Interview: Efrén Ocampo – CEO, Neolpharma, Mexico

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Efrén Ocampo, CEO of the Mexican pharmaceutical group Neolpharma, details the strategic thinking that has fostered the emergence of one of the most prominent healthcare groups in Mexico and the challenges and opportunities that lie ahead in Mexico and abroad.

Neolpharma Group encompasses five manufacturing companies and 14 other service providing companies. Could you explain the strategic thinking that has led the current structure of the group?

As CEO of Neolpharma, my overarching strategy has always been to ensure all our companies generate strong added value while always fostering substantial synergies throughout the vertically integrated structure of the group. As a result, our group's wide range of operations now goes from research and development, APIs and finished products manufacturing to drug distribution. Furthermore, since we started our operations, we always envisioned exporting our products to international markets. In terms of value, we already export 10 percent of our total production, mainly our cardio-metabolic, algological and central nervous system portfolios.

Nevertheless, Mexico remains our core market. Neolpharma gathers nine different treatment portfolios that are perfectly aligned with Mexico's evolving demographic and epidemiological profiles, which are mainly characterized by a developing burden of chronic, degenerative diseases. The significance of our overall portfolio puts us in a privileged position to service rural, urban and semi-urban areas of Mexico, which all display different epidemiological profiles that need to be distinctively approached. Our group's portfolio holds more than 250 different molecules that can be

offered in different presentations, thanks to our cutting-edge manufacturing capacity. As a result, Neolpharma stands as the largest manufacturer of solid medicines (pills and tablets) in Mexico, while we are market leader in central nervous system diseases (CNS) in Mexico.

In February 2016, you inaugurated a new manufacturing plant in Mexico City. Why does this plant stand as an important step forward for Neolpharma?

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Fundamentally, this new manufacturing capacity will essentially produce treatments that will be exported to North America and Europe, while the rest of our Mexican manufacturing footprint will focus on servicing South and Central America.

One of our greatest aspirations however is to become a major player in biosimilar production and exports. We currently run a pilot plant that started to produce several biotech products, but our initial plan was to transform this recently acquired manufacturing facility into a cutting-edge biotech facility. Biosimilar manufacturing is more complex than for chemical treatments, but – in Mexico –manufacturing stands as the easiest part of the overall production and market access process. The real barrier for us is the incredible and increasing number of regulations that frames biosimilars' market authorization. For example, in Mexico, specific clinical trials and bioequivalence studies required by Cofepris are excessively demanding and expensive, which ultimately increase the price of these treatments.

Furthermore, the recently signed Trans-Pacific Partnership (TPP) will probably stand as another obstacle in our biosimilar strategy, despite the new export opportunities it could nurture. By tremendously increasing data exclusivity period for biotech treatments, the TPP will indeed hinder our ability to rapidly develop these complex, life-changing biosimilars treatments and provide our patients and public institutions with affordable therapeutic solutions. Nevertheless, we want to remain positive and strive to look at different alternatives to overcome these regulatory challenges, in order to finally set up a competitive biosimilar branch within Neolpharma.

The FDA-certification of the manufacturing plant you acquired in Puerto Rico in 2013 has opened new export opportunities to Neolpharma. What role will this manufacturing asset play in the further development of the group?

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Operating in Puerto Rico has been a remarkable success since the beginnings. First, the island holds substantial, skilled human resources and holds enough raw materials to supply the

impressive numbers of pharma manufacturers implanted in Puerto Rico. Second, the island also offers special tax mechanisms that ease market entry to the United States.

As we speak, we already hold US market authorization for one of our main products that is manufactured in Puerto Rico: thyroxin. In Mexico, we already own a 30-percent market share with this treatment, so we also hold great expectations regarding this treatment's entry into the US market. Furthermore, accessing the US market will allow us to generate revenues in US dollars whereas the Mexican peso is currently plummeting. In turn, we want to reallocate a substantial part of these resources to further upgrade our Mexican manufacturing plants.

More importantly, setting up this manufacturing footprint in Puerto Rico has been a great learning experience with regards to our ability to comply with FDA requirements. The expertise and quality standards we developed to receive FDA certification for this facility can now be transferred to Mexico, from where we soon want to start exporting some of our products to the United States as well.

According to Cofepris, Mexican pharma exports should grow at an annual rate of 11.5 percent between 2015 and 2018. What is the outlook for Neolpharma's exports?

Our FDA-certified plant in Puerto Rico stands as our international platform, allowing us to export to any country in the world. We are now strengthening our commercial capacity to target other pharmaemerging markets or countries in parallel to our focus on the American market. The strengthening of our international strategy should allow us to display higher exports growth rates than the ones announced by Cofepris.

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In the meantime, the TPP should also open new export opportunities to the fast-growing Asia-Pacific region, while we also target some appealing countries in Africa. To fulfill our export ambitions, we currently hold 17 new drugs in our development pipeline, and some of them will be launched in 2017.

Psicofarma is the most important pharmaceutical company within the Neolpharma group, with a leadership position in the private, retail market in CNS. How would you describe Psicofarma's positioning in the Mexican market?

In Mexico, there is still a critical lack of recognition regarding the absolute importance to deepen and concentrate our efforts on mental health. As a company, we produce substantial data and information around the economic impact that neglecting these diseases have on Mexico's productivity. With this data, we want to raise public awareness on mental health-oriented mechanisms; and steadily remove the stigmatization that these diseases still carry in Mexico. Finally, by adding value to psychological and psychiatric treatments, we know our market share and profitability will increase as well – as a benefit of our contribution to improve health outcomes in this crucial field.

What is your growth objective for Neolpharma?

By 2020 we want to be able to display a 100 percent growth in comparison to where we stand in 2016. It may sound particularly ambitious considering we have already reached a respectable size. Nevertheless, if we manage to fulfill our growth objectives both in Mexico and in strategic markets like the US, I am confident we can fulfill this growth objective. As a matter of fact, if we can soon set up our biosimilar capacity and increase our presence in the oncology and metabolic fields, we will have already accomplished a great leap forward. In the meantime, we want to enrich our current product portfolio with four new therapeutic areas and start producing off-patent, high efficiency treatments and tremendously increase our current sales force.

We are not optimistic or ambitious *per se*: our self-confidence is truly nurtured by the unmet market needs and strong opportunity areas we currently identify in Mexico and abroad. Nevertheless, I still think successful Mexican pharma companies should be more strongly supported in their development. In Mexico, public authorities' support gets scarcer as soon as these companies start implementing international strategies and do not solely concentrate anymore their efforts on the Mexican market. Considering the overall contribution of the pharma sector to the Mexican economy and the great export opportunities these Mexican companies hold, we need to radically change this mindset and more closely accompany the ambitious and international development of Mexican companies.

Over the past three decades, you have been building and heading a company that has steadily become one of the most prominent players within the Mexican healthcare landscape. What has been your proudest achievement so far?

I have always been a firm believer in teamwork. I think that my main achievement has to do with the construction of such a strong, well-focused team, which has always proven being ready to tackle the next challenge. The present always is the result of everything that we did and learned in the past, so we need to focus on the future. As a matter of fact, we are already designing

Neolpharma’s strategy for 2030!

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