Interview: Stella Koukaki, Theodore Panagopoulos, Panagiotis Panagopoulos – Management Team, PharOS, Greece



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The management team of PharOS discuss the company's move from generics consultancy to co-developer, surviving in the Greek market, and internationalization plans.

Founded back in 2002, PharOS has gained a formidable reputation as a pharma development company for bringing best in class generics products to market and prolonging their life span. Could you please start by introducing the company and the main milestones in PharOS' evolution?

We started out in the early 2000s primarily as a pharmaceuticals consultancy company and, as such, were very much a first-mover and one of the first Greek companies of our kind. Back then, the Greek pharma market was already heavily populated by indigenous generics manufacturing entities and the affiliates of multinationals, but there was no player to offer product development assistance and regulatory support. We therefore identified a market gap to set up a company offering training and product development and regulatory affairs guidance.

Our initial clients were primarily local pharma manufacturers who had well established themselves in the generics segment, but lacked the expertise to spread their wings and take their products abroad. In many cases, their business would be concentrated on the domestic markets and they would be seeking someone to help them to navigate other European geographies. PharOS

possessed the know-how of how to efficiently and successfully bring products to market across Europe.

Then in 2005, we resolved to set about conducting our own product development instead of just fulfilling those services for others. When we first started out as a developer we were able to assess market niches in the therapeutic areas of oncology and anti-psychotics which set about re-wiring our business model into what it is today: a privately owned company developing generics and value added pharmaceuticals with a global portfolio of over 50 products and over 5,000 marketing authorizations worldwide.

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Tell us more about taking the leap from generics consultancy to co-developer.

Rather than possessing our own manufacturing we resolved upon a business model by which we partner with companies that own the hard assets and production facilities, and contribute with our expertise and know-how to secure the marketing authorizations for our common products. We can leverage the inherent flexibility that derives from not having our own in-house production sites, to select the optimum country and manufacturing partner for the particular task at hand and this affords us a certain degree of competitive advantage. The consultancy part of the business has now become internal and is the mechanism by which we support the products that we co-develop.

Our contribution starts early on with the screening and identification of what we analyze as being the optimum type and class of product to develop. We analyze the patent landscape and determine which are the most prospective products and therapeutic areas to go for.

The next steps generally relate to the sourcing of the most suitable API and the selection of the best match in terms of co-development partner. Our R&D team will subsequently develop the formulation using external laboratories, this formulation will then be scaled up at the selected manufacturing site and finally assessed via a clinical study. We next deploy our in-house teams to compile the dossier for submission and then our regulatory affairs department is charged with securing the necessary marketing authorizations.

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All in all, we represent a one-stop-shop to our partners. Crucially when we build a dossier for submission this will normally cover a whole array of geographies meaning that the product dossier will be aligned with and adhere to not just the European regulations but those of South East Asia, Latin America, Canada, Australia and much more. Over the years, we have managed to build an

extensive network of partner companies that are kept abreast of the products we are developing, which in turn allows us to conclude the most suitable out-licensing agreements as and when they occur.

In 2008 you opened a Polish affiliate and have subsequently bolstered your capabilities to be able to secure marketing authorizations across some 80 different markets around the world. How did you practically go about amassing the requisite know-how?

Strategically Poland represented a great launch pad and stepping-stone. As a B2B company as opposed to B2C we don't possess in-house marketing and sales teams, but we still had to bolster our knowledge base in a strategically astute way. It made sense to concentrate on the European marketplace where the regulatory frameworks were closest to what we were most familiar with, but we were also keen to penetrate emerging markets. In the early 2000s there was a great deal of buzz about the pharmemerging economies and how those would be the revenue drivers of the future and it was important for us to acquire the capabilities to accompany our clients into those sorts of geographies. Poland, as the EU's most emerging economy, was the obvious market for us to start with and simultaneously a great gateway for us to enter other growth markets like Russia and the CIS.

Understanding the different cultural mindsets and operating procedures can be very challenging and it takes perseverance and careful cultivation to develop the requisite expertise. In our experience, there is no such thing as a prototype or standard formula for emerging markets because each country in culturally and bureaucratically distinctive. Even within the same market, we sometimes encounter regulators requiring very different data and criteria for our different clients. Through our local partnerships and collaborations with high performance entities with boots on the ground, however, we have managed to bring ourselves to the point where our partners are nonetheless comfortable sourcing our products in their effort to penetrate these markets.

To date, we have managed to secure authorizations in many of the Latin American and Asia Pacific markets, and we are keen on taking on the challenge of pertaining China , Japan and the US.

How would you describe the make-up of your client base?

The client base very much changes according to the geography. From multinational generics companies having a footprint and presence around the world thus seeking a one-stop solution – like the one we offer, to strong local players in various markets.

Who do you see as your main competitors?

These days the competition can come from all sorts of different angles. There has always been a strong competition from well-established developers like ourselves in Europe as well as from abroad. We have recently encountered an increasing number of competitors being marketing companies which seek to earn a quicker return on investment through licensing-out their products.

How then do you go about differentiating PharOS?

One of PharOS' main points of differentiation is the brand and reputation that we have built up over 15 years. A large part of our workload actually comes from repeat business and that demonstrates the satisfaction and loyalty of our partners and clients. It is also a reflection of how we are tried and tested when it comes to meeting goals.

Clients will judge you on the speed of getting a product to market and on the fact that the products are marketed on the very first day following patent expiry. Failure to achieve this could very quickly result in the tarnishing of one's brand image so we are especially meticulous when it comes to the strategic design of our projects, including but not limited to requirements of compiling dossiers for different geographies, understanding country regulatory processes, and doing our homework with regard to possible patent circumvention. Also tremendously important for the brand image is in ensuring a continuous supply of top quality products that properly meets the requisite requirements.

We are also proud of our proactivity in offering backup solutions and alternative pathways for multiple scenarios. Part of the art of successfully bringing drugs to market relates to second guessing the actions of the competition and in foreseeing likely developments relating to the patent landscape. We cover our partners with plans for a whole range of different eventualities so that together we are not caught off guard.

These all make up the basics that enable us to remain in the game and competitive.

How have you been weathering the Greek financial crisis? And what are your aspirations for the coming few years?

Despite the Greek political and financial crisis we invested both in growing our workforce, which tripled to more than 80 employees, as well as in new product development. Each has driven the other and now we are proud to have a product list of 50 products and a client network of some 300 high-performance companies. Luckily our exposure to the Greek domestic market was limited as we had originally designed our strategy towards markets abroad. Our revenues have thus been insulated from the local price-cutting, claw-back and rebates. At the height of the crisis, being a

Greek company sometimes raised eyebrows when interacting with clients and partners, however they felt reassured, since over the course of 15 years operations, we have never yet failed to bring a product to market.

Our goals right now are to add more products to our portfolio as well as broadening our coverage across different therapeutic areas. At present, we possess a pipeline of some 20 products that we are seeking to bring to fruition. We will also be looking at fresh geographies with China being high up on our list of new markets where we seek to do business.

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