Andreas Moschos – Founder, NextCRO, Greece

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In a landscape starved for innovative medicine, clinical trials stand as a beacon of hope for critical care patients in need of the latest high-value treatments. Pioneering the development of a thriving CRO environment is Andreas Moschos, founder of NextCRO, who fully embodies the forward-thinking values invoked by the company's name. He spoke about the inspiration behind the company, its focus on harnessing top-quality scientific studies, as well as providing opportunities for proper care to Greek patients.

Mr. Moschos, you founded NEXTCRO in 2015 with the clear vision to provide high quality solutions across the entire research and development community. Could you please provide our global executive readers with a brief background of the inspiration behind starting the company?

The clinical research market is a very exciting one. I came across this field in 1998 when I ventured into my first CRO company, ZeinCRO. Prior to this, I've typically held sales and marketing roles in various pharmaceutical companies in Greece and the Middle East and therefore had a foundational understanding of the greater healthcare market at large. I came across the exciting area of clinical research at a time period when the market was at its mere emergence in many countries in Southeastern Europe and especially for Greece. The inception of ZeinCRO essentially opened the market for Greece and had set its benchmark standards and rule, alongside the authorities. It was important for us to not only work with the authorities, not only in regards with providing the regulatory framework, but also as a means to introduce the culture of clinical research at large and

open up mindsets to the advantages that they bring. It is imperative that we showcase the plethora of opportunities available in terms of growing and opening up the market.

It was very challenging as we pioneered the genesis of a new and exciting market to the country. We went through countless ideas and initiated many of the elements that are now available in the Greek market for clinical trials, which we truly take pride in. Once ZeinCRO grew and was sold, I moved on to another exciting opportunity in creating NextCRO. This company was fundamentally anchored on the premise of three main opportunities, namely: the new EU regulations for clinical trials, wherein the submission and approval of clinical trials have become more centralized, thus inciting more parity for the standards in all EU countries; the new regulations for the protection of private data, as changes are sure to emerge in this area; as well as the new regulation concerning the medical devices. These three pillars are spearheading the overall trend in the landscape and will shape the future of clinical trials.

Please explain the concept of a “plug and play team” and why this dynamic is valuable for your business model, especially for economies like Greece.

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One of the core problems that CRO managers face in running a business is the availability of resources. Once a project is conceived, a team ideally needs to be set up, but this is not readily available in all countries and they lack the resources to carry on. A typical case scenario then is that teams are built in the last minute when pressures are high and resources are sourced in a haste. In essence, the idea behind the solution we provide is that we have available resource ready to be deployed at all times, and therefore, leaders can make decisions more methodically and meticulously, as opposed to being in a rush.

One of the value propositions you convey is that as clinical trial costs and complexity continues to escalate, you strive to provide your customers with new possibilities and adapt new working practices. What are the new working practices available with your services?

The cost has risen dramatically across all countries for clinical trials. The global axiom for this landscape is that the more a market is regulated, the more it costs. However, it is an absolute necessity for an environment with clinical trials to be regulated, therefore the focus needs to shift on how to mitigate the costs associated with these regulations. The pharmaceutical market is the most regulated environment in the world, as it deals with value of human life as it bottom line. Dealing with patients in dire and critical conditions is of utmost importance, therefore it needs to

be regulated as we have seen their benefits. With more regulations, more business opportunities are also available.

Higher regulations naturally imply higher costs. It is exacerbated by the statistic that there is a growing aging population, which means that the social security funds will correlatedly not have sufficient money to reimburse new medications. It is an equation that might not reach equilibrium, but risk management mechanisms are currently in place to ensure that there is movement towards the direction of progress. Nonetheless, it remains to be seen as to what solutions will be implemented given rising life expectancy and its associated costs.

Our solution is driven through offering a more cost-efficient basket of goods. Selecting countries like the EU five, along with large markets like the US and Canada, and placing them in the same basket as low-cost economies such as Greece, Turkey and other Eastern European countries like Romania and Bulgaria will provide our customers with a basket of relatively cheap countries. In turn, this will increase the efficiency of clinical trials because high recruitment of strong talent could be done at lower costs.

What is the portfolio of your clientele? Is there a greater proportion of multinationals to local companies?

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We cater to both local and multinational companies. As it stands today, the ratio is 50-50 for both type of clients, but over time, it is forecasted that the multinational companies will surpass the locals. The reason for this is that there are limited amount of local companies available in the market, while there is a burgeoning number of innovative biotech start-ups that are strong prospective customers.

Countless models have surfaced in regards with how big pharma is working with clinical research firms, especially in the context of collaborations, partnerships or the selection of one or two key providers. What this means for a regional company like NextCRO is that what is relevant for us are not the large pharmaceutical players, but the newly-established mid-size companies wherein we can pinpoint a niche and a very specific segment.

The NextCRO brand is relatively new in the market. How do you communicate your value proposition to the market? As well, what differentiating factor do you offer to entice clients to choose your services as opposed to a multinational clinical research firm?

Many of the established multinational CROs are all present in Greece in the likes of Quintiles, Convance and many others that work directly with large pharmaceutical multinationals. There are also some pharmaceutical companies who opt to work with freelancers, but they run the risk of outcomes that are not properly checked and validated. An audit of our quality system is embedded in our operations for every project that we launch.

The key factor that differentiates us from large players in the likes of Quintiles and Convance is the fact that our main objective is to attract a higher volume of top-quality studies in our region, whereas the interests of the large global organizations is to attract business to their platforms. For the latter, there is very minimal difference whether the study comes to Greece or not. As a CRO company, our key objective is to bring studies in the countries that we are active in, which are currently Greece and Turkey. Efficiency is increased in our business model that begins with bring a study to a country, as opposed to having a presence in a country because it is mandated by the global headquarters, which is what the multinationals do.

Given this differentiating strategy, what are they key priorities in your agenda?

Our overarching objective is to make the entire clinical market attractive as a whole. This is why we work hard on selecting sites, educating sites, training sites, as well as promoting the sites because we have a vested interest in developing the market to its full potential. We are a strong advocate in promoting Greece, not only as a cost-efficient country, but more so as a place rich in potential that can optimize results for research in critical clinical areas such as rare diseases.

Especially given the epidemiological profile of the country, certain diseases have a higher prevalence in Greece, thus making it a fertile ground to conduct clinical trials. This element needs to be showcased at a wider, grander scale. For instance, it is not common knowledge that Hepatitis C is rather prevalent in the country and therefore it will be easy to facilitate the recruitment in this therapeutic area. The focus on our business development therefore is to convey this value.

From the series of interviews conducted thus far, there is a consensus that clinical trials is a severely underdeveloped activity in Greece. The country is rich with potential and talent to make this activity thrive and invite more investment. What do you believe has been missing in this landscape?

Prior to the crisis, no company had really look into investing in clinical trials because the state of business affairs were running rather smoothly. Though there were discussions and conferences about the topic, there was no impetus for executing any activities in this area. For us who were not only active but pioneers in this field, we were generating about 140 studies year partly accredited

to our supportive nexus of investors and clients with sound business acumen to recognize the value brought by these activities.

After the crisis, the predominant mindset was that of a state-oriented culture devoid of entrepreneurial and innovative thinkers. Indeed, the financial resources were lower, but the decision-makers in hospitals and different parts of the healthcare spectrum still had the capacity to make critical decisions to drive progress forward. Despite the austerity, there were many opportunities that arose within the crisis as well, but they were not acted upon because all the players are simply awaiting the decisions of the State. There should have been a faster reaction rate, especially in a crisis of this magnitude when the GDP is slashed fourfold.

Do you foresee a growing clinical trial market in Greece, if and when the mentality becomes more open?

There is undeniable potential in Greece. Firstly, we have the appropriate patients, which is an unfortunate reality but this is a key element for proper clinical trials. Secondly, given the drastic decline of the healthcare budget that created many hindrances for new medications to come to Greece – as exemplified in the regulatory landscape that necessitates innovation to be present in 14 European countries with 7 HTA systems and enter the market with a 25 percent rebate – the only way Greek patients in severe debilitating conditions have the possibility of accessing high quality care is through clinical trials.

Greece should be emulating the examples put forth by many countries in Eastern Europe wherein financial constraints in the healthcare system incentivized them to further grow clinical trials to ensure that critical care patients are tended to. If we consider the facets of a Phase III study, it can almost be certain that it is close to a perfect match to the patient. The benefits far outweigh the cons in participating because for patients in economically-striven markets, it might be the only hope.

What is your vision for NextCRO moving forward?

At the crux of our mission is to bring more studies to the Greek market, and ultimately, provide Greek patients with opportunities to access innovative medication that they might not otherwise have the chance to avail. I am a strong proponent of including a metric in the health system wherein the percentage of patients under clinical trials are recognized to contribute in alleviating some financial burden to the health system. For instance, for oncology patients, 10 percent are undergoing clinical trials and therefore do not contribute to the cost of the system. Health authorities need to recognize that clinical trials equals monetary savings, therefore generating a

win-win scenario for all players.

For NextCRO itself, our plan is to grow, not necessarily in scale, but in being able to carve out specific and targeted market niches to focus on. We intend to play a strong role in fostering the CRO landscape as a whole because we are not competitors with each other. I believe there is space for everyone in this field, but we need to grow this field in order to saturate it with more substantial actors.

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