



DRIVING INNOVATION

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◀ Delivering Affordability

The global economic crisis is far from over. Although businesses, large and small, are beginning to demonstrate greater fiscal prudence and implement tighter regulatory controls, the cycle of wealth creation is yet to be re-engaged. History will record this time for the collapse of conventional business models and linear approaches to growth. But perhaps more significantly, it will throw the spotlight on those companies that recognize and embrace the transformative power of innovation.

Over the last decade, Biocon has persisted along the high road to innovation. While pharma and biotech industries were grappling with methods to stem the exorbitant cost of drug development, Biocon had initiated an innovation strategy rooted in affordability. We were already employing low cost but high value resources and creatively thinking of new ways to deliver more from less, when the slowdown set in.

Owing to business foresight, Biocon is today in a position to advance affordable innovation, despite the current risk-averse business environment. Our ability to keep course in turbulent markets is supported by our investment in a prudent and well balanced innovation matrix. Biocon's innovation model strongly leverages the India advantage to mitigate the high risk of experimental science and deliver steady returns through incremental innovation. We draw on India's superior talent pool and low cost base to build on core competencies, explore adjacencies and manufacture therapeutics at a cost more patients can afford.

What good is affordable medicine if patients have little access to it? Biocon is located in a country that has the highest number of diabetics in the world. With cases of cancer and other debilitating diseases on the rise, there exists a desperate need to reach life-saving therapies to more people. Here is where Biocon's affordability platform can induce a trigger effect. With lower priced drugs in the market, the cost of medical insurance can be driven down, thereby making healthcare coverage affordable and accessible to more. Another factor in Biocon's favour is the rising affordability index of India's 800 million-strong middle class. With prosperity comes demand for improved health-care. Biocon's innovation-led strategy focuses on delivering better healthcare solutions to meet the growing expectations and medical requirements of India's patient population.

In good times, there is a tendency to over-extend the innovation spend. In bad, it is imperative to keep the innovation engine revving. Companies that step up with creativity and courage through stormy weather are often those that come out ahead when the tide turns. We are confident that Biocon is one such company. With a tightly focused innovation strategy and a well validated affordability platform, Biocon is capable of sustaining growth in challenging times and accelerating profitability when prosperity returns.



The Global Healthcare Crisis

The West cannot sustain the current cost of innovation. National and private insurance organizations are not willing to reimburse high priced new drugs anymore, unless there is a clear cost:benefit ratio. In the generics space, drug manufacturing is already moving to India and China as western manufacturers are unable to remain competitive. Clinical trials too are rapidly shifting in the same direction because developed nations do not have adequate patient population to carry out meaningful clinical investigations.

India Focus

This is the decade of the East. India especially, with its English speaking scientific resource base and low cost manufacturing is advantageously positioned to move up the drug value chain from imitation to innovation. Over the years, India has successfully pursued a low risk, low margin generics strategy. Today, with a combination of governmental incentives, cost effective manufacturing and a burgeoning domestic market, the Indian pharma and biotech industry is well prepared to take the next big leap towards high risk, high reward innovation.

Incentives

The Indian Government has played a key role in supporting various sectors that are challenged with inherent risk; the biotechnology sector being a front runner in this category. Through innovative incentives and funding models such as BIPP (Biotechnology Industry Partnership Program), SBIRI (Small Business Innovation Research Initiative), NMITLI (New Millennium Innovation Technology Leadership Initiative) and BIRAP (Biotechnology Industry Research Assistance Program), the Government has provided a springboard for Indian biotechnology to move up the value chain. Given our cost base, risk and failure are now affordable therefore providing Indian biotech with an edge in cost competitive innovation.

The Burgeoning Indian Market

India will soon be a Top 10 global pharma market with enormous demand for drugs, diagnostics and vaccines. Already known as the world's diabetic capital with a forecast of 70 million diabetics by 2020, other diseases like cancer, autoimmune and infectious illnesses will provide significant market opportunities for both generics and new drugs catering to unmet needs in all these segments.

The mushrooming of hospitals all over India has also stimulated a clinical development culture conducive to new drug development. MNCs are already leveraging India's investigators and investigation sites to augment their own drug development programs.

It is envisaged that by 2025, India will have approximately 800 million people in the middle to high income group who will drive up the affordability index. Insurance will also play a key role in providing this section of our population access and ability to afford generic and new drugs for large unmet medical needs in cancer, diabetes, autoimmune and other chronic diseases.



Biocon products are available in over 1,50,000 pharmacies across India.



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"When you ask people to do more with less, you make them think creatively. Shrinking budgets and diminishing revenues often force research professionals to think out-of-the-box and innovate."

Chetana Basavaraj, Laboratory Director - Central Lab, Clinigene

Advantage Biocon

We have on our team the best scientific talent India has to offer. Spread over 90 acres, Biocon has established the largest biotech park in the Asia-Pacific region housing world class, state-of-the-art infrastructure and facilities. In the areas of contract research and clinical services, we partner pharma and biotech majors providing them cost competitiveness and high value research and development. Further along the drug value chain, our capabilities in low cost manufacturing continue to give us a competitive edge. By leveraging the inherent India cost arbitrage we are able to push an innovation strategy that delivers affordability.

People Advantage

We have 3,500 of India's finest and sharpest minds working together at Biocon. Our innovation culture focuses on internal teamwork, synergistic collaborations with our business partners and an active global peer network to draw inspiration from. Keeping our people motivated and sustaining a creative work ethos is a crucial element of our long term strategy.

Service Advantage

India is today shifting its role as the world's back office to that of an innovation epicenter. Leading the foray into partnered services for high value innovation in India is Syngene, our Contract Service Company and Clinigene, our Clinical Research Organization.

Syngene has developed world class infrastructure and expertise to offer a spectrum of services on an integrated discovery platform. Clinigene too has acquired expertise in conducting human pharmacological studies and clinical trials for key players in the global biopharmaceutical industry. Both Syngene and Clinigene are positioned to leverage outsourcing opportunities created by drastic cuts in R&D spends and escalating operational costs. As clinical trials increasingly shift to India, Clinigene is well prepared to offer its services. Likewise, Syngene's model partnership with Bristol- Myers Squibb has set the stage for similar collaborations with its other large clients.

Manufacturing & Research Infrastructure Advantage

Biocon has incrementally invested in manufacturing and research infrastructure to meet escalating global demand for generics and biopharmaceutical products. Our strength has been the rapid conceptualization, execution and commissioning of custom research laboratories, and diverse/flexible large scale manufacturing facilities in support of our own programs and those of our international partnerships. The US\$ 200 million Special Economic Zone (SEZ), Biocon Park – Asia-Pacific's largest integrated biotech hub symbolizes the coming of age of India's biotech industry and its transition into high value innovation.



Biocon's team of 3500 co-workers is focused on delivering innovative healthcare solutions that are accessible and affordable to patients all over the world.

Incremental Innovation is about improving on existing innovation where lowering the cost is generally the driver.

Insulin Glargine

Biocon's Insulin Glargine represents a significant advancement in effective, cost-competitive diabetes therapy. Using a novel *pichia* technology, Biocon has leveraged its expertise in biological manufacturing to make Insulin Glargine affordable and accessible to patients all over India.

Approved for use in patients with type I and type II diabetes mellitus by US FDA and EMEA since 2000, Biocon has successfully completed the development of Insulin Glargine, brand name BASALOG™.

BASALOG™ is a long-acting biosynthetic human insulin analog. Clinical trials of BASALOG™ have been conducted in diabetic patients at 15 different centers all over India. The data from these investigations was accorded marketing approval by the Indian regulatory authority (DCGI). BASALOG™ is now available at pharmacies across India.

Biocon's Innovation Matrix

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Evolutionary Innovation is about leveraging known innovation to the next level by using existing, well-validated knowledge to create an improved, novel product.

BVX-20

Biocon is in the process of developing BVX-20 which targets CD20 receptors on B cells, as a next generation monoclonal antibody therapy for the treatment of non-Hodgkin's lymphoma (NHL) and B cell chronic lymphocytic leukemia (BCLL).

BVX-20 is a novel humanized MAb which is expected to provide an improved safety and efficacy profile. Pre-clinical studies in animal models have shown very encouraging results. Taking investigations further, first in-human phase I clinical trials will be initiated in 2010. By developing this therapy on an affordability platform, Biocon is rapidly moving towards bringing to market an improved novel product for a well validated therapeutic target.

Experimental Innovation is about exploring an emerging field to create a new class of product that delivers significantly enhanced value.

T1h

Addressing unmet medical needs in the autoimmune disease segment, Biocon is presently developing a humanized monoclonal antibody (MAb) which targets CD6, a cell surface protein predominantly expressed on human T cells, a natural target for immunomodulation.

Two ongoing clinical trials being conducted by Biocon in psoriasis and rheumatoid arthritis patients have clearly established the role of CD6 and the ability of T1h to target CD6 and significantly improve disease symptoms. With T1h, Biocon will have successfully entered an unexplored territory of science to create a novel yet affordable product that will effectively modulate the immune system and provide long term relief to patients suffering from these chronic diseases.

Biocon has systematically developed an innovation strategy that leverages the India Advantage to develop a robust pipeline of affordable therapies. This pragmatic R&D matrix balances low risk incremental and evolutionary innovation with high risk, high yielding experimental and breakthrough innovation.

In the current market circumstance, our four-dimensional innovation strategy enables us to pursue extremely challenging areas of innovation supported by growing market leadership in known spheres of services and diagnostics, vaccines and therapeutics.

Breakthrough Innovation is about creating radically new technologies and novel products that are derived from experimental innovation where inventions and discoveries are the drivers.

IN 105 (Oral Insulin)

Biocon's Oral Insulin IN 105 is a first-class, anti-diabetic drug that has the potential to alter treatment paradigms, truly exemplifying breakthrough innovation.

IN 105 has completed early phases of clinical development and received approval to conduct phase III clinical trials in India. Upon completion of these critical trials, Biocon is well prepared to take this advanced drug to patients. The Oral Insulin program is expected to revolutionize diabetes therapy.

