



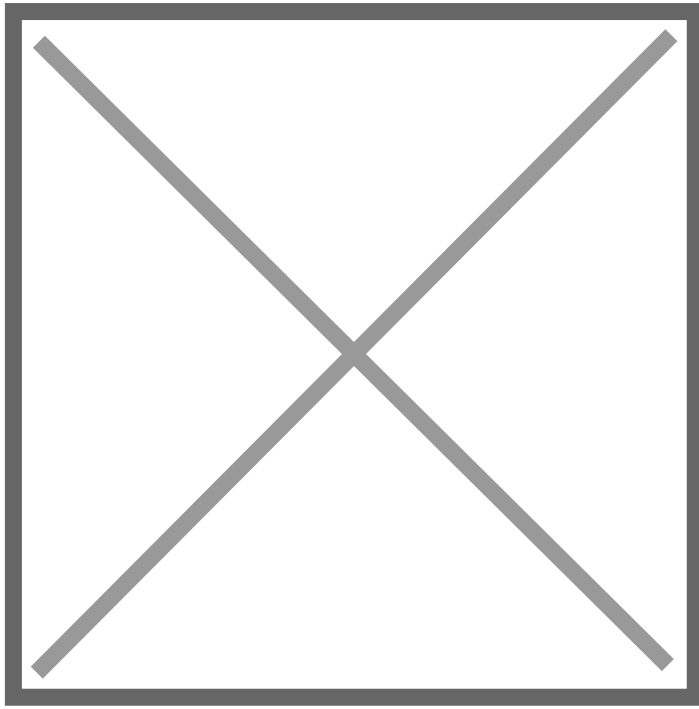
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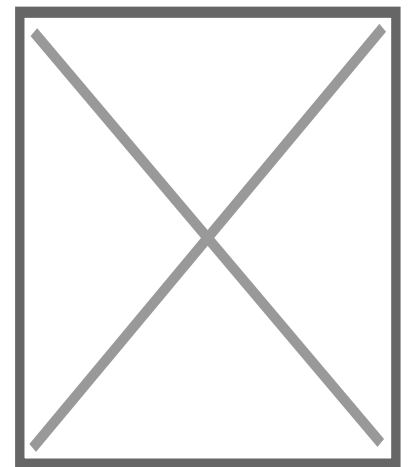
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SBIRI-funded companies taking wings

04 June 2008 | News



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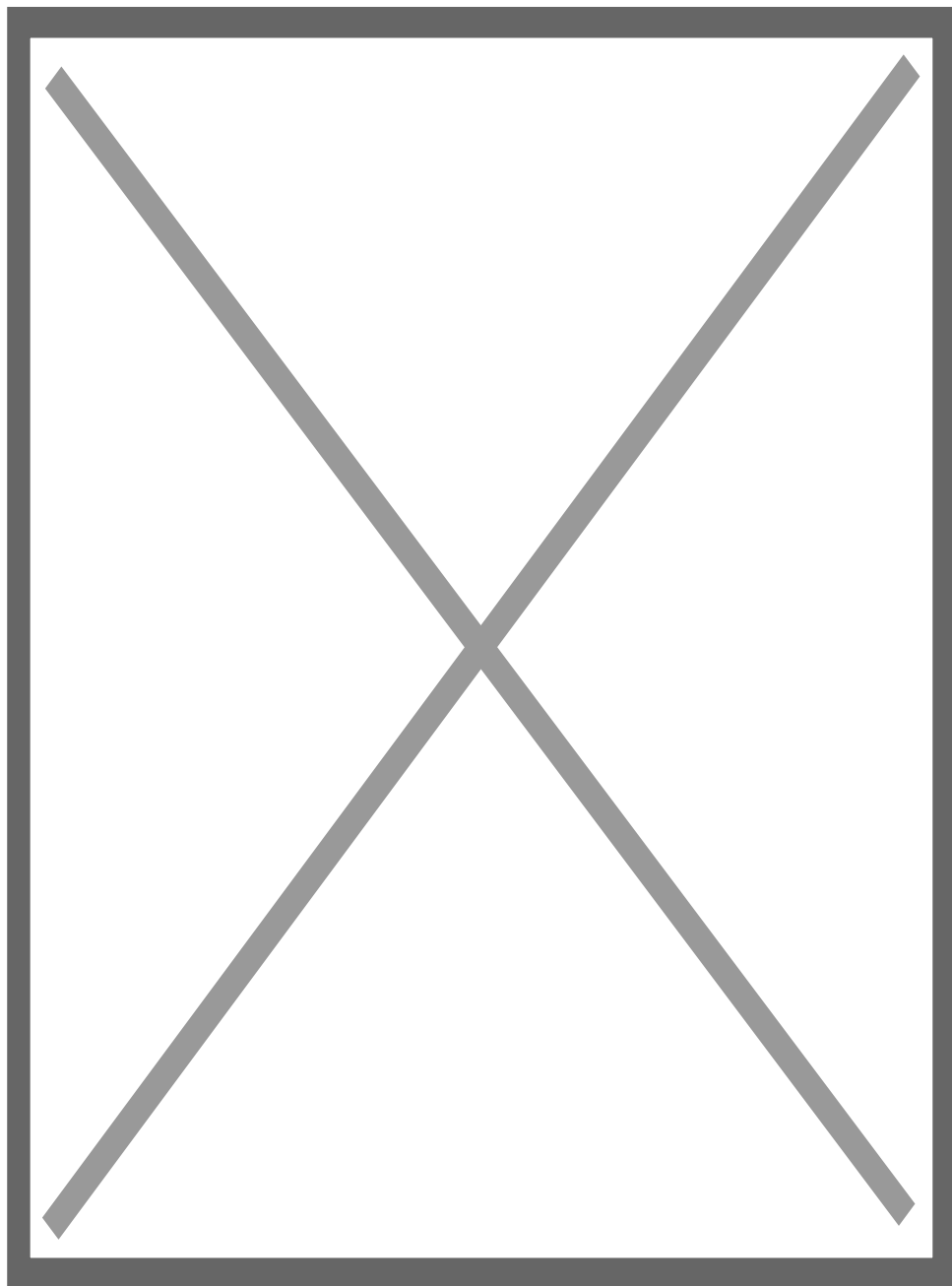
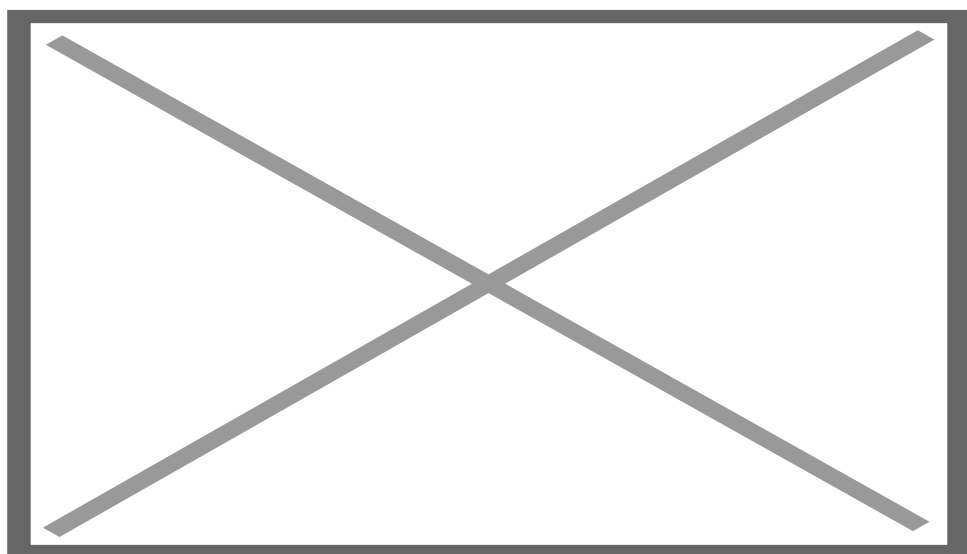
The Small Business Innovation Research Initiative (SBIRI) was launched by the DBT two years ago and the success is very much evident from the fact that today it has 37 projects up and running under its umbrella. BioSpectrum takes a look at few companies boosted by the SBIRI scheme.

Indian biotech companies may well be on their way to becoming the next global leaders in biotechnology, but if the spirit of innovation has to be fostered in the country, it is not only large companies, but small business units as well that have to be given a technological thrust. It was with these objectives in mind that the department of biotechnology (DBT) launched the Small Business Innovation Research Initiative (SBIRI) scheme in 2005. The main aim of the scheme is to strengthen existing private industrial units whose product development is based on in-house innovative R&D, encourage other smaller businesses to increase their R&D capabilities and capacity and cultivate the entrepreneurial spirit by creating opportunities for starting new technology-based or knowledge-based businesses by science entrepreneurs.

The scheme started with a vision to promote early stage funding to private industries for high risk innovative and commercializable product proposals. The scheme, which has been advertised seven times, has received a total of 398 proposals from around 250 companies till date out of which nearly 75 percent are for early stage research (phase I) and around 20 percent are for scale-up and late development of research leads in phase II category while a few (5 percent) are a

combination of the two. Out of this, 155 are collaborative proposals i.e with institutions/universities.

The excitement and enthusiasm of the companies to the scheme can be gauged from the fact that within the first two months of advertising the scheme, the DBT received 71 full proposals and 17 concept proposals. So far, 37 projects have been sanctioned to a total of 32 companies, which are worth Rs 155 crore. The private sector has committed an investment of around 48 percent of the total while the rest would be from SBIRI funds of the government. A sum of Rs 45 crore has been released to companies till date out of which 16 projects are in the health sector, nine for industrial product and process development and eight in agriculture and allied areas. So far the biotech industry in the southern region has shown the maximum interest with Karnataka being the topmost state to submit proposals followed by Maharashtra, Andhra Pradesh, Tamil Nadu and Delhi.



Actis Biologics

Project: Sustained delivery of MSP36

Mumbai-headquartered Actis Biologics (ABPL), founded in December 2005, is an emerging biopharmaceutical company developing new therapies for life-threatening diseases. It has a strong focus in the areas of cancer and cardiovascular disease. The company is building a strong pipeline of clinical stage products (some of which are already in human trials) through in-licensing and internal research. ABPL has in-licensed technology platforms in these areas -- ribozymes, gene therapy, vaccines and recombinant protein technologies, all of which have shown promise in either human (phase I and phase II molecules) or in animal models (preclinical molecules).

The company submitted a project titled "Delivery of MSP36 with Lenti Viral Vector" to the DBT in December 2005 that was approved for funding in 2006 with the loan sanctioned in April 2007 and funds dispersed in May 2007. The project is working on providing a cure for breast cancer through recombinant gene therapy. The gene in question is MSP36, whose inexpression represents a critical step in breast cancer progression and its replacement provides a key regulatory agent to inhibit breast cancer growth and metastasis at several levels; arrest the growth of the tumor cells, inhibit cell migration and metastasis, and down-regulate tumor neovascularization. The gene also targets a key growth factor than current therapies.

Actis is taking the HIV virus and removing its inside guts to make it a safe virus which has no harmful effect. This is called a viral vector and in this case, the tamed form of HIV virus is referred to as the lenti virus vector. The code/sequence needed to produce MSP36 is added into the lenti viral vector before it is delivered into the body where it is integrated with the body cells. MSP36 is delivered into our cells and the body starts to produce the FGF protein and kill the cancer cells. The cancer treatment in this case is being brought in the form of a gene being delivered into the body, so that a corrected gene is used to produce the protein inside the body. This gene normally exists in the body and continuously produces the FGF protein, but for some reason has malfunctioned. The protein when present in the body stops the formation of blood vessels, which are needed to supply nutrition into the cells for them to grow and divide. By delivering the gene, the body reproduces the protein so that the blood vessel formation is stopped and MMP9 production is inhibited. MMP9 is a key protein that triggers metastasis.

Yashraj Biotechnology

Project: Development of highly specific immunoassays for prostate and breast cancer through molecular characterization of existing markers and establishment of novel markers

Established in 1999, Yashraj Biotechnology is focused on molecular diagnostics. The company's major activities are in the field of isolation, purification and bulk production of native antigenic proteins; customized formulations of native antigens in accordance with their intended use; contract manufacturing of existing products; contract manufacturing of antigens either through joint R&D venture or exclusive technology transfer for buyback; development of customized monoclonal as well as polyclonal antibodies; and cell-derived antigens. The company's project under the SBIRI scheme aims to characterize existing tumor markers applied in prostate and breast cancers and to search for new markers in order to enhance specificity of diagnostic assays.

Speaking about the project, Dr Chander Puri, CEO, Yashraj Biotech, said, "This project is conceptualized on exploitable heterogeneity in molecules of prostate specific antigen (PSA) and breast cancer antigen (CA 15-3) and anticipates that extensive characterization of these molecules can lead to development of monoclonal antibodies having higher specificity and affinity. The characterized antigens and novel antibodies will be used to set novel assays for PSA and CA 15-3 cancer markers, which will help clinicians in differentiating prostate cancer from benign prostate hyperplasia as well as early stage specific diagnosis of breast cancer. The lack of specificity of PSA in PCa and BPH had lead to unwanted biopsies/misdiagnosis globally and has also has affected selection of therapeutics". Accordingly a time line has been set for each activity from sample collection, purification and characterization of markers, antibody development, assay set up, laboratory and clinical validation and up-scaling of processes. Yashraj Biotechnology has established the facilities targeted in the project for experimental work to progress, and the project monitoring committee of the DBT has appreciated the progress in achieving the objectives. The DBT has reviewed positively that the success of this project will have higher impact towards establishment of specificity for better clinical diagnosis of PCa, BPH and BCa, generation of patentable proprietary monoclonal antibodies, exploitation of novel cancer markers for the early diagnosis of BCa and indigenous manufacturing setup for continuous availability of various components for the benefit of Indian patients. This project, likely to be completed during the next three years, would thus have both technical and cost advantages, thereby making healthcare within the reach of resource constraint population.

USV

Project: Development of a vaccine capable of eliciting immunological memory for the prevention of typhoid

USV is a leading healthcare company with a focus in branded generics, Active Pharmaceutical Ingredients (APIs) and biosimilars. In the area of biotechnology research, the company offers rDNA proteins and peptides backed by validated bioassays, clinical trials and intellectual property rights. In India, by Rx (prescription), the company ranks No. 1 in diabetes and cardiovascular disease segments. The company also has an active in-licensing program to enhance its product portfolio with a strategy to introduce innovative specialized products while retaining a focus on brand building.

The company's project got sanctioned in 2007 and is designed keeping in mind that typhoid strikes children below five years of age and there aren't any approved existing vaccines for the same. Elaborating on the same, Dr KG Rajendran, head, knowledge cell, USV, said, "The present vaccine, which is a polysaccharide-protein conjugate vaccine, is expected to be effective in younger children below five years of age requiring less frequent dosing regimen. The incidence of typhoid fever is highest in this age group and there aren't any approved existing vaccines in this category. Typhoid fever remains a common and serious disease in many parts of the world, more prevalent in developing countries like India. There are a number of polysaccharide (Vi-Virulence factor) based vaccines currently available in the market for typhoid fever. However, the usefulness of these Vi vaccines is limited by its age-related immunogenicity and its T-cell independent properties; i.e., it does not elicit protective levels of antibodies in infants and young children, and reinjection at any age does not induce a booster effect".

Navya Biologicals

Project: Development of a platform for production of complex peptides and proteins

Navya Biologicals was formed in June 2006 by two enterprising individuals, Dr KR Rajyashri, a molecular biologist, and Vinay Konaje, a chemical engineer. The company is into cloning of genes and expression of proteins (by which the information in a gene is translated into a protein). Navya Biologicals is working on the development of a novel technology platform for expression of complex proteins (of therapeutic and industrial value) that today cannot be expressed in sufficient quantities due to inherent issues associated with existing expression systems. The project got sanctioned in June/July 2007 and was initiated in August 2007. Speaking on the progress of the project, Vinay Konaje, one of the founders, said, "This is a 'phase I' program of 18 months, which is progressing on schedule presently. We hope to begin validation of the platform in the next 3-4 months. The technology platform would enable complex proteins to be mass-produced. It is either technically unviable to produce these proteins today (despite their therapeutic potential) or is commercially unviable with the available technologies. A couple of high value but complex therapeutic molecules have been chosen to validate the platform".

Navya is expecting to address a potential global market of approximately \$10 billion on successful completion of this program and has already identified proteins of commercial/therapeutic value that can be produced economically using this platform. It hopes to complete the project by March 2009.

SBIRI, a boon

There is more to come in the next few years if we go by the response and the momentum that the scheme has gained in the first few years. It would only enable the translation of technological concepts from the laboratories into commercially viable products by providing companies the skills and financial capital. Dr KG Rajendran, head, knowledge cell, USV, commented, "SBIRI as a scheme has not only offered financial assistance to support the R&D, but also extended timely expertise as and when required. Besides it also helped us to get access to scientific resources leading to advancement of the project work".

Dr Sanjeev Saxena, CEO, Actis Biologics, said that though the entire process, from getting an approval for the proposal to getting the funds, is lengthy, it has its advantages. "Although it took us time from the time the funds were approved to the time they were disbursed, the process as a whole is very effective. It showed that the government had appointed people who were judicious in their approach and very committed and willing to do a thorough due diligence on all companies including ours to make sure only deserving candidate companies got the funds".

Dr Chander Puri, CEO, Yashraj Biotech, further validates the merits of the SBIRI scheme, "Our partnership with the DBT for this project under SBIRI program has helped in critical review and approval of the project concept by SBIRI core committee; availability of research grant and soft loan eliminating financial limitations; bringing accountability due to public money involvement and project monitoring system; and a feeling of the feather in the cap with in such a short time of existence".

It is also felt that with the reluctance on the part of venture capitalists to fund such projects, SBIRI is a boon for upcoming companies to realize their potential to be at the forefront of cutting edge research. Vinay Konaje, one of the founders of Navya Biologicals, is of the same opinion. "R&D projects of the kind that Navya Biologicals is today executing would be perceived as high risk by conventional lenders/banks/VCS who do not understand the dynamics of the biotech sector and are loathe to investing in high risk-high return projects these days". He added, "The Indian biotech industry cannot progress beyond a particular point by simply reverse engineering existing molecules. Hence initiatives such as SBIRI are absolutely required for

upcoming companies like Navya Biologicals who are keen on putting India at the forefront in areas like biotechnology and want to make a difference to the healthcare sector, but do not have enough financial resources of their own to do so". Dr Sanjeev Saxena added, "Generally venture capital (VC) companies throughout the world are reluctant to fund gene therapy companies as they perceive a high risk due to past failures of gene therapy companies, but SBIRI allows us to fund such projects". He is optimistic though that once the project starts showing promise, the PEs and VCs will take a step forward and will be willing to bet and take a chance and risk their investment.

Shalini Gupta with inputs from
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