

NuShores Biosciences receives commercialization readiness funding for NuCress™ scaffolds for dental indications

by Sharon C. Ballard
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Little Rock, AR – NuShores Biosciences LLC has been awarded a 3-year, \$2.9M commercialization readiness grant from the National Institute of Dental and Craniofacial Research (NIDCR), a branch of the U.S. National Institutes of Health. This funding follows an on-going previous grant and NuShores' successful execution of its SBIR Fast Track grant awarded in 2018. This new funding will enable NuShores to execute the required Design Controls processes required by the U.S. Food and Drug Administration (FDA) for the NuCress™ scaffold for dental indications, with the ultimate goal of receiving regulatory clearance to market.

"From the beginning of this technology investigation, we were convinced that craniomaxillofacial applications would benefit from the bone regeneration features we've developed in our research over the last few years. This exciting development compliments the work and the potential that our technology could have in the area of orthopedics," states Alex Biris, NuShores' CTO, inventor and co-founder as well as Director of UA Little Rock's Center for Integrative Nanotechnology Sciences. NuShores is the global exclusive licensee of the technology being advanced with this grant.

The work will be led by NuShores' CEO Sharon Ballard and the team of Malathi Srivatsan, PhD, Karrer Alghazali, PhD, Research Manager, Brittney Garner, PhD, Regulatory/Quality Manager, and Mark Pelo, NuShores Manufacturing Manager. Collaborators include Nelson Labs, Salt Lake City, UT, Charles River Laboratories, Montreal, Canada, with Stony Brook University's School of Dental Medicine as clinical consultants. According to Dr. Srivatsan, *"This award speaks to the confidence the NIH has in NuShores and our NuCress™ scaffold for dental indications."* Dr. Srivatsan led the earlier NIH funded dental studies and this successful proposal effort.

Sharon Ballard, NuShores CEO, added: *"Quality is personal at NuShores. We are eager to successfully execute the proposed project and offer a quality product to dental markets. This funding further confirms that NIH is convinced of the scientific as well as clinical potential for dental patients and is the next step in our medical device commercialization."*

Karrer Alghazali, PhD, Research Scientist and Research Manager at NuShores added: *"I am excited to work with the team to bring another NuCress™ scaffold indication for use to the marketplace for clinical benefit. It is exciting to see our technology being applied to dental applications"*. Dr. Alghazali has been integral in the material development of the NuCress™ scaffolds and is co-inventor on several issued patents and patent applications related to NuShores' licensed technologies. He has contributed scientifically since the original award of the SBIR Fast Track dental and craniomaxillofacial product development and preclinical studies. He received his PhD at UA Little Rock in material sciences.

Brittney Garner, PhD, Regulatory Scientist and Manager of Regulatory and Quality, led NuShores 510(k) pre-submission efforts and subsequent meeting with the FDA for the NuCress™ scaffold for dental indications. *“Thanks to this new award, NuShores has the opportunity to prove that the NuCress™ scaffold is safe, effective, and efficient for reliable bone formation in an oral environment,”* commented Garner. Dr. Garner received her PhD in Interdisciplinary Toxicology and a Graduate Certificate in Regulatory Sciences from the University of Arkansas for Medical Sciences.

Mark Pelo is NuShores' Manufacturing Manager as well as managing all company facilities. Pelo brings 30 years of medical device manufacturing experience with leading manufacturers such as J&J Dupuy Synthes and Medtronic to the NuShores team. Pelo states that *“the dental environment brings new manufacturing challenges. NuShores is ready for the challenge of this new effort by leveraging our of current Good Manufacturing Practices (cGMP) systems and our clean environmental facility.”*

About NuShores Biosciences LLC

NuShores' vision is to improve the quality of life for people globally and to compete successfully in the bone and tissue regenerative materials industry. Early studies suggest that NuShores' licensed, patented technology could deliver improved solutions for bone regeneration while cutting healthcare costs, lowering treatment risks, and reducing healing times. Research results show that NuShores' NuCress™ scaffold could offer several benefits that to date are not achieved by currently marketed bone regeneration products, therefore promising to bring better treatment outcomes to millions of people with severe injuries. NuShores has the exclusive, global license from University of Arkansas Little Rock to commercialize university-owned patented and patent-pending bone regeneration technologies.

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Contact

To learn more about this work, please contact:

Sharon C. Ballard, CEO
NuShores Biosciences LLC
sharon@nushores.com

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