



F O R A G E N VISIONS

TGN Biotech Creates Living Bioreactors for Complex Drugs



INDUSTRY
PROFILE

Thanks to Foragen's strategic investment in TGN Biotech Canadians won't have to wait until pigs can fly to see the benefits of using transgenic animals to create some of the world's most expensive and complex human drugs.

TGN is the brainchild of two Laval University researchers, Dr. François Pothier and Dr. Marc André Sirard, TGN Biotech is one of the world's first companies to use hogs as drug bioreactors.



TGN Biotech President & CEO, Jean-Francois Huc, with founders Dr. Francois Pothier (left) and Dr. Marc Andre Sirard (right).

Platform technology

The Quebec company offers a patented¹ technology platform called Semenesis™. It is ideally

positions to enter the rapidly advancing biotherapeutics market.

Semenesis™ embodies a method of inserting tailor-made genes into the ova of pigs, containing instructions for biosynthesis of complex human therapeutic drugs in the adult pig's seminal glands.

“The company has an exceptional team in place that will pave the way to the development of bio-therapeutics on a world-wide basis.” says Murray McLaughlin, President of Foragen Technologies Management Inc., the lead investor responsible for TGN's \$5.35M round of financing in May, 2003.



“Albert One”, the first transgenic pig containing TGN's Semenesis™ technology, born in Quebec 2001.

Attracting investors

Innovatech Quebec has funded development of the Semenesis technology from early stages.

“TGN is an excellent example of Innovatech Quebec's role in developing high-potential technologies from Laval University...the presence of Canadian and local investors confirms the quality of this technology that is contributing to the development of Quebec City as a leading biotech cluster in Canada,” states Francine Laurent, CEO of Innovatech Quebec.

Leopold Beaulieu, CEO of Fondation CSN, the third major investor in the project, explains, “This investment will maintain more than 20 high-skilled jobs in the biotech sector. The company has a very qualified team that has set high ethical standards both in animal care as well as environment preservation.”

foragen

\$40 billion global market

The market for secondary entry human therapeutics is over US \$40 Billion, according to Dr. Roger Bernier, VP Quebec & Atlantic Region for Foragen.

To bio-therapeutic drug companies worldwide, TGN offers substantial savings over current costly bioreactor platforms, as well as the opportunity to create new designer drugs under contract, using its patented Semenesis™ technology.

While there are presently no drugs derived from transgenic animals approved for human use, the TGN team plans to change that. Following in the footsteps of GTC Bio-therapeutics, who are in Phase III trials with a human plasma component from transgenic goat milk, TGN means to become the second company in the world to be granted FDA approval for a product from a transgenic animal production system.

Technology advantages

The tissues of higher vertebrates, such as pigs, can synthesize highly complex drugs that cannot be created in plant, fungal or bacterial systems. Moreover, pig semen has many advantages over other media (eg: milk, urine), including reduced drug absorption effects on the host animal, absence of disease risks such as prions, rapid time to market and a complete freedom to operate.

TGN has two human therapeutic drugs in its production and regulatory pipeline, and has plans to build a full-scale production

facility. The site will be a high-tech SPF² animal facility where the modified piglets will be born by Caesarian section to create the foundation herd. Drug-rich semen will be harvested daily from the adult boars.

Unlike conventional yeast and cell culture technologies, TGN will be able to produce high yields of complex biotherapeutics with high levels of recovery. By using the pig, a higher vertebrate similar to humans, TGN can achieve complex glycosylation, multiple poly-peptide chains, and other drug forms unavailable through other existing platforms.

The company's biotherapeutic production strategy is to develop processes in-house for all products up to pilot scale production level, and to supply custom pre-clinical trial materials. Technology transfer from pilot scale to production can be completed in a timely manner.

All biotherapeutics produced from transgenic pigs can have their specific bioprocesses developed in-house, in an efficient and scalable manner. This enables TGN to launch any given product further downstream for later phase clinical trials, dramatically accelerating the product's entry to the market, and reducing overall costs.

Performance plus

Compared with milk, blood, urine or egg based systems, the TGN production system is simplicity itself. The drug molecules are created in high concentration in the seminal fluid, sperm are easily filtered out, and there are no prions, proteases or drug inhibitors to deal with.

It is well-documented that the human and porcine (pig) physiologies are

very similar, demonstrating a high level of biocompatibility and freedom from allergic problems.

Human therapeutics and other medical products derived from porcine sources (eg: heart valves), have been on the market for decades, and global regulatory agencies have more easily approved products of porcine origin, including insulin, heparin, and pancreatic lipase.

TGN's production costs are competitive, due to the ability of pigs to reproduce at one of the highest rates of any domestic animal, allowing a transgenic IVF³ herd capable of providing a global supply of complex drugs to be created within 29 months.

Finally, the domestic pig is the most prolific semen source of all livestock, able to generate a whopping 500 mL of seminal fluid each day of harvest.

Winning management team

The recent appointment of Jean François Huc as TGN's President and CEO completes an international management team and seasoned board of directors comprising CEOs and senior scientists from some of the largest public and private companies. There is an outstanding complementarity interaction among the technical staff as well. And with effective product development and regulatory committees in-place, TGN's management structure is impressive.

In keeping with its policy of team-building and hands-on development of management, Foragen has created within TGN a structure of governance that will see the company through its

product development and further investment phases, and into the global marketplace.

For further information, visit the TGN website at: www.tgnbiotech.com

- 1 TGN has filed two US patent applications for its unique Semenesis(tm) technology.
- 2 Specific Pathogen Free
- 3 In Vitro Fertilization, where the animal is conceived by mixing the chosen sperm and egg of the parents together in the laboratory, then implanting the resulting embryos into the mother's womb, all under sterile controlled conditions.

President's Message

Change - An Everyday Occurrence



Dr. Murray McLaughlin PhD, P.Ag.

"All things change, nothing is extinguished.... There is nothing in the world that is permanent. Everything flows onward; all things are brought into being with a changing nature; the ages themselves glide by in constant movement."

Ovid, Roman Poet (43B.C. - A.D.17)

My personal history with agriculture began in the 1950s. Since that time we have seen continual change. Much of that change came about as advancing global communication drove home an increased awareness of world issues. Hunger, environmental degradation, disease epidemics among humans and food animals were part of every news day and

changed the way we look at the world forever. The pervasive consciousness of the world as a global village encouraged those involved in life science research and delivery to apply new tools, such as biotechnology, as they sought effective ways to improve global quality of life. As science generated new findings world issues were addressed with ever increasing sophistication.

In the 1980's the dominant concerns were the need for improved crop production that delivered, more stress tolerant crops more efficient uptake of nutrients in crops better control pests in crops, improved environmental management in the field.

In the 1990's research moved on to address the need for solutions to health and safety concerns. Breakthroughs occurred that led to the development of : comprehensive approaches to food safety, fuels from renewable sources reduced pollution in the production of crops and food animals biobased feed additives to boost nutrient uptake in food animals and

encourage specific carcass characteristics more efficient production of plant based therapies, and vaccines cost effective, high efficacy nutraceuticals and functional foods to promote wellness

In recent years, the work done in the 80s and 90s has provided building blocks for important advances in the provision of: advanced food quality and safety systems improved waste management systems animal based sources for transplant and molecular production of drugs plant based sources for therapies address chronic disease such as diabetes improved delivery methods for drugs and biobased pharmaceuticals These changes were made possible by scientists and entrepreneurs who recognized challenges and embraced the need for change. It is their foresight that has given

the world important tools with which to heal the planet and improve quality of life.

The economy of the 21st Century will be bio-based. We will see an increase in added-value in agriculture. Breakthroughs have been made in developing and

delivering bioproducts, biopharma, biofuels, and biomaterials. I believe the significant change that needs to be embraced is the further convergence of life sciences. TGN Biotech, the featured portfolio company in this issue of *Visions* is part of that future. Their technology uses pigs for molecular

production of drugs and captures the ability to deliver highly efficient drug innovations. TGN Biotech and all of the companies in the Foragen portfolio are leaders in the development of a new age in global advancement. I feel privileged to be part of the process.

Portfolio News

Pyxis Genomics New President/CEO for Pyxis Genomics

Mr Brendon Fox has been appointed as the President and CEO of Pyxis Genomics, Inc. Fox, has been a member of the Pyxis Board of Directors since August 2003, He will direct the expansion of Pyxis Genomics' commercial operations. Fox succeeds Dr. Lawrence Schook, a Director and Scientific Founder of the company. Schook will continue to provide leadership to the company as Executive Vice President and Chief Operating Officer.

Before joining Pyxis, Fox was President and CEO of Elanco Animal Health, a Division of Eli Lilly and Company. He is a past President of Comisa, the forerunner of the International Federation for Animal Health (IFAH), the world animal health industry association.

Foragen President and Pyxis Board member, Dr. Murray McLaughlin, is pleased with the appointment. "Pyxis is entering a new phase of growth. Fox's background and unique involvement in the

international network for animal health will give the company rapid access to commercialization on a global scale." says McLaughlin. He also acknowledged the outstanding development work done by Schook. "His leadership and able direction has positioned Pyxis as a strong entry into the animal based genomics market." says McLaughlin. Foragen is a key investor in the company.

Ag-West Bio Inc. invests in Pyxis

Pyxis Genomics recently received a \$100,000 equity investment from Saskatchewan's Ag-West Bio Inc. The funds will contribute to Pyxis' research and development of non-antibiotic feed additives.

Pyxis President, Mr. Brendon Fox says, "Our company's ongoing research and development activities in Saskatoon are vital to the our continued success. The development of our genomic tools will be available to meat production companies and animal health providers in the ever-increasing competitive agricultural markets."

"Pyxis Genomics is developing new, non-antibiotic, feed additives to activate, strengthen or enhance an

animal's immune system. These new feed additives will be used to fight disease at very specific times when risk of infection is high- say at weaning or hatching," says Dr. Lawrence Schook, Executive Vice President of Pyxis. "The staff we have assembled in Saskatoon is top-notch. Their work shows great promise for future applications. We greatly appreciate Ag-West's recognition of our presence in Saskatchewan and our potential for advanced commercialization."

The mandate for Ag-West Bio is to initiate, promote and support the growth of Saskatchewan's agricultural bio-based industries and the commercialization of related food and non-food technologies.

For more information on Pyxis see *Visions Volume 1 Number 2* or visit www.pyxisgenomics.com

To learn more about Ag-West Biotech go to www.agwest.sk.ca



MCN Bioproducts Inc. Receives Award for Innovation

Foragen investment recipient, MCN Bioproducts Inc. has been named winner of the third annual Innovation Place-Industry Liaison Office Award of Innovation.

“We are pleased to see such prestigious recognition for the work done by MCN Bioproducts,” says Armand Lavoie, Foragen’s representative on the board of MCN and business advisor to the fledgling company. “MCN has come a long way since Foragen made its initial investment. There is a strong expression of international interest in its products, particularly in the area of fish food development.”

MCN Bioproducts Inc. was created in 2000 to commercialize a process to fractionate canola meal. The meal is one of the highest quality plant-based protein sources in the world.

The MCN technology, developed by the company founders Dr. David Maenz, Dr. Henry Classen, and

Dr. Rex Newkirk, separates the meal into higher value products.

High-protein concentrates for the aquaculture industry, customized protein fibre for cattle feed, and various co-products for use in markets from food to cosmetics are included in the MCN family of products.

The Award of Innovation is sponsored by the University of Saskatchewan (U of S) Industry Liaison Office and Innovation Place Research Park. It honours U of S researchers who have brought forward new, commercially viable technology.

For additional information on MCN refer to *Visions Volume 1 Number 1* or visit www.mcnbioproducts.com

PerOs Receives Investment

An early stage Foragen investment moves toward a late stage technology company with a promising commercialization future ahead.

PerOs Systems Technologies Inc. (PerOs), a leader in the development of oral delivery technologies for animal health and disease control, has closed an agreement for an

\$8 million investment by Jormian Capital Inc.

Mr. Ian Kott, President of Jormian Capital Inc. says in a recent press release that his firm has made this investment “in anticipation of the imminent commercial release of the first PerOs products and the realization of its enormous potential.”

PerOs has developed efficient non-encapsulation strategies to provide oral administration of bioactive compounds such as peptides, vaccines and antibodies.

The company recently announced that it has received patent approval for its lead technology in Singapore and New Zealand. This represents an important milestone concerning the uniqueness and technological force of the company’s oral delivery platform technology. Oralject™ technology is pending in more than 20 countries at this time and we expect a second national patent confirmation in the next few months.

For further information see *Visions Volume 1 Number 3* or visit www.perosbio.com

The Agricultural Biotechnology International Conference

Signs of change

The **Agricultural Biotechnology International Conference** is one of the most important conferences on agricultural biotechnology. The Conference was established in Canada in 1996 under the auspices

of Ag-West Biotech Inc. It was the first international conference to bring together all aspects of the life science industry in one event.

As President of Ag-West Biotech Inc., I was the initiator of this unique global forum. The Signature Group

Inc., a Saskatoon based communications firm managed the conference and generated the support of major player in academia, governments

The logo for Foragen, featuring the word "foragen" in a lowercase, sans-serif font. A green curved line arches over the letters "o" and "r", extending from the top of the "o" to the top of the "n".

and industry. The first ABIC Conference was held in Saskatoon Saskatchewan. At that time the world was just waking up to the potential for advancement through the application of biotechnology tools. With its 57 speakers in 6 topic streams ABIC demonstrated to the world that the tools of biotechnology were delivering an interdisciplinary power house to the world. Delegates from more than 20 countries took part in the event and the biobased community came to know the truly global nature of biobased research and the powerful contributions made by Canadians to that body of work.

The event was created to encourage interaction among scientists and industry. That first year 30 Saskatoon research organizations and corporations signed contracts for international work. Since that time three more ABIC events were held in Canada. Attracting high profile world research leaders and delegates from around the world.

This year ABIC will be held in Germany - a sign of world recognition for its achievements. The theme of the conference is '*AgBiotech back to Europe*'. On the conference web site the organizers state. "With the imminent lift of the *de facto* moratorium on genetically modified food, the implementation of new

European regulations and a more competitive European market, this conference is important as ever to give new impulses to the European AgBiotech research and AgBiotech business in Europe."

It's a long way from Saskatoon to Cologne but the founding concepts remain the same. ABIC has grown up and continues to be a gathering place for the best scientific researchers and the corporations who lead the field biobased products and services. I encourage you to consider participation in ABIC 2004. It may be your opportunity of a lifetime.

For more information visit www.abic.net/ABIC2004

THE FORAGEN TEAM

In addition to our 5 full time employees, Foragen has a strong Board and Science Advisory Team, along with interns that work with our three regions. - In this issue I am pleased to identify our Board of Directors' and Science Advisory Team. You will hear from them in future issues of Visions.

FORAGEN BOARD OF DIRECTORS'

A strong part of our team, providing advice and guidance on governance, investments, and strategy.

Susan Smith, RBC Ventures Inc.,
Ontario

René Douville, RBC Ventures Inc.,
Ontario

John Oliver, Maple Leaf
Bio-Concepts

Janet Wightman, Investment
Saskatchewan

Murray Mucha, Investment
Saskatchewan

Michel Charlebois, SGF-SOQUIA,
Quebec

Bertrand Venne, SGF-SOQUIA,
Quebec

Jacques Goulet, Ph.D., Laval
University, Quebec