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Saudi Arabia is at a pivotal moment in its development journey, offering immense potential for growth and innovation for itself and the GCC region

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SaudiVax, a pioneering force in the halal vaccines field, has recently expanded its focus to include biologics, aligning with broader market trends towards vegan and Halal products. Co-Founder and Managing Director Prof. Mazen M. Hassanain outlines how the company has shifted its distributor strategy to form partnerships with small to medium-sized biotech firms, particularly in regions outside traditional pharmaceutical hubs, and is continuing to leverage its scientific expertise for commercial success and improved patient access.

Reflecting on our previous conversation in 2021, your business strategy centred around the development of Halal vaccines. Could you elaborate on whether this strategy remains unchanged, and if so, what adaptations has SaudiVax made over the past three years?

Overall, our business strategy remains centred around the development of Halal vaccines. We've expanded this focus beyond vaccines to include biologics as well. Delving into this field requires meticulous attention to detail, particularly regarding halal certification. Ensuring that every aspect of the product, from cell growth to container materials, adheres to halal standards is essential. Our aim is not only to cater to halal requirements but also to appeal to consumers who prioritize animal-free products, such as those following vegan diets. This move towards animal-free production aligns with broader market trends and preferences.

However, developing halal products is a time-intensive and resource-intensive endeavour. To balance our focus on halal products with the need for revenue generation, we established a new department dedicated to marketing, sales, distribution, and manufacturing. This diversification strategy allows us to generate cash flow while continuing to pursue our long-term goals in the halal product space. Additionally, we sought to differentiate ourselves from the regional market, which predominantly focuses on generics or partnerships with multinational companies.

Initially, we explored partnerships with multinational distributors, but it became clear over several months of discussions that our priorities and goals did not align with those companies. As a result, we shifted our focus to smaller and medium-sized international companies that do not currently have a presence in our market. This strategic shift allows us to collaborate with partners who better understand our market needs and are more aligned with our objectives.

What types of companies have SaudiVax forged partnerships with as part of its new distributor strategy?

As part of this new strategy, we have sought out partnerships with companies that align with our values and objectives. We prioritized integrity, research capabilities, and a shared commitment to our overall mission. Formulation quality, especially in biologics, was another crucial factor. We do not limit ourselves to specific geographic regions but instead focus on finding partners with the right expertise and capabilities.

While Europe and North America are obvious choices, we also explored opportunities in South Korea, Japan, and China. Our goal was to identify companies that excel in their field, even if they're located outside traditional pharmaceutical hubs. One of our first successful partnerships was with a small biotech company in South Korea called Pangea. Despite being relatively unknown at the time, we were impressed by their scientific ability and work ethic.

In particular, we see biosimilars as a significant market opportunity. Biosimilars offer the potential to show our technical capabilities for localization and manufacturing, aligning with Saudi's goals of cost efficiency and access to medications. Our value proposition to partners includes technology transfer for manufacturing in SaudiVax facilities, along with assistance in navigating the regulatory landscape while building the appropriate marketing strategies.

By partnering with smaller biotech firms abroad, we offer a streamlined process for entering the MENA region, which is often complex due to varied regulations and market dynamics. Multinational companies may already have a presence in both our target markets and their home countries, making exportation unnecessary. Our approach offers an alternative route to market entry, leveraging our expertise and local insights to facilitate successful expansion into the region.

It seems SaudiVax has transitioned from a predominantly science-focused approach to one more oriented toward business development and commercial activity. How has this shift in strategy impacted the company's trajectory?

By shifting towards a more business-oriented approach, we've been able to leverage our strengths in science and research to drive commercial success. One key aspect of this transition is our focus on bringing biosimilars to market. In our discussions with potential partners, we emphasize the benefits of conducting clinical trials locally, which not only helps finance the trials but also improves access to innovative treatments for patients. This approach allows us to select products

based on their potential impact on patient populations rather than simply financial considerations. As a result of this commercial success, we've established our own clinical research organization and set up clinical trial units to support our internal development efforts.

Have you experienced any government support or financing regarding the advancement of biosimilar development? Can you provide an overview of the current biosimilar ecosystem in Saudi Arabia?

I would say that the regulatory landscape has evolved to become more conducive to innovation, with improvements in stringency and international recognition. Saudi Arabia's FDA participation in PIC/S and receiving the highest level of the World Health Organization (WHO) classification for regulatory authorities has also facilitated regulatory approvals, making it easier to influence developments beyond the country's borders.

Moreover, there's a growing demand for innovative therapeutics driven by certain patient populations, although these patients are not typically involved in clinical trials. Organizations like the Saudi NIH have played a significant role in streamlining clinical trial regulations and making the environment more appealing for pharma-sponsored clinical trials.

In terms of the current biosimilar ecosystem, there are several Saudi companies engaged in biosimilar drug supply. These companies typically follow a similar business model, by being involved in marketing, sales, and distribution, often in collaboration with global partners. While this model yields good profits within the local market, it may not be as lucrative on a global scale due to the relatively small population size of Saudi Arabia compared to larger markets like Europe, the United States, and China, making it very challenging to do a true manufacturing localization.

Despite these challenges, there's still significant potential for biosimilar development in Saudi Arabia, especially through partnerships with smaller biotech companies. Many of these biotechs already outsource manufacturing, making technology transfers a feasible option without additional investments. This approach allows for the localization of biosimilar production and the potential for exportation to other markets in the region.

Given your original mission of halal vaccine development, where does SaudiVax currently stand in terms of progress achieved?

Currently, SaudiVax is in the preclinical phase of vaccine and biologics development where we are conducting animal testing to ensure safety and efficacy. Despite facing challenges in navigating stringent regulatory requirements for novel vaccines and biologics, the company remains committed to advancing its halal vaccine and biologics development efforts.

Over the past few years, we have seen significant developments in the halal market, particularly with the Saudi government's emphasis on halal development and the establishment of private equity firms investing in halal products. This increased attention to halal products has created a strong market demand and reinforced our dedication to halal vaccine development.

Collaborations with institutions like the National University of Medical Sciences (NUMS) in Pakistan and the Islamic Development Bank have highlighted the substantial demand for halal vaccines in Muslim-majority countries beyond the GCC region. However, affordability remains a significant concern, as many existing vaccines are either expensive or dependent on donations, raising doubts

about their quality and effectiveness among some patients who might not have a strong knowledge of the area. To address these challenges, we are focused on ensuring halal certification but also on making the product affordable. This dual objective adds some additional complexity to the development process since achieving affordability requires high operational efficiency and scalability. Still, we are optimistic about the market potential for halal vaccines and are actively seeking partnerships both in the East and the West.

What have been your experiences concerning investment search and fundraising efforts?

Securing investment and fundraising efforts have been pivotal aspects of SaudiVax's journey, especially given the competitive business landscape created by Saudi's rapid growth. Convincing investors to commit to healthcare ventures, which are inherently long-term endeavors, has certainly been a challenge.

In this evolving healthcare ecosystem newer players like SaudiVax must carve out a niche. Aligning investor objectives with the company's goals has been a significant learning curve. While there are receptive investors, the complexities of the biotech sector often deter some from engaging fully.

However, since 2020, we have successfully secured funding from the Hassanain Family group, followed by the successful investment from the Doctor Soliman Fakeeh Family Group in 2024, facilitating smoother operations and strategic alignment across various fronts, including training, research, clinical trials, innovation, and manufacturing. We proudly can say that this alignment has valued the company at an impressive \$45 million.

Moving forward, we anticipate a second round of private investment where we are aiming to achieve a value of approximately \$150 million before considering an IPO. In this phase, we are open to engaging with non-Saudi investors to bring regional expertise and add value beyond just the financial aspect. It's important to think beyond the local market and we want partners who can contribute to our regional expansion strategy beyond Saudi Arabia.

Is there a final message you'd like to convey regarding Saudi Arabia's future development potential?

Saudi Arabia is at a pivotal moment in its development journey, offering immense potential for growth and innovation for itself and the GCC region. We are in a time of a unique convergence of attractiveness and healthy competition, backed by plenty of financial resources.

One area of focus lies in nurturing local talent through comprehensive training. By investing in human capital development, Saudi Arabia can leverage its sizable population to bolster expertise and drive progress across various sectors, including biotechnology.

The recent launch of Saudi Arabia's biotech strategy underscores the nation's commitment to fostering innovation. We are seeing more and more important discussions surrounding regulatory policies, clinical trial facilitation, and public-private partnerships that will help shape the landscape for future development.

For those who want to engage with Saudi Arabia's biotech ecosystem, now is the right time to contribute to building the infrastructure and frameworks that will support future growth. Whether through collaboration, investment, or innovation, there is a collective effort underway to lay the groundwork for a prosperous future. I welcome those who want to come to Saudi Arabia and embark

on this journey of development to bring your ideas that will help build the road to prosperity for the future.

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