Leonard Paolillo – President North America, Merz Therapeutics

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Leonard Paolillo, President of Merz Therapeutics North America, shares what it means to be a growing player in the specialty neurology space. Two years after the company's acquisition of INBRIJA® (levodopa inhalation powder) and AMPYRA® (dalfampridine), and with XEOMIN® (incobotulinumtoxinA) continuing to anchor its portfolio, Paolillo reflects on how Merz Therapeutics has deepened its footprint in Parkinson's disease and multiple sclerosis while building a trusted reputation in a highly competitive market. He goes on to describe the advantage of a family-owned company in taking a long-term view on complex therapeutic areas like neurology, and the key role the US market will play as a driving force in the company's growing global ambitions.

Please share a brief overview of the company, its origins within the Merz Group, and the journey to establishing Merz Therapeutics as a standalone business in 2020.

Merz Therapeutics is part of the Merz Group, a global family-owned healthcare company headquartered in Frankfurt, Germany, with a history spanning over 117 years. In 2020, Merz Therapeutics was established as a standalone business. That gave us the opportunity to sharpen our focus on specialty neurology and accelerate investment in areas where patients still face significant unmet needs. Today, we are dedicated to improving the lives of people living with neurological disorders and other complex conditions that can profoundly impact quality of life.

Merz Therapeutics operates across neurology, hepatology, and dermatology. How are these strategic focus areas reflected and prioritized within the North American business?

Merz Therapeutics operates across several specialized therapeutic areas globally. In North America, our focus is specialty neurology, where we believe we can make the greatest impact for patients and healthcare providers. That focus is also reflected in our global development investments and our business development priorities.

We're primarily focused on neurological conditions such as Parkinson's disease, multiple sclerosis, sialorrhea, spasticity, and dystonia. Despite existing treatment options, significant unmet needs remain, and patients often require long-term, specialized care. From a business development perspective, you can see that strategy in our 2024 acquisition of INBRIJA and AMPYRA, which expanded our ability to serve patients across the neurology continuum beyond our longstanding flagship product, XEOMIN. We have also strengthened our engagement with advocacy organizations, healthcare professionals, care partners and patients to better understand community needs.

Two years after the acquisition of INBRIJA and AMPYRA, how have those brands strengthened Merz Therapeutics' portfolio and contributed to the company's strategy in North America?

The acquisition of INBRIJA and AMPYRA was a significant step for our specialty neurology strategy. Beyond expanding the portfolio, it took us deeper into Parkinson's disease and multiple sclerosis, and it also broadened our capabilities here in North America. That helped us become a much more diversified company, both from a product perspective and from an organizational perspective. It set the foundation for the next leg of growth we expect over the next two to five years.

The US specialty neurology landscape is highly competitive. What does it take to build and strengthen Merz Therapeutics' position and reputation in this market?

It starts with focus. Becoming a standalone business gave Merz Therapeutics the ability to focus specifically on specialty neurology. You have to know your strengths as an organization, and while the market is highly competitive, we all play a different role in that neurology space. There are a lot of companies out there. Some are small biotechnology companies focused on moonshot gene therapies and ambitious disease-modifying products that could change patients' lives. Others specialize in commercialization, or in bringing symptom relief in better, more convenient ways.

Is the space crowded? Yes. Is it competitive? Yes. But Merz Therapeutics knows its strengths. We have excellent R&D and commercialization capabilities, and bridging that gap between development and commercialization is a unique strength we've built here in the US.

In the specialty neurology space, you build a reputation one patient, one physician, one healthcare professional interaction at a time. That's why the people we bring into our organization, particularly those who are field-facing, engage with physicians, healthcare professionals, and payers daily. Their interactions and their professionalism are how our reputation is built, and I could not be prouder of the people we have doing that here at Merz Therapeutics.

You've held leadership roles across CNS, rare disease and specialty pharma. What lessons from those experiences have shaped your approach, and what do you believe are the most important ingredients for success today?

In rare disease, you're often dealing with extremely small patient populations. Sometimes, this means launching a product for a disease where there's never been treatment before. Therefore, you need to start the commercialization process by being patient-centered and by working your way back to the company. How does the patient get care delivered, and where are the gaps? What's important to physicians? Who are the key players, from both a pharmacy delivery and a payer perspective? While I learned this working in rare disease, I do think it's applicable across any launch.

Therefore, bringing that same discipline to our commercialization efforts is the key to success. If you start by focusing inward and with what you want to accomplish as a company, you'll inevitably miss things. You'll only find those disconnects once the product is already in the market. My experience has taught me that most companies say that the patient is at the center of everything they do. But if you don't actually plan your launch that way, you'll end up with suboptimal outcomes, and the patients who need your product most won't get it in a timely fashion.

Merz Therapeutics' "Pivot for Growth" strategy places significant emphasis on North America. How does the US market fit into Merz Therapeutics' broader global ambitions?

As the world's largest healthcare market, the US must be prominently featured in any strategy we have at Merz Therapeutics, and the Pivot for Growth strategy is no different. You'll hear from any healthcare executive that the US remains fertile ground for innovation in specialty neurology. Being close to that ecosystem helps us better understand evolving patient needs.

The US is also home to a dynamic network of researchers, biotechnology companies, patient communities, and healthcare providers. Therefore, it's an important source of innovation and partnership opportunities. As I mentioned, the acquisition of INBRIJA and AMPYRA helped us reach even more patients and more healthcare professionals within specialty neurology. Through continued investment in our portfolio and strategic business development, we'll continue to build a larger, more sustainable business here in the US.

Our Global Head of Business Strategy and Portfolio Innovation, Karen LaRochelle, is based here in the US, because we believe it's such an important market to source opportunities from. Here, we can identify strategic opportunities that align with our expertise in specialty neurology, complement our existing portfolio and capabilities, and create even more meaningful value for patients. Whether that's through an acquisition, an in-license, or a strategic partnership, the US will feature prominently in that effort. And these investments won't just advance our regional ambition to build a solid footprint here in the US; they will also contribute meaningfully to Merz Therapeutics globally over the long term.

The healthcare industry is navigating significant policy changes, including drug pricing reform, the Inflation Reduction Act (IRA), Most Favored Nation (MFN) proposals, and shifts in federal healthcare infrastructure. How do you view the impact of these developments on innovation, patient access, and the future competitiveness of the US market?

Changing legislation and a changing environment isn't a new occurrence. That will continue as administrations and priorities change in the future. The pressure on our industry to improve affordability and access is important, but so is continuing to support scientific advancement. The US has become the global leader in biopharmaceutical innovation because of a strong research ecosystem, world-class talent, and an environment that has encouraged investment in scientific discovery, drug development, and commercialization. Striking the right balance between access and innovation is going to be critical, not just now, but going forward.

Despite all the changes, the US remains the premier market for our investment and where much of our future success will depend. As in most environments, being overly reactive doesn't help. We need to stay close to what's happening and pay attention, but our investments in and commitment to the US have remained unaffected at this point.

As part of a privately owned group, how does Merz Therapeutics' ownership model enable the company to invest in complex and historically challenging therapeutic areas such as neurology?

As part of a family-owned, private company, we have the ability to take a long-term view of growth. Innovation and patient impact are at the forefront of our discussions, which is often in contrast to near-term market expectations. It gives us the flexibility to prioritize long-term value over short-term expectations. Our commitment shows through our corporate mission statement, "better outcomes for more patients."

I've met our shareholders through board interactions and other company engagements, and that mission truly starts with them. What's particularly rare is how personally invested they are in the vision of the company. As a family and as shareholders, they share a deep commitment to improving patients' lives and understand the importance of investing for the long term. They don't simply provide financial resources and walk away. That shareholder structure uniquely positions us to be a strong player in neurology where other companies have decided to exit.

Looking ahead, what are your top priorities for the North America business over the next two to three years?

Our focus is on three areas. First, we need to execute well with our existing products and drive sustainable growth with XEOMIN, INBRIJA, and AMPYRA. Second, we have exciting pipeline opportunities with XEOMIN itself, and we're looking for internal catalysts to help propel the company over the next couple of years. We are also interested in external opportunities to acquire more strategically aligned products that let us capitalize on our existing infrastructure. This will help bring even more products to the patients we serve. Third, is to focus on our people. The talent we have in the organization has to be of the highest caliber, both in integrity and in skill. It's critical that we invest in building a team and a culture that embraces change both internally within the organization and externally in the market as we bring in new products.

What is the final message you would like to share about Merz Therapeutics' vision, ambitions, and commitment to patients?

Everything we do here at Merz Therapeutics begins and ends with the patients we serve. With passion and purpose, we strive to deliver better outcomes for more patients. It's a simple mission, but one that speaks volumes.

Most importantly, if you met the people here at Merz Therapeutics, you'd see that we actually live that ambition. We want to become a leader in specialty neurology, but we want to do it sustainably and with growth based on innovation and staying true to the standards that have guided Merz for generations: scientific excellence, strategic long-term thinking, and a commitment to the patients we serve.

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