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Mystic Pharmaceuticals is emerging as a leading innovator in patient focused Drug Delivery for Ophthalmic and Intranasal drugs and biologics

Healthcare
Specialty Pharma

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Timothy Sullivan
President & CEO

BIO:
Timothy Sullivan is Co-Founder, President & CEO of Mystic Pharmaceuticals. Over the past 37 years he has created novel technologies, products, and services and grown seven companies, three of which were acquired by major corporations. Mr. Sullivan is co-inventor of Mystic's novel drug delivery technology platforms and responsible for defining both the technological and strategic direction of Mystic. He has recruited and led a highly accomplished team of scientists, engineers and business professionals through early stage R&D programs, clinical trials and the deployment of a cGMP production facility for Mystic's innovative delivery technologies. He holds ten issued/pending patents in the field of drug/biologic packaging and delivery.

About
Mystic Pharmaceuticals, Inc.:
Mystic Pharmaceuticals blends inspired creativity with scientific discipline to provide patient focused drug delivery solutions for pharmaceutical, biotech and healthcare companies worldwide. Mystic has engineered solutions to challenging drug delivery problems, and offers customized devices and packaging tailored to meet technical specifications and other market requirements. The company offers drug and biologic delivery systems for liquid and powder with delivery solutions designed for ophthalmic, intranasal, sublingual, buccal, and dermal delivery.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Mr. Sullivan, what was the concept when you founded Mystic Pharmaceuticals and where are you today?
Mr. Sullivan: The basic idea began with a fundamental question - "Why do eye drops always overflow when you put them in your eye?" It seemed like a simple question, and in fact the answer turned out to be pretty simple as well. However, developing a technological solution that also addressed the wide-ranging needs of all the stakeholders such as regulatory agencies, pharma manufacturers, physicians and patients was much more complex. That was back in 2002.

CEOCFO: Why do eye drops overflow and what have you figured out so that they do not?
Mr. Sullivan: It turns out to be a physics problem. The eye can hold about seven to ten micro liters of fluid and the traditional eye drop bottle usually dispenses about forty to fifty microliters, depending upon how hard you squeeze the bottle. The physics challenge occurs because the eye drop bottle generally relies on gravity to pull the drop off of the tip of the bottle. The eye drop has to be of sufficient mass for gravity to be able to overcome the surface tension and pull it off of the tip of the bottle. During that time, the patient has to hold the bottle above their head, steady it over their eye, aim it properly, squeeze the bottle and not poke themselves in the eye. Because the drop is four times what the eye can hold, once it hits the eye several things happen. Some of the drug will stay in the eye and be absorbed, a larger portion overflows and runs down your face and some of the excess drug flows into your lacrimal duct, which is your tear duct, through the nose and ultimately into your throat where it can be systemically absorbed into the body. That can result in side effects that, depending upon what the drug compound is, could be very undesirable.

CEOCFO: How have you solved the problem, or have you solved the problem?
Mr. Sullivan: We did. There has been very limited innovation in ophthalmic drug delivery to the front of the eye over the last one hundred years. Roughly ninety percent of all marketed eye drops are dispensed out of an eye drop bottle of some form. The big innovation that occurred about twenty years ago was the blow fill seal vial, which was a single use eye drop bottle. Basically, it is the little vial that you break the top off of, squirt it into each eye and

then throw it and whatever drug is left away. The innovation of the single use vial was that it utilized an aseptic manufacturing process which allowed the development of preservative free drug formulations. The single use vial kept the drug sterile until it was used. Preservative free formulations are desired by patients and pharma manufacturers for a variety of reasons. Preservative free can reduce the stinging sensation of some drugs as one benefit. Although there is some controversy over the relative merits of preservative free formulations, in general the pharmaceutical companies like the idea of "preservative free", because it gives them a marketing advantage. The use of preservatives, especially in drugs for treating chronic diseases such as glaucoma, can irritate the eye and be uncomfortable for the patient. Comfort and tolerability for a drug that is taken daily has a major impact on patient compliance. Improved patient compliance leads to improved health outcomes which is the ultimate objective of any therapy. The capability to support preservative free formulations was one of twelve key design inputs that we incorporated as we began to innovate our delivery platforms. Innovating a solution that would address all twelve of the key design input criteria demanded that we NOT take an incremental innovation approach and develop a better eye drop bottle. Although incremental innovation is a low risk approach employed by many of our competitors, we stepped back and looked at the mechanics of ophthalmic delivery from the patient's perspective. We also looked at what advances would benefit the key stakeholders in the value chain of developing and commercializing ophthalmic pharmaceutical products: these stakeholders included pharmaceutical manufacturers, the patient and the physician. We created the concept of a "value map", and identified those dimensions of value that would be important to those three different stakeholders in the product value chain. Those dimensions of value became design inputs that served as the foundation for our innovation and development program. The result was a very different approach to delivering ophthalmic drugs. We package each eye drop

individually in a tiny blister system. Then those blisters are packaged in multi-dose dispenser devices that are designed to be very patient friendly. The patient interfaces with the dispenser device, so they never see the blisters. This approach enables the device to very precisely control delivered dose volume. For example, while an eye drop bottle will dispense a minimum drop of forty micro liters with a variability of twenty microliters, we can calibrate a delivered dose to any volume between five micro liters and thirty microliters, and enable a patient to consistently self administer the dose with a precision of about two micro liters of variability. Our delivery systems operate consistently across a wide range of different types of patients. These capabilities offer very compelling opportunities for drug formulators. It overcomes the problem of excessive dosing and the side effects that can come about as a result of that, and provides the option to formulate low dose high potency products for improved safety. There are other key innovations our technology provides: our unit dose blister packaging technology employs an aseptic process. Therefore, we can support preservative free formulations. Our dispenser devices do not use gravity to move the dose into the eye; we actually dispense the dose as a gentle spray. This eliminates the need to hold the bottle over the head and aim the drop into the eye. Our dispensers include a dose counter so you always know how many doses are remaining and how many you have taken.

CEOCFO: Who is using your services today? Where are you in the process?
Mr. Sullivan: The company has been in R&D for several years. We successfully completed our first clinical trial. We are now looking at the next round of clinical studies and are working on an OTC ophthalmic product that could be in the market next year. We anticipate the first Rx products using our technology to enter the market in about three years.

CEOCFO: Will you be doing the manufacturing?
Mr. Sullivan: Yes. A key element of our technology innovation includes the manufacturing technology for aseptic packaging of the drugs in the blister system. While the devices themselves have certain novel aspects to them, they are made from a standard injection molding process. Producing and filling the unit dose blisters requires a novel technology that we have developed using existing form fill seal technology. We have advanced this technology to be capable of aseptic manufacturing at commercial scale production volumes that are very cost effective. We have deployed a pilot cGMP manufacturing facility in Austin Texas, which is our corporate headquarters. We will expand as we approach the commercial opportunity, either directly or in partnership with some large contract manufacturing organizations that are in the pharmaceutical packaging space already.

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"Change…there is nothing more difficult to take in hand, more perilous to conduct, or more uncertain in its success than to take the lead in the introduction of a new order of things."

I pull this out periodically to remind myself that innovating is not enough… one must also be tenacious, humble, intractable and sometimes slightly crazy to actually manifest a creative idea in the real world. A little bit of luck does not hurt either."- Timothy Sullivan

CEOCFO: In addition to the ophthalmic area I know that you are working on some other areas as well. What is on the back burner or in the pipeline?
Mr. Sullivan: There are a couple of things. In the ophthalmic space we are developing some of our own drug products and putting them into our delivery systems. Another opportunity we are exploring is the use of our VersiDoser® and VRx2™ technology platforms for delivering drugs and biologics via other routes of administration to the body. We have the capability to take this same technology and apply it for delivery of drugs systemically into the body through the nose, intracranial delivery to the brain, sublingual and buccal delivery into the body through the oral cavity, and dermal delivery. Being that we have limited resources we are focusing our development activities on intracranial and systemic intranasal delivery spanning small molecule drugs as well as biologics. We have developed a number of intranasal delivery devices and are actively pursuing partnerships to bring that technology together with those drugs and biologics for such applications as vaccines and central nervous system indications like pain and migraine. Another area of development for us is the evolution of "intelligent" devices. Intelligent drug delivery systems are the next wave of evolution. These devices will notify you when it is time to take your drug, track your compliance to the prescribed use, notify you when it is time to reorder, or just handle the reorder for you and advise you if you are about to take your drug too soon. This is the coming generation of pharmaceutical products that will facilitate patient compliance and lead to improved health outcomes.

CEOCFO: Will you be looking for funding as you go forward or do you have enough now?
Mr. Sullivan: Finding funding is an ongoing process. We are gearing up for another round of funding to take forward some of these new development programs that I just mentioned. Because we have a technology platform we are always looking at the potential for strategic partnering relationships with larger companies that may have a need for this type of technology to combine with their development pipelines of drugs and biologics. We would look to those potential partners as potential funding sources as well, to carry this technology into other areas.

CEOCFO: There seem to be cycles in what the investment community has interest in. Is drug delivery in favor these days?
Mr. Sullivan: Drug delivery is in favor as long as the focus is around a product; less so for a standalone technology platform. Strategic investors are looking at combining drugs with novel delivery system to produce combination products that offer a true competitive advantage in the market and can command higher prices than a generic. That is also true of the large pharma companies that are seeking to do product line extensions of their current products or license new combination products that are well along the development path. The interest in competitive drug device combination products is very strong.

CEOCFO: You personally have a long history in bringing concepts to success. What have you learned in your past ventures that is most applicable for you at Mystic?
Mr. Sullivan: For the past twenty years or so I have carried a quote in my personal journal attributed to Niccolo Machivaelli: *"Change…there is nothing more difficult to take in hand, more perilous to conduct, or more uncertain in its success than to take the lead in the introduction of a new order of things."* I pull this out periodically to remind myself that innovating is not enough… one must also be tenacious, humble, intractable and sometimes slightly crazy to actually manifest a creative idea in the real world. It is difficult to predict the shifts in the market, the shifts in the economy, the shifts in the priorities of the key stakeholders in a market; the very large companies that have a large vested interest that may be threatened by a disruptive technology like ours. Therefore, one has to maintain an awareness of the external operating environment and its driving forces to understand how those factors will drive the market interest for your innovations, and then be responsive to that. A little bit of luck does not hurt either.

CEOCFO: What are the next steps? What do you see in the next year or so?
Mr. Sullivan: We anticipate moving forward in two key areas. One is the development of combination drug/device products driven through our own efforts or in conjunction with potential partners in the ophthalmic space. We are also looking at those opportunities in the intranasal space. The other area that we are exploring is advancing the next generation of intelligent delivery systems. We built some early prototypes of intelligent delivery systems a number of years ago, and then decided to hold on advancing those until the market interest for that type of innovation had evolved. We were a bit ahead of time with those innovations. The concept of adherence packaging and adherence programs that serve to drive better patient compliance and a better patient experience with a product is gaining strength in the pharmaceutical industry right now. In the ophthalmic space in particular there are huge disconnects with compliance, particularly with the elderly population, in getting them to be able to consistently and accurately take their prescribed drug products. We have incorporated the concept of adherence packaging into our technology since day one.

CEOCFO: Why should Mystic Pharmaceuticals stand out for investors and people in the business community?
Mr. Sullivan: We lead with applied innovation, with the objective of developing commercial products that substantially improve the competitive differentiation from the perspective of the patient experience with the product. We generally focus on large market opportunities. Most of the products and therapeutic indication categories have market sizes of anywhere from several hundred million to several billion dollars. We also focus on drug/device combination products that are lower risk on a relative basis. These are typically proven drugs for

proven market and we can repackage in our delivery technology and offer a significantly better product. That presents some very compelling business and investment opportunities. Finally, Mystic has multiple shots on goal from an investment perspective. Because it is a technology platform there are a number of different directions that we can go. That means that an investor does not necessarily have their “eggs all in one basket” with our type of opportunity, because we have that flexibility.

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