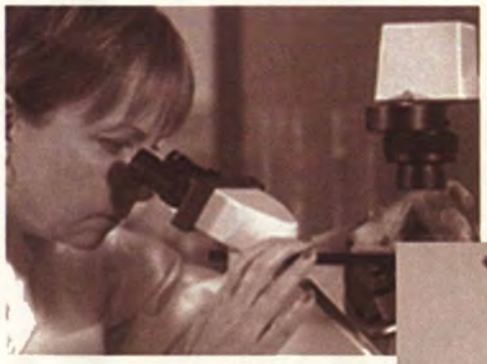
Industry Canada Industrie Canada

The Innovation Journey of Six Canadian Firms

Ocean Nutrition Canada Ltd.



The LiteBook Company Ltd.

4everSports Inc.

SemiBioSys Genetics Inc.

Neuromed Technologies Inc.

Tactex Controls Inc.

The Practice of Innovation II

Canada

THE INNOVATION JOURNEY OF SIX CANADIAN FIRMS

The Practice of Innovation II

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Tactex Controls Inc. — Dr. Robert Inkster, President and CEO; and Terry Rachwalski, Vice-President, Marketing

Ocean Nutrition Canada Limited — Robert Orr, President

SemBioSys Genetics Inc. — Andrew Baum, President and CEO; and Dr. Maurice Moloney, Founder and CSO

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Preface

The *Innovation Journey of Six Canadian Firms* is the second set of case profiles of the Practice of Innovation Initiative. It is a sequel to *The Practice of Innovation: Seven Canadian Firms in Profile* released in 2003. Those case studies are now being used in university classrooms and other educational and small and medium-sized enterprise (SME) learning environments across the country. The profiled firms exemplify the steps necessary to move through the innovation and commercialization process from idea conception to the market. Packaged with a video series, *The Face of Innovation*, featuring studio interviews with the CEOs of each of the companies, the materials produced under the *Practice of Innovation* project provide a comprehensive view of what the innovation journey entails. The objective of these materials is to transfer the knowledge and experience gained by highly innovative firms to individuals and SMEs that can benefit from their wealth of know-how. As well, these case studies serve to foster a stronger innovation culture, so that more Canadian firms will pursue the innovation path.

Readers will meet the CEOs and senior executives who are leading their firms through different stages of the innovation cycle. At each stage, they have to pay attention to certain key challenges in order to take their innovations forward. From this, readers will gain perspectives on the factors that are key to successfully undertaking the innovation journey.

The six firms profiled in this publication represent examples of companies with breakthrough technologies and products that can have a dramatic impact on how we work, live and conduct our daily lives. They all have world-first or world-only innovations, and are examples of which Canada can be proud.

Synopsis of Profiled Cases

Case study 1: The Litebook Company Ltd. in Medicine Hat, Alberta, is dedicated to improving quality of life by creating leading-edge light therapies to alleviate health problems caused by the effects of light deprivation, such as seasonal affective disorder. Their patents-pending Litebook®, the world's first hand-held light-therapy device, uses white light-emitting diodes as its light source. Litebook® products, also used as a remedy for jet lag, are sold in more than 29 countries around the world.

Case study 2: 4everSports Inc., a private company based in Sydney, Nova Scotia, develops and delivers wireless, solar-powered golf systems designed to give golf

courses all the technology they need to increase their golfers' enjoyment and maximize their course profitability. The company is the first in the world to do this. Its TeePod™ Information Systems provide customized, real-time golf services and Internet-based information systems that consolidate golf activities into a single, economical system. The long-term goal of the company is to be the number one provider of golf-related technologies worldwide.

Case study 3: Neuromed Technologies Inc., located in Vancouver, British Columbia, is the only biopharmaceutical company in the world focussed exclusively on developing calcium-channel drugs for the treatment of chronic pain caused by neurological diseases. It is committed to developing the next generation of chronic pain drugs with pipeline programs in anxiety, epilepsy, and cardiovascular diseases.

Case study 4: Tactex Controls Inc., based in Victoria, British Columbia, develops and manufactures Kinotex®, a fibre-optic pressure-sensing material that functions a lot like human skin, and which was originally developed for the Canadian Space Agency. Tactex Controls offers its technology platform for use in product innovations in computer input devices, health care and automotive markets. The company partners with large companies on product innovations, and sublicenses its extensive portfolio of patents in markets that are not central to its strategy.

Case study 5: Ocean Nutrition Canada Limited (ONC) is a rapidly expanding life-sciences company that develops natural health products from the harvesting of ocean marine organisms, and sells them globally to health-conscious customers interested in wellness and nutrition. Headquartered in Bedford, Nova Scotia, ONC currently supplies the world with high-quality, marine-based dietary supplements and functional-food ingredients, and is the world's largest manufacturer of high-quality omega-3 fish-oil concentrates.

Case study 6: SemBioSys Genetics Inc. is a Calgary-based biotechnology company focussed on developing pharmaceutical proteins, industrial reagents, food additives, protein-purification technologies, and delivery systems that take advantage of the company's proprietary oilbody/oleosin technology platform. It is the only company in the world involved in both the purification and bulk production of plant-based proteins.

Introduction

A Portrait of Innovation

Further to Industry Canada's 2003 The Practice of Innovation publication, Industry Canada was interested in continuing its quest to find out more about how executives of Canadians firms view innovation, and to get a better understanding of how they practice it. The firms we selected are primarily ones that have developed what might be called "disruptive" technologies: proteins produced in plants that dramatically reduce the time and cost of taking new pharmaceuticals to market (thereby reducing costs to users); chronic pain treatments without adverse side effects; proven, safe dietary supplements and functional foods based on the harvesting of marine organisms; "smart fabrics" that sense and feel; compact and portable light-therapy devices for people who suffer from seasonal affective disorder or other symptoms of light deprivation; and technology to revolutionize the game of golf. These are the dramatic innovations we are talking about. These technologies, based on the refinements of new science and on existing technologies, have or will dramatically alter the industries in which they operate, profoundly changing industry and consumer behaviour.

The executives of the firms profiled clearly see innovation as more than ideas or technology development. They all agree that research or technology development for its own sake is not very useful. Technology eventually has to find and solve a market problem — that's what makes innovation. "Innovation isn't just creativity," says Robert Orr, President of Ocean Nutrition Canada Limited (ONC), "it's the application of creativity. Nothing happens unless you can apply it in the marketplace. You have to understand what you want the business to do, how that delivers value in the marketplace, and how you are going to generate value at the end of the day. If you can't do this, then you can't make it — it's as simple as that." Robert Inkster, President and Chief Executive Officer (CEO) of Tactex Controls Inc., talks about innovation as a process that pervades all parts of an organization. "We generally think that innovation is technology and services, but I think innovation is equally involved in marketing and business strategies," he says. "I think you can make more money if you can come up with a good delivery strategy for your product than with the product by itself. So, I see innovation happening in business development, in marketing, in intellectual property (IP) strategy, and all of those areas. You have to keep that going all the time for small companies."

The six firms featured in this publication are diverse, but they are each the world's first or only company to do what they do. They are all quite young companies, ranging in age from five and a half years (The Litebook Company Ltd. and 4everSports Inc.) to eleven years (SemBioSys Genetics Inc.), with an average age of seven and a half years. Some of the firms are still very small, and others quite large, with their numbers of employees ranging from 10 (The Litebook Company) to about 220 (ONC), for a grand total of 337 employees among the six (as of early 2004). Although the CEOs of most of these companies commented on the problems innovating firms have in finding financing, they have, collectively, raised more than $162 million to get them to their current stages of commercialization. Their financing includes a significant amount of angel-investor and venture-capital financing, as well as provisionally repayable loans and other financial assistance from government agencies. Their financing totals range from $2.5 million to just under $68 million — not bad for such young enterprises.

The six companies are currently at varying stages of the innovation process, some still in the proof-of-concept or clinical-trials phases, and others already in the marketplace with a pipeline of new products following behind. Their revenues range from none yet to almost $25 million a year. They are located in small cities, like Medicine Hat, Alberta, and Sydney, Nova Scotia, as well as in large centres, like Vancouver and Calgary, proving that innovation is not place-dependent — it can happen anywhere.

Most of the companies profiled were started by teams of two or three people. Three of the companies remain founder-led (that is, the founder is still the president and CEO of the company), and, in the cases of two science-driven start-ups and spin-offs from university research, the founders perform as chief scientific officers while a "business-type" runs the company as CEO. In the remaining case, the firm is a wholly owned subsidiary of an established entrepreneur-led company that hired a president to turn a fledgling equity investment into a fast-growth, high-potential enterprise based on leading-edge science in the nutritional-food industry.

In terms of start-up motivations, there seem to be two categories of innovating firms among the six cases profiled here: those started as the result of technology pushes, and those started as the result of some kind of market pull. For example, Larry Pederson, founder of The Litebook Company, was a long-time sufferer of "winter blues" and was looking for a better light-therapy device to meet his needs. He went looking for technology that would help him invent one, which, as it turned out, was not an easy task. On the other hand, when Andrew Baum came into SemBioSys Genetics as its CEO in 1998, he found what he calls a Field of Dreams business approach of "We've got this powerful technology; surely someone will want to buy it." In some cases, the innovation was the result of a patentable invention, something entirely new (as with Neuromed Technologies and SemBioSys Genetics); in others, it was the result of taking an existing technology and adapting or reconfiguring it to meet a market need in a different domain, leading to new proprietary technologies and products (as with Tactex Controls, The Litebook Company and 4everSports). These innovations were often built on recent

technological discoveries or developments — genomics, gene sequencing, wireless technology, or the invention of white light-emitting diodes — without which the firms would likely not exist today. But, regardless of technology push or market pull, innovation for these firms often started with the questions "What if . . . ," "I wonder if we could . . . " or "What would happen if . . . ?" Taking action to answer those questions was a major impetus for innovation. Behind this may have been a mixture of inspiration and desperation, and a focus on the market, technology or science. The vision of the founder(s) was often critical to the genesis of the firm and what it would become.

Three of the firms were started by scientists and technologists. In fact, SemBioSys Genetics and Neuromed Technologies are spin-offs from university research laboratories. Three others were started by business people, two of whom had previous entrepreneurial experience with start-up companies. Regardless of their backgrounds, founding CEOs eventually hire on whatever expertise they need: the business people bring in technologists and researchers, and the scientists and engineers bring in management and marketing experts.

All of the companies, except for one, are privately held (Tactex Controls is publicly traded). However, the CEOs of most of the companies see going public or being acquired as exit strategies down the road. They all have external boards of directors and most have made efforts to attract highly credible and experienced people to join a scientific advisory board. Setting up scientific advisory boards is almost essential for early-stage, science-driven companies in helping them establish credibility in their fields and make their way through the maze of proof-of-concept and clinical-trial experiences.

Innovation is Hard — It Takes a Long Time

The amount of time to get to market varies depending on the complexity of a company's innovation. Neuromed Technologies, a drug development company, knows it will take 10–12 years to get its new pain-management drugs through the clinical-trials cycle. For companies that consider themselves in the early stage of commercialization, like 4everSports or The Litebook Company, it has taken about two to three years to get a workable technology or product into the marketplace. However, as ONC's case shows, it is possible for an innovative firm to generate first-year revenue from early products, while positioning itself to raise the first round of financing it needs for research and development (R&D).

So, what takes so long? Some of the major roadblocks for firms have been developing or finding the technology; refining the technology to get its costs down, shrink its size or reduce its power requirements; finding a way to mass produce the technology, which sometimes leads to companies having to invent their own production processes; raising capital; and waiting for a ready market. Larry Pederson from The Litebook Company describes his experience as follows: "My perception of how long all this would take was totally out of whack. We had our professional prototypes in June 2000 and it took until June 2001 to be able to introduce the product to the market. No one, including me,

had any experience in doing what we were trying to do. We had to have a mold. This was going to cost another $80 000 and raised a whole bunch of detailed questions I hadn't thought about before. What kind of plastic? What about this? What about that? The detail to get this into the actual marketplace was astonishing." Another good description of the many challenges in getting a prototype to work can be found in the 4everSports case profile.

The challenge of innovating can be daunting. Luckily, for many of these firms, the founders were naïve about what would be required. But, as Terry Snutch from Neuromed Technologies says, "Ignorance is bliss."

THE INNOVATION JOURNEY COSTS A LOT OF MONEY

Because innovations such as the ones profiled in this publication take a long time to get to market, and do not generate revenue during the formative R&D and precommercialization stages, raising money is a major preoccupation for innovating firms. They need working capital to hire researchers and technologists, build and test prototypes, set up production facilities, and hire management staff. Debt financing is not a viable option for firms in this stage of development, so they have to look at more innovative sources of funds. Most of these companies all started by raising $150 000 to $300 000 of seed capital from local angel investors. But, within a year they needed substantially more to move the innovation process forward. For all of them, government has played a key role in early financing. The Industrial Research Assistance Program (IRAP), the National Research Council Canada, the Atlantic Innovation Fund, the Cape Breton Growth Fund, and Technology Partnerships Canada were all mentioned as key supports, as were various provincial government programs.

Venture capital is also an option for new companies, but venture capitalists want to see an experienced and professional management team in place, a board of directors, filed patents, working prototypes, and evidence of primary research that validates demand. These are requirements not easily met by emerging firms still in the R&D stage. Success in attracting venture capital requires strategy, a compelling story, a strong belief in what you are doing, and at least a year of searching for the deal. Companies like Neuromed Technologies, ONC and SemBioSys Genetics have been successful at raising significant amounts of venture capital, but not before quantifying the market opportunities and targets, networking vigorously, shopping their business plan around, and making lots of presentations. As Natalie Dakers of Neuromed Technologies says, "You have to get used to rejection." After making several presentations, she finally succeeded in getting Neuromed Technologies its first $5 million in venture-capital financing — a year after the business plan was ready. For later and larger rounds of venture-capital financing, the key, according to Andrew Baum of SemBioSys Genetics, is finding the lead investor.

As innovative companies progress along their innovation journeys, they tend to become less dependent on government funding sources and more dependent on private investors (angel investors), venture capital, strategic partnerships and public markets. In the beginning, informal investors

and government programs are essential in financing early-stage operations.

THE INNOVATION PROCESS REQUIRES LOTS OF NON-FINANCIAL RESOURCES, TOO

Particularly in the early stages of innovation, firms need lots of help other than financial. IRAP assistance proved invaluable to firms wanting to learn about specialized technologies. Community support has ended up being very important to the innovating firms' capacity to succeed at the levels they have, by supplying: experts who can help with business planning, patenting processes, and technical expertise; experienced business people willing to provide advice, mentoring and angel investment; and government agencies willing to invest both time and development funding.

THE JOURNEY IS FULL OF TRIAL AND ERROR

None of these companies has taken a straight path to innovation success. Because no one has done before what they are trying to do, they have to deal with many scientific, technical and market uncertainties.

Robert Bobbett of 4everSports says, "We had oodles of obstacles to overcome doing the installation and testing of the prototype . . . . We became good at jumping hurdles, and we wouldn't give up. We had to take off-the-shelf technology bits, using them in applications for which they were not intended, and then solving the application problems. But we saw every problem as an opportunity. Each solution to a problem ended up being an innovation. We had committed employees and a board that was helpful in pointing us to financing sources and mentoring me on how to develop a sales team and monitor performance. I read a lot. . . . We've had to change everything, but I believe we now have a winning technology, a winning product and a winning business model."

Many things can go wrong along the way to the market, even among the successful firms featured here. Neuromed Technologies' first lead drug didn't make it through the first stage of the clinical-trials process; developments at SemBioSys Genetics were significantly stalled by the biotechnology meltdown; and 4everSports' first commercial installation of the TeePod™ on a Florida golf course was a nightmare. One of the particular trial-and-error journeys in this set of six profiles has had to do with business models. 4everSports, SemBioSys Genetics, ONC, The Litebook Company and, to some extent, Tactex Controls had to revisit their initial business model because it wasn't working, and change their strategic orientations to the marketplace. Dakers of Neuromed Technologies says, "The only way to describe this journey is as a roller coaster; the hills and valleys can be remarkable. And you just have to get yourself to the next peak." To survive the valleys takes determination, flexibility and creative thinking — all key attributes of the CEOs of these firms.

INNOVATION REQUIRES DISCIPLINE AND FOCUS

Another challenge of innovating firms is deciding what to work on next. Especially with platform technologies that have many market applications, like Tactex Controls' "digital skin," or compounds that could address a number of health-related problems, such as in the case of Neuromed Technologies, decisions have to be made

about which problems or markets to target first. And it can be expensive to get that wrong. ONC uses a system of prespecified screening of their marine organisms to discover possible product solutions, and then assesses different products for their commercialization potential. Andrew Baum at SemBioSys Genetics keeps his researchers and scientists focussed on market applications. But, all of this takes a considerable degree of discipline and focus, both on the market and on the milestones set by venture capitalists and other investors.

THE IMPORTANCE OF PATENTS

Patents are extremely important to innovating firms. Except for 4everSports, which made a conscious decision not to, all of these firms have patented their products or technologies. In fact, they share more than 100 awarded, filed or pending patents in countries around the world.

A company's patent portfolio is an asset that allows them to enter competitive market spaces with bargaining power and leverage, and is an asset in creating value for shareholders. Patents will be significant revenue sources for both SemBioSys Genetics and Tactex Controls, which use them to develop licensing and collaborative R&D agreements with large, multinational companies wanting access to their technology platforms. Patents were also essential in Neuromed Technologies' success in attracting venture capital.

"Venture capitalists look first at the patent portfolio, so we have to invest a lot of money in developing and protecting it," says Dakers. "In the beginning, we engaged outside patent counsel, and I can't stress enough how important it is to get the best people to help you, both from a strategic point of view as well as a technical point of view. Every time you do a financing, the first thing they look at is your patent portfolio, because, in our business, if you are raising a bunch of money to support a particular compound, everybody wants to know that you are going to have an exclusive right over that once it goes into the marketplace. And the only way you are going to have that is if you have patent protection." Neuromed Technologies now invests about $400 000 annually in its patent portfolio.

Inkster of Tactex Controls explains his strategy as follows: "A lot of our value is around this IP, or these patents that we have. Patents sound very impressive, but they really just give you permission to sue somebody. If you're a tiny company and somebody steals your patent, what do you do about it? You pay millions of dollars to hire lawyers? Well, you don't have that money. So in our case, the strategy is around teaming up with large companies with deep pockets who value what we've got and will prosecute on those patents. They will protect the IP. So, in order for us to be successful, we've got to be teamed up with the big guys — so that's quite central to our strategy."

THE IMPORTANCE OF STRATEGIC PARTNERS

All of these firms have strategic partnerships with either small or large firms in order to secure financing for their R&D, test prototypes, gain access to markets and distribution channels, or obtain technology. SemBioSys Genetics has strategic partnerships with large multinationals such

as Martek BioSciences Corporation and Syngenta. Tactex Controls has partnerships with NITTA Corporation out of Japan and Indiana-based Hill-Rom Company Inc. In return for licensing fees, up-front payments, and royalties, the firms collaborate on R&D and work on technology solutions for market-based problems, using their IP as a base. 4everSports, Tactex Controls and The Litebook Company show how even smaller, local partnerships can be indispensable to early-stage companies.

The decision of whether to partner is in itself strategic. Dakers, whose company, Neuromed Technologies, deliberately chose not to partner with a large biopharmaceutical company in the early stages, says, "In fact, it's a big decision for small biopharmaceutical companies . . . whether to do so, and at what point. It takes six to eight years to get a new drug to market. Alliances allow you to access resources and knowledge so you can grow faster, but we have been able to raise enough money to do it ourselves to this point. . . . Partnering with a pharmaceutical company would have meant a completely different business model for us. They would have paid for the drug development process, and we would have focussed on the pipeline. . . . We continue to ask ourselves whether we want to take the drug to Phase II or form a partnership with a pharmaceutical company. But, we get more leverage with human efficacy data, so, as long as we can finance the earlier drug development stages, we have decided to do it ourselves."

Making the Transition From One Stage of Innovation to Another

One of the challenges for all of the profiled firms has been in making the transitions from one stage of innovation to another. Moving from concept to pre-commercialization requires business planning, patent protection, focussing the product-market value proposition, financing, and a management team. Moving from precommercialization (making it work) to implementation (making it and getting it to market) requires an operational base (plant or otherwise); an expanded employee base; R&D discipline; marketing, technical and strategic positioning expertise; and more financing. Moving from commercialization to the next cycle of innovation requires discipline in technology/product development, financing to scale up, and a working environment that supports a culture of continuous innovation. The cases here show how different firms have dealt with different transition challenges. For example, they show firms moving from being science-driven to market-driven, or from focussing on R&D to making the technology work in customer applications.

What the companies share is the fact that they have survived the transition points to date. How do they explain their success in doing so? According to Orr of ONC, it has to do with having the right people, vision, investments, partnerships and leadership. For Bobbett of 4everSports, it's having a winning technology, a winning product and a winning business model. For Pederson of The Litebook Company, it's having the right partnerships, the right alliances, and the right people doing the research. And for Inkster of Tactex Controls, it's having the

right roadmap, the right strategic plan and the right people.

As for their visions for the future, Orr's goal is to build ONC revenues to $100 million by 2006; Pederson's is for The Litebook Company to be the leading light-therapy device company in the world; Bobbett's is for 4everSports to be the number one service provider of golf-related technologies worldwide; Baum's is for SemBioSys Genetics to be the world's leading supplier of transgenic and nontransgenic proteins for the pharmaceutical market; Inkster's is to grow the value of Tactex Controls to a $100-million market cap by 2008; and Dakers and Snutch's goal is for Neuromed Technologies to be a fully integrated biopharmaceutical company with more drugs in the pipeline and 100–150 employees.

Each case profile in the pages to come is full of candid "roller coaster" stories, survival strategies and useful information. *The Face of Innovation* video interviews with the CEOs of each of these companies provides additional insights and serves to personalize the innovation journey. Because, after all, firms don't innovate, people do. And it's from the people leading the innovation process that know-how will be transferred and lessons learned.

USEFUL QUESTIONS TO EXPLORE

Although written in story format, the six case profiles that follow hold many useful lessons for others interested in knowing more about the steps to take and the critical factors involved in moving innovative ideas to the marketplace. While reading through these case profiles, consider the following questions:

- What were the major drivers behind the innovation in this company?
- How did these drivers change as the company progressed?
- What were the major barriers or challenges that had to be overcome by this company in advancing its innovation? How did it overcome these?
- What stage of the innovation process is the company currently in?
- What were the key elements in the business's success in achieving its current position?
- What will be needed to get the company to the next stage of innovation? What are its major challenges likely to be?
- If you were the company's CEO, what might you do next?

The LiteBook Company Ltd.

Larry Pederson: President & CEO

The Litebook Company Ltd., based in Medicine Hat, Alberta, is dedicated to improving quality of life by creating leading-edge light therapies to alleviate health problems caused by light deprivation, such as seasonal affective disorder (SAD), and jet-lag recovery systems. The patents-pending Litebook®, the world's first hand-held light-therapy device, uses white light-emitting diodes (LEDs) as its light source. Litebook Company products are sold in more than 29 countries around the world.

Shedding Light on Seasonal Affective Disorder

According to researchers at the Yale University School of Medicine, a new light therapy developed by The Litebook Company from Medicine Hat, Alberta, could make winter blues and jet lhing of the past.

The Litebook is the brainchild of Hollywood film writer turned entrepreneur Larry Pederson, an Albertan who suffered severe depression every time he returned to Canada from California in the wintertime. The technology is a "better mousetrap" for people with SAD, a condition linked to winter depression. The Litebook is the world's first hand-held light-therapy device, producing an ultra-bright light without emitting ultraviolet radiation. The 15 cm-by-12.5 cm Litebook produces very low heat and weighs 225 grams. The average white fluorescent-tube bright light in the same price range as the Litebook weighs 13 times as much, is 30 times bigger and uses 13 times more power.

Based in Medicine Hat, Alberta, Pederson's enterprise, started in late 1999, started selling its products in June 2001. Since then, more than 10 000 Litebook Company products, including the Litebook and the Time Traveler™, have been sold to customers in more than 29 countries, including Canada, Sweden, Finland, Norway, the Netherlands and the United States. [1] The company, however, has not

1. The Time Traveler™, based on NASA software and Harvard University research, integrated a "body-clock calculator," storing 171 cities worldwide. Once the user inputs their departure and arrival cities and normal wake time, the program tells the user precise times to see or avoid light, and, thus, resets the body's internal clock.

been without its challenges: Pederson and his investors have yet to turn a profit on their $2.5-million investment. But, sales are growing by more than 200 percent a year. With eight employees in Medicine Hat, and off-site sales and marketing people in Calgary and Vancouver, the company is setting out on a mission to prove scientifically why light therapy makes you feel better, and to educate people about the wellness benefits of light therapy.

Many people in the world suffer from SAD, a mood disorder related specifically to changes in the seasons. The disorder causes sleeplessness, fatigue and depression.[2] First documented in the late 1800s, SAD's symptoms became evident as people moved away from farms and into factories, thereby lowering the amount of time they spent outdoors each day. The situation became exacerbated during the winter months when exposure to natural light was even less.

Once labelled the "winter blues" and considered a fringe disorder, SAD has been identified as a mainstream malady in recent years. An estimated 30 percent of North Americans suffer from SAD, with similar percentages in Europe. About 14 million Americans are believed to suffer from the adverse effects of light deficiency — about 1 in 20 of them from a pronounced form of SAD and another 1 in 20 from a milder version. Millions more suffer from a disruption of their circadian rhythms due to shift work, jet lag and various sleep disorders.

Only in the past 20 years have studies shown that megadoses of full-spectrum light can curb the ill effects of long, dark days. And only in the past 10 years have physicians learned more about light therapy. Light therapy is now so recognized as a credible remedy for SAD, that researchers are currently studying the potential of light therapy in treating other mood disorders like premenstrual syndrome, major depressive disorder, and bulimia nervosa. Doctors are also beginning to be convinced of the benefits of light therapy for people with certain sleep disorders or jet lag, or for those who work night shifts.

Therapeutic doses of light for SAD sufferers have to be bright enough to mimic dawn or twilight — somewhere between 2500 and 10 000 units of the light measurement called a lux.[3] Light from a household light bulb (which only produces about 600 lux) can't come even close to creating the light levels needed to relieve SAD symptoms. For years, only bulky fluorescent tube lighting in a metal box covered with a Plexiglas® panel to screen out dangerous ultraviolet light was effective in providing indoor light bright enough to help.

Research led by Pederson's company has resulted in an alternative: the Litebook has 60 light-emitting diodes[4] (LEDs) — pencil-eraser-sized discs of white light that, together, produce 5000 lux. The Litebook

2. The extra darkness stimulates the pineal gland, which secretes melatonin. The higher the level of melatonin, the sleepier and more lethargic a person becomes.

3. Lux is a unit of measurement for light that was developed to account for the eye's sensitivity curve, known as photopic response curve. This means that the light of one color may appear brighter than the light of another color, even if intensity is the same. It is a very good approximation of how well we will perceive the intensity of a particular light source.

4. A diode is the simplest form of semi-conductor. A semi-conductor is a material with the ability to conduct an electric current.

has been cited as one of the biggest gains in the treatment of SAD because it is a smaller, portable, lightweight appliance that minimizes the "freak factor" for many sufferers of the disorder. It uses only 6 watts of power compared to the fluorescent tube's 85 watts, and produces 20 times as much light as a 60-watt light bulb. Unlike the bigger boxes, which take two full-spectrum light bulbs that last about 5000 hours (two years), the Litebook uses LEDs that are good for about 100 000 hours.

From Darkness to Light — The Idea

Pederson grew up in Alberta. He started a pre-med program at the University of Alberta, but dropped out after the first year because he wasn't able to concentrate on his studies due to a form of depression linked to light deficiency. Of course, he didn't know at the time that that was the cause; he just knew he didn't feel good. He switched to an arts program and studied philosophy, graduating with a bachelor's degree in 1977.

In 1980, Pederson moved to California, where he later graduated with a degree in filmmaking from the University of Southern California in 1983. He then went into the industry, becoming a screenwriter and film producer. Life was good in sunny Los Angeles, and, fed by the sun, Pederson was happy. In 1994 his father was diagnosed with cancer and Pederson came back to Medicine Hat to spend time with him. Later that year, his father died and Pederson ended up staying at home to help out his mother. Very soon after that, Pederson got very depressed, to the point where he wasn't able to function in everyday life. "I couldn't even read the newspaper or follow the plot of a video," he says. "When I got to the point of seriously considering suicide, I sought help from a family friend." He was diagnosed with SAD, and his psychiatrist recommended Prozac®. Pederson didn't want to take an antidepressant because of the side effects, so his doctor suggested light therapy as an alternative. Skeptical, but desperate, Pederson arranged access to one of the big fluorescent light boxes. He soon started to feel his mood and energy levels improving, so he bought one of the boxes. Not only that, he started telling other people about his experience, which seemed to strike a chord with many of them, and he started thinking there might be a business opportunity in selling these light boxes. In winter 1995, he contacted the supplier in Montréal, Quebec, and negotiated a distribution arrangement to sell their light boxes in Alberta.

However, it was a large, bulky structure in his home and carried a lot of stigma among his friends, who, when they visited, would always ask what it was and why he was using it. Pederson started to wonder if there was a better solution.

From Idea to Concept Development

"On January 23, 1999, I had an epiphany on an airplane," says Pederson. "It was like a thunderbolt struck. There was going to be this light, it would fit in my hand — the size of a Walkman® — and it was going to look like Sony built it. What is happening now in my company is exactly as I saw it that day. It's uncanny. But I was a screenwriter living in Medicine Hat, and a long way from where I am today. I didn't have a clue how to proceed on the idea, didn't have any financial backing or the tools to do anything with it, so the idea remained just that." A

month later, Pederson suffered severe whiplash in a car accident and had to give up writing. With time on his hands, he started to do research on the Internet to see if anyone was making a product similar to the one he had thought of. No one seemed to be.

So, Pederson started talking to people about the idea. One of the people he talked to was an economic development officer from Medicine Hat who introduced him to the "brain trust" at the Defense Research Establishment Suffield, outside of Medicine Hat. Pederson set up a meeting with one of their researchers right away, a guy he had gone to grade school with but hadn't seen for 20 years. This childhood friend, Terry Meidinger, was working on landmine detectors — a far cry from light boxes. Over a coffee, Meidinger got excited about the challenge of finding a light source that would satisfy Pederson's size and design criteria. Meidinger arranged a meeting with some design and electronics specialists he worked with, people who held patents in things like infrared suppression systems for battleships. But, Pederson left the meeting not all that hopeful. Although they were intrigued by the idea, the team didn't normally work on this sort of technology problem, and, besides, they were all fully committed to their own projects. Later that night, however, Meidinger phoned Pederson to tell him the researchers were interested in working on his light box a couple of nights a week — in their spare time.

By May 1999, the team had come up with the first computer-assisted design drawings of a product about the size of a laptop computer. The device would use a compact fluorescent light that could deliver the same light intensity as the bigger light-therapy box Pederson used at home every day.

In the meantime, Pederson set out to discover everything he could about light, and about the possible applications for his product idea. He found a 1991 scientific article describing a NASA project to test the potential of full-spectrum fluorescent light to adjust the body clock of NASA astronauts on space flights. The article concluded that one day the technology might be used to treat jet lag. Pederson started talking to corporate travelers about his product concept and they agreed that jet lag was a big problem, but any solution would have to be small enough to fit in a briefcase. The laptop-sized design he had wouldn't work — it was just too big. Pederson's design research team would have to find a smaller light source.

Halogen was a possibility, but, although halogen lights were very compact, they were expensive, too hot and had a short life. So, in September 1999, the research team concluded they couldn't solve the problem and declared that there was no alternative, they were going to quit. "But," says Pederson, "I sat there thinking, this idea isn't finished yet. It has to work. And, three or four weeks later, in early October, I was at home one day and Hank [one of the Suffield

researchers] called to ask if I had ever heard of a white light-emitting diode. He had just read an article in some obscure electronics journal about a white light-emitting diode that had been invented by the Japanese." The inventor was a chemist working for a Japanese company that had spent about $450 million finding out how to use LEDs to reduce power costs in the country. LEDs are much more efficient than fluorescent light because they use one tenth of the power and last much longer. Red LEDs had been around for at least 20 years, followed by green and amber, and then blue, but no one had yet figured out how to make white LEDs. Their development had eluded all the scientists — until now. (The chemist discovered that by adding a yellow phosphor to a blue LED, he could get white light.)

Pederson and his team tracked down the manufacturer, ordered samples, and received nine of these LEDs, each the size of a pencil eraser.

Pederson then invited Calgary representatives from the National Research Council Canada (NRC) and the Industrial Research Assistance Program (IRAP) offices to come to Medicine Hat to have a look at the technology. "When I fired up this nine-LED panel, the NRC guys were astonished with the brightness of the cone of light on the ceiling. And, yet, the LEDs produced no heat. When one of them asked me if I had a patent lawyer, I knew this was a turning point. On October 20, 1999, I incorporated a company and started a process to patent the use of the technology for light therapy," says Pederson. It was now technically possible to realize his vision of making a light box that was dramatically smaller.

FROM CONCEPT TO WORKABLE PROTOTYPE

Pederson's first prototype was a rudimentary 6-by-5 inch panel with 120 LEDs on a circuit board with a wooden frame around it. He started treating himself with the prototype and found that it only took about 15 minutes a day, or half the time of a traditional fluorescent light box, to make him feel better (to reduce the affects of SAD). Yet, it only produced 5000 lux — half the lux of the traditional light box. Pederson now needed financing to pay for a proper prototype. He started showing his rough prototype to investors, a tight network of local entrepreneur and angel investors in Medicine Hat. He managed to attract a small number of people who invested a total of about $150 000 of seed capital on, as Pederson says, "the basis of the power of the idea, the power of the light, and the power of its potential to change the future. My ability to tell a story, which I learned from all those years in the film industry, really paid off," he says. "I was good at pitching ideas in elevators."

Next, Pederson wanted to surround himself with light-therapy professionals who could help him advance the product's development. In 1990 Pederson had lived in Vancouver for a year while working on a movie. That winter he had suffered from the effects of low light in rainy Vancouver, and had sought treatment from Dr. Raymond Lam who was using light therapy in his Mood Disorders Clinic at the University of British Columbia (UBC). But Lam had a six-month waiting list and the two never met. "In 1999 I called him again," says Pederson, "this time to talk about my light-therapy idea." He asked Lam if he would look at Pederson's prototype. Pederson says that

after seeing the prototype Lam's reaction was "This is going to change everything." Lam agreed to join the professional advisory board of Pederson's new company.

Pederson's rudimentary circuit board worked well enough to show it to informal investors from Medicine Hat, but he needed a more sophisticated one to show to formal investors. Again he sought advice from his buddies at Suffield, who told him he needed an industrial designer. He discovered an industrial design program in the Faculty of Engineering at the University of Calgary and contacted the Dean. From that visit, he hired two graduate students, one of whom had worked on LEDs in Nepal, and gave them his design criteria, a small salary, and a simple instruction: "Make it." By the end of that summer, they had produced workable designs, while another student from Mount Royal College was working on a logo design, branding, and the development of a "look" that would appeal to consumers. Now it was time for Pederson to once again turn to the government for help. IRAP approved a $40 000 project to help the company produce its first professional prototype, and another $30 000 to be put towards solving some of the technical challenges the designers still faced to make it all work. Pederson hired a company in Edmonton to build the first three prototypes of the latest design, and used these to show to formal investors.

"My perception of how long all this would take was totally out of whack," he says. "We had our professional prototypes in June 2000 and it took until June 2001 to be able to introduce the product to the market. No one, including me, had any experience in doing what we were trying to do. We had to have a mold. This was going to cost another $80 000 and raised a whole bunch of detailed questions I hadn't thought about before. What kind of plastic? What about this? What about that? The detail to get this into the actual marketplace was astonishing." Pederson finally hired his first company employee in March 2000. Up until then, he had only worked with contractors.

From Prototype to Market — Proving It Works

Pederson introduced the Litebook to the market in 2001. In May of that year, on Lam's advice and urging, Pederson took his three prototypes to the American Psychiatric Association annual conference and trade show in New Orleans. "The psychiatrists loved it," he says. "We took orders, but we only had three Litebooks. When I got back to Canada I hired housewives on a piece-rate basis to assemble the first 1000 units. We packed them in white pizza boxes. We didn't even have packing slips."

The following month, Lam also convinced Pederson to attend a conference in Stockholm to demonstrate his Litebook to the Society for Light Treatment and Biological Rhythms, the world body for light researchers. The Litebook attracted interest from a lot of people working on light therapies. "This is the best thing we ever did," says Pederson. "For three days we met the leading lights in light therapy. And, at that conference, George Brainard, from the Department of Neurology at Thomas Jefferson University in Philadelphia, presented a paper on the results of a four-year study on the wavelength of light and melatonin suppression." Brainard's research results showed that the best wavelength for

suppressing melatonin was 464 nanometres. It was the first time Pederson had heard about light wavelength, but, coincidentally, the wavelength of Pederson's Litebook light was also 464 nanometres. "This was another big turning point for us," he says.

Pederson knew his prototype was more effective than traditional light therapy, but he didn't really know why. Why was it taking only half the time with half the brightness? Now he had a clue that it could be the wavelength and not the lux.[5] Lam convinced him that they would need data to prove the science behind the light-therapy uses of the Litebook. "Researchers will beat you up unless you have some data," said Lam. "If we have unique technology, a unique product, and unique wavelength patents, then we have value."

The need for this data was exacerbated by the fact that medical health insurers would only cover the cost of 10 000-lux therapies — the standard for traditional light therapy. The Litebook produced only 5000 lux, so Pederson's next challenge became educating the market that it's less about lux (brightness) than about wavelength.

Pederson, therefore, next went to work on clinical trials to discover how light therapy works and what the relevance was of the wavelength of light. "The clinical-trial process took a lot longer than I thought, because first we had to figure out how clinical trials work," he says. Once again, Lam proved indispensable. From Lam's network of professional colleagues, he mobilized a team of researchers and doctors from UBC, McGill University, the Royal Ottawa Hospital, the University of Saskatchewan, Yale University in Connecticut, and the University of Groningen in the Netherlands to conduct clinical trials on the Litebook.

The results of the two-year, five-site, double-blind, placebo-controlled SAD clinical trial, the most extensive evaluation of LED light therapy performed to date, were expected in 2004. Should the results prove positive, the Litebook could be the first light box in the world to receive FDA approval for use in treating SAD. Pederson believes this approval is only a year away. The Litebook Company decided to underwrite the clinical-trial research and, even though this approach was anticipated to cost considerably less than that of a large pharmaceutical company, the company had to raise money to finance it. Again, Pederson was able to attract the investment he needed from a local community of

5. Research was showing that lux appeared to be an inappropriate unit of measurement for melatonin suppression. LEDs deliver a focussed, very narrow beam of light. Fluorescent tubes, on the other hand, were designed to light a room, making them largely ineffective in suppressing melatonin. The wasted energy from a fluorescent light tube was almost 3.5 times greater than that from the LEDs in the Litebook.

entrepreneurs and angel investors. At the end of this round of financing, the initial group of 10 private investors had grown to about 70.

The Litebook may be the subject of other clinical trials as well. Researchers at the Yale-New Haven Hospital want to conduct trials to determine whether light therapy can help depression by raising a patient's levels of the mood-affecting chemicals seratonin and dopamine. Meanwhile, researchers at McGill University hope to conduct a clinical trial to test light therapy's applications for police officers doing shift work (in this case the Litebook would be powered by a 12-volt automobile cigarette lighter). Pederson is also cooperating in clinical trials in the North Sea, underwritten by the Institute of Petroleum in the United Kingdom, to see if light therapy would be effective for shift workers on drilling platforms. All of this could mean very promising outcomes for the small but innovative Medicine Hat company.

Getting the Product to Market

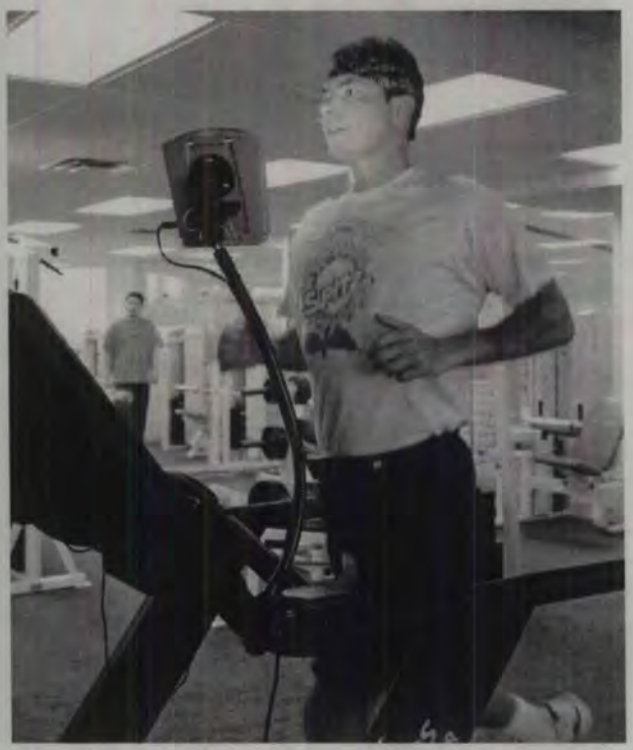
Identifying their market has been a major issue for The Litebook Company. Who are the people who would use this product? How and where do you find them? SAD often goes undiagnosed, as Pederson's did for many years, and sufferers are not commonly seeking light-therapy products. It hasn't been easy for The Litebook Company to find the right channel of distribution. The company tried to market the Litebook through home health channels, but the attempt didn't prove effective. "SAD people don't consider themselves sick," says Pederson. "They don't buy at home health stores. Our customer wasn't shopping there."

"We had never really had enough money to have a marketing budget," says Pederson. "It's been a lot of guerrilla marketing that we've employed. We don't have millions of dollars to put out an ad campaign that's going to put SAD on the minds of every man, woman, and child, even in Alberta, never mind Canada or North America."

What was really needed was an education and awareness program to get the message out about light therapy and wellness. In fact, that's the strategy Pederson is now pursuing. But, initially, since the Litebook was considered a medical device, Pederson's approach was to seek distribution in places already selling things like wheelchairs and home-health-care products. Later, he moved on to other venues such as health food stores and independent pharmacies.

Based on his mid-2001 conference successes, Pederson realized the importance of getting involved in medical trade shows to promote his product. Pederson now regularly attends meetings of psychiatrists, psychologists, and sleep disorder doctors, as well as attending medical, wellness and home health trade shows. Trade show participation has been highly effective in gaining market exposure for the Litebook. Through these sorts of approaches, Pederson has been able to identify possible distributors for the product in different countries. However, dealers weren't quite ready to embrace the Litebook initially, because the end price to the consumer was about $600. The company wasn't manufacturing at a large-enough scale to bring the production cost down. By improving production efficiency, turning his cottage industry assembly process into a

full-service subcontracting arrangement, Pederson has since been able to reduce his costs and lower the consumer price of the product considerably. The retail price in early 2004 was just slightly under $300.



Litebook units have now been sold in more than 29 countries, with this international presence assisted in large part by support from federal and provincial government agencies. The Litebook Company has benefited from the Department of Foreign Affairs and International Trade's Program for Export Market Development (PEMD), tapping into the expertise of Industry Canada officials in finding out how to take the company's product into different markets. Pederson acknowledges the contributions and partnerships of PEMD, Western Economic Diversification Canada's International Trade Personnel Program, and NRC's IRAP. Of phenomenal value have been Canadian consulates and embassies in various countries. Pederson explains, "We tapped into the Trade Commissioner Service, where they were able to say 'Okay, you come to our Embassy. We will do a reception. We will get the media involved. We will bring you local distributors. We will have an event. We will invite the leading doctors, and so forth — people who are interested in this technology and this product and this service.' We did that in several countries, and each time it helped to launch the product in that country." As a result of these events, the company has signed distribution agreements with companies in Norway, Sweden and Finland.

Over the past two years, Pederson's company has started to expand into other markets. For example, they now have a product-development agreement with a Dallas company to co-develop a light-based product for acne treatment. And NASA is evaluating the Litebook for use by astronauts in the space shuttle program and on the international space station. "We've gone from infancy to childhood," says Pederson. "I would say we are in early stage commercialization. We have a product. We know it works. And we are in the stage of creating the market."

MANAGING THE COMPANY

Pederson is a member of The Litebook Company's five-person board of directors, as well as being the company's president and chief executive officer (CEO). Like a number of highly innovative firms, the company has put together a professional advisory board to expand its network of expertise and contacts. Pederson's advisory board has invited six prominent researchers, technologists and business development

experts to the table, including Lam; Dr. James Maas, a professor of psychology at Cornell University; and a representative from the NRC. Pederson also takes advantage of other resources available in Alberta to help develop his management skills. In 2003 he approached Inno-centre Alberta, a business incubator in Calgary, for mentoring support and help in preparing for another financing round.[6] Starting in January 2004, Pederson will spend one day a week for a year with one of Inno-centre's network of mentors. "Through the assistance of folks like those at the Inno-centre, we have been very fortunate, and able to stay focussed, develop business plans, develop strategies and objectives, and sort of laser in on them," says Pederson.

THE FUTURE

Pederson admits his company still has a long way to go. "We have yet to be profitable; that's our goal for this year, to be profitable. The next stage is to look at forming strategic alliances. We've got a lot of interesting opportunities now coming our way as people see this technology and see what we are doing, and we are trying to learn how to validate those and prioritize those in a way that we can really help to grow the company," he says. The company is still undercapitalized and needs to increase its manufacturing and distribution. It recently obtained ISO 9001:2000 certification, as well as the certification that they meet compliance standards for medical devices. They are working on generations two and three of their product, looking at FDA regulatory issues, and preparing to attract venture-capital funding in 2004.

Pederson is very optimistic about the company's future. "We hope to continue to expand," he says. "We hope to become the leading light-therapy device company in the world. We want to lead the way to light and wellness. We believe that we've got the right technology. We've got the right partnerships, the right alliances, the right people involved in terms of the researchers. And we believe that it's a process of educating the people, the consumers, the public to understand that there's an issue involved with light and well-being; that without light there is no life. So, by doing that, and by enlightening people, we believe that we'll have an opportunity to grow into that. My goal as CEO of the company is to grow it by harnessing the energy of the people who work here so I can spend more time telling our story. Word of mouth is powerful."

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6. Inno-centre Alberta is a non-profit organization funded by IRAP, the NRC and the University of Calgary to provide mentoring support to innovative start-ups and early-growth companies.

4EverSports Inc.

Robert Bobbett:
Co-founder & CEO

4everSports Inc., a private company based in Sydney, Nova Scotia, develops and delivers wireless, solar-powered golf systems designed to provide golf courses with all the technology they need to increase their golfers' enjoyment and maximize their course profitability. The company is the first in the world to do this. Their TeePod™ Information Systems provide customized, real-time golf services and Internet-based information systems that consolidate golf activities into a single, economical system. The long-term goal of the company is to be the number one provider of golf-related technologies worldwide.

Bringing Technology to the Golf Course

4everSports started as an idea in fall 1999. Since then, brothers Alan and Brian MacArthur and their brother-in-law Robert Bobbett have been on the roller coaster ride taken by all innovating firms that try to do what no one else has done before. 4everSports was not their first start-up, but it was their most complex. This time, their goal was to bring technology to the game of golf.

The brainchild of these three Cape Bretoners, the TeePod, promises to do for golfing what the ATM did for banking. When the TeePod system becomes widespread, as the founders of 4everSports are highly optimistic it will, the day will come when golfers will no longer have to carry scorecards onto the course. Instead, after their round they can have a hard copy printed out for them in the clubhouse, or, if they wish, they can print a hard copy off at home from the Internet. TeePod will keep track of the number of putts, the number of fairways hit, the number of sand saves, and many other statistics that will let golfers analyze their rounds and see where they can make improvements.

The TeePod is a kiosk that sits at every tee on a golf course. It contains a computer with a touch screen LCD display several times brighter than a laptop monitor. The technology lets a golfer electronically track scores, players and real-time leader-board

statistics; calculate handicaps; get in-depth information on each hole; communicate with the clubhouse; and talk with golfing buddies through the Internet. The TeePod also lets golf course operators integrate many different services, including pace-of-play management, real-time messaging, Internet tee-time bookings, golfer/member management, advertising revenue management, and event planning. TeePod can also keep track of all the information related to holding a tournament, with a real-time leader board, automatic flighting, pairing and scoring, cart assignments, prize-pool allocation, and detailed reporting and analysis.

TeePod is solar-powered, using a Linux operating system driven by complex application software developed by 4everSports' founders, and is remotely monitored and managed by the company through a 128-bit encryption application that provides security-breach detection and automatic software upgrades for all kiosks over a course-wide Wi-Fi wireless network.

It all sounds pretty sophisticated now, but it wasn't always that way. Over the past five years, the product has gone through four versions, as the founders worked through the prototype and demonstration stages to find the right technologies and the right combinations of these technologies to make the system work.

Five years later, in 2004, their TeePod Information Systems had been installed on four golf courses, one in Canada and three in the United States. The company had 14 employees in Sydney and three sales agents in the U.S., had raised more than $3.5 million in financing, and was projecting $8 million in sales over the next three years.

TEEING OFF — THE IDEA

Alan and Brian MacArthur and Robert Bobbett were part of a group of a dozen or so men, who, as Alan puts it, "like to duff at golf." Every year for about 10 years, Bobbett, the MacArthurs and others would drive from Sydney, Nova Scotia, to New Brunswick for an annual golf weekend. Just before the September 1999 road trip, they were heading to Amherst, near the New Brunswick border, for a different reason. They were going to talk to someone about a potential business opportunity, but, on the way, most of the conversation in the car was centred on something else.

"We were talking about the golf weekend and about technology and that led to us wondering how technology would change the game of golf," recalls Alan. "We were thinking, wouldn't it be neat if there were computers on golf courses and stats could be stored forever and leader boards could be seen on the course." As they continued on, the excited trio became less interested in the Amherst meeting and more interested in a cutting-edge technological golf game. "We mapped out how it might work, and, knowing most people who have ideas don't follow through on them, we decided to do something with it, to make it happen," says Alan.

Bobbett started researching the concept to see if their idea was original. He searched the Internet and read golfing magazines, and within a couple of months concluded that nobody was doing anything like it. He also learned that the industry was growing rapidly, with 500 new golf courses being built each year in the U.S. alone. Worldwide, 80 million golfers a year played 1.4 billion

rounds of golf on 45 000 golf courses. The trio felt their idea could benefit every golfer on every golf course, so they decided to pursue it.

They quickly formed a company, brainstormed for a name and came up with 4everSports. Taking a generic name was strategic, because they believed that whatever technology they came up with for golf could potentially be applied to any game for which statistics are recorded. According to Alan, "Golf was only the first sport we would work on." Bobbett went to work for the new company right away.

Club Membership — No Duffers Here

Bobbett grew up in Toronto but moved to Cape Breton when he was in junior high school. He attended the University College of Cape Breton for two years, then transferred to the Technical University of Nova Scotia for a Computer Science degree. He went on to the University of New Brunswick to complete a Master of Business Administration degree, following which he worked for several New Brunswick companies. Bobbett's business sense and family connections (he's married to Alan and Brian's sister Kathy) eventually led him back to Cape Breton to work with Brian. Brian and Alan had both earned Bachelor of Business Administration degrees from St. Francis Xavier University, after which Brian went on to earn a Masters of Business Education from Suffolk University in Boston, Massachusetts, and Alan became a chartered accountant. Brian immediately joined the family business his father had started 45 years earlier, the Cape Breton Business College (CBBC). Alan, on the other hand, spent a number of years running a chain of food service outlets in Nova Scotia and New Brunswick, and later worked as an independent chartered accountant. In the mid-1990s, he returned home to Cape Breton to also join the family business.

The three men had already been involved in another start-up. In an attempt to stave off competition to the CBBC, they started DirectED in 1995, an Internet distance education delivery school with learning advisers. Their focus was corporate training. Finding that this market also had lots of competition, they sold DirectED in 2000, around the time when 4everSports was coming into full swing. The three partners were now committed to the concept of the new company. Alan became the chief financial officer and Bobbett the chief executive officer. Brian, by this time, was Principal of CBBC, and continued in that position. Somebody in the family had to be generating an income while the new business was getting off the ground.

Course Description

The three partners envisioned putting computers at each tee on the courses as a novel way to revolutionize the game of golf. Golfers could then record their scores automatically. From the tee box, they could have an aerial view of each fairway and green, order clubhouse food and beverages on-line and have it delivered to them, and access professional tips on how to handle each hole. Scores could be recorded and adjusted, handicaps could be calculated, and scorecards could be printed at the clubhouse. Everyone could access the leader board from each hole during tournament play. The system would not only benefit golfers, but would also serve as a management tool for the clubhouse, by

monitoring where every player was on the course and how fast they were playing. In addition, companies could advertise directly on-screen, providing major advantages for local restaurants, pubs, accommodation providers, and other golf courses.

So how would they do all this and get it onto a golf course? One of the first ideas they had was to incorporate the system into golf carts. Attending the 2001 PGA golf expo in Orlando, Florida, the largest golf trade show in the world, with 1600 exhibitors, gave the company a good view of the current golf industry. With a little research into the cost of other golf technologies, such as global positioning systems (GPSs), which are used at a small number of the bigger U.S. courses, the company soon realized that putting computers on golf carts would drive costs up too high. In addition, as Alan says, "Golfers are quite traditional people who don't like lots of change. We discovered that only about 400 of the 18 000 golf courses in North America had adopted GPS — and it was a seven-year-old technology. If the technology were on the tee, then it wouldn't be that obtrusive."

So, the next idea was to install the system at each hole. "The computer sits in a box. In the initial drawings of the concept they looked like pods so during a brainstorming session we came up with the idea of calling them tee-pods," Alan explains. "The pod is an outdoor kiosk, solar-powered with an LCD touch screen, much like an interactive laptop, and it allows us to provide services to the golfers wherever they are on the course. We collect the scores, run tournaments, and broadcast scores directly into the clubhouse and to the Internet in real time," says Bobbett. He sees the Internet connection capability as an important part of the TeePod system's selling point. "This is really neat about our product, because there's no golf course in the world where you can play a round of golf and somebody can be sitting at their desk watching you play hole by hole, see what you're doing, and even send a message out to you and comment on your last putting attempt," he says.

Arranging a Game — The Prototype

The first step before anyone could record a putt with the TeePod system was to develop the software. This took six months and was done by Bobbett with Dave Jackson, a graduate of the CBBC Computer Science program. "Three other programmers were added over the next few months, all graduates of the same program and taught by myself," Bobbett says proudly.

The next step was testing the alpha product to see both how it could work and who the actual customer was going to be, the golf course or the golfer. The company invited some golfers to the Business College one Saturday morning to play on a mock course. "We got them to enter their scores and work with the software. We got feedback from three groups — golf course managers, golf pros, golfers. They all came, and they had a lot of fun with the software," says Alan.

With a potential piece of software in the works, a physical prototype was needed to house it on the golf course. The three founders had invested about $60 000 of their own money to seed the business, but they would need more than that to build a workable prototype. They contacted the Enterprise Cape Breton Corporation

(ECBC)[1] for funding support, but first they needed a business plan. Based on that business plan, the Atlantic Canada Opportunities Agency (ACOA)[2] and the ECBC gave them a provisionally repayable loan of $289 875 to pay for a prototype of their computerized scoring system. To test the first version of the product the company formed a strategic partnership with the Lingan Golf & Country Club in Sydney, Nova Scotia, and set about installing the system for the 2001 summer golfing season.

Into the Sandtrap

"We had oodles of obstacles to overcome doing the installation and testing of the prototype, like putting a computer outside," says Bobbett. "We had to consider the effects of rain and sprinklers. It had to be wireless. How would we do that? We looked for solutions and ended up with a radio-frequency wireless LAN (80211b). At the time, wireless was quite new and we were stretching it to its limits by using it in an outdoor environment. We experienced all kinds of data communications problems so things had to be constantly modified. The computers on the course had to be powered, but there's no way to power anything on the course. So, we decided on batteries. But we needed too much battery power, about 400 pounds of batteries on the course, and they'd have to be changed every week. It wouldn't be practical. We looked into solar but that wouldn't work with the prototypes we had; the solar panels needed to supply the needed power would have been too big and obstructive on the course. A company that builds controls for generating systems wanted to work on a small generator for each TeePod, so we tried this, but there were too many moving parts. It would have been a maintenance nightmare."

At this point, the company only consisted of Bobbett, Alan and a couple of programmers. It was all trial and error; they didn't have an electrical engineer on staff to offer advice. In order to power every TeePod on the Lingan golf course, they finally decided they would have to electrically wire the golf course underground. They hired a guy with a tractor, bought some cable, dug the trenches, laid the cable and in a day and a half they had it done.

Driving Into the Sun and the Wind

"We contracted a firm in Phoenix, a digital systems engineer to build the computer screens for the first prototype — a touch screen," says Alan. "We had to shop for prices because industrial components are more expensive than consumer components. In the end, the design they sold us wasn't that good. You couldn't see the screen in the sun, so we needed extra back lights."

1. The ECBC is a Government of Canada crown corporation with a mandate to support economic development initiatives in Cape Breton. It also delivers the programs of the Atlantic Canada Opportunities Agency (ACOA) on Cape Breton Island and in the Mulgrave area.

2. ACOA is a Government of Canada department created in 1987 to aid and encourage Atlantic Canada economic development. Part of their mandate is to invest in innovation and develop and commercialize technology in the Atlantic region by improving the overall business climate in the region and the growth and competitiveness of small and medium-sized businesses like 4everSports.

This wasn't the only problem. The TeePod system drew about 110 watts of power, the same amount needed for 18 100-watt light bulbs. So, now they had a problem with the electricity supply. As well, the server was in the clubhouse and the screens were on the field, so they needed an antenna to relay signals. But if the wind was blowing, the signals could be intermittent. Bobbett adds, "We had lots of problems with the wireless, the way the software worked, the way the touch screen computer worked. You can only find out these things by doing a prototype." The company wasn't working in a complete vacuum, though. They drew on the expertise of the National Research Council Canada (NRC) wireless lab at the University College of Cape Breton, which, ironically, is located across the highway from the Lingan golf course.

With an accumulation of technological problems after the 2001 season at Lingan, the company sat down to consider what they'd have to do, including creating a different style of product with new software — essentially, a new design. Their big problem now switched from being a technological one to a financial one. By now, they'd gone through all of their own money, plus the ACOA/ECBC loan.

GREEN FEES

4everSports started to meet with venture capitalists who liked the idea of what they were trying to do but questioned whether there was a market. They wanted to see proof of customers — to know that golf courses were willing to pay for installation. "If investors aren't willing to come on board then you try family and friends," says Bobbett. "Using Nova Scotia's small business loan fund exemption as an incentive, we raised $462 000, topped it up with some more of our own equity, and then went back to ACOA for a matching loan to develop the new product formulation. Nobody wanted to fund us to do lots of development, they wanted us to have customers. And the customers wanted the technology, but we weren't sure we could deliver a marketable product. ACOA also wanted to see sales investors," he says. So, Bobbett hit the road and found two customers: the Diamond Players Club Golf Course in Florida, and the Dobson Ranch Golf Course in Arizona. In March 2002, with these contracts in hand, ACOA approved a loan to 4everSports for $500 000 to finance the purchase of machinery and equipment for up to three prototype locations.

The financing allowed 4everSports to redesign its software to make it less reliant on the network and ready for use for the 2002 summer season at the Lingan golf course. Unfortunately, the second version worked no better than the first. They had solved the wrong problem. The real problem was not the amount of network traffic, but, rather, the strength of the network. They needed to make the network stronger. With only two weeks to go before the 2002 season, they had to quickly go to a third

version of the software. This time the questions were how to make the network work better and how to reduce their power requirements.

On the financial side of the company, things were looking better. By the summer of 2002, the Cape Breton Growth Fund (CBGF)[3] made an equity investment of $2 million, which could be drawn down in $500 000 portions, or tranches, as long as 4everSports met certain agreed-upon milestones.

The initial business plan was designed for profitability in a similar manner to a cable company. Alan explains it like this: "We own the equipment, install it, put the system in place, maintain it, and the golfer pays two dollars per round for use of the system. This would be added to the golfer's fee. The golf course pays 4everSports for rounds at the end of each month. We thought this would be an easy way to price the system. We figured it would cost C$130 000 to install the system, we'd ask for a four-year contract for 30 000 rounds per year at two dollars a round (US$60 000). We'd have C$240 000 after four years, and the installation cost was only $130 000, so we'd have a good profit. It seemed like a good business model." With an idea everyone seemed to love, and a few million dollars of government and private money thrown in, it seemed the TeePod system could eventually spell profit.

3. The CBGF is responsible for delivering an economic adjustment fund (worth $98 million dollars), established by the federal and Nova Scotia governments, following the closure of the Cape Breton Development Corporation, the organization that operated coal mining in Cape Breton. The mission of the Fund is to foster sustainable economic growth and job creation on Cape Breton Island.

SLICE INTO THE BUNKER

With the newest version of the system in place, money lined up, and two U.S. courses sold on the idea, everything appeared ready to go for the new installations. 4everSports' plan was to use the same approach they used at the Lingan course, and they felt comfortable they could deliver on the C$130 000 installation charge, although, after some negotiations with Diamond Players on the contract fee, Bobbett agreed to a discounted price.

Then the company landed in the bunker again. As Alan describes it, "Wiring the course in Florida was a nightmare. Costs went through the roof. The pathways through the course were concrete, not gravel like at Lingan. You had to cross city streets to go from one hole to another. The installation took us forever. There were numerous permits to get, inspectors to satisfy, and the contractors charged by the foot. We had to dig 14 000 feet of trench, and they wanted 10 dollars a foot! We had to find another solution. If we did it their way, we'd lose money on the installation and that would be it."

Rather than lose money on the installation, the company bought a Ditch Witch® trenching machine on eBay for $15 000 and buried the cables themselves. The biggest problem then was hitting the underground sprinklers. If it hadn't been for the CBGF money, we would have been dead," says Alan. The installation on the Arizona course went more smoothly, but 4everSports came to the conclusion that they couldn't go any further until they figured out how to better predict their costs on installations. Plus they had to find a better way of powering their

pods. "We'd have to move to a solar-powered system," says Bobbett. "And that's where we are today."

To help them investigate ways of moving in this direction, the company turned to the NRC's Industrial Research Assistance Program (NRC-IRAP). With a $146 000 matching IRAP grant, they set about designing and developing the generating system they are currently using.[4]

The Sun Starts to Shine

By this time, the company had hired an electrical engineer. Several team members, working together under the engineer's leadership, designed the company's solar powered system. The challenge was to make the solar panel as small as possible so it wouldn't be aesthetically unpleasing on the course. To do this, they had to find ways of reducing the system's power consumption. For each component, they asked themselves if there was a way to accomplish the same result while consuming less power. In addition, they used some power-saving tricks, such as only powering the touch screen monitor when golfers were actually interacting with it. This let them put the computer into low-power sleep mode when it wasn't actually being used.

As the result of a development partnership with VIA Technologies Inc. in Taiwan, TeePod kiosks are now powered by a Mini ITX motherboard with an ESP processor that requires so little power (it has no moving parts) it can run fanless. Another major problem, that of overheating computer screens in the desert heat, was overcome by designing the enclosure and installation components in such a way as to allow as much free flow of air as possible around the components that heat up. The unit is also shaded with a lexan ultraviolet screening device.

Each individual TeePod unit now has its own separate solar-powered system. A 12-volt battery is buried in the ground near each TeePod, and the components of the TeePod are powered directly by the DC current from the battery. A 70-watt solar panel recharges the battery as the components draw the battery down. The truly innovative feature of the system is a controller unit that measures the battery voltage and the charging rate of the solar panel. 4everSports can remotely monitor both of these readings on any TeePod, through the Internet. Once the solar-powered system was developed, the TeePod system became truly wireless. Moving to solar power actually reduced costs and let the company predict with

4. The grant required that 4everSports put up an equal amount of investment.

greater certainty what their individual installation costs would be.

BACK ON THE FAIRWAY

By early 2004, 4everSports had grown from 2 to 14 employees, and had three sales agents working in the U.S. to market the product to prospective golf courses. The Landmark Golf Club near Indio, California, had signed a two-course deal to install the TeePod system at their premier course in the Palm Springs area. It would be the first installation of their new solar, wireless technology, the fourth version of the TeePod system.

With their new technology available for installation, 4everSports still had another set of challenges to overcome. This time, the challenges had to do with the company's business model. According to Bobbett's research, the golf industry in the U.S. is overbuilt. Overall, the number of rounds played in the U.S. has remained constant for about the past seven years, at around 600 million rounds per year,[5] but the number of golf courses is increasing. "The fact of the matter is everybody is cutting into everybody else's business," says Bobbett. "Golf courses don't want to put fees up because of competition from other courses, of which there are dozens in any particular area. Raising fees by as little as even two dollars could be suicide." Prospective courses wanted a plan where they could install the system without having to raise green fees.

Bearing in mind the biggest problem golf courses have is filling their tee sheets, or getting more golfers, 4everSports came up with a new revenue model. "I got the idea for a new business model from having a chance conversation with a golfer in Arizona," says Bobbett. "Why not trade tee times for a lower system-installation cost, arrange leasing for the courses through GE Capital over a four-year term, and then sell advertising to local advertisers giving them the tee times?[6] The course is already losing up to 40 percent of their tee times daily, so giving them away is no cost to them. 4everSports will provide the software and support, the golf course will give us two tee times a day, and we'll take the advertising, selling advertising packages (Internet banner and full-screen ads, etc.) and throwing in the tee times as part of the package."

In essence, the course gets the system for a reduced cost, 4everSports gets the system installed, which will help them sell more installations by allowing them to develop a

5. These rounds are played by 31 million golfers.

6. According to statistics quoted by 4everSports, golfers spend US$24 billion per year on travel, transport, food, and beverages, and more than half of golfers earn more than US$50 000 per year.

strong reputation, plus they make money from the advertisers. A portion of the profit made is shared with the golf course, which, in turn, can use it to offset the cost of the initial installation.

It was very important to get the revenue model straight from the beginning. As Bobbett puts it, "We could easily have given the system away, but that wouldn't make sense as a business model. We had to prove the club can take the system, we can make money from it, they can get value out of it, and the golfer can have the benefit of using the system. Advertisers can give away the tee times to valued and potential customers, many of whom are, of course, golfers, so they're happy, too. Everybody wins." With the new model, 4everSports guarantees courses they will recover almost 100 percent of their first-year costs of installing the TeePod Information Systems.

CHIP SHOT TO THE GREEN

Right now, the pods for the computers are made from fibreglass and look like birdhouses. 4everSports subcontracts its manufacturing to AB SeaCraft, a local Cape Breton firm, whose owner, Allan Burden, has helped design the TeePod unit around extreme heat and humidity issues. The company buys its screens and monitors from an Arizona company, its motherboards from VIA Technologies, and a control device from the highly successful DynaGen Technologies Inc. (of Cape Breton). It then assembles the units in Sydney.

With a dozen course installations planned in 2004, and 280 relationships with potential courses in the pipeline, 4everSports may soon have to move to more mass-scale production. But, for 2004, things are still under control. The company doesn't plan to stay in the hardware business, and sees itself contracting out the course installations to another firm in the future, but they plan to do the next 15 or so installations themselves.

According to Alan, what drives the company now is that every time they show a customer what they're doing, the customer loves it. "We really and truly believe we're on the right track," he says. "We're always asking ourselves, how could we have done it differently. People told us 'You've got to get to the market fast,' but, really, we didn't." About innovation he says, "Everyone who works here knows where we are. They're all behind the project and really believe in it." It's clear the dynamic and spirit of 4everSports is due to innovative and committed people.

"You have to make sure you select the right people in the beginning and then everything becomes a whole lot easier," says Bobbett. "We have talented people who really believe in what we're doing and go above and beyond what we require of them." To foster a climate of equality, the company offers stock-incentive plans and makes it attractive for their employees to take advantage of these. "We freely exchange ideas on an ongoing basis, because we need to move quickly, and that comes through communication," says Bobbett. Less bureaucracy and more interaction, at all levels, has made for a highly innovative team at 4everSports.

19TH HOLE — PUTTING ON THE GREEN JACKET

The company plans to focus primarily on the U.S. market for now because golf is a year-round sport in many states, whereas the Canadian season is too short to be profitable. Bobbett doesn't like using trade shows to create awareness — too much clutter and too much cost. Instead, the company has chosen to sponsor tournaments to introduce courses and players to their TeePod system. The first such event was a PGA-certified Pro-Pro tournament at the Dobson Ranch course in Mesa, Arizona, in March 2004, with 120 golf pros playing and using the TeePod system. This approach is proving to be very successful, and 4everSports is also making effective use of public relations and personal selling.

4everSports has had to be very innovative on the financing side, as well, especially given that there are no formal venture capital companies in their region. In February 2004, they concluded a limited public offering through the Nova Scotia Securities Commission under the Nova Scotia government's Community Economic Development Investment Fund. Investors with self-regulated plans are able to use their investments towards their RRSP deduction, and gain tax credits from the Province of Nova Scotia. The Province also guarantees part of the investment against loss during the first four years, thereby substantially reducing the capital at risk for those in higher tax brackets. 4everSports raised $500 000 in $5000 lots and used this to draw down their next tranche of CBGF financing. They also secured a $200 000 loan from Nova Scotia Economic Development to finance equipment purchases for the Landmark course installation in California.

"We've never been a product in search of a market," says Bobbett. "We always knew there was a market. But we were the first in. We needed early adopters — so we had to educate the market. We saw every problem as an opportunity. We became good at jumping hurdles, and we wouldn't give up. We had to take off-the-shelf technology bits, using them in applications for which they were not intended, and then solving these application problems. Each solution to a problem ended up being an innovation. We had committed employees and a board that was helpful in pointing us to financing sources and mentoring me on how to develop a sales team and monitor performance. I read a lot. *Built to Last*[7] and *Good to Great*[8] gave me lots of insight. We've had to change everything, but I

7. Collins, James, and Jerry Porras, *Built to Last: Successful Habits of Visionary Companies* (Toronto: Harper Collins Canada, 2002).

8. Jim Collins, *Good to Great: Why Some Companies Make the Leap . . . and Others Don't* (Toronto: Harper Collins Canada, 2001).

believe we now have a winning technology, a winning product and a winning business model."

Golfers, golf course operators and advertisers all stand to gain with TeePod Information Systems. With 12 installations set for 2004, the company and its investors are hopeful this year will establish the credibility of 4everSports and its revolutionary golf technology, a technology already recognized as a winner in the 2002 ECBC Technology Awards

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Neuromed Technologies Inc.

Dr. Terrance Snutch : Vice-President and CSO

Natalie Dakers : CEO 2002-2004

Dr. Christopher Gallen : President and CEO

Neuromed Technologies Inc. is a private biopharmaceutical company committed to developing the next generation of chronic pain drugs. Located in Vancouver, British Columbia, with an office in Philadelphia, Pennsylvania, the company has pipeline programs in anxiety, epilepsy, and cardiovascular diseases, and is the only biotechnology company in the world focussed exclusively on developing calcium-channel drugs for the treatment of neurological diseases. Neuromed's drug development programs are designed around validated clinical targets associated with large, unmet markets.

From The Research Lab to the Marketplace

Originally a spin-off from the University of British Columbia (UBC) that sold reagents to the research community, Neuromed has transformed itself into a drug development company that focusses on discovering and developing small molecule drugs for the treatment of neurological diseases, namely pain and stroke.

The science behind the company is led by Dr. Terrance Snutch ("Terry"), whose world-recognized claim to fame is that he described and cloned a family of 10 calcium channels found in animals.[1] He had uncovered the relationship between calcium levels and pain, the role of specific calcium channels in transmitting pain signals in the body, and the potential for "blockers" to intercept those signals and, thus, alleviate pain symptoms. Over time, he amassed an impressive portfolio of seven patents related to N-type and T-type calcium-channel blockers, and several U.S. and international patents- pending applications.

Snutch started Neuromed in 1995 to sell his reagents to other researchers as a way to fund some of his scientific research. The company was refocussed as a bio-pharmaceutical company in 1998 to realize the commercial potential of Snutch's science for the treatment of pain in humans. Pain management had only become a recognized medical specialty in 1993, after which U.S. health care centres were required to monitor patient pain along with other vital signs. But,

1. Snutch was the first to describe the molecular basis for the diverse types of clinically important calcium channels expressed in the cardiovascular, endocrine and nervous systems. His seminal contributions in this area have been recognized internationally through a number of scientific awards, including the International Albrecht Fleckenstein Award, the Killam Research Prize, and the Steacie Prize. Most recently, he was elected a Fellow of the Royal Society of Canada and named Researcher of the Year by the BC Biotech association.

effective treatment options were limited to morphine and related drugs, which have significant potential side effects, including addiction. There was now a demand for new, safer treatment options, and commercialization of Snutch's research could help meet that need.

Neuromed's initial target market is moderate to severe pain, including neuropathic and cancer pain. The company's drugs will be competing against centrally acting analgesics, including opioids like morphine. Neuromed's drugs are aimed at large, underserved markets that have resulted from either a lack of suitably effective therapeutics, or drugs fraught with considerable side effects.

Since 1998, the company has grown from 3 to 32 employees, raised almost $70 million in venture capital and advanced their lead drug to Phase I human clinical trials. Neuromed was issued a U.S. patent protecting the use of its core compounds as calcium-channel blockers in January 2000 and now has a U.S. and international patent portfolio consisting of 82 pending, issued, or allowed patents. The company has moved from the concept stage for an orally available molecule N-type calcium-channel blocker to Phase I clinical trials for its first pain-drug-development candidate, NMED-160.[2] It has also demonstrated proof of principle in animals of two other indications (anxiety and stroke), and generated proprietary in-house screens for its second major drug target, the T-type calcium channel for epilepsy and cardiovascular disease. Neuromed has identified and cloned the genes for the T-type channels found in brain, heart and endocrine cells.

But, these innovating entrepreneurs have had to overcome many challenges along the way. As Natalie Dakers, Neuromed's first chief executive officer, says, "It's been an emotional journey. The only way to describe it is as a roller coaster, and the hills and valleys can be remarkable." So far, however, the company has been able to do many things right. As a result, Neuromed is positioned to be a Canadian success story, taking its new drug from the pages of a scientific journal to the medical-treatment marketplace.

The Innovation — How Does It Work?

Calcium is an essential signalling molecule for many normal physiological functions in the human body, including all electrical pain

2. NMED-160 works by blocking N-type calcium channels located in the membrane at the synapse between two communicating neurons. The channel controls the entry of calcium to the neuron. When a pain signal is transmitted, the channel opens and the calcium content increases. NMED-160 blocks the channel, thereby preventing the pain signal from being sent.

signalling in the nervous system, and control of the heart, smooth muscle contraction, and hormone release. The entry of calcium into cells is regulated by a diverse set of proteins called calcium channels. While calcium entering through calcium channels is required for nerve function, too much calcium is toxic to cells. Improper regulation of calcium can contribute to epilepsy, migraine headaches, stroke and cardio-vascular disease. Most of the nerve-cell death that occurs after a stroke is caused by too much calcium. Selective blocking of N-type channels has been found to relieve pain more potently than morphine, to reduce nerve-cell damage following a stroke, and to help control anxiety, migraine headaches, and epilepsy. Blocking excessive calcium entry in order to treat neurological disorders has previously been hampered by a lack of compounds specifically targeting nerve-cell calcium channels.

Neuromed's drug candidates block specific channels, preventing an unwanted influx of calcium into the cell. The company's major research and development (R&D) programs focus on N-type calcium channels, a proven pharmaceutical target for stroke and pain, two of the most significant health burdens in North America. The only currently known agents that block N-type calcium channels in clinical trials are peptides derived from marine snails. But, these agents present significant drug delivery issues, are expensive to synthesize and do not readily cross the blood-brain barrier. An oral calcium-channel blocker specific to the N-type channel would provide prolonged pain relief to chronic pain sufferers without addiction.

The Birth of an Emerging Biotechnology Company

Natalie Dakers, Neuromed's first chief executive officer (CEO), grew up in Ottawa as the only girl in a family of boys. She graduated with an honours degree in Marine Biology from the University of Guelph in 1984, moved west and began working as a research biologist for a B.C. company that was researching salmon aquaculture, a new industry at the time. There, she says, she "learned the interesting dance of doing research in an industry setting." In 1989 she interviewed for a job at UBC's University-Industry Liaison Office (UILO)[3], where she would search for opportunities to incubate spin-off companies from promising research being done within the university. First assigned to environmental sciences, she later moved to the medical and pharmaceutical research area.

During the next eight years Dakers participated in the creation of more than a dozen high technology and biotechnology companies spun out of the university. She gained invaluable experience in negotiating venture financing, complex licensing agreements for technology commercial-ization, and university–industry alliances. She saw a lot, and, in the back of her mind, was inspired to one day be part of one of these opportunities herself.

3. UBC is known for its success in spinning off new companies. It was one of the first universities in the country to establish a preseed fund that faculty members could tap into to explore the commercialization potential of their scientific discoveries. This Prototype Development Program was partly financed by the B.C. government, and partly by the University itself. Faculty members could apply for seed funds from $10 000–$50 000 to move their research ideas to the incubation stage. Funding for UILO also came from the provincial government, and money for professional salaries was provided by the National Research Council Canada (NRC) and its Industrial Research Assistance Program (IRAP).

Dakers met the casual, leather-jacket-wearing Snutch in 1991 when he came to UILO looking for help in saving a million-dollar deal with a large United Kingdom pharmaceutical company that wanted to set up a research contract to collaborate using Snutch's calcium channel-related laboratory reagents.

Snutch was born in Preston (now Cambridge), Ontario, and, as a self-proclaimed army brat, had lived all over the world. His father's final posting was in Chilliwack, B.C., so Snutch finished high school there. In 1975 he started a biochemistry degree at Simon Fraser University. In the last term of his undergraduate program, one of his professors, David Baillie, encouraged Snutch to go into a doctoral program in molecular genetics — at the time an emerging branch of science. Genetics research was difficult at the time because the big genomics discoveries had not yet been made. "We had to do all of our gene sequencing by hand — you couldn't buy kits like you can today. We had to make all of our own reagents — you couldn't buy those either," says Snutch. Finishing his PhD in four years to graduate in 1984, Snutch had to decide what he wanted to do and where he wanted to go. He finally accepted an offer from the California Institute of Technology (Caltech) to do postdoctoral work with Norm Davidson, one of the founders of molecular biology. As a result, Snutch spent four and a half years working on molecular neurobiology research at Caltech.

"My claim to fame became the cloning of calcium-channel genes," says Snutch, who became a pioneer in identifying and cloning the different calcium channels found in the brain, heart, and other tissues. "I was interested in what the different calcium channels do," he says. "We have 10 of them. I wondered why we need 10, why that's so important, and how they interact with each other. I didn't care at all about the market relevance of this. I was only interested in the science. Step one for me was to clone the genes." It was, however, during that time that he developed the idea behind Neuromed. "I was using a snail protein venom to block calcium channels, and had to inject this into an animal's spinal cord," he says. "I started to think that there must be an easier way to do this than by using peptides. Wouldn't it be better if it could be a pill? But the question just sat there. I didn't pursue it at the time."

In 1988 Snutch moved back to Vancouver to accept a faculty position with UBC, where he would work with Dr. Michael Smith in his new Biotechnology Laboratory that had recently been set up as a separate entity within the University, through funding from the B.C. government. Snutch would be joining a team of 10 other faculty members hired to help existing faculty "get up to speed" in this new area of molecular biology. His own contribution was to be in neurobiology.

Snutch had isolated valuable reagents in his lab research, often giving them away to other academic researchers for use in their work. But as demand grew from large pharmaceutical companies wanting to use Snutch's reagents in their own drug screening, he decided to set up a small company, using the revenue from his sale of reagents to fund his scientific research. Snutch incorporated Neuromed in 1995 to do this, and during 1996–97 sold some of his reagents. When a large U.K.

pharmaceutical company approached him offering a million-dollar contract to access Snutch's research and technology, and the deal almost fell through at the last minute, Snutch sought advice from UBC's technology-transfer office. Dakers was the manager assigned to the file, and concluded the negotiations for him.

Snutch was very impressed with the way Dakers wrapped up the U.K. deal. A relationship of mutual respect grew from there and it soon became obvious to transform Neuromed into a biotech company. "From the very beginning, I felt I could think corporately, not just academically, I could see it as drug development — that we could build a biopharmaceutical company. Some academics can't," says Snutch. So, the two sought legal advice from lawyer John Swift, who took equity in the company in exchange for his services, and, together, they started on the innovation journey.

As soon as they decided to launch the biopharmaceutical company, they separated Snutch from his academic research. The work he had done on calcium-channel genes was already in the public domain through his publications. All research on the new compounds would be done within the company (not in the University), and they negotiated a waiver from UBC on future intellectual property (IP). "When the venture capitalists came in to do their due diligence, the IP portfolio was clean," explains Dakers.

In December 1997, they wrote a business plan based on using Snutch's electrophysiological screening method to identify high-affinity, highly selective novel compounds that could be used to alleviate pain. Recent developments in the genomics industry were now making commercialization of the idea Snutch had had several years before possible. "I have been doing research on calcium channels for 15 years," says Snutch. "I'm still doing basic science, but now I'm alerted to how it can help someone counter pain and other neurological diseases."

"Science and business go well together," he says. "Both are intellectually challenging. But I did have to learn a whole new way of answering the scientific question of how this calcium-channel blocker could help someone. I decided early that I couldn't be CEO of the company. I didn't want to be front and centre on the business side. If Natalie hadn't come along, I'd still be selling reagents and doing basic science."

The business plan was based on two things: Snutch's credibility as a scientist, and the proof of principle of what they were trying to do, which gave them confidence in the clinical relevance of what they were proposing in their business plan. The innovation was Snutch's work on N-type calcium-channel blockers and the novel structures he had developed to prove high-affinity, highly selective compounds. Dakers' contribution to the team was her 10 years of knowledge, experience and connections in the technology-transfer field. To get a sense of potential markets, the two consulted trade journals and used the Internet.

A Compelling Opportunity

Dakers believed in the science, and she knew Snutch's credibility as a researcher was impeccable, but to successfully attract venture capital, she also knew they would

need a compelling story that was easily understood. They would have to define and calculate their market opportunities. Through their market research, they discovered a huge, unmet need in the marketplace for

new pain-treatment options.

Pain management is one of the largest pharmaceutical markets in the world. It is expected to increase at an overall compounded annual growth rate of 10 percent, to reach $30.5 billion by 2006. No single pain drug dominates the market, and the top 10 account for just 50 percent of total sales. According to research compiled by Dakers, there are 50 million people in the U.S. who suffer from chronic pain, and half of them are not well treated. Effective treatment options are limited to morphine and related drugs with significant potential side effects.

Dakers and Snutch also identified other targets. The worldwide anxiety disorder market was $20 billion in 2002, with such disorders affecting 19.1 million U.S. adults alone. In addition, Snutch's research on T-type calcium channels could also be applied in the treatment of cardiovascular diseases.[4] Drugs in this area, the largest component of the pharmaceutical industry, were garnering global annual sales of $70 billion. Meanwhile, anti-epileptic drugs, yet another application for Snutch's research, have a market in excess of $7 billion worldwide. The potential for Snutch's research discoveries was huge.

Neuromed started in its new incarnation in early 1998 with three people — Dakers, Snutch and a technician. Snutch was the president and chief scientific officer. Dakers resigned from UBC to become the chief operating officer. They didn't yet have a chief executive officer.

Dakers recalls her decision at the time: "I had already decided that I would like to be directly involved in a spin-off company. When I worked with Terry on the business plan in late 1997, I was on maternity leave and ready to make a change. Terry was a stellar scientist with some business savvy not common in academics. He understood the business potential of the science he was working on. And from what I had seen over the years, that is the key to a successful spin-off. I was very impressed with Terry, and with the opportunity, and, although I was leaving the security of a good full-time job at the university and we had no financing at the time, I decided to jump into the venture with him. What excited us was that we were creating an entity that was moving down the path to an alternative pain-relief drug. We always believed in what we were doing. We never lost faith," she says.

4. In heart cells, T-type calcium channels regulate pacemaker activities. Clinical trials in humans show that blocking T-type channels is an effective treatment for hypertension and stable angina pectoris.

Even before it had an office, Neuromed formed a board of directors and a scientific advisory board — of world-class scientists in the ion channel field — to surround themselves with technological expertise and business advice, and to gain early credibility. "In the beginning no one got paid," says Dakers. "We both put in some personal money — about $250 000, some of which came from the reagent business and the rest from personal loans and a bank line of credit — rented a space at UBC, filed patents, and bootstrapped the company while we looked for venture capital."

The Road to Venture Capital

Even with all their credibility, it wasn't easy to raise venture capital, and the first round is always the toughest. A track record was yet to be established and the science was unproven. "We were fortunate to receive two term sheets for our "A" round, both from credible Canadian investors. We could have gotten private investment from some California contacts, friends of Michael Smith who were willing to write cheques, but they wanted us to come to California right from the start. We wanted to stay in Canada." The first venture capital round of $5 million was led by MDS Capital Corp., who put together a syndicate of top-tier Canadian venture capital firms, including GrowthWorks Capital Ltd. (manager of Working Opportunity Fund) and RBC Capital Partners (then Royal Bank Ventures Inc.). Dakers attributes Neuromed's success in getting this financing to four key factors:

1. That they had a top scientist, a leader in his field with an internationally acclaimed reputation, rock-solid, peer-reviewed science, and an award-winning publications record, who was known as someone with integrity who was doing novel work;

2. That they were offering an opportunity validated by proof of principle and validated drug targets;[5]

3. That the company already had a board of directors and an appropriate corporate share structure in place; and

4. That the related IP issues had been dealt with.

With the money from this funding, they were able to make their initial compounds, hire people to screen the compounds, and identify whether or not they were the right compounds to meet the intended pain target. As their early work started to meet the milestones set by the venture-capital investors for the release of the second half

5. According to Snutch, there are 40 000 different genes in the human body; only about 1 percent of these have been validated as targets by existing drugs.

of the investment, Neuromed continued to pursue other research funding. In June 1999, the Science Council of British Columbia awarded them a $161 000 grant to accelerate the development of small molecule compounds to treat pain and stroke. At the end of two years, they actually had high-affinity, selective calcium-channel blockers for their pain target.

The company's second round of financing was led by the Business Development Bank of Canada and included MDS Capital Corp. (Canadian Medical Discoveries Fund Inc.), GrowthWorks, Trian Equities, and a number of boutique funds and private investors. In the middle of Neuromed raising this "B"-round of financing, investors started asking the question of just who was running the company, because there was no CEO. In September 2000, Neuromed's board of directors promoted Dakers to CEO. By December of that year, they had raised another $17 million in financing, which would be followed by an additional $4 million in March 2001. This financing let the company take its pain compounds through preclinical studies, complete investigational new drug (IND)-enabling studies for its first chronic pain drug candidate and advance its extensive pipeline programs. The money also paid for a new 8400-square-foot lab and let Neuromed hire key management talent.

In March 2001 the company brought in Bruce Colwill, their first chief financial officer. With each round of financing, more people were added to the Neuromed board, and more people were hired. "By the time we got to the series-"C" round, we knew we were going to have to raise a lot more money," says Dakers, "so we started developing relationships with U.S. venture-capital companies back during the "B" round. We made lots of cold calls, used referrals, and, over time, built up a significant network. My job was to sell the company, so that's what I did — which meant meeting with a lot of people," says Dakers.

By October 2003, they had closed a series-"C" round of financing totalling US$32 million. This time, the lead investor was San Francisco-based MPM Capital, the world's largest dedicated venture-capital investor in life sciences. Neuromed's "C"-round investors also included an exceptional group of both U.S. and Canadian investors. Dakers' networking efforts had paid off. This was the first Canadian investment for MPM Capital, and the largest venture financing deal in Canada in 2003. The funds will be used to advance the NMED-160 compound by completing Phase II clinical trials. Dakers estimates that the last infusion of venture capital will last about three years. Not only will it get the company through completion of Phase II clinical trials, but it will also further the development of Neuromed's extensive preclinical pipeline, and fund the hiring of more basic research scientists, chemists, screeners, molecular biologists, and members of the management team.

PROGRESSING INNOVATION

Attracting venture capital was one thing, but meeting the requirements of each funding portion, or tranche, meant bringing a lot of discipline into the research lab. Milestones had to be set and met, both for advancing the lead drug through the preclinical- and clinical-trials process with FDA approval, and for bringing new drugs through the R&D pipeline.

"While I was raising money and promoting the company, Terry was continuing to focus on what we were doing with calcium-channel blockers," says Dakers. "By the time we were raising the series-"B" round in 2000, we had several candidates being tested in animals to prove their efficacy. But one of the major hurdles of a venture-capital-backed biotechnology company is that you can't take five compounds into the clinic — you have to focus on specific molecules."

Although he had other things in the pipeline, Snutch spent about 80 percent of his time working on that first pain drug target. He was focussing on, as he says, "what was going to add value to the company." Now, they "have been able to attract researchers from all over the world. People buy into our energy," he says, "and the stock options don't hurt!" Snutch gives his largely PhD-holding scientific staff license to explore new areas of discovery while ensuring a balance between what they are working on and the company's targets. Because most of Neuromed's research scientists come from academia, one of their main challenges is learning how to function in a corporate environment. For Snutch, this means demonstrating the right mix of leadership to foster innovation and yet meet milestones.

But the journey hasn't been without obstacles. The company ran into trouble meeting one of its milestones in 2001. In preclinical trials, Neuromed's lead chronic-pain drug compound failed to meet the company's criteria for a drug development candidate and had to be dropped. "This was an interesting point in Neuromed's history," says Dakers. "We lost a year of time. Luckily, we had a backup, and could quickly shift resources to accelerate work on the second compound. But, we had to develop a new business plan in the spring of 2002 and re-enamour our investors. We signed our term sheet in November 2002 for the "C" round, which indicated we would be in the clinic in 2003." Unfortunately, in the middle of putting together the syndicate deal for the "C" round of financing in mid-2003, unable to agree to terms, Neuromed lost its lead investor. They were making good progress on the new drug compound, and were able to sign a new deal with MPM Capital a few months later. In December 2003 Neuromed filed its first IND application, receiving FDA approval to go ahead, and in March 2004 commenced Phase I clinical trials. Finally, they were able to move to the human clinical trial stage.

"It's important to find out early whether a new compound is going to work, and then to move to other compounds in the pipeline. We're getting good at this," says Dakers. "Our main program is the pain program, but in our discovery research program we have scientists looking at new compounds, innovative screening approaches, and new assays. Our rational-drug-design affinity success rate is around 30 percent, much higher than the normal less than 1-percent rate typically found in big pharmaceutical companies."

Neuromed has established a highly integrated and effective drug discovery platform for the development of their novel therapeutics. It's grounded in target selection, exploiting only validated therapeutic targets associated with its strengths, namely the N-type and T-type calcium channels, which represent potential multibillion-dollar markets. The company performs all of its rational drug design and chemical synthesis, target generation, and electrophysiological and fluorescent screening in-house. To control R&D costs, Neuromed performs its animal pharmacology testing through strategic collaborations with world-renowned academic scientists in pain, anxiety and stroke. The company further streamlines its preclinical process by using contract clinical research organizations for much of the pharmacokinetic, safety and toxicology work.

Forming Strategic Alliances — Why and When?

Because of timelines, risk and required investments, it's not unusual for a company like Neuromed to make strategic alliances with other companies. In fact, it's a big decision for small biopharmaceutical companies whether to do so, and at what point. It takes 10 to 12 years to get a new drug to market. Drugs have to go through three stages of human clinical trials: the first to prove its safety, the second to prove how well it works in patients, and the third to validate how well it works against existing drugs already on the market. FDA approval is needed at each stage.

"Alliances allow you to access resources and knowledge so you can grow faster," says Dakers, "but we have been able to raise enough money to do it ourselves to this point. Our investors are not that supportive of early-stage alliances, so we are taking more of the U.S. path to commercialization, versus the Canadian path of developing strategic partnerships early. Yes, it could be difficult to enter the clinical trial stage alone, but given the nature of the market opportunity with Neuromed, it's feasible for us to do this. Partnering with a pharmaceutical company would have meant a completely different business model for us. They would have paid for the drug development process, and we would have focussed on the pipeline. As it is, we are running a parallel process, doing both."

"It has taken us five years to get to this stage," says Dakers, "and we likely have about six more years to go. We'll probably need another $100 million in financing, in addition to the almost $70 million we've already raised. We continue to ask ourselves whether we want to take the drug through Phase II, or form a partnership with a pharmaceutical company. But we get more leverage with human efficacy data, so as long as we can finance the earlier drug development stages, we have decided to do it ourselves. We spent a lot of time talking to pharmaceutical companies showing them our data and investigating their level of interest in what we were doing but we are waiting for the right moment to pull the trigger on a partnering deal."

Having said that, Neuromed has seven or eight selectively targeted academic collaborators in Calgary, Alberta; Tucson, Arizona; and San Diego, California, who help the company validate some of its ideas without requiring it to spend a lot of money. According to Snutch, comparable

companies doing what they are doing can often be twice or even three times as big at Neuromed's stage of development. Collaborations provide an efficient strategy for small companies, and, although they may slow things down a bit, they allow companies to move faster from one direction to another if their research suggests it would be better to move along a different path.

Managing the Intellectual Property Portfolio

Dakers and Snutch view their IP portfolio as being as important to Neuromed as its people. Their patent portfolio covers a diverse range of N-type and T-type calcium-channel blockers, the full family of calcium-channel clones, and a proprietary process of screening T-type calcium channels. "Venture capitalists look first at the patent portfolio, so we have to invest a lot of money in developing and protecting it," says Dakers. "In the beginning we engaged outside patent counsel, and I can't stress enough how important it is to get the best people to help you, both from a strategic point of view as well as a technical point of view. You can really muck things up if you do not do it well right from the get go. Every time you do a financing, the first thing they look at, from a due diligence point of view, is your patent portfolio, because, in our business, if you are raising a bunch of money to support a particular compound, everybody wants to know that you are going to have an exclusive right over that once it goes into the market place. And the only way you are going to have that is if you have patent protection. In an early-stage company you do not necessarily know which compound is going to be the best compound. So, what you have to figure out is, how am I going to protect a class of compounds or several classes of compounds? How do I protect as much as I possibly can until I can hold down to the particular molecule that I ultimately would like to take into clinical trials and, ultimately, marketing? So, you need to give it a lot of strategic thought. You have to make sure that you file at the right time." From a first-year patent cost of $10 000, the company now invests about $400 000 on its patent portfolio per year.

The Future

Big challenges lie ahead for Neuromed, including advancing NMED-160 through the clinical trials, moving new compounds through the pipeline, achieving proof of principle, adding new members to their management team (they plan to grow from 32 to 45 employees), and ensuring the company has sufficient financing.

In the short term, the company is focussed on taking its first drug through clinical trials with humans, to satisfy both safety and efficacy requirements. The big risk with biotechnology companies comes from the uncertainty of not knowing whether it will be the first, second or third drug that makes it through the whole FDA approval process. If the second drug fails, Snutch's team is ready to make sure that Neuromed survives long enough to advance development on the third drug in the pipeline.

So, what are the prospects for a company like Neuromed? Could they be a target for acquisition? Most definitely. What about going public? Again, it's a strong possibility in the future. But, for now, Dakers is happy with Neuromed's strong investor base, its good reputation, and a board that shares the same vision as the founders. They may need a partner in the last stage of the

clinical trials process, and, at that point, they will decide what to do. "We could go into the market alone with our own sales force and distribution system, but that would require a lot more money," says Snutch. "We'll have to wait and see."

Picturing the future, Dakers is optimistic: "We are going to be a fully integrated company, where we've got more drugs in the pipeline, probably three clinical programs, probably 100 to 150 employees, maybe more. We are public or we've been acquired. We aren't going to be this small, little company. Once we show that a small molecule N-Type blocker does, in fact, alleviate pain, then the sky is the limit. We will be able to raise all the money we need, build as big as we need, and go get other technologies that can enhance our pipeline. That is where we'll really show. And that is about three years away."

Looking back, Dakers reflects on the journey they have already taken. "To take an idea, raise $70 million in financing, and develop a new compound that can deal with pain — it's incredible," she says. "But the roller coaster can be hard on you." Dakers says if and when they are acquired by another company, "I would do another company. I don't know what that would look like, but next time we'd know a lot more about how to do it!"

In the meantime, Snutch is still a full-time full professor at UBC with his own biotechnology lab and 12 research scientists. He splits his time between his UBC lab and the Neuromed lab, which is located in one of UBC's four campus incubators. Dakers is also currently chair of BC Biotech, the association representing and promoting the province's biotechnology firms.

About 40 percent of Neuromed's 32 employees (their total staff as of early 2004) are PhDs and MDs. Another 30 percent are non-PhD researchers, and the rest are corporate and senior management team members, including a controller and a director of IP. In 2004, plans were underway to hire a vice-president of clinical development and a vice-president of research.

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Tactex Controls Inc.

Robert Inkster: CEO

Tactex Controls Inc., based in Victoria, British Columbia, develops and manufactures Kinotex®, a fibre-optic pressure-sensing material that functions a lot like human skin. It was originally created for the Canadian Space Agency (CSA). Established in 1998 to commercialize the patented Kinotex® technology, Tactex Controls provides its technology platform for product innovations in computer-input devices, health care, and automotive markets. The company partners with large companies and market leaders that grow through technical innovation, and it sublicenses its extensive portfolio of patents in markets that aren't central to its strategy. It is publicly traded on the Toronto Stock Exchange (TSX) Venture Exchange under the symbol "ttx."

A Technology Looking for a Market

Technology developed by a Canadian East Coast company for applications in space is now being commercialized by a West Coast company for terrestrial applications as wide ranging as medical devices, humanoid robotics and music controllers. The technology is Kinotex, a "digital skin," sometimes referred to as a smart fabric. It was originally developed for the Canadarm so scientists could tell if it bumped into anything while it performed maintenance tasks on the International Space Station thousands of miles from Earth. Dr. Ernie Reimer is the chief executive officer (CEO) and director of CanPolar East Inc. in St. John's, Newfoundland, a company that specializes in vision and tactile sensor systems. Reimer invented and patented the fibre-optic Kinotex material while doing contract work for the CSA in the mid-1990s.

"What the CSA had challenged us to do was develop a technology that could build a kind of digital skin for robots in space, something that could be put on the gripper pads of the robot and tell the robot when it was grasping a satellite," says Reimer. He started by trying to copy the workings of human skin. The prototype material he developed has hundreds or thousands of individual, little

pressure sensors scattered throughout the fabric, a lot like the nerve endings in human skin. The sensors are fibre-optic, embedded in a thin foam-rubber-like material. When connected to a computer, the digital skin can sense where it is being touched, by how many fingers, and with what pressure, at multiple points of contact.

Reimer called his new invention Kinotex, from "kineasthetic textiles." The end result provided a solution for the Canadarm and a platform technology for a new class of products for yet-unidentified markets.

Reimer's company wasn't the one to actually bring his new technology to market, but Reimer was the one who recognized that there must be licensing potential for his new fabric in solving problems in everyday life. The job of commercializing the technology fell into the hands of Dr. Robert Inkster, a serial entrepreneur, who lives in Victoria, B.C. A chance meeting between Inkster and Reimer in the early 1980s turned into a long-time friendship. When Reimer called him in 1997 with an offer to license the Kinotex technology if he could find some market applications for its unique qualities, Inkster spent a year looking for product ideas. In 1998 Inkster started Tactex Controls and, with some seed equity, a small team of engineers and scientists, and several research grants, he started building materials that demonstrated the advantages of the technology, and inventing the manufacturing processes that would produce the materials reliably and at a low cost to solve market problems.

Tactex Controls' is a story of how a technology developed from government-contracted research to solve an esoteric problem led to a company that is now bringing that technology to markets for which it wasn't originally intended.

Tactex Controls, which went public in 2000, now has 16 employees, sales of more than $2.2 million (in 2004), a strong patent portfolio, strategic alliances with major international companies in the United States and Japan, and prototype products in its pipeline that will deliver significant value in the health care and automotive markets. The company's goal is to be a $100-million company by 2008. Inkster, the company's president and CEO, believes he has the formula to get there.

GETTING THE TECHNOLOGY TO MARKET

Robert Inkster graduated with a PhD in Meteorology (specializing in cloud physics) from McGill University in 1977 after studying mathematics and physics in his hometown, at the University of Victoria. His dream was to start his own company, so when some of his friends from Calgary wanted to do the same, they each invested $5000 to $10 000 and incorporated Intera Technologies Ltd. Initially based in Calgary, the company later opened offices in Ottawa, Ontario; Houston, Texas; and the United Kingdom. The company's expertise was in remote sensing, including radar surveillance of Earth from aircraft and satellites. Their first business opportunity was a successful tender call from the Canadian Centre of Remote Sensing to commercialize some research and development (R&D) sitting in its government labs. "Basically, we were trying to grow a business out of research," says Inkster. "We lived in their incubator and helped to develop their radar technology, to make the stuff small enough for use in

planes doing exploration in the Arctic." Inkster was vice-president of the company's radar division.

They eventually developed other niche opportunities, applying their radar technology to ice reconnaissance in the Beaufort Sea and other map-making in both northern and tropical belts. In 1990, Intera Technologies went public, trading on the TSX and NASDAQ, and grew to $100 million in market capitalization. Inkster had learned his first lessons in growing a company and taking it public. But, in 1991, preferring to be part of a smaller business, he sold his shares and started looking around for new opportunities. Six months later he was approached by the Quester Tangent Corporation, a marginally profitable, emerging hydrographics surveying company, and was asked to become its CEO. Quester Tangent was trying to apply acoustic signal processing technology to measuring the ocean floor. Inkster was gaining experience in taking an existing technology and applying it in different ways — from air to land to sea. When he sold his interests in Quester Tangent six years later, Inkster had helped to grow the company to about 30 employees, but was still anxious to start his own company from scratch.

Then, one day, Inkster got a phone call from Reimer, a brilliant scientist he had met years earlier and befriended. "I've got this bizarre new technology," Reimer told Inkster. "The patents are filed and I have some simple prototypes of this skin-like material you could wrap around robots for use in space. Are you interested in finding some commercial applications for the technology? If you are, you could license the technology." Reimer's company, CanPolar East, in St. John's, Newfoundland, had pioneered several technologies, including machine vision and technologies used in the food-processing and environmental industries. Reimer's latest invention was Kinotex, a digital skin made from fibre optics that could be wrapped around the Canadarm to give it a sense of touch. Astronauts needed this tactile feedback from the Canadarm so they would know if it was colliding with other extraterrestrial objects while performing maintenance on the International Space Station. Reimer had done this work under a $1.5-million research contract with the CSA, with CanPolar East funding half. Since the CSA's policy was to turn any IP from its research contracts over to the private sector, CanPolar East owned the rights to license all the non-space applications of the technology.

Inkster fell in love with Reimer's Kinotex technology. "Here was something that emulated the performance of human skin. So I thought there must be applications for that," he says. "So I spent about a year looking at all the different potential applications that I could think of and we funded some commercial market research and came up with the idea that we could build touch-controllers. We could build surfaces that people could put their hands on and move their hands around and these surfaces could be used to control their computer or emulate a musical instrument or something like that. That was our first approach." The National Research Council Canada (NRC), impressed with Inkster's track record, agreed to cover part of the costs of the market research to study the value of the application in the touch-pad area, how the company might approach developing these applications, and what the

marketing strategy should be. Although Inkster had a road map of where the biggest potential markets for this new technology would be, including data on market sizes and possible applications, he settled on the music industry for the first application. This would become the blueprint for the company for the next couple of years.

Inkster incorporated Tactex Controls in 1998 and set out to raise about $300 000 of seed investment from local angel investors. Reimer became a founding shareholder in the new company, trading his technology for an equity stake. Next, the company had to figure out what its exact product would be, and mobilize an engineering team to design it. A year or so later, Tactex Controls entered the market with its first product, the MTC Express, a mouse pad-sized multitouch, pressure-sensing controller that appealed to animators and musicians for use in editing and composing. "Instead of a mouse, which is a pointing device, this touch pad keeps track of where all your fingers are and how much pressure each finger is exerting," says Inkster. "There are lots of creative applications out there where people are desperately looking for other ways to interact with the computer keyboard. It's a boon to animators, who can simultaneously move hands or fingers or features on a face." In early 2001, the MTC Express product won the *Electronic Musician* Editor's Choice Award for most innovative product, and at the time was touted by the industry as the most creative controller in the universe.

To expand its market, Tactex Controls' strategy was to design different versions of its product and supply them to other manufacturers as an original equipment manufacturer. Among these versions were a touch controller sensor and firm-ware for M-Audio, the fastest growing company in the music industry at the time, and a touch controller for Mercurial Communications that Tactex Controls hoped would become the standard for keyboard, drumming surface and mixer product manufacturers. Tactex Controls also produced an electronic drum, an electronic guitar attachment that adds sound effects, and a synthesizer component that incorporated the MTC Express as a touch-sensitive controller.

The manufacturing line for Kinotex resembles a high-technology loom process, with pressure sensor-embedded fibre-optic wires threading through the "looming" machine (which was crafted from scratch by Tactex Controls employees to meet their needs) and then laser cut for various uses.

"We found that we had to build not only the product but also the process," says Inkster. "How you assemble this and laminate it and weave it, and the process and the tooling to do that — we've had to invent all that ourselves. Local automation companies are helping us do it, and our own design engineers are designing tooling and so on. The product and the process have to evolve together, and we're doing all of that

ourselves. For very high-volume markets, it may be that we'd have to team up with a larger group that's experienced with different types of production processes."

In 2002, Tactex Controls wrapped up its production processes for touch-control pads and moved from development to production in a facility that could produce 10 000 units a month.

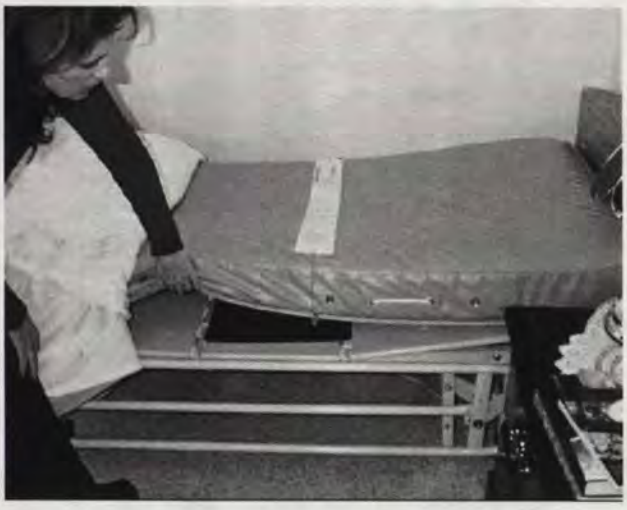
"We had lots of technical challenges to overcome. But in hindsight, it wasn't the technology," says Inkster. "We could hire the best people to solve these challenges. The real problem was in marketing." Inkster knew that his product applications for the technology so far were only in a niche market with limited scope, not the basis for rapid growth in a market that could take the company to $100 million. Sales in 2002 were less than $350 000. But it was a start.

In 2001 Inkster negotiated an expansion of Kinotex's domain license to include health care and security markets. On the R&D front, he shifted the company's focus to medical devices — the second niche market to be penetrated. The company moved quickly into the health care market. Its first medical application was for MammaCare, a Florida-based firm, and was a device for training health care professionals in breast-cancer detection. Inkster next contracted some independent market research for other medical/health care applications. The research revealed a strong market for bed sensors that could warn when elderly patients were leaving their bed and at risk of falling. The product would also have to be compatible with existing nurse-call and bed-alarm systems. U.S. sales for bed sensors were estimated to be $30 million to $40 million per year. So, Inkster led his company through a major strategic-development program to build flexible, pressure-sensing devices for use as bed or mattress sensors.

Over the next several months the company's researchers developed a variety of bed-sensor and patient-monitoring prototypes that showed promise. Their Bed Occupant Sensor prototype, developed with assistance from the NRC, would allow health care professionals to gather and log a variety of data to monitor patient motion. For example, motion could indicate restlessness — a predictor of nighttime toileting in altered patients who need assistance — or indicate increased pain for patients who are slow to ask for pain relief. The bed sensor could also be helpful in treating patients at risk of bedsores, or as a tool to diagnose disordered sleep.

To move these products into the market, however, Inkster would need to form strategic partnerships with large industry partners. At the end of 2003, Tactex

Controls announced a licensing deal with Hill-Rom Company Inc. of Batesville, Indiana, a market-leading manufacturer of hospital equipment. The deal yielded US$1.5 million in cash for Tactex Controls in exchange for certain rights to the technology.



In 2002, Lady Luck helped out further, when the Japanese giant, the NITTA Corporation, an Osaka-based robotic-controls manufacturer with about $900 million in annual sales, discovered Tactex Controls' patents. "We had a nice patent portfolio," says Inkster. "We had the underlying patent, and, then, as we kept building things, we'd file more and more patent applications. So, we had a piece of IP that had value. NITTA and other large companies often go out and explore the patent literature, through published patents, and, if they've got a problem to solve or an area of development that they want to pursue, then they'll dig around and try to find a patent. They found our patent listed in the U.S. patent database, got a hold of us and said, 'We want to talk about acquiring a license.' We didn't know the first thing about robots, but we listened."

A world first, NITTA was building sensors for humanoid robots for use in home care for the elderly and needed a digital skin with sensors and interpretive software to give the robots a sense of touch. The licensing agreement, which took five months to negotiate and was worth US$1 million to Tactex Controls, was signed in December 2002. The agreement gives NITTA the right to sell Kinotex technology in the Asia-Pacific market, with the two companies collaborating on R&D.

"Between the time of that first phone call and the time that we had cash in the bank — the first cash in the bank — was about five months. Within 12 months we had the deal completed and we were moving forward together as strategic partners," says Inkster. "They're doing the R&D on new products in Asia, and we're doing it here in North America. We're sharing results, they're paying us royalties, and so on. Over the long term, the real value is going to be a collaborative development effort with them. We've got a little group of six or eight research scientists and engineers — that's what our development team is. NITTA has a similarly sized group in Osaka. The two groups are working together on projects and sharing results back and forth, so we get a big bang for our development buck by collaborating in that way. And they're working on projects in some cases that are quite different than ours, markets that are not ready yet in North America — humanoid robots is an example. We couldn't take that on ourselves now because it's too far out for us, so we can allow them to do it and capitalize on the benefits that come back here."

According to Inkster, the actual market launch of humanoid robots in North America is probably five to ten years away. When it happens, Tactex Controls will be part of it. In 2003, Tactex Controls completed a technology transfer to NITTA by delivering a Kinotex manufacturing line. This will allow NITTA to manufacture Tactex Controls sensor products for the robotics industry in Asia and to develop new products.

Next, Inkster plans to target the $500-million automotive sensing and control market with a series of products, including a new seat-occupant classifier for use in intelligent airbag-deployment systems, and a crush-zone-intrusion sensor to detect collision impact on the sides of vehicles. Prototypes of these products are in various stages of development and performance testing, and the company expects to further their engineering and manufacturability in 2004. Again, Inkster will pursue strategic alliances with firms already in the automotive market, ones with the proper marketing and manufacturing expertise.

Protecting Intellectual Property

Tactex Controls believes in patenting everything it does. With a team of patent attorneys and IP lawyers, it religiously seeks patent protection for its IP. It has three issued patents and six patents pending in countries around the world. The IP protection lets the company develop partners and licensing opportunities in industrial markets where Kinotex properties have competitive advantages.

"A lot of our value is around this IP or these patents that we have," says Inkster. "Patents sound very impressive but they really just give you permission to sue somebody. If you're a tiny company and somebody steals your patent, what do you do about it? You pay millions of dollars to hire lawyers? Well, you don't have that money. So, in our case, the strategy is around teaming up with large companies with deep pockets who value what we've got and will prosecute on those patents. They will protect the IP. So, in order for us to be successful, we've got to be teamed up with the big guys — so that's quite central to our strategy."

Financing the Company

Since its inception, Tactex Controls has financed its operations through private sales of equity securities, cash generated from sales, government assistance, and a reverse takeover of a junior capital pool company in 2000 (which made Tactex Controls a publicly traded company). In addition to the $300 000 Inkster pulled together from local angel investors in 1998, he also raised $2 million from the reverse takeover. Inkster used this financing to fund R&D and commercial manufacturing, and to move into a larger facility suitable for large-scale manufacturing. The NRC, the Industrial Research Assistance Program (IRAP)[1] and the BC Science Council have also been important contributors to the company's R&D and commercialization efforts, providing total R&D and repayable assistance of well beyond $750 000.

Inkster still thinks the company's capital is limited. "If we had more financing, we'd do more," he says. Inkster says that, since 2000, it's been almost impossible to finance

1. Inkster was able to tap into the NRC's precommercialization assistance program to develop its NTP-01 touch controller, and received an IRAP grant to develop the Bed Occupant Sensor.

companies like his. So, the company's licensing deals with NITTA and Hill-Rom have been critical to its survival and growth. "You can't raise money through venture capital and you can't raise money through the public markets in these little techie companies — for the last couple of years, anyways. So many companies have failed. We've been lucky enough because we've got some of these large companies who really value what we've got and they're not going to let us go away — they're going to pay us for a license or they're going to pay us for product, or whatever. So we've been able to grow the company and to survive based on revenues from customers: you know — the old-fashioned way of running a business."

THE PEOPLE

Adding more staff to its team at each stage of development, Tactex Controls now employs 16 people, two thirds of whom work on the engineering side — as mechanical and electronics engineers, software scientists, and neurophysiologists — and the rest of whom work in manufacturing and marketing. Inkster also retains a stable of IP lawyers, stock brokers and marketing advisers, has an excellent board of directors, and leans heavily on Reimer for guidance on technology-market applications, referring to Reimer as his technical guru.

"You try to build a team where everybody understands the overall mission of where we're going and what we're doing, and you do that through very open communication; then everybody is innovating in their own way," says Inkster. "We're very open, which I think may be a little unusual in public companies. But, everybody in Tactex Controls owns shares or stock options, and they know everything that's going on right to the last minute detail."

"There's innovation throughout the operation," says Inkster. "We generally think that innovation is technology and services, but I think innovation is equally involved in marketing and business strategies. I think you can make more money if you can come up with a good delivery strategy for your product than with the product by itself. I see innovation happening in business development, in marketing, in IP strategy and all of those areas. You have to keep that going all the time for small companies."

WHAT DOES THE FUTURE HOLD?

"For 2004 we're focussed on health care products," says Inkster. "The Bed Occupancy Sensor, in nursing-home trials since January, will move into manufacturing, and several follow-on products are in the pipeline. Second, we will get started in the automotive market. This is a huge market where our technology has real value, but it requires a significant investment before we can expect revenue several years out." The U.S. government has passed legislation requiring every U.S. automaker to have intelligent airbag deployment systems in their 2006-model cars. Tactex Controls' seat-occupant classifer is a possible solution. It can tell whether a passenger is seated or leaning back, or whether it's a child in the car seat and the airbag shouldn't be deployed. But, many challenges have to be overcome to bring the product to market. "We've got the better mousetrap," says Inkster, "but turning it into a business is not trivial. Trying to find the right business strategy to get from where we are — from good technology to a successful product launch — is nontrivial."

Where does Inkster want to see the company in five years? "I want to grow the value of the company to $100 million in market capitalization," he says. Right now, it's at about $14 million. So, how will Inkster do this? "Well," he says, "you build that road map; you build that strategic plan. You start at the end point and you say, 'This is where we want to be in 2009,' and then you just back up, year by year — you come back from there. So, to have a $100-million market cap, you need sales of $40 million a year and you need to put 10 percent of it on the bottom line with a 20-times price-earnings ratio. If you do that, you're probably close to $100 million. So, how do you get to $40 million in sales with good margins? That allows you to focus. All of your marketing efforts come into focus now on the larger markets. I think that kind of plan ties it all together."

"I would say the focus on the market is really fundamental," Inkster says of what advice he would offer other innovators and entrepreneurs. "This business of innovation in technology is almost secondary. Eventually, somebody has to buy what it is that you're selling, and if you don't get that right then you're doomed. Moreover, as your business grows, you find that the strategy has to change. The market changes. And you have to be able to make rapid decisions that switch directions to keep up with the market. If you get that bit wrong then you're in trouble. Another fundamental I would say is on the people side. The people who are working on this enterprise with you are probably spending more time in this little office than they are with their families, so they have to have fun; they have to get along well together, and they have to collaborate. Unless you can meld a team that's like that, you've got big troubles and it's not going to be worthwhile. Last, I would say . . . try not to run out of money! That's the CEO's biggest concern; that's what keeps you awake at night."

Inkster is betting that the age of intelligent surfaces will be built on Tactex Controls technology. In April, Tactex Controls was awarded the 2004 Innovation Award by the Greater Victoria Chamber of Commerce. Sponsored by the University of Victoria, the award is given to businesses that exemplify successful innovation; display vision in the

development of new technologies, products and/or services; and demonstrate an ability to take risks. Accepting the award, Inkster said, "Innovation is something we do every day, and it is a concept that develops in our people as much as it comes from the unique processes, novel technology, and business model."

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Ocean Nutrition Canada Ltd.

John Risley: Chairman

Robert Orr: President

Ocean Nutrition Canada Limited (ONC) is a rapidly expanding life-sciences company built on a foundation of science and proprietary technologies to create "natural health from the sea." The company currently supplies the world with high-quality, marine-based dietary supplements and functional-food ingredients, and is the world's largest manufacturer of high-quality omega-3 fish-oil concentrates. ONC exports its products throughout Canada, the United States, Europe and Asia. The privately held company is a wholly owned subsidiary of Clearwater Fine Foods Inc., one of Canada's largest suppliers of quality seafood products, headquartered in Halifax, Nova Scotia. Its omega-3 fish-oil powder is a technological breakthrough in healthy food ingredients, and ONC is the first and only dietary supplement ingredient company in the 184-year history of the United States Pharmacopeial Convention, Inc. (USP) to achieve USP verification for its products, setting a new standard for the safety and purity of omega-3 fish-oil ingredients.

The Name Says It All

As the 20th century was the space age, the 21st century could well be the age of oceans, as medicine, pharmacology, nutrition and molecular biology follow ocean scientists to the sea for their research. Seventy-five percent of the medicines we use today come from nature — almost all of them from the land. Now that science is examining life forms from the sea, a whole new world is opening up. Ocean Nutrition Canada is dedicated to delivering natural, proven health discoveries from the ocean to as many people as possible. In the process, it is capitalizing on the wealth of Nova Scotian marine-science capacity, and is further exploiting the "value added" opportunities resident in fish by-products and underutilized species of seaweed and micro-algae.

Started in 1997, ONC is already a highly successful company. In just seven years, it has grown from a small family-run business that sold fish oil to veterinarians to one that employs more than 220 people in research and development (R&D), processing,

manufacturing, quality control and marketing activities to bring nutritional products to the global human-health and nutrition marketplace. The company's name tells its story. Ocean Nutrition Canada develops natural health products that come from harvesting ocean marine organisms like seaweed and salmon peptides, and sells them globally to health-conscious consumers interested in wellness through nutrition. Its main customers are dietary-supplements and functional-foods manufacturers, who use ONC ingredients in their products. Today, the original veterinary side of the business no longer exists.

ONC is the largest manufacturer in the world of concentrated omega-3 fish-oil ingredients and powdered omega-3 fish oil destined for functional-food and dietary-supplement applications. Omega-3s are members of a class of fatty acids known as long-chain polyunsaturated fatty acids, which play several roles in human health, including acting as key components in cell membranes, being essential for cell metabolism, and regulating cellular inflammation and gene expression. It's essential to consume omega-3 fatty acids because they can't be synthesized by the body. Changes in people's food preferences, along with the impact of modern food processing, has led to a significant decrease in the average dietary intake of omega-3 fatty acids. Many chronic diseases and conditions have been attributed to omega-3 deficiencies, including heart disease, mental illness and arthritis. Fish oil is the best-known, most efficient source for the omega-3 fatty acids EPA and DHA. In addition to being North America's leading supplier of omega-3 products, ONC has so far also brought two other key products to market: Respondin™, a dietary supplement ingredient that provides balanced immune support; and ONC-103, a dietary supplement for prehypertension support.

In Halifax, ONC houses one of the best R&D laboratories in the world, as well as a state-of-the-art quality-control laboratory. Its corporate headquarters and a micro-encapsulation pilot plant are also located in Halifax, and its 70 000-square-foot omega-3 refining, concentrating, packaging and pilot plant facility is in Mulgrave, Nova Scotia.

Starting with first-year sales of less than a million dollars, ONC's revenues have steadily increased, and are now forecasted to reach $100 million in revenues by 2006. It's not a bad growth rate for a company that was bought sight-unseen over dinner just a few years ago. Although ONC had the backing of its highly successful parent company, Clearwater Fine Foods, also located in Halifax, the story of how ONC grew so quickly can best be described as the one about the fish that didn't get away.

Little Fish in a Big Pond

ONC's story started in 1996. It cocooned as a small, family-run business called Laer Products operating out of Mulgrave, a coastal community with a population of a few hundred people, most of whom have traditionally worked in the fisheries. Laer Products had gotten its start in the early 1980s when Andre Boudreau's daughter's horse developed a coat problem. Someone mentioned to Boudreau that if he fed the horse fish oil the coat would improve, so he did, and the horse improved. Boudreau felt this could be a good business to get into, considering the easy availability of fish oil in his region, so, with his wife Sylvia, and son Jacques, he began processing bottles of omega-3 fish oil out of a small manufacturing plant, and marketing them to veterinarians to improve the coats of cats, dogs and horses. However, an early, and major, problem was the odour of the unprocessed fish oil. Animals didn't mind the smell, but their owners did. So, the Boudreaus started to look for technology that could deliver the product less pungently. They approached InNOVAcorp, a Nova Scotia government agency with a mandate to help partner businesses with technology. With InNOVAcorp's help, the Boudreaus discovered that one possibility was to micro-encapsulate the oil in small beads or powder, and then sprinkle it over pet food. The Boudreaus went on a search for encapsulation technology to do this.

After about four years of R&D investments assisted by the Nova Scotia Research Foundation Corporation; the Canadian Institute of Fisheries Technology; what was then the Technical University of Nova Scotia;[1] the Southwest Research Institute in San Antonio, Texas; Enterprise Cape Breton Corporation (ECBC); the Atlantic Canada Opportunities Agency (ACOA); and InNOVAcorp, the Boudreaus eventually developed some proprietary micro-encapsulation technology, but by 1996 they were still making revenues of under $750 000 a year. The company was suffering from undercapitalization and a lack of marketing capacity. InNOVAcorp, concerned about the financial sustainability of the company, facilitated a meeting for Andre Boudreau with John Risley (founder and president of Clearwater Fine Foods, chair of the board of Clearwater Seafood Limited Partnership, and one of Nova Scotia's most prominent entrepreneurs) about a potential equity investment. Over a 20-year period, Risley had grown a multimillion-dollar fish exporting company from its humble beginnings that saw him selling lobsters out of the back of a pick-up truck. From time to time he also made venture-capital investments in other people's companies. Risley and Boudreau met for the first time in mid-1996 and, over dinner, Risley agreed to invest $250 000 in Boudreau's company in exchange for a 50-percent equity position, without ever having seen the business.

Thinking he better take a look at the company and its potential, Risley called Robert Orr, whom he had done business with when Orr was an executive with Bolands Ltd., The Oshawa Group's Atlantic Canadian retail and wholesale food operations. Orr had several years of executive and management experience in the food retailing industry, both in Ontario and Nova Scotia. He also had entre-

1. Now the Faculty of Engineering at Dalhousie University.

preneurial experience from previous start-ups, both his own and those of others. He was known for his ability to innovate and to build things from the ground up. Risley had tried to hire Orr to work for Clearwater Fine Foods in the past but, happy with his job at Bolands, Orr had declined. However, he was preparing to return to Toronto with The Oshawa Group when he got Risley's call asking if he would be interested in going to Mulgrave and seeing what potential there was for turning Laer Products into a more substantial company. Risley explained that he wanted to use the Boudreaus' business as a jumping-off point to diversify his holdings into the health industry. He told Orr he wanted to do this by making better use of fish by-products, particularly omega-3 fish oils — the main ingredient in Laer Products' merchandise. Risley's idea was actually to build a life sciences business based on marine-organism extracts that could feed into the huge, global health and wellness trend being spurred by the baby-boomer generation.

"I told him that I didn't know anything about the nutraceutical market or micro-encapsulation, but he told me, 'That's okay, because nobody else does either,'" says Orr. But the concept of building an international health and nutrition business from Halifax out of marine products was exciting enough to lure Orr to the new company.

What Orr found in Mulgrave was a small company struggling with a new micro-encapsulation technology it had been working on for more than a year. Back in Halifax, Orr asked Risley if he knew what he had bought. "He said, 'No, and I don't want to know, just tell me what you're going to turn it into,' " says Orr. Orr started on market research to turn Laer Products into a global business. In December 1996, before the company's business plan was done, Risley bought the remaining 50 percent of the company's shares from the Boudreaus. In March 1997 he created ONC as a wholly owned subsidiary of Clearwater Fine Foods. He invited Orr to be the new company's general manager (he's now its president), and he convinced Andre Boudreau's son, Jacques, to stay with the company for the next four years, helping Orr learn about the business. Six months later, when Orr had finished the first version of the company's business plan, he knew a lot more about the industry and its market potential. The global dietary-supplement industry alone was worth more than US$50 billion per year, with even greater potential available in the emerging functional-foods industry.[2]

Swimming Out to See

According to Orr, Risley's vision of a large, global company was evident to him right from the start. "John had no interest in a little business with a local focus. He wanted a big business. After four weeks on the job, not the six months I requested, John came to me and asked me to present a business plan at the upcoming board meeting. What I gave them was a five-to-seven-year plan moving the company from less than three quarters of a million dollars, as Laer was doing at the time, to more than $50 million. I thought it was a pretty bullish plan," he says. "After the meeting, John came to me and said, 'That was pretty good, but you're not thinking big enough. We need to have a

2. A functional food is any food that has a natural product added to it to give it nutritional value. For example, some orange juices add calcium to supply calcium to people who don't normally consume dairy products.

$100-million business.' I told John that wasn't a problem — it was just a function of how much money he wanted to invest and how fast." Realizing a company's growth is based largely on its investment capital, ONC was in a better-than-average starting position, since Clearwater Fine Foods was highly successful and willing to front the start-up money for the new company.

ONC's market research showed that many health food and supplement companies aren't able to back their efficacy claims with scientific data. In fact, very little is known about the actual active compounds that lead to products' effectiveness in use. Risley immediately emphasized that a successful business strategy would have to be based on science. The company would have to scientifically prove that any product they would make was safe and effective. This would be ONC's competitive advantage, and the foundation of the business. ONC set up a scientific advisory board, and set about hiring the best scientists they could find. One factor that allowed ONC to grow so quickly and successfully was realizing early its need for good scientists to lead its research focus. "We were business people who needed scientists to help us be successful," says Orr. "The reverse is true for scientists who discover something, they need to find good business people to help them develop and market their product or technology."

Having started with this merger of science and business, ONC today has over 70 scientists working in various parts of the company. Forty of them, including 12 PhDs, work in the R&D labs. From science comes ideas. But it takes more than ideas to make a company successful. "Our vision was to discover compounds, develop technologies to extract them, then scale it up — and to do it all here in Nova Scotia," says Orr. "We believed that five facets of the business were available here: the scientific R&D capability; the proprietary products and technologies; the vertical integration to do the manufacturing; a skilled, hard-working, cost-competitive workforce; and global distribution and education for consumers. But, we soon realized we needed strategic partners to help with distribution and consumer education." Today ONC has strategic partnerships with major supplement, food and pharmaceutical companies in Asia, Europe and the USA.

The First Catches

One of the earliest manufacturing projects ONC started on was further developing the fish-oil delivery system that had first brought Risley and Andre Boudreau together. What Laer Products had developed and refined over the years was a unique micro-encapsulation method to shell coat and protect active compounds. The process enhanced shelf life and bioavailability of the active omega-3s in the fish oil, while completely masking any undesirable taste, odour or texture typically associated with

fish-oil products. However, the first thing the new company had to do was refine the micro-encapsulation technology to make it work. To help them do this, they hired a consultant from the Southwest Research Institute in San Antonio, one of the top three research labs for micro-encapsulation in the world, they hired their own micro-encapsulation specialists, and they opened a micro-encapsulation pilot plant. They also had to develop a technology that would be cost-efficient enough for the multinational food companies. ONC's existing micro-encapsulation technology had a production cost per kilo of over $100 — way beyond what the market would bear. They needed to find a new way to get the costs down to around $20 a kilo. ONC created a new paradigm for micro-encapsulation of omega-3 fish oils and today, four years since starting the process, they have a world-leading technology in this area that has massive potential in the functional-food ingredient field.

For its marine organisms-based product innovations, ONC first looked at the waste stream from Clearwater Fine Foods' commercial fishery. ONC's biggest revenue generator was still the omega-3 fish oil extracted from sardine and anchovy oils, but now the company examined the potential of extracting glucosamine from shrimp and crab shells. Glucosamine is believed to help rebuild cartilage, and is used in treating osteoarthritis. The Clearwater Fine Foods factory in St. Anthony, Newfoundland, offered ONC an easy and relatively cheap source of raw material with its abundance of waste shrimp and crab shells. Combining this with its scientific knowledge and technological know-how, ONC started producing glucosamine in no time at all.

"The company soon branched out from there," says Orr. "We began to look at any kind of marine organism that had a sustainable biomass and could provide extracts that would have natural-health benefits."

ONC also wanted to understand its competitors' landscape. "We had to learn how we were going to sell the product and to whom. This meant looking at the global marketplace," says Orr. The company soon learned they couldn't compete with Asian glucosamine manufacturers, so they eventually abandoned that project.

ONC's initial business model was based on complete vertical integration — from sea to shelf, so to speak. ONC would do the R&D, then manufacture and set up a marketing and distribution system with its own branded line of products for the U.S. market. They entered the market in 1997 under the Ocean Nutrition Canada™ brand, offering a line of dietary supplements for joint health, brain health, heart health and balanced health. But it was costing millions and would take millions more to build brand equity and develop a recognized national brand. So they determined it would be more cost-effective to get out of the branded products end of the business, instead developing strategic alliances with supplement brand marketers and other food manufacturers to get products to the end consumer. ONC could then focus on building sustainable points of differentiation through greater investment in R&D, and developing proprietary products and processing technologies.

IT TAKES MONEY TO SAIL A SHIP

But, by mid-1997, ONC knew it would have to find additional financing to realize its upgraded business plan, including its early-stage R&D. Its goal was to raise $38 million in outside equity, from venture capitalists, the provincial and federal governments, and additional Clearwater Fine Foods investment. Orr explored all the available sources of financing and, over the next year, made a series of presentations on ONC's business plan. In November 1998, ONC closed its first round of financing, $38 million — $19 million in private equity, and $19 million in provincial (Nova Scotia Business Inc.) and federal (ACOA and ECBC) government fully repayable loans. They also received a $1.5-million job grant for ONC's Mulgrave plant from Human Resources Development Canada.

"It doesn't take any more effort to raise $10 million than it does to raise $1 million, so you might as well go for what you need at the beginning. Money follows good ideas and good management, and we felt we had both," says Orr.

ONC used a portion of the financing to hire more scientists and technologists, build a new, state-of-the-art research facility in Halifax, and begin a serious campaign of screening marine organisms, including several species of seaweed. ONC also bought a second plant in Mulgrave, one that had been mothballed by a now defunct pharmaceutical research company that had been a leader in fatty acid research in Nova Scotia for close to twenty years. Ironically, when this company closed a few years ago many people highly trained in fatty acid science were suddenly available and prepared to carry on similar work with ONC. These employees were able to quickly transfer their expertise and knowledge in good manufacturing, laboratory and clinical practices to the new plant and R&D facility.

Other rounds of debt financing in 2002 and 2003 have let ONC further its micro-encapsulation technology and double its fish-oil production at its Mulgrave plant. This financing included $6 million from the Atlantic Innovation Fund (AIF), which is administered by ACOA, $2 million from the Cape Breton Growth Fund Corporation and a $300 000 nonrepayable contribution from the ECBC.

ONC uses the same approach for the discovery and development of its nutritional products, such as its omega-3 fish oil and blood pressure-lowering seaweed extract, as is taken to bring pharmaceutical drugs to market. "Seaweed from the waters surrounding Nova Scotia is screened for compounds that may be able to treat cardiovascular disease by lowering cholesterol or treating high blood pressure," says Orr. "We look for extracts that could boost the immune system or be used to treat the large Western disease systems. These extracts have to be not only natural, but efficacious, scientifically proven, and without side effects, so we aimed to build a rigorous, disciplined approach to our R&D process." Beyond proving usefulness with no side effects, toxicity tests are also conducted, followed by clinical human trials. The commercialization process to bring new compounds to the global market happens as products are deemed marketable. ONC first looks at its potential markets, examining applications in treating diabetes, cardiovascular diseases, high blood

pressure, and bone and joint problems. It then sets up bioassay-guided screening of its marine organisms to figure out possible product solutions, focussing on marine products that are already used in food, such as seaweed and salmon.

When ONC researchers identify a compound, they have to find ways to characterize it, extract it cost-efficiently, and assess the commercialization potential of each different product. A market intelligence group identifies viable market segments, looking at things like market size and growth projections; scientists and chemists screen for the compound against these targets; and a team of engineers develops innovative methodologies to turn the science into cost-effective, useable products. Many of its production methodologies and new products become proprietary technologies for ONC, including its patented immune-response modifier and micro-encapsulation technology. While Risley's original concept was for ONC to look exclusively at waste streams from the seafood industry, it now screens all kinds of marine organisms for compounds that can be extracted and scaled up for commercial production.

Staffed by about 40 PhD scientists and analytical chemists, the R&D/bioscience unit screens micro- and macro-algae, fin fish (such as salmon), and shellfish with the objective of discovering new compounds. About 150 people work in ONC's three Mulgrave plants producing products for the dietary supplement market, and another 20 or so work in the functional-foods unit, examining new market opportunities and operating ONC's micro-encapsulation plant.

By early 2004, there were more than a dozen new products in ONC's R&D pipeline, some of them developed through strategic alliances with research labs in other parts of the world. The dietary-supplements unit was expected to be in a positive cash flow position by the end of 2004, and the functional-foods unit was on the cusp of rolling out new products for a list of 30 potential customers, 15 of whom were doing initial market testing for foods which are adding ONC's omega-3 micro-encapsulated fish-oil powder to items like milk and bread. ONC was projecting that six to ten new food applications would be approved by the end of the year.

The Scientific Method in a Seashell

In early 2004, ONC had more than 12 000 square feet of custom-designed R&D laboratories and a 70 000-square-foot omega-3 refining, concentrating, packaging and pilot plant facility, making it the largest manufacturer of omega-3 fish-oil concentrates in the world. ONC's R&D laboratories include analytical chemistry, organic chemistry, biochemistry, natural-product chemistry, cell biology and micro-encapsulation-delivery technologies. ONC also has a research information group, which has developed a specialized in-house reference library with access to current biomedical resource literature and a patent-searching database.

ONC's natural-product chemistry group is an example of how innovative thinking can lead to scientific discoveries and processes. In many research companies a natural-products chemistry section would be either unheard of, or, perhaps, relegated to a small, out-of-the-way corner laboratory. At

ONC, this group's work is crucial to the mission of the entire company. The natural-product group works with the biochemists, cell biologists and analytical chemists to discover new marine natural products. They prepare various extracts and fractions for testing. Once a potentially interesting extract is identified, the scientists employ a process called "bioassay-guided fractionation" to lead them to the active compound. This starts with the extraction of an entire marine organism. The next step is a fractionation process, which results in a number of different fractions from the original extract. Each fraction then undergoes a bioassay to determine if it has any effect on whatever biological material (cells, tissues, etc.) is being tested. If it does, it is then fractionated further and bioassayed again. The fractionation and bioassay process goes on until a pure active compound is discovered.

What separates ONC's method from a typical reductionist approach to science is the sequential bioassay and fractionation method it uses. Rather than isolate every possible compound to test it individually, bioassays of combinations of compounds either rule out any possible efficacy of that compound or let research continue logically. Less time is wasted, and the chances of discovery are improved. Once a compound is discovered, its structure is determined, analytical methods are set up, its toxicity levels are determined, and human clinical trials are started. ONC only brings its products to market once all these conditions have been satisfied.

QUALITY COUNTS

A cornerstone of any successful company today is the implementation of quality standards and procedures, without which the company would fail against customers and competitors. ONC has met the standards for good manufacturing practice, a system of practices to ensure the safety, consistency and efficacy of its products, and has received Hazard Analysis Critical Control Point certification of its manufacturing and packaging facilities. Every part of the organization is geared toward continuous improvement, and all of its clinical trials are conducted according to good clinical practice.

ONC's focus on quality practices has paid off. In April 2004, the company achieved Generally Recognized as Safe status for its omega-3 powder fish-oil ingredients from the U.S. Food and Drug Administration (FDA). With this approval, ONC's omega-3 powder, considered a technological breakthrough, can be added to foods such as bread and milk, with the profound positive effect of reducing the risk of sudden death due to cardiovascular disease. In June 2004 the

company announced that its entire line of standard fish oils and omega-3 fish-oil concentrates had been validated through the USP verification program, setting a new standard for the safety and purity of omega-3 fish-oil products. This was the first time in USP's 184-year history that a dietary supplement ingredient company achieved USP verification.

Don't Waste the Waste

ONC also innovates in non-core parts of its business. When it acquired the Mulgrave plant it began heating it with a biodiesel fuel made from its own waste stream. The fish oil they use for omega-3 extraction comes from sardines and anchovies, but it contains saturated fats and shorter-chain fatty acids that aren't needed, so they are removed first. This waste oil accounts for 60 percent of the extracted fish oil, and is now used to heat the Mulgrave plant, which has never had to buy heating oil. One of the interesting things about a company that relies on innovative ideas and technologies is its willingness to form partnerships with other like-minded companies. "As we continued to expand, there was such an excess of waste product (fish oil) that we tried to run generators to produce additional electricity for the plant, but the system became too complicated, plus we couldn't sell the excess electricity, so Wilson Fuels approached us to do business with them," says Orr. Wilson Fuels now blends the fish oil with heating oil to produce a more eco-friendly fuel for commercial sale. In addition to this "green" home heating fuel there are now 20 buses in Halifax running efficiently on fish-oil biodiesel, and this winter a number of government buildings will reduce their reliance on 100 percent carbon-containing fuels by using the new fish-oil biodiesel from ONC and Wilson Fuels.

Sailing Ahead

With the market for omega-3 fish oil firmly solidified in the global marketplace, a large staff, including its 70 scientists, top-notch quality-control and manufacturing divisions, and four locations in two separate counties in Nova Scotia, ONC has been able to bring two other novel compounds to market.

Respondin™, a patented, water-based extract of *Chlorella pyrenoidosa*, an edible micro-algae, was the first product ONC discovered and developed. The specialized extract is essentially a concentrated chlorella powder that boosts the immune system and responds well to a variety of immune-system challenges, and it has substantiated its claims through the clinical trial process. After extensive research, ONC says that Respondin™ works by stimulating the B-cells (white blood cells that produce antibodies) to destroy foreign matter such as viruses, and that the extract also increases macrophage activity. Macrophages (another type of white blood cell) absorb and eliminate bacteria and viruses, making them crucial in the body's fight against infections like colds and the flu. According to ONC, Respondin™ also decreases the immune system's response during periods of hyperreactivity, which occur with allergies. Composition-of-matter and use patents have been granted for Respondin™ in both Canada and the U.S., with international patents pending.

Another important product for ONC is ONC-103, a fish protein hydrolysate of the Japanese bonito fish. It is said to reduce

blood pressure that is elevated beyond the normal range, supporting prehypertensive people who are trying to delay the need for future drug therapy through dietary modifications.

With the FDA approval of its omega-3 fish oil as an ingredient in other foods, ONC is well poised to move into the functional-foods marketplace. "By adding an ingredient like omega-3 to a traditional food like yogurt, you've made a functional food," Orr says. "Our goal is to make foods more nutrient-dense and to help prevent disease through diet and healthy eating." ONC has also just developed a new product from the protein of salmon waste that can be added to drinks, food bars or cereals to lower blood pressure.

Many things have contributed to ONC's success so far. "An important factor in ONC's success was selecting people committed to the ideals and vision of the business — being able to attract the best people to work for us," says Orr. "The Halifax region has one of the highest densities of marine scientists in the world. More than 500 marine PhDs and scientists study and work at various universities and research institutes here. But other things have also been critically important. Without John Risley's vision and the internal support structure of Clearwater, none of this would have happened. And, we have been helped a lot by the willingness of the provincial and federal governments to support innovation and new-product development, and we've filed for Scientific Research and Experimental Development Program tax credits every year. The Industrial Research Assistance Program was one of our earliest supporters in the development of our immune-response modifier. ACOA, the ECBC, InNOVAcorp, the Province of Nova Scotia, the National Research Council Canada Institute for Marine Biosciences and the Bedford Institute of Oceanography [in Dartmouth, Nova Scotia] have all been committed to the success of this company. It's this collaboration of the whole community of organizations that's made the difference for us."

Some of the company's biggest barriers in going forward from here appear to be regulatory hurdles. By early 2004, ONC was still waiting for approval to sell its encapsulation technologies in Canada, and for approval of its novel food application. Another of its barriers lies in gaining global market distribution. Entering the market using a vertical-integration strategy was much more expensive than the company originally projected, so it has started to look for strategic partners (large, multifood-ingredient multinationals) to help it overcome these issues. Finally, getting the technology refined and into the marketplace has also been difficult. Once its pipeline of new products makes it to the marketplace, ONC's challenge will be to meet the demand. The market for omega-3 and DHA concentrates has experienced more than a

20-percent, five-year compounded annual growth rate, and the trend is expected to continue for years to come.

"Innovation isn't just creativity, it's the application of creativity," says Orr. "Nothing happens unless you can apply it in the marketplace. What a good company needs is investment, partnerships and sound leadership. You need commitment through action, people that can inspire you, and partnerships built on trust. If you make a mistake, then you have to fix it and move on, while continuing to keep your vision always in front of you. Building a new business is just hard work, a constant roller coaster."

Orr advises "You must have the right strategy — you have to understand what you want the business to do, how that delivers value in the marketplace, and how you are going to generate value at the end of the day. And you need people who can execute against your plan. If you can't do this, then you can't make it. It's as simple as that."

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SemBioSys Genetics Inc.

Andrew Baum:
President and CEO

Dr. Maurice Maloney:
Chief Scientific Officer

SemBioSys Genetics Inc. is a Calgary-based biotechnology company focussed on developing pharmaceutical proteins, industrial reagents, food additives, protein-purification technologies and delivery systems that take advantage of the company's proprietary oilbody/oleosin technology platform. It is the only company in the world involved in both the purification and bulk production of plant-based proteins. Its goal is to become a fully integrated biopharmaceutical business and the world's leading supplier of transgenic proteins for the pharmaceutical market. The company strategy is to partner with other companies in these sectors, enabling the commercialization of products that might not otherwise be commercially viable because of high formulation and manufacturing costs.

Molecular Farming — A Revolution?

Some people saw a simple oilseed. In the 1980s, Dr. Maurice Moloney saw a tiny factory inside that oilseed that was capable of revolutionizing the production of biologics and protein-based pharmaceuticals.

SemBioSys Genetics Inc. is the fruition of Moloney's vision. Spun out of the University of Calgary in 1994, SemBioSys is still a privately held firm. Investors include Bay City Capital, the Business Development Bank of Canada, Dow AgroSciences (a Canadian subsidiary of The Dow Chemical Company), Royal Bank Ventures Inc. (now RBC Capital Partners), the University of Calgary, Ventures West Capital Ltd., and Moloney himself.

If SemBioSys' further evolution as a business is as successful as its scientific evolution to date, the company could play a key role in substantially lowering the costs of producing and purifying the commercial peptides and proteins needed to generate vaccines, pharmaceuticals, industrial enzymes, cosmetic ingredients, and nutritional products.

Stunning advances in areas such as immunology, genomics and molecular screening have dramatically increased the number of these kinds of products in the commercial pharmaceuticals pipeline. But the pipeline is not flowing as smoothly as it should. For the first time in biotechnology

history the marketing of many breakthrough products is being stalled. For smaller, innovative firms in particular, the daunting costs of building adequate production facilities, especially for expensive purification processes, can stand in the way of getting exciting new pharmaceuticals to market. And even when companies succeed, health care systems often find the resulting costs of the pharmaceuticals prohibitive.

SemBioSys Genetics is convinced that it has a worldwide solution to high production costs. It believes the answer lies in the unique gene-purification qualities of safflower seeds. The company sees itself as expanding the frontiers of plant biotechnology by fundamentally changing the way proteins are produced and purified.

PLANTING THE SEMBIOSYS SEED

Moloney, now chief scientific officer at SemBioSys, was born and educated in England. In 1974 he received a Bachelor of Sciences degree from the Royal College of Sciences, Imperial College, University of London. In 1979 he was awarded a PhD from Leicester Polytechnic, where he specialized in biochemistry.

Moloney immigrated to Canada in the early 1980s after a stint as head of the cell biology division of Calgene Inc. in California. Calgene is best known for its early successes in biogenetics — particularly for its development of the Flavr-Savr tomato, the first commercially successful genetically modified food. At Calgene, Moloney developed the first transgenic oilseed plants, using canola as a model. His work resulted in a landmark patent in plant biotechnology, and eventually became the basis of Roundup® Ready and Liberty Link® Canola.

Since canola was not a significant crop in the United States while Moloney was with Calgene, his research took him to Canada. "I was the first person to develop techniques whereby we could move desirable genes into canola, using what are now fairly standard plant-genetic-modification techniques but were then not very advanced. In doing so, I became enamored with this canola crop. I figured that if anybody in the world was going to be interested in canola, I would probably find them in Canada." In 1987 Moloney accepted a faculty position at the University of Calgary, where he holds the Industrial Research Chair in plant biotechnology sponsored by the Natural Sciences and Engineering Research Council of Canada (NSERC) and Dow AgroSciences.

Plant molecular biology was really only in its earliest stages in Canada at the time. There was limited activity at the National Research Council Canada (NRC) in Saskatoon, however, and Moloney built early alliances there. At the University of Calgary, Moloney and fellow researchers developed a program to better understand how the canola seed, as an oilseed, did various things in its own particular way. How did it store oil? How did it store protein? What genes were responsible for its ability to germinate? These questions led to other questions.

The team got interested in a group of seed proteins that nobody had really studied: oleosins, the proteins that act as organizers for the oil droplets that are found in cells. These are the source of vegetable oil when canola is crushed, and represent the basic

"value proposition" of canola, since the plant is grown for its oil. Looking at the proteins involved in the storage of oil, Moloney observed two things: that they accumulate in very high levels in the seed, and that they are only found near the oil. Most proteins on earth prefer to be near water. But it became evident that oleosins have a very high affinity for oil. The next step was flotation centrifugation. Just like a centrifuge separates the oil-rich part of milk — cream — from the less oily parts, so could the oil fractions in a seed be separated out by grinding seeds up in water and floating the oil part out through centrifugation. In the process, the protein that had migrated to the oil fraction would be purified. Moloney and his researchers believed that they could force these seeds to produce any protein they wanted. If that was a protein that could be used to stimulate the body's immune system, it could be induced by introducing a gene for that protein into the canola plant, where the protein would follow its inclination toward the oil part, or fraction.

In Moloney's words, "By grinding seeds in water, we could float out the fraction containing the oil, proteins attached. Since you can insert a gene into the plant to manufacture any protein, and the protein will go to the oil fraction in oilseeds, what we had discovered was a one-stop purification system for proteins."

This would become the basis of what would be SemBioSys' proprietary process. Seeds are extracted in a water-based solution, and the oilbodies are separated from the endogenous seed protein and material using flotation centrifugation. The native oilbodies are then recovered as a natural oil-in-water emulsion, and are then ready for use in topical products. The system can easily be scaled to generate clinical amounts of pure protein, and unprecedented manufacturing.

Moloney and his team soon replaced canola with safflower because there were proprietary problems with canola. Plus, safflower grows counter-seasonally in the northern and southern hemispheres and can be more readily contained because of its biology. It also has no weedy relatives in the western hemisphere, and its seed shows minimal dormancy, so the environmental risk was reduced.

MOVING FROM LAB TO FIRM

In 1994, Moloney decided to form a spin-off company from this promising research and founded SemBioSys Genetics Inc. According to Moloney, the University of Calgary's Office of Technology Transfer was more interested in licensing Moloney's technology to established firms than in supporting his spin-off attempts, since earlier spin-offs had not been particularly successful. However, the Office did lend their support. One of the first things that needed to be done was to sort out the intellectual property (IP) issues. The University of Calgary's IP policy

acknowledged inventors' ownership of scientific inventions, but insisted on proper recognition of its own significant financial interest in the invention if the invention was commercially exploited. The University's practice for spin-offs had been to maintain a 25- to 50-percent ownership. With SemBioSys, they wanted 50 percent because they had also agreed to provide the immediately needed funds (up to $50 000) for patenting, and they did not feel certain they would ever recover their investment.

For Moloney, the equity he was giving up was worth the cost, mainly because of the patents (SemBioSys now has 15 issued and 22 pending US patents). "It's crucial that anybody interested in creating a biotech company takes a fairly aggressive position on patenting," he says. "The inventions in the biotechnology sphere are generally very protectable inventions. They involve composition of matter and formulations and use. Because patents offer such clear protection for your intellectual property, they essentially form a solid platform for your company — they bring value to your investors. So, we have been very, very aggressive in this regard." One of Moloney's first employees was, in Moloney's words, "a brilliant IP person," so this part of the business has always been well taken care of.

Next, Moloney went about trying to raise some research dollars to pursue the commercialization potential of his patents. In the mid-1990s, high technology, particularly biotechnology, was becoming increasingly attractive to investors. Through his network of contacts, Moloney was put in touch with John Oliver, the since-retired chief executive officer (CEO) of Dow. Oliver was impressed with the technology that SemBioSys had patented. In 1996, Dow AgroSciences injected about $6 million into Moloney's project, acquiring a 30-percent interest in the company and, in cooperation with NSERC, created an industrial research chair in plant sciences for Moloney at the University. As part of the deal, SemBioSys would also conduct some research for Dow on modification of the nutritional properties of oilseeds. This early infusion of working capital, says Moloney, led to a plan of action that would involve bringing in a CEO who knew how to handle the business side of what had to happen next.

Happy to work as the chief scientific officer of the company, Moloney brought Andrew Baum in as president and CEO. Baum had worked with Moloney at Calgene in the 1980s, and had been ready to move on after Monsanto bought Calgene out in 1997–98. Baum, an engineering graduate from the University of California at Berkley, had been Calgene's first employee in 1981, and had worked within virtually every level of Calgene outside of the scientific domain, from raising money, to developing products, to the buying, running and selling of businesses. Before the Monsanto takeover, Baum had been president of Calgene's oils division. "It was my decision to bring in a heavy-hitter," says Moloney. "I just had a lot of faith that Andrew could manage this business. There aren't many people out there who have been in the plant end of the biotech industry for a number of years, and I knew that Andrew was very versatile in a number of areas that we needed in order to move the company forward." Says Baum, "I had always preferred a small company environment. When Maurice called me in February of 1998 to ask if I was interested in taking on the role of president and CEO of

his fledgling start-up, I was excited. I knew the area, I felt the technology he had developed had transformative potential, I was very impressed with his team of researchers, and my family liked Calgary. So, by August of 1998, I had moved and was part of the company."

Moving From Research to Product

In the early 1990s, Moloney realized that he had sound scientific concepts that could revolutionize the purification and production of proteins. His patents were for enabling technologies that allowed proteins to attach to oilbodies through direct targeting or "affinity capture." This set SemBioSys' system apart from other transgenic systems, animal or plant, by providing advantages for both protein expression and protein purification. By the mid-1990s, Moloney's concepts had been transformed into a platform to deliver cost-efficient protein production, complete with purification, across the biotechnology industry. The company's Stratosome™ Biologics System, in which recombinant proteins are grafted to oilseed proteins found in safflowers, offered the fastest proof-of-concept timeline of any commercially available transgenic system.

Preclinical amounts of purified proteins could be derived in six and a half months from arabidopsis (a plant which is used in rapid screening systems to evaluate multiple product constructs), and material could be derived from safflower for clinical trials in 14 months. After the harvest of a safflower crop, the desired proteins are easily extracted with the resulting safflower oil, using the same principles as Moloney's team used at the University of Calgary. The company felt that the system would be recognized as a winner because it could drastically lower the increasingly prohibitive production costs facing pharmaceutical developers trying to bring biologics that need large-volume production to market. The cost of purifying proteins was a big barrier to these companies. Purification through genetic modification had been a challenge that even mighty Calgene had never been able to meet. Both Moloney and Baum knew that because they had been there when Calgene had tried. Now a solution was at hand, and SemBioSys had even designed it so it could be integrated with traditional chemical-process development and protein-purification technology.

"We think that we are going to be able to rewrite the whole story of manufacturing drugs," says Moloney. "There are hundreds of exciting new medications, but they're very expensive to produce. Even more important is the lack of affordable facilities to manufacture at. Genentech in San Francisco built a production facility that cost $US 250 million, plus $US 100 million to validate. That kind of money can make or break even big companies, plus a lot of today's discoveries are coming from small companies. About 80 percent of costs involve purification. That's where we come in. We are confident production facilities can be built, using our technology, for about a tenth of what they are costing now."

However, when Baum arrived in Calgary in 1998, SemBioSys was still located on the university campus, its 8–10 employees were largely Moloney's graduate and postdoctoral students, and the company had a very weak revenue base. "It really wasn't a business at that point," says Baum. "It was a commercially-focussed academic organ-

ization with an entrepreneurial scientific leader. The saving grace was that Maurice is so smart, and he intuitively understood the business side of things. They were selling some products aimed at farmers — insect repellents and herbicides — but they really hadn't figured out the output side of the technology's capability." Baum started developing a business plan that would exploit their company's opportunities for both pharmaceutical applications (proteins for use in the human health field) and non-pharmaceutical applications (personal care products).

However, one of Baum's first challenges was getting the company's research team to move from an "If we build it, they will come" attitude to a market-focussed approach. "They wanted to focus on what the market *should* want rather than on what the market *did* want," says Baum. "It was a continual process of asking the questions 'What's the goal? Is this going to get us there?' I had to keep reminding them that the business side is not trivial. You can't filter out what market research data is telling you, no more than you would do that on the scientific research side. Some researchers can make the transition to a milestone approach, others can't."

Next, Baum had to raise money to finance the new business plan, to further develop the technology and its applications. In the 1990s, it wasn't all that difficult to raise funds, and Baum and Moloney considered two possible strategies. The first was to try to get more money from Dow. However, Dow Chemical's headquarters in Indianapolis made it clear that they would want at least a slim majority ownership of the company if they were to supply SemBioSys with significantly more funding. That would mean Dow would start calling the shots. Dow was also looking at other plant-biotechnology investments, so timing would be an issue for SemBioSys. SemBioSys, however, went with its alternative strategy.

Although it was his first time raising money for his own venture, Baum was well acquainted with Bay City Capital in San Francisco. When Bay City agreed to be lead investor, it didn't take long for Baum to pull the rest of a syndicate together. Included in the mix were Ventures West Capital Ltd. from Vancouver, Royal Bank Ventures Inc. and the Business Development Bank of Canada. This series-"A" financing took seven months to arrange, but it brought $16.5 million into the company. The deal was wrapped up in November 2000. Baum summarizes the company's success in raising the money as a combination of good science, good contacts and good timing. After the deal, Moloney still owned about 20 percent of SemBioSys, the University of Calgary owned about 20 percent, Dow owned a little less than 20 percent, the new consortium owned about 30 percent, and about 10 percent was set aside for employee stock options.

Although it was clearly still too early to take the company public, Moloney and Baum were confident that the sky was the limit. They had a solid grip on a technology that future producers would covet, and they had enough funding to move toward the marketplace. Both men were full of optimism about the future of the company.

SemBioSys immediately started construction of an off-campus facility. By May 2001 it had moved its operations into a new, 25 000-square-foot, state-of-the-art plant in northeast Calgary. It had also put in place its entire operating infrastructure, combining all its research and development activities, plant-growth facilities, and pilot plant groups, and it was ready to prove itself by making deals with companies to shrink their production costs. In its new, pilot manufacturing facility, SemBioSys would be able to deliver oilbody-based products and purified proteins to scale. The company revamped its board of directors, hired a director of finance and administration, started to expand its management team, and entered into a multiyear product development agreement with the Novartis Agricultural Discovery Institute, Inc.

But a not-so-funny thing happened on the way to marketplace glory. Suddenly, new biotechnology companies stopped coming on-line, and mature companies started to retrench. The bullish stock markets that had worshipped technology stocks started to plummet, and the price of technology stocks started to spiral downward. At about the same time that investment in the high-technology sector collapsed, moral, health and regulatory questions started being asked about the corporate rush into the world of genetic modification.

The question was no longer how quickly SemBioSys could churn out creative new applications for a hungry marketplace. The question had now become "How do we survive until all the fear out there blows over?"

HOLDING THE FORT

The 2001–02 period was very difficult for SemBioSys. Baum outlines the problem facing the company by saying "The overall biotech market and industry were having an extremely difficult time. It wasn't just us, it was everybody. So, that made the partner environment much more difficult, and the ability to raise cash dramatically harder, because everybody was revisiting their strategies in order to survive." Baum was concerned about the company's future. "My biggest worry was that we wouldn't survive," he says. "Any CEO who doesn't have that concern in the back of his mind isn't paying attention."

But, the company's staff wasn't worried that their efforts would fail — the technology was simply too good, and the patents too airtight. They felt that if everyone pulled together to get through these tough times, that rewards would come to them down the road. "By and large," says Baum, "morale

was remarkably good. It's my job, and Maurice's job, to make sure it stays up. We're very candid with our people about what's going on. We don't sugar-coat it. But, I believe completely in the technology. More importantly, I believe in the people in the company."

SemBioSys, however, had to adjust. In the fourth quarter of 2002, it laid off more than a dozen people, bringing its workforce down to 42 staff members. "That was difficult," says Baum, "because they weren't people let go because of poor performance."

Baum admits that the company's original business model wasn't working in this environment. "The board wasn't happy, and I wasn't happy with the company's progress. Markets just weren't developing the way we had hoped. The science worked, but we were a long way from making a technology work for products. We were trying to do something no one else had ever done. There was no precedent in producing proteins from plants, and it was taking more time to build credibility with the pharmaceutical giants."

The company would have to rethink its business model. "When markets were hot, which they were when we started out, you could have raised enough money to get your first drug to market on the basis of good technology," says Moloney. "With the markets not hot, we needed a break-even strategy. We could go public when the wariness about investing in markets improved. In the meantime, we needed to put ourselves in a position to make a modest amount of revenue. Our objective was to prove that we had workable technology as soon as we could, and to break even financially by the end of 2005. This meant identifying some short-term market opportunities in the non-pharmaceutical area." As Baum says, "Our field-of-dreams business model — we have this powerful technology, we will go out to the big pharmaceutical companies, we will describe to them what this technology can do, and we'll partner — wasn't working. Even when they loved the technology, they weren't prepared to step in and partner. We decided we had to pick some shots, develop our own products, and then, at a certain stage, partner on these. So, we totally refocussed every aspect of the business. We had to pick the targets ourselves, make the investment ourselves, and then develop the infrastructure to bring these products to the point where they were partnerable. We had to focus on projects that had a clear path to market and offered a shorter path to revenues than others might have."

What SemBioSys started to focus on had very little to do with the company dream of being a major player in a revolutionary process to produce purified proteins essential to several industries dependent on them. Instead, they started pursuing modest, short-term goals such as producing enzymes useful in the food industry, and licensing an intermediary process that would help companies produce their own proteins — not in the field, but in the lab.

"The technology we've developed lends itself as much to producing enzymes as producing pharmaceuticals," says Moloney. "The difference isn't technological. The difference is regulatory. You can have everything working perfectly to manufacture a pharmaceutical, but, from the time you actually have the purified material in your

hands, you're probably still looking at three to five years before it gets to market, depending on the pharmaceutical. With enzymes, once you have enough purified material you can be on the market in a year, a year and a half. The first enzyme was targeted to the food industry for food processing."

"The second short-term area where we can make money to keep us going depends on the separation factor in our technology," says Moloney. "We use separation to purify proteins. We can produce an intermediary that can provide a purification solution to certain other people to produce their own proteins. We could license our technology for the purification of antibodies to an antibody company. That won't hurt us, because there are a certain number of antibodies that, come what may, and for a number of different reasons, have to be made in cell cultures rather than plants. We know which ones they are. So, if we can get a piece of the action on this lab production of proteins, it won't hurt our long-term goal of setting up solutions based on the bulk purification of proteins in the field, and it will still enable us to pay the bills."

The company also looked at how to apply their biotechnology to the cosmetics industry. It then developed a way to facilitate the production of cosmetics products without adding a lot of chemicals that might make them not as consumer-friendly. This research led to the company's ninth patent, awarded in June 2003, for its DermaSphere™ Ingredient System, a breakthrough technology system that allows oilbodies to be used as carriers in virtually any personal care production system for formulating personal care and dermatological products. It seems that non-transgenic oilbodies act as naturally produced liposomes, making them ideal carriers of "cosmeceutical" actives.

But SemBioSys badly needed another infusion of cash as it bided its time developing short-term products. Assistance came from both the Government of Canada and the Alberta provincial government. Technology Partnerships Canada came through with a $5.5-million loan in November 2001, and in January 2002 the Alberta Value-Added Corporation followed suit, approving another $4.9 million for the company. The funds would allow the company to complete the development of its antibody-production technology platform and its StratoCapture™ Protein A Reagent purification system. The system would convert expensive batch processes into continuous ones using a disposable reagent, making it possible to transform oilseeds into bioproducts for the health sector.

"This money was totally timely," says Moloney. "You could argue a good case that if those programs hadn't come through, we would have had to severely curtail what we were working on. And what we're working on is so exciting. When we go and talk to companies about our technology, we get a very high level of interest — especially from all the technical people. It was just a question of whether the business development people had the intestinal fortitude, or at least the margin of tolerance, to take on another project. We needed more time."

THE TURNAROUND

Despite setbacks, the company continued to innovate and to be recognized for their innovation. In October 2002, they won the NRC/Alberta Science and Technology Innovation in Industrial Research Prize for "pushing the frontiers of biotechnology by changing the way proteins are made with their Stratosome™ Biologic System, which provides unique production and formulation advantages, thus enabling the commercialization of protein-based drugs that otherwise would not be economically or technologically viable."

SemBioSys' new business model was based on two development streams. For non-pharmaceutical applications (the use of oilbodies in the personal care market), the company would seek co-development partners at an early stage. In the pharmaceutical proteins market, SemBioSys would identify areas where the technology was relevant, take development to some stage of the clinical-trials process, and then copartner on the ongoing development of resulting drug applications. Baum started to focus on finding some co-development partners for short-term product opportunities that would generate revenue.

In 2003, things started to happen. One day, Baum got a call from Jim Metz, who now worked for Martek Biosciences Corporation but, at one time, had worked for Baum at Calgene. Martek, a world leader in manufacturing the nutritional oil DHA, saw an opportunity to use DHA in food products, and had decided to make their products inside plants, to reduce production time and costs. They wanted to work with SemBioSys, on a co-development basis, to look into an omega-3 fatty acids project. A short time later, a Syngenta employee who had once worked with Bay City Capital contacted Baum to see if they could collaborate on research for the development of a new pharmaceutical product. Syngenta, a world-leading agribusiness with 2003 sales of US$6 billion, was looking to reduce the downstream purification costs of its therapeutic proteins and monoclonal antibodies by using oilbody technology for existing and future products in its biopharmaceutical pipeline.

SemBioSys closed the deal with Syngenta in November 2003, and the deal with Martek a week later. The Martek deal was worth US$10 million in research and milestone payments to SemBioSys to develop plant-based DHA products for Martek. Details of the Syngenta deal were not disclosed, but it included an upfront payment, option-exercise fees, milestone payments and royalties.

By May 2004, the company had closed three more co-development agreements. These included a collaborative research agreement with Dow AgroSciences to determine if the Stratosome™ Biologics System could enable the commercialization of a plant-made animal vaccine; a licensing, marketing and sales agreement with Lonza Group[1] for global rights to use SemBioSys' DermaSphere™ Ingredient System in cosmetics and skin care products; and a development agreement with Arcadia Biosciences to use SemBioSys' safflower biotechnology capabilities to develop

1. Lonza Group, headquartered in Switzerland, is a leading custom manufacturer of chemical intermediates, active ingredients and biopharmaceuticals for pharmaceutical and agri-chemical industries.

safflower oils rich in omega-6 fatty acids for potential nutraceutical applications.[2] These agreements would bring SemBioSys a range of research, milestone, licensing and royalty payments.

The Future

After 10 years in business, SemBioSys is still spending more money than it generates in revenues. But, their new business model appears to be working. "I think, over the next couple of years, despite the extremely negative environment we've been working in, it's going to be mainly quite exciting," says Baum. "I think the science is going to be driven by the execution of additional partnerships for exciting new products and additional fundraising activities. We're working toward that objective."

Another major challenge facing the company comes from the difficulty in getting approval from the regulatory agencies, particularly the U.S. Food and Drug Administration (FDA), for products that use transgenic technologies on plants or animals. By early 2004, SemBioSys had seven transgenic biologics in clinical trials. These were establishing critical precedents in a conservative and highly regulated biopharmaceutical industry. The regulatory framework for such products is being mapped in both Canada and the U.S., as their respective regulatory bodies, including the Canada Food Inspection Agency, Health Canada, the FDA, and the U.S. Department of Agriculture, publish new guidelines. Again, SemBioSys is a pioneer. As a member of the board of directors of Bio, a U.S.-traded industry organization, Baum spends about a third to a quarter of his time working to make sure the regulatory process and the public acceptance for this industry is in place. He also chairs BioAlberta and sits on the board of BIOTECanada.

"Our biggest challenge is getting people to make the leap to considering transgenic technologies," says Baum. "Other companies have good technologies. The issue for us is getting people to make the leap to considering transgenic solutions, not looking to us to take their first step. And that's a challenge, even before the overall financial atmosphere being negative, but, together, it's a real hurdle for us."

Baum thinks that corporate success will follow quickly on the heels of SemBioSys' proof of concept. "Five years from now we want to be the world's leading supplier of transgenic and non-transgenic proteins for the pharmaceutical market," he says. "In 10 years we want to be recognized as a leading, fully integrated biopharmaceutical business. We believe our technology is that powerful. There are a lot of companies out there offering transgenic production of proteins, but we are the only company that addresses purification as well as bulk production. Beyond that, we can offer benefits connected to formulation, and potentially even delivery."

Based on his experience with Calgene and SemBioSys, Baum feels Canada can benefit more from the great IP generation machine that exists at universities, and talks about how researchers and academics from these institutions can be helped to develop their IP into innovations that can affect the economy.

2. Arcadia Biosciences, Inc. is an agri-biotechnology company focussed on developing agricultural products that improve the environment and enhance human health.

"I think the first thing that has to happen is that you've got to make it okay for people to succeed commercially," says Baum. "There is still a culture in a lot of academic institutions where, somehow, being involved with business or being successful in business is not necessarily as validating or legitimate as doing basic research. I think that is a fundamental institutional change that needs to take place. Then, there is a whole series of licensing and resource provisions that universities can adopt. It is very difficult to out-license technology, even now. It's getting easier, but it's still challenging. It's very difficult for professors to find the time they need to go outside and develop their own business while maintaining a teaching load. I think the first thing that has to take place is to create a situation where professors are rewarded as much for patents as for publications, and where developing businesses and going into that development world is as valued as doing the basic research."

"Innovation is so much more than the ideas you start with," says Baum. "You know, we have an embarrassment of riches with the SemBioSys technology platform. But what you need, with a company like ours, is to realize that research is relatively easy — it's the development that's hard."

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