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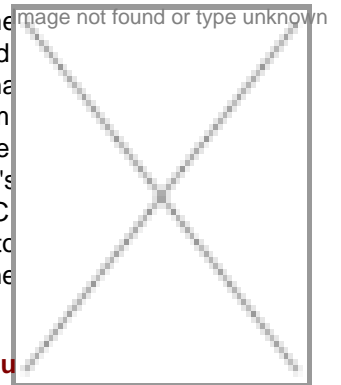
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When you are an entrepreneur venturing in to a new field, problems and controversies become your middle name. And so is the case with Varaprasad Reddy, MD, Shantha Biotechnics Pvt Ltd. With a vision to provide cost effective healthcare products to the masses, he established Shantha Biotechnics in 1993. Although an electrical engineer, he triumphed against the initial skepticism, funding problems and regulatory issues to launch India's first recombinant hepatitis B vaccine, Shanvac-B, in 1997. And since then, there was no looking back. In the news recently, on Shantha's latest launch, Shankinase (recombinant Streptokinase), being declared "illegal" by the GEAC, Reddy has no reason to worry as all the facts and figures speak for themselves. Talking to BioSpectrum, he recounts his initial trials and triumphs and traces the path of success for the Indian pharma biotech industry.

How did you set up the company? What were the challenges then and how did you overcome them?

In the year 1992, not many in India knew about Hepatitis B and its impact on human health. In fact, most of the medical fraternity also was not aware of this dreaded disease. At that time, only three companies globally were producing this vaccine, which was very costly to import and use. I came to know about this in one of the international seminars, which I attended by chance. There, the impression was that India and other neighboring countries only look towards subsidized vaccines and are not able to include Hepatitis B in their national immunization schedule. We were looked down upon as a country by the western society for not being able to take any initiatives either for developing the vaccine or for importing it. I



found this very disturbing and insulting. When I ventured to do something about it and approached a western company for technology, further insult occurred. The company spokesperson felt that neither India has the capacity to pay the high technology fee nor the scientists have the ability to absorb the technology. It was then that I took up the challenge, knowing fully well that India has a vast pool of talent.

I initiated the project as an R&D exercise to start with, at Osmania University, under the industry-university interaction program in 1993. Subsequently, we took shelter at the Centre for Cellular and Molecular Biology (CCMB), Hyderabad until such time we developed our own R&D facility. Many banks and financial institutions were skeptical about this project and they refused to fund because of two main reasons. The first being that the biotechnology segment was very nascent at that time and this particular Hepatitis B vaccine mortality data was not very encouraging with a meager 80,000 numbers per annum. In their perception, this was too small a number and no project can be viable with the sale of such numbers. The second reason was my background of electronic engineering, which they felt is not appropriate for the life sciences business. Venture capital funding had also not matured enough in the country by then. Luckily and by providence, Foreign Affairs Minister of Sultanate of Oman got in touch with me and participated in the equity to the extent of 50 percent and also arranged long term loan from Oman International Bank at a very subsidized rate of interest. Subsequently, ICICI came forward to give a loan for technology development. And when the R&D results were viable for commercialization of the product, the newly established Technology Development Board (TDB), under Ministry of Science & Technology came forward to fund, which has given the requisite impetus to the project.

What is the company presently focusing on?

Shantha's main focus is on new drug discovery using indigenous talent. The company is extending its manufacturing facility to facilitate manufacture of its various products coming out of R&D phase. Shantha's new drug discovery program involves work on monoclonal antibodies against non-small-cell lung carcinoma. Shantha's first indigenous development of recombinant Hepatitis B vaccine enabled India to join the select club of five countries to have the know-how to produce Hepatitis B vaccine.

What is the next level of progression for Shantha Biotech?

We are contemplating to do not only biogenerics but also new molecules. The main thrust is to go for monoclonal antibodies for various types of cancer. Per se, we are going to limit ourselves to health care products using biotechnology and we are not diversifying in any other area. There are three more products, which are going to be launched in coming four-five months time such as EPO, G-CSF, and combination vaccine of DPT+ Hepatitis B and Typhoid. Our main plans to bring more and more life saving drugs from our in-house R&D and also to provide contract research and contract manufacturing services. We are also looking for collaborative arrangement for co-development of any new drug/molecule.

What has been the total investment in the company to date and how have you raised the funds?

Our investment in the company is around Rs 125 crore. Shantha had raised the funds by equity through private placement and loans from banks and institutions.

What is the positioning of Shantha Biotech and what are the current research activities?

Shantha is a pioneer biotech company in the private sector and is the first biotechnology company to develop, produce and market the first recombinant product in India. Shantha's successful development of recombinant products has created a technology platform and this has motivated the scientists, given them enough confidence to try out indigenous development and production of other life saving drugs in the country without having to depend on imports. Many existing big pharma companies and new generation biotech companies have got motivated by the success story of Shantha's innovative R&D efforts in producing country's first Hepatitis B vaccine and country's first interferon alpha ('Shanferon').

Other products from Shantha under different stages of development and regulatory clearances include: EPO, GM-CSF, G-CSF, tPA, insulin, human growth hormone, combination vaccine of DPT + Hepatitis-B, typhoid vaccine, and monoclonal antibodies

What has been your marketing strategy and how successful have you been? How has been the market acceptance/response to the recombinant products?

Shantha is directly marketing its products all over India through its field force. We also started supplying to various countries directly and also through UNICEF agencies after SHANVAC-B got WHO-Geneva pre-qualification. Shanvac-B and Shanferon are widely accepted by the medical fraternity and the response was overwhelming from the public. Indian Medical

Association, NGOs, Rotary Clubs, etc have come forward to conduct mass vaccinations. Shankinase has not yet reached the market.

Since the launch of the indigenous recombinant drugs, what has been the effect on the domestic market and exports market?

Shantha's entry into market with its Hepatitis B vaccine (SHANVAC-B) brought down the prices of imported vaccine from Rs 780 to Rs 50 in 1997 and to Rs 25 in 2003 and similar has been the case with our second product Shanferon (Interferon Alpha-b) also.

How many manufacturing plants do you have now and how do you plan to gear them to address new products?

We have a facility at Medchal, a suburb of Hyderabad city, to manufacture our products Shanvac-B (Hepatitis B vaccine), Shanferon (Interferon Alpha-2b) and also Shankinase (Streptokinase drug). We have invested about Rs 50 crore on manufacturing facilities. We have already taken up to build a new facility in the same premises (Medchal) to manufacture bacterial vaccines, for which we are expected to spend about Rs 60 crore.

Strategic Alliances are important in any venture. How do you view this and how have you applied this at Shantha Biotech?

So far, we have not gone for strategic alliances, but we have joint ventures. Shantha Marine Biotechnologies Pvt Ltd, Chennai, a joint venture between ABL Technologies and Shantha Biotech, to focus on marine biotechnology products. Beta-carotene is already in the market. (Editor: This JV has since been discontinued)

Shantha West Inc. San Diego (USA), a joint venture between East West Laboratories, USA, and Shantha Biotech is involved in the development of novel therapeutic monoclonal antibodies for the treatment of different types of cancer.

Exports of Bioproducts still have to pick up. What do you feel is the stumbling block and what should be done to address the issue?

There are a lot of regulatory issues involved in exporting Bioproducts to developed/developing countries, which need to be addressed. We cannot enter each and every country just like that because of the patent and regulatory issues. Most of the developing countries are not ready with full-fledged regulatory systems and testing facilities resulting in enormous delays in getting the product registered. The Government of India should come forward to help its industry through our embassies in promoting the local industry in respective countries. This way, the products will get registered a little faster and the exports can pick up.

Recounting your experience, what is your message for the biotech industry, the policy makers and industry?

A separate Department of Biotechnology was set up by the Government of India in 1986 to give a boost to the development of biotechnology in the country. This was a laudable step. The Government has also initiated a \$20 million genome initiative to facilitate advances in pharmacogenomics and new drug discovery. The call is to make India a destination for cost-effective solutions for global biotech issues. The biotech industry in India is poised to emerge as a significant player in the global biotech map. The following factors are fuelling its growth:

• Low cost of innovation (R&D costs are one-seventh to one-tenth of that in developed markets).

• Availability of a large pool of scientists.

• Low cost manufacturing base

• Established pharmaceutical industry, which is a platform for the sunrise biotech industry.

• Financial support by the Government

• Large diversity in the genetic make-up of the population.

However there is a dire need for streamlining the processes—regulatory and funding. The infrastructure too needs to be strengthened. All this calls for a comprehensive National Biotechnology Policy.

Should the Biotech industry play a role in creating mass awareness on the diseases and the benefits of biotech products collectively? If so what would you outline as the three-four important measures?

Biotech industry need not play a role in creating mass awareness for each and every product they come out with, but they should do it, when they bring out any novel product like Hepatitis B vaccine. When we launched Hepatitis B vaccine in 1997, most of the Indian populace was not aware what Hepatitis B disease was. It was we who had to create mass awareness by conducting mass vaccination camps, conducting awareness camps through media. In fact, the Government should come forward to take up the necessary steps to create awareness among the public by way of warning advertisements like what it is doing in the case of AIDS control. It should also take up the eradication of diseases like Hepatitis B through the national immunization program.

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