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SANUWAVE Health (SNWV-OTC)

SNWV: Q4 Results, On-Track To Commence Enrollment

Current Recommendation	**Neutral**
Prior Recommendation	Outperform
Date of Last Change	01/29/2013
Current Price (03/27/13)	$0.90
Target Price	**$1.30**

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 now expected in Q2 2013.
Recent progress also includes new CEO brought on in early 2013 with incentive-laden contract, $2MM+ in 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	**$0.95**
52-Week Low	**$0.09**
One-Year Return (%)	**167.65**
Beta	**-0.02**
Average Daily Volume (sh)	**34,071**
Shares Outstanding (mil)	**21**
Market Capitalization ($mil)	**$19**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**24**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
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	165 E	174 E	212 E	225 E	776 E
2014					1,177 E
2015					2,170 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	-$0.07 E	-$0.07 E	-$0.06 E	-$0.05 E	-$0.24 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…

Q4 RESULTS

On March 26th SANUWAVE announced financial results for the fourth quarter ending December 31, 2012. Revenue came in lower than our estimate and was down 37% yoy. Management noted the economic weakness in Europe put downward pressure on sales of their orthoPACE device which was partially offset by an increase in applicator sales which benefitted from a larger installed base.

Meanwhile, the company made meaningful operational progress during 2012 which began to accelerate through the first part of the current year. Specifically, trial site selection and IRB approvals for the supplemental dermaPACE clinical trial is nearly complete, new CRO with specialization in wound trials in place, new CEO hired, additional financing was raised, initial patient enrollment is expected to be imminent (although this is delayed from prior expectations due to the need for financing - which is now in place), and ex-U.S. distribution is in-process of being further beefed-up. In addition, management laid out (on the Q4 call as well as in a recent investor presentation) their initial plans and vision for use/licensing of their patented technology in derivative applications in and outside of health care. Importantly, SNWV was able to make meaningful headway towards their goals while continuing to trim operating expenses and minimize cash burn.

Q4 revenue came in at $142k compared to our $225k estimate. Operating expenses ticked up sequentially in Q4 due to vesting of options but were well below the level in Q4 2011. For the full year, SG&A was $4.5 million, down 28% from 2011. The decrease is largely due to SNWV's cost containment efforts which the company implemented following the December 2011 FDA major deficiency letter which made it clear dermaPACE would not make it to market in the near-term.

Q4 and 2012 net income and EPS were ($1.7) million / ($0.08) and ($6.4) million / ($0.31) compared to the prior year periods of ($2.4) million / ($0.12) and ($10.2) million / ($0.52).

Cash
Cash used in operations was $743k and $4.3 million in Q4 and the full-year 2012 compared to $1.8 million and $7.0 million for the comparable year-earlier periods. SNWV exited 2012 with $70k in cash and equivalents. Subsequent to year-end the company raised an additional $1.6 million through the sale of 18% senior secured convertible promissory notes. SNWV also entered into a $1 million common stock financing arrangement (terms described below) in November with one of the company's largest shareholders which will provide additional operating capital. Through 12/31/2012 $25k was raised from this agreement.

Relative to the promissory notes, SNWV sold $430k worth during Q4 2012 and another $1.6 million worth in Q1 2013. The notes mature 6 months from the subscription date ($430k in May 2013, $1.6MM in August 2013), are convertible to common stock at anytime at $0.20/share and will automatically convert if SNWV consummates a qualified financing (common stock offering or a stock offering plus technology licensing/royalty agreement) of at least $4 million. The current market price of SNWV shares (~$0.90) has these convertibles well in-the-money.

SNWV expects to continue to raise additional funds in 2013 to support development and operations but noted on the call that initiating enrollment in the supplemental trial is not contingent on raising additional funds first.

Management noted on the call that 2013 cash burn is anticipated to be ~$350/per month prior to the commencement of the supplemental trial and ~$450k/mth - $550k/mth during the course of the trial (we ballpark ~$5.0MM - $5.5MM for the full year).

OPERATIONAL UPDATE

- **Supplemental Trial:**
  - As noted, enrollment in the supplemental trial is now expected to commence in Q2 2013. This had been delayed until additional financing was raised. With the $2MM+ raised over the last few months, IRB approvals in place at most of the targeted trial sites and CPC Clinical Research brought on as the CRO, enrollment should initiate imminently

- Indentified 20 clinical study sites and currently have contracts with 15 of these
- SNWV's anticipated timelines 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 week 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.

- **Derivative Applications**: Management is now 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 Q4 call 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.

LAUNCH IN AUSTRALIA / NEW ZEALAND

Earlier this week 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."

ADDITIONAL $2MM FINANCING / CEO HIRED *(per our 2/26/2013 update)*

Financing
On 2/26/2013 SNWV announced that they exceeded their goal of raising $1.25 million in bridge financing and were instead able to raise $2 million as a result of strong investor interest. The $2 million comes from the sale of 18% senior secured convertible promissory notes ($430k in Nov 2012, $1.6MM in Feb 2013) which will convert to common with a subsequent larger funding. This $2 million infusion comes on the heels of a $1 million financing agreement that was penned in December (see below).

CEO Comes With Experience and Strong Background
The second of the double shot of positive news was that SNWV hired a CEO who comes with experience and a strong background in the healthcare space and on Wall Street. Per SNWV's press release describing Joseph Chiarelli's background:

Since 2011, Joseph Chiarelli has been responsible for financial advisory, business development, and a healthcare hedge fund at Auriga Capital Management. Mr. Chiarelli was the Chairman of Clarent Hospital Management Corp delivering returns well above shareholder expectations. His success at achieving results is also demonstrated by his time with Wall Street Access and Oppenheimer & Company where, as the head of the healthcare research teams, he developed a team approach to fundamental and market-driven analysis of the healthcare industry, creating revenue streams and stock selection performance that far exceeded prior results and market indices' returns.

Mr. Chiarelli developed much of his healthcare industry knowledge while at JPMorgan Chase & Co. (JPM) where he was responsible for three healthcare sectors of the equity markets as the Senior Investment Research Analyst. Mr. Chiarelli is an

Institutional Investor All Star for both equity and high yield research with his work highly acclaimed for the quality, depth, and thoroughness of its fundamental research and for his knowledge of the industry sectors under coverage.

Prior to his work in healthcare, Mr. Chiarelli served JPM as the Chief Financial Officer of two large independent subsidiaries, J.P. Morgan Delaware and Morgan Securities Services Corporation and was a manager with Coopers & Lybrand (now PriceWaterhouseCoopers). He is a Colonel in the USAFR and a member of the board of directors of a private healthcare device company.

"Working the majority of my professional career in the healthcare industry, I have seen many emerging companies succeed. The opportunity to work with a highly qualified team of professionals and an unbelievable portfolio of products and product candidates is very exciting. I look forward to helping continue the development of innovative products and advancing the commercialization of SANUWAVE's PACE technology in many verticals," stated Mr. Chiarelli.

$1MM NON-DILUTIVE FINANCING *(per our 1/30/2013 update)*

On 12/3/2012, when the shares were trading at about $0.18, SANUWAVE announced that they entered into a financing agreement with one of the company's largest shareholders whereby he will purchase $1MM worth of common stock at $0.25/share over a period of about 18 months.

Terms of the subscription agreement include the sale of $50k (200k) worth of shares by 1/31/2013, $50k by 2/15/2013 and the remaining $900k (3.6MM shares) by 5/27/2014. If at any time after 2/15/2013 SNWV's cash balance falls below $100k the company has the option of requiring the subscriber to purchase $100k (400k) worth of shares of the balance of the total financing amount.

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 in the Q4 10-K). 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 has now pushed this back to Q2 2013 as they needed to secure financing. During Q4 they finalized selection of 15 (of the 20 in total expected) clinical sites, have IRB approvals and raised additional financing. With all of this now lined up and a new CRO brought on board that has experience with wound trials, SNWV now expects enrollment to commence in Q2 2013.

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.

Given the slight delay in the start of enrollment (now expected Q2 2013), we have made some updates to our timelines for launch of dermaPACE - pushing it back by about 8 months from our initial assumptions. Aside from that, our best-guesses regarding size, costs and timelines of the supplemental trial remain unchanged from our prior assumptions. 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 2.0x 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 $1.30/share. We are maintaining our Neutral recommendation.

FINANCIAL MODEL

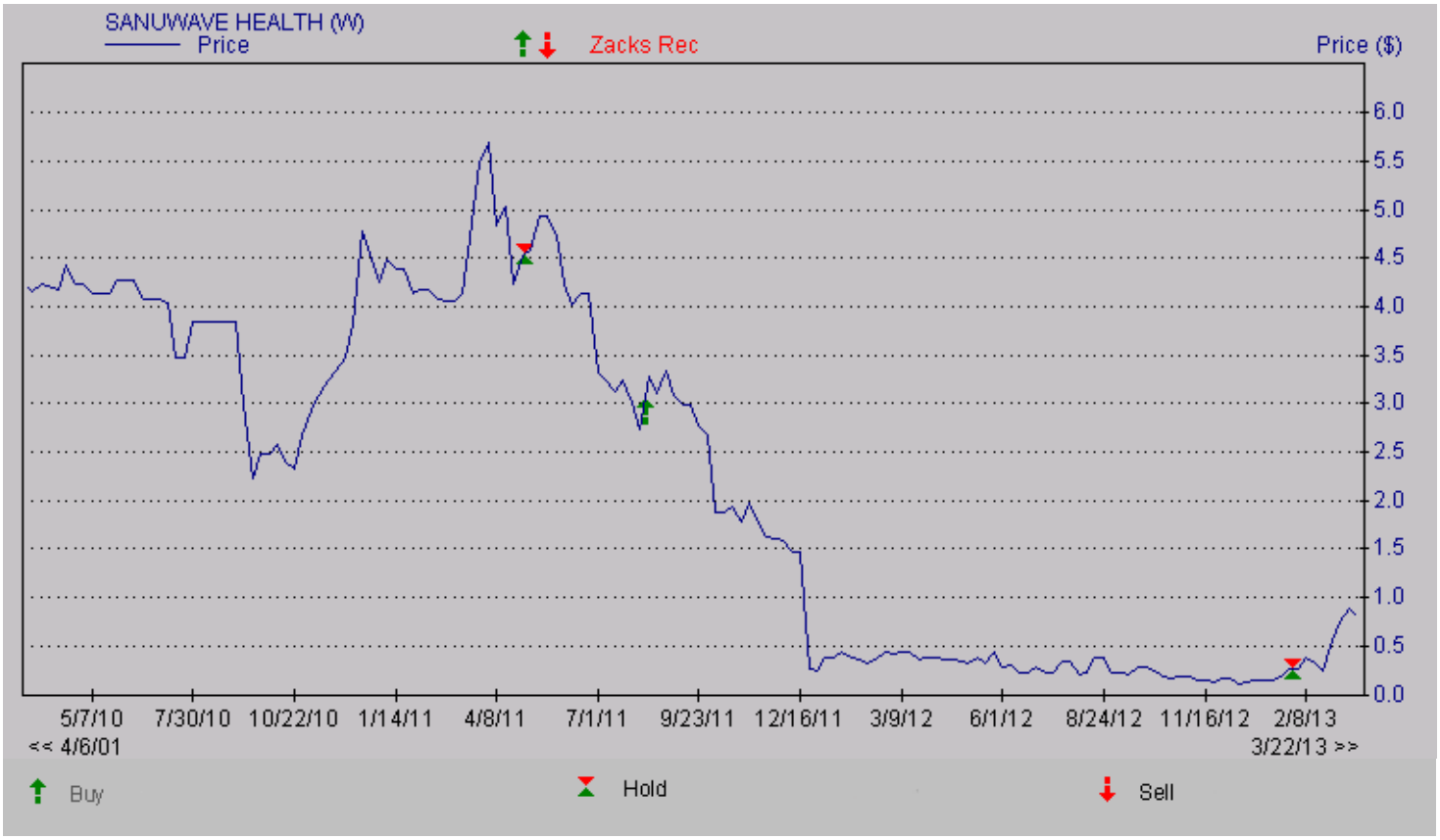
SANUWAVE Health, Inc.

	2012 A	Q1E	Q2E	Q3E	Q4E	2013 E	2014 E	2015 E	2016 E
Total Revenues	$769.2	$165.0	$174.0	$212.0	$225.0	$776.0	$1,177.0	$2,170.3	$16,972.7
YOY Growth	*-4.2%*	*-30.8%*	*-17.3%*	*18.9%*	*58.4%*	*0.9%*	*51.7%*	*84.4%*	*682.1%*
Cost of Revenues	$220.3	$49.5	$52.2	$63.6	$67.5	$232.8	$353.1	$663.5	$4,141.6
Gross Income	$548.9	$115.5	$121.8	$148.4	$157.5	$543.2	$823.9	$1,506.8	$12,831.1
Gross Margin	*71.4%*	*70.0%*	*70.0%*	*70.0%*	*70.0%*	*70.0%*	*70.0%*	*69.4%*	*75.6%*
R&D	$1,762.2	$375.0	$450.0	$725.0	$865.0	$2,415.0	$3,850.0	$3,350.0	$2,750.0
% R&D	*229.1%*	*227.3%*	*258.6%*	*342.0%*	*384.4%*	*311.2%*	*327.1%*	*154.4%*	*16.2%*
SG&A	$4,522.0	$1,050.0	$1,125.0	$1,222.0	$1,294.0	$4,691.0	$5,218.0	$1,606.0	$9,674.4
% G&A	*587.9%*	*636.4%*	*646.6%*	*576.4%*	*575.1%*	*604.5%*	*443.3%*	*74.0%*	*57.0%*
Depreciation	$20.4	$5.1	$5.1	$5.1	$5.1	$20.4	$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)	($1,391.3)	($1,535.0)	($1,880.4)	($2,083.3)	($6,890.0)	($8,590.9)	($3,836.1)	($25.1)
Operating Margin	*-788.2%*	*-843.2%*	*-882.2%*	*-887.0%*	*-925.9%*	*-887.9%*	*-729.9%*	*-176.8%*	*-0.1%*
Gain (loss) on asset sale	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$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
Interest expense, net	($331.7)	($125.0)	($165.0)	($140.0)	($85.0)	($515.0)	($360.0)	($250.0)	($50.0)
Loss of FX	($7.5)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($6,401.6)	($1,516.3)	($1,700.0)	($2,020.4)	($2,168.3)	($7,405.0)	($8,950.9)	($4,086.1)	($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)	($1,516.3)	($1,700.0)	($2,020.4)	($2,168.3)	($7,405.0)	($8,950.9)	($4,086.1)	($75.1)
YOY Growth	*-37.5%*	*-17.4%*	*19.3%*	*39.6%*	*28.0%*	*15.7%*	*20.9%*	*-54.4%*	*-98.2%*
Net Margin	*-832.3%*					*-954.3%*	*-760.5%*	*-188.3%*	*-0.4%*
EPS (continuing ops)	($0.31)	($0.07)	($0.07)	($0.06)	($0.05)	($0.24)	($0.15)	($0.06)	($0.00)
Diluted Shares O/S	20,916	21,400	23,500	35,000	44,000	30,975	60,000	69,000	74,000

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