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Sirona Biochem Tackling Twin Epidemics of Obesity and Diabetes Head-on

The most recent stats available from the World Health Organization (WHO) say 1.6 billion adults are overweight and as many as 400 million are obese. It is estimated that by 2015 these numbers will have grown to approximately 2.3 billion and 700 million respectively—about one third of the world's population.

By Jason Hagerman

High rates of excessive weight lead to high rates of diabetes, which has risen to epidemic proportions across the world. According to the World Diabetes Foundation (WDF), as many as 230 million people are affected by diabetes today, with somebody dying every 10 seconds from diabetes-related causes. In a world where HIV/AIDS draws much attention, diabetes makes its silent rounds killing just as many people annually. In 2005, an estimated 1.1 million people died from diabetes. By 2007 that number had grown to 3.5 million. The WDF expects death rates to continue to rise by as much as 25 per cent over the next decade.

Over the last two decades, Dr. Howard Verrico has experienced first-hand the complications related to obesity and diabetes while operating out of the emergency department at Ridge Meadows Hospital in Maple Ridge, B.C., and Mission Memorial Hospital in Mission, B.C., where he is currently the director.

When he isn't navigating the corridors of the hospital or working with a patient, Verrico serves as the Founder, CEO and Director of Sirona Biochem, Canada's newest publicly traded biotech company, which is currently developing a novel treatment for diabetes and obesity.

"Diabetes is endemic; the number of patients with diabetes



Howard Verrico (left), CEO, and Mark Senner, President, operate "virtually emerging biotech" Sirona Biochem in downtown Vancouver.

continues to grow," says Verrico. "Not just throughout North America, but throughout the world."

Sirona, initially a shell company under the name High Rider Capital, has set out to stake a claim on its share of this market.

"In the U.S. alone diabetes is going to be a \$25 billion market," says Mark Senner, President of Sirona and 24-year veteran of the pharmaceutical industry. Senner has extensive knowledge of the industry, having worked with Merck-Frosst Canada Inc., Bristol-Myers Squibb Canada Inc., Solvay Canada, Novartis Canada Inc. and Biovail Pharmaceuticals Canada.

"This field is so enormous that the competitive pharma

companies are going to want to enter the race," says Verrico.

"We've got the worldwide licensing rights to this technology as applied to this drug, that's why we have received interest from big pharma and expect to see more in the future," says Senner.

The technology

Sirona's focus is primarily on Type 2 diabetes, wherein the body produces an insufficient amount of insulin or does not properly use the insulin it does create, causing glucose to build up in the blood rather than supply the body with energy.

Most diabetes drugs currently on the market regulate the glucose in the body by increasing insulin. Insulin cannot be taken as a pill, as it would be broken down during digestion, so it must be injected into the fat under the skin to properly saturate the blood.

Sirona has licensed technology from a company by the name of TFChem, based in France, which it believes will expand a new class of drug called Sodium Glucose Transporter (SGLT) inhibitors.

SGLT inhibitors regulate glucose by blocking the uptake of glucose in the kidney. Instead of stockpiling, glucose is simply expelled from the body through urination.

Because SGLT inhibitor molecules do not work through the application of insulin, they can be developed in the form of a pill.

"We would like to ultimately see a once-a-day medication which will be used to help those that are obese to lose weight, and those who have diabetes will be better able to control their blood sugar," says Senner.

This class of drug has been around for some time but, according to Senner, robustness is the key to the future with these compounds. As many as 14 different companies have been involved in the development of the class. However, for many it has been slow going and some have even abandoned plans to build upon the notoriously unstable sugar-based molecules.

"What we're doing is attaching an atom to the molecule in various positions and conceptually that seems like it's very easy," says Senner. "But this isn't an easy science at all. This particular class of molecule is highly unstable and very difficult to work with and there are very few people around the world who have perfected the techniques to develop these drugs."

Dr. Geraldine Deliencourt-Godefroy, a renowned French scientist in the field of sugar-based molecules and partner in Sirona Biochem, happens to be one of these people.

Joining forces and saving money

"Very few of these big pharma companies are going to go out and invest the seven years that our chemist took to perfect these techniques," says Senner.

After meeting Deliencourt-Godefroy at a Starbucks in Paris at the urging of a business partner, Verrico saw the potential of her expertise and shortly thereafter entered into a worldwide licensing agreement.

Diabetes Facts

- Diabetes is responsible for more than one million amputations each year; a large percentage of cataracts and at least five per cent of worldwide blindness are due to diabetic retinal disease. Diabetes is the largest cause of kidney failure in developed countries and is responsible for extensive dialysis costs. The risk of heart disease and stroke are all significantly higher for people with diabetes.
- Type 2 diabetes accounts for 90 to 95 per cent of diabetes cases. The vast majority (80 per cent) of Type 2 diabetes is preventable by changing diet, increasing physical activity and improving the living environment.
- With an estimated 35 million people suffering from diabetes, India has the world's largest diabetic population.
- Diabetic neuropathy is damage to the nerves as a result of diabetes, and affects up to 50 per cent of people with diabetes. Common symptoms are tingling, pain, numbness or weakness in the feet and hands.
- Diabetes is among the leading causes of kidney failure. Between 10 and 20 per cent of people with diabetes die of kidney failure.
- Type 1 diabetes is characterized by a lack of insulin production. Without daily administration of insulin, Type 1 diabetes is rapidly fatal. Symptoms include excessive urination, thirst, constant hunger, weight loss, vision changes and fatigue.
- Type 2 diabetes results from the body's ineffective use of insulin. This variety of diabetes comprises 90 per cent of cases around the world, and is largely the result of excess body weight and physical inactivity. Symptoms may be similar to those of Type 1 diabetes, but are often less marked. As a result, the disease may be diagnosed several years after onset, once complications have already arisen.
- Gestational diabetes is hyperglycemia that is first recognized during pregnancy. Symptoms remain the same as other varieties of diabetes.

What's in a name?

Sirona is, aside from Canada's first public biotech company since 2007, the name of the Celtic goddess of healing. A fitting name for a company seeking to help almost a third of the world's population overcome what have been named the twin epidemics: obesity and diabetes.

Adding to the lore of the company, the logo it has chosen is a modernized Triskele, a Celtic symbol that Mark Senner, President of Sirona, says represents the elements. "Alchemy is all about putting those elements together to make something entirely new. That's really what our company is doing," he says.

Profile

"Being the only new biotech company out there means there are disadvantages, such as people aren't looking at the sector in terms of investment as much," says Verrico. "There are also advantages in that there's expertise available that would otherwise not be, there are also competitive advantages for us in terms of cost-savings."

One such cost-saving advantage is that the French government is actively trying to keep researchers of Deliencourt-Godefroy's calibre within its borders, and is willing to subsidize many of the costs associated with her research.

"We enjoy enormous government support in France," says Verrico. "She [Deliencourt-Godefroy] hires research assistants who are funded by the French government."

Adds Senner: "She's moving into a new laboratory that's being underwritten by their government."

Sirona has devised many other ways to cut expenses and minimize risks to investors.

For one, it doesn't have many staff. Gazing out into downtown Vancouver at the corner of Howe and Pender, Senner is the only one manning the 9th floor Sirona office most days.

"We operate virtually; we get services when we need them," says Verrico. "All of this is very specialized, and we're able to hire leading experts when we need them. It's enormous cost savings because we're so flexible. We can upscale and downscale very quickly. We keep our burn rate low; when we need a specialized test done we can have the latest technology available just for that time."

Without these lingering costs, Senner says, the small Sirona team is able to dedicate more funds and resources to the actual project.

"The trend nowadays is to go from a fully integrated biotech

to a virtually integrated one, and we're doing that. We're a virtual emerging biotech," says Senner.

As a small biotech with limited access to funds, and a goal centred on being acquired by a pharma giant, this is a prudent approach to capital management.

"We'd obviously never be able to raise half a billion dollars to bring this product to the market," says Verrico.

Instead, in the initial rounds of raising capital, they only had to bank a couple million.

"Private investors are, for the most part, scared of biotech," says Verrico. "Because the biotech industry is somewhat depressed, there's not a lot of venture capital out there."

Still, Verrico says there was no difficulty in raising the required funds.

"With the initial venture fund we raised \$1.25 million in cash. When we went in for the next round of funding we didn't require a full effort to raise the \$750,000 we needed. We raised a total of \$2 million and the straight answer is that we never had to put in our full effort to raise that money," says Verrico.

"We've been able to raise this money primarily through friends and family, along with a few angels," says Senner.

With that money holding up very well due to the low burn rate of the company, it is likely that the company will not have to conduct more fundraising until early 2010. By then, it is even possible Sirona will be working in partnership with a pharmaceutical company with the resources to bring the research through to a product.

As of July 28, the first shipment of Sirona's lead compound, a series of molecules based on a selected SGLT analogue, crossed the Atlantic Ocean and landed on Canadian soil.

A number of SGLT compounds have been identified by other companies, but many have ceased clinical trials due to instability. Deliencourt-Godefroy, Senner says, is working to stabilize one such compound with consideration of others in this category.

With molecules at the ready, Sirona will undertake preclinical development to further the quality of the molecule and plans to hand over development to a major pharma before reaching the clinical trials stage.

"A lot of people are interested in the manner in which we're approaching this project," says Senner. "We've got the right business model, we're in the right market, we've got a very strong management team and we've got great science happening." **BB**

