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# “Innovation and affordability must work hand in hand so that patients can benefit from cutting-edge therapies”

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**Pune-based Enzene Biosciences, a subsidiary of Alkem Laboratories has announced the launch of bevacizumab, a biosimilar of Avastin that is used for the treatment of metastatic colorectal cancer in June. With this launch, the company has now successfully introduced biosimilars for the treatment of critical illnesses such as squamous cell cancer of the head and neck, osteoporosis, postmenopausal osteoporosis, immune thrombocytopenic purpura (ITP), rheumatoid arthritis and metastatic colorectal cancer. The company is emerging as a key player in the biosimilar market. In an interaction with BioSpectrum, Dr Himanshu Gadgil, CEO, Enzene Biosciences shares the company’s plans in India and worldwide.**

**How will the recent launch of  Cetuximab and Bevacizumab disrupt cancer care?**

Cancer treatments have long been known to be extremely expensive, and in a country like India where health insurance is not a widely distributed concept yet, it becomes almost impossible to cover the expenses for cancer drugs, out of pocket. Hence, the goal of biosimilar drugs is to make them accessible to the masses. However, even after biosimilars are launched, these life-saving medicines remain inaccessible to millions of patients. Through our continuous manufacturing technology - *EnzeneX*, we can significantly disrupt the cost barriers of these products and make them more accessible to patients through partnerships with leading Indian pharmaceutical companies.

**The eight weeks of treatment costs about $30,000 for a patient. Don't you think this is a bit too expensive when everyone is talking about bringing in affordable treatment?**

The cost of the innovator drug is $30,000 for eight weeks, which is very expensive, especially considering the Indian market, and because of the socio-economic disparity, it creates an access inequality. Hence, it becomes necessary for Indian pharma to invest in innovative technologies to help lower the prices of these drugs. Enzene is on a mission to continue building on continuous manufacturing technology and bring more such innovations to the Indian manufacturing space that will aid affordable and more accessible treatment to patients in need. Compared to costs like this for innovative drugs, our technology enables a multi-fold decrease in cost to patients. Our ultimate goal is to create access equity for biopharmaceuticals for Indian patients.

**How challenging is the regulatory market when it comes to launching cancer drugs in India?**

India has a well-established regulatory framework for biosimilar products, governed by the Central Drugs Standard Control Organisation (CDSCO) and the Drugs Controller General of India (DCGI). It emphasises safety, efficacy, and affordability. Although there can be challenges due to multiple approval bodies in the process of submissions, the market has been working towards streamlining these processes and has most definitely been fostering innovation. Many initiatives have been taken to accelerate approval pathways for certain drug categories, thus aiming to simplify and expedite the regulatory approval process.

**Do you plan to launch any more biosimilars?**

Absolutely. We’re launching our 7th biosimilar soon. We continue to have a robust pipeline in early and late-stage development. Our goal is to have at least one product launch every year.

Our strategy with these products will always be to prioritise ‘India First,’ even as we execute plans to expand globally to other markets. We are driven by our purpose of increasing affordability for Indian patients and creating access equity so that they have the same access to medicines as patients in other countries. Having said that, we do have ongoing development of some of these products already launched in India, for the global markets, and we expect them to be registered globally over the next two to three years.

**Enzene Biosciences has picked Princeton, New Jersey as the location to open its first manufacturing facility outside of India. What will be your plans to launch facilities within India and abroad?**

We’re excited to get this project up and running. We do have plans for further capacity expansions in India to support our biosimilar market.

With our US site, we intend to create access equity for early-stage biological assets by providing cost-effective local manufacturing. The US has the maximum number of novel molecules, especially in small startup companies. These promising lifesaving molecules often struggle to find local manufacturing partners, which can significantly hinder their path to launch. Dealing with outsourced manufacturing poses challenges related to culture, time zone, language, and supply chain barriers. Project Indus, our first step in the US, aims to create access equity by providing state-of-the-art, cost-effective manufacturing to small and mid-size companies.

As a company that delivers not just biosimilars to the Indian market, but also focuses largely on contract development and manufacturing for our global partners the need for expansion is imminent. In the contract development and manufacturing organisation (CDMO) space, it is always essential to have the capacity to onboard newer projects. Depending on business needs and the needs of the market we will constantly expand to ensure the industry does not have supply chain crunches for these lifesaving drugs. Ultimately, we would want to expand in such a way that we should be able to meet the manufacturing demands of our global clients in their time zones.

**What's your five-year business outlook?**

While we have laid out expansion plans, we are also strategically looking at venturing into other aspects of drug development and building capabilities for advanced therapies. These strategic developments will reinforce our plans to become a global CDMO player.

In terms of the drug development continuum, we will soon start offering biologics discovery services to our partners. Cost-effective discovery services are an essential segue of low-cost drugs for patients. With our EnzeneX technology tied with discovery services, we will be a one-stop shop for our partners to make affordable drugs a reality. Currently, we can offer screening services to assess the developability of different modalities as a therapy.

We are also building capabilities to offer development and manufacturing services for advanced therapies including ADCs, mRNA and Cell & Gene therapy.

**Could you share the revenue details of the previous year and projection for the next year?**

Our previous year's revenues and projections are in line with our long-term growth plans. With a strong and growing pipeline of both biosimilars and CDMO projects, we expect to see very good growth in the coming years. Our revenue for the last financial year (2022-23) is Rs 144 crore. And we have in the past been growing at a healthy CAGR of more than 50 per cent (growth in the last two years).

**What are your thoughts on pharma innovation, moving beyond generics?**

Pharmaceutical innovation plays a vital role in advancing healthcare and improving patient outcomes. With access to these markets, it is important for companies to tap into innovative bioprocess and intensified solutions to significantly disrupt the cost barriers and make these biosimilars affordable and accessible for wider markets. It creates access equity for revolutionary medicines for patients across the globe.

It is important to understand that innovation and affordability must work hand in hand so that patients can benefit from cutting-edge therapies without undue financial burdens. We've been able to recognise this important association, the outcome of which has been our continuous manufacturing technology – EnzeneX.

**What will be your investment plans in R&D?**

We have had robust plans for R&D investments all along and continue to do so. We are expanding to newer modalities including ADCs, mRNA, and Cell & Gene therapy. We are also expanding in terms of capacity, number of people and adding new capabilities to cater to the pharma industry.

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