

**Final Report Summaries to Board - #15 Projects
January 2016**

#15-01 KarboLyn® A Unique Homopolysaccharide Compound for Glycogen Repletion in Athletes

Jeff Golini, All American Pharmaceutical - \$80,000

[Final Report approved 11/24/15]

Summary

This clinical research study had a two-fold goal. First, it sought to document whether or not KarboLyn® had a positive and sustainable impact on blood sugar level in normal individuals during light aerobic activity. Secondly, to observe the effect KarboLyn® had on pre-diabetic individuals, i.e. whether or not their glucose-resistant physiology would show the same controlled glucose utilization curve, as normal individuals, with this product. The study changed course with the success of the first human trial and it was decided to conduct two additional human trials instead of doing a cell culture study. The research consisted of three double blind clinical trials. The first study used healthy, active humans. The second study used pre diabetic subjects. The third study used full blown diabetics. Results of this study were inconclusive and a fourth study will be conducted outside of this grant. The overall success of the three studies was very positive and will aid the new marketing plan for this product as a designer sugar for not only athletes, but for pre-diabetics and possibly Type II diabetics. The research could also lead to a Medical Food Status and possibly an Orphan Drug.

Commercialization

Karbolyn® is a sugar-free, highly versatile powdered drink mix derived from potato, rice and corn. It is a fast-acting, long-lasting, high-performance compound that offers the best of both simple and complex carbohydrates. It absorbed into the bloodstream like a simple sugar but without the typical crash caused when muscles run out of fuel.

Target market including size

The base product was designed for, and targeted to, athletes of all ages, including children, and those individuals simply desiring enhanced physical performance.

Marketing strategy

The marketing penetration strategy is an “inside-out” approach. This is a \$8 billion market segment consisting of endurance-based athletes and performance-based sports where there is high demand for sustained energy to perform at maximum levels.

Estimate of sales revenues for five-year period into the future

\$2,500,000 in 2016 to \$5,000,000 in 2020

Economic Impacts

New businesses created or expanded

Expansion of All American Pharmaceutical as it approaches Montana schools and sport teams. Karbolyn® is now the referred sideline drink over Gatorade.

Increase in employment levels

As sales gear up, more people will be hired, which help the local work force.

Sales generated

As sales go up, so does the amount of state taxes paid.

#15-02 Leveraging Integrated Systems Technology for Real-Time Hyperspectral Image Processing

Ross Snider, Montana State University, \$57,535

{Final Report approved 1/04/16}

Summary

The goal of the research was to show that a design could be implemented in a Field Programmable Gate Array (FPGA) that would meet Resonon's computational requirements relative to its almond sorting system. FPGAs were found to be ideal for the image processing that Resonon needs to perform in real-time. FPGAs can easily handle the computational requirements needed by Resonon's Hyperspectral Image Processing well into the future. The objective of demonstrating that FPGAs can be used for Resonon's real-time image processing was a success and is potentially cost effective as compared with PCs that have added frame grabbers. Thus the commercial potential is high. However, getting the data to the FPGA fast enough is a bottleneck and will require custom hardware that integrates the CMOS image sensor with the FPGA. Thus a FPGA smart camera needs to be developed and is underway with a subsequent MBRCT award.

Commercialization

○ Product description

Resonon's machine vision system consists of an imaging spectrometer, a data acquisition and analysis system, a lighting system, a touch-screen interface, an encoder. This system images an object on a conveyor belt, uses the hyperspectral images to classify the objects on the belt and produces a map for an actuation system to separate the product.

○ Target market including size

The immediate target market is food sorting, primarily nuts. Additional markets might be plastic recycling and pharmaceuticals.

○ Marketing strategy

Resonon has developed an alliance with FANUC, the world's largest supplier of robots. A FANUC distributor with expertise in the food industry, Bratney, is actively marketing Resonon's machine vision for food sorting and has installed eight systems in California and will soon install four more in Arizona for almond sorting. They have likely prospects for more sales for almond and pistachio sorting. Bratney has informed the PI there is strong interest in higher resolution and faster speeds, and they would market directly to them should this project be successful.

○ Production or manufacturing plan

Resonon's machine vision systems are produced by a limited set of component vendors and on-site in Resonon's Bozeman facility. The FPGA data acquisition and computing units being developed during this effort would be purchased and integrated into Resonon's machine vision system in Resonon's Bozeman facility. Talks are currently underway with Flat Earth, Inc., a local Bozeman company, to develop the custom FPGAs boards needed for the FPGA smart camera.

○ **Business risk assessment**

Technical risk is deemed low that the effort will not integrate into the system, not cause losses of performance in any area, and not provide increased computing speed.

Cost risk involves hardware, software and labor, and is deemed low.

Market risk is loss of first-mover advantage as the market emerges. Because the food sorting industry has multiple possible applications, it is unlikely that Resonon would be overcome in all areas.

There is notable risk for the long-term commercial success of the effort, but it is felt there is more risk if Resonon does not pursue the improvements.

Economic Impacts

The FPGA Smart Camera itself could have additional potential in the machine vision space for generalized machine vision applications. This possibility is being explored with the involvement of another small company in Bozeman (Flat Earth, Inc.).

#15-05 Developing Fungal Bioinsecticides for Controlling Multiple Bark Beetles in Forestry

Clifford Bradley, Montana BioAgriculture, Inc. - \$57,400

[Final Report approved 11/13/15]

Summary

The project funded by the Montana Board of Research and Commercialization was an important component of an overall program to develop a mycoinsecticide effective against multiple species of bark beetles. MBAI was awarded a phase II SBIR grant from the National Science Foundation to develop a mycoinsecticide for mountain pine beetle. In the NSF project, MBAI isolated fungal insect pathogens from conifer forests in Montana and Arizona and screened these for efficacy on mountain pine beetle. MBAI's goal is to develop one of these newly isolated fungal insect pathogens as a commercial product to control multiple species of bark beetles. This would create expanded markets to support raising capital for US EPA pesticide registration and commercialization. The Montana R&C project expanded potential targets by evaluating fungal strains isolated in the NSF project for control of spruce beetle, pine engraver and southern pine beetle.

Commercialization

Product description

Commercial product will be a mycoinsecticide consisting of fungal pathogen spores formulated with carriers.

Target market including size

The mycoinsecticide formulations will be sold to the USFS and other public agencies and to private forest and agricultural land owners.

The market for a mycoinsecticide using a strain of pathogen effective on multiple beetle species is significant and could exceed \$2.5 million per year within five years of regulatory approval.

Production or manufacturing plan

MBAI will need to finance and construct a production plant to supply sales growth. Contract production may be available at the Laverlam facility in Butte and there are also two smaller production facilities which might have excess capacity.

Financing might come from a combination of equity capital and debt or possibly as part of a commercial market deal with Certis or another company.

EPA Registration

A mycoinsecticide will require US EPA registration as a microbial pest control agent. This requires submitting studies in three areas, will cost between \$500,000 and \$600,000, and will require 18 – 24 months from the time the decision is made to proceed.

Business risk assessment

Failure to demonstrate efficacy in large scale field trials represents the greatest risk to commercializing mycoinsecticides for bark and ambrosia beetles. This could result from a lack of funding or from product performance. A second risk comes from potentially competing products although MBAI does not know of any other mycoinsecticide development for bark and ambrosia beetles. However, new chemical insecticides and application technology could be competitors.

Estimate of sales revenues for five-year period into the future

Revenue and cost projections show potential for mycoinsecticides in forestry and agricultural tree markets but existing data supports only very rough estimates. The assumption is made that the company could become very profitable beginning I 2022 with substantial return on capital for production capacity.

Economic Impacts

MBRCT funding was key to MBBAI's growing expertise in targeting bark and wood boring beetles and resulted in ongoing collaborations with USFS and university researchers for expanded and long term development of mycoinsecticides for these insects. Ongoing collaborations were established with researchers at the University of Montana, Northern Arizona University, the University of Florida and Northern Arizona University.

Patents applied for or granted

Intellectual property developed includes specific fungal strains, boring deterrent compounds and application techniques. MBAI expects to make patent applications as technology is reduced to practice.

Other

MBAI has made invited presentations to technical meetings of the USFS and the Western Forest Insect Working Group.

Unique features/success stories/news clippings, brochures/other information

The work conducted with Northern Arizona University has been featured in a radio show on Arizona Public Radio.

Summary

Bacterin's goal for this project was to partner with Mayo Clinic to develop an acellular nerve allograft for peripheral nerve reconstruction. Processing conditions were developed to effectively decellularize nerve tissue to avoid immunogenicity, disinfect the tissue to prevent disease transmission, and preserve the tissue for practical clinical and commercial utility.

The project overall was a significant success.

- Novel processing conditions were identified.
- Remarkable results were generated in the animal model.
- Nerve allografts processing using the newly developed procedures, produced functional recovery not previously seen by the scientific community.
- Patents have been filed to protect the technology and a manuscript detailing the result is being prepared for peer-reviewed publication.
- Recent changes in FDA regulations have raised the barrier to commercialization and Bacterin is reevaluating the business case and the best path forward for commercialization of the technology. In light of this, the best option for generating revenue may be a licensing agreement.
- The findings generated through the project will be beneficial to Bacterin in achieving its future R&D objectives.
- Multiple less tangible benefits were generated, including training of future nerve microsurgeons and strengthening Bacterin's relationship with Mayo Clinic and other leaders in the field of regenerative medicine.

Commercialization

The original commercialization goal was to commercialize the product as a human, cell, and tissue-based product under Section 361 of the United States Public Health Service Act, which does not require formal approval or clearance from the FDA as long as certain controls are in place and followed by the manufacturer. However, recently the FDA changed the regulations for nerve allografts and has made allograft nerve tissue subject to a much more stringent and burdensome biological licensing agreement pathway. Approval of this path could cost as much as \$100 million and take up to 15 years to

complete. Bacterin, therefore, is reevaluating the business case for the project and exploring options to appeal the FDA regulatory classification. All options are being evaluated for the best commercialization path and that option may be a licensing agreement of the patent pending intellectual property generated through the project.

Economic Impacts

Until the business case can be reevaluated, an estimate of the economic impact is difficult to determine. A number of tangible assets have been generated:

- Bacterin has filed for patent protection for the processing methodology, which will be desirable for nerve and tissue processors and will make a welcome addition to Bacterin's patent portfolio.
- A paper is being drafted for peer reviewed publication and will provide good press for Bacterin, the Mayo Clinic and MBRCT.

Less tangible assets generated through the course of the project include:

- Research findings are expected to be broadly beneficial for Bacterin's future R&D objectives.
- Insights gained from nerve processing are expected to be broadly translatable to other soft tissue allografts currently being evaluated for development.
- Several future physicians were trained in nerve microsurgery.
- Bacterin's relationships with Mayo Clinic and several leaders in the field of regenerative medicine were significantly strengthened.

#15-07 Chemical Inhibition of Bark Beetle Fungal Symbionts

Kurt Toenjes, Montana State University, Billings - \$81,071

[Final Report approved 10/22/15]

Summary

Preliminary experiments found that BH31-1, an antifungal compound characterized in the lab, inhibits the *in vitro* growth of some fungal species found in bark beetles. Three specific aims were originally proposed to further investigate the potential of this compound and its derivatives to act as antifungal agents against bark beetle fungal associates. Overall, excellent progress was made during the course of this project although work is still in progress to test additional fungal species and establish minimum inhibitory concentration for one of the fungal species (*Ceratocystiopsis brevicomi*). Findings show that BH31-1 and several of its derivatives exhibit strong antifungal activity against three common bark beetle fungal symbionts.

Commercialization

BH31-1 and its antifungal derivatives have commercial potential as a bark beetle control agent to reduce the fungal burden in beetle infested trees. A product that is used on a small scale to protect high value trees on private property is envisioned. Before commercialization can occur, other important goals must be accomplished, including

refining the treatment protocol in trees themselves and determining the best delivery method. Those goals are currently being worked toward.

Economic Impacts

The project employed a full-time laboratory technician, two part-time students and two summer faculty members, one patent application was submitted, a NSF EPSCoR grant for \$20,000 was received.

#15-09 MEMS-Based Adjustable-Focus Mirror for Microscopy

Peter Roos, Bridger Photonics, Inc. - \$84,353

[Final Report approved 8/19/2015]

Summary

The purpose of the project was to advance the technology to a market ready state. The technology has been developed and refined over the years at MSU and in collaboration with Bridger Photonics. This project advanced the technology towards a commercial produce through work on two objectives: (1) Refining the fabrication process for repeatable production; and (2) Conducting market research to gain sales opportunities.

The results of the first objective provided confidence that usable mirrors would be yielded from a production run. Now, several high-quality, sellable mirrors are yielded per wafer. Though the yields are still low, this is a drastic improvement from just a year ago. Part of the effort involved researching transition of the process to a commercial foundry. This is currently cost prohibitive, but once demand for the mirrors requires sufficient production volumes, they will be well positioned to transfer manufacturing to a high-quality foundry.

Work on the second objective yielded over 50 contacts and 12 interviews mostly from the Photonics West Exhibition in February. This did not result in any direct sales, but provided a good opportunity to connect with three key early adopters and generate a plan for future sales and distribution

The most significant outcome of this project is the formation of a new company, Revibro Inc. This company was formed as a spin-off from Bridger Photonics to lead the effort to bring the deformable mirror technology to market. Revibro has had several commercial sales of the MEMS mirrors and is well positioned with a strategic partner for direct OEM component sales in the coming year.

Commercialization

Deformable mirrors that provide compact, high-speed focusing for demanding optical systems

- **Target market including size and marketing strategy**

Primary target market is scientific microscopy for use in industrial and medical instruments. The possibility of an exclusive supply agreement with Zeiss (one of the world's largest manufacturers of scientific microscopy equipment) would yield sales of 1000 units per year within the next 2-3 years.

In addition, sales quantity estimates from the Zeiss medical instrument group are projected at around 3000 units per year.

Work with Caliber I.D. to define a collaborative effort on a new handheld confocal microscope aimed specifically at skin imaging. The intention is to pursue a joint development effort in the next two years with Dr. Rajadhyaksha of Memorial Sloan Kettering Cancer Center and Caliber I.D.

- **Production or manufacturing plan**

Revibro will continue to manufacture the mirrors at the MMF for now. Sales volumes of more than 1,200 units per year will enable engagement of a commercial foundry, possibly within the next five years. A commercial partner, such as Zeiss, may be interested in funding a foundry engagement in order to reduce unit costs for this key component. This would enable moving processing to a commercial foundry sooner.

- **Estimate of sales revenues for five-year period into the future**

If these target markets are addressed as planned, sales will be up to 4000 units per year within the next five years. At a cost of \$500 each, which is half of the current price, this equals \$2 million in revenue to Revibro through commercial sales.

Economic Impacts

- **New businesses created or expanded**

Formation of a new Montana small business – Revibro! MBRCT funding has resulted directly in the formation of this company through the support of the PI, Chris Arrasmith, and Bridger Photonics to refine the technology and spin the company off.

- **Increase in employment levels**

Direct support of employment of Mr. Arrasmith

- **Sales generated**

Delivery of high quality mirrors to key initial customer and on track to generate OEM sales agreement with that customer in the next year

- **Other**

Website www.revibrooptics.com has resulted in quotes sent to potential customers for products and provides early indication of future markets to consider.