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Diabetes test adds to 'arsenal'

Irvine company's once-a-month device appeals to doctors, patients

By COLIN STEWART
REGISTER COLUMNIST

It all started at the El Torito restaurant in Buena Park.

A local immunologist and his biomedical engineer friend were eating there one day and agonizing over ideas they hoped would lead to a blockbuster business plan.

"We were sitting there, banging our heads," recalls Henry Smith, the immunologist. "We said, 'We have to come up with something earth-shattering.'"

Smith and his friend, biomedical engineer Asad Zaidi, had just formed Epinex Diagnostics with Zaidi's wife, Azra Zaidi. Their goal was to profit from their years of experience in quick-turnaround medical tests. They wanted to invent new tests for hepatitis, HIV and other infectious diseases.

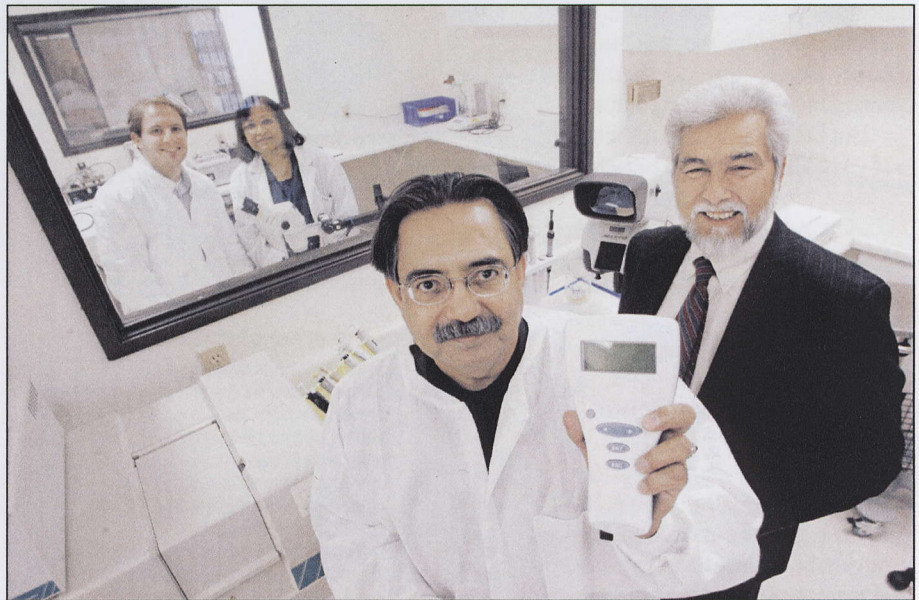
But they rejected all those suggestions at that 2003 dinner meeting because each one would face too much competition, Smith says. The tests would help medically, but the finances wouldn't work. Each man went home frustrated.

Then came the late-night phone call. It was Asad Zaidi calling Smith with another idea that had just come to him.

"I think I have something for you," he said. "Albumin."

"You know, I was thinking the same thing myself," Smith said.

That phone call set Irvine-based Epinex on the road to developing a once-a-month home monitoring device for Type 2 diabetes, which the company hopes can substitute for common glucose tests that require pinprick blood samples



EUGENE GARCIA, THE REGISTER

METER READERS: Epinex cofounders Asad Zaidi, left, and Henry Smith, right, developed the G1A prototype. Cofounder Azra Zaidi, back right, is seen with Daniel Klein. The diabetes test is designed to be used once a month.

many times a day. The Epinex test measures how much of the body's albumin protein has been damaged by excessive sugar in the blood.

Because a once-a-month schedule would be convenient for consumers, the three cofounders believed the test would be popular with diabetes sufferers, useful to doctors and attractive to investors. So far, they've been proven partly right.

Based on their work, including Smith's efforts as chief technical officer and Azra Zaidi's efforts as director of research, Epinex has won some support from all three groups, although would-be investors included people who wanted control of the company.

RADICAL OR MODEST GAIN

Damage to proteins in the blood, including albumin and hemoglobin, leads to some of the most devastating effects of diabetes, such as blockage of blood ves-

Epinex Diagnostics Inc.

Headquarters: Irvine

Business: Quick-turnaround, in-home medical tests

Employees: 11

Ownership: Private

Annual revenues: None; in development stage

History: Founded 2002

More info: www.epinex.com, 949-660-7770

sels in the legs, which can require amputation.

The Epinex G1A test, which the company has demonstrated in the laboratory, still needs to undergo clinical trials and win approval from the U.S. Food and Drug Administration.

For Epinex, the G1A test has “the potential to revolutionize the diabetes monitoring market” because it could drastically reduce the number of times diabetes patients need to prick their fingers for tests to determine whether the ailment was under control or worsening.

With a G1A device requiring only one pinprick per month instead several each day, fewer diabetics would be tempted to skip the test, says Asad Zaidi, the company’s president and chief executive.

But Dr. Ping Wang, director of UCI’s Joslin Diabetes Center, says FDA approval of G1A wouldn’t end daily glucose tests, but would add a valuable tool to doctors’ arsenal.

“When I go to war, I want to have a machine gun, a cannon, a pistol and a rifle,” Wang says.

The “gold standard” diabetes measurement is the A1C test for glucose-modified hemoglobin, a lab test that can be repeated every three to six months. The combination of daily glucose monitoring at home plus the A1C test gives doctors the tools they need in most cases, Wang says.

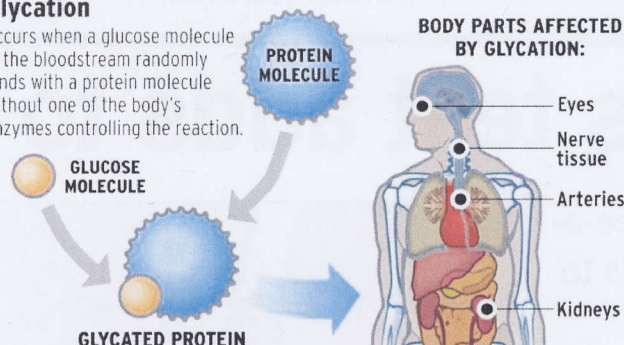
With those two, he says, doctors at the Joslin center and their patients succeed in keeping average A1C test results at or below the level the American Diabetes Association recommends. They accomplish that through a combination of diet, exercise and medication.

Keeping tabs on diabetes

Type 2 diabetes occurs when the body doesn’t make enough insulin, which it uses to deliver organic compounds such as glucose from the bloodstream to individual cells. Lack of insulin can cause a buildup of glucose in the blood, which can lead to health complications. A new test from Epinex Diagnostics that measures a reaction called glycation could help diabetics keep better tabs on whether they’re keeping the disease under control.

Glycation

Occurs when a glucose molecule in the bloodstream randomly binds with a protein molecule without one of the body’s enzymes controlling the reaction.



Glycated proteins form rigid, destructive tissue, which can cause hardening of arteries, cataracts, and nerve and kidney damage. Glycation occurs in everybody, particularly with age, but happens more frequently and at a younger age in diabetics.



Epinex test kit

Measuring glycation

Epinex’s recently-developed device determines the rate of protein glycation in a patient’s blood sample by measuring both the total amount of albumin, a common protein, and what percentage of it has been glycated. Performed monthly, the test may help determine if the disease is under control.

Sources: Epinex Diagnostics, FDA, American Diabetes Association

Phil Loubere, Colin Stewart / The Register

“But the Epinex test still can be valuable for certain patients,” he says.

Epinex faces an expanding number of competitors that make diabetes tests. These include the GlycoMark test for dangerously high levels of blood sugar after meals, made by the BioMarker Group of Kannapolis, N.C., and continuous glucose-monitoring devices made by DexCom of

San Diego and Medtronic of Minneapolis, Minn.

FOOTBALL AND FINANCES

These days, a promising medical innovation can’t just appeal to doctors and patients. It must attract investors too, which is where Epinex ran into a slowdown.

The company needed \$5 million to perfect the G1A test and make a prototype.

Prospective investors were willing to supply the money in exchange for control of the company.

Smith and the Zaidis balked. For help, they turned to Jeff Byrd, a Stanford University graduate and former football all-star at Rancho Alamitos High School.

He checked out Epinex with fellow alumni, then in early 2003 agreed to become vice president for corporate finance – basically the guy on the prowl for money.

“I figured I could get them \$5 million without them giving up substantial equity,” Byrd says.

Even before he had an office, he started calling wealthy individuals by cell phone from his bedroom and now has raised \$4 million of his \$5 million goal.

In exchange for that, the new shareholders will control only 16.7 percent of Epinex.

The company still needs \$10 million to create a production-model G1A for the FDA to approve, so it hired investment bank CB Capital of Newport Beach.

But with the boost that Byrd gave them, the co-founders are sure that the need for \$10 million won’t force them to give up control of what started with a late-night phone call in 2003.

“That’s not bad at all,” says Byrd.

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