

# THE WALL STREET TRANSCRIPT

Connecting Market Leaders with Investors

## SANUWAVE Health, Inc. (SNWV.OB)



**CHRISTOPHER M. CASHMAN** joined SANUWAVE as a member of the board of directors and as President and Chief Executive Officer in December 2005. Immediately prior, he served as President of Therapeutic Services for Kinetic Concepts, Inc, a global leader in advanced wound care. He 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. Mr. Cashman has 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. Mr. Cashman 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. He received his MBA degree in 2001 from The Kellogg School of Management at Northwestern University.

### SECTOR — HEALTH SERVICES

**TWST:** Let's begin with some background on SANUWAVE, a picture of what the company is doing now, your operations, products, etc.

**Mr. Cashman:** SANUWAVE is an emerging leader in the regenerative medicine category, utilizing 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 via a divestiture by HealthTronics, who is the leader in urology and lithotripsy — breaking up kidney stones using shock waves — services here in the U.S. Through the divestiture, we acquired all of the intellectual property, 50-plus worldwide and a legacy, global orthopedic product line. We're really focused in four areas today. We had a longstanding history in orthopedics, with two FDA Class III-approved indications, which is the highest-regulated FDA approval pathway — one for heel pain and one for elbow pain. Once I became involved, we built on this legacy and know-how with the development of next-generation devices for orthopedics, and have expanded our interests into wound care, plastic and cosmetic procedures and cardiac, for which we just filed some new, provisional patents for methods breaking up plaque and increasing vascularity in compromised heart muscle. 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 and has the European Community's CE mark. And we are currently pursuing our first clinical indication in the U.S. for diabetic foot ulcers (DFU), for which we expect to complete enrollment in the first quarter of 2010.

**TWST:** What do you consider a reasonable market for the technology behind dermaPACE?

**Mr. Cashman:** Well, whenever we evaluate an opportunity, it has to fit a few criteria. To start with, market size is important. With respect to wound care, it's 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 diabetics in the U.S. today and 54 million that are pre-diabetic. So unfortunately, this disease state is only getting worse, and therefore the opportunity and need is very large. We define the U.S. dermaPACE opportunity alone as exceeding \$5 billion. Secondly, we look at the companies that are servicing the need and evaluate whether they are doing a good job with the products that are available from both the cost standpoint as well as 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 that 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.

**TWST: Is this product in the European marketplace? If so, how much competition do you have there?**

**Mr. Cashman:** dermaPACE is in the European market. We have had a product in the orthopedic space and will be introducing next-generation products for orthopedics, plastic and cosmetic procedures early next year. We have used the European market 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. Once developed, 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's not just important to show clinical successes in the various indications, but also important that the insurance payers see the value. In this case, we are dealing with nationalized health care within the European community countries. They must understand the value proposition of clinical efficacy and costs. The only way to do that within each of those countries is to do additional local clinical trials, much like what we're doing here in the U.S. So before we gain significant revenues out of Europe, each of those

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countries will look for a specialized study. And of course, being an early-stage company, we don't have the financial or capital resources to do that country by country. So our plan is to complete our Investigational Device Exemption study here for diabetic foot ulcers, which would then be the gold standard, randomized, sham-controlled clinical trial that we would then take back to Europe and use it as a basis to build momentum with the payers and with the government on getting reimbursement in place country by country.

**TWST: What is the competition for Sanuwave in the wound care market? How do you compare your pricing?**

**Mr. Cashman:** There are multiple types of products that are on the market today. Historically, wounds have been treated by advanced dressings that absorb the exudate from the wound, and many have coatings or biologics impregnated into the dressing to help healing. From our standpoint, we utilize pressure waves, very high-energy pressure waves that are delivered in the shock wave spectrum. And those pulses, which we call PACE™ (pulsed acoustic cellular expression) pulses, once delivered elicit an angiogenic response. We see new vascularization that forms helping with the tissue regeneration and closure of wounds. There are other companies over the years that have tried to utilize energy, and there are also many companies of course that have been in the biologics realm. Some companies are utilizing energy like lasers, ultrasound and radio frequency, and all have certain side effects and risk. The leader worldwide is negative pressure wound therapy, which is essentially a basic suction pump that keeps the wound clean, and through that continued friction of the suction, helps to granulate tissue. However, the wounds don't always close and so require additional surgical procedures and costs. And then on the biologic front, many companies have tried to regenerate tissue by eliciting a response using different types of growth factors or platelets, either in a coating, a dressing or a tissue replacement

that can be applied to the wound. Unfortunately, some of these modalities are very expensive with varying efficacy rates. But in our case, we think we have something special. Pressure waves are safe and cause signaling at the cellular level. PACE pressure waves elicit a response from the body so that the body can actually restart in a normal manner, move from a chronic condition to a normal, acute healing condition and then take over the healing process, resulting in closure. In our European pilot clinical work for diabetic foot ulcers, we have seen significant healing rates in the 75% full-closure realm within 12 weeks. And we believe we can do this at less than half the cost of the leading therapies.

**TWST: What is the agenda? What are your priorities for the next 12 to 24 months? What would make that time frame a success?**

**Mr. Cashman:** We have several priorities that are critical and several that are moving in parallel. Of course our first major priority is moving dermaPACE through completion of the enrollment stage in our study for the DFUs. And of course when that happens, which we believe should be no later than March 2010, that will put us on a very predictable timeline with the FDA. We would expect to unblind on our data shortly after the six-month followup of the last patient enrolled is completed, and then move to an FDA submission, assuming that the data looks good

and is in a position that would be favorable for approval by the FDA in 2011. But in parallel, we are working diligently to find an agreeable path with the FDA to bring a product to market. That essentially would put a PACE device on the market in 2010 to address certain conditions that could be helped by improved microcirculation in the local area. Beyond that, based on the state of the company having just gone public, we are taking every opportunity to educate the investor community on SANUWAVE. We also continue to manage our cash very tightly, ensuring that we do all that we can to achieve FDA approval for dermaPACE in 2011, while being very opportunistic about finding quicker, more viable regulatory paths if possible for our other product candidates.

**TWST: Last week the company announced a ticker symbol change. Why the change?**

**Mr. Cashman:** SANUWAVE utilized a reverse-merger process to go public in September. Even though SANUWAVE, Inc., was essentially the acquirer of the public company, it is a subsidiary of the surviving entity. And so we have gone through the process of changing the corporate name to SANUWAVE Health. FINRA just recently issued us a new ticker symbol, SNWV. The process we used is now highly regulated by the SEC, and the filings and reporting are very much like going through the scrutiny of a full IPO without the significant costs associated with an IPO nor the long timeline.

**TWST: What do you see as your most valuable assets? Is it intellectual property, proprietary technology, the level of focus and the distance you might have ahead of potential competitors?**

**Mr. Cashman:** I think there are several, and you named a few. Certainly, we have a very special technology in PACE. We have very large market opportunities. This is not a one-trick technology or product; PACE could be very applicable to a broad range of market segments. We

have worked very hard to continue to advance our intellectual property portfolio and currently have well over 50 patents or applications worldwide, and definitely have new ideas each day. And I think 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 very refined focus, and we're going to make the most of the opportunities we have with the capital resources available to us.

**TWST: Would you share with us your financial outlook for the immediate future as well as your long-term financial goals?**

**Mr. Cashman:** Well, I think that being an early-stage company, we are going to continue to burn cash. We have scaled that back to a point where we are highly efficient, but we still are going to be conducting our clinical trials, which could cost a good bit of money. And you need to have the infrastructure to do that. Historically, we've burned somewhere around \$0.5 million a month. And now that we are a public company with the special nuances and reporting that go with it, I would expect that we are going to be somewhere between \$500,000 and \$600,000 per month going forward. The reality is this: Revenue will start to kick in once we have a significant product offering on the U.S. market and once we've finished the clinical trials so that we can go back to Europe, be very proactive about driving reimbursement there, resulting in a meaningful revenue stream. But I would say that for the next 12 to 18 months, a potential investor or shareholder won't see any significant revenues until then.

at Snowden Pencer, which was a premier medical device and instrument company that we sold to Cardinal Health. He came back to SANUWAVE with me in 2006. He also has large public company experience in the services industry, first with AHL Services and then as the CFO of ADP's Benefit Services division after Snowden Pencer and prior to coming to SANUWAVE. My R&D VP, Iulian Cioanta, has two Ph.D.'s, one from Duke which is specific to shock wave technology. He was most recently at Cordis, and before that worked in the biologics and biomaterials space for Kensey Nash. So he has a great background for what we are doing. Our VP of Operations, Clinical and Regulatory, Pete Stegagno, was most recently at Elekta, using gamma radiation for brain surgery. He was with Genzyme Biosurgery with me before that. And we just brought in two new additions, preparing for our transition to commercialization. Our Medical Policy Vice President, Anne Stefurak, whom I am pleased to have just brought back, has a long history with SANUWAVE and Healthtronics, and has been very involved in setting up clinical policies and reimbursement with payers over her career. Our new Vice President of Sales and Marketing, Bernie Laurel, comes to us from the wound care space. He led the wound care effort for Medela, a Swiss-based corporation and world leader in suction devices, where he launched their negative pressure wound therapy device into the \$1 billion U.S. marketplace. Most importantly, we all get along very well. It's a very strong, constructive environment, where a lot of good ideas are formed and challenged. It is very much of a team-oriented group with vast experiences focused on bringing this technology to the marketplace.

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**TWST: Will you be looking for strategic alliances?**

**Mr. Cashman:** We are very interested in both. We have many opportunities and can't do them all ourselves. One option is licensing opportunities for certain IP positions in our portfolio. For instance, in the cardiac area, we are very 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, utilize our research and development strengths, and then invest in trying to deliver that technology to the marketplace. We also have other offerings in spine and nerve regeneration that we most likely won't do ourselves, and these are very sizable markets. Secondly, as a company we'll always be interested in partnerships as well as potentially adding on product lines to what we are doing today that could be additive or important to the continuum of health care within our focus.

**TWST: How strong is SANUWAVE from a management standpoint? Would you mind telling us about some of the key members of your team now?**

**Mr. Cashman:** I've worked with these individuals for years at different companies, and so we all have history together. I've been with very large corporations as well as small. I was at Genzyme for six years, where we married up biologics with devices. I took a company private, Snowden Pencer, and sold it to Cardinal Health. And then I was at KCI as President of Therapeutic Services, the largest global wound care device company running therapeutics worldwide. My CFO, Barry Jenkins, was first with me

**TWST: What has been the investment history with SANUWAVE? What are the present needs and the schedule to satisfy those needs?**

**Mr. Cashman:** There has been well over \$30 million invested in SANUWAVE over the years. As we went public, we brought in just about \$2 million, which at the end of the third quarter left us with about \$3.3 million in cash. We are going to continue to have funding needs as we go forward into 2010, and so we'll continue to burn cash, and we will opportunistically look at that. But I would expect that if we stay on track with our study and we finish our enrollment in the first quarter of next year, we will have a valuation inflection point upon that enrollment completion, another towards the end of the third quarter or the beginning of the fourth quarter of next year — based on how the study data looks — and perhaps others based on our FDA submission and ultimate approval in 2011 to begin commercialization. These would all be very good signs that we are picking up momentum. And of course, we will continue to keep the market and our shareholders aware of other study progressions and results, new scientific partnerships, European distribution improvements, new product regulatory approvals and other important corporate developments.

**TWST: When speaking to potential investors, are there any recurring questions or misconceptions? Do investors have a sense of what you are trying to do?**

**Mr. Cashman:** I think they get it. They understand that the market, especially advanced wound care, is very, very large. They understand the unmet need in diabetic foot ulcers. These patients are very, very sick and very often these foot ulcers move to amputation.

There were almost 100,000 amputations last year alone, incurring significant cost and emotional distress. I think they do understand that we have a special technology that elicits response from the body so that it can actually reinitiate the normal healing processes. And we do it in a very efficacious way as compared to the products that will be competing against us, should we get approval. And we are going to be able to do it in a much more cost-effective manner. We think that we could actually be 25% to 50% of the cost of the standard products utilized today outside of basic dressings. So that would be significant savings to the health care system.

**TWST: What are some milestones or benchmarks that investors should be looking for? You mentioned 2011 and the FDA.**

**Mr. Cashman:** I think they should be looking at how the company is maturing from the standpoint of strengthening its position as we move toward 2011. And there will be multiple milestones and announcements that I would expect will be coming out. We continue to do a great deal of preclinical and clinical work outside the U.S. and some of it now in the U.S., and there will be announcements about that. We will continue to strengthen our team internally as well as externally, meaning medical advisers. There have been certain advisers, scientific advisers and doctors that we've worked with over the years, and I would expect to formalize some of those relationships that have shown a great deal of interest in working with us in developing the technology and helping bring it to market. I would also look for some more information on the various regulatory paths that we are working on with the FDA. And of course, there is the dfu IDE study timeline, which we expect to deliver on.

**TWST: What might be some of your major challenges?**

**Mr. Cashman:** Well, clinical studies are always challenging. You do your utmost to design a study that can't be questioned negatively and that is going to show the product, and how it performs in absolutely the best light. You want to be comparing apples to apples, oranges to oranges, so that it is very clear that it's the product that's making the difference and eliciting the change — in this case, healing the wound. And we think we've done that. In our dermaPACE study for diabetic foot ulcers, we've utilized a lot of contributions from three or four of the scientific leaders in the country in the area of wound healing with diabetes and in microcirculation improvement. And so we think we have a great study design. But at the same time, these patients are very sick. And since we are blinded to the results, you never really know until the end as to how things will go. But the good thing is that dermaPACE has worked

well in Europe. Our pilot studies showed that as high as 75% of all patients treated healed their diabetic foot ulcers within 12 weeks, the FDA evaluation guideline. That's an unheard of number for these chronic types of wounds. And of course, dermaPACE is not the only product candidate for the company. We have other product candidates in development, such as orthoPACE for orthopedics and evoPACE for addressing plastic and cosmetic applications, such as cellulite and scar healing. So the risk of not being successful is really spread across multiple market segments and product opportunities, limiting our exposure.

**TWST: What are the two or three main reasons you would give an investor to take a closer look at SANUWAVE today?**

**Mr. Cashman:** This is a significant technology that truly does make a difference. It has never been applied in the manner for which we are utilizing it today: tissue regeneration. On this merit alone, it deserves a closer look. We have very strong intellectual property. We have very large market opportunities that I think we can be very effective within, and we have a senior management team that is very committed and dedicated to ensuring that PACE is successful and gets to the market for commercialization. And finally, we have all done this many times before. It is our combined experiences over the years, taking products through development, clinical, regulatory scrutiny and ultimately commercialization that should give comfort to shareholders and potential investors alike.

**TWST: Anything you would like to add, anything we've missed here?**

**Mr. Cashman:** I appreciate the opportunity to discuss SANUWAVE with you today, and to introduce our company and our opportunities. Thanks very much.

**TWST: Thank you. (KL)**

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