Progenesis Technologies, LLC
One John Marshall Drive
BBSC Suite 314
Huntington, WV 25755

PROGENESIS TECHNOLOGIES, LLC

NEWSLETTER, FALL - 2016

Yes, Progenesis is still here! It is difficult to believe that more than a year has passed since we distributed our last newsletter. The company has been focusing on accomplishing the research objectives outlined in our funded NIH Phase I SBIR grant. For those of you not familiar with this grant program, it was instituted in 1977 through the National Science Foundation. Due to the success of this program, the Small Business Administration Lobbied Congress to extend it to all government agencies that award research grants with a budget in excess of $100 million. This government-wide SBIR program was signed into law in 1982 by then President Reagan. The program has been quite successful, resulting in 70,000 issued patents, the establishment of almost 700 new public companies and roughly $41billion in venture capital investments. The purpose of the SBIR program is to stimulate technological innovation through a highly competitive grant program that is only available to small US businesses. Presently Federal agencies with R&D budgets that exceed $100 million are required to allocate 2.8% of the R&D budget to this program. In general, WV has not competed very well in this program. For 2015 WV had 4 phase I awards and 0 phase II awards. The is the lowest of all the states contiguous to WV (PA, OH, KY, VA and MD). Progenesis was pleased to be one of the 4-WV phase I awardees and the only one awarded through the National Institutes of Health. As you will see, much of our non-laboratory effort during the first half of 2016 was devoted to composing and submitting a competitive Phase II SBIR proposal.

Research and Development Progress

We have finished 95% of the objectives stated in our awarded Phase I NIH award. The research has resulted in a new strain of Pseudomonas aeruginosa designated PGN4. We removed the genes that coded for the products of concern to the FDA and documented their absence compared to the VE2 bacterial strain. We also identified a gene called aroA that is reported to be crucial for causing infections in humans and demonstrated that its deletion in a normal strain of Pseudomonas aeruginosa resulted in 100% survival of mice. The normal strain

with an intact aroA gene caused death in ~70% of the mice. For the remaining work that is part of the Phase I SBIR grant, we will delete the aroA gene from PGN4 to create a new strain designated PGN5. This strain will then be injected into mice and its virulence compared to PGN4, and E coli K12, a strain of bacteria that is approved by the FDA to manufacture human pharmaceuticals such as insulin and human growth factor. If PGN5 is 100% non-virulent, then we will measure its alginate production to ensure that this biopolymer is still produced at high levels.

Dr. Ryan Withers has resigned his position at Progenesis and has accepted a position with the FDA in Morgantown, WV. Ryan and his wife's family all live in the Morgantown area and with the arrival of their second child, the excited grandparents can spend more time with the grandchildren. Ryan did an excellent job for Progenesis and composed the draft of the SBIR phase I grant that was funded after submission of a revised version. We wish Ryan success in his new position. Brandon Kirby has joined Progenesis as Lab Technician. Brandon graduated from Bluefield State in May of 2015 with 4.0 GPA. From October 2011 to October 2015, he worked with Dr. Tesfaye Belay on experiments involving mouse models and molecular biology. He studied *Pseudomonas aeruginosa* biofilm development and worked on mouse infection models. He presented at many national conferences including Annual Biomedical Research Conference for Minority Students (ABRCMS) 2012, American Society for Microbiology (ASM) 2013, and National IDeA Symposium of Biomedical Research Excellence (NISBRE 2014). He was awarded a research and presentation award at ABRCMS in 2012 and a capstone award from ASM in 2013.

Business Developments

With the departure of Dr. Withers from Progenesis and the retirement of Dick Niles from Marshall, Dick has assumed enhanced responsibility for the company as the Chief Operating Officer (COO). Also, the Principal Investigator status for the Phase I grant was transferred to Dr. Niles. Early on we made the decision to hire a consulting company, BBC Entrepreneurial Training & Consulting located in Ann Arbor Michigan to help in the development of the Phase II NIH SBIR application. This company has a strong track record in assisting small technology firms to successfully compete for SBIR funding. After deliberations with BBC, it was decided that for the Phase II application Progenesis would focus on producing unique alginates for the advanced wound care market. The global market for these products in 2014 was $9.9 billion USD and projected to grow to $13.8 billion USD by 2021. Alginate dressing comprise about 5-7% of this market, or $690 million USD by 2021. This increase is due to the evolving epidemic of diabetes and obesity as well as an aging population. Alginate dressings are typically used for wounds that release a fair amount of fluid, including burns, surgical incisions and chronic ulcers. Currently alginate plays a mainly passive role, i.e. absorbing fluid. This is due to the limitation of seaweed alginate. Therefore, the major manufacturers of alginate dressings are restricted in their ability to distinguish their product from that of their competitors. This presents a commercial opportunity for Progenesis to provide alginates of unique composition that will significantly improve wound care treatment by decreasing the amount of time for the wound to heal and to decrease the susceptibility of the wound to infection.

We have 3 objectives in the Phase II application. The first is to use genetic engineering to produce alginates that have different ratios of the M and G sugars that compose the polymer. Also, to have differing amount of the chemical modification of the M sugar (acetylation) that affects the ability of the polymer to absorb fluid. The second objective is to determine the best alginate composition and modifications for speeding wound closure in animal models. This part of the work will be performed by Dr. JinSong Hao, an Associate Professor in the Marshall School of Pharmacy. Dr. Hao has strong experience in testing topical formulations for delivery of drugs and for wound healing. The last section of the project will focus on altering the metabolism and the

production process of the PGN5 bacterial strain to increase the yield of alginate by 50% compared to our current methods.

BBCetc our consulting company provided vital critique, questions and suggestions for our application, especially for the 12-page Commercialization Plan that is required for Phase II applications. The application was submitted September 2nd and has been accepted without errors and assigned to a review group. While Phase I applications have a relatively small budget – ours was $145,000, the Phase II applications have much larger budgets. We requested $1.1 million for two years and should receive the score and critiques from the review group before Christmas.

Continuing in the SBIR grant area, we contacted a program officer at the National Science Foundation, to determine whether application of our, to be developed unique alginates, to improving performance of food and personal products would be of interest as an SBIR Phase I application. We were encouraged to apply, but cautioned that it would be highly competitive. The deadline for submission is December 5th, 2016.

Lastly we have been working with the TechConnect WV organization to determine if Progenesis can obtain assistance from their ScaleUp West Virginia Fund. This program provides up to $5000 to help defer the cost of a consultant company's charge for helping with the submission of an SBIR grant. We have just submitted all the required documentation and are waiting for the Board to review the request.

Plans for Fall/Winter 2016-2017

The following bullet points are a summary of our plans for late October – the end of February:

- Delete the aroA gene in PGN4 to create the PGN5 strain of P. aeruginosa
- Test the virulence of PGN5 vs PGN4, unmodified PAO1(a normal Pseudomonas aeruginosa) and E coli K12, in male and female mice
- Determine the amount of alginate produced by PGN5 vs the VE2 strain, our optimal alginate producer
- If the results from bullet points 1-3 are positive, then file a provisional patent on the PGN5 strain
- Work with our consulting company, BBCetc, to develop and submit a competitive Phase I National Science Foundation SBIR grant for the December 5th deadline
- If the results from bullet points 1&2 are positive, we will contact the FDA to schedule a second pre-petition meeting
- Meet with the wound care company Acelity (formerly J&J wound care) to discuss their interest in our unique alginates
- Meet with and tour the production facilities of the wound care company Molnlycke in Wiscasset and Brunswick Maine

We thank you for your patience and interest in the progress of Progenesis. If you have any questions about the information discussed in this newsletter, or any items that we have failed to mention, please feel free to contact Dick Niles, either by email (niles@marshall.edu) or by phone (304-617-2398). Lastly our website at www.progenesistechnologies.com will be undergoing extensive revisions during the month of November. We will send a brief email or note to all our investors when the site is re-launched.

An early reminder to enjoy the holidays that will be here before we are ready for them!

Sincerely,

Richard M. Niles, Ph.D.
Co-Founder and Chief Operating Officer

Hongwei Yu, Ph.D.
Co-Founder and Chief Science Officer