Interview: Bernard Fortier â?? CEO, Tetra Bio-Pharma, Canada

â??Tetra Bio-Pharma wants to be the first company to see a dried cannabis drug become a real prescription drugâ?•

03.04.2018

Tags:

Canada, Tetra Bio-Pharma, Cannabis, Pharma, R&D

With a diverse pipeline to back up its projects, Tetra Bio-Pharma wants to be the first Canadian pharmaceutical company to launch a cannabis-based drug in breakthrough pain. Bernard Fortier, CEO of Tetra Bio-Pharma, counts on the production of credible scientific data to overcome stigmas attached to medical cannabis and believes that Canada can be leading the way in that regard.

Bernard, you took over as CEO of Tetra Bio-Pharma in July of last year. How did you come to work for a natural health company focused on cannabinoid products after an extensive career in the pharma industry?

To me, the key motivator was meeting the challenge of bringing a cannabinoid-based pharmaceutical product to the market. I saw a company that was lending a lot of credibility to its drug development through its scientific work.

There had been studies conducted on cannabis-based medical products by some of the licensed producers in Canada for instance. However, although these studies were moving into the right direction, none of them were adhering to the actual process of developing a drug for Health Canada approval. At Tetra Bio-Pharma, we want to achieve a DIN (drug identification number), with studies that are comparable with the scale of pharmaceutical drug trials.

Tetra Bio-Pharma wants to be the first company to see a dried cannabis drug become a real prescription drug, and we are on the best way with our PPP001 drug for cancer-related pain that has just been approved for phase III trial, promising to be a landmark trial.

It is highly stimulating and exciting as well as very validating to be part of the first trial of this kind and be able to provide additional therapeutic options for those patients that suffer from pain for which there is no alternative treatment available once opioids have been fully leveraged upon as a therapy. In the end, this is what pharmaceuticals are supposed to be about: finding new treatment options with better safety profiles and higher efficiency.

What have been the milestones of your first months with Tetra Bio-Pharma?

They have been numerous! We finalized our phase I clinical results for PPP001. From this, we gathered a lot of data, looking at three cohorts, and were able to form a platform to finalize the protocol for our phase III trial that was approved by Health Canada. This green light by Health Canada for the first trial of its kind was of course another milestone and a major accomplishment in itself.

Thirdly, we have just completed a major financing of CAD 11.5 million (USD 8.9 million), which secures our projects and our pipeline as well as the beginning of our commercial operations for the next 12 to 15 months.

The signing of our agreement with Neptune Technologies & Bioresources, a technology company based out of Sherbrooke, was another highlight for us. Together, we will leverage on their newly developed technology in oil extraction. This will add value to the products we are looking to launch and develop both on the pharmaceutical and natural health/nutraceuticals side. Our goal in this partnership will be to gather data proving absorption capacities of cannabis-based oils and their therapeutic effects.

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Finally, a major milestone was achieved just this month of March 2018, when the FDA granted our PPP001 orphan drug designation for the treatment of complex regional pain syndrome. Not only will this give Tetra Bio-Pharma seven-year marketing exclusivity following approval, but it is also the first time, that a cannabis-based product is granted this designation. We can definitely sense that we are on the verge of disruption in the medical cannabis industry.

Looking forward, what will be Tetra Bio-Pharmaâ??s strategy in developing the business?

Moving forward, Tetra Bio-Pharma will have two strategic pillars on the commercial side: to develop a steady revenue stream from its pharmaceutical activity in prescription medication, and to use the data we gather trough that activity to start the development of a natural health products/nutraceuticals line for the time post-legalization of cannabis for recreational use. Within the second dimension, we will need to wait for the regulatory framework to be put in place in order to determine what the possibilities for product development are.

The fact that up-coming regulations are still foggy and that cannabis remains a controlled substance in most countries around the world are the two biggest challenges we are dealing with at this time and we need to find a way to work around those constraints when defining our path for the future.

Can you give us an overview of your development pipeline?

Today, there are two cannabinoid-based drugs available on the market: the first one is plant-based, use for the treatment of MS. It is not approved in the US and only has conditional approval in Canada.

The second is MarinolÂ®, a synthetic-based anti-nausea and anti-vomiting drug with worldwide approval. The latter has been pulled out of Canada years ago because its current delivery form is ill tolerated by patients. Thus, there is little precedent in -cannabis-based prescription drugs, but we believe we can develop drugs in a variety of delivery forms targeting different therapeutic goals.

In the smokable dried cannabis space, our development of PPP001 aims towards a very targeted product in the sense that smoking is one of the fastest ways to allow the active ingredient to enter into the system. Larger concentrations reach the brain faster, and this delivery form is hence ideal for breakthrough pain, which cancer patients often experience.

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In addition, we are developing PPP002 as a mucoadhesive tablet. Through its slow release of THC its action modus is very different from PPP001 and can target conditions such as chronic pain or vomiting. We are further developing eyedrops for ocular pain and inflammation and topical creams.

I believe this variety shows the genius and strength of our pipeline, as it is based on a reflection aiming to ensure effective delivery for various medical conditions.

What are the advantages of conducting research in Canada?

What we have in Canada today is expertise in the medicinal cannabis field that is unmatched by any other country in the world. We have a series of licensed producers that have been building up expertise in growing cannabis and extracting it for dried flowers or oil. This knowledge is something we can leverage on not only to export our brand and create a platform for Canada to showcase itself, but also in cannabinoid API production.

For our PPP002 for instance, we require pure THC, and at the moment our only choice is to use synthetic THC. However, some producers in the industry today have the capacity to provide almost pure THC through natural extraction. We partner with MedReleaf, a licensed producer that has been willing to enhance its production to meet GMP (good manufacturing practice) pharmaceutical levels. When we get to the point of commercialization and request a DIN, it will be essential for us to be able to prove that our partner has this label. Today, MedReleaf produces with less than four percent variation between their lots, while synthetic production is at three percent. This shows that natural extraction is very close to synthetic THC and Canada is a leader in this field, differentiating itself from the rest of the world.

How do you go about fighting the stigma attached to cannabis for medicinal use?

The surest way to overcome the stigma attached to cannabis is to produce scientific data that will be recognized as tangible proof for the efficacy and safety of cannabis-based drugs. While Israel is the country that has been most active in the development of medicinal cannabis products, they have only ever conducted small-scale studies. Today, we are still missing the big scale, peer-reviewed studies, double blind, placebo controlled, randomized trials. Without data of this scale and scientific backup, the medical cannabis industry does not match the entry criteria for pharmaceuticals and will never be recognized as bringing comparable therapeutic value.

Only three percent of physicians are prescribing medical cannabis today, for two reasons. Firstly, because the colleges do not necessarily encourage to prescribe and secondly, because the physicians do not recognize the provided data to be comparable to that of controlled trials for traditional pharmaceutical drugs.

Therefore, the development and gathering of credible information in a format physicians are knowledgeable about is our first priority in addressing stigmas. Canada can bring this data and lead the way, and we need more companies like Tetra Bio-Pharma to ensure we maintain and develop this chance.

What is the timeline for launches we can expect from your bustling pipeline?

Our first launch will be the PPP001. If we encounter no delays and our phase III trial goes as planned, we will complete it by the end of this year and hence be able to submit the drug for approval in late 2018, early 2019. If we were to be granted conditional review by Health Canada, we could introduce PPP001 to the market as soon as Q2 of 2019. Otherwise, we will face a 12 to 18 months submission process and launch it in early to mid-2020.

For our PPP002, we are also looking for an end 2018 submission date. Since we will file this product with the FDA as a prescription to counter vomiting and anorexia that are HIV-induced, we will go through a one-year approval process and launch PPP002 on the US market by the end of 2019.

We are further investigating cannabis oil products as an increasing trend in the field, partly because of the negative perception smoking triggers. Our PPP005 aligns with that direction, and we are currently in phase I with its development.

Considering the domain of pain management and the various pharmaceutical present in that space, where do you see your relationship with big pharma? Do they pose a threat or is there room for collaboration?

I think there we will see both. If they have not started developing their own programs yet, many of the larger pharmaceutical pain management companies will take an interest in companies such as Tetra Bio-Pharma to license their products or integrate them into their own operations. I see many opportunities arising in that sense, but we should also stress the fact that there will always be room for both opioids and cannabinoids. There is no such thing as the magic pill, and I consider the next step in our potential collaboration with big pharma to be combination therapies. The goal is to reduce the amount of opioids by alternating with cannabinoid-based products, and while we are sure to present serious competition to opioid products once we can leverage on scalable scientific data, the biggest leaps happenâ??as it is the case everywhereâ??when there is collaboration.

We have actually started working with a US-based company, Constance Therapeutics, that has shown in small studies the possibility of cannabis-based products to not only treat cancer-related pain, but significantly cure, stop or delay some types of cancer. Our goal is to upscale the R&D effort and prove that the development of tumor cells can be slowed down with cannabinoids.

What piece of advice could you give to someone just about to start leading a medical cannabis company?

It is primordial to remember that a company is based on the expertise of individuals, and that it is your role as leader to ensure that expertise is spread in the company. Succession planning is crucial, especially in small start-ups where the expertise is concentrated on one or two people. Duplicating and securing it is one of your most important tasks.

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