

## News Details

### **Bharat Biotech: incubating a healthcare plan**

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In these times of family businesses hitting the headlines, here is a couple that keeps family and business apart and makes a success of both. Meet 'bio-entrepreneurs' Krishna M Ella and Suchitra Ella who are developing next generation products through scientific biological research. With every cell, plant or any living organism fascinating Dr Krishna Ella and Suchitra Ella, these first-generation entrepreneurs and founders of Bharat Biotech International Ltd (BBIL) are upbeat about getting the country's many firsts in healthcare solutions through biomedical research.

Dr Krishna M Ella, chairman and managing director is an alumnus of the University of Wisconsin-Madison and Ms Suchitra Ella, is the founder-director who shared his vision to become the propelling factor for the development of the company. Says Ms Ella, "In the area of biotechnology, we have a long way to go. With biotech manufacturing slowly catching up in India, there's a lot more to do to gear up to competition against rising incidences of healthcare issues."

"New molecule development in biological research is always a constant effort. The R&D; becomes an on-going process in biotechnology as it deals with living systems unlike the pharma industry which is a ratio of few chemical compounds with a defined process," she says.

So, what's Bharat Biotech's prescription for success in the future?

The Rs 32-crore company is planning to launch a slew of vaccines for rabies, Japanese encephalities, Hepatitis A, combination vaccines, rotavirus and a recombinant malaria vaccine. Further, in the area of biotherapeutics, it proposes to launch recombinant lysostaphin, recombinant insulin and recombinant vascular endothelial growth factor besides diagnostic kits for HIV.

#### Spotting trend

Moreover, the company had diagnosed the emerging business quite early and prepared a business plan and focus areas. "Having operations in the country since 1996, we were able to visualise the technological requirements for countries like India. About 50% of our research focus would be for vaccines development which has almost become a necessity and the rest on biotherapeutics," she says. Though Ms Ella is reluctant to divulge the figure, she admits that the company has a huge spend on R&D; and almost the entire turnover goes back to the laboratories.

Further, for long-term sustenance and constant revenue generation, the ultimate business model for any biotech company is to strive for patents and more patents. "Whether a big or small company, intellectual property rights (IPRs) are the wealth generators," she quips.

On that front, BBIL seems to be well poised. The patents of the company include:

- Expression of recombinant mature lysostaphin
- Expression of recombinant streptokinase
- Novel process for Hepatitis-A preparation
- Novel process for purification of Hepatitis-B surface protein
- Process for preparing stable pharmaceutical formulation

BBIL also has some milestones to its credit. Consider this:

Indian patent for the new biotherapeutic molecule - lysostaphin that targets staphylococcal infection

To manufacture and market recombinant streptokinase — Indikinase in India

To manufacture Hepatitis-B vaccine Revac-B without the use of cesium chloride

Develops himax technology—a novel purification matrix

Two grants through Children's Vaccine Programme (CVP)—PATH (Program for Appropriate Technologies in Health) from the Bill & Melinda Gates Foundation to develop two new vaccines for rotavirus and malaria

#### Proactive steps

Hoping for a few more firsts in times to come, the company is now developing technologies in-house in a bid to have a lead in the manufacturing process too. "We are trying to become technologically advanced and not follow what has been done already," says Ms Ella.

The future outlook for the company is to develop genetic-engineering technologies for safe and cost-effective healthcare solutions.

With a state-of-the-art manufacturing plant which is claimed to be the largest in Asia-Pacific, it was built with an investment of Rs 1,000 million and offers process and products under cGMP (current good manufacturing practices).

Partnerships too are an effective and time-saving route to success. "While innovation and process R&D; is a continuous programme, we are increasing the volumes besides collaborating with national and international agencies to offer healthcare solutions," says Ms Ella. Technology collaborations of the company include the National Institute of Health, Washington, Indian Institute of Science, Bangalore, National Institute of Allergy, Stanford University School of Medicine and Department of Science and Technology to name a few.

Interestingly, biotech is an industry that's heavily dependent on contract R&D; and manufacturing for work and revenue. Riding on contract R&D; from its early days, BBIL continues to get business from this route. For instance, it is working with the Indo-US programme and National Institute of Health as a facilitator, the Centre for Disease Control, Indian Institute of Science, Stanford University and All-India Institute for Medical Sciences (AIIMS).

The company is active on the rotavirus project for diarrhoea, which is being supported to an extent of \$7 million through the Children's Vaccine Programme of Bill & Melinda Gates Foundation and PATH. "We are ready with doses for clinical trials and may undergo phase I trials. Perhaps, this vaccine could be one of the most important developments in the area of biology for a country like India where sanitary conditions are not on par with other developed countries," claims Ms Ella.

As of now, there is no medication to contain this viral infection and a vaccine is more a preventive mechanism to save those two lakh children who die due to diarrhoea in India. Besides diarrhoea, the company has developed vaccine for typhoid and is working on malaria vaccines through the National Institute for Health.

#### New plans

With a fund of about Rs 1.9 million, the Malaria Vaccine Initiative (MVI) of Bill & Melinda Gates Foundation for Plasmodium vivax and the European Malaria Vaccine Initiative-Plasmodium falciparum is being carried out in association with the International Center for Genetic Engineering & Molecular Biology.

As part of contract manufacturing, BBIL is manufacturing HibTITER, Haemophilus Influenzae for the US-based Wyeth (perhaps for the first time an MNC moved manufacturing of vaccine out of the US). It claims to have manufactured about 200 million doses and recombinant human lactoferrin for Agennix Ltd of the US.

Furthermore, having taken up a Spread Program of the World Bank with a grant of Rs 47.5 million, the company is looking at developing more products to expand its basket and tap the outsourcing segment. In this regard, the company has approached venture capital partners for funding. The company hopes to get the required funding soon. With this, the company is banking on using its domestic potential for development new vaccines rather than rely on overseas resources.

On the overseas front, the company is focusing on Africa which plagued by many tropical diseases is a huge market for vaccines and cost-effective generic medicines. In fact, the company has signed a memorandum of understanding (MoU) for a collaborative venture with a South African company, Mvelaphanda Holdings and Industrial Development Corporation of Africa. The MoU will help replicate its current Indian facility in South Africa.