

Karim Smaira & Kamel Ghammachi - Managing Partners, Genpharm, UAE



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The two founders and managing partners of Genpharm talk about the market dynamics of the UAE, and the gaps in the market that the company was able to fill with its portfolio offering.

Karim, can you speak to us about the birth of Genpharm, and more broadly about your personal transition from big pharma to setting up your own venture?

The transition was triggered by a couple of things. Initially, it was the entrepreneurial spirit that I had started to lack in a very centralized, corporate world. I was fortunate enough to have a wealth of experience at an early age and I found that it was the right time, both from an experience and knowledge point of view to do it.

Once the decision was made, the next steps were: 1- finding the right partner sharing the same vision and the right background. Kamel's profile was a perfect fit, a vast experience in both the corporate world and as an entrepreneur.

2- finding the appropriate niche. Looking at the segments that are growing in the market and matching them with our expertise, we needed to find where Genpharm could add value.

The three segments that are currently growing in the Middle East are generics, branded generics and new, innovative biotech products. Some of the largest disease areas are oncology, respiratory

diseases, and women's health, which governments have mandated as focus areas.

Factoring in another element, after a long period without new breakthrough products being approved, 2012 saw a record of new approvals by the FDA, which they expect to surpass this year as well. Most of this activity is coming from very niche indications— orphan drugs, rare disease, and if not directly from orphan drugs then usually in sub-indications. In neurology, like Alzheimer's or MS the sub-indication is spasticity, and in oncology it is pain management.

My experience has been selling evidence based, clinically supported products. In the years spent at Serono, we were pioneering the launch of the early treatments for multiple sclerosis (MS) and the hormones for fertility treatment, while Kamel's experience has been focused in the last years on Market access of rare genetic diseases.

So, given these market dynamics and our personal experiences, it was clear to us that Genpharm could add value in these type of segments. The key objective and the founding principle is to provide alternative therapies or new therapies for patients that had nothing except symptomatic treatments.

In addition, the Middle East is not a focus for orphan companies, which are usually a one-drug company. Their typical launch cycle is US, Europe, and then five or six years later in Latin America, Asia and the MENA region.

The legislation in the MENA region allows earlier entry but most companies do not know how to proceed due to lack of market and cultural knowledge. Product importation is allowed in several instances right after the FDA or EMA approval. Once we raised awareness, we got several companies interested by the opportunity and have partnered with us early on.

Now, one year later, we have experienced good traction. In this short period of time we have attracted several partners that are benefiting from sales upsides and early market penetration in MENA.

Karim, following your market analysis, which areas of focus have you chosen for Genpharm?

We decided to focus on four pillars in the company: oncology, CNS, women's health and rare disease.

Rare disease is one standing pillar. There are usually a very limited number of treating physicians. This is also attractive for us since we wanted a highly specialized model. Managing 200 medical reps that sell generics is not of interest. Instead, we wanted to compete on value and science rather than price. Having said that, the numbers needed to make sense in terms of investments, disease awareness programs and treatment awareness is costly. It is a where large part of our effort and investment go. We are mostly building markets from scratch for most of the companies we are working with.

Kamel, which are the companies that Genpharm is currently working with?

We have an agreement with Genzyme in the Middle East and North Africa to launch their MS portfolio. We are also working with Stallergenes in immunotherapy for treatment of moderate to severe allergies. There are many allergies in the region due to the environment— the desert, the dust, the constant use of air conditioning— and Stallergenes has over 90 allergens in its treatment regimen. They also have a device that monitors how effective individual, prescribed drugs are for people suffering with asthma.

We are working with Aegerion, a US orphan drug company specialized in hypercholesterolemia, which is another highly prevalent disease here due to the genetics.

Speaking about genetics, the Middle East and North Africa population is roughly 300 million people and certain countries, like Saudi Arabia for example, have about 60% of marriages that are consanguineous, which often lead to abnormalities. Hence we are working with LifeCodexx out of Germany, which has the only CE marked prenatal diagnostic test, PrenaTest. This is the only clinically supported test looking at fetal trisomies 13,18 and 21. It is through maternal blood testing rather than invasive techniques. We established the concept in the MENA region, since DNA sequencing technology was little known here.

We are also working with TiGenix, that has the only approved autologous cartilage of the knee repair, Chondroelect. It is a challenging area, since there is no clear legislation for stem cells. We are working very closely with the authorities to ensure that it is a smooth process because transportation of life tissue is meticulous and difficult.

We are in advanced discussions as well with several companies that have products in rare diseases to which there are currently no established therapies.

Kamel, given that Genpharm is such a young company with a relatively unconventional model, has it been difficult to attract talent?

I'm surprised that it has not been. I believe that if you have an inspirational vision that you can articulate and share clearly with people, it becomes easier. Our vision is simple: provide very innovative therapeutic solutions to patients with no alternatives.

We currently have around 16 highly qualified staff that are spread across the region in Levant, GCC, Saudi Arabia and Egypt, and we are now in the stage of recruiting for North Africa. We are hiring experts from big pharma and in specialty areas.

In addition our model is quite attractive and innovative. We plan a profit sharing scheme for our staff, in terms of incentives and equity shares. Our vision is to be self-sufficient financially, and later on, when the company reaches a value at which point we deem it ready for an inclusion of institutional or private investors, then we will do this.

We always tell recruits other than the financial motivation, you need to have a higher purpose in life and aspire to do good for the community. The higher purpose for us is to look at the suffering patients and understand that if we don't bring these companies in the early stages then there will be no therapeutic alternatives for them. When you can deliver this mission and be part of a profitable business journey than this should be motivating enough. IF this does not move people interested in joining Genpharm, then we definitely do not want them to join!

Karim, is Genpharm self-funded?

We are very proud to be entirely self-funded; my partner, Kamel Ghammachi and I have put up a nice start up capital for two individuals. The company value has already increased seven times over the last year, which is only based on independent audits that have looked at the value of our contracts and forecast of sales. We have had a lot of interests from people and institutions to invest with us early on.

The intention is to create value and then to make sure that we have shareholders that also add value. We are looking for people in the healthcare business that are aligned with our vision. We want to create a portfolio, establish our credibility and a track record. Subsequently, we are planning to develop our own brands, or license-in brands.

Kamel, earlier on you mentioned phasing in additional investors and sharing profits with your employees. What is the time frame for this?

By 2015 we would like to introduce private shareholders, people working in healthcare like major distributors and perhaps other companies, which is when we will also allow our employees to come in at a preferential rate.

Owning our own brands by 2016 and having another round of financing in 2017 will perhaps be followed by an IPO in 2019.

Also, the plan is to start looking at in-licensing in 2015 and onwards. As a businessman today, you don't want only contracts that can come and go. You want to fill the pipeline with new partners, new products and eventually assets. Currently, our assets are our people and the demand for our products. The second phase is to introduce the Genpharm brands.

Karim, if there are IPO plans in 2019, will that also mark the end of you?

Yes, it might be defined this way, since we wouldn't mind recreating something different, innovative challenging and rewarding. Will see what this would be when the time comes...

Karim, in terms of challenges, there are inherent risks in bringing these sorts of products here, like a lack of a framework, IP regulation, etc. At the same time Genpharm is such new company. How do you manage to convince these companies to trust you with their products?

Like any start-up there are a number of challenges. For one, this is not a model that is very common, so doing your homework before going in is essential.

The first question we always receive is, "what happens to our IP if we provide you with our regulatory file?" It is our job to explain that although a company might not have 100% percent protection, practice has shown that IP has not been violated. This is because in this region we don't have the manufacturing capabilities to produce these type of innovative products,. Also, the Ministry of Health provides data exclusivity, which is another way of protecting data for approximately 3-7 years, depending on the indication or products.

Another frequent concern is that there aren't approved therapies. But if a product has scientific backing and the FDA and EMA have already approved it, the product can then be imported on name patient sales for a period that can, extend for up to 2-3 years.

Pricing is another risk element. The population is growing, as are the medical needs and with all of the investments in clinics and hospitals, the healthcare bill is gigantic. Companies need to make sure they have reimbursement for these therapies, since counting only out of pocket will limit them to very few patients in the private sector.

Pricing has become more transparent. Today there is a very clear pricing process. The harmonization of pricing is gradual, but it is taking place.

The maturity of these markets is also being accelerated. Today a product is launched in Europe and the following year it is here, so these markets won't be "emerging" for a very long term. As this is a transitional phase in the pharmaceutical market, we think there are still windows of opportunity. The markets are heterogeneous and strategies have to be different and flexible. Some markets are very brand oriented others are moving towards a generic model.

Kamel, speaking about your financial performance, what do you expect in terms of your results in the next few years?

Our ambition is to hit EUR 1 million sales this year. We have a very solid plan going forward, which is dependent on companies and products. We expect to be a EUR 50 million company within 5-6 years. Granted, this is very aggressive, but we feel that with the partners we have and with the partners we are in discussions with we might be able to achieve it if we follow the original plan—having institutional products; low volume, high value.

In terms of diagnostics, a lot of activity is happening in the preventive field vs. only the therapeutic field, so we expect returns there as well.

Kamel, why Genpharm over competing companies?

Genpharm is a young company with a clear business model— providing market access to biotechs and rare disease companies and ensuring that the Middle East is introduced to them as an opportunity. We target medium to small sized companies since they typically lack the expertise or the resources to come and set up base themselves. We operate as their agents and we do the

registration, the medical & sales and marketing. We publically outsource the logistics to major distributors such as Gulf Drug and MPC, for example, since they are well established and logistics is not within our realm of expertise.

So, the experience and the model are different. We are very specialized and stick to the four pillars, which means we only target specific companies and have no intention of offering generics, or recombined products.

Karim, which sorts of strategies are you using to reach out to these companies?

We have sponsored every single orphan drug meeting that exists in the US and in Europe for the last year, attended international conferences, and we are also participating in writing articles on rare diseases in the Middle East. We have a very active social media and PR campaigns online. The network has been extremely helpful as well, since here in the region interpersonal relationships are key. Having been the secretary of the Pharma association in the region and sitting on several business councils, we have been able to operate very quickly.

Karim, speaking of the importance of having a network— what was your strategy for gathering together such an impressive collection of board members?

Genpharm has four board members: The CEO of Emirates NBD, Mr. Rick Pudner, the largest bank in the region; the CEO of NextPharma, one of the largest contract manufacturers in Europe (which goes in line with our vision of owning our own brands, since we will need a manufacturing partner); the third member, an owner of consultancy company specialized in staff alignment and staff engagement. The fourth board member is Sheikh Yasser Naghi, the chairman of the Cigalah group, a leading pharmaceutical company and distributor in Saudi Arabia, who also happens to be one of Saudi's richest families.

Focusing on human resources, owning our own brands, getting financing open in the next phase, and having people on board that bring value are Genpharm's visions. All the board members help align these visions and bring value in everything they do. They will also probably be part of the first phase of investors.

And that is how the puzzle makes sense.

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