the US has helped us avoid some of the challenges others face today and reflects the long-standing collaboration between Denmark and the US. For us, it remains a deliberate strategic choice that continues to create value, both locally and globally.

What does the appointment of Edward Jordan and the elevation of North America within the executive leadership structure signal about the regionâ??s role going forward?

A large part of our US presence has been built through acquisitions that we have fully integrated into ALK. While our origins are Danish, much of our organisation is deeply rooted in the US, and that has shaped both our operating model and our leadership needs. Given the complexity of the US market, strong local leadership is not optional, it is essential. We already have experienced US-based leaders across our operations. Tim Davis leads our source materials organisation from Post Falls, Idaho, while Andy Ameye oversees product supply from our manufacturing site in Port Washington, New York. Strengthening commercial leadership was therefore the natural next step. Appointing Edward Jordan as Executive Vice President and Head of Commercial Operations North America, and bringing that role into the executive leadership team, reflects the importance we place on execution and growth in the region.

Ed brings more than 30 years of biopharma experience, including senior roles at Merck, Schering-Plough, Teva and DBV. He understands the allergy space and, just as importantly, the practical realities of market access and commercial execution in the US. Having an American leader with that depth of experience gives us a stronger platform to unlock the regionâ??s potential. His mandate is both immediate and forward-looking. It includes continuing to grow our existing business, expanding the prescriber base, introducing new treatment approaches, and preparing the organisation to bring our pipeline to market. That includes our peanut allergy programme, where a sublingual immunotherapy tablet is in clinical development and has shown encouraging early data.

The opportunity in the US is substantial, but success will ultimately come down to execution. This is not only about competing within established segments, but about expanding the market and addressing unmet need. Many patients still do not have access to appropriate disease-modifying treatment, and our focus is on changing that in a disciplined and sustainable way. With the right leadership in place, we believe we are well positioned to do so.

What milestones do you see as most important for North America over the next two to three years, and what message would you leave with the US community?

North America is clearly a growth region for us, and the priority now is how we accelerate that growth through disciplined execution. In our strategy, we have set an ambition to grow the region by more than 10 percent annually towards 2028. I believe there is room to outperform that, particularly in the US, if we deliver consistently over time. Achieving sustained growth above that level would already represent a significant milestone.

Beyond topline performance, the focus is on strengthening the foundation of the business. That includes continuing to expand our existing portfolio, identifying new indications and partnership opportunities, and further consolidating our position across both the US and Canada. In parallel, an important part of the next phase is preparing the organisation to bring new products successfully to market.

A key milestone in that respect is our peanut allergy programme. We are hopeful of a Phase II topline readout for our sublingual immunotherapy tablet in the first half of 2026. If the results are positive, we plan to move rapidly into Phase III development, with a substantial part of that work taking place in the US and Canada. The goal would be to complete the programme and be in a position to launch towards the end of the decade, around 2029 to 2030, assuming everything progresses as planned. Peanut allergy remains significantly undertreated in the US, and the level of unmet need creates both urgency and responsibility.

If I were to summarise our message to the US community, it would be straightforward. ALK is a global company with a strong and established presence in the US. We see considerable opportunity here, and we are fully committed to realising it through focused, consistent execution in the years ahead.

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