

**ROCHESTER
BUSINESS JOURNAL
DAILY EDITION**

September 08, 2008

INSIDE TODAY

U.S./World News
Local Stocks
Business Calendar
Weather

THIS WEEK

Picture of the Week
In the Print Edition
Woodson on Sports

NEWSSTAND

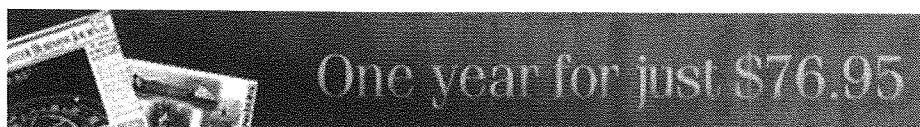
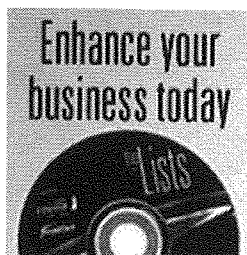
Weekly Print Edition
Subscription Payment
Subscription Renewal
Back Issues/Reprints
Databases/Directories
The Lists
Photographs

RBJ RESOURCES

About the RBJ
Search Archive
Contact Us
Advertising Info
Daily Report
RBJ Events
Help Center

OTHER RESOURCES

Stock Research
Other Net Resources
Economic Profile



Search News Archive



Advanced Help

TODAY'S TOP STORIES

iCardiac completes major validation study

By SMRITI JACOB
Rochester Business Journal
September 8, 2008

iCardiac Technologies Inc. Monday said it successfully has completed the pharmaceutical industry's largest validation study for an automated electrocardiogram analysis technology.

The results make iCardiac's technology the first to comply with the U.S. Food and Drug Administration's E14 industry guidance, company officials said. The validation program is the largest in the industry because it includes analysis of more than 1.5 million ECGs gathered over the last decade from cardiac safety studies of marketed drugs, and from drugs that were terminated in development due to high cardiac risk.

In the study, iCardiac's highly automated QT method demonstrated results equivalent to manual measurements performed independently by U.S. board-certified cardiologists, the company said.

Its automated QT method was shown to detect reliably the effect of the drug moxifloxacin, which is used as a positive control in cardiac safety studies and is included in FDA's E14 guidance. A QT interval is a short, millisecond period that occurs from the time a heart beats or contracts through to its recovery phase.

"iCardiac's highly automated QT analysis provides drug developers with the cost advantages of automation—which are significant—without compromising the rigor of drug safety testing," said Sasha Latypova, co-founder and executive vice president of iCardiac, in a statement.

Its QT technology combines advanced ECG signal processing algorithms with a quality assurance process conducted by cardiologists. It performs a precise automated QT measurement. Then, using sophisticated statistical models and algorithms, guides cardiologists to those ECGs that require attention or adjustment.

Highly automated QT analysis is part of iCardiac's software platform originally developed at the University of Rochester Heart Research Follow-Up Program.

Results of the completed validation study were presented at the FDA's interdisciplinary review team meeting last month and will be published by iCardiac and its partners over the coming months, officials said.

(c) 2008 Rochester Business Journal. Obtain permission to