



Danny Deadlock, Micro Cap Equity Analyst  
January 2, 2015

## Sirona Biochem (SBM.V 12 cents / SRBCF U.S.)

[www.sironabiochem.com](http://www.sironabiochem.com)

Shares Outstanding: 128 million

Market Cap: \$15 million

Sirona is a drug discovery company with their lab in France (TFChem) and head office in Vancouver. They specialize in stabilizing carbohydrate molecules and may be one of the best in the world at it. Their business model revolves around patents and licenses that have the potential to produce large milestone payments and long term royalty revenue.



## High Expectations

I have only featured a few biotechs this past decade and the most successful was YM Biosciences (YM.T). I started coverage in January 2009 at 45 cents because they had \$52 million cash worth 90 cents per share and with such a low market cap, the valuation assigned to their science was ZERO.

By December 2012 Gilead bought them for \$510 Million!

**More than ten times the 2009 valuation.**

At that stage YM had \$100 million in cash (through staged financings in 2012) so Gilead was paying \$400 million for licenses to technology under development for a bone-marrow disorder and a treatment they were working on for blood cancers.

What was fascinating at the time was that YM's core drug candidate CYT387 was not entering the 3rd phase of drug trials until the 2nd half of 2013 - YET **Gilead wanted it so bad they were willing to pay several hundred million dollars BEFORE YM even had FDA approval.**

Biotechs are high risk and require patience but the payoff can be enormous

If I am right on Sirona (assuming they control their dilution / shares outstanding), then the return over the next 12 to 24 months "could" be very strong.

By coincidence the same investment bank behind YM (**Bloom Burton**) is also partnered with **Sirona**. They are developing and licensing new anti-inflammatory compounds for commercialization. Toronto based Bloom is a Canadian leader in healthcare-specialized investment banking and this is a new approach for them (partnering to commercialize versus simply investing).

**July 31<sup>st</sup>** Sirona announced that they successfully synthesized the first anti-inflammatory compound under this joint venture and **the stock ran 60% in three days from 12 cents to 19 cents on 20 million shares**. The companies are addressing unmet market needs in the areas of rare or neglected inflammatory diseases and bacterial resistance. They are identifying and designing a library of compounds to address these large markets.

**But for Sirona, the partnership with Bloom Burton is only the tip of the iceberg.**

## Sirona Growth Opportunities

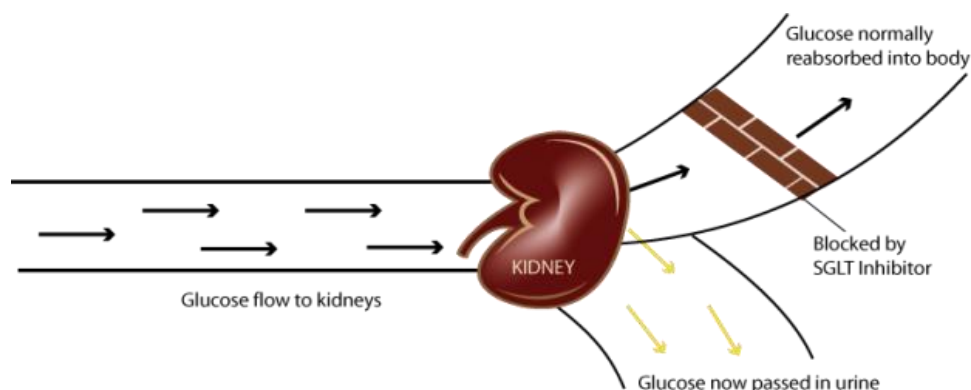
**Sirona French subsidiary TFChem is the recipient of multiple French national scientific awards and European Union and French government grants. The company's current growth opportunities lie in three distinct areas:**

1) **Skin Lightening** – A surprisingly huge market with sales forecasted to reach **\$20 Billion by 2018**. There is growing demand across Asia and India because lighter skin is a status symbol in these regions. Sirona may have one of the most promising (and safest) solutions coming out in the market and they are in a licensing partnership with a division of pharmaceutical giant Valeant (VRX.Z \$126). **I personally feel Valeant may eventually look at Sirona as a takeover target – if the Chinese don't target them first (Fosun Group a possibility).**



2) **Anti-Aging** – Analysts project this global market will approach **\$300 Billion annually by 2015** driven by an insatiable demand to defy the signs of aging. The U.S. market for anti-wrinkle products alone is estimated at \$20 billion annually. This aspect of Sirona's business model may be the most fascinating. It involves the development of **an anti-aging compound based on the naturally occurring antifreeze glycoproteins found in Antarctic fish**. Below you will see reference to an article written in April by a leading academic on the Arctic who says **this has the potential to revolutionize the cosmetics industry** and majors like L'Oreal are watching them closely.

3) **Diabetes** - Sirona has used their proprietary chemistry technology to develop a compound called an **SGLT2 Inhibitor**. Identified as SBM-TFC-039. You don't need to understand the intricate details of what this is but over the past two years, SGLT2 inhibitors have been acquired by giant pharmaceutical companies. **Two deals have been done that are worth several hundred million dollars to over one Billion dollars.** The final value depends upon future royalties but the initial agreements saw massive fees paid up front. **Sirona believes they will have one of the world's best SGLT2 Inhibitors for use with Type II Diabetes.**

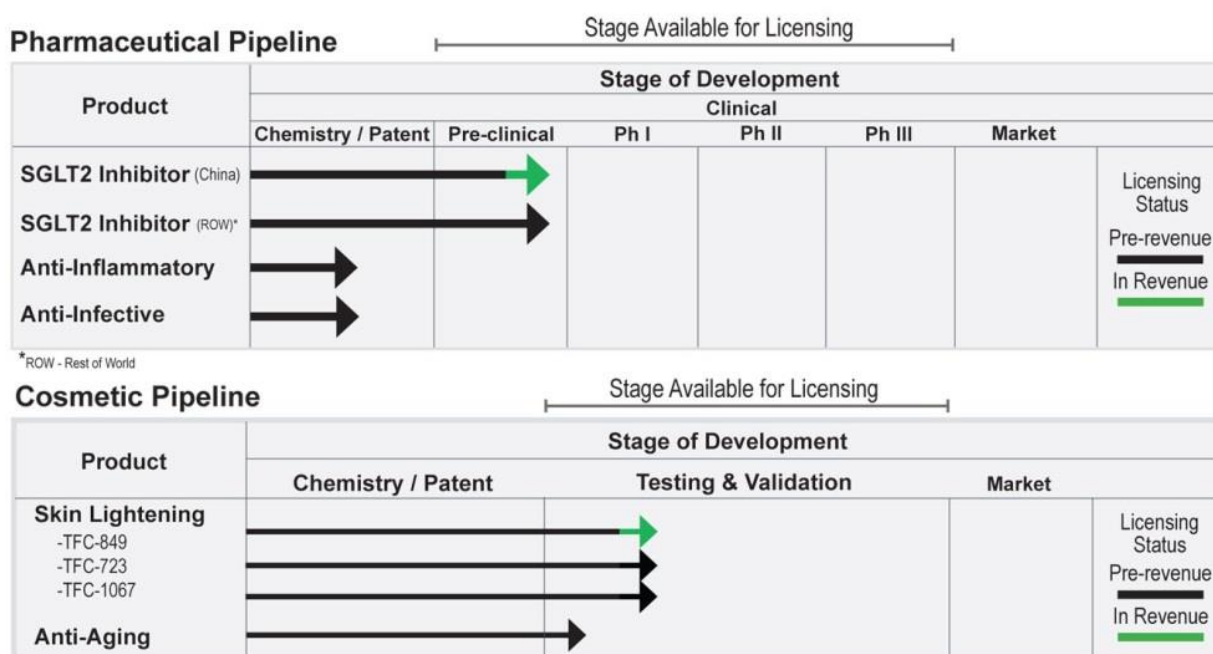


### Other Future Markets

1) Sirona's ability to synthesize and stabilize the antifreeze glycoprotein for human use (called TFC-837) goes well beyond anti-aging for cosmetic purposes. **It could be used to extend blood platelet storage, improve outcomes for cell transplants, improve stem-cell storage, and improve organ transplantation.**

2) Mid October Sirona signed a research collaboration with Aegilops of France. The objective of the collaboration is to develop a novel compound to **improve germination and growth in plants**, thereby enhancing crop production. The global seed market is worth more than \$40 Billion annually and as living things, anything that would improve seed vitality could have enormous commercial value to the agriculture industry.

3) Sirona and the **Cincinnati Children's Hospital Medical Center (CCH)** are working together to create an anti-aging skin care treatment that combines Sirona's patented cell preservation glycoprotein with CCH's patented **Synthetic Vernix technology**. CCH is a world leader in breakthrough research and is ranked #1 for cancer and in the top 10 for nine of 10 pediatric specialties. **The Sirona / CCH goal is to create a product that presents unparalleled efficacy and commercial opportunity.** This partnership was signed January 2014.



### Sirona Science / Technology

The Video on this page explains Sirona's Proprietary Platform Technology

<http://www.sironabiochem.com/products/proprietary-platform/>

Sirona's expertise is in the development of carbohydrate-based molecules. Essential to life, carbohydrates, or sugar molecules, have broad potential for ground-breaking pharmaceutical and cosmetic development. Despite this immense potential, **a major limitation of carbohydrate molecules is their lack of stability**. When coming into contact with omnipresent enzymes, for example, carbohydrate-based molecules can easily break down or become toxic, making them difficult to produce as pharmaceutical products.

Sirona's French subsidiary, **TFChem**, has developed a **proprietary chemistry technique that maintains the integrity of carbohydrate-based molecules** even after enzyme exposure. Through years of award-winning research by their synthetic chemists, **they learned how to strengthen the bond of a carbohydrate molecule by strategically placing fluorine atoms within the molecule**. This technique has yielded several compounds showing promise for the development of different kinds of therapeutics, cosmetic agents and as biological ingredients for laboratory use.

Their research so far has demonstrated that by applying their chemistry technique they can enhance the stability and bioavailability of carbohydrate-based molecules. **Their proprietary fluorine-based chemistry platform not only gives their company the chance to develop new robust compounds, but also allows them to improve previously-developed compounds by other companies**. Those compounds may have been put on hold because of the inherent challenges of carbohydrate-based chemistry.

Much like YM in the early stages, investors are not recognizing the enormous potential of these scientific achievements. Biotechs in general are difficult to understand so most people avoid investing in them. For small companies the challenge in attracting investors is even worse – **but these micro cap biotechs also hold the greatest potential for exponential capital gains.**

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### 1) Skin Lightening / Whitening

<http://www.sironabiochem.com/products/skinlightening/>

In Asia - particularly India, Japan and China, light or fair skin represents beauty, youth and affluence as tanned skin is seen as a result of manual labour outside. **In the Asia Pacific region it is estimated that over \$13 billion is spent annually on skin lightening products.**

The top markets in order of demand are: India, Japan, Indonesia, China, Colombia, Mexico, Middle East, Brazil, Turkey, UK, United States, Russia, Spain, and Australia.

In the three largest markets by population, skin lighteners are used by 33% of the Chinese population (daily or weekly), 55% of Japanese women, and 62% of women in India. A recent survey showed that 80% of Indian men use fairness creams.

Skin lightening products are a fast emerging market in North America and Europe as well. Demand in these regions has been driven by a desire to reverse sun damage and for the appearance of younger looking skin. Medical conditions such as hyperpigmentation, melasma, vitiligo and rosacea are also contributing to the demand for safer and more effective skin lightening creams.

### Safety and Efficacy Concerns

There is a recognized need for a safer and more effective skin lightening agent. The most common skin lightening agent worldwide is **hydroquinone (Benzene)**, which is linked to cancer and has been banned in Europe since 2001. In the United States, restrictions have been placed on concentration levels of hydroquinone; over-the-counter creams are restricted to no more than 2% hydroquinone and a prescription is required to

obtain a maximum 4% hydroquinone concentration. Despite the dangers, restrictions and bans, hydroquinone is still widely used around the world.

**Arbutin** is the current (but more expensive) compound that replaces hydroquinone. It is a natural extract of the bearberry plant and reduces or inhibits melanin production or darkening of the skin. There are, however, safety concerns surrounding Arbutin as well. Despite its success as an effective skin lightener, natural forms of Arbutin are chemically unstable and can release hydroquinone. As a result, the European Cosmetics Association placed a ban on the use of beta Arbutin in 2008. The German Institute of Food Research found that intestinal bacteria can transform Arbutin into hydroquinone, which creates an environment favorable for intestinal cancer.

This past month it was also reported that whitening cosmetics (produced in China) containing **mercury 58,000 times the permissible level**, were circulating in South Korea and being sold on the black market.

### The Sirona Solution

Sirona's proprietary chemistry technique that stabilizes carbohydrate molecules, has allowed them to develop a skin de-pigmenting agent which studies prove is **safer and more effective than Arbutin**. Sirona's skin lightener development program is directly supported by the French government and involved a cosmetic consortium that included The University of Rouen.

Several studies have been conducted to demonstrate the effectiveness and stability of Sirona Biochem's DE pigments agents TFC-723 and TFC-849:

TFC-723 is **7X more effective** than beta Arbutin

TFC-723 is **chemically stable and does not release hydroquinone**

TFC-849 is **14X more effective** than beta Arbutin

TFC-849 is 7X more effective than alpha Arbutin

TFC-849 is chemically stable and does not release hydroquinone

TFC-849 is **non-genotoxic**

TFC-723 is non-genotoxic

TFC-849 is shown to be a **non-irritant and non-phototoxic** in study against UVA irradiation

TFC-723 is shown to be a non-irritant and non-phototoxic in study against UVA irradiation

### Commercialization

Sirona Biochem licensed its patented skin lightening technology to Obagi Medical Products in **January 2014**. Obagi is responsible for manufacture and distribution of the compound as part of a line of skin care products which includes skin lightening.

### The Obagi Nu-Derm® System

For Skin That Looks and  
Acts Younger and Healthier





**Obagi (Obagi.com)** is a division of **Valeant Pharmaceuticals (VRX: NYSE \$126)** and is very popular with dermatologists, cosmetic surgery clinics, and skin care professionals. It is believed that Sirona's TFC-849 will make Obagi's products safer and more effective than the competition and this should expand their already large market share. **Sirona will receive ongoing royalty payments for global sales on any Obagi products using TFC-849.**

October 7<sup>th</sup> Sirona announced that Obagi had started manufacturing scale-up of TFC-849.

## 2) Anti-Aging – TFC 837

<http://www.sironabiochem.com/products/antiaging/>

In 1969, an antifreeze glycoprotein was discovered in fish living under the Antarctic icecaps. The discovery was groundbreaking because this specific glycoprotein enabled the Antarctic fish to survive in sub-zero temperatures.

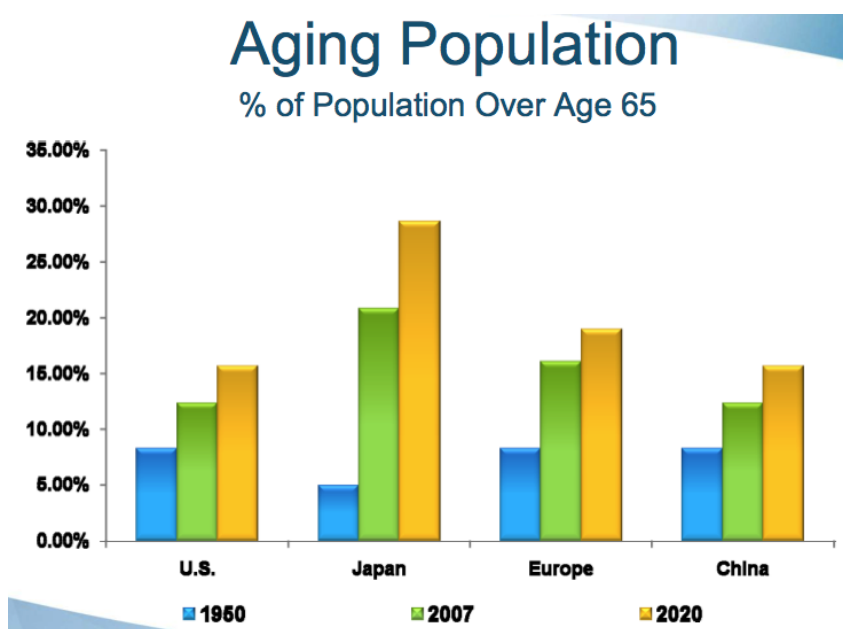
Sirona's subsidiary, TFChem of France, synthesized and stabilized its derivative of this antifreeze glycoprotein for human use; in the process greatly expanding the protective abilities of the original antifreeze glycoprotein.



Industry analysts project the anti-aging marketplace will approach \$300 Billion in global annual sales by 2015, driven by an insatiable demand to defy the signs of aging. The U.S. market for anti-wrinkle products alone is estimated at \$20 billion per year.

More than ever, consumers are requiring data to support their decisions, particularly in Japan and the western world, and are driving the need for companies to prove that their products are truly effective.

With the skincare market forecasted to continue double digit growth in the foreseeable future, there is a significant opportunity for new, scientifically proven, safe and effective ingredients.



## The Sirona Anti-Aging Solution

Sirona Biochem has created a library of anti-aging compounds and has begun studies testing each compound's effectiveness in anti-aging and conditions related to skin cell damage. **80% of visual aging is related to cell death; Sirona believes their compounds can protect these skin cells from damage, allowing them to live longer.**

**In May 2014 Sirona announced ground-breaking results from their anti-aging compound TFC-837.** The study subjected unprotected and glycoprotein-protected fibroblast cells to a serum-deprived environment for a period of 12 days. By day 10 of the study, 100 per cent of the unprotected cells were dead. In contrast, 75 per cent of the glycoprotein-protected cells continued to be fully viable at the conclusion of the 12-day study.

**September 22<sup>nd</sup> Sirona launched the next stage of development for their anti-aging compound** library using funding from Bpifrance (the French public investment bank) and the District of Haute Normandie.

The research will provide preclinical data supporting multiple targeted applications using novel in vitro tests with varying stress conditions and cell types. The purposes are to validate the compounds and to satisfy the standard cohort of cosmetic safety studies. The data will then be used to determine the optimal commercial applications and joint venture partners.

A huge percentage of the population are always looking for methods to improve their appearance and help them look and feel younger than their biological age. They look for new and effective anti-aging products that reduce blemishes, wrinkles, dark spots, and any other marks and help their face look bright and youthful.

## 2) Type II Diabetes

<http://www.sironabiochem.com/products/diabetes/>

There are an estimated 370 million people afflicted with diabetes and almost \$500 Billion was spent on treatment last year. Diabetes is the fourth largest pharmaceutical market in the world.

In India, 61 million people have diabetes (8.3% of adult population)

In China, 90 million have diabetes, estimated to reach 130 million by 2030

By 2030, global diabetes prevalence will increase to 552 million people

Despite the large number of therapeutic options available, many diabetics are unable to control their disease and face significant health risks.

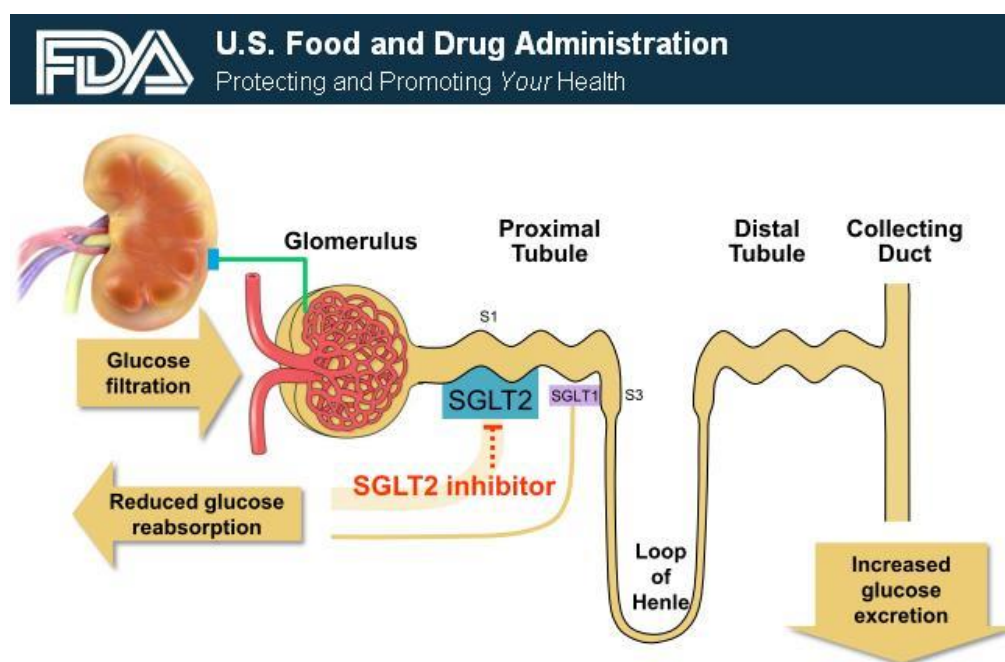
## The Sirona Solution

Sirona is developing an **SGLT2 Inhibitor for the treatment of Type 2 diabetes and obesity.** SGLT2 Inhibitors work differently from other diabetes therapeutics which increase insulin production in the pancreas and affect metabolism. **SGLT2 Inhibitors act in the kidneys to reduce the reabsorption of glucose into the bloodstream.**



The kidneys filter approximately 180 gm of glucose per day from our blood, which is largely reabsorbed back into the blood by SGLT2 transporters. **SGLT2 inhibitors regulate glycemia by inhibiting the glucose reabsorption process, resulting in excess glucose being excreted in urine rather than being reabsorbed into the bloodstream. This is**

**a novel and ground-breaking treatment option for Type 2 diabetes and obesity.** SGLT2 Inhibitors also have the potential to be strong add-on therapies to current diabetes treatments.



Using their proprietary chemistry technology, **Sirona developed SGLT2 Inhibitor compound SBM-TFC-039.**

Their goal is to develop a best-in-class SGLT2 Inhibitor with optimal pharmaceutical characteristics including, but not limited to, enhanced stability, bioavailability, selectivity and/or efficacy.

**The first SGLT2 inhibitor to receive market approval in the U.S. is Johnson and Johnson's SGLT inhibitor, Invokana™ (canagliflozin),** which is also being considered for market approval in Europe. **Forxiga™ (dapagliflozin), an SGLT2 inhibitor developed by**

### SGLT2 Inhibitor Program Status

Milestone	Status
Compound synthesis	Complete
Efficacy in mice	Complete
Pharmacokinetics in rats	Complete
Metabolic profiling in rats (in vitro / in vivo)	Complete
Efficacy in normal and diabetic rats	Complete
Selectivity for SGLT2 vs. SGLT1	Complete
Pharmacokinetics in monkeys	Complete
Tolerability in rodents	Complete
Ancillary pharmacology	Complete
<b>Licensing with potential partner(s)</b>	<b>In Progress</b>

**AstraZeneca and Bristol-Myers Squibb received European market approval in November 2012** and is being considered for U.S. market approval by the Food and Drug Administration (FDA). .

Several studies have been conducted to demonstrate the effectiveness and stability of Sirona Biochem's SGLT2 Inhibitor SBM-TFC-039.

- In a glucose challenge, SBM-TFC-039 reduced blood glucose excursions by 34%
- SBM-TFC-039 reduced blood glucose in obese diabetic rats to a level of lean rats within 6 hours
- In a 28-day chronic study, SBM-TFC-039 reduced blood glucose levels in obese diabetic rats by 71%
- SBM-TFC-039 reduced blood glucose by 44% in diabetic rats compared to **canagliflozin** at 26%
- At 36 & 48 hours after treatment, SBM-TFC-039, at a dose of 1.0mg/kg was still effective at reducing blood glucose; **canagliflozin** lost its effect after 36 hours.

In head-to-head preclinical studies, Sirona Biochem's SBM-TFC-039 outperformed Johnson and Johnson's **canagliflozin**.

## SGLT2 Inhibitor Licensing Deals By Third Parties

In March 2013, Johnson and Johnson's **canagliflozin** (Invokana™) became the first SGLT Inhibitor to be approved by the U.S. Food and Drug Administration. SGLT Inhibitors are a new class of drugs bringing hope to Type 2 diabetes patients who may not be getting adequate relief from currently marketed drugs. This new SGLT Inhibitor treatment approach has resulted in significant licensing deals. Two published SGLT Inhibitor licensing deals include:

- Empagliflozin, one of a two-compound licensing deal between Boehringer Ingelheim and Eli Lilly for at one time payment of €300 million and milestone payments of €625 million.
- Dapagliflozin (Forxiga®), one of a two-compound licensing deal between Bristol Myers Squibb and AstraZeneca for upfront payment of US\$100 million and milestone payments of up to US\$1.25 billion
- Bristol Myers Squibb and AstraZeneca expand licensing deal of dapagliflozin to include Japan; deal estimated to bring more than US\$1 billion

Sept 3, 2014

Sirona Biochem Corp. **licensee Wanbang Biopharmaceuticals** has successfully completed another study in the preclinical validation of its anti-diabetic SGLT2 inhibitor, SBM-TFC-039, for the treatment of Type 2 diabetes. The pharmacokinetic (PK) study of SBM-TFC-039 confirms an excellent oral bioavailability of SBM-TFC-039. Bioavailability refers to the drug's ability to be absorbed into the body. The results are in accordance with results of an earlier study conducted by Sirona Biochem.

The first milestone of the licence agreement with Wanbang Biopharmaceuticals is expected after the next scheduled study, assessing toxicology in rats during a 14-day test. This will trigger a second payment to Sirona from Wanbang Biopharmaceuticals as part of the \$9.5-million in upfront and milestone payments.

<http://www.chinawanbang.com/en/about/Default.aspx>

**Wanbang Biopharmaceuticals** is a leading anti-diabetic pharmaceutical company in China. It is a **subsidiary of Fosun Group, the largest privately-owned conglomerate in mainland China.**

<http://www.fosun.com/en/about/about.html>

Since 2010, Fosun has spent billions buying up foreign firms and says it is eyeing healthcare, tourism and fashion firms in the US and Europe.

## Management

Sirona has a strong board and scientific advisory committee. Of particular importance:

### 1) Géraldine Deliencourt-Godefroy - **Chief Scientific Officer & Director**

An award-winning synthetic chemist and the founder of France-based biotechnology company TFChem. Previous to founding TFChem, Dr. Deliencourt-Godefroy was a scientific leader at INSA (National Institute of Applied Sciences) in Rouen, France, where she developed a new technology on stabilized carbohydrates. She is the author of several publications and patents and is also the recipient of the acclaimed Francinov Research and Innovation Medal, French Ministry of Research Award and the French Senate Award.

### 2) Attila Hajdu - **Chief Business Development Officer**

Appointed October 27<sup>th</sup>, this was a tremendous addition to Sirona. Prior to joining Sirona, Mr. Hajdu held various senior leadership positions within **GlaxoSmithKline (GSK)** and Astellas Pharma. He has 17 years of experience in Sales, Marketing, R&D Finance, Medical Affairs and Business Development. Mr. Hajdu received an MBA from Queen's University and an MSC in Biochemistry from the University of Western Ontario.

As business development medical lead for GSK, Mr. Hajdu was responsible for leading projects that assessed in-depth drug opportunity/risk profiles. He led cross-functional teams in the valuation and presentation of potential revenue-generating assets to GSK's worldwide business development team.

He accomplished successful endorsement and financing of investigator-driven clinical trials through leadership, influence and negotiations with senior global executives that resulted in top-tier medical journal publications and biotechnology spinoff opportunities for other compounds.

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### TFChem Laboratory and Research Facilities

<http://www.cosmetic-valley.com/>

Dior, Chanel, Hermes, ...



Sirona Biochem's research is conducted at their 5,400 square foot laboratory facilities in Val de Reuil, France, home of their subsidiary company, TFChem. This state of the art facility is located in **France's Cosmetic Valley where the world's leading cosmetic companies conduct their research and development.** As part of a pharmaceutical park, TFChem is also surrounded by large pharmaceutical companies.



- ▶ **State-of-the-art laboratory built for TFChem by the French Government**
  - ▶ **Located in France's Cosmetic Valley, where the world's leading cosmetic companies conduct their R&D**
-



## Arctic Fountain of Youth ?

April 2014

<http://arcticjournal.com/opinion/555/ponce-de-leon-should-have-headed-north>

The author is the director of the Arctic/Antarctic policy programme for the Institute for European Perspective & Security (IPSE) and the managing director of Polarisk Analytics. He is a regular contributor to The Arctic Journal.

*As the Arctic Economic Council becomes reality, let's share one with you today: an Arctic success story in the making – in a non-Arctic country.*

*Let's head to 'Cosmetic Valley', located in Val-de-Reuil, France, 110km northwest of Paris. This small town of 13,000 hosts a handful of extremely innovative French start-ups. Amongst them, TFChem.*

*A small biotech company founded in 2007, TFChem dared to go bio-prospecting in the high north. In the 1950s, Canadian scientist PF Scholander understood that Arctic fish could swim in water colder than the freezing point of their blood thanks to an intriguing 'anti-freeze' factor. Biologist Arthur DeVries isolated the protein that accounted for that anti-freeze effect in 1969. Today, TFChem has found more.*

### **An Arctic fountain of youth ...**

***Arctic fish produce a temperature-resistant molecule that helps them survive in waters down to -2C. These 'anti-freeze proteins' (AFPs) have been used in cosmetics since the early 1990s. And yet, TFChem just patented this week an enhanced synthetic imitation of that Arctic anti-freeze molecule.***

*Such scientific research is called 'bio prospecting': searching for previously unknown organisms or genes that can form the basis of a new drug or cosmetic. Indeed, TFChem's new glycoprotein is made from just sugar, instead of being extracted from actual Arctic fish, as the industry does today.*

*"We began to mimic these natural molecules and we managed to identify a new family of molecules that not only protected from temperature-related stresses such as coldness, but also from other stress factors," explains Géraldine Deliencourt, founder and director of TFChem.*

***This new "Arctic molecule" is aimed at protecting humans from oxidative stress. Since oxidative stress is involved in skin ageing, and thought to be involved in the development of cancer, heart failure and Parkinson's disease, among others, TFChem envisions numerous business applications for its enhanced glycoprotein.***

*First and foremost would be anti-wrinkle creams that work. Today a market estimated at \$291 billion the anti-ageing cream industry would be the first one to benefit from TFChem's enhanced glycoprotein. **High-end brands currently use real polar fish. This, though, is an ecological disaster: it takes about 100 tonnes of fish to actually produce one kilogram of that protein naturally.***

***TFChem's discovery thus allows for cheaper, more sustainable and more effective anti-ageing products for men and women around the world. Needless to say, this all-synthetic protein could be further enhanced in the future.***

***In the medical industry, for example, TFChem's synthetic protein would allow for numerous applications, such as the extension of blood shelf life by a factor of four.***

***With innovation naturally comes growth and jobs. TFChem plans to triple in size, from nine to 30 employees in the next 24 months thanks to this discovery. L'Oreal and a few other major cosmetic makers are said to be closely monitoring TFChem's progress. Are we talking about another global success story in the making for the French cosmetics industry? Certainly. And it originated in the Arctic.***

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<http://www.skinmagazine.co.uk/fish-antifreeze-is-new-skin-anti-ageing-secret>

#### **Fish Antifreeze is new skin anti-ageing secret**

Article Excerpt:

**An anti-aging compound based on the naturally occurring 'antifreeze' glycoproteins found in Antarctic fish may be the next big thing in anti-ageing skin care.**

***"The ability of these compounds to modify the rate and shape of crystal growth and protect cellular membranes means that they have potential for use in skincare for the preservation and hypothermal storage of skin cells and tissues. Skincare giant L'Oreal has already singled out the new ingredient for use in their future anti-ageing skincare products."***

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**This video is an excellent overview of Sirona's Chemistry / Biology**

[https://www.youtube.com/watch?v=P6Md\\_pNzY9s](https://www.youtube.com/watch?v=P6Md_pNzY9s)

Dated March 2014 but just as relevant.

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Disclosure: Danny Deadlock owns 200,000 shares of Sirona purchased in the open market during 2014

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