

Q&A with Jim Moran, President and CEO of Biocoat, Inc. developing and licensing Lubricious Hydrophilic Biocompatible Coatings for Interventional Medical Devices such as Guidewires, Catheters and Microcatheters



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CEOCFO: Mr. Moran, what is the concept behind Biocoat Inc?

Mr. Moran: Biocoat is a company that develops and licenses biomaterial coatings for medical devices that are custom engineered to meet our clients strict design parameters. We specialize in supplying lubricious (slippery) hydrophilic coatings to medical device manufacturers, OEMs and contract manufacturers for application on interventional medical devices such as guidewires, catheters, microcatheters, etc. These devices are made of materials that are not lubricous naturally and if used without hydrophilic coatings, they would exhibit a high degree of friction during vascular procedures, which could lead to negative patient outcomes. Biocoat’s Hydak® (a registered trademark of Biocoat, Incorporated) coatings are not only lubricous but extremely durable with best in class particulates and because of the nature of our technology, large neurovascular, cardiovascular, peripheral vascular and ophthalmic companies can access areas within the vascular structure to help patients manage difficult medical conditions such as blocked arteries and blood clots.

CEOCFO: What is the coating made of?

Mr. Moran: The coating is made of a hydrophilic material called hyaluronic acid or HA. This is naturally occurring substance or product found in the human body, so it is inherently biocompatible. Biocoat uses this material for coating medical devices such as coronary catheters, guidewires and neurovascular microcatheters. And because Biocoat is the only company who manufactures coatings based on HA, versus using a synthetic coating, it is a bit different than other hydrophilic products available on the market today.

CEOCFO: Where are you getting the hyaluronic acid from?

Mr. Moran: That is a good question. HA is naturally occurring within your body, within everyone’s body, and acts as a lubricate for joints and the cartilage of the body. There are two ways that you can obtain HA, one is

from animal sources and another is from non-animal sources. Biocoat has chosen to source our pharmaceutical grade HA from non-animal sources.

CEOFCO: *Why non-animal sources? What is the advantage?*

Mr. Moran: There is a high level of scrutiny from FDA when it comes to endotoxin and Bioburden levels on interventional medical devices; in addition, raw materials sourced from animal sources may pose safety risks. At Biocoat we take the quality of our coatings very seriously and have decided to use Pharmaceutical grade HA from non-animal sources that is extremely pure and has lowest possible endotoxin levels. Further, sourcing from non-animal sources provides additional control over molecular weight specification to produce products with consistent high quality and performance.

CEOFCO: *What is the competition in the lubricant field?*

Mr. Moran: Within the hydrophilic category in which Biocoat operates there are two main products available to provide lubricity, or that make a medical device slippery. Biocoat manufactures our coating using HA, and the second type of hydrophilic coating is referred to as a PVP or polyvinylpyrrolidone which is a synthetic lubricant. A majority of the market has chosen to use hydrophilic coatings, especially for medical devices in the areas of the body I mentioned earlier. We believe that Biocoat's Hydak coatings have an advantage because it is naturally occurring within the body as opposed to PVP coatings. Both are effective, however over 27 years ago our founder Ellington Beavers, recognized the advantages of using HA and since 1991 this is the technology we've built our company upon.

CEOFCO: *Who is making the choice on the coating for a medical device?*

Mr. Moran: Essentially, it is the company who will be commercializing the product, which could be an Original Equipment Manufacturer (OEM) of the product or a contract manufacturer. However, in either case we work directly with the design and development engineering teams to help customize the hydrophilic coating design to meet their specific needs. Ultimately, they will make the decision based on three main factors. The first is that the product must be lubricious, or slippery, so it can reach the region of interest (ROI) of the body where it is designed to be used. The second criteria is durability, which is how long the device will remain slippery within the body during lengthy surgical procedures. And the third is in the area called particulates, which is a measurement of what, if anything, is coming off the device during the procedure. These are the three main areas that are considered when companies make their decision. Also, these decisions are made early in the design and development phase of product development, and once they determine which will help their product perform the best, then they include it in the products design history files.

CEOFCO: *When the end user is choosing a product do they care? Do they recognize, do they know or is it just that they like what the manufacturer has?*

Mr. Moran: There is a trust that takes place between the manufacturer and the surgeons who are using these products. While the companies chose the coatings that enable their devices to perform, ultimately the surgeon is really making their decision. Whether it is a clot retrieval device, or a stent, they are making their decision based on the

performance of the medical device, as opposed to the coatings. However, in the design and development phase the hydrophilic coating chosen plays a big factor because it is the 'enabling technology' that allows the device to work correctly.

CEOCFO: *When you are working with a manufacturer what goes into the decision? What might you look for when you are helping a company decide the best way, that less experienced companies do not take into consideration?*

Mr. Moran: Biocoat prides itself on working very closely with our manufacturing partners with the goal of helping them determine which of our hydrophilic coatings will work best with their product(s). The process starts with them sending us 10 of their prototypes, which we will coat and send them back. Once it is received, companies will conduct their own internal testing criteria of the coating performance. As I mentioned; the lubricity, durability and particulate counts data is very important and when the data shows we are acceptable, we then work with them to refine the coating for their specific device. It is not a one size fits all. We must make sure that we meet their requirements, and this may take months to refine the coatings solution design. For instance, they may want a product that is more lubricious for one application, where for another product application it is durability that's most important. And when it comes to particulates, the lower the better! Therefore, we really customize our solutions to meet our customers' requirements.

CEOCFO: *You have been CEO at Biocoat for several months now. What attracted you and what did Biocoat like about you to bring you on board?*

Mr. Moran: Growth opportunity! What attracted me to Biocoat is that as a privately held company it has been operating with steady year-over-year growth for over twenty-seven years.

And as I became more familiar with technology and the unique proposition our products bring to the healthcare market, I felt that I could add considerable value by being a part of the team. Now that I've been working with the team we've been able to identify and execute on the core of our growth and expansion strategy. We recently opened our new ~40,000 sq.ft. manufacturing facility and are looking forward to expanding our capabilities to support our aggressive growth plans.

As for what Biocoat saw in me, I believe that it was by background and diverse experience working within different markets selling differentiated products. Also, I bring a more global mindset from having worked with and in different countries such as Europe and Japan. And because part of our growth strategy will be to expand our Business Development activities both inside and outside of the U.S. market, these experiences will be important to the organization.

CEOCFO: *Why now? Why is this the right time for the growth?*

Mr. Moran: In my estimation, the Board of Directors and Shareholders saw this growth opportunity about three years ago, and they positioned the company to be 'ready' for the next phase of growth for Biocoat. The team in place at that time, and I applaud them, chose to accelerate the growth when they decided to build a new manufacturing facility. On May 11th of this year we moved into our new facility and had our official grand opening. Biocoat's growth is coming from both existing and new product development. Our customers are looking for high quality products to

meet their needs and with expanded manufacturing capabilities and services, we are prepared to realize the opportunity.

Growth for Biocoat is coming from several areas, including both existing and new customers and products. The market dynamics are showing that less invasive procedures are increasing and, in the areas, where our products are utilized they are growing faster than the general market. Biocoat's hydrophilic coating products are designed to perform in some of the deepest and most tortuous vascular structures of the body, and due to our high lubricity, durability and low particulates we are seeing a shift by more companies towards using our unique HA technology. So, the foundation of the business is in place. The manufacturing capabilities are in place. We have the right people, the right leadership, the right board of directors and we have the support of our shareholders. All those aspects are aligned which will continue to offer opportunity for our employees to grow as we increase company value.

CEOCFO: *Are there newer technologies that you can take advantage of in manufacturing? Does it change much in your industry?*

Mr. Moran: Manufacturing can change in terms of the production processes. For instance, we receive all the raw materials here at our headquarters in Horsham, Pennsylvania where we manufacture the different products we offer to our customers. While the components may not change over time, the process of 'how' manufacturing can improve significantly. In our new facility we are working to optimize batch production which will be necessary to meet the increasing demand from our customers. And, we are very confident that based on the changes we've already put in place that we will be able to meet our customers' expectations.

CEOCFO: *You recently announced a partnership with Adam Spence on development. Would that be a typical engagement for you? Would you tell us how that works?*

Mr. Moran: Working with Adam Spence is a unique opportunity for us and one that we will replicate as we move forward. As I mentioned earlier, when you are looking to develop a coating on a medical device you want to work as far upstream as you possibly can with the research and development teams. Adam Spence is a nationally recognized contract manufacturer of these devices, and therefore is a perfect fit for us. Biocoat benefits from working closely with them as they design and develop products for their customers. And, should their customers be looking for a high-quality hydrophilic coating, then Biocoat can be that partner. It is a value-added service for Adam Spence and it allows Biocoat to move closer to the development process, without becoming a competitor with our own customers.

CEOCFO: *What is your strategy for reaching out over the next year or so? How are you going to reach people who may not know about you or may not recognize the value you provide?*

Mr. Moran: That is a great question. The company has done a solid job of growing our business over the last 27-years, despite the fact that we have had limited focus on marketing and business development. However, we have recently hired a business development person who has extensive experience uncovering different areas of opportunity and monetizing it for Biocoat. The Adam Spence partnership is a great example of how taking a business development mindset can uncover an opportunity and develop a new stream of business for us.

As for the future, our Strategic Business plan will call for continued growth across all four (4) of our business units. Focusing on our business development, marketing and communications will also be areas of focus for Biocoat. As an organization we will continue to market, not only our products and services, but we will highlight the advantages of working with us versus others. We have done internal testing on our products verses our competition and believe that there are clear advantages a clear differentiation between our unique HA coating and the competition.

What is exciting to me is that under our laboratory test conditions using commercially available products, we have been able to prove to ourselves that we have a line-up of *'best in class products'* on the market. Therefore, for us it is making sure that the research, design and development teams, whether it is contract manufacturing organizations or OEMs, know about the advantages of using Biocoat. For me, as the CEO, all I want from OEM's and CMO's is an opportunity to prove that our products are best in class and to earn their business. And, if the past 8-months of growth is any indication, the market is now understanding the value of working with Biocoat and are beginning to experience the value our products and people can bring to enhancing the performance of their products.

