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LifeSync Corp.

No-strings-attached monitoring improves patient care

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Industry Segment: Monitoring Equipment
and Devices
Business: Wireless communication devices
Founded: 2000
Founders: Motorola; GMP Companies Inc.
Employees: 55
Financing to Date: \$17.2 million
Investors: Janus; MPM Capital; BBT Fund
Louisiana Ventures;

Motorola Inc.
Board of Directors: Shelley
Hartman; Charles L. Brown III, MD (Fuqua
Heart Center, Atlanta, GA); Paul A. Brooke
(Ithaca Acquisition Corp.); Eric Hecht,
MD (Ithaca Acquisition Corp.); B. Kristine
Johnson (Affinity Capital); Matthew Rebold,
(Osprey Partners); Alan Sebulsky (Apoth-
ecary Capital LLC)

Wireless technologies have been eagerly anticipated in medicine, as agents of change that will transform the care of patients with chronic diseases, people, who by definition, spend most of their time outside of hospitals and other health-care settings. Wireless technologies promise to link patients to caregivers as they go about their daily lives. According to one analysis, the global market for wireless medical technologies will reach \$10 billion by the year 2011. In the short term, however, clinicians and technology providers are struggling to find the right delivery infrastructure and business models for technologies used in the care of chronic diseases. That may not matter because it's turning out that many of these new medical communications technologies, originally intended to serve ambulatory

patients, are, surprisingly, demonstrating clinical and economic benefits in the setting where you'd least expect to find them necessary: the hospital.

Witness the migration of new continuous glucose monitoring systems under development, from original target markets in home-based glucose monitoring to hospital critical care units. These continuous glucose monitors have been able to make a case, in critical care, for helping physicians improve clinical outcomes and making nurses more productive.

Likewise, patient monitoring company **Visicu Inc.**, which, after successfully going public in April 2006 reported a 65% increase in revenues over the previous year, is applying the technologies of telemedicine to in-hospital solutions for intensive care units. Visicu's remote monitoring systems allow hospitals to centralize the work

of monitoring patients and to leverage scarce critical care staff. That company has been able to advertise the benefits of its systems in published papers that demonstrate reductions in critical care mortality rates.

Now, **LifeSync Corp.** is discovering that the introduction of its wireless electrocardiogram (ECG) data communication system, which eliminates the lead wires of traditional ECG systems, while not necessarily enabling remote communications, is bringing clinical and economic advantages to hospitals.

LifeSync was spun out of technology incubator **GMP Companies Inc.** (GMP), which was founded in 1999 to in-license and develop a portfolio of medical technologies in both pharmaceuticals and medical devices. One such technology resulted in the 2000 formation of LifeSync (then known as

GMP Wireless Medicine Inc.) as a wholly owned subsidiary of GMP. LifeSync has exclusive rights to patents from **Motorola Inc.** (an equity stakeholder in GMP) concerning the digital two-way wireless transfer of data from a patient to a receiver station.

The LifeSync business is now the sole operational unit of GMP. In 2004, after more than 18 years in the investment banking industry, Shelley Hartman left a position as managing director in the health-care department of Goldman Sachs to head up GMP as president and CEO. At the time, GMP was managing a portfolio of some 15 diverse technologies, and Hartman's assignment was to identify the most promising technology on which to focus the company's resources; others would be out-licensed. GMP, like other early-stage developers, had discovered that as its projects advanced in development, they required increased amounts of funding support. Maintaining adequate funding for so many different projects was a constant challenge.

Hartman liked the near-term commercial prospects for LifeSync, which is selling the first wireless ECG data communication system for hospital and out-patient settings. LifeSync has replaced traditional ECG cables with a disposable that operates just like lead wires, except that it is a flat, flexible piece of material

incorporating radiolucent electrodes—a printed flexible circuit—that adheres to the patient. The disposable serves as the conduit for the aggregation of the ECG signal into the LifeSync patient transceiver.



“We can take a 10-year-old or 2-year-old monitor and upgrade it into a wireless format.”

—Shelley Hartman

er, a little device like a radio that can either attach to a patient's arm or sit in the pocket of a gown. That transceiver sends a radiofrequency signal to a second transceiver, which is connected to the bedside monitor. Essentially, LifeSync uses *Bluetooth* technology to replace the ECG cable between the patient and the patient monitor.

Hartman stresses that LifeSync is not a patient-monitoring company. “We designed a technology that allows for the wireless transfer of ECG and respiration data from the patient to the patient monitor. We do data communications. We are agnostic about the monitoring devices.” Hartman says that LifeSync can

work with the monitors of any of the major manufacturers; those already installed in hospitals, and future devices: “We can take a 10-year-old or 2-year-old monitor and upgrade it into a wireless format.”

Enabling wireless communications between an ECG monitor and a patient in the same room may seem like an incremental advance, but the clinical and economic benefits are great. Many of the advantages of a wireless ECG are immediately obvious; the patient, untethered to a monitoring device, can walk about freely, and doesn't risk dislodging the cable by rolling over during sleep. Having a wireless communications device attached to the patient saves nurses time as well. Now when patients come into the emergency room and get *LeadWear* (LifeSync's brand name for its disposable), it can stay with them as they are moved to the OR, to the ICU, or to telemetry. Today, each time a patient is moved from one department to another, nurses take the wires off and put new ones on. Hartman explains that if the patient is put on a transport gurney to go from the ICU to radiology, for example, nurses attach lead wires for the transport gurney monitors. Nurses spend 40 minutes per patient per day managing lead wires, according to a study conducted by the health-care consulting firm the Lewin Group.

Exhibit 1

Infection Control Facts

● Attributable mortality rate for infections originating in hospitals ¹ :	4.31%
● Deaths attributed to hospital infections (US):	100,000
● Excess charges associated with a single hospital-acquired infection ¹ :	\$38,656
● ECG leads are a source of infection:	77% of ECG lead wires that were cultured after they were reprocessed exhibited antibiotic-resistant bacteria, according to a University of Wisconsin study ² An outbreak of VRE in a Texas hospital burn unit was traced back to a contaminated ECG lead

¹Zahn C., Miller MR. *JAMA* 2003;290:1917-1919. ²Jancin G. *Cardiology News*, March 2004; 2:14.

SOURCE: LifeSync Corp.

These benefits are only ancillary, however. LifeSync's raison d'être was to improve the quality of the ECG signal, which today is compromised by low-quality wires, noise artifacts caused by multi-stranded copper wires rubbing together, the failure of leads to adhere properly to the body, the movement of leads after placement, and the deterioration of the quality of leads, which are frequently reused well beyond their advertised useful life. Compounding the problem, cardiac monitors are typically set for high sensitivity at the expense of specificity because of the critical purpose of ECGs: to signal the likelihood of a heart attack within a short period of time.

The majority of ECG alarms today are false, due to motion artifact or other causes. Not only does this create unnecessary labor for nursing staff, but in the presence of so many false alarms, health-care workers tend to become desensitized to the alarms, with the consequence that they might fail to respond to a critical situation.

LifeSync conducted a small initial study in 47 patients at five different hospitals. The hospitals found that alarm accuracy using traditional lead wires was about 46%, that is, the majority of alarms were false. In the study, the LifeSync system boosted alarm accuracy to 92%. Hartman says, "We give them quality of the alarm. If the alarm goes off, they can now be certain that there is a 90% chance that it is an alarm they need to respond to." Today, Hartman says, hospitals purchase multimillion-dollar monitoring systems, but the weak link is still the commodity lead wires. "We can fix that," she says.

LifeSync's wireless communications technology offers other clinical advantages. A big part of the story, Hartman says, is infection. "Everybody knows that you shouldn't put reusable products on open wounds. Yet, the first thing that happens after a patient comes out of open heart surgery is that

a nurse puts lead wires on." LifeSync's disposable product has already demonstrated that it can reduce infections in patients, according to Hartman. She says, "The average hospital has a 5% infection rate. But one customer claimed that infection rates in units using the LifeSync system went to zero." The infection reduction was not limited to sternal wounds, but it also included central-line- and ventilator-associated infections, according to Hartman.

Infection is a serious problem for hospitals. Hospital infection rates increased by almost 23% from 2000 to 2003, according to Health Grades' *Second Annual Safety in American Hospitals Report*. Hartman points out that if a medium-size hospital having an annual census of 36,000 patients experiences the national average infection rate of 5%, it faces 1,800 infections annually. There are more than 100,000 deaths associated with nosocomial infection in the US each year, regardless of sex, race, and age.

Infections are also costly to hospitals. A paper published in JAMA in 2003 indicated that the average cost of a nosocomial infection was \$38,000 above and beyond reimbursement. (See Exhibit 1.) In 2006, **Medmined Inc.**, a division of **Cardinal Health Inc.**, collected data from 55 hospitals in 20 different states and found that the 4.07% of patients with hospital-acquired infections wiped out 185% of the operating profits of those hospitals.

LifeSync won't initially be conducting clinical trials to quantify the infection benefits of its device because disposable leads are only part of a comprehensive solution to a complex problem. That ECG leads are a source of infection, however, has been frequently documented in literature.

Their multiple surfaces are difficult to clean and they frequently come

into contact with patients' blood and other body fluids. According to Hartman, when nurses see a new patient, they put on a new pair of gloves. Next, they check their leads, after which they check the patient's catheter. "You have just transferred those superbugs sitting on the lead wires directly into the catheter." In a study headed by Paul Brookmeyer, MD, of the **University of Wisconsin**, 77% of ECG lead wires were found to be contaminated with antibiotic resistant bacteria, after they were reprocessed and before they were reattached to a patient.

Next in the pipeline, LifeSync hopes to create a product that is multi-parameter and multi-functional, by incorporating pulse oximetry, temperature, blood pressure, and other critical measurements, and it may provide industry partners with access to a license or product on an OEM basis.

In 2006, the Company raised \$17.2 million in a Series A-1 venture round of convertible preferred stock to Janus, MPM Capital, BBT fund (affiliated with the Bass family), and Louisiana Ventures.

It is still early for LifeSync, in terms of gaining market experience, but it's off to a good start. The LifeSync system is in some 40 hospitals today. With the capital raised last fall, the company re-launched the product (which had received FDA approval in 2003) and significantly increased its sales force. Although LifeSync's wireless data communications device is a very simple and straightforward innovation, the company's value proposition is great. In offering hospitals clinical improvements, productivity gains, and a solution to the pernicious problem of infection control, LifeSync believes it takes aim directly at the bottom line.—**Mary Stuart**

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