

Benefits Point Biotech Firms to Buffalo

Research Spending Increased 43% in Five Years, and a 400,000 sq. ft. Research Facility Was Built

Vicki Brower

Buffalo is sprouting a number of biotech companies to commercialize capabilities in life science research and expertise in oncology, neurology, pharmacology, and bioinformatics.

The Buffalo Niagara region has been a center of medical device and biotech tool innovation for some time.

Among the locale's benefits is the proximity to the Canadian border within the Golden Arc, an area between Toronto and Rochester. In the past Buffalo was one of

the most expensive air routes but more recently it has become one of the least expensive ones in the U.S., according to Allen Barnett, Ph.D., CEO and founder of Kinex Pharmaceuticals (www.kinexpharma.com), located in this northwestern region of New York.

A number of factors work together to make Buffalo a destination for consideration by life science companies. The cost of living is low while a skilled workforce is fueled by 6,500 life science graduates

annually. There is also a set of financial incentives in place that are attracting individuals, some new to the area and many natives who are returning.

Buffalo is currently home to over 130 life science companies. It is also within an hour and a half by land to 650 biomedical companies. America's first cancer center, Roswell Park Cancer Institute (RPCI), where the prostate-specific antigen test and photodynamic therapy were developed is located in Buffalo. The Hauptmann-Woodward Medical Research Institute, a center of structural biology, and a number of life sciences companies including Invitrogen (www.invitrogen.com) and Greatbatch, where the first internal cardiac pacemaker was developed, are also situated here.

An indicator of Buffalo's growing life sciences sector is its basic research spending. In 2006 this figure increased 43% from 2001 to \$300 million. Also, in the past seven or eight years Buffalo has strengthened research itself by recruiting 140 scientists, points out Dave Tyler, business development manager at Buffalo Niagara Enterprise. The company is a nonprofit private-business development group launched in 1999 by the local business community to attract businesses and jobs to the area.

"A number of key administrators have also been brought in to help direct new initiatives in technology transfer, translational research, and to oversee cooperation among our major research institutions," remarks Richard Matner, Ph.D., director of technology transfer and commercial development at RPCI.

Another sign of growth is that in 2006 a 400,000 sq. ft. research facility, the Buffalo Life Sciences Complex, was completed. Located in downtown Buffalo in the heart of the Buffalo Niagara Medical Campus, its mandate is the facilitation of collaboration between University of Buffalo, RPCI, and Hauptmann-Woodward. "The underlying mission of the new campus is to bring together pieces that were already assets and to focus on strengths," comments Marnie LaVigne, Ph.D., director of business development at the University of Buffalo's New York State Center of Excellence in Bioinformatics and Life Sciences.

New Firms in the Area

Strategic planning and an influx of new investment has resulted in the creation of three new biotech companies so far in 2007. Buffalo BioSciences, nearly two years old, is located in the new Life Sciences Complex and is providing upstart biotech ventures with expertise in financing and management.

Empire Genomics (www.empiregenomics.com), one of the new companies, is focused on the development of molecular diagnostics and genomics-based tests. Its CSO, Norma Nowak, Ph.D., is the author of a number of landmark papers related to the Human Genome Project (HGP). The Buffalo native also led the extramural NCI Cancer Chromosome Aberration Project.

While working on the HGP, Dr. Nowak's team developed Comparative Genomic Hybridization (CGH). "CGH

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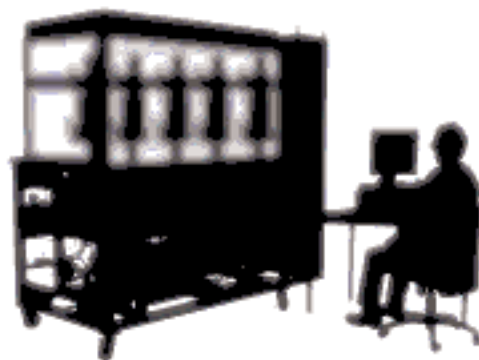
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detects the smallest-known damage to DNA, whether additions or deletions, in a 24-hour assay and helps identify disease susceptibility in complex genetic diseases," she explains. "Until now, there has been a whole spectrum of microdeletion syndromes that have been undetectable."

Using amniotic fluid for prenatal testing and blood for postnatal testing, Empire's diagnostic tool reportedly identifies 100 different chromosomal abnormalities that can aid early intervention for disorders including a number of learning disabilities, autism, schizophrenia, and mental retardation. "Approximately one-half of babies born have indications that require such in-depth testing, which we believe will lead to earlier treatment and better outcomes," says Dr. Nowak.

Another new diagnostics company, **PersonaDx** (www.personadx.com), is commercializing technology developed by Lionel Coignet, Ph.D., an RPCI cancer genetics researcher. Dr. Coignet discovered a marker that indicates an increased risk of metastasis in cancer patients. While less than 15% of breast and prostate cancers metastasize in the first five years, there is currently no way to predict those that will.

Dr. Coignet discovered that in certain metastatic cancer cell types, a protein called SMRT (silencing mediator for retinoic & thyroid, also known as NCoR2, or nuclear corepressor 2) is down-regulated. The gene for the SMRT protein is located in band 24 on the long arm of chromosome 12, where two fragile sites are found. "When a fragile site is located in the middle of a gene, the cell can no longer express that gene's protein," explains Dr. Coignet.

FRA12E is one such fragile site located in the SMRT gene locus, which forms the basis of Dr. Coignet's diagnostic. Dr. Coignet hypothesized that this breakability, which appears in every cell and is inherited in Mendelian fashion, could indicate which cancer patients are at greater risk of metastasis.

PersonaDx tested this hypothesis in 120 breast and 120 prostate cancer patients and the same number of controls. The company found that those with a strong SMRT gene, called the Coignet Factor, were over 25 times less likely to develop metastases. Those with a breakable SMRT gene, however, had greater metastasis risk.

Andro BioSys (www.androbiosys.com), the third spinoff this year, is developing prostate cancer therapeutics based on the research of James Mohler, M.D., and Gary Smith, Ph.D. Their work focused on stem cells, angiogenesis, and androgen metabolism, according to CEO Michael Zwick, Ph.D.

"Our goal is to find new targets that will make androgen-deprivation therapy curative not palliative," Dr. Zwick notes. "While initially effective, androgen-deprivation therapy lasts only a few years." Dr. Mohler's research on the androgen receptor led to the discovery of a third form of the 5- α -reductase gene, which he hypothesizes could be a better target than the two current targets of the treatment.

Because prostate cancer stem cells survive androgen-deprivation therapy, the company

is working to selectively kill or differentiate those cells. Andro BioSys is also analyzing drugs to target endothelial cells, which form the basis of tumors and while sensitive to androgen-deprivation, eventually return in the absence of those hormones.

Near term, the company is offering prostate cancer drug screening services and longer term will develop its own therapies.

Recently, Andrei Gudkov, Ph.D., was recruited by RPCI from the Cleveland Clinic
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Roswell Park Cancer Institute (RPCI) and AndroBioSys (ABS) recently signed an agreement that gives ABS exclusive rights to patented technology held by James Mohler, M.D., (shown) and Gary Smith, Ph.D., coleaders of the Prostate Cancer Program at RPCI and founders of ABS.



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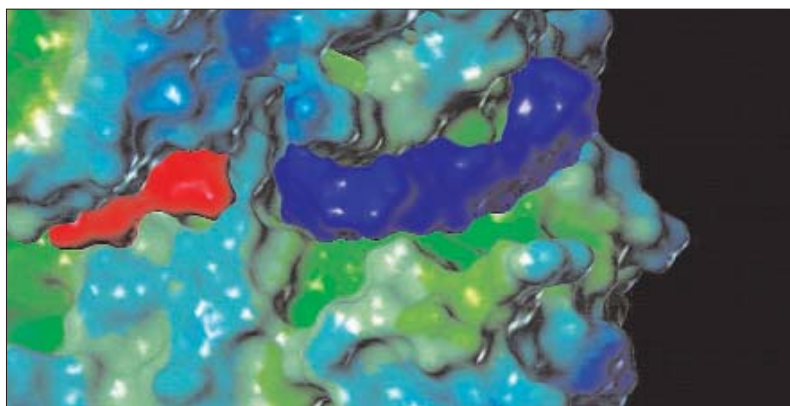
to serve as its new senior vp for research program development and chair of cell stress biology. Dr. Gudkov relocated his biotech company, **Cleveland BioLabs** (www.cbio-labs.com), as well. With the company's primary focus in cancer and secondary interest in tissue protection, the opportunity to team up with RPCI was a strong draw.

Like other early-stage biotechs, Cleveland Biolabs benefits from numerous financial incentives, tax rebates, and credits through the Empire State Development and the Buffalo Empire Zone programs.

The company is developing a class of radioprotectant drugs, protectans, that shield healthy cells from radiation exposure. The firm is also working on a second class of drugs, curaxins, which promote apoptosis of cancer cells.

"These two drug classes work by modulating expression of p53 and NFκB," explains Michael Fonstein, Ph.D., president and CEO. Its first-generation curaxin, CBLC-102, is in Phase II testing in advanced prostate cancer. The company plans to file an IND for its first protectan—

Kinex' KX2-391 bound on Src kinase. Kinex' compounds bind in the peptide binding site as opposed to the ATP binding site, which, it says, results in exquisite selectivity and the potential for less drug resistance.



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CBLC-502, a modified microbial protein—by year's end, Dr. Fonstein says.

Another relatively new company in Buffalo is Kinex Pharmaceuticals. It recently began a Phase I trial with KX2-391, an orally available Src kinase inhibitor, in solid tumors. The company has plans to expand development to drug-resistant leukemias.

"KX2-391 is the first non-ATP-competitive kinase inhibitor to enter clinical trials," reports Dr. Barnett. "This drug has a highly selective mechanism of action that is less likely to induce drug resistance than other Src inhibitors, which are ATP-binding molecules." The Src protein is a key regulator of tumor growth, vascularization, and metastasis.

Dr. Barnett spent many years at **Schering-Plough** (www.schering-plough.com) developing Claritin, Clarinex, Zetia, and Doral. He maintained professional and personal ties to Buffalo, where he received his Ph.D. He has long served as adjunct professor in pharmacology and toxicology at the University of Buffalo. While teaching there, Dr. Barnett met David Hangauer, Ph.D., whose research on substrate-specific, non-peptide kinase inhibitors led them and two other colleagues to found Kinex in 2004 to bring promising Src research to the clinic.

The company is using its Mimetica technology to generate small molecule inhibitors of protein kinases and phosphatases that bind to the Src substrate pocket. Kinex also has early-stage R&D programs in osteoporosis, restenosis, myocardial infarction, arthritis, and diabetes, all diseases in which Src plays a key role.

The most recently formed company, **CH3 BioSystems** (www.ch3biosystems.com), will provide products and services for the discovery of protein methylation pathways to aid research in cancer and autoimmune, cardiovascular, and neurodegenerative diseases, says T. J. Lukasiewicz, CEO.

Besides the new players, Buffalo is also home to a number of older biotech companies, which have continued to evolve to meet newer needs of the biotech industry. Invitrogen has a 45-year history in this area. It has traditionally manufactured cell culture media and reagents for biotech drug and diagnostics discovery.

In 2005 Invitrogen started a new business unit, PD-Direct Bioprocess Services, to provide custom services to companies developing therapeutics, according to Steve Gorfien, Ph.D., director of bioproduction products and direct services.

PD-Direct is currently working with approximately 200 companies to create recombinant cells for therapeutic protein

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production and to optimize processes used in product manufacturing.

"Many of our clients began on Invitrogen's research side and transitioned to working with PD-Direct once they began planning for clinical trials," Dr. Gorfien notes. Its projects often result in the creation of customized raw materials used in manufacturing of biotech drugs.

Another older Buffalo company is **Zeptomatrix** (www.zeptomatrix.com), founded in 1982. It is a research products and services company focusing on

immunology, virology, and oxidative stress. It houses biological level 3 labs and one of the world's largest commercial archives of human disease specimens.

"We can manufacture any culturable microorganism and for viruses such as HBV and HCV, we can inactivate them without destroying them and purify them from plasma and other biological fluids," states James Hengst, Ph.D., CEO.

As well as turning out 30–40 new products a year, Zeptomatrix also offers customized lab services. It has been growing rapidly over the

past five years due to a boom of AIDS, SARS, and general PCR research. In 2007, its business had grown by 35% since 2005.

A significant factor in its growth is optimal business conditions in Buffalo, says Dr. Hengst. He specifically points to a wealth of well trained graduates, subsidized salaries while training, and no property taxes for new life science businesses.

The growth of older companies and an ongoing initiative to develop new biotech firms, has Buffalo poised as a hot spot for the life science industry. **GEN**

Diagnostics

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Ipsogen states that the NPM1 products will integrate with its quantitative and standardized technology, FusionQuant® and ProfileQuant®.

bioMérieux to Design Companion Assay for Ipsen Breast Cancer Drug

bioMérieux (www.biomerieux.com) agreed to develop a companion test for Ipsen's (www.ipsen.com) Phase I breast cancer drug candidate. The assay is intended for both the clinical development of the compound as well as a diagnostic test potentially for future commercialization.

BN 83495 is designed to block the steroid sulfatase enzyme, which is found in hormone-dependent breast cancer in postmenopausal women. bioMérieux will devise a tool to determine the patients best suited to benefit from this steroid sulfatase enzyme inhibitor.

The test will be developed on bioMérieux' NucliSENS EasyQ® molecular diagnostics platform. The company will use the NASBA® amplification technology. bioMérieux will cofund the project with Ipsen.

TriCore to Perform Validation Studies for Biomoda's Lung Cancer Detection Instrument

TriCore Reference Laboratories (www.tricore.org) will help Biomoda (www.biomoda.com) validate its detection tool for early lung cancer. TriCore will conduct assay preparation, testing, and analysis of the instrument.

Biomoda's technology is based on a porphyrin application that preferentially binds to cancerous or aberrant cells extracted from lung sputum samples. Cancerous cells glow red under fluorescent light to allow detection under a microscope. This noninvasive cytology-based assay is designed for cancer screening of large populations at a reasonable cost, according to Biomoda.

Celera and Merck to Work On Pharmacogenomic Tests Related to Oncology

Celera (www.celera.com) entered into a research collaboration with Merck & Co. (www.merck.com) to develop biomarker and pharmacogenomic tests for cancer patients.

Celera will evaluate the use of certain gene expression profiles identified by Merck. The goal is to develop diagnostic predictors for use in Merck's clinical trials. The companies believe that this could form the basis for commercial companion diagnostic tests for oncology therapies.

Celera will receive an undisclosed payment for this collaboration. The company is also eligible for additional fees should Merck decide to transfer a Celera validated gene expression assay to a clinical reference laboratory.

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