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Sequella tackles TB epidemic

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by Steve Berberich
Staff Writer

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Biotech starts with diagnostic improvements

"Shorter, faster and better" are the keys to solving the global epidemic of tuberculosis, says Carol Nancy, CEO of Sequella Inc.



Nancy

The Rockville company is emerging as a leader in developing new TB tools to shorten the time for diagnosing TB, to get patients back on their feet faster, and to make drugs that work better.

Nancy launched Sequella in 1998 to fight global infectious diseases with biotechnology. Already, the small biotech's "drug and diagnostic program is considered to be quite good," says Christine Sizemore, acting director of TB grants program at the National Institute of Allergic and Infectious Diseases, part of the National Institutes of Health.

The concept for Sequella popped into Nancy's head in 1996 when she was "astonished" by statistics on the expanding TB epidemic. Nancy had taken three days off from her job as executive vice president of EntreMed Inc. in Rockville to be on an expert panel at the NIH to review achievements of its tuberculosis grants program.

"How long will this take?" I thought," she now jokes, as TB was under control in the United States by the 1960s. "Then, I learned there was this huge unmet medical need that I did not even know about. If I did not know about it, as an infectious disease immunologist, then most people didn't know about it."

According to the NIH and the World Health Organization, TB is the No. 1 infectious disease killer in the world, with 8,000 deaths each day. Each infectious or contagious TB patient spreads it to 10 to 15 other people every year he remains untreated. Ten percent of those people will become contagious within two years contracting TB.

At the time of Nancy's three-day "sabbatical" from EntreMed, co-infection of HIV/AIDS patients with TB was just coming to light. Today, TB is responsible for 40 percent to 50

Started Sequella in 1998

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HIV infection at 1.4 million worldwide.

Nacy was again astonished when she realized that NIH grant researchers in 1996 were working with drugs that were 50 years old and diagnostics that were 100 years old. Globally, an additional 500,000 people a year were being infected, and there was a mini-epidemic of TB in New York City.

Unlike most biotech companies that are built on a scientific idea, Nacy says, Sequella is built on a disease. The first priority for slowing the TB death train, she says, is earlier diagnosis. She wants to earmark the company's first venture capital funds, expected later this year, toward marketing a diagnostic skin patch that looks like an ordinary Band-Aid.

Sequella's diagnosis patch is in phase 3 clinical trials in Peru. The company describes it as the world's first diagnostic that can distinguish between active infectious TB, latent TB and prior TB vaccination. "The epidemic will never be under control until we get a diagnostic out there that can accurately detect active TB before a person becomes infectious," Nacy said.

The sick are fueling the epidemic because the disease is currently diagnosed only after someone is out of work and drags himself into a clinic for treatment, she said. "Then they have very infective TB and there is no screening technique that can be used."

She said Sequella chose to focus its efforts first on development of an accurate diagnostic for TB because "we cannot effectively develop a drug for the treatment of TB without being able to easily and precisely diagnose this disease."

She said the familiar label of "disease of the poor" no longer fits TB. In India, for example, the disease is rampant among the 350 million people in the middle class, most of whom can pay for their own treatments in the private sector.

"A better label would be, 'TB is the disease that creates the poor,'" Nacy said. It takes six months to diagnose TB, and six to nine months to treat. "That means you are out of work as a breadwinner. And you are paying for your treatment."

So far, Sequella has raised \$15 million in research grants, many of which are for specific pieces of the company's diversity of TB products, including the following:

*TB drugs developed by Sequella in-house using NIH grants. The company has compiled a library of 200,000 different compounds that might work on TB and found about 30 that show controlling effects on TB. The company is taking one of them to clinical trials, which has a synergistic effect of accelerating current TB treatment drugs.

*A two-day device to specifically diagnose the disease and evaluate drug resistance of TB. An underlying reason for a high incidence and death rate for TB is that TB-causing bacteria develop resistance to anti-tubercular drugs. The new device is designed to identify the exact strain of TB in each patient and better target therapy.

*A wristwatch-like device that can monitor whether patients have been complying with their treatment regiment.

*Vaccine preclinical studies in cooperation with researchers at the National Institute for Medical Research in London. To move commercialization along, Sequella is working with Cobra Therapeutics in the United Kingdom, a leader in manufacturing DNA vaccines. "A therapeutic TB vaccine would shorten drug therapy and reduce emergence of drug-resistant TB," according to Sequella's Web site.

In the late 1990s Nacy, along with co-founder and EntreMed colleague Leo Einck, plus a few others, invested the first \$600,000 into the new company.

"We walked through the process of learning about the culture of the disease to find where the bottlenecks are" by visiting researchers and TB hospitals in Ethiopia and South Africa. Then they visited with university TB researchers in the United States and officials with the Maryland Department of Health and Mental Hygiene to find technologies that were ready for development, to help shorten the diagnostic and treatment processes. The company got its first Small Business Invention Research grant from the U.S. Small Business Administration in 1999. It has 13 employees.

Currently, investment companies are conducting lead due diligence on Sequella, Nancy said. The company also has a working relationship with a large pharmaceutical company to guide its products through regulatory processes in the 165 countries where it sells its drugs, she said, while declining to identify the partner.

In five years, Nancy wants Sequella's diagnostic patch to be "everywhere."

If so, "we should begin to see treatment of people earlier and easier and the ability to get rid of that reservoir of people for that next phase of the epidemic. With that you will see the sales of the drugs go up. With the new diagnostic you will see the epidemic level off and go down. Getting the new diagnostic out will be the No. 1 thing we can do globally."

NIH's Sizemore said NIH provides TB research funds to a consortium of academic and commercial laboratories. In Maryland, that includes Sequella, Aeras Global TB Foundation, Johns Hopkins University's Bloomberg School of Public Health and the Institute for Genomic Research in Rockville.

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