

TriPath unveils research-use breast, cervical cancer tests

By **KAREN YOUNG**
Medical Device Daily Staff Writer

On the same day that **TriPath Imaging** (Burlington, North Carolina), maker of the SurePath liquid-based Pap test, joined in the Nasdaq market opening in New York last Friday, the company reported that it was releasing two new molecular diagnostic products for cancers of the breast and cervix to leading experts who will evaluate analytical performance and initial clinical feasibility.

"We believe that the release of these innovative new products to leading experts is a major catalytic event for TriPath Imaging," said President and Chief Executive Officer Paul Sohmer, MD. "The release of these products . . . reflects a significant milestone in our commitment to develop and commercialize solutions to redefine the early detection and clinical management of cancers of the cervix and breast."

The company's appearance at the Nasdaq opening was to celebrate achieving profitability for the first time in its history, which it reported earlier last week, and the seven years since it began listing on the market on Sept. 5, 1997. TriPath reported last Wednesday preliminary second-quarter sales of \$17 million, which it noted were "driven by increases in reagent sales."

The diagnostic products the company reported on Friday have been released for research use only.

For cervical cancer research, the test initially will be made available to several leading academic institutions and teaching hospitals, including **Johns Hopkins University School of Medicine** (Baltimore, Maryland), **Massachusetts General Hospital** (Boston, Massachusetts) and the **University of Colorado Health Sciences Center** (Denver, Colorado).

For breast cancer staging research, TriPath Imaging is finalizing arrangements to make the test available to one or more top researchers in the field, the company said, and added that additional or alternate researchers will be selected based on expertise and availability.

Johnny Powers, senior vice president and general manager of **TriPath Oncology**, the division of TriPath Imaging that is responsible for the assay development,

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BTE's PrimusRS system targets rehab of high-function athletes

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The Baltimore Ravens are the latest professional sports team to train with the PrimusRS system from **BTE Technologies** (Baltimore Therapeutic Equipment; Hanover, Maryland), having recently entered into a rental agreement with BTE for the new, high-performance rehabilitation system.

Since the first unit was shipped in December 2003, professional sports teams, athletic trainers and physical therapists have been using the system to aid in the rehabilitation and training of athletes and patients, BTE reports.

"After two years in the making, PrimusRS expands BTE Technologies' capabilities and takes its product offering to new levels based on its ability to treat and rehabilitate areas of the entire body," said Ken Johnson, director of clinical integration for BTE. The PrimusRS received FDA approval in 2003. It is the third generation in the Primus

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Report from Europe

NHS anti-fraud efforts pay off to tune of £478M in savings

A Medical Device Daily Staff Report

A report issued last month by the UK National Health Service's (NHS) Counter Fraud and Security Management Service (CFSMS) said the NHS has benefited from an additional £478 million for patient care since 1998 thanks to work to deter, prevent and investigate fraud against the NHS.

The NHS said those savings could pay for 60,000 kidney transplant operations or 100,000 hip replacements.

Other findings of the report noted that:

- There have been 216 successful prosecutions and 275 successful civil legal and disciplinary cases.
- The CFSMS has a 97% successful prosecution rate.
- Overall losses from patient fraud have been cut nearly in half.
- In some areas, claims by NHS professionals have fallen by 31% to 46% after processes were fraud-proofed
- The £478 million represents a 13 to 1 return on the

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BTE

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product line, which has evolved through a combination of physical evaluation and therapeutic technology.

"We're advancing at this point as fast as the technology industry will allow us," Johnson told *Medical Device Daily*.

The system, entirely computer-controlled, displays and stores patient input and output during a physical evaluation or exercise session and then uses this information to chart progress over time. It provides four resistance modes and the ability to measure velocities up to 4,500 degrees per second – a feature BTE says is unique to PrimusRS – to assist trainers and therapists dealing with patients who demand highly functional outcomes, particularly athletes. The sophisticated cable system lets therapists simulate 3-D open- and closed-chain activities, such as throwing, kicking and lifting.

With a total footprint of less than 15 square feet, the system features software, called Primal Pictures 3D Interactive Functional Anatomy, that animates specific muscle groups and joint actions, allowing trainers or therapists to show stripped-away muscle layers to help educate the patient.

PrimusRS charts and reports include peak force, rapid exchange, torque vs. speed, dynamic endurance, interactive neuromuscular re-education, real-time work and printed progress reports.

"It's a very detailed, outcomes-oriented approach," Chuck Wetherington, president of BTE Technologies' products group, told *MDD*.

A new feature of the PrimusRS that Wetherington said has attracted the attention of the professional sports world is a mode that provides unequal concentric and eccentric torques isotonicly. The system also is attracting the interest of non-athletes, such as patients in the early recovery stages of a stroke or following knee surgery. The unit is able to support a variety of therapies, including orthopedics, industrial rehabilitation, hand therapy, functional tasks and sports medicine.

"The foundation of our equipment is that it's very real world, very functional," Wetherington said.

In terms of benefit to the patient, Johnson said PrimusRS is "able to use forces that are approximately a third or less than what would typically be encountered isokinetically."

That benefit translates into a safer product, he said, noting "our risk of injuring or causing residual pain or soreness after testing is greatly mitigated." And from an exercise standpoint, the patient benefit of using less force is reduced muscle fatigue, thus enabling longer exercise duration, he said.

"The longer that we do something, or the more repetitions that we have, improves our body's ability to control the muscles from a neurological standpoint," explained Johnson, who also is a physical therapist. "We're able to recruit and train muscles more effectively, with better long-term performance."

Other rehabilitation systems take either an isotonic approach – using fixed width and variable speed, but requiring the user to manually record and track performance – or an isokinetic approach – a form of single joint isolation with fixed

speed, which Johnson said is good for research but "has very little to do with function and little to do with the real world."

"What we do differently from everything else is [to] take a quantitative and qualitative measure. We [use] work as the measure of quantity and power as the measure of quality," Johnson said. "That leads us to much more successful outcomes because we eliminate the variables of guesswork."

When applied to a treatment program, those measurements allow a trainer or therapist to "make very calculated decisions on when to progress somebody," he said.

PrimusRS is being marketed to physical therapy and occupational health clinics worldwide. BTE is hoping to drive sales of the PrimusRS through placements with high-profile customers such as the Baltimore Ravens and the Baltimore Orioles.

"We are trying to show the breadth of the application and breadth of capabilities of the machine by going directly to these 99.9 percentile kind of performance athletes in professional sports," Wetherington said. "By showing [that] we can work in professional football and professional baseball, we can clearly provide for the needs of a weekend warrior, or the traditional post-operative rehab areas that everyone knows we do well. It's really a matter of stretching our wings a bit by showing we can go to those extremes, helping, we believe, to show we're the right application for every physical therapist and athletic trainer."

The system also is being used by **Athlete's Performance** (Tempe, Arizona), which Johnson described as "the best of the best in terms of performance centers in the country." The training center is working with BTE on product R&D and data collection from high-performance athletes.

The system can be purchased or rented, extending options for customers. PrimusRS sells for about \$50,000, Wetherington said, which includes training at BTE facilities in Hanover or Greenwood Village, Colorado. Rental is about \$1,400 a month. A positioning chair that attaches to the work head and a package of attachments specifically for sports therapy are also available.

BTE has 60 employees in three offices in the U.S. and Canada. Its products fall into two groups: testing, training and rehabilitation systems like the PrimusRS; and products predominantly focusing on industrial rehabilitation, evaluation and testing. The company's Multi-Cervical Unit, used for evaluating and treating conditions of the cervical spine – and the only system that can test and strengthen in all planes of movement in the neck and head, the company says – is currently being used in an international study gathering data on a protocol for the testing, evaluation and treatment of cervical injury.

BTE earlier this year completed a merger with **Hanoun Medical** (Toronto, Ontario), a international med-tech and employer services company specializing in the evaluation and assessment of physical performance (*MDD*, Jan. 12, 2004).

It has filed four patent applications in the past eight months. With a focus on building its technology base, investing in R&D for future products and via collaborations with academic institutions, BTE, Wetherington said, is working to take its products and services "to the next level." ■