

## Actis to bring down cancer treatment cost

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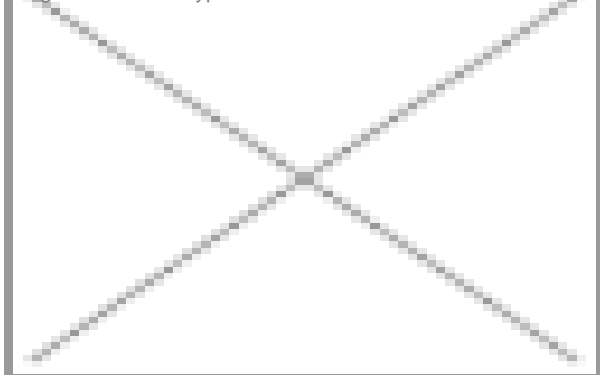


*Mumbai-based Actis Biologics has a vision to bring to market, high-end technologies and biotechnology products, at affordable prices. With its star product, 'Angiozyme' recently entered phase III trials in India, this dream could perhaps see the light of the day*

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A successful business plan is an amalgamation of ideas, passion, putting in place a sound team, getting in the right investors, funds, and above all, e in the way.

In 2003, when a group of scientists in San Francisco (US) came together to form Actis Biologics Inc, their sole purpose was to pool in their patents, research accomplishments, and funds; not just to derive maximum return on investment, but also to come out with high- end technologies manufactured at low costs, so that the end product would reach the consumer at an affordable price. Hence in this case, the germination of an idea was not enough; but it required a sound business plan and tactful dealing of logistics. Similarly, setting up its Indian counterpart, Actis Biologics Private Ltd (ABPL) was no cakewalk for the founders of the

company. Challenges came in the form of limited funds, limited manpower, finding like-minded partners on board, and procuring the right technologies.

With the business strategy to be a low-cost manufacturer of products, without compromising on manufacturing quality products in the field of biotechnology, today, the company has a host of exciting molecules in the pipeline, with their 'star product' for colorectal cancer molecule 'Angiozyme' recently entering phase III trials in India. Once successfully commercialized, Angiozyme is expected to reduce the cost to treat cancer to one-fifth the conventional costs.

### **The Genesis**

In 2003, a group of biotechnology scientists congregated in San Francisco with biomedical engineer Sanjeev Saxena, co-founder and molecular biologist Dr Dave Toman besides other practicing clinicians; to give expression to Actis Biologics Inc. Recalls Sanjeev Saxena, CEO, Actis Biologics, "Besides contribution of patents and research accomplishments, this group of engineers, scientists and doctors, has contributed their limited funds to build the company, and expand to other parts of the world. Thus, Actis Biologics Group was formed."

Within a few years, Actis Biologics Group spread its wings and established presence in India and Malaysia.

During various visits and interactions with the Government of India, particularly, the Department of Biotechnology (DBT) and Department of Science and Technology (DST); it became evident that a market like India was in dire need of a next generation biotechnology company, that had lower cost structure besides a diverse gene pool. With the support of the DBT, Actis Biologics was established in December, 2005; and valuable patents were transferred to Actis Biologics in India.

Thereafter, Actis Biologics grew with private investments and support of governmental agencies with schemes such as the Small Business Innovation Research Initiative (SBIRI). The company submitted a project titled "Delivery of MSP36 with Lenti Viral Vector" to the DBT in December 2005, and that was approved for funding in 2006; with the loan sanctioned in April 2007, and funds dispersed in May 2007.

In May 2007, Actis entered into a strategic tie-up with the Malaysian government in Melaka, to develop Actis Biocity on the lines of biotech centers in San Francisco (birth place of biotechnology), San Diego, Seattle, Boston in the US.

Every business has its set of challenges and obstacles. "We had no money when we started the company, so the issue was how do we in-license and acquire technologies? Further, how do we hire the right people, and motivate them to join and work with us? The other questions, which we had to deal with, were what technologies to bring on board, and who all do we want as partners; writing a business plan and preparing the financial, and then finding the relevant investors," reveals Saxena. And then the issue of pricing the company's shares.

Subsequently, after tackling these issues, the funds were raised on a project basis. Even though their biotechnology molecule for colorectal cancer, Angiozyme, held a lot more promise, ABPL was unable to work on further development of this technology, due to limitation on resources. Further, the management had to contend with a paradigm shift of diverse molecules in their portfolio.


### **Business Model**

ABPL follows a business model that has already been implemented by many international companies, wherein, the company will develop and manufacture products, but market it through experts, who have a large marketing network. However, what is unique about the marketing strategy is to spin each technology platform (after incubation phase) as a separate company; and develop other products using the technology, besides bringing a partner into that spin off venture.

"As an example, we already did spin out our CAD technology into a company called Telesto Diagnostics in Malaysia; and are in the process of looking for appropriate partners, to further develop the company, and the various products which will be generated, using this technology," reveals Saxena.

On the same lines, Actis Biologics has also incorporated under its banner, Kohinoor Biotech to focus on a ribozyme tech platform; Aum Life Sciences to focus on development of various recombinant proteins and mAbs; Mercury Biotech for the development of gene therapy-based products; and Deep Biotech for development of various immunotherapies, using a novel cytokine.

### **Promises of Angiozyme**

The company recently made news with its star product, Angiozyme, a biotechnology molecule targeted at colorectal cancer, entering phase III trials in India. The phase III clinical studies are expected to cost the company  233.5 crore (\$50 million), a part of which will be funded through soft loans by the DST, Government of India. The phase III multi-centric trials will be conducted among 150 patients in select centres in the country. "The trials are expected to be completed within 18 months from now. The company is also looking at conducting the trials in locations like Malaysia, China, Latin America and the

US,â€? confirms Saxena.

Angiozyme is a unique technology which is a hybrid of RNA and enzyme; and is, thus termed ribozyme. Since it targets the mRNA, it comes under the category of antisense. As an antisense catalytic enzyme that combines with a specific RNA and then cleaves off, it helps in stopping formation of unwanted blood vessels; thus stops the nutrition from being supplied to tumor cells, and also starving these unwanted cells. But, what is important about this technology, is that it works where ever we need to stop blood vessel formation, be it in obesity, AMD or as a contraceptive, since Angiozyme is a hammerhead ribozyme. â€œWith modifications to ribozyme, we should be able to create other signal blocking mechanisms, or signal enhancement mechanisms to prevent or fight other diseases. Now, specifically, in the case of colorectal patients, the team at ABPL believes it should work by eliminating any side effects, as well as, allowing for subcutaneous injections by patients themselves. Further, it can be made so inexpensively, that it should bring down cost of colorectal cancer care,â€? informs Saxena.

The technology proposal was studied in depth by a team of over 20 scientists from various departments (such as DST,ICMR, DBT, DCGI), and was found to have a strong potential, due to its anti-angiogenesis methodology. It was found that the cost of manufacturing this drug in India, and its method of delivery, provided for drug costs to be brought down by a factor of 10; and hence made affordable to the general population. Due to this consideration, DST agreed to fund the project.

The market size for Angiozyme just for colorectal cancer in India, is a 1,341 cr (\$300 million) and 6,707 cr (\$15 billion) on a global basis (Angiozyme can be used for other indications as well, breast cancer for example). Over 1,564 cr (\$350 million) has gone in the development of this molecule. It will cost another 290.5 cr (\$65 million) to develop this molecule of which 223.5 cr (\$50 million) has already been raised. This 223.5 cr (\$50 million) has been funded through soft loans from the DST, Government of India. â€œWe are just starting the process of exploring potential strategic tie-ups and hence it is too early to discuss the same,â€? says Saxena.

#### Other Developments

This apart, ABPL's Department for Scientific & Industrial Research (DSIR)-recognized R&D centre is also conducting research of recombinant proteins, gene therapy and antisense drugs. ABPL also has over 20 patents around a very promising technology which was reviewed by the US FDA and given an Orphan drug status. The LIV1 technology is focused on making existing drugs more effective and less toxic, by creating a more targeted delivery mechanism.

Looking at the future, growth for the company would come through both organic and inorganic route. â€œThis means, internally through soft loans and grants from the governments of India and Malaysia and the National Institute of Health, USA. We are looking at inorganic growth by raising another 134.11 cr (\$30 million)â€?, concludes Saxena.

**Nayantara Som** in Mumbai