

JPMorgan H&Q Healthcare Conference

Coatings an emerging platform for Angiotech Pharmaceuticals

By JIM STOMMEN

Medical Device Daily Executive Editor

SAN FRANCISCO, California – A company whose name was much in the medical technology news during 2002 attracted an interested audience during the first day of 2003's first healthcare investors' conference.

Angiotech Pharmaceuticals (Vancouver, British Columbia) has gained attention for its role in providing the paclitaxel coating for two of the companies involved in the drug-coated coronary stent sector, but CEO William Hunter, MD, emphasized during his presentation at the JPMorgan H&Q Healthcare Conference that those stents are just the first of their kind for the firm.

While acknowledging the role its licensing deals with
See Coatings, Page 5

Report from Europe

EP MedSystems seeks CE mark for ViewMate ultrasound device

A Medical Device Daily Staff Report

EP MedSystems (West Berlin, New Jersey) reported that it has submitted its ViewMate intracardiac ultrasound catheter system product dossier to the European Notified Body for approval to affix the CE mark.

The ViewMate intracardiac system consists of an advanced ultrasound console with an image monitor, and a thin disposable catheter fitted with a 64-element phased-array transducer on its tip, according to the company. It says that the system allows cardiologists and electrophysiologists to view the interior anatomy of the heart to enable diagnosis and treatment of "a number of heart abnormalities." It said also that this will enable improvement in electrophysiology procedures, including treatment of atrial fibrillation; implants of cardiology devices, such as heart valves, pacemakers and cardiac defibrillators; and less invasive cardiac procedures, such as catheter treatment of congenital heart defects.

See Europe, Page 8

Bush administration sees a more competitive Medicare

By KEVIN NEW

Medical Device Daily Washington Editor

WASHINGTON – The Bush Administration appears to be moving ahead with ambitious plans to overhaul the Medicare program, according to sources at the White House.

The president will likely have an easier time at getting legislation through Congress now that Senator Bill Frist (R – Tennessee) is Senate Majority Leader. Frist, the only physician in the Senate, has lobbied for changes to the nation's federal health program for the elderly since he was elected to office.

Administration officials are mum on when any proposals will be released, but the President appears likely to push for more private competition in the program. Beneficiaries would likely be able to enroll in either a private health plan or the traditional fee-for-service plan, with higher expanded services but higher out-of-pocket premiums. Beneficiaries who enrolled in the private health plan
See Medicare, Page 6

Deals roundup

Gliatech sells Adcon Gel line; Quest to divest in N. California

A Medical Device Daily Staff Report

Consummating half of a "going out of business" sale, **Gliatech** (Cleveland, Ohio) on yesterday reported that it has sold its Adcon Gel assets to **Wright Medical Group** (Arlington, Tennessee) for \$8.4 million and future royalties, with any final agreement subject to bankruptcy court approval. The transaction is expected to close sometime this quarter, Gliatech said.

Gliatech reported in September that it is conducting an auction of its Adcon assets as part of its bankruptcy proceedings, announced in May (*Medical Device Daily*, Sept. 24, 2002/May 13, 2002)

The company said it continues to hold discussions with what it termed "interested parties" regarding the sale of its Adcon Solution assets, with Harkness & Hill serving as Gliatech's investment advisor to manage the auction.

Gliatech is the developer of biosurgery products, the Adcon products being its main offerings in this arena.
See Deals, Page 7

INSIDE: VASCULAR ARCHITECTS ADDS \$16 MILLION IN D ROUND (FINANCINGS ROUNDUP)	2
INSIDE: POLYMEDICA OKAYS FBI INTERVIEWS OF LIBERTY EMPLOYEES (COURT REPORT)	3

*Financings roundup***Vascular Architects adds \$16M
Endocardial adds private \$8.5M****A Medical Device Daily Staff Report**

Vascular Architects (San Jose, California), a developer of devices to treat vascular disease and nonvascular obstructions, has closed a \$16 million private placement of its Series D preferred stock.

Foundation Medical Partners led the round, joined by Edwards Lifesciences LLC as a new investor. Existing investors included Domain Associates, Thomas Fogarty, MD, ARCH Venture Partners, Johnson & Johnson Development, The Vertical Group, Atherton Venture Partners and Three Arch Partners.

"This financing will allow us to expand the distribution channels for our products in the U.S. and internationally," said Bruce Barclay, president and CEO of Vascular Architects. "We will also continue to enroll patients in our two FDA-approved clinical trials in the U.S., which evaluate use of the aSpire Covered Stent to treat iliac (GALAXY) and superficial femoral artery (SFA) and popliteal artery (VALIANT) stenoses and occlusions. Finally, future product and drug delivery stent development activities will be accelerated." Barclay said that the funds also will be used for other general corporate purposes.

The company's aSpire Covered Stent is a spiral nitinol design completely covered by a thin layer of ePTFE (expanded polytetrafluoroethylene) which is intended to provide greater artery wall coverage and eliminate all metal-to-artery contact. The stent is designed to preserve many of the native artery's desired elements, including the ability to maintain laminar blood flow and side branch access. The device is delivered using the company's Controlled Expansion delivery system, a stent delivery system that separates the steps of complete stent apposition to the artery wall from release of the stent from the delivery catheter.

Endocardial Solutions (St. Paul, Minnesota)

announced the sale of about \$8.5 million of common stock in a private placement to institutional investors through U.S. Bancorp Piper Jaffray, as agent.

"This financing will allow us to fund the launch of the company's new EnSite NavX navigation and localization technology that will introduce new methods of navigating conventional ablation catheters using the EnSite 3000 System, as well as accelerating the development of three compelling new applications," said Jim Bullock, president and CEO.

"These projects include integrating a patient's cardiac electrical activation information from the EnSite 3000 System with digital images of the patient's cardiac anatomy, incorporating conventional electrophysiology recording features into the EnSite 3000 System, and combining advanced mapping with new diagnostic capabilities for congestive heart failure applications," Bullock added.

Endocardial Solutions develops technology for diagnostic mapping of complex arrhythmias. The EnSite 3000 System provides a 3D graphic display of the heart's electrical activity. The FDA cleared the EnSite 3000 System for use in diagnostic mapping of complex arrhythmias in the right atrium of the heart in 1999.

In other financing news:

- **Cardima** (Fremont, California), developer of the Revelation Tx and Helix microcatheter systems for treating atrial fibrillation (AF), has completed a private placement of 4.36 million shares of common stock to select accredited investors at a price of about 75 cents per share. The private placement also included the issuance of warrants to purchase up to an aggregate of about 2.4 million additional shares of common stock at an exercise price of approximately 82 cents per share. Net proceeds to the company were about \$3 million.

Gabriel Vegh, CEO of Cardima, said the funding "will allow us to focus on efforts to bring a potential cure for AF to the U.S. market. As we have stated previously, our PMA

See Financings, Page 3

MEDICAL DEVICE DAILY™ (ISSN# 1541-0617) is published every business day by American Health Consultants®, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. BBI® and MEDICAL DEVICE DAILY™ are trademarks of American Health Consultants®, a Thomson Healthcare Company. Copyright © 2003 American Health Consultants®. All Rights Reserved. No part of this publication may be reproduced without the written consent of American Health Consultants®. (GST Registration Number R128870672)

ATLANTA NEWSROOM: Executive Editor: **Jim Stommen**. Managing Editor: **Don Long**.
Staff Writers: **Holland Johnson, Karen Young**.
Washington Editor: **Kevin New**.

BUSINESS OFFICE: Vice President/Group Publisher: **Donald R. Johnston**.
Marketing Manager: **Chris Walker**.
Account Representative: **Steve Roberts**.

REPRINTS: For photocopy rights or reprints, please call our reprints department at (404) 262-5479.

SUBSCRIBER INFORMATION
Please call (800) 688-2421 to subscribe or if you have fax transmission problems. Outside U.S. and Canada, call (404) 262-5476. Our customer service hours are 8:30 a.m. to 6:00 p.m. EST.

EDITORIAL
Don Long, (404) 262-5539
Fax: (404) 814-0759

VP/GROUP PUBLISHER
Donald R. Johnston, (404) 262-5439

INTERNET
www.medicaldevicedaily.com

THOMSON
★
**AMERICAN HEALTH
CONSULTANTS**

*Court report***Embattled Polymedica okays
FBI interviews of employees****A Medical Device Daily Staff Report**

PolyMedica (Woburn, Massachusetts), known for its Liberty diabetes products advertised on television, said it has reached an agreement with the U.S. Attorney's Office for the Southern District of Florida to allow the government to interview the employees of its Liberty subsidiaries directly. The company, which is a target of criminal and civil inquiries by federal agencies and the U.S. Attorney's office for the Southern District of Florida, called this move "an unusual step."

Samuel Shanaman, lead director and interim CEO, called the interview approvals "a very positive development" and does not imply a widening of the investigation. "These interviews are the anticipated next logical step in the government's investigation. PolyMedica representatives met recently with government investigators in order to identify ways in which we could speed up the investigation and resolve it at the earliest possible time."

The company said it held meetings with its employees to explain the agreement and has urged cooperation with the government agencies. Shanaman sent a letter to employees, in which he said, "If you are contacted, it is our strong desire that you fully cooperate with the federal investigators and that, if you agree to meet with them, you answer their questions completely and truthfully." He also said the FBI could issue grand jury subpoenas.

Alleged abuses include healthcare fraud within the government's Medicare program, including improper revenue recognition, and obstruction of justice.

In other legal activity:

- Laser developer **SurgiLight** (Orlando, Florida) said that it plans an aggressive defense against a lawsuit filed by Merrill Lynch over a \$500,000 credit line previously granted to the company, declared by Merrill Lynch as in default. SurgiLight said that terms of a \$10 million credit line issued by another lending source had been finalized and a commitment letter issued. The company said it will repay the Merrill Lynch obligation in full "at the earliest possible moment after the new funding is in place" and expected, it said, within the

See Courts, Page 6

Financings

Continued from Page 2

has been accepted by the U.S. Food and Drug Administration, and the FDA has granted us an expedited review."

- **Nanosphere** (Northbrook, Illinois), a nanotechnology-based life sciences company, said it has received an additional \$5 million in third round financing, bringing the total third round to \$15 million. The company said the proceeds will provide further capital to fund the commercialization of the company's first biomolecular detection system, which will be released in the second half of 2003. Third round investors include Lurie Investments, NextGen Partners LLC and Takara Bio. Nanosphere's technology utilizes nanoparticle probes in conjunction with an integrated biomolecular detection system to provide processes for nucleic acid and protein identification.

- **New Enterprise Associates** (NEA; Baltimore, Maryland) has invested \$15 million in **lomai** (Gaithersburg, Maryland), a privately held biopharmaceutical company focused on Transcutaneous Immunization (TCI) delivering improved vaccines using a patch.

NEA was a new investor, co-leading the \$54 million financing round. NEA General Partner James Barrett has joined the lomai board as a result of the investment.

The capital raised in this financing will be used to move lomai's vaccines into late-stage clinical trials and to facilitate commercialization of the company's products.

lomai has pioneered the successful delivery of vaccines to the skin. Its technology allows delivery of vaccines to the skin using a patch. lomai has initially targeted a vaccine to prevent and treat influenza.

- **Ivax Diagnostics** (Miami, Florida) said its board of directors has authorized the additional repurchase of up to 1 million shares of its publicly held common stock. The company has about 27.6 million shares outstanding, of which 7.6 million are publicly held. Parent company, Ivax (also Miami) holds the remainder. These purchases will be made from time to time on the open market or in private transactions in such amounts as market conditions warrant.

Ivax Diagnostics develops diagnostic reagents, instrumentation and software in the U.S. and Italy through its three subsidiaries: Diamedix, Delta Biologicals S.r.l. and ImmunoVision. Ivax owns about 72% of Ivax Diagnostics. ■

"Bulge Bracket Capabilities With a Middle-Market Focus"

 <p>RBC Capital Markets</p> <p><small>RBC Dain Rauecher Inc.</small></p>	<ul style="list-style-type: none"> • Corporate Finance • Mergers & Acquisitions • Institutional Sales & Trading • Private Placements • Leveraged Finance • Equity Capital Markets • Private Equity • High Yield • Equity Research 	<p><small>For investment banking inquiries, contact Robert E. Johnson, Head of Healthcare Investment Banking at (415) 637-8622. For general information, go to www.rbc.com.</small></p>
--	--	--

Tenet adopts new policy for outlier payments as of Jan.1

A Medical Device Daily Staff Report

Buffeted on a variety of legal and ethical fronts, hospital operator **Tenet Healthcare** (Santa Barbara, California) reported that it is changing its policy on Medicare outlier payments.

In a letter sent to Tom Scully, administrator of the Centers for Medicare and Medicaid Services (CMS), the company said it is adopting "new approaches," including: a guarantee that the ratio of cost-to-charges (RCC) used in calculating outlier payments be based on the most recent cost report available, and elimination of the "statewide average" method of calculation. "Because these calculations are performed by a Medicare fiscal intermediary, not by Tenet, Tenet representatives are working with representatives from the fiscal intermediary to ensure the changes become effective immediately," the company's president, Trevor Fetter, said in a statement.

Tenet estimates that by adopting these policy changes, outlier payments to its hospitals will drop from about \$65 million per month to about \$8 million per month, "consistent with assumptions used by Tenet in forecasts it gave to investors early last month for both its fiscal 2003 and fiscal 2004 results." It said it would report 2Q results on Jan. 13.

Tenet acknowledged what it called CMS's "public dissatisfaction" with the organization's current method of calculating the outlier payment formula, specifically the use of historical cost reports to determine a hospital's RCC and use of a "statewide average" default producing significantly higher outlier payments.

Not incidentally, Tenet also was hit last week with an administrative subpoena from the Justice Department, related to the outlier payments.

Tenet said that it was volunteering to adopt the new policy changes "as a show of good faith to the agency, based on the company's conjecture that these changes may be central components in any rule change CMS makes."

Fetter said that Tenet continues to believe that its hospitals properly followed the existing rules regarding outlier payments and that the larger payments to Tenet hospitals was the result of "formulaic rules combined with increases in hospitals' gross charges."

In related news, dissident shareholders said that they are calling on the federal government to widen its investigation of Tenet. It is asking the Securities and Exchange Commission to review the company's SEC filings, charging that the company's audit committee failed to meet the definition of "independence" under New York Stock Exchange rules. ■

BRIEFLY NOTED

Group to set 'bar coding consensus'

A group named the **Industry Coalition on Patient Safety (ICPS)** has been formed by the **Healthcare Distribution Management Association (HDMA; Reston, Virginia)**. HDMA said that the ICPS was formed to be "a cross-sectional representation of the entire healthcare system" and that its formation comes "in response to the FDA's forthcoming regulation on bedside barcode scanning in hospitals." The group recently held its first meeting and set its primary goal as developing a consensus "on bar coding recommendations to present to the FDA that will noticeably improve patient safety, while causing the least amount of interference with current business processes and allowing for the future growth of healthcare industry technologies."

HDMA also said it hopes to continue its work with the ICPS to focus on broader healthcare distribution issues affecting the industry. The initial meeting saw representation from 25 organizations, including branded and generic manufacturers, distributors, hospitals, GPOs, pharmacies, representative associations for various industry sectors and business communication standards organizations, HDMA said. Bill Hubbard, senior associate commissioner of the FDA's office of policy, planning and legislation, spoke at the meeting to highlight the FDA's position on the barcoding issue and to communicate the status of the pending regulation.

"HDMA believes that by forming the ICPS, we are creating a valuable opportunity for the healthcare industry and government to collaborate," said Ronald Streck, HDMA's president and CEO. "Because the ICPS has representation of every member of the supply chain, we believe that it will take a lead in fostering change in the healthcare industry that will streamline costs and provide better overall healthcare for patients."

HDMA said it would draft recommendations to be reviewed and then submitted to the FDA for review during its open comment period. ■

**Med-tech news . . . and
a whole lot more!**

medicaldevicedaily.com

Coatings

Continued from Page 1

stent makers **Boston Scientific** (Natick, Massachusetts) and **Cook** (Bloomington, Indiana) have played in bringing Angiotech to the threshold of financial break-even, Hunter noted that investors should think of the firm as a “device coatings company.”

Even though the drug-coated stent sector is the hottest thing going in the medical technology arena, he pointed out the much broader potential for the device market overall, pegging it at \$180 billion in the U.S., with some 280 million implants done worldwide each year.

That’s the market Angiotech is looking at, believing it can replicate the clinical success its coatings have realized in the coronary stent space in various other sectors. “We feel the device industry has plateaued, as far as engineering is concerned,” Hunter said, and that drug coatings represent “the next wave of innovation for companies that want to differentiate their products” from those of their competitors.”

Saying that “many device sectors are stagnant,” Hunter noted Angiotech believes it can “grow those markets” through application of its paclitaxel coatings.

He used what has happened with stents as an economic model of what is possible in other device sectors, noting that coating stents – and the clinical benefits that have ensued – has allowed application of “premium pricing,” for instance raising reimbursement for stents from \$1,100, as a bare-stent model, to \$3,000 with a drug coating. Addition of such coatings “has seen us start to change the dynamic of the entire market,” Hunter said.

As an example of replicating its success in coating coronary stents, he cited Angiotech’s efforts in the vascular arena, where it has developed a paclitaxel “Saran Wrap” to go around arteries.

That product, licensed to **C.R. Bard** (Murray Hill, New Jersey), has been shown to reduce restenosis in peripheral arteries by as much as 85% in animal testing. He said it will go into the clinic toward the end of this year.

Hunter also cited Angiotech’s planned acquisition of **Cohesion Technologies** (Palo Alto, California), announced two months ago and anticipated to close by the end of this month or early in February. He said that Cohesion’s CoStasis and CoSeal products are a great fit with his company’s technology, with numerous new applications possible after the companies come together.

Touching only briefly on the litigation brought by Boston Scientific against Cook in its effort to ally with **Guidant** (Indianapolis, Indiana) in the coated-stent area, Hunter cited the “18-month legal battle” preceding last week’s decision by Guidant to pull the plug on its plan to

acquire Cook.

Noting that Guidant had cited less-than-satisfactory results from the DELIVER trial using the Achieve stent as a key reason for not proceeding with the acquisition, he suggested that more than the single dose of paclitaxel that was used in that trial should have been tried. Hunter had said earlier that one point that has come out of the various trials being conducted by Boston Scientific and Cook is that “dosage is very important.”

Despite the fact that **Johnson & Johnson’s Cordis** division (Miami Lakes, Florida) is seen as having a substantial lead in getting a coated stent on the market in the U.S.,

Hunter said Boston Sci and Cook will benefit from much broader clinical trial results, with an eventual total of some 7,500 patients being enrolled in studies conducted by the two companies.

Boston Scientific in particular will be “one of two players in a very dynamic market,” he said. ■

PEOPLE IN PLACES

- Jeffrey Williams has been named executive vice president and general manager of **Ambion RNA Diagnostics**, a division of **Ambion** (Austin, Texas). Williams has held several senior level positions in R&D, operations and corporate management, most recently as vice president and U.S. site manager for Roche Diagnostics. Ambion is a leader in the development and supply of RNA-based life science research and molecular diagnostic products.

- Gordon Troup has been named executive vice president and president of the **Nuclear Pharmacy Services** business of **Cardinal Health** (Dublin, Ohio). Additionally, Mark Parrish has been named executive vice president and group president of Pharmaceutical Distribution and Robert Storch, president of Medicine Shoppe International.

Troup recently served as executive vice president and group president of Pharmaceutical Distribution. Parrish previously served as president of Medicine Shoppe International. Storch joined Cardinal Health in early 2002 as vice president of Pharmacy Initiatives. Cardinal Health is a provider of products and services supporting healthcare.

- Scott Kantor has been promoted from vice president and corporate controller to vice president, finance, and chief financial officer for **LeCroy** (Chestnut Ridge, New York), effective Feb. 1. LeCroy is a supplier of high-performance digital oscilloscopes. The company core competency for the analysis of complex electronic signals is called WaveShape Analysis.

Medicare

Continued from Page 1

would receive cash rebates or lower premiums if the plan keeps costs down, according to White House officials.

The Federal Employees Health Benefits Program is a model both Bush and Frist favor, according to administration officials. Under that program, the government contributes a set amount per employee, and individuals who want more expensive plans pay more.

Critics say the proposals won't work. Most significantly, many say that beneficiaries can't afford any increases in premiums. Vicki Gottlich, an attorney with the **Center for Medicare Advocacy** (Willimantic, Connecticut), says the proposed changes would harm beneficiaries. "It could shift costs to individual beneficiaries so that people with the greatest medical needs pay the most for their health care," she warned.

Any proposed changes could likely include parts of a demonstration project CMS is conducting in Florida. **United Healthcare** (Minnetonka, Minnesota), a private insurer, started the project Jan. 1 in five counties: Hernando, Hillsborough, Lee, Pasco and Pinellas. The project includes the cities of St. Petersburg, Tampa, and Fort Myers. About 550,000 Medicare beneficiaries live in this five-county area, according to the **U.S. Department of Health and Human Services** (HHS; Washington).

"This demonstration program gives seniors new options for their Medicare coverage similar to that available in the private insurance market," HHS Secretary Thompson said last month in announcing the project. "Greater access and expanded options and choices in health care are key goals of this Administration."

Congress created Medicare+Choice in the Balanced Budget Act of 1997 to expand the types of healthcare options available to Medicare beneficiaries, enabling them to receive new preventive benefits and greater patient protections. Preferred provider type coverage was previously unavailable to Medicare beneficiaries.

"Whether beneficiaries enroll in a PPO or another Medicare+Choice plan, or fee-for-service Medicare, we are doing more to guarantee they understand the Medicare options available to them," CMS Administrator Tom Scully said. "The under age 65 market is rapidly flocking toward PPO products, which give patients the flexibility they need. Seniors want the same options, and this is the big first step in getting them there."

Currently, Medicare+Choice health maintenance organizations (HMOs) are available where private companies choose to offer them. About 5.6 million Medicare beneficiaries – out of a total of nearly 40 million aged and disabled Americans – have enrolled in Medicare HMOs. Original fee-for-service Medicare, available to all beneficiaries, is currently chosen by more than 34 million beneficiaries. Unlike traditional HMOs, the new options will allow beneficiaries who choose to enroll, access to services provided outside the contracted network of providers.

The demonstration program, announced last August, includes new health plans that will ultimately be available in 23 states and will expand health care options to approximately 11 million Medicare beneficiaries, according to HHS.

The demonstration plans will be considered Medicare+Choice plans and must offer all of Medicare's required benefits, but will also have the flexibility to offer additional services, including prescription drugs. The project will offer beneficiaries a wider choice of health care providers than currently offered in HMOs, according to HHS.

The **Advanced Medical Technology Association** (AdvaMed; Washington) has supported, in principle, the idea of greater competition in the Medicare environment, as a way of promoting faster uptake of new medical technologies. In one of its recent policy statements, it said: "When held accountable to consumers' choices through market competition, health plans will quickly adopt the high-quality, innovative products and services that patients need."

In the same statement it said also: "A competitive Medicare system will foster and reward innovations that improve outcomes, reduce costs and enhance patients' quality of life."

The organization has frequently indicted the Medicare system as being relatively difficult to decipher and, to consumers, extremely opaque. What is needed, it says, are "reasonable, objective coverage standards that reflect the rapid, incremental nature of technology innovation." ■

Courts

Continued from Page 3

next few weeks. The Merrill Lynch suit seeks repayment of the principal balance and certain other remedies.

SurgiLight also reported a private placement agreement for \$450,000 has been signed with a group of accredited investors, to be completed later this month. The investors will purchase, for about 29 cents each, a unit consisting of one share of SurgiLight restricted common stock and a warrant with an exercise price of 42 cents per share.

According to Colette Cozean, PhD, SurgiLight chairwoman and CEO, the Merrill Lynch action "is a surprise. They were well aware of our ongoing negotiations for the new line of credit, as well as our stated intent to repay outstanding obligations with Merrill Lynch the moment that line of credit was finalized."

• **PeachTree Clinical Research** (Fayetteville, Georgia) has filed a lawsuit against biotech company **Inhibitex** (Alpharetta, Georgia) over a contract termination. PeachTree said it is seeking more than \$221,000 from Inhibitex in the dispute, noting that 23 people were laid off as a result of the contract termination. The firm performed clinical monitoring services for Inhibitex's Veronate drug, designed to prevent staph infections in premature infants. Inhibitex has said it has fulfilled all of its financial and contractual obligations to PeachTree. ■

Deals

Continued from Page 1

Adcon Gel and Adcon Solutions are biopolymer devices designed to inhibit scarring and adhesions following surgery. Gliatech's pharmaceutical product candidates include proprietary monoclonal antibodies designed to inhibit inflammation.

Quest Diagnostics (Teterboro, New Jersey) and **Unilab** (Tarzana, California) reported that they have executed the amendment of their previously announced merger agreement under which Quest would acquire Unilab.

Additionally, Quest Diagnostics announced that it and a third party purchaser – the name undisclosed – have submitted a proposal to the Federal Trade Commission (FTC) related to the proposed divestiture of certain assets of the combined company in Northern California following the completion of the merger with Unilab. The proposed divestiture of assets in Northern California is intended to address issues raised by the FTC in its review of the Unilab transaction, which has been held up and extended several months because of that review.

The assets to be sold include the assignment of capitated contracts with independent physician associations (IPAs), as well as the leases for certain patient service centers and rapid response laboratories located throughout Northern California, the company said. The divestiture is contingent on the completion of the Unilab transaction and is subject to FTC review and approval.

As previously announced, the changes to the merger agreement reduce the value of the overall transaction by roughly \$60 million, based on the closing price of Quest Diagnostics common stock on Nov. 29, 2002. Under the amended terms of the agreement, Unilab shareholders have the right to elect either 0.3424 of a share of Quest common stock or \$19.10 in cash for each Unilab share. In the exchange offer and the merger, Quest will not issue more than 8.5 million shares (including shares reserved for options outstanding at the consummation of the merger) or pay more than \$297 million in cash.

Based on these amounts, up to about 42% of the outstanding Unilab shares may be exchanged for cash, and up to about 66% of the outstanding Unilab shares may be converted into Quest Diagnostics shares. In addition, the termination date of the merger agreement was extended from Nov. 30, 2002 to Jan. 31, 2003. The companies said they hope to complete the exchange offer by the Jan. 31 date.

Unilab says it is the largest provider of clinical laboratory testing services in California, and Quest bills itself as the nation's leading provider of diagnostic testing, information and services.

In other dealmaking activity:

• **Quinton Cardiology** (Bothell, Washington) reported that it has closed on the previously announced acquisition of **Burdick** (Deerfield, Wisconsin), a cardiology business subsidiary of the Spacelabs Medical division of

Instrumentarium for \$24 million (*MDD*, Dec. 27, 2002), subject to a working capital-related holdback and certain post-closing adjustments, Quinton said. Quinton funded the purchase with about \$20 million in cash remaining from its May 2002 initial public offering, plus a partial draw-down on a \$12 million bank credit facility.

"The acquisition of Burdick strengthens our cardiology product lines and expands our markets," said John Hinson, president of Quinton. "Burdick's strength in ECG cardiographs, Holter monitors and cardiology information systems, combined with its distribution network focused on U.S. physicians' offices, makes the company an excellent complement to Quinton's strength in cardiac stress testing and cardiac rehabilitation monitoring, as well as our hospital focused direct sales force." Burdick, with about 150 employees and had 2001 sales of about \$38.8. Quinton is a provider of cardiology solutions such as cardiac stress testing systems, cardiac rehabilitation equipment, Holter monitoring devices, ECG management systems and hemodynamic monitoring solutions. It reported FY01 sales of nearly \$43 million.

• **AmerisourceBergen** (Valley Forge, Pennsylvania) reported completing its purchase of **Bridge Medical** (Solano Beach, California), a provider of barcode-enabled point-of-care software designed to reduce medication errors and decrease costs in healthcare facilities (*MDD*, Nov. 6, 2002). The acquisition includes a base purchase price of \$27 million and contingent payments of up to \$55 million, based on Bridge's achieving certain earnings targets in 2003 and 2004. AmerisourceBergen said it expects to pay the base purchase price and any contingent amounts primarily in shares of common stock. AmerisourceBergen said it expects the acquisition to be neutral to earnings in FY03 and accretive in FY04 after the effect of any contingent payments. Bridge Medical is a provider of patient safety solutions, including its MedPoint and InfoPoint software, and is a pioneer in the use of bar code technology.

• **Charles River Laboratories** (Wilmington, Massachusetts) reported that it has increased its ownership interest in **Charles River Japan**, a joint venture with **Ajinomoto Co.**, established in 1981 as a player in the Japanese research models market. Charles River purchased 404,321 shares of Charles River Japan for 1.3 billion yen, or \$10.4 million at current rates of exchange, increasing the company's ownership interest to 85.01%. Ajinomoto will continue to be a partner in Charles River Japan, providing administrative and other support to the joint venture. The transaction has been approved by the Japanese government, Charles River said, and the effect of the transaction will be slightly accretive to 2003 diluted earnings per share. Charles River Laboratories is a leading provider of critical research tools and integrated support services for drug discovery. The company operates 76 facilities in 16 countries worldwide. ■

Europe

Continued from Page 1

An estimated 400,000 routine electrophysiology diagnostic and ablation studies are performed in the U.S. each year, and up to 25% can require the placement of a catheter through the atrial septum, a procedure that consists of a long needle puncturing the central wall of the heart. "With the detailed information that the ViewMate provides, this procedure can be performed with increased safety, efficiency and speed, EP Medsystems said.

ViewMate also has the ability to assist with less-invasive cardiac surgeries and pacemaker lead extraction, allowing cardiologists and electrophysiologists to visualize internal heart structures and perform these types of procedures with greater clinical confidence and ease. According to the company, "The ViewMate intracardiac ultrasound system replaces older transesophageal echocardiography (TEE) technology by offering improved intracardiac images and eliminating the need for high levels of sedation or anesthesia typically needed for TEE procedures. The ViewMate console also has a small footprint, taking up little space in the EP/cath lab or the operating room."

EP MedSystems product line includes the EP-WorkMate Electrophysiology Workstation, the ALERT internal cardioversion system, the EP-3 Stimulator, diagnostic electrophysiology catheters, internal cardioversion catheters and related disposable supplies.

French Chinese in HIV immunotherapy effort

A team of Chinese and French researchers has shown success in treating rhesus macaques infected with the simian immunodeficiency virus (SIV) with a novel type of immunotherapy. The scientists, working in Paris, plan to begin a clinical trial to treat patients infected with HIV using the same approach in early 2003.

Louis Wei Lu, chief investigator at the Saints-Peres Biomedical Center in Paris, told *Medical Device Daily's* sister publication *BioWorld International*, "We are tremendously excited about the macaque study. This discovery is very important for those with HIV and AIDS. It is also extremely important for all those suffering from chronic viral infections, such as hepatitis B, and infections with intracellular pathogens, such as *Mycobacterium tuberculosis*, because we believe that it will be possible to generalize this technique to treat these types of infections."

Wei Lu's group had the idea of stimulating dendritic cells (differentiated *in vitro* from peripheral blood monocytes) with inactivated virus. Virus can be inactivated with AT-2, a chemical that wipes out the virus' ability to replicate, without altering the conformation of its proteins in any way. The group had already shown that, *in vitro*, dendritic cells that had been exposed to HIV, which had been

inactivated, with AT-2 could stimulate potent antiviral cytotoxic T lymphocytes.

For their latest study, the group isolated dendritic cells from 10 SIV-infected monkeys. In the laboratory, they added to these cells that had been inactivated with AT-2. Next, they infused back into each animal its own treated cells. The animals received five subcutaneous injections at two-week intervals.

Wei Lu said, "Just five weeks after the first immunization, we saw in the 10 vaccinated animals a 1000-fold drop in plasma SIV RNA, and a 50-fold drop of blood cellular SIV DNA, coupled with a peak increase of circulating anti-SIV cytotoxic T lymphocytes. The blood CD4 count increased significantly from week 13, and neutralizing antibodies appeared in the bloodstream."

By contrast, in four infected but unvaccinated animals, viral load and CD4 counts remained unchanged, and there were no neutralizing antibodies during 300 days of follow-up.

The team is currently trying to find the best protocol for the immunotherapy of SIV-infected macaques, with the aim of trying to eradicate the virus from the body. "We hope we will be able to do that," Wei Lu said. "If we can, this could be a real cure for chronic infections of this type." ■

BRIEFLY NOTED

Atlas Medical moves, triples space

Atlas Medical Technologies (Ontario, California) moved to a 25,000-square-foot facility in Ontario. The new location, it said, more than triples the company's previous capacity for producing refurbished CT and MRI scanners. Atlas Medical said the move was precipitated by the heightened demand for quality pre-owned imaging equipment as a result of the budget constraints many imaging centers are facing today.

The facility is ISO compliant and is equipped with a state-certified paint booth, a service engineer training facility and sufficient power to operate five CT scanners plus three custom trailers, simultaneously. "Our relocation to larger quarters enables Atlas Medical to produce over 20 fully refurbished machines per month," said President Richard Stockton. ■

Take a walk through our archives.

medicaldevicedaily.com

PRODUCT BRIEFS

• **Affymetrix** (Santa Clara, California) reported the upcoming launch of the new GeneChip Scanner 3000, a next-generation microarray scanner about the size of a personal computer. The company said that the scanner design “lays the foundation for continued evolution of the GeneChip platform as an integrated genetic analysis system, supporting continued feature size reduction for higher resolution and greater information content of microarray-based products.” The scanner is designed to give researchers peak scanning performance for a range of applications, including RNA expression and DNA analysis. Data from the GeneChip Scanner 3000 is compatible with data from previous experiments using GeneChip arrays, as well as with other Affymetrix instruments and software, providing a seamless transition for customers. The GeneChip Scanner 3000’s worldwide commercial launch will be at the Lab Automation 2003 convention in Palm Springs, Calif., Feb. 2-4, 2003.

• **BioSurface Engineering Technologies** (BioSET; College Park, Maryland) said that it has obtained an exclusive worldwide license to a novel growth factor technology developed by scientists at the U.S. Department of Energy’s **Brookhaven National Laboratory** (Upton, New York) in collaboration with BioSET researchers. The Brookhaven-BioSET team made biologically active synthetic analogs of two growth factors, including basic fibroblast growth factor for use in wound healing and radiation protection, plus other applications. Fibroblast growth factor (FGF) refers to a family of proteins in the human body responsible for the proliferation, repair and survival of cells in many tissues, including the brain, vascular system and muscle. The new analogs developed at Brookhaven are proteins that are easier to produce than natural growth factors or growth factors derived by recombinant techniques, BioSurface said. BioSET has taken an exclusive license to Brookhaven’s bioactive analogs and improved techniques for making the analogs.

• **Given Imaging** (Atlanta, Georgia) said the Centers for Medicare and Medicaid Services (CMS) has established a code and payment rate for capsule endoscopy for the Medicare Physician Fee Schedule. The decision comes just 16 months after the M2A capsule endoscope received FDA clearance in August 2001 and should expand use of capsule endoscopy by gastroenterologists treating Medicare patients. “By establishing a code for capsule endoscopy, CMS has acknowledged the vital role that capsule endoscopy plays in diagnosing gastrointestinal disorders,” said Gavriel Meron, president and CEO of Given Imaging. “We believe this is a significant step toward making capsule endoscopy even more widely available to the physicians and patients who need it. Recently published studies show

that capsule endoscopy helps physicians diagnose gastrointestinal disorders faster and with greater precision eliminating unnecessary costs and procedures for patients.”

• **Metrika** (Sunnyvale, California) has received FDA clearance to make its AlcNow diabetes monitor available to patients over-the-counter. AlcNow is the only diabetes test for use at home to obtain immediate glycated hemoglobin (HbA1c or A1C) results, a gold-standard indicator of diabetes control and risk of complications. The disposable, pager-sized AlcNow Monitor provides quantitative A1C results in just eight minutes from a small drop of blood. AlcNow is certified by the National Glycohemoglobin Standardization Program (NGSP) and waived under the Clinical Laboratory Improvement Amendments (CLIA) – a regulatory status reserved for those diagnostic technologies deemed so simple to use that the likelihood of an erroneous result is negligible. A recent survey by the American Association of Diabetes Educators found that 75% of people with Type 2 diabetes do not know their A1C number. Studies have shown that A1C testing, previously performed only in a hospital laboratory or physician’s office, is widely underutilized.

• With the release of MedicSync, **QRS Diagnostic** (Minneapolis, Minnesota) now enables users of its Office Medic and Pocket Medic software to synchronize databases of patients’ physiological data collected with QRS computer card medical devices. The MedicSync feature synchronizes data between two different Office Medic databases or between a Pocket Medic and Office Medic database. “This new feature offers more functionality to our customers,” said CEO Spencer Lien. “For example, using our SpiroCard PC Card device with Pocket Medic on a handheld, a home care nurse can test a patient’s lung function in the patient’s home, and then synchronize that new data with an existing patient database back in their office.” Office Medic Workstation is a patient information system that complements QRS PC Card medical devices to support real-time diagnostic testing. Pocket Medic software is compatible with portable Microsoft Windows CE Handheld and Pocket PCs. With QRS PC Cards, Pocket Medic turns off-the-shelf, portable PCs into mobile medical devices.

• **SurgiLight** (Orlando, Florida), which focuses on the development of laser systems for various ophthalmic applications, reported results from the first two clinical trials previously cleared by the FDA under an Investigational Device Exemption (IDE) to test reversal of presbyopia using its OptiVision system. After one to two weeks, all of the 10 patients treated at two U.S. sites were able to read the daily newspaper without the aid of glasses, while six of the 10 showed successful accommodation – optimal overall eyesight at varying distances (increased accommodation of one to three diopters). The trials were conducted at the Weill Cornell Medical Center at New York Presbyterian Hospital and at the Las Vegas, Nevada clinic of Jon Siems.