KV Subramaniam – President, Reliance Life Sciences

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KV Subramaniam, president of Reliance Life Sciences, a research-driven medical biotech with a fully integrated value chain that covers everything from research to manufacturing, comments on the firm's unique positioning and its efforts to diversify its portfolio. Moving beyond plasma proteins and biosimilars, Reliance looks to

expand into vaccines and diagnostics, as well as gene therapies, peptides, and mRNA products. He also touches on the company's exponential growth of about 25 percent and the new campus that is set to fuel further growth from both Indian and international markets.

Can you provide insights into how Reliance Life Sciences fits within the broader Reliance Industries conglomerate, its structure, and the evolution of its focus on medical biotechnology?

Reliance Life Sciences operates as a private limited company, fully owned by the investment companies of the promoters of Reliance Industries, under the ownership of Mr Mukesh Ambani. Established in 2002, the company initially explored various biotechnology applications in areas like medical, plant and industrial biotechnology. However, recognizing the vast potential and societal impact of medical biotechnology, particularly in the fields of plasma proteins, biosimilars, and small molecule oncology, the company strategically refocused on medical biotechnology around 2006.

Reliance Life Sciences has emerged as a leader in the field of plasma proteins, having the status of being the largest integrated plasma protein player in South Asia. The company is engaged in the entire process, including plasma collection, fractionation, purification, and fill-finish.

Within biosimilars, Reliance Life Sciences has positioned itself as a global player with an extensive portfolio. Currently, the company offers 23 biosimilar products, making it a companies with the largest biosimilar portfolios globally. Additionally, there are 15 biosimilars under development, further showcasing our commitment to this segment.

The company has also made significant strides in the small molecule oncology sector. This involves the development and production of small molecules for oncological applications.

Beyond its current strengths, Reliance Life Sciences is proactively diversifying its portfolio. This includes entering the vaccine business, with a focus on both human and animal vaccines. Furthermore, the company is venturing into the diagnostics sector, enhancing its capabilities in disease detection.

In pursuit of cutting-edge advancements, Reliance Life Sciences is actively involved in exploring innovative technologies. This includes efforts in gene therapies, peptides, mRNA products, and oligonucleotides. These endeavours aim to position the company at the forefront of emerging biotechnological trends.

Reliance Life Sciences envisions a future characterized by a diverse and extensive portfolio. This involves not only a variety of product streams but also depth in terms of the number of products offered in each stream. The strategic approach involves a comprehensive expansion into different healthcare segments, ensuring a holistic presence in the industry.

In defining Reliance Life Sciences today, is it more accurate to categorize it as a biotechnology company, an industrial supplier, or something distinct in the Indian market?

Reliance Life Sciences is primarily positioned as a research-driven medical biotechnology company with a fully integrated value chain encompassing research, animal studies, human clinical research, manufacturing, and marketing. The company’s emphasis on manufacturing sets it apart, as it produces everything it markets, focusing on hospital products, particularly those used in intensive and critical care. While rooted in India, where it primarily operates, Reliance Life Sciences is expanding globally, with approximately one-third of its revenues already derived from exports, and

the company envisions further growth in this global trajectory.

How does Reliance Life Sciences plan to extend its competence to areas like gene therapy, vaccines, and diagnostics, maintaining a strong commitment to the Indian market while envisioning a comprehensive approach for the future?

Reliance Life Sciences is dedicated to the Indian market, aiming to offer competitively priced high-quality Western products in the biological sciences sector. The expansion into gene therapy, oligonucleotides, and mRNA products is driven by the goal to provide accessible prices for a broad range of gene therapy products. Additionally, the company is strategically venturing into vaccines, covering both human and animal vaccines, leveraging its expertise in biologicals. The long-term vision includes a holistic approach, spanning diagnostics, prophylactics, and therapeutics, to address diverse healthcare needs.

How does Reliance Life Sciences approach research and development for emerging technologies like mRNA, cell, and gene therapies, and what role do in-house efforts play in these advancements?

Reliance Life Sciences primarily conducts in-house research for its projects, including mRNA, cell and gene therapies. While some technology-platform licensing deals are in place, the majority of the work, from cloning to manufacturing, is carried out within the company. For vaccines, strains are sourced from established institutes globally, with some cases involving reverse engineering, showcasing the company’s commitment to independent research and development.

How does Reliance Life Sciences navigate the evolving regulatory landscape in India for biosimilars and innovative therapies, especially considering challenges like regulatory clarity and changing dynamics?

Navigating the regulatory landscape in India, particularly in the realm of biosimilars and innovative therapies, is a nuanced process for Reliance Life Sciences. Since its inception, the company has witnessed significant evolution in the regulatory environment for biosimilars, and it continues to adapt to changing dynamics.

One key strategy involves closely monitoring global regulatory practices. For biosimilar clinical trials, a distinctive approach is adopted – conducting clinical trials of innovators' products, involving 200 to 300 patients. This not only ensures adherence to regulatory requirements but also positions Reliance Life Sciences within the evolving landscape of biosimilar development.

In areas of innovation, such as gene therapy, the company adheres to well-established Western standards. Following the conventional phase I, phase II, and phase III approach, Reliance Life Sciences plans to ensure that its gene therapy products meet rigorous regulatory criteria. The commitment to Western standards extends beyond clinical trials to encompass the entire value chain.

Crucially, all facilities operated by Reliance Life Sciences are constructed to meet the stringent standards set by the US FDA and European authorities. This dedication to compliance has resulted in approvals from both these regulatory bodies, underscoring the company's commitment to quality and global best practices.

A notable departure from some Indian companies is Reliance Life Sciences' insistence on maintaining a consistent standard globally. Whether a drug like temozolomide is sold in India, the UK, or Canada, the company upholds a single standard for efficacy and safety. This approach ensures that the quality of products remains uniform across diverse markets.

This commitment to consistent standards is further extended to the animal health and vaccine business of the company. Even if a biosimilar, or a small molecule, is intended for use in animals, Reliance Life Sciences maintains the same high standard. This approach recognizes the importance of ensuring quality not only for human therapeutics but also for veterinary applications, reflecting a comprehensive and uniform approach to regulatory compliance.

It seems common for many companies to adopt dual standards due to considerations such as labor costs. However, your approach suggests a commitment to a single standards. Could you elaborate on why maintaining this uniformity in manufacturing, production, and P&L is crucial for Reliance Life Sciences?

From the outset, our focus has been on enhancing competitiveness in a capital-intensive industry. By managing capital costs effectively, we establish a foundation for sustained competitiveness. Additionally, our strategy involves extensive in-house development, covering research, preclinical work, clinical development, and manufacturing. This approach minimizes outgoing external

royalties and provides cost benefits. Crucially, it affords us greater control over timelines, indirectly impacting costs. Our commitment to a single standard in manufacturing and production stems from the advantages it offers in terms of both cost efficiency and operational control.

Moreover, recognizing the importance of nurturing talent, we have invested in our competency development through the Reliance Institute for Life Sciences. This initiative involves comprehensive training programs, combining academic learning with practical experience, to cultivate a skilled workforce. While it has posed challenges, our ongoing commitment to talent development is integral to maintaining our high standards and competitiveness.

Reliance Life Sciences appears unique in its approach, avoiding the common trajectory where generic companies aspire to transition into innovation. With the largest portfolio of biosimilars, what gives you confidence that biosimilars are a significant part of the future, especially considering the challenges faced by other prominent players?

Our strategy involves developing biosimilars across various therapeutic areas without imposing filters like focusing solely on oncology or cardiology. Unlike larger entities like Sandoz or Samsung, we prioritize a broader base of products, leveraging the flexibility to operate within the boundaries of intellectual property. It is essential not to draw comparisons with bigger players in the pharmaceutical industry. We acknowledge our smaller scale, but emphasize steady growth, buoyed by the advantage of a large and growing home market, particularly in India. The stringent price control regulations in India call for competitiveness, a factor that may be challenging for multinational companies. However, we view this as an opportunity to find the right pricing points and serve the growing healthcare market in India, where institutional business, including collaborations with state and central government entities, is witnessing positive growth.

With a focus on biosimilars extending to orphan indications, how does Reliance Life Sciences navigate patient identification challenges for rare diseases? Does the company foresee a transformation requiring specialized teams for therapeutics?

In areas like gene therapy for rare diseases, we collaborate with clinical partners who specialize in specific domains, ensuring a better understanding of patient needs and clinical aspects. While we are enhancing our in-house capabilities, especially in molecular biology, the emphasis remains on working with external clinical experts to guide us in clinical trial protocols. Unlike other companies,

we have never imposed filters on therapeutic focus, preferring a platform-agnostic approach. The platform serves as a means to an end, and we believe this strategy offers more flexibility, freeing us from the constraints imposed by single therapeutic focuses. We value the platform's versatility and prioritize patient needs over investor pressures, resulting in steady growth and a positive financial position. Our recent exponential growth, approximately 25 percent, is a testament to our strategic deployment of internal resources and reinvestment for sustainable development. The forthcoming Nashik campus, scheduled for completion by March 2024, is expected to further propel our growth trajectory, accommodating larger-scale facilities for various product categories, including plasma proteins, biosimilars, small molecule oncology products and vaccines. The 25 percent growth includes contributions from both the Indian and international markets, with expectations of Nashik bolstering future growth prospects.

Could you elaborate on Reliance Life Sciences' international expansion plans, particularly in relation to the Nashik plant? How do you navigate the challenges of entering global markets, especially Europe and the USA, and what is your approach to partnerships in these regions?

Our international plans are strategic and involve a phased approach. Initially, our focus is on obtaining approvals in our home country, India, as a prerequisite for global expansion. While the Nashik plant would initially primarily cater to the Indian market, it is designed with international standards and quality to facilitate future exports. Currently, we have products reaching the USA and Europe in the small molecule space. However, for Europe and the USA, we opt for partnerships due to the complex regulatory processes, clinical trials, and marketing nuances in these regions. We have established partnerships for specific products and territories. For instance, we recently signed a co-development partnership for a peptide with a European company. In these collaborations, we handle the entire development process, from preclinical to clinical, and manufacturing. Our partners contribute to the clinical trial aspects and are involved in the marketing phase within their respective regions. This collaborative model allows us to leverage our strengths while navigating the intricacies of different global markets.

What types of partners are ideal for Reliance Life Sciences in the European context? What characteristics or size range do you consider when seeking collaborations, and how do you navigate potential challenges when working with European companies?

In the European context, our ideal partners fall within the mid-size range, typically ranging from USD 400 million to USD 3 billion in global revenue. We prefer companies with a strong marketing team and capabilities. The nature of partnerships varies, including distribution, licensing, and co-development partnerships. These collaborations involve sharing costs and profits. While negotiations may take some time, the process is not significantly different from other sectors. We have not encountered substantial barriers, and once partners visit our facilities and observe our track record of approvals in stringent markets, any initial reservations tend to dissipate. Our decision-making process is streamlined, and we have the autonomy to make decisions within the biotech domain, reporting directly to Mr Mukesh Ambani. This enables agility in decision-making, a trait valued in our partnerships.

We envision ourselves as a company with a strong commitment to collaboration. Our focus lies in contributing to the development aspect, and we aspire to work in tandem with partners who bring expertise in clinical trials, regulatory navigation, and marketing. This collaborative approach has been a cornerstone for us, leading to several successful partnerships. It encapsulates our strategy for building a future where we acknowledge our strengths and limitations, emphasizing our awareness of what we excel at and the importance of complementary skills. This strategy aligns with our belief that strategic partnerships can play a pivotal role in navigating the complexities of the global landscape.

With your extensive experience and notable success in the industry, what advice would you offer to other managing directors?

Reflecting on the trajectory of many prominent companies, it is evident that innovation and technology, as well as strategic acquisitions, have been pivotal in their success. I encourage leaders to contemplate how they can deliver products at more competitive prices to customers. Take gene therapy, for instance, where the life cycle costing approach is inappropriate. Instead of focusing on exorbitant pricing, a perspective oriented towards public good and social impact, can be more meaningful.

Making products affordable and accessible globally should be a priority, considering the diverse economic landscapes. It is essential to acknowledge that pricing decisions, often based on insurance coverage, can disproportionately affect patients in regions where out-of-pocket spending is prevalent. Having personally witnessed family situations where financial burdens resulted from medical crises, I can see the importance of empathizing with those facing such challenges. While

some countries benefit from robust healthcare systems and insurance coverage, this is not universal.

For companies eyeing global expansion, especially in regions like India, recalibrating the paradigm to prioritize high-quality products at competitive prices becomes imperative. Collaborating with diverse markets can facilitate not only product development, but also manufacturing, contributing to a more inclusive and accessible healthcare landscape.

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