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SANUWAVE Health (SNWV-OTC)

SNWV: Trial Enrollment Off To Strong Start

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	05/15/2013
Current Price (08/14/13)	$0.80
Target Price	**$1.60**

OUTLOOK

In May 2012 FDA gave the green-light to SNWV's proposed IDE Supplement and add'l clinical trial. With treatment boosts, the trial could show endpoint-hitting efficacy. Important to understand is that this is not a replacement trial but is instead a supplement in every sense of the word - this supplemental data will be in addition to and build on the already very strong and compelling initial trial data. Enrollment for supplemental trial off to strong start and now one-third complete.
Recent progress also includes new CEO brought on in early 2013 with incentive-laden contract, new financing, game-plan to expand ex-U.S. distribution, investigating derivative applications of technology for possible out-licensing.

We remain big believers in dermaPACE and SNWV's management. If all goes well dermaPACE could be on the U.S. mrkt in 2015.

SUMMARY DATA

52-Week High	**$1.59**
52-Week Low	**$0.09**
One-Year Return (%)	**100.00**
Beta	**0.50**
Average Daily Volume (sh)	**62,147**
Shares Outstanding (mil)	**22**
Market Capitalization ($mil)	**$17**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-4.1**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2013 Estimate	**N/A**
P/E using 2014 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**N/A**
Type of Stock	**N/A**
Industry	**Med Products**

ZACKS ESTIMATES

Revenue
(in 000s of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	239 A	210 A	178 A	142 A	769 A
2013	201 A	161 A	205 E	210 E	777 E
2014					1,140 E
2015					2,155 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	-$0.09 A	-$0.07 A	-$0.07 A	-$0.08 A	-$0.31 E
2013	-$0.25 A	-$0.04 A	-$0.08 E	-$0.05 E	-$0.31 E
2014					-$0.15 E
2015					-$0.06 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW…

Q2 RESULTS

On August 14th SANUWAVE announced financial results for the second quarter ending June 30, 2013. Aside from a slightly greater uptick than modeled in R&D expense and non-cash gain related to revaluation of embedded derivatives, results remain largely tracking our estimates.

Q2 revenue came in at $161k compared to our $174k estimate. Gross margin was very strong at 85% and benefitted from greater sales of (higher margin) applicators. Operating expenses of $1.9 million ticked up meaningfully from Q1 as a result of increasing enrollment and other trial related expenses. We continue to model operating expenses to increase in the second half of the year related to the trial. Operating income was ($1.7) million, compared to our ($1.5) million estimate. Q2 net income and EPS were ($818)k and ($0.04) and benefitted from a $2.3MM non-cash gain related to revaluation of embedded derivatives (conversion feature) of the senior secured notes.

Relative to the supplemental DFU trial, importantly, meaningful progress continues with enrollment and anticipated timelines relative to enrollment completion, patient follow-up, and FDA submission remain unchanged. IRB approvals have now been attained at all trial sites. The first patient was enrolled in early June and through mid-August, 30 of the minimum 90 patients have been enrolled. All enrolled patients have started treatment. Anticipated trial timelines remain intact including; final patient expected to be enrolled in Q1 2014, last patient follow-up in Q2 2014, submit PMA in Q4 2014, and FDA approval in 2015. As we've noted in the past, we believe the trial design, including using treatment boosts to improve on efficacy, the use of Bayesian statistics, and the detailed preparatory work in putting the study together and executing the study (experienced CRO and Chief Medical Officer, investigator meetings, strong relationships with trial sites, detailed selection of patients, etc.) bode well for the chances for hitting the primary endpoint.

Management also talked more about potential derivative applications of their PACE technology. One of which is in microsurgery. Dr. Maria Siemionow, Head of Microsurgical Training at the Cleveland Clinic, made a presentation at the 2013 World Congress of Microsurgery in July of pre-clinical results using PACE technology in reducing tissue injury from surgery by inducing an anti-inflammatory effect. SANUWAVE expects to investigate a potential application for use as an adjunct during microsurgery procedures - management noted that they may have more details on this in the next few months - although this is still a back-burner project. The other potential near-term application that management appears to be excited about is for use in cleaning frack water which is used to extract gas from shale in gas well drilling. Management noted on the call that they have completed a proof of concept and is now in process of building a small scale model which can be used for demonstration purposes - which could be completed in the next couple of months. With the recent explosion in hydrocracking for natural gas extraction and concerns over toxicity of frack water, this would be a potentially very large market.

Cash

Cash used in operations in Q2 was $939k but excluding changes in working capital, cash used in operations was $1.4 million. SNWV exited Q2 with $71k in cash and equivalents. However, subsequent to the end of Q2 SNWV raised $1.65MM ($1.5MM net) from the sale of common stock. In addition the balance sheet was cleaned up with the conversion of all of the senior secured notes which were issued in late 2012 and early 2013. Including accrued interest, $2.2MM was converted to common stock. Management continues to expect monthly cash burn to average about $575k - $625k during the course of the trial and estimates direct costs of the trial will be about $3.8MM through 2014. They also estimate that they will need about $8.5 million total to get them through FDA approval. They will be looking to opportunistically raise additional capital in the near term.

OPERATIONAL UPDATE

- **Supplemental Trial:**
  - CRO in place, Dr. Jorgensen overseeing study, trial site training completed
  - Indentified 20 clinical study sites and have IRB approvals at all sites. Seven of these sites are the highest enrolling sties from the pivotal trial and are expected to enroll ~70% of the ~90-patient total enrollment of the supplemental trial

- Enrollment commenced in June. Currently have 30 patients enrolled which have commenced treatment. Patient screening continues for remaining enrollment.
- SNWV's anticipated timelines (intact from earlier guidance) include; final patient expected to be enrolled in Q1 2014, last patient follow-up in Q2 2014, submit PMA in Q4 2014, and FDA approval in 2015

- **Distribution:** SNWV is now pursuing additional ex-U.S. distribution for dermaPACE, orthoPACE and Evotron to help build on the current relatively meager revenue contribution. Earlier this year SNWV announced entry in the Australian and New Zealand markets (see below). The game-plan going forward is to expand their footprint further in existing geographies including Europe and Asia. SNWV had previously not pursued much in the way of expanding their ex-U.S. presence - partly due to the focus on the U.S. development of dermaPACE. Reimbursement is also an issue outside the U.S. - so we expect SNWV will be picking its spots - both geographically as well as engaging distributors that have experience with navigating the reimbursement issues inherent in these countries.

- **orthoPACE FDA Pathway:** SNWV is now in the early stage of investigating the FDA regulatory pathway for orthoPACE, which is currently sold only outside of the U.S. Management recently had a meeting with FDA to discuss a pathway for approval and hope to be able to potentially build off of the approval for their legacy OssaTron device (used for Plantar Fascitis and heel pain), which is the successor to orthoPACE but unlike the ~800lb OssaTron, orthoPACE is compact and portable. Goal of the meeting was to find the quickest pathway for approval of orthoPACE. Management could only provide minimal detail on the Q2 call of the result of their meeting with FDA but did say they expect to provide more information in the coming months.

- **Derivative Applications**: Management recently announced that they started looking at derivative applications for its shockwave technology including non-medical uses such as in energy production (enhanced oil extraction, fracking water cleaning), in food applications (food preservation, meat tenderizing) and in other industrial applications. Management provided some color on this on the last few earnings calls and clearly views this as a real opportunity. The company believes there are real potential out-licensing opportunities for its technology and noted on the call that early/initial discussions have already begun with at least one potential interested party. Indications are that this is still on the very front end with no expectations of near-term financial contribution from this - but we think it's fair to categorize this as having a potential mid-to-long-term opportunity.

  Along the theme of derivative applications, in April SNWV announced receipt of a U.S. patent to sterilize blood using shock waves. Blood sterilization could potentially be one of the low-hanging-fruit opportunities for SNWV outside of the medical space. Shock wave technology has been used for years in lithotripsy devices to break up kidney stones. In fact SNWV acquired Healthtronics' orthopedic business in 2005 which facilitated the development of the company's dermaPACE device. HealthTronics is a leading manufacturer of lithotripsy devices. It was found that when lithotripsy devices were first being used to break up kidney stones that the shock waves also had the effect of killing bacteria. This anti-bacterial effect has also been observed during wound treatment therapy. Shock waves have also shown to have a similar effect on viruses. Given this anti-bacterial/anti-virus efficacy and a significant unmet need for a safe and effective means to clean blood (for example for blood transfusions and blood donations), blood cleaning seems like a natural pursuit for SNWV's endeavor to broaden the potential market for their technology.

  On the Q2 call management also talked about applications for microsurgery and frack water cleaning. Dr. Maria Siemionow, Head of Microsurgical Training at the Cleveland Clinic, made a presentation at the 2013 World Congress of Microsurgery in July of pre-clinical results using PACE technology in reducing tissue injury from surgery by inducing an anti-inflammatory effect. SANUWAVE expects to investigate a potential application for use as an adjunct during microsurgery procedures - management noted that they may have more details on this in the next few months - although this is still a back-burner project. The other potential near-term application that management appears to be excited about is for use in cleaning frack water which is used to extract gas from shale in gas well drilling. Management noted on the call that they have completed a proof of concept and is now in process of building a small scale model which can be used for demonstration purposes - which could be completed in the next couple of months. With the recent explosion in hydrocracking for natural gas extraction and concerns over toxicity of frack water, this would be a potentially large market.

Launch in Australia / New Zealand

Earlier this year SNWV announced that dermaPACE has received regulatory approval in Australia and New Zealand for treating acute and chronic wounds, an annual market opportunity estimated at approximately 500k+ patients. In connection with the launch in those countries, the company penned a distribution agreement with Aurora BioScience, which caters to a number of large customers including public departments of health, the

Australian Red Cross Blood Service, and public and private hospitals. Relative to the opportunity for dermaPACE in Australia and New Zealand, Aurora BioScience's Managing Director, Darren Banks noted, "We believe the dermaPACE device can provide improved patient outcomes at reduced costs. We are expecting the first procedures to be undertaken in Australia in late March with many hospitals and clinics extremely excited to evaluate the product."

Supplemental Trial Enrollment Slated to Commence Q2 2013 *(per our 11/16/2012 report, with current updates)*
On May 8, 2012 SANUWAVE announced that the FDA approved its IDE Supplement for an additional clinical trial for dermaPACE. Aside from being smaller than the than the initial 206-patient trial and also incorporating treatment "boosts", the trials will be very similar. The statistical methods (Bayesian) apply sequential analysis allowing for the supplemental data to build on the positive results from the initial larger study. Importantly, the FDA typical approves Bayesian methods when there's already compelling data to build upon (the totality of which will presumably show statistical significance on the primary endpoint). This is a key point and underscores that this is not a replacement trial but is instead a supplement in every sense of the word - this supplemental data will be in addition to and build on the already very strong and compelling initial trial data.

As we've noted previously, the pivotal trial data already indicated dermaPACE was effective in healing diabetic foot ulcers - the hurdle to clear hitting the primary endpoint (100% wound closure), while not attained in the pivotal study, may very well be able to cleared with additional dermaPACE treatments. Safety was also excellent in the initial study, which was obviously a consideration of the FDA in allowing for more aggressive (i.e. - treatment "boosts") treatment with dermaPACE.

SANUWAVE believes the new trial can be completed (including data analysis) in as early as 20 months following initiation (management reiterated this timeline on the Q2 2013 call). Enrollment is projected at 90 patients (~45 treatment / ~45 control). Similar to the initial study, the treatment group will receive four dermaPACE procedures during the first two weeks. In order to improve on the efficacy from the initial trial (which just missed statistical significance on the primary endpoint) up to four treatment "boosts" can be delivered during weeks four and ten. The primary endpoint, 100% wound closure at week-12, will be the same. Assuming statistical significance is met on the primary endpoint, the data will support an amendment to SANUWAVE's existing PMA which could potentially happen sometime in late 2014 with FDA approval possible in early 2015.

SANUWAVE hoped to initiate enrollment in during Q3 2012 but this was pushed back due to the need to secure additional financing. With bridge financing in place, enrollment commenced in June 2013 and through August, 30 of the minimum 90 patients had been enrolled and started treatment. IRB approvals have now been attained at all 20 trial sites. An investigator meeting was held in May 2013 which drew about 75 representatives from 18 of the expected 20 clinical trial sites and was overwhelmingly positive. Management outlined the importance of completing training of the site participants to ensure effective and maximum enrollment, adherence, and to maximize the chances to hit the study endpoints to study protocol - the message from management has been that there was substantial success in this regard.

As we noted in our prior updates, the supplemental trial should provide a much less ambiguous decision-point for the agency than if SANUWAVE had decided to just use the original data to go in front of an advisory panel - a final decision from which can end up being a long, drawn-out affair which may not have come out in SANUWAVE's favor. Clearly avoiding the potential pitfalls of an advisory-panel review played a major role in management's decision to pursue a supplemental trial.

Importantly, safety was excellent in all studies to date which opened up the door for more aggressive treatment within the standard 12-week treatment window in this supplemental trial. These treatment "boosts" may very possibly increase efficacy and get them over the primary endpoint hurdle. Also very important is that the 12-week treatment window used in the initial trial will also be used in the supplement trial. If this supplemental study achieves 100% wound closure with the help of these treatment boosts, that would be an obvious major positive for SANUWAVE.

Our long-term outlook remains intact and we continue to believe dermaPACE can eventually be highly successful in the $2+ billion diabetic foot ulcer market.

VALUATION / RECOMMENDATION

We use 2016 P/S comparables to value SNWV. Smith & Nephew currently trades at approximately 2.2x analyst's 2016 forecasted revenue. We currently model SNWV to generate revenue of about $17 million in 2016 – based on the SNN comp 2016 P/S multiple, this values SNWV at about $1.60/share.

FINANCIAL MODEL

SANUWAVE Health, Inc.

	2012 A	Q1A	Q2A	Q3E	Q4E	2013 E	2014 E	2015 E	2016 E
Total Revenues	$769.2	$201.2	$160.6	$205.0	$210.0	$776.9	$1,140.0	$2,155.3	$16,972.7
YOY Growth	*-4.2%*	*-15.6%*	*-23.6%*	*15.0%*	*47.9%*	*1.0%*	*46.7%*	*89.1%*	*687.5%*
Cost of Revenues	$220.3	$55.8	$23.8	$61.5	$63.0	$204.1	$342.0	$659.0	$4,141.6
Gross Income	$548.9	$145.4	$136.8	$143.5	$147.0	$572.8	$798.0	$1,496.3	$12,831.1
Gross Margin	*71.4%*	*72.3%*	*85.2%*	*70.0%*	*70.0%*	*73.7%*	*70.0%*	*69.4%*	*75.6%*
R&D	$1,762.2	$344.7	$624.5	$725.0	$865.0	$2,559.2	$3,850.0	$3,350.0	$2,750.0
% R&D	*229.1%*	*171.3%*	*388.8%*	*353.7%*	*411.9%*	*329.4%*	*337.7%*	*155.4%*	*16.2%*
SG&A	$4,522.0	$851.9	$1,157.1	$1,222.0	$1,294.0	$4,525.0	$5,218.0	$1,594.9	$9,674.4
% G&A	*587.9%*	*423.3%*	*720.4%*	*596.1%*	*616.2%*	*582.5%*	*457.7%*	*74.0%*	*57.0%*
Depreciation	$20.4	$5.0	$5.0	$5.1	$5.1	$20.2	$40.0	$80.0	$125.0
Amortization	$306.8	$76.7	$76.7	$76.7	$76.7	$306.8	$306.8	$306.8	$306.8
Write down of assets	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($6,062.5)	($1,132.9)	($1,726.5)	($1,885.3)	($2,093.8)	($6,838.5)	($8,616.8)	($3,835.5)	($25.1)
Operating Margin	*-788.2%*	*-563.0%*	*-1074.9%*	*-919.7%*	*-997.0%*	*-880.3%*	*-755.9%*	*-178.0%*	*-0.1%*
Gain (loss) on asset sale	$0.0	$7.5	$0.0	$0.0	$0.0	$7.5	$0.0	$0.0	$0.0
Svcs provided to Pulse Vet.	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Extinguishment of debt	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Loss on derivative revaluation	$0.0	($3,737.0)	$2,328.0	$0.0	$0.0	($1,409.0)	$0.0	$0.0	$0.0
Interest expense, net	($331.7)	($508.9)	($1,416.1)	($445.0)	($85.0)	($2,455.0)	($360.0)	($250.0)	($50.0)
Loss of FX	($7.5)	$1.9	($3.7)	$0.0	$0.0	($1.8)	$0.0	$0.0	$0.0
Pre-Tax Income	($6,401.6)	($5,369.3)	($818.3)	($2,330.3)	($2,178.8)	($9,287.8)	($8,976.8)	($4,085.5)	($75.1)
Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Discontinued Operations	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	($6,401.6)	($5,369.3)	($818.3)	($2,330.3)	($2,178.8)	($9,287.8)	($8,976.8)	($4,085.5)	($75.1)
YOY Growth	*-37.5%*	*192.6%*	*-42.6%*	*61.0%*	*28.6%*	*45.1%*	*-3.3%*	*-54.5%*	*-98.2%*
Net Margin	*-832.3%*					*-1195.6%*	*-787.4%*	*-189.6%*	*-0.4%*
EPS (continuing ops)	($0.31)	($0.25)	($0.04)	($0.08)	($0.05)	($0.31)	($0.15)	($0.06)	($0.00)
Diluted Shares O/S	20,916	21,278	21,757	31,000	44,000	29,509	60,000	69,000	74,000

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