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Interviews & News!

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Artes Medical is creating a completely new category in the injectable aesthetics market with their dermal filler ArteFill® product that permanently corrects wrinkles



Healthcare
Medical Devices
(ARTE-NASDAQ)

Artes Medical, Inc.

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Diane S. Goostree
President and CEO

Interview conducted by:
Lynn Fosse, Senior Editor
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BIO:

Diane S. Goostree has been Artes Medical's Chief Executive Officer since November 2006 and President since March 2006. She also served as Artes Medical's Chief Operating Officer from March 2006 to November 2006. From September 2002 to February 2006, Ms. Goostree was

employed with SkinMedica, Inc., a dermatology specialty pharmaceutical company, most recently serving as Senior Vice President, Corporate Development and Operations. From May 2002 to September 2002, Ms. Goostree served as a consultant for SkinMedica, Inc. From November 2000 to May 2002, Ms. Goostree served as Vice President, Business Development at Elan Pharmaceuticals, a biotechnology company. Prior to that, Ms. Goostree worked for Dura Pharmaceuticals in a variety of roles, including Regional Sales Director, and most recently as Vice President of Business Development from September 1995 until its acquisition by Elan Pharmaceuticals in November 2000. Ms. Goostree holds a B.S. in Chemical Engineering from the University of Kansas and an M.B.A. from the University of Missouri in Kansas City.

Company Profile:

Artes Medical is a medical technology company focused on developing, manufacturing and commercializing a new category of aesthetic injectable products for the dermatology and plastic surgery markets. The Company's initial product, ArteFill®, is being marketed to men and women as a treatment option for the correction of nasolabial folds, known as smile lines.

CEOCFO: Ms. Goostree, you are new to the CEO position at Artes Medical; what is your vision and how are you getting there?

Ms. Goostree: "Our company is in the medical device space marketing an injectable aesthetic product, ArteFill, that is a treatment for facial wrinkles. As we all know, baby boomers are aging and looking for a way to age gracefully. We have

developed the first and only injectable wrinkle filler that has a permanent component that provides a long-term effect compared to the existing dermal fillers on the market that are all temporary in nature and required repeated and frequent injections. Therefore, our product is very differentiated. We have just launched it into the marketplace in the US, and we will be reaching out to physicians and consumers who are interested in a long-lasting wrinkle filler. This product competes in the area that most people have heard about—the injectable aesthetics market which includes Botox® (Botulinum toxin) from Allergan, Inc. (AGN-NYSE), Restylane® (a clear hyaluronic acid-based gel dermal filler), and collagen. ArteFill is the first and only product approved by the FDA with a permanent component and we have clinical data showing that smile-line wrinkles can be corrected for up to 5 years, so it is really a break-through product in this category."

CEOCFO: How do you get the medical community to pay attention, and do you go to the people first, the doctors first or both?

Ms. Goostree: "It is important to reach out to both interested constituents there. We reach out to our physicians by making sure that all of our scientific information is readily available to them. Recently at the annual American Academy of Dermatology, a meeting held in Washington D.C., with over 9000 dermatologists in attendance, we presented our five-year data at one of the dermal filler sessions. We will also be publishing it in a peer-reviewed journal and will be submitting it to the FDA in order to obtain enhancement of our labeling, which contains the official guidelines for using the

product. Separately we are reaching out to consumers to help them become aware of this new product, ArteFill®, by working with various women's and beauty magazines. We will be having a beauty editors luncheon in New York in the next couple of months with some of our key opinion leaders who are very active in helping women's magazines and beauty editors understand what new technologies have been approved by the FDA, and are available. We will be educating them at this event in the near future and they will be reaching out through selective PR and articles in these women's magazines to help get the word out to women that there is a new option available to them and for those who would like to have longer-term wrinkle correction."

CEOCFO: How is your product unique?

Ms. Goostree: "All of the other dermal fillers on the market essentially act as plumping agents, which is a non technical way of explaining it. Basically all of these other products are injected under the wrinkle to provide volume underneath the wrinkle to hold up the wrinkle and smooth out the area. The dermal fillers are usually used on the lower half of the face. Botox® is also used for wrinkles, but it is used in the top half of the face and it actually paralyzes muscles so that you cannot frown. As you can imagine, you would not want to use a paralytic agent such as Botox® on the lower half of the face. Therefore, that is where the dermal fillers are used---for wrinkles such as smile lines between the mouth and the nose. Our product is different from the other dermal fillers because in addition to being a plumping agent like the others, we also have a permanent component. The permanent component, a synthetic polymer, is incorporated into our injectable gel in the form of very small and round particles called microspheres. The microspheres are so small that you cannot feel

them in the gel, but they are the right size to stimulate a cell in the body called a fibroblast that naturally produces your own collagen. With all dermal fillers, the body reabsorbs the plumping material usually in three to six months. However, with our product, after that plumping material is reabsorbed, we still have the permanent part of our formulation, which is the microspheres, stimulating the cell in the body to make collagen. It makes human collagen the same natural way that collagen is always made throughout

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the body to smooth out the skin. We can stimulate this natural process in the body to make additional collagen, even when you have a situation such as when you age where your body is not making as much collagen as when you were younger. We are stimulating those cells to behave as if they were in a younger body."

CEOCFO: Do you own this technology?

Ms. Goostree: "Yes, we own the technology and our scientific founders originally developed the technology. They have assigned the rights to the company as we have further developed the technol-

ogy and done all of the work for approval from the FDA. We have worldwide ownership of this technology and we have the ability to use it for a variety of applications. The initial approval is for wrinkles on the face such as a smile line or nasolabial folds. In addition, there has also been some work in other countries with our technology using it to repair scars and for reconstructive uses for things like reconstruction after mastectomy. There are many areas we are considering for this technology beyond wrinkles. At this time, we are excited about this initial use of ArteFill for wrinkle correction. ArteFill provides a long lasting wrinkle correction option for consumers who would like to have a longer lasting treatment."

CEOCFO: Often a new idea or technology will come out, and years down the line people find out that it was not quite what thought it was thought to be; how can you be sure this is the real deal?

Ms. Goostree: "ArteFill is an FDA approved product; in fact, ArteFill is the only dermal filler that is approved by the FDA that contains a permanent component. The FDA has very strict requirements for development, manufacturing, quality control, and clinical trials showing both safety and efficacy. The FDA has reviewed our data and found our product to be safe and effective. It was a very long

long process, taking millions of dollars to do that. Because we have been approved by the FDA, I think consumers and physicians can be comfortable, that the safety and efficacy of the product has been well reviewed and approved by the FDA as part of this process."

CEOCFO: You are going from being an R&D company to a commercial stage; what is the financial picture?

Ms. Goostree: "When we previously developed ArteFill®, Artes Medical was a private company. We raised about \$80 million from private investors including

venture capital during that time. After we received approval for ArteFill® from the FDA in October of 2006, we then moved forward with an initial public offering to take the company public. We went public in December of 2006 and raised \$30 million. Therefore, we believe we now have sufficient capital in the company and on our balance sheet to execute on our launch plans, so we started shipping product to our customers in February of 2007. We have a great management team on board. We have a head of sales and a head of marketing who combined have over 25 years of experience selling dermal fillers and marketing dermal fillers in the US market. We have a head of regulatory affairs who was previously responsible for the approval of Botox® Cosmetic at Allergan. We have a very experienced team and they are doing a great job now launching our product and reaching out to the physicians and consumers who have an interest in a longer-term wrinkle correction product like ArteFill®.”

CEOCFO: How do you produce the product; do you own facilities or contract out?

Ms. Goostree: “Artes Medical is a fully integrated medical device company unlike a number of medical device companies that rely on outside contract manufacturing. We have our own sterile manufacturing facility here in San Diego. We have gone through a full FDA inspection of our facility including a full eight-day inspection during the review and approval process. We have our own staff of manufacturing and quality control associates here that do all of our manufacturing. Our heads of manufacturing and engineering previously had extensive experience with collagen and a variety of dermal fillers and our quality control people had experience in sterile manufacturing. Therefore, we have a great team and full ability to control our manufacturing, to scale up as needed and continue to enhance those manufacturing processes as we grow.”

CEOCFO: What is the marketing opportunity in the male area?

Ms. Goostree: “Currently the dermal filler market in the US is a market that is 95% female. Only 5% of the patients who

use a dermal filler are men. When we have conducted focus groups with potential male patients, what they tell us is that at some point in the future, they may have an interest in looking younger, but they do not want to go back and visit the physicians again and again for temporary fillers. They do indicate that when they hear about ArteFill®, a product that can provide long-term correction with a single injection; they are quite interested in it. We believe that we have an unprecedented opportunity to expand this market into the male segment because of the characteristics of ArteFill®. We will be doing that initially working with physicians to make sure that they are familiar with the data in our clinical trials, which included men as well as women. We will also be implementing a public relations outreach through men’s magazines to help them become aware of this option for those who would like to look younger with minimum time investment compared to temporary fillers.”

CEOCFO: How do you attract the patients with injection fatigue and credit card fatigue?

Ms. Goostree: “We believe we are creating a new category of a permanent dermal filler with our product ArteFill®, which meets the needs of patients who may have tried a temporary filler. They may like the way it looks but then they experience injection fatigue or credit card fatigue when they realize how often they have to come back for treatment, and how expensive it is. There is a large group of patients who have already tried a temporary filler and eventually have dropped off that temporary filler treadmill and are interested in a longer-term option like ArteFill®. Our physician customers tell us many of their patients have been waiting for a long-lasting solution like ArteFill®.”

CEOCFO: Do you see those people as your best potential customers?

Ms. Goostree: “We would see them as the initial low-hanging fruit so to speak. There is already a pool of patients out there who have previously tried fillers and have dropped out. Many physicians that we speak with tell us they have a waiting list of patients waiting for ArteFill®, a permanent filler. That will get us

started very quickly. As we continue to educate physicians and patients about ArteFill® and its long-lasting effects, there will be more and more patients who are interested in trying and switching to a longer-term filler.”

CEOCFO: Why should investors be looking at Artes Medical now?

Ms. Goostree: “Artes Medical is a very attractive investment for a number of reasons. We are what can be considered a “pure play” in the medical device area, in the aesthetic space. We have a very attractive business model. First of all, we conduct our own manufacturing at our facility in San Diego. Therefore, we not only have full control of our manufacturing, we have very attractive gross margins as we scale up our sales revenue. Secondly, this market is highly concentrated from a physician perspective. There are in the US, over 23,000 dermatologists, plastic surgeons, and cosmetic surgeons, but we only need to reach out to 1000 of those physicians to cover 50% of the procedure dollars for dermal fillers. We can cover those physicians with a relatively small sales and marketing organization. The cost of manufacturing the product, and the cost and expenses associated with reaching out to sell and market the product are relatively modest compared to many other sectors and types of products. Therefore, we think it is a attractive business model that will provide very attractive net income and operating margins to investors in the future.”

CEOCFO: Is the investment community paying attention to Artes now?

Ms. Goostree: “I think they really are. Because we are a new company in the public market and we have a new technology that is a breakthrough technology, there has been a lot of interest on the part of equity analysts to speak with us and learn about ArteFill® and Artes Medical. We currently have 4 equity analysts covering the company and virtually every other analyst that does cover a dermal filler or Botox® has indicated an interest in speaking with us and has wanted to know about ArteFill® so that they can develop a complete model of the entire dermal filler and aesthetic injectable business. Therefore, we are seeing a lot of interest from the investor community and

we expect that will likely grow as we get the word out more about our ArteFill® product and our technology here at Artes Medical.”

CEOCFO: In closing, what should people remember most about Artes Medical?

Ms. Goostree: “What people should remember is that we have a truly differentiated product for wrinkle correction with

our ArteFill® technology and the permanent component of our ArteFill® formulation. When we asked patients in our clinical trial whether they preferred a temporary filler or ArteFill®, our long-term filler, over 90% of the patients in the temporary filler group requested to switch over and be treated with ArteFill®. When we asked the ArteFill® patients if they were satisfied with the re-

sults, over 90% said they were satisfied or very satisfied and they still had full wrinkle correction 5 years after their treatment. ArteFill provides a new technology for physicians who wish to offer new products to meet the desires of patients who want to look younger with long-lasting wrinkle correction.”



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