Mazen M. Hassanain – Co-Founder and Managing Director, SaudiVax (December 2021)



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SaudiVax intends to be the premier developer, manufacturer, and supplier of vaccines and biologics in Saudi Arabia and the MENA region, including halal vaccines. Co-Founder and Managing Director Professor Mazen Hassanain comments on the company's ambitions, the opportunity that halal vaccines represent, how its J&J partnership will create the first tech transfer for biologics manufacturing in Saudi Arabia, and how its Merck partnership will move SaudiVax closer to its goal of offering world-class CDMO services.

Professor Mazen, can you start by briefly introducing your academic and professional background and what led you to co-found SaudiVax?

I studied medicine at King Saud University and, after graduating with an honors degree, was recruited by the university, earning a scholarship to train abroad at McGill University and do my residency in surgery. During that time, I became interested in lab research which allowed me to enter a graduate program and finish a PhD in science; simultaneously, I did my fellowship in transplant immunology.

As part of my PhD studies, I obtained a patent on a new use for insulin as an anti-inflammatory treatment to support liver regeneration. This exposed me to the pharmaceutical industry, allowing me to work closely with Eli Lilly and Roche for their VGEF inhibitor, Avastin. My work led me to the

academic side of research and development.

My entrepreneurship experience came after that, mostly in the healthcare sector where, together with partners, I opened a private clinic in Canada, staying there for a few years before moving back to Saudi Arabia.

I became a professor of surgery at the college of medicine, King Saud University and was recruited by the Saudi Ministry of Health to lead its research and development department, establishing policies and procedures for clinical trials, approvals, ethics review boards, national biobanks and usage of data for clinical research. My work with the MoH coincided with the Middle East respiratory syndrome coronavirus (MERS-CoV) outbreak, which led me to work on vaccine development and manufacturing. I spent time working with stakeholders inside and outside of the country to close the knowledge gap that existed not only in the country but in the region in general. At the time, there were almost no local capabilities on the development side, whether clinical or preclinical, and no manufacturing capacity at all. We highlighted the need for more biotechnology and manufacturing companies in the country.

After leaving the MoH, I returned to academia and became an adjunct professor in oncology at McGill and an adjunct professor of paediatrics at the Baylor College of Medicine, working closely with Professor Peter Jay Hotez to support vaccination R&D for neglected tropical diseases which are majorly affecting Muslim countries.

Finally, in 2016, I co-founded SaudiVax along with my brother, Mutaz Hassanain, Dr Donald Gerson and his son, Eng. Jonas Elliott Gerson. The objective was clear: to establish a biotech company that could do both development and manufacturing of vaccines and other biologics in the country for the region.

Where is SaudiVax today in terms of development capabilities and what does the company’s focus on halal vaccines mean?

While Saudi Arabia is a high-income country with the capacity to enjoy a sustainable supply of high-quality products, our mission is to support the entire MENA/OIC region. The lack of strong regulatory bodies in the region’s low- and middle-income countries is worrisome as it relates to the safety and efficacy of medications. We believed that it was time to establish a high-quality developer and producer of vaccines & biological products in this part of the world.

As a country, Saudi Arabia wants to match the well-established regulatory systems of North America, Europe, and Japan, but adding a halal component, which is of great value to Muslims, one of the largest religious groups in the world. There is a global trend away from using any animal by-products in bioprocessing, and we are working to ensure that none of the components have any animal derivatives at all.

The goal is not about religion, it is about increasing quality to make sure that biological products coming out of Saudi Arabia enjoy the same quality as those from North America and Europe. The Kingdom is taking its position as a global leader in halal products, and it has the right socioeconomic status, brainpower, and research funding to do so.

Can you elaborate on the vaccine-related learnings you obtained during the first MERS-CoV outbreak in 2012?

What we witnessed during the first MERS-CoV outbreak, which fortunately did not match the scale of the current SARS-CoV-2 pandemic, was a devastating effect on the health of the population exacerbated by the fact that, since the outbreak was regional, we did not receive enough external assistance.

There are many viruses residing in this region today which is a big challenge at a time when the authorities in Saudi Arabia and as part of its Vision 2030, are looking to increase the number of visitors and tourists. High levels of tourism comes with the burden of having to assure health security for both the local population and visitors from all the potential endemic diseases that could spread. If we do not act upon those risks, no one will, and by the time they do, it will be too late. Over the last two years we have seen the socio-economic impact of such outbreaks and the objective is to get ahead of the situation. Building up our biological capacity is an integral part of the defence system; you do not build it because you have a problem, you build it to avoid one.

Developing Saudi Arabia’s capabilities around biologics requires a strong regulator that ensures their safety and quality. What is your perception of the Saudi FDA, which has been praised by many of your colleagues?

The Saudi FDA has changed significantly in recent years as it attempts to benchmark with other reputable regulatory bodies. COVID-19 put pressure on the Saudi FDA to process documents and review facilities at a similar pace to its counterparts in the UK, Europe, and the US, but they rose to

the challenge. We will continue to demand more from the agency by creating our own products, but I am sure that they will be able to manage the learning curve as the first homemade innovative products reach local markets.

Building biologics capabilities remains a difficult venture, especially in places where the supportive ecosystem requires further development. How is SaudiVax planning to build up its own capabilities?

SaudiVax has been working for five years, more or less, to develop the Saudi biotech ecosystem. We took the toughest route – first establishing an ecosystem before then creating a business model with sales and distribution activity – which does not align with the biotech mindset. The company opted not to take the easy way to obtain financial returns immediately, rather choosing to invest time and effort to bring experts from across the world that have experience and could come and train Saudis.

The second step was hiring promising Saudi scientists with a strong educational background with an interest in biotechnology; we already have around 25 of them in our team, 70 percent of which are female which demonstrates our commitment to female empowerment in Saudi Arabia. Our team had limited knowledge of the industry at the beginning but can now teach the group of employees to come; they understand every step of the biotech journey, from development to manufacturing. We essentially built a knowledge school. This was done in partnership with international and local players in the field.

A frequent dilemma for biotech ventures is choosing a technological platform. Has SaudiVax made a choice in that regard yet?

SaudiVax started by focusing on mammalian cell-line based protein productions, which five years ago were among the newest approved technologies. Since then, we have added viral vector and nucleic acid platforms, adjusting our trajectory to adapt to what is coming up from the worldwide pipeline. However, we are basing the first wave of our pipeline on mammalian cell line based protein production.

SaudiVax made international headlines recently with the announcement of partnerships with Johnson & Johnson (J&J) and Merck. What are those agreements about and how do they fit into the company's long-term strategy?

The J&J and Merck collaborations are part of the partnership network we have decided to establish; we are proud of them and more to come before the end of this year.

With Johnson & Johnson, we are working on the first tech transfer of biologics manufacturing in the history of Saudi Arabia. J&J knows the country very well after many decades of local presence; they have worked closely with local players in the small molecule business but have not yet done anything in the large molecule business line. We started discussions for their biologic pipeline before COVID-19 and it has been a successful journey so far and a great learning curve for SaudiVax in proving our technical capacity, know-how and ability to execute properly.

Since the partnership is the first of its kind for J&J in the region, we want to set an example. The first tech transfer will take time, but, hopefully, the second and third will be easier. We are happy with the partnership and are exploring other potential R&D projects relevant to the region from a public health perspective. J&J also signed a partnership with King Abdullah University of Science and Technology (KAUST) to explore opportunities for research and innovation in neglected tropical diseases with a specific focus on dengue fever.

Our partnership with Merck is a different arrangement and we are excited to work with them in bringing their life science expertise to the region. Merck will help SaudiVax design a best-in-class, multi-modality manufacturing facility to localise manufacturing of biologics and vaccines for the MENA region. We are working with them on several avenues including designs, technology-transfer, training, and co-development of new molecules, benefiting from their CDMO experience in France and the USA.

It is a complex multifaceted collaboration that will hopefully help us anchor our second line of business, which is establishing a solid contract development manufacturing capacity (CDMO) for the region.

We are doing our own innovative development but are also interested in building this CDMO capacity in the country. Evidently, we would not be able to develop these collaborations without a surrounding ecosystem. We aim to be an example of the multifaceted game plan that Saudi Arabia is implementing; the government has made all this possible on many levels, from supporting the industry to investing in academia and research led by the Saudi Ministry of Industry, Ministry of Investment, Ministry of Education, Ministry of Health and KAUST.

As the company continues its development of innovative products, it will eventually need to run clinical trials in the country and the region. How ready is Saudi Arabia to accommodate an increasing number of clinical studies?

Clinical trials will play a big role in the country because we have patients, hospitals, and adequate regulatory bodies. The Saudi Arabian ecosystem is, however, lacking the industrial and the investment mindset, but the Ministry of Investment has created the Clinical Trials Coalition in collaboration with pharma and stakeholders to overcome current obstacles, similar to their amazing efforts around intellectual property for example, making the country much more attractive to investors.

What is your view on the country's Vision 2030 and how can companies like SaudiVax leverage the transformation and investment it is bringing?

It is an exciting time for Saudi Arabia as the country moves forward with a full transformation, almost a 180 degree turn, changing not only the bylaws but also the entire socio-economic mindset. People are very optimistic with high patriotism and SaudiVax wants to leverage the transformation to grow and achieve a sustainable business. What we have is a win-win situation where the government is reaching its objectives, local players are flourishing, and multinational companies can find a great market in which to invest.

Is there a final message you would like to convey to our international audience about SaudiVax's future?

SaudiVax is a biotechnology company that is driven by a strong passion and clear goals. It's objective is to supply the region with high quality products that meet international standards by filling the gaps in vaccines and biologics manufacturing, and prompt translational R&D of innovative biologics. We can transform locoregional opportunities into realities and are able to generate the correct business model that supports successful development, manufacturing and innovation.

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