

# Peter Anastasiou - Executive VP & Head of North America, Lundbeck

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*Industry veteran Peter Anastasiou, executive VP and head of North America for Danish CNS specialist Lundbeck, outlines the performance of Lundbeck's specialty portfolio in the US market, the challenges of working in the CNS space, and how the company is adapting to the problems posed by the COVID-19 pandemic.*

**Peter, could you briefly introduce yourself and your journey with Lundbeck's affiliate in the US overseeing North American operations over the past decade?**

I have been in the industry for 28 years. The first 12 of those years, which I spent at Eli Lilly, were very formative years for me. Not only did I acquire a lot of industry experience, including in sales, marketing and leadership, during this time, I also developed my passion for CNS. In the 1990s and 2000s, Lilly was one of the preeminent companies in the CNS space, with the launch of drugs like Prozac®, Zyprexa® and Cymbalta® (which I worked on as Global Marketing Manager). Subsequently, I joined BMS, during which I worked on Abilify®, another CNS blockbuster. In 2006, I joined a CNS start-up, Neuronetics, for a few years.

CNS conditions are highly symptomatic diseases that have a huge impact on patients, they are associated with significant morbidity, and they often have high rates of mortality, too. I think most people have a loved one or two suffering from a psychiatric or neurological disorder. The broad

societal impact and the highly personal connection so many of us have are what fuel my passion for this therapeutic area.

I came to Lundbeck in 2009 to help establish its North American operations. Lundbeck is a 105-year-old company, but we are relatively new to the US market, only entering the US in 2009 through the acquisition of Chicago-based Ovation Pharmaceuticals. Previously, Lundbeck products were sold in the US through partners. I helped to set up the Psychiatry business unit here and then I became Chief Commercial Officer in 2014. Four years ago, I was appointed President of Lundbeck North America and in October 2017, I became EVP and Head of North America, joining Lundbeck's global executive leadership team.

Lundbeck's journey over the past decade has been truly fantastic. We launched seven drugs in about eight years, so we were in growth mode constantly, building infrastructure and capabilities along the way. We also expanded our presence and investment strategically. For instance, we acquired Abide Therapeutics in 2019 and established the Lundbeck La Jolla Research Center in Southern California, which gave us access to an entire platform of promising earlier-stage molecules. The same year, we also acquired Alder BioPharmaceuticals, that gave us access to VYEPTI™, which was launched earlier this year, as well as another investigational migraine asset, Lu AG09222. This acquisition also gave us new capabilities in the biologics space, which will allow us to advance the existing antibody programs in our pipeline, as well as any that we may acquire or develop in the future.

Our leadership team came from a number of different companies, many of them well-established Big Pharma players. We came to Lundbeck understanding how things were done traditionally, but we also had the opportunity to put our own touches on operations. The team and I really focused on building a more agile and nimble organization here at Lundbeck North America. We have the results to show for it - and I can honestly say it has also been a lot of fun!

### **How has Lundbeck's portfolio performed in the US?**

The strategy is to continue to evolve the organization here: bring new therapies to the market, continue the momentum on our strategic brands, and invest in lifecycle management for our established products. Since CEO Deborah Dunsire joined Lundbeck in 2018, we have worked hard to support the company's new 'Expand and Invest to Grow' strategy.

For our strategic brands, we have four actively promoted products at the moment: Trintellix®, Rexulti®, Abilify Maintena® and Northera®. All of them are performing well, growing at double-digits even though they have already been on the market for several years. This is a testament to the strong unmet needs that exist in this space. Trintellix and Rexulti are indicated for different phases of depression. We believe the strong growth of these products demonstrates not only their value as differentiated products that positively impact patients but also the continuing appreciation of that value in the US market.

At the same time, we continue to invest in each brand in different ways. For instance, for Abilify Maintena, we added a new indication for bipolar disorder I, which gave renewed momentum to the product. For Trintellix, we secured a label expansion for improved processing speed, an important aspect of cognitive function that may be impaired in patients with major depressive disorder, as well as a label expansion to include TESD, or treatment-emergent sexual dysfunction, data. For Rexulti, we have invested in Phase III programs for post-traumatic stress disorder (PTSD) and agitation in Alzheimer's disease.

For new therapies, our most recent product, VYEPTI, was approved in February and launched in April. It is an option for the preventive treatment of migraine in adults and we have high expectations for it. It only needs to be administered once every quarter, and it is the first and only IV treatment for migraine prevention. We also have ongoing Phase IV studies and plan studies in other indications.

**Different countries have very different approaches to CNS disorders and there is typically a lot of stigmas attached to these diseases. How do you assess the approach towards brain disorders in the US in terms of both the diagnosis and treatment landscape, as well as the regulatory environment?**

CNS is an extremely difficult space to work in. Firstly, these diseases are characterized by significant heterogeneity. Depression is the example I always use to illustrate this point. Imagine a disease where both sleeping too much and sleeping too little can be symptoms. Eating too much, but also eating too little are symptoms. No two people experience depression in exactly the same way. Secondly, there are no biomarkers for these diseases. We cannot simply take a blood sample and look for biomarkers to diagnose the condition or gauge treatment efficacy, the same way you can for diabetes or heart disease. There are no objective endpoints defining disease onset and progression. Taken together, CNS diseases are very challenging to diagnose and treat, as well as to

develop drugs for.

In addition, as you highlighted, there is a lot of stigmas attached to CNS disorders, whether we look at migraine, mental health disorders, or neurodegenerative disorders like Parkinson's disease and Alzheimer's disease. I think compared to other regions in the world, the level of stigma in the US is lower, and the situation is constantly improving. However, we are committed to further reducing and eventually eliminating the stigma associated with CNS conditions.

This is why we partner so closely with patient advocacy groups to address these challenges. We are very proud that despite having only been in the US for ten years, we have been ranked top amongst pharmaceutical companies in terms of corporate reputation according to the *PatientView Corporate Reputation of Pharma (USA Edition)* for five of those ten years. That is a great achievement for our team and testament to the efforts we have invested in building these stakeholder relationships.

When it comes to the regulatory landscape, we have seen a lot of progress and we are committed to continuing our work here. Historically, according to the FDA's own data, products in the neurology and psychiatry spaces have a much lower rate of approval. However, in the past few years, the industry has become a lot more productive in the CNS space and the FDA has also been very open-minded and collaborative. As a result, many new products and indications have been approved, including those of Lundbeck's, over the last couple of years. We are headed in the right direction, and I feel good about the progress being made.

### **How has Lundbeck managed to cultivate such successful and productive relationships with patient groups in the US?**

We are the largest biopharmaceutical company in the world exclusively dedicated to CNS. We are singularly focused on our purpose of improving the lives of patients with CNS disorders. That sets us apart from other players, and patient groups see and value our commitment.

They appreciate us because we approach issues and collaborations in a very authentic way. They know we genuinely care about doing the right things for patients. That is in Lundbeck's ethos and DNA. We have a deep and long-term commitment to partnering with these groups instead of viewing projects or initiatives in a purely transactional way. For us, it's always more of a handshake than a hand-out. Our partners experience that we are truly invested in them and the programs we work on. We invest resources in engaging with these groups at the grassroots level, in addition to

at the HQ level. We sponsor local walks, our employees sit on the boards of local chapters, and we volunteer our time with them. Much of the work gets done at the grassroots level so this is very important.

**The US market is well-known as one of the most innovative markets globally but on the other hand, access and affordability have been enduring issues as a result of many factors. What kind of positive change do you hope to see in the US market?**

Innovation certainly occurs globally, including where Lundbeck is headquartered in Copenhagen, Denmark, but I will say that the US ecosystem fosters innovation perhaps more than any other country in the world. We have some of the best universities in the world, well-funded and resourced capital markets, and thriving start-up and business environments.

In terms of biopharmaceuticals, what is important, too, is that the US market still rewards innovation with prices that justify the significant investments – and failures – that each successful drug entails. Reimbursement rates in Europe are comparatively much lower. If the US had a similar system, there would be less incentive for companies to take the kind of risks they have to in an industry like biopharmaceuticals, and lower incentive for capital markets to continue investing at the rate that they have been.

In terms of access and affordability, we are committed to removing barriers to care. We support industry efforts to ensure that rebates granted to different players in the medicines supply chain (payers and pharmacy benefit managers, as example) are passed on to patients. Lamentably, numerous independent analyses have shown that, on average, nearly half of every dollar spent on brand medicines goes back to the supply chain. We are pleased to see the administration is pursuing a commonsense solution to this patient-affordability obstacle. We also support reforms to improve access to treatments – for example, step therapy reform or “fail-first” reform so patients can benefit sooner from innovation their doctors believe will provide the most meaningful clinical outcome

At Lundbeck, we help where we can. Through a variety of programs, we work to provide appropriate assistance to people who depend upon our therapies. We offer access-related support programs for qualified eligible patients who may require additional support, such as benefit verifications and co-pay assistance. Separately, we offer the Lundbeck Patient Assistance Programs, which provide free medicine to eligible patients, including those who are uninsured or do not have insurance coverage for their medication.

## **2020 has been a challenging year for everyone. How do you think the COVID-19 pandemic has changed the industry?**

Whether there is a pandemic or not, brain diseases don't stop. For Lundbeck, our most important consideration has been ensuring the supply of our medicines to patients who need them, which we continue to do. We are also proud that we were able to launch VYEPTI in April in spite of the pandemic. Some companies chose to delay product launches during the pandemic, but there were patients and healthcare professionals waiting for this product, so we thought it would have been self-serving for us to delay the launch. We had to adapt all our plans for a virtual launch, and though it took a significant effort, we quickly pivoted our plans to meet patients' and HCPs' needs in this new environment.

The pandemic has accelerated the industry's adoption of technological advances, out of sheer necessity. I do not think we can now put the toothpaste back into the tube, so to speak. All our virtual initiatives and programs will stay even when we return to some semblance of normality and pre-pandemic practices—some of which is already happening. Adhering to guidance from the CDC and prioritizing the health and safety of both our employees and the physician practices that we call on, some of our reps are meeting with physicians face-to-face again. But digital and virtual activities will supplement these conventional operations in the future.

Even when things begin to return to normal, however, we know the effects of the pandemic will be felt for a long time to come. We are very aware of the significant mental health impacts in our patient communities, and in society as a whole. Stress can exacerbate symptoms of mental illness and migraine in people who live with those conditions, and we know that many people who had no previous mental health disorders are now struggling with anxiety, depression and PTSD. The mental health crisis caused by the pandemic will be significant and long-lasting. With our long history in brain diseases and our commitment to supporting people impacted by mental health disorders, we are uniquely positioned to lend our expertise and energy to addressing this crisis. I know our colleagues across North America are ready to support our patient communities and bring our unique Lundbeck commitment to this unprecedented time.

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