

New Letctin Labs products come from this laboratory



# Carson City biopharma firm using botanical products to take on infectious diseases

## Legere Pharmaceuticals prepares rollout of over-the-counter powder

Mike Sion, correspondent

Legere Pharmaceuticals Ltd. based in Carson City has a breakthrough product aimed right at consumers' guts.

More specifically — at the frequent culprit of chronic stomachaches, including the piercing pangs of indigestion, ulcers and worse:

*Helicobacter pylori* — a form of bacteria experts believe causes most of the upset stomachs or gastritis among the estimated 60 million cases a month in which Americans take something to relieve a constant bellyache.

Legere (which is doing business as Lectin Labs Ltd.) has developed an over-the-counter powder, NutraLec, based on proteins known as lectins naturally found in most plants and animals (in NutraLec's case, wheat). Lectins are weapons against *H. pylori* (as it is more commonly called by scientists), which seems to be quite the terrorist among human pathogens.

*H. pylori* (pronounced pie-LOR-ee) was discovered in 1983 by two Australian researchers. Until then, scientists believed that stress, poor diet or too much alcohol caused ulcers. Now researchers know that *H. pylori* is the culprit, and that chronic infection can lead to stomach cancer — which trails only lung cancer as the most fatal human malignancy on the planet, according to the World Health Organization.

*H. pylori* thrives in the stomach's highly acidic environment, colonizing and spreading and ranks as the most common human pathogen in the world. *H. pylori* infects half of all Americans and two-thirds of the world population, according to the WHO and the U.S. Centers for Disease Control.

The market for a product such as NutraLec would seem to be huge. Lectin Labs has been developing the anti-pathogen since 1992 and set up shop in Carson City in 1996. Carson proved to have the best price for land and facilities compared to next-door California, Reno

and Sparks, says Howard C. Krivan, company president and chief scientific officer.

The company has filed for patents on NutraLec and now is bringing it to market. The first order for bulk shipments to a distributor — which will sell the powder to retailers, who will package the supplement under their own brand names — is expected by October, says company chairman/CEO Bruce F. Rose. NutraLec will hit northern Nevada store shelves before the end of the year, offered either in pouches or plastic bottles, Rose says. Consumers — either on their own in response to chronic stomach troubles, or on the recommendation of their physicians as an alternative to prescribing antibiotics — are directed to take 20 grams daily of the powder, mixing it in tea, water or other beverage to absorb NutraLec's mildly mocha-like taste.

Rose and Krivan are two of three officers in the company, which has six full-time employees at its 10,000-square-foot facility at 3123 Research Way. There are corporate offices, laboratories and a pilot plant to produce NutraLec and a range of other lectin-based products the company is in various stages of developing.

The officers bring a range of experi-

ence to the company:

- Rose, with 40 years in the pharmaceutical/healthcare industry, help led two companies — VLI Corporation, Inc. (maker of the TODAY contraceptive Sponge) and UltraFEM, Inc. (maker of the INSTEAD Female Sanitary Protection Device) — each to \$100 million capitalization and listing on the Nasdaq.

- Krivan is a microbiologist with an extensive résumé in the public and private sectors. He was a staff fellow at the National Institutes of Health. He also founded the vaccine-maker MicroCarb, Inc. (now called Antex Biologics, Inc.) and helped lead it to an initial public offering. Krivan holds 14 U.S. patents.

- Richard C. Potter, executive vice president/chief operating officer, is a chemical engineer who developed such products as the No-Pest Strip and the Hartz Flea Collar.

Legere plans to package and market NutraLec under its own label in addition to meeting orders for a distributor with whom Legere has signed a multimillion-dollar contract to last three to five years.

The company forecasts \$80,000 in sales of NutraLec in 2002, \$2.5 million in 2003 and \$36.8 million by 2006.

"The global marketplace for NutraLec is estimated to be in excess of \$5 billion and consists of 5,500 U.S. health food stores, 55,000 U.S. pharmacies, mass merchandisers such as Wal-Mart, network marketing companies, e-commerce and international retail outlets," Rose says.

The company expects to have up to 50 full-time employees by 2006 — the same year Legere anticipates U.S. Food & Drug Administration approval of a far more advanced form of NutraLec to be available by prescription. The current

Someone suffering an upset stomach — perhaps after eating at a restaurant — may reach for an over-the-counter product such as Tums or Zantac. But recurring pain should signal a trip to a physician for a test to reveal whether *H. pylori* is in a patient's stomach, Krivan says. And those who suffer gnawing gastritis may suspect that the bacterium is at work and seek to medicate themselves with NutraLec without initially seeing a doctor, he says.

The battle between lectins and *H. pylori* is conducted on the molecular level. Carbohydrates bristling with various chemical receptors cloak living cells. The receptors bind with different molecules to transfer chemicals that keep the cell alive. *H. pylori* and other pathogens have surface proteins that can attach to a cell's receptor and wreak havoc. That beachhead is the beginning of a battle that can result in infection that can spread to other cells.

Lectins, however, can bind with and destroy many types of pathogens, such as *H. pylori*, and thus ward off disease.

Not only is reaching for a bottle of Maalox not a cure for the cause of indigestion or ulcers (as opposed to the symptoms), but even mega-doses of antibiotics aren't always effective, since *H. pylori* is known to resist certain antibiotics, Krivan says.

Legere also is developing a range of microbicides (bacteria-killers) to use in pharmaceuticals or over-the-counter nutraceuticals to treat skin disorders such as acne and body odor, digestive ailments and sexually transmitted diseases.

"The company has several core technology-based products in varying degrees of the development," Krivan says. "The company intends to introduce other

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version falls under the federal Dietary Supplement and Health Education Act as a supplement, and did not need FDA approval, Rose says.

Clinical trials have shown that NutraLec relieves stomach pain and also arrests the infection of *H. pylori*, Krivan says. This means that NutraLec should be taken daily — as with standard vitamins and mineral supplements — by those who suffer from frequent gastric discomfort. Depending on the retailer's price, NutraLec can cost \$20 to \$50 a month — far less expensive than an antibiotic treatment, Krivan says.

nutraceutical, dermaceutical (skin care-based) and RX products. For example, lectins have been found to specifically target bacteria that cause acne and body odor; lectins also have been found to arrest infection of the Type I herpes virus, which is responsible for cold sores. And a vaginal microbicide is under development to prevent STDs in women, such as chlamydia, gonorrhea and HIV/AIDS," he says.

"This lectin technology has endless applications in fighting microbial disease — and the company has a long pipeline of exciting product opportunities."



Legere Pharmaceutical works from this building at 3123 Research Way in Carson City.