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GangaGen has been focused on the development of proprietary products for prevention and treatment of bacterial infections, particularly infections that are resistant to antibiotics, through the application of contemporary molecular and clinical sciences. Since its inception in 2001, the company has been having a long-term objective to commercially develop products to control multiple species of bacteria that are pathogenic to humans, particularly antibiotic-resistant strains, based on its knowledge of bacteriophage. Under the leadership of Dr J Ramachandran, the research team, comprising of 35 scientists have developed a proprietary recombinant protein, P128, for the topical prevention and treatment of Staphylococcal infections, including methicillin-resistant Staphylococcus aureus (MRSA) infections.

Q: Can you shed some light on P128?
P128 is a recombinant protein developed based on a key protein from bacteriophage. When the phage first interacts with a bacterial cell, they damage the cell wall in order to insert their genetic material. Our research team has identified the active portion of the phage molecule that causes this damage, and coupled it with another protein sequence that allows binding to the surface of Staphylococcus aureus. The hybrid molecule is capable of binding to, and damaging the surface of all the strains of S. aureus tested. This damage results in the death of the bacteria.

Q: What is the current status of P128?
We have started phase I and phase II clinical trials for P128 at the National University Hospital, Singapore from the last week of March 2013. We have received positive response for single dose in Part A trials on healthy volunteers. Considering that Health Sciences Authority, the local regulatory body in Singapore has given green signal for conducting multiple dosing trial again on healthy volunteers (12 in numbers), we are hopeful of completing this by June this year.

Q: How much money have you invested in developing this protein?
Since the beginning of this project, our business strategy has been to pursue specific human, initially topical, applications where there is an opportunity to shorten the long product development timeline by focusing on those indications that require

shorter clinical trials and enable faster regulatory approval.

We are the first Bangalore-based Indian biotechnology company to develop such a new therapeutic product. So far we have invested about $22.1 million, which is one-tenth of the total cost that any global company used to spend on a similar kind of research initiative. We were able to achieve this milestone because we are located in Bangalore, which has an abundant talent pool, high retention rate, and biotech friendly government policies.

Q: When will the efficacy studies be completed?
We are looking at completing the efficacy studies by November 2013, which we are planning to start from July this year.

Q: What are the other research initiatives of GangaGen?
Our team is pursuing research on the control of Pseudomonas aeruginosa in burns and wounds. The product is also expected to be valuable in treating P. aeruginosa infections in the lungs of patients with cystic fibrosis. We have generated platform technologies that can be used to address any bacterial infections and also novel, propriety methods for vaccine development. We are developing therapies for gram negative pathogens which are increasingly proving to be multidrug resistant and life threatening.

Q: Speaking of developments, are you looking at raising more funds in future?
Although we started our operation in 2000 in Bangalore as GangaGen Biotechnologies Private Ltd (GBPL), to develop novel therapies for treating antibiotic-resistant infection, we received permission from the Ministry of Commerce and Industry, Government of India on December 21, 2001 to convert GBPL into a fully owned subsidiary of GangaGen, which was incorporated as a Delaware Corporation in August 2001 in the interest of investors in the US and Canada. Since then, we were successful in raising $6.1 million in funding. We are already looking on raising additional funds to the tune of $5million, to take care of clinical trials. Hopefully, we might close this before the end of 2013.