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# THE WALL STREET TRANSCRIPT

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Connecting Market Leaders with Investors

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## THE FOLLOWING REPORT IS EXCERPTED FROM THE WALL STREET TRANSCRIPT

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MEDICAL DEVICES REPORT

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Vicor Technologies, Inc.

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## Vicor Technologies, Inc. (VCRT.OB)



**DAVID H. FATER** joined Vicor Technologies, Inc., in 2002, and he also serves as Chief Executive Officer of ALDA & Associates International, Inc., a business and financial consulting firm specializing in health care and life sciences. Prior to joining Vicor, Mr. Fater held senior executive positions with three public health care companies. He led the initial public offering process for BMJ Medical Management, Inc. (1997-1999), and Community Care of America (1995-1996). He also led Coastal Physician Group, Inc. (1993-1995) to a NYSE listing and \$1 billion market capitalization. Previously, Mr. Fater was employed by Ernst & Young, where he completed his 24-year tenure as a Senior International Partner advising senior management and boards of directors (1969-1992). Mr. Fater is a certified public accountant in Georgia, Illinois, North Carolina and New York. He holds a

B.S. in accounting from the University of North Carolina.

### SECTOR — HEALTH SERVICES

**TWST:** Would you start with a brief historical sketch of the company and a picture of the things you are doing at the present time?

**Mr. Fater:** Vicor has been in existence for 10 years. We celebrated our 10th anniversary on August 11. In a lot of respects, that's a major accomplishment because there aren't too many startup biotechnology companies that can say they've lasted 10 years. In that 10-year span, we've managed to develop some significant, breakthrough medical diagnostic technology and actually had our first product introduced into the marketplace in 2010. Our products provide a new measure of heart rate variability that enable physicians to accurately put their patients in one of two buckets — high risk, low risk — and do that easily. Importantly, physicians are able to receive reimbursement from public and private insurers under existing procedural codes for tests performed using our products. So from both a financial perspective and a clinical perspective, the physicians find this technology very worthwhile.

We're focused on three areas right now. The first of these is autonomic nervous system dysfunction, which is a co-morbidity complication of diabetes. There are 24 million diabetics in the United States, and that number is growing significantly. The American Diabetes Association has recommended diabetics receive annual screening for autonomic nervous system dysfunction. We're also focused on cardiology. There are 81 million patients in the United States with cardiovascular disease. And we also have a technology for triaging trauma patients that we're developing in collaboration with the United States Army.

**TWST:** Tell me about your own background and a little about some of the key members of your team.

**Mr. Fater:** I spent 24 years as an International Audit Partner at Ernst & Young, and when I left them in 1992, I went into health care and became the CFO of three public health care companies, two of which I took public, one of which I took to the New York Stock Exchange. I was recruited to Vicor by the founding scientists in 2002. The inventor of our technology was the first Ph.D. in neuroscience from UCLA in 1967. His lifelong area of study has been detecting how the brain and the heart are connected in such a way that the brain really controls irregular heartbeats and ultimately fatal arrhythmias. Most physicians just focus on the heart and the health of the heart. He was hired out of UCLA by Dr. Michael DeBakey at the DeBakey Heart Institute, where he spent 24 years as a full Professor of medicine at Baylor. And that's where he performed his seminal experiments and actually developed the science behind our technology. Our Vice President of Product Development is Dr. Jerry Anchin, a Ph.D. from Texas A&M. Jerry spent 25 years in Southern California in drug discovery, diagnostics and medical devices. Our Chief Operating Officer is Dr. Richard Cohen, who has spent 30 years in worldwide sourcing and operations and is a key relationship person for a lot of the international deals we're negotiating, as well as our relationships with several important universities where we conduct clinical trials. Our Chief Medical Officer is Dr. Daniel Weiss, who's an electrophysiologist and electrical engineer by background. Danny left his practice three years ago to join us full time as our Chief Medical Officer. Our Chief Technology Officer is Lloyd Chesney. Lloyd has constructed what we believe is a very unique delivery model for both the physician and the health care community.

In addition to these individuals, we have a scientific advisory board that provides direction to the company on where the science should be concentrated. These individuals are considered the world's thought leaders in their areas. For example, Mark Josephson is a member of our scientific advisory board. He is the Chief of Cardiology at Beth Israel Deaconess Medical Center, in Boston at Harvard, and the author of *Clinical Cardiac Electrophysiology*, the single-authored textbook that's used in every medical school in the country. His counterpart in Europe is Dr. Hein Wellens. Hein is also on our scientific advisory board. Between the two of them, they've authored 24 textbooks and 1,000 manuscripts. We also have Dr. Bob Hauser, who is a Senior Cardiologist out of Minneapolis and CEO of Cardiac Pacemakers, an implantable device company that was acquired by Guidant, which is now Boston Scientific. We also have Jonathan Kaplan on our scientific advisory board. Jonathan is the Medical Director for Fidelis Care, in New York. Before that, he was the Medical Director for Excellus BlueCross BlueShield. His background brings an insurance perspective to our company. We also have Dr. Ed Lundy. Ed is the Chief of Cardiothoracic Surgery at Good Samaritan Hospital in Suffern, N.Y., and a Class I trauma surgeon. The members of our scientific advisory board are in the disciplines we're targeting, and they're thought leaders other physicians listen to.

*"Physicians are extremely gun-shy about introducing new technology, especially technology that's going to cost them money. That's why we've constructed a business model with an interesting delivery mechanism that really should appeal to most physicians' need."*

**TWST: How would you describe the outlook for your industry and for the company in particular right now?**

**Mr. Fater:** That is an interesting question, given the times and circumstances. First, let me start off by saying I think our prospects are excellent because of our technology and the fact that physicians want it and will want to use it in both their practices and in hospitals. The reason that's an interesting question is the prospect of health care reform, which has really shaken physicians, and they've had their Medicare payments withheld three times this year as a result. Up until the end of last month, they were facing the prospect of a 20% cut in their Medicare reimbursement rate. So physicians are extremely gun-shy about introducing new technology, especially technology that's going to cost them money. That's why we've constructed a business model with an interesting delivery mechanism that really should appeal to most physicians' need for additional clinical information and the need to conserve cash while increasing their practice revenue.

A lot of medical devices for physician practices cost a physician, out-of-pocket, \$30,000 to \$40,000 up front. That is a huge hurdle for a lot of physicians. And for the device company, there is no recurring revenue stream; it's a one-time sale. We take a different approach. We sell the PD2i® Analyzer, which consists of a laptop computer paired with a digital ECG via a USB cable that collects the ECG data for our analysis, with an automated blood pressure collection built into the software for \$6,500. We then charge the physician a per-test fee for analyzing the ECG data and producing a report for him to interpret and make a diagnosis. At the end of the collection period, the software automatically via the Internet sends the

data file that's been collected during the test to our remote server, where our software analyzes the data, produces an electronic health record with the report and the billing information for the doctor, and transmits it back to that laptop in a period of about 60 seconds. So the physician has an electronic health record that's compatible with the EMR he is being pushed to generate to conform with health care reform goals. It has the information he needs to interpret the report and make the diagnosis of the patient, and he has the information needed to bill the insurance company. The cost of the hardware is modest — if physicians don't pay something, they'll think it's a toy and not use it — but by no means prohibitive. And then we receive a recurring source of revenue that comes from the performance of each test.

**TWST: What's the competitive landscape like?**

**Mr. Fater:** We are aware of one competitor in the autonomic nervous system marketplace. They have a \$45,000 piece of equipment and no recurring service revenue. And at the end of five years, the physician has to pay another \$25,000 to relicense the software. We know they've got an installed base, although not necessarily a large installed base. We also know, given the current health care reform landscape, that physicians who don't have this equipment today are less likely to get it because of that upfront cost. That's the only competitor we have in the ANS arena.

In the cardiology arena, there's one competitor: Cambridge Heart. Cambridge Heart is a publicly held company with a T-Wave alternans test for assessing the risk of sudden cardiac death. This machine also costs \$45,000, plus the physician has to buy single-use, special-purpose electrodes that cost \$80 a pair, for which he's not separately reimbursed. And their test requires a treadmill and a stress test, which introduces all sorts of complications that really render the test of small interest to physicians. Requiring a sick patient to complete a stress test introduces the risk of cardiac arrest. So the physician has to be present, the nurse has to be present, the technician has to be present, a crash cart has to be present, and it takes 20 to 30 minutes to do the test.

Our test, by contrast, is a 15- to 20-minute test in which the physician's only involvement can be the writing of a prescription to authorize the test. The test can be performed by a technician. The physician's next involvement is to review the final report and make the diagnosis. There is no treadmill involved. It's a resting ECG with the patient performing three standard of care maneuvers for an autonomic nervous system dysfunction diagnosis. These maneuvers are metronomic breathing, a Valsalva maneuver, which is a forced exhalation, and two minutes of changing from a recumbent position to a standing position. That's the entire extent of the test.

**TWST: You launched your first product in January?**

**Mr. Fater:** That's correct.

**TWST: How are things going sales-wise?**

**Mr. Fater:** Sales have been slower than expected. This is partially because from a company standpoint, we've never been appropriately capitalized. So when we launched this product, we had an opportunistic

agreement that enabled us to put in place 25 independent sales reps in North and South Carolina, and we had one other internal person involved in selling. All of this was geared around our going to the markets to raise some capital. We have an S-1 on file that covers raising as much as \$10 million, which would primarily be used to drive sales and marketing. As a result of what transpired in the second quarter with health care reform and the physician community, getting the product out has not been as fast as we'd have liked. We've seen some activity and are seeing more encouraging activity in the third quarter. We're in the process of signing up additional distributors. We hired a national sales manager two weeks ago. By the middle of the third week in September, I believe we could have at least 12 or so additional distributors and their sales representatives pounding the pavement with minimal cost to Vicor. Of course once we get our funding squared away, we can hire additional company sales personnel in select areas. I don't intend to have a Pfizer-type sales force; we will be using a hybrid-type sales force consisting of company sales personnel augmented by distributors and independent sales reps.

*“Many of the physicians on our scientific advisory board believe we’re measuring the key to metabolic syndrome, which is really the key to health.”*

**TWST: What's the time frame for raising money?**

**Mr. Fater:** Fourth quarter or early in the first quarter of 2011.

**TWST: Is it a platform technology for several devices?**

**Mr. Fater:** It's a platform technology for applications. Many of the physicians on our scientific advisory board believe we're measuring the key to metabolic syndrome, which is really the key to health. For example, we've demonstrated in our clinical trials, which have not yet been reviewed by the FDA, that we're able to identify trauma patients — whether they're soldiers or civilians — who are at imminent risk of death and need to have what's called a life-saving intervention performed on them immediately. In the cardiology area, we just completed a major clinical trial, the MUSIC Trial, with the University of Rochester and the Catalan Institute of Cardiovascular Science, in Barcelona, Spain. The MUSIC Trial studied 537 congestive heart failure patients over 44 months. Our PD2i technology was able to retrospectively identify those patients at elevated risk of cardiac mortality and pump failure mortality with a hazard ratio of better than 2 to 1 and a p-value of 0.004, which is almost statistical certainty. That abstract has been submitted by the researchers for publication and has been accepted for presentation at the 2010 Heart-Brain Summit at the Cleveland Clinic later in September.

In December of last year, we conducted a study to test the ability of the PD2i to detect acute hypovolemia in blood donors as a preliminary step toward determining whether the PD2i could be a useful noninvasive diagnostic for detecting blood loss from internal bleeding. The study was conducted in cooperation with the University of Mississippi Medical Center and Mississippi Blood Services. All 18 participants in the study were tested prior to donation to determine a baseline PD2i value, and retested during and after collection. The average PD2i value of participants prior to donation was 2.60; the average PD2i value following donation was 1.80. With a p-value of 0.001, the study results are highly statistically significant; this indicates a better-than-99% probability that the results were not achieved

randomly. An abstract of this study was accepted for presentation at the AABB 2010 Annual Meeting in October.

On August 7 of this year, we filed a patent for our ability to analyze respiratory waveforms and identify which of those patients on ventilators may be safely removed from their ventilators in order to avoid having a patient removed from the ventilator only to then require re-intubation to be put back on the ventilator.

Our technology is capable of analyzing any series of biological data collected over time; which is unique. We have an anesthesia study that we'll be starting shortly in which the PD2i will be used in the operating room as a continuous monitor to provide an early warning to the anesthesiologist and surgeons that a patient is about to crash. The ability to identify the risk of crash would lower fatalities during surgery. We're attempting to accomplish the same thing in an ICU unit: identify which patients are safe to discharge to a step-down unit. We are also conducting a study of patients with severe brain trauma in the neurological ICU unit at the University of Mississippi Medical Center to identify

those patients who may recover well and those who may not. So we have a wide variety of applications for our technology. What we ultimately hope, with enough studies and use, is to establish the PD2i as a new vital sign to be used alongside the current standard vital signs of pulse, blood pressure, heart rate, respiration and temperature.

**TWST: So over the longer haul you see a lot of potential and a very broad application?**

**Mr. Fater:** That's correct.

**TWST: Your investor presentation said that you had some products that you were hoping to get 510(k) clearance on in the first half of this year. How is that coming along?**

**Mr. Fater:** On July 1 we filed a 510(k) for a cardiac claim based on the results of that MUSIC Trial. It is currently under FDA review. We're also hoping to submit our 510(k) for a trauma application before the end of this year. We're currently trying to obtain additional clinical trial data and reviewing the 325-patient data sets we already have. So we are hoping for additional applications and clearances. That said, I'd like to make sure it's perfectly clear: with the marketing clearances we already have, we have the capability to generate a substantial amount of revenue. Although we currently have only nonspecific labeling for the measurement of heart rate variability, some physicians are using our technology in the cardiology arena based on the data we've published.

**TWST: You mentioned briefly building a bigger sales force. What have you got going on internationally?**

**Mr. Fater:** We are currently in negotiations with distributors in the Far East, the Middle East, Israel and Europe, and South America. Some of those agreements should come to fruition shortly.

**TWST: Your investor presentation also says that you sell high-margin, high-operating-profit products. Would you tell me a little bit more about that?**

**Mr. Fater:** The hardware, which is the \$6,500 component, has a margin in the 30% range. The test fee — we charge \$40 a test — has a

70% margin. Our revenue model is driven by the higher-margin test fee, not the lower-margin hardware sale. In other words, revenue from test fees increases exponentially based on the number of analyzers in use and how often they're used.

**TWST: That presentation also says you offer a substantial cost-savings, public and private insurance. Would you explain that a little bit more?**

**Mr. Fater:** There are at least two ways currently in which our technology provides a cost-savings to insurers and the health care system as a whole. The first — using the cardiology claim we're currently seeking as an example — involves the cost of implantable cardioverter defibrillators. The current treatment for congestive heart failure patients and ischemic patients at risk of sudden cardiac death is implantation of a \$100,000 automated implantable cardioverter defibrillator or ICD in the at-risk patient. The ICD "shocks" the heart into normal rhythm when it fails to maintain normal rhythm on its own. Published studies reveal that 76% of the people who have received an ICD have never experienced a shock, which means they didn't really need it. Yet 80% of the people who die every year from sudden cardiac death don't meet the current criteria for an ICD. So you have complete chaos in the area of risk stratification technology to enable proper identification of those patients. Patients are aware of this dilemma and resisting physician recommended implantation. The defibrillator companies are in a complete state of stagnancy.

Where we think we can help the Medtronic, Boston Scientific and St. Jude's of the world is to, "A," identify those patients who are at risk for cardiac mortality but don't meet the current criteria for a device and "B," identify those patients who might meet the criteria for a device but don't really need one. It takes a lot of \$160 to \$200 tests before you've run up the cost of implanting a \$100,000 device in somebody who doesn't need it. Now I understand that we need a lot more data before the insurance companies are going to go out on a limb, given the existing criteria, but that's coming because there is wide acknowledgement that the current criteria isn't accurately identifying those in need of an ICD. So that's one way we think we can save the health care system money.

The second way is by providing a test that enables physicians to identify diabetic patients with the early stages of autonomic nervous system dysfunction and do something about it. The ability to minimize the impact of ANS dysfunction, which leads to co-morbidity such as silent heart attacks, stroke and kidney failure, is huge. Diabetes itself is not the problem. The problem is the co-morbidity resulting from the disease when it goes unchecked and untreated. Heart rate variability is the standard of care for identifying diabetic autonomic neuropathy, which is ANS dysfunction in diabetics. I'll give you a different example from a past life. When I was with a different company, we had 70,000 Medicare enrollees in Southern Florida, for which we were at full risk, meaning we were at risk for all of their health care — just like an insurance company. They paid us the insurance company portion of their premium, and we were responsible for their health care. If we had a diabetic patient, we insisted they come into the clinic once a month whether they needed to or not. If they did not come in, we invested the extra money to send a van to their home and bring them into the clinic, because the cost of that clinic visit could potentially save a \$100,000 hospitalization. Preventing a diabetic from crashing either through noncompliance with diet and medication, or some complication that

would have been spotted in a clinic visit and otherwise wouldn't have been spotted until they hit the emergency room, was well worth the effort and the cost. That's how I view our technology. We can stave off economic disasters by identifying those patients at risk, properly treating those patients and managing those patients not truly at risk more conservatively at a lower cost.

**TWST: Are you forecasting profitability at any point? What's it going to take to get there?**

**Mr. Fater:** I think we should get there at the end of 2011.

**TWST: Does the company give a great deal of attention to investor relations? Do you feel people have an understanding of what you have to offer?**

**Mr. Fater:** I do pay a great deal of attention to investor relations, but I don't feel that a lot of people understand what we have to offer. I can't put my finger on it. I've got several different investor relations efforts going on. We work with a traditional investor relations firm, which puts us in front of institutions every month. We're also working with other sources that help us get in front of the retail investor, who I think our stock will appeal to. As brokers no longer have discretionary authority with Bulletin Board stocks, this is very important.

**TWST: Looking ahead, what might be some year-by-year milestones or indicators that investors should look for when keeping an eye on Vicor Technologies?**

**Mr. Fater:** The first of these are additional 510(k) clearances. Following that is increased revenues and then profitability.

**TWST: What would be the two or three best reasons for a long-term investor to look closely at Vicor?**

**Mr. Fater:** I appreciate your use of the term "long-term investor." Clearly we are a great value play. While every CEO believes his stock price is cheap, I'm going to be a more realistic CEO: Our stock price is what it is. As an entry point to getting into our stock, it's a great value. All an investor needs to do is consider all the applications and our revenue model. With just what we have today, we have the potential to touch 77 million patients annually in the United States alone on a recurring basis. That's a \$3.9 billion market, without counting the international market or any future applications. So long term, which I'd say is probably a two- to five-year horizon, things will manifest themselves, and they'll start to do so over the rest of this year and into next year. Vicor is a great opportunity. It's just that a lot of people are not aware of the story, so they can't appreciate it.

**TWST: Anything else you want to cover?**

**Mr. Fater:** I don't think so. I've covered all of the points.

**TWST: Thank you. (MJW)**

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