

# **The John Carroll Collaborative with Industry**

**An update for the Faculty Forum    November 2003**

**D.W. Ewing, Director, JCCI**

## **JCCI Vision**

*The John Carroll Collaborative with Industry (JCCI) is a catalyst for realizing the University's mission to serve through innovative and collaborative efforts with the regional community in science-based education, research, and public service.*

## **JCCI Mission**

*The John Carroll Collaborative with Industry (JCCI) is an innovative and flexible program for enhancing the role that scientific activities and experiences can play in more broadly educating students, enhancing faculty and student research opportunities, assisting local businesses, and otherwise engaging the regional community. In all these roles, the JCCI emphasis is on collaboration among participants, a positive impact on students, and maintaining the prestige of John Carroll University.*

## **Benefits of JCCI**

JCCI will provide science, business, and other students with unique internship opportunities in technology driven, entrepreneurial companies. Faculty will benefit from the opportunity to collaborate with JCCI partner scientists. JCCI partner companies will benefit from the resources and setting of an academic environment. JCU and JCCI partner companies will benefit from synergistic funding opportunities which will enhance JCU's academic programs and JCCI partner research. Northeast Ohio will benefit from JCCI's contribution to the economic growth of the area, as JCCI partner companies grow out of their JCU incubator space. The region will also benefit from JCCI's contribution to stemming the "brain drain" from Northeast Ohio, as some student interns will stay on with partner companies, or take positions in similar industries in the region.

## **JCCI and the Faculty Forum**

An *ad hoc* committee of the Faculty Forum was established in late 1999 to study JCCI. A report was produced in January 2000. The study focused on four areas: the process by which JCCI was pursued; oversight; academic issues; "additional substantive issues".

Problems with the process by which JCCI came about stemmed largely from inadequate communication. Steps have since been taken by the Administration to attempt to improve campus communication, although more progress still needs to occur.

The oversight, academic, and “additional substantive” issues raised by the *ad hoc* committee are, by and large, being addressed by the JCCI Oversight and Development Committees, both largely faculty committees (*vide infra*), and the Graduate School & Office of Faculty Research, Grants, and Development. Indeed, the Oversight Committee was formed by recommendation of the Faculty Forum *ad hoc* committee, and the Development Committee was formed by recommendation of the Oversight Committee. The “outstanding issues”, listed below, being grappled with by the JCCI committees encompass most of the issues raised by the *ad hoc* committee. See also the minutes of Development Committee meetings at <http://www.jcu.edu/graduate/jcci.htm>.

### **Progress to date**

Edward Glynn, S.J., President of John Carroll University, promulgated the creation of JCCI in 2000, establishing an Oversight Committee to develop guidelines for this new program. In 2001 the Oversight Committee produced its guidelines.

Battelle Memorial Institute was commissioned to develop a strategic framework for JCCI. A report was produced in March 2002. The overall conclusion of the report was that JCU has the ability and resources to fulfill the vision and mission of JCCI. The major strategies recommended in the Battelle report were:

- Initiate proactive marketing and communications efforts to improve the image and knowledge of the JCU sciences within the broader external community.
- Establish the operational infrastructure to support the full implementation of JCCI.
- Engage regional industry partner through JCCI to provide and enhance science-based education and research opportunities at JCU.

All of these strategies are currently being implemented.

A Steering Committee was formed in November 2002. This group includes leaders in the Northeast Ohio technology business development community and JCU faculty and administrators.

David Ewing, Ph.D., Professor of Chemistry, was named Director in April 2003. A Development Committee was established to interview potential partner companies and to work with the Oversight Committee on developing policies and procedures.

Laboratory and office space for JCCI was set aside in the new Dolan Center for Science and Technology. Generic biotechnology and physics research lab spaces are now being designed, as these are the likely types of companies to be initial JCCI partners. The first JCCI partner company could be working in the Dolan Center as early as late winter 2004.

## **Ridgeway Biosystems, Inc.**

JCCI's first potential partner is Ridgeway Biosystems, Inc. A profile of the company is attached. Ridgeway is an ideal first partner for the new JCCI program. Ridgeway's research will be very attractive to many JCU students, and has good potential for collaborative efforts with faculty. Ridgeway's technology platform is very promising; many benefits will accrue to JCU when Ridgeway realizes its potential.

## **Outstanding issues**

Many policies and procedures need to be developed or more fully worked out as they apply to JCCI. These include intellectual property, various compliance issues, instrument use, student involvement, fee structures, administrative structures, technology transfer, and assessment. All of these issues are being worked on in the Oversight Committee, Development Committee, and the Graduate School & Office of Faculty Research, Grants, and Development. Draft policies for those issues seeking broader faculty input are attached. While everything possible will be done to minimize risks, there is some degree of risk in JCCI, risk to JCU and risk to partner companies. The potential benefits are too great not to take these risks.

## **JCCI Oversight Committee**

Dr. Nick Baumgartner, Chair  
Dr. Paul Challen  
Dr. Miles Coburn  
Dr. Marilynn Collins  
Ms. Christine Gibbons  
Dr. Paul Lauritzen  
Dr. Douglas Norris  
Ms. Sarah Wagner

## **JCCI Development Committee**

Mr. Peter Anagnostos, *ex officio*  
Dr. Anthony Roy Day  
Dr. David Ewing, Chair  
Dr. Jeffrey Johansen  
Dr. Beth Martin  
Dr. Frank Navratil  
Dr. Daniel Palmer  
Dr. Michael Setter

## **Contact information**

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# Ridgeway Biosystems Inc.

## Corporate Profile

### Company History

Ridgeway Biosystems, Inc. is a Cleveland-based biotechnology company that has been operating under its present name since 2001. The company is developing a drug platform for the treatment of viral infections and cancer. This platform is based on company patented technology surrounding the ubiquitous antiviral enzyme, RNase L. In essence Ridgeway's technology can be used to target any disease-causing RNA. However, it is particularly well suited to single-stranded RNA viruses, including hepatitis C virus (HCV), SARS coronavirus, influenza virus, and respiratory syncytial virus (RSV).

RNase L has a natural role in the defense against viral infections where cleavage of viral genomic RNA by RNase L eliminates the capacity of the virus to replicate. In fact, RNase L is a key enzyme in the antiviral and antitumor activities of interferons. It is activated by a completely unique small molecule, called "2-5A". Ridgeway's antiviral strategy is to link 2-5A to an oligonucleotide guide sequence targeting specific RNA.

Our approach activates the cellular antiviral pathway itself effectively obviating the need for interferon with its adverse effects and other limitations.

Ridgeway has nearly \$700,000 in current SBIR/STTR funding from the NIH, and nearly \$3 million in additional grant applications pending. Ridgeway has been structured to operate in the near term solely on these grant revenues. All full-time employees are focused exclusively on research and development activities, and the company carries extremely low administrative and management overhead. Ridgeway will achieve significant milestones in the next 6-12 months that will enable the company to return to the venture capital markets for funding if market conditions allow. With adequate funding, the company will expand its operations at that time to prepare for late-stage preclinical and early clinical studies on its lead therapeutics.

### Management and Personnel

#### **Executive Management:**

Chief Executive Officer: Duncan McVean, Ph.D. and Chief Operating Officer: Karl Wolcott,

#### **Science Management:**

Director of Chemistry: Dr. Hagen Cramer, Ph.D. and Director of Biology: Dr. Zan Xu Ph.D. Five additional research staff, including Ph.D. and BS/MS level researchers in Biology and Chemistry, completes the team.

**Science Advisors:** Ridgeway co-founders Drs. Robert Silverman and Bryan Williams of The Cleveland Clinic serve as consultants to the company and leaders of its Scientific Advisory Board. Other key advisors and collaborators include Dr. George Stark, National Academy of Sciences member and Distinguished Scientist at CCF, Dr. Eric Klein, Section Head, Urologic Oncology at the CCF Urological Institute, and Dr. Michael Vogelbaum, Director of Translational Therapeutics at the CCF Brain Tumor Institute, the University of Colorado Health Sciences Center, Baylor College of Medicine, Northern Arizona University, and the NIH. The collaborations and support are expected to continue through Phase I/II clinical trials.

## Science Platform - Proof of Concept

Respiratory syncytial virus (RSV), a RNA viral pathogen, can be deadly to patients with weakened immune systems, including newborn and the elderly. Each year in the U.S., RSV hospitalizes about 100,000 infants and is fatal to ~4,500. About an equal number of elderly and immunocompromised patients are also hospitalized. Aside from a preventive antibody treatment for infants, there is no effective drug for treating infected patients.

Ridgeway's lead drug for the treatment of RSV infections provided a potent antiviral effect in three mammalian species (monkey, cotton rat and mice). A selective and potent antiviral effect was achieved in the African green monkey, up to four log<sub>10</sub> units inhibition of viral replication [Leaman, D.W., et al. *Virology*, 292, 70-77, 2002]. The drug targets a conserved sequence present in all strains of RSV.

Hepatitis C virus (HCV). There are an estimated 170 million people infected with HCV worldwide. While interferon and Ribavirin combination therapy is effective in some patients, there is a high failure rate (about 50%) and significant adverse effects. Using 2-5A-antisense avoids limitations associated with alternative approaches involving RNAi and conventional antisense. By attaching a 2-5A cassette to an oligonucleotide complimentary sequences in HCV genomic RNA, RNase L in intact cells is directed to specifically degrade the viral RNA, thus preventing replication. Ridgeway is developing a 2-5A-antisense drug active against a broad range of different HCV genotypes. The company is screening and optimizing candidate drugs that target sequences in targeted regions of HCV RNA (present in 5' and 3' untranslated regions) to obtain the lead 2-5A anti-HCV compound. In addition, Ridgeway is developing a proprietary, novel cell based assay system for evaluating its anti-HCV drugs. Specificity of the lead compound will be verified and its efficacy will be determined in our novel assay system. The success of the proposed studies will enable us to progress to studies of safety and pharmacokinetics and prepare for clinical trials.

Cancer: In 2002 the long sought after hereditary prostate cancer 1 (HPC1) gene was mapped to the RNase L gene (Carpten, J. et al., *Nature Medicine*, 30, 181-184, 2002). Ridgeway is carrying out preclinical testing of a 2-5A compound that halts the growth of tumor cells and causes them to commit cell suicide (apoptosis). Encouraged by data that show a marked anti-tumor effect of the drug candidate against several different human cancers (prostate, glioma, & bladder) in an animal model, Ridgeway is focusing on the development of a therapy for late-stage prostate cancer and malignant glioma. Both are aggressive and deadly cancers with extremely poor long term prognosis.

## Intellectual Property

Ridgeway controls a broad portfolio of over 30 issued and pending US and foreign patents. The patents cover the 2-5A antisense platform as well as specific applications of this technology against telomerase and RSV. Ridgeway will have rights to future proprietary technology related to 2-5A therapeutics resulting from work done in the laboratories of its scientific founders.

## Future Research Focus

**Cancer:** Pancreatic, Prostatic, and Brain

**Viral:** HCV, SARS, and HIV

**Other Applications:** Adjuvants for vaccines, inflammatory process, and Bioterrorism

## Contact Information

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JCCI Collaboration Flow Chart DRAFT Nov. 2003

