

NewCo News

New Entity AmpliPhi Emerges From Biocontrol, TGEN Merger

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Through a process of business combination, restructuring, refocusing and a change in leadership, the entity formerly known as Biocontrol Ltd., of London, has emerged as a new company based in the U.S. called AmpliPhi Biosciences Corp.

Having shed its prior pursuit of gene therapy, AmpliPhi is developing antibacterial therapies using bacteriophages.

Before the discovery of penicillin, bacteriophages were used to treat infections in millions of patients, but the technology was eclipsed by modern antibiotics and, until now, the benefits were not tested and developed to rigorous clinical standards.

"The company was renamed AmpliPhi, as a play on what phage do when they hit host bacteria. That new company is totally and solely focused on developing bacteriophage for infection," CEO Phil Young told *BioWorld Today*.

AmpliPhi contended that bacteriophage therapy will be the answer to the problem of antibiotic resistance, and the firm recently made a first close of \$2.7 million in its first financing round to advance its products for ear infections and cystic fibrosis.

Founders of Biocontrol looked at many types of resistant bacteria, and settled on *Pseudomonas aeruginosa* as a prime candidate for their first attempt at creating a therapy.

Phase I/II studies in ear infections showed that bacteriophages could overcome bacteria that were resistant to antibiotics.

The study showed a cure rate of just under 30 percent, and an improvement rate of more than 80 percent, for a class of infections that had resisted antibiotic treatment for a very long time.

"These ear infections are chronic infections that people have had for 30 to 40 to 50 years. They are totally resistant to antibacterial treatment," Young said.

The history of bacteriophage as an anti-infective dates back to the turn of the century. Bacteriophages are a sort of virus that invades a bacterium and hijacks its mechanisms to reproduce itself, eventually killing the cell.

Bacteriophages were identified in the environment, and around the turn of the 20th century, scientists in various parts of the world studied them for use as treatments for bacterial infections, with significant success.

Penicillin came on the scene during the second world war, and was hailed as a miracle drug. Bacteriophage fell out of favor, and was eventually viewed with suspicion as systematic, well-documented studies on its effectiveness were never carried out.

Antibiotic "miracle drugs" have lost their shine in an era when drug-resistant organisms appear almost immediately when a new drug is released. There is a widespread and concerted effort to discover new antibiotics to stay a step ahead of rapidly adapting bacteria.

Although there are some promising efforts on that front, AmpliPhi contended that bacteriophage-based therapy may be more sustainable.

When a patient is treated with bacteriophage, the phage directs itself to the infected area, identifies the target bacteria and attacks it, then amplifies itself.

It can break down and break through biofilms of Gram-negative organisms, and it is self-limiting because the phage disappears when the infection is cleared. "It is designed to do one thing, it does that one thing, does it well and goes away," Young said.

It is possible for bacteria to develop some "minor resistance" to bacteriophage over the long term, according to Young, but he noted that phages also have the ability to adapt, a property that antibiotic drugs completely lack.

AmpliPhi's lead product, BioPhage-PA, a liquid phage mix, is at the Phase I/II stage for chronic otitis, and is ready for Phase III trials. BioPhage-PR is another mix that AmpliPhi is developing for *P. aeruginosa* infections in cystic fibrosis patients.

The company is advancing those products first. It also is doing preclinical studies of phage therapies for a number of other infections including methicillin-resistant *S. aureus*, *S. maltophilia*, *A. baumannii* and *C. difficile*, targeting wounds and hospital-acquired infections particularly.

The recent investment round was led by private investors Jim Mellon and Gwynn Williams. The company also has received grants from the Cystic Fibrosis Foundation of America to support clinical trials of BioPhage PR, and from the UK government for natural antimicrobial products for the personal care industry.

Young said the company was oriented toward seeking defense contracts in the future, and has opened its Richmond, Va., facility in part to provide optimal access to Washington for seeking those contracts.

"Phage therapy is applicable across the whole spectrum of what the government is worried about," Young said. "We couldn't do that in the past because we didn't have a U.S. presence." ■