BioSpectrum the business of Bio & Health Sciences

Biotech firms head towards new direction

07 October 2009 | News

Image not found or type unknown

Biotech firms head towards new direction

Realizing the fact that traditional approach will not yield optimal results in the market, Indian drug makers are heading towards a new direction to strengthen their business. With this series on business models, BioSpectrum will highlight those Indian biotech companies that have embarked on novel strategies to augment their growth.

India, the world's largest democracy with intense domestic competition is steadily shifting its focus from the primary sector to the secondary and tertiary sectors. Unperturbed by the international competition, the economy of the country is becoming a knowledge-based one. And giving a fillip to the life sciences sector, India is emerging as one of the five biotech leaders in the Asia Pacific region besdies Singapore, Taiwan, Japan and Korea,

During the inauguration of the golden jubilee celebrations of the National Institute of Technology Karnataka (NITK), Mangalore, Karnataka, held in August 2009, the Union minister for Law and Justice, M Veerappa Moily had said that the Union government is planning to set up nearly 50 centers of training and research in the areas of biotechnology, bioinformatics and nanotechnology. This itself is a testimony to the booming biotech industry, which is emerging as a big employer. And to achieve success in the market, Indian drug makers are enroute to a new direction.

The Mumbai-based biotech company, Yashraj Biotechnology, uses human biological fluids for extracting antigens and antibodies rather than applying recombinant technologies. This method cuts down the cost of diagnostic kits. Another advantage of using this method is that the antigens derived are of the same nature as they exist in the human body. It also has its environmental benefits as the biological fluids are treated before being disposed off, which would otherwise become an environmental hazard.

Similarly, NovaLead Pharma, apart from focusing on new chemical entities (NCEs) in oncology, has also adopted drug repositioning model. Under this model, it screens the existing drugs for new therapeutic uses. Although, drug repositioning model is not a new concept, it has gained momentum in the last few years, mainly due to the shrinking size of drug manufacturing in the industry, and the lack of strong R&D team.
As an interesting idea, after completing the phase II trials, some biotech companies are signing licensing deals with other companies who will take the task of marketing the product. Besides minimizing the cost of production, adhering to such a concept will also give the companies, an opportunity to explore other marketing avenues.
Yet another biotech company that has come up with an indigenous plan is Actis Biologics Private Limited (ABPL). It has designed a unique business model of in-licensing promising targets. After this, values to the targets are added through the biopharma vertical product life cycle, which significantly reduces cost. But discovery of new molecules through internal research is also one of its targets. The important aspect of this model is that for each product or technology platform that the company acquires, it forms a collaboration or joint venture, and after a certain stage it spins them off as a separate entity (with ABPL holding a majority stake) even though the research is done under one umbrella company.
Considering the fact that the manufacturing costs, human resources and research expenses (both preclinical and clinical) in India are cheaper as compared to other developed countries, the country has certainly made its presence felt in the biotech industry. Its prominent rise in the biotechnology sector, is attracting many global players for bilateral technical cooperation in biotechnology. „

Yashraj goes from strength to strength

Rather than applying recombinant technologies, Yashraj Biotechnology extracts antigens and antibodies from human biological fluids with the idea to cut down costs of diagnostic kits.

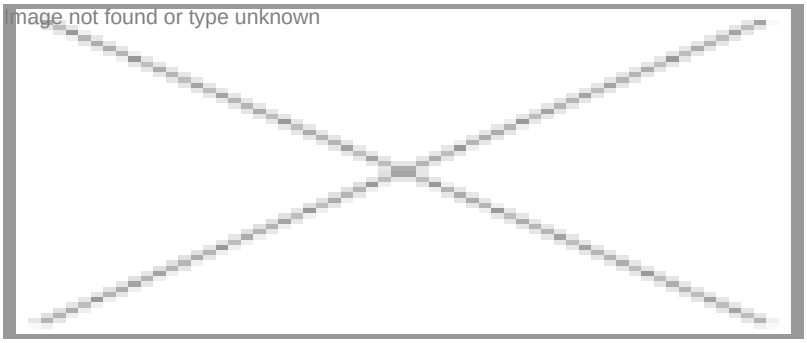
Established in 1999, Yashraj Biotechnology Limited (YBL) was the brainchild of Arvind K Bhanushali, the founder director of the company and his brother Paresh B Bhanushali, the present director of R&D and production of the company. YBL deals with the business of manufacturing and supply of diagnostic antigens, mainly monoclonal to kit manufacturers and distributors.
Ideally, extraction of antigens and antibodies can be done either through purification of proteins from human biological fluids or through recombinant technologies. However, YBL chose the former one not only due to its cost-effectiveness, but also because antigens extracted through this methodology is of the same nature, which exists in the human body. These human biological fluids are of no commercial value.
Dr Chander P Puri, CEO, YBL, says, “We extract these antigens and antibodies from the human biomedical waste. Usually, these biomedical fluids are disposed off by hospitals and are left unused. YBL negotiates with these hospitals to have a storage center for these biomedical waste, which is subsequently transported to our laboratories. This ultimately comes under affordable diagnostics. It is affordable because the ingredients which further go into the diagnostic kits are indigenously produced. We were always looking at methods, which could be affordable to the people.”
Interestingly, this methodology also has its environmental benefits. Biological fluids when disposed as unused waste plays a major role in causing pollution. Moreover, with this methodology, the cost of protein purification comes down drastically. The only cost factor is in transporting the fluids to YBL’s manufacturing facility.
YBL needs to place a proposal to the concerned hospital which is reviewed by the Clinical Ethics Committee (CEC). It isonly after the CEC approval, fluids can be collected. YBL also has to take the approval from the Central Pollution Board Control (CPBC) that reviews whether the methodology of collection is environmentally viable and in tune with the World Health Organization (WHO) guidelines. The board reviews the mode of transportation, containers and the manner in which YBL disposes off the unused matter of these fluids.
Before getting involved in the collection process, the team undergoes a training program, wherein they are trained onaspects like collection methods, transport and tackling emergency situations and regulatory methods. At present, the company is focusing on diseases like tuberculosis (TB), malaria and sexually transmitted diseases like HIV/AIDS. YBL is also in the process of launching a cell-driven antigen for TB diagnosis. Monoclonal antibody is under evaluation. For HIV/AIDS, the company is coming out with an antigen extracted from human saliva. It has brought out 13 products into the market, and nine are in the R&D phase.
The company is also in the business of contract manufacturing using its own or customer supplied raw material. In this case, projects of antigens is taken up either through joint R&D venture or exclusive technology transfer for buy-back. The research team also conducts a viral safety testing for all products to be released.
New business opportunities for YBL are in the areas like supply of cell-derived antigens and antibodies, monoclonal antibodies using hybridoma technology and polyclonal antibodies; cell culture facility for expression of patented clones (diagnostic and/or therapeutic), and the use of experimental animal facility for drug development.
Having achieved milestones and success in the indigenous production of antigens and antibodies, YBL is now looking at diagnostic kits manufacturing space. The company has already identified technologies and land for the facility, and is in talks

with the funding agencies. The new venture is expected to be up and running by mid-2010.
Manufacturing its own diagnostic kits would in turn reduce YBL's cost by 50 percent. YBL also intends to build a facility that spread across 150,000 sq. m., for contract manufacturing or as a JV set-up. „

NovaLead looks beyond the obvious

Apart from focusing on new chemical entities (NCEs) in oncology, NovaLead Pharma follows the drug repositioning model, wherein it screens existing drugs for new therapeutic uses.

The genesis of NovaLead Pharma can be traced back to the inception of its parent company, VLife Sciences Technologiesin 2002. VLife Sciences Technologies focused on developing screening technologies, which in turn would accelerate the whole drug discovery process. During this course, the company developed a computer-aided drug development technology that allowed them to focus on a couple of in-house research projects, some of which included new chemical entities (NCEs) in disease areas like cancer.
In 2007, the drug discovery team was demerged from VLife Sciences Technologies to form NovaLead Pharma, now based in Pune. The business model of NovaLead is to develop its discoveries up to the proof of concept in animals and then out-license or partner with either pharmaceutical or biotechnology companies to generate revenues, which are milestone and royalty driven. Supreet Deshpande, CEO, VLife Sciences Technologies and the brainchild behind Novalead Pharma, says, "We decided to demerge our drug discovery process to finally develop the discoveries in human trials using the screening technologies developed from the parent company, VLife Sciences Technologies. What is different in this case is the manner in which we handle the discovery process."
Initial investment of Rs 1.5 crore, came from personal funding of founders and angel investors. A venture capital investment was raised in April 2006, through Kotak Mahindra-Private Equity Group.



The company at present pursues two in-house research programs – NCE program in oncology and new indications program in unmet needs area. Along with Deshpande, co-founder and COO, Atul Aslekar who is also a part of the VLife Sciences Group, has the responsibility to lead technology development and sourcing to continuously improve on NovaLead drug discovery process. In the avenue of technology, NovaLead has come up with virtual screening technologies like VLife Amadeus screening platform and VLife Biblica knowledge compendium (developed along with VLife Sciences).

This business model, which Despande terms as the drug repositioning model, was followed by some pharma and biotech companies in the past. Drug repositioning has been gaining importance in the last few years as an increasing number of drug development and pharmaceutical companies see their drug pipelines drying up. They have realized that several promising technologies in the past have failed to deliver as assumed. Using drug repositioning, pharmaceutical companies have achieved a number of successes. For example; Pfizers's Viagra in erectile dysfunction and Celgene's Thalidomide in severe erythema nodosum leprosum.
NovaLead's lead compounds in oncology, VLI27 and Galnobax, the new indication diabetic foot ulcers, have both been filed for Patent Cooperation Treaty (PCT) and are exclusive output from VLife's technologies. The candidate pipeline of NovaLead Pharma has an interesting mix of new chemical entities and new indications for FDA approved drugs, majority of them qualifying for fast-track approval from the FDA.
Currently, there are six promising candidates in the pipeline, one in its human trial phase, two in their animal phase andthree in the in-vitro phase. After the completion of phase I trials, NovaLead usually announces the discovery processes on the basis of the data available to attract prospective licensing partners. "We do not take the drugs to the market. Instead, after phase II, we sign licensing deals with companies who will in turn take it to the market for commercialization," says Deshpande.
A drug for diabetic foot ulcer, Galnobax, will be the first to hit the market in another two-three years as estimated by Despande. But this depends on who will ultimately take the product to the market. In the preclinical trials, Galnobax has demonstrated 42 percent improvement in curing wounds in diabetic patients. At present, clinical trials for Galnobax is partly happening in India and the US, where 40 patients have been recruited.
With India positioning to become world's diabetic capital, Despande is hopeful that the drug should hit the jackpot. "By 2011, it should be out-licensed, with the deal touching around $400-700 million (Rs 1,924-3,368 crore) mark," he maintains. NovaLead is also looking at other therapeutic areas like age-related wrinkles, asthma and CNS-related diseases. The other

two promising targets in the pipeline include colon and pancreatic cancers. „

Actis Biologics thinks out of the box

Licensing promises drug candidates with more research and development, spinning out a company for each product makes Actis Biologics a cut above the rest.

In 2005, Mumbai-based Actis Biologics Private Limited (APBL) chalked out a unique business model which is yet to be emulated by its Indian counterparts. The company, an offshoot of California-based Actis Biologics, in-licenses promising targets, then adds value to the targets by accelerating the progression through the biopharmaceutical product life cycle, while reducing costs by a significant margin. At the same time, it targets discovery of new molecules through internal research. The company acquires technologies with demonstrated applications and well-protected intellectual property. The distinguishing factor is that for each product or technology platform that it licenses or acquires, ABPL forms a joint venture or inks a collaboration, and after a certain phase spins them off as a separate company (with ABPL holding a majority stake) rather than bringing them under one umbrella.

Sanjeev Saxena, chairman and MD, Actis Biologics, says, “Actis Biologics was formed by a group of scientists, who over the years made a lot of achievements.” However, he maintains that they did not get any return of investments for their work apart from awards and acclaims. “This is the reason why we decided to form Actis Biologics. Henceforth, each of these scientists, some of them at present are on the scientific advisory board of the company (and who are equity holders as well) contribute their own technologies and research work, they are working upon. And at the same time get their share of returns too,” adds Saxena.

“We looked at India when biotech was in its nascent stage, and we also analysed the manner in which we would pump funds. We started talking to Indian biotech companies, evaluated the cost and decided to form ABPL in 2005,” says Saxena. Over the years, the company has established academic and industry collaborations with the US. Today, the team has identified 20 disease segments. The main focus so far has been oncology and has filed 65 patents till date. Six companies which have already been registered will start the operations soon.

According to PN Venugopalan, president, Actis Biologics, the six registered companies include Kohinoor Biotech, Aum Life Sciences, Mercury Biotech, and Deep Biotech. The Ribozyme platform division of the company would undertake development of Angiozyme, a novel platform based on nucleic acid technology. The recombinant protein platform division will develop a proprietary technology, a novel technology based on the expression level of certain cells for any protein. The gene therapy platform division is developing next generation therapies using a novel vector technology (tame virus) for delivery of a predetermined genetic sequence. The molecules will be developed and tested in human trials and partnered with larger biotechnology and pharmaceutical companies in the US, Europe and India.

Once these divisions get spun out, ABPL will partner with a pharma or biotech company for marketing the product or the technology. The company has also got the Department of Biotechnology (DBT) approval for the project titled ‘Delivery of MSP36 with Lenti Viral Vector’ in 2006. The company was also in the news recently for the acquisition of its technology platform for effective treatment of hepatic cancer from CellPoint Diagnostics, US.

As far as funding is concerned, ABPL intends to raise funds of approximately $25-30 million (about Rs 120-144 crore) through private placement of equity with reputed investors. Under the name of Actis Biologics Malaysia Sdn Bhd, the company has its foothold in Malaysia. Under this, it has Telesto Diagnostics to develop coronary artery disease-based diagnostics for various abnormalities and Cogenesis to develop novel respiratory products. To tap the market, it has tied up with the Malaysian government to come up with a biocity.

“Malaysia offered a lot of opportunities, first being the direct inflow of funds from the US and Europe. The Europeans are familiar and keen to invest in Malaysia,” says Venugopalan. ABPL plans to set up a manufacturing facility targeting South Asian market. ABPL’s much-awaited product, Angiozyme, is expected to hit the market in another two years. Angizoyme, will target mainly the lung and breast cancer market.

Anjana Pradhan and Nayantara Som