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Changes in market push GE to buy Abbott's lab diagnostics

By AMANDA PEDERSEN

Medical Device Daily Staff Writer

General Electric's (Little Chalfont, UK) \$8.13 billion acquisition of **Abbott's** (Abbott Park, Illinois) core laboratory diagnostics business — a deal of mega-proportions that the companies disclosed late last week (*Medical Device Daily*, Jan. 19, 2007) — may have taken some industry-followers by surprise.

Deals roundup, p. 4

After all, Abbott is known as a leader in this \$24 billion market that grows 6% to 8% a year, and its *in vitro* diagnostics business, including point-of-care, is expected to generate net sales of about \$2.7 billion in 2006, according to Joe Hogan, president/CEO of GE Healthcare.

Thus, during an evening teleconference last Thursday, See *GE/Abbott*, Page 5

Hawaiian Eye Meeting

NeoVista's radiation device is AMD treatment option hope

By LARRY HAIMOVITCH

Medical Device Daily Contributing Writer

POIPU BEACH, Hawaii — The Hawaiian Eye Meeting, which takes place here on one of the Islands each year in mid-January, has become a highly-regarded event for ophthalmologists and industry. This year attendance was once again at record levels, with more than 1,400 ophthalmologists registering.

The meeting generally attracts specialists from two critical areas of ophthalmology today — the cataract and refractive surgery specialist, by far the largest category of ophthalmic doctors and retinal specialists, whose prominence has surged in recent years.

The reason for the upswing in prominence for retinal physicians relates to the introduction of several new medications for the treatment of age-related macular degeneration. See *NeoVista*, Page 6

International report

Bayer Schering in Japanese agreement on imaging agents

A *Medical Device Daily Staff Report*

Bayer Schering Pharma (Berlin) has signed a license and option agreement with **Taisho Pharmaceutical**, **Nihon Nohyaku** and the **National Institute of Radiological Sciences** (NIRS) in Japan to develop novel imaging compounds for the detection of neurodegenerative diseases such as Alzheimer's disease, Parkinson's disease and other disorders associated with neuroinflammation, such as multiple sclerosis.

"We are convinced that innovations in molecular imaging have the potential to fundamentally improve the diagnosis of neurodegenerative disorders, particularly Alzheimer's disease," said Hans Maier, MD, head of the Diagnostic Imaging business unit at Bayer Schering Pharma. "[We are] already pursuing the development of tracers [targeting amyloid plaques, a hallmark of this disease. Imaging of neuroinflammation as another important pathology will complement these activities."

See *International*, Page 7

Rex says vena cava filter is best retrievable Option for patients

By HOLLAND JOHNSON

Medical Device Daily Managing Editor

While other companies have developed what has become a kind of *de rigueur* retrievable vena cava filter for pulmonary embolism (PE), one company believes that it has a device that can be successfully removed for a much longer time than anything else on the market. Additionally, it claims that its product design is better than anything that the big boys in the space have come up with.

Rex Medical (Conshohocken, Pennsylvania) is the company making these claims, and it reported last week that in an international clinical study it has been able to successfully retrieve its Option vena cava filter thus far at up to 107 days.

The company reported that 29 patients enrolled to date in that international study have been successfully implanted with the Option filter for the prevention of PE resulting from blood clots or deep vein thrombosis (DVT), under the direction of Adrian Ebner, MD, chief of interventional procedures and cardiovascular surgery, **French**. See *Rex*, Page 8

INSIDE: INVERNESS TO RAISE UP TO \$228M; CLAROS CLOSING \$7.8M 'A' ROUND2
FDA: BONE GROWTH STIMULATOR RECLASSIFICATION INPUT SOUGHT3

 **AHC Media LLC**

*Financings roundup***Inverness to raise up to \$228M;
Claros closes \$7.8M 'A' round****A Medical Device Daily Staff Report**

Inverness Medical Innovations (IMI; Waltham, Massachusetts) reported that it is offering to sell up to 5 million shares of its common stock in accordance with a shelf registration statement in an underwritten public offering.

The company said it also expects to grant the underwriters a 30-day option to purchase up to an additional 750,000 shares of common stock to cover any over-allotments. All of the shares in the offering are to be sold by IMI.

If all the shares are exercised, including the over-allotments, the company could raise up to \$228.62 million, before expenses.

The company said it intends to use a portion of the proceeds from the offering to repay outstanding indebtedness and for working capital and other general corporate purposes, including the financing of potential acquisitions or other investments, and for capital expenditures.

Inverness has already made its first acquisition this year. Earlier this month, the company bought Canadian distributor **Med-Ox Chemicals** (Ottawa, Ontario) for \$5.4 million (*Medical Device Daily*, Jan. 17, 2007).

Jefferies & Co. and UBS Investment Bank are acting as joint book-running managers for the offering. Cowen and Co. and Leerink Swann & Co. are acting as co-managers for the offering.

In other financings:

Claros Diagnostics (Woburn, Massachusetts) reported the closing of a \$7.8 million Series A financing to develop a handheld diagnostic testing system for point-of-care use. The round was led by Oxford Bioscience Partners with additional investments coming from Bioventures Investors, Accelerated Technologies Partners, and Commons Capital.

Claros says it has developed a handheld immunoassay system incorporating a lab-on-a-chip configuration which produces high performance quantitative laboratory blood test results with the ease-of-use of rapid qualitative diag-

nostic test strips.

The company said the device will enable the physician to quantitatively analyze a blood sample in the office, allowing completion of the examination within the time-frame of the visit.

The company will initially focus on developing its diagnostic system for urological cancer, incorporating an established panel of biomarkers, anchored by prostate-specific antigen (PSA). The data from diagnostic tests that quantitatively detect PSA and PSA velocity drive the decision by urologists to perform about 1 million prostate biopsies annually on patients.

"This simple, rapid and elegant technology offers the potential to transform the diagnostics landscape by transitioning critical tests from the centralized lab directly into the hands of the physician," said Michael Magliochetti, PhD, president/CEO of Claros. "Our initial focus is the development of a point-of-care assay for established prostate cancer diagnostics, which we believe will provide significant incentives for both physician and patient. The applications of our technology platform extend well beyond cancer diagnostics, encompassing infectious disease, women's health, and critical care, as well as the potential for companion diagnostics to existing therapeutics."

In other financing news:

• **Tyco International** (Pembroke, Bermuda) reported that it filed documents with the **Securities and Exchange Commission** to register equity securities for its **Tyco Electronics** and **Tyco Healthcare** subsidiaries, and debt offerings in connection with its upcoming separation into three independent, publicly traded companies.

Tyco reported in January of 2006 its intent to divide the company's portfolio of diverse businesses that generated \$41 billion in net revenue in FY06, into three independent companies through tax-free stock dividends to Tyco shareholders — after which they will own 100% of the equity in three public companies (*MDD*, Jan. 17, 2006).

Subject to review by the SEC and subsequent registra-

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*Around the Beltway***FDA: bone growth stimulator reclassification input sought****A Medical Device Daily Staff Report**

Last year's orthopedic device advisory panel review of a petition to reclassify non-invasive bone-growth stimulators as class II devices ended up with a nay vote by the panel (*Medical Device Daily*, June 6, 2006), and the agency is now seeking public comment on the matter.

The window for comment expires April 17, but according to the notice, "FDA is no longer accepting comments submitted to the agency by e-mail." In an effort to expedite the process, the FDA wants the public to submit its comments via "the Federal eRulemaking Portal or the agency web site."

The petitioner, **RS Medical** (RSM; Vancouver, Washington), wanted to make this class of devices available to manufacturers as a 510 (k) device, and the morning session of the panel last year seemed to bode well for RSM. But the panel's reservations about the reproducibility of electromagnetic waveforms sank the application despite assurances by an FDA engineer that such emissions are not at all impossible to replicate.

Opponents of the reclassification included manufacturers of the devices, such as **Healthonics** (Bethesda, Maryland) and **DJO** (Vista, California), and they made the waveform argument based on the fact that the petition included two types of waveform generators, capacitive coupling and pulsed electromagnetic fields. These generators are each used solo as well as in tandem.

Abigail suit vs. FDA returns to circuit court

The FDA caught no small amount of grief over the Vioxx episode, with critics charging that it is too close to industry and too ready to put bad drugs and devices on the market. Flip the coin and on the other side find a number of criticisms, many from industry, that the reverse is the case — that FDA is far too slow to approve products.

Not all in that latter group are members of industry.

The **Abigail Alliance for Better Access to Development Drugs** (Arlington, Virginia) is forging ahead with its lawsuit against FDA to push the agency to allow access to unapproved drugs for patients who face deadly diseases. Last year, the Court of Appeals for the District of Columbia rejected the DC's circuit court's 2004 dismissal of the suit in a 2-1 decision and reinstated the case.

A document posted at the web site for the **AEI-Brookings Joint Center** (Washington), a policy think tank, lays out the rationale for the suit in a friends-of-the-court brief, penned by a group of economists that includes John Calfee, a resident scholar at the **American Enterprise Institute** (AEI; Washington). In that document, they lay out a three-pronged argument in favor of allowing drugs that are still in development to be used on patients.

The first argument is "FDA staff incentives are skewed

toward excessive caution." The team asserted that a type I error — one in which a drug or device is deemed safe when it is not — would result in the agency being buried under a barrage of criticism and that aversion to such criticism is the motive for slowing things down. No other possible motive was acknowledged.

The opposite error, the type II error, involves keeping an item off the market because of safety concerns that are not valid.

The authors aver that "the public health consequences of a failure to approve a beneficial drug may be even more severe than the approval of an insufficiently safe drug."

The underlying logic is that the type I error is "often quickly corrected precisely because insufficiently safe drugs cause public problems," but that a type II error "may go uncorrected for years," the net effect of which "is to bias even the best-intentioned FDA regulators towards excessive caution and delay in approving new drugs."

They also argue that the U.S., "Spain and the U.K. have yielded essentially identical drug withdrawal rates despite the more rapid drug approval timelines in the European countries."

The authors also point out that public aversion to risk and the **Institute of Medicine** (Washington) have played a role in this drama. The brief says the controversies over Vioxx and selective serotonin reuptake inhibitors have tilted the public debate toward criticism of the agency and that such criticism "exceeds any criticism of agency sluggishness in approving the hundreds of drugs in development in recent years."

The second argument essentially rebuts the agency's assertion earlier in this action — which the Abigail Alliance initially filed in 2003 — that increased access will blunt interest in participation in clinical trials. As a riposte, the authors state that "a long series of post-approval trials of the statin class of cholesterol-reducing drugs — currently among the most prescribed classes of drugs worldwide — has greatly expanded scientific knowledge of the role of serum cholesterol in heart attacks and strokes."

"In the universe of oncology treatment, post-approval trials are becoming standard practice," the paper states, with the examples of Erbitux, Herceptin and others offered as evidence that "[t]he sheer number of patients involved in post-approval trials is evidence of the widespread willingness of patients to enroll in randomized trials of drugs that are readily available outside of clinical trials."

In the last of the three arguments, the economists insist that a successful suit will not reduce the incentive for drug and device makers to roll out Phase III trials. The paper states that large trials are often needed to buttress off-label use, and that in any case, those trials are needed to persuade specialty societies of the value of the drug or device.

In their conclusion, the authors state that Phase I trial data "often reveal drugs that are of great potential value to patients who lack any alternative treatments," and claimed that the FDA clinical trial paradigm results in "long and unjustified Phase II delays in authorizing Phase I-approved and potentially life-saving drugs." ■

Deals roundup

Kyphon closes buy of St. Francis for \$525 million in upfront cash

A Medical Device Daily Staff Report

Kyphon (Sunnyvale, California) last week reported closing the acquisition of **St. Francis Medical Technologies** (Alameda, California), a privately held company that manufactures the X-Stop Interspinous Process Decompression System, the first FDA-approved interspinous process device for treating lumbar spinal stenosis.

Kyphon in December reported its plans to acquire St. Francis Medical in a transaction valued at \$525 million in upfront cash, plus additional revenue-based contingent payments of up to \$200 million, payable in either cash or a cash/stock combination (*Medical Device Daily*, Dec. 5, 2006).

Kyphon says that the transaction broadens its focus on minimally invasive spine by adding the X-stop technology to its existing KyphX balloon kyphoplasty technologies for repairing vertebral compression fractures and its recently launched Functional Anaesthetic Discography procedure for diagnosing the source of low back pain, the company said.

"The acquisition of St. Francis is a key element in executing our strategy and advancing our mission to become the recognized global leader in restoring spinal function through minimally invasive therapies," said Richard Mott, Kyphon's president/CEO. "We believe this is an excellent strategic fit for Kyphon and further expands our innovative treatments for the aging spine to include less invasive treatment of lumbar spinal stenosis."

Kyphon financed the transaction through a combination of cash on hand and bank financing, including a \$425 million syndicated term loan and \$200 - \$300 million credit facility, arranged and led by Bank of America N.A.

Kyphon develops systems designed to restore and preserve spinal function and diagnose low back pain using minimally invasive technologies. The company's products are used in balloon kyphoplasty for the treatment of spinal fractures caused by osteoporosis or cancer, in the Functional Anaesthetic Discography procedure for diagnosing the source of low back pain, and in the Interspinous Process Decompression procedure for treating lumbar spinal stenosis.

In other dealmaking news:

- **Quest Diagnostics** (Lyndhurst, New Jersey) reported signing a worldwide license agreement with **U.S. Genomics** (Woburn, Massachusetts). The companies called the licensing deal a move that will advance physicians' ability to widely screen for Fragile X Syndrome (FXS), the most common form of inherited mental retardation.

The agreement gives Quest the rights to develop an advanced screening method for FXS based on Quest Diagnostics' and U.S. Genomics' jointly developed genetic testing technology. No financial terms of the agreement were

disclosed.

Using U.S. Genomics' applications, Quest said it plans to develop an automated testing process, resulting in a simpler, more efficient test that allows physicians to have access, for the first time, to widespread population-based carrier testing.

Quest said it would develop the new test to address and resolve the limitations of current FXS screening. Such tests currently involve a complex combination of techniques, which makes testing cumbersome and impractical for prenatal and pregnancy screening programs. The new test also should help physicians, including pediatricians, neurologists and obstetrician-gynecologists, more efficiently screen patients with mental, neurological or endocrine symptoms that may be caused by a Fragile X gene mutation, Quest said.

Quest develops diagnostic tests and advanced health-care information technology solutions designed to improve patient care.

- **RehabCare Group** (St. Louis) and **Methodist Medical Center** (Peoria, Illinois) reported their intention to form a joint venture that would develop, own and operate a new 50-bed long-term acute care hospital (LTACH) near downtown Peoria. The proposed partners are applying for a Certificate of Need (CON) through the State of Illinois and hope to begin construction of the new hospital following CON approval, as well as necessary licensure through the Illinois Department of Health. Financial terms were not disclosed.

The 56,000 square-foot LTACH, to be called **The Greater Peoria Specialty Hospital**, will be located in the three-block area bordered by Richard Pryor Place, Romeo B. Garrett Avenue and Hightower Street in Peoria. An early 2009 opening is projected. Once fully operational, the LTACH would provide jobs for an estimated 150 full-time employees, the partners said.

LTACHs provide specialized, around-the-clock care for extended-stay patients with chronic or medically complex conditions, such as ventilator dependency, brain injury, cardiopulmonary disease, chronic pain and neuropathy. Patients are typically admitted to an LTACH following treatment in a traditional acute care hospital, and the average length of stay is 30 days.

- **OSF Saint Francis Medical Center** said it views the LTACH as an important addition to the Peoria medical community and has provided a letter of support to accompany the CON application.

Established in 1982, RehabCare is a provider of rehabilitation program management, servicing over 24,000 patient visits each day in conjunction with more than 1,400 hospitals and skilled nursing facilities in 42 states, the District of Columbia and Puerto Rico.

Methodist Medical Center of Illinois is a 353-bed care provider serving the more than 300,000 residents of the Greater Peoria area. ■

GE/Abbott

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Miles White, Abbott's CEO and chairman, explained the company's thought process behind the sale by offering an evaluation of how this market has evolved in recent years.

In the 1980s and 1990s the core laboratories and diagnostics market was one where the most advanced assays were run on low-cost bench-top instrumentation, White said.

But over the past decade Abbott has seen fundamental changes in the nature of this market, White said, and those changes are what led to Abbott's decision to sell its core laboratory diagnostics business to GE.

"Today, it's a market driven by automated, capital-intensive, mainframe systems that are integrated with institutional IT systems," White said. "These capital-intensive technologies require a financing, sales and service infrastructure more suitable for large capital equipment manufacturers such as GE."

In making its decision to sell the business, Abbott also considered its five strategic objectives — strategic fit, ability to generate high growth, capability for innovation and differentiation, ability for high profit and high returns, and potential to generate strong cash flow — White said.

"And so when we considered the evolving dynamics of the core laboratory diagnostics market against the backdrop of our strategic goals it was clear to us that a large capital equipment manufacturer would be a better fit to take this business to the next level," White said.

Still, White said Abbott did not take the decision to sell its core diagnostics business lightly.

"It was a decision that we carefully considered, given our long-standing legacy and commitment to this market. We would only consider this divestiture if it was the right situation for this business and we found that ideal situation with GE, one of the world's largest and most respected companies with a leading imaging and healthcare systems [business] that made for a compelling strategic fit," White said.

In a separate teleconference Friday, GE also said it sees the acquisition as a good fit for its company.

"This is an amazing amount of technology," Hogan said, "and that's why it fits so much better in a GE portfolio because we have that capability. We have 4,000 software engineers . . . as this business evolved within the Abbott portfolio it wasn't in their core competency because they had more biochemistry and organic sciences capability."

Hogan said GE actually had been eyeing the possibility of acquiring Abbott's core diagnostics offerings for about five years.

"Overall this is the world's premiere *in vitro* diagnostics business," Hogan said. "Our capabilities — combined with Abbott's *in vitro* diagnostics and point-of-care diagnostic businesses — will allow GE to provide customers with better tools for the full care continuum, enhancing their decision-making capabilities in key disease areas

such as oncology and cardiology, and enabling early disease detection, diagnosis and treatment."

Financially speaking, White said the \$8.13 billion purchase price gives Abbott about \$6 billion of after-tax cash, and the company will most likely use the bulk of that to pay down debt.

For Abbott, the deal is expected to be neutral to earnings-per-share in 2007 before specified items and accretive thereafter.

In case investors are wondering, White said, the company does not have any properties or businesses on its radar screen for any other upcoming acquisitions. But, he added, "We're always evaluating the landscape and continuing to look for the best ways to build a high growth, high margin business."

"The most important thing to understand is we are and will remain a diverse broad-based company. That has not changed and it won't," White said. "What has changed over the last seven to eight years is the strength of Abbott's diversification, specifically the mix of our cash flows and the diversification of our long-term earnings growth drivers."

"[This transaction] is one of several transforming changes that we've made to strengthen our diverse framework in a way that aligns Abbott for higher growth, higher margins and higher returns, in businesses that are driven by continual medical innovations." ■

Financings

Continued from Page 2

tion statement effectiveness, the separation is expected to occur early in the second calendar quarter of 2007.

Tyco Healthcare manufactures medical devices and supplies, diagnostic imaging agents, pharmaceuticals and other healthcare products for use in clinical and home settings. Its portfolio of products is sold under brand names including **United States Surgical, AutoSuture, Valleylab, Mallinckrodt, Nellcor, Puritan Bennett** and **Kendall**.

Tyco Healthcare said it expects to announce a name change, and the NYSE and BSX ticker symbol for which it will apply, later this month.

• **Trimedyne** (Lake Forest, California), a maker of Holmium lasers and fiber optic laser devices for minimally invasive surgical procedures, reported that its amended registration statement, covering slightly less than 2.92 million shares of common stock sold in a previously disclosed private placement, became effective last Wednesday. The amendment reflects the issuance of an additional 265,000 shares to the investors.

The company said the proceeds of the private placement of about \$3 million will be used to finance the increased sales of its new side-firing laser fiber by **Boston Scientific** (Natick, Massachusetts) in the U.S. and Japan, and by **Lumenis** (Yokneam, Israel) throughout the world, expected to begin late in 2Q07.

The amended restatement also covers 212,000 shares issuable under warrants issued to two investment bankers. ■

NeoVista

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tion (AMD), which has dramatically improved the outcomes for elderly patients suffering from this disease. As its name implies, AMD is associated with aging, afflicting 18% of those between 70 and 74 years old, surging to 47% among people 85 years and older. It is a chronic, progressive disease of the macula, the central part of the retina, causing irreversible loss of central vision and the No. 1 cause of severe vision loss and blindness among those over age 50 in the developed world.

Prior to 2000, there were essentially no effective treatment options for halting or reversing the course of AMD, which causes a horrid decline in an elderly person's quality of life. However, since that time, three new pharmaceutical agents have reached the U.S. market, producing vast improvement in patient outcomes.

In particular, Lucentis, a potent anti-VEGF agent introduced by **Genentech** (South San Francisco) in mid-2006, has had an enormous impact on the treatment of AMD. Its clinical trials have not only demonstrated that Lucentis can stop the progression of the disease but that in a significant number of patients it has been shown to actually reverse its progression and substantially improve visual acuity.

With 200,000 new cases of late stage (wet) AMD diagnosed annually in the US alone, the market opportunity for newer, possibly better or less costly approaches to remain fertile. In a session titled "Treatment of Neovascular AMD: Other Options" at the "Retina 2007" section of this meeting, a highly promising and relatively new technology was discussed by Andrew Schachat, MD, who is the vice chairman of Clinical Affairs, Vitreoretinal Department at the **Cole Eye Institute, Cleveland Clinic Foundation** (Cleveland, Ohio). The technology, developed by privately-owned, venture capital-backed **NeoVista** (Fremont, California) features the use of an ionizing radiation source that delivers strontium-90 directly to the macula.

The current device has two components, a reusable strontium-90 applicator and a multi-channel tester. Strontium-90 is attached to the distal end of a guidewire built within the device and a lever extends the wire to the cannula tip and then retracts within a housing post-therapy. The company intends to introduce the product with a disposable tip at the time of commercial launch to ensure a completely sterile procedure and reduce the amount of reprocessing time within the operating room. The multi-channel tester is used for source verification prior to each treatment. The goal of this therapeutic device, trade-named the EPI-Rad Ophthalmic System, is to permanently disable the proliferating new cells — the culprits in causing central vision loss — by damaging their DNA structure.

The procedure itself is minimally invasive, since performed under local anesthesia during a partial vitrectomy, a common surgical procedure performed by retinal specialists, and taking only about 30-45 minutes in total treatment time. The radiation

is delivered at a controlled penetration depth of about 3 mm, with the EPI-Rad focal therapy irradiating the treatment area.

Schachat presented the data from three relatively small feasibility trials that have been completed so far. Two trials were conducted using just strontium-90 at two different dosage levels while the third trial incorporated the use of an anti-VEGF agent Avastin as part of the protocol. The first trial showed solid results, comparable to the results of the gold standard Lucentis in its early months, but then the benefits trailed off. The second trial, using a higher strontium-90 dose, showed better durability and even more promise. Most intriguing, however, were the results of the third pilot trial, which incorporated two Avastin injections along with the irradiation process, one at the time of radiation treatment, the other at day 30 post-op.

In this study, which followed 20 patients for three months, there was dramatic improvement in visual acuity, with a mean gain of nearly 15 letters read on a visual acuity chart. This compares extremely favorably to the approximately six letters gained at three months reported from Genentech's pivotal MARINA trial, which supported its New Drug Application FDA approval.

There appear to be several potential advantages of the NeoVista approach. A key advantage, assuming its benefits are durable, is that it will be far more convenient for most patients, who are now required to continue a monthly regimen of Lucentis injections for many months or even years.

Even more importantly it could slash the overall cost of treating AMD. Each monthly Lucentis injection costs the health-care system about \$2,200 (drug cost plus the physician injection fee), including a monthly patient out-of-pocket, co-pay cost of \$400 — an annual cost of about \$26,000 per patient, with the out-of-pocket annual cost approaching \$5,000.

Meanwhile, the Medicare reimbursement system faces a potentially enormous financial burden, with thousands of patients being treated at \$2,200 per month. For this reason, many ophthalmologists are using Genentech's Avastin, a "sister" drug to Lucentis for treating AMD.

Avastin, a larger molecule variety of Lucentis — FDA-approved for various cancers — has shown anecdotal efficacy and safety for treating AMD off-label. Its huge off-label use, which was confirmed by a straw poll of retinal specialists at this meeting, is being driven solely by its cost, about \$50 per dose when used to treat AMD. By comparison, a Lucentis injection costs \$1,950.

Indeed, off-label use has become so rampant that the **National Eye Institute** (Bethesda, Maryland) has decided to fund a large trial that will compare the safety and efficacy of the two Genentech agents. This two-year trial, called Complications of Age-Related Macular Degeneration Treatment Trials (CATT), is slated to begin in April 2007.

NeoVista is planning to commence its pivotal clinical trial in the U.S., beginning in the second quarter of 2007, with the goal of completing the trial in about one year.

See NeoVista, Page 8

International

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He said the Japanese agreement “underscores our commitment to Alzheimer’s patients by developing [new] diagnostic methods for the early detection of the disease.”

Taisho Pharmaceutical, Nihon Nohyaku and the NIRS, a government-owned research institution, jointly own patent rights for a compound class that may be applied for various non-invasive imaging technologies, such as positron emission tomography (PET) scanning.

Under the terms of the agreement Bayer Schering Pharma receives worldwide exclusive rights to develop and market the respective products for use with PET scanning technology.

Bayer Schering said epidemiological surveys estimate that 24.3 million people suffer from dementia today worldwide, with about 4.6 million new cases occurring every year. Such studies indicate the number affected will double every 20 years to an estimated 81.1 million by 2040. Of these cases, 50% to 75% are associated with Alzheimer’s disease.

In other Bayer Schering Pharma news, Bayer Schering Pharma Aktiengesellschaft — formerly Schering Aktiengesellschaft — has filed a solicitation/recommendation statement with the U.S. Securities and Exchange Commission with respect to the offer of cash compensation by Bayer Schering GmbH — formerly Dritte BV GmbH, a wholly owned subsidiary of Bayer Aktiengesellschaft — in connection with the domination and profit and loss transfer agreement between Bayer Schering GmbH and Bayer Schering Pharma Aktiengesellschaft.

Holders of ordinary shares and American depository shares of Bayer Schering Pharma Aktiengesellschaft may obtain the solicitation/recommendation statement and other filed documents free of charge at the Securities and Exchange Commission’s website, www.sec.gov, and at Bayer Schering Pharma Aktiengesellschaft’s website, www.schering.de.

New CIS module for anesthesia

VisualMED Clinical Solutions (Montreal, Quebec) has released a new clinical module to support inpatient and ambulatory anesthesia practice. The module, which has been in development for five months, has been developed in conjunction with staff anesthesiologists at one of the company’s client hospitals.

The company said: “Though the VisualMED Clinical System has been used to document pre-operative, post-operative and intra-operative care since its inception, the system is now at the fingertips of the anesthesiologist. Real-time, by-the bedside data entry is supported, as is automated entry of vital signs and gas exchange parameters.”

Data entry as well as medical record notes are entered exclusively through touch and are automatically integrated into the electronic patient record.

Werner Pfisterer, MD, a staff anesthesiologist at **Mt. Sinai Hospital** (New York), said, “Anesthesia has become

so complex that it is increasingly difficult to fully document every aspect of entire procedures. This clinical module will allow practitioners to document more completely the quality of care provided to patients undergoing surgery.”

VisualMED Chairman Gerard Dab said last month that new modules released in 1Q07 would be “a critical step in our strategy to diversify our product lines.” With respect to the new Anesthesia module, Dab said, “Anesthesia systems have in the past primarily been sold as stand-alone systems. The fact that our module can be fully integrated with any clinical system gives potential customers a low-risk way to learn about our enterprise-wide solution.”

He said the company is “still on track to triple our install base from five to 15 sites by the end of this calendar year, and we expect to generate revenue around the \$1.8 million mark for the current fiscal year.”

VisualMED said its Clinical Information System “is the only solution of its kind to have been wholly designed by practicing medical staff in terms of both workflow and user interface. [It is] the only CIS that can be implemented across a single care unit, hospital or region,” with unique design features allowing system decision support to conform to local practice, yet incorporate best practice guidelines across a region as a turnkey solution, depending on needs of individual clients.”

TheraSphere treatment gets 1st use in India

MDS Nordion (Ottawa, Ontario), a global provider of medical isotopes and radiopharmaceuticals used to diagnose and treat disease, said its TheraSphere cancer treatment has been used in India for the first time, marking the beginning of the product’s broader introduction into that country.

Three patients were the first to be treated for primary liver cancer in India using TheraSphere. Two of the infusions were conducted at the **Lilavati Hospital and Research Center**, while the third took place at the **Jaslok Hospital and Research Center** (both Mumbai, India).

Comprised of tiny radioactive glass beads, TheraSphere is injected by a physician into the main artery of the patient’s liver using a catheter. This allows the treatment to be delivered directly to the tumor, resulting in fewer side effects than traditional cancer therapy.

MDS Nordion said TheraSphere will be used in India to treat both primary and secondary liver cancers.

The company also was one of 89 Ontario-based companies and organizations participating in a trade mission to India last week, organized by government of Ontario.

“The first-time use of TheraSphere in India represents an incredible opportunity for us to expand the use of this innovative treatment to help people in India and increase MDS Nordion’s global market reach,” said company President Steve West. “It also supports our strategy to explore and capitalize on opportunities in the health and life sciences sectors in this growing market.” ■

Rex

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Hospital (Asuncion, Paraguay).

In several patients evaluated for retrieval, the filter was successfully retrieved most recently at times ranging from 84 to 107 days following filter implant by Anthony Venbrux, MD, professor of radiology and surgery, director, cardiovascular & interventional radiology at **George Washington University** (Washington).

PE occurs when thromboemboli become dislodged from the deep veins located in the legs and travel through the blood stream to the lungs. If left untreated, PE has a mortality rate in excess of 30%.

The Option filter is designed to remain either permanently in place or to be removed from the patient if the doctor determines the patient is no longer at substantial risk for PE.

"The big buzz in the industry today is the ability to retrieve these filters," Lindsay Carter, VP of sales and marketing at Rex, told *Medical Device Daily*. "The fact that you're able to take these implants out when the patients is not at risk is a very big deal. If you're not retrievable and you're entering the marketplace, you're not going to go anywhere."

Carter said early on that the company knew that it had to develop something better than a "me-too" product to compete with the larger players in the \$250 million vena cava filter market. These biggies include **Cordis** (Miami Lakes, Florida), **Cook** (Bloomington, Indiana) and **CR Bard** (Murray Hill, New Jersey).

"We have to come out with something on the market that's significantly better," he said.

Aside from what he said are the company's use of the view of thought leaders in the development of these filters — terming them "the filter gurus" — he noted that the Rex instrument has the lowest profile of any device on the market at 6Fr.

Additionally, Carter said that the Option has the largest cable diameter range. "We can cover the widest range of vena cava up to 32 mm. Nobody else can cover up to 32 mm. The largest is 30 mm by Cordis."

He noted too that the device's nitinol construction allows for precise delivery of the device and "zero migration" once the filter is in place.

There is active interest in the Option from some of the big players, Carter said, noting that Rex is in the "final stages with a lot of big companies right now," including Cordis.

What will cause the vena cava market to explode, Carter said, are new opportunities to use the devices in bariatric patients, orthopedic patients — particularly in hip and knee replacements — and trauma patients.

"That's why retrievable filters are going to play a big role in the future," he said.

A prospective, multi-center clinical study (10 sites, under 100 patients), approved under an investigational device exemption (IDE) from the FDA, is planned to begin early in February to collect data to support the filter as a permanent and retrievable device.

Matthew Johnson, MD, associate professor of radiology at **Indiana School of Medicine** and chief, vascular and interventional radiology, **Clarian Health Partners** (both Indianapolis), will be the lead investigator.

The company noted that extensive pre-clinical study data collected and analyzed in support of the clinical studies demonstrated excellent filter performance, including effective self-centering complete clot resorption at 90 days, and no migration or adverse events associated with filter implantation and retrieval up to 90 days. All implanted filters were successfully retrieved.

The IDE trial, Carter said would "take on all comers," including the aforementioned uses in bariatric, orthopedic and trauma patients, and will have two arms: one for permanent filter placement and one for retrieved devices.

"Hopefully, [that study] is concluded by the third or fourth quarter of this year, and we can make it commercially available," he said. He added that Rex is seeking to make marketing claims that the device can be retrieved "up to 100 days."

While the company is a small entity, purely angel-funded, it is developing more than the Option filter and is developing devices for several disease states. These, in addition to the cardiovascular market, it is working on minimally invasive devices, either commercialized or under development, in oncology, venous access and endosurgery.

Venous thromboembolic disease is a leading cause of morbidity and mortality in the U.S., with PE being the most severe complication of the disease. PE is the third leading acute cardiovascular cause of death in the U.S. resulting in as many as 240,000 deaths annually. ■

NeoVista

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The main features of this trial, dubbed the CNV Secondary to AMD Treated with Beta Radiation Epiretinal Therapy (CABERNET) trial, is that it will be conducted at roughly 30 sites worldwide (20 in the U.S.) and will randomize patients to either strontium-90 plus Lucentis or to just Lucentis. A total of 450 patients will enter the trial, 300 on the NeoVista arm and 150 in the Lucentis arm.

Elias Reichel, MD, vice chair for research and education, Department of Ophthalmology at **Tufts New England Medical Center** (Boston) told *Medical Device Daily*: "The NeoVista system is extremely promising and could become a very important and valued addition to our AMD treatment options. I am eager to see the results from the pivotal trial."

Reichel, an experienced AMD specialist, is an advisor to the company, and Tufts is expected to be one of the clinical sites for the CABERNET study.

NeoVista, which was founded in 2002 by The Innovation Factory (Duluth, Georgia), has been funded by a group of venture capital firms since its inception. The company closed on a \$41 million venture capital round in December 2006, which will be used to complete the company's pivotal trial and begin commercialization. ■

PRODUCT BRIEFS

• **Hill-Rom** (Batesville, Indiana) reported the release of a new portfolio of transport and specialty stretchers. All stretchers in the new line are designed with a reinforced frame and other components to support up to 700 pounds, it said, and they are the first of several upcoming additions to its line of products and services designed to improve caregiver efficiency and patient and caregiver safety. Hill-Rom produces medical technologies and related services for the healthcare industry, including patient support systems, non-invasive therapeutic products for a variety of acute and chronic medical conditions, medical equipment rentals, and workflow information technology solutions.

• **Neoprobe** (Dublin, Ohio), a developer of oncology and cardiovascular surgical and diagnostic products, reported receiving FDA authorization to commence patient enrollment in two Phase I clinical studies to evaluate the safety and efficacy of Lymphoseek, a lymphatic tissue targeting agent being developed by the company, in prostate and colon cancers. The two studies are being undertaken at the **University of California, San Diego** and are being funded by grants provided by the **National Cancer Institute**.

• **Nikon Instruments** (Melville, New York) said it is expanding its line of Nexiv Video Measuring System products to include the iNEXIV VMA-2520. The new multi-sensor measuring system is lightweight and compact enough to be used in the factory on the bench top, with fast, fully automatic and high accuracy features that make it suited for a variety of industrial measuring, inspection and quality control applications, Nikon said. The iNEXIV is designed to measure 3D workpieces, is touch probe ready, integrates the latest imaging processing software and incorporates a new 10x optical zoom system and Laser Auto Focus option. Nikon develops advanced optical technology. Its product line includes microscopy equipment, digital imaging, preci-

sion measuring and semiconductor wafer inspection equipment.

• **Ophthonix** (San Diego) has received its 14th patent, including the diagnostic capabilities of the Z-View Aberrometer to profile the high-order aberrations of a patient's eye with an algorithm. The high-order profile is used to manufacture the iZon High Resolution Lens, giving the patient high definition vision. The patent also covers the use of the high-order profile to generate a simulation of the high definition vision quality provided by the iZon Lens, for use by the practitioner in explaining the iZon Lens benefits to the patient. Ophthonix is an ophthalmic company marketing technology that enables patients to see with fully optimized vision.

• **Possis Medical** (Minneapolis) reported that Mercy Hospital in Coon Rapids, Minnesota was the first hospital to use its new AngioJet Ultra Thrombectomy System. The next-generation Ultra System, which was approved by the FDA in December for blood clot removal (thrombectomy), was successfully used by physicians at the Mercy Heart & Vascular Center in multiple thrombectomy procedures over the past two weeks, the company said. Possis develops pioneering medical devices for the cardiovascular and vascular treatment markets.

• **Viasys Respiratory Care** (Conshohocken, Pennsylvania), a subsidiary of **Viasys Healthcare**, received FDA clearance to market its PulmoLife spirometry screener. The PulmoLife screener is a device designed for assessment of lung disease associated with chronic obstructive pulmonary disease (COPD). The PulmoLife device uses spirometry to measure lung function. According to the National Institutes of Health, "Spirometry is the most sensitive and commonly used test of lung functions. It can detect COPD long before you have significant symptoms." Early detection of decreased lung function by the PulmoLife device may help a smoker realize the damage smoking can cause and encourage them to seek smoking cessation advice as well as appropriate medical treatment. VIASYS is focused on respiratory, neurology, medical disposable and orthopedic products.

PEOPLE IN PLACES

• Cliff Hults has joined **Dynamic Imaging** (Allendale, New Jersey) as VP, client services. In addition, Ranjan Jayanathan, the company's former VP, client services, has been appointed VP, systems solutions. Dynamic Imaging provides web-based image and information management.

• Ranch Kimball has been appointed president/CEO of the **Joslin Diabetes Center** (Boston), effective Feb. 1. Kimball will succeed C. Ronald Kahn, MD, who in September announced his intention to step down as president. Kimball previously served as secretary, economic development for the State of Massachusetts under former Gov. Mitt Romney.

The Joslin Diabetes Center bills itself as the world's largest diabetes research center, diabetes clinic, and provider of diabetes education.

• Michael Mamaux has been named CFO for **MedServe** (Houston). MedServe serves hospitals and smaller-quantity medical waste generators across the southern, midwestern and western parts of the country, with turnkey medical waste management solutions through its Med-Shred, Enserv and EnviroSolve subsidiaries.

• Rohini Hira has been appointed VP, sales and marketing, for **Perceptronix** (Vancouver, Canada). Perceptronix said that Hira's career spans 20 years in healthcare marketing, including progressive sales and marketing management positions with Merck, Genentech and Baxter. Perceptronix is a privately-owned cancer diagnostic company.