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We are steadily transforming from a relatively smaller player in generics and early-phase clinical studies to a broader and more relevant Contract Research Organization for our global clients

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Under the leadership of Ajay Tandon and the foundational work of Dr Kiran Marthak, Indian firm Veeda Clinical Research has strategically expanded its capabilities and global footprint. The company has transitioned from focusing primarily on clinical research to incorporating preclinical services through the acquisition of Bioneeds, aiming to offer end-to-end services in the drug development process. Tandon and Marthak emphasise the importance of adapting to the evolving pharmaceutical landscape, including regulatory changes in India that have made it a more attractive destination for clinical trials. The company is increasingly engaging with innovative drug development, with a strategic focus on areas like oncology, enhancing capabilities in late-phase clinical trials and positioning itself as a preferred partner for global pharmaceutical companies.

How did your collaboration with the company begin?

Ajay Tandon (AT): The company was founded in 2004, by Mr. Binoy and Mr. Apurva Shah. The company, over its initial 14 years, experienced consistent growth under the dedicated leadership of its co-founders. However, in 2018, recognizing the potential for further advancement, both financially and strategically, the founders decided to bring in a private equity partner. The motive was not solely financial; it also aimed to infuse diverse perspectives into the company’s governance, steering it towards accelerated growth.

The private equity fund, specializing in a multi-industry portfolio but with a significant focus on healthcare and life sciences, assumed majority ownership in 2018. The founders, maintaining a substantial but minority stake in the company, opted for a strategic shift that involved professionalizing the leadership. In May 2019, I assumed the role of CEO, charged with steering the company into a new phase of growth. This transition emphasized the need for a balance between maintaining the scientific integrity cultivated by the internal team and introducing management expertise to drive the company's strategic objectives.

Dr Kiran Marthak (KM): I've been with the company since its start, investing my expertise rather than capital. Over the years, I played a crucial role in aligning the company with scientific best practices, building client relationships, and ensuring compliance with quality assurance and regulatory standards. My background in the pharmaceutical industry facilitated strong connections with key players and regulatory bodies, enhancing the company's credibility. After a brief break, I returned three years ago, focusing on drug discovery and early clinical development, particularly in conducting Phase 1 studies and providing regulatory training. Additionally, my involvement with organizations like the American College of Clinical Pharmacology, contributes to our growth, allowing us to undertake more complex studies and stay abreast of industry developments.

Can you shed light on your business strategy, especially considering the diverse landscape of contract research organizations (CROs)? What parts of clinical development capabilities are you taking on board?

AT: It is essential for us to evolve gradually into a more integrated CRO, strategically aligning with the needs of our clients. Therefore, the acquisition of Bioneeds in 2021 was a deliberate move towards expanding our capabilities in the preclinical space. Bioneeds, based in Bangalore, specializes in toxicology studies on animals and other preclinical / non-clinical work crucial before drugs enter clinical trials. We saw this as a natural extension backward, enhancing our relevance to clients by offering end-to-end services. While our focus historically was on clinical research, this step into preclinical territory allows us to have a broader service portfolio.

The challenge lies in finding the right balance. While we are gradually transforming, it is crucial to recognize that we cannot be everything to everyone. The pharmaceutical landscape is dynamic and making strategic choices about what to build, partner, or acquire is crucial. The current ecosystem demands a thoughtful approach, considering what is critical to handle in-house versus seeking partnerships.

Our journey has taken us from being predominantly generic-focused to embracing biosimilars and gradually entering the innovator space. We are keen on being relevant to our clients and are actively exploring the right mix of services to bring onto our board.

Looking ahead, we are placing a significant emphasis on the biopharma sector, an area where we were practically non-existent a few years ago. We believe that having an integrated portfolio of Biopharma services including product development, structural and functional characterization, pre-clinical, early and late phase clinical and clinical bioanalysis will be of competitive advantage both in building integrated expertise as well as for providing comprehensive servicing to the clients. With a fully-fledged lab in Bangalore, we aim to offer comprehensive services in the non-clinical development of biopharma biosimilars. Additionally, we intend to expand our global footprint in late-phase clinical trials, and we are actively pursuing overseas acquisitions to strengthen our position in this competitive space.

The key to success in this evolving landscape lies in striking a balance between service extension and specialization. As biotechs increasingly look for consultative partners rather than just service providers, our goal is to provide depth of knowledge and therapeutic expertise, ensuring we stay at the forefront of the evolving pharmaceutical industry.

While acknowledging India as our backyard, we are committed to global outreach, with over 50 percent of our revenues coming from clients outside India. Our clientele spans Europe, the US, South Asia, Southeast Asia, China, and Central Asia. Recognizing India’s strategic advantages, including a large patient population, scientific talent pool, and maturing clinical trial ecosystem, we position ourselves as a global platform leveraging India’s strengths. The cost advantage is not the primary driver but an outcome of the comprehensive ecosystem that India offers for drug development. Our vision is to be a preferred partner for global clients, providing a robust platform for efficient and effective drug development, and leveraging India’s unique strengths in the pharmaceutical and biotech landscape.

Many countries in Asia, like Korea and China, have proactively shaped policies to boost clinical trials, offering significant advantages. In comparison, India seems underutilized in this aspect. Could you shed light on any initiatives or policies in India that might enhance its appeal for clinical trials, especially considering the large and diverse population and the potential benefits for the country?

KM: The landscape of clinical trials in India has undergone significant positive changes, making it an increasingly attractive destination. A pivotal factor has been the revamped regulatory environment, notably the new drug clinical trial rules implemented in March 2019. These guidelines provide clear timelines for approval processes, including expedited approvals for specific situations, as evidenced during the COVID-19 pandemic, where approvals were granted within a week.

Moreover, India has developed comprehensive guidelines for orphan drug development programs, emergency marketing authorization, and stringent pharmacovigilance reporting. The latter extends not only to clinical research but also requires rigorous reporting for marketed products. The prompt and efficient response during emergencies and the emphasis on patient safety, including compensation for adverse events, have strengthened India's regulatory framework.

Ethics committees, playing a crucial role in protocol approval and study monitoring, have gained increased authority. These committees must be registered with regulatory authorities, follow specific compositions, and undergo periodic renewals. Their responsibilities include not only approving protocols but also actively monitoring study progress and ensuring the safety and well-being of trial subjects.

The regulatory authorities in India have fostered international collaboration and learning. Exchange programs, meetings, and training initiatives between Indian regulatory bodies and counterparts such as the US FDA and European authorities have facilitated knowledge sharing. This proactive engagement has instilled confidence in global health authorities and enhanced India's standing as a reliable hub for clinical trials.

The evolving regulatory landscape, coupled with the diverse patient population and scientific expertise, positions India as a robust platform for efficient and effective drug development. The comprehensive regulatory reforms and the ongoing commitment to international standards make India an increasingly attractive destination for clinical trials.

In addition to regulatory reforms, are there other factors that make India an attractive destination for clinical trials? For instance, is the population diverse enough? Are there specific therapeutic areas where India's patient pool provides unique benefits?

KM: Beyond regulatory reforms, India offers several compelling factors making it an attractive destination for clinical trials. One notable advantage is the diversity of the population. India's

diverse demographic profile provides a unique opportunity for clinical trials, especially in therapeutic areas like oncology, diabetes, hypertension, infectious diseases, and special diseases such as kala-azar, leishmaniasis, and malaria. The richness in patient diversity allows researchers to access treatment-naive patients, which can be challenging in more developed countries.

In contrast to developed countries where many patients have received prior treatments, India's patient pool often includes individuals who haven't undergone any treatment for their specific diseases. This is particularly beneficial for trials investigating new therapies that require treatment-naive patient populations.

Furthermore, India has a diversified pool of experienced and well-educated investigators with many having global exposure. These investigators bring a wealth of knowledge and understanding of international standards, contributing to the quality and efficiency of clinical trials.

Economically, India presents a significant advantage in terms of cost. The cost-effectiveness of conducting clinical trials in India is remarkable. Investigational procedures, such as imaging studies, can be conducted at a significantly lower costs compared to more developed countries. This cost advantage extends to investigator grants and other operating costs, making India an economically feasible option for clinical trial sponsors.

India also excels in infrastructure availability; including the widespread use of electronic data capture (EDC) platforms. The country's expertise in software development and its efficient utilization in clinical trials contribute to streamlined processes and timelines. The transition from paper-based to electronic systems has not only enhanced data accuracy but has also significantly reduced the time required for data management. This practice has been widely accepted by Indian regulators and Sponsors.

Language proficiency, especially in English, is another advantage in India. Unlike some other countries where translation can be a time-consuming process, India's proficiency in English expedites communication and collaboration in clinical trials. This linguistic advantage contributes to compressing timelines, ensuring efficient execution of trials.

India's appeal for clinical trials extends beyond regulatory considerations. The diverse patient population, experienced investigators, economic advantages, and robust infrastructure collectively position India as an optimal destination for efficient and impactful clinical research.

AT: The diverse patient population in India is a significant factor contributing to the country's attractiveness for clinical trials, particularly in the context of innovative medicines. Genetic

diversity is crucial in clinical trials, especially for new medicines, as representative populations ensure that the results are applicable to a broader demographic. This diversity allows researchers to observe variations in drug responses across different ethnicities, providing a more comprehensive understanding of the drug's efficacy and safety profile.

Can you provide some financial indicators for your company's growth in India over the past few years? How has the development of Indian generic manufacturers impacted your business?

AT: Over the last four years, our company has experienced significant growth, averaging over 25 percent year-on-year. We foresee continued growth in the future, driven by additional preclinical work, increasing involvement in clinical trials, and expanding capabilities in biopharma. While the industry has faced challenges, especially in the generic sector, our focus on building relevant capabilities has positioned us for sustained success.

Regarding financial aspects, our business is not working capital-intensive, as we primarily deal with services rather than manufacturing. Receivables from the services we provide constitute the bulk of our working capital, and we haven't encountered significant challenges in this regard due to our association with high-quality clients.

The global pharmaceutical industry, especially the generic sector, has witnessed pricing pressure and profitability erosion. As a service provider, we have managed to maintain reasonable profitability though the challenges of our end clients does impact us. The key focus is on growing profitably, with a particular emphasis on biopharma, clinical trials, and leveraging technology for improved productivity and quality.

Digitization plays a crucial role in our strategy, helping enhance productivity, control people costs, ensure quality by design, and contribute to cost reduction. As clients seek ways to bring down the cost of drug development, our role as a service provider becomes essential in optimizing productivity and deploying technology effectively.

The pharmaceutical industry, with its high failure rates in drug discovery and development, poses inherent challenges. Even in the generic and biosimilar segments, which have been significant parts of our business, competition is intensifying. Despite the difficulties, our focus remains on staying relevant, being productive, and exploring new complex technology platforms to address evolving market demands. The industry may be challenging, but our commitment to growth,

profitability, and innovation remains steadfast.

What strategies do you employ to attract and engage global clients in more innovative areas?

AT: Until recently, our company’s business was significantly from generic manufacturers globally. Over the years, we have maintained strong connections with leading generic companies worldwide, engaging in various capacities. However, our involvement with innovator companies was limited due to a lack of late-phase clinical trial and initial drug development experience. In the last two to three years, our expansion into the preclinical business has positioned us to start engaging more meaningfully in innovative drug development. We already have notable strength in conducting clinical bioanalysis work for global clients We efficiently analyze global samples in India and provide prompt results. By enhancing our global capabilities in late-phase clinical trials, we aim to position ourselves as valuable partners for large global pharmaceutical companies.

Within innovative drug development, oncology will be of strategic focus for us, with a further specialization in indications in which we will be able to offer in-depth therapeutic expertise, , strong networks for key opinion leaders and principal investigators, and focused global execution. Geographically, we are exploring possibilities for expanding to Europe and the US in the near to medium term, in line with our intention to offer global execution to our clients in addition to our strong Indian operations.

Do you have a final message to share?

AT: We are steadily transforming from a relatively smaller player in generics and early-phase clinical studies to a broader and more relevant Contract Research Organization for our global clients. We will continue to add more capabilities to our portfolio to keep enhancing our relevance to our clients and becoming a preferred partner for innovative pharma companies globally.

Being owned by private equity provides us with the necessary access to capital to support our growth ambitions. While we had considered going public about a year and a half ago, that you might have read about, external factors such as escalating geopolitical conflicts and market uncertainties compelled us to reassess the timing. Despite this, our growth focus has remained

agile, and our Board and shareholders will continue to explore suitable strategic and financial options in the future.

KM: Additionally, the changing regulatory landscape in India has made it an attractive choice for global clinical trials, no longer viewed as a last resort but a planned destination. The shift towards India as part of the global study from the outset highlights a significant change. The evolving scenario and cost-effective conduct of studies in India are contributing factors. We, as a CRO, play a pivotal role in supporting both generic and innovative companies in new drug development, helping navigate regulatory pathways and contributing to their competitive edge. Our emphasis on specializations in various therapeutic areas, such as biopharma, metabolic disorders, oncology, and unique studies, positions us as a versatile and reliable partner for our clients. Our commitment to excellence, specialization, and adapting to the changing global landscape is what sets us apart.

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