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Developing their Drug/Device Combo Asprihale, OtiTopic, Inc. is offering a Quicker Way to Deliver Aspirin at the time of a Heart Attack

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“By having a rescue drug device that is easy to carry, and where they can rapidly inhale the aspirin with Asprihale, patients will be able to benefit from having quick access to the drug for multiple indications.” - Kambiz Yadidi

CEOCFO: Mr. Yadidi, what is the vision behind OtiTopic, Inc?

Mr. Yadidi: The vision behind OtiTopic is to develop a drug/device combo for the dry powder inhalation of aspirin. It will be used by patients at the time of heart attack as a quicker way to deliver aspirin. Cardiologists have always recommend taking aspirin as soon as possible because “time is muscle” in stopping a heart attack. We know oral aspirin enters the blood stream after thirty minutes. We are hoping that inhaled aspirin will be able to enter the blood and block platelet clotting more quickly than oral aspirin.

CEOCFO: How do you take aspirin and make it inhalable? Would you give us a little bit of the science behind what you have created?

Mr. Yadidi: Throughout the years we have developed several different formulations and ways of manufacturing inhalable aspirin. Although it has taken some time, we have finalized the new formulation of inhalable aspirin which should penetrate the deep lung periphery for faster delivery.

CEOCFO: What was the challenge in creating that?

Mr. Yadidi: The rules and regulations of developing dry powder inhalation formulations are extremely challenging and on top of that to match a formulation with a device is an additional challenge we faced. However, we have overcome these obstacles and finalized a powder that constantly delivers the same required dose.

CEOCFO: You have two new patents. What is the difference? Why two?

Mr. Yadidi: The two new patents awarded are additional to several other patents we have been awarded. OtiTopic has been awarded four additional patents in the United States; these two patents are for our final formulation and method of delivery of aspirin. With our growing patent portfolio, we will be able not only to use aspirin for the cardiovascular arena. Our patent portfolio can also support other indications. When we partner with a big pharma company, we will be exploring other indications as well. Since we have concluded a twenty-eight-day toxicology study, the data from our Tox study have the potential to support different indications other than the cardiovascular indication. As a matter of fact, this is brand new information that I am going to give you! Yesterday, we were awarded additional patents in Canada, which provides additional security for our patent portfolio. We have 23 additional patents pending internationally.

CEOCFO: Would this be administered by a professional in the hospital or a first responder, or would people have this in their house just in case?

Mr. Yadidi: Our drug / device would be recommended for high risk patients to carry it on their person. The device is portable and small enough to be taken anywhere allowing patients to utilize it effectively during an episode of a heart attack immediately. High risk patients will always be able to travel with Asprihale™ and have it in their pocket, office, home or car.

CEOFCO: *Don't most people that know they are at risk take a daily aspirin today? How does this come into play with you Inhaler use?*

Mr. Yadidi: Correct, high risk patients are being told by the cardiologists to take a daily dose of aspirin and on the onset of heart attack to additionally take one hundred and sixty-two milligrams of aspirin. However there has been a study on "Effect of Aspirin on Cardiovascular Events and Bleeding in the Healthy Elderly" by the New England Journal of Medicine published a few months ago <https://www.nejm.org/doi/full/10.1056/NEJMoa1805819> summarizing results from nineteen thousand high risk patients. In that study, they concluded "The use of low-dose aspirin as a primary prevention strategy in older adults resulted in a significantly higher risk of major hemorrhage and did not result in a significantly lower risk of cardiovascular disease than placebo. (Funded by the National Institute on Aging and others; ASPREE ClinicalTrials.gov number, NCT01038583.)". Based on my understanding of the above article, the side effects of daily use of aspirin outweighing the benefits. Hence, healthcare professionals should come up with a general consensus as to whether the use of daily aspirin is appropriate for their patients. OtiTopic will be conducting our pilot clinical study soon and we hope to demonstrate that our drug is absorbed faster as a rescue type of treatment with Asprihale than aspirin administered orally.

CEOFCO: *Are there any potential side effects?*

Mr. Yadidi: Our IND is open with FDA and we are cleared to start our pilot human clinical study. We have not tested in human yet, but we are going into human clinical trials later this year. We are not anticipating any problems, since our toxicology studies have shown that there is no adverse reactions to our product.

CEOFCO: *What has been the reception from people in the medical community who are aware of OtiTopic?*

Mr. Yadidi: In our market research study, we have interviewed doctors, several payers, the largest payers in the country, and high risk patients. Overall, they are very open to the idea. We have interviewed physicians from emergency rooms, internal medicine, and cardiologists, and they all had a positive response to our product. They thought it was extremely interesting and since aspirin is over one hundred years old, the safety aspect of it is very well known. With the concept of time is muscle, delivering aspirin and inhabiting the platelets as soon as possible would be greatly advantageous.

CEOFCO: *Are you seeking investments, funding or partnerships? Where are you today?*

Mr. Yadidi: We are a small, self-funded company and are open to partnership conversations..

CEOFCO: *Do you find that if you are talking with a potential investor that it is an easy concept to understand? Do people respond as it is so understandable?*

Mr. Yadidi: Our product is simple and so is easy to explain and understand. We are seeking partnerships with big pharmaceutical companies that are interested in taking our product to the commercialization level. We have been extremely selective on who we are speaking with. With our current timeline, we are on track to file our NDA by the end of 2020. We have been under the radar for the last four and half year, but with our patent portfolio, we are open to speaking with potential investors. The Asprihale product we are developing is revolutionizing a simple concept and, many investors are responsive and understand what we are going after.

CEOFCO: *What surprised you as you were developing ASPRIHALE™?*

Mr. Yadidi: With Aspirin's history in the drug market it was fairly surprising that no one has pursued aspirin as a dry powder inhalation for cardiovascular or any other method of delivery.

CEOFCO: *Why are OtiTopic and ASPRIHALE™ so important? Why should people pay attention?*

Mr. Yadidi: Aspirin is a drug that has been on the market for very long time. Because of its duration in the pharmaceutical industry, the medical community has been able to do extensive research and analysis on the drug. With the findings of the side effects pertaining to daily aspirin dosing, I think it is important to look at new ways to innovate this product. This New method of delivery will allow patients to receive the benefits of aspirin for other indications as well without the side effects. By having a rescue drug device that is easy to carry, and where they can rapidly inhale the aspirin with Asprihale, patients will be able to benefit from having quick access to the drug for multiple indications.