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NITI set to launch in vivo studies of nano-derived implant coating

By Russell A. Jackson

Nano Interface Technology, Inc. (NITI) is set to begin in vivo trials and then go to market with a nano-derived implantables coating process that it says could yield more than $100 million in annual revenues in the very near future.

The first step: raising venture capital.

Eight-year-old NITI's version of an implantables coating material makes use of its key intellectual property, a micro-emulsion-based technology for synthesizing nanoparticles where the ratio of metals is "very important," explains C.P. Singh, PhD, CEO, and president at the Lorton, VA-based firm. That IP platform allows the firm to create tailored particles of hydroxyapatite anywhere from 10 nm to 80 nm in diameter. The ratio of calcium to phosphate in them is roughly 1.667, permitting the creation of nanocrystalline HA with no other phases or components.

That's important, because if the nanobiomaterial used is not "phase pure," the coating containing it "will dissolve faster than micron-size biomaterials with the same degree of impurity, which will result in a loosening of the implantable device." Now, though, the U.S. FDA reports that, while dental implant coatings of HA applied by plasma spray may reach a maximum of 66% purity, an HA purity level of 50% to 60% is more common.

Additionally, Singh says, "there are large variations in purity from the same manufacturer. The FDA has stated that the higher the amorphous phase, the faster the coating will dissolve and the faster the implant will, therefore, loosen." The same applies to orthopedic implants.

Another common problem with current coating processes involves the heat used to fuse coating to device. "The high temperature used -- usually around 1700 degrees C -- breaks the HA into other phases," Singh explains. "And it weakens the titanium alloy, which leads to corrosion in the implants." NITI's process, though, uses temperatures below 400 degrees C. And, while he won't discuss proprietary coating technology, he says "due to the smaller size of the nanoparticles we use -- 20 nm to 30 nm -- the bond strength of the coating is two to three times better than that of plasma-sprayed coating. The nanosized coating also provides more surface area for the bone to bind with."

It works

"The science is already completed," Singh points out. "HA-coated implants are already in use, so we will need only 510(k) approval from the FDA verifying the chemical and mechanical quality of our coating." Phase I and II clinical trials, in other words, aren't needed. The project was funded by the National Institutes of Health and all research data are reviewed by an NIH panel. The company, he adds, is in the process of raising funds to carry out the in vivo studies.

Assuming all goes well, NITI's financial future could be bright. "We will provide coating for orthopedic implants, which have a total market size of $10 billion," Singh reports, "and will license our IP platform for dental implants, which have a market size of $5 billion, to other manufacturers." That licensing, he adds, "will bring in a significant amount of revenue to develop a new coating facility and to enhance the market penetration of coated orthopedic implants."

The company, he reveals, is in "advanced stages of negotiations" with dental implant companies.

The $15 billion combined implant market is growing at about 15% a year -- a figure that could rise to 25% "because several pain killers for arthritis have been pulled from the market, which will lead to more hip and knee replacements."

Increasing the lifespan of implants

Specifically, Singh tells *NanoBiotech News*, the life span for hip and knee implants is 10 to

12 years, and their revision rate is 17% a year. If the life span rises, of course, the revision rate drops. NITI's technology, he says, can increase that life span to 20 years and, thus, significantly reduce the revision rate. And because the same biomaterials that NITI employs are already used in implants, devices developed using purer biomaterials "will easily capture the market," he comments.

First comes the dental implant market. "Our success in the dental application will validate the benefits of nanotechnology-derived implant coatings," he reports, "which will help us penetrate the orthopedic market more easily."

Indeed, he predicts, "based on a very conservative estimate, our products can capture about 5% of the nanomaterials-based dental implant market and 0.4% of the orthopedic implant market by 2010. We foresee annual revenue potential of some $45 million from implant products by then." Further, NITI believes its products can capture closer to 10% of the nanomaterials-derived dental implant market and 1% of the orthopedic implant market by 2012, resulting in some $133 million a year in revenues. By 2015, he continues, "our nanotechnology-based products, based on worldwide market size, have the potential to capture 25% to 30%, leading to annual revenues of $400 million to $450 million." And by 2020, NITI's market share is expected to increase to 50% to 70%.

Positioning for an IPO

As that's taking place, Singh adds, executives will plan the initial public offering of the still-private NITI. "The combined strategy of licensing and manufacturing," he says, "will position the company for a high IPO value." That, though, will wait until the in vivo studies are completed in the next three years.

"One of the major scientific challenges for material scientists has been developing processes that can help control ultra-homogeneity in material properties at the molecular stage," Singh says. "We plan to commercialize our products by licensing technologies and developing products for private companies. And we believe we have hit upon the Holy Grail of material production, where we can synthesize molecules under highly controlled conditions for specific applications. With the right reaction system and specific ambient conditions, we can control the properties and purity levels of our products."

Importantly, he adds, "all of our processes can be easily scaled up for large-scale production at commercial levels. Our vision is to significantly alter the processes and purity levels of materials by creating them at the molecular level."

Indeed, implantables coating isn't NITI's only nano-application, just its first.

"The cost of carbon nanotubes is $100,000 to $200,000 a pound, depending on their quality," Singh reports. "At that price, you can't use carbon for nanocomposites. To provide leapfrog improvement in the strength of nanocomposites and other applications, we have developed mesoporous nanorods that are 30 nm to 32 nm across and 100 nm to 500 nm long. They're synthesized by sol-gel chemistry and surfactant self-assembly -- and those made of silica, aluminum or copper can easily be produced for $20 a pound."

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