

BIOMEDICAL BUSINESS & TECHNOLOGY

Formerly
The BBI
Newsletter

January 2012

Vol. 35, No. 1

The *BB&T* interview:

Ran Bronstein

Founder of medical simulation firm Symbionix discusses growth and change in training sector

Interview by JIM STOMMEN, *BB&T* Contributing Editor

Ran Bronstein has been a pioneer in the field of medical simulation for nearly 15 years, having started as one of the three founders of Symbionix in 1997, creating the vision for the Israel-headquartered company and leading the development of the technologically advanced medical simulators. The company's U.S. headquarters are in Cleveland. Today, as company president and chief operating officer, Ran oversees company operations both internally and externally.

Prior to the founding of Symbionix, he co-founded and managed the R&D team of Kidum Multimedia, a software company focused on 3-D technologies, which was acquired by SEA in 1997. At Tecnomatix Corp., which provided manufacturing process managements, Ran was 3-D and simulation project leader.

Bronstein talked with *BB&T* Contributing Editor Jim Stommen on growth and changes in the medical simulation sector.

BB&T: Before we get into the specifics of what your company supplies, could you give me an overview of what's involved in what I think of as the simulation/training sector? I'm wondering, for example, how the segment sees itself today versus the training of the past.

The Inside Story

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Pittsburgh's burgeoning med-tech sector is nurtured by investors, universities

By JEFFREY BERG, PhD
BB&T Contributing Writer

PITTSBURGH – The Pittsburgh Life Sciences Greenhouse (PLSG), Innovation Works, along with the technology transfer offices of the University of Pittsburgh and Carnegie Mellon University are the backbone of the med-tech sector through their combined efforts at creating, funding and providing support services for companies that encompass the full range of fields in the life sciences.

PLSG was founded in 2001 and serves as a quasi economic development organization to propel and sustain the growth of Western Pennsylvania's life sciences industry and accelerating technology commercialization with seed and early-stage life science companies. PLSG has a purely life sciences focus and has made 151 investments totaling \$17.4 million in 64 companies, of which nearly half are in medical devices (See Table 1 below). It promotes the region's innovations in biosciences through media

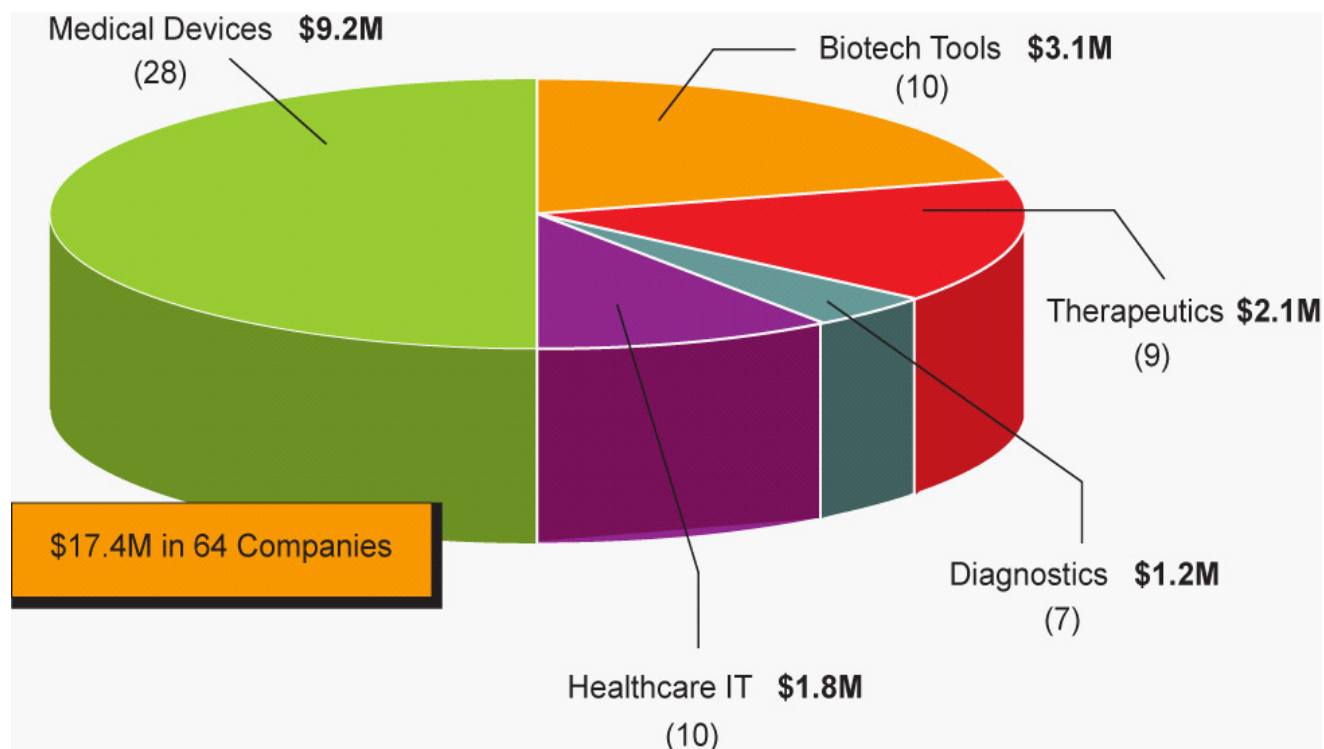
relations, industry events and relationship building with investors. PLSG primarily focuses on guiding researchers, entrepreneurs and emerging companies through the early stages of company development by helping them build business models and secure capital investments.

PLSG offers a unique Executive Program that attracts entrepreneurs with deep domain expertise possessing track records of having successfully created new businesses and exited companies. These Executives-in-Residence (EIR) provide emerging life sciences companies with proven C-level leadership. They are given the opportunity to explore and select new technologies and product opportunities upon which to base a startup company.

PLSG is a nationally-recognized investment firm committed to empowering entrepreneurs to build innovative and successful life sciences companies. The PLSG Accelerator Fund, LLC venture fund was recently formed to make investments in PLSG life sciences portfolio companies. This is a \$10 million for-profit venture fund with an investment period of up to five years. The fund is designed to make early stage investments in life sciences companies located in western Pennsylvania.

Lynn M. Brusco, PLSG's Vice President, Marketing and Public Relations, noted that "we make it possible for companies to deliver biomedical innovations to the marketplace

Table 1: PLSG Investments



more quickly and efficiently than they ever could alone.”

Innovation Works is part of a statewide network of four Ben Franklin Technology Partners which provides 60% of its funding. It brings together talent, ideas and technologies within Pennsylvania and serves as a catalyst for advancing the state’s knowledge-based economy. It invests in a range of industries and one-third of its portfolio companies are in the life sciences (See Table 2). Innovation Works pairs its companies with Executives-in-Residence (EIR) to provide mentoring and guidance. They serve as an extension of a startup’s management team

Innovation Works makes 12 to 15 seed capital investments each year for which it receives equity which is a convertible note that is entered as debt on the balance sheet. It is the single largest investor in seed-stage companies in Southwestern Pennsylvania and has invested \$52.3 million in 152 technology startups since 1999. Innovation Works also collaborates with Carnegie Mellon University to mentor 16 startup companies per year as part of the unique Agile Innovation program which is funded by a federal i6 Challenge Grant.

University of Pittsburgh’s Office of Technology Management (POTM) was started in 1996. About 75% of the 80 startup companies spun out from the university are in the health sciences. POTM draws upon innovations emerging from the university’s 30,000 students and faculty and from researchers that are affiliated with the University of Pittsburgh Medical Center that hold dual positions with the university. The

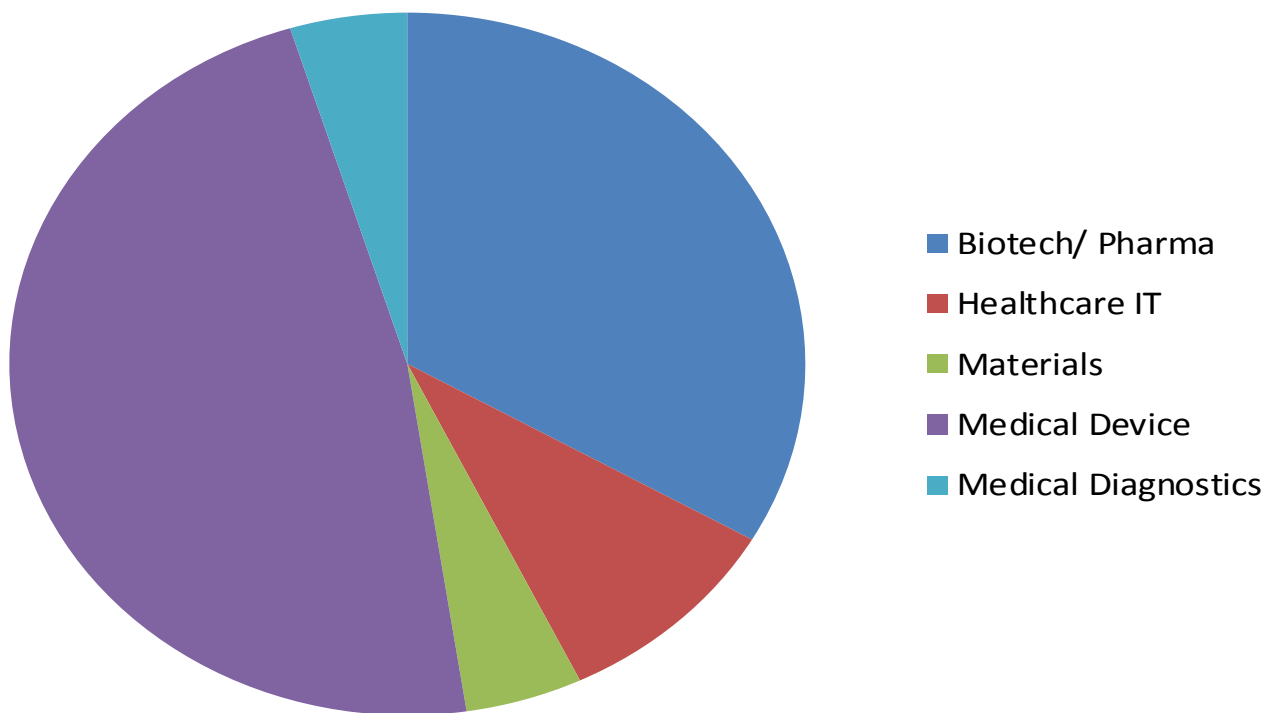
University of Pittsburgh ranks fifth in the country in research funding. Research expenditures exceeded \$800 million in fiscal 2011 (end June 30) during which POTM received a record of 257 disclosures of ideas for commercialization, up from 74 disclosures in 2003, completed 105 licensing agreements and options, and filed 87 patent applications on behalf of its inventors, a 26% increase over the prior year. POTM initiated an EIR program this past year that targets medical devices and computer software. It recruits veteran technology entrepreneurs with extensive startup experience.

Carnegie Mellon University’s Center for Technology Transfer and Enterprise Creation (CTTEC) provides pre-seed and gap funding for its researchers that seek to create startups to develop their technologies for future commercialization. Support services are also provided for staffing, preparing a business plan and developing corporate partners. For companies seeking exclusive licensing of the university’s technologies, CTTEC receives a 6% equity position and 2% royalty on sales. For non-exclusive licensees, the figures are 5% equity and 1% royalty. CTTEC averages ten startups per year from its professors and an additional ten annual startups by students. About 80% of the companies founded on technology licensed from the university are located in Pittsburgh.

Profiles of companies receiving seed capital from PLSG and Innovation Works

The following companies are representative of the

Table 2: Innovation Works



wide range of medical technologies and products that began as startups with seed funding from both PLSG and Innovation Works.

- **Cohera Medical** was formed in 2006 and is based on the research of Drs. Eric Beckman and Michael Buckley at the University of Pittsburgh. The company has developed TissuGlu Surgical Adhesive, a lysine-derived urethane polymer, for use after surgery to hold together layers of internal tissue and prevent the accumulation of fluid. The product is delivered in a grid pattern using a handheld applicator, three drops at a time onto the open surgical site. This approach is intended to eliminate the need for drainage tubes to remove accumulating post-operative fluids.

Cohera received the CE mark for TissuGlu in September 2011 and has recently begun selling the adhesive in Germany for use by plastic and reconstructive surgeons in abdominoplasty (tummy tuck) and other large-flap surgical procedures. The company plans to expand into additional Western European countries in 2012 using its own direct sales force. Cohera is also developing a unique and proprietary bowel sealant, and a strong adhesive mesh formulation. TissuGlu has been submitted for FDA approval. The company recently completed a new round of financing, bringing the total of invested funds to just over \$50 million.

- **Carmell Therapeutics** is developing biologically active materials made from freeze-dried human plasma obtained from a blood bank and then processed into a plastic-like material. The resulting biomaterial contains a concentration of growth and regenerative factors and can serve as a natural wound healing catalyst for soft and hard tissues. It can be processed into a variety of forms, including films, pellets, putty, suture and powder. The company is initially focusing on sports medicine and orthopedic applications. Its first product is a bone putty that also contains tricalcium phosphate and glycerine as a plasticizer and will be used for augmenting and accelerating the healing of bone injuries. It plans to soon begin a 30-patient pilot clinical trial in South Africa on patients with tibia fractures. Carmell has licensed its technology from Carnegie Mellon University.

- **Biosafe** has developed a patented antimicrobial agent that has potential application in a wide range of consumer, industrial and medical products. The active agent is produced by polymerizing a silane/quaternary ammonium monomer. It can be dried and formed into a powder that can be compounded into a plastic such as polyurethane, acrylic or nylon from which it does not leach out. Its mechanism of action is by disrupting the cell membrane. Compatibility studies have been conducted for use on medical devices and a development program is underway for use in an endotracheal catheter with **Egret Medical Products** (Dallas). It is currently being used on face masks sold in the Far East by **Minntech**, a subsidiary

of **Cantel Medical** (Little Falls, New Jersey). Consumer products that use Biosafe's antimicrobial agent are surface wipes and a spray for use as a fabric freshener that are sold by **Union Springs Pharmaceuticals** (Erlanger, Kentucky).

- **Blue Belt Technologies** is developing the next generation of "smart" surgical instruments for use initially in orthopedic procedures and for other surgical subspecialties such as neurosurgery and otolaryngology. The company's Navio PFS system incorporates patented technology to provide precise control to surgeons via an intelligent, handheld, computer-assisted bone cutting tool. The Navio PFS system provides the surgeon with a layer of safety and enhanced accuracy while performing bone shaping tasks through minimally invasive incisions. The company recently filed for CE mark in Europe and plans to file its initial 510(k) application in the U.S. during the first half of 2012. Blue Belt was acquired by **Healthpoint Capital** (New York) in December 2011.

- **NeuroInterventions** was spun out from the PLSG. It is developing a thrombectomy catheter to be introduced through the carotid artery for trapping and extracting blood clots in cerebral vessels, thereby restoring the brain's blood supply and increasing chances of survival for patients suffering an ischemic stroke. The patent-pending device employs a balloon mounted directly on a guidewire that possesses an extremely small diameter. TPA is used to dissolve the blood clot and it weeps out of the balloon as it expands. Preclinical trials of the device on rabbits and mini swine were successfully completed.

NeuroInterventions operates as a virtual company. Its Chairman, Mark Wholey, MD, is chairman of the **Pittsburgh Vascular Institute** and Director of Interventional Radiology at the **University of Pittsburgh Medical Center** (UPMC). Lawrence Wechsler, MD, and Tudor Jovin, MD, serve as consultants to the company and are both affiliated with the Department of Neurology and Neurological Surgery at the University of Pittsburgh School of Medicine and are directors of the Stroke Institute at UPMC. NeuroInterventions is seeking to receive market clearance via a 510(k) and is in discussion with potential strategic corporate partners.

- **ALung Technologies** has developed the Hemolung respiratory assist system, an artificial lung for temporary use by patients to overcome an acute episode of respiratory failure, to protect the lungs from high pressures while on a ventilator, or for use in weaning patients with chronic respiratory disorders off of a ventilator. The Hemolung's advantages over mechanical ventilation are no need for patient intubation or sedation. The system uses the proprietary Hemolung cartridge that is integrated with a centrifugal pump for removing carbon dioxide from blood which is exchanged for oxygen. The cartridge employs a siloxane/heparin-coated closed membrane

with the intended use of 7-day duration. A 23-patient clinical trial on patients with acute respiratory failure was conducted in Germany at ten clinical test sites and completed in mid 2011. The company is in the process of obtaining the CE mark and is in discussion with the FDA. It plans to begin product sales in Europe in 2Q12. The cost of the console is about \$30,000 and the special catheter and tubing sets are \$6,500. ALung envisions that its system will find application for treating many types of respiratory disorders that result in an acute elevation of CO₂ in the blood (acute hypercapnic failure). These disorders may include acute respiratory failure due to lung trauma or acute-on-chronic conditions such as an exacerbation (i.e., pneumonia) of COPD (emphysema, chronic bronchitis and chronic asthma). Since its founding in 2000, the company has received investments totaling \$40 million.

- **ClearCount Medical Solutions's** SmartSponge and SmartWand-DTX are radio frequency identification (RFID)-enabled systems for detecting and counting surgical sponges that contain embedded RFID tags. These products are co-branded and sold by **Medline** (Mundelein, Illinois). Approximately once in every 1,500 chest or abdominal surgeries, a sponge or other item is accidentally left inside the patient, putting the patient's life at risk. Follow-up surgery and a longer hospital stay is nearly always required and also results in total liability estimated at \$50K to \$250K. The Medicaid and Medicare policies are changing and by 2014 hospitals face a reduction in overall reimbursement for these incidents. The SmartSponge system allows for sponges to be scanned by swiping each unopened pack. The data on each sponge is instantly validated and the inventory counts are updated. The SmartWand-DTX is used to verify out-counts with a scan of the wand over the soiled sponges. Audible and visual indicators on the console will alert the user of any sponges, and their size, that are detected during the scan. ClearCount's system takes less than 2 minutes to locate a sponge that is missing, vs. about 20-30 minutes when using current manual counting protocols for tracking sponges used during surgery. The listed sales prices are \$14,900 for the SmartSponge and \$4,000 for the SmartWand-DTX.

- **Ib2C** (Intimate Bridge to Conception) is a development-stage medical device company focused on reproductive health to aid in natural fertility and conception in the privacy of a patient's home. Its lead technology, Focus Touch, is a take-home conception aid system that is designed to address the growing unmet need of delayed and/or unsuccessful natural fertility. It is intended to fill the gap between natural fertility and in vitro fertilization. The device is a silicone-based condom-like receptacle that can be rolled back to become a cervical cap. An applicator is used to insert the cap in the area of the cervical os. The product is intended to be marketed directly to consumers. The company is seeking a strategic corporate partner.

University spinoffs play an important role

Ortho-Tag is using transcutaneous near field communication to develop a "smart" tag for tracking and monitoring prosthetic joints such as hips and knees. It is based on the research of Dr. Marlin H. Micklessor Nickolas, a professor at the University of Pittsburgh's Swanson School of Engineering and Dr. Xiaoyu (Ray) Liu, a post-doctoral fellow. A tiny RFID tag is attached to the implanted prosthesis which allows the orthopedic surgeon to obtain specific information about the orthopedic joint by simply touching the skin in the area of the implant with a patented touch probe to capture the recorded data using RF energy traveling through the tissue. The Ortho-Tag also will have the option of reading the pH levels in the proximate area of the implant to provide an early warning of any infection.

Medrobotics (Raynham, Massachusetts) emerged from research conducted at the Carnegie Mellon Robotics Institute, a world class robotics research center. The company has built a flexible robot platform which allows for minimally invasive procedures for many parts of the anatomy. Initial efforts focused on the use of its highly-articulated small surgical snake robot in minimally invasive cardiovascular surgery but the company's efforts have been redirected for application in ENT procedures. FDA approval is being sought. The flexible robot platform includes on-board visualization and contains multiple open device channels to accept a variety of flexible surgical and interventional tools. The robot enables physicians to operate through non-linear circuitous paths, self-supported, and through a single-site access into the body. Research is ongoing at the Carnegie Mellon's Robotics Institute on applications of robots in natural orifice surgery.

InVivoMon was founded in 2008. It is a Carnegie Mellon University spinoff that provides technological solutions to medical problems through embedded systems development. It is developing a benchtop, point-of-care system that will provide an oncologist with immediate blood levels of the cancer drug 5-FU, enabling fine tuning and optimization. The interaction between a blood sample and a 5-FU agglutinating immunoassay developed by **Saladax Biomedical** (Bethlehem, Pennsylvania) will be overseen by an embedded system controller that will manage metering, mixing and turbidimetric measurement.

In the area of glucose monitoring, InVivoMon has eliminated the need for repeated testing by coupling a microdialysis probe to an embedded system controller that continuously monitors diffusion, convection and osmosis within the microdialysis probe and makes corrections to the glucose sensor readout. This allows for the accurate measurement of glucose levels continuously and without nurse intervention. The company also is developing in collaboration with **VA Pittsburgh** a handheld unit for nurses that includes a smart algorithm called GENIE for blood sugar management in patients. ♦