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Feature Interview with Eugene Anton, Co-Founder and CEO of NuVascular Technologies, Inc.

NuVascular Technologies, Inc. was established in Ashland, Mass. in August 2014. The company was formed to commercialize hemodialysis access medical devices based on patented nanotechnology developed over the past decade and licensed from NuSpun, LLC.

Under the direction of an experienced management team as well as scientific and business advisory boards, the company is developing medical solutions that provide better healing, reduce complications and incorporate a patented “first-in-class” targeted drug delivery system for the multi-billion dollar renal disease hemodialysis market.

BusinessInterviews.com: What problem are you solving?

Eugene: Currently, more than $2.9 billion is spent annually in the U.S. alone (representing 16 percent of the worldwide market) on secondary procedures because current hemodialysis access procedures, including arteriovenous fistula, arteriovenous graft and central venous catheters have high failure rates due to lack of healing, infection and clotting. This not only adds billions in added cost to the healthcare and medical systems, but dramatically affects the lives of millions of renal disease patients through reduced quality of life, increased hospital stays and higher incidences of death.

BusinessInterviews.com: Can you talk about the process of taking your idea from concept to successful pre-clinical studies and any challenges that you encountered along the way?

Eugene: Industry leaders have been trying to address the high rate of failure by modifying or adding to their current technology with limited success. Our thought was to address the problem from a completely different angle and develop a new process based on cutting-edge nanotechnology.

The development of our technology was painstaking slow as we relied on sporadic grant awards because there were no investment dollars available. Grant funds were not always allocated toward aspects of the technology that were commercially viable. Our technology was developed in a piecemeal instead of a linear way, adding years in development time and money. We also spent an extraordinary amount of time and effort working with leading vascular surgeons to ensure our solution met and exceeded their needs.

Yes, we have successful pre-clinical results. However, in seeking regulatory approval, we find the objectives of government grant funded studies do not necessarily coincide with FDA requirements. We will be expanding our biocompatibility and pre-clinical studies with new directives from the FDA. Grant funding would dramatically extend the time frame to get these studies going, so the hunt for investment dollars is underway.

BusinessInterviews.com: Your devices specifically treat patients suffering from end-stage renal disease. Could your products have a broader application into other areas of illness and disease?

Eugene: Our platform technology is not only applicable to hemodialysis access devices, but medical devices ranging from wound dressings to those that treat peripheral arterial disease and cancer. The broad range of medical devices that can benefit from our technology stem from the superior healing of our nanofibers compared to what has been used in the industry for more than 60 years with no major improvements. But what really sets our technology apart is the versatility of physical properties we can incorporate into each device and our ability to infuse various drugs and bioagents directly into our nanofibers. Our medical devices can reduce complications such as infection, clotting, and cell overgrowth at the site, limiting the need for follow-up procedures or the prescribing of drugs that treat the entire body in the hopes of addressing a site-specific issue.

BusinessInterviews.com: You have a number of products in your pipeline, which ones are you most excited about at the moment?

Eugene: We are extremely excited about our hemodialysis access grafts, both the non-drug and drug-loaded versions. The pre-clinical results are astounding and the prospect of being able to affect the lives of millions of renal disease patients in such a positive way is an extremely rewarding endeavor. The positive results from our access graft research and development directly translates to all of the other products in our pipeline. As they are all based on our nanotechnology platform, every improvement in our access graft technology advances every other product we have worked on, which to date is approximately 40 medical devices.

BusinessInterviews.com: Since first launching the company last year, which milestone has felt the most significant to reach?

Eugene: Our journey started more than a decade ago, long before our launch date last year. The concept stage, which involved observing the process of textile dying and applying that model to the incorporation of drugs into nanofibers of medical devices, was a game-changer. This technology is decades ahead of anything else on the market today. The second milestone was the successful completion of our first pre-clinical study. The results were amazing in regards to reducing the complications that plague current medical devices. We knew we had something that was both significant and disruptive. It was this moment we knew we had to do whatever it took to move this technology forward. Our next milestone is securing funding to move our product to the marketplace.

BusinessInterviews.com: What advice would you give to a company about to start the FDA regulatory process?

Eugene: In short, start the process early. I recommend six to nine months earlier than you estimate. FDA guidance on what will be required to secure regulatory compliance is useful in fine-tuning your process and adjusting your study parameters, which results in saved money and time. Hire a regulatory expert to help guide you through the regulatory process and in your dealing with the FDA. Most first-time companies overthink and overestimate study requirements. The cost of the expert will be more than offset by the savings in final FDA study requirements. Lastly, do your homework. There are likely companies closely related to yours that have gone down the path before you. Learn from their published studies, data, news releases, and also look into industry data and trends – there is a wealth trove there.