

Marc Ayers CEO, Romark Puerto Rico



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Based in Tampa, Florida, Romark is a research-based pharmaceutical company focused on developing innovative treatments for infectious diseases. The company recently inaugurated its first finished products manufacturing facilities in Puerto Rico, transforming itself into a vertically integrated organization. CEO Marc Ayers extols the strengths of Puerto Rico as manufacturing location and explains how the new facility will help Romark meet its global ambitions.

Could you introduce our international readers to Romark, your history, product offering and your game-changing approach in developing new treatments for respiratory virus infections?

Romark is a 25-year old research-based pharmaceutical company headquartered in Tampa, Florida. We are a vertically integrated multinational organization that discovers, develops, manufactures and markets its own products. We have grown significantly over the past 25 years and are now looking to expand on a global scale. We have an API manufacturing facility in Landen, Belgium, and a pharmaceutical manufacturing facility in Manatá, Puerto Rico.

We focus primarily in the field of infectious diseases. We discovered and developed the only product in the world for treating *Cryptosporidium* infection, a potential life-threatening infection of the gastrointestinal tract, currently marketed in the United States.

Moreover, we are rethinking the current approach to treatment of viral respiratory infections. Historically, pharmaceutical companies have designed drugs to specifically target a single virus. But this one-bug-one-drug antiviral approach is insufficient to address the challenge of treating illnesses caused by the body's innate immune response to a broad range of difficult-to-diagnose and rapidly changing viruses. We are developing broad-spectrum antiviral drugs to treat respiratory virus infections such as influenza, rhinovirus and respiratory syncytial virus (RSV).

We are very much excited about our development program targeting a functional cure for chronic hepatitis B virus (HBV) infection, a condition that the World Health Organization (WHO) estimates to affect 350 million people worldwide.

Romark prides itself in being a vertically integrated organization that discovers, develops, manufactures and markets its own products. Where do you see the advantages of insourcing the entire pharma value-chain?

We were born a virtual company and we managed ourselves as such for many years. But we realized that there are certain critical aspects of bringing a drug to market that are important for us to control. The investment in the Manatã plant is the result of this realization. We found that it is better for us to take control of manufacturing. There are a lot of good contract manufacturing organizations (CMOs) out there, but they do not have the same interest in the product as we do. Moreover, by outsourcing manufacturing, we take on all the financial, quality and regulatory risks the CMO may face. By insourcing manufacturing, we take control of product quality and ensure business continuity.

On the R&D side, we do contract out discovery, pre-clinical and early clinical research to research laboratories and contract research organizations (CROs) with specializations in given fields. We sometimes use CROs for phase II and III clinical trials, but we also have the capabilities to do them in-house. In general, I think the closer we are to the work product, the better the work product. It is simple human nature.

Today, Romark's commercial footprint is mostly limited to the US but you mentioned you are now looking to expand on a global scale. What is your strategy to develop your commercial presence outside the US?

That begins with developing and bringing new drugs to market. We are developing products for conditions that affect hundreds of millions, perhaps billions of people around the world. These products are going to be used on a global basis. As we begin to expand globally, in terms of distribution, we will either establish our own commercial presence in markets where it makes sense for us and where we can move quickly, or we will partner with large pharmaceutical companies with strengths in given markets.

We will of course focus on the European Union and Japan, but also other markets in Asia as chronic hepatitis B represents a huge issue the region, and China in particular. Of the 350 million individuals worldwide infected with the hepatitis B virus, one-third reside in China. I think we have the opportunity to have a lot of impact in this region.

Romark successfully opened manufacturing operations in Manatã in May with a total investment of \$80 million creating 200 jobs in the next five years. What convinced you to

establish manufacturing operations in Puerto Rico?

We were at a point in the development of our company where we needed to be able to control the pharmaceutical manufacturing process. We were looking for opportunities to be able to manufacture large quantities of product, and ideally to be able to do it ourselves. I was visiting a contract manufacturer in Puerto Rico, and I saw a friend in the airport on my way back to Florida who told me I should build my own facility here. He explained the economic development packages offered by the Puerto Rico Industrial Development Company (PRIDCO), and I realized that the economic development incentives were significant. That was the first thing that got my attention.

After getting back to Florida, I consulted with our lawyers and accountants to determine how we might take advantage of some of these opportunities. Ultimately, however, it was the caliber of the talent and the quality of the infrastructure available here in pharmaceutical manufacturing that made the difference. While Florida has a growing presence in biopharma, it does not yet compare to Boston, New Jersey, and the San Francisco Bay area. As a result, it is difficult to find and attract talent well-versed in pharmaceutical manufacturing. Over the past ten years, as our company grew, we experienced difficulties in attracting people to Florida, especially in technical fields. When we came here, we were able to attract industry veterans interested in building something special together. For instance, Ricardo Zayas was Senior Vice President of Global Manufacturing at Bristol-Myers Squibb. I was able to attract him to Romark to manage the operations of the new Manatã plant, as he wanted the opportunity to invest himself back in Puerto Rico. Ricardo is now our Executive VP and Head of Operations. Veronica Cruz, our VP Global Quality, was VP Quality & Compliance at Johnson & Johnson. She has incredible experience and expertise. If you go to our facilities, you find people from Pfizer, Lilly, Abbott and so on. Even though Tampa is a wonderful place to live, you cannot find that kind of expertise and talent, nor the ecosystem and infrastructure around the pharmaceutical industry conducive to quality and speed. Puerto Rico has a 50-year history of being one of the key global pharmaceutical manufacturing hubs, and that is something that cannot be replicated easily.

Establishing our manufacturing facility here helps us ensure business continuity, mitigate risks and reduce costs. In addition to our manufacturing facility, we also opened an analytical laboratory in Dorado. Together with our API facility in Belgium, we have the ability as a vertically integrated pharmaceutical company to develop new products and bring them to market. We created a lot of value for the company just by having the additional capability to manufacture the product. But the real value is to come. When we launch a new product generating billions of dollars in revenue on an annual basis, the value of the facility will increase substantially. Today we are manufacturing our existing products, Alinia, a treatment for *Cryptosporidium* infection, and NT-300, our investigational antiviral treatment for colds and flu. Alinia is an orphan drug and does not address the kind of markets that our new products will address.

What have been the main challenges in establishing operations in Puerto Rico?

We literally took a warehouse which used to be part of a Schering-Plough plant, and converted it into a manufacturing space. We used the outside walls, the floor and the roof. Everything else is completely new. As the facility and the land were a pharmaceutical use property historically, the licensing and permit issues were already taken care of. The main challenge was Hurricane Maria which delayed us to some degree. Otherwise, we have not faced any major issues.

Other life sciences companies have told us about the lessons they learned from Maria and the changes they implemented to improve business continuity such as satellite communication, co-generation plants, equipment redundancies, and dual inventories. What are you doing to hurricane-proof your own facilities?

Hurricane Maria was an unusual event and it has definitely made the industry more cognizant of the potential consequences of these storms. In our case, we were still in construction at the time and were not manufacturing. Since the building was not completely enclosed yet, the facility suffered a little damage that it would not have suffered otherwise. We did have a lot of inventory here at a contract warehouse which was not affected. We did not experience any significant issues that could have disrupted our business.

One of the things we are trying to do is to increase our energy independence. We are working on a potential solution with a microgrid adjacent to our property.

You are seen as the poster child of a new wave of mid-sized pharma companies investing in Puerto Rico. What would you say to pharma executives considering Puerto Rico as a manufacturing and R&D location?

I would say that Puerto Rico is an island of opportunity for companies seeking to mature to the product commercialization stage because talent is readily available. People are highly educated, have unmatched experience in the industry and a quality-driven culture. When you post a job application, you get applicants within minutes, literally. At the end of the day, people are the heart of any business. Our people are not only talented and experienced, but they have a good spirit as well. The people here are invested in Puerto Rico and are willing to partner with companies that are willing to come and make investments. They have seen many companies leave the island over time, and when somebody brings business to the island, they appreciate it. The government and the people are ready to embrace new businesses. I am incredibly impressed by the quality of the work we see from employees in our manufacturing facility and the laboratory. The people do the highest-quality work that you can possibly imagine. In addition to the amazing talent, good business environment and government support, Puerto Rico is a US territory located a stone throw away to the US mainland. Last but not least, it is a beautiful place to live.

What will be your priorities in the coming years to drive performance?

We have invested heavily in infrastructure to become a vertically integrated pharmaceutical company. What we need to do at this point is to bring revenues by introducing new game-changing products to the marketplace and distribute them globally from Puerto Rico. We have the people, the facilities, and the right partnership with the government to be able to do that. We want to be successful, not only for ourselves, but also to be able to give back to Puerto Rico. I would really like to see Puerto Rico thrive in the pharmaceutical sector.

On a more personal side, what were your motivations to start Romark 25 years ago?

My partner Dr. Jean-François Rossignol studied chemistry at the University of Paris where he received a doctorate degree in synthetic organic/medicinal chemistry, and then studied medicine specializing in Clinical Parasitology & Tropical Medicine. He then spent more than 30 years developing and registering drugs around the world with large pharmaceutical companies. I came

from a finance background and worked as an investment banker. The two of us had worked together because I financed a company he was working with. We started Romark because we were both passionate about discovering and developing innovative new medicines. I remember sitting with him telling me: this is the only thing I know how to do, but I need a partner. It was a time in my life when I was looking for a challenge and an opportunity to do something greater than just money and leave my mark on the world. I am incredibly grateful to be able to do what I do.

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