Marco Monrouzeau – General Manager and CFO, Neolpharma Puerto Rico



Neolpharma's main business is in Mexico, but the Puerto Rican affiliate has opened the door to the US market for the company

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Marco Monrouzeau is the general manager and CFO of the Puerto Rican affiliate of Mexican drug maker Neolpharma, which has manufacturing operations at its site in Caguas. Monrouzeau highlights how Neolpharma has started its operations on the island in 2013 and since then has developed significant R&D capabilities to be able to roll out its product to the US market.

You have been in charge of the affiliate since taking over the former Pfizer plant in 2013, so can you highlight the milestones of Neolpharma's operations on the island?

I have been working on this site for Pfizer for many years and eventually retired in 2008. When Pfizer made its intent of selling this site public, I received a call from Efren Ocampo, the CEO of Neolpharma. His strategy was to enter the US market, however Mexican plants are not FDA-approved, so he saw an opportunity here in establishing an affiliate in Puerto Rico to have access to the US generics market. I served as his connection to Pfizer and we started in 2011 to lay out the plans for acquiring the plant, closed the deal in Q4 of 2012 and took over the facility in February 2013. Pfizer still asked us to serve as contract manufacturer for their products for a period between one and five years, depending on different products. The initial plan was to do a tech transfer for Neolpharma products from Mexico to Puerto Rico and then start rolling out our products in the US.

What were some of the challenges you have been facing in this process?

There has been a big gap between the Mexican products and the quality standards required by the FDA. We eventually figured out that an ordinary tech transfer would not be feasible and that we needed to develop our own generic products here in Puerto Rico. This required bioequivalence studies, so the approval process will require three to five years instead of being on the market within twelve to 18 months. However, due to our CMO activities for Pfizer and other clients we were able to navigate through the transition process. Our main strategy remains to bring our generic products to the US market, which we successfully did with our product LEVO-T, which amongst the Top 3 generics in the US for the treatment of low thyroid. We acquired this product in 2014, but due to contractual requirements we are only able to fully manufacture LEVO-T at our facilities here in Caguas since 2019, which resulted in the expansion of our plant here. Additionally, we continue our R&D operations, as we currently have added more than ten products to our pipeline.

While we still continue with contract manufacturing, we will focus on developing our own products, get them FDA-approved, acquiring ANDA’s and sell them on the US market. Additionally, we are looking to roll out our flagship product LEVO-T in markets like Canada, Mexico and eventually even Europe.

What have been the main reasons for bringing operations to Puerto Rico?

The first reason was that the plant here in Caguas was put on sale by Pfizer, which means that it was a lot cheaper than acquiring any running plant or even building a new one from scratch. Incentives offered by the government and PRIDCO also played a big role in bringing our operations here. We have registered two local companies here on behalf of Neolpharma – one for manufacturing and the other for our research activities. We have received tax incentives for being registered as Puerto Rican company and also for acquiring a plant that was scheduled to be closed. Additionally, under Act Number 73 of July 2008, we receive 50 percent tax credits in Puerto Rico due to our R&D operations here. Unfortunately, we were not able to do our bioequivalence studies here in Puerto Rico, but we are working hard in collaboration with universities on the island to make this possible in the future.

Neolpharma has significant manufacturing capacities in Mexico as well, so how do you rate Puerto Rico's importance for the company?

Neolpharma's main business is in Mexico, but the Puerto Rican affiliate has opened the door to the US market for the company, which is of course the largest pharma market in the world. While the current plan sees continuous investment from Mexico to Puerto Rico to continue growing the affiliate here, in the long-term we might be able to support operations in Mexico by providing capital.

We are now in a win-win situation, as our Mexican headquarters have a lot of experience in drug development, which they can pass on to our teams here. However, our teams here in Caguas have experience in complying to FDA regulations, so we aim to exchange our knowledge to help the businesses in both countries grow. This happens through sending teams from Mexico to Caguas and vice versa.

With your health of experience in the industry, what do think is necessary to see more R&D in Puerto Rico?

One first step is to have more companies or academic institutions offering bioequivalence studies here in Puerto Rico.

On a different note, we see more countries like India and China entering the life sciences field, so low costs and flexibility is needed to remain competitive. Big branded pharma companies have a long tradition of manufacturing in Puerto Rico but may be attracted to go elsewhere due to lower costs. This opens the door for small- and medium-sized generics companies to come to Puerto Rico for manufacturing and even for research. The island has incentives, talent and infrastructure and will be the best place for new companies entering the US market. We have seen this trend with companies like Avara and Romark acquiring former big pharma plants on the island and we will see this to a larger extent in the future.

With eleven of the Top 20 pharma companies manufacturing on the island, there must be strong competition for talent on the island?

Due to the consolidation and mergers that have happened in our industry in recent years, we have still a lot of talent available. Moreover, Puerto Rico has excellent training institutions especially with

the UPR in Mayaguez for pharmaceutical manufacturing so finding trained, highly qualified people has not been an issue for us. We provide excellent benefits and medical plans for our employees and are one of the employers of choice amongst Puerto Rican generics manufacturers.

What is your vision for Neolpharma for the next five years?

I would like to see at least 20 of our products on the US market and we will continue to look out for acquiring new generic products, as we did with LEVO-T. This is a great alternative to the development of our own products, as acquired ready-to-market products safe us a lot of time. Another priority will be to roll out LEVO-T in other markets in the Americas and Europe, as we see a lot potential in this product, as men are increasingly using this product and we are looking to develop this product for other therapeutic uses.

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