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"Innovator of therapeutics for Alzheimer's and other chronic diseases"

Delivering novel Devices-and-Odorants combination Therapeutics for Alzheimer's Disease and other Neurological Diseases

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CEOCFO: ***Mr. Nwaokobia, MBA, what is the concept behind EvON Medics, LLC?***
Mr. Nwaokobia: EvON Medics is a medical research and medical devices company. We develop therapeutic solutions, which are modifications of our novel, unique and patented Olfactory Treatment Delivery System (OTDS). This was invented by our Co-founder and Chief Scientific Officer, Dr. Evaristus Nwulia. The OTDS is an advanced device that delivers nerve enrichment and protective compounds, including botanical extracts, into the olfactory regions of the brain. It has been refined for intensive stimulation of selective brain regions that serve important functions, such as emotion control, regulation of drives, and cognitive appraisal. These devices and therapeutics were borne out of our passion for the treatment of Alzheimer's Disease and other neurological diseases.

CEOCFO: ***How does the device work?***
Mr. Nwaokobia: We have several devices, which are modifications of the OTDS. Some of the devices have been modified for treatment of Alzheimer's Disease (AD), Traumatic Brain Injury (TBI), Opioid Use Disorder (OUD), treatment refractory depression, and chronic pain. Each of these modifications have minor tweaks in their functionality. One of the devices is the COT, Computerized Olfactory Training system, used for the treatment for Alzheimer's. Another is the CBOT, Computerized Chemosensory-Based Orbitofrontal Training system, used for treatment of Opioid Use Disorder. The devices have plant-based odorant compounds housed in cartridges.

These odorant plant-based compounds have been determined as GRAS (Generally Regarded as Safe) by the FDA. The compounds are delivered through a cannula into the olfactory system of the patient. With the aid of our proprietary algorithms for cognitive training, the specific parts of the brain underlying different disease conditions are targeted to reverse the disease processes.

CEOCFO: ***How does it get to the right part of the brain? How does it know where to go? What happens in the body?***
Mr. Nwaokobia: The uniqueness and competitive advantage of our devices using odorant stimulation through the olfactory system over transcranial stimulation or electromagnetic stimulation is that our devices can stimulate the innermost parts of the brain, including the hard to reach Orbitofrontal Cortex. To answer your question, the device leverages neuroscience evidence of differences in brain regional patterns of activation and desensitization to stimuli for targeting particular brain regions versus others. We created a map or encyclopedia of stimulation paradigms specific to particular brain regions in the developmental stages of our products.

CEOCFO: ***Would it be the same dosage for everyone or would it be customized depending on the person that is using the device?***
Mr. Nwaokobia: For our SBIR Phase I clinical trials, we used the same dosage for all the participants, except those on the placebo who were given a sham device, and we got encouraging results. However, as we progress into Phase II, we will check to see if we get encouraging results with lower doses or if it works better with higher doses. We will also continue to test to see the effects of dosage on age, size, and other demographics. We have enough participants lined up for the study for these tests.

CEOCFO: ***Why use botanicals?***
Mr. Nwaokobia: Botanicals are natural substances. When you use natural substances, most of which are abundant in food, you minimize the risk of adverse and unwanted side effects. Also, natural botanicals are more acceptable to people of different cultures. There is also a trend or tendency towards using natural substances as the average person is now very health conscious.

Everyone knows that with synthetics compounds, there is the possibility of unwanted side effects. For instance, you would be surprised at the number of side effects that you can get from taking something as commonly used as aspirin.

Some of the compounds we have discovered in some of the botanicals we use are very efficient and effective in the treatment of many diseases. Hence, there is a huge pipeline for other indications for our devices. We are excited about the botanical extracts we use, and we know that going natural is something for now and the future.

CECFO: ***Which botanicals are you using? Would it vary by patient?***

Mr. Nwaokobia: We use a mixture of botanicals and this is confidential information. As stated previously, the botanicals have been confirmed GRAS by the FDA, so they are safe to use. The botanicals used will vary by indication and not by patient.

CEOCFO: ***Has anything similar been tried in the past?***
Mr. Nwaokobia: No, nothing similar has been tried in the past. This is completely novel and unique. Using botanicals as odorants and inhaling them into the olfactory system for different indications has never been tried in the past.

CEOCFO: ***What has been the interest from the medical community who are aware of what you have created?***
Mr. Nwaokobia: In the medical community, of course, many are interested in our solutions. It is exciting to many. However, everyone is interested in the data and confirmation of the efficacy of our technology, as well as the therapeutic effects.

We have preclinical data, and we have data from our SBIR Phase I clinical trials, which are exciting. However, as we progress through Phase II, of course, the sample size is much larger, we will have enough data to verify the efficacy and safety of our solutions.

CEOCFO: ***What have you learned so far that may have surprised you from the concept to the point where you are today?***
Mr. Nwaokobia: The number of indications that we continue to discover for our solutions. For example, during our SBIR Phase I clinical trials for the treatment of Opioid Use Disorder, we serendipitously discovered the effect of our solution in relieving pain. The study participants were calling us and telling us, "I don't know what you have in this device, but it us actually helping to relieve my pain, my pain is reduced and I am sleeping a lot better."

This is what spiked our interest for the development and refinement of our device for the treatment of chronic pain. There are a number of indications that we continue to discover, and this has been surprising, albeit encouraging. They are pleasant surprises, and we are working towards discovering more indications.
CEOCFO: ***What is your funding situation? Development is always expensive.***
Mr. Nwaokobia: Yes, definitely expensive. Before we started seeking SBIR (Small Business Innovation Research) funding from the NIH, the Co-founders had spent a lot of their personal funds on research and product development; close to $1 million. Luckily, we discovered the route of undiluted funding through SBIR from the National Institutes of Health. To date we have received about $2.4 million for our clinical trials. This has been helpful. We also apply a very lean approach to our operations. We are a small, but very focused and resourceful team, and I try to keep our overhead really low and manage the resources we have. These have been key to sustaining the business.

By the end of next year, we should have received an additional $5 million in undiluted funding for other SBIR projects. However, as we progress towards commercialization there will be the need for additional

funding. We are constantly in discussions with companies for strategic partnerships, but this approach has been deliberate. We are also open to investment opportunities but, I am willing to wait for the right valuation at the right time.

CEOCFO: ***How do you know when someone is experiencing pre-Alzheimer's conditions? How are you able to measure the effect of what your treatment might have, either separate from what else someone might be doing or in conjunction with something else?***

Mr. Nwaokobia: For pre-Alzheimer's, you may not be able to give an accurate diagnosis because these patients present with no symptoms. You can, however, carry out brain scans to check for deposits of beta-amyloid, which is one of the biomarkers for Alzheimer's. We also know that people that carry one or two copies of a variant of apolipoprotein E gene (APOE), known as APOE-4, have greatly increased risk of Alzheimer's disease, and that progressive smell loss in middle age is a harbinger of dementia. Therefore, we combine molecular imaging of brain amyloid levels with genetic testing and highly sensitive smell testing to determine probable predementia. In the future, we will include new blood markers of proteins known as Tau, for increased certainty in calling pre-dementia.

We can measure the effect of our treatments on patients versus what the patients might be doing with something else through well designed and controlled clinical trials. We partner with the best of medical researchers and physicians from the Johns Hopkins University and Howard University, to mention a few. Our SBIR phase I study was well designed with controlled placebo groups. We also closely monitored the properly screened participants to ensure they were not on other treatments. We continue to check for these in our SBIR phase II studies.

CEOCFO: ***The same question would apply to a relapse from opioid addiction. How can you validate what part your treatment might play along with some of the other things; maybe emotional or psychological?***

Mr. Nwaokobia: That is a good question. For this, the emphasis will also be on the design of the clinical trials and monitoring of the participants. During the screening process and periodically during the study, we ask questions to check for possible effects of positive emotional and psychological changes due to lifestyle changes or/and situational changes. This is quite tricky as there is also the possibility that these changes were triggered by using our treatments. Then of course, we have the placebo group that will be given a sham device as a control group. It is highly improbable that a similar proportion of a randomized placebo group would experience similar positive emotional and psychological changes and not present with improved conditions.

CEOCFO: ***With so many possibilities and so many possible indications for where you can help, how do you decide what to work on more actively than others?***

Mr. Nwaokobia: We are laser focused on our therapeutics for Alzheimer's Disease. This is our flagship product. We know there is a huge market for Alzheimer's Disease with the growing geriatric

population and lack of effective treatment options. There is also the pathos side of the decision as I lost my grandfather to Alzheimer's Disease. I know what it is like to care for someone living with Alzheimer's and this is what drives me to ensure we get our solution to the market as quickly as possible to help alleviate the sufferings of patients and caregivers all over the world.

The opioid crisis is also a concern to us. Opioid addiction is not something that anyone should have to go through. There are sixty million people with Opioid Use Disorder, and none of them should be experiencing this. We are also passionate about helping to curb this crisis.

There is also the option of going the wellness route of cognitive improvement in the geriatric population. This ties into our mission to enrich the quality of life through mental wellbeing. The projected global geriatric population by 2050 is 1.5 billion. This is a huge market and all we have to do is to change the claims on our Alzheimer's device.