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Kinos Medical Inc. is transforming the Total Ankle Replacement Market via Anatomically and Biomechanically Accurate Implant Designs

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CEOCFO: *Mr. Garvey, you have a long history in the orthopedic industry. What led you to co-found Kinos Medical Inc?*

Mr. Garvey: Kinos actually started at Drexel University with implant design concepts that was developed after years of biomechanics research focused on the ankle joint. Certain intellectual property, originating from Sorin Sielger, Ph.D., director of that the biomechanics lab at Drexel University was licensed by Kinos.

We started the company specifically to transform the total ankle replacement market via anatomically and biomechanically accurate implant designs. There is a significant opportunity to improve the product offerings that are on the market and our technology allows us to recreate the natural biomechanics of the joint with our implant, which is not done by any other device.

CEOCFO: *How often does an ankle get replaced? What leads to an ankle replacement?*

Mr. Garvey: Unlike hip and knee osteoarthritis, which is predominantly degenerative in nature, end stage ankle arthritis is mostly the result of a prior trauma or other conditions that lead the joint to breakdown. For instance, if you have a severe ankle sprain in your teenage years, fast forward twenty or thirty years, you may develop end stage ankle arthritis. Ankle fractures, sports injuries, and motor vehicle accidents also contribute to a growing number of ankle arthritis patients.

CEOCFO: *How is this addressed medically today?*

Mr. Garvey: The standard of care is ankle fusion, which limits patient's mobility and could cause them discomfort as well as lead to a more sedentary lifestyle. Depending on a patient's co-morbidities, fusion has been linked in the literature to a decrease in activity that accelerates declining health. There are other companies that offer ankle replacement; however, historically they have not fared very well. They have failure rates that are much higher than the failure rates of other joint replacement procedures such as hip and knee replacement and two to three times higher failure rates with the ankle prior to our product being introduced. This is not surprising to us, because none of the other implants on the market provide accurate biomechanics of the joint. Rather, they over-constrain and/or oversimplify the joint motion sacrificing performance.

CEOCFO: *How does the axiom anatomic total ankle replacement system work?*

Mr. Garvey: The Kinos Axiom Total Ankle System is the first biomechanically accurate implant to reach the market. It has an articulating surface that mimics the native and natural surfaces of the ankle joint. The inherent motion of the Axiom implant provides the patient with a similar same motion profile they would have had prior to the injury. This includes motion in all three anatomic planes, which is needed for walking, particularly on uneven terrain, descending stairs, etc. The other products on the market over simplify the joint and are based on outdated research that really dates back to the 1950s.

Our product is based on research where we have utilized CT scans and other more contemporary imaging and analytical modalities that allow us to better understand the motion of the ankle joint and then recreate that motion through our device. We actually offer motion in all three anatomic points whereas the other implants act as a simple hinge, not dissimilar to a hinge on a door, which is not how your ankle functions in reality.

CEO CFO: *What were some of the challenges in developing the system?*

Mr. Garvey: The main challenge in developing a system is providing the balance between that anatomic range of motion and the constraint necessary to ensure that the implant can function when subjected to the rigors of daily activity. People walking up and down stairs, walking on uneven ground, not walking on flat level ground, pivoting can cause excessive loads, so our product uniquely addresses those excessive loads that can be placed on the joint. We conducted years of research to create an implant that restores natural and accurate motion for the patient.

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Additionally, the precision that is necessary in placing the implant during the surgery is very important for the long-term success of the implant. Therefore, we spent a lot of time focused on developing instrumentation that can reduce the amount of time that the surgeon spends in the operating room and allows him or her to more easily reproduce precision placement for that joint, regardless of the deformity or other unique aspects of an individual patient's anatomy.

CEO CFO: *Is there much training involved for the surgeon?*

Mr. Garvey: There is a specific training course that surgeons go through prior to using our system in the operating room. It is a fairly low learning curve, compared to some of the competitive offerings. We have reduced the number of steps required to perform the surgery. Also, we have developed some unique concepts and training models that allow surgeons to train in a very, hands-on approach in a rather short period of time. Therefore, coupled with the implant and the instrumentation, we will be able to show faster implantation times and more reproducible outcomes.

CEO CFO: *Is it a "one size fits all" or would there be several models depending on age, size of a person or some other criteria?*

Mr. Garvey: That is a good question. There are actually two different platforms that we offer. One is entirely custom to the patient, so we can take a CT scan and, working with our surgeon facing pre-operative software together with the surgeon, create custom operative plans, addressing the specific needs of each patient, that can lead to custom, patient-specific implants. Even with our standard sizing options, which come in a multitude of configurations to address the majority of anatomy, the per-operative planning software tailors the surgery to each patient.

CEO CFO: *Is that a matter of cost? Why the two versions?*

Mr. Garvey: It is mostly a matter of anatomic constraints or needs. For the average patient, our "off the shelf" product works very well. For some of the more complex surgeries where deformities may be greater or there are other anatomic anomalies, the patient specific or custom implants tend to have better outcomes. There is a level of cost, although at the end of the day it is not overly significant.

CEO CFO: *Would you tell us about your recent 510K clearance?*

Mr. Garvey: It is, in a lot of ways, the culmination of years of research, both on the natural and native anatomy as well as the implications of our technology. We spend a lot of time and energy and mental horse-power, to ensure that we were developing something that exceeds the options available on the market in terms of functional performance. Therefore, we spent a lot of time testing the product in various different settings, so that we could establish with the FDA a meaningful demonstration that our product is at least equivalent, if not superior to those other options on the market.

CEO CFO: *Would you explain where the software part comes in? On your site it shows, "Eliminates the need for traditional systems to remove native bone." How so?*

Mr. Garvey: The software allows the surgeon to efficiently analyze the diseased joint, make the necessary surgical corrections to any deformity, select the appropriate implants and place those implants in a manner that provides the best chance for long-term success for that individual patient. We have another product that is still in development, and we anticipate to launch next year, that allows the surgeon to utilize a CT scan to create a patient specific implant that minimizes the amount of bone removed in order to place the implant. This has the potential to provide younger patients with an joint preservation implant, where today they are only considered candidates for a fusion procedure. The goal is to give patients more mobility where they are currently not able to receive a replacement and are forced to get a fusion or live with the pain.

You have to take out a little bit of bone in order to place the implant, so the most time-consuming aspect of the surgery is getting everything aligned and positioned, so that that bone can be removed with precision. Therefore, our custom, patient specific instruments and implants allow the surgeon to expedite that process of alignment and then bone removal and reduce the amount of bone that must be removed.

CEO CFO: *Are you seeking funding, investment or partnerships as you move forward?*

Mr. Garvey: We actually have a funding round open now, though we expect to close it in the next few weeks. We have forged meaningful partnerships in terms of research, software development, 3-D printing and other high-technology manufacturing areas. Coupled with our biomechanically accurate implant portfolio, these partnerships allow for cutting edge technology to improve ankle replacement in ways not previously thought.

CEO CFO: *What has been the response from people in the medical community who are aware of what has been developed?*

Mr. Garvey: There has been an overwhelmingly positive response from the medical practitioners when they see our technology and they see the comparison of our technology's function to the other options that are available! In some ways, we have always known how great our product can be and what that can deliver, but to see the surgeon community embrace that and get behind that and really demand that they can incorporate it into their practice has been a great motivator and has propelled us forward!

CEO CFO: *There are so many new products and new ideas in all fields, but health certainly. Why should people look at Kinoss Medical Inc? Why do your ideas stand apart?*

Mr. Garvey: We have the good fortune of coming upon this marketplace with a lot of technology available to us. Whether that is technology we use to develop new and better instruments and implants or whether it is technology that we provide to our customers so that they can perform their job as a surgeon and healthcare practitioner better, we are giving them the tools that they need to make their patients' lives better

Historically, the orthopedic community, from the development standpoint, has been rather slow to innovate and we have amalgamated several technologies together that allow us to really step in front of the current market and provide meaningful improvements to our customers.