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ev3/FoxHollow merger seen as endovascular space 'LEGO-fit'

By AMANDA PEDERSEN

Medical Device Daily Staff Writer

Citing "greater critical mass and revenue-generating opportunities" as key benefits, **ev3** (Plymouth, Minnesota) and **FoxHollow Technologies** (Redwood City, California) Sunday unveiled a plan to merge in a \$780 million cash and stock transaction. The proposed merger would create a new company with a market capitalization of about \$1.7 billion, based on the companies' closing stock prices on Friday.

"The two companies fit together like hand-in-glove," Jim Corbett, president/CEO of ev3 told *Medical Device Daily*. "It's like a LEGO-fit."

ev3 is focused on endovascular technologies for minimally invasive treatment of vascular diseases and disorders. FoxHollow develops minimally invasive devices for the removal of plaque and thrombus for the treatment of

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Teleflex expands in med-tech with \$2 billion buy of Arrow

By OMAR FORD

Medical Device Daily Staff Writer

Teleflex (Limerick, Pennsylvania) continued its recent expansion into the realm of medical technologies Monday with the \$2 billion acquisition of **Arrow International** (Reading, Pennsylvania), a manufacturer of disposable catheters and related products for critical and cardiac care, recently troubled by profit shortfalls.

The merger agreement, unanimously approved by the boards of both companies, would provide a cash payment of \$45.50 a share for each outstanding share of Arrow, a premium of 20% over Arrow's closing share price on July 20, 2007.

The agreement was an all-cash transaction valued at \$2 billion.

"Arrow International has been on the Teleflex radar for a number of years now," said Ernest Waaser, president of

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International report

Volcano wins Japan approval of s5i Integrated IVUS System

A *Medical Device Daily Staff Report*

Volcano (Rancho Cordova, California) reported approval of its s5i Integrated IVUS (intravascular ultrasound) System by regulatory authorities in Japan.

Volcano said it expects to launch the s5i into Japan — which it says represents the largest IVUS market worldwide — this quarter. The company noted that it has already launched the s5i Integrated IVUS system into the U.S. and Europe.

Volcano said that the s5i is its first IVUS system that can be integrated into new or existing cath labs. The company said it can now tailor an integrated IVUS solution to the unique user and workflow needs for virtually any vendor's cath lab type or configuration, including multiple controllers and monitors, as well as flexibility in the physical location of the console. The s5i also incorporates Volcano's real time VH IVUS tissue characterization functionality that enhances the interpretation of IVUS images, and Chro-

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ProModel software offers virtual healthcare predictive scenarios

By ROB KIMBALL

Medical Device Daily Staff Writer

If you're a decision-maker for a healthcare organization, or any company for that matter, imagine how much more efficiently you could run your facility if you knew ahead of time the different variables of your work environment so as to predict how to do things better and more cost-effectively, as well as being better ready for surprises and emergencies.

ProModel (Orem, Utah), while it has no crystal ball to predict the future, does have innovative computer informatics for futuristic planning in terms of business process optimization and decision support.

Its market targets are the healthcare, pharma and manufacturing industries, its software and support services designed to help companies predetermine results, risks and rewards of their processes.

To understand how ProModel can help a company, it recommends thinking of the facility as a collection of

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ILLUMINA IN COLLABORATION TO DEVELOP VASCULAR DISEASE CHIP3

 **AHC Media LLC**

Experts say HIV/AIDS vaccine essential to contain the disease

By **MARK McCARTY**

Medical Device Daily Washington Editor

WASHINGTON — The July/August edition of *Health Affairs* is dedicated to global healthcare funding, and the journal's publishers hosted a conference at the National Press Club last week to discuss how such funding affects efforts to contain the HIV virus and its disease, AIDS.

The paper, authored by John Stover, president of the **Futures Institute** (Glastonbury, Connecticut), and four others, discusses a model of the outcome of AIDS vaccines, with the most pessimistic of the three scenarios reducing the rate of new infections to roughly 2.5 million new infections per year in low-income nations by 2030, down from approximately 3.5 million per year at present.

This scenario involves the use of a vaccine with a 30% efficacy rate that 20% of the populations in question would receive.

At the opposite, more optimistic end of the model — one calling for a vaccine with an efficacy rate of 70% injected into 40% of the population — infections would drop by 81% by 2030, when less than 1 million infected.

Stover said that several analyses conducted by the **World Health Organization** (Geneva, Switzerland) have attempted to estimate the burden that specific diseases impose on a system, but such work "is still in the early stages."

Stover said that abstinence-only programs have returned mixed results, but the efficacy of such programs might be dependent on things such as the degree of interaction between counselors and members of the local population.

Stover said that in some nations, "up to 85% of spending on AIDS comes from PEPFAR" and that the anti-retroviral therapies thus provided have saved a lot of lives.

"Could we use more? — absolutely," he said, but the boost to \$30 billion is a meaningful difference.

Today's MDD food for med-tech thought

The battle against AIDS is "a marathon, not a spring."
— *Tom Lantos, U.S. congressman from California (6th district), describing the type of effort needed to fight the worldwide spread of AIDS. "Experts say HIV/AIDS vaccine essential to contain the disease," pp. 2, 5.*

Tom Lantos (D-California) led the discussion of U.S. appropriations for AIDS, and said that "[t]he modern scourge of HIV/AIDS has stolen 30 million lives, more than any war in human history" with the exception of WWII.

He said that in 2007, there will be 4 million new infections and 3 million deaths.

Among the consequences is that 15 million children will be orphaned to lead "utterly shattered lives," he said, adding that no assistance program "can ever make them whole."

Lantos lauded the Bush administration's proposal to double the President's Emergency Plan for AIDS Relief (PEPFAR) funding from \$15 to \$30 billion over the next five years, and promising, "I will do my utmost to guarantee" that the White House's proposed increase goes through.

Lantos also said that he has grown weary of the rhetoric coming from some leaders such as Iran's president, Mahmoud Ahmadinejad, who routinely castigates the U.S. as "the great Satan . . . denouncing us as a self-centered, mindless, only money-interested group of people." He said that such characterizations fly in the face of the tremendous sums of donated funding and the numerous Americans who work overseas to improve the lives of those in other nations.

"There is a great deal for us Americans to be proud of," Lantos said, while adding that the battle against AIDS is "a marathon, not a sprint."

Lantos said that the next authorization will attempt to move efforts from an emergency mode in dealing with AIDS to sustainable programs.

"We cannot treat our way out of this pandemic. We will

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*Agreements roundup***Illumina in massive collaboration to develop vascular disease chip****Medical Device Daily Staff Report**

Illumina (San Diego) reported a collaboration with the **Institute of Translational Medicine and Therapeutics** (ITMAT) at the **University of Pennsylvania** (Philadelphia), the **Broad Institute**, and the **National Heart, Lung, and Blood Institute's** (NHLBI, Bethesda, Maryland) Candidate-gene Association Resource Consortium (CARE) to develop a customized chip for vascular disease.

Called the IBC (ITMAT, Broad, CARE) chip, this array will be developed to analyze more than 55,000 single-nucleotide polymorphisms (SNPs) in candidate genes selected for cardiovascular and other associated phenotypes. Using Illumina's iSelect Custom Genotyping Bead-Chip, researchers will assess the genetic diversity within pathways of about 2,100 genes believed to underpin primary and secondary vascular disease processes, such as blood pressure, myocardial infarction, heart failure, stroke, insulin resistance, metabolic disorders, dyslipidemia (changes in lipid levels in the blood), and inflammation. At the study's completion, more than 120,000 samples from large population studies and clinical trials will be analyzed for genetic links to vascular disease.

The collaboration, led by the University of Pennsylvania, the Broad Institute and the CARE Consortium is the first major cardiovascular initiative to use the iSelect Infinium Custom Genotyping array. iSelect custom panels enable researchers to focus on specific disease-related or pathway-related SNPs. The multi-sample BeadChip format increases throughput and shortens sample processing time.

"The University of Pennsylvania's interest in customizing this genotyping panel to tackle vascular-disease research underscores the creative ways the research community is working with Illumina to unravel the complexities of human disease," said Jay Flatley, president/CEO of Illumina. "Our whole-genome genotyping technology continues to raise industry standards by delivering unparalleled data quality, format and content flexibility, and cost-effectiveness. This is helping researchers accelerate discoveries that will help us better understand, cure, and ultimately prevent disease."

Illumina is a developer of life-science tools and integrated systems for the large-scale analysis of genetic variation and biological function.

In other agreements:

- **Affymetrix** (Santa Clara, California) and **Partners HealthCare** (Boston) reported that they have extended their translation research collaboration with a new contract array manufacturing (CAM) supply agreement, enabling Partners researchers to transform recent microarray discoveries into fully validated, laboratory-developed molecular diagnostic tests. The array-based tests will help physi-

cians better diagnose and tailor treatments for individual patients, the companies said.

Affymetrix will create custom microarrays based on the recent discovery data from Partners researchers. The arrays will be used to produce molecular diagnostic tests, which will then be validated and implemented in Partners HealthCare's CLIA (Clinical Laboratory Improvement Amendments)-certified environments. The team at Partners will begin focusing on array-based tests for hypertrophic cardiomyopathy (HCM) and will explore many indications in a large number of diseases.

The latest agreement builds on the success of the parties' translational research collaboration. For the past year, researchers at **Harvard Medical School** (Boston), Partners HealthCare and HPCGG have been using the Affymetrix technology to identify genetic sequences and signatures associated with a number of complex diseases.

Affymetrix' GeneChip microarray platform offers a number of unique benefits and advantages for developing and implementing molecular diagnostic tests. The cost-effective array format enables researchers to analyze more genetic content per test, and the proven GeneChip system is the only microarray instrumentation platform cleared for use in molecular diagnostic laboratories in both the U.S. and European Union.

Partners is an integrated healthcare delivery system.

- **Language Access Network** (LAN; Columbus, Ohio), reported that **Miami Valley Hospital**, (Dayton, Ohio) has signed a two year service agreement for MARTTI (My Accessible Real Time Trusted Interpreter), the company's live video/audio interpretation service.

LAN will now provide Miami Valley Hospital with live video/audio interpretation services for American Sign Language (ASL) for the deaf and hard-of-hearing, Spanish, and 150 other languages, to its more than 800,000 patient encounters a year.

Miami Valley Hospital will be billed for the video/audio interpretation service on a per minute usage fee, with a minimum usage requirement of 1,000 minutes a month.

LAN estimates an average of 20% of all patients in the U.S. are limited English proficient, deaf and hard-of-hearing, or do not speak English well. LAN estimates that each patient encounter in a hospital environment, ER, Labor and Delivery, Clinic, etc. lasts between 7-12 minutes of time on the MARTTI unit, with a cost range of \$1.75-\$2.95 per minute.

All institutions receiving federal money are required through the American Disabilities Act and Civil Rights Act are required to provide interpretation services free of charge to deaf and hard-of-hearing and limited English-proficient patients.

LAN offers video language interpretation services for 150 foreign languages and American Sign Language. ■

Court report**Gen-Probe action against Digene dismissed by California court****A Medical Device Daily Staff Report**

Digene (Gaithersburg, Maryland) reported that a California state court has dismissed a complaint filed against the company by **Gen-Probe** (San Diego), without option to amend.

Gen-Probe's complaint asked the court to declare that an agreement between it and **F. Hoffman-LaRoche** (Basel, Switzerland) and **Roche Molecular Systems** (Pleasanton, California) for the supply and purchase of certain human papillomavirus-related (HPV) materials was permissible under the terms of a pre-existing cross-license patent agreement between Roche and Digene.

Ruling in favor of Digene's request for dismissal, the Superior Court for the County of San Diego said that there is "no actual controversy between Digene and Gen-Probe." By prohibiting any further amendment of the complaint, the court has terminated the litigation brought by Gen-Probe against Digene, with no option to re-file.

"The court's dismissal of this petition with no option to amend and re-file clearly recognizes the merits of our posi-

tion. Digene is the worldwide leader of products for the detection of human papillomavirus, the cause of cervical cancer, and this is due in large part to our strong portfolio of intellectual property, as well as to our innovation in science and excellence in marketing execution," said Daryl Faulkner, president/CEO of Digene,

On Dec. 8, 2006, Gen-Probe filed a complaint in the Superior Court of the State of California for the County of San Diego, asking for a declaration that a 2005 supply and purchase agreement between Roche and Gen-Probe relating to certain HPV materials is a permissible activity under a pre-existing patent cross-license agreement between Digene and Roche. In response, Digene filed a general demurrer on March 26, 2007, asking the court to dismiss the action on the basis that Gen-Probe is not a party to the 1990 cross-license agreement between **Institute Pasteur** (Roche's predecessor) and **Life Technologies** (Digene's predecessor), and therefore has no basis for bringing an action against Digene.

Digene is a developer of molecular diagnostics. It makes DNA and RNA tests, with a focus on women's health. The company's flagship product, the Digene HPV test, is the only FDA-approved and CE-marked test for the detection of human papillomavirus. ■

Boston Sci said to be planning cuts at Massachusetts facilities**A Medical Device Daily Staff Report**

With sales of its top medical devices continuing to drop, the *Boston Globe* reported over the weekend that **Boston Scientific** (Natick Massachusetts) is planning broad job cuts that could affect its Massachusetts employees.

Executives of the company, facing shifts in how doctors treat coronary problems, are planning an extensive restructuring of the company as well as a sell-off of most of its \$500 million in stock and other investments the *Globe* said.

Boston Scientific employs 28,000 people worldwide, including 2,400 in Massachusetts, chiefly at its Natick headquarters, its Marlborough endosurgery division, and a Quincy distribution center. On a conference call with analysts on Friday to discuss second-quarter earnings, new CFO Sam Leno said the company expects to disclose an expense-reduction plan, including job cuts, by year-end.

"There is no one business or no one corporate staff function that is being singled out," Leno said during the call.

Asked about specific effects on local operations, a company spokesman said jobs in Massachusetts "may or may not be affected."

"We won't know until the review is completed later this year," spokesman Paul Donovan told the *Globe*.

To help its bottom line and pay down \$7.4 billion in net debt, mostly incurred when it acquired **Guidant** (Indianapolis) for \$27.2 billion last year, the company is plan-

ning to restructure operations, cut the workforce, and sell most of its investment portfolio, both stock and private venture-type holdings. It is also considering a partial initial public offering of its growing endosurgery division (*Medical Device Daily*, March 14, 2007).

In May, Donovan told the *Globe* the potential public offering and the asset sell-off would not affect Massachusetts jobs, but did not address restructuring. In his interview on Friday he said the restructuring could have a local impact.

On Friday, the company reported a 2Q07 profit of \$115 million, or 8 cents a share, slightly below consensus Wall Street estimates. That compares to a \$4.3 billion loss last year, when the company declared a massive writeoff associated with the Guidant purchase. But the underlying business is struggling, with worldwide sales of its flagship Taxus drug-coated stent falling more than 30% to \$437 million from \$647 million in the same quarter last year. In the U.S. the Taxus sales decline was even more pronounced at more than 40%.

Sales of implantable defibrillators, which the company acquired by buying Guidant last year, were \$377 million, down slightly from \$383 million a year ago. ■

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*Financings roundup***ConnectivHealth raises \$2.1M to back web-based roll-outs****A Medical Device Daily Staff Report**

ConnectivHealth (Scottsdale, Arizona), a healthcare information company, reported that it has raised \$2.1 million in financing to accelerate its expansion in the national healthcare digital media space. The news follows ConnectivHealth's recent acquisition of **Relegent** (Nashville, Tennessee), which delivers online healthcare information to the hospital and education industries.

In addition to original company investors, Chrysalis Ventures, Petra Capital Partners, and Scott McQuigg, the company's president/CEO, other members of the management team also participated in the financing.

"The financing comes at an opportune time as we prepare to launch several innovative Web products for physicians and consumers," said McQuigg.

McQuigg added that part of the funding also went toward the recently acquired Relegent and its two core brands:

HealthTeacher, which provides K-12 health curriculum online to more than 7,000 schools; and Discovery Hospital, offering consumer health content via more than 150 hospital websites in partnership with Discovery Communications

"The continued support of our investors enables us to acquire and market unique companies that align with our vision of connecting physicians, schools, hospitals and consumers through a common healthcare information platform. At the same time, it also allows us to aggressively grow our customer base through new products," said McQuigg.

In other news, the company said it is relocating its headquarters from Scottsdale, Arizona, to Nashville, Tennessee and will be moving into a new 7,000 square-foot office in the Nashville area to accommodate recent growth. McQuigg noted that ConnectivHealth will add 10 new positions this year, with as many to follow in 2008.

In addition to its online hospital and education products, ConnectivHealth reaches 150,000 physicians through VerusMed, a company which delivers independent clinical news briefs. ■

Vaccine

Continued from Page 2

have to dedicate substantial resources toward evidence-based prevention programs," Lantos said.

And he said that the requirement that one-third of spending on prevention should target encouraging abstinence has not worked well enough to justify the investment.

In June, the House of Representatives approved an FY08 foreign aid bill that will permit the president to waive the abstinence spending requirement. The margin of 57.5% for the winning vote is not veto-proof ratio, but the total vote was 419, which leaves another 16 members whose reaction to a veto cannot be tabulated.

"Healthcare infrastructure is either weak or non-existent" in sub-Saharan Africa, Lantos said, and that labs and clinics either don't exist or are run down, and that healthcare workers in developing nations have exited for better-paying jobs in developed nations.

"Any discussion . . . must include the Holy Grail" of the fight against AIDS, namely a vaccine, Lantos said, which will require "a major commitment, a tremendous investment in resources."

Stover reviewed some of the dilemmas faced in development and deployment of an AIDS vaccine. He said that the various entities who are aligned to do battle with AIDS are "doing a better job of scaling up the prudent interventions we have today," including male circumcision.

However, he said that "an AIDS vaccine could be our best hope" of blunting the impact of the disease.

Stover said that 25,000 volunteers across the world are participating in trials of AIDS vaccines, but any early vaccine "probably is not going to be 100% effective" and might

only alter the progression of the disease rather than block infection. ■

BRIEFLY NOTED**Guava to cover international HIV market**

Guava Technologies (Hayward, California), an on-demand, benchtop cell analysis systems company, reported that it was successfully audited to the requirements of ISO13485:2003 by BSI Management Systems. With this certification, the company will redouble efforts on medical devices for the international market, covering a variety of therapy areas, beginning with HIV/AIDS.

ISO is a network of the national standards institutes of 157 countries, and ISO 13485 is an internationally recognized standard to establish the quality management systems applicable to manufacturers of medical devices. It is harmonized to FDA 21 CFR part 820.

"We are proud to receive this international recognition," said Lawrence Bruder, president/CEO. "It's a clear indication of our ability to consistently meet regulatory and customer requirements for medical devices, and reflects our intense commitment to the highest possible standards for design, development, manufacture, and service for all of our products."

"ISO certification was the first step in our initiatives to deliver quality medical devices to the global healthcare community," continued Bruder. "We can now focus on international commercialization of our new CD4 T-cell System for monitoring treatment of HIV/AIDS."

ev3/FoxHollow

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peripheral artery disease (PAD), its flagship product the headline-making Silverhawk device.

FoxHollow shareholders would receive 1.45 shares of ev3 common stock plus \$2.75 in cash for each share of FoxHollow common stock they own. Based on the companies' closing stock prices on Friday, this represents \$25.92-a-share consideration to be received by FoxHollow shareholders, or roughly \$780 million, and a premium of more than 20% to the 30-day average trading price for FoxHollow's shares.

With transaction close, FoxHollow stockholders would own about 41% of the combined company, and ev3 stockholders about 59%.

The companies said they expect to complete the merger in the fourth quarter.

According to the companies, ev3 and FoxHollow's combined scale will create an organization that will have one of the largest U.S. distribution footprints in endovascular devices with one of the broadest and most technologically advanced product offerings.

The combined portfolio would include a broad spectrum of products to treat vascular diseases in both the peripheral and neurovascular markets, including atherectomy and thrombectomy, PTA balloons, stents, embolic protection devices, infusion catheters/wires, embolic coils and liquid embolics. It would also have direct operations or independent distributor presence in more than 60 countries, with more than 1,500 employees.

Corbett told *MDD* that he has become acquainted with John Simpson, CEO and founder of FoxHollow, over the past 18 months, and that they had discovered that they are like-minded. He said they both believe the primary way to drive a company is through product innovation.

"This combination," Corbett said, "brings together two organizations that share a deep commitment to advancing the treatment of peripheral and neurovascular disease. By combining our respective strengths, we believe we can develop innovative technologies to address the needs of endovascular specialists and their patients, while also providing significant growth opportunities for employees and shareholders."

Following transaction close, Corbett would become CEO and chairman of the combined company, and Simpson will become chief scientist and vice chairman. The new company's board will include 10 members, six nominated by ev3, four by FoxHollow.

The merged company will be headquartered in Plymouth, with operating and manufacturing divisions in Irvine and Redwood City, California. Its main international office will be in Paris.

"Let me just say I'm very excited about this transaction, certainly it provides opportunities and it will provide opportunities for our employees, our customers, and our

shareholders," Simpson said during a Monday morning conference call. "[W]e will expand our position as a global leader with a larger portfolio of products to better serve our patients' needs."

The companies said that the merger is expected to produce annual cost savings in excess of \$40 million. As a result, the combined company expects to generate adjusted EPS of 60 cents-70 cents in 2008 and 90 cents-\$1.10 in 2009.

The operating income of an ev3/FoxHollow combination will be significantly enhanced, via added resources to fund R&D programs, future innovations and clinical studies, the companies said.

"A now-larger, more diversified [ev3] is closer to becoming a more profitable, faster-growing company sooner than expected as they leverage the combined sales force and eliminate duplicative expense," Rick Wise, med-tech analyst with Bear Stearns, wrote in a research note.

ev3 and FoxHollow expect sales of the combined company to reach \$585 million-\$615 million in 2008 and \$700 million-\$750 million in 2009.

Wise also said that the combined sales force of the new company would be one of the largest in the endovascular space at nearly twice the size of other players like **Johnson & Johnson** (New Brunswick, New Jersey), **Boston Scientific** (Natick, Massachusetts), **Abbott Laboratories** (Abbott Park, Illinois), and **Medtronic** (Minneapolis).

"There are multiple areas of cross-selling here for both businesses, but one of the areas where there may be potential for channel conflict would be atherectomy vs. stenting, and John historically has not been a huge believer in stenting and obviously stenting is an important component of ev3 going forward, so how do you deal with that channel conflict?" asked David Lewis, an analyst with Morgan Stanley, during the conference call Monday.

Corbett and Simpson responded that they do not see a channel conflict.

"Some of what I've said about stenting is a little bit tongue-and-cheek in the past," Simpson said, "but I do believe that there's an opportunity to use both technologies. I think there's an opportunity to now absolutely give the physicians all the technologies that they would like to have to treat peripheral artery disease. We all have our biases for what might be the most favorable, but inevitably the patient is better served when more alternatives are available, and this is a huge commitment to doing that."

FoxHollow is best known for its Silverhawk technology for mechanical removal of plaque from the vasculature and last year it made headlines via a deal with **Merck** (Whitehouse Station, New Jersey) to supply the big pharma with biological samples for new drug discovery.

Merck paid \$95 million to buy stock equaling an 11% stake in the company and committed to another \$100 million over the next four years to expand the collaboration. ■

Teleflex

Continued from Page 1

Teleflex Medical, a division of Teleflex, during an audio conference yesterday morning.

"The message here is that while sharing similar customer distribution channels and manufacturing processes, we have very little overlap in terms of specialty areas where we focus. We can leverage each other's infrastructure for cross selling and manufacturing purposes."

Waaser said that one reason for the acquisition was because of Arrow's success with critical care disposables, a line of products producing strong revenue.

Waaser pointed out that Arrow was very strong in specialty catheters and products for anesthesia.

Teleflex specializes in neurology, respiratory surgery and other types of neurological products.

"With the execution of this merger agreement, Teleflex is redefining its portfolio and its Medical Segment by creating a \$1.4 billion medical technology business that will be the largest source of the company's revenues and profitability," said Jeffrey Black, CEO and chairman of Teleflex. "With the addition of Arrow, we expect that by fiscal 2008 the Medical Segment should achieve annual revenues of approximately \$1.5 billion and generate operating margins in the 20% range."

Teleflex says that the merger with Arrow will enable the company to:

- create a medical technology company with a leading global position as a provider of disposable medical products used in critical care and surgical applications;
- accelerate global expansion and new channels for each company's well-known brands, in particular enhancing opportunities for growth in Asia and Eastern Europe, utilizing Arrow's established sales network;
- provide customers with a broader range of medical disposables, with medical disposables and single-use devices serving as a source of recurring sales representing in excess of 80% of total Teleflex revenue;
- focus investment in innovative technologies that provide less invasive access during diagnostic and therapeutic procedures;
- and enhance the company's ability to improve overall operating margins, reduce cyclicity and expand its medical portfolio through expanded offerings, new product development and provide economies of scale.

The company predicted that synergies from the transaction could reach \$70 million-\$75 million by FY10 through reduction of administrative and global infrastructure expenses, increased efficiencies and added revenue. Revenue synergies are expected from expanded channels, growth in Asia and Eastern Europe, faster introduction of new products and new cross-selling opportunities.

The merged company will have 11,000 employees worldwide.

Teleflex said it has secured the necessary financing for the transaction.

Bank of America Securities is acting as financial advisor and Simpson, Thacher & Bartlett is acting as legal counsel to Teleflex, and Bank of America and its affiliates and J.P. Morgan Securities have provided financing commitments. Lazard is providing financial advisory services and Dechert is acting as legal counsel to Arrow.

Circumstances earlier this year affecting both Pennsylvania-based-companies, set the tone for the merger.

In June Arrow essentially put up the "for sale" sign by dismissing its CEO Carl Anderson Jr. and reporting the formation of a committee to "explore alternatives."

The company said that it had "lost confidence" in Anderson's leadership after four years at the helm and that during that time it had "failed to meet . . . sales and earnings targets" set by him. That announcement also was accompanied by a report that it was facing a potential takeover by the McNeil Trust which was offering an alternate slate of directors.

Arrow, at the time, reported that it expected FY07 sales and EPS to come in near the low end of targets provided in its 2Q press release of March 27. At that time, Arrow expected earnings of \$1.40-\$1.48 a share on revenue of \$515 million-\$525 million.

Earlier in the year Teleflex made deal-making news by acquiring the assets of **HDJ** (HDJ; Lancaster, Pennsylvania) and its subsidiary **Specialized Medical Devices**, a provider of engineering and manufacturing services to medical device manufacturers (*MDD*, April 13, 2007).

Teleflex said the purchase of HDJ added another line of medical components, devices, implants and instruments used in orthopedic procedures to the Teleflex portfolio. Terms of that deal were not disclosed, but revenue from the HDJ product lines was reportedly about \$14 million in 2006.

Teleflex is a supplier of disposable medical products, surgical instruments and medical devices in three main areas: respiratory care; urology instruments; and specialty sutures used in surgery. It markets its products under the HudsonRCI and Rüsck brand names, and surgical instruments and medical devices under the Beere, Deknatel, KMedic, Pilling, Taut and Weck brands.

In other dealmaking news: **Misys Healthcare**, (Raleigh North Carolina) a division of **Misys plc** (London) reported two divestitures.

The first is an agreement to divest the company's computerized patient record (CPR) assets to **QuadraMed** (Reston, Virginia) for \$33 million in cash.

This transaction is expected to close within 60 days.

The components of the QuadraMed Care-Based Revenue Cycle include solutions for access and identity management, care management, health information and revenue cycle management that combine with CPR to create a product line for improving patient care quality and safety.

Misys also signed an agreement to transfer the ownership of its **Diagnostic Systems** business to Vista Equity

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International

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maFlo Stent Apposition analysis which helps physicians confirm proper stent expansion and placement.

Volcano said that the s5i IVUS is the only IVUS system to have undergone extensive safety and compatibility testing with the hardware imaging systems of the major providers, **GE, Siemens, Philips** and **Toshiba**.

Scott Huennekens, president/CEO of Volcano, said the approval “makes Volcano the only company to offer an integrated IVUS console to the largest worldwide IVUS market . . . and believe that the lessons learned through IVUS by Japanese physicians will help increase the use of IVUS in the U.S. and Europe as well.”

Ron Waxman, MD at the Washington Hospital Center, said, “We recently performed an analysis of 7,000 patients at our center and concluded that the incorporation of IVUS guidance into everyday PCI procedures can reduce the patient risk of stent thrombosis by a statistically significant margin. We have always been IVUS advocates, but these new findings have driven IVUS use at the Hospital Center to its highest level ever. I recently presented this data in Japan where it was well received as interventional cardiologists in Japan have a high usage of IVUS and low rates of stent thrombosis.”

Conditional approval for U.S. IDE

China Medical Technologies (Beijing) said it has received conditional approval for its investigational device exemption (IDE) application from the FDA to begin a U.S. clinical trial of using its high-intensity focused ultrasound (HIFU) tumor therapy system in a limited number of patients with pancreatic cancer.

Conditions of the approval include a requirement for the company to provide responses to the questions raised by the FDA within a specified period of time.

The clinical trial will be performed at the **University of Washington Medical Center** (Seattle) after receiving approval from the university’s Institutional Review Board.

The company’s HIFU tumor therapy system is intended to be used in this trial to ablate targeted tumor tissue of the pancreas, with an indication for the palliation for pain associated with locally advanced or metastatic pancreatic cancer.

China Medical’s HIFU system was approved for sale by the State Food and Drug Administration of China in 1999. To date, more than 40,000 tumor patients in China, including patients with pancreatic, liver, breast, kidney and other solid tumors in the pelvic cavity, have received treatments by using the system.

“We are excited to have received the conditional approval of our IDE application from the FDA. We believe this marks an important milestone toward our application for pre-market approval of our HIFU tumor therapy system in the U.S.,” said Xiaodong Wu, chairman and CEO of China Medical. “We believe that our extensive clinical experience in [China] together with the experience of pre-clinical ani-

mal tests performed at the University of Washington for the IDE application will help us demonstrate the clinical safety and efficacy of using our HIFU system in treating pancreatic cancer patients during the clinical trial.”

Rosetta cites study on microRNA

Rosetta Genomics (Rehovot, Israel/North Brunswick, New Jersey), a microRNA company, said research findings published in the journal *Molecular Cell* suggest the potential for a specific, single microRNA — miR-34a — to be used as a drug candidate in cancer therapy to increase apoptosis, or programmed cell death, in the context of the tumor suppressor p53, which has been shown to prevent or slow the spread of cancer cells by facilitating apoptosis.

In this study by scientists from Rosetta Genomics and the **Weizmann Institute of Science** (Rehovot), activation of p53 *in vivo* in mice as well as in cultured human cells induced the expression of miR-34a.

Believing that miR-34a could itself play a role in cellular apoptosis, researchers introduced miR-34a directly into human cancer cell lines to determine its impact on tumor cell behavior. They said the results “clearly demonstrated” that over-expression of miR-34a led to increased cancer cell death as well as promoted other anti-proliferative activities.

The data presented in *Molecular Cell* is supported by other recent studies showing that miR-34a is under-expressed in central nervous system tumors.

“This is a groundbreaking study shedding light on the critical role microRNAs play in fighting cancer and highlights their potential to act as novel drug targets,” said Dr. Dalia Cohen, global head of research and development at Rosetta Genomics. “The results suggest the potential that a synthetic miR-34a-like agent could be used as a cancer therapy.”

MicroRNAs are a recently discovered, naturally occurring form of RNAi. They act as protein regulators and according to Rosetta Genomics, “have the potential to form the basis for a new class of diagnostics and therapeutics.” The company added that “since many diseases are caused by the abnormal activity of proteins, the ability to selectively regulate protein activity through microRNAs could provide the means to treat a wide range of human diseases.”

It said microRNA expression levels have been shown to be correlated with various disease states and to hold great potential as diagnostics and prognostic markers. ■

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ProModel

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resources that are intended to function together cost-effectively. Now, what if you could disassemble all or part of the factory and reconfigure the pieces to find ways to make the entire system run more efficiently? What if you could actually see which new configurations work best and which ones fail by watching them for a week, a month or a year on a trial basis?

ProModel says that its software will test these multiple alternatives in a short time.

"We run models that give you tomorrow's history today," Kurt Shampine, VP of the company's life science group, told *Medical Device Daily*.

The company's healthcare-centered products include MedModel and ED Simulator.

The software is a simulation tool that helps hospital decision-makers build a virtual model using the specifics of the organization's healthcare environment so as to predict future scenarios such as patient admissions, staffing decisions and cost containment.

MedModel is a simulation tool designed used in the evaluation, planning and redesign of hospitals, clinics and other healthcare systems, identifying inefficiencies in an existing process and test a variety of alternative scenarios.

Shampine said that the software has a wide application base.

"We build models of the actual environment; in some cases it's an animated model, where you actually see people running around the facility. We build it with all the variability's that happen within a hospital.

"For instance, if there was a bus crash, or any catastrophic event, you could model that scenario," he told *MDD*.

The scenario is then incorporated virtually into the normal flow of the hospital so that the hospital administrator can evaluate how many extra staff, beds and equipment are needed in an emergency situation.

An additional feature of the software program is what the company calls "resource interdependencies."

"Say, for example," Shampine said, "there is a clinic near an army base. The clinic's schedule could be highly predicated on how the army base operates. When are people going to be off duty, so that they can actually visit the clinic? The scheduling, the traffic and the staffing have to be aligned with that variability, and that is exactly what our tools allow [the clinic staff] to do — to build a model, either attach the data directly to it, or a spreadsheet interface where you enter different cycle times and schedules and have them be variable. Then have the actual model run many futures."

"The reason you add variability is so you can run 100 futures with that variability and get a confidence interval answer back that is a robust way to run that process," Shampine said.

ProModel offers software configured specifically for the emergency department (ED) facilitator. The EDS simulator enables its users to test possible solutions and alternatives to an ED's most pressing problems, see the possible results and quantify the effects of changes on such issues.

Dale Schroyer, senior consultant with ProModel, explained how the program is designed to function.

"EDS is aimed at people that need to make quick decisions about operating the ED to its best capability," he told *MDD*. "The ED simulator has a front-end interface and is user-friendly in a ribbon format, much like Microsoft Office."

"Processes are done in trees [called tree folders], similar to Windows Explorer, so that adding or subtracting resources should be familiar to the user."

Similar to MedModel, EDS builds a virtual ED experience, with all the resources, patient processes, typical patient loads, and the number of patients coming in per day/week.

The program builds all of this into a model and runs it through a specified time period. It then produces predefined reports using the ED's exact operational metrics and presents them in formats that administrators are familiar with and used to seeing.

"We provide length-of-stay information as canned reports," Schroyer said, "but instead of just giving you an average, we give you a whole histogram that also tells you the mean length of stay, the median length of stay, and then with a couple of clicks of a mouse you can slice through that info any way you want. You can look at it by acuity level or you can look at by what the patient's final disposition was, discharged or sent on to hospital. You can be as specific as you want."

ProModel was founded in 1988 and banners a list of prestigious hospitals among those it has served: **Baylor Health System, HCA Hospitals, Mayo Clinic and Miami Valley Hospital.** ■

Teleflex

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Partners (San Francisco), focused on investing in software and technology. The sale includes all business assets, technology and products associated with the current hospital systems diagnostic portfolio, including the Misys Laboratory, Commercial Laboratory, and Clinical Financial products, and stand-alone systems for radiology and pharmacy departments. Terms of this deal were not disclosed.

Vista said the acquisition gives it "another strong presence in the acute care market."

Misys Healthcare said that divestiture of the Diagnostic Systems business — including the Misys Laboratory product — marks "a new strategic direction and market focus."

QuadraMed is a provider of IT solutions for healthcare companies. ■

PRODUCT BRIEFS

- **Medtronic** (Minneapolis) reported the completion of implants in its U.S. clinical study of deep brain stimulation (DBS) for the treatment of medically refractory epilepsy, a form of the neurological condition that does not respond to antiepileptic drugs. With 110 patients now implanted with the Intercept Epilepsy Control System, results of the study — the SANTE (Stimulation of the Anterior Nucleus of the Thalamus in Epilepsy) trial — are expected to be available during 2008. The trial is using existing Medtronic DBS technology to determine whether bilateral stimulation of the anterior nucleus of the thalamus — the brain's central message and relay station - can safely and effectively reduce seizure frequency in people with epilepsy. The same technology is approved for treating motor symptoms of Parkinson's disease and essential tremor — the two most common movement disorders. To qualify for enrollment, study patients were required to have had an average of six or more seizures per month. They continue to receive their epilepsy medications while participating in the trial.

- **Mediware Information Systems** (Lenexa, Kansas) has introduced its BloodSafe system, an FDA-cleared, bedside point-of-care, transfusion administration package designed to extend blood-safety controls outside the blood bank. It consists of remote release refrigerators that make units available throughout the hospital and handheld devices to verify blood units transfused in surgery or at the bedside. Mediware is offering the BloodSafe system in North America either as a stand-alone solution or as a fully integrated component of the company's transfusion-management system, HCLL. Mediware's BloodSafe system will be available as a complementary technology for use with third-party transfusion management systems.

- **NeuroTherm** (Middleton, Massachusetts) reported the introduction of the Stimject RF cannula designed to

reduce procedure time and increase treatment accuracy of radio frequency therapy. The cannula is a typical hollow RF needle, but it also incorporates a sideport that allows injection of a numbing agent without removing the stimulating electrode from the cannula. This is designed to ensure that the cannula remains at the proper position for treating the nerve. The cannula's special sideport allows the physician to touch only the injection tubing rather than the cannula as a whole. NeuroTherm makes radio frequency generators and related consumables used in the treatment of chronic pain.

- **Siemens Medical Solutions Diagnostics** (Tarrytown, New York) reported the introduction of the ADVIA centaur cyclosporine (CsA) assay, an automated test offering laboratories a highly specific immunoassay for the cyclosporine A parent compound. The assay has a simplified extraction process and fully automated processing yielding an 18-minute turnaround time, the company said. The assay's linear range reduces the need for dilutions, reducing the time required for testing and the associated cost. The system features one-tube processing, reducing the need for pipetting, and delivers hundreds of test results per hour. Siemens Medical Solutions Diagnostics provides diagnostic solutions that assist in the diagnosis, monitoring and management of disease.

- **PatientKeeper** (Boston) reported the availability of PatientKeeper P4P, a measurement module which extends the company's Charge-Capture offering. PatientKeeper P4P automates the process of collecting and reporting quality metrics under the **Centers for Medicare and Medicaid Services'** (CMS, Atlanta) 2007 physician quality reporting initiative (PQRI). With this product, hospitals can manage the data collection and reporting processes for PQRI. Instead of creating a separate process to collect the necessary information for each CMS measure, the PatientKeeper P4P solution offers a way for physicians to automatically trigger the appropriate questions as charges are being entered. PatientKeeper is a provider of physician information systems.

PEOPLE IN PLACES

- Michael Lahoud was named president of **CardioMag Imaging** (CMI; Schenectady, New York). Lahoud previously worked at VSM MedTech, where he was responsible for operations, development, engineering and manufacturing. CMI makes cardiac diagnostic devices called MagnetoCardioGraphs.

- Gary Bucciarelli was promoted to chief administration officer of **Medrad** (Warrendale, Pennsylvania). Bucciarelli is responsible for all corporate services functions and

the role of CFO. Bucciarelli has been with Medrad since 1993. Additionally, Joseph Havrilla was named senior VP of Medrad's magnetic resonance strategic business unit. Havrilla joined Medrad in 1983. Medrad is a provider of medical devices and services that enable and enhance imaging procedures of the human body.

- Richard Gordon was named VP of business development and sales & management of **Pacific Biometrics** (Seattle). Gordon previously worked at Molecular Devices. Pacific Biometrics makes specialized central laboratory and contract research services to support pharmaceutical and diagnostic manufacturers conducting human clinical trial research.