

Winnipeg Free Press - PRINT EDITION

Challenging U.S. market in biotech firm's sights

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11/03/2010 1:00 AM | [Comments: 0](#)[Enlarge Image](#)

Regardless of how effective Kane Biotech's technology becomes in preventing and removing microbial biofilms, the Winnipeg company ultimately will need to find a way to sell the product in the for-profit U.S. market. At a seminar in Winnipeg this week, Karin Roof, a partner with MedLinX Consulting of St. Paul, Minn., walked Manitoba biotech companies through the complexities of the U.S. marketplace.

Quoting the CEO of a large U.S. medical device company, Roof said whatever direction health-care reform takes in the United States, medical technology will always be in demand.

But, she said, the challenge in the U.S. is that it's not just the public medical insurance system that needs to be sold on the technology; it's also patients, service providers and private-sector insurance companies.

To break into the U.S., market, new medical devices first need to be seen as having high clinical value for patients. (Kane's bacterial biofilm dispersant technology is classified as a medical device.)

Then they need to be issued reimbursement codes from Medicare and Medicaid. That's no different than getting approval from provincial health departments in Canada.

But in the U.S. they also have to hope to get private insurance companies -- the payers -- to buy in, which can be an intensive process.

Then to really establish the product's presence in the market, physicians, clinics and hospitals have to believe it is cost-effective technology before they will agree to use it.

It's important for Canadian companies to remember that in many cases, there is a profit motive behind most of those decisions.

By every measurement, Kane Biotech is a small company. It has about \$1.3 million in assets and burned through about \$300,000 in its last reporting period for the quarter ending Sept. 30, 2009.

It is referred to as a pre-revenue company. But in Kane's case, rather than relying totally on raising risk capital to develop its technology to the point where it will be eligible for regulatory approval for sale in the commercial marketplace, it has established research partnerships with five organizations -- four in the United States and one in Ireland.

"What that allows us to do is to keep going, even during periods of slow cash," said Kane's president and CEO Gord Froehlich.

Like most early-stage medical-device development companies, Kane's shares were dragged down with the market collapse in the fall of 2008 and now trade at around 16 cents.

But even in that climate it was able to raise \$500,000 in December, enough cash to keep its five-employee operation going for another year.

But it is deals like the one announced last September with the U.S. Army's Walter Reed Army Institute of Research in Silver Springs, Md., that fuels optimism that Kane's work will someday be put to use as a health-care tool to treat some of the most challenging infections.

Kane's DispersinB biofilm technology is seen as one of the most promising ways to inhibit and disperse bacterial biofilms.

It is not an antibiotic, but a means to isolate bacteria that get embedded in a gooey film that make the bacteria impervious to traditional antibiotic treatments.

The U.S. Army is looking at developing ways to do early treatment of combat wounds far from field hospitals.

Kane's arrangement with Walter Reed -- as well as three U.S. companies that make hemodialysis, endotracheal and urinary catheters and an Irish company that makes animal catheters

-- means that when the technology is advanced to the stage where it can apply for regulatory approval in the U.S., those partners will be perfectly positioned to work the technology into the commercial stream.

"It also means that we are advancing the technology in many different paths so that if one area slows down, we have another one that might be more active," Froehlich said.

The U.S. market is Kane's primary target and having U.S. partners will be essential for a small company like Kane.


"It's a complicated system and they understand how it works," he said.

For instance, Froehlich is familiar with a U.S. company that developed an innovative wound-care technology that physicians wanted to use and that was effective care for patients, but insurance companies refused to pay for it.

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