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“India is well positioned to emerge as a major market and a manufacturing hub for monoclonal antibodies”

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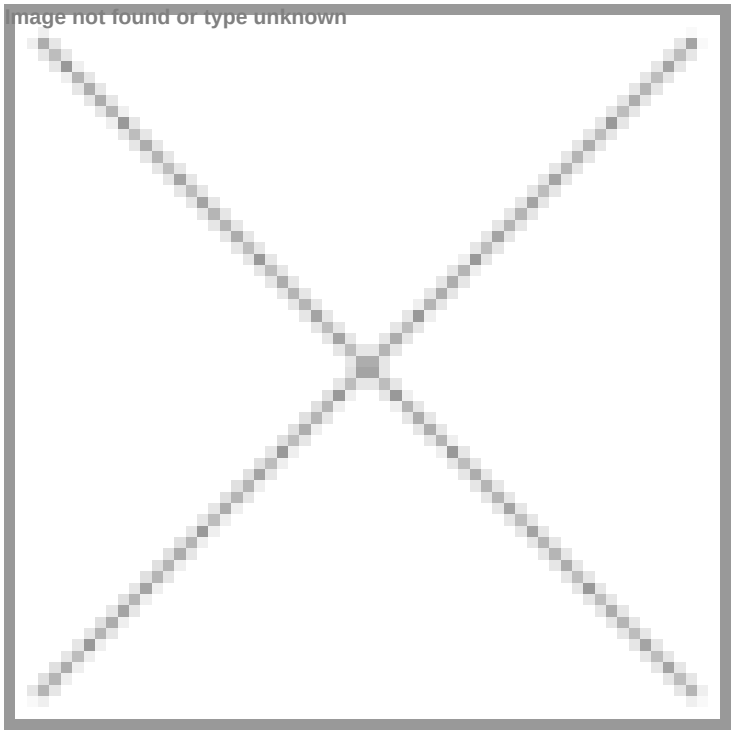
Ahmedabad-based biopharmaceutical company Kashiv BioSciences has recently secured funds for advancing its world-class infrastructure, to pursue research, development, and manufacturing strategy in both US and India. The company’s new facility in Pipan, Ahmedabad, is emerging as one of India’s largest single-use commercial manufacturing facilities of monoclonal antibodies, serving customers in the US, Europe, and rest-of-world markets. In alignment with the Biotechnology Policy and schemes implemented by Gujarat State Biotechnology Mission, Dr Sandeep Athalye, Global CEO, Kashiv BioSciences spoke to BioSpectrum about the company’s journey to expand biomanufacturing capacity in India.



The company has recently secured financing of Rs 648 crore from the Union Bank of India. What are the major plans in utilising these funds?

The capital is being deployed across three strategic priorities: capacity expansion, quality and regulatory excellence, and innovation-led manufacturing. At the core is the rapid development of our single-use commercial biologics facility in Pipan, Gujarat, with a planned capacity of up to 50,000 litres. This facility is designed to enable commercial-scale production of complex biologics and reinforce India’s role in advanced biopharmaceutical manufacturing. We are also advancing digital manufacturing, automation, and data-enabled process control to drive efficiency, consistency, and scalability.

In parallel, we are strengthening globally aligned quality systems and advancing regulatory readiness to meet the expectations of the most stringent international markets. This strategic focus is aligned with broader national priorities to position India as a global biopharma hub, including the Biotechnology Policy, key schemes implemented by GSBTM (Gujarat

State Biotechnology Mission), and the Biopharma SHAKTI programme announced by the Government of India in the Union Budget 2026–27. Beyond infrastructure, our focus on talent development, workforce upskilling, and collaboration with academic and public-sector partners ensures we continue to build long-term scientific and manufacturing leadership.

How do you plan to strengthen the company's presence in India, and globally? What challenges do you foresee in this process?

Strengthening our global presence is anchored in a vertically integrated, dual-engine strategy that combines scale and cost efficiency in India with regulatory proximity and market access in the United States. This integrated approach allows us to maintain the value chain from development to commercial manufacturing.

Our focus is on building a seamless innovation-to-manufacturing ecosystem. The expansion of our manufacturing facility in Pipan, Gujarat is central to this vision. Designed for commercial-scale production of complex biologics, the facility strengthens India’s role as a credible hub for advanced biopharmaceutical manufacturing while enabling us to serve both domestic demand and global markets efficiently. Additionally, we are expanding and strengthening our US manufacturing footprint in Piscataway to support our global markets. This US presence enhances our ability to engage closely with regulators, partners, and customers, while accelerating global filings and marketisation.

Together, the India–US research to manufacturing ability provides strategic flexibility, resilience, and scalability. While challenges such as regulatory complexity, supply-chain volatility, and competition remain, our investments in integrated infrastructure, talent, and partnerships position Kashiv for sustainable growth and long-term leadership in the global landscape.

How do you view the growth of the monoclonal antibody market in India?

The monoclonal antibody (mAb) market in India is one of the most compelling growth segments within the biopharmaceutical landscape. Over the past decade, mAbs have evolved from niche, high-cost therapies to essential treatments for cancer, autoimmune, and chronic inflammatory diseases, driven by India’s rising burden of non-communicable diseases and increasing clinical adoption of targeted therapies.

Several forces are converging to accelerate this growth. Demand for mAbs and biosimilars is rising as clinicians gain confidence in the therapies. At the same time, cost-competitive mAbs and biosimilars are significantly expanding access to patients.

Policy momentum will also play a catalytic role. The launch of the Biopharma SHAKTI programme by the government will strengthen the ecosystem through investments in clinical trial infrastructure, regulatory capacity, and research institutions, all of which are critical for next-generation monoclonals.

Challenges will remain, including high development costs, stringent regulatory requirements, and the need for robust clinical evidence. However, the outlook is positive. India is well positioned to emerge as both a major market and a manufacturing hub for mAbs, reinforcing its role in the global biologics value chain.

What do you believe will define success for biopharma companies in the next 5–10 years?

Over the next decade, success in biopharma will be defined by impact, both scientific and societal. Companies that deliver differentiated, meaningful therapies while building resilient, future-ready organisations will emerge as industry leaders.

Innovation will remain foundational, but the future will reward companies that combine scientific excellence with scale, capability, and speed. The ability to translate breakthrough science into globally accessible products both rapidly and reliably will distinguish leaders from followers.

Manufacturing excellence and resilience will be a decisive competitive advantage. Companies must move beyond incremental advances toward next-generation biologics, supported by AI-enabled discovery and data-driven development platforms. Simultaneously, flexible, scalable, digitally enabled manufacturing systems, built on quality-by-design and adaptability will be essential to managing complexity, ensuring supply continuity, and accelerating time-to-market. Ultimately, those that combine manufacturing strength with speed and disciplined execution, moving efficiently from lab to launch will secure meaningful market advantage.

Global regulatory integration will further shape competitiveness. Proactive engagement with regulators and alignment to multi-jurisdictional standards will be critical for companies operating in regulated markets.

Equally important will be accessibility and affordability. As healthcare systems prioritise outcomes and value, companies that expand access to advanced therapies will create lasting societal and commercial impact and value.

Capital, however, will stand as a defining enabler of success. In a capital-intensive industry, sustained investment across research and development, infrastructure, regulatory pathways, and global expansion is essential. Equally important is disciplined capital allocation, deploying funds strategically to balance growth, risk, and long-term value creation.

Lastly, long-term success will hinge on ecosystem leadership: nurturing talent, building partnerships across academia and industry, and contributing to stronger public-private frameworks.

Which set of skills will the next generation of biopharma leaders need to develop?

The future of biopharma leadership will require a multidimensional skillset that blends scientific depth with strategic, regulatory, and ethical leadership.

Scientific and technological fluency will remain foundational. Leaders who understand the complexities of biologics, cell and gene therapies, AI-enabled discovery, and digital biomanufacturing will make high-impact decisions in increasingly complex environments. Equally important will be regulatory intelligence. As global frameworks become more rigorous and interconnected, leaders need to anticipate change, guide cross-border strategies, and embed quality and compliance into decision-making. Apart from intellect, a collaborative, adaptive, and ethical approach will distinguish long-term winners, as the industry delivers the next wave of transformative therapies.

What are your expectations from the government to strengthen the biopharma sector?

Looking ahead, a few priorities remain central. First, regulatory harmonisation for approval pathways with global benchmarks can shorten development timelines and improve investor confidence. Second, sustained support for high-risk biologics research, stronger academia-industry collaboration, and expanded funding mechanisms can help build a robust innovation pipeline. Complementing this, there will be clinical infrastructure including accredited trial sites, streamlined approvals, and robust data frameworks. Lastly, enhanced manufacturing incentives for advanced biologics would further accelerate capacity creation.

Finally, talent development and investment in specialised skills will be a forward-looking trade framework that can help Indian companies scale globally and position India as a trusted, innovation-led biopharma leader on the global stage.

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