3D Printing Technology Revolutionizing the Orthopaedic Industry enabling the development of Complex Medical Devices and Custom Patient Specific Implants

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CEOCFO: Mr. Kowalczyk, would you tell us the focus for Additive Orthopaedics today?
Mr. Kowalczyk: We focus on the development of complex surgical devices leveraging 3D printing technology to treat simple to complex foot and ankle orthopaedic conditions.

CEOCFO: Why is it particularly effective in foot and ankle?
Mr. Kowalczyk: It is effective in all of orthopaedics, but our initial focus is in the lower extremities. The complex geometries and intellectual property we are developing are unprecedented. These are designs that could have never been made before with traditional manufacturing. First, we are able to manufacturer quickly and cost effectively with a goal to improve patient outcomes due to the complex features of the devices. Secondly, we can manufacture custom and patient specific implants where we utilize CT scans to design implants specifically tailored to a patient’s anatomy.

CEOCFO: Where do the implants in foot and ankle typically come into play?
Mr. Kowalczyk: Every day people are living longer and becoming more and more active. Innovative orthopaedic devices allow people to stay active, with less pain. The foot in particular consists of very complex articulating joints which can see up to 5 times or more body weight when walking so it makes sense that foot pain affects up to 25% of the US population. Implants come into play when treating the more common cause of this pain. These includes: Hammer toes, bunions, flatfoot treatments, midfoot and hindfoot fusions, reconstructions, total ankle implants, other arthritis treatments and many others.

CEOCFO: What is your first product that recently received FDA clearance?
Mr. Kowalczyk: Our first product is a device to treat hammertoes which is a common procedure occurring over 1M times per year in the US. Our
innovative hammer toe product has features only possible through the use of the additive manufacturing process.

CEOCFO: When would a doctor turn to you?
Mr. Kowalczyk: Our hammertoe device is an off-the-shelf product that comes in multiple sizes. When the surgeons sit down with their patients, they explain the surgical and non-surgical treatment options. Our device is a surgical option. There are other implants on the market, however, we are the next generation. We have some very unique features that allows for a straightforward and effective procedure. Although it is too early to tell long-term results, we have only had 30 surgeries to date, but early indications are showing less swelling, good fixation and stability, and fusions.

CEOCFO: What can your implant do that the others available today cannot?
Mr. Kowalczyk: You can imagine a hammer toe implant is very small; it is about 20 millimeters in length and it is only 2.5 to 3 millimeters in diameter. For another implant with traditional manufacturing to have similar features, the manufacturer would have to have special tooling with very high costs of goods sold. Our implant has the features printed on and completed in one overnight manufacturing build. These features increase stability, pull-out resistance, and create a surface finish that bone has proven to grow against for better fusions and outcomes.

CEOCFO: How will you reach potential customers?
Mr. Kowalczyk: We have a network of independent and direct sales reps and they have pre-existing relationships with surgeons. We have marketing programs which will start to initiate where we will reach foot and ankle surgeons. In our conversations, surgeons have acknowledged that 3D printing technology is the future of surgical orthopaedic treatments.

CEOCFO: Have doctors been looking for something better or will they just be happy to find out there are nuances they can now put into play?
Mr. Kowalczyk: Doctors are always trying to improve patient care. That is the reality. If you can supply a product that is going to allow them to do that, with faster and more effective surgeries, getting patients up and walking faster, that is important. With 3D printing, we have the ability to do all that. In addition, with products customized for a specific patient, inevitably they will have better outcomes because the product is tailored directly and specifically for their anatomy.

CEOCFO: Is there much training involved for the doctor?
Mr. Kowalczyk: The surgeons are experts with the surgery and typically have experience with other implants. However, we do require simple training prior to surgical use of our products. The training is important but it is not something that is a significant learning curve for them. We have additional innovative technology currently being reviewed by the FDA and several other products in development. We work with orthopaedic surgeons, surgical podiatrists and engineers as we develop the products and the surgical techniques to treat the patients. For instance, one of our key developers is Dr. Selene Parekh at Duke University. He is a world renowned foot and ankle orthopaedic surgeon and is extremely talented as a surgeon and a designer. We also have some other surgeons in Pennsylvania who are involved with the
company and collectively are assisting us to develop products and bring them to market.

**CEOCFO: How does cost compare with what is currently available?**

Mr. Kowalczyk: We are able to offer competitive prices which is a function of our 3D printing process.

**CEOCFO: Do you have the funding for your next steps?**

Mr. Kowalczyk: We raised a seed round of capital, which enabled us to execute three product designs and get one product cleared through the FDA, which is quite remarkable. We are now at a stage where we are seeking growth capital for intellectual property and to further our product designs.

**CEOCFO: Do you feel it is easier to get attention for a product that is simple to understand?**

Mr. Kowalczyk: From an investor and customer standpoint, we are doing something that only a few are doing. 3D printing is the future of orthopaedics, not only with metal and plastic implants, but with bioprinting, and we feel strongly that we are offering a disruptive technology mainly because of our intellectual property, competitive prices and customizable implants. We are right at the beginning of the technology curve and that is why we are getting so much attention. Currently, we are printing metal but we are currently starting a bioprinting program where we are looking at printing bone and other biological implants, which is fascinating. From a hospital perspective, if we can offer improved patient care at a lower cost, they will take notice.

**CEOCFO: Why pay attention to Additive Orthopaedics?**

Mr. Kowalczyk: 3D printing is the future of orthopaedic surgical treatments and we are only touching the surface of its potential. We’ve assembled a team of industry experts, product development engineers, surgeons, and 3D printing pioneers, to help realize this potential and create value to surgeons, patients, and the overall healthcare system. That is what is exciting about what we are doing.