Nikolaj SÃ¸rensen â?? CEO, Orexo

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20.08.2019

Tags:

Sweden, Orexo, Pharma, Opioids

As one of few Swedish companies, Uppsala-based Orexo has made the leap to commercialize its star product for treating opioid addiction in the US, even before entering the European market. In this interview, CEO Nikolaj SÃ¸rensen highlights the impact of Orexo in finding solutions to tackle the US opioid crisis, gives an update on companyâ??s patent litigation case and underlines the benefits of operating in an innovation-friendly Swedish ecosystem.

You have been appointed as the CEO of Orexo in 2013. Since then, the company has been growing significantly, so can you highlight to our international readers what have been the milestones since you have taken over as the CEO?

Orexo has decided on a strategy of commercializing its developed products without external help, even before I joined the company in 2011. I was appointed as the CEO in 2013, with the task of creating a commercial unit and the board agreed to this plan. 2013 then became a pivotal year for Orexo, as we received FDA approval for our product Zubsolv, to treat opioid addiction, and we then built our US entity for commercial operations from scratch. Our goal was to control our own destiny through revenues, cashflow and profit, rather than relying on milestone payments and royalties. As part of this target, I promised the board that Orexo would become profitable within three years â?? a goal we achieved in 2016. Having created its own commercial unit and actually becoming profitable is what sets us apart from most other Swedish pharmaceutical companies. Today, we are a fully integrated, profitable, pharma company with a strong cash position and own commercialization capabilities. While most companies in the world start commercialization in their own country first, our key strategy is to focus our commercialization efforts on the US market and to out-license our products to partners for markets outside the US.

Orexo won a lengthy and costly patent battle against Actavis last year. Why was the win so important for the company?

We have had a patent litigation case with Actavis on our main product Zubsolv, that has been followed us since the start of 2014 until last year. Zubsolv is currently creating more than 80 percent of our revenues, so a generics threat would obviously have a large impact on our business. However, we prevailed as our patent was validated in the federal court and now will be in place until 2032. This gave us some rest, as we know now that Zubsolv can serve as the foundation for further development of Orexo. We have learnt that it takes an immense amount of resources to fight in this patent litigation case for a small company like us, so it put many projects on hold. After the case was settled, one could feel a sense of relief throughout our whole company, as the whole process was very draining. The current situation allows us to launch more own or acquired products with the same field force, which lowers the operational costs dramatically due to synergies created. Our R&D team is working on very exciting opportunities currently and the financial attractiveness of these are much higher, as we already have a commercial unit in place.

In 2016 Opioid addiction was declared a public health priority by former FDA commissioner Scott Gottlieb, with more than 130 people a day dying after overdosing. What has been Orexoâ??s approach in addressing the unmet medical need to treat addiction and proposing a holistic solution to this issue?

Even the President of the United States of America has called the opioid crisis a public health emergency and made it a high priority. Orexo is proud of taking significant responsibility for finding solutions to the crisis â?? far more when what is expected from companies of our size. When entering the market, we identified a major bottleneck related to the access to treatment, as physicians had a limit of 100 patients, which they could treat for opioid addiction. However, the number of patients is far higher, so doctors face a dilemma as the DEA will revoke their license, if they treat more patients than they are allowed to. On the other hand, they would break their doctorâ??s oath when not treating a patient. Orexo then started a lobby campaign at the congress in Washington DC in 2016, to extend the number of patients that can be treated from 100 to 275. In a speech, President Obama highlighted how he was very encouraged by the support he received from Senators and Representatives from both parties to the motion, Orexo is proud to have played an active role in this process, educating the politicians about the issue and encouraging them to act. A small company from Sweden therefore played an instrumental role in extending patient numbers for opioid dependence that can be treated by one doctor.

Your star product Zubsolv has received the FDA stamp in 2013. What do you see as the next development milestones to be achieved in the US market moving forward?

While in 2013, many people were dying from heroin overdoses, today the majority is dying from synthetic opioids, such as fentanyl. Addicts are mixing heroin with these synthetics to create a stronger drug, however this makes it incredibly difficult to control the dose, with one may give you a high, while the next one may kill you. To treat an overdose with these drugs, which are more powerful and longer-lasting than heroin, a new way of treatment is needed, which hopefully have found in with our drug candidate OX124. In this case, we have identified a problem, with our researchers finding a solution. However, we could not fully develop the product ourselves, as part of this solutions is based on a device. Hence, we approached a partner in the US to have this device manufactured, according to our expectations and needs. All of our development programs follow the same approach, looking at the problem and see if we can solve it internally or if we need external competences. Despite having a smaller R&D department today than in 2013, we have more advanced projects running, because we are involved in more partnerships with other companies in Sweden and around the world. Our products are developed for the US market, however, sadly we may see a need in Europe and other parts of the world for our drugs as well. Therefore, we are looking for partners in commercialization for some of our products for markets outside of the US.

Sweden is known for its tradition of excellence in medical research embodied by the Karolinska Institutet, which awards the Nobel Prize in Medicine. How does Orexo leverage this outstanding academic research landscape to find treatments for unmet medical needs?

I think the innovation-friendly environment we have here in Sweden is one of the reasons for our success. All of our products are developed here in Uppsala, as we have an excellent academic environment with the Pharmacy and Pharmaceutical Chemistry school of the University of Uppsala. Especially in areas of chemistry and formulation, Uppsala has been a stronghold for many years, which helps us a lot. While the US is our main market, the competition for talent there is much higher and the same goes for the cost of employment in the US, when compared to Sweden. We are a big fish in Uppsala, and this helps us a lot in our efforts to retain talent, by offering many freedoms and a great work-life balance. Orexo is a local company with global ambitions and we hope that through success we can inspire other companies to go the same way.

You have very unique experience, working at Boston Consulting Group and then from having several senior management positions at Pfizer Inc. How have you leveraged these experiences to make Orexo the success it is today?

Life science has always been an area close to my heart, as my father is a professor in medicine and my mother is a nurse. While I am not a scientist from a medical perspective, my upbringing familiarized me with medical terms. Working at Boston Consulting Group, I was very involved in healthcare and life sciences, which eventually led me to Pfizer. These two experiences helped me a lot when I took over my position here at Orexo. As a consultant you learn to become a generalist with an umbrella perspective, as you have to understand different industries and business cases. When starting at other companies, the perspective is usually narrower, as it was the case at Pfizer, where I did not get too many insights into manufacturing and R&D but was more focused on commercialization and marketing. In turn, Pfizer helped me to understand the pharma part of a business better, where I could integrate my experience in identifying customer needs. Nevertheless, my position here at Orexo is very different from the roles I had at Pfizer and it required a steep learning curve initially, as my current position requires a holistic perspective, rather than only focus on commercialization.

What key milestones would you like to achieve in the next three to five years?

My hope for Orexo is to have a broader portfolio, which we aim to achieve by expanding within opioid addiction and through a branch-out strategy. By the latter we want to move in areas, which go beyond our current offer. Working with patients suffering from opioid addictions, we see that most of them also suffer from other CNS conditions, such pain or psychiatric disorders. In my opinion, it would be natural for Orexo to move or â??branch-outâ?• into the CNS field as well and grow a platform in this area, with an overlap in target and patient groups.

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