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Issue: June 10, 2024

Retriever Medical – Transforming the Treatment of Deep Vein Thrombosis and Pulmonary Embolism with Their ClotHound™ Technology

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CEOCFO: ***Mr. Bobo, what is the idea behind Retriever Medical?***
Mr. Bobo: Retriever Medical initially focused on a neuro product designed to treat blood clots in the brain. We then adapted the design to address peripheral conditions, specifically Deep Vein Thrombosis (DVT) in the legs and Pulmonary Embolism (PE) in the lungs. Early on, we identified a significant unmet need: while there are other thrombectomy products on the market, we discovered that 70% of DVT cases involve wall-adherent chronic clots in the legs. Most 510(k)-approved devices are not effective at removing these chronic clots; they can remove acute and soft thrombi, and some subacute thrombi, but not the chronic ones. Since DVT is a 10 to 15-year process, patients often present with advanced disease, and doctors struggle to remove these chronic clots. Consequently, many patients leave the hospital with these clots still in place, risking them dislodging and traveling to the lungs, leading to PE. Literature shows that 45% of PE patients have concomitant DVT.

Additionally, we found that 30% of PE cases involve impacted and wall-adherent clots in the lungs, which current 510(k)-approved devices cannot effectively remove. Physicians often resort to suction aspiration, but this method is insufficient.

To address this clinical need, we developed ClotHound™. This device is designed to remove a wide range of thrombi, including acute thrombus, subacute medium-hard thrombus, and chronic, wall-adherent hard clot. ClotHound™ effectively removes the entire spectrum of thrombi that physicians encounter.

CEOCFO: ***Why can this get out of the wall-adherent clots? How does it work?***
Mr. Bobo: The ClotHound™ features a handle with three sliders, allowing for precise control. The first slider enables the physician to move it forward and backward, which actively expands two independently movable uni-axial mechanical spheres. This mechanism, known as Active Control Expansion (ACE), lets the physician open the sphere within the clot for effective engagement.

Unlike other mechanical devices that use passive expansion—where the spheres merely pop open when pushed out of the delivery catheter—the ClotHound's active expansion ensures the spheres can penetrate organized chronic thrombi. Passive spheres often stay closed when encountering such thrombi, whereas our spheres can actively open within the thrombus material.

The ClotHound™ has two spheres: a distal sphere at the catheter's tip and a proximal sphere that can move along the catheter body by centimeters. This allows for thorough engagement with the clot, enabling the physician to move the spheres back and forth to remove the thrombus from the vessel wall. No other device on the market offers this capability. Other devices rely on aspiration, TPA (a clot-busting drug), or passive mechanical expansion, which does not provide the same level of clot engagement. Active engagement with the clot allows for more effective removal.

CEOCFO: ***Is the medical community beating a path to your door at this point?***
Mr. Bobo: Currently, we are in the development phase and working on a Series A raise of $12 million. We've conducted wet labs with several scientific board members, interventional cardiologists, and interventional radiologists. In these labs, we used a chicken liver model to simulate wall-adherent clots. The model involved a clamshell with spikes that embedded the liver into the wall, creating an extreme test case. The physicians advised against using this model for peer training due to its challenging nature.

From these labs, the physicians recognized the effectiveness of our device in dealing with extreme wall-adherent thrombi. They mentioned that they would choose our catheter 100% of the time because it effectively handles clots of varying consistency—hard, medium, or soft. This is crucial, as the quality of the clot is often unknown beforehand. Our device can remove impacted thrombi in 30% of PE cases and wall-adherent clots in 70% of DVT cases, making it highly versatile.

To complete the development and proceed to FDA 510(k) clearance consideration, we need to finish the Series A raise, which will fund Phase 2 and Phase 3 development work.

"We are in Series A raise of $12 million, to complete Phase 2 and Phase 3 development work. It is a fun and exciting journey. I am excited about the technology. I think we have great patent protection and we believe that when this comes to market it will transform how it is treated, especially with the drug component. We are excited about the development and the future." Ben Bobo

CEOCFO: ***Would you tell us about your Australian patent and where you are with your patents in general?***
Mr. Bobo: Our strategy has always focused on both the US and international markets to ensure a broad and comprehensive reach. When starting a medical device company, securing Intellectual Property (IP) is crucial. We have eight issued patents in the US and two issued patents outside the US, one in Australia and one in China, totaling 132 issued claims. This is impressive given the competitive landscape, but our unique design and approach have allowed us to secure this extensive patent portfolio.

Australia is a healthy and maturing market for PE/DVT technology, attracting competitors. China, with its large and developing market, uses technology like the Penumbra Catheter, which is already distributed there. Hence, we've established a presence in these markets.

We also have pending applications in the European Union and additional applications in Australia, Canada, China, Mexico, Hong Kong, and Japan, aligning with our global IP strategy. Recently, we obtained a US patent covering our entire system, including ClotHound Gold (PE device) and ClotHound Blue (DVT system), as well as the mechanical thrombectomy handle and aspiration catheter. We also filed a PCT application with 50 claims for our Vascular Occlusion Removal System (VORS™) technology.

Aspiration is vital for removing soft and some subacute thrombi, but for organized chronic material, our VORS AMD combines aspiration, mechanical action, and drugs. This broad patent enables us to coat the spheres with drugs, allowing real-time vessel remodeling and targeted treatment of the vessel wall. This technology not only removes thrombus but also addresses the endothelial lining, offering a tailored treatment strategy using coated spheres.

Additionally, our technology provides prophylactic treatment to prevent, mitigate, or reverse vascular injury stenosis. For instance, carotid artery disease patients can benefit from early-stage treatment with our coated spheres, preventing full occlusion.

Our platform technology, enhanced by the drug component, offers a novel approach to clot removal and vessel repair. The distal sphere anchors the device, ensuring protection, while the proximal sphere offers flexibility. Access ports between the spheres allow for the injection of EDTA, rapidly dissolving clots in about five seconds, which can then be aspirated out. We believe this drug component is the future, not only for clot removal but also for vessel remodeling and repair.

CEOCFO: ***How many procedures a year might be done in the US?***
Mr. Bobo: Another great question. According to a publicly traded company, the total available market is estimated at about 5.8 million. In the US, there are 430,000 deep vein thrombosis (DVT) patients and 280,000 pulmonary embolism (PE) cases annually. Interestingly, approximately 80% of DVT and PE cases are treated with TPA, which is only effective against soft thrombus and not against subacute or chronic clots. Currently, about 20% of the market is treated with mechanical thrombectomy, a figure expected to grow with efforts by companies like Boston Scientific aiming to change the treatment paradigm.

With 430,000 DVT and 280,000 PE patients, there is a significant market opportunity. Mechanical thrombectomy is preferred over TPA because it is a single-session procedure that can remove clots within an hour, allowing for same-day discharge for many DVT patients. On average, DVT patients can be discharged the same day, while PE patients may stay in the hospital for about 1.5 days, according to literature. Compared to TPA treatment, which often requires longer hospital stays—three to four days in the ICU for DVT patients and two and a half days or more for PE patients—mechanical thrombectomy offers a more efficient treatment, enabling quicker patient discharge and recovery.

CEOCFO: ***You have a long history in the industry; what have you learned from experience that is helpful as you move forward here and how do you deal with the frustration of knowing you have something that can help so many people and it is such a long and arduous process to get to that point?***
Mr. Bobo: We are deeply committed to making a meaningful impact in people's lives through our innovative solutions. However, it's admittedly frustrating when we believe we have a unique offering that stands out in the market, yet investors may struggle to see what sets us apart. In the eyes of potential investors, the challenge lies in understanding how our product differs from existing options and whether it has the potential to significantly impact market share and adoption rates.

In the competitive landscape of venture capitalism, standing out among the 800 deals that cross investors' desks requires a compelling differentiation strategy. Despite the challenges of securing funding, our focus remains on efficiently deploying capital and forging the right partnerships for design and development. To maximize flexibility and minimize overhead costs, we have strategically outsourced development work to highly skilled organizations while maintaining a lean footprint. As we continue to progress, we remain mindful of the cautionary tales of funded technologies failing to materialize in the market and strive to position our technology effectively to resonate with both investors and clinicians.

Fortunately, when given the opportunity to showcase our technology in the wet lab, the response from industry experts is overwhelmingly positive. Clinicians like Dr. John Moriarty from UCLA readily grasp the value proposition of our device, recognizing its potential to address critical pain points in procedures. Bridging the gap between investor skepticism and clinician endorsement remains a significant challenge, but conversations with strategic partners who understand the market dynamics offer encouragement. Their recognition of the pressing need for solutions to remove subacute and chronic clots underscores the potential impact of our technology.

CEOCFO: ***Final thoughts?***
Mr. Bobo: We are in Series A raise of $12 million, to complete Phase 2 and Phase 3 development work. It is a fun and exciting journey. I am excited about the technology. I think we have great patent protection and we believe that when this comes to market it will transform how it is treated, especially with the drug component. We are excited about the development and the future.