Interview: Anders Hedegaard, President & CEO, Bavarian Nordic



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Bavarian Nordic's 2012 financial results were very positive, with annual revenues doubling. How satisfied were you with this performance, and which factors drove this growth?

We were extremely satisfied with what was a remarkable year for Bavarian Nordic, where the company not only doubled its turnover but also significantly improved its bottom line. The company also generated much more cash than originally planned. These were all critical steps for the business, and have come as a result of improved execution over the last two years.

Although we might have started as a more traditional biotech company, smallpox vaccine orders from the US government have helped us to make the leap towards an industrial scale pharmaceutical company. Now, our primary objective is to generate profit.

The US Food and Drug Administration (FDA) gave Bavarian Nordic the clearance to initiate the delivery of the smallpox vaccine IMVAMUNE® , which began an effort to shift to a more industrial scale operation, with a focus on improving efficiency and quality. This was initially challenging. Upscaling our facilities, which had only previously operated to produce on a trial basis, proved rather difficult due to the nature of the product, which is biological, essentially a live virus. To meet this challenge, the company made several changes to its processes and management, completely overhauling our leadership team in 2010 in order to reach our new targets.

We saw the initial results of this strategic shift at the start of 2011, and by 2012, our financial situation had improved significantly, which was very satisfying. This was a direct result of focusing on execution. We still have a number of ongoing improvement projects, however, which we hope will even further improve efficiency in the long-term.

Production of the smallpox vaccine actually began in Germany, with large-scale production moving to Denmark once the contract had been finalised. Now it is our time to deliver. Compared to other

Danish companies that work with biological products, we have limited experience, but we are pleased with the way we have developed our capabilities in such a short period of time. We hope that the skills we have demonstrated to the US market will help us win more contracts in the future.

Aside from its contract with the US Government, Bavarian Nordic also has a project for prostate cancer in Phase 3 development. Can you comment on that?

This project is a very important part of the overall story and future growth of Bavarian Nordic, and why we still consider ourselves being a biotech company at heart. We are investing heavily in a Phase 3 trial. In 2012 approximately 50% of our revenue was channeled into R&D.

The results from the project Phase 2 trial were announced in 2008. The data was extremely exciting because in a randomized double placebo controlled study we saw significant improvements in overall survival in a patient group that otherwise had limited alternatives. The data was considered extremely encouraging from a clinical point of view, adding 8.5 months of overall survival to a patient group that otherwise had only 18 months. The feedback from the FDA and European authorities justified moving into Phase 3 with the product. Phase 3 began in late 2011, and we are still recruiting patients into the study. We need 1200 patients in total in order to assess its benefits.

Are you also preparing to manufacture the product at your facilities here in Denmark?

After efficient production of the smallpox vaccine in Denmark, we have decided to consolidate our production facilities in Kvistgaard, Denmark. There were many good reasons behind this decision. The prostate cancer vaccine is also a live pox virus, which means there are synergies in production. This is going against the trend of Danish companies that often move their production facilities out of the country, but for us it is the best way to drive the future growth of the company.

Although the Danish facility will provide product for commercialisation, we will pursue a partnership model. The strategy of Bavarian Nordic is to run Phase 3 until data readout, and then hopefully, based on attractive data, we will seek appropriate partners, such as a global pharmaceutical company with the ability to achieve a worldwide product launch. While some biotech companies think they can take on that marketing challenge themselves, we are more realistic. Establishing a fully-fledged global approach and utilizing its full potential requires a partner.

When in India, we met some companies in the vaccine business that explained that in order to be successful in vaccines it is essential to work with the government, instead of just focusing on growth. Would you agree? What do you think it takes to have a successful vaccine business?

When it comes to the smallpox business, there are no commercial customers, but only

governments and their stockpiling strategies. We established Bavarian Nordic through a partnership with the US government. The dialogue began in 2000, before the events of 9/11. We saw a market potential and wanted to work on the next generation of smallpox vaccines, which were interesting to the US government before the terrorist attack, but even more interesting afterwards, with the government allocating much more funding and opening the doors for even deeper involvement.

So far, we have won more than $ 1 billion worth of contracts with the US government, with options for further investment in the future. By investing in us, the US government has made it possible for us to build up our infrastructure and build a successful company. That could only happen with a very close partnership. With the US government as our only client for the vaccine, the development process is very different to how it works with a normal pharmaceutical product. It is based on dialogue and mutual benefit.

Our prostate cancer product, however, will be marketed like any other product, but this still involves a partnership as a major element. We acquired the rights to develop a vaccine for prostate cancer from the National Cancer Institute (NCI) in 2008. We have a strong research collaboration with the institute, which extends beyond prostate cancer to new agents and vaccines. The NCI does the research, and we get the results in order to develop new products. This relationship helped us in moving to Phase 3 trials with our prostate cancer vaccine, as we had access to some of the most prominent researchers in the field thanks to the NCI. However, when it comes to commercialisation, the marketing strategy will be very similar to any other biological product for the mass market.

It seems that every company in this industry strives for partnerships and that everyone has the same agenda. How will Bavarian Nordic do things differently?

For us, partnership is essential. Without a strong partnership with the US Government, there wouldn’t have been any Bavarian Nordic because we wouldn’t have had the financial ability to move where we are. However, it also creates challenges. When we meet investors, it’s challenging to explain the business model and win confidence in its sustainability.

It’s a challenge because some investors do not consider government partnership sustainable, but here we need to communicate our 10 years successful US partnership and the ability to acquire contracts at a value of $ 1 billion.

The government business gives a huge advantage in many ways, but the challenge is to get investors to accept it and rank it on par with a normal commercial contract.

In this regard, why should investors be optimistic about Bavarian Nordic’s value?

We have a successful track record of delivering to the US government. We are producing a vaccine that has a profile that is not available from alternative sources. Our contracts so far are a result of the US Government’s desire to cover its bases, which we believe will continue to happen. This

mitigates the risk of having a cancer vaccine in Phase 3, which is by definition somewhat risky. Although we are convinced of its future success, we admit the risk. Finally, the cash flow that comes from a business in infectious diseases gives us a strong market position. We hope this cash flow will one day allow us to expand further, either in infectious diseases or cancer. Having infrastructure in place and commercialised products will help us open the business in new areas.

As the CEO of Bavarian Nordic for the past six years, what are your goals for taking the company forward?

Right now we are on the edge of creating a sustainable business. It's a challenge because we currently have two Phase 3 trials running, which requires a sustainable flow of income. The ambition is to put the company in a more sustainable situation in the medium-term and then get these two products to the next stage. We have recently received an additional supply contract from the US government and the clear priority is to execute on this. From there, it's a question of getting our cancer vaccine PROSTVAC finalized in Phase 3 and establishing a partnership, which will make things much easier financially.

After working most of your career with Danish companies, what do you think the world today has learned from the Danish way of doing business?

I started out in basic research then soon moved to Novo Nordisk with a more commercial focus. It's a great company, and I was given a lot of challenges and opportunities. Novo Nordisk has been doing extremely well and I was pleased to work for the company for almost 10 years. I then moved on to ALK and I am now here in Bavarian Nordic.

The Danish companies I have worked for have all been very international. Their strengths lie in their ability to build on what they have inherited from Denmark, but to also look outward and be international. Being Danish, it's so important to look outward. Being cynical, sometimes we have a tendency to look too much into ourselves, and believe that we are better than everyone else. But we are not. We have been most successful those times that we looked outward with a global approach. I think that the boost for flagship Danish pharmaceutical companies came when they started to take on global perspectives on business.

Also, some companies started out because of strong public private partnerships. Today we all benefit from that. Of course, we sometimes recruit employees from one another and for years we were the ones attracting talent. But overall it's very healthy because we are in a field where we can get highly qualified people as well as generate that expertise, and that is ultimately why we have a chance to continue our success.

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