

Xenex maps ‘clean’ transition from Russia

Medical device company working to commercialize Russian sterilization technology

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Mark Stibich of Xenex Technologies: ‘Now we’re running with it.’

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Reporter

Russian-speaking infectious disease epidemiologists with some business savvy are hardly a dime a dozen.

So when Alex Goldman, president and CEO of Fair Lawn, N.J.-based AG Group International, needed one to help with a company he’d recently launched, his list was a fairly short one.

Top-of-mind was Julie Stachowiak, who had served as an executive director of an AIDS clinic in Brooklyn, in which Goldman was an investor. The clinic dissolved soon after the Sept. 11 terrorist attacks, and Stachowiak moved to Baltimore to get her PhD from Johns Hopkins University.

Earlier this year, she received a call from Goldman saying he’d obtained the rights to two devices, dubbed ALFA-01 and ALFA-05, that were already being marketed in Russia as the “only effective portable ultraviolet (UV) sterilization systems in the world.” Goldman had started a company called DisinfectPro Inc., which was exploring the retail and commercial aspects of the technology.

For Goldman, it was crucial to get Stachowiak, who had happened to study Russian in graduate school, on board.

“She’s the top of the top in infectious disease,” Goldman says. “If it wasn’t for her, then we’d probably never get to the point where we are now or where we want to be. She would make it or break it.”

By August, Houston-based Xenex Technologies was born out of DisinfectPro, and Stachowiak and fellow Johns Hopkins PhD Mark Stibich had become CEO and chief operating officer, respectively. They also joined the company's board of directors and became part owners of Xenex, which was formed with the specific purpose of bringing the ALFA-01 and ALFA-05 to the U.S. market.

As one of the two firm's employees so far, Stibich admits the company is "still very much in bootstrap mode."

Goldman, who remains CEO of AG Group, is Xenex's primary funding source, although Stibich and Stachowiak have also contributed start-up funding.

CLEAN SWEEP

Stachowiak and Stibich were intrigued with using the sterilization devices for their original purpose of disinfecting noncritical surfaces in hospitals such as door knobs, bed rails and any commonly touched surface.

The pair spent three months of this year investigating the business structure and researching the technology and its potential.

Stachowiak admits to wanting to see the technology in action before committing to anything.

"I wanted to understand how it could be so powerful to do in seconds and minutes what other forms of UV take hours to do," she says. "It was an impressive piece of technology."

Specifically, they found that the technology can kill 99.9 percent of some germs in about 2.5 minutes, and an emerging superbug called Cdiff — more officially known as Clostridium difficile — in 12 to 15 minutes.

The Centers for Disease Control estimates that there are some 2 million hospital-acquired infections every year, costing hospitals some \$30 billion, according to Stibich, who says about 90,000 people die from the infections.

"We can change the world by having these machines at hospitals by guaranteeing people a clean environment," Goldman says. "Instead of going in with one disease and catching another six."

behind the technology

Xenex's devices use high-intensity ultraviolet Xenon impulse lamps to kill airborne and hard-surface pathogens.

Since they can be used with instant startup, or no wait time, the devices have potential for a variety of medical, biohazard and other settings where microorganisms pose a threat to health.

The technology behind the devices is patented in the United States, the Russian Federation and in several other countries. Since being released for use in 2005, hundreds of ALFA-01 and ALFA-05 devices have been used in the Russian Federation, including at oncology centers and The Central Scientific Research Institute of Trauma and Orthopedics.

The technology was originally developed in conjunction with Moscow State Technical University and tested by the Russian National Academy of Sciences and the Russian Ministry of Health.

The manufacturer of the devices, Moscow-based Melitta NPP, is known to commercialize technology and inventions out of Moscow State Technical University, including ALFA-01 and ALFA-05.

“Now we’re running with it,” Stibich says of Houston’s Xenex.

FROM RUSSIA WITH LOVE

Stibich and Stachowiak are performing confirmatory testing on the devices with a focus on ALFA-01 in an effort to validate the Russian data, including replicating the Russian studies and conducting some of their own experiments.

The next steps are to help the manufacturer convert the products to operate on 110V for American standards, as opposed to the current 220V. Also, the firm is hoping to get a product safety mark on the devices by early 2009 so it will be accepted by Occupational Safety and Health Administration.

The long-term goal is to get U.S. Food and Drug Administration clearance to market the devices for use in operating rooms and on critical surfaces, but Stachowiak says such clearance isn’t needed to start basic operations in patient rooms.

Simultaneously, the pair is working on finding partnerships to validate technology and to reach out to distributors.

“We need a bigger-name partner with experience bringing medical devices out to market,” Stibich says. “For us to attempt to do that alone would be overwhelming.”

Xenex also hopes to convince Melitta to move the manufacturing of the devices to Houston.

Deborah Mansfield, director of the Houston Technology Center’s life sciences program, says companies usually have to work over a longer time period before getting as close to commercialization as Xenex, which recently became an HTC client.

“Since the technology is already utilized in Russia, we have earlier-to-market upside with Xenex Technologies,” she says. “We feel that their entry here in the U.S. market should be fairly streamlined. I’m excited about that.”