Final Reports as of November 2009 - #07 Projects

#07-03 Immobilized Metal Polyamine Composites (IMPACS) for Removal and Recovery of Negatively Charged Species from Contaminated Waters and Mine Leaches
Edward Rosenberg
$217,459
Final report approved: September 2008

Summary:
This project has advanced the ability to remove specified minerals from mine leaches, surface waters and waste streams using Immobilized Metal Polyamine Composites (IMPACs). Achieving the objectives of the project has led to the development of commercial IMPAC, ZrBPAP, which is now being marketed and tested by the parent company for arsenic and selenium remediation and remediation of the carcinogenic chromate ion. The technology that is being commercialized is directed at positively charged ions and represents a new direction for supramolecular silica polyamine composite materials.

Commercialization:
Product description:
The product is a line of IMPACs for selective negative ion remediation and recovery sold by the Kg or metric ton as particles in the size range of 0.1 to 0.5 mm for use in small filter housings or large fixed bed reactors.

Target market:
Three key market segments:

- Environmental engineering companies charged with remediation of abandoned mine sites and waste streams from operational mines. There are 400 such mine sites in Montana alone.
- Growing gallium arsenide, glass and xerography industries where arsenic and selenium are key ingredients and where recovery and remediation are coupled processes.
- Agricultural areas where contamination of surface waters by arsenic is common

Competitive technologies and the advantages of the innovation:
Three commercial processes for removing arsenic and selenium from waste waters exist and numerous other technologies have been tried or are under development, but these have shown to be either inefficient or not viable for commercial production. The most important advantage of this technology is the basic idea of the innovation: to use different metals in different oxidation states and bind to appropriate matrices to accomplish finely tuned selectivity on a full range of negatively charged species.

Prior commercialization results:
During the NSF and previous MBRCT support, PSI/UM completed development of its copper-selective composite, CuWRAM, in 2003. The promising results of this technology led to the arrangement with Ammtec, Ltd. Ammtec is an internationally recognized metallurgical testing firm which specializes in mining, metals processing, and environmental remediation on mine sites. This arrangement led to Ammtec's becoming a 25% minority owner in PSI and enabled PSI to enter in a second partnering arrangement with a toll manufacturer that has produced six tons of PSI composites for delivery to customers. Also, Ammtec's confidence in PSI's technology was borne out last year with the first commercial sale of a related composite, WP-1, to Metal Recovery Technologies, of Irvine, California. Ammtec estimates that the total market for CuWRAM for copper recovery is $15-$20 million over the next two to three years.

Business Risk Assessment:
A feasibility report for manufacturing silica polyamine composites in Montana was conducted as part of this project and contains costs for manufacturing and an estimate of required capital investments.

Economic Impacts:
Increase in employment levels:
One part-time chemist's position is now full-time.

Sales generated:
The first significant sale occurred in 2007 as a large scale commercial project using one of the silica polyamine composites was started.

Development of intellectual property/patents:
PSI has supported the development of four patents to date. The patents were assigned to the UM with exclusive license to PSI in return for 2% of gross adjusted sales. The arrangement is covered under an intellectual property agreement between PSI and UM and any new intellectual property resulting from Phase I or Phase II efforts will be covered under this agreement.

Acquisition of investment capital:
Purity Systems has a distribution arrangement with Ammtec Limited in Balcatta, Western Australia, and they are minority shareholders in PSI. Production and sales of the products will be financed with additional private capital. Ammtec bought a controlling interest in PSI in 2007. Bruce Arnall, of Ammtec, is now supervising manufacturing and marketing of PSI materials.

Other:

- **A**t the end of 2006 PSI established a toll manufacturing agreement with Synergetica Inc., a Shanghai based company with five manufacturing plants. This company is working with PSI to develop GMP- IS9000 protocols for the PSI product line.

- Seven publications have resulted from the work and MBRCT has been acknowledged in each.
- Five presentations have been made at meetings and universities.
- The project has garnered $460,000 in follow-on funding from NSF, a STTR Phase I and a GOALI grant.

#07-04 Montana Infrastructure via Science and Technology Enhanced Partnerships – INSTEP (NSF EPSCoR)
Charles Thompson
$750,000
Final report approved: May 2008

Summary:
This project represents the third year of a three-year NSF/MBRCT award. The NSF EPSCoR grant proposed to build eighteen programs and develop four research areas: (1) to enhance and develop a Center for Biomolecular Structure and Dynamics with a concurrent PhD program at UM (CBSD – Center for Biomolecular Structure and Dynamics; (2) to redirect/transform the MSU Engineering Research program to take advantage of the advances in the basic sciences at MSU (BIOE); (3) to create and develop a Center for Bio-inspired Nanomaterials (CBIN) at MSU; and, (4) to enhance and augment the Neuroscience research cluster groups at UM and MSU, thereby building the first EPSCoR-supported inter-institutional PhD program (CSFN – Center for Structural and Functional Neurosciences). The Montana NSF EPSCoR has worked towards the overall goal of developing these research focus areas by enabling faculty hires, graduate and undergraduate student support, technician hires, equipment for core support facilities, information technologies upgrades, web development and information dissemination, seminars, conferences, and support for visiting scholars at UM, MSU, Montana Tech and Tribal colleges. The program has joined together past, current and future scientists into Centers of Excellence that build and sustain specific scientific expertise in Montana.

Results:
All of the milestones for this award have been met, exceeded, or terminated with funding moved to another successful already-underway program. Projects completed or established include:

- Two new centers – Center for Biomolecular Structure and Dynamics (CBSD) at UM, and Center for Bio-inspired Nanomaterials (CBIN) at MSU
- 26 new faculty hires (19 in the four research focus areas and 7 in subprogram areas)
- New, stronger Tribal College connections and research collaborations including co-funding of five new faculty hires
- K-12 and community outreach programs aimed at enhancing Montana's science and technology infrastructure, including the creation of spectrUM, a hands-on science learning center at UM.
- Co-invested in S&T-based businesses

- Enhanced Montana's non-PhD granting institutions, research and science education capacity, and generated new research space.
- Invested in local and regional businesses through SBIR Phase 0 and 1.5 awards and new SBIR-based incentives under MTIP (Montana Technology Innovation Partnership)

Commercial Potential:
EPSCoR's co-investment with the MTIP (Montana Technology Innovation Partnership) has:

- Facilitated the provision of more competitive funding
- Provided counseling and promotion of SBIR award and business plan writing
- Increased faculty involvement through seminars and conferences and more in-depth investment in Montana-based company infrastructure.
- Through its Outreach Program counseling services, the MTIP program has changed the SBIR award odds from one win in 12 submissions to one win in six submissions, a 50% improvement in the chances of receiving federal funding. As the award rate has risen from 20 in 1999 to 40 in 2006, the amount of these awards has also risen from $4.0 million in 1999 to over $15.0 million in 2006.

#07-06 Evaluation of Oilseed Crops for Biodiesel Production and Quality in Montana
Jerald W. Bergman
$75,000
Final report approved: September 2009

Summary:
The project evaluated oilseed crops for: (1) yield performance and agronomic characteristics under irrigated production in eastern Montana; (2) oil extraction from the oilseeds; and, (3) biodiesel production from the resulting vegetable oils. Eight different oilseed crops were tested: high linoleic safflower, high oleic safflower, high oleic sunflower, flax, soybean, Canola, camelina and crambe. High oleic safflower, high oleic sunflower, high linoleic safflower, soybeans, and flax produced significant seed and oil yields. Canola, crambe and camelina yielded poorly due to weather and seedling emergence problems. The project demonstrated that oilseeds may be successfully grown in Montana to produce biodiesel. The results of the study document that Montana grown safflower and sunflower will produce more oil or biodiesel per acre in eastern Montana than soybeans in the Corn Belt states and will support biodiesel processing and manufacturing in Montana. The bottom line is that the project has resulted in expansion of a host of research capabilities, infrastructure and equipment that is available to Montana's producers and private companies to further diversify Montana's agricultural industry.

Commercialization:

- The project developed, produced, and evaluated value-added safflower genetic lines and seven oilseed crops for comparative biodiesel yield per acre and for the physical and quality factors of each biodiesel.

- A research and demonstration production biodiesel system was purchased, and protocols were developed and utilized to produce ASTM quality biodiesel from the vegetable oils**.**
- The protocols have been documented for biodiesel companies and others interested in producing ASTM quality biodiesel.
- The biodiesel produced from each vegetable oil was analyzed for physical and quality factors.
- The biodiesel physical and quality factors for each of the unrefined vegetable oils were determined and documented for use by biodiesel manufacturers, farm cooperatives, and others interested in establishing oilseed and biodiesel manufacturing plants in Montana**.**

Economic Impacts:

- EARC has the land and plot research field equipment for planting, care and maintenance, and harvesting of experimental specialty oilseed crops/varieties.
- EARC has the laboratory facilities and equipment for analyzing the oil and meal quality characteristics of oilseed crops to assess biodiesel characteristics and attributes of any oilseeds of interest to potential biodiesel manufacturers.
- EARC has the research capabilities to grow, produce, and evaluate unrefined specialty vegetable oilseed crop varieties for biodiesel as well as for biolubricants, cosmetics, livestock nutrition, food and other value-added biobased products in joint efforts with private companies and producers.
- New value-added safflower products are available for further research and development for commercialization in Montana and globally.
- Future research will help diversify crop production in Montana from wheat and barley and promote agricultural manufacturing and processing of biobased oilseed products.

#07-08 NeuroSys Innovative Computer Software for Rapid Database Generation
Gwen Jacobs
$400,000
Final report approved: January 2009

Summary:

The purpose of the project was to determine the extent to which a data management software application (developed from NIH Human Brain Project program funding) could be extended to the commercial marketplace. In the first year of the project, efforts were directed toward finalizing a commercial release of the prototype software NeuroSys. The commercial version was named HeirLogic (HL) and corrected problems existing in the NeuroSys release. The MSU software development team evaluated the NeuroSys and HL code bases and determined there were barriers to developing a robust, software application that would meet the aims of the NIH funded project. A new direction was chosen using the Ruby on Rails programming language, which is considered the most easy to learn and most well-thought-out web application environment currently available. During the second year of the grant, the focus was on determining if there were elements of HL that could be leveraged into the commercial market place. The possibilities with

the tools appeared unlimited, but operation and functionality of the system was difficult to describe and sell. The objectives of the proposal were fulfilled in that the technology architecture and features and functions of the software were vetted in many market places. The objectives for the tool are viable and would meet a market need if implemented. However, the framework and architecture that were implemented were not maintainable and did not provide a market advantage over currently available technology.

Commercialization:
The plan for commercialization of the HierLogic Software suite is no longer feasible, in part because the previous developers are no longer part of the project and also because the new team of developers, supported by NIH funds, is pursuing a different development platform. However, based on market research done by Bridger Informatics and feedback from current users of the four prototype applications, the belief is that there are many commercial opportunities for the new Yogo Data Management Toolkit.

Product description
Yogo Data Management Toolkit

Marketing strategy
Change of direction from marketing a stand-alone, turn-key system to marketing a customized hosted solution that meets the needs of particular sets of customers. Each prototype is specifically designed for a particular marketing niche with input from user groups. Commercial versions will require a blend of basic functions the application supports and the level of customization required by each user. Two major marketing strategies are apparent at this time, and will be pursued for future tools that are developed using federal funding sources:

(1) Developing a generic, turn-key application that can be purchased and downloaded without requiring any customization from the team.
(2) Host the application, customize it for the user and provide ongoing support as part of a service contract arrangement.

Economic Impacts:
Although there are no direct economic impacts at present, opportunities for future impacts exist through the development and marketing of the prototype applications. MSU has realized significant cost savings through the use of the Faculty Activity Database prototype. Further development of this application and other productivity tools for the university will reduce its dependence on proprietary software and free up time for University staff to pursue other duties. Highly marketable programming skills have been developed by developers on the MSU research team as a part of this project. Individuals with little or no programming experience are now competent programmers whose skills are in great demand by companies and software development groups using the Ruby on Rails environment.

#07-11 Smart Adaptive Antennas for Wireless Communications in Rural and Sparsley Populated Areas
Yikun Huang
$199,431
Final report approved: October 2009

Summary:
The purpose of the collaborative project with Advanced Acoustic Concepts Inc. (AAC) was to design and develop an adaptive smart antenna to achieve improved performance for mobile nodes and to suppress potential interference from unwanted signals.

Achievements include:

- Construction of an 8-element circular array antenna that covers a 360° field of view and forms a beam as low as 4°.
- Design of a LabVIEW PC interface
- Design of a translation board for DOA (direction of arrival) estimation
- Development of a digitally controlled analog beamforming board for two-way beamforming.
- Test and evaluation of the system performance – the results show that the smart adaptive antenna is capable of tracking mobile targets, directionally communicating with desired users, suppressing interference and jamming, covering a long range with high throughput and reliable connection. The design enables effective solutions to major problems in wireless networks in sparsely populated and remote areas.
- This is the first commercial technology to consolidate several advanced techniques in one small size, lightweight, multi-function, low cost communication unit. It provides users with easy access to a communication network where wired transmission is too costly, inconvenient, or unavailable.
- The adaptive smart antenna system is applicable for military and hi-quality commercial wireless applications.
- A physical prototype has been demonstrated with sufficient laboratory evaluations and field tests to determine the engineering feasibility of the product or technology and its producibility. The ability to achieve full-scale production and fielding is the key to commercialization success of this project.

AAC and MSU are pursuing applications of the technology both as an integral system to the U.S. Navy and commercial applications. They are also working closely with Harris Radio Company to develop a communication system with the company's Sealancet Radio and the smart antenna for the U.S. Navy. AAC will soon start negotiations with Thales, a Netherland based company, for providing smart antenna, radio systems and full service. Research results have been presented at major conferences, including IEEE AP-S symposium, IEEE Aerospace conference, and IEEE Mobile WiMAX symposium. Seven papers have been published in IEEE proceedings.

Commercialization:

Product description
Effective, low cost data link antenna beamforming system. Work is under way between MSU and AAC to develop a Harris Radio-AAC/Montana State Beamforming Antenna Interface for US Navy. Called the Harris' SeaLancet, this is a tactical, wideband OFDM networked radio solution designed specifically to meet the demanding communications requirements of military maritime missions. Negotiations are under way with Thales, a Netherland based company, for providing smart antennas, radio systems and full service line-of-sight radio communication sub-systems.

Marketing strategy
Other potential customers for the adaptive antenna beamformer would include the U.S. Air Force, FAA, Department of Labor, U.S. Army, Department of Homeland Defense and commercial utility companies. AAC is currently working on programs in areas in which the wireless data link with adaptive beamformed antenna capability could be applied. A stand-alone system for commercial homeland security application can be readily available to the commercial marketplace with little development costs.

Other commercial industry applications when an effective, low cost, low power adaptive beamformed system is developed for long range wireless data links include: NOAA offshore buoys, animal tracking, farming and agriculture, first responder rescue, mass transit broadband backbone (ferry, trains), and commercial shipping broadband backbone.

A memorandum dated 7/22/09 describes the plans to interface the Harris SeaLancet radio to the AAC/MSU beamforming antenna, to define the interface, and the scope and goals of tests and demonstrations.

Estimate of sales revenues for five-year period into the future
Harris' SeaLancet – success of this collaboration could bring hundreds of thousands of dollars in revenues. Thales – success of these negotiations could also bring hundreds of thousands of dollars in revenues.

Economic Impacts:

Development of intellectual property
The smart antenna developed under this project allows wireless experiments and characterization of various array algorithms under realistic channel condition so as to solve fundamental problems facing commercial wireless networks, emergency networks and military networks alike.

The project also inspired the study of the feasibility of implementation of smart antennas in conjunction with cognitive radio technologies to create antenna array systems capable of reconfiguring their spatial and spectral receiving and transmitting characteristics in response to dynamic environmental demands. The project is particularly timely because

dynamic spectrum access for wireless communication is at the forefront of next generation wireless networks.

The technology resulting from this project will be implemented in a wireless device which will continue to remain fully functional in a multi-station environment by implementing multi-beamforming whereby retaining the capability to service multiple stations while maintaining the varied benefits of a beamformed antenna system.

Other:
The project will also have broader impacts in that it will continue to serve the scientific community through its educational component by providing undergraduate, graduate and postdoctoral candidates with a comprehensive learning experience. From summer 2006 through summer 2009, 31 undergraduates are involved in basic smart antenna system design, testing and communication networking research. Three of these undergraduates are Native American students and three are female students. The research has resulted in development of vehicles suitable for achieving an advanced level of education and training in electrical engineering and computer science areas.

Unique features/success stories/news clippings, brochures/other information:
"Counter Detection White Paper"

#07-17 New Red Laser-Excited Fluorescent Dyes for Ultrasensitive Multiplex Detection in Proteomics and Diagnostics
Edward A. Dratz
$50,000
Final report approved: April 2008

Summary:
The goal of this project was to complete testing on the red laser-excited Zdye needed as the third member of a set of three ultrasensitive Zdye proteomic detection dyes for the first commercial Zdye product package. Using a new type of "constrained" Zdyes, a more stable red laser-excited Zdye was designed and synthesized. This was essential for obtaining a key NIH Phase II STTR proposal recently funded at $1.2 million for three years that will support the commercialization of the Zdyes. Others awards for continuing the work have been received: a two-year NIH STTR Phase I for $400,000 and an award from BioRad, Inc. for one year for $300,000.

Although it has taken longer than expected to develop the products to the point of external testing and commercialization, the commercial potential of the results of this project appear considerable. The new three-year NIH Phase II STTR recently awarded for Zdye commercialization reviewed extremely well by NIH. BioRad, a major player in proteomics equipment and supplies, has determined the Zdye technology is worthy of investment and plans to cooperate in marketing and distribution of new types Zdyes.

Commercialization:

Product description
The Zdye detection dyes will be commercialized in cooperation with Zdye LLC. The initial product is a set of three fluorescent protein detection Zdyes. These are excited by blue, green and red lasers that are standard in virtually all the large installed laser scanner bases in the United States and world wide. There are ultimately 12 steps, or product phases, planned. Zdye also plans to market a hyperspectral scanner in cooperation with Resonon and possibly a fluorescence lifetime imaging scanner in cooperation with Fluorescence Innovations.

Target market including size
Proteomics is a rapidly growing field representing a growing multi-billion dollar business. The market is segmented into three broad areas: apparatus, consumables and informatics. Zdye will focus its efforts on serving the growing consumables demand through multiplex 2D gels, but is also developing a presence in the instrumentation market segment and an evolving presence in informatics. These markets include: basic biomedical and agricultural research, biomarker discovery, drug discovery, and healthcare.

Marketing strategy
Marketing will occur by way of presentations at scientific meetings, publications in scientific journals, beta testing collaborators in the United States, Europe and Australia, an informative web site and by Zdye booths at trade shows. A marketing relationship with BioRad would leverage its long-standing marketing machine that is active and effective world-wide.

Production or manufacturing plan
Production and marketing can be conducted in current facilities for about two years. An experienced Masters degreed chemist has been hired to carry out larger scale production runs. When the scale of production increases, a larger laboratory will be established in Bozeman.

Business risk assessment
The largest current risk appears to be in the area of intellectual property because earlier patent work done by MSU using a previous law firm ran into difficulties. The patent applications are being amended, a number of new provisional patent applications are being developed, and the patent portfolio is being shored up.

Estimate of sales revenues for five-year period into the future
Total estimated gross sales revenue is broken down into seven product lines: 1D gels, 2D gels: amino labels, 2D gels: thiol labels, differential LC, posttranslational modifications, hyperspectral imager, differential enzyme activity.

Economic Impacts:
New businesses created or expanded

The Zdye technology, developed at MSU, has fostered the creation of a new company, Zdye, LLC. It has also developed close, synergistic connections with Resonon, Snider Technologies, Fluorescence Innovations, and Goldenhelix.

Increase in employment levels
Zdye LLC employs or supports four PhD, two MS technicians, a BA technician and six graduate students/PhD candidates in addition to the principles. In addition, the collaborating companies employ about 20 high-level professionals.

Patents applied for or granted
MSU has five patent applications pending on Zdye technology licensed exclusively to Zdye LLC.

Other
Zdye LLC's technology is well positioned to make a very significant market penetration in this greatly expanding proteomics market.

#07-24 Demineralized Bone Matrix Putty for Transplantation
Gregory A. Juda – Bacterin International, Inc. - Belgrade
$165,974
Final report approved: February 2008

Summary:
The focus of this project was development of DBM putty to be engineered, manufactured, and distributed by Bacterin. Emphasis was placed on producing the best handling characteristics for the surgeon while maintaining the highest potential for bone formation. Funds were used to drive research toward product handling, potential for bone formation, and process validation. The product is a complement to Bacterin's life enhancing allografts that are produced in a new state-of-the-art tissue processing facility in Belgrade.

Early analysis of the material in an athymic mouse implant model indicated potential to form new bone, an essential design requirement for the product. Further research was conducted to determine the effects of terminal gamma irradiation on the bone formation of the DBM putty. Results of that study indicated that, while gamma irradiation decreases bone forming potential, it is still maintained at doses of up to 20 kGy. This is important because Bacterin intends to terminally irradiate its DBM putty in order to obtain a "Sterile" claim, which is consistent with other allografts manufactured by Bacterin. Funds were also used to validate Bacterin's production of DBM for inactivation of potential viral contaminants, a FDA regulatory requirement for market approval of biologic derived medical devices.

All of the original objectives were met. A DBM putty formulation was developed with excellent handling characteristics and proven bone forming potential. The necessary production equipment and supplies have been obtained and a process validation plan has been developed. Pending regulatory approval, commercialization is anticipated in 2008.

The final studies, including a preclinical implant study in a rabbit and validation of the DBM manufacturing process, for submitting a 510(k) application to the FDA are underway.

Commercialization
Product Description*:*
Demineralized bone matrix (DBM) putty for use in repairing and replacing bone during orthopaedic and maxillofacial surgical procedures.

Target Market:
Although the U.S. DBM market is expected to remain flat over 2006 (112,458 procedures), growth in the international orthopedic spine sector is expected to grow at a rate of 20% per year over the next five years due to cervical procedures on an aging population.

Marketing Strategy:
Market position will be obtained comparing published data from other nationally recognized DBM manufacturers with the superior osteoinductivity results of Bacterin's DBM putty.

Production or manufacturing plan:
Process validation plans which detail what is required to validate every step of the manufacturing process and identify who in the company is responsible for validating these steps. A process validation plan is an essential component of Quality Systems Regulation and is a FDA requirement for control of medical device manufacturing.

Business risk assessment:
Single business risk exists in the FDA regulated domain where issues with product safety remain a concern when using any human derived product even though there have been no documented cases of disease transmission using human freeze-dried demineralized allograft products to date.

Estimate of sales revenues for five-year period into the future:
Total sales of Bacterin's DBM putty are projected in the range of $5MM to $10.4MM.

Economic Impacts:
Increase in employment levels:

- Specialized requirements for the production of DBM will result in the employment of more local scientists, quality assurance personnel, and allograft processing technicians.
- Manufacture of the product will generate higher paying salaries for current and future employees of Bacterin.
- Over 50% of current staff is Montana natives or graduate of Montana schools and all of Bacterin's scientists are graduates of MSU-Bozeman.
- Bacterin hired six new employees in 2008 – positions include allograft processing technicians, quality assurance personnel, sales and customer service, and clinical

laboratory scientists. Each position was filled by an individual currently residing in the Gallatin Valley.

Patents applied for or granted:
The DBM technology will create more jobs, investment capital, and expedite the potential acquisition of other vertically

Development of intellectual property:
Intellectual property involving production of an antimicrobial version of Bacterin's DBM products is under consideration.

Other:
In 2007, Bacterin hosted a grant opening for its allograft processing facility in Belgrade. The first allograft tissue processed by Bacterin in this new facility was distributed for transplant in November 2007. Bacterin's processing infrastructure was inspected by the American Association of Tissue Banks in January 2008 and no deficiencies in the processing operation were found. Full accreditation is expected by March 2008.

#07-27 High-Performance Biobased Motor Oils from Vegetable Oil Estolides
Brett Earl – Peaks & Prairies - Malta
$170,000
Final report approved: September 2009

Summary:
The purpose of the project was to create high-performance biobased motor oil for military and consumer use. The goals were to keep the formulation non-toxic and biodegradable, create a product equivalent, or superior, to conventional and synthetic motor oils, and maintain a competitive pour point. The PI collaborated with USDA and Montana State University Northern to create superior biobased motor oil using the patented estolide molecule licensed from USDA. Three grades of motor oil, 5W40, 10W30, and 15W40, were developed. The 10W30 is the most promising.

Commercialization:
Product description
The product is biobased motor oil, Eco Oil 4, a 10W30 competitive in the synthetic lubricant market. The goal is to keep the biodegradability of the product at 90% plus, increase fuel economy in an automobile by 3%, and improve wear performance.

Target market including size
The market is the synthetic motor oil market, which represents 8% of total motor oil sales, 78 million gallons, in the U.S. Peaks & Prairies anticipates taking 3% of the synthetic motor oil market, 2.3 gallons, in the US within five years.

Marketing strategy
Two avenues will be executed simultaneously: (1) premium blenders that work directly with major automotive or equipment companies. Peaks & Prairies would act as an OEM

for a larger company, which will purchase product from Peaks & Prairies; (2) become a distributor for a nationwide Oil Club. The marketing strategy will be executed in the final stages of product development and testing. Through the Oil Club program, consumers are offered an engine warranty for five months or 5,000 miles for purchasing eco-friendly motor oil. This program has the potential to bolster Peaks & Prairies biobased motor oil sales and break into the retail market. Peaks & Prairies will focus on negotiating an arrangement for the sale of its biobased motor oil to the Oil Club, creating promotional literature, and organizing a recycling plan.

Production or manufacturing plan
Peaks & Prairies has determined not to build a motor oil plant initially. Instead, it plans a more cost-effective approach by building an estolide plant to produce the base oil, estolide, for the biobased motor oil. The base oil will be shipped to a blender for mixing and bottling. (As sales increase, a separate production plant for blending lubricants may be built.) The pilot plant will have an annual output of 175,500 gallons. A full-scale production plant will likely be built in year three which would produce 5 million gallons of estolide per year. By year five, it will outgrow the production plant if the requirements of a company currently showing interest are to be met.

Business risk assessment
An in-depth Business Risk Assessment is included in the Final Report. The assessment includes the results of a risk assessment survey and a risk mapping tool.

Economic Impacts:
Increase in employment levels
Employment levels were at their peak in 2006, with a full-time business manager, a full-time plant manager, and four part-time employees. The biobased motor oil project was being executed and the crushing facility was producing oil, meal, and a small amount of biolubricant products.

Patents applied for or granted
In 2007 Peaks & Prairies signed a license agreement with the USDA for two patented technologies for the estolide molecule.

Development of intellectual property
The company owned the intellectual property of the estolide molecule, which was worthy of investor interest.

Acquisition of investment capital
In 2007 a venture capital consultant firm was retained for consulting services and for the purposes of gaining venture capital. The company was dismissed in late in 2007 because it had not fulfilled their promise. An investment group in the United Kingdom, invested in Peaks & Prairies biobased motor oil project from spring of 2008 until February 2009; however, its funding dried up due to other investments and the economic down turn.

Other
An agreement is now being finalized with a business management team comprised of three experienced businessmen, each with experience taking struggling start-up companies and turning them into "multi-million dollar businesses".

Unique features/success stories/news clippings, brochures/other information
"Going Green: Are Bio-Based Motor Oils in Your Future?" Sept. 2007, *National Oil & Lube News*, www.noin.net.
"Company Sees Oilseeds as Economic Fuel in Montana" April 2008, *Billings Gazette.*

#07-28 Research Support for the Development and Manufacturing of a Rapid Biofilm Analysis Test Kit
Darla Goeres – Center for Biofilm Engineering – Montana State University - Bozeman
$151,250
Final report approved: February 2009

Summary:
The goal of this project was to develop a second, more modern, rapid and simple method for analyzing numbers of active biofilm bacteria and then design a test kit based upon the method. Results data showed that the CTC elution technology upon which the analysis method was based, is suitable as a laboratory screening tool, but is not ready for field applications and consequently commercialization. A need exists for a rapid biofilm analysis test kit and this project represents an initial attempt to standardize a modern microbiology research method into a field ready standard method. Once the method is standardized, a test kit can be built by simply assembling all of the components necessary to execute the method.

Commercialization Plan
BioSurface Technologies Corporation licenses biofilm reactor system technologies from MSU Center for Biofilm Engineering and has established a market for these technologies. It has returned royalties to MSU for a total in excess of $50,000. Primary products from these technologies have been the Biofilm Annular Reactor, Rotating Disc Reactor and the Drip Flow Reactor.

Product Description:
The Rapid Biofilm Analysis Test Kit concept is based on providing a quick and simple evaluation of biofilm deposits for bacterial activity using a spectroscopic assay. The technology used provides quantitative data within a 1-3 hour incubation period, which greatly improves on the culturing methods used in competing technologies that take from days to weeks. The test kit is also compatible with many types of microorganisms without regard to growth requirements. The Rapid Biofilm Analysis Test Kit developed under this project using the CTC activity stain has proven to have limitations that prevent commercialization at this time. The limitations include cost of the activity stain that is

required to generate a test data point, the variability of the stain product as received from the manufacturer, and the variability of the bacterial reduction of the stain. The cost of the kit does not compare favorably with competing products nor does the technology provide advantages in sensitivity, accuracy, or time compared to other technology. Although commercialization of the Rapid Biofilm Test Kit using CTC is not viable, a relevant technology has been identified that may be used as a sampling aid for biofilm coupon evaluations. The project has identified a need for a tool that allows manipulation of biofilm coupon surfaces to minimize handling and hasten the coupon sampling process.

Economic Impacts:
An important outcome of this project was the evolution of a coupon manipulation system that would enable researchers to more efficiently process multiple biofilm coupons during disinfectant efficacy testing. This system would include a tool designed to compliment BioSurface Technologies current biofilm reactors and might result in a product that BST can immediately manufacture and sell.

Three undergraduate students, all graduates of Montana high schools, were involved in the project.

#07-41 Enhancement of Applied/Translational Research in Biomedicine
Richard Bridges – University of Montana - Missoula
$67,880
Final report approved: October 2007

Summary:
This report marks the conclusion of the one-year performance period for the fourth award that the MBRCT made to the NIH Center for Biomedical Research Excellence (COBRE) in Structural and Functional Neuroscience (CSFN). The overall goal of the NIH-funded COBRE award was to establish *CSFN* for the purposes of increasing critical mass of researchers and providing the needed infrastructure to increase the competitiveness of biomedical research efforts in Montana. As part of this five-year effort, the overall goal of the MBRCT award was to supplement this effort in a manner that would positively impact economic development in Montana within the area of applied biomedical research. In addition to the University of Montana, this project also included St. Patrick Hospital and Health Sciences Center and the Montana Neuroscience Institute in Missoula, as well as collaborative efforts with emerging biotech companies in Montana.

Significant progress has been made utilizing the MBRCT award to extend the COBRE funding and enhance applied biomedical research efforts in the state. Specifically, considerable success has been achieved in relationship to the original goals in the areas of: increasing research-related funding and jobs (Aim I), supporting shared instrumentation (Aim II), training students (Aim III), increasing opportunities for private sector collaboration and IP commercialization (e.g., SBIR awards, university-private sector collaborations) (Aim IV). It is important to note that this grant award period overlapped with the final year of funding for MBRCT award #05-31, consequently both reports share several of the same benchmarks and accomplishments.

Commercialization:

Product description
The purpose of this project is to develop infrastructure in the area of applied biomedical research and, therefore, does not fall easily into the typical commercialization model.

Economic Impacts:
This project is a continuation of several previous MBRCT projects and is positively impacting economic development in Montana within the area of applied biomedical research.

New businesses created or expanded
Four spin-off companies – Big Sky Biotechnologies, TranSynaptic, ATERIS, and GT Pharma

Increase in employment levels
Project has contributed to the salaries of more than 70 employees, including 30 students

Sales generated
Project has brought in more than $13 million in federal research contract dollars in the past year.

Patents applied for or granted
Five provisional patents were filed during the award period.

Development of intellectual property
Intellectual property has been the foundation for the establishment of four new Biotech companies, Big Sky Biotechnologies, TranSynaptic, ATERIS, and GT Pharma Inc.

#07-51 Development of a Novel, Nanoparticle Vaccine Adjuvant
Jon Nagy, Ph.D., NanoValent Pharmaceuticals
$274,000
Final report approved: August 2008

Summary:
The goal of the project was to expand the development of a novel vaccine delivery and adjuvant system and to demonstrate its utility to a problem of bioterrorism and agricultural concern. The study demonstrated that for plague vaccine applications, the nanoparticle adjuvant protection is much stronger than the protection induced by the currently approved human vaccine adjuvant, ALUM. Based on these results, NanoValent Technologies applied for, and received, a patent 10/23/07. The study suggests that vaccines using this technology will provide superior protection to humans and livestock for diseases that would otherwise be minimally treatable or untreatable. The commercial potential is quite large. The company will use the results to attract a vaccine development partner to begin toxicity studies and enter into human clinical trials.

Commercialization:

Polymerized Liposomal Nanoparticle Adjuvant (PLNA) is a platform technology that is applicable to an array of new vaccine adjuvants to treat a variety of human pathogens. The candidate is ready to enter preclinical toxicity, dosing, metabolism, and pharmacokinetic studies either in NanoValent labs or with a partnered biotechnology firm.

Product description

The product is a new nanoparticle adjuvant/vaccine delivery plateform and subunit vaccine that can combat the biological threat posed by the plague. The adjuvants developed through this research will pave the way for improved versions of current vaccines (including reduced dosing requirements and reduced side effects.) Better adjuvants will help create new vaccines for infectious agents where no vaccination is currently available. The first candidate vaccine will target *Yersinia pestis. A*dditional indications with larger potential markets including vaccines for *Candida albicans,* anthrax and vaccines against various cancers will be targeted later.

Target market

Current total vaccine market is approximately $6 billion and is expected to grow to $20 billion by 2010. The market is driven by geological threats, the need for cancer vaccine adjuvants, emerging viral infections such as West Nile, and limits on flu vaccine supplies. These factors present a commercialization opportunity for products using improved vaccine technology.

Product commercialization strategy

NanoValent will enter into application specific full licensing agreements or optionable licensing agreements with biotechnology firms involved in marketing novel vaccine technologies. NanoValent has contacted the National Security Division of Battelle Memorial Institute at Columbus, Ohio, regarding applications and possible partnerships involving Biodefense and bioterrorism applications of NanoValent's adjuvant technology. Further experimentation and studies are necessary and will be funded through commercial development partnerships or venture capital sources.

Manufacturing plan

NanoValent plans to manufacture PLNA particles in house for R&D and to supply its vaccine technology partners the PLNA needed to carry out preclinical studies. Later, NanoValent will outsource the scale-up and production to a contract liposome nanoparticle manufacturer such as Northern Lipids, Inc.

Patents and development of intellectual property

NanoValent is the owner of a patent application granted on 10/23/07. The patent "covers a vaccine delivery system comprising polymerized and partially polymerized liposomes and an antigen associated with the liposomes, wherein the antigen is capable of eliciting a protective immune response".