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Profile: Medical Device Company

VivoMetrics Ventura, Calif.

An interview with James Utterback, president, pharmaceutical division, and Alex Derchak, director, clinical development

Year founded: 1999

Employees: 40-45

Active clinical projects: 20

Tel: (805) 667-2225

Web site: www.vivometrics.com

Tell me about the LifeShirt.

JU: In addition to the electronic patient diary, the LifeShirt captures three data streams—respiratory, cardiovascular, accelerometry data. The FDA [U.S. Food and Drug Administration] gave LifeShirt market clearance in the U.S. after we had obtained a CE mark in Europe. We have been commercializing the product since mid 2002 from phase I through phase IV from pediatrics through geriatrics.

AD: The LifeShirt is a shirt that has sensors woven into it. You can wear it under your clothing at work. It can continuously collect laboratory quality data in an ambulatory environment. We measure the whole range of physiologic activity that is for the most part insensible—how fast your heart is beating, what your breathing rate is, how deep are your breaths, what the oxygen saturation in your arterial blood is, etc. Being able to analyze those changes in time with subjective patient entries offers significant advantages in the ability to understand the interaction between mind-body and body and drug in different environments.

Do you offer services around LifeShirt?

JU: Our core competencies are signal processing, data collection and analysis, algo-

rithm development, and the support services that allow that to be wrapped around a clinical trial setting. We offer everything from protocol support at the front end to back end data archiving and everything in between, including project management support, 24/7 call center support, site training, and working with sponsors and/or their CROs data teams to come up with tables and reporting structures, etc.

What are the economic advantages of LifeShirt?

JU: In a recent cough study, the LifeShirt System performed with 99% accuracy when compared to video analysis, the gold standard for cough measurement. The study validated the use of the LifeShirt System as the preferred testing model for cough measurement. The return on investment in areas like sleep are also compelling, even in a post-marketing, peri-approval world. How does my drug compare measurably, quantifiably against yours in terms of sleep quality, sleep efficiency, total sleep time? We can do it at home, turn around the data in 24-48 hours.

What are your plans for growth?

JU: We're opening an office in Geneva in the first half of 2004 to expand our presence in

Europe. We have also partnered with Perceptive Informatics, a subsidiary of Parexel, as a re-seller of our technology. But the company's opportunities are going to expand along two dimensions. The hardware itself will get more enabled, meaning there will be more peripheral devices, better recording systems, a wireless world of data capture and collection, miniaturization and everything will become lighter, smaller and ultimately cost less. The list of additional validated, peripheral devices that also plug in to the LifeShirt, will expand. Today they include: core and skin temperature, pulse oximetry, capnography, EEG and PLM, etc. On the software side, we are actively pursuing the development of new biomarkers, which will provide new clinical insight into disease states that have historically been dependent on clinical observation or subjective self-report. In the CNS [central nervous system] area, we are data mining for anxious, panicked or depressed patients' pre-markers in order to create an objective physiological algorithm for the disease. We are currently designing proof-of-concept studies in Europe. If we can do that in CNS, the LifeShirt System will revolutionize clinical trials in this therapeutic area and others that we turn to for biomarker development.