

## City biotech firm closer to goal

Anti-bacterial gel step toward approval of company's enzyme

By: Martin Cash

KANE Biotech is one step closer in its efforts to develop a treatment to unlock bacteria suspended in biofilm that are 1,000 times more resistant than normal bacteria. The Winnipeg company teamed up with a contract manufacturer in Prince Edward Island to successfully make DispersinB Topical Wound Gel.

It is an important step in the ongoing process to get regulatory approval for Kane's technology. The company needs to have a finished product to present to the regulators for ultimate approval before it can become commercially available.

"We are very excited about this," said Kane CEO Gord Froehlich. "This is a major, critical step for us. We now have a finished product that we can use to do a biocompatibility study."

The key component of Kane's technology is the development of a new enzyme that it has shown will prevent and disperse microbial biofilms -- micro-organisms grouped together and stuck to a wetted surface.

Studies indicate that 80 per cent of all human bacterial infections involve biofilms.

Kane's DispersinB has been shown to break down the bacteria locked in biofilms -- making the bacteria much harder to treat with conventional antibiotics -- into individual cells, exposing them to more traditional treatments.

Kane developed its own fermentation process to produce the enzymes and now, in association with BioVectra Inc., it has produced a gel product, not unlike other antiseptic gels, in which DispersinB can be applied.

Froehlich said he expects it will take eight to 10 months to complete the biocompatibility study. When that is done, Kane will submit its full regulatory package to the U.S. Food and Drug Administration and Health Canada.

After that, it will likely need to conduct a clinical trial on human patients.

The company will then start negotiating with potential commercial partners to license Kane's technology.

Kane has already received a ruling from the FDA that will allow it to seek regulatory approval for the gel as a medical device rather than a drug, requiring much less data and testing.

"The successful manufacturing represents a significant milestone in the development of a commercial product," said Dale Zajicek, BioVectra's chief operating officer. Kane's technology is designed to address chronic wound care, an ailment that costs the U.S. health-care system alone \$20 billion annually to treat.

Kane already has a licensing agreement with Harland Medical Systems of Minneapolis to coat urinary and venous catheters with another anti-biofilm compound Kane has developed.

Many biofilm infections originate from contamination related to medical devices.

Kane has not yet started generating any revenue from its products, but Froehlich said it is in a good position to be able to continue to finance ongoing development.

Last week, the company altered a common-share purchase warrant that it sold last year before the collapse of the global equity markets.

The warrants, which were part of an equity offering in February 2008, entitled to the holders to buy one Kane common share for 40 cents until Aug. 28, 2009.

But Kane's share price fell like most of the North American biotech stocks and opened Monday at 12 cents.

As it is very unlikely those 40-cent warrants would be exercised, Froehlich said Kane's board decided to lower the warrant price to 12 cents and extend the period of time for warrant holders to Sept. 21, 2009.

If all warrants are exercised before the deadline, the company would receive gross proceeds of up to \$372,000.

Froehlich said the company will have funds to complete the work it needs to get ready for a likely clinical trial.

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