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The Use of AI Technology is Increasing the Potential of Mydecine Innovations Group to Successfully Commercialize Psychedelic Drug Candidates

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CEOCFO: ***Where is Mydecine Innovations Group headquartered?***
Mr. Bartch: We have human capital in the United States and a partnership with Johns Hopkins University for smoking cessation, where we support the initiative. All the research and drug development is done at a facility at the University of Alberta in Canada through an exclusive partnership with Applied Pharmaceutical Innovation (API). We are headquartered in Vancouver, BC.

CEOCFO: ***On a personal note, what led you to the addiction and mental health areas?***
Mr. Bartch: Addiction affects everyone, personally or via a loved one. I witnessed my family suffer from two severely alcoholic parents. When I was seventeen, my dad lost his job and faced financial troubles, family conflicts, and the effects of alcoholism. After decades of hardship, I helped them become clean, happy, and healthy. I saw no accurate answer to addiction, especially at that level.

Addiction therapy is based on failure because big drug companies profit from retention. They claim they want you to be well, but their business model is based on patients failing and having them continue to come back, which is an unethical system. Psychedelics will overcome some of those challenges and provide a highly effective solution. Pharmaceutically, it is safe and has long-lasting benefits—something completely different from typical drugs in terms of administration, etc.

The opioid epidemic has started; fentanyl killed my best friend a couple of weeks ago, but his disease is preventable. Once we have a solution, addiction can be prevented. Mydecine's research and psychedelics can be a great starting point to end addiction once and for all eventually.

CEOCFO: ***The other problem is that they can't treat people who have both addiction and mental health problems, for example. Do you offer hope in that area as well?***
Mr. Bartch: Addiction and mental illness coexist. Untreated mental illness often leads to addictions. Psychedelic therapy treats both. We want to deal with the patient's deep-seated depression and other problems that may be making him or her turn to cigarettes, alcohol, or opioids as a way to feel better.

CEOCFO: ***Mr. Bartch, would you give us a little background, the history of psychedelics, and how we have gotten to where we are today with all of this clinical research and its potential use to help people?***
Mr. Bartch: First, I'll begin with psychedelics' mainstream origins. Fungi and other organic substances have produced psychedelic compounds. Ancient societies like the Inca Empire used them. A recent discovery shows that Europeans used psychedelics more than 3,000 years ago. The Stoned Ape Theory suggests hallucinogens help humans develop rapidly and boost brain capacity. In the 1950s, the first clinical studies of psychedelics were started to help people with severe depression. Much of the therapy used LSD or mushroom-derived psilocybin. Combat veterans, Holocaust survivors, and millions of other traumatized people developed PTSD, but at that time, PTSD was just looked at as a generalized depressive condition. Thousands of people took part in hundreds of clinical trials. The results were promising, with immediate benefits and lower costs than anything else on the market.

"AI lets you digitally construct the drug, eliminating molecular synthesis and guesswork. Digitally observe that drug bind, metabolize, and interact with receptors. With these quantum computers, long physical tests can be done in almost no time, analyzing billions of compounds at once instead of one at a time." Josh Bartch

The antiwar movement, hippie movement, and events like Woodstock protested the government in the 1960s and 1970s. The people behind these movements used psychedelics when the drugs left the lab and were used recreationally. The authorities blamed the peaceful revolution on psychedelics, which started the drug war. All research on psychedelic medicine was halted, and all psychedelics were placed in the Schedule I drug category, which meant that psychedelics have no currently accepted medical value and a high potential for abuse.

During the height of the war on drugs, the media portrayed these excellent chemicals as dangerous devil drugs. making statements like "If you take LSD, you will think you are orange for the rest of your life." "Be a psychopath and homeless," "Speak to yourself in the corner," and "Smash your head against the wall." Though inaccurate, the public has been taught this over decades, and civilization has lost touch with the incredible value of these medications. We must all do our part to overcome stigma and promote these treatments, especially when they are ready to be commercialized.

CEOCFO: ***What needs to be done for that perception to change?***
Mr. Bartch: There are two things to consider: FDA approval to market the pharmaceuticals, and second, public adoption where people feel safe taking them. The FDA clearance will arrive before the public is comfortable taking it, primarily due to the past misleading media efforts. JHU researchers requested an FDA psilocybin clinical trial in the early 2000s. Psychedelic mushrooms have a chemical called psilocybin in them. Psilocybin is a prodrug that changes into psilocin, the active compound that gives the substance its moiety. JHU asked for a clinical trial using psilocybin to help people with terminal illnesses deal with the pain and sadness of knowing they are dying. Most patients given such information are miserable and live poorly. "I'm going to die, and there's nothing I can do" is a thought they deal with daily. JHU gained recognition when the FDA gave the respected research institution clearance to study psychedelics. These treatments have excellent results for these patients. Their dread of death nearly evaporated, improving their remaining lives. That breakthrough inspired many researchers to use these compounds in their studies, which became popular.

During 2015–2017, COMPASS Pathways, the first for-profit company in this field, made a psychedelic drug. At the same time, MAPS (Multidisciplinary Association for Psychedelic Studies), a non-profit focusing on MDMA-assisted therapy, was also progressing. Their well-controlled, well-funded clinical trials made headlines. This allowed companies like Mydecine to raise capital since investors started paying attention and sought other investment opportunities.

Given our background, knowledge of naturally occurring substances, and their potential to help people, we monitored the space for a long time. For several reasons, the drug's natural form is not commercially viable. The half-life, onset, and overall experience are too long. Hence, our drive to evolve the molecule. We want to make medicines that can be used in the current medical infrastructure so patients won't need to rely solely on traveling to dedicated psychedelic clinics. We want to make a drug that all doctors and psychiatrists may prescribe and provide to their patients.

CEOCFO: ***What have you developed so far?***
Mr. Bartch: Mydecine now has several families of molecules, each with a specific purpose. Concerning our primary goal of helping people quit smoking, you're talking 80% of biologically verified abstinence in life-long smokers at 12 months on a single macrodose. These are results that are unheard of. Unprecedented results. MAPS main indication targets PTSD with MDMA-assisted therapy. MDMA relieved 67% of PTSD patients after three sessions. Psilocybin has worked well for treatment-resistant depression at COMPASS Pathways. So, Mydecine has made it its goal to keep the compounds' best qualities while adjusting the half-life to drastically shorten the time it takes to feel the effects, speed up the time it takes for the effects to kick in, and reduce the unpredictability of these treatments, such as the health and safety risks they potentially pose. Other factors to consider include dose levels, how the body metabolizes the drug, and better consistency than in its generation-1 form.

We started with psilocybin/psilocin and adjusted it to improve stability and onset because half of our drug families are tryptamine compounds. We made the molecule more accessible and patchable. The other half of our drug families are MDMA analogs, which accelerate the onset and shorten the duration of the experience. The experience time will be one to two hours, down from six to eight hours, as seen in MAPS MDMA-assisted therapy. This cuts costs, makes the medicine easier to get to, makes it easier to treat more patients, and helps make it more affordable.

It's a goal for Mydecine to make these medications affordable and accessible to all. We've improved a lot recently. Our animal studies for our compounds are showing outstanding results. We haven't talked about this much publicly, but the data coming out is incredibly compelling and something the entire team is excited about.

CEOCFO: ***What advantage does the patch delivery system give you?***
Mr. Bartch: There are many benefits to patch delivery, and our patch technology is similar to standard IV (intravenous) administration, but needles aren't used. Needle phobia and anxiety are common. A patch is more soothing, comfortable, and non-invasive during therapy.

We needed to match the IV treatment's heightened and precise commencement. Researchers at Imperial College London (ICL) found that giving psilocybin through an IV decreased experience time and increased onset time. This was done without changing the molecules, and you've already solved a few problems that our patch distribution technique would help with, especially with the generation-2 molecules we're making. ICL discovered that psilocybin typically causes people to feel sick and vomit when taken orally.

CEOCFO: ***You are making therapeutic drugs out of psilocybin, which is a hallucinogen found in magic mushrooms, and MDMA, which is also known as molly or mandy. Let's start with the psilocybin side. Would you tell us about psilocybin?***
Mr. Bartch: Psilocybin has always been around. It is a natural form of psilocin found in mushrooms and truffles. The liver metabolizes psilocybin-containing mushrooms. It converts it to psilocin, the hallucinogenic and psychedelic component of psilocybin. Since the 1950s, psilocybin has been clinically used to treat anxiety, depression, alcoholism, opiate addiction, smoking cessation, and eating disorders. Neurological disorders such as cluster headaches, dementia, Alzheimer's, PCS, and CTE may also benefit from it.

Psilocybin is highly therapeutic. It helps with all these conditions because it resets the brain, boosts neuroplasticity and neurogenesis, and gives patients deep insights. You have had a tremendous, unfathomable experience. The treatment provides the patient with a deeper, more thorough awareness. When you come out of the experience, you finally realize

why you used the drug you became addicted to in the first place or how it truly affects you and your family from a profound perspective.

During and after the treatment, neuroplasticity (brain rewiring) creates sober, unprogrammed neural connections. So, post-therapy can help reorganize your brain to help the patient become a better person without using addicting medications. Instead of the band-aid that traditional treatments offer, the patient can grasp the experience and create a purposeful adjustment.

CEOCFO: ***Would you tell us what psilocybin offers in smoking cessation treatment and where you are in clinical trials for your drug candidate MYCO-001?***
Mr. Bartch: Our MYCO-001 pure psilocybin drug candidate is going into a NIDA (National Institute on Drug Abuse) grant-funded study, a pre-site study. (National Institute on Drug Addiction) It extends Johns Hopkins' decade-long smoking cessation research. A decade ago, over a dozen people who had always smoked got three psilocybin treatments. At twelve months, 80% of them were still not smoking, which led to a more extensive study group to continue the research on a larger scale. JHU equated it to a nicotine replacement treatment, not a placebo. Fifty people got a single large dose of psilocybin, and fifty participants got a nicotine patch. Both groups behaved the same way. The nicotine patch cohort had a 20% success rate, whereas the psilocybin group had over 50%, more than double the current gold standard.

NIDA, a government-funded drug and addiction research arm of the NIH, was a big fan of the data showing these promising results. NIDA granted JHU $4 million for the project. This was the first time in over 50 years that the federal government supported psychedelic research, which is inspiring and unprecedented. This shows how the tides are changing and how promising NIDA's funded psychedelic smoking cessation program with JHU is.

CEOCFO: ***What is the market today for smoking cessation therapies?***
Mr. Bartch: The current market size for smoking cessation is several billion dollars. More than 500,000 people die needlessly every year from smoking nicotine-related products, and many more get sick from smoking-related illnesses. Vaping is also increasing these numbers; it's a misconception that it's safer than tobacco. Smoking kills more individuals than other addictions and is entirely preventable. Chantix is the "most effective" drug on the market, considering there are few other treatments. Chantix sales were over $1.3 billion last year. Chantix only has a single-digit 12-month efficacy rate; this is incredibly low, making this treatment inadequate. Chantix's cancer-causing toxin prompted the FDA to recall the drug. So you're offering smokers a cancer-causing drug to prevent a cancer-causing addiction? It seems a little backward to me.

Ultimately, there is a significant unmet need for a psychedelic therapy that does not come with current drugs' main side effects and health issues and has a long and fundamentally different treatment path that's effective after 2.5 years. You're treating the brain's fundamental cause rather than taking a medication that functions as a band-aid. Most people will continue to smoke after stopping a pill such as Chantix, which is a risky and ineffective drug. Mydecine will continue to develop safer and more promising solutions with our 1st and 2nd generation psilocybin medications. Psilocybin has no long-term consequences. It is non-addictive, non-invasive, and safe in the context of approved psychedelics that exist today.

When NIDA saw this medication's positive results, promise, and potential coming out of the JHU studies, they ultimately decided it was worth providing significant funding for. The FDA already approved our IND (Investigational New Drug) for Mydecine's MYCO-001 product; we are shipping that product out in a matter of days to two to three test sites: the University of Alabama at Birmingham, Johns Hopkins University, and NYU.

CEOCFO: ***Can you touch on your patent protection?***
Mr. Bartch: The first drug we developed and manufactured to commercialize is MYCO-001. MYCO-001 is a chemical that occurs in nature but doesn't have a composition of matter patent. We think that patents written about molecules found in nature, like the one that COMPASS filed for psilocybin, don't offer enough protection.

Mydecine's MYCO-003, MYCO-004, MYCO-005, MYCO-006, and MYCO-007 drug families all hold composition of matter patents, use patents, and other layers of patent protection. These molecular families exhibit the design features of numerous similar molecules with enhanced qualities.

CEOCFO: ***You are also developing short-acting MDMA analogs and an anxiolytic for anxiety, MYCO-006. Would you tell us about that, some advantages over current treatments, and where you are with it today?***
Mr. Bartch: MYCO-006 is currently undergoing animal studies and showing auspicious results. Not only are we studying anxiety but also pain because of its analgesic properties, and we think it might help manage severe and chronic pain. Non-treatable pain remains the largest medication market. Our MDMA compounds produced new molecules that look and act like generation-1 MDMA but have enhanced qualities. The goal was to keep the drug's overall impact the same as MDMA while speeding up its onset and shortening the experience, to name a few enhancements.

MAPS is a non-profit organization that has been around since 1987. MAPS is working on the most cutting-edge psychedelic research and shares our excitement about MDMA. MAPS is utilizing the party drug "Molly"—generation-1 MDMA. MDMA-Assisted Therapy at MAPS is designed to treat PTSD, and its clinical patients are showing 67% complete remission. This surpasses any other PTSD treatments by far. Before the 1980s, PTSD was considered a general depressive disorder, and the only drugs prescribed to treat PTSD were off-label use drugs such as SSRIs.

There still have not been any PTSD medications or other advances commercialized. Generation-1 MDMA is safe and effective, with higher success rates than existing products. We hope it will be the first approved psychedelic drug and receive FDA approval this year. The industry and PTSD patients are highly anticipating this, which will also be a massive catalyst for the market. Still, because generation-1 MDMA is hard to work with, there will likely be problems with scalability, commercialization, cost, human capital, and infrastructure problems.

If you can cut a patient's time in the clinic by several hours and still get the same result, you have a blockbuster treatment. We intended to create this during the development of our generation-2 MDMA compounds. In animal testing, we have observed just that: a faster onset, a shorter time course, and increased potency, which allows the patient to take a lesser dose of the drug and receive the same effect in a shorter time.

CEOCFO: ***You tout your use of cutting-edge technology, drug development infrastructure, and artificial intelligence. Are these tools in everyday use today in drug development, and what advantages do they give you?***
Mr. Bartch: I think every new-age medicine development company that wants to succeed must use AI (artificial intelligence). Mydecine is working with Dr. Khaled Barakat's UofA AI drug research lab, which is recognized as one of the world's top AI labs for drug research. They have published in Nature and applied AI to revolutionize cancer therapy. Drug development no longer requires as much guesswork, time, and associated costs as it once did before this incredible technology.

There have been countless hypothetical drug designs, but you don't know how they will act in animals or humans, so you have to synthesize those molecules, which is expensive and time-consuming. Benchtops and assays can produce and test only so many chemicals. If they show promise on the benchtop, you move them into animal models, which are expensive and time-consuming. A quick Google search will tell you it normally costs hundreds of millions to develop a single drug. This is primarily due to guessing throughout the elimination phase to find your lead drug candidate.

AI lets you digitally construct the drug, eliminating molecular synthesis and guesswork. Digitally observe that drug bind, metabolize, and interact with receptors. With these quantum computers, long physical tests can now be done in almost no time, analyzing billions of compounds at once instead of one at a time. It will list your top selections. It expands your library with your initial idea. Then it makes billions of possible changes, runs them digitally through benchtop chemistry, picks out the best candidates, and brings the candidates into the next stage of research.

AI vastly improves drug development. It lowers the costs of making new drugs and speeds up finding lead candidates, which is lengthy and costly. AI is changing the pharmaceutical landscape as we know it, hopefully leading to personalized

medicine. As we run all animal and human models digitally with AI, the need for animal studies will be eliminated next. AI can, in advance, explain how your drug affects animals without even having to administer the drug to the test subject.

CEOCFO: ***In December 2022, you announced the sale of your subsidiary, Mindleap Health. What did that mean for you, and can you tell us how the company was doing as you closed out 2022?***
Mr. Bartch: Like many enterprises, we entered a new industry. When psychotherapy and drugs are used together for the first time in psychedelic-assisted therapy, pharmacological development, and training in therapeutic protocols can be a big obstacle. Traditional medication development differs. How to get patients and psychotherapists trained on psychedelics is one of the verticals I think should be formed. It is specialized and not taught through traditional education systems, but the number of skilled specialists who can provide these drugs and administer these treatments has quickly grown in demand. The equation still has a big gap.

We thought there wouldn't be enough clinics in different parts of the country for people to go to once a week or more than once a month. We decided to look into telemedicine and make a platform like a Zoom portal so that patients and therapists could talk to each other remotely. Mindleap was designed for this. Our game-changing product is something we're proud of and is a live app you can currently download. Regrettably, biotech stocks and capital markets were devastated over the last 18 months. Money is scarce. We had to assess where we were spending money, its potential and return, and where we might have the most targeted impact.

Ultimately, we realized that drug development was our strongest suit. The capital-intensive ancillary industries necessitated tough decisions. Selling Mindleap was challenging for us, but at least it's now in good hands with PanGenomic.

CEOCFO: ***Are you looking for more funding, investors, and partnerships? Will you be attending industry and investor conferences in 2023?***
Mr. Bartch: I believe a company must constantly communicate with the market and its shareholders if it is publicly listed. We don't plan to go after traditional funding any time soon, but we are always willing to talk to people interested in the investment opportunity Mydecine presents. We currently have an open equity line that we can use. We are now relatively lean in terms of operations, and we are at a sustainable point.

We will communicate with open market investors and will always urge them to look at our stock. Given the milestones, IP, and fundamentals we have already established, we believe we are grossly undervalued. There are a lot of other companies like Mydecine that we think will do well but aren't being correctly valued. We feel we are in the same boat, and the market offers a colossal purchasing opportunity.

CEOCFO: ***Tell us about your cofounders and how you all came together.***
Mr. Bartch: I knew our COO, Damon Michaels, and CSO, Robert Roscow, from our previous endeavors with Colorado cannabis companies. I founded and ran a nationwide cannabis company. We started in Colorado and now cover several states. I also launched and sold a tech platform. Companies were sold. ebbu employed Damon and Rob. Damon was a corporate principal, and Rob was a key scientist as head of genetics. ebbu concentrated on drug development and science, modifying molecules, isolating compounds, establishing a patent portfolio, and doing distinctive work. Canopy Growth bought ebbu for C$429 million in November 2018. That deal was one of the most significant acquisitions in the history of cannabis. ebbu was pre-revenue and was purchased for its assets and IP portfolio.

Rob was the first known scientist to apply CRISPR-Cas9 gene editing technology to enhance the cannabis plant by increasing its cannabinoid production. ebbu was one of the first companies to pioneer molecular cannabis research to map the entourage effect of mixing numerous cannabinoids for specific precision effects. a huge success. After that, we gathered, assessed our next initiative, and saw this as a great prospect. We founded Mydecine in March 2020 while the world was shutting down due to COVID.

Our Chief Medical Officer, Dr. Rakesh Jetly, and Senior Director of Clinical Trials and Regulatory Affairs, Jessica Riggleman, also deserve recognition. Rakesh came on board to work for Mydecine after retiring from a 31-year career as Head of Psychiatry for the Canadian Armed Forces.

I admire our core personnel.

CEOCFO: ***In closing, what is the significance of Mydecine, and why is your success critical to the areas you work in?***
Mr. Bartch: Mydecine was founded on the concept of "mycology medicine," which relates to the study of fungi; hence, our name, Mydecine, and our slogan is "Medicine Evolved." It was also founded on the emphasis on the mission to one day develop personalized medicine, "my medicine." It's a play on words that combines our objective of improving and eventually personalizing medicine with using all the fantastic hallucinogen and entactogen compounds throughout our evolutionary mission.

We are developing medications for target indications with extremely high mortality rates that lack innovation and are entirely dominated by the large pharmaceutical sector. They do not require innovation because many medications function commercially well with low efficacy rates and rely on how much the patient relies on them. They are stuck in an infinitive loop of taking the drug. It's a flawed and corrupt system that has to be fixed, and I believe psychedelics can make the change happen.

Finally, we are here to strive to create things that will positively impact people's lives and provide hope to many hopeless individuals. I believe that our team is highly committed and enthusiastic, which pushes us every day. Even with all of the ups and downs of the market obstacles, we have never contemplated giving up on the journey and mission we're on. We're here to see it through and do whatever it takes.