

## **Investor Presentation**

September 2024



# Forward Looking Statements

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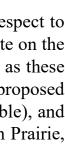
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Readers are referred to the most recent reports filed with the SEC by SANUWAVE. Readers are cautioned not to place undue reliance upon any forward-looking statements, which speak only as of the date made, and SANUWAVE undertakes no obligation to update or revise the forward-looking statements, whether as a result of new information, future events or otherwise.

#### Important Information About the Transactions and Where to Find It

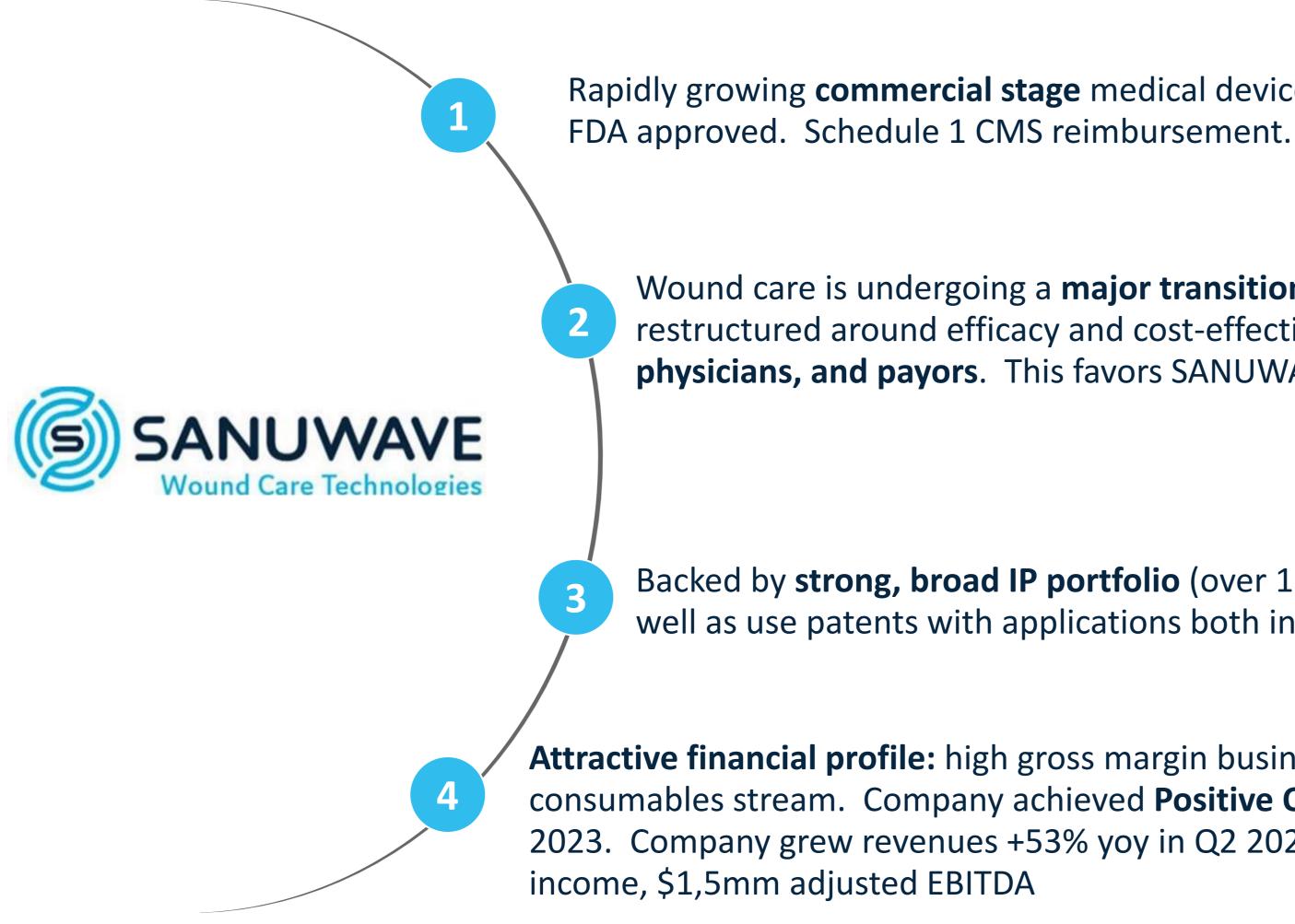
SANUWAVE and SEPA will file relevant materials with the SEC, including a Form S-4 registration statement to be filed by SEPA, which will include a prospectus with respect to SEPA's securities to be issued in connection with the proposed Business Combination and a proxy statement with respect to SEPA's stockholder meeting at which SEPA's stockholders will be asked to vote on the proposed Business Combination and related matters. In addition, SANUWAVE will file a proxy statement with respect to SANUWAVE's stockholder meeting at which SANUWAVE's stockholders will be asked to vote on the proposed Business Combination and related matters. SANUWAVE'S stockholders and other interested persons are advised to read, when available, the Form S-4 and the amendments thereto, the proxy statement and other information filed with the SEC in connection with the Business Combination, as these materials will contain important information about SANUWAVE, SEPA and the Business Combination. When available, the proxy statement and other relevant materials for the Business Combination will be mailed to stockholders of SANUWAVE as of a record date to be established for voting on the proposed Business Combination and related matters. The preliminary Form S-4 registration statement and definitive proxy statements and other relevant materials in connection with the Business Combination (when they become available), and any other documents filed by SANUWAVE with the SEC, may be obtained free of charge at the SEC's website (www.sec.gov). SANUWAVE's stockholders will also be able to obtain a copy of such documents, without charge, by directing a request to SANUWAVE at 11495 Valley View Road, Eden Prairie, Minnesota 55344.





2

# Investment Highlights



Full year 2024 revenue guidance of **50% growth** vs 2023 (**\$30+ million** in 2024 revenues)

Rapidly growing **commercial stage** medical device company in the \$45 billion US wound care space.

Wound care is undergoing a major transition to evidence based medicine. Re-imbursement being restructured around efficacy and cost-effectiveness. Need to align the interests of **patients**, physicians, and payors. This favors SANUWAVE directed energy products.

Backed by strong, broad IP portfolio (over 165 patents). Foundational patents in the space as well as use patents with applications both in and outside wound care.

Attractive financial profile: high gross margin business (73%) with 55-65% of revenues from consumables stream. Company achieved **Positive Operating Income** and Adjusted EBITDA in Q4 2023. Company grew revenues +53% yoy in Q2 2024, \$7.2 mm revenues \$2mm operating







# Market Opportunity

### **Growth Drivers**

- Centers for Medicare and Medicaid Services (CMS) and commercial providers increasingly classifying regenerative technology products as medically necessary
- Aging population
- Increase in obesity, diabetes, cancers and autoimmune disorders
- Trend to move "care to the edge" and away from hospital settings

~\$18 Billion Venous Leg Ulcers (VLUs)<sup>2</sup> Annual treatment costs Inpatient only, all payors

~\$12 Billion Pressure Ulcers (PUs)<sup>3</sup> Annual treatment costs Inpatient only, all payers



### **Targeting a** ~\$45 Billion Market in the US

**Estimated Annual Wound Care** Costs in the United States

## ~\$15 Billion

Diabetic Foot Ulcers (DFUs)<sup>1</sup> Annual treatment costs All care settings, all payers

## **Treatment Opportunity in the U.S.**

2,200

Wound care centers

## 10,000

Physician offices

## 15,000

Skilled nursing facilities

## 28,900

Assisted living facilities









<sup>1)</sup> Rice et al. Diabetes care 2014;37.

<sup>2) 651-658. 2</sup>Rice et. al J Med Econ 2014;17 (5): 347-356.

<sup>3)</sup> National Pressure Ulcer Advisory Panel (NPUAP).

# UltraMIST<sup>®</sup> Therapy System

- A low-frequency, non-contact ultrasound energy delivered through a fluid mist
- Device never touches the wound surface. Treatment is pain-free
- Reduces wound size and speeds healing<sup>1</sup>
- Reduces ongoing pain<sup>2</sup>
- Promotes wound healing below the surface by modulating cell membranes to drive increased blood flow and capillary formation
- Kills bacteria by lysing cell walls
- 3 to 20 minute treatment time with simple, self-contained system
- Highly portable: weighs only 7 pounds

### Durable device, consumable applicator: one per procedure.

1. Ultrasound therapy for recalcitrant diabetic foot ulcers: results of a randomized, double-blind, controlled, multicenter study

2. 15. A Prospective, Randomized, Controlled Trial Comparing the Effects of Noncontact, Low-frequency Ultrasound to Standard Care in Healing Venous Leg Ulcers



## Indications for use

### **FDA** Approved

- Diabetic Foot Ulcers
- Pressure Ulcers
- Venous Leg Ulcers
- Deep Tissue Pressure Injuries
- Surgical Wounds







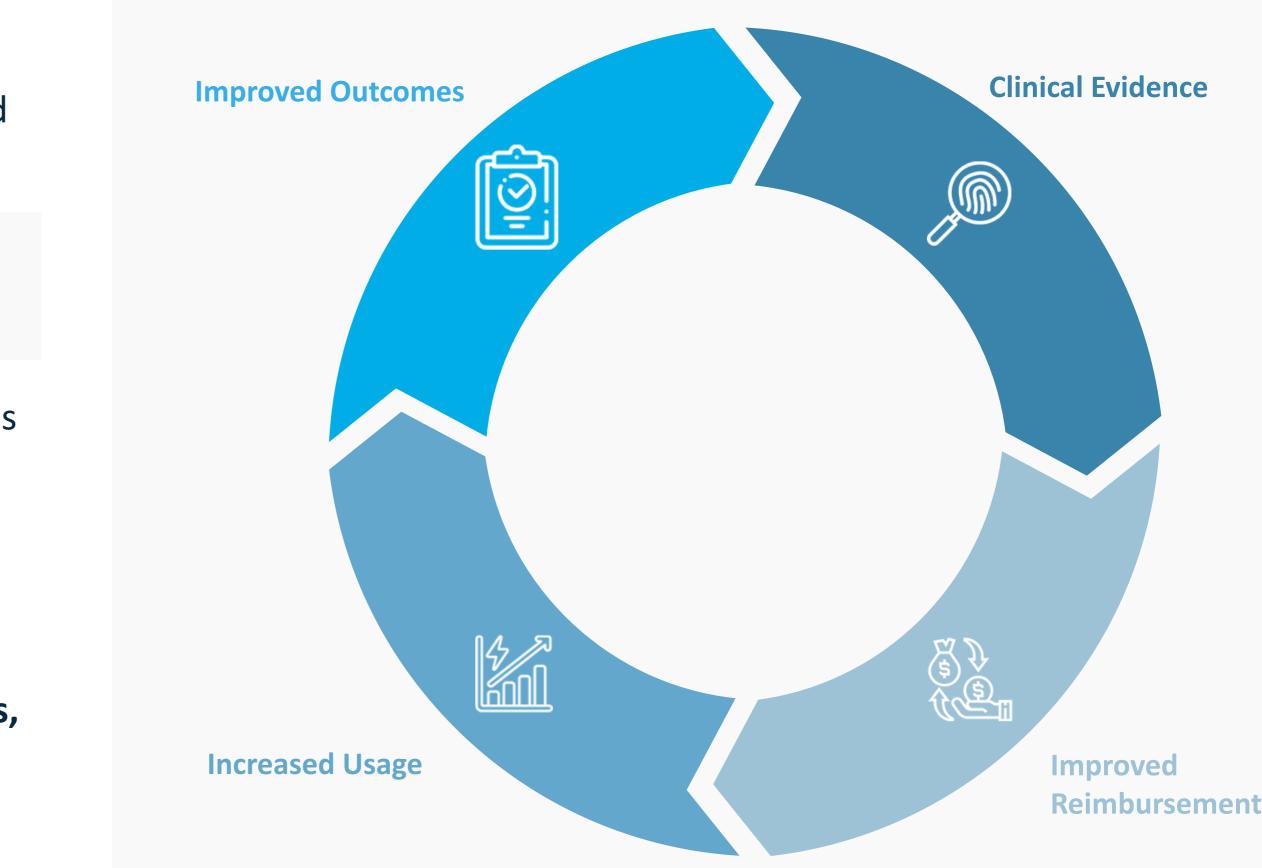
# Transition to Evidence **Based Medicine**

Concerns about the efficacy of several common treatment practices such as skin substitutes, grafts, and hyperbaric have led to payor reassessment of reimbursement

In meta study (Driver et al) non-contact low frequency ultrasound showed 72% greater healing rate at 12 weeks than standard of care<sup>1</sup>

- Reducing or terminating reimbursement for numerous modalities
- Increased reimbursement for energy-based treatments
- UltraMIST is one of only two only energy products that currently qualify for a schedule one code for woundcare
- To change a category, a product must align the needs of patients, physicians, and payors.

## The Wound Care Market is Transitioning to Evidence Based Medicine









# Payor Economics Driven by Patient Benefit

**Cost to close wound in hospital:** 

**Energy:** \$4,500<sup>1</sup>

VS

Skin Substitutes: \$14.3k<sup>1</sup>

Heal time: 16 weeks drops to 8.2 weeks

### **Recurrence:**

 $\sim$  50% of Diabetic Foot Ulcers recur with standard of care.

Revascularization resulting from energy treatment may represent a cure, not just symptom relief.

1. Per CMS prices at 8.2 week treatment time

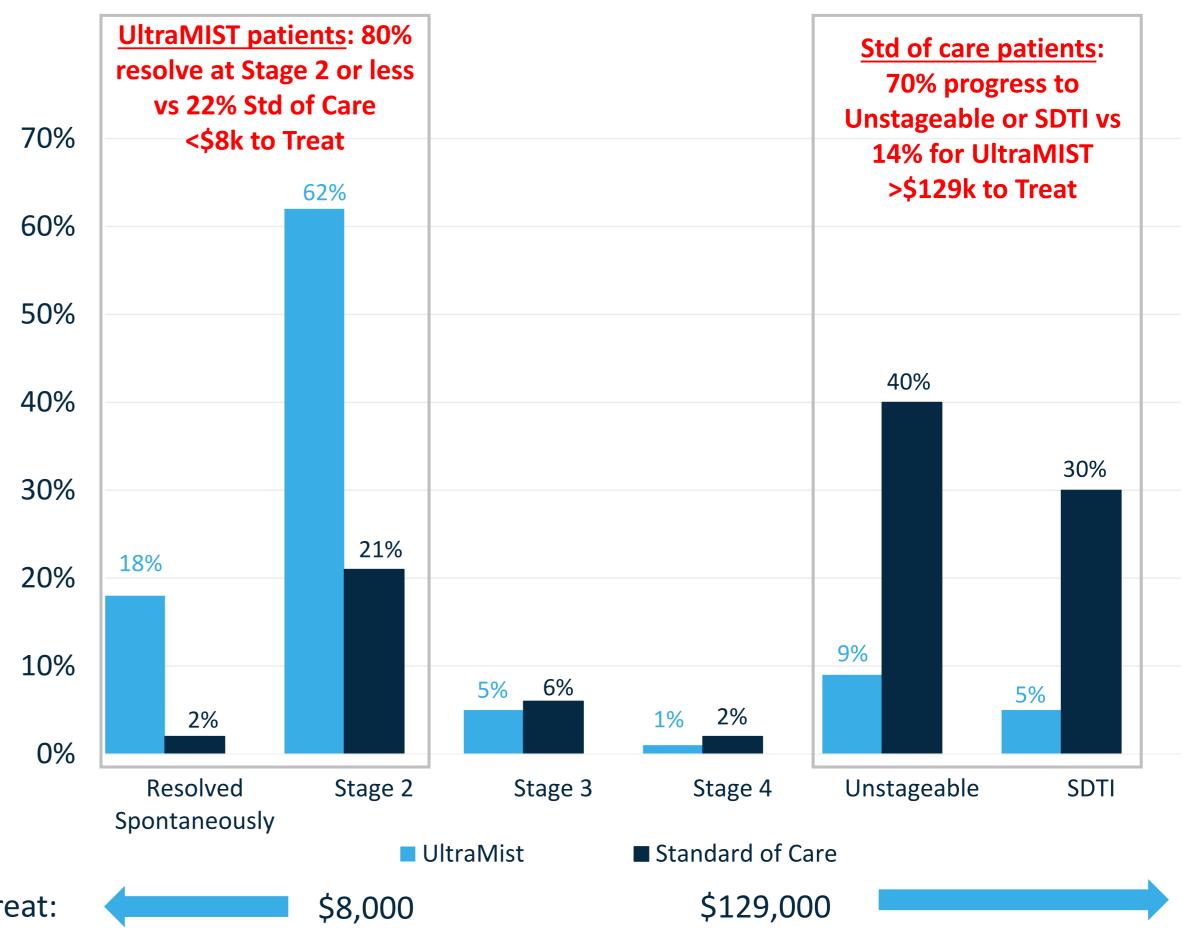
2. Graphic from "Effects of non contact low-frequency ultrasound on healing of suspected deep tissue injury: a retrospective analysis" Jeremy S Honaker et al; Int wound J 2012

Cost to treat:

Sta Sta Sta Un

### Wound/Ulcer Progression from Deep Tissue Injury in ICU

UltraMIST vs Standard of Care



- Stage 2: partial dermal thickness
- Stage 3: full dermal thickness
- Stage 4: visible bone, muscle, tendon
- **Unstageable:** full thickness obscured with slough and/or eschar
- SDTI: severe sub dermal wound without surface opening



# Physician Economics

## UltraMIST

Schedule 1: Reimbursed under CPT code 97610: "low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day"

Extremely limited code as nearly all ultrasound devices are contact

**Reimbursement** = \$400-700/procedure in physician office

100% Medicare reimbursement, significant private

Consumable costs = ~\$100/procedure (list price)

Can be used by Nurse Practitioner

3 to 20 minute treatment time

~85 procedures to pay for device









# Unit Economics

# Classic "Razor/Razorblade" model



\* Pricing reflects manufacturer's suggested retail price (MSRP)





# Manufacturing

### Moving to dual source contract manufacturers for UltraMIST device: Production, Summer 2024 (Now live)



Lower cost, better supply chain management Capacity to 100-120 systems a month in first stage

### **Redesign of Applicators to enhance manufacturability:** Production in late Q4 2024



New four cavity molds: easier assembly, better quality, lower cost

### **Consumables Capacity**

- 6,000 applicators/wk in June 2023
- 9,600 applicators/wk in June 2024
- ~24,000 applicators/wk by December 2025

Significant upside to Gross Margins from cost reductions





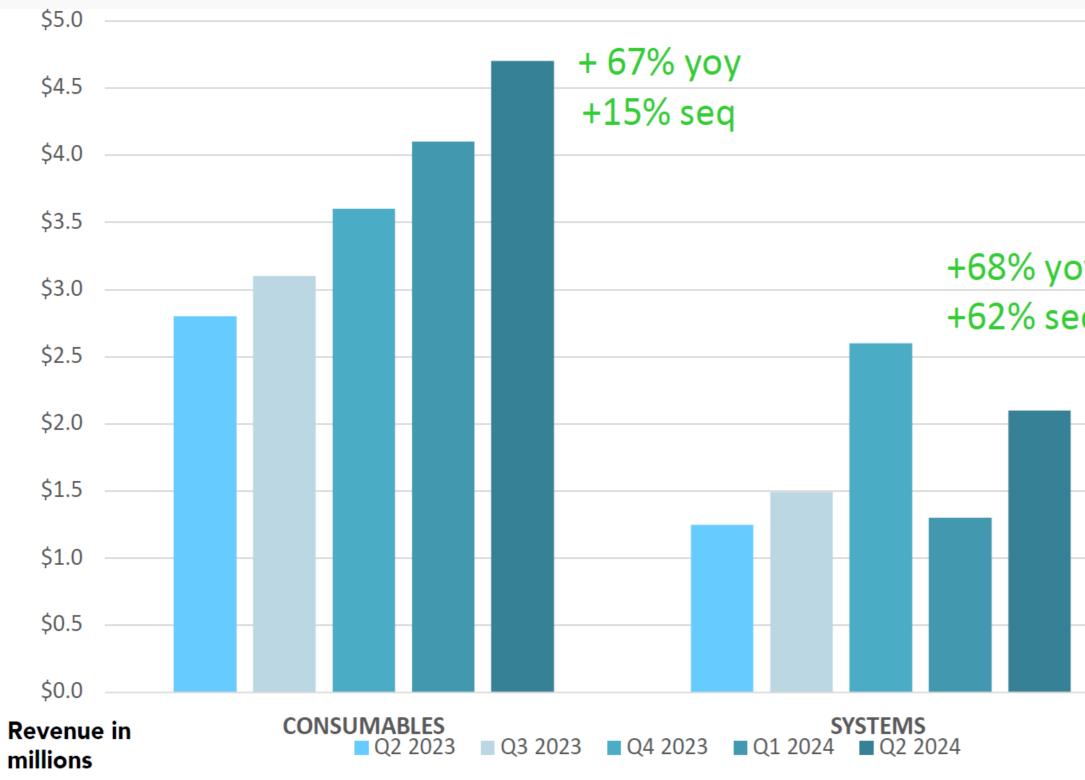


# UltraMIST now over 95% of Sanuwave Revenues

### **Fundamentally a Consumables Model**



### **Continuous UltraMIST revenue growth throughout 2023.** Strong year on year growth in Q2 2024.



Higher consumable pricing

Rapid growth in recurring revenue

		Active Ultral	IIST Sys	<b>tems in Use (</b> Future Targets, End of Period)					
	Q4 2023A	Q1 2024A	Q2 2024A		CY 2024E	CY 2025E			
	666	709	78	8	1,000+	2,000+			
oy	Active Syste	788 ems* in the field end Q2	d at	<b>72</b> Systems sold in Q2 2024 (vs 49 in Q1 2023 and 43 in Q1 2023)					

\*Active systems defined as customers who have ordered consumables in prior 6 months























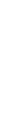
















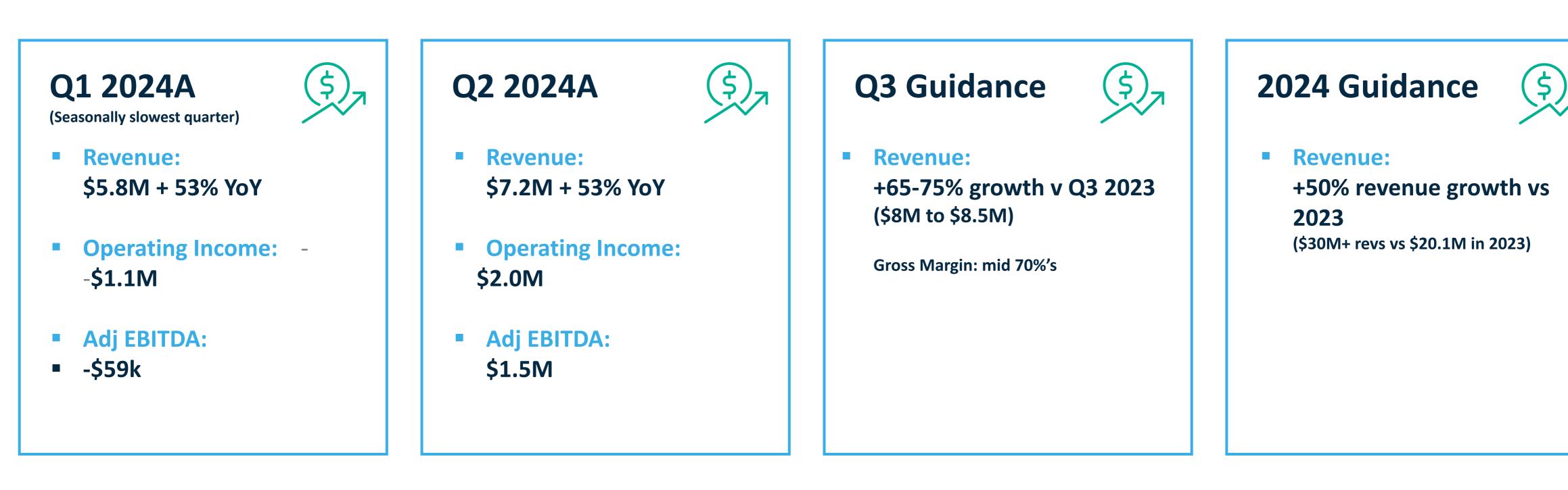






9

# Rapid Growth in Revenue













# Summary

based medicine and reimbursement.

This has aligned incentives for Patients, Payors, and Providers.

### **SANUWAVE** is in a prime position to benefit:

- Approved products protected by broad IP
- Strong existing reimbursement with room to improve
- Experienced, focused sales force
- Ability to meet demand with expanded manufacturing

profitability.

# Wound care is undergoing a **payor led shift to evidence**

Rapid growth poised to accelerate and bring company to









# Management Team

### Morgan C. Frank

#### CEO/Chairman

Morgan C. Frank joined SANUWAVE as chairman of the board of directors in August of 2022 and became CEO in May 2023. Mr. Frank has been a principal at the life sciences focused investment fund Manchester Management since 2003 and a director of Manchester Explorer Cayman Ltd since 2013. Prior to that, he was a founder and managing director at First Principles Group, a boutique consultancy and principal investor specializing in corporate restructuring, restarts, intellectual property assessment and salvage, and spin-outs. Prior, Mr. Frank spent approximately five years as an analyst and portfolio manager at Hollis Capital, a San Francisco-based hedge fund. He currently sits on the board of directors of Modular Medical (Nasdaq: MODD), a development-stage insulin delivery company. Mr. Frank holds BA's in Economics and in Political Science from Brown University.

### Andrew Walko

#### President

Andrew Walko joined SANUWAVE as President in July of 2023 and brings over 17 years of progressive leadership experience in the medical device industry and the US Army. Andrew held key leadership roles at Biomerics Advanced Catheter, Minnetronix Medical and Greatbatch/Integer where he focused on operations, new product scale-up and launch, and cost improvement initiatives before joining SANUWAVE. In addition to his medical device experience, Andrew served in the US Army and graduated from the US Army Ranger School. He has deployed to Iraq, Afghanistan, and Haiti. He is also actively engaged with the Leukemia and Lymphoma Society and has served as the Executive Challenge Chair and the Corporate Walk Chair for the Light the Night event in the Twin Cities. Andrew has a Bachelor's Degree in Business Management from West Virginia University and an MBA from the University of Minnesota.

### Peter Stegagno

#### **COO**

Peter Stegagno joined SANUWAVE as Vice President, Operations in March 2006. Stegagno has nearly 30 years of experience in the medical device market, encompassing manufacturing, design and development, quality assurance and international, and domestic regulatory affairs. He has been instrumental in the development and deployment of international operational processes for leading medical device companies. Prior to joining SANUWAVE, Stegagno served as Vice President of Quality and Regulatory Affairs for Elekta and director level roles in medical device companies including Genzyme Biosurgery. Before focusing on the medical field, he enjoyed a successful career in production roles in the space industry, including avionics guidance systems for military applications and control computers for the space shuttle. Stegagno graduated from Tufts University with a B.S. degree in Chemical Engineering

#### Peter Sorensen

#### **Chief Financial Officer**

Peter Sorensen joined SANUWAVE as Chief Financial Officer in April of 2024 and brings over a decade of finance experience including the medical device industry since 2017. Peter was most recently the Vice President of Finance and Human Resources at Endogenex, Inc., a venture-backed medical device company focused on the treatment of type-2 diabetes. Prior to Endogenex, he spent time at LivaNova PLC in the new ventures group with the Transcatheter Mitral Valve Replacement and Vagus Nerve Stimulation for Heart Failure divisions. He also spent time in consulting at eCapital Advisors implementing FP&A solutions for large public and private companies. Sorensen brings strong finance, forecasting, analysis, and capital markets experience as well as abilities in software, process automation, and human resources to SANUWAVE. Sorensen earned his bachelor's degree from Bethel University and his Master of Business Administration from St. Cloud State University.

### **Tim Hendricks**

### Executive Vice President of Sales – U.S. Wound

Tim Hendricks joined Sanuwave in February of 2023 as the Executive V.P. of Sales for the U.S. Wound business. Across his 20 years of industry experience, Hendricks has taken on progressive roles in sales leadership, training & development, and professional education with responsibilities both internationally and in the U.S.

Tim has led sales and sales leadership teams in medical devices, biologics, specialty pharmaceuticals, and durable medical equipment. His passion for collaboration and growth has allowed him to thrive at start-ups and Fortune 500 companies such as Boston Scientific (formerly Advanced Bionics), Smith & Nephew (formerly Osiris Therapeutics), and most recently Byram Healthcare as the Vice President of Sales.

Having spent a decade working in the chronic wound market, Hendricks will continue the build-out of Sanuwave's team and growth strategy. He earned a Bachelor of the Arts in Advertising from Southern Methodist University.

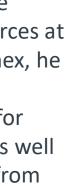
#### Nanci Gilmore

#### **Chief Commercial Officer**

Nanci Gilmore joined SANUWAVE in February 2023 as the Vice President of Commercial Operations. Gilmore has over 25 years of progressive experience in the medical device industry, specifically focusing on start-up, rapid-growth enterprises. Gilmore's passion and commitment to bringing innovative technologies to clinicians, with a patient-centric mindset, results in high-yield, consumer program development and implementation. Gilmore's diverse experience spans multiple medical specialties, representing organizations including Entellus Medical, SenoRx, Echosens, and most recently, THINK Surgical. Gilmore earned her bachelor's degree from Clark University and her master's degree from the University of North Carolina at

#### Chapel Hill

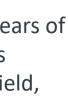
14















Appendix



# Advanced Wound Care Continuum

### **ACUTE WOUND CARE**

Wound Discovery	Primary Care Physician		Specialist Referral	Specialist Treatment		Wound Closure	
Weeks 1-2	Weeks 2-4		Weeks 3-5	Weel	ks 4-6	Weeks 5-12+	
<b>Home Treatment</b>	Standard of Care		<b>Initial Visit &amp; Treatment</b>	Continue	Treatment	<b>Treatment &amp; Closure</b>	
Self-cleaning and wound dressing	debridement	am, cleaning, , wound dressing, d pressure	Diagnostics, debridement, advanced therapy	Physician assessment, advanced therapy		Cleaning, advanced therapy, wound closure	
	at the second se						
OTC & Prescription cleaners, gels, films, foams, antibiotics Debridement Prescription gels, films, foams, antibiotics Antibiotics		Hyperbaric	Hyperbaric	Negative Pressure	Hyperbaric		
Wound dressings	Wound dressings	Walking boot	Negative Pressure		Extracellular Matrix	Negative Pressure	
Compression				SANU	WAVE		

**SANUWAVE's ENERGY FIRST** products added to standard of care.

### **CHRONIC / ADVANCED WOUND CARE**









# Intellectual Property

**165+ patents including broad** foundational patents in technology for forming penetrating shockwaves and in medical use cases.

Cover reflector/electrode commination and structure and application to wounds, lungs, bacterial cleansing, and other applications including software, personalized treatment algorithms, and direct consumables links to billing.

SANUWAVE PATENTS											
	ТЕСНИО	LOCK					FIELDS				
	TECHNOLOGY				INDICATIONS						
DEVICES			MEDICAL			NON - MEDICAL					
US 7,867,178	Reflector piezofibers	GB/FR/DE/IT/ES (EP 2451422)	Extracorporeal special reflectors	US 8,343,420	Cleaning and sterilization	GB/FR/DE/IT/ES/FI/		US 8,685,317	Cleaning fluids	CA 2,909,661	Fracking with SWs
US 8,088,073	Movable reflector	KR 10-2255975	Distributor applicator programming	US 8,728,809	Stem cells	BE/DK/IE/NL/NO/SE (EP 3117784)		US 9,057,232	Fracking with SWs	GB,FR (EP 2984280)	Energy - European
US 8,092,401	Hydraulic SW			US 9,119,888	Tissue cleaning and sterilization	AU 2016250668	Tissue disinfection with shock waves	US 9,095,632	Meat tenderizing	DK, GB, FR, NO (EP 3352578)	Underwater structures cleaning
US 8,556,813	Inclined reflectors			US 10,238,405	Intracorporeal plaque treatment	GB/FR/DE/NL (EP 3461438)	Extracorporeal and intracorporeal - cosmetic	US 9,840,313	Underwater structures cleaning	GB/FR/NO/DE/NL/DK/ IE/CH	Energy - pellets to produce SW
US 8,961,441	Medical systems	1		US 10,569,106	Tissue disinfection with shock waves	GB/FR/DE/NL (EP 3285661)	Tissue disinfection with shockwaves	US 10,053,376	Fluid processing	(EP 3415710)	
US 9,161,768	Reversed reflectors			US 10,639,051	Intracorporeal occlusions and clots		Tissue disinfection with	US 10,246,349	Freeze desalination	PCT 14/033614 Saudi Arabia	Energy - world
US 9,198,825	New tips			US 10,888,715	DFU personalized medicine	BR 11 2017 702276 8 PCT 18/126,166	Shockwaves	US 10,378,314	Pipes cleaning	PCT 17/027457 (EP,CA)	Fluid processing
US 9,522,011	Movable electrode					(EP, BR, IL, AU, CA)	medicine	US 10,457,571	RO desalination and membrane cleaning	EP 3,628,814	Pipe cleaning
US 9,566,209	New tips with fluid holes			US 16/789,029	Infected prostheses	PCT 21/203,019	Lung infection/COVID	US 10,562,793	Heavy water	PCT 18/085540	Meat processing
	Multiple reflectors	TOTAL 64 medical and 38 non-medical patents issued or pending and not		US 17/221,562	Lung infection/COVID	PCT 21/226,401	Ventilators and endoscopes disinfection			(EP, AU, BR, CA)	meat processing
US 10,058,340	applicators			US 17/380,791	Vaccines production and delivery	PCT 22/020,354	Vaccines production and delivery	US 10,874,124	Meat processing		
US 10,769,249	Distributor applicator programming		pired.	US 17/313,951	Ventilators and endoscopes disinfection		-	US 11,028,670	Far field oil stimulation		
US 22/xxx,xxx	Nitinol Tulip reflector	For recently expired ones, if infringement occurred before expiration date. Lawsuits still can be filed in 5 years after their expiration.		US 17/065,261	Patch drug delivery	AU 2020244575	Infected prostheses	US 11,072,997	Oil separation		
US 17/064,844	Applicator variable penetration			US 17/065,054	Massaging combined with rollers and suction			US 11,254,589	Floating materials separation		
US 17/188,812	Intracorporeal multiple sources			US 63/140,713	Combination energy medical treatments			US 17/676,495	Sludge deactivation and dewatering		
US 22/xxx,xxx	Intracorporeal shockwave sources				DECENTLY			US 21/068,431	Segmented reflector for meat processing		
RECENTLY EXPIRED											
			US 6,080,119	Water catalysts (2018)	DE 10100974	Water catalysts (2021)	US 6,666,834	Water catalysts (2022)			

Water catalysts

(2021)

Tips' material (2021)

DE 10100973

DE 10112461

Tips' material ( 2022 )

SIM Cards (2022)

US 6,972,116

US 7,364,554

Applicator design (2018)

Applicator design (2018)

US 6, 186, 963

US 6,036,661

US 22/xxx,xxx	Nitinol Tulip reflector
US 17/064,844	Applicator variable penetration
US 17/188,812	Intracorporeal multiple sources
US 22/xxx,xxx	Intracorporeal shockwave sources



