

Interview with Krishna M. Ella, Chairman & Managing Director, Bharat Biotech International Limited

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If we first take a step back and look at how Bharat Biotech was established, we see quite a remarkable story. It is rather exceptional to see scientists becoming entrepreneurs. What made you this exception, and what drove you to set up Bharat Biotech?

I was based in the US for 14 years pursuing a Ph.d & an academic career. During a visit to India in 1994, I would like to quote my mother: "Son, you have 9 inch belly, no matter how much money you make, you cannot eat more than that. Come back to India, I will feed you. Take all the risk you want in your life, and do whatever you want to do." At the same time, my wife was also a strong proponent of returning to India. There was also a dearth for challenging employment opportunities in the field of biotechnology in the country. We became first generation entrepreneurs to research, develop & manufacture recombinant healthcare products with Intellectual property & patent rights.

Bharat Biotech was co-founded by me & my wife Suchitra in July 1996 upon returning to India, fuelled by our dreams & passion for developing affordable world class technologies in the field of vaccines & biologicals. The first challenges were "pioneering awareness & acceptance, securing financial funding for the project, lack of internationally standardized expertise, equipment & raw materials, building infrastructure, facing acute shortage of trained & skilled human resources, creating regulatory awareness within the Indian regulatory system / facilitating agencies & convincing the medical fraternity to accept indigenous products.

Starting off was definitely not easy at first, as India was not geared up for biotechnology & its applications at that time. In addition to that there was deep skepticism in the govt. / bureaucratic system, social, financial & academic institutions that cutting edge R & D technologies can be commercialized. As first generation entrepreneurs, we had to build our business literally from grass roots. There were additional challenges in building the necessary support structure in terms of supply chain & logistics, scaling up operations, product development, low cost indigenous process manufacturing & proving international quality standards, innovation & IPR creation thus enabling a strong research/ product base in life saving technologies for the developing world.

Indian biotech did come a long way since then. How did the landscape change?

The landscape itself is a slightly disturbing to me. The pharmaceutical industry has created a generic model in India. Unfortunately, my peers in the biotech industry are also talking about biosimilars today. This is not the right approach for the country, and should not be the way forward. Biosimilars

is an interesting area, if considered as a separate model. This should not be the focus of the country, because it will eventually lead to the loss of innovation.

• If another company can copy your product better and bring it to the market more efficiently, where is the incentive to innovate? • This is one of the reasons why even today we are yet to create a single new molecule from India. This applies to both the corporate, as well as the academic fraternities in the country.

Do you see this changing?

The landscape will change. Entrepreneurs like us are simply not passionate about the biosimilar model. It does not matter if our revenues are slow but steady, or if they only come after 5/7 years. It does not matter if one company does not succeed what matters is that you are building knowledge & technology base to counter global initiatives.

We need more avenues in the country to support an ecosystem, opposite of the biosimilar model. Government policy is one thing, but you also need visionary entrepreneurs to create innovative spirit of competition. The spirit today is one of competition in marketing, which is not the way forward.

Do you think the Indian sector needs a pioneering company as a role model?

The problem is that most of the players do the same things. They are all working on the same monoclonal antibodies. This is shortsighted. While their biosimilars models can generate cash now, it is not a sustainable strategy for the longer term.

The generic companies are a good example of lower sustainability. Today, they are not able to withstand the export pressure, which is one of the reasons they are being sold off.

Do you feel the right regulation is in place then?

India is regulated by its entrepreneurs, not by its government. This is a strong contrast with China, where the industry is heavily subsidized to execute the policies that have been designed by their government.

Clearly, you have to be patient to achieve higher revenues. Yet, over the years Bharat Biotech has grown into one of India's largest manufacturers of biopharmaceuticals and vaccines. How satisfied were you with the company's financial performance in 2010, and what is your current outlook for 2011?

Bharat Biotech has been doing very well, and profit is definitely not a problem for us. However, rather than giving out dividends, we re-invest our profits on a continuous basis. Our interest is to enhance innovation and capital investment on product development. To do so, we re-inject all of our revenues into manufacturing and R&D.

The majority of our business, roughly 80%, is driven by vaccines. Looking at the global regulatory system, vaccines are most stringent in terms of safety, efficacy, potency & shelf life, while pharma products are the least, and biotech products are somewhere in between. The underlying reason is that vaccines go to healthy children & adults. The quality standards are extremely high & have to conform to WHO cGMP norms.

At the same time, you need to build sufficient capacity. A company cannot survive producing 1 million doses. You need to be able to scale up production and produce at least 100 million doses. Unfortunately, the vaccine sector has become commoditized, which has made volume more

important than value.

To succeed, Bharat Biotech has enhanced its scientific capabilities, has built the required scale-up capacity, and has established cold chain distribution all over the country. Creating such infrastructure has required a lot of work from our side, but has enabled us to progress in the business significantly.

Last year, the company also made the headlines by being the first to launch a cell culture swine-flu vaccine HNVAC, the key benefit being the potential to scale up. How did the market receive this?

The market did not receive this well. H1N1 was more of a political vaccine. The scale was created by the demand for the vaccine, as a result of a high degree of media attention.

For the development of the vaccine, we have always considered the cell-culture based technology as far less cost-efficient than the egg-based technology. The egg-based approach however, is a 50 year old technology. Being a new company, we have instead decided to pursue the latest technology. I am a strong believer that the Indian consumer should get the best technology available.

Cell-culture technology is a tough area, but Bharat Biotech has become the only company in India to capitalize on this. We had to take our time to learn how to scale up this technology. While this obviously takes time, it has been a good learning experience in terms of tackling viruses & infections that are a threat to national security & public health.

So far, you have sold 1.5 billion doses already. Is this in line with your growth ambitions?

While this is in line with our growth, we are not too focused on such growth per se. My focus is on how to solve public health problems on a global scale. This is more important for me than bottom, top-line, growth analysis etc. I just ask my colleagues to ensure that there is no shortage of funds for R&D, capital investments, and to pay all salaries on time.

While Indian companies have the capability to work on small molecules, and for example develop products against the malaria parasite, they are primarily looking at the cardiovascular and diabetic areas. The reason for this is that the US and Europe are asking for these products.

Instead, we should be looking at what the public health problems of India are. Every company should be solving at least one problem, but I do not see many companies in India thinking in that direction. With more conceptual thinking, we can have better drugs for neglected diseases and truly address India's unmet needs.

Many MNCs have also been entering the unmet clinical needs area, with an increased focus on neglected diseases. Do you feel that they are heading the same direction as Bharat Biotech?

Part of the MNCs' strategies is indeed to focus on neglected diseases, but I do not think that it will help the developing economies greatly. Primarily, the thinking is that today's neglected disease is tomorrow's global disease. Naturally, MNCs are pursuing this area.

In your view, can this be a sustainable competitive edge for Bharat Biotech then?

We cannot excel in all areas, but we have a commitment & goal to solve some of the challenging infectious disease burden we face as a country. We need to use this mindset as a framework to build our science and technology in the realm of public health care.

In a past interview, you stated that you spend 90% of your time problem-solving, and that you cannot sleep without explore new ideas. Which ideas or developments are giving you sleepless night

nowadays?

On a day-to-day basis, there are so many issues to deal with. Attending to minor issues easily takes up 90% of my time. Yet, you need to be out there, build your network and sustain your connectivity & be up to date to what is happening around the world. . I have a scientific mind, and cannot intervene for routine day-to-day activities. My task is to generate ideas, create a business model, and delegate it to my team to execute accordingly.

My major job is to motivate my colleagues. My fellow scientists enjoy sufficient job security, which should thus not stand in their way to take the necessary risks.

Rather than having 300, 500 or even 1,000 scientists, glossy R&D buildings, etc., it is more important to focus on novelty, quality & productivity of your people.

Scientists should not be working as technicians that are merely there to keep a job. It is an area where high risks should be taken, and unless your scientists can take these risks, you cannot succeed.

At Bharat Biotech, I encourage our scientists to take 2 projects: one project of their own interest and one project related to a public health problem.

At the same time, you have been continuously investing heavily in R&D. Last year was also another important year, as you mobilized Rs 250 crore for clinical research. What have these additional resources brought to your research capacity so far?

We have also just been awarded another USD 30 million from the Gates Foundation. We want to be the first biopharmaceutical company in India to launch a new molecule. Apart from that, I want to launch 3 other molecules in the following years. Our expertise & in house capabilities has immensely grown in the areas of product development, standardization & formulation techniques, process optimization, international quality & testing parameters, protocol development, site management, data management, project monitoring & clinical research services.

Worldwide, many of our interviewees have proclaimed public-private partnerships as the way forward for the industry. In India, after your involvement in Genome Valley, you successfully partnered with the Orissa government. How important was the recognition of working together with the public sector?

I am a strong believer of public-private partnerships (PPPs). Working with the government is very tough, but the PPPs do indeed represent a very good model for India. The only issue is that the mindset of the government should change. They should realize that such cooperation does not only help the industry, but also creates innovation for the future of the country. It paves way for the future of technology based entrepreneurship, which is the only way forward to become a knowledge based economy.

As Bharat Biotech is now set to grow even larger, do you feel that acquiring additional people is a challenge for you in India?

It has always been my strategy not to depend on hiring people from other companies. Such people come with certain skills and a certain mindset. Such mindset is not always conducive for the Bharat Biotech environment, where we have created a culture that encourages learning, risk-taking and open-mindedness. Therefore, we generally recruit people that are fresh out of college, train / skill them & encourage them to build a career in the organization. I consider this as one of our secrets of success.

Bharat Biotech is a fast growing technology focused company, & is quite complex in its scope & nature of work. It probably takes 1 year before they understand the organization completely. We look at 2 main factors when recruiting: the person has to be a good human being, and be passionate about science and technology. If this is in place, everything else can be built around it. As a consequence, the attrition rate at Bharat Biotech is not even 5%.

In terms of innovative power, my humble suggestion to other companies is to take on fresh candidates & create a comfort zone that encourages innovation in young minds.

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