Is a Trojan Horse the Key to Curing Cancer?

Theralase Technologies Inc. (TSX: V.TLT, OTC: TLTFF) is currently doing business with some of North America’s premier professional sports teams and organizations. Among these entities are the Toronto Blue Jays, Oakland Athletics, and San Francisco Giants (MLB); Toronto Raptors and Washington Wizards (NBA), Montreal Canadiens (NHL), Carolina Panthers (NFL), and the ATP (tennis). The Company uses its patented super-pulsed laser technology to help some of the world’s highest paid professional athletes return from injuries much sooner.

It’s a high-margin form of laser therapy, with numerous established and potential applications. But that’s not what Theralase’s President and CEO Roger Dumoulin-White wanted to discuss when he recently spoke with Stockhouse via conference call. He wanted to talk about the interesting part of their business: curing cancer.

The Company isn’t there, yet. But after having stunning success at the laboratory level, Theralase has now been approved to move to the clinical level with the testing of its (potential) cancer cure on human subjects.

How does a medical practitioner use laser light to cure cancer? If it was just as simple as pointing a laser at a cancer tumor and using the correct wavelength of laser light, someone would have already done it. Theralase wanted to target internal forms of the disease. This makes treating cancer with lasers much more problematic.

Why are cancer cells so difficult to kill? CEO Dumoulin-White provides an illustrative analogy.

“Cancer cells are skilled at hiding from the immune system by the markers they express on their cellular membranes, fooling the immune system into thinking they are healthy cells. In this sense, they resemble a fortified castle with big thick walls, impenetrable to even the strongest attacks. This is also why cancer cells are notoriously difficult to kill and why the conventional standard of care for most cancer involves brute-force therapies: surgery, (highly toxic) chemotherapy and radiation treatment.”

How could the Company successfully fight these strongly fortified cancer cells with laser light mild enough to avoid damaging healthy tissue? The ancient Greeks knew how to get past the walls of a heavily fortified castle - with a Trojan Horse. This was the mission of Theralase Technologies: finding a Trojan Horse which could slip inside cancer cells and (with the help of laser light) destroy the cancer from within.

The basic technology at work here is called Photo Dynamic Therapy (“PDT”): using laser light to fight cancer. The Trojan Horse that the Company was searching for is referred to as a Photo Dynamic Compound (“PDC”) combined with transferrin.

The science behind identifying an ideal PDC to use as a Trojan Horse is highly complex. The bottom line was that after...
a significant commitment of time and research dollars (more than $30 million CAD), management found the right partners to manufacture a customized molecule which could penetrate cancer cells: TLD-1433.

TLD-1433 is able to enter cancer cells by passing through cancer cell “transferrin receptors”. All cells have transferrin receptors designed to aid in the absorption of Iron. TLD-1433 exploits this Achilles’ Heel of all cancer cells: their insatiable thirst for iron.

In order to grow and spread so aggressively, cancer cells consume and require much greater amounts of many nutrients. In particular, cancer cells need 10 to 15 times the amount of iron as a normal, healthy cell. TLD-1433 combines inside the body with transferrin. Transferrin is a naturally occurring glyco-protein that transports iron to every cell in the body.

Cancer cell receptors greedily absorb this transferrin + TLD-1433, fooled into thinking that they are absorbing iron and hold onto it for longer periods of time, while healthy cells reject the TLD-1433 PDC quite quickly. The Trojan Horse is now inside the castle. Then what?

To be a cancer-killing Trojan Horse, able to destroy cancer cells from the inside requires two chemical-biological properties: the ability to slip past the tough cell walls of cancer cells plus the capacity to do damage once inside. This leads back to laser light.

Once the TLD-1433 has been given time to penetrate these cancer cells it’s time for the actual laser therapy – and the cancer-killing begins. When laser light targets cancer-diseased tissue with TLD-1433 inside, a photo-chemical reaction takes place.

Using laser light with the correct wavelength (i.e. colour) causes TLD-1433 to begin to generate a form of oxygen. But this form of oxygen isn’t the nourishing element essential to life. What TLD-1433 is able to produce is a form of “cytotoxic” (cell killing) oxygen known as Reactive Oxygen Species (ROS).

These ROS molecules are like tiny cancer-bombs. TLD-1433 generates enough of these ROS cancer-bombs to destroy cancer cells from the inside, with enormous success. Laboratory results indicate the destruction of more than 99% of cancer cells from Theralase’s PDT technology, with virtually no damage to surrounding tissue.

As impressive as this sounds, in the minds of many readers this will still not be seen as good enough. Part of cancer’s plague is its ability to recur and reproduce. Almost getting rid of cancer falls far short of a cure.

This leads to perhaps the most important aspect of PDT treatment of cancer. This form of laser therapy is a “smart” cancer treatment. Essentially, killing cancer cells with TLD-1433 + transferrin teaches the body how to fight the cancer.

Theralase’s PDT cancer treatment also functions like a cancer vaccine: permanently improving the body’s capacity to target and destroy cells of that particular type of cancer. PDT doesn’t merely fight cancer. If it can be perfected for human use, it will genuinely cure cancer – benignly. No surgery; no chemo; no radiation.

Which particular form of cancer has Theralase targeted first in its quest to banish this ruthless killer? Bladder cancer. There were several reasons why the Company chose this form of cancer for its first version of PDT cancer treatment.
1. Bladder cancer is the 5th most-common form of cancer (4th for men, 8th for women).

2. In the U.S. alone, there is an average of 76,960 new cases each year, with 16,390 deaths, and the total value of cancer treatment is $3.9 billion (2016).

3. Despite its prevalence, bladder cancer has been relatively under-researched by mainstream medicine.

With its high prevalence and mortality rate, bladder cancer was a potentially high-reward branch of research. One more factor made bladder cancer ideal as TLT’s first target: bladder cancer tumors are relatively accessible compared to many other forms of internal tumors.

Physicians can conduct PDT bladder cancer treatment without any invasive secondary procedures (such as minor surgery). TLD-1433 can be delivered to cancer tumors intravesically, meaning inside the bladder — through the use of an ordinary catheter. With a management team stacked with PhDs, these were details which did not escape notice.

As already noted, the Company is led by President and CEO Roger Dumoulin-White. He is TLT’s founder, who has run Theralase since its inception in 1994. Previously he served as Product Team Manager of Ford Electronics, a division of Ford Motor Corporation. While there, he managed a $40 million per year business, directing approximately 400 employees.

Chief Scientific Officer for Theralase is Dr. Arkady Mandel. Dr. Mandel was a pioneer in the use of lasers for dermatology and other branches of clinical medicine. He is an esteemed researcher who has produced more than 100 original papers and 200 international patents.

Supporting senior management are two teams of medical advisors. The Company’s PDT Division (anti-cancer) boasts a medical team with an abundance of experience and expertise in oncology — especially uro-oncology (bladder cancer). Here Theralase has drawn heavily from the personnel of the renowned Princess Margaret Cancer Centre, University Health Network (“UHN”).

The Company’s other branch is its TLT Division (pain/injury laser therapy). Theralase’s team of medical advisors for this division possess a wealth of expertise in sports medicine, orthopaedic surgery, and physical therapy, including Dr. James Andrews, founder of the American Sports Medicine Institute.

The anti-cancer division has now progressed to the level of Phase Ib human testing with respect to NMIBC, meaning bladder cancer which has not spread into the muscle wall of that organ. This is a nine patient study.

Testing has begun with three patients placed on a lower dosage of TLD-1433 for a 30-day period. If the initial 30-day trial is deemed successful, meaning that the patients are able to tolerate treatments with no adverse effects, then six more patients will be enrolled and tested at a higher dosage. The clinical study is expected to require a full year to complete.

Management is already busy on its next anti-cancer initiative: targeting an especially aggressive form of brain cancer: Glioblastoma Multiforme (“GBM”) cancer. The Company anticipates commencing Phase Ib human trials for GBM toward the end of 2017, carrying forward to the end of 2018. After that comes Phase II clinical trials: larger scale human testing, aimed at moving Theralase’s PDT cancer treatment(s) much closer to the FDA and Health Canada approval necessary to bring this potential cure to market.
For most bio-tech companies, a research initiative of this scale would consume all of their energy and financial resources. However, Theralase is not a typical bio-tech company that is years away from any substantial revenue streams.

The Company’s TLT Division already has well-established, super-pulsed laser technology which it has commercialized in the form of (first) the TLC-1000 and (now) the TLC-2000. This multi-purpose technology has been FDA- and Health Canada-cleared for use in treating knee injuries and knee pain.

However, in principle, the technology is conducive to many varieties of chronic pain ailments and injuries, in different parts of the body. Because of this reality, some of the medical practitioners using these devices are engaging in “off label” treatment: treating pain/injuries beyond knee problems. Indeed, Theralase is already looking to obtain FDA and Health Canada clearance to officially extend use of the TLC-2000 to shoulder injuries/pain.

There are 1,000 of these TLC-1000 patented Low-Level Laser Therapy (“LLLT”) devices deployed world-wide, with the TLC-2000 having just been rolled out for use.

The TLC-2000 is superior to the TLC-1000 in several important respects. In addition to improved performance it offers greater flexibility. The TLC-2000 is available in either “single-probe” or “multi-probe” versions. Each probe is a separate laser emitter, meaning that multi-probe units can treat either several areas of the body simultaneously, or even several different patients simultaneously.

More than 100 million Americans suffer from some form of enduring pain condition. The “pain market” is currently worth more than $100 billion per year – just inside the U.S. The TLC-2000 can treat pain (and/or heal injuries) with no drugs and no side effects, meaning the long-term potential to capture a significant chunk of this major market.
As management spreads the news about these exciting, innovative, hi-tech applications, their difficulty is in choosing a focal point. Do they trumpet the tremendous blue sky opportunity of a potential cure for cancer? Or, do they emphasize the near-term commercial potential of their pain/injury therapy in this $100+ billion per year market? It’s a nice problem. Curing cancer, healing stars. For investors, it’s an easy decision: take a position for both reasons.

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