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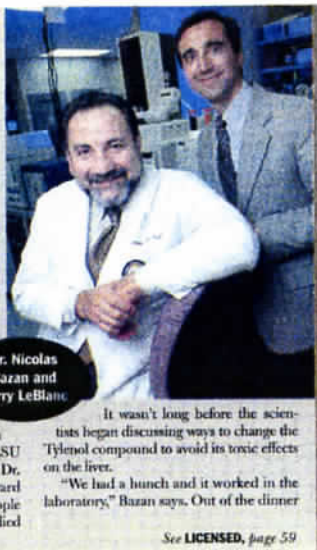
Licensed to deal

A pharmaceutical start-up takes its first steps toward cashing in on its years of research

By Chris Bonura Staff Writer

IF NEW ORLEANS is able to translate research at its two medical schools into a booming new pharmaceutical industry, it may owe a debt of gratitude to Spain.

A compound that start-up drug company St. Charles Pharmaceuticals hopes to develop into a drug was conceived at Lorenzo, a smoke-filled restaurant in Madrid known for its Galician cuisine. In September 1992, two chemists from the Universidad de Alcalá, Julio Alvarez-Bullón and Carlos Sunkel, were having dinner with LSU Health Sciences Center neuroscientist Dr. Nicolas Bazan. Talk gravitated toward European headlines: Some young people in the United Kingdom had recently died by overdosing on alcohol and Tylenol.



Dr. Nicolas Bazan and Barry LeBlanc

It wasn't long before the scientists began discussing ways to change the Tylenol compound to avoid its toxic effects on the liver.

"We had a hunch and it worked in the laboratory," Bazan says. Out of the dinner

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grew a collaboration between the Universidad de Alcalá and the LSU Neuroscience Center of Excellence, which Bazan chairs.

The collaboration culminated in the patent of a new class of analgesics or anti-inflammatory pain killers, as well as a patent that protects the process for making the new compound and prevents other researchers from marketing slight variants.

Last month, the Foundation for the LSU Health Sciences Center (formerly LSU Medical Center), which held the patents, licensed them to St. Charles Pharmaceuticals, a start-up company founded by Bazan. So far, he and two other executives have provided the capital to get the company started. Terms of the licensing deal have not been disclosed.

St. Charles Pharmaceuticals has negotiated with the foundation to have the right of first refusal for other discoveries that come out of collaboration between Alcalá and LSU. The pharmaceutical company is now bargaining with the foundation for the second

discovery to come out of the collaboration, a compound that Bazan believes will prevent brain damage in people who experience trauma.

The start-up is a welcome sign for some who hope New Orleans can use discoveries at Tulane University Medical Center and LSU Health Sciences Center as a new economic engine.

Discoveries can lead to lucrative licensing and royalties deals for the universities if they sell to major pharmaceutical firms.

"When a new compound goes to a big pharmaceutical company, in most cases the product gets killed. It certainly moves outside of the state," says Barry LeBlanc, chief administrative and financial officer for St. Charles Pharmaceuticals. LeBlanc, the former chief executive officer of eye care products company Akorn Inc., also is an investor in the new company.

Pitfalls of licensing

A lawsuit between Tulane University and Swiss drug company DelphiPharm reveals some of the difficulties a university can encounter when it licenses its discoveries. Tulane is suing DelphiPharm for \$380 million, saying that the drug company did not meet its contractual obligations to introduce in the U.S. an anticancer drug discovered at Tulane. That diminished Tulane's ability to cash in on royalties, which are usually the most lucrative part of the licensing agreements.

Carla Fishman, Tulane's director of research, administration and technology development, says the experience with DelphiPharm does not mean that the school automatically favors start-ups over licensing deals. Both situations have their pitfalls, she says.

"You have to look at what is the best shot of getting it to the marketplace," she says.

The difficulty of raising capital can complicate start-up companies, says Louis Berneman, president of the Association of University and Technology Managers.

"There is no question that start-ups have a risk that is far greater than licensing agreements with major companies for development," he says.

However, start-ups may be a better choice

if the research could lead to an entire platform of products, if the research is "too embryonic," if the faculty researchers have entrepreneurial ambitions or if the university has an economic development agenda.

Economic ripple

Berneman, who is a technology transfer manager at the University of Pennsylvania, says 79% of research-driven start-ups stay in the state where the research originated.

In the new technology- and information-based economy, political and business leaders are realizing the value of university research and encouraging researchers to develop their ideas into products, Fishman says.

Kevin Reilly, secretary of the state Department of Economic Development, acknowledges that the "painfully slow" process of getting Food and Drug Administration approval means slow starts for new drug companies. Nevertheless, he's excited about the possibility of bringing new business to the state through discoveries at its medical schools and universities. His office has been targeting the pharmaceutical industry.

"We want to help in any way we can on the state level," Reilly says.

There was never any question in Dr. Bazan's mind that he wanted to develop his discoveries in New Orleans. He says he wanted to make sure that his adopted hometown had the economic benefit he believes his discoveries will lead to.

"I've been in New Orleans for 19 years. I came from Argentina. I have grown effective roots and feel I belong here," he says.

"We don't have the culture of start-up companies (in Louisiana). In a way it is difficult to be the pioneers, but it's nice to be able to contribute," he says.

If Bazan's drugs receive FDA approval, they may have a wide market waiting for them. Bazan says the analgesic would be a good pain treatment for children, the elderly and those who suffer chronic pain because of its low liver toxicity. Because the analgesic does not reduce fever, it may be more appropriate for use after surgery, Bazan says. Post-surgery fever is often a sign of infection; therefore, it is preferable to have a painkiller that won't mask any signs

which indicate whether the patient is having a recovery problem.

The second compound the researchers have hit upon arises out of research that Bazan has done on a "chemical cascade" — a series of chemical reactions common to many forms of brain cell death, such as trauma, Alzheimer's disease, stroke and epilepsy.

Bazan says he and his collaborators in Spain have found a compound that stops the cascade. They have not yet received a patent for their discovery. Bazan envisions a time when the drug will ride aboard every ambulance so that it can prevent brain damage in people injured in car crashes.

Tough tests ahead

Both the analgesic and the anti-trauma compound have a long road ahead, though, to make it to the corner drug store. First, they must go through preclinical trials on animals to establish their safety and efficacy. That helps researchers win "Investigative New Drug" status for their discovery.

Next, the research enters a three-phase clinical trial process, during which it is tested on humans throughout the country. It's an arduous and expensive process, but if all goes well, the drugs win FDA approval.

Now that St. Charles has received the license for the analgesic, LeBlanc says his first priority is to nail down capital to get the clinical trial process in gear. He says he will target venture capitalists and "angel investors," individual investors who see the value in developing the drugs and a local pharmaceutical industry.

LeBlanc says leaving a locally based start-up ensures the funding for the clinical trials stays close to home. "A large portion of the funds go back to LSU, paying the salaries of the very people who worked on this," he says.

St. Charles Pharmaceuticals' ties with LSU also give it a boost in the pharmaceutical industry because it doesn't have to make the investment in laboratories.

"It's very efficient," LeBlanc says. "We don't have to have a facility. It allows our company to get started without bricks and mortar."



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THE BUSINESS NEWSPAPER OF METROPOLITAN NEW ORLEANS

DECEMBER 4, 2000

Local investor puts \$4 million into fledgling drug company

By Chris Bonura Staff Writer

NEW ORLEANS BUSINESS and medical leaders have lately preached the wisdom of developing a local pharmaceutical and biotechnology sector rooted in research conducted at Louisiana State University and Tulane University medical centers. Last week, a local investor kicked the effort into gear by making a \$4 million commitment to a pharmaceutical start-up.

Koerner Capital Corp. invested the money to bring St. Charles Pharmaceutical Inc.'s low-toxic painkiller through the pre-clinical trials that precede the long Food and Drug Administration approval process.

Koerner Capital is a company owned primarily by John Koerner III, the executive known for brewing up a national market for Barq's root beer and selling it to the Coca-Cola Co. Koerner has invested in other medical technology companies located outside of Louisiana. His company will gain an undisclosed equity stake in St. Charles Pharmaceuticals with the capital investment.

He says there is ample opportunity to make money and grow jobs from the drugs and therapies that New Orleans' best doctors are concocting in their research labs.

"I'm going to continue to do more of this, if I don't run out of capital first," he says.

Koerner says usually a medical technology sector develops around the periphery of medical schools, but that hasn't happened yet in New Orleans. Nevertheless, he thinks the quality of the Crescent City's two medical schools, some of the genetic features of Louisiana's population and a lifestyle centered on eating and partying prime the city for medical research.

Koerner says he has been keeping an eye on cancer and genetic research at Tulane Medical Center.

St. Charles Pharmaceuticals is a company started by Dr. Nicolas Bazan, director of LSU's Neuroscience Center. The Foundation for the LSU Health Sciences Center has licensed to the company the patent that it holds for a series of compounds that Bazan and a chemist from Spain designed as an alternative to Tylenol and other analgesics. Bazan and Julio Alvarez-Builla of the Universidad de Alcalá designed the compound to avoid the toxic effect on the liver that most analgesics have.

Some analgesics are not ideal for after-surgery pain relief because they reduce fever, which can be an important sign that a patient has a surgery-related infection. If a patient is developing an infection, doc-

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tors and nurses need to know about it so they can treat it. Bazan thinks his compound could fill the after-surgery pain relief niche because it doesn't mask the indication that infection could be setting in.

"We need this type of pain reliever at patients' bedsides," Bazan says.

St. Charles Pharmaceuticals has the right of first refusal to license other discoveries that arise from the collaboration between Bazan and Alvarez-Builla. Koerner says he is investing in Bazan as

"Once this becomes successful, people are going to start looking at us. You need to gradually build these things," he says.

Barry LeBlanc, chief administrative and financial officer for St. Charles Pharmaceuticals, says the financial backing from Koerner will fund the testing on animals that is required before the FDA allows clinical trials on human volunteers to proceed. These pre-clinical trials are done in laboratories that specialize in this kind of research. LeBlanc says St. Charles Pharmaceuticals is in the process of choosing a lab.

"This will allow us the funds to submit

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well as the new pain killer. "I'm betting on Nick, the man. I'm investing in a pipeline for fresh ideas that will come out of his collaboration."

Bazan says he is focusing his research attention on ailments that lead to blindness, such as strokes and retinitis pigmentosa, an inherited disease that causes the retina to deteriorate.

LSU Health Sciences Center Chancellor Merv Trail says the infusion of venture capital in St. Charles Pharmaceuticals speaks to the quality of Bazan's research. He hopes St. Charles will become a model for more companies that arise from research at New Orleans' medical centers.

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an investigational new drug application in an 18-month time period. If approved, that will allow us to proceed in the human clinical trials," LeBlanc says.

During that time, the company will decide which of several similar compounds that it has a license for under the agreement with LSU offers the most promise as a low-toxicity analgesic.

LeBlanc says once St. Charles Pharmaceuticals gets the go-ahead from the FDA, it will look for a large drug company to partner with to help bring the drug through clinical trials. ■