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Using Resorbable Barbed Sutures, Zelegent, Inc. has developed a revolutionary new way to Treat Simple Snoring

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CEOCFO: *Dr. Arrow, what is Zelegent® about? What have you developed up to date?*

Dr. Arrow: Zelegent is a four-year old company, co-founded by a couple of sleep specialist otolaryngologist physicians -- that is E.N.T. or Ear, Nose and Throat physicians -- who noticed that the available medical interventions to treat simple snoring, that is primary snoring without sleep apnea, were not optimal. They also noticed that in the last couple of decades plastic surgeons had been achieving a new degree of minimal-invasiveness in face lifts and other cosmetic surgical procedures by using a new kind of suture -- barbed resorbable sutures. Observing that, these sleep specialist otolaryngologists decided that we ought to be able to use resorbable barbed sutures to perform a minimally invasive procedure in the soft palate. Such a procedure could treat snoring in a way that would avoid all of the drawbacks of the currently available snoring interventions. Those main drawbacks being either (1) requiring the patient to wear an appliance at night, which inevitably leads to non-compliance for most people or (2) relying on moving the base of the tongue, which has the limitations that it only really treats the source of the snoring if the base of the tongue was the source of the airway obstruction. In most patients it is the soft palate, rather than the base of the tongue, that is the source of the airway obstruction. And third, (3) those technologies that do work on the soft palate tend to be very invasive or painful procedures, like Uvulopalatopharyngoplasty, or the "U-triple-P" procedure, in which the soft palate is resected. Therefore, the founders of Zelegent said, "All we have to do is create a minimally invasive tool for deploying resorbable barbed suture into the soft palate in a way that can be done in an office setting, without having to bring the patient to the operating and use general anesthesia and we would have a really attractive therapeutic option for primary snoring without sleep apnea." That is what Zelegent was founded to do and that is what we have developed over the last four years. We first had to take the concept and reduce it to a manufacturable, commercializable product.

CEOCFO: *What is the physician actually doing during the procedure?*

Dr. Arrow: The physician is deploying a set of three eighteen-millimeter long barbed suture implants into the patient's soft palate, using a specialized tool that we provide in our kit. It is a mechanically simple device consisting of a curved specialized metal needle with a divot on the end that couples with the distal end of our suture implant. The purpose of the curved needle is simply to push the suture implant into the soft palate. If that sounds painful, contrast that with *cutting* the soft palate. It is far, far less painful than that. You simply need a couple of shots with lidocaine, the same very mild local anesthetic that's used for short acting local anesthesia. It's the kind of small needle shot you'd receive if you went to an E.R. because you cut your hand and you needed stitches, for example. This is what they would do numb up your skin before they give you stitches. This is lidocaine. It is also often used in dental procedures. It is the same kind of short acting local anesthetic. That is all that is necessary to numb up the soft palate in order to perform Elevoplasty®. The physician then picks up the handle of our tool (there are three of them, each preloaded with one suture implant), and inserts them into the soft palate, one after another and then removing the needle out of the same whole that it entered.

Each needle is disposed of after a single use. Then the physician tugs or gently pulls on the black thread coming out of the patient's mouth. Those are the silk suture threads to which the implant suture is attached. That gives the soft palate a little bit of a *lift* by compressing it a bit, which is what creates more airway space and then cutting off those threads, the silk suture, and leaving the implant in place. That is what they physician does.

CEOCFO: *Is it the same for everyone? Are there variations from one person to another?*

Dr. Arrow: Yes, the procedure is one size fits all. You may have a patient that has an unusually narrow soft palate and then you might use only two implants instead of all three. Patients who have a lot of obstruction would not be good candidates for this procedure. That's because what we are doing is fairly mild compared to other kinds of interventions. Elevoplasty is minimally invasive, easy to do, and does not require the operating room. However, we are not shortening the soft palate as much as a UPPP would do. That is a more drastic procedure.

CEOCFO: *What percentage of snorers might this help?*

Dr. Arrow: The best way to answer that question is from the data from our clinical trial in which we measured efficacy. Of the fifty-two patients in our clinical study, the average reduction of snoring severity, as judged by the patients bed partner, was twenty-five to thirty percent at all three time points that we measured -- which was one month, three months and six months after the procedure.

“The non-reimbursed, lifestyle improvement or cosmetic procedures are traditionally the realm of plastic surgeons, dermatologists and to some extent ophthalmologists. However, many ENT physicians are open to offering this kind of procedure their patients. Some of them say that it is “about time” that they have a self-paid, self-improvement procedure to offer patients. Some of them even say they “should be taking a page from the playbook of our plastic surgeon colleagues.”- Dr. Alexander K Arrow

CEOCFO: *Is it a permanent procedure?*

Dr. Arrow: No, it is not permanent. The soft palate is a malleable and soft tissue that remodels over time and gets longer as we age. Elevoplasty is inherently temporary. The suture implants are made of a resorbable material that is entirely absorbed by the body in six months. It is the same material that plastic surgeons use in barbed sutures in face life procedures. However, the benefits of Elevoplasty may last for more than six months because during the time while the suture implant is intact, before it absorbs, the tissue remodels to adapt to its new position. Therefore, there may not even be a reason for a permanent implant holding the tissue up, because a permanent implant might not actually be serving any purpose after a few months anyway. Over time the tissue is expected to sag again and return to its original state. Therefore, this is a procedure that you would want to do periodically as a touch up, somewhat like the way Botox is used in cosmetic Botox procedures for wrinkles. You go in for a touch up once a year. It's a minor enough procedure that people do not mind doing that. It's a similar idea with Elevoplasty®.

CEOCFO: *What has been the response from the medical community?*

Dr. Arrow: The Elevo Kit just received its FDA 510K clearance last month, so it is not yet out to the medical community. Stay tuned and we'll tell you about their response.

CEOCFO: *What has been the response from the people who are aware of Elevoplasty?*

Dr. Arrow: Only 52 people have had an Elevoplasty procedure. There were the patients in the SILENCE clinical trial. Most of them noted a significant benefit from the procedure, and perhaps more importantly, most of their spouses or bed partners did. These data have been submitted for publication later this year. The relatively small number of ENT physicians who have been working with us (the eight who were investigators in the SILENCE clinical trial, the five on our clinical advisory board, and the nine practicing ENT physicians who chose to invest in our company) believe that this could be a useful treatment option for snoring patients who do not have sleep apnea and do not want to wear an appliance at night and do not want surgery. For those patients, this may be an excellent alternative to alleviate snoring.

CEOCFO: *Are many snorers looking for a solution or are they more forced into it by a partner? Should people be worried about snoring?*

Dr. Arrow: Compared to other medical ailments, snoring is not normally a life threatening condition like cancer or heart disease. Although snoring is a pre condition leading to sleep apnea and sleep apnea is thought to lead to arrhythmias and other forms of heart disease. Therefore, it is, perhaps a gateway condition toward other more serious conditions. And by itself, it may a serious disruptor of quality of life for many couples. It is, as you mentioned and alluded to in your question, often times it is the spouse or the bed partner that brings the patients in for treatment, and that is fine. That's important.

That's one of the benefits of having this. In our clinical trial, all fifty-two patients who were in the trial had to have a bed partner who was able to judge their snoring before and after the procedure. We think it is legitimate to be treating the patient for the benefit of the bed partner. The patient stands to benefit him or herself as well, because it could reduce daytime sleepiness, improving quality of life.

CEOCFO: *Have there been other attempts at something similar or is this a brand new way of approaching the issue of simple snoring?*

Dr. Arrow: There have been dozens of attempts to intervene to correct snoring. Most of them have involved moving the jaw forward, which only really works if the base of the tongue is the source of the patient's airway obstruction. But with non-obese patients suffering from simple snoring without sleep apnea; the source of the obstruction is not usually the back of the tongue. It's the soft palate; that floppy piece of tissue that hangs down onto the back of the throat while we lie on our back. There have been relatively fewer attempts to treat the soft palate, but there have been some. There was a notable device that came out about fifteen years ago called the Pillar Palatal system and that is still in use today and has some loyal followers. We think the Pillar system did not break into the main stream because it has a couple of limitations; namely that it (a) stiffens, but does not shorten the soft palate, and (b) it is a permanent implant so it has a rate of extrusion. There have been other attempts to treat the soft palate, but most have been surgical, and most patients are not interested in surgery.

CEOCFO: *What surprised you during the trials or during the process from conception to reality?*

Dr. Arrow: We were surprised at how long it takes for institutional review boards to approve a clinical trial protocol at certain hospitals. It took us a full year at some of the hospitals where we thought we could participate in a clinical trial. The trial was completed before we could start enrolling patients at some of the hospitals with physicians who were enthusiastic about enrolling patients. That was a surprise. We were pleasantly surprised by some of the outcomes. We had patients that were anecdotally telling us that this was a life-changing procedure for them, because the results were so good. It did not help everybody. But if you can help most of the people achieve a significant amount of reduction then you are doing something worthwhile, and we feel good about that.

CEOCFO: *Would you tell us about your agreement with Cook Medical, Inc.?*

Dr. Arrow: Cook Medical, Inc. is large but innovative medical device company with an excellent reputation among physicians, and a mandate to grow their ENT division. We are pleased to be partnered with Cook, because of the terrific team and sales force there but also because Cook is known as a particularly data-driven and result outcomes oriented medical technology company by physicians. It is a conservative company that does not take chances on many unproven things, so it was a vote of confidence that they have chosen to work with us and make Elevoplasty a flagship item in their plan to grow their ENT business. Cook is a much bigger company in its interventional cardiology and interventional radiology lined business. Its ENT business is relatively newer and smaller but it has the resources and the plan to grow perhaps catch up with the size of some of their other divisions like cardiology or urology.

CEOCFO: *Do you have or do you need a reimbursement code? What is the status of reimbursement right now?*

Dr. Arrow: Elevoplasty is a self-improvement or wellness procedure. We treat snoring without sleep apnea. Treating sleep apnea is reimbursable. Snoring by itself is not, at least not currently. Therefore, we are in the self-pay part of that equation. If the CMS or 3rd party insurers change their mind about that and begin reimbursing for snoring therapies without sleep apnea in cases in which it can be documented to improve the patient's health, then we will apply for a code. Until then, patients will invest in their own quality of life improvement similar to the way people pay for Botox cosmetic therapy.

CEOCFO: *Are ENTs involved with many life style procedures today or would this be something a bit newer for them?*

Dr. Arrow: This is a bit newer, yes. The non-reimbursed, lifestyle improvement or cosmetic procedures are traditionally the realm of plastic surgeons, dermatologists and to some extent ophthalmologists. However, many ENT physicians are open to offering this kind of procedure their patients. Some of them say that it is "about time" that they have a self-paid, self-improvement procedure to offer patients. Some of them even say they "should be taking a page from the playbook of our plastic surgeon colleagues."

CEOCFO: *Is it more of an opportunity than a challenge?*

Dr. Arrow: I guess it is a little of both. It is a challenge because you are getting physicians to think and act in ways that they may not be used to. On the other hand, we think we are tapping into a need that some of them have already expressed -- for wanting to have that kind of a business and cater to client who are paying voluntarily for a self-improvement procedure. Some cosmetic surgeons and cosmetic dermatologists have large lucrative practices in which

one hundred percent of what they do is self-pay, self-improvement cosmetic procedures. Some ENTs would like to have something similar to that.

CEOCFO: *Is there much training involved for the surgeon performing Elevoplasty?*

Dr. Arrow: Elevoplasty is a training-dependent procedure. That means that we are not going to be selling this kit to doctors before they have been trained on the procedure. It is not a lengthy training process, because the procedure is quite simple. However, there are a few key points that the physician should be coached on to make sure that they get optimal results.

CEOCFO: *What are the next steps? What will happen over the next six months or a year as far as rolling out?*

Dr. Arrow: 2019 is a year focused on physician training for us, now that we have our FDA 510K clearance. We have our sales and marketing partner and we want to get a substantial number of physicians trained on Elevoplasty, so that when patients become aware of it they will have places to go. We think it would be a mistake if we were to go directly to public advertising and get a lot of patients interested in the procedure now, because there just are not enough physicians yet that are trained. First, we train the physicians. That should take the course of this entire year if we do it right, as we methodically enter major cities.

CEOCFO: *What is the key to getting attention from the physicians or will Cook Medical, in addition to distribution, be doing part of that as well?*

Dr. Arrow: Cook is in charge of marketing, which includes the outreach to physicians (other than the ones that I meet at physicians conferences and trade shows).

CEOCFO: *Doctors of all types have people approaching them with new ideas, new products and new services, both medically and administratively. What is the key to gaining attention?*

Dr. Arrow: The key is making it clear to them that there's a new alternative for patients who have who have been asking for a particular kind of therapy -- like relief from snoring for patients who are not interested in painful surgery with a three week recovery period and do not want to wear an appliance at night. In our case, those patients are already well known to most sleep specialist/ENT physicians. If you talk to most sleep specialist/ENT physicians and ask if they have patients who want snoring therapeutic intervention and are not interested in what is available today and they will say, "Yes, I have ten or twelve patients who are exactly like that. I can enroll ten or twelve patients without having to do any outreach or advertising, because these are the people who have already asked me about a solution and they do not want to have surgery or wear an appliance."

CEOCFO: *Are you seeking funding, investments or partnerships as you move forward?*

Dr. Arrow: We had the good fortunes to have raised enough capital in 2015, the year that we started to company, that has funded us to date. Zelegent has an unusually higher proportion of physician ownership. We are some 43% owned by practicing physicians.

CEOCFO: *Why is Zelegent an important company and Elevoplasty important concept?*

Dr. Arrow: Zelegent is on a mission to improve the lives of snoring patients, which affects one out of every five adult males and one out of every ten women in the developed world. That's a lot of people whose lives we could improve. Once when we were at our assembly plant making the Elevoplasty kits someone pointed to a stack of Elevoplasty kits and said, "Look, every one of those is a saved marriage." Therefore, what we are doing is important and is an improvement in the quality of life for many couples and many people and we feel good about that. We have a worthwhile mission.