

# The Pulse

**Newsletter, Spring 2019** 

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# SANUWAVE EVENTS CALENDAR

#### **Medical Conferences:**

April 26- 27, 2019: MWCM in Greensboro, NC.

May 7 – May 11, 2019: SAWC/WHS in San Antonio, TX

May 17 – 18, 2019: NPWTJ in Poznan, Poland

May 22 – 25, 2019: ISDF in The Hague, Netherlands.

#### **Investor Conferences:**

April 1 -2, 2019:

Spring Investor Summit 2019, New York, NY.

April 30 – May 2, 2019: Planet MicroCap, Las Vegas, NV. Happy Spring SANUWAVE Friends,

An appropriate season which also characterizes the forward advancement of SANUWAVE's Q1 activity and focus for the year. Spring is often viewed as a new beginning synonymous with growth. This edition of **The Pulse** showcases what we are positioned to achieve this year and the following articles explore and explain, why and how. Our spring edition of The Pulse concludes with an abbreviated shareholder letter from Kevin, our Chairman and CEO, outlining our commitments for the year. The PACE is set. The activities are encouraging and thanks to your engagement and support, our momentum will only continue to grow. Cheers to "Spring" ing forward!

- Shri

### SANUWAVE, Proud Winner of JWC 2019 Innovation in

# Chronic Wound Healing Award for dermaPACE®

On Friday, March 1, 2019, the Journal of Wound Care (JWC) celebrated excellence and innovation at its 7<sup>th</sup> awards ceremony,



which took place at the Banking Hall in London. More than 100 guests from all over the world attended the event. At this ceremony, health professionals were granted different awards for their work in pressure care, diabetic foot care, and surgical site infection, among other areas.

The JWC is the definitive wound-care journal and the leading source of up-to-date research and clinical information on tissue viability. The journal was first launched in 1992 and caters to the needs of the multidisciplinary team. JWC is the official journal of the World Union of Wound Healing Societies (WUWHS). It is also the media partner of the European Wound Management Association (EWMA) and affiliated to over 40 other associations, societies, and charities. In the United States JWC is affiliated with the Association for the Advancement of Wound Care (AAWC), the National Pressure Ulcer Advisory Panel (NPUAP), and the Academy of Physicians in Wound Healing (APWH), giving unrivaled access to the global wound care community.

SANUWAVE's flagship technology, the **dermaPACE® System**, which is used to treat chronic wounds such as diabetic foot ulcers (DFUs) in the U.S., as well as venous ulcers, arterial ulcers, pressure ulcers, burns, and acute surgical wounds in select non-U.S. markets, was nominated by JWC for the title of most innovative technology in Chronic Wound Healing. The dermaPACE® System was considered the front-runner amongst several other prestigious companies and technologies.



## JWC AWARD Winner: Innovation in Chronic Wound Healing



It was a proud moment for SANUWAVE when the JWC announced that SANUWAVE 's dermaPACE® System was named the winner of the Innovation in Chronic Wound Healing AWARD category.

Shri Parikh, President at SANUWAVE, was in attendance to accept this prestigious award in London, as seen in the photo above (third from left).

As we know, chronic wounds represent a global problem. Each step in finding new solutions to alleviate this medical challenge represents a victory for everyone. The SANUWAVE team developed, tested, and successfully navigated the approval process for our flagship product, the dermaPACE® System, which is now approved to treat a variety of chronic wounds and skin conditions in the European Community, Canada, South-East Asia, and other selected markets. The dermaPACE® System is also FDA cleared in the United States for the treatment of diabetic foot ulcers (DFUs).

The use of our proprietary Pulsed Acoustic Cellular Expression (PACE) technology to treat chronic wounds by promoting cellular expression, tissue regeneration and revascularization of the wound bed is a novel application of shockwaves in the medical field. Using energy devices such as the dermaPACE® System to promote healing, and in the future combined with other wound care technologies, is an interesting and exciting step forward in adding new treatment options to the wound care portfolio.

- Iulian Cioanta, Chief Science and Technology Officer

# Clinical Update—Placement Program, Perfusion Study

### SANUWAVE's dermaPACE® System Early Adopter Placement Program

We have a number of dermaPACE® Systems looking for a good home...

SANUWAVE is beginning the commercialization process in the U.S. of our dermaPACE® System and we are seeking to place the product in key locales for evaluation and support in our efforts seeking Category I reimbursement codes. SANUWAVE is placing the dermaPACE® System for evaluation for a defined period at no cost, to treat diabetic foot ulcers (DFUs) in outpatient and physician office settings.

The dermaPACE® System is intended for the treatment of DFUs in conjunction with standard of care. To date, SANUWAVE has placed 15 dermaPACE® Systems across New Jersey, South Carolina, Ohio, Pennsylvania, Wisconsin, Alabama, Louisiana, Texas, and California. The systems are placed at no cost for the evaluation period. We are asking that you use the product in your normal treatment flow to 1) gain a working knowledge and opinion of the dermaPACE® System and 2) support SANUWAVE towards the creation of a Category I reimbursement code. We are initially targeting the following states: California, Texas, Illinois, Pennsylvania, North Carolina, and South Carolina. At the end of the evaluation period, we will work with you in either keeping the product via a number of cost-effective solutions or returning the product to SANUWAVE.

If you are interested in this program, please contact Lorraine Bittinger, Clinical Affairs Manager for SANUWAVE via email at:

lorraine.bittinger@sanuwave.com.

# Upcoming Clinical Case Series and Presentations Evaluation of Perfusion Levels Using the dermaPACE® System

One of the dermaPACE® System's key means of promoting the body's natural healing process is to increase blood perfusion and neo-angiogenesis.

We've seen and performed limited measurements of these results in animal and human trials. SANUWAVE is sponsoring a case series, to be performed at two sites, to specifically measure and monitor perfusion levels before, during, and after a treatment regimen using the dermaPACE® System on DFUs. We expect to have these two sites initiated and running before the end of March. Work will be performed at:

- University Hospital/Rutgers University (Newark, NJ) with Dr. Mark Grannick and Dr. Oscar Alvarez as Principal Investigators.
- UCLA/Olive View (Sylmar, CA) with Dr. Aksone Nouvong as the Principal Investigator.

Drs. Grannick and Alvarez will be presenting an interim report of the results in an Industry Supported Symposium at the Symposium of Advanced Wound Care (SAWC Spring) in San Antonio in May 2019.

Be sure to look for this exciting presentation while at SAWC.

We expect the study to be completed in Q3/Q4 and results published soon thereafter.

#### **Additional Clinical Studies**

As we are gaining additional knowledge and experience of the effects of the dermaPACE® System for the treatment of DFUs via our Early Adopter Program and also via our Perfusion Case Series, we will also be actively designing and planning a major follow-on study using the dermaPACE® System for the treatment of DFUs. This study will serve as a confirmatory study for wound closure, management, and overall safety while measuring other meaningful, patient-centric endpoints as well as economic data.

For further information please contact Pete Stegagno at <a href="mailto:pete.stegagno@sanuwave.com">pete.stegagno@sanuwave.com</a>. Our participants in the Early Adopter Program will have an advanced start for consideration as a study site!

- Pete Stegagno, Chief Operating Officer



# dermaPACE® System Training in the Field

#### What an Exciting Time to be at SANUWAVE

As we move to the commercialization phase of the dermaPACE® System, wound care clinics and podiatry offices are getting the opportunity to apply dermaPACE® treatments to patients with diabetic foot ulcers (DFUs) and to provide valuable feedback. Having been in a field role at SANUWAVE for about four months now, I would like to summarize what physicians, clinicians, and patients have been telling me about this exciting, wound healing technology.

In multiple wound care clinics, physicians are documenting decreases in wound size and depth after only a couple weeks of treatment. The DFUs are showing an increase in tissue proliferation in the wound bed. John Sammies MD, from Orangeburg, SC noted: "These wounds are slowly improving, which is great because nothing else was working."

Prior to dermaPACE® treatment, most of the already evaluated DFUs have become recalcitrant and physicians had exhausted all other advanced wound therapies. The wounds had become stalled in the inflammatory phase of the healing trajectory.

As a wound care clinician, it was great to see patients excited to tell me how this device was helping their wound. On several occasions, patients would say to me, "I can feel that it is working."



Initially from a strategic standpoint, as we continue to place dermaPACE® Systems across the US, we are focusing primarily on the following states: *CA, TX, IL, NC, SC, & PA*. If your wound care clinic or podiatry office would like to get involved in a revolutionary emerging wound care technology, please contact Lorraine Bittinger, RN, BSN, Clinical Affairs Manager or Pete Stegagno, Chief Operating Officer.

**KEEP UP THE PACE!!** 

- Lorraine Bittinger, Clinical Affairs Manager



# The Pulse Newsletter, Spring 2019

# dermaPACE® System Training in the Field, cont...



Lorraine Bittinger, Clinical Affairs Manager (SANUWAVE) and Dr. Brian Lepow, DPM at the Bailor Clinic in Houston, TX.

Thank you Brian Lepow, DPM for a successful dermaPACE® training at Baylor Clinic!



Dr. Niezgoda's son, Jon Niezgoda, providing a dermaPACE® treatment



## **NAM Membership**

#### SANUWAVE Announces Membership with the National Association of Manufacturers as it Ramps Up US Commercialization Strategy of the dermaPACE® System

SANUWAVE is excited to announce its membership with National Association of Manufacturers (NAM) to advance corporate values including free enterprise, competitiveness, individual liberty, and equal opportunity. NAM is driving solutions to build a talent pipeline for the manufacturing industry and to improve manufacturers' bottom lines.

As SANUWAVE commercializes in the United States, it is looking forward to membership benefits that include forceful advocacy, first-rate policy expertise, top-quality legal strategy, high-level brand exposure and innovative business solutions that increase profits.

Most manufacturing companies in the United States are quite small. In 2015, there were 251,774 companies in the manufacturing sector, with all but 3,813 companies having fewer than 500 employees. Three-quarters of these companies have fewer than 20 employees. In the most recent data, manufacturers contributed \$2.33 trillion to the U.S. economy in the first quarter of 2018. Additionally, there are currently 12.75 million manufacturing workers in the United States, accounting for 8.6 percent of the workforce.

Over the next decade, nearly 3.5 million manufacturing jobs will likely be needed, and 2 million are expected to go unfilled due to the skills gap. Subsequently, world trade in manufactured goods has more than doubled between 2000 and 2014, from \$4.8 trillion to \$12.2 trillion.

In response to continued explosive growth and the NAM membership opportunity, SANUWAVE company President, Shri Parikh stated, "SANUWAVE has and will continue to have many employment and growth opportunities over the next 5 years. We are looking forward to the partnership with NAM to harness the power of the manufacturing community, increase our talent pipeline, work through growth challenges, improve our brand exposure and navigate through critical commercialization opportunities like reimbursement advocacy and production demand."

CEO and Chairman of the Board, Kevin Richardson further stated that "The NAM and its member companies annually host hundreds of meetings and manufacturing events in Washington DC and around the country. We

are looking forward to members of our SANUWAVE leadership team representing SANUWAVE by connecting with legislators on the latest policy issues related to manufacturing and government during these events. NAM's efforts create a policy environment that fosters competitiveness, job creation, and economic growth. We couldn't be more pleased to align with NAM to ensure future growth and sustainability."



#### The National Association of Manufacturers

was founded in Cincinnati, Ohio, in 1895. The United States was in the midst of a deep recession, and many of the nation's manufacturers saw a strong need to export their products to other countries. One of the NAM's earliest efforts was to call for the creation of the U.S. Department of Commerce. The NAM also helped launch the National Council of Commerce, which later became the U.S. Chamber of Commerce.

In the 1930s, the NAM launched its first public relations campaign for the "dissemination of sound American doctrines to the public." Over a 13-year period, the NAM spent more than \$15 million to inform the public about the vital role manufacturing plays in the U.S. economy. These efforts included movie shorts, leaflets, radio speeches, films for schools and a daily NAM column that appeared in 260 newspapers nationwide.

During World War II, the NAM created a plant-level employee morale program, titled "Soldiers of Production." The association also conducted community relations efforts and assisted companies with such wartime problems as priorities and allocations. Before the end of the war, the NAM concentrated on helping manufacturers prepare for the postwar period, helping them with issues such as recycling surplus materials, conversion to civilian production and training of veterans for careers in manufacturing. The advent of commercial television led to the NAM's own 15-minute television program, "Industry on Parade," which first aired in 1950. By 1952, the Peabody Award—winning show was being telecast in 76 of the 78 U.S. television markets.

President John Kennedy's speech to the NAM audience in December 1961 helped initiate the effort that led to the enactment of the Trade Expansion Act of 1962,

# NAM Membership & Open Positions

which resulted in lower tariffs. In 1964, the NAM led a successful trade mission to Europe. Members of the NAM delegation met with President Lyndon Johnson and Pope Paul VI during the mission. Taking advantage of new technology in the early 1970s, the NAM held four closed-circuit television conferences reaching as many as 8,000 business executives in 26 cities at one time. The NAM also established its headquarters in Washington, D.C. in order to increase the association's impact on policy development.

As the 1980s began, the NAM unveiled its six-point "Revitalization Agenda" to combat inflation and invigorate manufacturing and the economy. It became a major part of President Ronald Reagan's economic program in 1981. In 1987, long before the Internet became common, the NAM provided its members with online, customized communications through NAMnet, including a first webpage.

In 1995, a series of 16 different vignettes on the importance of manufacturing aired on CNN television during the NAM's centennial commemoration. During this period, the NAM founded The Manufacturing Institute after research showed legislators, the administration, the media, policy –influencers and the public had an antiquated view about manufacturing's vital leadership in innovation, job opportunity, technological progress and economic national security. The Institute conducts

groundbreaking research and educational and innovative programs to combat misperceptions and stereotypes about manufacturing.

On January 15, 2011, Jay Timmons became president and CEO of the NAM. "Jay has a keen understanding of manufacturing, and he has relationships on both sides of the aisle in Washington. Jay has helped lead the NAM during good economic times and has remained unflappable during the most difficult economic times manufacturers have ever faced," stated NAM Chairman Michael Campbell. Timmons followed John Engler, the former three-term governor of Michigan, and Jerry Jasinowski who led the NAM with distinction for six and 15 years, respectively.

Throughout its history, the NAM has been one of the nation's most influential advocates for manufacturing. The NAM has proudly stood with manufacturers and their employees in times of war and peace and in periods of economic strength and uncertainty. The NAM will continue to be the most powerful and unwavering voice for policies that support manufacturers' ability to grow the economy, create good-paying jobs and improve standards of living.

- Melissa Miller, Human Resources Director

# SANUVAVE® Healing today. Curing tomorrow.



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## Regulatory Update

# SANUWAVE Successfully Transitions to ISO 13485:2016

As part of our ongoing efforts to ensure that the products and services which SANUWAVE provides to its customers are aligned with our Mission, Vision, Quality Policy, and Regulatory Requirements, we are pleased to announce that SANUWAVE has successfully completed the transition of our Quality Management System (QMS) from ISO 13485:2003 to the current revision ISO 13485:2016. The British Standard Institution (BSI) performed the audit of SANUWAVE's QMS on February 26 – 27<sup>th</sup> 2019 and upon completion of the audit has recommended the company for certification. Each employee at SANUWAVE played a major part in the success of the audit.

ISO 13485:2016 is the Medical Devices – Quality Management Systems – Requirements for regulatory purposes. Organizations that design, manufacture, install and service medical devices seeks to obtain the voluntary ISO 13485 certification to demonstrate to regulatory agencies like the U.S. Food and Drug Administration, Health Canada, the European Commission, and others that they are committed to operating under a defined quality management system.

For SANUWAVE, this is another step in our journey to qualifying for the Medical Device Single Audit Program in Q3 of 2019 and the new European Medical Device Regulations by the year 2022.



#### SANUWAVE Quality Road Map A Look Ahead Q2 2019



This is an exciting time to be a part of SANUWAVE. As we prepare for the commercialization of the dermaPACE® System in the United States, we are also gearing up for major changes in our Quality System.

With superior quality being our focus, SANUWAVE will embark on the following Quality System Initiatives in 2019:

 Q2 2019, complete preparation for certification to the Medical Device Single Audit Program (MDSAP). The MDSAP certification will ensure that the Quality Management System (QMS) at SANUWAVE is meeting the regulatory requirements for production, marketing, and sales of medical devices in the five participating countries in this program (United States, Canada, Brazil, Australia, and Japan). For more information on MDSAP and MDSAP certification, please visit the following link on the U.S. Food and Drug Administration webpage:

https://www.fda.gov/MedicalDevices/ InternationalPrograms/MDSAPPilot/

- Q2 2019, standardize our process for conducting post-market clinical evaluations and reporting
- Q2 2019, SANUWAVE will select an electronic Quality Management System software application for housing conducting quality system related documents and records of required activities.
- Q2 2019, the SANUWAVE Quality team will implement an improved method for assessing training competencies.
  - Leon Lambry, Director Quality & Regulatory Affairs

# **SANUWAVE Video Blog**

# 11 Minutes With Shri—A New Video Blog Series from SANUWAVE

For the first installment of SANUWAVE's new video blog series "11 Minutes With Shri", SANUWAVE President Shri Parikh interviews American surgeon and researcher Dr. David Armstrong, renowned for his work in amputation prevention, wound healing, and the diabetic foot. Dr. Armstrong is Professor of Surgery and Director of the Southwestern Academic Limb Salvage Alliance (SALSA) at the Keck School of Medicine of the University of Southern California and has produced more than 475 peer-reviewed manuscripts and more than 80 book chapters.

Over the course of the interview, Dr. Armstrong:

- Applies his 'cancer analogy' to reveal sobering statistics on the diabetic foot, the economic and quality-of-life impact on sufferers, and the challenges that DFUs and other diabetes-related complications pose to providers in the industry.
- Stresses the importance of raising awareness, including improved messaging, public affairs, and an increase in affiliate organizations such as 'Save A Limb, Save A Life' that play a crucial role in getting the word out.



- Discusses the difference between being healed and being in remission, the likelihood of recurrence, and why it is important to focus on longterm follow-up vs individual events.
- Discloses his choice of The Lakers or The Clippers,
   The Rams or the Chargers, and reveals his all-time favorite team ©

To view the video, please click <u>HERE</u>.







# A Summary of Our CEO's Letter to Stakeholders

# A look back at 2018, and a glance forward to 2019.

#### Dear SANUWAVE stakeholders,

This past year marked a turning point for SANUWAVE. We achieved several milestones, including record top-line revenue. Most importantly, we set the stage for even more dramatic growth as we begin the domestic commercialization of our FDA-cleared product, the dermaPACE® System. Each year we establish 4-5 goals which investors can monitor to make sure we are on the path to achieve our ultimate goal: a dermaPACE® System placed anywhere a Diabetic Foot Ulcer (DFU) is treated in the U.S. We will achieve this goal in the next 5 years and when we do, we will have at least 2,000 devices placed, performing more than 500,000 treatments per year and generating north of \$100 million in revenue. We are following a playbook that other successful medical device companies have followed when rolling out a new and innovative technology. To achieve this long-term objective, we have broken down the crucial steps along the way, usually five steps per year, and we share them with you, our investors, so you can measure our progress against our ultimate goal.

#### How did we do in 2018? Putting the foundation in place

We began the year with the FDA granting us clearance for use of the dermaPACE® System to treat DFU's. Diabetes is a disease state that is growing in the US and around the globe. One of the ailments that affect over 1.9 million Americans annually is a DFU. There are billions spent in the healthcare system to treat this issue and it touches everyone. The statistics are staggering when it comes to patients' struggles. The statistic that fails to get enough attention is the morbidity rate of DFU patients who suffer an amputation. Within 5 years 65% of DFU patients will die - a rate much higher than most cancer morbidity rates. The dermaPACE® System works to allow clinicians to manage and ultimately heal wounds. Our data indicates that treatment with dermaPACE® System will reduce the number of amputations that occur compared to Standard of Care alone, with the ultimate goal to subsequently save lives. As a company, we have financial goals, but our top goal remains improving patients' quality of life and ensuring everything we do cascades from this.

Having an approved device is just the first step, a MAJOR step, but the first step in commercialization. During 2018, domestically, we were successful in the following areas: hiring a president, paving a path for reimbursement, supporting publications and establishing distribution partners and financing partners. These steps were part of the process needed to develop a solid foundation from which to expand.

- In late May we hired Shri Parikh to be President of our healthcare unit and implement the rollout plan. He joined

us most recently from Molnlycke Health Care and before that had a successful and progressive career with other successful large health care companies.

- The reimbursement tracking code was published for our procedure, so the reimbursement process can begin with payors. It is a long process, and this first step allows facilities, doctors, and insurance to benefit from the device. The tracking code went into effect on January 1, 2019, which means we can now begin our rollout in earnest.
- The 336 patient trial results were published in a peer review article in the Journal of Wound Care (JWC) in December adding more credibility to the already positive results.
- We signed and began shipping dermaPACE® Systems to our partner, Premier Shockwave, who is handing our Veterans Administration (VA) and Indian Health Services (IHS) business. Under the agreement, they have minimum yearly commitments and both companies share in the procedure fees.
- We inked a deal with NFS to help finance the rollout of our equipment, allowing us for rapid expansion during 2019.

Internationally, we set a goal of adding 4 new countries. We exceeded that by adding 15. The largest of these international deals was announced in June involving our JV partner, FKS Medical. The agreement establishes a beachhead in Southeast Asia among 10 countries. They began making payments to us during 2018 and aggressively developed a plan to obtain product registration. Device licenses in Taiwan and Malaysia were obtained and devices were shipped; three clinical studies were kicked off to support the rollout. We also launched an agreement with 2 eastern European countries and began the registration process in Panama, Costa Rica, and Mexico. These international seeds were planted over the past three years and are now coming to harvest at the same time we are seeing a launch in the U.S.

Lastly, we continued to invest in the science and clinical work that helps build a competitive moat around SANU-WAVE. During 2018 we expanded our patent portfolio with 9 additional issued patents, bringing the IP active patent applications and issued patents up to 62. We have a full pipeline for 2019 including several projects that began in 2018, which we will report on in the future.

# What shall we accomplish in 2019? Placements, training and spreading the gospel

The groundwork laid in 2018 allows for disciplined growth in 2019. The goal remains the same, a dermaPACE® System placed and utilized everywhere and anywhere a DFU is treated in the U.S. During 2019, the incremental goals by which you should measure us are placements, training, reimbursement, and clinical support. If we are successful

## A Summary of Our CEO's Letter to Stakeholders



with these goals, investors will see a clear path to achieving our ultimate goal.

- Placements of dermaPACE® in support of continued performance surveillance and reimbursement policy development will begin en-masse during 2019. If we plan to be at 2,000 in 5 years we need to start now and measure our success along the way. Our goal in 2019 is 100 device placements. We will start with a modest Q1 goal of 15 (35 by Q2 & 65 by Q3) and as our target base expands, create a groundswell to reach 100 by the end of the year. Our business plan is modeled to generate revenue each time our device is used to treat a DFU. The first step towards achieving this is placing the device and developing a knowledge base which we will leverage to expand numbers of placed dermaPACE® Systems. As we succeed in reaching 100 placements this year, and we scale accordingly, 2020 will lead us to a multiple of that installed base.
- Training is critical with any new medical device or system. Our expectation is to certify 4-5 professionals per placed system. A continuous training program is extremely important to make certain patients receive the proper treatment on an on-going basis as we help heal the wound. Investors will be able to monitor the number of trained users as we progress through 2019.
- Our tracking code for reimbursement began on January 1, 2019. This does not guarantee payment; however, it is a necessary stage essential for unencumbered claims payment. We put the right team in place to move the reimbursement process along through the claims process and begin to derive revenue for the facility, doctor, hospital, and us. We have targeted 6 states initially where we can gain claims volumes needed for coverage. Our goal for the year is 10 million covered lives.
- Clinical work will never stop at SANUWAVE. We currently have four (4) clinical initiatives kicked off internationally. Domestically we will have 2-3 studies launched to support the product rollout. These will have various outcomes measured to support the clinical community and the reim-

bursement community. We plan to provide updates when we launch a major study, with enrollment updates throughout the year. This clinical work is vital for driving usage of the device. Although 2019 is not a year focused on driving usage, which is a 2020 goal, the work we do this year will allow for measurement of patient-centric outcomes and expansions in the indications for using the device and leads for increasing the daily usage in the future.

- Internationally we will continue to harvest the seeds we have planted. We expect another record shipment year in 2019, most likely doubling our 2018 shipments. We may not add as many countries as 2018, but we will ship more product and run more clinical trials. We are hopeful to gain at least one more of our joint venture models which pay us an upfront fee during 2019.

Ultimately, the goals listed for 2019 must translate into revenue and profit. The leading indicator will be placements and certified users. As a reminder, placements will take 4-6 months to reach revenue maturity. The first few months we will work through the reimbursement challenges and help train the staff on proper usage of the dermaPACE® System, but once that is flowing well, we expect a device to be used at least once a day, if not more. We hope the metrics and goals laid out for 2019 will help investors understand what we are striving to achieve. This is another step to get to the bigger goal and needs to be monitored along the journey.

#### **CLOSING: THANKS!!!**

As always, we want to thank you as our investors for believing. You believe in our goals, the playbook we are following to achieve them and for patiently supporting us through the years. 2019 will be monumental, as the year the rollout began. We also want to thank all the doctors and nurses on a global basis who support us and most important treat the patients with so much loving care. Our employees deserve a huge thank you for staying the course even during the darkest of times and are now increasingly energized you and seeing a paved way to continued success.

Feel free to call or email with any concerns or questions. Also, visit our website (www.sanuwave.com), explore the blogs and the science sections, it is filled with fascinating information.

Sincerely,

Kevin Richardson II, CEO and Chairman of the Board

For the full letter, please click <u>here</u>.