



With a Pharmaceutical that is a Molecular Fusion of a Growth Hormone and Collagen Binding Domain, BiologicsMD is developing a New Compound that Pre-Clinical Data shows has the Ability to Promote Bone Growth and Reverse the Effects of Osteoporosis

**Healthcare  
Biologics  
(Private)**

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**Paul Mlakar, Jr.**  
President

**BIO:**

Paul Mlakar, Jr. joined BiologicsMD as President in 2009. He has over 15 years of government, corporate, and small business leadership experience. He has spent the last 5 years leading start-ups and recently guided a company from \$10MM in revenue to \$50MM in 5 years. From 1995 to 1998 he served in the United States Army with tours in the Middle East and Central America commanding units in key humanitarian and infrastructure campaigns. Mr. Mlakar earned his MBA

from the Sam M. Walton College of Business at the University of Arkansas and is a graduate of the United State Military Academy, West Point.

**Company Profile:**

BiologicsMD is based in Fayetteville, Arkansas and was formed in 2010 to accelerate the development of academic discoveries into new medications that will enhance people's lives. The company won over \$600,000 in cash, awards, and investments at six major entrepreneurial business plan competitions. In 2011 the firm was selected to receive a \$2.3 million U.S. Department of Defense research contract to continue research on its innovative osteoporosis compound. The award was through the U.S. Department of Defense Peer Reviewed Medical Research Program of the Office of the Congressionally Directed Medical Research Programs (CDMRP). This program received more than 600 applications and fewer than 10 percent were recommended for funding.

**Interview conducted by:  
Lynn Fosse, Senior Editor  
CEOCFO Magazine**

**CEOCFO:** Mr. Mlakar, your website shows that BiologicsMD is building quality of life. What are you doing?

**Mr. Mlakar:** We are developing a new innovative pharmaceutical compound that will actually reverse the effects of osteoporosis.

**CEOCFO:** What have you figured out that others have not?

**Mr. Mlakar:** If you look at the osteoporosis treatments that are available today, it is a largely unmet medical

need. There are many medications on the market that are referred to as antiresorptives. Basically they work by slowing down the rate at which you lose bone and thereby indirectly hoping that you grow new bone. We are innovative in that we actually grow bone. Our pharmaceutical is a molecular fusion of PTH (Parathyroid hormone) which is a growth hormone and CBD (collagen binding domain). The CBD binds to collagen (which occurs naturally in bones) delivering the PTH directly to the bone where it "sticks" and can promote bone growth. This unique binding effect is what sets us apart. We have seen the effects in our pre-clinical data.

**CEOCFO:** Has a similar approach been tried in the past?

**Mr. Mlakar:** There are similar approaches dealing exclusively with PTH. In fact, Ely Lilly's Forteo, which is on the only anabolic on the market today, is similar in that it uses PTH. However, we are different in that we combine PTH with CBD, which creates that unique binding effect. In our direct comparison to Forteo, we achieve better results without the inconvenience of daily shots.

**CEOCFO:** What is the origin of your concept?

**Mr. Mlakar:** We have three inventors. In their collaborative efforts, they realized the potential of possibly joining a linker molecule between PTH and CBD.

**CEOCFO:** Where are you in the development process?

**Mr. Mlakar:** We are in the preclinical stage.

**CEO CFO:** What are the next steps?

**Mr. Mlakar:** The next step for us will be to complete the manufacturing process development. From there, we will conduct toxicology testing and this will prepare us for a Phase 1 human trial.

**CEO CFO:** Has the medical community started to pay attention or is it a little early?

**Mr. Mlakar:** It is a little early because we are preclinical stage. The medical community in a broader perspective wants to see safety more specifically toxicology, immunogenicity, pharmacokinetic data. They want to see early indications that what you have is actually going to be safe. Once we complete our Phase I human trial, that is about the time they really get interested. We have already had some discussions with one big pharma company in particular who has looked at our preclinical data and has expressed quite a bit of interest.

**CEO CFO:** Do you see partnerships and collaborations in the future or will you be going it alone?

**Mr. Mlakar:** It is a tough and challenging environment. Venture capital funding is down particularly within pharma. Therefore, what has happened is early stage companies have flocked to grants in a survival mode. This has created an unintended consequence of making grant funding more competitive. We are fortunate that we have a large DOD contract. Looking forward, all options are on the table at this point.

**CEO CFO:** Is the Department of Defense research contract typical for biopharma or drug development?

**Mr. Mlakar:** Valid question. The largest healthcare provider in the US is the VA and we do not necessarily think about that but the government makes large provisions to provide healthcare for our veterans. So obviously there is a long-term, vested interest in reduction of healthcare cost. Secondly, we have a potential indication for open fracture repair so that falls into combat medicine.

**CEO CFO:** What is the market potential for people who need quantification?

**Mr. Mlakar:** The market for osteoporosis medications is about \$3 billion in the US and about \$10 billion globally. There are about 75 million people worldwide that are affected by osteoporosis and those numbers are going

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to increase. If you look at the aging demographics of our population, the US in particular has the baby boomer generation that will significantly increase the number elderly in the next twelve to fifteen years. So the market opportunity is huge particularly for a drug that can grow bone, which we do, and do so at a lower cost to consumers than what is currently available on the market. That is where we fit.

**CEO CFO:** Why are you working with Japan?

**Mr. Mlakar:** First, one of our co-inventors is in Japan. Secondly, a very large percentage of the population is elderly. The CAGR for sales of

osteoporosis medications is the largest in Japan. This fits our strategy and is why we have an international patent as well as US patent.

**CEO CFO:** What else needs to be put in place? Are there any challenges ahead?

**Mr. Mlakar:** We need a strategic funding partner. The biggest hurdle moving forward will be financing. Our scientists are passionate in their belief and efforts that our product will work. In fact, we have met our scientific goals to date and that is not necessarily common in the preclinical stage. My challenge will be to continue our financing, so the research can keep moving forward.

**CEO CFO:** How do you deal with the frustration of knowing you have a product that can potentially make a big difference in the lives of people but it takes so long to get it to market?

**Mr. Mlakar:** Simple. I remain fiercely optimistic. As CEO, I have absolute faith that what they are working on will come to fruition and that permeates throughout the team. We are constantly looking for plan B. I leave no stone unturned our opportunity explored.

**CEO CFO:** Why should BiologicsMD stand out from the crowd?

**Mr. Mlakar:** First, we have hit our milestones. Second, we have utilized the funds that we did raise very efficiently as we said we would. We are an early-stage company that has significant scientific promise with a proven record of utilizing our funds to create scientific value. That is why we are different.

**BiologicsMD**

