

**11-TTAG-012**

<b>Company Name</b>	BiologicsMD
<b>NAICS</b>	541712
<b>Address</b>	535 W. Research Center BLVD Suite 135
<b>City</b>	Fayetteville
<b>State</b>	AR
<b>ZIP</b>	72701
<b>County</b>	Washington
<b>Number of Employees</b>	17
<b>Year Established</b>	2009
<b>Company Web Site</b>	<a href="http://www.biologicsmd.com">http://www.biologicsmd.com</a>
<b>Contact Person</b>	Paul Mlakar
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<b>Resource Provider</b>	BiologicsMD
<b>RP Address</b>	535 W. Research Center BLVD Suite 135 Fayetteville, AR 72701
<b>RP City</b>	Fayetteville
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<b>RP ZIP</b>	7270

<b>RP County</b>	Washington
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<b>Project Area</b>	<a href="#">None of the above - 32 - (Please provide short description in box provided below)</a>
<b>Project Area Brief Description</b>	BiologicsMD™ is developing a new prescription osteoporosis solution based on a unique patent-pending compound that binds to bone and stimulates new bone growth thereby reversing osteoporosis. Pre-clinical animal studies demonstrate that it is three times more effective at increasing bone density than the leading medication with no observed side effects.
<b>Federal Agency</b>	<a href="#">U.S. Department of Health and Human Services</a>
<b>Project Title</b>	11-TTAG-012 - PTH-CBD
<b>Competitive Challenges</b>	SBIR-BiologicsMD, LLC is developing PTH-CBD, a new protein-based drug, for the treatment of osteoporosis. PTH-CBD provides the unique ability to both directly target bone and stimulate new bone growth. PTH-CBD can become the new gold standard in osteoporosis by delivering best in class performance with medication needed only monthly, or possibly even just once yearly.
<b>Specific Problem</b>	Division of Musculoskeletal Diseases. The Division of Musculoskeletal Diseases of the NIAMS supports research aimed at improving the diagnosis, treatment, and prevention of diseases and injuries of the musculoskeletal system and its component tissues. Key public health problems addressed by this research include osteoporosis, osteoarthritis, and muscular dystrophy. Research is conducted at every level, from fundamental biology to clinical intervention.
<b>Solution</b>	Extensive pre-clinical animal studies have demonstrated that PTH-CBD results in significantly increased bone mineral density for over 6 months after a single injection. Investment in PTH-CBD is important because most osteoporosis therapies are limited by low efficacy (2-3% increases in bone mineral density). PTH-CBD can become the new gold standard in osteoporosis by delivering best in class efficacy with injections only once monthly, or possibly even once yearly. Importantly, no evidence of acute or long-term toxicity has been observed. It should be noted that both PTH (1-34) and collagenase clostridium histolyticum (which contains CBD), as separate

	medications, have been approved by the FDA for treatment of osteoporosis and Dupuytren's Contracture, respectively.
<b>Implementation Plan</b>	BiologicsMD, LLC is moving PTH-CBD forward by generating data that will be part of an Investigational New Drug Application (IND) to the FDA. Towards this goal, BiologicsMD, LLC is proposing development of analytical methods (including detection of PTH-CBD in serum and potency assays) and the manufacturing platform necessary to build the Chemistry, Manufacturing, and Controls section of the IND application.
<b>Maintenance Plan</b>	BiologicsMD, LLC will maintain the solution by obtaining any federal regularity. Also, BiologicsMD will partner with manufacturing services to help produce the product commercially. We will also see investment funding.
<b>Step 1</b>	Preparatory Work -Define Research Objectives - Outline Proposal - Discussions with funding agencies - Literature search and review - Identification of potential users and partners
<b>Step 1 Time</b>	20.00
<b>Step 1 Budget</b>	\$1,000
<b>Step 2</b>	Proposal Content Development - Technology Description and significance - Work plan development - Budget development - Commercialization Plan
<b>Step 2 Time</b>	50.00
<b>Step 2 Budget</b>	\$2,500
<b>Step 3</b>	Final Proposal Preparation - Proposal Review - Formatting and Proofreading - Letters of support, consultant letters - Agency Forms - Cover letters, copies, mailing
<b>Step 3 Time</b>	30.00
<b>Step 3 Budget</b>	\$1,500
<b>Increased Sales</b>	\$0
<b>Retained Sales</b>	\$0
<b>CS Inventory</b>	\$0
<b>CS Labor</b>	\$0
<b>CS Materials</b>	\$0
<b>CS Other</b>	\$0
<b>II Plant</b>	\$0

<b>II IS</b>	\$0
<b>II Workforce</b>	\$0
<b>II Research</b>	\$0
<b>II Other</b>	\$0
<b>AUI</b>	\$0
<b>SOI</b>	\$0
<b>Job Retention</b>	1
<b>Job Creation</b>	1
<b>YN 90Days</b>	No
<b>YN Affiliation</b>	Yes
<b>YN Agreement</b>	Yes
<b>YN Total Project Price</b>	Yes
<b>Explain Total Project Price</b>	
<b>YN Cash Match Agreement</b>	Yes
<b>Copied</b>	No
<b>TTAG ID</b>	11-TTAG-012
<b>Signature Panel - RP AR Name</b>	Paul Mlakar
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<b>Include in Batch</b>	Yes
<b>Batch Number</b>	NA
<b>Application Status</b>	Pending
<b>Organization</b>	ASTA
<b>BatchTest</b>	Processed

<b>Batch Date</b>	
<b>Set Batch Number</b>	
<b>Lvl4</b>	No
<b>Application Description</b>	8-Biotechnology, Bioengineering & Life Sciences
<b>SBIR-STTR</b>	Yes