

Cannabis Derived Pharmaceutical Products



John B. Hollister
CEO

CEOCFO: Mr. Hollister, what is the concept behind NEMUS Bioscience?

Mr. Hollister: We are a biopharmaceutical company that specializes in cannabis derived pharmaceutical products. What makes us unique is that we are the sole partner of the University of Mississippi. The University of Mississippi is the only entity in the United States authorized by the federal government to cultivate cannabis for research and commercial purposes. We have licensed from the University a novel chemical entity, a new version of THC, which appears to give us many options for administration that have the potential to overcome the issues associated with the parent compound.

Working with the University gives us access to a great wealth of knowledge. They have been working with cannabis since 1968 under federal license and international law, supplying the research community with cannabis or extract of cannabis for clinical trials that have been almost entirely funded by the National Institutes of Health and serves as basis of our understanding why our perceptions are increasing. Cannabis has many medicinal purposes as it has been used for upwards of five thousand years as a medical product, until the prohibition of it in the 1930s, and increasing marginalizing of it in the 1960s, 1970s and 1980s. What is really exciting is happening at the University of Mississippi, which is one of the leading schools of botanical sciences and pharmacy schools. They are experts in how to process and how to extract the individual active elements within cannabis. They are called cannabinoids. The well known ones are THC and also cannabidiol (CBD), which is now gaining a lot of popularity. There are one hundred and four other cannabinoids, all of them which have vast effects on the human system. We are isolating those and making compounds that are unique for treatment of a variety of different diseases. We are working with the team at the University in a variety of areas.

CEOCFO: How do you break through the noise? There are so many companies developing around cannabis and so much hype. How do you get the attention that obviously this background and history should have?

Mr. Hollister: We think that we are very unique in that we are actually going down the FDA pathway to where the greatest unmet need is. That is, providing physicians with cannabis-derived products that have gone through the rigors of FDA review, in order to provide evidence of a predictable effect on a patient. Physicians want to know what they are prescribing, know what the patient will get and has a pretty good idea of the effects, both good and bad, of the compound, which is in contrast to the dispensary world and the personal use world.

CEOCFO: Are physicians jumping on the bandwagon? What is the overall physician mindset towards cannabis?

Mr. Hollister: Generally favorable now. Obviously in states where there are dispensaries, physicians have a much higher level of familiarity. Most physicians that get asked by their patients in those states where medical marijuana is available; there are twenty three of them, write a prescription. While they feel comfortable in writing the prescription, they do not know what the patient is getting. The patient goes to a dispensary and something is dispensed. However, it could be an edible, it could be something to smoke, it could be something to drink or it is a different variety of plant. As a result, the feedback is very anecdotal. For a physician that is not the model they work in. Therefore, they would like something that they could predict. When people go to CVS or Walgreens or Rite Aid, they would get a certain experience. There are actually two licensed products in the United States that are THC synthetic compounds. They have been approved since the late 80's and early 90's. The two compounds are subject to high variable from patient to patient, so there is too much or too little. Therefore, the physician experience in the United States with synthetic cannabis derived products is that they kind of work, but they are also unpredictable. We are trying to resolve that problem with our new compound.

CEOCFO: *What have you found? What are you working on today?*

Mr. Hollister: We have licensed a novel chemical entity from the University of Mississippi, a new form of THC. It is a form of THC that can be absorbed in other ways than through the stomach. It can be absorbed in the eye, which the THC compound that everyone else is working with cannot. It can be absorbed through the mucosa of the mouth, the skin or intranasal. Importantly, all of those ways bypass the liver. By bypassing the liver, we hope to better control the dosing effect. What we hope to see with our THC compound is a much more predictable in terms of its affect in bioavailability. Our first target with that is glaucoma. From a drug developers perspective it is a non systemic approach. It is much more predictable, because it is measured by intraocular pressure, which is an objective measure. It is a very large market that has a high level of dissatisfaction. Therefore, all of those are attractive for us as a lead target. We are also working on a formulation to be licensed for a transmucosal patch to be placed in the mouth. Imagine between your cheek and gum on your upper mouth, you put a little, tiny patch in there and it absorbs through your cheek. We are looking at that to be used for spasticity in patients suffering from multiple sclerosis. We also have licensed a formulation for a suppository and we are determining which indication would be most appropriate for that right now. On another research pathway, we are working on developing a compound for MRSA, for methicillin-resistant staphylococcus aureus, because there is evidence in literature that cannabinoids are effective in inhibiting MRSA, which is a huge problem in hospitals and in the military and anyplace where people congregate. Then lastly, we are developing a compound that would be appropriate for anxiety and epilepsy. However, that is still a little bit earlier.

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CEOCFO: *What is the timetable? What is going to happen over the next year with your lead product?*

Mr. Hollister: We are finalizing our formulation right now. This is for the THC candidate, to be used in glaucoma. We need to complete an additional animal study in dogs. Dogs actually suffer from glaucoma. About twenty percent of dogs, by age seven, have glaucoma. Among other things, we are working towards a Pre-IND meeting with the FDA later next year, with anticipation of an IND filing by Q1 of 2016 and begin our Phase 1b/2a study in Q2 of 2016.

CEOCFO: *Are you funded for the steps you would like to take?*

Mr. Hollister: We had completed a funding round earlier last year. We also went public and completed that process on October 31st of last year. Therefore, we are now a public company that is listed on the OTCQB as NMUS. We are in the midst of a funding round right now and anticipate working in banks next year for a larger funding round later in the year.

CEOCFO: *Are you confident that the medicinal aspect will set you apart when you are working with banks, with investors and with the medical community? It seems easy to understand once you explain it, but I know there are so many companies, as I mentioned before. What are you finding?*

Mr. Hollister: It gets back to the fact that there are many, many companies talking in the cannabis state that are active. However, most of them are working towards the dispensary world, which is, for all intents and purposes, at this stage, unregulated and not the answer to physician prescriptions. There are two answers to your question. One is the probability of success, which in pharmaceutical development is always one of the questions that you ask. What is the probability that you will be successful with your compound; that your compound has a positive affect? I have been in this space for twenty five years, starting at SmithKline Beecham and after that to a small biotech called Aviron and then to Amgen and then to a couple of device companies. Therefore, I have a great deal of experience and I can very easily say that the probability of success is much higher than I have ever had in any sort of field that I have been in. This is because the literature supports the efficacy. Now, what I do not know is how big an effect it will have. That we will see in clinical trials. In terms of getting people’s attention, the distinction is that with what we are doing, we have access to the only truly legal cannabis in the country as it is seen by the federal government. States have the right to deem cannabis legal, but it still, in the eyes of the federal authority, not legal. While there is movement towards more legalization or less intervention from a federal level, we have a big head start. We also have intellectual property that gives us access to a novel compound. Therefore, all of those are very helpful from the perspective of conscientious investors who like legal and also like novel and they like intellectual property.

CEOCFO: *Would you tell us about your team?*

Mr. Hollister: We have brought together a great team. I was very fortunate in identifying Dr. Brian Murphy. He joined the group with a very rich background in drug development with companies like Roche, Intermune and Valeant. He actually has experience with cannabinoids and then a couple of startup companies. Therefore, he has big pharma experience and startup environment experience and has been a tremendous asset. We also have a Chief Financial Officer, Elizabeth (Liz)

Berecz, who has a tremendous background as a CFO in public and in private companies, which has been very useful and very helpful to us. We are extending ourselves to add a group of advisors who will be, bar none, best in class. We also admire what the leader in the field is doing; GW Pharmaceuticals PLC (GWP London Stock Exchange). They pioneered the path and are ahead in their field in many clinical trials and are doing partnerships with two big pharmaceutical companies. They are really an inspiration to us and we are also learning from what they are doing. We think that being an American based version of what they are doing will serve us well and also being able to learn from them is serving us well. We think we have a novel compound that will compete very favorably with them. From a financial perspective the market the market has valued them somewhere between \$1.3 and \$1.4 billion at this stage. That is very encouraging too, for investors.

CEOCFO: *What, if any, challenges do you see on the horizon?*

Mr. Hollister: The challenge for any company at our stage is access to capital. It is a very expensive undertaking that is drug development. As smartly as we try doing it, it still costs a great deal of money. Therefore, a fair bit of our time is consumed in raising the capital and a meeting our milestones. However, our team and I feel that hitting the milestones is something that we are very, very good at doing.

CEOCFO: *Why does NEMUS Bioscience standout?*

Mr. Hollister: NEMUS is the only US based cannabis derived product drug development company that has access to federally authorized product from the University of Mississippi. They have forty six years of rich understanding of this that serves as our development engine. We now have a novel product candidate that will distinguish itself, because it will achieve the predictable outcomes that physician's want and now we have a lead product.

Interview conducted by: Lynn Fosse, Senior Editor, CEOCFO Magazine



NEMUS Bioscience, Inc.
OTCBB-NMUS
www.nemusbio.com