

NxStage says 2009 good despite economic crisis

By AMANDA PEDERSEN
Medical Device Daily Staff Writer

When the ball dropped in Times Square on New Year's Eve just a little over a month ago, many companies were more than happy to bid farewell to 2009 – and the economic hardships that defined the year for so many businesses and individuals. But at least one medical device company says that very little of its business was impacted by the economic crisis and that 2009 was a continued growth year for the company.

In 2009, **NxStage** (Lawrence, Massachusetts), maker of the only FDA-cleared home hemodialysis system, experienced 205% growth from the previous year and grew about 30% in year over year revenues in the home hemodialysis market.

In fact, last May the company was recognized as the fourth largest revenue gainer in Massachusetts by the
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California biomedical industry 'holding its own' despite economy

By LYNN YOFFEE
Medical Device Daily Staff Writer

While most U.S. states and industries have been hard hit by a tough economy, nearly two-thirds (64%) of California biomedical companies have either maintained or expanded their overall workforces in the last year.

"The biomedical industry has weathered the recession with incredible resilience," said David Gollaher, president/CEO of **California Healthcare Institute** (CHI; La Jolla, California), as he presented an annual analysis of the state of the biomedical industry there on Tuesday. "Whether it can continue to do so in California is in question."

California has been, and remains, the hub of the U.S. life sciences industry. With 2,000 biomedical companies anchored there, it's home to one-third of U.S. biotech, medical device and diagnostics firms and one in six of 1.6 mil-
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International report

Staar Surgical gets Japanese approval for its Visian ICL

A *Medical Device Daily Staff Report*

Staar Surgical (Monrovia, California), a developer of minimally invasive ophthalmic products, reported regulatory approval from the Japanese Ministry of Health, Labor and Welfare (MHLW) to market the company's Visian Implantable Collamer Lens (ICL) in Japan.

Japan's MHLW approved marketing the Visian ICL for the treatment of myopia. The Japanese population is believed to suffer one of the highest rates of myopia in the world, with a much higher percentage of the population in the high myopic range than the worldwide norm. Market Scope, the industry leading ophthalmic research firm, reports that the worldwide average prevalence of myopia is 23% of the population, while the prevalence in Japan is 45%. This compares to an estimated 27% prevalence of myopia in the U.S. Over 150,000 Visian ICLs have been

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Ideal Life combines bluetooth, devices to monitor patients

By OMAR FORD
Medical Device Daily Staff Writer

Here's the scenario. A patient with congestive heart failure steps on a scale in their home while brushing their teeth. The scale detects that they've gained two pounds over night, possibly because of fluid that surrounds the heart. An instant notification goes off via a special chip that's in the scale and is transmitted wirelessly to a clinician's office. Within minutes, the clinician is in communication with the patient.

From that point, the patient is notified and the appropriate steps are made to reduce these symptoms and handle potential problems without readmission to the hospital.

The scenario depicted above is what **Ideal Life** (Toronto) is calling the "perfect union" between healthcare devices and bluetooth technology.

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*Deals roundup***Thermo Fisher agrees to acquire molecular bio company Finnzymes****A Medical Device Daily Staff Report**

Thermo Fisher Scientific (Waltham, Massachusetts) said it has signed a definitive agreement to acquire **Finnzymes** (Espoo, Finland), a provider of integrated tools for molecular biology analysis, including reagents, instruments, consumables and kits. Financial terms of the deal were not disclosed.

Finnzymes has 90 employees and generated revenue of \$20 million in 2009, the company noted.

Finnzymes provides comprehensive solutions for high-performance polymerase chain reaction (PCR), reverse transcription-PCR and real-time quantitative PCR (qPCR). The company's expertise in DNA polymerases has led to significant increases in the performance of these enzymes, making the PCR process faster and more accurate, Thermo Fisher said. The ability to quickly and reproducibly amplify and quantify particular DNA sequences benefits a variety of applications, including basic genomic research, genetic testing, forensics and food testing.

The acquisition of Finnzymes expands Thermo Fisher's portfolio of reagents and other consumables for the molecular biology research and diagnostics markets through the addition of its DNA polymerases, Phire and Phusion, and high-speed miniaturized thermal cyclers and innovative plastic tubes and plates. These products complement the recently launched Thermo Scientific Solaris qPCR gene expression assays and, together, deliver a more complete solution for customers. Combining the gene-specific MGB-based probes from Thermo Scientific with the advanced enzyme performance from Finnzymes will further enhance

Today's MDD food for med-tech thought

"I think we're seeing a trend and that patients and clinicians will move toward an application-based way of remote care. I think what we're going to see are a lot more [patient monitoring] products becoming web-enabled."

– Jason Goldberg, CEO of Ideal Life, on the value of remote patient monitoring which he predicts will see a dramatic upsurge, "Ideal Life combines bluetooth, devices to monitor patients," pp. 1, 10.

qPCR assay technology.

"The addition of Finnzymes' innovative enzyme portfolio and unique PCR instrument platform strengthens our broad range of life science reagents and consumables, as well as our specialty diagnostics product offering," said Marc Casper, president/CEO of Thermo Fisher Scientific. "This combination brings together key complementary technologies for molecular biology and diagnostics, allowing us to create significant value for our customers."

Finnzymes will be integrated primarily into Thermo Fisher Scientific's Analytical Technologies Segment, with some equipment and consumables product lines being added to the Laboratory Products and Services Segment. The transaction is expected to close during the first quarter of 2010. The company does not expect this transaction to have a material impact on its 2010 financial results.

In other dealmaking activity:

• **Medco Health Solutions** (Franklin Lakes, New Jersey) reported the acquisition of **DNA Direct** (San Francisco, California), a provider of guidance and decision support for genomic medicine to patients, providers, payors and employees. Financial terms were not disclosed.

"DNA Direct has been a recognized pioneer in assimilating knowledge about molecular diagnostic testing and

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*Restructuring roundup***SPO reduces manufacturing focuses on development****A Medical Device Daily Staff Report**

SPO Medical (Simi Valley, California) a developer of biosensor and microprocessor technologies for use in portable monitoring devices, reported it has restructured the company operations to focus primarily on licensing its core technology for non-medical market applications. A restructuring plan has now been completed which involved the reduction of the company's corporate and manufacturing workforce and a licensing agreement for the existing medical PulseOx product line. Going forward, SPO Medical will operate as a development and licensing company. These corporate changes were designed to streamline the organization and right-size the G&A and overhead structure.

Under this new structure, the PulseOx medical product

line will be marketed by **SPO Medical Systems**, a private company owned and managed by the original founder of SPO Medical, Israel Sarussi.

As per the license agreement, all worldwide sales, marketing and manufacturing of the PulseOx line has been transferred to SPO Medical Systems.

The licensee has retained much of the workforce previously employed by the company in connection with manufacture and marketing of the PulseOx medical product line. Additional details relating to the license are included in the company's report on Form 8-K that was recently filed.

During 2010, SPO Medical plans to embark on business development activities that will focus on commercial applications relating to the implementation of reflectance pulse oximetry for non-medical markets. Applications include the consumer sports watch and associated wellness devices, a baby movement monitor and various other mass-market product opportunities that could use pulse oximetry in a non-invasive, convenient manner enabling accurate and effective measurements of vital sign information. ■

Deals*Continued from Page 2*

deploying certified genetics professionals to help rationalize the opportunities and implications faced by many in this new and rapidly evolving field," said David Snow Jr., Medco CEO/chairman.

By integrating DNA Direct's physician, client and patient support services and capabilities with Medco's growing portfolio of personalized medicine capabilities and extensive customer base, Medco intends to deliver a broader suite of precision health services, ranging from consumer education to clinical decision support.

- **National Health Investors** (NHI; Murfreesboro, Tennessee) said it has completed its purchase of six Florida skilled nursing facilities from **Care Foundation of America** (CFA; also Murfreesboro) for \$67 million.

The facilities are leased to affiliates of Health Services Management for \$6.2 million annually, plus a 3% escalator starting at the beginning of the third lease year. The lease expires in 2014 and the tenant has a three-year optional renewal term. The facilities total 780 beds and have been part of NHI's mortgage loan portfolio for 16 years. The purchase resulted in the dismissal of pending litigation between NHI and CFA. The earnings before interest, taxes, depreciation, amortization and rents for these facilities for the trailing twelve months ended Nov. 30, 2009 totaled \$10.6 million and provides a lease coverage ratio of 1.71. NHI will fund the purchase with the full satisfaction of the \$23.3 million in principal and interest on a mortgage note due to NHI from CFA, \$29.7 million in cash deposits and \$14 million in advances from NHI's revolving credit facility.

- **Gentag** (Washington) and **The Core Institute** (Sun City West, Arizona) reported a license agreement to

develop and sell a disposable wireless skin patch to allow patients to self monitor themselves at home after orthopedic surgery in hospitals through the use of cell phones. The technology will help reduce post-orthopedic surgical-related medical costs by reducing the time spent in hospitals and detecting possible problems much earlier with less pain and risk, and costing much less than existing technology, the companies said.

The technology combines advanced MEMS sensors and Gentag's disposable wireless platform sensor that is directly compatible with cell phones integrating standard NFC-ISO 15693 hybrid reader chip technology. Such cell phones include the iPhone via a soon-to-be released RFID retrofit, thereby ensuring broad access by consumers to the technology, the companies noted. Clinical trials are expected to begin in 2010.

- **Amedisys** (Baton Rouge, Louisiana) said it has acquired **De Queen Home Health Agency** (De Queen, Arkansas). The acquisition will expand Amedisys' coverage to all or part of eight new counties, bringing our total coverage of Arkansas to 32 counties. De Queen had annualized revenue of \$2.9 million, but is not expected to add materially to Amedisys earnings in 2010. ■

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Washington roundup

Warning to ELA for ICDs may be tied to cleaning validation

By MARK McCARTY

Medical Device Daily Washington Editor

The Nov. 6, 2009, warning letter to **Sorin Biomedica** (Saluggia, Italy) and its subsidiary **ELA Medical** (Paris) was the second in eight days, coming on the heels of an Oct. 29, 2009, warning (*Medical Device Daily*, Dec. 10, 2009). As was the case with the earlier warning, the latest letter to the firms dealt largely with medical device reports, although the November letter also took issue with the company's operational qualification of equipment that was apparently used to sterilize the Ovatio line of implantable cardioverter defibrillators.

In the only citation relating to good manufacturing practices (GMPs), FDA cited the firms for a validation study of a sterilizer unit that led the agency to conclude that "the cleaning process is not capable and . . . was not validated with a high degree of assurance." The warning letter states that the operational qualification of the sterilizer, a description of which was purged from the letter, failed to "conform with the expected result," a quote attributed to the company's validation report.

All the same, the firms conducted a risk analysis and concluded the likelihood of any untoward consequences of suboptimal sterilization on the ability of the device to function properly was "improbable" or "incredible," according to the warning letter.

FDA also notes in the warning letter that employees at the plant, located in Montrouge, France, routinely performed visual inspections "after cleaning on all hybrid modules." However, the agency said that the proposed correction for this finding was lacking because the July 10, 2009, response "did not contain documentation showing implementation of the correction."

The balance of the warning letter deals with medical device reports, a remarkably persistent theme in warning letters across at least the past decade. In addressing an MDR for a patient in France who received the Ovatio model 6750, the warning letter informs the firms that MDRs filed in other nations regarding any device that is marketed in the U.S. must be filed with FDA. As was the case with the earlier warning letter, FDA argued that adverse events occurring in other countries "could have a significant bearing on our ability to recognize and act upon" an impending health issue in the U.S.

FDA also cited the firms for failure to disclose all information in their possession regarding two adverse events, although the warning letter offers no details about the two events other than to note that both events were resolved by the use of external shock.

At press time, ELA had not responded to a call for comment.

OST required to hire GMP consultant

The Jan. 27 warning letter to **OST Medical** (Warwick, Rhode Island) was short on details, but FDA's New England district director, John Marzilli, sent a clear signal to OST to get its operations in order by mandating that the manufacturer of enteral feeding pumps obtain outside certification of compliance with the quality systems regulations (QSRs). The agency's move was apparently prompted by what the warning letter describes as "ongoing systemic violations in the quality management system" in place at OST's plant in Warwick.

While it is not clear what previous issues the agency might be referring to, FDA issued OST a July 19, 2004, warning letter dealing largely with distribution of feeding pumps with changes to the design for which the firm did not obtain a 510(k). In a subsequent passage, the letter states that OST "may wish to contact the recall coordinator" at FDA in connection with "product in commercial distribution," adding that it is "necessary to take action on this matter now." The warning does not specify the reason behind the withdrawal of the unnamed product.

The warning letter from 2004 also notes problems related to contract manufacture of the Sentinel feeding pump, including issues related to transfer of the original design to the contractor.

The more recent of the two warning letters suggests that OST has yet to master the contract manufacturing labyrinth. FDA states that OST "has not performed testing for three out of four incoming lots received" from an unnamed supplier of disposable feeding delivery sets, and had received delivery sets from a supplier that was not on OST's approved supplier list. The problem with unapproved suppliers extended to product labels for the Sentinel, a situation FDA said led to reports of labels "smudging and chipping off."

The warning letter also notes deviations from QSRs in the areas of device history records and complaint handling, with the latter problem feeding two citations. One of these two citations states that OST had no procedure that described "the review of service calls for potential complaints," and the other that the firm closed six complaint files without documenting any investigations into the complaints. FDA also states that the company had no documentation that it had validated a correction in response to a complaint; that a complaint was "verified and closed by a person who was not employed" by OST; and that two complaints opened in 2008 had yet to be closed at the time of the November-December inspection.

OST did not return a call for comment.

Surgical gowns still on FDA radar screen

FDA's keen focus on sterility as part of its push for safety continues with another warning letter to a maker of surgical gowns and other such items. In this instance, the

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Washington

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target of a Jan. 19 warning letter is **Crown Health Care Laundry Services** (Pensacola, Florida). Crown battled slightly better than .500 with its responses to the 11 findings listed in the warning letter, but FDA promised to double-check the adequacy of those successful responses in a future inspection.

The warning letter states that two recent audits of the company's quality system were conducted by the company's quality assurance manager rather than by a disinterested third party, and FDA found adequate the company's response, which the warning letter did not describe.

A highly conspicuous finding for a firm in this line of work was one that cited Crown for failure to validate "with a high degree of assurance" the cleaning and drying processes used on operating room towels and sheets. The company's response to this finding was not described, but FDA states that the response did not measure up because "cleaning and drying processes, along with sterilization, would be considered parts of the total manufacturing process." All the same, the agency states that the information included in the firm's response "will be verified along with [standard operating procedures] and associated process validation data" in a future inspection.

The warning letter indicates that Crown came up with the right answer for six of the 11 citations, including a citation for failure to document the disposition of non-conforming product, which either went back for rework or were used as rags.

Crown did not respond to a call for comment.

FDA announces pediatric workshop

FDA's new emphasis on workshops continues in force with the announcement in yesterday's edition of the *Federal Register* that it will hold a workshop dealing with assessments of neurological responses to cardiovascular devices in pediatric patients.

The March 25 workshop will commence at 8:00 a.m. at the agency's new campus in White Oak, Maryland, and FDA reminds attendees to leave time for passage through the security check-in, which will commence at 7:30. The *FR* notice states that prior registration is required but that seating is on a first-come-first-serve basis with preference given to those involved in clinical trials, healthcare professionals and patient advocates. The results of the session will go toward the drafting of a guidance on those measures.

CMS announces additions to NOPR

The Centers for Medicare & Medicaid Services has reported a number of additions to the facilities that are participating in the National Oncology PET Registry (NOPR), bringing in at least 70 facilities since the end of January. Among the facilities are **Athens Cancer Center** (Athens,

Ohio) and a facility located in the metro Atlanta area, **Gwinnett Medical Center** (Lawrenceville, Georgia).

The NOPR serves as a clearinghouse for patient data for the use of f-18 fluorodeoxyglucose positron emission tomography (FDG-PET) in conditions not currently covered by Medicare. According to the NOPR web site, the group's database boasts information on more than 100,000 patients collected since 2006. ■

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Court report

Collectricon files patent suit against Fluxion Biosciences

A Medical Device Daily Staff Report

Fluxion Biosciences (South San Francisco, California) said that a lawsuit alleging patent infringement has been filed against it in the U.S. District Court of Northern California by **Collectricon** (Gothenburg, Sweden), its competitor in the field of automated ion channel screening systems for drug discovery.

Collectricon has asserted U.S. Patents Nos. 7,390,650, 7,470,518, and 7,563,614 in the litigation, as well as U.S. Patent No. 5,376,252, which is owned by **Gyros** and licensed to Collectricon. Fluxion says it believes the lawsuit is without merit and that its IonFlux automated patch clamp system does not infringe the asserted patents. Fluxion said it intends to defend this lawsuit vigorously.

"Fluxion has invested considerable time and resources to develop its own intellectual property position for cell-based screening systems, and we respect the intellectual property rights of others," said Fluxion CEO Jeff Jensen. "Collectricon's claim of patent infringement is a baseless attempt to block Fluxion's penetration and growth in the ion channel screening market."

Annelie Persson, Collectricon CEO, said the company has an "extensive intellectual property portfolio with novel cell-based screening technologies based on 15 years of world-renowned research."

"To ensure a fair return on our research and development efforts we must protect our intellectual property and we will take all necessary steps to prevent its unauthorized use," Persson said. ■

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*Agreements/contracts***NeoMatrix awarded agreement for its new breast cancer test****A Medical Device Daily Staff Report**

NeoMatrix (Irvine, California) has been awarded a new technology agreement by **Novation** which includes the Halo Console, Halo Cart, Halo Patient Interface Cassette and Halo Specimen Collection Cups.

The agreements between NeoMatrix and Novation are effective Feb. 1, 2010-Jan. 31, 2013. The contracts will have an initial three-year term with two one-year extension options, with firm pricing for the initial term.

"We are quite proud of being awarded this new technology agreement and look forward to a long-term, mutually beneficial partnership with Novation," said John Stroh, CEO/director of NeoMatrix. "We consider this contract to be a sign of the dedication of NeoMatrix to improving the breast health of women across the country."

Based on the same science as the PAP test for cervical cell changes, Halo is the only FDA-cleared risk assessment tool for non-hereditary breast cancer.

In other agreements/contracts news:

- **Camstar Systems** (Charlotte, North Carolina) reported that **Terumo Cardiovascular Systems** (Ann Arbor, Michigan) has selected the Camstar Enterprise Platform to support continuous improvement, and to ensure consistent process enforcement and top product quality across the enterprise. The multi-site deployment of Camstar's integrated enterprise Manufacturing Execution, Quality Management – including Corrective and Preventive Action, Event Management and Nonconformance Management – and Manufacturing Intelligence capabilities, will help close the loop on manufacturing and quality processes.

- **Premier Purchasing Partners** (Charlotte, North Carolina) said an agreement for purchasing cards and electronic payables has been awarded to **PNC Bank National Association** (Lutherville, Maryland). Effective Nov. 1, 2009, the agreement is available to acute care and continuum of care members of the Premier healthcare alliance. Also, **Banner Health** (Phoenix) is expanding its relationship with the Premier healthcare alliance to include Premier's OperationsAdvisor web-based labor benchmarking solution. All 22 hospitals in the Phoenix-based healthcare system will use OA, part of Premier's LaborConnect program, to better manage labor costs while improving quality and safety.

- **Capario** (Santa Ana, California), a provider of revenue cycle management solutions that connect healthcare payers and providers nationwide, reported partnerships with two vendor organizations, **AdminHealth** (Miami) and **EHR Live** (West Palm Beach). AdminHealth will use Capario's revenue cycle management portal, including real-time eligibility verification, electronic claims adjudication and electronic remittance advice. EHR Live will also use

Capario's real-time eligibility and claims management technology to complement its EHR product set.

- **California Stem Cell** (CSC; Cambridge, Massachusetts) and **ALS Therapy Development Institute** (ALS TDI; Irvine, California) have extended and expanded a collaboration aimed at advancing a potential stem cell therapy for amyotrophic lateral sclerosis (ALS). This effort will build on work that has already been completed as part of this ongoing partnership to understand how stem cells, and their derivatives, may be applied to treatment of this fatal neurodegenerative disease. In this round of experiments, ALS TDI will use a CSC high-purity line of stem cells, called MotorGraft, to deliver gene expression modifying payloads to specific locations within the central nervous system. The Institute's Knowledgesphere, a database of information on gene and protein expression changes related to disease, contains several gene candidates to transfect into stem cells and deliver into the body. The initial phase of this new collaboration will confirm the expression of these genes in vivo. Once expression is confirmed, the collaborators will initiate the second phase of this new collaboration, which calls for several full efficacy experiments in order to measure for any potential ameliorating disease.

- **Click4Care** (Powell, Ohio), a provider of care management software for payers, has forged a partnership with **iWay Software**, a provider of service oriented architecture-based enterprise integration tools, to help Click4Care clients quickly and cost-effectively integrate disparate information technology systems with its care management platform. Click4Care's strategic relationship with iWay helps clients more readily design and deploy these technology-driven programs to ultimately enhance the quality of member care, improve member satisfaction, advance care coordination, and reduce clinical and administrative costs."

- **Aetna** (Pittsburgh) has signed a three-year agreement with **Grove City Medical Center**, expanding network access for its members in Western Pennsylvania's Mercer County. Under this new agreement, which takes effect Feb. 15, Aetna members will be able to receive covered services, at in-network rates, from Grove City Medical Center.

- **HealthPort** (Alpharetta, Georgia) said that **National Health Services** (NHSI), a 12-site Federally Qualified Health Center with locations throughout Kern County, California, has achieved 100% provider adoption of HealthPort's electronic medical record (EMR) technology. With high EMR failure rates and mounting national pressure to adopt electronic records, the success of NHSI bodes well for both the organization and HealthPort, their EMR partner. HealthPort boasts an industry-leading track record of successful implementation with more than 80% of EMR installations fully live and operational for one year or more. "We started with HealthPort EMR in October 2007 and have witnessed steady progress ever since," said Petrus Tjandra, director of General Services, NHSI.

- **Twin Cities Orthopedics** (TCO; Minneapolis), one of

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NxStage

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Boston Business Journal, ranked by percent change in revenue. NxStage said it was also the 111th company on the *BBJ's* overall Massachusetts Top 150 Public Companies, ranked in terms of total 2008 revenue (*Medical Device Daily*, May 26, 2009).

Jeff Burbank, CEO and founder of NxStage, told *Medical Device Daily* that because the company has a therapy that treats end stage renal disease, a chronic condition, the demand for the therapy goes on regardless of the economic backdrop. "Very little of our business was impacted" by the economic downturn, Burbank said.

Last year was marked by a number of strategic relationships and announcements for NxStage, Burbank said. In May the company reported plans to form a business alliance with **Asahi Kasei Kuraray Medical** (Japan), a company Burbank referred to as "the largest dialysis company in Asia." As part of the alliance, Asahi provided \$40 million of debt financing, which NxStage used to pay off its entire debt obligation owed under its GE credit facility.

The agreements with Asahi also leverage NxStage's production expertise in its existing dialyzer manufacturing facility in Germany and Asahi's expanded high performance polysulfone hollow-fiber membranes (*MDD*, May 20, 2009). "It's a pretty broad, far-reaching relationship," Burbank said.

Additionally, NxStage will assemble and label its dialyzers for Asahi under the Asahi name brand at NxStage's facilities in Germany. Also, under a royalty-free license, Asahi will sell the dialyzers exclusively in Asia and non-exclusively in the rest of the world. However, NxStage is retaining all its rights in North America. When Asahi desires additional capacity from NxStage, Asahi will fund the construction of a new facility to provide both companies with additional dialyzer production capacity. The new facility would be owned by Asahi and operated by NxStage.

NxStage will also license certain rights for Streamline blood tubing set technology to Asahi under similar conditions. Any improvements obtained through the combination of the dialyzer manufacturing or bloodline technologies of the two companies are to be mutually cross-licensed on similar terms.

Last year, NxStage also reported that its **Medisystems** subsidiary extended for three years a supply and distribution agreement with **Fenwal** (Lake Zurich, Illinois). Medisystems provides needle sets and assemblies to Fenwal (*MDD*, July 22, 2009).

NxStage also reported a five-year distribution agreement between Medisystems and **Gambro** (Stockholm, Sweden) in which Medisystems will supply blood tubing sets, including the ReadySet and the Streamline to Gambro. Gambro, in turn, will exclusively supply the bloodlines to certain customers for use with specific dialysis machines (*MDD*, June 18, 2009).

So far, the company says it is off to an exciting start in

2010. The company recently hired John Mullen to direct and expand additional international distribution channels (*MDD*, Jan. 20, 2010).

Also this year the company reported that 12 patients on its dialysis therapy took a Caribbean cruise together with their portable dialysis machines – something they would not have been able to do without the portability of the NxStage therapy system.

It's that portability that sets NxStage apart in the hemodialysis market, Burbank said. "At the moment, and I think for a couple more years, we're the only company that has a product cleared by FDA for home hemodialysis use," he said.

"The technology is significantly smaller, lighter, easier to learn, easier to install, you don't need to modify anything in the patient's home to do it, and it's quite safe . . . we have a wonderful track record to date on safety and performance," Burbank told *MDD*.

NxStage estimates that competition in the home hemodialysis market is at least two years out because it takes about two years to get through the regulatory process for it and as of today, the company doesn't know of any others that have started trials for it yet. But the company knows it probably won't be long before someone tries to develop a technology that would compete with NxStage. "Our competitor Baxter has said that's the direction that they're headed," Burbank said.

In the background, Burbank said NxStage has been trying to play a role in the recent tragedy in Haiti, helping to provide its portable hemodialysis machines to victims there. "Because it doesn't require a lot of infrastructure and support for these structures . . . that's a benefit of the kind of technology that we've developed here, we can do things that others have really struggled to do," Burbank said. ■

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Agreements

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the largest orthopedic practices in the U.S., has selected Indigo Identityware's physician office product, Indigo MD, as an enterprise solution for secure identity management and single sign-on.

• **Tenet Healthcare** (Dallas) reported that it signed a multi-year agreement with **MultiPlan** (New York) effective Jan. 1, 2010. The agreement includes participation in the PHCS (formerly Private Healthcare Systems) Network, the MultiPlan Network and, in select markets, PHCS Savility, which is MultiPlan's newest primary PPO network. The agreement includes all hospitals owned and operated by Tenet subsidiaries as well as Tenet's 59 freestanding diagnostic imaging centers and ambulatory surgery centers. Tenet Physicians, which contracts for the more than 400 physicians employed by various Tenet subsidiaries, also is part of the new agreement. ■

California

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lion U.S. biomedical jobs.

“Our industry has actually grown,” Gollaher said. “Biomedical company managers see future growth while large sectors of the California economy have reduced employment drastically.”

CHI, along with **PricewaterhouseCoopers** (New York), presented key findings from the *California Biomedical Industry 2010 Report*, which is based on interviews with industry leaders and a survey of the largest 200 biomedical companies conducting business in California. Some of the more interesting findings include:

- The number of direct biomedical employees grew to 273,559 in 2008, up from 271,000 in 2007 and they had an average salary of nearly \$75,000 in 2008, a figure that was unchanged from 2007. The total biomedical workforce, including indirect jobs, is 750,000.

Medical device companies lead the job growth with 111,942 employees, biopharmaceuticals employ 81,268, academic research has 43,038 employees, wholesale trade reports 31,920 employees and lab services has 5,390 employees, according to the report.

The California biomedical industry shed 2,572 jobs or less than 1% of its workforce between March 2008 and March 2009, ending the period with 272,181 jobs. During this time, the biomedical industry tied with aerospace manufacturing for the smallest percentage loss among high tech industries in California. Those biomedical job losses were primarily driven by the decline of 2,955 positions in the medical devices and wholesale trade industries, which were offset by a gain of 428 positions in academic research, biopharmaceuticals and laboratory services.

- Approximately \$3.15 billion in National Institutes of Health grants went to California’s universities and research institutes in 2008, down slightly from \$3.2 billion in 2007.

- The biomedical industry is the second highest employer in that state. Only computer and Internet-related services employ more high tech workers, but by a slim margin at 275,615 jobs.

- California life sciences companies attracted \$2.6 billion in venture capital in 2009, which was down from \$3.5 billion in 2008, but more than any other industry or any other state.

Despite this apparently rosy picture, challenges remain. The biggest: Access to capital. A majority of survey respondents, 92% of leading California biomedical employers, rank access to capital as a somewhat important or extremely important threat to the biomedical industry over the next five years.

Tracy Lefteroff, partner, Pharmaceutical/Life Sciences at PricewaterhouseCoopers, pointed out that although the biomedical industry is on the brink of a new era in discovery, particularly related to personalized medicine, venture capital fell to its lowest level in years.

“One quarter of biomedical executives think access to capital will increase while 16% think access to capital will be more difficult,” Lefteroff said. “Half of biomedical executives think there will be an increase in bankruptcies even though we haven’t seen that many historically. And even though the IPO market seems to be reawakening, less than half of those surveyed think they will be successful. Access to capital is the lifeblood and that will continue to be a major challenge to the industry.”

Add to the mix an unprecedented fiscal crisis at the state level, which dominos down to an educational funding crisis. Without continuing investments to develop new minds, Michael Drake, MD, chancellor, **University of California, Irvine**, said “We’ve had difficulty growing. Everyone knows the biomedical industry is knowledge-based. Products cycle back to improve the quality of life for people around the world. We think that it’s critically important for the state and nation to invest in people and ideas.”

Fostering the highly educated work force is a key component to keep the biomedical industry growing there, he said.

In addition to workforce development, uncertainty surrounding healthcare reform, policy and regulatory challenges, and competition from other regions are all threats to future progress.

When asked what can be done to stop the drain of manufacturing jobs to other countries, Gollaher told *Medical Device Daily*, “To keep jobs in California, the state needs to maintain tax incentives to keep biomedical manufacturing in the state. Especially important is the single sales factor.”

The single sales factor is a different way to tax companies and would reward businesses with significant investments in property and payroll in California, providing an incentive for businesses to increase their investment and employment in this western state.

Most of the biomedical companies in California do not have commercialized products yet.

“Historically, as companies expand into manufacturing, they move off shore or to other states where it’s more cost effective,” Gollaher said. “This presents a challenge to California.”

A majority of survey respondents, 72%, said corporate taxation issues are extremely important to keep the biomedical engine in California humming and 69% said tax incentives for innovation are also extremely important.

On the federal level, 89% ranked the regulatory process as being extremely important to keep biomedical research, innovation and investment in California.

With a business infrastructure facing enormous challenges, not the least of which is the issue of healthcare reform, survey respondents were still extremely optimistic. Eighty one percent expect to maintain or add jobs.

“One reason this industry is optimistic even in the face of a recessionary environment is that this industry is

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implanted worldwide since its introduction.

"Today's announcement represents the achievement of a major milestone for STAAR, and presents us with an opportunity to pursue a very attractive market for the Visian ICL," said Barry G. Caldwell, President and CEO of Staar Surgical. "The Tajimi Study, which evaluated the prevalence of myopia in Japan, reported that the prevalence of myopia was much higher in Japan than in most other parts of the world. Japan is currently the third largest refractive market and offers an opportunity for additional growth. This also represents the first approval of the Collamer lens material in Japan and hopefully this can lead to future Collamer lens approvals."

"We are very excited to introduce the Visian ICL technology in Japan," added David Bailey, President of International Operations. "Our organization has been working with the regulatory agencies for several years, and this marks the first Phakic lens approval for the Japanese market. With the Visian ICL approval, our team at Staar Japan is swiftly executing our controlled launch plan to maximize both surgeon adoption and patient satisfaction, and we currently expect to hold our first ICL Certification Course at the end of March and begin generating revenue from the product line during the first half of 2010."

Having achieved ICL approval, the company now intends to file a partial change application for approval of the Visian Toric ICL approval in Japan as soon as practicable following discussions with the Pharmaceuticals and Medical Device Agency. MHLW generally requires up to one year to fully process a partial change application, although that timeline can change based on the nature of the product under review.

Valtech Cardio completes \$17.8M 'B' round

Valtech Cardio (Or Yehuda, Israel) reported that new and existing investors (OXO Capital Valve Ventures, NGN Biomed Opportunity II, and Peregrine VC Investments II,) recently completed a Series B financing of \$17.8 million.

Valtech is engaged in development of a portfolio of minimally-invasive surgical and transcatheter mitral valve repair and replacement technologies designed to correct or significantly improve mitral valve function in ways that reduce or eliminate mitral regurgitation (MR). MR is a serious heart disorder characterized by incomplete closure of the mitral valve. The valve leakage (from the left ventricle into the left atrium), often called regurgitation, reduces the amount of blood that is pumped out of the heart during each contraction and is associated with other serious medical conditions, including atrial fibrillation. MR is believed to be the most common form of valvular heart disease.

"The enthusiastic support from our investor group provides us with the capital necessary to complete develop-

ment and initial clinical evaluation of several products designed to dramatically improve mitral valve function," said Amir Gross, founder/COO of Valtech. "The Valtech team is focused on improved annuloplasty and chordal repair technologies that will help physicians more effectively treat their patients undergoing surgical (open and minimally-invasive) and percutaneous transcatheter mitral valve repair procedures," Gross said.

Valtech is a privately held medical device company, based in Or Yehuda, Israel with a U.S. office in Waltham, Massachusetts, committed to the development and commercialization of therapies for the millions of patients afflicted with mitral valve disorders.

CMC closes on \$66.5M placement

China Medicine Corp. (CMC; Guangzhou, China) reported that it has closed the equity private placement contemplated in its stock subscription agreement dated Dec. 31, 2009 with One Equity Partners (OEP), the global private equity investment arm of JPMorgan Chase & Co.

At closing, China Medicine sold 4 million of the company's common shares at \$3 per share for \$12 million in gross proceeds and 1,920,000 of its redeemable convertible preferred shares at \$30 per share for \$57.6 million in gross proceeds resulting in aggregate net proceeds of \$66.5 million. Of the proceeds, \$57.6 million has been placed in escrow and will be released to fund additional capital expenditures and acquisition projects subject to approval from OEP and the company's board of directors. Each redeemable convertible preferred share is initially convertible into ten common shares.

"The closing of this transaction further augments our ability to execute our growth strategy. With the newly added manufacturing capabilities from the LifeTech Pharmaceuticals acquisition, we are well on our way to becoming a vertically integrated pharmaceutical company with self-manufactured products sold through our extensive distribution network," said Senshan Yang, chairman/CEO of China Medicine.

The company also reported that Ryan Shih, resident partner in OEP's Hong Kong office, has joined the company's board.

CMC is a developer, manufacturer and distributor in China of Western pharmaceuticals, traditional Chinese medicine products, other nutraceuticals, medical devices, and medical formulations.

Elbit announces restructuring of holdings

Elbit Imaging (Tel Aviv, Israel) reported that it intends to restructure its bio-tech and medical holdings (InSightec - 60%, and Gamida Cell - 28%; both on a fully diluted basis) under a wholly-owned Elbit Imaging subsidiary and to offer the shares of the subsidiary in a public offering on the Tel Aviv Stock Exchange. The move is part of the company's

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Ideal

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"We're in an exciting time in healthcare, Jason Goldberg CEO of Ideal Life told *Medical Device Daily*. "We're seeing technology play a much greater role in [how healthcare is administered]. What we've done is design medical devices that you would see in a drug store – such as blood pressure cuffs, scales, glucose monitors. We've taken these devices and implanted next generation bluetooth tech within the device."

The chip, which is actually a remote monitoring system, collects the patient's biometric data and wirelessly transmits the results via a variety of communication channels – including telephone land lines, cell phones, and the Internet – to a secure data repository where it can be read by healthcare providers, according to the company.

Ideal Life recently partnered with **Saddleback Memorial Medical Center** (Laguna Hills, California) to enable wireless remote health monitoring systems to help reduce congestive heart failure readmissions. The program was so successful that Saddleback decided to expand the model to monitor those patients with obstructive pulmonary disease.

Goldberg said that the expansion shows the impact the company was having on patients' lives with the use of the remote patient monitoring.

"In addition to the focus on the patient's home, we can even place self-serve kiosks at local communities and senior centers to enable large scale community connectivity between patients, physicians and hospitals," he said.

Plans call for there to be further outreach and expand on connectivity offerings. To date, the company serves many other institutions throughout the U.S.

"We serve other clients in addition to [Saddleback Memorial] and most groups tend to start with congestive heart failure or with diabetes," Goldberg told *MDD*. "But we offer our services across the board, no matter the disease state."

Goldberg said that the company would only continue to grow its product offerings in the healthcare field and that there doesn't seem to be a stopping point on the horizon in this particular market.

Part of this is because hospitals are more prone now to look for patient remote monitoring opportunities, because if done correctly it can severely reduce readmission into hospitals – a key point in upcoming healthcare reform initiatives.

A recent healthcare proposal is calling for the government to slash Medicare payments to facilities that readmit patients within a specific time period – to encourage hospitals to operate at greater efficiency.

According to statistics from the **American Hospital Association** (Dallas), these new regulations are slated to raise cost to hospitals an estimated \$19 billion over 10 years.

He added that most hospitals were putting themselves in a position to look toward the future, which includes a slightly different way to view how patient data is gathered.

"I think we're seeing a trend and that patients and clinicians will move toward an application-based way of remote care," Goldberg said. "I think what we're going to see are a lot more [patient monitoring] products becoming web-enabled." ■

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young," he said. "At the same time, the markets for medical devices and drugs are growing because the world population is aging and is more in need of the products this industry makes."

George Scangos, chairman of CHI, and president/CEO of the biotech firm **Exelixis** (San Francisco) and part of the panel that presented the report findings, admitted that the industry has been weakened by the current financial climate and said the state's attempt to save money is short sighted.

"We're not asking for a hand out or TARP money, but for an environment in California that allows us to grow our company to keep and increase our competitiveness," he said. ■

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ongoing restructuring and the streamlining of business activities throughout its divisions.

"As part of the company's restructuring, we intend to restructure our medical and bio-tech holdings, InSightec and Gamida Cell, under one wholly owned subsidiary. We intend to use the IPO's proceeds, should such be executed, to accelerate InSightec's development of several applications to treat major cancer diseases such as including, bone, prostate, breast, liver and brain," said Dudi Machluf, co-CEO of the company. "This will help InSightec to take rapid strides towards receiving both FDA and CE approvals for these cancer treatment technologies as well accelerating its efforts to obtain widely spread reimbursement coverage for its FDA and CE commercially treatment for uterine fibroids. Additionally, the IPO proceeds will help accelerate the FDA approval process for Gamida Cell's flagship product, StemEx, which is currently in Phase III testing, as well as advance the product development of additional therapies." ■

People in the News

- **BioClinica** (Newton, Pennsylvania) has named Robert Sammis as the new VP of finance for the company's eClinical Division. Sammis most recently was GM of U.S. operations for unithink. BioClinica is a provider of clinical trial services.

- **Fibrocell Science** (Exton, Pennsylvania) said that David Pernock, chairman of the board, has been named CEO of the company. Pernock most recently was Senior VP, Pharmaceuticals, Vaccines (Biologics), Oncology, Acute Care and HIV at GlaxoSmithKline. Pernock joined Fibrocell's board last September. Fibrocell Science specializes in regenerative cell therapy for aesthetic, medical, and scientific applications.

- **NextBio** (Cupertino, California) has named Kevin Cronin as VP of sales. Cronin was most recently the Senior VP of sales at Symyx Technologies. NextBio makes a platform that enables life science researchers to search, discover, and share knowledge locked within public and proprietary data.

- **Predictive Biosciences** (Lexington, Massachusetts) has named Kim Blickenstaff as the seventh member of the company's board. Blickenstaff is currently president/CEO

of Tandem Diabetes Care. Predictive Biosciences makes cancer diagnostic products.

- **RedBrick Health** (Minneapolis) has named Gregg Waldon as CFO and Glen Gunderson as chief business officer. Waldon previously was senior VP/CFO, secretary and treasurer for SoftBrands. Gunderson was VP of strategic business development at Life Time Fitness. RedBrick Health provides the Health Earnings System that replaces or turns around the performance of traditional health and wellness programs.

- **Synectic Medical Product Development** (Milford, Connecticut) reported the promotion of Adam Lehman to VP/COO. Lehman was most recently the director of engineering and manufacturing operations and has been with Synectic since 2004. In addition, Rick Granger, former President of Covidien's Valleylab Division, who was named as Synectic's Interim CEO last year has stepped down from that position but retained his position as a board member. Synectic makes catheter based delivery systems and minimally invasive surgical devices for orthopedic, cardiac, gynecological/urological, neurological, general surgery, as well as consumer healthcare products.

- **VSP Global** (Rancho Cordova, California) named Donald Ball as its CFO. Most recently, Ball was senior VP/CFO of Raley's grocery store chain. VSP Global makes eyecare and eyewear products.

Product Briefs

- **ConforMIS** (Burlington, Massachusetts) said that Leisure Yu, MD, an orthopedic surgeon at Loma Linda University Medical Center in California, is performing surgery with the iUni and iDuo, the company's personalized uni-compartmental and bicompartamental knee resurfacing implants. The implants are designed as a bone-sparing alternative to traditional total knee replacement in patients whose arthritic damage is limited to just one or two compartments of the knee. The implants resurface only the affected areas, preserving far more bone on both the femur and tibia than traditional total knee replacement surgery. It also preserves the patient's ligaments, helping to maintain a more natural feeling knee, and it safeguards options for future surgical procedures. The implants are made using a computer modeling system and software to extract individual and atomic information from CT or MR images. This 'image-to-implant' technology provides a 3-D image of the knee which is used to design and manufacture a personalized implant that conforms to the exact shape and size of the individual patient. Because of its precise size and shape, a ConforMIS implant reduces the need for tissue resection and preserves more of a patient's natural anatomy.

- **GE Healthcare** (Chalfont St. Giles, UK) said that it has

expanded its portfolio of ecomagination products aimed at helping healthcare companies and hospitals reduce cost and waste while positively impacting the environment. The GE ecomagination portfolio of more than 85 products now includes two new healthcare products and three product categories, including the Centricity Enterprise Electronic Medical Record (EMR) solution. GE says the Centricity Enterprise software solution is an integrated clinical, financial and administrative EMR solution that assists hospitals in saving lives, time and money. By recording patient demographic and clinical information electronically, the solution makes this information more accessible to clinicians and can help reduce costs, improve productivity, and eliminate or reduce the number of forms that comprise a patient's medical record—reducing the amount of paper used, stored and ultimately sent to landfills.

- **Mesynthes** (Wellington, New Zealand) was granted FDA clearance for the company's Endoform Dermal Template. Endoform, an extracellular matrix biomaterial, provides a biologic template for tissue regeneration. The extracellular matrix contains a complex mixture of important biological molecules, including structural and adhesive proteins, such as collagens, elastin, fibronectin and laminin, and glycosaminoglycans. Endoform Dermal Template is presented as a sterile dry sheet in a peel pouch and is strong and easy to handle in a dry or wet state. It is applied directly to the wound bed, then rehydrated, covered with a non-adherent dressing, and secured in place.

MDD'S ONCOLOGY EXTRA

ADDITIONAL DEVELOPMENTS IN ONE OF MED-TECH'S KEY SECTORS

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Keeping you up to date on recent developments in oncology.

Hyperthermia evolving to become major new adjuvant cancer therapy . . .

BSD Medical (Salt Lake City) reported publication of an article by the *Journal of the National Cancer Institute* on the evolving role of hyperthermia in cancer therapy. The article reviewed the history of hyperthermia in cancer therapy, including the challenges faced by advocates. The article stated that, "Successful use of targeted heat therapy with chemotherapy in treatment of soft-tissue sarcoma has given U.S. advocates of local hyperthermia new hope that the treatment they so believe in will now be taken seriously." The article reviewed the EORTC/NCI Phase III multicenter randomized study on 341 high risk soft-tissue sarcoma patients, which showed a significant improvement in disease-free survival and demonstrated that patients were 30% more likely to be alive and cancer-free almost three years after starting treatment if hyperthermia was added to their chemotherapy treatment. All institutions who participated in the study, including **Duke University Medical Center**, used the BSD 2000 Deep Regional Hyperthermia System to administer hyperthermia. Rolf Issels, MD, PhD, a professor of medical oncology at Klinikum Grosshadern Medical Center at the **University of Munich** and the lead researcher on the Phase III sarcoma study, said the findings, "provide a new standard treatment option, and we believe they are likely to change the way many specialists treat these tumors." Elizabeth Repasky, PhD, of **Roswell Park Cancer Institute** (Buffalo, New York) and president of the **Society for Thermal Medicine** (Lawrence, Kansas), said, "We are on the verge, I think, of a major new adjuvant cancer therapy that will not replace chemotherapy or radiation, but will make them work a lot better."

How to prevent radiation mistakes in cancer patients . . .

Recent media stories have reported isolated cases of cancer patients who were injured by incorrect doses from intensity-modulated radiation therapy (IMRT). Despite such reports, IMRT remains one of the most powerful cancer treatments, and extensive safety measures can ensure patients receive the proper doses, said radiation oncologist Kevin Albuquerque, MD, of **Loyola University Health System** (Maywood, Illinois). IMRT uses computer-controlled linear accelerators to deliver precise radiation doses to a tumor or areas within a tumor. It focuses high doses within the tumor while minimizing the dose to surrounding normal tissue. Albuquerque said these are among the measures a hospital can take to prevent the type of radiation injuries that were the subject of a recent *New York Times* series on radiation injuries:

- A team of physicians, therapists and physicists does several levels of checking before treating a patient. For example, the team does a trial run on a "phantom patient" with radiation detectors. This ensures the machine is delivering the proper dose of radiation.
- Accreditation by the American College of Radiology assesses the qualifications of personnel, policies and procedures, equipment specifications, quality assurance activities, patient safety and quality of patient care.
- State inspections ensure the hospital meets state regulations on radiation use.
- A comprehensive quality assurance program includes tests on equipment and software on a daily, weekly, monthly and annual basis.

Early cancer test in development . . .

A new testing method is being developed to detect cancer soon after the tumor has formed. It will identify characteristic substances in the blood which accompany a certain type of tumor. The first steps in the development have already been completed. A new testing method aims to detect the disease in its initial stages. The technology is based on a microfluidic chip with tiny channels in which a blood sample from the patient circulates. The chip traces marker proteins which are indicative of cancer. The measured concentration of the tumor marker in the blood will help doctors to diagnose the disease at an early stage. Similar testing systems already exist but their measurements are not very precise and they can only detect molecules that are present in the blood in large

quantities. What's more, the tests have to be carried out in a laboratory, which is time-consuming and costly. A project funded by the German Ministry of Education and Research and coordinated by the **Fraunhofer FIT** (Sankt Augustin, Germany) aims to improve matters. Biofunctionalized nanoparticles developed by research scientists at the **Fraunhofer Institute for Silicate Research ISC** (Würzburg) are the key element in the new sensor. The detection limit has been improved, compared with the present state of the art by a factor of one hundred, said Jörn Probst, head of the Business Unit Life Science at the ISC. Whereas previously 100 molecules were needed in a certain quantity of blood to detect tumor markers, this test requires only one. This means that diseases can be diagnosed much earlier than with present methods. The researchers are now developing a first demonstrator combining four independent single-molecule-sensitive biosensors. The experts are also working on the simultaneous detection of several tumor markers, which will increase the clarity of tests.

New computational tool designed for cancer treatment . . . Many human tumors express indoleamine 2,3-dioxygenase (IDO), an enzyme which mediates an immune-escape in several cancer types. Researchers in the Molecular Modeling Group at the **Swiss Institute of Bioinformatics** (Lausanne) and Benoît Van den Eynde's group at the **Ludwig Institute for Cancer Research** (Brussels) developed an approach for creating new IDO inhibitors by computer-assisted structure-based drug design. The study was presented in the January 2010 online issue of the *Journal of Medicinal Chemistry*. The docking algorithm EADock, used for this project, was developed by the Molecular Modeling Group over the last eight years. It provides solutions for the "lock-and-key" problem, wherein the protein active site is regarded as a "lock", which can be fitted with a "key" (usually a small organic molecule) able to regulate its activity. Once an interesting molecule has been obtained, synthesis and laboratory experiments are necessary to confirm or reject the prediction. This algorithm will soon be made available to the scientific community worldwide. The scientists obtained a high success rate. Fifty percent of the molecules designed in silico were active IDO inhibitors in vitro. Compounds that displayed activities in the low micromolar to nanomolar range, made them suitable for further testing in tumor cell experiments and for in vivo evaluation in mice. If these studies are successful, scientists can begin evaluating these new compounds in patients undergoing cancer-immunotherapy.

– **Compiled by Lynn Yoffee, MDD Staff Writer**
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