Partners in Innovation
Technology Commercialization

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University of Rochester Medical Center

CATALYSTS FOR REGIONAL GROWTH

The New Clinical and Translational Sciences Institute & Building

In 2006, the University of Rochester received a $40 million, five-year NIH Clinical and Translational Science Award (CTSA). Now the University embarks on the construction of a new 150,000 square foot building to house the Clinical and Translational Sciences Institute (CTSI), serving as a catalyst for economic growth in the Rochester region. The CTSI will bring together under one roof scientific disciplines, support operations, education and training programs, and specific clinical research programs. CTSI will facilitate regional economic development by propelling growth in employment, creating regional research initiatives, and developing new technologies with commercial potential.

Harnessing the collective talent and resources of the region's biomedical research community, the building represents the potential to transform Upstate New York into a leading center for biomedical and translational research with a robust biomedical economy.

The largest NIH grant in the University's history, the award enables the Medical Center and its partner institutions to assemble the enabling technologies, trained personnel, and operational support necessary to accelerate the process of translating medical breakthroughs into improved treatments and diagnostics.

The new building will provide a physical and intellectual home for clinical and translational research that will accommodate investigators as well as study participants. The new research building, along with the hiring of new faculty, further establishes the University as a national leader in clinical and translational science while also creating hundreds of new jobs.

With the UR as the region's largest employer, the Center for Governmental Research (CGR) projects substantial incremental gains in employment with the construction of the Clinical and Translational Sciences Building (CTSB). Expanded clinical and translational research initiatives will lead to approximately 600 new, permanent positions at the University, resulting in $43 million in labor income. In addition to new researchers and staff, the impact of the $57

million construction phase alone (CTSB and related refitting and infill construction) will add labor income of an additional $40 million and the equivalent of about 830 “person years” of full-time labor.

CGR's analysis indicates that the immediate and indirect impacts of the new clinical and translational science enterprise add up to nearly $30 million annually once the entire venture has matured in its fifth year. These impact estimates are specific to New York State and are a combination of the grant, the institute, the building, and other investments anticipated, particularly the increased research made possible by the CTSB.

Reinventing Clinical Research

A key to the growing national presence of the University of Rochester in clinical and translational research is the partnerships we are proud to have forged with other innovative academic institutions, healthcare systems, and businesses that share our scientific vision and mission.

As a result of the Clinical and Translational Sciences Award (CTSA) received in 2006, a new Upstate New York Translational Research Network has been assembled with the University of Rochester Medical Center as the lead institution. The network includes: The University at Buffalo, State University of New York (SUNY) Upstate Medical University in Syracuse, SUNY Binghamton, Cornell University, Ordway Research Institute, Albany Medical College, Albany School of Pharmacy, Bassett Healthcare System in Cooperstown, and Guthrie Healthcare System in Sayre, PA.

The consortium will foster research collaboration, expand important resources, and create economies of scale in the field of clinical and translational research across the region. Collectively, member institutions receive $750 million in extramural funding, $370 million from the National Institutes of Health. Rochester, specifically our new Clinical and Translational Sciences Building, will be a physical hub for the consortium.

The Clinical and Translational Sciences Institute (CTSI), formed as a result of the award, brings together a wealth of relevant intellectual capital and research experience. At the School of Medicine and Dentistry in Rochester:

- More than 1,100 current individual clinical research projects are underway;
- The projects are supervised by 375 investigators;
- Clinical research accounts for nearly half of the research funds from external sources and is concentrated in neurosciences, cardiovascular disease, cancer, immunology, vaccine biology, infectious disease, and musculoskeletal diseases.

In a re-engineering of how the University conducts and supports clinical and translational research, CTSI comprises: technical and regulatory resources and support; recruitment networks; clinical and translational research education programs; and low-risk pilot studies.

As our clinical and translational research achieves new milestones, it is our privilege to keep our academic and industrial partners up to date through this newsletter and other URMC communications.

David S. Guzick, M.D., Ph.D.
Dean, School of Medicine and Dentistry

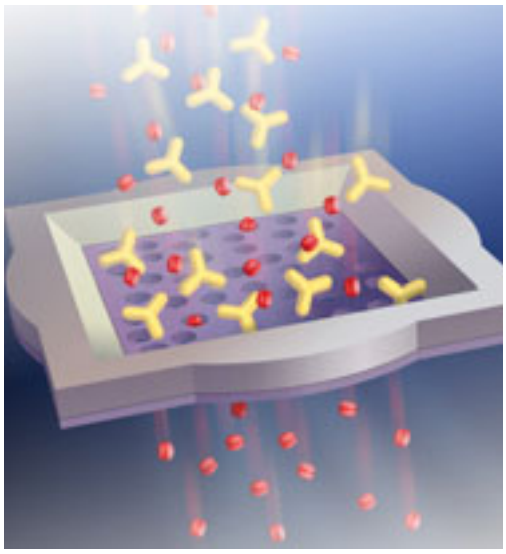
START-UP PROFILE

SiMPore

In January 2006, the Johnson & Johnson/URMC Discovery Concept Fund awarded $100,000 to James McGrath, Ph.D., UR Assistant Professor in Biomedical Engineering, to pursue his work in the separation and purification of biomolecules and other nano-sized particles. McGrath, along with Thomas R. Gaborski, Ph.D., also in Biomedical Engineering, is looking at identifying practical uses for an ultra-thin silicon-based membrane developed by Philippe M. Fauchet, Ph.D., and Christopher C. Striemer, Ph.D., in the UR's Department of Electrical and Computer Engineering.

In less than a year and a half, this work has led to the launch of SiMPore Inc., a newly-formed company dedicated to commercializing these innovative separation technologies. The company is led by CEO Rick Richmond, a business development specialist, previously CEO of STS Biopolymers, a leading developer and producer of polymeric coatings for medical devices. Richmond holds an MS and MBA from the UR Simon School of Business where he has taught economics and mathematics. He is a member of the Advisory Board of Excell Partners, Inc. a pre-seed venture investment company. McGrath is President; Gaborski VP of Product Development; Fauchet serves as Chair of the Advisory Board; Striemer is Scientific Advisor, and OCA's James Roussie is VP of Sales and Marketing.

At the core of SiMPore's proprietary technology portfolio is a remarkable silicon-based porous membrane less than 20 nanometers thick. This unique material has the potential to revolutionize the separation of small molecules in a variety of applications.



Artist's rendering of the separation of IgG from albumin using ultrathin silicon membranes—the purple silicon membrane is as thin as the molecules it is separating.

"Initially we are packaging the filters in a small format that most biomedical scientists are very familiar with," says McGrath. "These inexpensive systems will allow scientists in universities and industries to separate biomolecules in minutes rather than hours and with better precision and less loss of valuable material than ever before. We are expecting that traction in that market will give the company a core business upon which it can build. The filter should also make its way into a number of small scale devices that simply don't exist today. The silicon platform and the filter's efficiency should allow tiny sensors for biomolecule analysis, pathogen detection and the like. Large filters can also be made, and with these we hope to develop portable blood dialyzers and filters for large-scale production and removal of nanoparticles."

Richmond says that SiMPore's membrane filters have potential for significant sales in the multi-billion dollar markets for biological and pharmaceutical separations, microelectronic and other nano-scale industrial processes, and for beverage production. "The Rochester area has the skilled people and infrastructure to enable SiMPore to grow and become a major manufacturer and employer in the region," he says. "Especially helpful are the rich engineering and biomedical resources at the University of Rochester and RIT, which have collaboratively supported the development of SiMPore."

The Johnson & Johnson Discovery Concept Fund has played a key role. "We are grateful to J&J for the shared vision and funding that has taken us to this point as a company," said McGrath.

NY and URMC Loves BIO

URMC has long participated as an exhibitor at BIO, the annual biotech conference held by the Biotechnology Industry Organization. This May, BIO was held in Boston and attended by over 20,000 participants in the biotech industry from around the world. URMC participated in the NY Loves Bio Pavilion, and brought 8 Rochester collaborators to share the experience:

- Diffinity Genomics
- Finger Lakes Community College
- Greater Rochester Enterprise
- iCardiac Technologies, Inc.
- Lighthouse International
- Litron Laboratories
- Quantum Technology Associates
- Rochester Institute of Technology

"We were very pleased with the results from the event as we were able to make connections with several venture capital firms for potential future iCardiac projects," said J. Mikael Totterman, CEO of iCardiac Technologies, Inc.

Partnering meetings with industry participants such as Procter & Gamble and Merck also provided opportunities to gain insights about the marketability of new technologies and products. "We appreciated all that URMC did to make it possible for Diffinity to participate," said Rick Richmond, Diffinity CEO. "We made many contacts and had many meetings that helped us with our product and market direction."

Participants are already looking forward to the 2008 BIO in San Diego, June 17-20. "We appreciated being part of the Rochester BIO team," says Dallas Kaiser, Director of Engineering for Quantum Technology Associates. "Count us in for next year!"

Dallas Kaiser of Quantum Technologies talks to a potential investor in the NY Pavilion at the BIO conference.

For more information about the 2007 and 2008 BIO conferences, go to http://www.bio.org.

FOCUS ON RESEARCH

Preparing for Pandemics

A URMC research team was awarded $26 million to establish a research center with the goal of making future influenza pandemics less deadly. The seven-year grant, announced by the National Institute of Allergy and Infectious Diseases (NIAID), creates the New York Influenza Center of Excellence (NYICE), a collaboration of the University of Rochester, Cornell University, the University of Tennessee at Knoxville, and community partners. NYICE is one of six centers nationally that together will receive approximately $138 million in new flu research funding.

Despite new vaccine technologies, flu remains the most common cause of vaccine-preventable death in the United States, causing 40,000 deaths annually and up to 150,000 hospital stays. In addition, the H5N1 subtype of avian flu viruses ("bird flu") continues to spread with migrating waterfowl, increasing the risk of bird-to-human infection and the chance that the virus will become more easily passed from person to person.

Drugs are available to treat influenza—amantadine, rimantadine, zanamivir and oseltamivir—but many flu strains, including the bird flu subtypes, have developed drug-resistant strains. Available bird flu vaccines so far offer only limited protection, and the ability of the virus to change rapidly precludes stockpiling vaccine in advance of an outbreak.

Each of the six new centers will focus on basic research, surveillance studies or both. Teams will breakdown the molecular and environmental factors that influence the transmission and evolution of flu viruses and further study the immune system's reaction to them. Others will seek to identify strains with pandemic potential, to create new vaccine candidates or to bolster pandemic preparedness. Along with the University of Rochester, recipients of the new grants are Emory University, Mount Sinai School of Medicine, St. Jude Children's Research Hospital, University of California at Los Angeles and University of Minnesota at Minneapolis.

"The current strategy of relying on vaccines that match each year's particular strain imposes severe limitations on our ability to prepare for a pandemic," said John J. Treanor M.D., URMC Professor of Medicine and of Microbiology and Immunology and principal investigator for the new center. "Our goal is to transform our understanding of influenza through intensive and synergistic exploration of the virus, the human host, and the immune system. We hope that this will lead to more effective control of the viruses through a single vaccine that can be effective against many strains."

Researchers will follow college students, healthy adults and 150 families with young children in the Rochester area for seven years, monitoring them for exposure to flu and responses to vaccination. All data will be captured and shared through an NIH database.

"The threat of an influenza pandemic is a growing source of concern for those charged with protecting public heath," said Bradford Berk, M.D., Ph.D., CEO of the Medical Center. "The new center will facilitate the nation's preparations for a potential pandemic and further our understanding of influenza viruses."

NYICE Goals

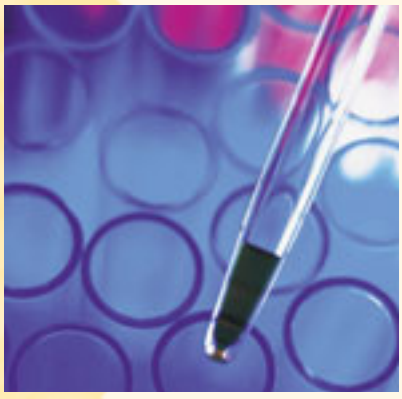
Five distinct goal-driven projects now are underway:

- **Project 1:** Study how white blood cells (T cells and B cells) recognize qualities shared by many different influenza strains on the way to designing a vaccine that would confer permanent immunity.
- **Project 2:** Determine the specific proteins within the virus that turn on "helper" T cells, causing them to attack infected cells and result in better antibody responses to infection or vaccination.
- **Project 3:** Understand how immune cells communicate with one another in response to infection and vaccination.
- **Project 4:** Explore how the viral protein, hemagglutinin, changes as avian viruses genetically jump from birds to mammals. The protein is involved in the ability of the virus to stick to mammalian cells, a first step in invasion. This project will be led out of Cornell University.
- **Project 5:** Study the qualities of viral polymerase, the enzyme used by the virus to copy its genetic material, and how it becomes better at encouraging viral reproduction in mammalian cells.

Bypassing Eggs, Flu Vaccine Grown in Insect Cells Shows Promise

An experimental flu vaccine made in insect cells—not in eggs, where flu vaccines currently available in the U.S. are grown—is safe and as effective as conventional vaccines in protecting people against seasonal flu and a possible bird flu pandemic, according to results published in the April 11 issue of the *Journal of the American Medical Association.*

Using eggs to grow vaccine takes time; large supplies of flu vaccine grown in insects using a different technology can be produced much more quickly, a key advantage if a bird flu pandemic were to occur, researchers said. In the study led by the URMC's John Treanor, M.D., the team tested a vaccine called FluBIOk that is made by Protein Sciences Corp. of Meriden, CT. FluBIOk relies on a virus known as baculovirus, which normally infects insects, to churn out the key components of the flu virus in a cell line drawn from caterpillars.



UNIVERSITY OF ROCHESTER MEDICAL CENTER

SCIENCE BRIEFS

Research Agreement to Advance New Imaging Technology

The University of Rochester Medical Center (URMC) and T.I.E.S., LLC, a Rochester-based start-up company, have entered into a research partnership to evaluate a new technology that could ultimately represent a major advance in medical imaging.

T.I.E.S.—which stands for Tomographic Image Enhancement Systems—has patented a new image processing technology called "Image Surgery" that allows scientists and radiologists to selectively focus on a specific organ or region of the body and, as a result, create clearer and more precise side-by-side images. The company, which is led by two former Kodak imaging systems executives, will work with researchers in the URMC Department of Imaging Sciences to apply this technology to images from actual patients.

T.I.E.S.'s imaging technology potentially overcomes what have been significant limitations in medical tomography or three-dimensional imaging. Today's advanced imaging technologies such as gamma cameras, CT, MRI and PET scanners reconstruct images by converting a sequence of two-dimensional images that are captured by a receptor as it rotates around the patient into a three dimensional image. While these technologies have provided doctors an invaluable view into the human body, the images often contain flaws.

The T.I.E.S. technology overcomes these problems by segmenting the raw data before it is converted into an image. This allows radiologists to exclude objects that are not of interest and, as a result, heighten the resolution of the remaining target image.

New URMC Start-Up Introduces Statistical Analysis Software

Random Technologies, the newest start-up company to emerge from the University of Rochester Medical Center, has launched its software package that helps research organizations analyze data gathered in clinical studies on new medications.

Random Technologies' software is based on the most widely used statistical computing and graphics system in biomedical research: the open source software system "R." R was developed by a global network of thousands of volunteer programmers and has become the preferred research tool of the scientific community because of its flexibility to address novel research problems and its capacity to produce rich graphic representations of data.

However, industry has been reluctant to adopt the software to perform critical functions, such as submitting data from drug studies for regulatory approval, because the system is not commercially supported.

"Random Technologies intends to do for R what Red Hat did for Linux," said Gregory Warnes, Ph.D., the company's founder, an associate professor of biostatistics and computational biology, and co-director of computational software development at the University of Rochester's Center for Biodefense Immune Modeling. "R is an exceptionally useful system with tremendous capabilities and has been widely adopted by academic and research statisticians. Random Technologies will provide the enterprise level support that will enable corporations to deploy this software as a critical component of their business."

EVENTS

Getting Smart About Venture Capital

This year the SmartStart Venture Forum joined forces with UNYTECH (Universities of Upstate New York Venture Forum) to present the Seventh Annual SmartStart Venture Forum in Albany on May 22-23. Universities, venture capital firms, and private investors came together to learn about medical informatics, next-generation software platforms, renewable energy, and homeland security markets, to name a few. The event displays the very best early-stage companies from throughout New York State. Keynote speakers included Alex Zapesochny, co-founder of iCardiac Technologies, Inc., and Mark Heesen, president of National Venture Capital Association.

Jack Fraser, UR Office of Technology Transfer, was responsible for coordinating presentations from across the University.
For more information, go to: www.smartstartvf.com

Partners in Innovation is produced by the University of Rochester Medical Center to communicate technology commercialization news and facilitate successful alliances between academic scientists and commercial partners.

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