

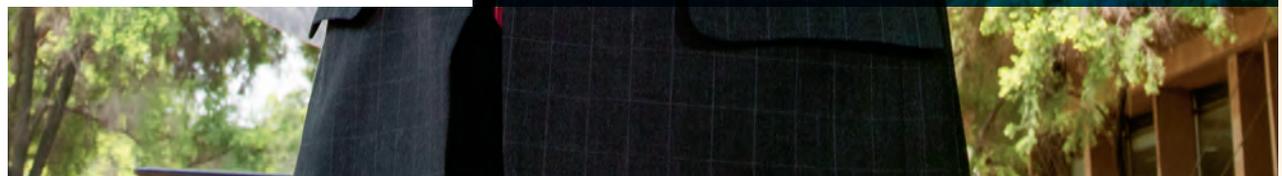


## Q&A with the CEO

Dr. Arun Chandavarkar,  
CEO & Joint Managing Director

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# The Executive Edge

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## What are Biocon's core values that help it create an 'enduring edge' ?

Biocon aims to create an 'enduring edge' by a consistent focus on value creation through innovation and differentiation with significant investments in cutting-edge R&D and efficient, compliant operations. Our strategy is aligned to the global imperative of improving access to high quality, affordable biopharmaceuticals and speciality medicines in chronic therapies such as diabetes, oncology and immunology. This has translated into a diversified and differentiated pipeline of fermentation-derived complex generics, biosimilars that include insulins and monoclonal antibodies, and novel biologics.

Sustaining an 'enduring edge' requires a deeply ingrained corporate culture that places a premium on good governance, compliance, integrity and collaboration. We have consistently attracted top talent that shares these core values and believes in making a difference to patients globally.

## Being amongst the few companies globally to have received approvals from developed countries like the U.S., EU and Japan, how does Biocon propose to maintain an 'enduring edge' in biosimilars ?

Our credibility as a serious player in the biosimilars sector was first established with the Japanese approval for Insulin Glargine partnered locally with FUJIFILM Pharma. Our credibility was enhanced by the U.S. FDA approvals for biosimilar Trastuzumab and Pegfilgrastim and the European and Australian approvals for Insulin Glargine, both in partnership with Mylan. We have also established our presence in key emerging markets through safe, effective and high quality biosimilars including recombinant human insulin.

Maintaining an 'enduring edge' in biosimilars entails nurturing internal scientific talent and R&D infrastructure to support existing programs as well as an expanding pipeline; being in constant dialogue with key stakeholders to drive biosimilar adoption; seeking cost advantages through technology and operational excellence; being ever vigilant on quality and compliance through continuous improvement; and striking strategic partnerships to manage risks and bridge near-term experience gaps.

The foundation lies in our strong internal R&D capabilities across the entire development continuum spanning clone generation, process and analytical, pre-clinical and clinical development. Our regulatory strategies have benefited from the experience of navigating an evolving regulatory landscape as agencies gain confidence in delineating abbreviated approval pathways for biosimilars.



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Our 'enduring edge' also stems from our strategic choice of not operating as a virtual company. We have made significant investments in commercial scale, globally compliant manufacturing facilities across diverse technology platforms spanning insulin analogs, monoclonal antibodies and other recombinant proteins. We continue to expand our infrastructure in a capital efficient, modular way.

The long gestation period for development and the capital intensity of creating new capacity for biosimilars do entail effective management of scientific and regulatory uncertainty and financial risk. We have created an 'enduring edge' by mitigating these risks through shared risk-reward partnerships that bring in complementary skills and experience. Our long standing, successful global partnership with Mylan for a range of biosimilar antibodies and insulin analogs continues to expand. We recently entered into a global partnership with Sandoz (a division of Novartis) to prepare for the next wave of biosimilar opportunities that open up towards the middle of the next decade. We also have strong regional partnerships in many key emerging markets.

It is our endeavor to create an 'enduring edge' by establishing our brand with patients, prescribers, payors and regulators through robust quality systems at an affordable price.

**How do you see the biosimilars opportunity panning out and what can biosimilar players do to accelerate the adoption of biosimilars?**

Targeted therapies, especially monoclonal antibodies, have revolutionized treatment paradigms for many chronic diseases. Almost 70% of new drug approvals are predicted to be biologics by 2025. As innovator biologics lose patent protection or exclusivity, it presents a significant opportunity for high quality affordable biosimilars to ease the strain on healthcare budgets. Where approved, there has been rapid penetration of biosimilars in price conscious emerging markets. Among developed markets, Europe has led the way with over 40 products approved, many of which have captured significant market share in a relatively short time. Importantly, the growth in biosimilar

prescription volumes indicates a dramatic expansion of access to biologic treatment naïve patients.

Governments and regulatory agencies have recognized the role of biosimilars in addressing issues of access and affordability. They have introduced several measures to support biosimilar development and approval, encourage uptake across multiple indications and foster reimbursement. Product approvals based on a tiered, scientific evidence based approach aim to provide confidence to patients and prescribers in the safety, efficacy and quality of biosimilar products whilst enabling abbreviated clinical development, which often consumes two-thirds of the development budget. Judicial pronouncements such as those related to the Biologics Price Competition and Innovation Act (BPCIA) in the U.S. have brought much needed clarity. These, coupled with patent related strategies and discouraging anti-competitive responses by innovators, have provided greater predictability on accelerated launch timing and biosimilars adoption.

**The small molecule generics industry has encountered significant headwinds this past year. How is Biocon geared to face these challenges and ensure an 'enduring edge'?**

Historically, the U.S. has been the largest value driver for the small molecule generics industry. This has changed as consolidation and alliances have led to a handful of players controlling a large percentage of generic purchasing. The accelerated rate of product approvals and the increase in the number of applicants have dramatically increased the competitive intensity even during the period of shared exclusivity.

Biocon has focused on its core biotech capabilities in selecting its differentiated API portfolio largely comprising fermentation-derived molecules such as statins, orlistat, immunosuppressants, and other speciality molecules. We have strategically embarked upon capturing a larger portion of the value chain by developing our own formulation dossiers incorporating such differentiated APIs. This vertical integration across APIs and formulations is well appreciated by potential customers who recognize Biocon's long track record in quality compliance and wish to secure their supply chain from a continuity of supply perspective.



The catalysts for securing an 'enduring edge' in the novels portfolio are all about achieving successful proof of concept especially in diseases with unmet needs.

We will also derive synergies in terms of knowledge sharing across our complex generics and biosimilar development programs, especially in the areas of characterization, bioassays, clinical equivalence and delivery devices. We expect these initiatives to deliver an 'enduring edge' over time and enable us to succeed in limited competition opportunities. Meanwhile, our mature portfolio will deliver modest growth until the new opportunities manifest upon expiry of relevant patents.

#### How do you plan to accelerate growth and profitability in the Branded Formulations segment?

Biocon's Branded Formulations business, currently operational in India and UAE (through a JV), grew 11% in FY18 over the previous year. Whilst the business in UAE showed a robust growth, we have had challenges in India.

Our focus has always been to create large anchor brands comprising speciality molecules in chronic therapy segments. We intend to sharpen our attention on key markets and key segments to drive market share. Our key brands continue to do well; in FY18, 10 of our brands featured among the Top 3 in their respective categories and accounted for over 75% of our India sales. We will improve our execution, tracking and sales force effectiveness by leveraging technology. We expect our differentiated product portfolio to expand in sync with the global development and approval cycle of our biosimilars and complex generics. Meanwhile, we continue to seek opportunities for partnerships and in-licensed speciality products in our core therapy areas as we have done previously. Branded Formulations is a peoples' business and we will ensure that our core values and global reputation will continue to be a magnet for top talent who wish to create large enduring brands in India and elsewhere.

#### What are the key catalysts that will pave the way for an 'enduring edge' in novel biologics?

Our foray into novel biologics predates our entry into the biosimilars segment and is core to our diversified business model spanning low risk investments in research services and generics, moderate risk in

biosimilars and high risk in novels. Whilst product portfolio attrition can be high in the novels segment, it is our hope that the few that succeed will have a disproportionate impact on value creation.

Our existing novels portfolio has diverse assets acquired through early stage partnerships. These include monoclonal antibodies against novel targets like CD6, against established targets like CD20 and EGFR, and a pipeline of bispecific fusion antibodies that exploit the recent understanding of the role of checkpoint inhibitors. We continue to make clinical progress with Insulin Tregopil, our orally delivered insulin analog. The results of a large investigator initiated study on head and neck cancer patients at the Tata Memorial Hospital, Mumbai, showed that Biocon's novel biologic molecule Nimotuzumab combined with chemo-radiotherapy shows superior efficacy and safety over Standard of Care.

The catalysts for securing an 'enduring edge' in the novels portfolio are all about achieving successful proof of concept especially in diseases with unmet needs. We intend to initiate clinical development under an IND/ IMPD or equivalent and ensure that strong science and experience underpin our development efforts. We will focus on accelerating development of select high potential assets like the fusion antibodies which are at the forefront of technological innovation. We already leverage the strong development and operations capabilities that we have created in Biocon for our biosimilars portfolio. The endorsement of our approach is evidenced by the financial and scientific participation of credible organizations like JDRF (U.S.) in the development of Insulin Tregopil for people with Type 1 diabetes. Such partnering, combined with a prudent stage gate approach to development will mitigate our financial exposure in these high risk but high reward initiatives.