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Leadership Summit on Healthcare Quality & Pay-For-Performance

Meeting dips 'foot in water' of tough payment reform plan

By MARK McCARTY
***Medical Device Daily* Washington Editor**

BOSTON – "Assessing the sustainability of payment reform" is not only an exercise in prognostication – one that is difficult to avoid indulging in of late – and also the title of a discussion at the fourth annual Leadership Summit on Healthcare Quality & Pay-For-Performance held here at the Marriott Copley Place hotel.

The event, which opened Sunday and closes today, boasts a select group of executives, government officials and highly regarded researchers with a variety of experiences and plenty of ideas on how to fit the round pay-for-performance (P4P) peg into the square hole of the traditional service reimbursement scheme.

From the first day, however, it was made obvious that

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Incentives, quality reporting, public participation debated

By MARK McCARTY
***Medical Device Daily* Washington Editor**

BOSTON – The second day of the fourth annual Leadership Summit on Healthcare Quality & Pay-For-Performance commenced with a session that addressed incentives, physician engagement and public disclosure, moderated by Michael Millenson, a visiting scholar at the Kellogg School of Management at **Northwestern University** (Evanston, Illinois).

Six panelists with varying perspectives joined Millenson on the dais, including Troyen Brennan, MD, now the chief medical officer for **Aetna** (Hartford, Connecticut). Brennan's early studies on medical errors formed the basis for the well-known 1999 report on medical errors by the **Institute of Medicine** (Washington).

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Report from Europe

Misonix in Hungarian market with the Sonablate 500 system

A *Medical Device Daily* Staff Report

Misonix (Farmingdale, New York), a developer of ultrasonic technology for the treatment of cancer and other health conditions, reported the continued expansion of its European high-intensity focused ultrasound (HIFU) business with its entry into Hungary.

The company said it has formed a strategic relationship with Euro-Open KFT for the marketing of Visually Directed HIFU using the Sonablate 500 (SB500) for prostate cancer treatment in Hungary through direct equipment purchases or on a fee-per-use basis.

The SB500 is a device developed by **Focus Surgery** (Indianapolis) and manufactured and distributed in Europe by Misonix. Visually Directed HIFU is a new, non-invasive technique developed by Focus Surgery and Misonix and is available only with the SB500 device. Misonix has a minority equity position in Focus Surgery.

The company's European HIFU strategy now includes

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Deals roundup

Orthofix to acquire Blackstone in cash deal valued at $333M

By DON LONG
***Medical Device Daily* Managing Editor**

Orthofix International (Huntersville, North Carolina) yesterday reported proposing a transaction that will produce consolidation in the therapeutic spine space while pushing its rate of growth from the "high single digits to more than 15%" annually, according to CFO Alan Milinazzo.

Orthofix has agreed to acquire **Blackstone Medical** (Springfield, Massachusetts/Wayne, New Jersey) – a private company specializing in the development of spinal implants and related biologic products – for $333 million in cash.

The deal combines Orthofix's spine stimulation franchise with Blackstone's portfolio of fusion, non-fusion and biologic products.

In a morning conference call, Milinazzo said that the combined spine segment is pointed to grow at more than 25% annually and projected to generate revenue of about

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THOMSON™

Utah Medical requests review of the 'abusive' FDA process

By HOLLAND JOHNSON
***Medical Device Daily* Associate Managing Editor**

Utah Medical Products (UTMD; Salt Lake City) said it has asked the federal government to review its allegations that the FDA was abusive in the way it inspected a company plant.

The company, which focuses on gynecological and neonatal products, said it has filed an administrative claim with the Department of Health and Human Services (HHS), the parent of the FDA, alleging "abuse of process in relation to the negligence and wrongful acts of FDA employees."

It filed the same administrative claim with HHS in July 2005, which HHS denied this past February (*Medical Device Daily*, Feb. 16, 2006). The company is now requesting that HHS reconsider the claim.

The matter goes back to August 2004, when the FDA issued a press release alleging that the Utah plant was not in compliance with quality system regulations.

The FDA later sued the company alleging the plant failed to comply with good manufacturing practices. The FDA ultimately lost that suit (*MDD*, Oct. 25, 2005), which was originally designed to permanently enjoin UTMD from making and distributing medical devices, and the company has hoped to regain its good name and reputation which it said were damaged by the unnecessary regulatory actions.

The negative publicity has continued to hurt sales of company products, the company said, even though it was found to be in compliance with U.S. quality regulations.

Among other things, UTMD's administrative claim requests that the FDA remove the Aug. 10, 2004, press release that remains posted on the agency's web site.

It also asks that the FDA inspectors and reviewers involved in the company's plant inspections between 2001 and 2003 be barred from any future involvement with Utah Medical.

The company also has requested a public declaratory statement from the Secretary of HHS that the FDA must comply with its own regulations, and that "unethical conduct that violates the Standards of Ethical Conduct for Employees of the Executive Branch will not be tolerated."

As part of informing public shareholders of the HHS denial in February, UTMD indicated that it had an Aug. 9 deadline to file suit against the FDA in U.S. District Court, or file a request for reconsideration. In order to disseminate an answer to shareholder follow-up questions fairly, the company revealed that it filed a request for reconsideration with HHS on July 12.

While the company is taking the road toward reconsideration at this point, Kevin Cornwell, CEO of UTMD, told *Medical Device Daily* that the litigation avenue "remains open" if the company's grievances are not addressed, although he said he would prefer not to go down that path. "Everybody loses if you go back to court, so why not do everything you can possibly do [first] without going back to court?"

While saying he would prefer not to pursue the litigation path, Cornwell stressed that the company has proof that certain officials affiliated with the FDA committed fraud. "We've got a solid case," he said

Cornwell said the statutory rules state that HHS should provide the company with a written response to its reconsideration response within six months

In a public statement, Cornwell took umbrage with recent comments made by David Elder, director of the FDA office of enforcement, in the August 2006 issue of the *Guide to Medical Device Regulation*.

"FDA enforcement cannot be properly judged by counting the number of actions taken by the agency," Elder said. "FDA has increasingly used an enforcement strategy based on efficient risk management principles that focuses on combating the greatest public health risks and maximizing our deterrent effect against potential violators."

"To my knowledge, the lawsuit brought by FDA in 2004

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Court report

Delcath suit cites omissions by Ladd in potential takeover

A *Medical Device Daily* Staff Report

Delcath Systems (Stamford, Connecticut), a developer of perfusion technology for delivery of therapeutic agents, reported filing a lawsuit against Laddcap Value Partners and certain related parties in U.S. District Court for the District of Columbia.

The lawsuit alleges that the Ladd defendants have made a series of material omissions and misstatements in violation of securities rules, most recently in a proxy statement for a proposed consent solicitation. It said that the statement omits a variety of negative facts concerning some of the nominees being offered by Ladd.

Delcath contends that the Ladd defendants' preliminary consent solicitation also misleads shareholders about the true motive of the Ladd Defendants' proposed consent solicitation – which is "to force the immediate sale of the company so that they can extract a quick profit and boost the short- term performance of the under-performing Laddcap hedge fund."

Delcath said that "after nearly a year of repeated attempts to force a sale of the company, the Ladd defendants would have shareholders believe that they suddenly have a newfound interest in developing Delcath's long-term business."

Delcath also alleges that the Ladd defendants have mischaracterized discussions with the company in an effort to discredit its directors and that "they have failed to disclose the identity of and nature of their relationship with persons and entities with whom they are acting together as a group for the purpose of acquiring, holding, voting or disposing of Delcath stock.

"Less than three weeks after reaching an agreement with Mr. Ladd that resulted in the withdrawal of his request for a special meeting of shareholders (*Medical Device Daily*, July 12, 2006), it is once again apparent that Mr. Ladd will stop at nothing to achieve his goal of forcing a premature sale of Delcath Systems, including misleading investors and violating securities law."

Samuel Herschkowitz, chairman and chief technical officer of Delcath, said that the company's management and board members "have helped Delcath to reach a great number of important milestones, including receiving Fast Track status from the FDA, garnering a Special Protocol Assessment (*MDD*, March 3, 2006) and drawing support from the **National Cancer Institute** (*MDD*, Jan. 6, 2006) . . . The Delcath system, which has shown promising results, including the ability to prolong life in certain terminally ill liver cancer patients, constitutes a true breakthrough for the treatment of liver cancer and represents a multi-billion dollar addressable market."

The company says that its technology is designed to allow aggressive chemotherapy while preventing the serious side effects that have precluded the use of high-dosage treatments.

In other legalities, **SSI Surgical Services** (Orlando, Florida) said that it would pursue a breach of contract claim against **MSI Surgical Solutions** and its affiliate, Empire Investment Holdings (Miami), a private equity investment firm.

SSI said that in June, MSI agreed to acquire SSI's off-site surgical reprocessing division in Syosset, New York (*MDD*, June 6, 2006), but that it has failed to complete the transaction. SSI has filed suit in Delaware Chancery Court and said it intends to explore alternatives for the division.

MSI has filed a counterclaim.

Chris Tihansky, president/CEO of SSI, said, "During this period of transition, the Syosset division will continue to provide reliable, high-quality services to its customers."

SSI provides surgical support services to hospitals and ambulatory surgery centers throughout the U.S. including endoscopy management services, SPD staffing and surgical instrument sterilization. ■

Financings roundup

Biomaterials storage company BioStorage raises 'A' $5 million

A *Medical Device Daily* Staff Report

BioStorage Technologies (BST; Indianapolis), a provider of biomaterial storage, inventory management and cold chain logistics for the biopharmaceutical market, reported securing a $5 million Series A financing led by Radius Ventures (New York) and joined by returning investor Twilight Venture Partners (Indianapolis).

In connection with the investment, Dr. George Milne and Arthur Spiegel III, board members of Radius, have joined the BST board.

F. John Mills, MD, PhD, chairman/CEO of BST, said, "The market for pharmaceutical outsourcing is expected to experience double-digit growth in the next five years and the company is well-positioned to capitalize on this trend."

Spiegel said, "As the scientific value of biological samples continues to increase, BioStorage Technologies will be a major force [with] their high-integrity storage and management."

BST offers storage and management of a range of specimen and sample types, including fixed tissue preparations, donor materials, stem cells, plasma, serum and body fluids. It says its competitive advantages include a custom-built biorepository facility; validated storage processes and technologies; compliance with Good Laboratory Practices, Good Manufacturing Practices and Good Tissue Practices; and a proprietary, Title 21 CFR Part 11 sample inventory management system designed for compliant biomaterial storage, tracking and reporting.

Radius is focused primarily on early- to mid-stage

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Agreements

StatSure in accord with IMI to market HIV diagnostics

A *Medical Device Daily* Staff Report

StatSure Diagnostic Systems (Framingham, Massachusetts) said it has signed a binding term sheet with **Inverness Medical Innovations** (IMI; Waltham, Massachusetts) to develop and market consumer diagnostic products for HIV using StatSure's "barrel" technology.

The companies said this collaboration will utilize Inverness' leadership in marketing and distributing rapid diagnostic tests throughout the world.

StatSure has developed a technology platform for screening for the presence of antibodies to certain infectious diseases. IMI will receive an exclusive worldwide license for all consumer markets and a non-exclusive license to market the HIV barrel product to the professional markets. StatSure will be responsible for completing the development and for manufacturing the product, as well as for performing clinical trials in cooperation with IMI and obtaining regulatory approvals for sales in both the professional and consumer markets.

StatSure's barrel technology, marketed under the name StatSure, is a self-contained, rapid whole-blood testing format for the detection of antibodies to a broad spectrum of infectious diseases. The sample is obtained though a small (~3 microliters) fingerstick. Results can often be read within several minutes and do not require any instrumentation. This product line is designed for on-site testing in clinics, doctors' offices, the military, mobile health vans, emergency situations and those places where immediate results are necessary.

Misys Healthcare Systems (Raleigh, North Carolina), a provider of healthcare information technology solutions, reported that it has partnered with **Ware Langhorne & Associates** (WLA; Richmond, Virginia), a medical practice management company, to provide Misys' Electronic Medical Records (EMR) software to its clients.

Through the collaboration, WLA – a full-service management service organization – is adding Misys EMR to the solutions it offers medical practices to enable WLA's physicians and medical practices to "streamline productivity and maximize profitability."

With Misys EMR, physicians should be able to spend less time on administrative details, ensuring that all physician offices have the resources available to focus on offering their patients the best care possible. Furthermore, Misys EMR integrates seamlessly into many practice management solutions, meeting the organization's interoperability needs. System implementation is flexible and the interface design is user-friendly, with three graphical screens displaying the bulk of information physicians and staff need to access during a patient visit.

"After nearly two years of due diligence we selected Misys EMR because of its proven stability and robust functionality," said Ann Langhorne Lilly, vice president of WLA.

In addition to offering Misys EMR to healthcare organizations, WLA will provide the infrastructure, hosting and application support through its ASP business model. This option allows those physician offices which may not have the expertise to support EMR solutions to implement technological innovations like Misys EMR to achieve the same efficiencies as their larger counterparts. By offering EMR on a subscription basis, WLA may also minimize the cost to physicians while offering local training, development and support.

WLA provides medical practice management, billing services, accounts receivable management, accounting, consulting, regulatory compliance auditing, and electronic medical record products and services to more than 140 physicians in Central Virginia. ■

UTMD

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seeking an injunction to shut down UTMD's operations because of alleged violations of the Quality System Regulation [QSR] has been the only such action litigated through trial on behalf of the FDA in the 10 years since promulgation of the QSR," said Cornwell. "After three years of intensive and extensive inspections of UTMD and 'review' by so-called agency experts, the federal court decided unequivocally against the FDA.

"I question the basis for Mr. Elder's statements, because his representation about FDA using efficient risk management principles does not comport with UTMD's experience with the FDA."

Cornwell added that in contrast to Elder's statement, his company found "the FDA's action was neither prompt nor based on any risk to the public. The fact that no risk assessment was ever done by the FDA was a travesty. There were no FDA allegations that UTMD's devices were defective, or not safe or not effective. The agency never investigated whether UTMD's finished devices met specifications, and never challenged the soundness of the risk assessments that we had performed."

Finally, he expressed frustration at what he sees as a double standard being promulgated by the FDA. "I do not understand how the leadership of the FDA can reconcile the fact that it is a significant violation of the Quality System Regulation when companies do not follow their written procedures, but when employees of the FDA, which is charged with the enforcement of the QSR, do not follow important agency procedures, it is simply ignored." ■

Summit

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herding the many cats of U.S. healthcare into this approach will be quite a task, despite convincing early returns on the subject.

Peter Lee, CEO of **Pacific Business Group on Health** (PBGH; San Francisco), served as the moderator for Sunday's sustainability discussion, and commenced by asking rhetorically: "What payment reforms?"

He said that the healthcare payment system is "dysfunctional" and that "we've hardly put our foot in the water" of payment reform.

Lee chided any rosy scenarists in the audience, insisting that addressing payment reform "is something that we all have to step up to." Lee's employer is, according to its web site, "a business coalition of 50 purchasers [that] seeks to improve the quality and availability of healthcare while moderating cost."

Presenting at the event for the **Centers for Medicare & Medicaid Services** (CMS; Baltimore) was Barry Straube, MD, acting director of the Office for Clinical Standards and Quality. He remarked that every payment reform carries some risk of creating a new problem or exacerbating an existing problem and that "we're still in a nascent period" in this effort.

And he had, like Lee, a sobering message for the audience: "We're kidding ourselves when we take pride on the few [quality] measures" currently available. Straube said that "multiple payment silos" are one of the banes of the current system, noting that one path to the ideal would be to encourage voluntary reporting on quality and outcomes, then pay healthcare entities to provide those reports, and then make the leap to P4P.

"We have to ensure joint accountability" between providers and payers, Straube insisted.

Allan Korn, chief medical officer of the **Blue Cross Blue Shield Association** (Washington), identified three issues of central importance in modern healthcare: namely cost, the population of the uninsured and the population of the underinsured.

He noted that the "silo effect" could be addressed by the notion of a medical home, where one provider could tie together all the threads of specialty care and multiple facility use for a patient.

"We have a very difficult time paying for" the expertise needed to provide this medical home, though the notion of a "medical home has been around for some time," he said. And he said that the likelihood is that a primary care practitioner – often a role filled by internists rather than by a general practitioner – will not be able to play the part until something is done to make such a practice feasible.

George Bennett, chairman and CEO of **Health Dialog** (Boston), said that "unwarranted variation" in care might account for as much as 30% of the cost of Medicare services. He described prophylactic care and chronic disease care as healthcare opposites, the former being insufficiently pursued and the latter excessively deployed.

Bennett cautioned that "P4P will not solve all the problems" of modern healthcare.

On the other hand, he championed at least one cure for excessive care: group compensation. "The integrated system . . . is where we seem to get the most efficiencies," Bennett noted.

An integrated system might be, but need not be, one in which all providers work under one corporate roof. At the very least, it should be one that "at least make[s] sure that the [patient's] information is disseminated" to all the providers and sites involved in his or her care."

Bennett said that he hears "lots of talk about how much we pay," but questioned whether "we have enough emphasis on whom we pay." The medical home might be addressed by the use of a mechanism not unlike a general contractor in the construction industry, someone who would coordinate and oversee the entire spectrum of care for the individual patient.

In the discussion that followed, Lee voiced a notion that may have occurred to many stakeholders, namely that U.S. healthcare is suffering from "pilot paralysis," meaning a lack of leadership

Straube disagreed, insisting that CMS "has numerous demonstrations" under way for P4P, but that "there is a misconception as to the duration and turn-around" of such projects.

He also cited the hospital quality effort jointly managed by CMS and the **Premier** (Charlotte, North Carolina) hospital consortium, which has already shown that "all five areas improved" in just the first two years of the P4P field test. Straube added that the data from many such projects are reported quickly.

Volume of services is another feeder to the increasing cost of care, but Korn admitted that "we're shy of parameters" to clearly identify how much help new medical technology provides. He said that X-ray angiography looks good on paper but that the exposure to radiation is excessive.

"We can withhold coverage until we know [a technology] improves outcomes," Korn added, but the algorithms currently available for cost/benefit analysis simply are not vigorous enough to prospectively evaluate new medical technology.

Bennett suggested that to address the element of treatment efficacy, a fully working P4P system may have to loop back around to the patient.

"Part of the answer is public education," he said, noting that much information on the side effects of drugs is not communicated very adroitly. To say that the use of a drug can double one's chances of dying of heart attack might not be as meaningful as defining the risk as going from 1 in 1 million to 1 in 500,000. Such information, he insisted, should be presented "in a professional way, not in a hysterical way."

In an informal discussion after the meeting, Bennett told *Medical Device Daily* that to ask physicians to take on the task of educating patients probably would make it that much more difficult just to get an appointment with a doctor, but he said that other means are available.

One method, as one might guess, would be computer-based tutorials. "Nurses can do it, too," he added. ■

P4P

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Millenson said that he believes that "P4P is the last, best chance for American medicine to get it right" before healthcare ends up buried in "regulation, litigation and legislation."

R. Adams Dudley, associate professor of medicine and health policy at the **University of California San Francisco**, said he is of the opinion that when it comes to physician behavior, "even small incentives work very well" if they are not tied to a disproportionate amount of work.

However, past efforts to improve the quality of care in the U.S. have been pockmarked by confusion and misinterpretation, Dudley said. He said that he is impressed with "how often brilliant people can get it stunningly wrong" – using capitation as an example.

This fixed-fee-per-patient system for treatment of a group of patients was not utterly flawed as is commonly assumed, but might have worked if properly deployed, he said, explaining that capitation was flawed largely because it made providers responsible for downstream costs over which the initial provider had no control.

Dudley said that incentives also can be structured in a way that is murky at best. His employer has given him incentives "off and on for five years, and I still don't know what they're for." And any incentives would have to have physician buy-in before they could be expected to shape medical practice.

Jeffrey Kang, MD, chief medical officer at **CIGNA** (Philadelphia), said health plans genuinely believe that incentives work, but they are concerned about perversion of those incentives. For instance, he insisted that employers would have to get past the tendency to base their purchasing decisions on the question, "How low can we get unit [coverage] cost?"

Kang advocated the development of just one report card for providers, stating that "it makes no sense" to promulgate a number of report cards, especially given that most non-HMO practices have to do business with more than one payer and hence are subject to several standards of reporting and of quality.

He recommended that state governments or the federal government take up the task of putting together such a report card.

Kang insisted that "health plans should not be in the report card business" and that "you would see a dramatic movement toward P4P" if this type of reporting was handled by the public sector.

Brennan suggested that with each change to the system of physician compensation, babies go out with the bathwater. "We swing from one thing to another," he said, without retaining the positive elements of the system to be jettisoned.

"I'm very much in favor of market incentives," Brennan said, emphasizing patient commitment as key. And he urged stakeholders to bear in mind the need for sophistication "about how we drop incentives into the healthcare system."

Evidence-based medical practice is making headway in the norms of medical practice, but "there are devils in the details," he noted, citing problems with risk adjustment that physicians have not found a way to incorporate into their daily work despite mounds of published data.

Bruce Bagley, MD, medical director of quality improvement at the **American Academy of Family Physicians** (Leawood, Kansas), said that, by and large, the "culture in medicine is where I went to school," which does not "tell you anything about what I do" day-to-day.

Bagley said that there is good news from his association. About 30% of members report that their records are electronic and that the figure should be up to 40% in a year, although this is more meaningful, thus far, in terms of chart retrieval than in care analysis.

The typical general practitioner, he said, feels that risk assessment is suspect and thinks that "all my patients look like my sickest patient." However, a bell-shaped curve most likely represents the reality of most practices.

As for best practices, Bagley reminded the audience that "if you have the right measures, the answer is always 100% right," but the data do not cover all scenarios and comorbidities, so the optimal treatment regime is not always known.

Donald Fisher, PhD, president and CEO of the **American Medical Group Association** (AMGA; Alexandria, Virginia), said, "we don't think P4P goes far enough." He derided the current batch of incentives as templates of practice having more to do with physician behavior than with outcomes. AMGA is of the opinion that "we need to incentivize patients as well as doctors."

He described P4P as "a good first step that we can't be satisfied with for long," advocating a results-based system that would focus "on outcomes, not just systems and processes."

Bagley told *Medical Device Daily* that getting providers to look at the individual patient's outcome is an essential ingredient, especially given that medical resources are limited. In reference to an earlier comment on an alleged overuse of coronary stents, he noted that "there has to be a balance" between treating patient A aggressively and not using resources that might be better applied to patient B.

He acknowledged that the pressure to link general and specialty practices could lead to consolidation in the provider end of the healthcare industry, but that such a prospect is not necessarily problematic "if this is done for the right reasons" – such as to provide better service rather than simply for bargaining power with payers and suppliers. ■

Europe

Continued from Page 1

access through in-country and cross-border distribution channels into 11 countries, including some of the largest markets in Europe, such as France, Germany and the UK.

Michael McManus Jr., president and CEO of Misonix, said, "This expansion into the Hungarian market represents another integral step to extend [our] reach in the European HIFU market. [Serving] a population of 10 million people, Hungarian physicians may now offer their patients treatment using our Visually Directed HIFU on the Sonablate 500."

McManus said the new HIFU procedure would allow patients in Hungary to benefit from access to "far superior results to algorithm-based treatments that require a surgical procedure in advance of the treatment." He said the technique "represents twice the results, with half the time and in only one procedure, unlike any other HIFU system available today in this market."

Dr. Zsolt Nemeth, general manager of Euro-Open KFT, said, "We are excited about the prospect of delivering the promise of HIFU that has been proven in other European markets to patients and physicians in Hungary. The device is far superior to other technology we have reviewed."

Studies boost T-SPOT.TB test's effectiveness

Immunotec (Oxford, UK), which is focused on T-cell measurements, reported the outcome of two studies comparing its T-SPOT.TB assay with other diagnostic tests for latent tuberculosis (TB) infection

Both studies' results demonstrated that T-SPOT.TB is "significantly more sensitive than other diagnostic tests for tuberculosis, far less affected by immunosuppression and is able to provide an accurate result each time a test is carried out," the company said.

The first study, published in *The Lancet*, was conducted in Modena, Italy, by Giovanni Ferrara and colleagues. Their study compared the performance of the three main assays for detection of TB infection -- the traditional Tuberculin Skin Test (TST) and two blood assays, T-SPOT.TB and QuantiFERON-TB Gold (QFT) from Australian firm **Cellestis** in routine clinical practice.

The study involved 383 patients enrolled on suspicion of active or latent TB disease. The key findings of the study were that T-SPOT.TB identified more TB-positive individuals (38%) than did QFT (26%). In their analysis of the results the authors confirmed their belief that the higher number of positive results identified was explained by the higher sensitivity of T-SPOT.TB.

In a sub-cohort of 24 patients with a diagnosis of active disease, 83% (20 patients) were positive by T-SPOT.TB, 74% (17 patients) were positive by QFT with one indeterminate result and 70% were positive by TST (14 patients).

Indeterminate results were reported both for the study as a whole and also for a variety of higher risk subgroups within the study. An indeterminate result occurs when a test is completed but the result cannot be interpreted. This may be caused by a lack of sensitivity in the assay or by the patient having too few T cells to elicit a response.

The overall difference in indeterminate rates was statistically significant and shows that the QFT assay was unable to produce results in a substantial number of immunosuppressed groups, as well as patients of very old and young age. In contrast, T-SPOT.TB gave evaluable results in 97% of subjects and was only significantly affected by the severe immunosuppression associated with cancer chemotherapy.

Another study completed at the **Asan Medical Center** (Seoul, South Korea) by a group led by J.Y. Lee was published in the April issue of the *European Respiratory Journal*, comparing the performance of T-SPOT.TB, TST and QFT in a group of patients with a high clinical suspicion of active TB. The results from this group were compared against a low-risk control group of healthy patients.

The overall sensitivity of T-SPOT.TB in the 87 patients diagnosed with active TB disease was 95.4%, significantly higher than the results achieved with QFT (70.1%) and TST (66.7%). Eight patients gave indeterminate results using QFT, while no indeterminates were observed with T-SPOT.TB.

Peter Wrighton-Smith, CEO of Oxford Immunotec, said, "It is clear from the results presented in these two papers that T-SPOT.TB is significantly more sensitive than its competitors, far less affected by immunosuppression and is able to provide an accurate result each time a test is carried out, with very few indeterminates."

Firms launch jointly developed IuS microsource

Incoatec GmbH (Hamburg, Germany), a manufacturer of X-ray optics, and **Bruker AXS** (Madison, Wisconsin), a global provider of X-ray solutions for life and advanced materials sciences, launched their jointly developed IuS X-ray microsource, the brightest sealed-tube X-ray generator eve, at ECM 23 (the European Crystallographic Meeting) in Leuven, Belgium.

IuS is a high-brilliance X-ray source incorporating a 30-watt micro-focus sealed tube together with high-performance Montel multi-layer X-ray optics. The companies said the IuS has no moving parts, a long lifetime without maintenance, is extremely stable, does not require water-cooling, is easy to replace and has low cost of ownership comparable to common sealed tubes.

Incoatec and Bruker AXS said IuS is "significantly more intense than previous microfocus source designs," providing a photon intensity up to five times higher than a conventional sealed tube system. They said it can be integrated into a variety of X-ray analytical systems for a range of applications. ■

Deals

Continued from Page 1

$260 million in 2007, making it "one of the largest and most unique spine businesses in the world."

The deal, he said, gives the company "tremendous momentum in our spine business, with our orthopedic and **Breg** business [Vista California]" and will make "significant contributions to our overall performance."

Calling the deal "transformational," Milinazzo said that targeting Blackstone for acquisition was the product of a "long, deliberate search" and added that the company met Orthofix's criteria for "significant critical mass and profitability."

He said the company's distribution network provides opportunities "to significantly expand the availability of Blackstone's unique product portfolio around the world," with the distribution systems of the two companies being highly complementary.

Blackstone was founded in 1996 by brothers, Mike, Matt and Bill Lyons.

Matt Lyons, president and CEO of Blackstone, said, "We are especially excited about the benefits of combining our advanced product development capabilities with Orthofix's experience in developing innovative minimally- and non-invasive medical devices."

Blackstone reports that it has launched 14 new products over the last two years. It also pointed to annual revenue growth of more than 25% in each of the last three years, with total revenue increasing 39% during the first half of 2006 compared with 2005. In the second quarter ended June 30, the company recorded unaudited sales of $22 million, $1.9 million in income and net income of $1.2 million.

A not-so-bright spot on Blackstone's record is its recall in late 2005 of its ICON Modular Fixation System – marketed since June 2005 – classified as a Class I recall by the FDA earlier this year (*Medical Device Daily*, April 2006). Blackstone said that the system could fail after being implanted, based on reports of construct loosening in the early postoperative period. The company removed from distribution products not yet implanted.

Blackstone reported sales of its biologic products increasing from less than 5% of total revenue to greater than 15%. This includes Trinity, its brand name for Osteocel, manufactured by **Osiris Therapeutics** (Baltimore), distributed nationally to spine surgeons by Blackstone under an agreement inked by the companies in October of 2005. The product is an allogeneic bone matrix containing viable stem cells, an alternative to autograft in orthopedic procedures.

Orthofix reports that its spine business generated $102 million in sales during 2005, and revenues in the first half of 2006 were up 20% from the prior year. Last year the company launched the only FDA-approved cervical spine stimulator in the world, the Cervical-Stim, after late-2004 agency approval (*MDD*, Dec. 28, 2004).

Orthofix said it anticipates the deal closing as early as September, subject to regulatory approvals, consummation of the senior debt financing and other conditions. Wachovia Bank and Citigroup have provided a commitment for senior debt financing for the acquisition.

The company's products are distributed worldwide to orthopedic surgeons via sales representatives and its sub-

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Orbasone Mobile unit formed to provide shock wave service

A *Medical Device Daily* Staff Report

Orthometrix (White Plains, New York) reported that it has formed **Orbasone Mobile** as a subsidiary to offer providers, such as those with podiatric and orthopedic practices, access to its new Orbasone Extracorporeal Shock Wave Therapy (ESWT) Pain Relief System for treating patients in their surgical suites or offices.

Orbasone Mobile is starting its operations with six Orbasone units offering treatment in six regions of the U.S., not only in ambulatory surgical centers but also in physicians' office. It also will provide insurance billing through continuation of an agreement with **Health Reimbursement Solutions**, Orthometrix said.

The Orbasone received FDA market clearance in August 2005 for the treatment of chronic plantar fasciitis (foot pain).

Reynald Bonmati, CEO and chairman of Orthometrix, said, "We are very pleased with our sales for the first half of 2006, which came close to the sales we booked for the entire year 2005. A new Category III Current Procedural Terminology (CPT) Code became effective as of Jan. 1 for Medicare coverage of ESWT procedures." He said that while this led to private insurance coverage, it also tends to reduce reimbursements rates already covering such procedures.

"This situation is already exerting pressure on the ESWT mobile service industry which uses equipment that is two to three times more expensive than our Orbasone and too large to be used in the doctor's office. This can be a real opportunity for our company to enter that segment of the market."

"Unlike other mobile service companies, because our company also manufactures the Orbasone, we [can offer customers] the opportunity to purchase their own ESWT system . . . Orbasone Mobile will either develop into a separate stand-alone entity or continue to be a subsidiary of the company and serve as a strong marketing tool for our Orbasone system."

Orthometrix sells and services several musculoskeletal product lines used in diagnosis and monitoring of bone and muscle disorders, sports medicine, rehabilitative medicine, physical therapy, pain management and pharmaceutical research. ■

Deals

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sidiaries, and through partnerships with other orthopedic product companies, such as **Medtronic Sofamor Danek** (Memphis, Tennessee) and **Kendall Healthcare** (Mansfield, Massachusetts).

Its distribution channels include a direct sales force of more than 170 across the U.S., along with more than 100 distributors worldwide, selling more than 1,200 surgeons, and several group purchasing contracts.

Orthofix also is collaborating in R&D partnerships with the **Orthopedic Research and Education Foundation** (Rosemont, Illinois), the **Cleveland Clinic Foundation** (Cleveland), **Innovative Spinal Technologies** (Boston) and the **National Osteoporosis Institute** (Long Island, New York).

In other dealmaking:

• **Reflect Scientific** (RSI; Orem, Utah), a manufacturer of laboratory equipment and related supplies to life sciences, has agreed to acquire **All Temp Engineering** (ATE; San Jose, California). Financial terms were not disclosed.

ATE's assets will be integrated with RSI's recently acquired **Cryometrix** business unit to support sales and service of the new Cryometrix ultra-low-temperature freezers. The existing infrastructure of ATE will be used to attain improved manufacturing efficiencies and quality assurance, Reflect said.

John Hammerman, general manager of Cryometrix, called ATE "a strong and profitable organization. We look forward to completing the final documentation and closing the transaction as quickly as possible."

ATE has been a provider of engineered solutions to the cryogenics industry for more 23 years, serving more than 1,450 companies in the biotech, medical device, pharmaceutical, university, semiconductor, aerospace, military and industrial food processing.

Reflect provides products for the biotech, pharmaceutical and medical industries.

• **HealthSouth** (Birmingham, Alabama) reported that it has signed an agreement to sell **Cedar Court Rehabilitation Hospital** (Melbourne, Australia), and related assets to Epworth Foundation and ING Management.

Cedar Court assets include a 74-bed rehabilitation hospital and outpatient center, a stand-alone rehabilitation facility at the Oasis Leisure Center and an occupational medicine rehabilitation therapy business.

The transaction is subject to customary closing conditions, including clearance under the Australian Competition and Consumer Commission, the Victorian Department of Human Services and other regulatory approvals.

HealthSouth said that Cedar Court was the last of its international facilities and that the transaction signifies termination of its non-domestic operations.

Mark Tarr, president of HealthSouth's Inpatient Division, said, "We are pleased [Cedar Court] will be able to continue to serve the community under new ownership while we focus on strengthening HealthSouth's core businesses and growing in our target markets throughout the U.S."

HealthSouth is a major provider of outpatient surgery, diagnostic imaging and rehabilitative healthcare.

• **Pediatrix Medical Group** (Fort Lauderdale, Florida), a leading provider of neonatal, maternal-fetal and pediatric subspecialty physician services, reported the acquisition of **James River Neonatology** (Richmond, Virginia), consisting of three physicians and three neonatal nurse-practitioners who staff three neonatal intensive care units (NICUs), including two Level III units at **CJW Medical Center** and one Level II unit at **Southside Regional Medical Center**. The group also provides well-baby physician services.

Pediatrix paid cash for the practice – the amount undisclosed – and said the transaction is expected to be immediately accretive.

Founded in 1979, Pediatrix Medical's physicians provide services at more than 240 NICUs, and through Obstetrix, its perinatal physicians provide services in many markets where Pediatrix's neonatal physicians practice. ■

Financings

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opportunities in the health and life sciences industries. Radius currently manages two funds with total capital of about $100 million.

In other financing activity, **Dynatronics** (Salt Lake City) reported that its $500,000 stock buyback program, previously reported, is "well under way."

The company said it is actively purchasing its common shares on the open market. Since announcing the program in 2003, Dynatronics said it has purchased 134,000 shares. "Reactivating our stock repurchase program highlights the current undervaluation of our stock," said Kelvyn Cullimore Jr., president/CEO of the company.

Dynatronics makes products for treatment of chronic pain, rehabilitation and aesthetics. ■

PRODUCT BRIEFS

• **Collagen Matrix** (Franklin Lakes, New Jersey) said it has received FDA 510(k) clearance of its Collagen Nerve Wrap for the indication of management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue and where gap closure can be achieved by flexion of the extremity. Collagen Nerve Wrap is a resorbable collagen matrix that provides a non-constricting encasement for injured peripheral nerves for protection of the neural environment, designed to be an interface between the nerve and the surrounding tissue. When hydrated, Collagen Nerve Wrap is easy to handle, soft, pliable, nonfriable and porous, and can be spread open for easy placement over the injured nerve to maintain closure without sutures. The product is packaged for single use only, in a variety of sizes.

• **Dynatronics** (Salt Lake City) said it has begun shipping its Dynatron X3 light therapy unit. The X3 features advanced light therapy technology, commonly used for treating muscle and joint pain as well as arthritis pain and stiffness. The company said the stand-alone unit is capable of delivering three independent treatments and uses an interactive touch screen display that helps make treatment setups fast and easy. The device has the ability to drive two Dynatron Light Pads and a light probe simultaneously, making it the company's most powerful light therapy device available on the market. The company also plans to introduce the DX2 combination traction/light therapy device – the first combination device of its kind – during the present quarter.

• **Medistem Laboratories** (Scottsdale, Arizona) has filed a patent application with the U.S. Patent and Trademark Office for a potential stem cell therapy for erectile dysfunction (ED). Medistem's potential stem cell therapy targets the market for ED drugs and other treatments, a market estimated at some $3 billion a year. The company's invention contemplates the use of stem cells to restore erectile function through the treatment of various physical factors, including the regeneration of smooth muscle cells inside the penis, neural regeneration and restoration of endothelial cells lining the inside of blood vessels, and the formation of new blood vessels, among other functions.

• **MicroIslet** (San Diego), which is engaged in the development of technologies in transplantation therapy for people with insulin-dependent diabetes, said that primate subjects in ongoing studies have continued to exhibit improved glycemic control over a six-month period by means of the company's microencapsulated porcine islet transplantation treatment approach. MicroIslet said the breakthrough was achieved without the need for chronic immunosuppressive therapy to prevent rejection of the transplanted insulin-producing islets. "We believe that with these positive data, we are setting the cornerstone for a new and vastly improved treatment for diabetes," said James Gavin III, MD, PhD, president and CEO. "We have achieved long-term survival of transplanted insulin-producing islets in our primate subjects [and] these islets have substantially reduced the need for injected insulin to control blood glucose levels and prevent the progressive damage to the heart, kidneys and other vital organs that make diabetes so devastating," he said. The company plans to submit abstracts documenting its findings to major transplantation symposia this fall and at the American Society of Cell Biology annual meeting in San Diego Dec. 9-13.

• **Varian** (Palo Alto, California) has introduced two new high-throughput vacuum pumps, the Turbo-V 81-M and Turbo-V 81-T. The Turbo-V 81 series pumps can increase instrument sensitivity in application areas that demand high vacuum integrity such as mass spectrometry, electron microscopy and high-energy physics. The Turbo-V 81-T represents a cost-effective solution that in a more compact design offers what Varian termed "significantly higher performance" than most turbo pumps of the same class. The higher foreline tolerance of the Turbo-V 81-M allows the use of smaller primary pumps, reducing overall system costs.

PEOPLE IN PLACES

• J. Richard Iler has been named CFO of **bioMetrx** (Jericho, New York) and has been appointed to the company's board of directors, succeeding Frank Giannuzzi, who resigned to pursue other interests. Previously Iler was CFO and a member of the board of SiriComm. In addition, bioMetrx reported that it has begun a search for two independent directors who have the financial and accounting qualifications to serve on the company's audit committee. bioMetrx, through its subsidiaries, develops biometrics-based products to the consumer, health information, medical devices and small business markets under the brand name smartTouch.

• C. Evan Ballantyne has been named senior vice president and CFO of **Clinical Data** (Newton, Massachusetts). Ballantyne replaces Israel Stein, MD, who recently served as interim CFO. Ballantyne was most recently senior vice president and CFO of ZymeQuest, and before that CFO of Knowledge Impact. Clinical Data is a provider of molecular and pharmacogenomics services as well as genetic tests.