

11-TTAG-025

Company Name	PhytoTEK LLC
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City	Little Rock
State	AR
ZIP	72227
County	Pulaski
Number of Employees	2
Year Established	2009
Company Web Site	
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Project Area	Biotechnology, Bioengineering, Agriculture and Life Sciences - 17 - Other Medical Biotechnologies (Please provide short description in box provided below)
Project Area Brief Description	Botanical drug for the treatment of staphylococcal biofilm infections
Federal Agency	U.S. Department of Health and Human Services
Project Title	11-TTAG-025 - Synergistic Compositions for the Eradication of Staphylococcal biofilms
Competitive Challenges	<p>Every year, invasive <i>Staphylococcus aureus</i> infections kill more people than HIV/AIDs in the US. This issue is due in large part to the recalcitrant nature of biofilms formed by the bacteria. These infections present the problem of intrinsic resistance. In other words, our current antibiotics can not penetrate the biofilm and we have no drugs available on the pharmaceutical market to successfully treat such infections. At PhytoTEK, we have discovered a new botanical drug that IS effective at treating this problem. A provisional patent on this technology has been recently filed through UAMS, and we are in the process of seeking funds from multiple SBIR grants to support research necessary to the pursuit of clinical trials. Upon securing the funds to initiate this research, UAMS will license the patent to PhytoTEK (whose CEO is the principal inventor listed on the patent). We plan to work closely with UAMS Bioventures in the early stages of the company's development.</p>
Specific Problem	<p>We plan on applying for 2 SBIR grants. The submission deadlines for these awards are 12/3 and 12/5, respectively. NSF 10-067 SBIR (Biomedical technologies, BM1, Materials for Biomedical Applications) For \$150,000 for six months, we will prove the feasibility of using a plant extract (patent pending) as a coating for the prevention of biofilm-associated <i>Staphylococcus aureus</i> infections on implanted medical devices. To prove the feasibility of using the extract for this prophylactic purpose, we need to answer these 3 questions using in vivo infection models: 1) Is the extract coating effective at preventing infection onset in an implanted catheter model? 2) Is this effect evident in a variety of pulsed field type (PFT) strains of <i>S. aureus</i>? 3) What is the minimum effective dose necessary for the prevention of biofilm formation on the implanted catheter? Upon proving the feasibility of the extract as</p>

prophylactic coating for the prevention of implanted device biofilm-related infections, we will then use this data to submit a Botanical Drug Application (BDA) and begin clinical trials. This work will lead to the reduction of patient morbidity and mortality due to staphylococcal infection, which is responsible for the deaths of more people than HIV/AIDs in the USA every year. NIH - SBIR/SHIFT application (NCCAM), PA-10-122 For \$200,000 per year for 2 years, we will prove the feasibility of using synergistic compositions of a plant extract (patent pending) combined with conventional antibiotics for the treatment of biofilm-associated Staphylococcus aureus infections. To prove the feasibility of this therapeutic composition and collect data necessary for the submission of a botanical drug application (BDA) and initiation of clinical trials in the SBIR phase II award, we need to answer the following 5 questions using in vivo models: 1) What is the minimum effective dose of the extract necessary for a significant outcome in infection recovery? 2) What is the optimal route of administration for the drug composition (IV, IM, oral, etc.)? 3) What is the stability of the extract during storage? 4) What is the bioavailability of the extract? 5) What is the toxicology of the extract (is it within acceptable limits)? Upon proving the feasibility of the extract as an adjuvant therapy to conventional antibiotics in the treatment of biofilm-associated S. aureus infections in animal models, we will then use this data to submit a BDA and begin clinical trials (in a SBIR phase II). This work will lead to the reduction of patient morbidity and mortality due to staphylococcal infection, which is responsible for the deaths of more people than HIV/AIDs in the USA every year.

Solution

There are 2 major commercial applications that we foresee developing via work conducted under SBIR grants. The first is the application of our botanical drug product as a coating for implanted medical devices (intravenous catheters, orthopaedic implants, cardiac valve replacements, and etc). If the feasibility of the drug is proven in R&D described above, this application would be useful for the prevention of bacterial colonization on implanted devices, and result in declining morbidity and mortality and healthcare costs associated with biofilm-associated infections. The second commercial application of our product will be as an adjuvant to conventional antibiotics, which will increase the efficacy of the antibiotic in a synergistic manner. In other words, the product could either be sold as a pre-formulated mix with conventional antibiotics (i.e. daptomycin, clindamycin, vancomycin, linezolid and etc.) or as a separate drug to be given as a concurrent therapy in the treatment of recalcitrant biofilm-associated infections.

Implementation Plan

As described in the "Specific Problem" section, we plan to use the SBIR phase I grant period to demonstrate the feasibility of our drug product in several

	<p>ways: 1) drug toxicity (acute toxicity – genotoxicity, carcinogenicity, and chronic toxicity will be examined in the SBIR phase II period prior to initiation of Phase III clinical trials) 2) strain specificity (does it work with all main S. aureus strain types?) 3) dose 4) route of administration 5) bioavailability 6) product stability (during storage) The culmination of these studies will result in the compilation of all data necessary for submission of a Botanical Drug Application to the FDA. Moreover, upon completion of these studies, we will be in a good position to pursue clinical trials via the botanical drug application route, which we will seek to fund through a SBIR phase II award.</p>
Maintenance Plan	<p>If successful in phase I and II of the SBIR grant process, we plan to identify corporate partners in the pharmaceutical and medical device manufacturing industries. Our strategy will be to negotiate partnerships with such companies in order to incorporate our drug product into their products. For example, we plan to work with manufacturers of intravenous catheters to coat their products with the PhytoTEK drug. Likewise, we plan to work on the development of combination therapies in concert with pharmaceutical companies producing conventional antibiotics currently used to treat staphylococcal infections. If necessary, we will also seek to raise VC with suitable partners.</p>
Step 1	<p>We will use the TTAG funds to receive coaching from EnableVentures in the development process of the 2 grant proposals and assistance in identifying individuals to serve on the PhytoTEK advisory board. We plan to meet weekly via internet and phone channels (skype, email, etc) and create a new version of the proposals on a weekly basis until the time of submission in December 2010. This coaching will be essential for improving our chances of success in attaining the SBIR funds necessary for this R&D work.</p>
Step 1 Time	35.00
Step 1 Budget	\$5,000
Step 2	
Step 2 Time	0.00
Step 2 Budget	\$0
Step 3	
Step 3 Time	0.00
Step 3 Budget	\$0
Increased Sales	\$0

Retained Sales	\$0
CS Inventory	\$0
CS Labor	\$0
CS Materials	\$0
CS Other	\$0
II Plant	\$0
II IS	\$0
II Workforce	\$0
II Research	\$5,000
II Other	\$0
AUI	\$0
SOI	\$0
Job Retention	0
Job Creation	0
YN 90Days	Yes
YN Affiliation	No
YN Agreement	Yes
YN Total Project Price	Yes
Explain Total Project Price	
YN Cash Match Agreement	Yes
Copied	No
TTAG ID	11-TTAG-025
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Include in Batch	Yes
Batch Number	NA
Application Status	Pending
Organization	ASTA
BatchTest	Processed
Batch Date	
Set Batch Number	
Lvl4	No
Application Description	8-Biotechnology, Bioengineering & Life Sciences
SBIR-STTR	Yes