Christopher M. Cashman, CEO, SANUWAVE Health, Inc.

SANUWAVE is an emerging leader in the development and commercialization of noninvasive, biological response activating devices in the regenerative medicine area for the repair and regeneration of tissue, musculoskeletal, and vascular structures. SANUWAVE’s portfolio of products and product candidates activate biologic signaling and angiogenic responses, including revascularization and microcirculatory improvement, helping restore the body’s normal healing processes and regeneration. In this month’s CEO Spotlight, meet SANUWAVE’s CEO, Chris Cashman, who provides a look inside the day in the life of a C-Level Executive as well as an in-depth interview about the company’s perpetual success and what opportunities are on the horizon.

Chimere G. Holmes

Q: SANUWAVE Health is an emerging leader in the development and commercialization of noninvasive biological response activating devices in the regenerative medicine area for the repair and regeneration of tissue, musculoskeletal, and vascular structures. As the CEO, what do you feel our readers should know first and foremost about your company?

A: SANUWAVE utilizes high-energy pressure waves delivered in the shock wave spectrum. The shock waves elicit a biological response, resulting in the release of angiogenic growth factors and ultimately new blood vessel formation. This process helps the body get back to a normal healing response for tissue or bone regeneration. The SANUWAVE platform was formed in August of 2005. We have an intellectual property portfolio of 50-plus patents and applications worldwide.

We’re really focused in four areas today: advanced wound care, orthopedic/spine, plastic and cosmetic and cardiac uses. Our major focus is in our lead product, dermaPACE®, dermaPACE® is addressing the advanced wound care market, which we define as about a $5 billion opportunity in the U.S. dermaPACE® is already approved in Europe with the European Community’s CE mark. We are currently pursuing our first clinical indication in the U.S. for diabetic foot ulcers (DFU), for which we have completed enrollment in our 206-patient, pivotal Phase III, randomized, double-blinded, sham-controlled Investigational Device Exemption (IDE) clinical trial and submitted our first 2 of 3 modules of the PMA application to the FDA. We are preparing for the final clinical module submission.

We have had a longstanding history in orthopedics, with two FDA Class III-approved indications, one for heel pain and one for elbow pain. PACE™ shockwaves have had a terrific safety profile over the years. Once I became involved, we built on this legacy and know-how with the development of next-generation devices for advanced wound care and orthopedics, and have expanded our recent development into plastic and cosmetic procedures as well as cardiac, for which we just filed some new, provisional patents for methods to break up plaque and increase vascularity in compromised heart muscle.

Q: Please describe your work experience that prepared you for your current position as SANUWAVE’s CEO:

A: I joined SANUWAVE as a member of the board of directors and as President and Chief Executive Officer in December 2005. Prior to this position, I served as President of Therapeutic Surfaces for Kinetic Concepts, Inc, a global leader in advanced wound care. I conducted a management buyout in November 2001 of Snowden Pencer, a minimally invasive surgical device manufacturer, and assumed the role of CEO and President. In March 2004, Snowden Pencer was sold to Cardinal Health. I have also served as a Business Unit Head with Genzyme Biosurgery, and held several senior sales and marketing positions with Genzyme Surgical Products and Deknatel Snowden Pencer. I graduated from the United States Naval Academy in 1989 with a B.S. in economics and served on a fast-attack submarine as Supply Officer. I received my MBA degree in 2001 from The Kellogg School of Management at Northwestern University.

My healthcare career has been focused in combining biologics with devices for use in wound care, orthopedics, cardiac, plastic and cosmetics, and various fringe surgical specialties.
Q: Please expand on the latest news surrounding the clinical trials the company is working on and the types of results each trial could potentially yield:

A: SANUWAVE recently reported compelling data from our 206-patient, pivotal Phase III, randomized, double-blinded, sham-controlled clinical trial of dermaPACE® to treat diabetic foot ulcers, which clearly demonstrated that dermaPACE® alone significantly accelerated the rate of ulcer closure and significantly reduced ulcer size. This data showed with high statistical significance that at 12 weeks, 48% of patients treated with dermaPACE® compared to 31% of Sham control patients experienced wound closure of 90% or better (p=0.016). Additionally, the median wound closure exceeded 99% for dermaPACE® treated patients achieving ≥90% wound closure at 12 weeks. Of the patients treated with dermaPACE® that achieved wound closure at 12 weeks, only 4.5% had recurrence at 6 months. These results were achieved with four simple and fast, noninvasive procedures over a two-week period.

Through the acceptance of a shell application in August 2010, SANUWAVE received FDA permission to file the PMA for dermaPACE® in a series of three sections or “modules”. In December 2010, the company submitted the first module, which included preclinical data and the results of prior clinical testing. The second module containing the Quality System and Manufacturing review was submitted in January 2011. The company plans to submit the third and final module of the PMA in the next month or two of 2011. This final module will contain the PMA application, data from the company’s recently completed pivotal Phase III, IDE clinical trial, proposed DFU labeling, and a summary of safety and effectiveness.

Q: How does SANUWAVE value the use and many dimensions of its PACE™ technology?

A: Certainly, we have a notably special technology in PACE™. We have significantly large market opportunities. This is not a one-trick technology or product; the PACE™ portfolio is applicable to a broad range of market segments. SANUWAVE priorities remain focused on chronic wounds first and orthopedics and sports medicine second. We have worked incredibly hard to continue to advance our intellectual property portfolio and currently have over 50 patents or applications worldwide, and definitely have new ideas each day. Additionally, I believe that the executive team, as well as all of our employees that we’ve put together here, make a formidable team. Ultimately, we have a refined focus on the $5 billion U.S. wound care market in the immediate future. We’re going to make the most of the opportunities we have with the capital resources available to us.

While we have many opportunities on the horizon, it is neither possible nor feasible to do it all by ourselves. One option is licensing opportunities for certain IP positions in our portfolio. For instance, in the cardiac area we are interested in two applications — utilizing PACE™ technology to break up plaque in the arteries and using it to stimulate new blood vessel growth within the heart muscle. We don’t define ourselves as a company that’s going to be able to take this cardiac opportunity to commercialization, so that will be a perfect opportunity for a cardiac-focused corporation to partner with us. We also have other offerings in spine and nerve regeneration that we most likely will not do ourselves, and these are sizable markets as well.

Q: Please describe the mission/vision of your company:

A: We believe we are developing a safe and advanced technology in the wound healing and tissue regeneration market with PACE™. We often talk about “Healing today, curing tomorrow” and we don’t take this lightly. We want to develop a long-term platform that meets the immediate need for healing, but also prevents recurrence and the need for later interventions. dermaPACE® is non-invasive and does not require anesthesia, making it a cost-effective, time-efficient and painless approach to wound care. Physicians and nurses look for therapies that can accelerate the healing process and overcome the obstacles of patients’ compromised conditions, and they prefer treatments that are easy to administer in addition to being minimally disruptive to the patients or the caregivers’ daily routines.

We are now entirely focused on developing PACE™ technology to stimulate tissue healing in all wound healing
conditions to include diabetic foot ulcers (DFU), decubitus ulcers (pressure sores), burns and other skin eruption conditions, and orthopedic and spine applications such as fracture healing and fusion, and the elimination of chronic pain from trauma or arthritis. In the mid to longer term development, we will focus on plastic and cosmetic applications such as preconditioning for graft and transplant acceptance, skin tightening, scarring and other potential aesthetic uses; and potential developments in cardiac indications for removing plaque due to atherosclerosis and improving blood supply to the heart muscle.

Q: How exactly does your personal vision fit with the company’s goals?
A: The number one reason I am in the healthcare sector is because I want to make a difference in peoples lives. Here at SANUWA VE our PACE™ platform of products has the chance to do just that. The degenerative conditions and tissue regenerative markets we are addressing have major needs that can benefit from the ability of PACE™ to activate neovascularization, healing, and long-term tissue stability and durability.

Q: Please provide information regarding the company’s market overview:
A: With respect to wound care, it is a significant opportunity. If you just look at diabetic foot ulcers, there are up to 3 million foot ulcers in any given year. Diabetes is a significant problem in the U.S. There are 27 million people today with diabetes throughout the U.S. and 79 million who are pre-diabetic. So unfortunately, this disease state is only getting worse, and therefore the opportunity and need is large. We define the U.S. dermaPACE® opportunity alone as exceeding $5 billion. We look at the availability of options to meet the entire market need from both a cost and an efficacy standpoint. We feel diabetes and diabetic foot ulcers specifically are underserved from a product-performance perspective. Finally, we have to be able to do something well, to do it efficiently, and to provide it in a manner so both the customer, in this case the caregiver, and the patient are going to want to incorporate it into their standard of care. We think we have this in dermaPACE® and in other planned products in the portfolio.

Q: What products or projects is SANUWAVE working on, on an international scale?
A: dermaPACE® and orthoPACE™ are in the European market. We have used the European market the last few years mainly for proof of concept, developing protocols, conducting pilot studies, and really getting an outstanding expertise of how the product works and what the optimal ranges are in the different types of indications. However, we are now ready to start accelerating our marketing activities with our country distribution partners.

We use that pilot work to not only commercialize in Europe, but also to start clinical studies here in the U.S. Europe is always a difficult market, especially for U.S.-based companies because you need to understand the local cultures and distinct government, reimbursement and regulatory policies of each country. In our scenario, it is important to show clinical success in the various indications, but it is also important that the insurance payers see the value. In this case, we are dealing with nationalized healthcare within the European community countries. They must understand the value proposition of clinical efficacy and cost. The only way to do that within each of those countries is to do additional local clinical trials, much like we’re doing here in the U.S. So before we gain significant revenues out of Europe, each of those countries will look for a specialized study. Now that we have completed the gold standard, randomized, sham-controlled clinical trial for diabetic foot ulcers in the U.S., we can now take that back to Europe and use it as a basis to build momentum with the payers and with the government to get reimbursement in place in each targeted country.

Q: Looking ahead, what types of things will take place in order for SANUWAVE to continually grow laterally in such an evolving market?
A: We are excited to make our clinical submission report and finalize our PMA package with the FDA. dermaPACE® has the potential, as shown in our robust clinical results from our pivotal Phase III, IDE study in diabetic foot ulcers, to help a great number of individuals who suffer through the physical and emotional distress of these terrible foot ulcers. We look forward to the opportunity, should the FDA approve dermaPACE® for the U.S. market, to bring the product to caregivers. In the end, we hope to make a significant impact on healing and the quality of patients’ lives.

Once our efforts are established in the DFU space, we will continue to expand up the leg into venous and complex wounds. We are also poised to start a Phase III fracture/truma clinical trial here in the U.S. that will include the lower leg and extremity bones.

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