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Dream big. It's essential to envision where you want to be in the future, not just what you're capable of today

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Karim Smaira and Kamel Ghammachi, founders of Genpharm, underscores the strategic significance of the recent majority acquisition by Abdul Latif Jameel Health, part of Abdul Latif Jameel, driven by a shared vision and the imperative for accelerated growth. They discuss their expansion into diverse therapeutic areas, emphasizing the importance of early diagnosis and treatment in rare diseases. Karim encapsulates Genpharm's entrepreneurial journey with the mantra: "Passion drives resilience, despite the challenges and the losses along the journey to success".

What significant changes have occurred within Genpharm over the past few years, and how have these developments shaped the company's trajectory?

Karim Smaira (KS): In recent years, Genpharm has undergone significant transformations, both internally and due to external environmental factors. One of the most notable changes is our strategic partnership with Abdul Latif Jameel Health, part of Abdul Latif Jameel a renowned family-owned international diversified network of businesses originally founded in the Kingdom of Saudi Arabia, in 1945.

Abdul Latif Jameel Health acquired a majority stake in Genpharm, providing us with additional resources and a broader platform for growth. This partnership is particularly strategic as Abdul Latif

Jameel, with its extensive history and success across multiple industry sectors and markets, has recently entered the healthcare sector and recognized the value of Genpharm’s work, especially in the rare disease space.

We’ve also expanded into new markets, such as Türkiye and Saudi Arabia, obtaining scientific office licenses in both countries. Leveraging Abdul Latif Jameel Health’s presence and expertise in these regions, we are poised to accelerate our growth and make significant strides in providing innovative healthcare solutions. Additionally, our product portfolio has seen remarkable growth, particularly in gene therapy. With a focus on addressing rare genetic pediatric diseases, we’ve introduced several innovative gene therapy treatments, aligning with our vision of “Bringing cures treatments to MEN patients”.

Furthermore, we’ve undergone an organizational restructuring, transitioning to a country manager model and expanding our support functions, to give a stronger focus on the territories we serve, enhance our engagement with local stakeholders, and increase the pace of our adaptability to an evolving landscape. This restructuring, coupled with our expanded portfolio and strategic partnerships, reflects our commitment to advancing healthcare in the region and making a meaningful impact on patient lives.

How did the decision to pursue the acquisition with Abdul Latif Jameel Health come about, and how do you foresee it impacting Genpharm’s overall organization?

Kamel Ghammachi (KG): The decision to explore the acquisition with Abdul Latif Jameel Health was prompted by several converging factors. As entrepreneurs, my partner Karim and I had started Genpharm, nurturing its growth to a point where it attracted attention from institutionalized players. Recognizing the value of our work and the need for accelerated growth, we saw the potential of this transaction as an opportunity to accelerate growth while earning a return on our decade-long investment. Abdul Latif Jameel’s reputation for fostering business growth and their strategic focus on healthcare further solidified our decision to pursue it. Their track record indicated a commitment to collaborative growth rather than seeking short-term exits, aligning with our long-term vision. Moreover, given Saudi Arabia’s significance as a key market, Abdul Latif Jameel Health’s support in navigating this landscape was deemed critical for our expansion strategies. Ultimately, the partnership with Abdul Latif Jameel Health represents a pivotal milestone for Genpharm, providing the resources and support needed to drive impactful growth initiatives.

How do Abdul Latif Jameel Health’s values align with Genpharm’s future direction?

KS: Beyond financial considerations, the synergy lies in shared visions. Abdul Latif Jameel Health’s commitment to addressing healthcare challenges in the Global South resonates deeply with our aspirations. Their strategic focus on innovative technologies and licensing new medical breakthroughs aligns with our mission to pioneer impactful solutions in healthcare. Ultimately, it is this shared vision for transformative healthcare solutions that forms the foundation of our partnership.

How is your portfolio evolving, and what’s propelling its growth? What dynamics do you see shaping its trajectory across various therapeutic areas?

KG: The landscape has indeed evolved significantly since our last discussion. Notably, Saudi Arabia’s initiatives in managed access programs and health technology assessments necessitate selecting products that offer tangible clinical outcomes for patients. We’ve strategically expanded our portfolio to address unmet medical needs, particularly within the region. For instance, one of our collaborations focuses on new biologicals for atopic dermatitis, while another pioneers gene therapy for epidermolysis bullosa. A third collaboration targets genetic obesity, a condition with profound pediatric implications, with a breakthrough therapy addressing multiple genetic mutations and holding promise across various clinical indications. Other significant partnerships focus on myasthenia gravis, genetic neuromuscular and ophthalmic diseases, further enriching our portfolio with treatments that target the root causes of these diseases rather than their symptoms. This strategic expansion reflects our commitment to addressing critical unmet medical needs and underscores our focus on transformative healthcare solutions.

The intricacies of the rare disease niche, coupled with the need to develop market access strategies anew for each partnership, present unique challenges. How do you effectively manage the acquisition and dissemination of expertise in these specialized areas, especially considering the need to build knowledge from scratch with each new endeavour?

KS: Our approach entails a dynamic allocation of resources and expertise tailored to the unique requirements of each partnership. At our headquarters, we’ve cultivated comprehensive support functions encompassing medical affairs, strategy and commercial excellence, pharmacovigilance,

quality assurance, and compliance amongst others. Yet, the cornerstone of our operational model lies in our customer-facing teams, particularly our adept Medical Science Liaisons (MSLs). These individuals bring a wealth of experience and insights specific to the therapeutic area under consideration, ensuring a clear understanding of crucial factors such as disease pathophysiology, patient diagnostic pathways, existing diagnostic and treatment protocols as well as key opinion leaders and stakeholders engagements.

By assigning dedicated teams to each partner, we eschew generic resource allocation in favor of a bespoke, partner-centric approach, thereby fostering deep-seated collaborations rooted in mutual understanding and alignment. Furthermore, our engagement extends beyond internal capabilities to encompass proactive collaboration with the broader scientific community. Through advisory boards and strategic partnerships with diagnostic labs, we facilitate early diagnosis. We also engage with the different paying and reimbursement bodies to discuss the key clinical benefits of the treatments and the available funding mechanisms.

Additionally, our proactive involvement in regulatory affairs ensures swift and seamless registration processes, minimizing time-to-market and bolstering our competitive edge. In essence, our approach hinges on meticulous planning and strategic resource allocation, underpinned by a steadfast commitment to delivering on our promises and driving sustainable long-term growth in the ever-evolving landscape of rare diseases.

Given your significant presence in some markets, could you outline your international strategy for providing rare disease treatments in the region, particularly in strategic markets like Saudi Arabia?

KG: Across key strategic markets like the UAE, Saudi Arabia, Kuwait and Türkiye, we’ve established local partnerships and footprint, supported by our scientific office licenses. Additionally, we maintain a presence through our key distribution partners. Our strategy revolves around aligning resources to reflect the commercial potential and access opportunities, bearing in mind varying regulatory and pricing landscapes. The GCC notably offers expedited access and fast track approvals. Moreover, we’ve expanded our reach to encompass Egypt, North Africa, and recently, Libya and Iraq. By prioritizing phased expansions, we ensure alignment between commercial prospects and our internal capabilities, thus optimizing our approach for sustainable growth.

What are your ambitions for Genpharm’s presence in Saudi Arabia as its regulatory landscape evolves?

KS: Our initial step was securing our scientific license, a foundation upon which we’re expanding our operations through our local partners. The rapid pace of change in Saudi Arabia towards market maturity is unprecedented, presenting both opportunities and challenges. While this pace heralds a more predictable market landscape in the long run, the ongoing transformations sometimes lead to uncertainty. To navigate this, we remain vigilant and adaptable, ensuring alignment with evolving regulations and processes. Notable developments include accelerated regulatory pathways for orphan drug designation and approvals, alongside collaborations with the Ministry of Health to establish a centre of excellence for rare diseases. Concurrently, initiatives like patient registries and epidemiology studies are shaping the healthcare landscape. By swiftly adapting and fostering capabilities to support market changes, we’re witnessing a larger patient pool benefiting from the availability of treatments in particular in key tertiary institutions such as King Faisal Hospital, the National Guard Hospital and the Military Hospital.

With the recent achievement of a new Level Four classification by the WHO for the SFDA, allowing them to approve products independently, how do you perceive this development, particularly in the context of rare diseases?

KS: This advancement presents a significant opportunity, especially for addressing unmet needs in rare diseases. The removal of the requirement for FDA or EMA approval prior to submission to SFDA streamlines the process, potentially expediting access to innovative treatments. We’ve already seen interest from potential partners exploring this pathway for products targeting significant diseases in Saudi Arabia. However, it’s essential to note that this is a nascent pathway, and the specifics regarding timelines and processes are still emerging. Nonetheless, it signifies a positive shift, placing Saudi Arabia on par with mature markets in evaluating clinical trials and fostering local expertise. Moreover, the focus on developing centers for clinical trials aligns with Saudi Arabia’s broader healthcare objectives, facilitating early diagnosis and enhancing patient care. Overall, this development underscores the interconnectedness of research, clinical expertise, and access within the healthcare value chain.

How does Genpharm fit into the Saudi national biotech strategy, particularly regarding vaccines, manufacturing, and genomics?

KG: While the national biotech strategy primarily focuses on biotech product manufacturing, including vaccines and biosimilars, Genpharm’s scope lies more in providing solutions for patients already afflicted with diseases rather than prevention. Our involvement with genomics typically revolves around genetic diagnostics in collaboration with several genetic labs. Therefore, our contribution to the strategy may be indirect, centred on supporting genetic diagnostics rather than direct involvement in prevention initiatives. However, the Saudi government is undertaking a major genetic population study with extensive testing, like the rest of the GCC countries, to help better understand the local genetic variations and the prevalence of genetic diseases amongst the national populations.

How mature do you feel the ecosystem and government institutions in Saudi Arabia are towards rare diseases, considering Genpharm’s pioneering role in bringing attention to this area?

KS: Rare diseases have become a strategic concern for Saudi institutions, evident in the creation of new policies and committees. While the market is maturing, processes are still evolving, indicating progress towards comprehensive maturity. However, further refinement is expected as we learn and adapt. One challenge lies in budget allocation, which is dispersed among institutions unevenly. This disparity impacts patient treatment, with some institutions having more resources than others, leading to access inequalities. The discrepancy between diagnosed patients and those receiving treatment highlights the need for streamlined access pathways and improved budget distribution. Discussions between the pharmaceutical industry and the Ministry of Health are ongoing to address these access challenges. Additionally, cultural factors, such as consanguineous marriages, contribute to a significant number of undiagnosed cases, particularly in remote areas. This underscores the importance of enhancing diagnostic capabilities and expanding treatment access across the country.

Looking ahead to 2024-2025, what strategies is Genpharm planning to implement to continue its mission of providing access to gene therapies and treatments for rare diseases?

KG: Our strategy has always been focused on growth, particularly in bringing innovative treatments to the forefront as early as possible in the life cycle of the product. An example of our passion-driven work is evident in Duchenne muscular dystrophy, where we’ve significantly improved

diagnosis timelines from eight to nine years old to as early as three. This is in large part thanks to all the disease awareness activities that we have conducted over the years and the extensive scientific collaborations with the key stakeholders. This early diagnosis window presents a crucial opportunity for effective treatment before the degenerative disease progression becomes too advanced and irreversible. Our aim is to replicate this success across all disease areas we operate in.

Was the initial delay in diagnosis primarily due to a lack of knowledge or education?

KS: It wasn't solely a matter of knowledge; it involved several factors. Alongside limited awareness, there was a scarcity of genetic testing facilities for confirmation and a lack of treatment options, especially for conditions like Duchenne muscular dystrophy where we pioneered early with the launch of the indicated therapies. Additionally, there was a deficiency in expertise among clinicians and the wider public. To comprehensively address these challenges, we've undertaken extensive initiatives. These include educational campaigns in collaboration with scientific and broader communities, facilitating genetic testing access through laboratory partnerships, and engaging with payers and health authorities to ensure treatment availability for eligible patients. We've even collaborated with schools to educate teachers on recognizing symptoms and promptly referring potential cases to specialists. This multi-pronged approach aims to enhance awareness and early intervention across various platforms.

As entrepreneurs in the rare disease space, what personal lessons would you like to impart to our international audience?

KG: Dream big. It's essential to envision where you want to be in the future, not just what you're capable of today. We've always had lofty aspirations.

KS: Our journey began with audacious goals, despite naysayers warning of failure and pointing risks. The challenges only fueled our determination. Passion is paramount; it fuels resilience in the face of adversity. In rare diseases, setbacks often outnumber victories. Yet, each small win is cause for celebration and drives us to persevere. Our team understands the profound impact of our work, driving us forward despite the hurdles. It's about making a tangible difference, being resilient, and staying true to our passion, even when the road ahead seems daunting.

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