

# SANUWAVE®

Healing today. Curing tomorrow.

*Applying shockwave technology to repair and regenerate skin,  
musculoskeletal tissue, and vascular structures*

**OTCQB: SNWV**

**March 2016**

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# Forward-Looking Statement Disclaimer

This presentation may contain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, such as statements relating to financial results and plans for future business development activities, and are thus prospective.

Forward-looking statements include all statements that are not statements of historical fact regarding intent, belief or current expectations of the Company, its directors or its officers. Investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, many of which are beyond the Company’s ability to control. Actual results may differ materially from those projected in the forward-looking statements.

Among the key risks, assumptions and factors that may affect operating results, performance and financial condition are risks associated with the regulatory approval process and subsequent marketing of the Company's product candidates and products, unproven pre-clinical and clinical development activities, regulatory oversight, fluctuations in the Company's quarterly results, the Company's ability to continue and manage its growth, liquidity and other capital resources issues, competition and the other factors discussed in detail in the Company’s periodic filings with the Securities and Exchange Commission. The Company undertakes no obligation to update any forward-looking statement.

**SANUWAVE** Health (SNWV), Inc. is an emerging shockwave technology company focused on the development and commercialization of patented noninvasive, high-energy, acoustic shockwaves for the repair and regeneration of tissue, musculoskeletal and vascular structures.

## **The Diabetic Foot Ulcer Wound Market Is Our First Focus**

# Investment Highlights

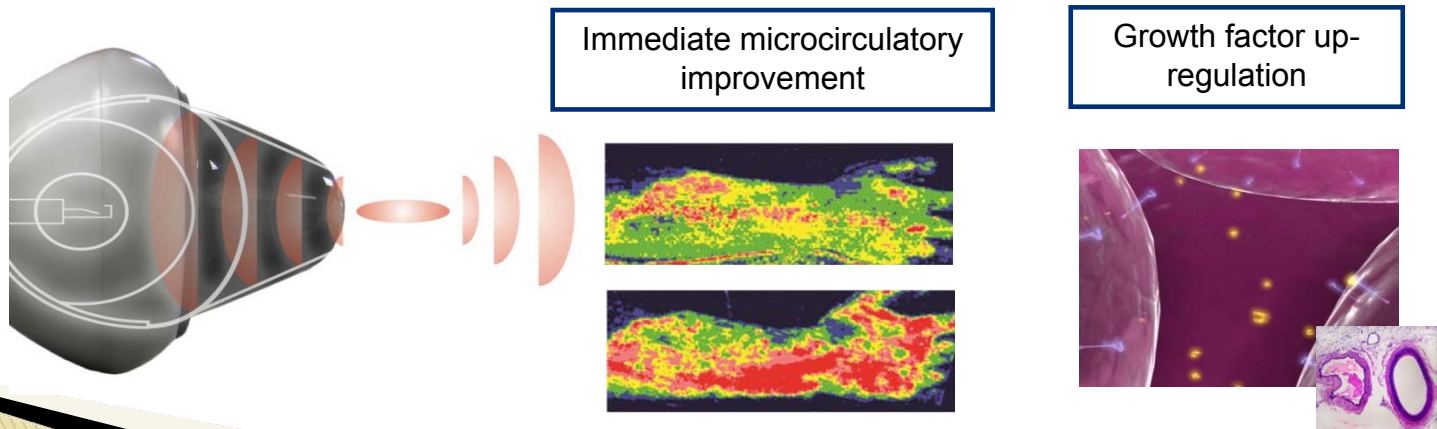
- Proprietary technology uses focused shock waves – PACE® (Pulsed Acoustic Cellular Expression)
- Lead product, dermaPACE® has completed Phase III and Supplemental clinical trials in U.S. for diabetic foot ulcers
  - dermaPACE offers a lower cost treatment and non-invasive treatment. dermaPACE addresses a large and growing wound care market - \$3B U.S. for DFU's, \$22B Worldwide
  - Enrollment of 130 patients in the supplemental trial and a combined 336 patients have now completed the two studies. We announced the top-line results for the Supplemental trial publicly in October 2015 and are in the process of drafting the clinical study report for the supplemental trial and the combined results of the two trials.
  - SANUWAVE and its FDA regulatory advisors, Musculoskeletal Clinical Regulatory Advisers, LLC (MCRA), will meet with FDA in late April/early May 2016 to work interactively with the FDA review team to bring dermaPACE to market in the quickest possible manner.
  - Formal submission to FDA for dermaPACE approval expected in Q2 2016
- Approved devices in Europe, Canada, Australia, S. Korea and Gulf Coast region – expanding distribution
- Significant future applications – medical and non-medical – including blood sterilization and biofilm disruption. Working with major universities for proof of concept.
- Extensive patent portfolio – 52 patents (issued or pending) – working to monetize



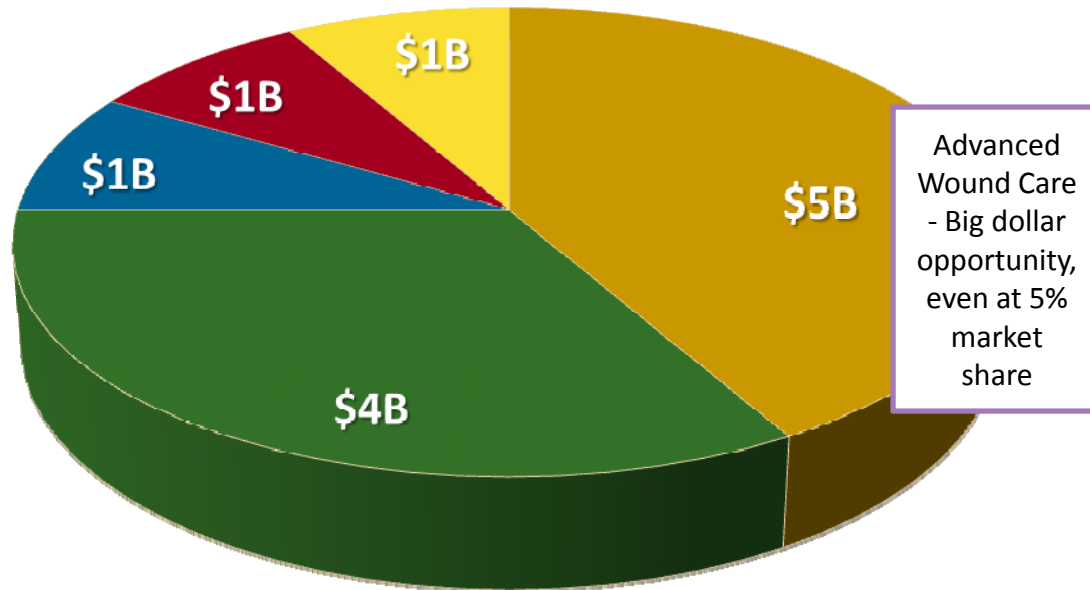
# A Leader in Shock Wave Technology

## Development and Commercialization

- Patented, non-invasive devices for the repair and regeneration of:
  - Skin
  - Musculoskeletal tissue
  - Vascular structures
- Devices **activate biologic signaling and angiogenic responses**, producing:
  - New vascularization
  - Microcirculatory improvement
  - Tissue regeneration



# PACE – Total Addressable U.S. Market - \$12B



## Advanced Wound Care

- Diabetic Foot Ulcer
- Chronic Mixed Wounds
- Pressure Sores
- Infections and Biofilms
- Burns

## Orthopedics

- Sports Medicine
- Tendon / Pain
- Trauma / Fracture
- Osteoarthritis
- Spine

## Stem Cells

- Stem Cell Proliferation
- Soft Tissue Regeneration

## Plastic/Cosmetic

- Scar Modulation
- Reconstructive and Grafting
- Body Contouring

## Vascular/Cardiac

- Blood Sterilization
- Peripheral Artery Disease
- Atherosclerosis
- Myocardial Ischemia

# dermaPACE – Market Opportunity

## U.S. Market

- Diabetic Foot Ulcers - \$3B+ market size.
- 29 million people living with diabetes and 86 million pre-diabetics.
- 25% of diabetics will acquire a non-healing ulcer in their lifetime; ~3 million diabetic ulcers annually.
- Diabetic foot ulcers lead to over 73,000 amputations annually at a cost that is estimated to exceed \$5.1 billion annually.
- Hospitalization costs of ~\$20,000 for a patient with a DFU; ~\$70,000 for an amputation.

## International Market

- Globally there are 382 million people living with diabetes and it is expected to reach 592 million by 2035, an increase of 55%.
- dermaPACE is CE Marked and currently marketed by independent distributors in Spain, Australia, Canada, and the Middle East.
- **dermaPACE can be licensed or joint ventured in these markets to speed market penetration while minimizing operating costs.**

*The international global wound care market of \$22 billion offers significant expansion opportunity for CE marked dermaPACE*

# dermaPACE - Treating Diabetic Foot Ulcers

## Treatment Advantages

- Robust closure with extremely low recurrence rates
- Non-invasive, convenient and safe
- Mechanism of action (MOA) allows :
  - Increased blood flow (perfusion) and increased vascularization (angiogenesis)
  - Restores oxygenation to ischemic area
  - Accelerated tissue repair—may decrease long-term DFU complications
- Cost-effective
- May be used as an adjunct therapy



# dermaPACE Phase III Supplemental DFU Trial Design

## Design

- Double-blinded, randomized, sham-controlled
- 90 patient minimum at 20 U.S and Canadian sites; approval up to 200 patients
- Doubled the number of treatments - Up to 8 total treatments - 4 dermaPACE treatments administered in first 2 weeks, then 4 additional treatments bi-weekly between weeks 4 and 10 following enrollment
- Standardized debridement procedures, central independent review by Core Lab of wound images for closure determinations, and concise training materials
- Primary endpoint: complete wound closure at 12 weeks

## Rationale

- FDA approval of Bayesian Statistics - layering original plus supplemental results - requires smaller patient population to achieve FDA approval
- Scientific research (published after original trial initiated in 2007) supports additional treatments during trial

# dermaPACE DFU Trial Results

## Primary Endpoint – Complete Closure at 12 Weeks post initial application

- At the 12 week endpoint a total of 39 out of 172 (22.7%) of dermaPACE patients had complete wound closure, compared to 3 out of 164 (18.3%) in the control group.
- There was no statistically significant difference in wound closure at the 12 week follow up between the dermaPACE and control group;
- Subsequent visits exhibit a trend towards significance resulting in a significant difference by the 20 week endpoint that was maintained through the end of the study.
- At the 24 week endpoint, the rate of wound closure in the dermaPACE cohort was 37.8% compared to 26.2% for the control group, resulting in a p-value of 0.023

*Primary Endpoint of Complete Wound Closure*

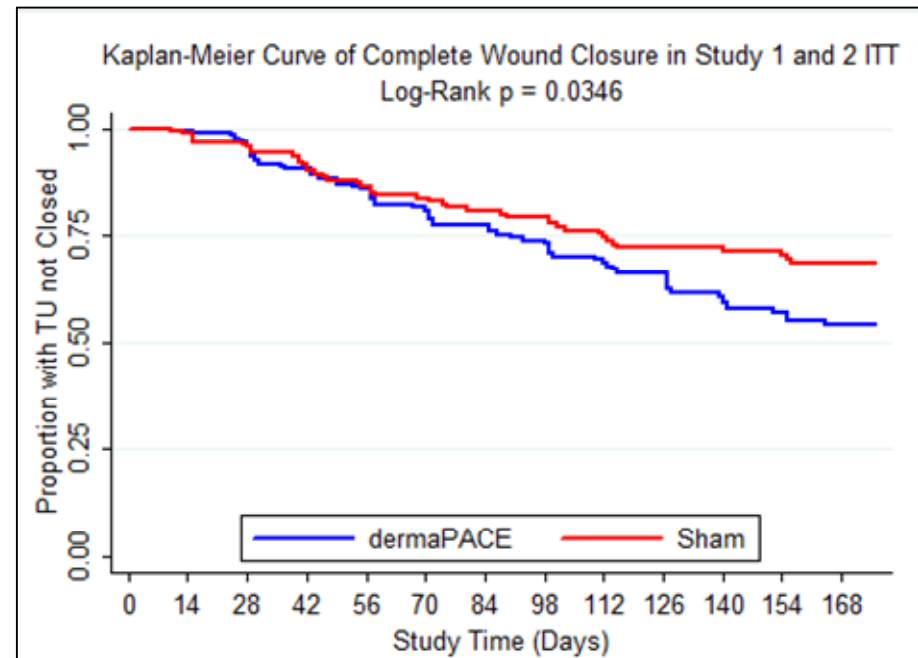
Study Visit	Complete Wound Closure				X <sup>2</sup> p-value
	dermaPACE (N=172)		Sham Control (N=164)		
	n	%	n	%	
Week 2	2	1.16	5	3.05	0.226
Week 4	15	8.72	9	5.49	0.250
Week 6	21	12.21	18	10.98	0.724
Week 8	28	16.28	23	14.02	0.565
Week 10	35	20.35	27	16.46	0.350
Week 12	39	22.67	30	18.29	0.320
Week 14	45	26.16	34	20.73	0.241
Week 16	50	29.07	39	23.78	0.272
Week 18	56	32.56	39	23.78	0.074
Week 20	61	35.47	40	24.39	0.027
Week 22	64	37.21	43	26.22	0.031
Week 24	65	37.79	43	26.22	0.023

# dermaPACE DFU Trial Results

## Primary Endpoint – Proportion of Patients with Wound Closure

- The proportion of patients with wound closure can be seen in this graph. The results of this Kaplan-Meier curve indicate a statistically significant difference between the dermaPACE and the control group in the proportion of subjects with the target ulcer not closed over the course of the study (p-value=0.0346).
- Approximately 25% of dermaPACE subjects reached wound closure per the study definition by day 84 (week 12). The same percentage in the control group (25%) did not reach wound closure until day 112 (week 16).
- These data indicate that in addition to the proportion of subjects reaching wound closure being higher in the dermaPACE group, subjects are also reaching wound closure at a faster rate when dermaPACE is applied.

*Kaplan-Meier Curve of Complete Wound Closure*



*Note: This graph presents the percentage of patients who did not have closure of their target ulcer. As such a lower y-value indicates a higher rate of closure.*

# dermaPACE DFU Trial Results

## Additional Efficacy Analyses

- At 24 weeks, several sub-populations demonstrated a statistically higher percentage of wound closure in dermaPACE subjects compared to the control subjects.
  - Subjects with age less than 65 years,
  - BMI less than 32, height greater than or equal to 70 inches, and
  - Male subjects
- All had success rates statistically significantly higher than the control group (p-value =  $\leq 0.050$ ).

*Results Stratified by Demographic Characteristics at 24 Weeks (% Wound Closure)*

Demographic		dermaPACE			Sham Control			p-value
		N	n	%	N	n	%	
<b>Age</b> (years)	<65	120	45	37.5	129	33	25.6	0.043
	$\geq 65$	52	20	38.5	35	10	28.6	0.341
<b>Sex</b>	Male	137	55	40.1	132	33	25.0	0.008
	Female	35	10	28.6	32	10	31.3	0.811
<b>Smoking Status</b>	Non-Users	146	54	37.0	133	35	26.3	0.056
	Users	26	11	42.3	31	8	25.8	0.188
<b>BMI</b> (kg/m <sup>2</sup> )	<32	84	38	45.2	87	22	25.3	0.006
	$\geq 32$	88	27	30.7	77	21	27.3	0.631
<b>Weight</b> (pounds)	<220	86	35	40.7	78	21	26.9	0.063
	$\geq 220$	86	30	34.9	86	22	25.6	0.184
<b>Height</b> (inches)	<70	72	20	27.8	72	25	34.7	0.369
	$\geq 70$	100	45	45.0	92	18	19.6	0.0002
<b>Ulcer Age</b> (months)	<6	91	44	48.4	75	27	36.0	0.109
	$\geq 6$	81	21	25.9	89	16	18.0	0.210

# dermaPACE DFU Trial Results

## Additional Efficacy Analyses – Wound Area Reduction

- The mean wound reduction for dermaPACE subjects at 24 weeks was 1.92cm<sup>2</sup> compared to 0.16cm<sup>2</sup> in the control group.
- There was a statistically significant difference between the wound area reductions of the two cohorts from the 6 week follow up visit through the end of the study.
- Because means can be influenced by outliers in the data, the median wound reduction was also reported and favored dermaPACE.

*Mean and Median Wound Area Reduction*

Study Visit	Wound Area Reduction from Baseline						T-test p-value
	dermaPACE			Sham Control			
	N	Mean (cm <sup>2</sup> )	Med. (cm <sup>2</sup> )	N	Mean (cm <sup>2</sup> )	Med. (cm <sup>2</sup> )	
Week 2	100	1.05	0.98	88	0.49	0.70	0.112
Week 6	93	1.77	1.18	84	0.49	1.00	0.003
Week 12	86	1.90	1.36	73	0.16	1.14	0.005
Week 18	82	1.99	1.51	66	0.54	1.17	0.017
Week 24	72	1.92	1.47	67	0.16	1.28	0.047

# dermaPACE DFU Trial Results

## Additional Efficacy Analyses – Wound Area Increase/Worsening of Wound

- A significantly greater proportion of sham control subjects had an increase of at least 10% in their wound area.
- This indicates that not only does dermaPACE aid in wound healing (decrease in wound size), dermaPACE also may prevent wounds from getting worse (increasing in wound size).
- The differences are statistically significant in favor of dermaPACE with the exception of Week 2 and Week 24 which are both trending towards significance.

*Percentage of Patients with Wound Area Increase  $\geq 10\%$*

Study Visit	≥10% Increase in Wound Area				χ <sup>2</sup> p-value
	dermaPACE (N=172)		Sham Control (N=164)		
	n	%	n	%	
Week 2	15	8.7	25	15.24	0.065
Week 6	25	14.5	43	26.2	0.008
Week 12	31	18.0	51	31.1	0.005
Week 18	40	23.3	54	32.9	0.048
Week 24	44	25.6	56	34.2	0.086

# dermaPACE DFU Trial Results

## Safety Analysis

- The adverse event rates between the dermaPACE and control subjects were similar with no statistical significance between the two cohorts in treatment-emergent adverse events (55.8% vs. 51.2%), device-related treatment emergent adverse events (7.6% vs. 3.7%), or all adverse events (73.2% vs. 68.9%).
- The only statistically significant difference between the two cohorts was in the rate of serious adverse events with 32.0% of dermaPACE patients reporting a serious adverse event compared to 43.3% of control patients (p-value=0.042).
- No treatment-emergent or serious adverse events were considered definitely related to the treatment.
- dermaPACE exhibited a lower rate of target ulcer recurrence and amputations.
  - The recurrence rate for dermaPACE patients was 7.7% compared to 11.6% in the control group (p-value=0.490).
  - The percentage of patients that had to undergo amputation of the foot containing the target ulcer was lower in dermaPACE as well (2.3% vs. 5.5%)

### Safety Endpoints

Safety Endpoints	dermaPACE (N=172)	Control (N=164)	p-value
<b>Primary Endpoint</b>	<b>n (%)</b>	<b>n (%)</b>	
All Adverse Events (24 Weeks)	126 (73.2%)	112 (68.9%)	0.338
<b>Secondary Endpoints</b>			
Treatment-Emergent AEs	96 (55.8%)	84 (51.2%)	0.444
Serious AEs	55 (32.0%)	71 (43.3%)	0.042

# dermaPACE Commercial Plan

- SANUWAVE's business model is a per procedure pricing model
- RFID card readers are built into each generator box. Sell individual procedure kits which contain procedure specific protocol RFID cards that activate the device for treatment
- Patients receive up to eight noninvasive procedures of 500 impulses which take approximately 20 minutes each, including patient preparation time



dermaPACE being used to treat a diabetic foot ulcer



RFID Protocol Card



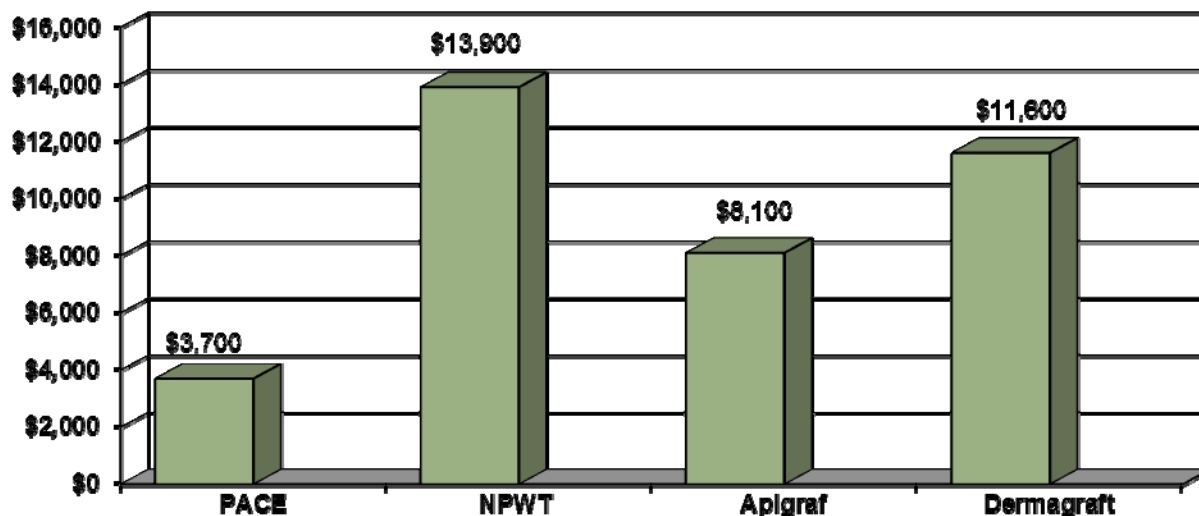
# dermaPACE – Compelling Cost and Convenience

## Potentially less than half the cost of existing therapies

### dermaPACE offers:

- ✓ Non-invasive treatment
- ✓ Lowest total treatment cost
- ✓ Convenient, efficient treatments for clinicians and patients
- ✓ Significantly lower recurrence rates

**Advanced Modality Cost Comparison for DFU Treatment**



\*Data on File – Based on published reports/literature

\*The dermaPACE device is currently the subject of an Investigational Device Exemption (IDE) study and is not available or for sale in the United States.

Estimated costs associated with full 12 weeks of DFU treatment including physician and nursing time, facility charges, treatment costs and associated standard of care.

NPWT – Based on 16 weeks of DFU treatment of NPWT in accordance with RCT.

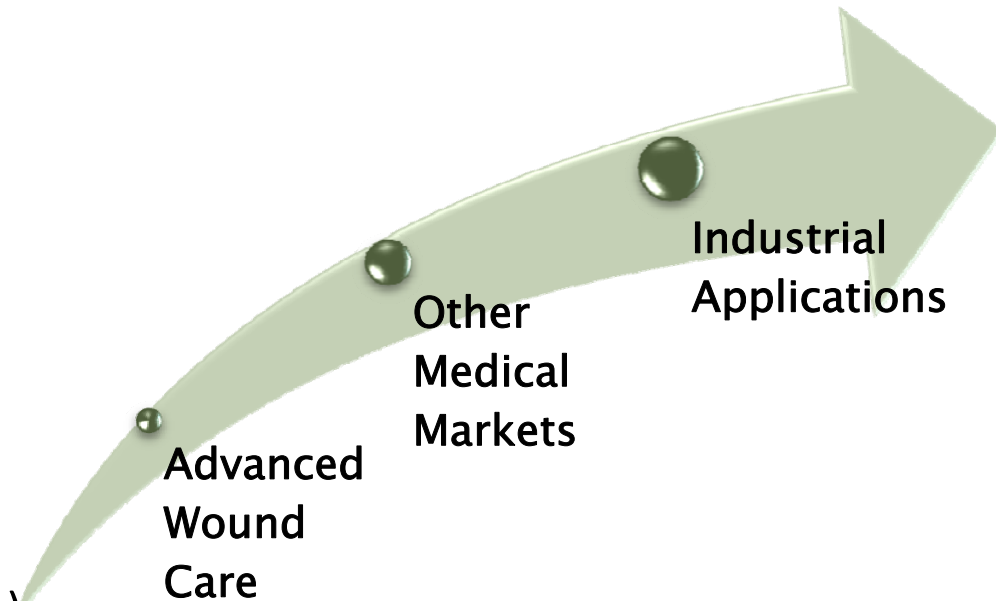
Apligraf – Based on an average of 4 surgical applications (per Policy up to 5 surgical applications are allowed)

Dermagraft – Based on an average of 6 surgical applications (per Policy up to 8 applications are allowed)

# Growth Strategy

## Seek relationships with qualified partners and JV/licensing agreements

- **Address** advanced wound care market - large and growing
- **Serve** other medical markets – blood sterilization, orthopedics, plastic/cosmetic, vascular/cardiac
- **Expand** to non-medical industrial applications (biofilm destruction, water cleaning, energy production). Working with major universities in proof of concept



# Non-Medical Markets

## Addressable Opportunities Covered by Patents

### Energy Production

- Advanced Fracking
- Improved / Enhanced Oil Extraction Recovery

### Food Industry

- Preservation
  - Milk
  - Fruit Juices
- Meat Tenderizing

### Water

- Fracking Water Cleaning
- Industrial Water Cleaning
- Drinking Water Cleaning

### Industrial Biofilms

- Biofilm Destruction
  - Industrial Equipment
  - Cosmetic/Food Industry Equipment



# Select Financial Information

Cash and Cash Equivalents - Sept 30, 2015	\$0.6M
Common Shares Outstanding	63.1M
Warrants	38.3M
Options	7.9M
Notes Payable - Due January 31, 2017	\$5.4M <sup>(1)</sup>

**(1) Due to HealthTronics, Inc. as part of original 2005 purchase price**

# Management Team

## **Kevin Richardson II, Chairman of the Board – Joined August 2005**

- Joined the Company as chairman of the board of directors in August of 2005. Brings a broad array of financial knowledge for healthcare information technology, financial services, business services and other industries. Since 2004, Mr. Richardson founded and has served as managing partner of Prides Capital LLC, an investment management firm.

## **Iulian Cioanta, Ph.D., VP R&D – Joined in 2007**

- 18+ years experience in medical device industry. Previously with Cordis Endovascular, a Johnson & Johnson company, Kensey Nash Corporation, ArgoMed Inc. and the Institute for the Design of Research Apparatuses.

## **Lisa Sundstrom, CFO – Joined in 2006**

- 20+ years finance and accounting experience. Previously with Automatic Data Processing (ADP) and Mitsubishi Consumer Electronics.

## **Peter Stegagno, VP Regulatory Affairs, Quality, and Operations – Joined in 2006**

- 20+ years experience in medical device market encompassing manufacturing, design and development, quality assurance and international and domestic regulatory affairs.

# Summary.....

- Lead product, dermaPACE® completed U.S. Phase III clinical supplemental DFU trial
  - Enrollment of 130 patients in the supplemental trial and a combined 336 patients have now completed the two studies. We announced the top-line results for the Supplemental trial publicly in October 2015 and are in the process of drafting the clinical study report for the supplemental trial and the combined results of the two trials.
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  - Formal submission to FDA for dermaPACE approval expected in Q2 2016
- Significant future applications – medical and non-medical including blood sterilization and biofilm disruption
- Extensive patent portfolio- 52 issued or pending patents – working to monetize
- Market valuation of SNWV(\$4.23M); DSCI (\$77.16M); MDXG (\$879.31M); OSIR (\$158.48M)

\*Company valuations based on closing stock prices on March 15, 2016



# SANUWAVE®

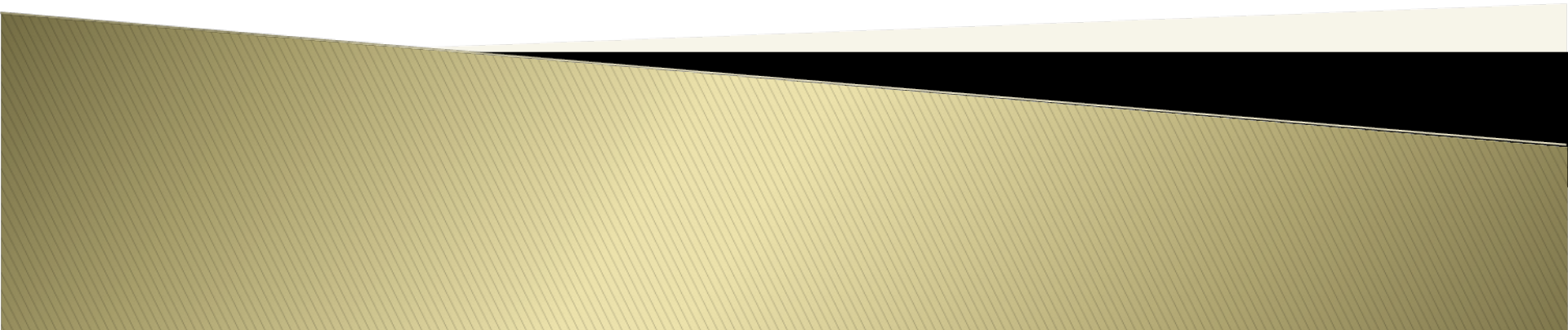
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