

HEALTHY LIVING

FEAR factor

When combined with therapy, D-cycloserine 'extinguishes' terror

BY BILL HENDRICK
Cox News Service

You're in a staff meeting of 150 people and all of a sudden, the boss does what she's never done before — asks everyone to get up and introduce themselves. You're terrified. When it's your turn, your voice quivers.

Or you're so afraid of flying that even the sight of a big jet up close sets your heart to racing.

Or the mere thought of stepping into an elevator makes you huff up eight flights of stairs.

Most likely, with any of these symptoms, you're one of 40 million Americans with an often debilitating anxiety disorder that could make it tougher for you to climb the corporate ladder.

But here's some good news: an Atlanta biotechnology company is planning to market a drug within a few years that has been shown to extinguish such fears, or at least to make them easier to handle.

The capsule has had Food and Drug Administration approval for more than 50 years as a treatment for chronic tuberculosis. But recent research has found that it does something else — it "extinguishes fear" if taken before only a few sessions with a therapist, and the response comes faster and seems to last.

Harold Shlevin, chief executive of the Tikvah Therapeutics biotechnology firm and former CEO of Solvay Pharmaceuticals USA, says that when the drug D-cycloserine hits pharmacy shelves as an aid in the treatment of anxiety disorders, it could bring in

at least \$1 billion a year in the United States.

That has raised more than eyebrows on Wall Street — where venture capitalists are always on the lookout for the next Viagra.

It also has raised more than \$15 million in financing for Tikvah.

Shlevin says he's seeking at least \$25 million more. The money is needed to fund research to win FDA approval.

Big-time investors take chances on ideas — and make fortunes when they pan out.

Dr. Russell Ellison, an executive with the New York-based Paramount BioSciences venture capital firm, says 85 percent of people with anxiety disorders will see a doctor once a year, and D-cycloserine appeals to patients because it doesn't require prolonged psychotherapy sessions. Rather, several studies have shown that taking a single dose of the drug before just three or four sessions of exposure therapy can "teach" social phobics that they had nothing to fear after all.

Exposure therapy can take several forms. Often, therapists take patients on elevators or on airplane flights to teach them that their fears are irrational. This often takes a lot of time and is costly.

With D-cycloserine, also called DCS, the cost would be much cheaper.

The drug is being used now in studies at Emory University in Atlanta on war veterans with post-traumatic stress disorder.

"It works pretty well," said Dr. Barbara Rothbaum, director of the Trauma and Anxiety Recovery Program at Emory's School of Medicine. "We're going to see untold thousands of Americans from Iraq and Afghanistan with PTSD in coming years."

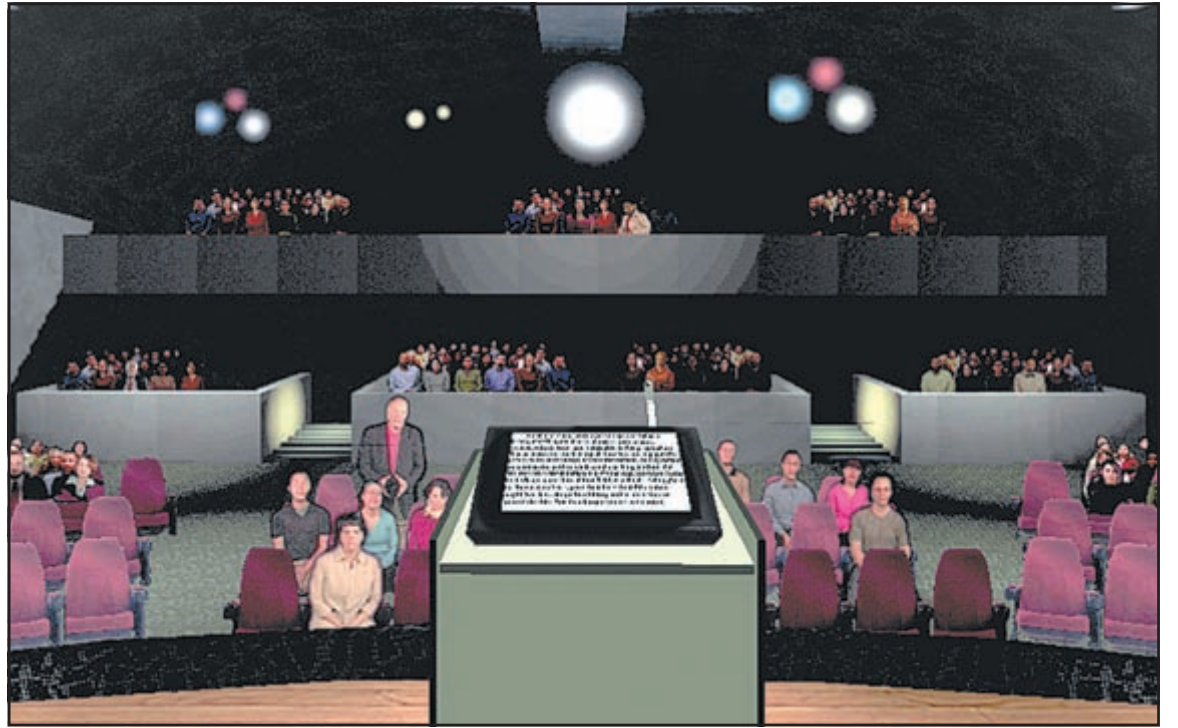
DCS does nothing "in and of itself," but together with exposure therapy, it teaches the brain not to be fearful in previously terrifying situations, she says.

"This could be huge," said Rothbaum, who stands to gain "a little" from her stake in Virtually Better Inc., the Decatur, Ga., firm that creates many virtual environments, such as elevators, jet planes and combat. "Think of people who can't go up on ladders or are afraid of driving over Spaghetti Junction (a series of cloverleaves where major interstate highways merge in metro Atlanta)."

Georgia's fast-growing biotechnology industry is excited about Tikvah and other firms on the verge of hitting it big, says Mike Cassidy, president of the Georgia Research Alliance. He adds that the industry already accounts for more than 15,000 jobs, a payroll of close to \$1 billion and \$7 billion in revenues. He says the "life-science sector is emerging as an important component of Georgia's economic landscape."

Charles Craig, president of Georgia Bio, a biotech partnership, says that many companies already have gone public. New drugs often pay off handsomely, which is why they attract venture capitalists, as has Tikvah.

"Think about a person afraid of dogs," Ellison said. "With DCS and virtual reality, the fear is reduced, and what's intriguing is,



VIRTUALLY BETTER INC.

Scared of public speaking? A medication that has been around for more than 50 years is showing potential as an anti-anxiety drug that should be marketed within a few years.

it could be a long-lasting response. FDA has to approve Tikvah selling it for this purpose, but we don't think that's far away. With regular therapy, drugs have to be taken daily, often indefinitely, and just reduce the symptoms associated with the fear, and these can return as soon as the drug is stopped, but not with DCS."

Right now, 90 percent of Tikvah is owned by Paramount. Shlevin, a vice chairman of Georgia Bio, owns 7 percent, and the rest is owned by others in Tikvah, which means "hope" in Hebrew.

It signed a licensing agreement with a drug-development company, Therapade Technologies, founded by Emory researchers Drs. Michael Davis and Kerry Ressler, plus Jason McDevitt, now at the College of William & Mary.

Tikvah has worldwide rights to commercialize DCS for the treatment of mental illnesses. Therapade's scientists have no ownership in Tikvah but stand to gain financially from their licensing agreement if the biotech firm hits the jackpot.

Rothbaum is now using a "Virtual Iraq" that transports veterans back to the war. She still is recruiting volunteers, but she says DCS treatment appears to be highly effective after only a few sessions in the virtual war zone. She presented some results recently at the American Psychiatric Association's annual convention in Washington. Shlevin says the potential market is enormous.

Discovered by Eli Lilly, DCS is used

mostly in the developing world because it's cheaper than newer antibiotics. Michael Otto, director for anxiety and related disorders at Boston University, says sales also could boom in the developed world.

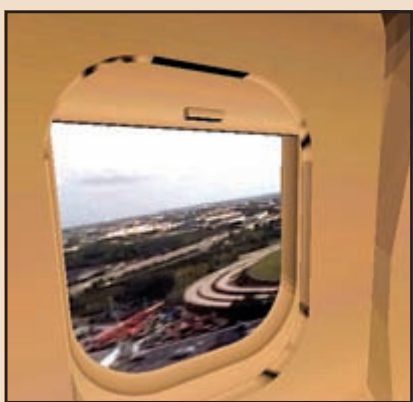
Davis, who became fascinated with DCS more than 10 years ago, found in experiments on rats that animals given low doses of DCS lost their fears more often than those that received training alone. Rothbaum thinks the recent discoveries constitute a breakthrough because other anxiety drugs either wear off quickly or are addictive.

Shlevin says DCS without exposure therapy doesn't work.

"The VR (virtual reality) is one of many forms of exposure therapy," he said. "We are doing large-scale clinical studies to get the product approved for this use. We expect approval in two or three years. The evidence is overwhelming. And we're just beginning early discussions with the U.S. military because they think it could ease horrific battlefield exposures."

He says Tikvah wants to get the drug on the market, then take the company public. First, there will be two clinical trials at 30 sites across the country, each costing about \$15 million, with 300 people either taking DCS or a placebo. If the results are positive, it will go to drug stores, and then its stock to Wall Street.

Shlevin says the "potential of this drug's use could represent a great opportunity for investors." ■



VIRTUALLY BETTER INC.

Many people are so afraid of flying, they will drive long distances if travel is necessary.

Nothing to fear, but many do

People fear public speaking more than they do death, said Dr. Rick Winer, a Roswell, Ga., psychiatrist, who says he is asked all the time for a cure.

He is also asked by patients to help them get over their fear of flying or of being stuck in an elevator.

"People don't want to go to restaurants if they're at the top of hotels," he said. "And one patient is so fearful of flying, he'll drive all the way to California."

He's not sure any drug can be a cure-all. But he says phobias are common among his patients, and medications are often in order.

Anxiety phobias run the gamut. Some people are deathly afraid of spiders, cockroaches, open spaces, subways, feathers, pigeons, and many are afraid of leaving their homes for fear they'll run into strangers.

Nervous Nation

- 40 million Americans have anxiety disorders
- 6.8 million Americans have generalized
- 2.2 million Americans have obsessive-compulsive disorder
- 6 million Americans have panic disorder
- 7.7 million Americans have post-traumatic stress disorder
- 15 million Americans have social-anxiety disorder
- 19 million Americans have specific phobias (like fear of spiders)

