Marc Wayne – CEO, Canopy Health, Canada



The cannabis industry is a good example of where Canada is able to take a lead over the US and the world

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Marc Wayne, serial entrepreneur and a pioneer within the field of medical cannabis discusses his dedication to the field, how cannabis-based therapies have the potential to disrupt the pharmaceutical industry and how now is a SMART time to conduct medical cannabis research.

Marc, you are regarded as a pioneer in the medical cannabis industry: you co-founded Bedrocan, one of Canada's first licensed producers of medical cannabis; you were founding chairman of Cannabis Canada and instrumental in developing the CCIC (Canadian Consortium for the Investigation of Cannabinoids). Where does this dedication to medical cannabis originate?

My fascination with cannabis started when I was at a young age, when my mother was affected with cancer and was using cannabis back in the mid-1980s. Although this event did not get me involved right away, it was my friend and colleague Dr. Mark Ware who got me intrigued when he asked me to help him develop the CCIC (Canadian Consortium for the Investigation of Cannabinoids) back in 2007 and it is this project, which led me to pursue a path focusing on the research and education around cannabinoids and take the approach of medical cannabis from a very high level, scientific perspective.

Canopy Health Innovations was formally incorporated as a private company in August 2016. Were you given a particular mandate to steer the organization in a particular direction?

My mandate was to establish Canopy Health as the research and development arm of Canopy Growth, where we focus on clinical research, products and the development of intellectual property. Essentially, we are leveraging the sophisticated and consistent production platform of Canopy Growth to take the cannabis plant through the various stages of clinical testing in order to validate safety and efficacy with the goal of developing approved medicines with therapeutic claims. Currently medical cannabis is considered an unapproved drug which serves only to limit patient access. These are particularly exciting developments in what I would call a “S.M.A.R.T” time for cannabis research:

S – Supply. Previous to the evolving federal Canadian production platform, there were only four organizations in the world legally producing cannabis: one of them was the US government, and we naturally could not tap into their resources. Additionally, there were GW Pharmaceuticals in the UK, Plant Prairie Systems (Cannimed) and Bedrocan—compared to the almost 90 licensed producers in Canada today.

M – Money. Previously, we did not have money and to be frank, nobody cared about investing in clinical research in the cannabis field. Today, we have tremendous access to capital and millions of dollars are being targeted for cannabinoid research. This is very encouraging.

A – Analytics. Analytics and testing standards of medical cannabis have evolved, which allows us to characterize the plant and the associated chemical molecules much better.

R – Regulatory. We have a regulator in Health Canada that is becoming increasingly focused on opening up channels for cannabis research. For example, we will soon see regulations for natural products containing CBD changing. We will most likely see a cannabis-type Directorate within Health Canada that will be dedicated to regulating the clinical research in this area, specifically around natural health products.

T – Talent. Top researchers now actively pursuing areas of cannabinoid investigation. In Canada, we have very talented research professionals in the fields of mental health and pain, two of the main indications cannabinoids are being used for.

To conclude, SMART really means that the time for cannabis research is now!

What have been some of the main highlights since Canopy Health's inception?

In the last 15 months since we launched, we have been running hard. We have built a very strong team, successfully completed two funding rounds, secured stable and consistent drug supply and products, developed our main clinical pipelines, formed collaborations with world class researchers and institutions, secured IP protection for our main indications, created an Animal Health subsidiary and formed a new biopharmaceutical partnership in the UK.

How would you define the therapeutic value cannabis-based therapies can bring to patients?

The therapeutic value really depends on the individual and the indication. For example, it can be a primary option for some indications, whereas for others it might a good adjunct therapy along with their primary medication. It is a complex plant with many molecules. Different cannabinoids are used in different therapeutic areas, which is a primary reason why clinical research is so important. We need to understand this better and there is so much to learn. We aim to isolate the plant's components and research which ones may be most effective in which areas. There is a lot of anecdotal evidence from patients in the field of pain, anxiety or sleep and those are some of the major indications where cannabis-based medicine can be true disruptors to traditional pharmaceutical drugs.

Talk about disruption in the pharma sector—how would you characterize your relationship with pharmaceutical companies?

The larger pharmaceutical companies tend to be rather risk-adverse towards cannabis and cannabinoids. They may view the plant as too difficult to conduct research on, given that there are multiple actives in the cannabis plant, and as a result stay clear of this area. Similar to traditional biotech, Canopy Health, as a specialty pharma type play, aims to take away some of the risk associated with early stage clinical testing for these larger pharma companies. We are dedicated to carrying out the Phase 1 and robust regulatory scale Phase 2 clinical work.

We believe that pharma companies will become much more receptive to taking a Phase 3 ready asset through final development and would be open to discussing potential partnerships with larger companies on later stage projects. I believe that across the board, pharma players should be looking into the field of cannabis/cannabinoids and if they are not, they are missing a huge

opportunity.

The endocannabinoid system is a very important modulatory system in the function of brain, endocrine, and immune tissues. It is an important system that provides a lot of functions and we have only scratched the surface in terms of research.

Can you give us an update on your portfolio development timelines?

We have completed exploratory signaling studies and we have filed patents in areas, such as insomnia and anxiety. We are about to launch several large regulatory scale Phase 2 trials in both therapeutic areas with strong institutional collaborators. Cannabis research at this scale is rare and within the next several months you can expect some big announcements from Canopy Health.

Canada is entering a golden age in cannabis research: access to supply and interest from the public and private sector increases on a daily basis. Canopy Health to this day has risen over CAD 15.8 million (USD 12 million). Where do you see the future of the medical market in terms of research and funding?

Drug development is expensive but also quite valuable. An approved drug with protection commands strong valuations. An approved cannabis medicine in our view is no different. However, cannabis is also unique in this regard. We believe the path to proving safety and efficacy will be shorter and in fact, less risky than traditional synthetic molecules.

At Canopy Health, we have raised sufficient capital to proceed with the studies that we have planned. If our current Phase 2 programs are successful, the valuation of our company will go up, which in turn allows us to raise more money to take our intellectual property to a pivotal Phase 3 trial—whether we will conduct it by ourselves or in collaboration with a large pharma company—. These will be trailblazing developments and we are excited to be in a position to drive value creation for patients and the healthcare system overall. However, we also believe regulators will need to work together with the industry to allow for product innovation to thrive.

As an industry leader, how can Canopy Health contribute to an increased understanding of cannabis as an effective and safe method of treatment?

This is where the work of the CCIC becomes crucial. As an organization of basic and clinical researchers and healthcare professionals it aims to promote evidence-based research and education concerning the endocannabinoid system as well as therapeutic applications of endocannabinoid and cannabinoid agents.

The current slate of published research consists of small studies, which are limited in scope—which has always been the main criticism of the industry—. We are hopeful to see investment into bigger studies like we are working on at Canopy Health. Eventually, we will, as an industry, have to disseminate this data to physicians and healthcare professionals, so they can become more educated and more comfortable prescribing cannabinoids. At the moment 85 percent of Canadian physicians fall into cover my ears and eyes category and as a result, physicians commonly refer patients to cannabinoid clinics to free themselves from any concern or liability around this drug.

My hypothesis is that as the research in medical cannabis accelerates, and we advance some of these programs towards approval, not only will regulators take notice but also doctors will become more comfortable prescribing such products.

What does the Canopy Health brand stand for?

The Canopy Health brand stands for cannabis, clinical research, good science and approved medicine. We want to be a credible research partner the goal of developing therapeutic and health products both for human and companion animals. We want to be able to elevate the image of cannabis to be a true medicine, which is prescribed as a proper pharmaceutical or natural health product. This is what I call Medical Cannabis 2.0.

How should Canada position itself globally in the cannabis space?

The cannabis industry is a good example where Canada is able to take a lead over the US and the world. While the US contemplate their governance over the drug, and a fragmented Europe begins to sow the seeds of federally regulated medical cannabis, Canada should accelerate its current global leadership position. With the legalization platform unfolding, Canada is viewed as the world leader in the sophisticated production of both safe and reliable cannabis and this is the basis of any drug development. As a result of this and the restriction on the movement of the drug, Canada has the ability to conduct and regulate clinical work on this product to a standard that is required on the global level. Given the fact that the US makes up approximately 30 percent of the global

pharmaceutical market, we ultimately want to take advantage of this potential but in order for Canada to succeed, we would like for the US to wait some time until it wakes up to this fact.

Do you have a piece of advice to a newcomer to medical cannabis research?

Newcomers to the space need to understand the complexities of the plant and related science and understand how to navigate the highly regulated aspect of Schedule 1 class research (i.e.: transfer of product, license). It would also be important to be connected the top researchers, labs and drug substance/ product suppliers.

Finally, you have to go be very credible in your approach. You cannot cut corners; as an industry we are working heavily on reducing the stigma still attached to this plant. We want to raise our credibility to pharma standards and thus, all players need operate at the highest level.

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