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Executive Summary

The Problem

Elevated core body temperature is a problem for athletes, firefighters, industrial workers, miners, military personnel, and those afflicted with diseases such as multiple sclerosis. When core organ temperatures rise, fatigue sets in and strength, endurance and cognitive functions deteriorate. Blood servicing the active muscles by delivering oxygen and fuel and removing metabolic waste is diverted to the epidermal tissue for heat dissipation. The greatest stress imposed on the human cardiovascular system (except for severe hemorrhage) is the combination of exertion and hyperthermia. Heat-related illnesses can develop and even become fatal.

The Solution

**CoreControl™** is a noninvasive, painless, handheld device that cools the body from the inside out using precise temperature control and a slight vacuum. **CoreControl™** reduces the risk of heat related injuries while preserving peak strength, endurance and cognitive functions. The current model weighs 6½ lbs., uses ice water as the cooling source and is powered by rechargeable batteries.

The Technology

**CoreControl™** uses patented technology developed at Stanford University and licensed exclusively to AVAcare.

The device interfaces with radiator-like, high-volume, low-resistance blood vessel shunts called arteriovenous anastamoses, or “AVAs”, in unique combination with venous plexus. These radiator like vascular structures are found only beneath the body’s hairless skin regions, including the palms of the hands and soles of the feet.

This technology has evolved from years of research at Stanford University, has been scientifically assessed in performance laboratories and field-tested by collegiate and professional athletes and teams as well as industrial and military focus groups. The results show:

- Increased cooling rates of 2 to 5 times faster than skin cooling methods
- Slower heating up during exercise and faster cooling down after exercise
- Reduced risk of heat injuries (dehydration, cramping, and heat fatigue)
- 20-80% performance increase

Product and technology research and development continues under Defense Advanced Research Projects Agency (DARPA) grants issued to Stanford University totaling $2.950 million (see Appendix VI for summary of DARPA grants). DARPA is expected to make a large grant to Stanford University in the 3rd quarter of 2005 to accelerate technology validation and fund design and development of wearable devices (boots and gloves) for military applications. AVAcare has been and will continue to be a Stanford subcontractor for the DARPA programs.
Target Markets

CoreControl™ is initially targeted at the athletic and fitness market. AVAcore will next target those afflicted with multiple sclerosis heat debilitation. The military market will be developed as the DARPA project progresses.

The current direct sales price is $3,200. Sales to distributors are at $2,500. The value proposition is the savings to a team or institution by reduced heat related injuries as well as the costs associated with impaired job performance. Developing a direct sales strategy for the early target markets is underway. In the future, AVAcore will add distributor/reseller channels and sublicensees to penetrate other markets and international markets.

Athletics – The athletics and fitness market for CoreControl™, which includes professional, collegiate, high school and health club/equipment segments, is estimated at 5,000 – 7,000 units/year. AVAcore has the most exposure in this market to date as prototype units have been evaluated by:

- Professional Teams – San Francisco 49ers and Oakland Raiders, Milwaukee Bucks and New York Rangers
- College Teams – University of Miami and Stanford University
- World Football League – Manchester United and Chelsea Football Club
- British Olympic Team, US Decathletes and Chinese Olympic Team
- Japanese Baseball Teams

Multiple Sclerosis – At least 350,000 people in the U.S. alone are afflicted with heat debilitation caused by MS. Present treatments are ineffective for most patients. Early anecdotal evidence suggests that CoreControl™ can reduce this heat debilitation. The potential exists to improve the quality of life for these patients and to slow the progression of the disease. Initial sales can be made under existing AVAcore 510K approvals. These sales will be made through direct contact with MS support groups. AVAcore recently received the prestigious Da Vinci Award from the Michigan Chapter of the National MS Society. Numerous medical researchers, including the neurology department of the University of Michigan Medical Center, have asked to conduct a broad range of studies applying CoreControl™ to MS and similar diseases.

Future Markets

Military – DARPA has made clear its goal is to have CoreControl™ deployed by the military in a wide variety of applications from aid stations to aircraft carriers to front line soldiers. AVAcore is building wearable military prototypes to be delivered to DARPA over the next six to twenty-four months. AVAcore has received its first military order to provide 135 units (at a price of $2,000 per unit) for use in Iraq.

Firefighters, Emergency Responders and Extreme Industrial Environments – There are 26,000 fire departments in the U.S. There are countless industrial applications in foundries, steel mills, mines, power plants and construction. As a safety device, the market adoption rate for CoreControl™ should follow the same path as the automatic defibrillator rollout. With this rollout schedule, unit sales could approach 60,000 units for the firefighter market alone.
**Medical** – Applications that could require either the cooling or heating capability of CoreControl™:

- Heart attack and stroke victims – rapidly lowering body temperature of a heart attack or stroke patient during the acute episode could reduce the damage done to tissue
- Chemotherapy and radiation treatments – warming the patient improves the uptake in cancer cells and efficacy of therapy
- Uses in the operating room – certain procedures require a managed, below normal body temperature. Post surgery re-warming is being studied
- Women experiencing hot flashes during menopause
- Rehabilitation from heart attack, stroke, and amputation
- NIH plans to use the unit in treating the morbidly obese
- Pain Management

The potential US medical market addressable with CoreControl™ under current FDA approvals is estimated at approximately $720 million, comprising over $400 million for the MS patients, $120 million for amputees and $200 million for heat stress. Ultimately, this technology will evolve into other vertical markets within the medical community, which AVAcore estimates will expand the total addressable market to $1.2 billion (see Appendix IV for a detailed addressable market analysis). As confirmation of this cross-vertical potential, AVAcore has had recent discussions with medical companies to explore the in-hospital treatment of both hypothermic and hyperthermia patients for use in pre and post surgery, radiation oncology, heart attack and stroke treatments.

**Competing Products**

Competing products to cool core body temperature are less effective, impractical and/or unsafe.

Methods which cool the skin only (such as misting fans or cooling vests), or help with cramping only (ice water or electrolyte drinks) do not cool the core of the body as quickly as CoreControl™.

Methods that do work are invasive, impractical and/or painful (IV’s or full immersion in an ice bath.) IV’s must be administered by a medical professional. An ice bath is painful and impractical for most applications.

**Funding & Uses**

*The first generation of CoreControl™ is available now. The Company is seeking to raise $5 million in private equity to finance the following near-term goals:*

- Expand the sales and marketing team and fund the design and implementation of a direct marketing program to the athletic market.
- Increase engineering staff to continue product development and implement product upgrades.
- Build product inventory.
- Continue to expand the Intellectual Property portfolio.