



CARDIOVASCULAR DEVICES & DRUGS

A BioWorld monthly publication

Vol. 14, No. 1

January 2008

New name — same mission

The publication you have known as *Cardiovascular Device Update* is now *Cardiovascular Devices & Drugs*.

This new name reflects an expanded emphasis but the same mission as before — to bring you news of the most up-to-date developments in cardiovascular technologies. The rationale for expanding this emphasis to drugs is multiple.

Every day, this sector produces news concerning the combination of cardiovascular devices and cardiovascular drugs and the critical clinical interplay between the device and pharma sectors. The sentinel event highlighting some of these new combinations was the approval of drug-eluting stents in 2004, and DES technology remains closely linked to the need for a follow-on regimen of antiplatelet therapies.

Additionally, the sector has always been marked by both complementary therapeutic uses of devices and drugs and a competition between them, that competition playing out in clinical studies, the physician's office and aggressive market battles.

Cardiovascular Devices & Drugs will continue to highlight its original focus on developments in device therapies, but it now will also provide news concerning cardiovascular pharmaceuticals, from early inception to final commercialization, in order to provide a broad look at this important clinical and business landscape.

Cardiovascular technology continues to play out as the No. 1 therapeutic pathway for the development of all types of groundbreaking advances in med-tech. We invite you to continue with us as we travel this exciting path — and its entrepreneurial highways and byways.

— DON LONG, *CD&D* Executive Editor

The pulse

- ❑ Robert Jarvik, MD — Heart pump pioneer. The *CD&D* interview, p. 2.
- ❑ Cardiovascular tech finds fertile ground in Israeli innovation. Story, p. 5.
- ❑ Researcher pushes for cardio testing of non-cardio drugs. Pharma developments, p. 9.
- ❑ New study finds in-hospital delays for defibrillation. Story, p. 12.
- ❑ Scaffolds are used to steer growth of new beating rat heart. Story, p. 13.
- ❑ Cancer drug used by Angiotech as new CVC anti-infective. Story, p. 14.
- ❑ VC director: Dealing 'anemic, not awful' as new year begins. Story, p. 15.
- ❑ Ottawa CAD study using Affymetrix SNP Array 6.0. *International report*, p. 16.
- ❑ Non-strategic' sales initiative completed by Boston Scientific. *Business developments*, p. 23.
- ❑ Bristol Myers-Squibb sells cardiac imaging unit for \$525 million. Sidebar, p. 25.
- ❑ Beckman Coulter reports research partnerships. *Agreements*, p. 27.
- ❑ Catheter ablation reduces ICD shocks, study concludes. *Market updates*, p. 28.
- ❑ James Cox named medical director for ATS Medical. *Personnel file*, p. 32.
- ❑ Abiomed's iPulse is FDA-approved for acute heart failure. *Product pipeline*, p. 32.

Our 14th year of covering this dynamic industry

Now available online: Go to www.ahcmedia.com/online.html for details

Cardiovascular tech finds fertile ground in Israeli innovation

By JEFFREY BERG
CD&D Contributing Editor

Israel has provided fertile soil for developing a broad range of medical technologies. The reasons are probably several-fold, but two of them stand out: Israel is an inherently entrepreneurial culture, given the everyday risk-taking required to live there; and the country has a disproportionately high percentage of physicians, often with innovative ideas that can be turned into commercializable products.

Still another factor is that seed-stage firms in Israel can draw on a variety of incubators formed by the country's universities, research institutes and government-funded organizations.

Several towns in Israel are home to medical technology companies, chief among them Yokneam and Caesarea. And there is an expanding network of venture capital firms in Israel that invest in high-tech medical products. This sector is beginning to draw increased attention from the venture capital community and corporations in the U.S.

Out of this med-tech hotbed of incubation has entrepreneurship has grown a particularly high number of cardiovascular companies and products, such as stents and other implanted devices, telemetry for heart monitoring, catheter-manuevering systems, imaging technologies and vascular treatment products.

Peregrine Ventures (Or Yehuda) focuses on seed-stage investments and has financed three of the companies profiled in this article. And as these emerging companies grow, they represent acquisition candidates.

Years ago, **Johnson & Johnson** (New Brunswick, New Jersey) acquired **Biosense** (Tirat Ha'Carmel), which has since been renamed Biosense Webster **Cordis**. This past year, **Edwards Lifesciences** (Irvine, California) acquired **Percutaneous Valve Technologies** (Caesarea), and **Guidant** (Indianapolis) acquired **X Technologies** (Yavne). Guidant, now part of **Boston Scientific** (Natick, Massachusetts), also has been an investor in several cardiovascular device companies.

Stents, other implanted devices

• **B-Balloon** (Ariel) is developing devices that will allow for quick and successful percutaneous interventions at ostial and coronary bifurcation lesions, two of the biggest unresolved challenges in percutaneous coronary intervention. Ostial lesion procedures account for roughly 5% of coronary interventions, and bifurcated lesions account for about

20% of coronary lesions.

B-Balloon's devices may also be used in the carotid and renal arteries. They employ innovative delivery systems, including novel balloon designs that enhance the accuracy of stent implantation and reduce the dependence on fluoroscopic imaging. The company's stents offer improved scaffolding of the treated area, provide support during the procedure and enable future access. Preclinical trials are underway and are showing promising results.

• **Neovasc Medical** (Or Yehuda) has developed a minimally invasive treatment for patients with ischemic heart disease that are not candidates for revascularization by existing medical procedures.

Neovasc's Reducer is a stent-like device that is implanted percutaneously through the venous system. It increases the supply of oxygen to the heart muscle and improves cardiovascular function by slowing blood drainage and flow from arteries to the venous circulation. The Reducer is designed to establish a permanent and controlled narrowing of the coronary venous system. It can be implanted in the cath lab. Large animal studies have demonstrated elevated intramyocardial pressure, the formation of new blood vessels and increased blood flow in the hearts that were implanted with the device.

The company has received IRB approval, and eight patients have been treated with the Reducer without complication or adverse event. The Reducer has potential for reducing or eliminated chronic chest pain from angina.

• **Elutex** (Herzliya) specializes in surface modification of medical implants with current emphasis on cardiovascular stents. It has developed a novel approach to coating vascular stents using its proprietary electropolymerization process which forms an extremely thin (less than 2 microns), highly adherent and stable coating on the stent surface. This process can precisely control the thickness and homogeneity of the stent coating and enhances its drug loading ability. Several hundred stents can be produced under identical conditions.

Elutex is currently using Paclitaxel as the active agent for demonstrating its proof of concept. The company's electropolymerization process is patent pending in the U.S. and in Europe.

Elutex — founded in Meytav Technological Enterprises Innovation Center — in February 2007 raised NIS 24 million, the offering oversubscribed by 45%.

• **CorAssist Cardiovascular** (Yokneam) is developing products for treating diastolic heart failure. Its ImCardia is an elastic self-expanding device attached to the external left ventricular surface of the heart through an off-pump, closed-heart procedure. It applies an outward expansion force to the ventricular wall, thereby reducing the intraventricular filling pressures and improving the diastolic function. The

use on coronary and peripheral arteries, respectively, and NaviEP for electrophysiology procedures. They provide physicians with a radiation-free tool for navigating catheters and guidewires and offer improved accuracy for stent positioning. They minimize the exposure of the interventional cardiologists to X-ray radiation and the need to wear a heavy lead apron for long hours.

The system has so far been tested in animal trials and in pilot clinical experiments and shown to be feasible for accurate percutaneous coronary intervention with stent implantation.

- **F.D. Cardio** (Tel Aviv) is developing a novel catheter technology for advancing and maneuvering catheters and stent delivery systems from their front distal therapeutic part for use in interventional cardiology, neurology and other medical interventional procedures. Currently, pushing force is applied by the physician to the rear end of the catheter which is outside the patient's body.

Using the company's Front Drive (F.D.) catheters, the physician can apply force to the distal part of the catheter and by so doing advance and steer the catheter to reach and treat blood vessel lesions and sites that are currently unreachable. The front drive mechanism allows for the use of very flexible catheters that can pass through small diameter and curved blood vessels.

Non-invasive vascular treatment

- **FlowMedic** (Caesarea) is developing a family of medical and consumer devices for the non-invasive treatment of various circulatory disorders of the lower limbs, such as deep vein thrombosis, peripheral arterial disease and related clinical conditions such as critical limb ischemia and intermittent claudication. The products are cauterized by their light weight, portability and ease-of-use for treatment both at home and in the hospital. This proprietary technology increases circulation in the lower extremities by rapidly apply-

ing and releasing pressure to the lower limbs, resulting in more effective blood flow to the limbs. Clinical studies are currently being conducted to quantify the efficacy of this therapy.

- **NeuroSonix** (Or Yehuda) is engaged in the development and commercialization of non-invasive embolic protection technology and devices to be used in surgical and catheter-based cardiovascular procedures.


The company's first product is the EmBlocker intended to provide embolic protection during cardiovascular surgical procedures, such as coronary bypass grafts, valves and congenital procedures. Clinical studies with the EmBlocker are due to start in mid-2005.

The company in 2007 received the Techno-College Innovation Award from the European Association of Cardio-Thoracic Surgery Techno-College Innovation Award for the EmBlocker, the award established to honor technological breakthroughs in areas related to thoracic and cardiovascular research.

Vascular closure

- **CardioDex** (Tirat Ha'Carmel) is the developer of disposable vascular closure devices, the Epiclose and Epiclose Plus, that do not use any glue, collagen, suturing or other foreign materials, thus leaving no residual material in the patient's body.

The EpiClose vascular closure devices are designed for rapid closure of punctures in the femoral artery following catheterization procedures. It is introduced into the vessel through an interventional 6 Fr introducer sheath and employs a balloon inflation/deflation technique that is commonly used in invasive cardiology and radiology. The device has the CE Mark

The Epiclose devices are designed to expedite arterial closure through hemostasis. The process relies on familiar balloon inflation/deflation techniques, which apply selective pressure precisely over the puncture site. The products do not require exchange of the introducer sheath. 

Advances in Cardiovascular Technology State of the Industry and Emerging Markets, Vol. 4

The publishers of *Cardiovascular Device Update* and *Medical Device Daily* have released *Advances in Cardiovascular Technology, Vol. 4* — a report on the developments, trends and outlook of the cardiovascular technology markets. Now in its fourth edition, this year we have updated and expanded the report with the most current information available concerning emerging technologies in the cardiovascular sector and the most recent advances in mature cardio technologies.

Vol. 4 provides more than 200 pages of market information and technology developments, from the latest in drug-eluting stents to new stem cell therapies for heart disease.

To order call 1-800-688-2421 or 1-404-262-5476.