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Cleveland area seen as hotbed of medical innovation

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CLEVELAND – The medtech community in Cleveland and the surrounding region is experiencing dynamic growth from its expanding network of world-class research and clinical facilities along with financial firms and government programs that collectively support the creation and growth of companies in many medical fields, most notably cardiovascular, imaging, neurology and orthopedics.

Today, the region is home to 600+ biomedical businesses with more than 230,000 healthcare and bioscience workers. The origin of many of these companies can be traced to research programs initiated at the nationally ranked medical institutions, hospitals and universities in northeastern Ohio which encompasses Cleveland and Akron (*see Table 1*). As evidence of its growing medical community, sixteen cardiovascular companies have moved into the region in the past two years. The region attracts more than \$150 million a year in healthcare investments.

The **Cleveland Clinic**, a world renowned health system, established in 2007 the Global Cardiovascular Innovation Center (GCIC) which was formed after receipt of a \$60 million grant from the State of Ohio's Third Frontier Program. It is a cardiovascular product development consortium that is focused on the formation, attraction, expansion and retention of cardiovascular companies and whose aim is to create jobs and facilitate economic development in the State of Ohio. It has resulted in the construction of a new incubator facility to house start-up companies developing innovative solutions for the diagnosis and treatment of cardiovascular disease. GCIC's portfolio comprises 21 companies.

The Cleveland Clinic hosts the annual Medical Innovations Summit, a major conference that features presentations by the CEO's of the largest medical device companies and attracts more than 1,000 investors, entrepreneurs, business development executives, clinicians and policy makers.

The Cleveland Medical Mart and Convention Center is expected to transform Cleveland and the surrounding area into a globally competitive location for attracting and growing biomedical companies. It is scheduled to open in 2013 and will be one of the only facilities in the nation targeted specially to the medical and healthcare industries, housing 120,000 sq. ft. of permanent show-

Table 1
Hospitals and Research Universities in Cleveland and Akron

Cleveland	Akron
Cleveland Clinic	University of Akron
Case Western Reserve University	Akron Children's Hospital
University Hospitals	Akron General Health System
MetroHealth System	Summa Health System
Cleveland State University	Northeastern Ohio Medical University
	Kent State University

rooms for major medical manufacturers and service providers. The showrooms will focus on cardiology, surgery, imaging, orthopedics, Ob/Gyn, sterilization, healthcare furnishings, patient care, and healthcare IT. The center is expected to host more than 50 healthcare-related conferences and events each year.

Biomedical engines of innovation

BioEnterprise (Cleveland) is a leading institution that is driving the development of the biomed and medtech industries in Cleveland's metro area. BioEnterprise is a business formation, recruitment and acceleration initiative designed to grow healthcare companies and commercialize bioscience technologies. Its founders and partners are: **Case Western Reserve University, Cleveland Clinic, University Hospitals, Summa Health System** and the **Austen BioInnovation Institute in Akron**. Benefited by a team effort with these institutions, and sustained by an entrepreneurial ecosystem, BioEnterprise has succeeded in accelerating more than 100 companies of which half are medical device companies and the re-

mainder about evenly split between IT services and therapeutic/clinical research services. Its 20-member professional staff provides ongoing assistance and guidance in a wide range of areas to these portfolio companies but does not serve on their boards. BioEnterprise selects 15-20 new companies each year to assist that have strong growth potential. It assists these companies in developing their businesses and specifically in their fund raising efforts, but is itself not an investor.

BioEnterprise is succeeding in achieving its goal of making Cleveland and environs a national center for medical innovation. The region can be compared to the established med-tech community, known as Medical Alley, around Minneapolis and the drug and biotechnology hub around Research Triangle Park, North Carolina.

BioEnterprise's portfolio includes several Israeli med-tech companies which it has attracted for setting up operations in Cleveland and for using local hospitals to conduct clinical trials. BioEnterprise partners with several venture funds that are housed within its facility. The Bridge Investment Fund, which also has an office in Tel Aviv, specifically invests in Israeli medical device companies that have completed their initial clinical trials and are looking to the U.S. market for further clinical validation and to establish a U.S. sales and marketing organization. Additional on-site venture firms at BioEnterprise include Arboretum Ventures, RiverVest Venture Partners, Medical Growth Fund and Johnson & Johnson's COSAT (Corporate Office of Science and Technology).

Twelve of the Cleveland region's health care companies were acquired since 2008 (see Table 2).

Cleveland's Early Stage Partners (ESP) was formed in 2000 and raised an initial \$44 million in Fund I. In late 2007, an additional \$55 million was raised for Fund II. It has made investments in 30 companies and currently has 22 companies in its portfolio, mostly in Ohio and Michigan, of which half are in med-tech. ESP fills an important niche as first round investors of seed capital, typically in the \$1-2 million range. It is the lead investor in many of its deals. One noteworthy investment is the Cleveland-based Symbionix, a leading provider of medical education and

Table 2
Cleveland Region Healthcare Acquisitions Since 2008

Company	Acquirer
Computer Systems Company	Hyland Software (Westlake, Ohio)
Edgepark Surgical	Clayton Dubilier & Rice (New York)
Noteworthy Medical Systems	CompuGROUP Holding (Koblenz, Germany)
OncoDiagnostic Labs	Predictive Biosciences (Boston)
Therapy Partners	HealthPro Rehabilitation (Atlanta)
Innovative Process Administration	Mercer
IntellisEPM (Product Line)	Carefx (Scottsdale, Arizona)
Home Care Solutions	Invacare (Elyria, Ohio)
Theken Spine	Integra LifeSciences (Plainsboro, New Jersey)
NDI Medical's MedStim	Medtronic (Minneapolis)
Whole Health Management	Walgreens (Chicago)
Intelect Medical	Boston Scientific (Natick, Massachusetts)

simulation technology.

The Austen BioInnovation Institute in Akron (ABIA) is also contributing to the growth in the Cleveland-Akron corridor. It was launched in 2008 with an announcement of \$80 million in commitments, as follows: \$20 million from the John S. and James L. Knight Foundation; \$20 million from the State of Ohio; \$20 million from other founding members (**Akron Children's Hospital, Akron General Health System, Northeastern Ohio Universities Colleges of Medicine and Pharmacy, Summa Health System**, and the **University of Akron**); \$10 million from First Energy; and \$10 million from other sources including federal agencies and private foundations.

ABIA is focused on patient-centered innovation and commercialization at the intersection of biomaterials and medicine. It is comprised of four Centers of Innovation (see Table 3) that are interrelated in that they are designed to accelerate translational research to biomedical innovation and commercialization as well as community transformation, thereby encompassing the entire life cycle for biomedical innovation and discovery.

In September 2010, ABIA received a \$2.6 million research and commercialization grant for biomedical sensor technology at Cleveland State University's Wright Center for Sensor Systems Engineering through Ohio's Third Frontier initiative, a technology investment program which grants funds to companies that have also received private capital and have a partnership with an Ohio institution. Grants are typically \$1 million.

ABIA was also the recipient, together with the University of Akron Research Foundation, of the i6 Challenge which is awarded by the U.S. Department of Commerce for research programs that epitomize innovation and minimize the time from ideation to commercialization of new technologies.

The University of Akron has an established reputation as an innovator in biomaterials and polymer science. Several of the nearby large chemical and industrial companies are utilizing the university's polymer technology and getting involved in medical devices such as Lubrizol and Parker Hannifin. Additional beneficiaries are the medical companies, **Steris** (Mentor, Ohio), a provider of sterilization and sanitation products, **Invacare** (Elyria, Ohio), a marketer of rehabilitation equipment, and **Norman Noble** (Highland Heights, Ohio), a contract manufacturer of medical devices including stents and orthopedic implants.

JumpStart is a nationally recognized non-profit organization that offers intensive entrepreneurial development assistance to Northeast Ohio entrepreneurs leading high potential, early-stage companies. It is funded by the state, corporations and hospitals and provides early stage companies with grants of \$500,000, which have been awarded so far to 50 companies. This program exists in several other states and was created by the U.S. govern-

Table 3
Centers of Innovation within
Austen BioInnovations Institute

- Center for Biomaterials and Medicine
- Medical Device Development Center
- Center for Clinical and Community Health Improvement
- Center for Simulation and Integrated Healthcare Education

ment to stimulate the economy and create jobs.

BioEnterprise's medical device companies

A diverse sample of medical device companies within the BioEnterprise portfolio are reviewed below:

- **MDG Medical** (Aurora, Ohio and Lod, Israel) markets systems that automate the dispensing of medications by health professionals in hospitals. Some sales are also made to long-term care and correctional facilities. MDG's flagship product, ServRx, is a complete medication management system consisting of automation software, medication cabinets, supply cabinets, bedside solutions and computerized order entry devices. This system provides a closed loop solution for medication management by tracking from the order entry to the actual administration of medication. Its modular design allows for the installation of individual components. The principal benefits of MDG's systems are increasing patient safety by reducing human error when medicating patients and greater cost efficiencies by reducing paperwork and improving medication inventory management. MDG can be distinguished from its competitors, **CareFusion** (San Diego) and **Omniceil** (Mountain View, California), because its systems allow for the patient's safety to be taken directly to the bedside.

- **Quality Electrodynamics (QED ; Mayfield Village, Ohio)**, established in 2006, is an engineering and manufacturing company that is an OEM supplier of radio frequency coils used in MRI scanners. The coils translate signals received from patient anatomies into images used for diagnostic purposes. QED produces state-of-the-art advanced clinical coils that are dedicated for use in imaging the head, neck, knee, heart, shoulder, foot, spine and abdomen. QED works closely with its two main customers, **Siemens Healthcare** (Erlangen, Germany) and **Toshiba Medical Systems Corporation** (Tochigi, Japan). The company has 66 employees. It will achieve sales of \$16 million in 2010 and has been profitable from year two (i.e., 2007). More than 90% of products are shipped outside the U.S. and they are distributed worldwide by Siemens and Toshiba. QED plans to enter the renewable energy market with the launch of eQED in 2011 and with the introduction of next-generation inverters that change sunlight energy from DC to AC and are integrated in solar panels. QED was named 11th in the nation in 2009 by *Forbes* magazine's American Most Promising Top 20 companies and was also cited by *Inc* magazine as one of America's

Top 500 Fastest Growing Private Companies and 13th in the category of "Healthcare."

- **CardioInsight Technologies** (Cleveland) is developing the first non-invasive, real-time, beat-to-beat simultaneous mapping and localization solution for the treatment of cardiac arrhythmias and heart failure. The company's electrocardiographic mapping technology was licensed from Case Western Reserve University. It is being developed for intra-procedural guidance of ablation therapy for arrhythmias and cardiac resynchronization therapy for heart failure. Its targeted conditions are for treating atrial fibrillation and congestive heart failure. The patient wears a disposable multi-electrode vest that is used in conjunction with a CT scan to provide a 3-D map of the heart's electrical topography and enables the physician to determine where to ablate. The company plans to launch its product in Europe in June 2011 and anticipates receipt of 510(k) clearance by the end of 2011. The regulatory approval is not expected to be onerous because the product is non-invasive.

- **NDI Medical** (Cleveland), established in 2002, has a 22-member staff that focuses on generating ideas for innovative neurodevices that can be used to inhibit, accelerate or restore lost neurological function. It holds 150 issued or pending patents and has raised \$25 million from about 20 research grants and private investment. NDI's objective is to spin off individual companies and to assist these companies in the areas of research & development, manufacturing and quality assurance. NDI also is an investor in the companies that it creates. Its first product, the MedStim bladder pacing system for control of urinary urge incontinence, was acquired in April 2008 by **Medtronic** (Minneapolis) for \$42 million. NDI continues to create high-growth companies. Its 2nd and 3rd operating companies, **Checkpoint Surgical** and **SPR Therapeutics**, are housed on-site at NDI.

- **Checkpoint Surgical** has developed a single-use stimulator/locator for applying electrical stimulation to exposed motor nerves and muscle tissue to locate and evaluate nerves during surgery. The stimulation intensity can be varied, allowing for the activation of nerves and muscles at different depths and through surrounding tissue. The principal applications of the device are for use during surgery on upper extremities such as the shoulder and elbow, ENT and oncology procedures, and for nerve and tendon transfers. The Checkpoint stimulator/locator received 510(k) clearance from the FDA and has been used in a pilot launch by 40 surgeons in the U.S. in over 300 procedures. The company plans to expand its U.S. sales and launch its device in Canada, Europe and Australia in 2011.

- **SPR Therapeutics** is commercializing the patented, short-term Smartpatch system to reduce or eliminate patient's severe pain and improve their overall quality of

life. The Smartpatch system consists of a skin-mounted external stimulator, percutaneous lead and small adhesive patches that contain the power source for the system. It delivers peripheral nerve stimulation (PNS) for up to 30 days after placing the lead through the skin into the muscle in an outpatient procedure. The patches are replaced regularly, based on the prescribed dosage. A 510(k) submission is pending for the Smartpatch PNS system. Also under development is the fully implantable SPR long-term system which is being investigated in FDA-approved clinical trials.

- **AxioMed Spine** (Garfield Heights, Ohio) develops devices designed for restoring function to patients who have symptomatic degenerative spine disease. The company's Freedom lumbar disc is the first one-piece elastomeric total disc replacement. It is based on an invention of surgeons at the Cleveland Clinic and is cleared under an IDE for ongoing clinical trials randomized against the ProDisc-L from **Synthes Spine** (West Chester, Pennsylvania). The Freedom one-piece design utilizes a proprietary metal-polymer bonding technology. The company has an exclusive license for the CarboSil polymer, a proprietary polymer that is supplied by the **Polymer Technology Group** (Berkeley, California), a subsidiary of **DSM Biomedical** (Geleen, the Netherlands). The Freedom lumbar disc has the CE mark and is being marketed in the UK, Germany and Switzerland. In the U.S., the company needs a 2-year follow up before filing for a PMA with the FDA. AxioMed is developing the Freedom cervical disc that is more anatomically correct in fit and function than existing commercial cervical discs. Both devices incorporate titanium endplates and their viscoelastic mechanical properties mimic the natural disc. It plans to file for the CE mark in the fall of 2011 for the Freedom cervical disc. ❖

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