

**With the Vision to Commercialize the Proprietary Therapy Perfusion on Demand™, Advanced Circulatory Strives to Improve Survival Rates from Severe Medical Emergencies such as Cardiac Arrest, Stroke and Traumatic Brain Injury**

**Healthcare  
Medical Devices**

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**Mike Black  
CEO**

**BIO:**

Mr. Black has ten years of financial, manufacturing, clinical, product development and sales and marketing experience in the medical device industry. During Black's tenure at Advanced Circulatory, the company has evolved from a pre-revenue research and development organization to a break-even commercial operation with a \$7 mm retail book of business. He joined the company as Controller

and moved to Chief Financial Officer and Chief Operating Officer prior to being named CEO in 2008. Prior to Advanced Circulatory, he was involved in the financial and operational management of two early-stage technology ventures. Mr. Black started his career at Deloitte & Touche as a certified public accountant and consultant. He has an MBA from the University of Minnesota's Carlson School of Management and a B.S. in Accounting from the University of Iowa.

**About Advanced Circulatory**

Advanced Circulatory has developed a novel platform therapy called Perfusion on Demand™- a therapy that has life saving implications for multiple emergency medical and critical care conditions with a total estimated global market opportunity of \$4.1 billion. Perfusion on Demand is a non-invasive therapy that increases circulation, protecting the heart, brain and other vital organs when blood flow is compromised. This gives rescuers and caregivers the potential to return people to a full life after severe medical emergencies, including sudden cardiac arrest, stroke and traumatic brain injury. Comprehensive clinical research shows that Perfusion on Demand therapy improves survival with good neurologic function from sudden cardiac arrest, for example, by 53%.

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

**CEOCFO:** Mr. Black, what is the overall vision at Advanced Circulatory?

**Mr. Black:** The overall vision is to commercialize our proprietary therapy

that we call Perfusion on Demand and the technologies that deliver it. We want to do this in order to help improve survival rates from severe emergency medical conditions such as sudden cardiac arrest, traumatic brain injury, and other clinical conditions where there currently is a high degree of mortality and an opportunity to use our therapy to help improve those survival rates.

**CEOCFO:** Would you please explain the technology used?

**Mr. Black:** Our technology, Perfusion on Demand, is a therapy that non-invasively increases circulation and blood pressure by creating a low-level vacuum inside the chest. We create that vacuum non-invasively through the airway. That vacuum has the physiologic mechanism of improving circulation and lowering intracranial pressure to promote better perfusion – or blood flow - to the brain and the other vital organs.

**CEOCFO:** Is the ability to perform this care something new or are there ways currently being attempted that you would be replacing?

**Mr. Black:** This is an entirely new concept, and it is complementary to the other care that would be currently delivered to the patients in the emergency or critical care settings as of today.

**CEOCFO:** Please explain a little further about the non-invasive technique.

**Mr. Black:** Perfusion on Demand therapy is delivered through a series of products that are non-invasive. Our primary product on the market today is a device called the ResQPOD® Impedance Threshold Device (ITD) which increases circulation in patients in

sudden cardiac arrest and has been shown in studies to increase neurologically intact survival by 25% or more. During CPR, chest compressions push blood out of the heart and deliver it to the brain and the other vital organs. As the chest wall recoils, it creates a slight vacuum inside the chest. That vacuum is critical to helping blood flow return to the heart and to decreasing intra-cranial pressure. The ResQPOD ITD enhances this vacuum by preventing the entry of air into the respiratory circuit and allowing twice as much blood to be pulled back to the heart. This “primes the pump” and helps improve circulation because more blood is pushed out of the heart during compressions to the brain and other vital organs.

We also have the ResQGARD ITD, which is a product that improves circulation and increases blood pressure non-invasively by as much as 30% in spontaneously breathing patients who are in shock. This technology, which was co-developed with NASA and the US Army, creates a small amount of resistance when patients breath through it to enhance the vacuum in the chest and increase circulation.

Beyond these products, we have a pipeline of next generation products that will transition us from the passive, mechanical technology of the ResQPOD to a version of the therapy which will actively draw a low-level vacuum in the respiratory circuit. The products that deliver this active form of our Perfusion on Demand therapy will be used to improve neurologically intact survival rates in sudden cardiac arrest and other severe emergency medical conditions that compromise blood flow to the brain.

**CEO CFO:** Would the same person who is performing CPR be handling the ResQPOD or would it require specialized personnel?

**Mr. Black:** The technology does not require a change in current practice or protocol. It is complementary, and because it is a non-invasive device, it is relatively simple to use. It would not change the way CPR is performed or the way they would treat a patient,

rather it is easy to integrate and does not require additional personnel or specialized practitioners.

**CEO CFO:** Who is using the therapy today?

**Mr. Black:** Both the ResQPOD and ResQGARD ITDs are used by EMS systems such as ambulances and first response systems outside of the hospital and by first response teams inside the hospital, where they are placed on crash carts along with the other resuscitation tools. The military is also a significant user of this technology. The therapy is currently in clinical studies for use in critical care applications.

**CEO CFO:** Is the product being widely used now, and what methods do you use in order to capture people’s attention toward it?

**“...the strong clinical evidence that we have which demonstrates that we can impact survival rates through our therapy platform, combined with the fact that we are already a revenue generating company with a number of regulatory hurdles out of the way are all important milestones in today’s environment and help us stand out from other companies in this space.”**  
- Mike Black

**Mr. Black:** In today’s environment, clinical data is the way to get people to pay attention. We have a significant amount of clinical data that has been generated both by the company and independent investigators. Clinical studies show that that the ResQPOD ITD is capable of improving long-term neurologically intact survival from cardiac arrest by 25% or more over current outcomes. That clinical evidence is used to help clinicians either in the pre-hospital or hospital environment understand the value proposition of the therapy, and from a decision-making standpoint that is critical in terms of its level of adoption in United States. Our data has helped us to significantly penetrate in the markets both outside and inside of the hospital, but we do have the room to gain more adoption in the US and to grow internationally as well.

**CEO CFO:** Are you available internationally or is that a plan for your company?

**Mr. Black:** It is a plan for us. While our products are available internationally, we are just now starting to focus in on key strategic markets overseas where we want to develop a market for our therapy and products.

**CEO CFO:** Is the equipment simple to use?

**Mr. Black:** It is very simple. For example, a patient in sudden cardiac arrest would have a face mask or a secured airway such as an endotracheal tube and a ventilation bag that is used to deliver a positive pressure ventilation ten times per minute. Our device fits in between the ventilation bag and the face mask or the secured airway. It also has lights that help rescuers to perform better CPR by guiding ventilation and compression rates.

**CEO CFO:** What does the current timetable look like for your next products?

**Mr. Black:** We anticipate the next products to enter the market in mid-2014. We have had the benefit of having a lot of research support from the National Institutes of Health and the Department of Defense. This has allowed us to invest in some early stage clinical and product development activities that have resulted in a product pipeline that we will be bringing forward to the market place during the next two to three years.

**CEO CFO:** Having the ResQPOD already in place, is that helpful as you plan to develop the other products, or do people look at each one individually?

**Mr. Black:** It certainly is helpful. The intent of our product pipeline is to help take our Perfusion on Demand therapy across the entire continuum of care. The ResQPOD is primarily used today during sudden cardiac arrest when somebody is performing CPR. The ResQGARD and additional products we are bringing to market will allow us to use the therapy in multiple clinical conditions and to use it throughout the entire continuum of

care. The use of the technology would start in the EMS setting when the ambulance and the first responders arrive, but then it will continue to be used during transport to the emergency department, in the emergency department, and ultimately in the critical care department inside of the hospital.

**CEO CFO:** Are the devices reusable; is there a disposable component or a shelf life?

**Mr. Black:** The ResQPOD and ResQGARD are single use devices. Our next generation devices will be reusable with disposable components.

**CEO CFO:** Where do you manufacture and are you ready for the 2014 rollout of your additional products?

**Mr. Black:** We manufacture in a couple of key locations in the United States and overseas, and the manufacturing is already established for those additional products that are coming through the pipeline.

**CEO CFO:** Funding development is always costly; is the company funded for the next steps?

**Mr. Black:** We are partially funded for the next steps and are anticipating that additional capital will be needed to help accelerate the product and market development activities. We are being funded today by private

equity as well as the benefit of having research funding from the NIH and the Department of Defense.

**CEO CFO:** Is the level of interest in the area you are working with strong today, or is it as weak as some of the others, and do you see that as being a big factor when you need additional funds?

**Mr. Black:** The interest in the resuscitation space we operate in is very strong today, particularly because our technology is non-invasive and it is a platform technology that can be used in multiple clinical conditions. Therefore, the ability to leverage our initial success in sudden cardiac arrest with a pipeline of products that will help treat other severe clinical conditions has a lot of appeal for the investor community and industry.

**CEO CFO:** What has been the most helpful to you with previous ventures from Advanced Circulatory?

**Mr. Black:** Having the right people on our team with a passion for what we are doing, particularly since we are working in the medical device industry, is extremely important. For a disruptive therapy like ours, pushing forward into the medical community and gaining significant adoption takes a lot of effort and a lot of work from the entire team to get it done. I think that has been key for what we are doing.

The other key piece is being able to operate the company in a relatively conservative manner from a financial perspective, particularly in today's capital markets. From a research and development standpoint, the benefit of our federal funding has certainly helped us get to the point where we are today, which is a revenue generating company with break-even operations. Being able to do that without seeking significant outside institutional investments has been important.

**CEO CFO:** Why is Advanced Circulatory a company that stands out?

**Mr. Black:** We stand out because of the platform nature of our Perfusion on Demand therapy, and the ability to leverage that platform to help treat multiple severe clinical conditions where there is a high degree of mortality today. Furthermore, the strong clinical evidence that we have which demonstrates that we can impact survival rates through our therapy platform, combined with the fact that we are already a revenue generating company with a number of regulatory hurdles out of the way are all important milestones in today's environment and help us stand out from other companies in this space.



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