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# PHILADELPHIA BUSINESS JOURNAL

## Artificial pancreas awaits FDA

JOHN GEORGE  
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WEST CHESTER — Animas Corp. is getting ready to begin human clinical testing on its first-generation artificial pancreas technology.

All it needs is the Food and Drug Administration OK to proceed.

**Anhalt**  
"We have gone to the FDA and presented a plan to them," said Dr. Henry Anhalt, chief medical officer of Animas and director of its artificial pancreas program: Project Manya. "We expect to hear back from them in short order and begin our clinical trials."

One year ago, the Juvenile Diabetes Research Foundation (JDRF) formed a

SEE PANCREAS, P30



Owner April Hidouri opened Cornbread and Coffee in a once-derelict building.

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CLIFF HUDSON



# PANCREAS: Animas preparing to test first-generation technology for diabetics

FROM PAGE 1

partnership with Animas Corp. of West Chester to continue the foundation's efforts to develop an automated system to help people with type 1 diabetes better control and manage their disease.

Under that development and commercialization agreement, JDRF is providing Animas with \$8 million in funding over three years.

"This is a great example of how JDRF partners worked with industry to translate promising research to help patients," said Dr. Aaron Kowalski, the foundation's assistant vice president of treatment therapies.

An artificial pancreas, essentially a device that would both measure blood sugar and dispense appropriate amounts of insulin to keep levels in optimal range, would take much of the guesswork out of daily management of the disease. In the long run, controlled blood sugar levels will help to lessen or avert the devastating complications (blindness, heart and kidney disease) from type 1 diabetes.

An estimated 3 million people in the United States suffer from type 1 diabetes, a condition in which the body's immune system attacks and kills off the cells in the pancreas that produce insulin. Insulin is the hormone the body uses to convert food into energy.

The automated system is expected to serve as the first step toward an artificial pancreas capable of dispensing insulin to diabetics in response to real-time changes in their blood sugar levels.

JDRF in 2006 provided funding for the creation of an artificial pancreas consortium, consisting of university-based mathematicians, engineers and diabetes experts working collaboratively on the feasibility of — and computer programs for — an artificial pancreas device.

Animas was recruited for the project because of its expertise as a provider of high-tech insulin pumps.

The Chester County company, founded in 1996 by Katherine D. Crothall, went public in 2004 raising \$63.75 million with an initial public stock offering. Animas was bought for about \$518 million by Johnson & Johnson in 2006. It now operates as a subsidiary of Johnson & Johnson.

JDRF was founded in Philadelphia in 1970 by a group of parents, led by Lee

tients participating in studies and how safety and effectiveness should be measured.

"The panel believes, with certain safeguards, artificial pancreas systems can be safely tested in real-world settings," said Dr. Robert Sherwin, Yale University's chief of endocrinology and an internationally known diabetes researcher, who served as chairman of the panel.

Anhalt said Animas' first step after the company formed its partnership with JDRF was to assemble a team of about a

creas system platform developed by researchers at UCSB and the Sansum Diabetes Research Institute is being combined with Animas' insulin pump technology for the first-generation system about to be tested pending FDA approval.

Anhalt said the first-generation system also includes blood glucose level monitoring sensors developed by Dexcom Inc. of San Diego. The device, he said, measures blood sugar levels every five minutes, interprets the results and then issues commands to the pump — after a series of safety measures incorporated into the system are satisfied.

"The first iteration will minimize low blood sugar reactions," Anhalt said. "Right now 3 to 6 percent of diabetics die from severe low blood sugar reactions. The system won't be able to keep blood sugar levels completely normal. Decisions will still need to be made by users until the device is completely automated, but this device is leaps and bounds above technology that is currently available."

Kowalski said children with type 1 diabetes will have high blood sugar levels, on average, 12 to 13 hours a day. He said for all diabetics, keeping their blood sugar levels at optimal levels is a constant challenge that requires testing multiple times a day.

"People don't realize how hard it is to do that 24 hours a day, seven days a week, all year long," Kowalski said.

The goal of the artificial pancreas, he said, is to help diabetics maintain desirable glucose levels in a way that makes their life easier.

"Right now, the devices that are available are, for the lack of a better word, 'unintelligent' devices," Anhalt said.

Anhalt said the devices collect data and dispense insulin, but require users to input and interpret a lot of data. Such devices, he said, can't make adjustments while blood glucose values are in flux.

"We have a device that can assist the patient and in many ways take over the decision-making process," he said. ■



Artificial pancreas technology automates glucose monitoring, insulin delivery.

*'Right now, the devices that are available are unintelligent.'*

Dr. Henry Anhalt  
Animas

Ducat, of children with type 1 diabetes. The foundation, now based in New York, has raised more than \$1.4 billion to fund juvenile diabetes research.

In November, at a meeting convened by the FDA and the National Institutes of Health, diabetes experts put forth their clinical guidelines recommendations for testing artificial pancreas technology in "real-life situations" of people with type 1 diabetes. Up until now, the technology has only been tested in controlled hospital settings.

The panel's guidelines covered identifying what standards should be used for selecting patients to test artificial pancreas systems, what measures are needed to ensure the safety of the pa-

dozen "world-class" scientists and engineers to work on the project. By March, the team was in place and working on both the software, developing algorithms that would be needed to operate the device, and the hardware that would determine what the product would look like.

"Our single greatest achievement is signing an agreement with the University of California-Santa Barbara (UCSB), where the first clinical trials will be conducted," he said. "Conducting a clinical trial with a device like this has challenges because you don't have a way of testing the pieces of the puzzle. The algorithms we are using reside within the device itself."

Under the agreement, an artificial pan-



Kowalski