

Department of the Navy SBIR/STTR Transition Program

STATEMENT A. Approved for public release; distribution is unlimited.

ONR Approval # 43-2203-16

Topic # N13A-T013

Evaluation of safety and efficacy of commensal probiotics, *L. salivarius* MMP strain and *L. senioris* Accacia strain for maintaining dolphin (*Tursiops truncatus*) health

Accacia International Inc

WHO

SYSCOM: ONR

Sponsoring Program: ONR Code 34

Transition Target: U.S. Navy Marine Mammals Program (NMMP), Space and Naval Warfare Systems Center Pacific (SSC Pacific)

TPOC:

Dr. Laura Kienker
laura.kienker@navy.mil

Other transition opportunities: In addition to dolphins, the same probiotics could be effective in other marine mammals such as seals, walrus, sea lions etc. Further, aquatic animals including fish and shrimps will be benefited from similar probiotic products. The same strains can be applied to develop probiotics targeting the veterinary sector and human health since similar strains can be found in the human gastrointestinal (GI) tract.



Left Image: Courtesy of U.S. Navy 030318-N-5319A-002
MAR 2003; Right Image: Copyright 2014, Accacia
International, Inc. (Accacia)

WHAT

Operational Need and Improvement: SECNAV Instruction 3900.41G states that the Navy's marine mammals will be provided the highest level of care and treatment, so the NMMP is seeking dolphin probiotics to maintain general fitness, as well as protection from GI diseases, inflammatory disease and potential pathogens. Antibiotic treatment is the current regimen to mitigate pathogenic bacteria, however, antibiotic-resistant GI pathogens in bottlenose dolphins are on the rise. Therefore, alternative health promoting strategies are needed to prevent diseases and maintain dolphin health. There is currently no probiotic developed exclusively for dolphins.

Specifications Required: The probiotic is to be isolated from indigenous commensal microbes of bottlenose dolphins (*Tursiops truncatus*), and possess *in vitro* immunomodulatory and dolphin gastric and enteric pathogen growth inhibitory activities. The candidate probiotic microorganism will be microencapsulated to enable selective delivery to, and release in, the dolphin intestine. Microencapsulation will also enhance viability of the probiotics during delivery into the body, and during storage. The product's shelf life and the feasibility for its long-term production will be assessed.

Technology Developed: Accacia has isolated probiotic candidates from captive and managed bottlenose dolphins reared in SeaWorld and the NMMP, respectively, and developed a microencapsulated and freeze dried probiotic product that has excellent stability and long shelf life. Since the probiotics are microencapsulated, the bacteria are able to survive the harsh acid conditions of the stomach and bile salts in the intestine, and better colonize in the intestine than corresponding uncoated probiotic organisms. This is the first probiotic product developed for dolphins from their indigenous microbiota.

Warfighter Value: Maintaining Navy dolphin health is a priority in order to improve the fitness and readiness of these animals for defense missions. In spite of high-quality medical and preventive care throughout the lifetime of Navy bottlenose dolphins, infections can occur with a wide range of pathogenic bacteria. Healthy, mission-ready dolphins are essential to protect harbors and Navy assets and to detect and/or mark underwater mines.

WHEN

Contract Number: N68335-16-C-0089 **Ending on:** August 7, 2017

Milestone	Risk Level	Measure of Success	Ending TRL	Date
Demonstrate <i>in vitro</i> safety	N/A	Safe candidate probiotic with no adverse properties	4	April 2016
Develop encapsulated probiotic product	N/A	Final encapsulated probiotic product	5	July 2016
Demonstrate <i>in vivo</i> safety	Low	Probiotic product is safe to administer	6	February 2017
Demonstrate efficacy	Low	Probiotic product is efficient in improving health	7	August 2017
Antibiotic challenge	Low	Probiotic product maintains/restores healthy microbiota in dolphins following antibiotic challenge	7	May 2018

HOW

Projected Business Model: Accacia will initially control production efforts under collaboration with their production partners and will take the lead in marketing, sales and customer development. Accacia's partners will handle stocking, shipping, and quality control. In order to achieve broader and more rapid scale up, Accacia plans to license their intellectual property (IP; i.e. probiotic strains, patents on the bacterial strains, and patents on anti-pathogenic activity compounds and on encapsulation materials) to manufacturing partners. The licensees will independently increase product sales and global distribution, while Accacia continues its new product development efforts to yield unique probiotic formulations for marine mammal needs.

Company Objectives: Accacia is seeking additional partners for probiotic product commercialization as well as new customers who are interested in preventive measures to address marine mammal GI health. Market opportunity expansion to various dolphinaria and international marine mammal programs will also be sought. In the long term, opportunities will be sought to develop human probiotics for Navy personnel. Accacia is also seeking to explore other funding opportunities and collaborations for diagnostic assay development for infectious diseases and related instrumentations with Navy relevance.

Potential Commercial Applications: Accacia's novel microencapsulated probiotic capsule is the first commercial probiotic product developed for dolphins, and Accacia conservatively approximates the present probiotic market for marine mammals to be around \$1 million annually. Probiotics are also used very successfully in veterinary feeds to improve animal health for cattle, cats, poultry, dogs, goats, sheep, swine, turkeys, and other species. These are already successfully commercialized, setting precedence for Accacia's entry in the market place for marine mammals. Therefore, Accacia's product may be modified to also be applied to other animal populations.

Contact: Austin Sequeira, CEO
austin@accaciabio.com 512-782-8218