

Company Report

SANUWAVE HEALTH, INC.

A Paradigm Changing Approach To Regenerative Medicine

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September 27, 2011

SANUWAVE HEALTH, INC. (OTC:QB – SNWV - \$2.80)

Price Target: \$7.00

Rating: Speculative Buy

COMPANY SNAPSHOT

SANUWAVE Health, Inc., a regenerative medicine company, produces non-invasive, biological response activating devices to repair and regenerate tissue, musculoskeletal and vascular structures. SANUWAVE's proprietary Pulsed Acoustic Cellular Expression (PACE®) technology is designed for wound healing, orthopedic/spine, plastic/cosmetic and cardiac applications. Its lead product, has CE mark approval to treat skin and subcutaneous soft tissue, and has completed a pivotal Phase III, Investigational Device Exemption (IDE) clinical trial for the treatment of diabetic foot ulcers with highly positive and clinically significant results.

KEY STATISTICS

Price as of 9/26/11	\$2.80
52 Wk High – Low	\$5.72 - \$2.15
Est. FD Shares Out.	20.9M
Market Capitalization	\$62.3M
3 Mo Avg Vol	9,000
Exchange	OTC:QB

COMPANY INFORMATION

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INVESTMENT HIGHLIGHTS

Leveraging its proprietary non-invasive technology, SANUWAVE is well positioned to garner a share of multiple regenerative medicine market segments totaling \$10 billion. The Company's groundbreaking PACE® (Pulsed Acoustic Cellular Expression) PACE technology is designed for wound healing, orthopedics, plastic/cosmetic and cardiac applications. PACE® is a proprietary form of Extracorporeal Shock Wave Technology (ESWT) that uses high energy acoustic shock waves as treatment therapy.

The Company has already completed a pivotal Phase III Investigational Device Exemption (IDE) clinical trial for the treatment of diabetic foot ulcers for its dermaPACE® device. The trial was very favorable, demonstrating statistically and clinically significant results.

The dermaPACE® device to treat diabetic foot ulcers could be approved sometime in 1H12. The Company recently submitted the final module of its Premarket Approval application to the FDA, including the Phase III data, which typically represents the final stage prior to FDA approval consideration.

The size of the market is vast and SANUWAVE is primed to quickly win market share, upon approval. More than 1.5 million diabetic foot ulcers are treated annually costing \$3 billion. SANUWAVE's non-invasive, efficacious method will cost less than half of existing therapies, enabling the Company to win as much as 5% of the market within the first 5 years.

We believe SANUWAVE's shares are a tremendous value at current levels. With a potential approval around the corner, as well as other developmental and product pipeline milestones, we rate these shares Speculative Buy. In our view, this news-driven stock could easily reach \$7.00 upon approval, which is just 22% higher than the stock's 52-week high.

PACE OVERVIEW

In our view, SANUWAVE Health, Inc. is well positioned to change the wound care management therapy market. Based upon its PACE® (Pulsed Acoustic Cellular Expression) technology, a proprietary form of Extracorporeal Shock Wave Technology (ESWT) that uses high energy acoustic shock waves as treatment therapy through an electro-hydraulic method.

The product consists of a console and an applicator that applies positive and negative pressure through shock wave therapy. The acoustic pressure waves prompt a biologic response which causes mechanical stresses on cells, thus initiating the process. This process results in new vascularization and ultimately complete wound healing.

Management believes that this technology can be utilized in treatment of advanced wound care a \$5 billion market, along with orthopedics, plastic/cosmetic and cardiac applications. The first market in which the Company has elected to target through its completed clinical trials is the treatment of diabetic foot ulcers, a \$3 billion annual market.

It should be noted that SANUWAVE has an enviable intellectual property portfolio. The Company has been awarded 15 U.S. patents for treating a variety of conditions using acoustic shock waves, and has an additional 35 U.S. and foreign patent applications pending.



Image I. *dermaPACE*® Device

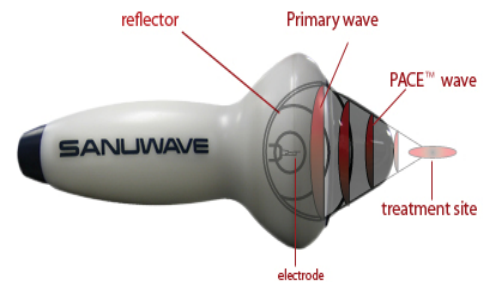


Image II. *dermaPACE*® Applicator

Source: SANUWAVE Health, Inc.

THE DFU MARKET & THE PHASE III TRIAL

A major component of the advanced wound care market, the diabetic foot ulcer (DFU) treatment therapies vary. In the U.S. alone, there are roughly 27 people diagnosed with diabetes and an estimated 1.5 million DFU's treated each year. An estimated 25% of all diabetics may acquire a non-healing DFU. Left untreated, or undiagnosed and treated early on, DFUs can result in 80,000 amputations each year. Hospitalization costs approach \$20,000 while amputations are nearly triple that expense.

As noted above, the Company has already completed a pivotal Phase III Investigational Device Exemption (IDE) clinical trial for the treatment of diabetic foot ulcers for its *dermaPACE*® device. The trial was very favorable, demonstrating statistically and clinically significant results. SANUWAVE enrolled 206 patients enrolled in this a randomized, double-blinded, sham-controlled, multiple center site, 24-week pivotal trial. The trial's objective was to demonstrate *dermaPACE*®'s safety and efficacy compared to the sham application.

Patients were treated with four non-invasive procedures using its flagship and a sham application devices, over a two-week period. Patients treated with the SANUWAVE therapy enjoyed a 54% reduction in the size of the affected area compared with only 7% for the sham control group, after 12 weeks.

Company Report**LOOKING AHEAD**

We believe that the *dermaPACE*® device to treat diabetic foot ulcers could be approved sometime in 1H12. The Company recently submitted the final module of its Premarket Approval application to the FDA, including the Phase III data, which typically represents the final stage, prior to FDA approval consideration. It should be noted that Kinetic Concepts (NYSE:KCI) has a competing product to SANUWAVE that generates \$1 billion in annual sales. With a direct sales business model that includes a pay per procedure pricing model, we believe that penetration should be higher than typical products sold into this market. This is especially the case when considering that the pricing model of this non-invasive procedure is less than half of the standard-bearers. Thus, we deem it possible that SANUWAVE could capture as much as 5% of the market in the 5-7 years following approval.

It is expected that new product trials in the wound care and other segments, along with new product introductions and approvals will fall right behind the *dermaPACE*® device approval, as the Company's technology, has, in our view, been validated in the DFU trials.

We should note that our current estimated shares outstanding figure of 20.9 million excludes warrants that expire late next year. SANUWAVE has \$8 million worth of warrants priced at \$2.00 which will expire in December 2012. Those warrants are owned by insiders who have historically funded the company with cash infusions of loans and equity as the company needed money.

RISK FACTORS

In our view, SANUWAVE's biggest risk is clearly the approval of its flagship product. Execution risks, upon approval, include the time it may be required to educate the market regarding its technology, thus pushing revenue generation out to a later date, or in smaller initial quantities, thus impacting sales goals. Lack of access to necessary capital, while a possible risk, is something we view as a negligible factor at this time, as upon approval, we believe SANUWAVE will have access to capital. Slower sales penetration as a result of Competition from larger firms is not uncommon and is also consistent with firms of SANUWAVE's size and standing.

CONCLUSION

We believe SANUWAVE's shares are a tremendous value at current levels. With a potential approval around the corner, as well as other developmental and product pipeline milestones in the coming months, we rate these shares Speculative Buy. In our view, this news-driven stock could easily reach \$7.00 upon approval which is just 22% higher than the stock's 52-week high. Our confidence is buttressed by not only the Company's stellar Phase III results, but its underrated Tier-1 management team, which in our opinion, is more akin to a Company with a market cap greater than \$1 billion, rather than a sub-\$100 million market capitalization.

SANUWAVE HEALTH, INC. (OTC:QB - SNWV)

Recent Trading History For SNWV

(Source: Stockta.com)



Company Report**Analyst: Robert Goldman**

Rob Goldman has over 20 years of investment and company research experience as a senior research analyst and as a portfolio and mutual fund manager. During his tenure as a sell-side analyst, Rob was a senior member of Piper Jaffray's Technology and Communications teams. Prior to joining Piper, Rob led Josephthal & Co.'s Washington-based Emerging Growth Research Group. In addition to his sell-side experience Rob served as Chief Investment Officer of a boutique investment management firm and Blue and White Investment Management, where he managed Small Cap Growth portfolios and *The Blue and White Fund*.

Analyst Certification

I, Robert Goldman, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report.

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