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Genetic Roadmap Targets Drug Therapies

Genomas Among Pioneers Of New Personalized, Medical Approach

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Twenty people diagnosed with diabetes are prescribed the usual medications to help them manage the debilitating disease caused by irregular blood sugar.

But it's those four patients in 20 who don't respond, or who experience severe side effects, which leaves physicians scratching their heads. Typically, different drugs are prescribed in various combinations and doses in hopes of eventually finding one that works — a time-consuming exercise that delays the patient's recovery and runs up their or their insurer's prescription bill.

It's into that hit-or-miss void in patient care that has motivated Hartford medical entrepreneur Gualberto Ruaño and his latest research venture, Genomas Inc.

Ruaño, along with two Connecticut hospital partners, Puerto Rico's leading medical school and National Institutes of Health, the nation's top backer of disease research have poured about \$10 million into Genomas to discover a tool — a genetic roadmap — that may be the key to future medical treatment.

The Puerto Rico-born physician, who struck gold when his previous Connecticut company, Genaissance Pharmaceuticals of New Haven, went public a decade ago, is confident his newest venture can be the long-sought breakthrough that moves today's random drug therapy into tomorrow's more precise, personalized treatment of human ailments.

"This is a new industry," said Ruaño, who is CEO and chief-of-almost-everything-else



PHOTO/STEVE LASOHEVER

Gualberto Ruaño and his latest research venture, Genomas Inc., have developed software that analyzes patients' DNA samples to identify proper medications and doses.

at Genomas, sitting in his office inside a non-descript lab at Hartford Hospital, where he also directs the hospital's genetics research. Hartford Hospital is one of Genomas' financial backers.

"The future is bright," Ruaño said. "What will happen over the next five years makes us very optimistic."

The work of his 10-member team revolves around one central question: What drug or drug combinations in the proper doses are most effective for those patients whose biologies don't respond to treatments designed for the average patient.

To get at the answer, Genomas attacks the equation with two operating labs. One is a state-licensed clinical facility doing real application of its proprietary PhysioType genetic prescription technology on hundreds of patients — partly to prove it has a market.

"Investors will only listen to you if you can

show them that you can be self-sufficient," Ruaño said.

In 2009, two years after the first commercial launch of its PhysioType examinations, Genomas will do an estimated 800 tests for drugs to treat diabetes and mental debilities such as depression and bipolar. Each test, which costs \$400 to \$500 and qualifies for Medicare and Medicaid reimbursement, can assess the efficacy of 24 of the most commonly prescribed brands and their generic equivalents that account for \$50 billion in annual sales, Ruaño says.

The other lab is involved in esoteric research led by Ruaño to broaden the scope of its discoveries to even more drugs and patients.

In Genomas' understated lab nestled in a brick building in the shadow of Hartford Hospital, computers and technicians are on the

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frontline of Rúaño's research and product development. It is the company's genotyping process and proprietary mathematical-modeling software that crunches and analyzes patients' DNA samples, searching for any one of 31 key markers that translate to how a particular body metabolizes — or doesn't — certain drugs.

Equipped with the baseline information, Genomas can extrapolate a patient's potential response to certain drugs, helping the doctor pinpoint the most effective course of treatment right away.

"The concept he's selling is the right drug the first time," said Rochelle Long, who administers grants to researchers such as Rúaño for the National Institutes of Health.

That concept, Long said, is what drew NIH to fund in August the final phase of a three-year, \$5 million grant to promote Genomas' work in the emerging field of "pharmacogenomics" — using genetic research to understand the human response to medicines.

"It's a bona fide field," Long said, adding that Rúaño in particular stands out. "He's much more uncommon because he's also trying to bring his product to market."

So far, Rúaño has developed two products — one for devising genetics-based treatments for diabetics, the other for patients suffering mood disorders.

In the case of the patients with such mood disorders as bipolar or depression, Genomas has assembled, with the aid of about 90 mental-health clinicians statewide, a genetics and treatment database of 6,000 patient-volunteers. Using that information, Genomas is able to predict how a new patient will respond to a treatment based on his or her comparative genetic makeup.

The best part, Rúaño says, is that those calculations grow more accurate with each patient profile added to the database.

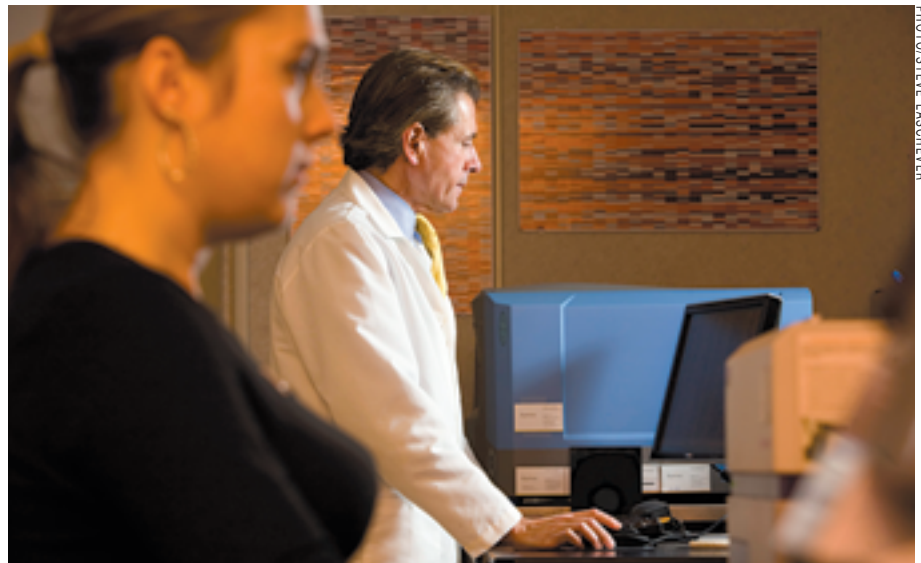
South Windsor psychiatrist Dr. Lori Calabrese says her patients often are leery of psychiatric medications because they automatically assume they'll suffer the side effects — weight gain, jitteriness, insomnia, etc. — they've heard or read about from the drug. Calabrese said Genomas' tests help her reassure them the drug will help but not hurt them.

"This is the most exciting development in psychiatry in the past 20 years," she said. "The ability to plumb genetic information for a given patient and use that information to guide the choice of appropriate treatment.

"I really think this is the direction we're moving in medicine," Calabrese adds.

▶ **'The concept he's selling is the right drug the first time.'**

Rochelle Long, grant administrator, National Institutes of Health.



PHOTO/STEVE LASCHER

Gualberto Rúaño, pictured at right, has attracted about \$10 million in his latest research venture, Genomas Inc.

Dr. Paul Thompson, the director of cardiology at Hartford Hospital, said Genomas' research into blood-related illnesses has yielded another new testing product.

For example, patients respond differently to blood thinners, such as Coumadin (warfarin), said Thompson, who also is a researcher. With a Genomas test, physicians can immediately implement the right drug and dosage, he said.

"To remove worry in life is the best thing a physician can do," Thompson said.

While research funding is one leg of Genomas' financial underpinnings, so are sales. Rúaño declined to reveal the private company's annual revenue, but earlier this year the company hired a full-time salesperson to market the PhysioType test in Connecticut. He plans to roll the product out to Massachusetts and Rhode Island in the first part of the year.

Sales of PhysioType test products have more than doubled this year from last year, said Robert Scherrer, who started or ran several Connecticut bioscience companies, including Protein Sciences in Meriden, over the years before joining Genomas as chief financial officer.

The third funding leg comes from investors. Rúaño estimates a third of his time is spent preparing for and talking to potential "angel" investors who have "home-grown capital in Connecticut." But with the economy struggling to emerge from the deep recession, his timing couldn't be worse.

"You backup five or seven years, you wouldn't have any trouble finding money," said Dr. Steven

Hanks, chief medical officer for The Hospital of Central Connecticut who is a member of Genomas' board of directors. "All the money is on the sidelines. Everybody's nervous."

Hospital of Central Connecticut invested \$500,000 in Genomas to leverage both parties' research into diabetes treatment, said Hanks, who met Rúaño in the 1990s when the researcher was running his first bioscience company, Genaissance Pharmaceuticals in New Haven.

"I was intrigued with his research even back then," Hanks said.

With Rúaño as CEO, Genaissance went public in 2000, raising \$115 million. In 2006, it was acquired by Clinical Data, a Massachusetts pharmacogenomics company.

Rúaño, a married father of two boys, was born in Mayaguez, Puerto Rico. He earned his undergraduate degree from Johns Hopkins University in Maryland and medical and doctoral degrees from Yale University.

An art aficionado, Rúaño is on the board of the Wadsworth Atheneum Museum of Art and The Bushnell. "I'm very interested in art and the interface of science and art," he said. DNA collages adorn the walls of Genomas.

The tie with the Medical Sciences Campus of the University of Puerto Rico, where Rúaño is an adjunct professor, is more than a homecoming. Genomas is also running clinical protocols in Hartford and Puerto Rico that will bring these technologies to the medical needs of the Hispanic population. The diverse genetic mélange of the island territory's residents is ideal for testing and refining Genomas' technology, he said.

Recently, the Food & Drug Administration approached Genomas about doing the first pharmacogenomics conference on Hispanics in May 2010 in San Juan, Puerto Rico.

"I'm very proud of that," he said. ■