

# BIOMEDICAL BUSINESS & TECHNOLOGY

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## The *BB&T* interview:

### *Don Gerhardt*

INDUSTRY ASSOCIATION CEO

*Booster of 'structured serendipity' to create opportunities*

Interview by JIM STOMMEN, Executive Editor

Don Gerhardt is president/CEO of **LifeScience Alley**, a regional industry association based in the Minneapolis area. He has held a variety of healthcare industry posts, including CEO of MedCenters Health Plan, administrator of Michigan State University's medical facilities, with Kaiser Permanente, as a consultant for healthcare start-up companies and business coalitions, as an officer for a high-tech healthcare data company, and with several international healthcare businesses. He sits on the boards of two med-tech companies.

Don is a frequent speaker and contributor to healthcare-related articles and books. He is a faculty member at the University of St. Thomas and serves on the advisory boards of the University of Minnesota's Biomedical Engineering Institute, College of Pharmacy, Institute of Technology and School of Nursing.

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**BB&T:** You have viewed the life sciences industry, especially the healthcare services and med-tech sectors, from a variety of viewpoints over a number of years. How did you get started in the business, and how has the point from which you have viewed them changed over the years?

**Gerhardt:** I've been at it for more than 30 years now, starting on the clinic and hospital management side, mainly in the outpatient side, so this long career in the healthcare and caregiving world has taken me in a lot of directions. There's only a few of "me" running around, in that I've been able to be on the caregiver side, on the financing side. I've run HMOs and been closely related to the health insurance world for a long time. I've been on the academic side – ran the healthcare facilities at Michigan State University – and on the technology side. I was an officer of a company making healthcare information systems, and I've sat on the boards of medical device companies. So I've been able to see it from a broad spectrum and lots of different angles, and I still love it. I think it's an absolutely fabulous field to be in.

**BB&T:** The offshoot of that would be, what are some of the most significant changes that you have seen in the life sciences sector overall in that period of time?

**Gerhardt:** I'll call it the changes, or new factors. To me the first one really is the financial situation and the difficult problems we have in dealing with it. And then, as you well know, the big-cost things that are coming at our healthcare system, and what we need to do with it. The ones that I see that are going to be the most difficult in the future for this sector that you and I enjoy so much. The building and financing of technology is going to become very difficult in the next few years.

Then there's the issue of paying for the services and the care. And there's the accessing of coverage – the everyday person on the street accessing not just emergency room coverage, but accessing the whole world of "What can I get to help this thing that makes me ill, or inhibits my ability to act in a healthy way on a day-to-day basis?"

There are three others that I see. For a number of reasons, caregivers, insurers/payers and the technology side have moved apart. I don't think we can solve the major problems that are coming at us with them moving apart. I think they have to move closer together or they have to cooperate in different ways. It has



Patrick M. Kelly photo

### DON GERHARDT Heads LifeScience Alley

become kind of a zone where they are afraid to step across the aisle to cooperate with each other to attempt to do something new or different, and I think we need to encourage new ways of approaching the challenges. The second one is clearly the increase in technology.

The best example is my wife. She was a long-time nurse. She left the nursing profession about eight years ago. She was a high-tech nurse – she was an intensive care and recovery room kind of nurse. She says she couldn't go back today. She looks at what goes on where she worked just a short time ago and says, "I couldn't do it . . . I'm too far behind in technology."

The third major change is the new waves of epidemic-proportion health problems that are different from the black plague, or the polio epidemics that used to wreak havoc among us. The HIV/hepatitis, obesity/diabetes, the age wave, the change in movement and exercise. I'm involved in a small company with some people right now that is getting into what those changes in movement and exercise are doing to our health. Finally there is the convergence with biotech. Those major waves have strong implications for the med-tech world.

**BB&T:** The greater emphasis on dealing with chronic disease is certainly going to be one of the pillars of the industry moving forward, and really, it involves everybody – certainly from the payer perspective backward.

**Gerhardt:** I absolutely agree with you. It causes a kind of a whiplash effect. As new technology or new applications get developed, the questions will be "How much does it cost?" and "How much does it save?" Those are hard things to define and prove. At the same time, they're not illegitimate questions.

**BB&T:** You're right, and I think those two questions might even be reversed from the way you just posed them. That is, before you even consider the cost of a potential new technology, you have to answer the question, "How much can you save?"

**Gerhardt:** At times, I think our industry doesn't understand what's happening with the providers and payers. Providers and insurers are developing these very aggressive, dollar-saving formulae out of their tech evaluation committees or processes – and parts of our industry think they're still going to be able to sell the same way in the future as they're doing now.

**BB&T:** *We spend a lot of time and focus on looking at what's coming down the road, both from the regulatory and payer sides. And it's really obvious that companies still have a little blind spot to a certain extent, saying, "Well, maybe we can get one more iteration out there that is simply a bells-and-whistles thing. But if that hasn't already dried up, it's just about to. The puddle has just about evaporated. There are a lot of habits built into business models that are changing quite slowly.*

**Gerhardt:** And while someone can say, very legitimately, that's the way we improve these devices, these new technologies, the person that's paying for it is saying, "We agree – improve it on your own dollar and bring it back to us when it works."

**BB&T:** *One of the things that I love about the device industry is that there is so much emphasis on development-stage companies. My question is, do you see med-tech business as differing from other sectors with which you have at least a passing familiarity in the way it treats such companies? In a lot of retail industries, for instance, start-ups aren't necessarily encouraged. Ideas are encouraged, and companies like to buy them, but at a whole different stage than in med-tech.*

**Gerhardt:** I think that while IPOs are disappearing relatively quickly, at the same time M&A activity kind of mirrors what you're talking about. But clearly they are expecting down-line M&A activity rather than early-on idea stage, as in retail. Med-tech is treated very differently, and obviously biotech has the same thing. I'm kind of speaking for biotech as well with these responses, because med-tech and biotech are converging so fast.

You've got that payment from Medicare, which is different from other industries. You've got that long investment period. When I first came into the tech side about 10 years ago, it was a substantially shorter turn on investment than it is now. It was in the range of five to seven years to come to liquidity or whatever kind of event, and now it's very typically seven to 10 years. That changes lots of ratios, as you can well imagine – much higher investment amounts are now needed to get the product to market, and then there's that IPO challenge. There is a lot more "angel" money around now, but not all of them are sophisticated investors or sophisticated evaluators of technology.

**BB&T:** *Few sectors can legitimately lay claim to having a "higher purpose." Does the medical technology sector – or let's say life sciences in general – have the rights to such claims?*

**Gerhardt:** Absolutely. We do have a right to that claim for a higher purpose, but we need to under-

stand that we're not the sole claimant, that we're in a boat with others, some of whom are non-profit or government claimants. So it's a tough position to be in during a cost inflation or cost increase time as we're experiencing right now. The "not-for-profits" or the government can quite easily point back at the technology side and say, "Hey, you guys are the cause of all this."

Another piece of information: If you look through mission statements of those governmental or those not-for-profits and in the med-tech arena, all of them typically have "patient" in their statements. And it's true – they're focusing on the patient. So we can't be the only claimant to that.

**BB&T:** *Let's talk a bit about LifeScience Alley. How did it get its start, and how has it changed as it has evolved and grown over the years?*

**Gerhardt:** It got started in 1984, really as an assistance to spotlight the state's emerging and growing, but still quite young medical technology industry. It was focused on the medical device industry and then getting the caregivers and academia and government and then the infrastructure together. From Day One, it was literally in initiating the verbiage of putting it together that they wanted to get all of those sides involved.

Three key people involved in that early on were Earl Bakken from Medtronic, our then-Gov. Rudy Perpich and a guy named Lee Berlin, who was another entrepreneur from here in town. They spent a lot of their own time, the two entrepreneurs did, and some of their own money, on getting it going.

Early on, it was more of a med-tech focus, with those caregivers, insurance companies, etc. involved. There were about 50 member organizations, and we're sitting at just under 600 now. We merged with MNBIO, the biotech association, about three years ago.

We're now really focused on that full ecosystem – we call it an ecosystem that is focused on the health and well-being of humans, animals, plants and the environment. Now, some people might say that is taking on too much, but we're having a hard time proving that it is not appropriate to look at that broader spectrum as we're thinking about the healthcare of the people that we deal with every day. It is an ecosystem.

We do about 110 educational and information programs a year. We have two annual conferences – the Med-Tech Investing Conference we do with IBF [International Business Forum] and our own annual conference. We do a lot of lobbying, and we have national and regional connects that we provide service to and participate in, including AdvaMed and the Biotechnology Industry Organization.

**BB&T:** *How does the LifeScience Alley model compare to other regional associations with which you are familiar?*

**Gerhardt:** We can't find many that are much like ours. We have found one that parallels us – that's Bio-com in San Diego. They're both med-tech and bio, as we are, and they're about the same size and do about the same thing. Others might parallel us a little bit, but they're not a combined med-tech and biotech organization.

**BB&T:** *Matters pertaining to corporate governance and ethics are increasingly in the news. What are your members saying on the subject?*

**Gerhardt:** Two points. I was in a conversation just last week at a board meeting of a not-for-profit. There was an employee from one of our large member companies – and I've had the same comment from large-to-small companies – that their organizations are strongly emphasizing and then spending lots of time and effort toward instilling that high ethical standard that's appropriate for this industry.

The other thing we see is that we've been doing more and more seminars on ethics and governance and that kind of thing among those 110 programs that we put on, the topics of which are driven by our members' requests. So we're seeing positive interest and follow-through on it.

**BB&T:** *If you were President, or maybe Speaker of the House, what actions would you take to better enable the delivery of promising new healthcare technologies to those who would benefit from them? And if cost were not the primary consideration, how would you change the system of healthcare in the U.S.?*

**Gerhardt:** First of all, I'd upgrade the pay scale for the Speaker of the House and the President (laughter). There are four major things that I'd get after. First, I'd identify a number of "quick to market" situations, seeing a major clinical need and then a major dollar-saving potential or need, and how much. I would encourage tech providers and payers to get together to work on it, because out of that I think might evolve a new style of reimbursement if all of them were

working on it together – because they're fighting each other way too much now. Getting them to work together, coming up with new style of reimbursement and then quick to market. That would be the government's participation. Government can help find the quick-to-market approach and help apply a formula or plan for it. That would be No. 1.

Second would be tort and patent reform. We're strangling ourselves without such reform.


Third would be funding of the National Institutes of Health, and then funding of early-entrepreneurship schools. As you look at how the NIH operates, we fund all this scientific/clinical stuff, but then we don't train anybody to bring it to market. That doesn't make sense to me. I think we could, relatively inexpensively, put together entrepreneurship training in junior high schools, high schools and some colleges to help get that really cool technology to market in the right way.

Then the last one, I'd build a system somewhere between the U.S. and Canada and between the U.S. and Europe's healthcare systems. I've lived in them all, and I know them pretty well. I truly believe that healthy lifestyles should be rewarded – if you're going to live a healthy lifestyle, you should be rewarded in some way for it.

**BB&T:** *Is there any question I haven't asked that you wish I had?*

**Gerhardt:** What are we at LifeScience Alley doing to help make all this work? Last year at our annual conference, we saw things happen that wouldn't have happened if we hadn't done what we did. We get people from about 25 states and 12 countries for just a single day – about 1,500 of them this year. What we get to see for that intense time is people exchanging information and network.

For example, some really terrific new things have happened between the University of Minnesota and Stanford. We've seen new fellowships, new investment, new products, etc. That's what we're here for and that's our best example to you of what we do well.

We call it "structured serendipity." It's trying to create multiple situations where serendipity can happen between the right people. ————— 

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# Emerging

## *Interest grows in the least-invasive approaches taken by interventional oncology practitioners*

By LARRY HAIMOVITCH  
BB&T Contributing Editor

LOS ANGELES – Interventional oncology, the treatment of cancer with a device-based approach, is a fledgling subspecialty within the field of minimally invasive medical devices. These procedures are typically performed by interventional radiologists, who utilize image guidance and minimally invasive devices and procedures to treat cancer in the least invasive way possible.

Interest in this new field is clearly increasing. The first meeting of the **World Congress of Interventional Oncology** (WCIO; Beverly, Massachusetts) took place in 2005 in London, and attendance has increased steadily with improving technologies and the desire by patients and insurers to avail themselves of less-invasive approaches. Attendance was at a record level at this year's meeting, held for the second time in the U.S.

**BB&T at  
the World  
Congress on  
Interventional  
Oncology**

As the industry leader in the broader field of interventional radiology (IR), with annual sales in its fiscal year ended May 31 of about \$167 million, it was no surprise to see the significant presence of **AngioDynamics** (Queensbury, New York) at the meeting. With the strategic acquisition of **RITA Medical** (Fremont, California) for about \$225 million in January 2007, AngioDynamics instantly became a major player in interventional oncology.

Its major products in this area, all acquired via the RITA deal, include radio frequency ablation (RFA) devices, the Habib line of conventional and laparoscopic surgical resection devices and embolic microspheres, which are also called drug-eluting beads (DEBs).

These latter two product lines were distributed by RITA under exclusive licensing deals prior to the AngioDynamics purchase. The Habib bipolar resection device, which uses RF energy has been widely used in liver cancer resection procedures and has proven to decrease operative and anesthetic time as well as blood loss.

Drug-eluting beads have the ability to actively sequester a chemotherapeutic agent (for example doxorubicin) from solution and release it in a controlled and sustained fashion into a cancerous tumor. Clinicians

often refer to this modality as transcatheter arterial chemo-embolization (TACE).

Whereas Habib and DEBs are relatively new to the field of interventional oncology, for more than a decade, RFA has been used to treat tumors that were considered unsuitable for conventional forms of treatment such as surgery, radiation, or chemotherapy.

A well-attended AngioDynamics evening symposium, titled "Novel Approaches in the Management of Primary and Metastatic Cancers: Thermal and non-Thermal Ablative Techniques: DEBs and TACE," addressed the use of RFA and DEBs in oncology, as well as the company's newest and potentially most significant technology, irreversible electroporation (IRE).

Riccardo Lencioni, MD, an interventional radiologist from **Cisanello University Hospital** (Pisa, Italy), cited two key studies that validate the thesis that an interventional approach to cancer therapy is effective. Leoncini, one of the world's authorities on RFA, described the AngioDynamics' DEBs, trade-named LC Beads, for intra-arterial injection. He reported on a pilot study, conducted in Italy, of 20 patients with liver cancer which showed that intra-arterial administration of DEBs clearly enhanced the effect of RFA. This regimen led to a high rate of sustained complete response in tumors that had been resistant to standard RFA treatment.

He noted that this small trial showed the first evidence of the synergy between RFA and a controlled, sustained local delivery of a chemotherapeutic agent in human cancer treatment. More importantly, he said that the combination of DEBs and RFA "has the potential to become the standard approach" for treating certain liver cancers. The full results of this study appear in an article titled "Doxorubicin-eluting bead-enhanced radiofrequency ablation of hepatocellular carcinoma: A pilot clinical study" in the August issue of the European periodical *Journal of Hepatology*.

Leoncini also provided information on the landmark Radiofrequency Ablation of Pulmonary Tumors Response Evaluation (RAPTURE) trial, which is believed to be the largest study ever to evaluate RFA for treating lung cancer. According to the **American Cancer Society** (Atlanta), about 161,000 Americans will die from lung cancer in 2008. It is the leading cause of cancer death in U.S.

Some of the details of the study, which were pub-

**Table 1**  
**Key Details of RAPTURE Study**

- A prospective, intention-to-treat clinical trial which enrolled 106 patients with 183 lung tumors) at seven centers in the U.S., Europe and Australia.
- Diagnoses included non-small-cell lung cancer (NSCLC) in 33 patients, metastasis from colorectal carcinoma in 53 patients, and metastasis from other primary malignancies in 20 patients.
- Patients underwent radiofrequency ablation in accordance with standard rules for CT-guided lung biopsy and were then followed for a minimum of two years.
- Correct placement of the ablation device into the target tumor with completion of the planned treatment protocol was feasible in 99% of patients.
- A confirmed complete response of target tumors lasting at least 1 year was shown in 75 (88%) of 85 assessable patients. No differences in response were noted between patients with NSCLC or lung metastases.
- Cancer-specific survival was 92% at 1 year and 73% at 2 years in patients with NSCLC, 91% at 1 year and 68% at 2 years in patients with colorectal metastases, and 93% at 1 year and 67% at 2 years in patients with other metastases.
- Overall survival was 70% at 1 year and 48% at 2 years in patients with NSCLC, 89% at 1 year and 66% at 2 years in patients with colorectal metastases, and 92% at 1 year and 64% at 2 years in patients with other metastases.
- Patients with stage I NSCLC (n=13) had a 2-year overall survival of 75% and a 2-year cancer-specific survival of 92%.
- No procedure-related deaths, defined as any death within 30 days after treatment, occurred following any of the 137 ablation procedures.

lished in the July 2008 issue of *The Lancet Oncology* are provided in **Table 1**. In commenting on the trial, Leoncini said that "RFA could become a treatment option for all patients who cannot have standard surgery, whether they have concomitant chemotherapy and radiotherapy or not."

Robert Martin, MD, a surgical oncologist at the **University of Louisville**, further supported the use of LC Beads for liver cancer in an informative talk. He noted that while there are a plethora of options to treat liver cancer (see **Table 2**), the use of drug-eluting beads affords the advantages of more precise drug delivery and consistent results with significantly reduced patient side effects.

Martin reported the first results of an LC Bead registry, which was launched over a year ago and to date has enrolled over 100 patients at 11 active U.S. sites. It is currently enrolling liver cancer patients, the vast majority of whom have already failed first-line chemotherapy, with the goal of embolizing the vessels which are feeding their hypervascularized tumors. Physicians are employing two different chemotherapeutic agents — doxorubicin for liver and most other cancers, and irinotecan primarily for metastatic colorectal cancer.

Martin indicated that the result of the registry so far is showing that most patients are experiencing a "dramatic response rate." He said that "this is a viable drug-delivery concept, is safe and effective and may represent a paradigm shift." However, he also sounded a cautionary note, saying that "we still have many more questions than answers about how this will fit into the management of our cancer patients."

### *Surgery at the cellular level*

The final two talks at the AngioDynamics symposium were devoted to a detailed discussion of its exciting new technology, irreversible electroporation. In introducing this new concept to the interventional oncology community, AngioDynamics describes it as "NanoKnife – Surgery at the Cellular Level."

IRE energy is delivered through needles and image guidance very similar to existing ablative technologies such as radio frequency or cryothermia but instead of heating or freezing to kill the targeted tissue, it uses electrical fields to cause cell death. The powerful electrical field, which passes through an electrode array, causes permanent nanoscale defects or pores in the cell membranes. The permanently impaired cells, killed through the process of virtually instantaneous apoptosis are then removed through the body's natural immune system.

As compared to other ablation methods, it is highly selective and does not damage adjacent critical structures such as ducts and blood vessels. It appears at this early juncture that it could have very broad

**Table 2**  
**Treatment Options for Liver Tumors**

- Surgical resection
- Liver transplantation
- Cryoablation
- RF ablation
- Ethanol injection
- Hepatic artery infusion pump
- Systemic chemotherapy drug
- Chemoembolization (TACE)

Source: Robert Martin, MD, presentation at the 2008 World Congress on Interventional Oncology

application within the field of tissue ablation, spanning benign tissue removal such as BPH and malignant tissue represented by cancer.

The technology was developed at the **University of California, Berkeley** and then licensed to a private company called **Oncobionic**. In October 2006, AngioDynamics signed an agreement to acquire Oncobionic, making an initial investment of \$5 million and a commitment to pay an additional \$20 million within two years, subject to successful human use of IRE.

In April, AngioDynamics reported that the first human clinical cases, treating prostate cancer, had been performed and that it was moving forward with its plans to complete the acquisition of Oncobionic. As per the agreement, an additional \$10 million was paid, with two more payments of \$5 million each scheduled within the next 18 months.

Two speakers fluent about IRE discussed its attributes at the evening symposium. Stephen Kee, MD, associate professor of radiology at **University of California Los Angeles (UCLA)** noted in his talk that IRE has been thoroughly investigated at his institution from a variety of standpoints. A series of key questions (see **Table 3**) have been investigated and appropriately answered and now the company will be aggressively moving forward with both animal and human trials.

The university has funded a two-year animal trial, which began in September 2007. A tumor is implanted in rabbits, with one-third followed up as controls, one-third treated with RFA and one-third treated with IRE. The endpoint will be the growth rate of the tumors, or lack thereof.

According to Kee, IRE has several important advantages, including its very short procedure time, its larger ablation zone, the absence of a heat-sink effect and its ability to be monitored with ultrasound in real time.

IRE has broad application within the field of cancer, but given the large number of prostate cancer cases that occurring annually, the company has opted to begin working with this area. Six human prostate cancer cases have been performed to date, taking advantage of a 510(k) approval received in November 2006 for soft tissue ablation. AngioDynamics is planning to proceed with a prostate-specific clinical trial, first treating animals and then moving into human trials.

In its recent 4Q08 conference call with analysts, the company indicated that it hopes to begin placing the first 20 NanoKnife units with "thought leaders" in the U.S. and Europe. It also noted that a clinical trial will begin soon in Italy and that additional prostate cancer patients will be treated in the U.S. AngioDynamics said it expects to invest \$5 million in its current fiscal year ending May 31, 2009, in developing and commercializing IRE.

The final speaker was Gary Onik, MD, who is one of the three founders of Oncobionic and also has been a driving force in minimally invasive cryoablation of the prostate.

Onik, an interventional radiologist from **Celebration Health Florida Hospital** (Celebration, Florida), is widely recognized as one the earliest adopters in the field of interventional radiology. Onik compared surgery for women with breast cancer and surgery for prostate cancer. He contended that breast surgeons have shown that a minimally invasive lumpectomy, which spares breast tissue, can be as effective as a more aggressive procedure.

Prostate cancer patients can be safely treated with a "middle ground" between the two extreme methods of treating prostate cancer – the gold standard of radical prostatectomy and the more controversial and passive approach of "watchful waiting." Armed with data from several studies, Onik suggested that about two-thirds of all prostate cancer is amenable to a less-invasive approach, which he calls the "male lumpectomy."

He disclosed the results of his series of 120 focal cryoablation patients, which demonstrated excellent efficacy and reduced morbidity, especially as it relates to urinary incontinence and sexual potency.

As portrayed in **Table 4**, on the next page, Onik noted that IRE has numerous potential advantages in treating prostate cancer and relatively few drawbacks. The early human data in the treatment of prostate cancer has been very encouraging, with negative biopsies and full continence and potency for all six patients. He did note that there are potential disadvantages that remain, including "the great unknowns," i.e., finding a problem or challenge that heretofore has not been addressed or surfaced.

Onik concluded by saying, "While we have a lot more work to do on IRE to establish its specific role, I am very excited about its potential."

An intriguing variation on the theme of attacking cancer cells through interventional means was presented at a main WCIO session by Tony Reid, MD, associate professor at the **University of California**,

**Table 3**

**IRE — Key Questions That Have Been Investigated**

- Do IRE pulses actually kill tissue?
- What are the optimum parameters?
- How far apart should the electrodes be?
- How clearly defined is the "kill zone"?
- Can anything be imaged?
- What happens to blood vessels and bile ducts?
- What is left behind (i.e., scar, cyst etc.)?
- What happens to cancers?

*Source: Stephen Kee, MD, presentation at the 2008 World Congress on Interventional Oncology*

**Table 4**  
**Potential Advantages and Disadvantages of Irreversible Electroporation**

**Advantages**

- Predictable
- Narrow transition zone
- Uniform tissue destruction
- Structure sparing (nerves, vessels, ducts)
- Immunologic effect
- Rapid
- Cost-effective

**Disadvantages**

- Requires general anesthesia and neuromuscular blockade
- Mechanism of destruction still unknown (potentially toxic?)
- The “great unknowns”

Source: Gary Onik, MD, presentation at the World Congress on Interventional Oncology 2008

**San Diego.** He discussed the use of a breakthrough product class of cancer therapeutics – vaccinia viruses – that have been engineered to target, attack and eradicate cancer without harming the surrounding cells.

These agents are derived from a proprietary class of targeted and armed oncolytic poxviruses. They can multiply selectively within cancer cells, leading to their destruction. These newly created copies are then released and are able to infect and eradicate other tumor cells both locally and in distant sites in the body. This cycle of replication, cancer cell destruction, release and spread is then repeated. Normal cells are not affected, resulting in safety and tolerability.

The developer of one of these products, **Jennerex Biotherapeutics** (San Francisco), has been reporting data on its virus JX-594 at recent medical conferences. Preliminary Phase I data, which were published in the


June issue of *The Lancet Oncology*, in an article titled “Use of a targeted oncolytic poxvirus, JX-594 in patients with refractory primary or metastatic liver cancer: a Phase I trial,” showed strong evidence of safety and efficacy. The 14 patients who were treated in this trial received an ultrasound-guided intratumoral injection of JX-594.

Reid said that JX-594 early results are “extraordinarily good” and that this approach could potentially become a “major weapon” against cancer, especially lung and liver. A larger Phase II trial is now under way.

**Emphasis on image guidance**

One of the recurrent themes of this conference was the need for better image guidance, which cast the privately-owned company **Traxtall** (Toronto) in the limelight. Its FDA-approved PercuNav system guides a needle or probe to any pre-defined target using pre-operative or intra-operative images derived from CT, MRI or ultrasound.

By tracking the tip of either rigid or flexible instruments using tiny sensors embedded in the instruments, its system provides real-time 3-D visualization and navigation during RFA and other interventions such as biopsies, ultrasound trackers and probes. The system transforms 2-D patient images into dynamic maps showing the location of the instrument in the patient.

The company refers to its system, which sells for about \$100,000, as a “GPS system for the human body.” It has recently placed systems at several prestigious sites such as **Massachusetts General Hospital** (Boston) and the **National Institutes of Health** (Bethesda, Maryland) and has several more key hospitals in its pipeline that will soon be accepting shipment and installation. The company is now ramping up its sales force for a big commercial selling effort. 

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# New developments broadening reach of biomaterials makers

By JEFFREY BERG, PhD  
BB&T Contributing Editor

AMSTERDAM – The World Biomaterials Congress, held here in early June, drew 3,000 participants from 54 countries with the largest representation from the U.S., followed by the UK and the Netherlands, the host country. This congress convenes every four years and will be held in 2012 in Chengdu, China.

The **Dutch Program for Tissue Engineering** (DPTE; The Hague) was launched in 2004. It is a consortium of research groups involving most Dutch universities, medical centers and several research institutes.

The program covers three platform technologies – stem cells, scaffolds and bioreactors. It aims to standardize procedures in stem cell research since laboratories are currently using stem cells from many different sources, including cord blood, bone marrow, fetal cells from amniotic fluid and fat tissue. It focuses on optimal conditions and signaling pathways involved in the growth and differentiation of stem cells. In the field of scaffolds, collaboration has accelerated the development of optimal carrier materials for cells, often with a mixture of biological and synthetic components.

Bioreactors provide an optimal environment for the growth of tissues. Researchers aim to develop the technology to grow tissue grafts, primarily cardiovascular tissues (heart valves and small vessels) and cartilage. Living cells (myofibroblasts on the inside and endothelial cells on the surface) are seeded on a biodegradable polymer scaffold and grown under conditions of pulsatile mechanical stimulation. In three to four weeks of cultivation within the bioreactor, much of the polymer is degraded and replaced by collagen fibers produced by the myofibroblasts. The architecture of these fibers has a close resemblance to the natural heart valve of a newborn baby.

A company has been started to produce heart valves under GMP conditions and perform pre-clinical testing of the valves in collaboration with **Zurich University Hospital** in Switzerland and **Utrecht University Medical Centre** (Utrecht, the Netherlands). The collaboration may yield a new approach in which cells obtained from amniotic fluid may be used to start growing the heart valve upon diagnosis of congenital heart disease after 20 weeks of gestation, so when the baby is born he heart valve would already

be available for implantation.

Researchers at DPTE are developing bone from a syringe to be used as an injectable bone substitute, and the engineering of bioceramic scaffolds that may include small bioactive agents within the scaffold, such as growth factors. Progress has been made toward the development of injectable scaffolds that could be used to mend herniated intervertebral discs.

A new electrostatic spray deposition apparatus has been developed to deposit calcium phosphate and biological agents. An electrospinning technique is used to create nanofibers with different properties. The bone-forming properties of polymers can be enhanced by coating them with a layer of bone-like apatite of calcium phosphate ceramic.

## *Biocompatible polymers for devices*

**DSM Biomedical**, a division of **Royal DSM** (Heerlen, the Netherlands) has identified biomedical materials as an important growth area and is aiming for \$150 million in sales of medical biomaterials by 2012. DSM's Dyneema Purity, made from polyethylene and developed for medical applications, is claimed to be the world's strongest fiber. It is flexible, soft, possesses abrasion resistance and can be bent, twisted or stretched. It is being used in orthopedic sutures.

A new grade of Dyneema Purity with thinner diameters was launched at the conference. It was designed for smaller and lower-profile implants for use in minimally invasive procedures without sacrificing strength and durability.

Consistent with its strategy for growth, DSM acquired the **Polymer Technology Group** (PTG ; Berkeley, California) which makes synthetic fibers, engineered plastics and resins used in coatings. PTG touted the strength of its thermoplastic polycarbonate-urethane. A paper was presented on the use of this biomaterial with permanently bonded surface-active alkylammonium chloride end groups for imparting antimicrobial surface properties. PTG expects 2008 sales to exceed \$40 million, with a projected 20% annual growth over the next three to five years.

PTG has been supplying device makers with biomaterials since 1989. It is collaborating with **Bezwada Biomedical** (Hillsborough, New Jersey, and Hyderabad, India) in offering synthesis, scale-up and processing of both generic and novel bioresorbable polymers for medical applications. In September 2007, PTG spun out **Emergence**, a life science incubator that focuses on opportunities in biostable polymers, resorbable polymers and polymers for therapeutic use.

**Solvay Advanced Polymers** (Alpharetta, Georgia), a division of **Solvay** (Brussels), and **FMC BioPolymer**, a division of **FMC Corp.** (Philadelphia), have also targeted biomaterials for growth of their

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businesses. This is an area which many companies avoided after **Dow Corning** (Midland, Michigan) declared bankruptcy under the weight of liabilities from silicone breast implants. Suppliers of implantable materials now have product liability protection offered by the 1998 Biomaterials Access Insurance Act.

Solvay Advanced Polymers markets Solviva biomaterials, a family of polymers launched late last year that are used in implantable medical devices for both short-term and long-term applications. They include PEEK (polyetheretherketone), self-reinforced polyphenylene, polyphenylsulfone and polysulfone. It recently launched Ixef polyacrylamide, which can be sterilized by gamma radiation and still maintains its mechanical and chemical resistance properties. It is intended for use in disposable instruments.

### *Polymers, ceramics for orthopedic use*

**Ceremed** (Los Angeles) markets Ostene, an alkylene oxide copolymer that is a water-soluble bone hemostasis material and is pressed into the bone to stop bleeding. It dissolves in 48 hours, does not swell and is not metabolized. To date, Ceremed has sold over 125,000 units in the U.S. for sternal closure after coronary bypass graft surgery and is currently developing its international markets. Ostene is an alternative to the controversial bone wax which is made from beeswax.

AOC, another version of alkylene oxide copolymer, is a carrier system for drugs or biologics such as antibiotics, bone morphogenic protein and demineralized bone matrix, as well as other pharmaceuticals. The company has developed a porous polyethylene (PPE) coated with AOC for ease of insertion due to tissue grab, and for use in augmenting or reconstructing the cranio-maxillofacial skeleton. It also can be applied as a coating on other medical devices for ease of insertion or to carry an antibiotic to fight infections.

**Orteq Bioengineering** (London) is awaiting CE-mark approval for Avtfit, a polyurethane-e-caprolactone copolymer foam for use after meniscectomy. This biodegradable meniscal implant has 80% porosity, is sutured in place and serves as a scaffold. Blood cells enter the pores and meniscus-like tissue is regenerated. The company completed a 52-patient clinical trial in Europe with 12-month follow up in which arthroscopic procedures were performed on patients with irreparable meniscus tears. U.S. clinical trials are planned for the last quarter of this year.

**Oxford Performance Materials** (Enfield, Connecticut) markets OXPEKK (polyetheretherketone) thermoplastic polymers for use in long-term implantable devices. It is used by **PINA Medizintechnik** (Neuhausen, Switzerland) and **Orthopaedic & Spine Development** (Avignon, France) in spinal

fusion cages. PEEK is widely used in cages and spacers for cervical spine fusion applications.

The company claims that OXPEKK has a wider processing window than PEEK for injection molding. Also, unlike PEEK, it is available in an amorphous form that is not quenched or alloyed, and can be steam sterilized without altering its crystalline structure.

**Promimic** (Gothenburg, Sweden) is working in the field of bioactive nanotechnology to produce hydroxyapatite with the same structure and shape as it exists naturally in the human body. The material can be applied onto various substrates including metals, ceramics and some polymers. Promimic HA<sup>nano</sup> was shown in *in vivo* studies to increase bone-to-implant contact after only a few weeks and to increase osseointegration.

**CAM Implants** (Leiden, the Netherlands) is a supplier of custom-made bioceramic powders and granules for orthopedic and dental applications as bone substitutes and as coatings on orthopedic prostheses and dental implants. The materials are hydroxyapatite alone or in combination with tricalcium phosphate usually in a 60/40 ratio. Other ratios of the combined materials will result in different densities and particle sizes.

Other bone replacement materials that were exhibited include:

- Clacibon, a synthetic bone substitute comprising a calcium phosphate paste sold in Europe by **Bio-met** (Warsaw, Indiana).
- Mozaik from **Integra LifeSciences** (Plainsboro, New Jersey), an osteoconductive scaffold used as a bone void filler, comprising 80% tricalcium phosphate and 20% Type 1 collagen.
- OsSatura TCP, a bone void filler composed of pure tricalcium phosphate, and OsSatura BCP, made with biphasic tricalcium phosphate, which has a slower resorption rate, from **IsoTis OrthoBiologics** (Irvine California), a subsidiary of Integra LifeSciences.
- chronOS from **Synthes** (Solothurn, Switzerland), a synthetic bone graft substitute that serves as an osteoconductive scaffold and is made from beta tricalcium phosphate.

**Vivoxid** (Turku, Finland) displayed its BonAlive bioactive silicon oxide glass that is used in orthopedic and cranio-maxillofacial applications. It was shown in clinical trials to have better bone-growth promoting properties than Bioglass.

BonAlive granules are bioactive and resorbable. MetAlive is in development for use as a coating for metals, ceramics and polymers. It possesses osteoconductivity and provides a safe attachment to soft tissue, reducing inflammatory reactions while speeding up the healing response. It is being evaluated in two clinical trials for use in dental implants and in a bone-anchored hearing aid.

### *Polymers for drug delivery, devices*

**Purac Biomaterials** (Gorinchen, the Netherlands), a supplier of monomers and resorbable polymers, is the world's largest producer of lactic acid and lactide and polylactide derivatives. Purasorb polymers are used in controlled drug delivery systems and in soft tissue fixation devices such as screws, pins, anchors and tacks in knee and shoulder surgeries. A new product is a copolymer of L-lactide and ε-caprolactone, a flexible and resorbable material that is used in a composite with ceramics for spinal fusion applications. It also is being used in tissue-engineered scaffolds.

**Boehringer Ingelheim** (Ingelheim, Germany) markets an extensive line of Resomer polylactide/polyglycolide copolymers which biodegrade by hydrolysis after implantation or injection. Varying degradation rates and degrees of mechanical stability can be achieved by modifying the molecular weight and copolymer composition. The company's newest product is thermoplastic polydioxanone for use in medical implants.

**Durect** (Cupertino, California) displayed its Lactel absorbable polymers fabricated from polylactide/polyglycolide copolymers for use in drug delivery applications and implanted medical devices. **Ortec** (Piedmont, South Carolina) featured its glycolide and lactide monomers. **Innocore** (Groningen, the Netherlands) gave a presentation on its SynBiosys family of multiblock polymers for use as a biodegradable drug delivery system which is currently in clinical trials for use as a coating on coronary stents, and as microspheres for subcutaneous drug delivery applications

### *Chitosan and collagen products*

**NovaMatrix**, a business unit of FMC BioPolymer, markets alginate foam and ultrapure chitosan. It featured Novatach peptide-coupled alginates for enhancing cell attachment, and the Novafect series of highly deacetylated low molar mass chitosan, which is being evaluated for non-viral gene/oligonucleotide delivery.

**Pharming** (Leiden, the Netherlands) has produced large quantities of recombinant human procollagen. Several variants of collagen will be prepared from this procollagen.

**CollPlant** (Rehovot, Israel) is developing rh-collagen that is produced from transgenic tobacco plants. **iGen** (Taipei) has a collagen matrix implant that serves as a biodegradable scaffold for use in ophthalmic surgery. It improves the remodeling of the regenerating tissue and prevents scar formation.

**Syntacoll**, a division of **Innocoll Pharmaceuticals** (Ashburn, Virginia), produces CollaRx, a resorbable collagen sponge or membrane implant for use in drug delivery. Collatamp G is its gentamicin-impregnated collagen implant that is used following surgical

debridement for the treatment of bone infection.

**CollTech Australia** (West Perth) supplies OviColl, collagen of ovine (sheep) origin, and **Devro** (Chryston, Scotland) supplies Apcoll, bovine collagen.


### *Therapeutic and diagnostic Applications*

**TiGenix** (Belgium) is developing products for the treatment of articular cartilage defects. ChondroCelect, its lead product, is a cell-based therapy focusing on durable repair of cartilage defects of the knee and has completed a randomized Phase III trial. The product is used in combination with autologous chondrocytes for implantation. The aim is for ChondroCelect to aid in the durable repair of cartilage defects and postpone the onset of osteoarthritis.

**Biocompatibles** (Farnham, UK) has entered into a new business area with CellLuminate, nanoparticles that are able to enter and deliver a payload into any cell with active endocytosis. It can deliver an encapsulated fluorophore to fluorescently track cells in 2-D and 3-D environments for extended periods. It has been tested on stromal, epithelial and endothelial cells.

**3D Biotek** (North Brunswick, New Jersey) is engaged in the research and development of 3-D porous devices for stem cell culture, stem cell delivery and tissue engineering applications. Its first product line is 3D Insert, a series of 3-dimensional porous scaffolds for use with multi-well cell culture plates. They are made from both biodegradable and non-degradable polymers and are composed of struts/filaments that are joined together to form a porous structure. They are available in polycaprolactone and polylactide/polyglycolide. A polystyrene scaffold will be the next product.

### *Biological vascular graft*

**Arterion** (Gothenburg, Sweden) is developing biosynthetic vascular grafts suitable for human applications that are made from microbially derived cellulose using *Acetobacter xylinum*. Vessels can be made with an internal diameter of less than 6 mm. They are produced by electrospinning of nanofibers, a proprietary process developed by Professor Paul Gatenholm at **Chalmers University of Technology** (Gothenburg) that was the subject of several posters. 

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# Minimally, non-invasive technology detects diseases of GI tract

By DIANA TUCKER  
BB&T Contributing Editor

SAN DIEGO — Nearly 16,000 physicians, researchers and academics from around the world gathered here in mid-May under brilliantly sunny skies and record-breaking warm temperatures to attend the 2008 Digestive Disease Week 2008, the largest conference of its kind.

Advances in micro-technology have expanded the options available for endoscopists to treat, in addition to diagnose, certain alimentary tract diseases in an even less-invasive manner than laparoscopy, a minimally invasive technique usually performed by surgeons.

Many innovative products were showcased here, from the latest advances in colon cancer surveillance and treatment to novel endoluminal techniques for obesity and GERD, all of which access the gastrointestinal tract through an endoscope.

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Digestive  
Disease  
Week**

Standard goals for new medical technologies are to provide for better patient care and/or reduce cost, both of which are captured with Confocal Laser Endomicroscopy (CLE). This new real-time microscopic technique may eventually lead to skipping the entire step of sending biopsies to pathology and could change the way gastrointestinal diseases are detected.

CLE, a technology currently FDA-cleared and marketed by **Pentax Medical** (Montvale, New Jersey) and **Mauna Kea Technologies** (Paris), places a tiny microscope at the tip of an endoscope that magnifies the image by 1000 times, helping endoscopists to determine on-the-spot whether a lesion is suspicious, or even cancerous, or not.

While the Pentax Medical system has the microscope incorporated into the endoscope, Mauna Kea's Cellvizio system — which has completed more than 1,000 procedures to date — allows its miniaturized microscope to be threaded through all endoscopes.

At that magnification, the resolution is almost as reliable as a pathologic sample, and may eliminate the need for biopsy to diagnose gastrointestinal conditions including reflux disease, colon cancer, and inflammatory bowel disease.

"Up until now, patients waited days or weeks for a diagnosis; further, it has been difficult to detect subtle precancerous lesions, often leading to time-consuming procedures as well as uncertainty about missing something important" said Pankaj Pasricha, MD,

professor of medicine, gastroenterology and hepatology at **Stanford University School of Medicine** (Stanford, California). "New techniques such as CLE will change the way we diagnose patients, allowing us to treat them more accurately, quickly and appropriately."

Kerry Dunbar, MD, of the department of medicine-gastroenterology at the **Johns Hopkins Medical Institutions** in Nantes, France, has performed 2,102 CLE examinations and found that the overall accuracy rate for CLE was 91% in the upper GI tract and 93% in the lower tract. "This has the potential to help patients more quickly," said Dunbar, adding that given the rapid progression of cancers, earlier detection and treatment is critical.

In her study, she found that 20% to 30% of the cases would have had a changed diagnosis using CLE. At this point, biopsies are still taken and sent to the lab, but in the future with more experience with CLE, it will be possible to be able to immediately diagnose and treat, eliminating the weeklong trip the specimen takes to the pathology lab.

With that as the great promise for the future, today's advantage is that the number of biopsies taken per CLE examination are significantly reduced, offering a cost savings for pathology exams and a reduction in time the patient is under sedation — another savings in cost as well as providing better patient care.

In another collaborative study reported on by Dunbar, CLE was used to diagnose patients with Barrett's esophagus, a disease in which dysplasias are difficult to see with an endoscope. "We were able to take 60% fewer biopsies and still detect the same amount of cancers," she said. "We were able to better target our lesions and could take five biopsies instead of 20, realizing a tremendous cost and time saving without sacrificing accuracy."

Another CLE researcher who presented at DDW, Michael Wallace, MD, of the **Mayo Clinic** (Jacksonville, Florida), found that, "The probe-based confocal microendoscopy system allows immediate diagnosis of colorectal lesions with malignant potential and can distinguish them from non-neoplastic polyps with a high level of accuracy." He also noted that this method has the potential of obviating polypectomy of non-neoplastic polyps.

With these positive early reports and only two players, it is safe to assume that there will be new entries in this market in the near future.

Yet another interesting diagnostic technology is that of capsule endoscopy, introduced by **Given Imaging** (Yokneam, Israel) in 2001 and now boasting more than 730,000 PillCam video capsules having been sold.

The PillCam video capsule is a disposable, miniature video camera contained in a capsule that can be

easily ingested by the patient and whose images are then captured and stored in a belt worn around the patient's waist for eight hours.

The capsule transmits high-quality color images of the gastrointestinal (GI) tract, enabling physicians to visualize distinct portions of the tract.

Given's first product, cleared by the FDA in 2001, captured images of the small intestine, followed by the clearance of the esophageal PillCam in 2004, and the PillCam Colon that already has its CE-mark will be FDA-cleared for use in the U.S. next.

Swallowing a pill is much easier for many patients who cannot or will not have an endoscope placed in their GI tract, or who cannot undergo the sedation required for endoscopic procedures.

In addition to ease of use for the patient, the PillCam also is the only non-invasive device able to visualize the entire small bowel mucosa, previously visible only by surgery.

The results of an eight-center European study presented here by Jacques Deviere, MD, of **Erasme Hospital** (Brussels, Belgium), demonstrated encouraging results for detecting colo-rectal polyps compared to colonoscopy.

"The promise of PillCam Colon is increasing the number of colo-rectal screenings, which remain disappointingly low in Europe," he said. "This patient-friendly alternative could become a key tool in the effort to reduce the more than 212,000 colo-rectal cancer deaths annually in Europe."

Deviere added, "Patients who can't or are unwilling to undergo a colonoscopy have a new way to be screened in a very easy, painless way. If polyps or cancerous lesions are found, then the physician can perform a subsequent procedure to remove the lesions."

He said the initial data on PillCam Colon is "extremely promising, and we look forward to additional clinical information to determine how best to use this valuable diagnostic tool."

### ***Taking NOTES on a surgical option***

No gastrointestinal meeting would be complete without a session on NOTES, or Natural Orifice Translumenal Endoscopic Surgery, a marriage between flexible endoscopy and laparoscopic surgery that was designed to be scarless, and now is found to also be almost painless, and with shorter recovery times than laparoscopic surgery.

DDW featured Anthony Kalloo, MD, professor of medicine and gastroenterology at **Johns Hopkins University School of Medicine** (Baltimore) and a pioneer of NOTES in the U.S. Discussing "Breakthroughs in Endoscopic Techniques and NOTES," Kalloo had the attitude of "If you can imagine it, it can happen."

Expounding on the very latest experiments that have been done using the NOTES procedure, he pointed out that the initial goals of NOTES were to be

**Table 5**  
**Fundamental Principles of Surgery**  
**Required for NOTES**

- Safe access
- Secure closure
- Prevention of infection
- Suture application
- Spatial orientation
- Control of hemorrhage

able to practice fundamental surgical principles, such as those listed in **Table 5**, while operating through a flexible endoscope.

Kaloo described early glimpses into research that have the opportunity to change the way medicine is practiced today.

1) The opportunity to perform surgery outside of the operating room. Early studies have shown that a sterile environment such as the OR may not be required for NOTES procedures nor anesthesia in many procedures, alleviating the need for the costly OR.

2) Acute trauma may be able to start treatment onsite. Paramedics may be able to begin treatment of an acute trauma at the site of the injury using NOTES techniques, such as applying cellulose to stop intraperitoneal hemorrhage.

3) Previously non-accessible areas of the spine could be treated. There has never been access to the anterior spinal column, but with NOTES, this could present a big opportunity for spinal repairs such as disc replacements, and other interventions that have been considered inaccessible.

4) Mobile robots may be able to treat from a distance. Mobile robots may be able to be passed down the scope, make incisions, and have a surgeon perform the actual surgery from a remote place. These are all possibilities for this new technology and are being investigated worldwide.

5) Intrauterine fetal procedures. Another new frontier that is being tested is the use of NOTES in pregnancy. Kalloo cited research presented here by Samuel Giday, MD, of the department of medicine and gastroenterology at Johns Hopkins, titled "Successful Diagnostic and Therapeutic Intrauterine Fetal Interventions by NOTES."

"An intrauterine fetal intervention is an area where morbidity and mortality using standard laparoscopic techniques is substantial," said Kalloo. Current transabdominal laparoscopic fetoscopy is less invasive, but limited by rigid instruments that only allow anterior access to fetal parts.

Giday introduced transgastric and/or transvaginal flexible endoscopes fitted with high-resolution ultrasound into the peritoneal cavity and allowed for full viewing of the fetus with visualization that was equivalent or superior to transabdominal ultrasound. He also was able to perform transuterine intracardiac

**Table 6**  
**Futuristic Research Being Done in NOTES**

- Move out of the OR
- Acute trauma treated on-site
- Spinal interventions
- Intrauterine fetal procedures
- Mobile robot

injections with no immediate complications or evidence of induction of preterm labor following the procedures. "Although far away from clinical applications, NOTES has potential for intrauterine diagnostic and therapeutic fetal procedures," Kalloo said.

After mentioning that several new products were developed quickly by industry in order to enable the physician to practice these fundamentals, he stated that even further futuristic research is continuing in NOTES, as listed in **Table 6**.

### *New roles for endoscopists*

Endoscopic procedures were first introduced as a diagnostic tool that allowed the physician visualization of the alimentary tract and resulted in well over 2 million scope procedures being performed in the U.S. annually. The next step – to be able to treat through the endoscope – required advanced enabling technology, an example of which are polypectomies, which occur in 20% of all colonoscopies, where the polyps are removed with the same scope and at the same time as the screening procedure.

Advanced technologies allow for new clinical applications to rapidly spring up. Such is the case with flexible therapeutic endoscopy which now also includes NOTES procedures, as well as new methods to treat Barrett's disease, GERD and obesity, to name a few. Endoscopists, initially thought of as diagnosticians, are assuming more treatments, using the latest advances in their primary tool: the endoscope. Now there are a myriad of procedures – from treatment for GERD and Barrett's esophagus to novel bariatric procedures– that can be performed through a flexible endoscope, with the numbers of new advances and applications for these new technologies growing almost daily.

"Bariatric surgery is one of the most common surgical procedures in the U.S., with more than 240,000 surgeries performed annually and the prediction of laparoscopic gastric bypass becoming the most commonly performed surgical procedure in the US during this decade," said Adam Slivka, MD, associate chief of gastroenterology, hepatology and nutrition at the University of Pittsburgh Medical Center.

"A new role for endoscopists is that of managing the complications of bariatric surgery where the endoscopist is playing an increasing role in post-op care," said Lawrence Friedman, MD, professor of medicine

at **Harvard University** and **Tufts University School of Medicine** (both Boston). Bariatric surgery patients are, by definition, a high-risk population and as they age will continue to present with late stage surgery-specific issues, most of which can be handled endoscopically.

In addition to endoscopic repairs for bariatric procedures post-op, several new technologies are addressing other novel approaches to performing once-surgical procedures through an endoscope.

Charles Filipi, MD, of **Creighton University School of Medicine** (Omaha, Nebraska), presented a new transoral gastropasty device for GERD and obesity, which is expected to be available for human trials later this year.

The noninvasive gastropasty device can treat two separate disorders: GERD and morbid obesity, both of which "are particularly serious health issues in the western hemisphere and major contributors to the escalating cost of health care in the U.S.," Filipi said.

He added, "We believe that this device will result in much more effective treatments for both conditions, fewer complications and less patient expense, while permitting each procedure to be performed on an outpatient basis."


Conventional treatments for GERD and obesity are performed surgically, requiring hospitalization and the potential for complications. GERD is the third-most-prevalent disease in the U.S., with more than 19 million people suffering from it weekly and 61 million Americans reporting heartburn monthly.

The device, a flexible tube with a metal capsule at the tip, is introduced through the mouth and esophagus, suctions two sides of the specified juncture in position for suturing, removes the mucosal lining, then stitches the two sides back together. The theory being that by suturing mucosa-to-mucosa, a stronger bond is formed and the resulting durability allows it to last longer, distinguishing this procedure from other noninvasive methods that have been developed.

**Safestitch Medical** (Miami) has developed the device with licensed intellectual property from Creighton University.

Also competing in this space is **Endogastric Solutions** (Redmond, Washington), which recently reported that 85% of patients remain symptom-free and off daily GERD medication at one year after transoral incisionless fundoplication surgery using the company's EsophyX device.

The EsophyX device also enables surgeons and advanced interventional gastroenterologists to offer their patients substantive anatomical repair without incisions for gastroesophageal reflux disease (GERD).

Earlier entries in the area of endoluminal procedures for GERD were **C.R. Bard's** (Murray Hill, New Jersey) Endostitch and **NDO Surgical's** (Mansfield, Massachusetts) Plicator. 

# Wide range of device approaches seen at Biomed Israel event

By JEFFREY BERG, PhD  
*BB&T* Contributing Editor

TEL AVIV, Israel – This country’s national life science and technology conference, Biomed Israel, held here in late May, drew 6,000 attendees from around the globe that were treated to an extensive program of company presentations and exhibits.

The Israeli life science industry is young, growing and exuberant. According to **Israel Life Science Industry** (ILSI; Herzliya), a non-profit organization and the conference’s main sponsor, there are about 900 life science companies in Israel, of which 72.5% were founded during the last decade and 23.7% of them are revenue-generating.

Medical devices account for 53% of Israel’s life sciences industry. Their product offerings are in over 20 areas, the leading ones being cardiology, gynecology, oncology, neurology and neurodegenerative disease, ophthalmology and orthopedics. A smaller number of companies focus on medical fields such as endocrinology, wound management and infectious diseases. See **Table 7**.

On a per-capita basis, Israel is in first place in the total number of granted patents in the medical device area and ranks seventh in the absolute number of patents. Israel is ranked second in the number of papers in leading life science publications per 100,000 inhabitants.

Exhibitors at Biomed Israel included several countries and U.S. states that are seeking to attract Israeli companies to open branch offices or create joint ventures. Indeed, many Israeli companies already have facilities in the U.S., while retaining research and development activities in Israel. For example, **BioLineRx** (Jerusalem), Israel’s leading drug development company, recently announced the establishment of operations in Rockville, Maryland.

Many of the emerging med-tech companies featured below are housed within one of Israel’s many groups of incubators. Their initial funding often is only \$500,000, provided by Israel’s Office of the Chief Scientist. Also present were the technology transfer organizations which are affiliated with the country’s universities and research institutes.

### Cardiovascular therapies

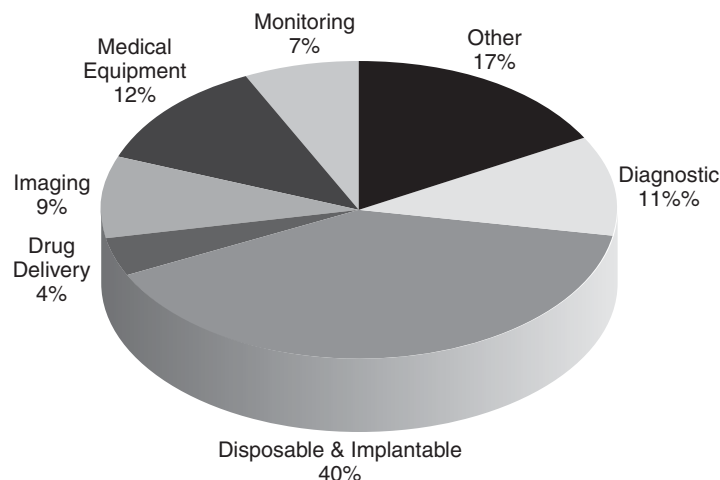
**ArioMedica** (Tel Aviv) is developing ARIO (Apparatus for Removing Intra-luminal Occlusions), a minimally invasive, disposable atherectomy device with a powerful cutting head for excising and removing all types of plaque from both partially and totally occluded peripheral arteries. The device’s high excision moment of the cutting head enables removal of all plaque types (calcified, fibrotic or fatty). It employs three positioning balloons for steering and stabilizing the cutting head and an imaging guide wire for obtaining a cross-sectional view to distinguish between the artery and plaque.

The company has tested in pigs a prototype of the ARIO device and is seeking additional funding before entering human trials.

**Cardiogal** (Omer) is developing a non-invasive cardiac monitor for continuous evaluation of hemodynamic and cardiac functions that are performed on

**BB&T at Biomed Israel 2008**

**Table 7: Israel’s Medical Device Companies – Subsectors**



Source: ISLI database 2007

patients with cardiac failure or following an open heart procedure. This information is currently gathered by an invasive catheterization procedure using a Swan-Ganz catheter which has risks of complications.

Cardiogal's product obtains information using multiple ultrasound transducers that are placed over the anterior chest wall in a similar manner to the use of ECG monitoring leads. Based on standard Doppler and tissue Doppler techniques, it uses well validated measurements to assess cardiac function and body fluid status. Measurements are taken automatically and the procedure can be performed by a nurse.

**BioControl Medical** (Yehud) is developing CardioFit, an implantable device for treating heart conditions through the use of unidirectional vagus nerve stimulation. It is currently in clinical trials in Europe, Australia and Israel. BioControl's technology targets electrical stimulation at selected nerves in a manner that mimics natural physiological activity and minimizes non-related side effects. The Cardiofit system is intended as a therapeutic treatment for class II-IV heart failure patients with left ventricular dysfunction who have failed to achieve symptom relief from standard pharmacological management.

**CorAssist Cardiovascular** (Herzliya Pituach) is a preclinical-stage device company that is focused on the treatment of diastolic heart failure by directly enhancing the elastic characteristics of the left ventricle wall. ImCardia, the company's first product, is an elastic self-expanding device that is attached to the external left ventricle surface of the heart through an off-pump procedure.

The device assists diastolic function through reduction of filling pressures, and does not require an external power source. It applies outward expansion force on the ventricular wall to enlarge left ventricular and diastolic volume.

ImCardia MIS is a second-generation and minimally invasive version of the ImCardia device that allows for smaller incisions, less patient trauma and faster recovery. The device can be delivered by a left thoracotomy or by a laparoscopic approach.

Aurora is an elastic device that is implanted inside the left ventricle in a minimally invasive or percutaneous procedure. It applies direct internal expansion forces distributed on the left ventricle wall and the septum to improve diastolic function.

### *Aesthetic devices and implants*

**Applisonix** (Rehovot) is developing innovative ultrasonic devices for the aesthetic market. The first application is for long-term hair removal for use by professionals, to be followed by a product for the consumer market. The devices are powered by Impresa, the company's proprietary ultrasonic hair removal technology that is applicable to all skin tones, hair colors and body areas.

The Impresa technology utilizes hair and skin characteristics to make the hair serve as an accurate and efficient ultrasonic waveguide. An ultrasonic head is used to focus the acoustic energy directly into the hair shaft which channels the acoustic energy to the hair root, where the energy is converted into heat. The surrounding skin is not affected.

The company's initial commercial product will be the Selectif device for use by professionals. It can complement currently available laser and intense pulse light (IPL) treatments used by aesthetic professionals to achieve a high level of accuracy. The device requires only minimal training.

**Aesthetics Point** operates within the **Ashkelon Technology Incubator** (ATI ; Ashkelon), a subsidiary of **Biomedix Incubator Ltd.** (Ramat Gan) which trades on the Tel Aviv Stock Exchange. It is developing an implant for aesthetic facial wrinkle treatment. The product is a dynamic miniature stent that can expand and maintain its new configuration underneath the skin for facial skin-shape procedures.

The implant is made from biodegradable materials. It is released from a trocar and automatically retracts to the unloaded extended shape, stretching the adjacent tissue and wrinkled skin.

**CollPlant** (Rehovot) has developed Type I recombinant human collagen that is derived from transgenic tobacco plants. It is based on the expression of five different genes required for the synthesis of recombinant collagen in plant compartments.

CollPlant will initially be a bulk supplier of medical-grade collagen and will transition into collaborative relationships for producing collagen-based end products. Ultimately, it plans to produce in-house new products addressing unmet needs.

The company announced at the conference a new program to develop an elastin-like fibrin protein having strong mechanical and elastic properties for orthopedic applications. It will be modeled after resilin that is used by fleas to jump to great heights.

CollPlant's technologies have been licensed from **Yissum**, the technology transfer company for **Hebrew University** (Jerusalem).

### *Diagnostics and monitoring*

Professor Aaron Palmon from the faculty of dental medicine at Hebrew University described a saliva-based device for the detection of low levels of biomarkers. The disposable device clears from saliva in a single pass amylase which constitutes about 60% of salivary proteins. Studies indicate that saliva may be useful for detecting various cancers, heart disease, diabetes and periodontal disease. The technology is available for licensing from Yissum.

**EarlySense** (Ramat Gan/Dedham, Massachusetts) is the developer of signal-processing technology designed to advance proactive healthcare and enable

better patient outcomes. The **Institute for Healthcare Improvement** (Cambridge, Massachusetts) has estimated that 2.5 million people are unnecessarily harmed in hospitals in the U.S. each year.

EverOn, the company's lead product, recently received FDA clearance and will be launched this year for use in hospital wards. It is a continuous and contact-free patient monitoring system that identifies early warning signs of patient deterioration, allowing for early intervention by medical professionals. It measures the heart and respiration rates as well as bed entries and exits.

The device displays real time vital signs and corresponding trend lines, providing early notification for the medical team of any significant increase or decrease in heart and respiration rates. This aids medical professionals in predicting the likelihood of deterioration in a patient's health.

### *Orthopedic, neurological, surgical implants*

**Orthogon Technologies** (Ofakim) has entered into a collaboration with **Smith & Nephew's** orthopedic unit (Memphis, Tennessee) to develop a magnetically actuated intramedullary nail for fracture fixation and limb elongation of the femur and tibia. External manipulation of the nail is used with a magnetic coil for force induction.

This collaboration is partly funded by a grant from Israel's **Bird Foundation** (Binational Industrial Research and Development; Tel Aviv). The technology can potentially be used as a cosmetic procedure for limb lengthening to achieve greater height. It also is believed to have application for treating non-union fractures by applying internal axial vibration through the intramedullary nail.

The **RAD Biomed Incubator** (Tel Aviv) this year granted its "outstanding project" award to **Tavor**, a company that is developing a prosthetic ligament for use as a replacement for anterior and posterior cruciate ligaments.

**Brainsgate** (Caesarea) is developing neurostimulation technology focused on the sphenopalatine ganglion (SPG), a natural organ that controls cerebral blood flow. By electrically stimulating the SPG, cerebral perfusion can be augmented in a natural, physiological way.

Brainsgate's device is a one-inch-long implant that is inserted into a patient's palate in a minimally invasive 15-minute procedure under local anesthesia. The implant is externally activated by a headset worn by the patient during the treatment session.

The company's efforts are directed at treating acute ischemic stroke (AIS) as the primary use of this technology. A pilot human trial for AIS is nearing completion and the company is planning a pivotal trial this year under FDA guidance and approval is anticipated in 2010.

**NiTi Surgical Solutions** (Netanya) is the process of commercializing a family of CE-marked and FDA-cleared disposable tissue closure devices, the CAR Series compression anastomosis ring-based devices, and the CAC Series compression anastomosis clip-based devices. The nitinol alloy-based surgical rings, clips and applicators are used to press together the ends of resected tissue for a tissue-sparing and uniform compression anastomosis, for facilitating a natural healing process, eliminating leakage, and reducing strictures and adhesions.

NiTi's devices are designed for the treatment of colorectal, gastric and upper gastrointestinal disease requiring surgical anastomosis. Surgical instruments were designed for side-to-end as well as endoluminal end-to-end and for other circular techniques.

### *Externally worn devices*

**Headway** (M.P. Misgav) has developed Occiflex, a non-invasive medical device for use by patients that suffer chronic headaches and neck pain. It consists of a specialized head cradle that is adjusted to the patient's head and neck and moves the head gently along a pre-defined 3-D course set by the practitioner, a physician, physical therapist or pain specialist.

Treatment is done individually with a cradle that moves in 6 degrees of freedom and is controlled by a computer. Headway's products are focused on treating neck muscle dysfunction for use by physicians and caregivers and it is developing a personal device for home use.

**Hadasit**, the technology transfer company of **Hadassah University Hospitals** (both Jerusalem), jointly with **Ramot**, the technology transfer company of **Tel Aviv University**, demonstrated the LuboCollar for use by medical personnel to quickly and safely evacuate semiconscious and unconscious patients who can't breathe on their own. It simultaneously secures the spine and prevents suffocation. The LuboCollar was found to be safe and effective in preliminary clinical studies. It is meant to help patients suffering from trauma.

**Innovent Medical Solutions** (Jerusalem) is developing a non-invasive device for clearing airway secretions in ventilator-dependent patients to prevent ventilator associated pneumonia, a common critical care infectious complication. The device works on the principle of cough simulation. It has two components, a suction unit and a disposable valve that connects the suction unit in-line with the patients' ventilation circuit. The ventilator fills the patient's lungs with air.


At the point of peak inhalation, the valve momentarily stops airflow from the ventilator and switches the direction of airflow to the suction unit, which performs sudden exhalation. This rapid switch from inhalation to exhalation simulates a natural cough, clearing the patient's secretions.

Compared to treatment using invasive catheter suction, Innovent's device removes more secretions, is less traumatic and prevents the need for intubation. The company plans to conduct clinical trials on ICU patients in 2008 and to seek FDA clearance via a 510(k) submission.

### *Insulin delivery pump*

NiliMEDIX (Haifa), a subsidiary of **D. Medical Industries** (Ramat Gan), plans to launch in Israel by the end of this year an insulin pump with a disposable cartridge. It is seeking a U.S. distribution partner.

The pump employs a passive system that has a control unit with a pressure sensor and pressure reader that calculates the time and duration for opening of the pump valve to release insulin that is kept under pressure. This is different from other insulin pumps, with the exception of the OmniPod insulin management system from **Insulet** (Bedford, Massachusetts), by its use of a DC motor with reduction gear and lead screw that pushes a piston to release insulin through an administration set.

NiliMEDIX's pump is lightweight and will be the smallest on the market. It will have a bubble detector, along with an occlusion and leakage alarm. It is claimed to have a low manufacturing cost due to its simple design. 

## Weight loss is taking a back seat clinically to diabetes resolution

By DIANA TUCKER  
BB&T Contributing Editor

WASHINGTON — The **American Society for Metabolic and Bariatric Surgery** (ASMBS; Gainesville, Florida) met here in mid-June with its new banner that added "metabolic" to its previous name, remarking on the newest understanding of the complexity of obesity.

No longer is it believed that a mechanical reduction of the size of the stomach, or bypassing part of the intestine, is the long-term cure for obesity.

This group of surgeons is dedicated to the treatment of metabolic disease and obesity, leading the path to better understanding of the root causes – and

then hopefully cures – behind this worldwide epidemic that is caused by a plethora of various factors that are still baffling.

**BB&T at the  
American  
Society for  
Metabolic  
and Bariatric  
Surgery**

Previous thinking was that morbid obesity led to diabetes and could be cured by mechanically altering the alimentary tract, but current thinking proposes that it is a complex neuro-hormonal feedback to and from the brain and gut that

allows for obesity and diabetes to occur, initiated by poor eating and exercise habits.

Long-term studies following patients who had bariatric surgery 10 to 15 years earlier have shown that weight re-gain is a common occurrence, suggesting more than just a re-routing of the intestines can cure it.

According to ASMBS, about 64 million adults in the US are considered obese, which is associated with many other diseases and conditions including Type 2 diabetes, heart disease, sleep apnea, hypertension and cancer. While 15 million people in the U.S. have morbid obesity and are clinically eligible for surgery, only about 1% – or 205,000 in 2007 – are being treated through bariatric surgery.

In an industry-sponsored workshop, "Economics and its Influence on the Evolution of Bariatric and Metabolic Surgery," Eric Finkelstein, PhD, director of public health economics at **RTI International** (Research Triangle Park, North Carolina) and author of the book *The Fattening of America*, offered his opinion on how America – and soon the world – became obese.

"Economics drove us to obesity and economics may be our way out," he said. "It is no longer a problem of poverty. There are economic causes of obesity,

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such as the fact that we have made it easier and cheaper to consume bad food and more difficult and expensive to consume good food. Sodas and snacks have gone down in price and are quick and easy to eat (thanks, in part, to the microwave), while vegetables and fish have gone up in price and require some time to prepare.”

He added, “It is harder to get accidental exercise, it costs more to get intentional exercise, and our leisure-time activities, which are passive, crowd out exercise. Obesity is a side affect of our own success,” Finkelstein said.

Besides the economic drivers mentioned above, the consequences of obesity have been diminished due to pharmaceuticals such as statins and blood pressure meds that counteract the medical conditions caused by obesity. In addition, the costs of the cures (i.e., surgery, etc.) are borne by the entire population — both thin and not — through government or insurers, resulting in thin people contributing to the cure of the obese.

All of these reasons contribute to the finding that more rational people, and not just the uneducated, are becoming obese. “A successful obesity prevention program should make it cheaper and easier to be thin,” Finkelstein said. “Currently the economics are working against this.”

According to Finkelstein, for a change to occur the economics have to be reversed such that the thin are rewarded and the obese suffer financial consequences.

An economic factor preventing many of the potential patients in this 19 million-person pool is the cost of bariatric surgery, specifically the gastric bypass and Lap-Band procedures that can range from \$20,000 to \$30,000 and are the two most common procedures performed in the U.S.

In a nationwide survey of 409 bariatric patients conducted by **Harris Interactive** (Rochester, New York), affordability was cited as the No. 2 reason patients did not have the surgery, second only to not knowing enough about it (see **Table 8**).

One way to capture more patients into having the life-saving surgery is to make it more affordable as well as conquer their fears of surgery, which has several companies developing new products and procedures to meet these requirements.

Other than avoiding major surgery as it exists today by using a less-invasive, less-costly, yet possibly less-effective method for weight loss, another way to skirt the economics of reimbursement for bariatric surgery is to position the procedure as a cure for diabetes as opposed to weight loss.

Recent studies have shown a reversal of diabetes among bariatric surgery patients even before any weight has been lost.

Several reports delivered here showed a resolution of diabetes after patients received a gastric

bypass, sleeve gastrectomy or other novel weight loss procedure. Although the mechanism of action is still unclear, the fact that many bariatric procedures reverse diabetes almost instantly is not only newsworthy, but may also be lucrative. When it comes to paying for a surgical procedure, bariatric surgery is held to a different standard than other procedures. Insurance companies would prefer to pay for prevention of obesity rather than surgery. But if the surgery is medically necessary to treat a disease such as diabetes, then they may be more likely to pay.

Unlike bariatric surgeons, endocrinologists have aligned themselves tightly with insurance companies and along with the American Diabetes Association, are a formidable advisory to get things done and reimbursed. Because of this, diabetes resolution was featured as a prime endpoint — not just weight loss — in measuring outcomes of bariatric procedures. Reimbursement for diabetes control may be the key to expanding the bariatric surgery market.

This new line of thinking pervaded the meeting in regards to focusing on diabetes resolution, as opposed to percent excess weight loss (EWL), once considered the gold standard for measuring bariatric surgery outcome. Now diabetes resolution — often measured in days — has stolen the limelight and for several reasons, some of which are economic as opposed to medically driven.

Type 2 diabetes affects 20 million Americans, or 7% of the population, and has much co-morbidity associated with it. Type 2 was once thought to be a disease of obesity and caused by excess weight, so the resulting reversal of diabetes, along with weight loss, that was found after bariatric surgery was not surprising.

A landmark study in rats that showed an immediate reversal of diabetes without accompanying weight loss when a plastic sleeve was placed in the duodenum forced thought leaders to re-think the mechanism of diabetes and the role gut hormones and peptides may be playing in root cause of the disease.

This study caught industry by surprise and several companies benefitted, while others may have to re-group based on this finding because they were not looking for diabetes resolution, but rather, weight loss.

One young company, **GI Dynamics** (Lexington,

| <b>Table 8</b>   |  |
|--|--|
| <b>Top Reasons Patients Don't Have Bariatric Surgery</b> |  |
| • Didn't know enough about it (51%)                      |  |
| • Couldn't afford it (38%)                               |  |
| • Fear of surgery (28%)                                  |  |
| • Inadequate insurance (25%)                             |  |
| • No health insurance (18%)                              |  |
| <i>Source: Harris Interactive</i>                        |  |

**Table 9**  
**Interventional Therapies for**  
**Obesity and Diabetes in Development**

*Neuromodulation*

- Enteromedics (St. Paul, Minnesota)
- Leptos Biomedical (San Francisco/Minneapolis)

*Endolumenal implants that may mimic surgical procedure*

- GI Dynamics (Lexington, Massachusetts)
- Valentx (Wilson, Wyoming)
- Endosphere (Silicon Valley, California)

*Endolumenal surgical platform*

- TransEnterix (Durham, North Carolina)
- USGI Medical (San Clemente, California)
- Ethicon Endosurgery (Cincinnati)
- Covidien (Mansfield, Massachusetts)
- C.R. Bard (Murray Hill, New Jersey)
- Satiety (Palo Alto, California)
- Endogastric Solutions (Redmond, Washington)
- EndoVx (Napa, California)
- BaroNova (Goleta, California)
- Barosense (Menlo Park, California)
- Safestitch Medical (Miami)

*Endolumenally-placed balloons*

- Fulfillium (Napa, California)
- Allergan (Santa Barbara, California)

*Source: Biomedical Business & Technology*

Massachusetts), has everything to gain from the movement to diabetes resolution. It has developed an endoscopically placed Teflon liner placed just beyond the pylorus.

This device, called the EndoBarrier, creates a mechanical bypass of the duodenum and proximal jejunum. It allows food to pass through the device, and allows bile and pancreatic enzymes to travel outside the liner, allowing bile and gut hormones to travel around the liner without touching the food until later in the gut, thus mimicking a gastric bypass.

The initial findings from an interim analysis were presented at the **American Diabetes Association** (Alexandria, Virginia) annual scientific session in San Francisco earlier in the month, where they were able to demonstrate resolution of diabetes in advance of weight loss one week after placement of the device. GI Dynamics has implanted 109 devices and has demonstrated 19% excess weight loss (EWL) at three months and 29% at six months.

These results of EWL alone are outstanding, and add to it the immediate reversal of diabetes, along with it being a simple outpatient procedure performed through the mouth without incisions, and the mix sounds like a winner.

Another novel company exhibiting here was **EnteroMedics** (St. Paul, Minnesota), which has developed the VBLOC vagal blocking system and a neuromodulation system that is comprised of a pacemaker-type and leads that are implanted laparoscopically around the vagal nerve.

The company's intermittent vagal blocking system involves a less-invasive option to gastric bypass and lap banding and provides a means of tricking the alimentary tract into feeling full after a small meal. Should the patient's digestive system outsmart the sensory impulses delivered by VBLOC, the therapy can be non-invasively adjusted to a new waveform to which the digestive tract may respond more optimally.

In a presentation by J. Toouli, MD, PhD, professor of surgery at **Flinders University of South Australia** (Adelaide), he compared the first-generation device with the company's second-generation system and was able to show a continued favorable safety profile with improved efficacy as measured by EWL.

EnteroMedics has begun a pivotal trial at 13 U.S. and two Australian sites, enrolling 300 patients in a double-blinded, 2-to-1, placebo-controlled, randomized trial that is anticipated to be unblinded in 3Q09.

Because the vagal nerves affect the release of gut hormones, some anticipate that the therapy may also help to reverse diabetes prior to significant weight loss – something the company did not plan to evaluate specifically in its pilot trial and something worth investigating in today's market.

Revisional bariatric surgery has created its own new market. With about 20 million Americans who would qualify for bariatric surgery and only 200,000 of them actually having the surgery, one would think that the remaining market is so large that growing this market would be unnecessary.

But markets — like the gut — have a mind of their own, and just as we found the diabetes reversal a new market frontier, now revisional surgeries are creating a new market, albeit much smaller.

Weight re-gain is a sad but significant problem among weight loss surgery patients. Many require additional surgery following their original surgery, either because of side effects or weight regain. This market opportunity has allowed some companies a way to enter the market earlier than they would have if addressing the primary bariatric market.

One such company is **USGI Medical** (San Clemente, California), which has developed a platform for a variety of incisionless surgeries, including NOTES procedures, and whose device functions extremely well for restorative obesity surgery endolumenally, nicknamed ROSE procedures.

Chris Thompson, MD, director of bariatric endoscopy at **Brigham and Women's Hospital** (Boston), said in a postgraduate course on Therapeutic Endoscopy and Emerging Endoscopic Technologies, "There is significant industry activity in endoscopic treatments for obesity."

He presented results of 20 patients on whom he had used the USGI EndoSurgical Operating System (EOS) for ROSE procedures and demonstrated clinical evidence showing that it enabled surgeons and physi-

Table 10

**Ideal Bariatric Procedure Attributes**

- Endolumenal placement (incisionless)
- Outpatient procedure
- Quick reversal of diabetes
- Excess weight loss of at least 60% at one year
- Costs less than \$6000
- Does not permanently alter intestinal architecture
- Allows for future procedures if necessary
- Reversible/removable/adjustable

*Source: Biomedical Business & Technology*

cians to use an incisionless technique to reduce the size of the gastric pouch and stoma in patients who have regained weight after initial success with gastric bypass.

In poster presentation, "Endolumenal tissue plication with tissue-anchors as a treatment for dilated gastrojejunostomy and gastric pouch after gastric bypass: early clinical experience," Daniel Herron, MD, and colleagues used the EOS to create tissue folds around the stoma and in the stomach pouch of eight patients and found no major complications occurred and the only minor complications were sore throats.

"The patients in the study all had lost significant weight after gastric bypass, but slowly began to regain weight over time," said Herron, chief of bariatric surgery at **Mount Sinai Hospital** (New York). "Due to the scarring from the original procedure, open revision options have generally been excessively risky to perform for all patients with a large pouch or stoma."

He added, "By enabling us to perform this new incisionless revision procedure, these patients are back on the path to weight loss with barely any side effects."

Another not-so-new but revived surgery is that of sleeve gastrectomy, which has grown in popularity tremendously because it is easy to do, can now be performed endolumenally, and patients can later add another procedure if necessary.


Sleeve gastrectomy is the suturing of the stomach such that only a sleeve is left that allows for a limited amount of food passage and was once part of a procedure that also included a bypass component to it.

Super-obese patients often are unable to undergo surgery because they require dangerously high amounts of sedative due to their large size, have interrupted breathing patterns, and often chronic obstructive pulmonary disease (COPD).

These factors put them at risk for surgery, so it has been felt that if they could lose some of their excess weight prior to surgery, they could become a candidate for surgery with less associated risk. By performing the simpler sleeve part of the surgery first – called "staging" their surgery – they may lose enough weight to go back for the rest of their surgery.

Performing just the sleeve procedure caused enough weight loss that some of them never returned for the rest of the surgery, and also resulted in a new wave of "sleeve-only" procedures to be performed.

Simpler, easy to perform surgically, and now without incisions, the fad has caught on, with good weight loss results awaiting long-term studies to verify its durability.

Companies that may benefit from this new concept are those that have endoscopic staplers, among them **Ethicon Endo-Surgery** (Cincinnati), **Covidien** (Mansfield, Massachusetts) and **Power Medical Innovations**. 

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## International report

# IT competitors link to meet UK changes

By JOHN BROSKY  
BB&T European Editor  
and Staff Reports

On the heels of a report that is expected to redefine primary care delivery across England, three providers of clinical information systems reported that they will join up to integrate their products, anticipating adoption of the recommendations by the **National Health System (NHS)**.

**EMIS** (Leeds) and **INPS** (London), the market leaders for general practice software, along with **Adastra Software** (Ashford), a specialist in systems for connecting primary and secondary care systems for urgent care clinics, said they will jointly develop a system to support a proposed model for GP-led equitable access centers (GPEACs) outlined in the recently completed "Next Stage Review" led by Under Secretary of State Lord Darzi for the NHS.

A colorectal surgeon, Ara Darzi is a consultant at **St. Mary's Hospital** and **Royal Marsden NHS Trust** who in 2002 was awarded knighthood for his services to medicine and surgery.

After a series of reports covering each of the eight regions covered by England's Strategic Health Authorities, Darzi in his summary delivered June 30 to the prime minister, chancellor of the exchequer, and secretary of state for health sets out how the NHS can respond to the challenges of the next 10 years.

Those challenges include meeting the rising expectations that are driven by demographics, continuing development of an information society, advances in treatments, and the changing nature of disease.

Among the recommended measures is a focus on accelerating changes "that frontline staff want to make to meet those challenges, [while] continuing to raise standards."

A key assumption, "which remains largely aspirational at present," according to the British Medical Association, is access for NHS staff to information about care, including a new NHS Evidence Service where staff can view through a single web-based portal authoritative clinical and non-clinical evidence and best practice.

Development and configuration of next-generation health informatics already is under way, according to the three collaborating companies, who aim to

offer a conjoined system "well before the April 2009 deadline for many GP access centers to go live."

EMIS and Adastra announced a joint project in April to deliver instant access to summaries of patient primary care records for after-hours urgent care clinicians.

The initial pilot was launched for the **Gateshead Primary Care Trust**, near Newcastle upon Tyne.

The two companies also were cooperating on a project for the Liverpool Primary Care Trust to link link primary and secondary care delivery informatics.

Adastra systems are used in 95% of unscheduled care hubs in the NHS system and the Republic of Ireland, while EMIS systems support more than 56% of GP surgeries.

The third partner, INPS, is part of the **CEGEDIM Group** (Paris), and provides clinical management systems as well as Vision software, which is compliant with the NHS' Connecting for Health programs Choose & Book, Electronic Prescription Service and GP2GP.

The companies said the new product will build on the components and data of the three existing systems, assuring full interoperability before adding additional functionality to meet next-generation requirements.

The reforms and recommendations in the report anticipate a new model for care delivery that recognizes demands driven by demographic shifts, primarily the rapid aging of the population.

The **British Medical Association (BMA)** (London) devoted considerable discussion in its response to the London proposals released in September 2007 to significant shifts in how primary care will be organized and funded by the NHS in the future, especially the call for polyclinics and a heavy emphasis on community-based care.

Telemedicine, which is dependent on health informatic systems for following a patient through the care system and for follow-on care, drew the wrath of the BMA, which said flatly, "We believe that the introduction of telemedicine for intensive care would have a detrimental effect on outcomes, given that critical care is a 'hands-on' skill and requires a multidisciplinary team approach, both of which telemedicine would not be able to provide.

Another concern of the BMA being addressed by the collaboration among the health IT providers is "the widespread introduction of urgent care centers, accessible by patients both in-hours and out-of-hours, which has the potential to sideline GP practices from the delivery of urgent care.

Using the patient history and medical records held at GPs and primary care team-level help to avoid inappropriate hospital admissions, said the BMA, brings the coordination of patient care that will lead to the best possible health outcomes.

The BMA concludes that Darzi's proposals

require “significant advances in information technology and an increased use of electronic data in order to allow continuity of care between providers.”

### *NHS valued, but challenges await*

Sixty years from its inauguration, the UK’s **National Health System** (NHS), funded through general taxation, is “still the fairest and most cost-effective health system in the world,” said Niall Dickson, chief executive of **The King’s Fund** (London), commenting on the 60th anniversary of NHS. “It removes fear and creates what is in effect a huge compulsory insurance scheme that is valued by patients, staff and the public.

According to Dickson, the last six decades have seen “remarkable advancements” in medical technology, new drugs and faster treatments. “Anyone around at the inception of the NHS would no doubt be hugely impressed by the transplant surgery and chemotherapy that patients now routinely benefit from, or how the NHS has combated AIDS or improved the way we care for people with mental illness. In that time the NHS has changed from a £400 million business (roughly £11.5 billion in today’s prices) compared with the £107 billion it costs today.”

“But this is not to say that the NHS should be immune from change — major challenges lie ahead that will largely determine whether the NHS, funded through general taxation and available to all free at the point of need, will survive. Coping and caring for an ageing population, many of whom will have dementia; combating the rising tide of obesity and other lifestyle conditions; and keeping pace with new drugs and medical technologies will make fresh demands on our finite resources. The other major challenge is to make the NHS significantly more responsive to patients.

Dickson said it would be crucial to reform the NHS from a state-run monopoly business to a commissioner of comprehensive health care, free at the point of need, where NHS care can be provided by public, private or voluntary sector organizations.

“Doing this and addressing public concern that the NHS remains fair and equal will go a long way to safeguarding its future for another 60 years,” Dickson said.

The King’s Fund is an independent charitable foundation working for better health, especially in London. It carries out research, policy analysis and development activities, working on its own, in partnerships, and through funding.

### *Diabetes linked with amputations*

A hundred people a week in the UK have a lower limb amputated as a result of diabetes, warns **Diabetes UK**. The health charity says to reduce this figure there is an urgent need for greater awareness of the impact of the condition, which as well as lower limb amputation can lead to other devastating complications such as

heart attacks, stroke, blindness and kidney failure.

Amputation is a complication of diabetes caused by damage to the nerves and blood vessels that serve the limbs. Alarmingly, up to 70% of people die within five years of having an amputation as a result of diabetes. Currently more than half of the general public do not associate diabetes with amputations and worryingly one in three people with diabetes do not realize that having the condition puts them more at risk of having an amputation, the organization noted.

“This situation is shocking given that most amputations can be prevented with better awareness and management of the condition. People with diabetes need to have optimum support, guidance and clinical care to help minimize the risks of amputation,” said Douglas Smallwood, chief executive of Diabetes UK.

“We want to see all people with diabetes have better access to podiatrists and to a regular foot check as part of their annual medical review. People with diabetes who are assessed as being at risk of foot problems need to have access to high quality integrated specialist foot care services to save the foot and reduce the likelihood of amputation.”

According to Smallwood, there are 2.3 million people already diagnosed with diabetes in the UK and over 500,000 people who have the condition but are not aware of it. In the UK, 5,000 people with diabetes have an amputation every year. Diabetes is the second most common cause of lower limb amputation in the UK after trauma. People with diabetes are 15 times more at risk of lower limb amputation than people without the condition, he noted.

The organization also says that people at high risk for amputations are those who have a previous history of ulcers, neuropathy or nerve damage, circulation problems, foot deformities and those who cannot self-care. Foot ulcers can be treated successfully, especially in the early stages, Diabetes UK said. If they are left untreated though, the risks of infection are high and in extreme cases this could lead to gangrene and even amputation. More than 10% of foot ulcers result in amputation, the organization said.

Diabetes UK is working with the **Foot in Diabetes UK Group** and the **Joint British Diabetes Societies Inpatient Care Working Group** to produce guidance for the proper management of acute onset, or deteriorating, disease of the diabetic foot. The guidance is expected to be available later this year.

### *U.S., Vietnam agree on food, drug safety*

The U.S. and Vietnam have signed a memorandum of understanding (MOU) to enhance the safety of food, feed, drugs and medical devices traded between the two nations.

The plan is the product of discussions between U.S. Secretary of Health and Human Services (HHS) Mike Leavitt and senior Vietnamese officials in Hanoi

just two months ago and it exemplifies the new import-safety strategy adopted by the U.S. government last November. Historically, U.S. authorities have primarily relied on intervention at the border to intercept unsafe goods. The new strategy, crafted by a cabinet-level interagency working group on import safety chaired by Leavitt, calls for actively working with trading partners to help ensure they build quality into every step of a product's life cycle.

"Trade between our two nations has grown exponentially in recent years and our societies are better off as a result — and our cooperation in health is stronger than ever," said HHS Deputy Secretary Tevi Troy, in signing the memorandum. "With this agreement, we're increasing our joint efforts to ensure the safety of goods our citizens consume on a daily basis. This is an important step forward for the health of the American and Vietnamese people."

The memorandum calls for cooperation in the following areas:

- Information-sharing — the U.S. and Viet Nam governments will exchange information on their respective regulatory systems, such as details on laws and regulations; guidance documents; lists of drugs approved by FDA for use in aquaculture; training opportunities on key topics, such as safety surveillance of products after marketing; and timely information on potential or emerging issues of product safety (food-borne illnesses, food contamination, etc.).

- Workshops and training — the two countries hope to conduct or participate in workshops or other training that concerns food, animal feed, and medical products, including those offered by international organizations. The two sides will also make efforts to find opportunities for joint training for food-borne illnesses and the oversight of food traded internationally.

- Best practices in clinical trials — HHS/FDA and its counterpart agencies intend to cooperate on training and inspections of clinical trials for the development of medical products.

- Seafood safety — In cooperation with Vietnamese authorities, the U.S. will undertake a detailed review of safety issues regarding fish and fishery products exported from Vietnam to the U.S.

The memorandum takes effect immediately, has an initial life of three years, and is subject to revision and renewal, contingent upon the approval of both nations.

Since signing of the United States-Vietnam Bilateral Trade Agreement in 2001, commerce between the two nations has increased eight-fold, fueled, in part, by the agriculture and aquaculture sectors. Two-way trade exceeded \$12.5 billion in 2007, according to the Foreign-Trade Division of the U.S. Census Bureau.

### ***New cancer treatments eyed***


Scientists of the Division of Theoretical Bioinfor-

matics at the **German Cancer Research Center** (Deutsches Krebsforschungszentrum DKFZ; Heidelberg) have simulated on a computer how cells decide whether or not to migrate. Using their results, the researchers were able to predict the molecular targets within a cell that have to be hit so that its behavior changes in a particular direction. This method may help to develop new treatments against cancer metastasis. The scientists have published their results in the latest issue of *Molecular Systems Biology*.

One hundred and thirty years ago, Paul Ehrlich, pioneer of chemotherapy, speculated that when a cell gets sick, this is caused by a molecular change that has taken place inside the cell. Ehrlich surmised that if one could specifically hit this place of change, the "molecular target," then the disease could be cured.

When it comes to cancer, this concept has only limited applicability, because tumor cells are altered in many places, the DKFZ said. For cancer treatment to be successful, it needs to hit several molecular targets — and in a specific order, too. However, with the number of targets growing, the number of possible combinations of hits increases exponentially. If one aims to influence the genetic activity of a cell, there are several thousand targets to choose from. In this case it is impossible to test all possible combinations experimentally in order to find an efficient therapy. In this area, biologists and medical researchers are seeking help from mathematicians or physicists. They provide computer models that simulate a cell's behavior and, thus, make "testing" possible at all. This new research field is called systems biology.

In an interdisciplinary collaboration, research groups at DKFZ have now succeeded in elucidating the process underlying a cell's decision about how it is going to behave. Scientists in the teams of biologist Dr. Axel Szabowski, physicist Dr. Hauke Busch and mathematician Professor Roland Eils have investigated what makes human skin cells migrate into a wound to make it heal. They showed that the cells take several steps to decide to "start moving," how fast to do so, where to go and when to stop again. For the process to start, various external signals have to be received in a particular order. The scientists subsequently simulated this process on the computer. In doing so, they succeeded in predicting the molecular targets by which a cell's behavior can be changed in a particular direction, the DKFZ said.

According to the DKFZ, metastasizing cancer cells, too, migrate through the body — though in their case, it is undesired. They decide to migrate even when normal cells would not move. Using the new simulation method developed by the DKFZ researchers, it is possible to simulate how the genes involved in this process interact and, thus, find out the molecular targets and the order in which they need to be hit so that tumor cells stop migrating. ———— 

## Acquisitions

- **Biomagnetics Diagnostics** (Orangevale, California) reported beginning the process to acquire other businesses. It said it has secured acquisition capital and has contracted with Southbridge Business Resources (Tulsa, Oklahoma) to acquire deals for Biomagnetics. The company said it is looking at six companies which Southbridge will be able to help it acquire, potentially bringing an additional \$15 million or greater and EBIT-DA greater than 20% through acquisitions in 2008. Biomagnetics, through its subsidiary, **Biospectrum Technologies** (also Orangevale), has patented diagnostic equipment and assays designed to be qualitative, quantitative and easily performed.

- **Neovasc** (Vancouver, British Columbia), formerly known as **Medical Ventures**, a company developing specialty vascular devices, reported its name change and the expansion of its product portfolio, as the company completed the acquisition of two vascular product development companies and the closing of an \$8.3 million private financing. The company's previously reported share consolidation is also now in effect. With the closing of the acquisitions of **Neovasc Medical** and **B-Balloon**, both pre-commercial-stage device companies based in Israel, Neovasc said it has significantly expanded its new product pipeline. The pipeline includes a specialized stent for the treatment of refractory angina, as well as devices designed to improve the treatment of commonly occurring ostial lesions in the coronary and peripheral arteries. On closing the transactions, the new company's issued share capital is about 18 million shares (23 million fully diluted), including about 12 million shares, warrants and options issued in connection with the acquisitions of Neovasc Medical and B-Balloon, some three million shares and warrants issued in conjunction with the private financing and just under 2 million incentive options available under a 10% rolling plan.

- **Novartis** (Basel, Switzerland) and **Nestlé** (Vevey, Switzerland) reported that they have completed the first-step purchase and sale of 74 million shares of eye care company **Alcon** (Huenenberg, Germany/Fort Worth, Texas) common stock currently owned by Nestlé pursuant to an agreement between the two firms. With the completion of the first-step transaction, Nestlé remains Alcon's majority shareholder with about 52% of its issued capital; Novartis now owns a minority stake in Alcon of about 24.85% of Alcon's issued capital. Via this first step, Novartis will pay Nestlé \$11 billion. Novartis will then have the exclusive right to buy Nestlé's remaining 52% stake in Alcon for about \$28 billion between January 2010 and July 2011. In that phase, Alcon's shares will be valued at about \$181, though Nestlé could get a 20.5% premium above the price for Alcon shares when finally sold. While the

second step is optional, both companies would have to agree not to exercise their rights for it to fall through.

- **Signalife** (Los Angeles) reported that it has received board approval to proceed with its previously disclosed merger with **Heart One Global Research** (London), and that a specially-formed committee has been appointed to proceed with due diligence and other matters incident to completion of the transaction. It is anticipated that the respective businesses of Signalife and Heart One will be operated in two separate wholly-owned subsidiaries, with the subsidiary holding Signalife's current business to be managed by Signalife's current management team, and the subsidiary holding Heart One's current business to be managed by Heart One's current management team. After the merger is effected, Signalife shareholders will own 94% of the surviving company.

- **St. Jude Medical** (St. Paul, Minnesota) said it has completed its acquisition of **EP MedSystems** (West Berlin, New Jersey) and reported the final allocation of cash and stock to EP shareholders in connection with the deal. St. Jude agreed to pay about \$91 million, consisting of some \$54,558,607 in cash and about 898,000 shares of St. Jude stock. St. Jude's board also approved an additional \$50 million stock buyback authorization, which will offset the shares issued in the transaction. As previously reported, EP shareholders will receive either \$3 in cash or 0.0738 shares of St. Jude common stock for each share of EP common stock, subject to proration so that 60% of the EP shares are exchanged for cash and 40% are exchanged for shares of St. Jude common stock. EP develops a line of products for use in the cardiac rhythm management or electrophysiology market.

- **Theragenics** (Buford, Georgia) said it would pay \$47.8 million in cash for **NeedleTech Products** (Attleboro, Massachusetts), a private manufacturer of specialty needles and related devices. The deal is expected to close in the third quarter. With revenue of \$16.9 million in 2007, NeedleTech's products include coaxial needles, biopsy needles, access trocars, brachytherapy needles, guidewire introducer needles, spinal needles, disposable veress needles, and other needle-based products. End markets served include the cardiology, orthopedic, pain management, endoscopy, spine, urology, and veterinary markets, the company said. Theragenics expects to finance \$24.5 million of the purchase price with borrowings under its existing \$40 million credit facility, and the remainder will come from the company's current cash and investments. These borrowings will bring Theragenics' total outstanding borrowings under its current credit facility to \$32 million. Theragenics operates two business segments: its surgical products business and its brachytherapy seed business.

## Business developments

# Buoyed by solid data, Xience DES wins OK

By AMANDA PEDERSEN  
BB&T Staff Writer  
and Staff Reports

Independence Day wasn't the only thing **Abbott** (Abbott Park, Illinois) celebrated over the July 4th weekend. FDA approval of the company's Xience stent was reason enough to shoot off fireworks.

Abbott received approval of the Xience V everolimus-eluting coronary stent for the treatment of coronary artery disease on July 2, making it the second of the second-generation family of drug-eluting stents to win marketing approval in the U.S.

**Medtronic's** (Minneapolis) Endeavor DES, which won approval in February, was the first second-generation DES to hit the U.S. market. Both products are expected to elbow aside to a considerable extent the first-generation DES devices, the Cypher from **Johnson & Johnson's** (J&J; New Brunswick, New Jersey) **Cordis** (Miami Lakes, Florida) unit, and the Taxus from **Boston Scientific** (Natick, Massachusetts).

Abbott says its Xience stent, which went on commercial sale immediately, is the only DES to have demonstrated superiority over Boston Scientific's Taxus paclitaxel-eluting coronary stent system.

Kelly Morrison, an Abbott spokeswoman, told *Biomedical Business & Technology* that the first implant was performed the morning of July 3rd at **New York Presbyterian Hospital-Columbia University Medical Center** (New York).

"The strength of the data supporting Xience V is really unprecedented," she said. "It's the first to show superiority over the market leading drug-eluting stent in clinical trials, it demonstrated a 45% reduction in major heart related events compared to Taxus at two years."

Because the device is based on Abbott's market-leading Multi-Link Vision bare-metal stent platform, Morrison said the company expects a healthy physician adoption of Xience.

"I think physicians have been waiting for a next-generation technology that really delivers on the promise of drug-eluting stents," she said. "We've been hearing from physicians that they're very excited [about Xience] based on the clinical data."

Abbott is expecting a 25% to 30% market share in the U.S. within the first year of launch, Morrison said.

"Xience V represents an important treatment

advance for the estimated 13 million people in the U.S. suffering from coronary artery disease, and we believe Xience V will quickly become the new standard for drug-eluting stents given its outstanding clinical results," said John Capek, PhD, executive VP of medical devices at Abbott.

The stent will be available on both over-the-wire and rapid exchange (RX) delivery systems.

Xience was launched in Europe and other international markets in October 2006. It is an investigational device in Japan and is currently under review for approval by Japan's Ministry of Health, Labor and Welfare and the Pharmaceuticals and Medical Devices Agency.

Everolimus, developed by **Novartis Pharma** (Basel, Switzerland), is a proliferation signal inhibitor, or mTOR inhibitor, licensed to Abbott for use on its drug-eluting stents. Everolimus has been shown to inhibit in-stent neointimal growth in the coronary vessels following stent implantation, due to its antiproliferative properties, the company noted.

Approval of Xience also was good news for Boston Scientific, which will share profits from the device. **Guidant** had been developing the stent and when Boston Scientific acquired that company, it had to divest the stent to Abbott, but it retained the right to sell the same device as the Promus under a private-label arrangement.

### *Hemopure trial may be Biopure's final hope*

Financially embattled **Biopure** (Cambridge, Massachusetts) could be seeing some small rays of hope in initiating a clinical trial for Hemopure, its blood oxygenating therapy.

Just a few weeks after Biopure reduced its staff by 60% to cut costs the company reported in early July that it has been in discussions with the FDA to initiate a clinical trial of Hemopure for patients suffering from leukemia.

"We haven't gotten the protocol written yet regarding how many patients will be involved in the trial," Tiana Gorham, a spokeswoman for Biopure, told BB&T. "We're very much at the beginning stages of discussion with the FDA."

Hemopure [hemoglobin glutamer - 250 (bovine)], or HBOC-201, is approved for sale in South Africa for the treatment of acutely anemic surgical patients.

Biopure has proposed to study use of Hemopure in patients suffering from acute myelogenous leukemia (AML) who refuse transfusion with blood components.

Currently, AML patients who do not accept blood transfusions are unable to undergo potentially life-saving induction chemotherapy because of the profound anemia the chemotherapy causes. Patients would give informed consent before being enrolled in this study.

Hemopure, consists of hemoglobin that has been taken out of the red blood cells of cattle and then purified, chemically cross-linked for stability and formulated in a balanced salt solution similar to Ringer's lactate. The resulting hemoglobin solutions do not contain any cells.

"Hemopure is an attractive application because it doesn't need to be refrigerated and it is universal," Gorham said. "There is no need for a type or cross match."

According to the company, an effective treatment for this patient population represents an unmet medical need because of an expected 100% mortality within six months in the absence of induction chemotherapy. The purpose of the study would be to assess the efficacy of Hemopure in providing an oxygen carrier in lieu of transfusion with red blood cells, as an adjunct to other special procedures, following induction chemotherapy for AML.

Biopure has struggled to get U.S. approval for the human product. The company said that if this proposed trial is successful it could be pivotal to establish an intended use for Hemopure in this clinical setting.

"We are very excited at the possibility of initiating a new clinical trial with Hemopure in the U.S. If this trial provides convincing evidence of benefit in this high mortality population, it has the potential to become a pivotal trial for Hemopure's use as an adjunct to AML induction chemotherapy when transfusion with blood components is refused by the patient," said Zafiris Zafirelis, Biopure president/CEO.

The company has four ongoing Phase II trials of Hemopure for these indications: during percutaneous coronary intervention; for patients undergoing coronary artery bypass graft surgery; for use in lower limb amputation resulting from critical limb ischemia; and in-hospital use in trauma patients.

Biopure also is developing Hemopure, with support from the U.S. Navy, for a potential out-of-hospital trauma indication.

### ***Synthetic Blood now Oxygen Biotherapeutics***

Elsewhere in the synthetic blood sector, the company known as **Synthetic Blood International** (Costa Mesa, California) has changed its name to **Oxygen Biotherapeutics**. The company's new trading symbol on the Over-the-Counter Bulletin Board is OXBO.

"Our new name better reflects the broader scope of our development activities," said CEO Chris Stern. "We have several exciting bio-therapeutic applications for Oxycyte, yet none of them is synthetic blood. What we're doing is developing advanced oxygen-based therapies using Oxycyte including traumatic brain injury, sickle cell pain crisis, wound treatment, organ transport, heart attack, stroke, and, as a long shot, spinal cord injury."

The company is the developer of Oxycyte, a perfluorocarbon therapeutic oxygen carrier.

### ***Northstar Neuroscience under pressure***

After turning down an unsolicited takeover offer from **Tang Capital Partners** (San Francisco) in early July, **Northstar Neuroscience** (Seattle) is under pressure from a major stockholder to sell itself off or split its sizable cash hoard among shareholders.

Tang had offered to buy Northstar for \$2.25 a share in cash, but the company's board said the proposal, representing a 50% premium to the closing sale price of Northstar's common stock on July 1, was "not in the best interests of all shareholders. That offer valued the company at \$58 million.

In a letter, **RA Capital Biotech Fund** (Boston) said it was "surprised" by the company's rejection of the offer from Tang, another major shareholder. RA Capital asked Northstar to maximize shareholder value by "reducing expenses and either finding a buyer or making a cash distribution." Northstar's value plummeted after its lead therapy – which sought to stimulate the brain to improve motion in stroke survivors – failed in a clinical trial in January.

Tang's offer was about a 47% premium to Northstar's average trading price since Jan. 22, when the company reported its disappointing EVEREST clinical trial results. The company had \$73 million cash as of March 31, considerably larger than its market capitalization of \$49 million. RA Capital owns about 2.5 million Northstar shares, about 9.6% of its outstanding stock.

### ***Angiotech creates new biz***

**Angiotech Pharmaceuticals** (Vancouver, British Columbia), a specialty pharmaceutical and medical device company, reported in early July that it is creating a new subsidiary, **Angiotech Pharmaceuticals Interventions** (API), with an investment of up to \$300 million from Ares Management and New Leaf Venture Partners.

Angiotech said the new subsidiary would hold most of its assets outside of its Taxus coronary stent business, a product sold by **Boston Scientific** (Natick, Massachusetts) for which Angiotech provides the paclitaxel drug coating.

The company also reported that the British House of Lords has confirmed the validity of one of its patents for its DES coating. The company said that Britain's highest court had overturned the rulings of the lower courts that claimed the patent issued to Angiotech by the European Patent Office for its paclitaxel stent coating was invalid.

Rival stent maker **Conor Medsystems** (Menlo Park, California) and four other companies had launched various challenges to the validity of Angiotech's patent.

The House of Lords ruled against the decisions of the lower courts, noting that it "did not agree with the reasoning that the lower courts had used in justifying revocation." Instead it based its argument on an earlier Dutch decision.

### **Registry gathering data on Sonablate**

It's common to hear a med-tech company mention a "global" solution, but to pin down what is meant by a global solution is sometimes a tad difficult.

There is no question however, about what the word means when it comes to a new registry aimed at tracking the progress of USHIFU's (Charlotte, North Carolina) Sonablate 500, a prostate cancer therapy that uses ultrasound.

The Sonablate International High-Intensity Focused Ultrasound (HIFU) Registry is expected to contain information on nearly 6,000 patients across the U.S. and around the globe who have been treated with the device – a feat the company touts as a first.

It doesn't get any clearer than that, according to representatives from USHIFU.

"To my knowledge this registry is the first of its kind in a global sense," Amanda Willis, a spokeswoman for USHIFU told *BB&T* last month. "From (USHIFU's) perspective, this registry will give participating physicians all across the world larger sets of data to draw from."

While there have been other device registries, this marks the first to incorporate data from outside as well as inside the U.S., Willis said.

The database was established by USHIFU along with **Misonix** (Farmingdale, New York) and **Takai Hospital Supply** (Tokyo) to offer what all parties are calling a single, secure, standardized repository of treatment information for those users.

"The Sonablate International HIFU Registry was created to capture the 'real life' practice of prostate cancer treatment, which for the most part fell outside the responsibility of clinical trials," said Rowland Illing of the clinical effectiveness unit at the Royal College of Surgeons of England. "Sponsorship of this registry by the worldwide distribution partners of the Sonablate demonstrates their high level of confidence in the technology."

### **Bioheart adds in-home monitor for HF**

The list of companies hoping to offer heart failure patients peace of mind through at-home monitoring of their disease just got a bit longer. **Bioheart** (Sunrise, Florida) said it has secured worldwide non-exclusive distribution rights to the Bioheart 3370 heart failure monitor, an interactive device designed to improve available healthcare to patients outside hospitals who are suffering from heart failure.

The device, made by **RTX Healthcare** (Noerre-sundby, Denmark), is FDA-cleared for marketing in

the U.S. and has CE-mark approval in Europe. Bioheart said it planned to begin commercial distribution immediately.

"What you have is a patient population that really is ill and they do go home and they live their lives and things happen to the patient and oftentimes they go to the emergency room because it's an onset of something," Marty Schildhouse, a spokesman for Bioheart, told *BB&T*. "Daily monitoring allows for that constant awareness of any potential changes."

The compact Bioheart 3370 heart failure monitor engages patients through personalized daily interactions and questions, while collecting vital signs and transmitting the information directly into a database. It is available in both a wireless configuration and through hook-up to regular telephone lines, the company said. A remotely located medical professional regularly monitors the data for any abnormal readings that may signal a change in the patient's health status. These changes are reported back to the treating physician.

### **Promising results with ovarian cancer assay**

**Laboratory Corporation of America Holdings** (LabCorp; Burlington, North Carolina) said last month that its new product, OvaSure, will be able to assess the presence of early stage ovarian cancer in high-risk women. The company reported that the device – a blood test that uses six biomarkers to determine the presence of cancer in the body – is available for commercial use.

"LabCorp is offering the OvaSure test as a laboratory-developed test, which is regulated by CLIA and CMS," Eric Lindholm, a spokesman for LabCorp told *BB&T* via e-mail. "LabCorp does plan, however, to continue to seek guidance on the regulatory status of our offering from the FDA."

The test identifies six biomarkers in its detection of ovarian cancer; MIF, Prolactin, CA-125, Osteopontin, Leptin and IGF-II.

The report says that the potential implication of early detection of ovarian cancer on patient outcome is shown by the differential survival rates of women diagnosed at different stages of disease progression. The 10-year survival rate is nearly 90% when the disease is localized to the ovaries at the time of diagnosis and drops to 20% when the disease has spread to distant sites at the time of diagnosis.

According to a Phase II clinical trial, the test was shown to discriminate between disease-free women and ovarian cancer patients (stage I-IV) with high specificity (99.4%) and sensitivity (95.3%).

### **Invitrogen's Herceptin test approved**

Oncologist now have another weapon to add to their breast cancer armamentarium with the addition of a test that can help to determine if a patient is like-

ly to respond well to Herceptin, a drug developed by **Genentech** (South San Francisco, California) and FDA-approved for the adjuvant treatment of HER2-overexpressing, node-positive or node-negative breast cancer.

**Invitrogen** (Carlsbad, California) has received PMA approval from the FDA for its Spot-Light HER2 CISH Kit to help in the assessment of breast cancer patients for whom Herceptin treatment is being considered.

The approval is a significant marker for the company, since it is the first PMA won by Invitrogen, thus giving it a first step in a different direction. Invitrogen previously has specialized in products for the research community in the U.S. rather than those for clinical use.

"The PMA approval is a milestone for us. We plan to launch in the U.S. during the second half of August," Brett Williams, senior director of cellular analysis and Invitrogen's molecular probes unit, told *BB&T*. "We already sell this kit outside of the U.S. There are reimbursement codes — those used for other *in situ* tests — already in place, and it will be priced at \$1,400 for 20 assays, or \$70 per test."

#### **Longitude closes \$325M VC fund**


**Longitude Capital** (Menlo Park, California) reported the closing of its first investment vehicle, Longitude Venture Partners, a \$325 million venture capital fund dedicated to life sciences investments.

The fund exceeded its target of \$250 million, the company said.

The team at Longitude Capital includes managing directors Juliet Tammenoms Bakker, Patrick Enright and Marc-Henri Galletti, venture partner Jeffrey Gold, principals Douglas Foster and David Hirsch, and CFO Elaine Erickson. The firm was formed following the team's spin-out from **Pequot Capital**, where they were responsible for venture capital investments in life sciences companies since 1997.

"We have a strong team and a unique style of investing that has produced excellent returns over multiple fund vintages," said Bakker, Longitude co-founder and managing director. "As has been the case in the past, we are active investors across all sectors and stages but tend to favor earlier-stage medical device companies and later-stage opportunities in biotech."

Prior to forming Longitude, the team was collectively responsible for more than 100 venture capital investments in the life sciences. Representative investments include Ablation Frontiers, Acufocus, Align Technology, Cephalon, Codexis, CryoVascular Systems, Embolic Protection, eyeonics, Eyetech Pharmaceuticals, Horizon Therapeutics, Insulet, MAP Pharmaceuticals, Oratec, Prestwick Pharmaceuticals, Sequenom and SUGEN.

The team's experience spans all stages of companies in most therapeutic areas within the medical device and biotechnology sectors. ————— 

## *Medical Device Daily State of the Industry Report 2008*

This report is the "reference of choice" used by executives, investors and analysts to understand where the med-tech industry is heading, which sectors are rising and declining, and what opportunities lay ahead. This industry report covers company financial data, product development, sector trends and more!

Individual market sectors covered in this report include:

- |   |   |
|---|---|
| <ul style="list-style-type: none"> <li>▷ Cardiovascular</li> <li>▷ Clinical diagnostics and imaging</li> <li>▷ Orthopedics</li> <li>▷ Biomaterials</li> <li>▷ Surgical/anesthesia/monitoring</li> <li>▷ Healthcare IT</li> <li>▷ Neurology</li> </ul> | <ul style="list-style-type: none"> <li>▷ Interventional radiology</li> <li>▷ Genetics/stem cells</li> <li>▷ Oncology</li> <li>▷ Urology</li> <li>▷ Ophthalmology</li> <li>▷ Diabetes/obesity</li> <li>▷ Women's health</li> </ul> |
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## Agreements

- **America Hears** (Bristol, Pennsylvania) reported it will standardize its family of premium digital hearing aids on the Voyager digital signal processing (DSP) platform from **Sound Design Technologies** (Ontario, Canada). The two companies also reported a joint development agreement to enhance the Voyager semi-conductor platform with new capabilities "to deliver the world's best listening experience to hearing-aid customers." Standardizing on the Voyager DSP platform, America Hears said it will deliver customer benefits that include smaller hearing aids, longer battery life, and better sound processing utilizing the Adaptive Dynamic Range Optimization (ADRO) amplifier algorithm developed by **Dynamic Hearing** (Melbourne, Australia) for America Hears.

- **CompuMed** (Los Angeles), a medical informatics company serving the healthcare community with diagnostic software solutions, reported a contract to provide electrocardiogram (ECG) remote interpretation services for state correctional facilities in Arizona through the Arizona Department of Corrections (ADC). CompuMed will provide remote cardiac screening on an as needed basis for more than 30,000 detainees at the Department's correctional facilities statewide. CompuMed now has 44 CardioGram systems at correctional sites throughout Arizona. The ADC agreement contains options for multiple renewals/extensions.

- **Conmed Healthcare Management** (Hanover, Maryland), a provider of correctional facility healthcare services, said it has signed an initial contract with Pima County, Arizona, to immediately establish and implement, in coordination with the county and its existing vendor, a transition plan designed to effectuate a seamless transition of medical, dental and behavioral health services at the Pima County Adult Detention Center from the existing vendor to Conmed by Aug. 1.

- **InSight Health Services Holdings** (Lake Forest, California) reported that one of its subsidiaries has entered into a long-term agreement with Los Angeles County in California to provide MRI services at four county-owned academic medical centers: Harbor-UCLA, Martin Luther King, Jr./Drew Medical Center; Olive View-UCLA Medical Center and Rancho Los Amigos National Rehabilitation Center.

- **Gamida Cell** (Jerusalem) reported a collaboration agreement with **Biologics Delivery Systems Group** (BDSG), a unit of **Cordis** (both Miami Lakes, Florida). BDSG will supply catheters for the upcoming Phase I/II clinical trial of Gamida Cell's CardioCure product for the treatment of post-myocardial infarction (heart attack) patients. CardioCure is a proprietary *ex vivo* expanded autologous (from the patient's body) bone marrow product. The randomized, controlled multi-center Phase I/II

clinical trial, due to start in 4Q08 in Israel, will evaluate the safety and efficacy of Gamida Cell's CardioCure in 48 post-MI patients. CardioCure will be injected directly into the myocardium using the latest generation of the BDSG NOGA cardiac navigation system and MyoStar injection catheter. Pre-clinical results demonstrate that CardioCure may offer a better therapeutic alternative to existing treatments. The data indicate that it may prevent or lessen some of the damage caused to the heart muscle as a result of a heart attack.

- **Hoana Medical** (Honolulu, Hawaii) reported new partnerships with a large healthcare system in Pennsylvania, the Veterans Administration (VA) with VA hospitals in Florida and Nebraska, and the U.S. Army to improve patient safety in acute-care hospitals. Hospital experience has shown that rapid response teams (RRT) are not effective if the patient is found too late - many times patients are found deceased. Hoana's LifeBed Patient Vigilance System identifies patients as they begin to deteriorate and immediately notifies the hospital nursing staff with no visible connection to the patient whatsoever. This partnership, referred to as PIMA (for Personal Intelligent Medical Assistant), will examine how finding a patient in distress early reduces the risk of negative outcomes, injury or death, and reduces the cost to the hospital. Although the VA recently awarded Hoana a federal supply contract to outfit VA hospital beds at \$16.20/day/bed, this program is funded with \$1.7 million from the U.S. Army Medical Research Command and the Telemedicine and Advanced Technology Research Center.

- **NorthPoint Domain** (Boston) has reported a collaboration with the Cardiovascular Center of **Boston Medical Center** (BMC; Boston) to apply advanced Internet patient engagement instruments to BMC's cardiac robotic surgery program. Also known as medical informatics instruments (MIIs), these tools are used by clinicians as informational and interactive tools that involve patients and their families in the care process. The partnership is an extension of the relationship between NorthPoint and the BMC Cardiovascular Center. NorthPoint will work with the Cardiovascular Center to tailor its MII platforms, complementing the advanced robotic surgery technology being used at BMC.

- The **Premier** (Charlotte, North Carolina) healthcare alliance is collaborating with the Centers for Disease Control and Prevention (CDC; Atlanta) on an initiative to eliminate occupational injuries from needlesticks and other sharp objects. As part of this initiative, a comprehensive workbook on sharps injury prevention, along with wall signs and an educational CD-ROM, are being made available to healthcare administrators and staff involved in sharps injury prevention activities.

## Market & technology updates

# Eye diseases could find new hope via use of microneedles

By LYNN YOFFEE  
BB&T Staff Writer  
and Staff Reports

Of all the problems that reduce quality of life for aging populations, eye diseases are certainly among the most intractable. While other illnesses have rapidly attracted a broad array of therapeutic strategies, the eyes – their delicacy and complexity – have stymied the development of broad advances, especially on the device side.

Now, researchers at the **Georgia Institute of Technology** (Georgia Tech; Atlanta) are pursuing a new method to deliver therapy to the eyes that could provide a platform for large advances in this sector. They are developing tiny needles – micro-needles – coated with drugs that could treat glaucoma, macular degeneration, diabetic retinopathy and other diseases leading to blindness, while avoiding the complications associated with current intraocular injections and systemic administration of drugs.

“The concept of microneedles existed a long time ago,” Samirkumar Patel, a researcher at Georgia Tech, told *Biomedical Business & Technology*, noting that patents on these types of devices were filed in the 1970s. The patents described small needles “to create pathways into tissues to allow drugs to diffuse across a given tissue faster.”

But Patel said these needle types targeted the penetration of skin.

Patel is part of a team that includes researchers from **Emory University** (Atlanta) who are working to exploit this concept for new therapeutic applications. “Our group at Georgia Tech designed and fabricated these microneedles in the 1990s,” Patel said. “The reason they didn’t exist until then is because the technology didn’t exist to fabricate them at that [micro-sized] scale. We decided to branch out of transdermal delivery and started looking to deliver drugs into the eye, which is a completely new idea.”

The solid metal microneedles, measuring 500 to 750 micro-millimeters in length, go only as deep as a half-millimeter into the tissue, not far enough to cause the damage — such as retinal detachment – associated with traditional needles. And only local anesthetic

is needed for their use.

They overcome the disadvantages of other system for delivering drugs to the eyes, according to Patel – such as eye drops, that fail to reach the back of the eye; injections with standard hypodermic needles that are invasive, penetrating across eye tissues; and regular needles associated with a variety of vision complications. Invasive because the needle penetrates across eye tissues.

Patel said, “With eye drops, only 1% to 3% of the drug actually gets into the front portion of eye. It’s a very low percentage for drug delivery efficiency. For older people who have serious vision issues, the drug needs to be delivered to the back of the eye and these injections are not one-time treatments. They are typically done multiple times over four to eight weeks. It’s very invasive and repeated injections can cause complications.”

Besides being less invasive, micro-needles are able to reduce the amount of drugs used, have fewer side effects and are likely to be less costly overall.

Whatever drug is delivered “can be designed to stay longer in the tissues and eventually diffuses into the retina,” Patel said. “The microneedle has versatility to deliver drug to different parts of the eye. Now they just try to get it into the eye and hope it reaches the target. With the microneedle, you can selectively deliver to a region of the eye.

“So far, tests indicate the microneedles showed very little reaction from rabbits,” he said. “In visual tests done within a matter of hours after delivery, you couldn’t tell that anything happened.”

Research on this method of ocular drug delivery is at a very early stage, the team so far working with eyes from cadavers and rabbits. Thus, Patel predicted that it could be at least five years until they enter clinical trial status.

### *Diabetes continuing rapid increase*

For those looking to put their medical investment chips on the fastest-growing categories of disease, the best bet would appear to be diabetes. Nearly 24 million people in the U.S. have diabetes, an increase of more than 3 million over the past two years, according to new 2007 prevalence data estimates for 2007 released in late June by the Centers for Disease Control and Prevention (CDC; Atlanta). This means that nearly 8% of the U.S. population has diabetes.

In addition to the 24 million with diabetes, another 57 million people are estimated to have pre-diabetes, a condition that puts people at increased risk for diabetes. Among people with diabetes, those who do not know they have the disease decreased from 30% to 25% over a two-year period.

Dr. Ann Albright, director of the CDC’s Division

of Diabetes Translation, called the agency's estimates "good news and bad news." He said, "It is concerning to know that we have more people developing diabetes, and these data are a reminder of the importance of increasing awareness of this condition, especially among people who are at high risk.

"On the other hand, it is good to see that more people are aware that they have diabetes. That is an indication that our efforts to increase awareness are working, and more importantly, that more people are better prepared to manage this disease and its complications."

Diabetes currently is considered the seventh-leading cause of death in the U.S., while associated with a variety of other serious complications.

Among adults, diabetes increased in both men and women and in all age groups, but still disproportionately affects the elderly. Almost 25% of the population 60 years and older had diabetes in 2007. And, as in previous years, disparities exist among ethnic groups and minority populations including Native Americans, blacks and Hispanics.

After adjusting for population age differences between the groups, the rate of diagnosed diabetes was highest among Native Americans and Alaska Natives (16.5%). This was followed by blacks (11.8%) and Hispanics (10.4%), which includes rates for Puerto Ricans (12.6%), Mexican Americans (11.9%), and Cubans (8.2%). By comparison, the rate for Asian Americans was 7.5% with whites at 6.6%.

The data are an update of diabetes prevalence estimates last reported two years ago and now published in the 2007 *National Diabetes Fact Sheet* developed by CDC in collaboration with multiple agencies under the U.S. Department of Health and Human Services and other federal agencies.

CDC also is releasing estimates of diagnosed diabetes for all counties in the U.S. Derived from the agency's Behavioral Risk Factor Surveillance Survey (BRFSS) and census data, the estimates provide a clearer picture of areas within states that have higher diabetes rates. Nationally, the data indicate increased diabetes rates in areas of the Southeast and Appalachia that have traditionally been recognized as being at higher risk for many chronic diseases, including heart disease and stroke.

"These data are an important step in identifying the places in a state that have the greatest number of people affected by diabetes," said Albright. "If states know which communities or areas have more people with diabetes, they can use that information to target their efforts or tailor them to meet the needs of specific communities."

CDC, through its Division of Diabetes Transla-

tion, funds diabetes prevention and control programs in all 50 states, as well as the District of Columbia and eight U.S. territories and island jurisdictions. The National Diabetes Education Program, co-sponsored by CDC and the National Institutes of Health, provides diabetes education to improve the treatment and outcomes for people with diabetes, promote early diagnosis, and prevent or delay the onset of diabetes.

### *Pneumonia top cause of hospitalizations*

Heart disease (including stroke) and cancer are the top two killers in the U.S. – as well as worldwide – but the No. 1 reason for hospitalization in the U.S., as the result of illness, is pneumonia.

According to figures from the **Agency for Healthcare Research and Quality** (AHRQ; Washington), more than 1.2 million Americans were hospitalized for this lung infection – often deadly for older people – in 2006 (though coming in second to childbirth, which produces the largest number of hospitalizations).

That figure is considerably deceptive however, since the agency breaks out a variety of diseases that generally are placed in the general category of heart disease: hardening of the arteries, heart attack, congestive heart failure, heart rhythm problems and chest pain, some of which may be heart-related.


The figures come from AHRQ's *News and Numbers* report, the agency noting that the 1.2 million pneumonia admissions is roughly equivalent to the population of Dallas.

The '06 hospital bill for treating the disease was \$10 billion.

That, however, turned out not to be the largest dollar figure, since four other causes of hospitalization were in the \$10 billion-or more category.

Following are AHRQ's figures for 2006 hospitalizations, by hospital costs and estimated admissions, for eight other common conditions:

- Hardening of the arteries: \$17 billion – 1,198,000 admitted.
- Heart attack: \$12 billion – 675,000.
- Congestive heart failure: \$11 billion – 1,099,000.
- Osteoarthritis: \$10 billion – 735,000.
- Heart rhythm problems: 749,000 \$7 billion – 749,000;
- Chest pain: \$4 billion – 857,000.
- Complications of labor and delivery (other than injury to mother); \$3 billion – 767,000.
- Injuries to mother during birth: \$2 billion – 818,000.

AHRQ's *News and Numbers* is based on 2006 data in HCUPnet, a free online query system based on data from the Healthcare Cost and Utilization Project, providing access to health statistics on hospital inpatient and emergency department utilization. ———— 

## Product briefs

# GPS-like device sees deep into lung areas

By AMANDA PEDERSEN  
BB&T Staff Writer  
and Staff Reports

Pulmonologists at **Presbyterian Hospital** (Dallas) have begun using a new type of bronchoscopy that uses GPS-like technology to generate 3-D images of the far reaches of complex lung structures. This electromagnetic navigational bronchoscopy is expected to help pulmonologists better diagnose lung cancer, pneumonia and various pulmonary infections.

"This new technology allows us to see safely and clearly into those deep regions of the lungs and diagnose exactly what's causing the respiratory problem," said Presbyterian pulmonologist Suneel Kumar, MD.

The inReach system from privately-held **superDimension** (Minneapolis) was cleared for marketing in the U.S. in September 2007. According to the company, the new imaging tool helps doctors reach smaller, harder-to-reach lung lesions.

Presbyterian has been using the new device since January, Kumar told *Biomedical Business & Technology*. He says the device is unlike anything else on the market that he is aware of.

"The big benefit is that we can certainly go after lesions that are smaller and even go after them more accurately by being able to plan out the procedure beforehand using the patient's CT scan," Kumar said.

Until now, most lesions beyond the reach of a standard bronchoscopy were further investigated with more invasive procedures that had side effects some patients could not tolerate, according to Presbyterian.

"This new technology allows us to more aggressively investigate the origin of disease in the lungs with less impact on the patient," said pulmonologist Howard Mintz, MD. "We're able to more accurately diagnose the condition of the lung and, in turn, better care for the patient."

superDimension says the inReach system provides a 3-D virtual "roadmap" of the lungs that enables a physician to maneuver the inReach catheters through multiple branches of the bronchial tree to reach targeted lesions. The new system uses a steerable catheter that also can access and biopsy lymph nodes that are near the bronchial tree or trachea.

According to the company, after a patient's CT scan of the lungs is imported into the inReach planning laptop, a three-phase process occurs: planning, registration and navigation.

"There's a big need for a reliable diagnostic tool that's minimally invasive for patients but still provides quality analysis of tissue deep in the lungs," Kumar said. "This system is a major step in that direction."

Elsewhere in the product pipeline:

- **Aethlon Medical** (San Diego) said it has added a second HIV/AIDS clinical study location at the Bhvani Hospital (Bihar, India). Aethlon previously disclosed plans to initiate its "first-in-man" clinical study of a medical device to treat HIV. The Aethlon Hemopurifier is a medical device created to provide real-time therapeutic filtration of infectious viruses and immunosuppressive proteins. The Hemopurifier provides real-time therapeutic filtration of infectious viruses and immunosuppressive particles, and is positioned to address the treatment of drug and vaccine resistant viruses. Additionally, the device holds promise in cancer care, as research studies have verified the Hemopurifier is able to capture immunosuppressive particles secreted by tumors. The Hemopurifier holds promise to extend the lives of AIDS patients by removing HIV strains that cause drug failure and reducing the presence of viral proteins that kill-off immune cells. Aethlon Medical makes the Hemopurifier, a medical device designed to treat infectious disease.

- **AngioScore** (Fremont, California) reported the launch of new longer and larger AngioSculpt PTA scoring balloon catheters for the treatment of peripheral artery disease (PAD). The new devices have received FDA clearance to market for the dilatation of lesions in the iliac, femoral, ilio-femoral, popliteal, and infra popliteal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The PTA catheter is not labeled for use in the coronary or neuro-vasculature. The new AngioSculpt devices incorporate longer (40 mm) balloons and scoring elements in the larger-diameter (4.0 mm and 5.0 mm) balloons. These new sizes are expected to be particularly useful in treating long and diffuse lesions typically encountered in the treatment of complex PAD. AngioScore makes angioplasty catheters for use in the treatment of cardiovascular disease.

- **AirStrip Technologies** (San Antonio) said it is in the advanced stages of development for its AirStrip OB medical application for the new Apple iPhone 3G. AirStrip OB, which is already available for use on PDAs and Smartphones, will allow obstetricians to use their iPhones to remotely access virtual real-time and historical waveform data for both the mother and baby directly from the hospital's labor and delivery unit using only a cell phone connection.

- **Arkray USA** (Minneapolis) reported FDA clearance for the Glucocard 01 blood glucose monitoring system. The Glucocard requires no coding, displays results in 7 seconds, and requires a 0.3 microliter sample size. Glucocard 01 is AST approved and has a 360-count test memory with time and date stamp.

- **ATS Medical** (Minneapolis) said it has obtained new *in vivo* data to support the wear characteristics of the ATS Open Pivot Mechanical Heart Valve. The first ATS Open Pivot valve was implanted in Lausanne, Switzerland, in May 1992. The patient was 70 at the time of his surgery and enjoyed another active 15 years with his ATS Open Pivot valve. He recently died of non-valve-related causes and his physician and family permitted the explantation of his Open Pivot valve for scientific analysis. Scanning electronic microscopy and laser profilometry were used to quantify the wear on the carbon portion of the valve. After 15 years of use and an estimated 560 million opening and closing cycles, the Open Pivot valve displayed no detectable wear.

- **Aureon Laboratories** (Yonkers, New York) has introduced Prostate Px+, a test that predicts prostate cancer progression and disease recurrence at the time of diagnosis. "Prostate Px+ is the first prognostic test to provide this critical information at diagnosis. This technology represents a new integrated approach known as systems pathology that combines molecular biomarkers, histological and clinical information with advanced mathematics," said Ricardo Mesa-Tejada, MD, VP of pathology and medical director of Aureon Laboratories. "At the time a man is diagnosed, Prostate Px+ will forecast disease progression after treatment, detect high-risk patients presenting as low risk and undetectable by other methods, reclassify intermediate-risk patients and help identify those with less aggressive disease.

- **Axway's** (Scottsdale, Arizona) Synchrony Healthcare Compliance Suite is now available as a Software-as-a-Service (SaaS) solution, giving companies the only all-in-one platform solution that can improve supply chain agility, efficiency and cost-effectiveness without making a significant investment in IT infrastructure. Synchrony Healthcare Compliance Suite On Demand fits Axway's "start anywhere, use anything" architecture, allowing companies to use one or more of the applications as needed to meet their business requirements. The Suite helps the pharmaceutical supply chain significantly increase the availability of information, ensure compliance, gain insight into the performances of the supply chain and reduce operations expenses. Companies using the Healthcare Compliance Suite are able to improve operational efficiency through supply chain visibility, enable product authentication and assure data integrity across all supply chain transactions.

- **Biolase Technology** (Irvine, California) report-

ed the launch of its new Waterlase C100 hard- and soft-tissue laser. Designed for the restorative general dentist, the Waterlase C100 provides clinical procedures including cavity preparation, early stage periodontal therapy and soft tissue procedures with more patient comfort compared to conventional instrumentation. The Waterlase C100 all-tissue laser combines Waterlase YSGG technology with reliability, clinician control, operating efficiency, and flexibility in tip and accessory selection. While it offers a narrower scope of applications than Waterlase MD, it provides for an advanced level of clinical results and patient comfort in a wide range of hard- and soft-tissue procedures.

- **Biotronik** (Lake Oswego, Oregon) reported the release of the Stratos LV cardiac resynchronization therapy pacemaker (CRT-P). Stratos LV is a CRT pacemaker – a device which provides low-voltage stimulation for resynchronization therapy, but not defibrillation. CRT devices are indicated for certain types of heart failure patients and may improve the pumping action of the heart by helping to synchronize the heart's lower chambers (the ventricles). Stratos LV offers a feature to help assure that resynchronization therapy is delivered continuously with RVsense Triggering. RVsense Triggering helps maintain resynchronization by forcing the pacemaker to pace the left ventricle whenever there is activity in the right ventricle (whether it is a paced event or the heart beats on its own). This assures that there will be no "one-sided" cardiac activity, and may help to preserve ventricular ejection fraction (a standard measure of the heart's ability to pump blood efficiently), reduce symptoms of heart failure, and synchronize ventricular intrinsic contraction within 2.5 ms of a sensed or paced event in the right ventricle.

- **CardioTech International** (Wilmington, Massachusetts) said that it has received FDA approval to export its 4 mm graft in further support of the ongoing European clinical trial of CardioPass, the company's synthetic coronary bypass graft. CardioPass is designed to be an alternative for patients who have undergone repeat procedures or have insufficient native vessels for bypass. Repeat surgeries account for up to 20% of all bypass procedures. CardioPass is made from ChronoFlex, the company's biodurable medical-grade polymer and engineered to be pulsatile, biostable, torque-resistant and suturable. Once it is implanted, the graft's polymer construction allows it to incorporate the patient's own cells and tissue, so that the inner surface mimics the normal environment for blood contact.

- **CBaySystems** (Annapolis, Maryland) reported the launch of Kyps, the brand name for CBaySystems' web-based practice management and electronic medical record (EMR) system targeted at small- and medium-sized physician practices in the U.S. Kyps combines a practice management system, an electronic

medical record solution and a medical transcription service into a single, integrated web-based program offered as a “pay as you go” service. The Kyps service allows physician practices to avoid the upfront capital and ongoing hardware and software costs of traditional practice management and EMR solutions.

- **Clariant** (Aliso Viejo, California) reported its new offering, KRAS, which has been validated as a laboratory-developed test to be used as a predictive molecular biomarker for patients with colorectal cancer (CRC). In colorectal cancers, EGF-receptors transmit a series of signals through a complex path of intracellular proteins. These signals ultimately instruct the cancer cell to undergo a transcription process leading to cancer progression. Anti-EGF-receptor therapies such as panitumumab (Vectibix from Amgen) and cetuximab (Erbix from ImClone Systems) work by blocking the activation of EGF-receptor. By blocking activation of the receptor, these drugs are successful in inhibiting downstream events that lead to malignant signaling. KRAS is located downstream of EGF-receptor and is a vital component in orchestrating this signaling process.

- **Core Essence Orthopaedics** (Yardley, Pennsylvania) has introduced a line of surgical solutions focusing on soft tissue and skeletal repair of the extremities. The products include the Securus Knotless Suture Anchor System, initially targeted at arthroscopic rotator cuff repair. Other key products are the nABLE Percutaneous Suture Management System, PONTiS Endotendonous Repair System, reVERTO Shape Memory Staples, SEGWAY Synchronized Endoscopic Guide System, and the reNOVO Suture Anchor System.

- **Covidien** (St. Louis) said that its imaging solutions business is launching the Optistar Elite contrast delivery system. The product is designed to inject contrast media-related drugs into a patient’s vascular system to aid in obtaining diagnostic images when used with magnetic resonance (MR) imaging equipment. One of the features on the Optistar Elite injector is Patency Check, which aids in preventing extravasation, assists in reducing the potential of certain medical errors and helps enhance clinical and work flow efficiency. The Optistar Elite, combined with the use of Covidien’s Ultraject prefilled syringes for contrast media-related drugs, can help decrease the risk of certain medication errors that may be caused by manually filling syringes.

- **CryoLife** (Kennesaw, Georgia) reported that positive mid-term performance data on the CryoValve SG decellularized pulmonary human heart valve were presented at the Western Thoracic Surgical Association meeting in Kona, Hawaii. The results showed that there was a statistically significant reduction in structural valve deterioration in patients who received the CryoValve SG for right ventricular out-

flow tract reconstruction procedures (RVOT) as compared to the conventionally processed valve. Valvular insufficiency occurs when the valve leaflets do not completely seal when the valve is closed, causing regurgitation, or the backward flow of blood into the heart chamber. The CryoValve SG pulmonary human heart valve is indicated for the replacement of diseased, damaged, malformed or malfunctioning native pulmonary valves. The valve can be used in conjunction with RVOT, commonly performed in children with congenital heart defects.

- **Dale Medical Products** (Plainville, Massachusetts) has introduced a bariatric abdominal binder which includes a Velcro strip that can be placed anywhere to secure drainage bulbs and tubing, without pins or tape. The Dale Bariatric Abdominal Binder is an all-elastic, latex-free post-op support that features paneled construction to prevent riding, roping, and folding over. Evenly distributing compression to brace abdominal muscles, the binder includes an EasyGrip Strip which can be placed anywhere on the binder to secure drainage bulbs and tubing without pins or tape. The Dale Bariatric Abdominal Binder can be cut to create a hole for the drainage tube prior to positioning the EasyGrip Strip for holding up to four drainage bulbs. The device is available in 11 sizes.

- **Derma Sciences** (Princeton, New Jersey) said it has launched its Medihoney dressing line by securing reimbursement codes for the three recently released new product formulations. The Statistical Analysis Durable Medical Equipment Regional Carrier (SAD-MERC) – a contracted intermediary and carrier for the Centers for Medicare & Medicaid Services – has notified the company of its decision regarding HCPCS codes for billing purposes for the Medihoney formulations. The new codes will allow applicable customers to bill for all the new Medihoney dressing formulations. Customers will include Medicare’s Part B program, private insurance plans, and the various Medicaid programs.

- **eCardio Diagnostics** (The Woodlands, Texas) reported the launch of an extended monitoring device, the eTriggerPLUS, in conjunction with an extended monitoring service (EMS). Extended monitoring devices provide real-time data analysis allowing physicians to capture daily ECG information through pre-defined and programmable intervals. The eTriggerPLUS is the first generation of extended monitoring devices offered by eCardio. The single component device contains features such as the eTimer automatic data capture which expands the flexibility of the eTriggerPLUS for use in various patient therapies or clinical study applications such as: device monitoring, post-ablation follow-up, drug titration, and the documentation of abnormal cardiac function.

- **Echo Therapeutics** (Franklin, Massachusetts) said it has initiated a clinical study of its Symphony

Transdermal Continuous Glucose Monitoring system (tCGM system) in patients with Type 1 and Type 2 diabetes. Echo's non-invasive Symphony tCGM system consists of its Prelude SkinPrep system, which incorporates patented and leading-edge skin permeation control technology, and wireless transmission and proprietary transdermal biosensor technologies. Echo's symphony tCGM system is designed to provide both diabetes and hospital patients with a continuous glucose monitoring device.

- **EnteroMedics** (St. Paul, Minnesota) said a new implantable medical device, developed in collaboration with Mayo Clinic (Rochester, Minnesota) researchers, shows promise as a reversible and less-extreme alternative to existing bariatric surgeries, according to findings published in the current issue of *Surgery*. In the company-funded trial, the 31 obese participants who received the vagal nerve blocking device, also called VBLOC vagal blocking therapy, lost an average of nearly 15% of their excess weight. A quarter of the participants lost more than 25%, and three patients lost more than 30%. VBLOC therapy is similar to a heart pacemaker, but instead of stimulating a normal, regular heartbeat, it uses high-frequency electricity to block the nerve impulses between the brain and the stomach and pancreas. A pacemaker continuously monitors the heart and regulates its beating. But the patient flips a switch to activate the VBLOC device when the system is worn during the daytime hours so that the blocking signal can influence how the stomach functions and food is digested following a meal.

- **Gambro BCT** (Lakewood, Colorado) said that it received FDA clearance for the commercial sale of Atrius Whole Blood Processing system in the U.S. The Atrius device automates the manufacturing process of a unit of whole blood. Replacing balances, centrifuges, expressers, sealers, and scales, the Atrius system reduces variability from the manufacturing process. In the future, the company also will distribute specialized tubing kits, including a single collect bag and a compatible processing kit. The initial offering allows blood centers to leukoreduce the Red Blood Cell unit by gravity filtration after processing. Gambro BCT, soon to be known as CaridianBCT, provides technology, products and services in automated blood collections, therapeutic systems, whole blood processes and pathogen reduction technologies.

- **Inion** (Tampere, Finland) said that it has received FDA clearance for its biodegradable graft containment systems for spinal fusion procedures. The clearance has been received for the Inion S-1 anterior cervical fusion system, the Inion S-1 double-level plate and the Inion S-2 anterior thoraco-lumbar fusion system. These systems consist of biodegradable plates and screws, which are designed for bone graft containment in spinal fusion procedures. Such proce-

dures are carried out as a treatment for a range of spinal conditions including ruptures and displacement of inter-vertebral discs. Inion's S-1 and Inion S-2 graft containment systems include implants intended for use along the entire length of the spine in conjunction with traditional rigid fixation.

- **InTouch Technologies**, dba **InTouch Health** (Santa Barbara, California) reported the launch of a new product feature, StrokeRespond, to extend the functionality of its Remote Presence robotic technology for stroke experts. Remote Presence (RP-7) systems have already been deployed in stroke networks around the country, with results including improved geographical reach of stroke specialists and more timely delivery of appropriate stroke care. StrokeRespond is an enhancement to the Remote Presence platform and has been designed specifically to support the expert physician's acute stroke management workflow. Remote Presence is a telemedicine technology platform which combines the power of robotics, wireless, and the Internet to enable hospitals and physicians to bring the right care to a patient at the right time.

- **Lutronic** (Princeton Junction, New Jersey) said that it has received regulatory clearance from the FDA for the eCO<sub>2</sub> system. Using the controlled chaos technology, this next-generation fractional CO<sub>2</sub> laser is designed to offer ways to treat deep ablative indications such as resurfacing and coagulation of soft tissue, textural irregularities, fine lines, pigmented lesions, vascular dyschromia and rhytides. Of note is the ability to combine two operational modes in one delivery system, which is important when deep penetration and greater patient comfort is required. With both static and dynamic operation modes, users have the capability to stamp up to a 14 mm x 14 mm scan area as well as the option to "feather" the treatment area to reduce the "checkerboard" appearance that is common with currently available fractional CO<sub>2</sub> devices.

- **Masimo** (Irvine, California) said that a new clinical study, published in the June issue of the *British Journal of Anaesthesia*, concluded that under the study protocol Masimo's PVI measurement "can predict fluid responsiveness in mechanically-ventilated patients under general anesthesia." PVI is a new measurement available in the Masimo Rainbow SET technology platform that allows noninvasive, automated, and continuous monitoring of the variation in the pulse oximeter waveform amplitude during respiration. Masimo Rainbow SET continuously and non-invasively measures total hemoglobin, oxygen content, carboxyhemoglobin, methemoglobin, and PVI, in addition to oxyhemoglobin, pulse rate, and perfusion index, allowing early detection and treatment of potentially life-threatening conditions.

- **Medtronic** (Minneapolis) reported that data

from a multi-center, prospective, randomized, single-blinded, controlled investigational study using its neurostimulation system to stimulate the occipital nerves as a potential approach to treating medically refractory chronic migraines will be presented during a late-breaking session at the annual scientific meeting of the American Headache Society. In the study, thin lead wires were placed under the skin near the occipital nerves, which arise from the spinal cord and branch out across the back of the head carrying sensory signals from that region to the brain. The leads were connected to an implanted Medtronic neurostimulator that delivered controlled electrical pulses to the occipital nerves. Patients were randomized to three groups to receive: either a neurostimulator and have the ability to control the level of stimulation; or a neurostimulator as part of a device control group; or only standard medical management instead of an ONS implant. A positive response was defined as at least a 50% reduction in the number of headache days in a month, or a reduction in the pain intensity of at least three points on a standard 0-10 pain scale.

- The Certification Commission for Healthcare Information Technology (CCHIT) said that **Misys** (Raleigh, North Carolina) MyWay Version 2008 is CCHIT-certified, and meets the commission's ambulatory electronic health record (EHR) criteria for 2007. Ambulatory EHRs are designed for physician offices and clinics where most Americans get their healthcare. The Misys MyWay solution, available as both an on-demand and on-premise product, offers capabilities for EMRs, practice management and claims management.

- **MIV Therapeutics** (Atlanta) said that its Protea ultra-thin cobalt-alloy bare metal stent has excelled in animal studies. The Protea is the company's next-generation bare metal stent with a strut thickness of 65 microns, a fixed geometry and uniform cell size for homogeneous delivery of drug to the local tissue, and a superior surface finish when compared to currently available cobalt alloy stents. Animal results showed that the Protea is statistically superior to one of the best and most deliverable cobalt-alloy bare metal stents on the market today.

- **Monogram Biosciences** (South San Francisco, California) said that, effective July 15, the HERmark Breast Cancer Assay will be available to physicians throughout the U.S. for assessment of HER2 status in patients with breast cancer. HERmark provides a precise and quantitative measurement of HER2 total protein and HER2 homodimer levels and will be offered as a CLIA-validated assay through Monogram's CAP-certified clinical laboratory. Physicians currently use semi-quantitative measures to determine HER2 status as an indicator of HER2 protein over-expression or HER2 gene amplification to determine whether or not to prescribe Herceptin. Inaccurate

measurements of HER2 status may lead to inappropriate therapy selection. HERmark is a diagnostic that accurately quantifies HER2 total protein levels and HER2 homodimerization in patients with breast cancer. HERmark is a CLIA-validated assay that is performed exclusively in Monogram's CAP-certified clinical reference laboratory in South San Francisco. Robust, accurate, sensitive and reproducible measurements of HER2 status are reported to physicians with a turnaround time of seven days.

- **Neoprobe** (Dublin, Ohio) said it has introduced an enhanced gamma detection control unit, the Neoprobe GDS (Model 2300), in connection with the company's marketing partner, Ethicon Endo-Surgery. The Neoprobe GDS control unit contains internal circuitry that enables it to communicate with Neoprobe's other wireless probes without the necessity of an external adapter. Neoprobe's wireless probes are available with either straight or angled tips and can also be used with all previous models of the company's neo2000 control unit (Models 2000, 2100 and 2200) using an external serial port adapter.

- **NewCardio** (Santa Clara, California) reported the results of its second external validation study of QTinno (the NCE2 Study). The study was led by an independent industry leading cardiac safety expert with extensive experience in pharmaceutical clinical trials. The NCE2 study evaluated the accuracy, precision and speed of NewCardio's lead product, QTinno, in producing fully automated measurements of drug-induced QT prolongation, a key cardiac safety indicator. QTinno is a software suite that provides automated, comprehensive analysis of QT intervals and other ECG-based cardiac safety for the pharmaceutical industry and drug regulators. NewCardio is a cardiac diagnostic and services company focused on the development of a proprietary platform technology to provide higher accuracy to, and increase the value of, the standard 12-lead ECG.

- **Nikon Instruments** (Melville, New York) introduced its new WES-3000 wafer edge Inspection Tool, designed to identify defects often experienced with immersion lithography as well as other IC manufacturing processes. The WES-3000 incorporates high-throughput, in-line inspection with a review station featuring high-resolution and clear-color images for fast assessment of unknown defects. The WES-3000 has the ability to review the wafer edge area based on the KLARF file input. KLARF converts the coordinates from the wafer inspection tool to wafer edge coordinates to help users understand the relationship between near edge defects and edge defects. Additionally, the WES-3000 features a newly developed illumination system that lights up the wafer edge surfaces to more easily identify defects. Topcoat film boundary position at bevel can also be precisely measured through an Apex camera at the wafer edge.

• **NovaBone Products** (Jacksonville, Florida) has released a new form of the synthetic bone graft, NovaBone Putty (bone graft substitute). NovaBone, a calcium-phosphate silicate, goes through an ionic dissolution process that signals the body to send more precursors to the wound site earlier and forms an apatite surface layer that acts as a framework for osteoblast attachment and new bone formation. This results in an increase in osteoblast function over the first few weeks. The FDA has approved the term osteostimulation to describe Nova Bone's capability. NovaBone is the only synthetic that is osteostimulative, directly increasing the proliferation and activity of osteoblasts, the cells responsible for new bone growth. This results in more extensive early bone formation than seen for other synthetic graft materials when evaluated during *in vivo* testing.

• **OBS Medical** (Carmel, Indiana) said that its predictive patient safety technology, Visensia, was the focus of a study and peer-reviewed paper published in the June 23 issue of *Archives of Internal Medicine*. The company said the findings support its data fusion platform – a validated technology that fuses multiple vital signs into one predictive and actionable index. It said that this approach is more reliable and timely than manual scoring systems and improves single-channel vital sign monitoring and its associated alarms. The paper provided evidence supporting Visensia's ability to detect clinical instability early and thereby avert a clinical crisis.

• **PatientKeeper** (Boston) said that its Meditech customer base has grown to more than 200 hospitals, representing a significant portion of the hospitals running Meditech in the U.S. The Physician Information System gives physicians a modern browser-based view of patient data on tablets, laptops and PCs, and offers a mobile companion that runs on most major Smartphones and PDAs. PatientKeeper's technology connects disparate systems that physicians typically access throughout their workday into a single physician portal. The PatientKeeper Portal enables providers to review clinical data from multiple sources – including lab and test results, EKG, PACS, fetal monitoring, ambulatory EMRs and medication histories; hand off patients to other physicians at the end of a shift; and electronically sign medical record documentation. PatientKeeper makes integrated physician information systems.

• **Pinnacle Data Systems** (Columbus, Ohio) reported general availability of its newest compact computing board, the COMX-S1 COM express module. This powerful embedded computer-on-module (COM) features mobile AMD technologies, including single- and dual-core AMD Sempron processors and AMD Turion processors and the AMD M690 chipset. Designed to the modern industry-standard known as COM express, the PDSi COMX-S1 module enables

OEMs to bring to market their embedded solutions, including providing custom I/O requirements, without the difficulty of developing the complex core circuitry of the computer.

• **Radi Medical** (Uppsala, Sweden) reported improvements to its latest-generation pressure-sensing guide wire, PressureWire Certus. The upgraded PressureWire Certus features a new ergonomically designed proximal connector which provides three key advantages for physicians. The new entry funnel allows for wire reconnection into the proximal connector, while also exhibiting less insertion friction. In addition, the new locking cap provides positive reinforcement when the wire and the connector are locked in place via a user intuitive on and off twist function.

• **Realtime Technologies** (Dublin, Ireland) introduced Shimmer, a hardware research platform designed for wearable health sensing in both connected and wireless environments. Shimmer — which stands for Sensing Health with Intelligence, Modularity, Mobility, and Experimental Reusability — uses a technology that Realtime has licensed from Intel Corp. The platform features a 2GB removable storage capacity and low-power standards-based wireless communication technologies that enable standalone applications such as robust motion capture. Shimmer can also stream data to other devices to expand the scope of research applications.

• **Rosetta Genomics** (Jersey City, New Jersey) said that the results of a study conducted by its scientists and collaborators and describing the use of microRNAs in accurately differentiating primary from metastatic tumors of the brain, have been published online in the peer-reviewed journal *Brain Pathology*. The findings demonstrate microRNAs' potential to act as effective biomarkers that may be applied in a diagnostic test designed to identify primary tumors in patients with brain cancers.

• **Seal Shield** (Jacksonville, Florida) has begun shipping a new family of fully submersible, 108 key, International keyboards with Silver Seal antimicrobial protection to help reduce the risk of worldwide cross contaminations, including Norovirus and the "super-bug," MRSA. According to the company, the Silver Seal international keyboard is the world's first 108 key, multi-language keyboard to be dishwasher safe and embedded with Silver Seal Antimicrobial protection. The Silver Seal antimicrobial devices use all natural, pure silver ions which are embedded in the plastic to create a safe and effective, inorganic, antimicrobial solution.

• **Sharps Compliance** (Houston) launched a larger version of its flagship product, the Sharps Disposal By Mail System, which it said is designed as a safer and more efficient alternative for medical waste pickup. The 18-gallon system (model number 11800) can

be used to collect all of the medical waste including red bag (biohazard) waste as well as existing sharps containers located in each examination room. The product is permitted by the U.S. Postal System for transport to the Sharps medical waste disposal facility located in Carthage, Texas.

- **Smiths Detection** (Edgewood, Maryland) reported the launch of SmartBio Sensor (SBS), a real-time detector for biological agents or airborne toxins. SBS provides a visual or audio alarm when a bio-threat is detected and classifies the agent by threat category. SBS takes continuous samples of the air, trapping bio-agents on to coupons. The onboard computer then classifies the threat and triggers the alarm. Bio-agents are retained for confirmatory analysis and archiving. SBS also has an onboard particle counter to maintain a low response to natural chemical and biological interferents in the air. Smiths Detection is part of the Smiths Group. It provides integrated security solutions for customers in civil and military markets.

- **Splintek** (Kansas City, Missouri) reported that the SleepRight dental guard has received over-the-

counter (OTC) clearance from FDA. According to the FDA, the SleepRight dental guard is indicated for protection against nighttime teeth grinding called bruxism. It is intended to reduce damage to the teeth and to prevent the noise associated with bruxism or grinding. The SleepRight is a "no-boil" dental guard, which combines self-adjust technology for an individual custom fit.

- **Summit Doppler Systems** (Golden, Colorado) introduced an upgrade to the Vista AVS, a full-featured arterial physiologic exam system. The new Vista AVS has advanced features, one of which allows clinicians to perform the ankle brachial index (ABI) exam for the diagnosis of peripheral arterial disease (PAD) in the seated position, the patent-pending Seated ABI. The ABI exam, which compares systolic blood pressures obtained at the ankles and arms, was traditionally performed with the patient in the supine position to prevent error from hydrostatic pressure. This position requirement made the exam difficult for patients with disabilities or mobility impairments. Recent studies have shown these patients have

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reduced access to many diagnostic exams. The new Vista AVS calculates ABI values for seated patients by compensating for the effects of gravity on the lower extremity pressure.


- **Texas Instruments** (TI; Dallas) reported a new fully integrated analog front end (AFE) for portable ultrasound equipment. The second device in TI's AFE58xx family for the medical ultrasound market, the AFE5804 is specifically designed for ultrasound systems that require low power and small size. The AFE5804 features 102 mW/channel at 1.25 nV/rHz at 40 MSPS. The eight-channel device contains a low-noise amplifier, a voltage controlled attenuator, a programmable gain amplifier, a low-pass filter and a 12-bit, 10 MSPS to 50 MSPS analog-to-digital converter with LVDS data outputs.

- **ThermoGenesis** (Rancho Cordova, California) said it has received authorization from the FDA to begin marketing its MarrowXpress device for use in a clinical laboratory setting or intraoperatively for preparation of a cell concentrate from bone marrow. Bone marrow derived stem cells are the dominant source of stem cells studied in regenerative medicine clinical trials for treating several large patient population diseases and injuries including blood disorders, ischemic heart diseases, peripheral artery diseases, and diabetes.

- **Trumpf Medical Systems** (Charleston, South Carolina) has introduced what it said is the first in-light high-definition (HD) operating room camera. The TruVidia HD captures and transmits images with 1080 lines horizontal resolution and 2 million pixels.

Images, captured in wide-screen format, can be transmitted for telemedicine applications and displayed on screen for education. Remote consultations can be conducted with a greater degree of confidence as the HD images essentially place the remote physicians in the OR. The TruVidia HD is integrated into the central handle of the Trumpf iLED surgical light. The camera also is available on a separate arm. Camera functions, including zoom and rotate can be controlled directly from the sterile field or from the control panel. Captured still images and even entire video sequences can be shared and archived on USB memory sticks.

- **Vermillion** (Fremont, California) said it has submitted a 510(k) pre-market notification application to the FDA requesting regulatory clearance of its ovarian tumor triage test known as OVA1. Previously, the OVA1 prospective clinical trial met its primary endpoints, indicating that the test is capable of stratifying women with pelvic masses into high- and low-risk categories to help determine whether the patient should be referred to a specialist prior to surgery. Vermillion is a molecular diagnostics company.

- **Vistakon** (Jacksonville, Florida) introduced Acuvue OASYS brand contact lenses for astigmatism. The OASYS for Astigmatism combines the accelerated stabilization design (ASD) technology of Acuvue Advance brand contact lenses for astigmatism, with senofilcon A, the silicone hydrogel material of Acuvue OASYS lenses. The lens also features Hydraclear Plus, the improved formulation of the Hydraclear technology that combines high performance base materials with a moisture-rich wetting agent. — 

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Senior Vice President/Group Publisher: **Donald R. Johnston**, (404) 262-5439  
Executive Editor: **Jim Stommen**, (404) 262-5402

**BB&T in Japan:** Techtran Ltd., 8240 Nishiide, Ohizumi, Kitakomagun, Yamanashi 409-1501, Japan. Phone: 3 0551 20 5530. Fax: 3 0551 20 5531.

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