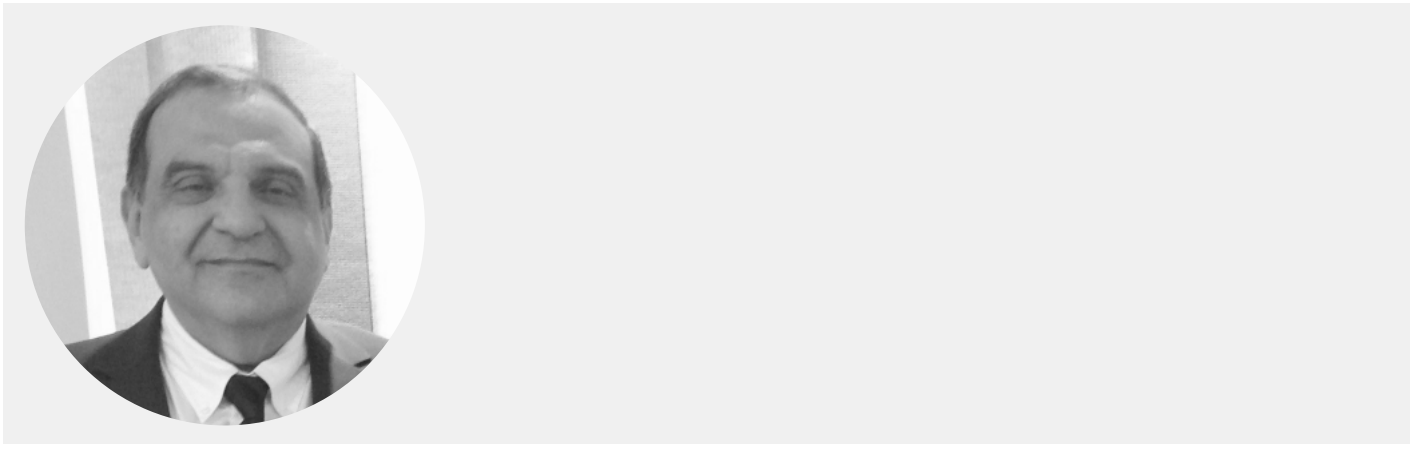


Interview: Dr. Wagdy Mounir - General Manager; Farid Habib - Chairman; Dr. Saad Ibrahim - Scientific Office GM, Marcyrl, Egypt



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Marcyrl grew 40 percent and jumped from 15th to 9th place in the Egyptian market in 2014. With growth remaining strong, the board explains the keys to success for doing business in an unstable environment, and shares their plans for expansion, including a nearly completed hormonal facility.

Marcyrl has expanded enormously over the past five years, despite the two revolutions that have occurred in Egypt since 2011. How have you done it? What is the key to driving growth in the midst of external instability?

Farid Habib (FH): Belief, focus, and faith are all essential. You must believe that the problems will pass, that the situation will improve, and do your best to focus on your goals and make progress towards achieving them. I started Habib Scientific Office with the goal of being the best in the market, and we achieved as a sales and marketing organization. Likewise we started our manufacturing business Marcyrl with the goal of being number one in manufacturing. Political changes didn't affect our goals or capabilities as an organization, so we remained focused on this target.

Wagdy Mounir (WM): If you look at Egypt's modern history, you will see that there have been many changes that have taken place over the years and the January 25th revolution was not the

first. Mr. Habib started this company in 1963 and has led it through periods of turmoil and political change before. Thus, he insisted that we must be in the market, must continue to develop our manufacturing capabilities, and must continue to do our very best to succeed, despite the tumultuous external environment. Mr. Habib is an excellent motivator who has constantly pushed us to do our best, and his determination and enthusiasm has driven the entire company forward on difficult days.

Saad Ibrahim (SI): The last five years were very challenging for each and every company and manufacturer in Egypt, and this was certainly true for Marcyrl as well. Commitment and focus are essential, and we must recognize Dr. Habib's commitment to this company and our employees, as he financially supported the company at a time when we had very limited cash flow. Marcyrl is a community of more than 1000 people, a very close knit community that works together, supports one another, and focuses on the same goals; the importance of having this strong company culture cannot be understated, as it allowed us to continue to operate and work through a very uncertain and unstable period.

We had the conviction that the instability and risk would pass, so we remained focused and put all of our power in the market. As leaders of this company we worked extremely hard to motivate the employees; gathering them together and ensuring they felt supported by the company and their peers so they could focus on doing their job to the best of their abilities. In fact, we worked the hardest during the toughest and most uncertain days, and through this effort we created an opportunity and gained ground on our competitors who lost focus. Most companies were scared, reluctant and hesitant which made this an ideal moment to expand, and we capitalized upon this opportunity.

If we talk about your portfolio, what form did these opportunities take?

SI: Throughout this period, we continued to drive forward our pipeline, getting new products ready to launch and driving growth of our newer products. This led us to the position that we were able to launch seven products in 2015 alone.

One such product was our sofosbuvir product, MPIVIROPACK, alongside other antivirals used to treat hepatitis C; an essential development given the hepatitis C epidemic in Egypt. Our preparation for this era of product releases begun a few years ago, and our readiness translated into a strong jump in sales when we received marketing approval; 40 percent sales growth in 2014 alone, which brought us to 9th in the market from 15th. However, in general we have been achieving at least 25 percent annual sales growth since we started manufacturing our own

products in 1999, via a toll manufacturer at that time.

Now that the political situation has stabilized and economic growth has increased somewhat, what are some of the challenges you are facing in the market today?

SI: Drug pricing and the shortage of hard currency is at the top of the list certainly; the price for sofosbuvir generics has been brought down to EGP 900 (USD 110) per bottle on the retail market and EGP 520 (USD 65) in the tender market, from an initial price of EGP 2670. In general, Marcyrl focuses primarily on the retail market as it is more stable than the tender market, prices are significantly higher, and this is where our marketing power can be utilized as an effective asset.

WM: Another challenge that has arisen is that the Ministry of Health is constantly becoming more restrictive than before and while this is certainly a positive development in terms of safety and regulating product quality, it increases the time and investment required to develop new products; reports on stability, bioequivalence, and more must now be completed to get marketing authorization.

SI: At the same time we face more patency restrictions than we did in the past, and the stance of the Ministry of Health is somewhat unclear. Egypt is not a signatory to the TRIPs Plus agreement and the original TRIPs agreement allows governments to license companies to produce generic versions of patent protected products; Egypt has exercised this right for sofosbuvir and other molecules used to treat Hepatitis C due to the scale of this epidemic. At the same time, the Ministry of Health generally tries to respect the patents held by multinational companies; a grey area exists between these two dynamics, where there are valid arguments for the ministry to allow generic versions of certain patented products to be produced, but MNCs can also make a strong case against licensing such products; the ministry has not taken a clear stance on how decisions in such instances will be determined. As our portfolio is geared primarily towards newer molecules, this grey area is highly relevant to our product pipeline, and the lack of clarity regarding where Egypt stands on this issue as a country has made it difficult to strategize as a company in some instances.

Could you give our readers an overview of your manufacturing capabilities and standards as they stand today?

WM: From the beginning we planned to eventually start manufacturing our own products, and we started building our facility in 2002. This facility is our only active facility today, and today this facility is one of the larger facilities in Egypt with three tablet manufacturing lines, two for creams, one for syrups, and newer lines for soft gelatin capsules and sachets.

SI: We currently manufacture products for several European and Japanese companies like Merze, Ingelhard, IBSA, Schwabe and Takeda, and thus operate according to European and Japanese GMP standards, however our plans to get EMA and FDA certification have been delayed repeatedly. With the rapid pace of our growth and the demands of the local market, we are continuously expanding and updating our capabilities, acquiring new machinery and building new storage areas, so it has been difficult to settle the facility long enough to focus on getting everything validated and audited.

Marcyrl is currently building a hormone production facility; could you expand on this and other steps Marcyrl has taken to develop more technically complex capabilities?

WM: As Dr. Saad mentioned, we are constantly enhancing our facilities and acquiring new machinery and technology. For example, we have already purchased the machinery to produce bilayer tablets, an important technology for manufacturing controlled release products, and once operational this will be the first bilayer tablet manufacturing line in Egypt.

The most significant project that we are currently undertaking is the development of a separate hormone manufacturing facility. This is a project that will take Marcyrl to the next level in terms of working with multinational pharmaceutical companies and export activities; there are only a few such facilities in the Middle East, and capacity is limited in Europe as well. The plant has been designed to meet all international standards, and we will be seeking EMA and FDA approval from the outset with the goal of exporting products from this facility to markets all over the world.

SI: Looking one step further, we will be developing an oncology facility in the next few years in collaboration with some foreign investors and are in discussions with a few other leading Egyptian manufactures to co-develop an API production facility. These discussions are still in the beginning stages, but we are very excited to be a part of such a project. Having access to API manufacturing facilities will give us the capability to produce difficult to acquire niche molecules, so we can be the first to bring generics versions of certain products to market.

If we look further upstream to product development, has Marcyrl been able to successfully bring any incrementally innovative products to market so far?

SI: Seven years ago we launched a unique fixed dose combination of sulfonylurea and metformin. Several Egyptian professors of diabetology had expressed the need for a product with a higher concentration of metformin, but same dosage of sulfonylurea, than the existing products on the market contained. At the time, there was no exact reference product for our combination, and we had to complete three multi-center clinical trials to get it approved.

Just two weeks ago, we received the approval for a unique dosage form of bromocriptine. This is a product used to treat women with high levels of prolactin which can inhibit ovulation and normally this product comes in tablet form; however, nearly 40 percent of patients experience gastric issues as a side effect. To avoid causing this side effect, we have developed a vaginal suppository containing bromocriptine. We completed a series of phase II and phase III trials to get it approved, and now that we have approval we will soon be launching this product. This is a unique product, although we are aware that an Indian company has been working on developing a bromocriptine vaginal suppository as well.

Valeant and Hikma have both recently bought Egyptian pharmaceutical companies; what is your opinion on this Dr. Habib? Would you ever sell Marcyrl?

FH: Never. Never ever. This company was built to bring medicines to the Egyptian people, to serve our country and community. The Habib Scientific Office and Marcyrl are family, a big family of more than 1000 people plus their families and children and we must stick together. If I were to sell this company, I am not sure what would happen to this family, how they would be treated and looked after under another owner. Marcyrl is one the only companies that despite the financial pressures and hard currency issues has increased salaries over the last five years, giving support to families and helping to build them.

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