



ceocfointerviews.com  
© All rights reserved  
Issue: November 12, 2018

CEOCFO Magazine

## **Q&A with Susan Wuollett, President and Co-Founder of Protege Biomedical bringing to market their recently FDA Cleared patented IHM Bandage a Hemostatic Product that Stops Bleeding in Humans and Animals with Minor Cuts, Scrapes and Abrasions**

**Susan Wuollett**  
President & Co-Founder

**Protege Biomedical**  
[www.protegebiomedical.com](http://www.protegebiomedical.com)

**Contact:**  
**Susan Wuollett**  
**952-855-7163**  
[susan.wuollett@protegebiomedical.com](mailto:susan.wuollett@protegebiomedical.com)

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

**CEOCFO: *Ms. Wuollett, would you give us a little background on Protege Biomedical?***

**Ms. Wuollett:** Protege Biomedical is a company that has a line of patented hemostatic products that stop bleeding in minor to severe wounds for animals and most recently, humans. It was started by my husband Michael and I when we were in grad school at the University of St. Thomas, studying to get our MBAs. My husband was reading an article about how they stop bleeding in the military using lyophilized fibrin, which is freeze-dried human derived biologic, and it stops the bleeding fast. He was asking why they don't make this on a smaller scale for minor cuts and scrapes. That was the premise for the ideas – what are they using in the military, and how it can be done small-scale? We learned fibrin was very expensive, and started to explore to other things and did some research around what types of all-natural treatments might stop bleeding and we came up with a bunch of ideas and got out a razorblade and cut our fingers to see if the things that we thought might work conceptually, actually did work.

**CEOCFO: *Would you tell us about the wound care market in general?***

**Ms. Wuollett:** Wound care is huge, but it is a subset of that. The hemostatic market is enormous, and there are a lot of different subsets of the human hemostatic market. There is trauma and nuisance bleeding for over-the-counter, internal, and surgical, and there is an animal market, which can be broken down further into veterinary, consumer, and professional. Vascular closure is another area that is growing now with hemostasis products. There is definitely a lot of interest in a variety of different areas.

**CEOCFO: *Would you tell us about the IHM bandage and how it fits in with the rest of your patents?***

**Ms. Wuollett:** Our patent is on the technology itself – base powder and then a variety of different forms from that. The IHM bandage, which recently got 510(k) clearance, is a bandage which is impregnated with our patented technology. We have other patents in the works and filed that are around the delivery methods including the gauze delivery method. This particular 510(k) clearance is for topical use, so minor cuts, scrapes and abrasions. It would not be for trauma and it would not be for vascular closure, and it would not be for internal surgical yet.

**CEOCFO: *Does the average person pay much attention to what they put on a wound, and is the medical community paying attention?***

**Ms. Wuollett:** We did a study and the overwhelming majority of people that answered it, said that there is a need for our particular bandage that stops bleeding in a minor cut or scrape. I think that when we are ready to launch, the market is

ready for it, and they are looking for something that will stop the bleeding in minor cuts and scrapes. Right now in the bandage market, you are seeing a lot of different deviations from the finger bandage, and a lot of the bandages have antibacterial barriers, there is non-stick and enzymes that are supposed to help with the healing. Adhesive bandages are definitely not just something to cover a wound anymore.

**CEOCFO: *Would you explain the technology for us please?***

**Ms. Wuollett:** Our technology works by ionically attracting the red blood cells and platelets to get them close together, allowing the clotting factors, the red blood cells and platelets to clump together quickly in a process called flocculation. Then, it helps to activate Factor 12 of the coagulation cascade. That is the way that your body will naturally clot the blood, and it creates a microscopic web that holds those red blood cells and platelets together, and that is what creates a solid clot. This whole process happens in as little as 11 seconds.

**CEOCFO: *What do you understand with your technology that others do not?***

**Ms. Wuollett:** There are a lot of technologies out there that will help to stop the bleeding through absorbing the fluid, but ours takes it a step further with the flocculation effect, by getting those red blood cells and platelets to stick to each other, and then with the activation of Factor 12, it helps the body stop the bleeding. Ours is a lot faster than anything else that is out there.

**“We have been hiding behind the scenes until now. Now that we have our FDA clearance, I think that people are going to start hearing more about us.”- Susan Wuollett**

**CEOCFO: *Why was now the time to go from animals to people?***

**Ms. Wuollett:** Pivoting from animals to people has been in the works since the beginning, but it takes a long time to get a product through the FDA. We have been working on it for about four years to get it cleared for humans.

**CEOCFO: *You mentioned going to market; what are your plans and is it something that doctors should be recommending to their patients or for most cuts? Where does the medical community fit in?***

**Ms. Wuollett:** There are two pathways for this first product that was cleared. One would be for an OTC where it can be found in convenience and drug stores, and people would buy that without consulting a doctor necessarily. The other route we would take is clinical, such as dermatology or small cuts and possibly using it in clinics maybe when they are doing finger pricks or different procedures that might cause minor bleeding.

**CEOCFO: *What has been the response for the veterinary products and how are you reaching customers there?***

**Ms. Wuollett:** We have a fantastic response and a high repeat customer rate. We have not put a lot of resources into getting the word out about our product. We attend the major tradeshows, but beyond that, we have a very small budget for reaching the animal market. It is one sales rep pretty much on his own and we are in with all the major distributors. It has been a challenge to gain widespread market adoption, but the adoption that we do have continues to grow year over year. Our customers are loyal and they love the product.

**CEOCFO: *Are you seeking funding, investments or partnerships?***

**Ms. Wuollett:** We are. We are just about to open a round for \$5 million.

**CEOCFO: *What has been the interest from the medical community?***

**Ms. Wuollett:** It is high. We have had amazing feedback on the product, on the technology, especially since our preclinical studies have shown us to be so much faster than what is out there right now. There is a huge need and companies are looking for technologies like us. The feedback that we have received is to go launch our product, get some sales traction, and this is going to be something that people are very interested in.

**CEOCFO: *Is this story easy to understand for the investment community and do you find it being helpful as you approach people?***

**Ms. Wuollett:** I think investors are looking for products that they can relate to, and in the medical device community it is challenging when you have a complex niche product that fits a tiny market. This is a huge market and product that a lot of product can relate to. Of our current investor pool, we hear stories of “Oh, I would love this for....” People want something they can relate to and I think that helps them get behind the company, and it makes it easier for them to understand.

**CEOCFO: *What is next?***

**Ms. Wuollett:** We have a couple of paths that we are pursuing right now. One of them would be launching the product independently, and the other is entertaining some partnership opportunities. We have to decide what we are going to do in the near future. Whatever we choose, the products will be launched next year.

**CEOCFO:** *Do you have a name in mind?*

**Ms. Wuollett:** If we launch it ourselves, we do have two names. Our clinical name would be Fermata, and that is a musical term that means “stop” or “hold.” There is a symbol for it; it is like a rainbow with a dot underneath. If you are a musician, when you see that symbol, you hold that note as long as the conductor tells you to. That would be the clinical brand name. For the over-the-counter brand name, we would use the ClotIt name that we have for animals, but this would be ClotIt PRO.

**CEOCFO:** *What do you understand about getting attention from retail establishments and will you need to add to your team?*

**Ms. Wuollett:** If we launch it ourselves, that is part of what the money we are about to raise will go towards. We will need a big marketing campaign and then we will add six people to our team.

**CEOCFO:** *What are you looking out for in terms of challenges?*

**Ms. Wuollett:** Our company has always been focused on “protecting the downside, and the upside will take care of itself.” That was a quote from one of our investors. Now that we have our FDA clearance, we need to be careful to make sure that our quality systems are compliant and that our manufacturing is compliant with all of the FDA regulations, and that as we launch we are not making any claims that we are not allowed to make or shouldn’t be making. Those are the things now that we are being mindful of. We will be also be pursuing additional FDA clearances for other indications.

**CEOCFO:** *Often when putting out a product that is challenging existing providers, there is a great deal of resistance?*

**Ms. Wuollett:** Coming in as a small company with essentially one product or one family of products, going against the big established brands is a challenge. That is one of the reasons we have to allocate marketing support towards launching our brand. We plan to use a third party, if we launch ourselves we would be using a sales rep organization that reps to the convenience and drugstores. They would help us get the product out there. There are creative ways.

**CEOCFO:** *Would you tell us more about the other products?*

**Ms. Wuollett:** Our studies have shown that we can stop bleeding in the femoral artery, which would be one of the worst traumas that you would endure. If you get a femoral artery bleed, you can die in as little as four minutes. Our product can stop the bleeding in a femoral artery with just a little gauze pad. As soon as you put the gauze pad on and apply pressure, the femoral artery is going to stop bleeding. After three minutes, you can lift your finger off, and that little tiny gauze pad will stop the bleed entirely and could potentially save that person’s life. That is the next one we are going for. The products on the market right now that the military is using cannot stop the bleeding as fast as we can, so that is a clear next step for us. The other area that we are looking at is vascular closure. There are so many new technologies out there and new surgical procedures that are accessing through the artery like the femoral artery. Closing up those access areas is a huge challenge and is a multibillion dollar market for femoral artery and vascular closure devices. Our product would be an adjunct to that. It would be a bandage that you put at the site.

**CEOCFO:** *Why is Protégé Biomedical an important company?*

**Ms. Wuollett:** We have been hiding behind the scenes until now. Now that we have our FDA clearance, I think that people are going to start hearing more about us. We are getting ready to enter the market and be a game-changer in the space. I think we are a new up-and-comer and finally on the map.