

## OcuMedic has Conquered the Ability to Deliver Drugs from a Contact Lens that has Eluded the Industry for 50 Years Replacing Eye Drops Addressing a Multi-Billion Dollar Un-Met Medical Need



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**CEOCFO: Mr. Ignatz, what is the focus for OcuMedic™, Inc?**

**Mr. Ignatz:** OcuMedic is focused on timed drug delivery to the eye via a contact lens or better termed a clear bandage lens with extended wear to replace eye drops. We are addressing a very large available eye drop market of sixteen billion dollars (\$16B) with an average compound growth rate of eight percent (8%) as a first mover in the space. In our pipeline our initial target is focused on a seven billion dollar (\$7B) segment of this particular market. I wanted to preface this by saying that for many, many years, eye doctors have been soaking contact lenses in ophthalmic drugs with the hope that they would get some kind of sustained release of the drug through the lens. However, because the lenses are not engineered to hold the drug it diffuses out immediately. With eye drops, through blinking and wash out, less than five percent of the active therapeutic gets to the target tissue. Patients are required to treat themselves and take multiple drops per day over extended periods of time, sometimes for weeks to recovery from surgery or for life in the case of a chronic disease. This dosing, lack of bio availability and poor compliance according to the literature, leads to complications in the range of about seventy billion dollars (\$70B)a year.

**CEOCFO: What is the OcuMedic approach?**

**Mr. Ignatz:** OcuMedic is engineering the material in the contact lens to hold the drug and allow it to diffuse over time. That eliminates the need for treating yourself with eye drops and provides for continuous dosing with enhanced bio availability and potentially a quicker recovery.

**CEOCFO: What about the acceptance of the patient? How do you overcome some of the reluctance from the patient about actually putting something in their eye or perhaps dealing with discomfort?**

**Mr. Ignatz:** For OcuMedic's lead indication the doctor places and replaces the device on the eye and patients are generally compliant with what the doctor prescribes. The best way to think about this is just to turn to a recent published article in Contact Lens Anterior Eye, dated the 13th of November, 2018; in other words, the last sixty days. This is basically a study that says patients and prescriber perception of contact lenses as a potential ocular drug delivery system are very positive. It was a cross sectional survey targeting patients and healthcare providers. In that survey, which came from Oxford University and Moorfields Eye Hospital in London, the following results were reported. More than sixty percent of the patients indicated they would accept the use of contact lens for ocular treatment. The most frequently used conventional treatment formulation were eye drops. More than half of the eye drop users indicated they would accept using contact lenses and that by doing so they would expect to reduce the frequency of the application of the medicine

and be less time consuming. Half of the healthcare providers were not aware of contact lenses as an ocular drug delivery method. A total of more than half of the doctors surveyed stated that they would prescribe and dispense contact lenses to treat ocular diseases if they were available. There are no contact lenses available to deliver ophthalmic drugs today.

**CEOFCO: *What is the challenge in creating a lens that will work?***

**Mr. Ignatz:** The challenge is to formulate the materials such that they will hold the drug and allow for a diffusion rate that is acceptable for the treatment of the condition. OcuMedic technology is based on the work of Mark Byrne, Ph.D. Distinguished Professor of Chemical and Biomedical Engineering and Founding Head of the Biomedical Engineering Department at Rowan University and his research team. The technology is centered on creating a memory for the drug produced in polymer synthesis with monomers complexed non-covalently to the drug that is crosslinked to the commonly used silicon hydrogel lens / corneal bandage material to provide controlled drug release over time. The contact lens industry has, for over fifty years, been attempting to develop a format of materials that would provide this benefit unsuccessfully. OcuMedic's technology is sort of the Edison story. You try a thousand different ways to create a light bulb and at one point you have the solution. That is what we have in OcuMedic's bio material science engineering. It is a solution to deliver drugs over time in a controlled fashion to the eye.

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**CEOFCO: *Is there a certain time period? Might it be only something if you want to do it for thirty days? Would it work longer or shorter? How do you know what is right? How do you equate an eye drop to your long release?***

**Mr. Ignatz:** That is a good question. What OcuMedic is focusing on are certain indications for use. We are focused on pre and post cataract surgery, where the patient is required to take eye drops for up to six weeks, post LASIK corneal ablation or corneal modeling and also for corneal abrasions. The reason why I mention a contact lens at opening that has the extended release over a seven day period is because it mimics the recall pattern of patients back to the provider. By example, if you are a cataract patient and you just completed the surgery the doctor places the lens that will deliver the anti-inflammatory pain therapy to the eye. The general standard of care is that you will return to that doctor in about a week and he will determine the course of therapy and your improvement in the reduction of the pain and inflammation. If it persists he would then take that lens or corneal bandage off and place another one on the eye. Then you would return again in another five to seven days which is the standard of care in the practice. Regarding your earlier question about patient interaction, there is no patient involvement in this delivery of therapy. The therapeutic burden of the patient having to remember to deliver eye drops and having potential compliance problems is eliminated and the delivery of the therapy is placed totally under the control of the eye care provider. For the FDA the end point of our clinical trial is proposed to be OcuMedic's delivery of drug is not inferior to the eye drop delivery of drug, and OcuMedic expects to see far better bio availability and quicker recovery times.

**CEOFCO: *Where are you today?***

**Mr. Ignatz:** The technology has been in development for some time to the point OcuMedic can routinely build prototype lenses to deliver a variety of ophthalmic agents. The company now has ten issued patents and a Freedom to Operate opinion. We have developed a platform for the delivery of a drug, that is termed as a 'first line' anti-inflammatory. First line means that the drug is commonly used by the doctor and one he or she would pull off the shelf to treat a patient post cataract or LASIK surgery for inflammation and pain. The anti-inflammatory drug is very safe and it is called bromfenac. This drug is complexed with the material and placed within the silicone hydrogel lens material. Silicone hydrogel makes up eighty percent of the contact lens market. That is what everybody is wearing; tens of millions of people, it is well accepted, it is very, very safe and we have a wear time as stated of seven days. As I mentioned, that wear time matches the patient recall pattern. That is currently the technology that we possess. We have excellent in vivo data that shows the release of bromfenac over time. We can literally dial in the number of days that this drug can be released from a week to a month. We have also demonstrated our ability to put two drugs into a lens; bromfenac anti-inflammatory and moxifloxacin which is an antibiotic. The company's main strategy is focused on the anti-inflammatory. It is a foundational drug, a "first line" drug, a popular drug used most often in recovery and treatment of the cataract and LASIK patient and those patients with corneal abrasions. This represents a very large market segment for OcuMedic and with just five percent penetration would equal a one hundred million dollar (\$100M) business. The second product in our pipe line OM004 is for Dry Eye currently in in vitro studies and a 5% share of that high growth market would be a (\$275) million dollars business. Third product in earlier development is OM006 for glaucoma with research funded by government grants.

**CEOCFO: *On the business side, might you license out the technology? Might you partner with the anti-inflammatory maker company? How is it going to work to get the pieces together?***

**Mr. Ignatz:** That is a good question. Our strategy is based upon clinically developing the technology toward the completion of a Phase I, II study; Phase I being safety and Phase II demonstrating efficacy in the human being. The M&A market is very interesting in that there are currently a number of take outs at Phase II of companies that have developed technology to reduce the number of eye drops a patient must take or to eliminate drops totally. None of the relevant competitors are utilizing a contact lens technology, which is well understood and accepted by clinicians, but with different kinds of devices that you put under the lid of the eye or a gel that you put on top of the eye, to reduce the number of eye drops. I will point out that there are two recent take outs; one with EyeGate Pharmaceuticals Inc., which licensed out to B&L-Valeant Pharmaceuticals for \$135 million with Phase 2 data and the other ForSight VISION5 licensed out to Allergan plc (NYSE: AGN) for \$95 million. These are take outs. Our objective is to advance this technology towards an exit in a short period of time over the next thirty to forty eight months with human Phase II data. We also expect that as we move forward that we will provide technology to a variety of companies to assist them in their drug development to demonstrate an improved "Therapeutic Index" over drops and potentially a new patent or in their contact lens efforts to expand wear times by delivering comfort agents.

**CEOCFO: *What is your financial picture like today at OcuMedic?***

**Mr. Ignatz:** Earlier the company received \$1.5 million dollars from NIH and the NSF. Now we are focused on a Series A financing. Currently, the company has an open Series A term sheet priced by the Rowan Innovation Venture Fund. The fund provided an initial \$250,000 investment to the company and they are committed to a follow on investment of \$250,000, when the company has raised an additional \$1.75 million dollars. Our pre money evaluation is \$7 million with a price per share of \$1. The offering is \$4 million. We have a minimum of \$25,000 investment. There is fifty percent warrant coverage on the investment at an exercise price of \$0.01. In addition, we have a recently issued due diligence report through Keiretsu Forum Mid-Atlantic. It is a forty five page report that is authored by two third party Ph.D.s that discusses the technology, benefits, and the market opportunity for the investment.

**CEOCFO: *Do you find when people in the investment community hear the story that they understand easily?***

**Mr. Ignatz:** Immediately! They immediately get the idea of eliminating eye drops. They may not be sensitive to the amount of activity currently focused in the eye care space around different ways to reduce or eliminate eye drops, but they clearly understand the key benefits of what we are talking about; that one, blinking and wash out and tearing is a factor in taking eye drops. Most people have experienced that. They do not understand that less than five percent of the drop is actually getting to the target tissue. Second, they do understand that you have to take multiple drops per day and even those that have experienced this say, "Yes, I forgot to take my drops today or for a couple of days and I have had to go back to the doctor more frequently." Thus compliance is an issue. They do understand and get the idea that if you have a continuous delivery of drug to the target tissue it can speed recovery; they do understand that there is no patient involvement. The doctor puts it on and takes it off, so patient self-treatment is eliminated. They get the idea that if you can treat more effectively you can recover more quickly thus the technology can really impact healthcare costs. Therefore, they get that. The most important thing that I have to continue to emphasize is that the eye care professionals are already trained to deliver our therapy at the point of care. In a typical eye care office contact lenses are inventoried. They are there on the shelf. Providers basically pull inventory off the shelf and these doctors know how to put it on and take it off the eye and they train people to do it if they are correcting vision. In this case we have a clear lens that is a bandage and the doctor knows how to put it on and take it off and there is no training required. It is already in their DNA and they understand the concept.

**CEOCFO: *Has this or something similar been tried before? What is the competitive landscape?***

**Mr. Ignatz:** I will say there has never been a contact lens / corneal bandage on the market however there have been some gel bandages and other technologies on the market; Alza Corporation had Ocusert®, and Bausch & Lomb had LACRISERT®. These are little disks that you put under the lid that would deliver a drug and the purpose is to reduce pressure in the eye due to glaucoma. They suffered from foreign body sensation. They had issues with the drug bursting out thus not constant delivery or they would fall out halting drug delivery and that is not a good situation. Both of these devices are off the market. There are others that have been in development; Ocular Therapeutix and Mati Therapeutics that have a drug in a plug, a punctal plug that goes into this little hole in your lid and they are proposing to deliver glaucoma therapies through this approach. There are other novel approaches to delivering eye drops in development. One is Eyenovia, and they use an ink jet sprayer in a little hand held device and they spray the drug onto the cornea in micro pixels. The company has reported that they try to do this fast, better than the eighty millisecond blink rate of the eye; if you have ever had wind blowing in your eye and such, I question the patient acceptance. As mentioned the two companies that have been taken out recently, EyeGate Pharma (NASDAQ: EYEG) had a corneal bandage with a gel to extend the release of a drug or they used iontophoresis, which is an electronic technology that the doctor would place on

the eye to drive drugs to the target tissue. That was bought by B&L-Valeant. Additionally, there is a ring that goes around and under your lid; again a non-standard kind of technology to basically deliver a glaucoma therapy. All of these require doctor training or patient training. None of the competition has the wide safety and wear ability acceptance of a contact lens that all doctors know how to deliver. That is the competition.

**CEO CFO: *It sounds like you have an edge on competitive technologies!***

**Mr. Ignatz:** All non-standard technology, all requiring new training and I think that we have a nice fit with what the profession knows how to deliver.

**CEO CFO: *How do you stand out at a conference? There are so many people and so many ideas. How do you garner exposure?***

**Mr. Ignatz:** OcuMedic has a very direct and focused story that has been risk reduced up front addressing investor questions so they better understand the opportunity. There are really two things here. One is patient and provider acceptance of the technology thru survey data and strong in vivo data. We point out the enabling intellectual property with ten issued patents and a Freedom to Operate (FTO) opinion from our attorney's and the compelling in vivo data demonstrates our ability to dial in the delivery of the drug over time. OcuMedic thus has a clear focus on a large un-met medical need that doctors know how to deliver. Additionally, the opportunity for a potentially quick EXIT. I like to state this Series A could be the last money in this deal toward an exit based on the benchmarks that I have already highlighted to you. Beyond that, from a commercial point of view a compelling aspect of our technology is that reimbursement will be immediate for the technology once approved and reimbursement drives adoption. Doctors will get paid to put OcuMedic's corneal bandage on a patient's eye where they do not get paid today. The reason for that is that there are CPT codes, 92070 and 92071, that calls out the use of a corneal bandage with silicon hydrogel material for; corneal abrasion, dry eye, ulcers and erosions. After approval we will be making submissions to AMA and CMS for a HCPCS code for the delivery of the drug. It usually takes a little bit of time after approval. Therefore, that is an aspect of the commercial opportunity that we like to point out to investors as well to acquirers of our technology it can fit seamlessly into the industries current manufacturing processes without costly additional tooling.

