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"The regulatory scene for phage products is becoming more favorable"

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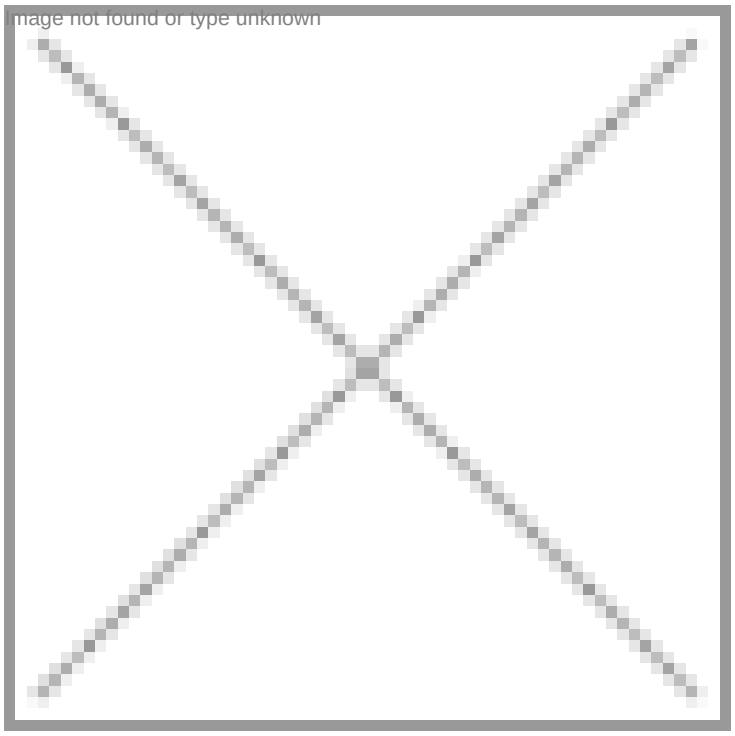

"The regulatory scene for phage products is becoming more favorable"

-Dr J Ramachandran, president & CEO, GangaGen Biotechnologies, Bangalore

Patents are an integral part of development of any biotech company. GangaGen Biotechnologies has always focused on developing strong intellectual property rights (IPR). "We now have three major broad patents issued in the US and one of them is also now issued in the European Union and we have about another nine patents pending," said Dr J Ramachandran, president & CEO, GangaGen Biotechnologies.

GangaGen is actually now much closer to the market than it was two years ago. In the veterinary business domain, its products are directed at fighting E. Coli infection in pre-slaughter cattle (that causes hamburger disease in humans), dairy cattle and salmonella-prone poultry and will be in the form of feed additives.

On the human safety side, its first product is for controlling Staphylococcus aureus bacteria, which causes hospital infections and is spreading into the community.

GangaGen is now gearing up to be in Phase I clinical trials with this product early next year.

The second human product GangaGen is working on is against another major pathogen called Pseudomonas aeruginosa. Pseudomonas causes infection in burns and wounds and this is a major issue in India. This problem exists even in the US. In the US and other western countries, Pseudomonas is also known to cause cystic fibrosis, a condition where there is congestion in the lungs. And GangaGen's phage product can also be helpful there. However, it is developing this mainly to

address the burns and wounds market. "If the western pharma companies evince interest in this product to tackle cystic fibrosis, we would be more than willing to partner with them," added Dr Ramachandran.

In an exclusive interview to BioSpectrum, Dr Ramachandran shares the company's plans and initiatives.

Since GangaGen is purely an R&D company, how do you plan to market your products and peg revenues?

ELANCO, the animal health division of pharma major Eli Lilly, entered into an agreement with GangaGen in August 2005. As per the agreement, ELANCO will market our phage product directed against E.Coli and we are expecting to submit for approval at the end of this year. Hopefully the product will be in the market early in 2008.

The company has already brought in some revenues in terms of the technology access fee, milestone payments and the project now is fully funded by ELANCO. We have already done four field trials and we will do a major trial in spring this year, which we will be finishing in summer.

Regulatory agencies like the US FDA and the agencies in Canada and Europe have become much more aware of the potential of phages and are getting proactive. Now this is a major change compared to what the scene was like two years ago. Phage is being viewed as an ally in the fight, especially against antibiotic resistant infection. So we foresee less regulatory hurdles for the phage products that we are developing. We are also now being approached by other big US and European companies as well as a few Indian companies for phage products in food safety and animal health. Also we have started talking to some pharma companies as well for human therapeutics and we are reasonably optimistic about the outcome. We will conclude at least one agreement by the end of this year or may be even two, which will add to the revenue stream and more importantly, add to the validation of our technology and the value of the company.

Will GangaGen be going in for another round of funding?

We have turned a corner for a variety of reasons. The funding was difficult in the initial stages but we have been very fortunate to have investors who are primarily individual investors mainly from the US and a few from India and they have had strong faith in our technology. In fact we completed a major round in November last year which was primarily initiated by one of the existing investors. The round started in September last and by the end of November, we closed with $4.5 million. This provided us enough resources coupled with the fact that we have been getting revenues from ELANCO already and we are in a reasonably comfortable situation. Additional revenues will come in with other agreements. We will probably need more funds next year to accelerate a few projects and go into clinical trials in human therapeutics. The existing investors are very supportive and if things go on track, I anticipate that they will step forward to lead the next round of funding.

Are you looking at mergers and acquisitions (M&As)?

We would like to add value to the company and make more progress. We would want to advance our products to a later stage before we look at M&As. But the nature of our business is such that there are many opportunities. We have our food safety and veterinary businesses progressing well. If there is a separate possibility for M&As, we would certainly consider it, provided the terms are very attractive and we will retain the human therapeutics for ourselves until a later stage.

What are your expansion plans?

We are expanding as we are taking up new projects. The primary expansion will be in Bangalore. There would some expansion in our Canada setup as well. As we conclude other agreements, we will dedicate people to these projects. In Bangalore we are now 30 of us and we will probably grow to 40-45 in the next 18-24 months. And in Canada, the number may grow to 15-20. This is the anticipated growth.

What are your other plans?

As I mentioned earlier, the regulatory scene for phage products is now becoming more favorable because phage is really nature's solution and phages have kept bacteria in check for nearly 3.5 billion years now. By taking this ancient cure and developing modern medicines, we can address a large number of heath-related issues in the developing world. Diarrhoeal diseases which cause infant mortality in the developing world and diseases like TB, cholera can be controlled very effectively with affordable phage products. It is my dream to make these products available in the developing world.

Namratha Jagtap