

SANUWAVE Health (SNWV-OTC)**SNWV: On Edge of Our Seat for DMC
Recommendation – Expected in April**

Current Recommendation	Outperform
Prior Recommendation	Neutral
Date of Last Change	05/15/2013
Current Price (03/03/15)	\$0.19
Target Price	\$1.00

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 has been brisk and has completed the 130-patient minimum. DMC recommendation, expected in April, will likely have huge implications – positive or negative.

We remain very positive on chances of supplemental trial hitting efficacy endpoint. Other parts of the business also progressing including expansion of ex-U.S. distribution and in exploring 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. mkt in 2016.

SUMMARY DATA

52-Week High	\$0.81
52-Week Low	\$0.04
One-Year Return (%)	-59.58
Beta	1.10
Average Daily Volume (sh)	367,862

Shares Outstanding (mil)	51
Market Capitalization (\$mil)	\$13
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 (%)	5.6
Earnings Per Share (%)	N/A
Dividend (%)	N/A

P/E using TTM EPS	N/A
P/E using 2015 Estimate	N/A
P/E using 2016 Estimate	N/A

Zacks Rank	N/A
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Risk Level	High,
Type of Stock	N/A
Industry	Med Products

ZACKS ESTIMATES**Revenue**
(in 000s of \$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	145 A	238 A	228 A	237 A	847 A
2015	252 E	261 E	274 E	288 E	1,075 E
2016					4,573 E
2017					18,859 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-\$0.06 A	-\$0.04 A	-\$0.03 A	-\$0.00 A	-\$0.12 A
2015	-\$0.02 E	-\$0.02 E	-\$0.01 E	-\$0.01 E	-\$0.06 E
2016					-\$0.03 E
2017					\$0.00 E

Zacks Projected EPS Growth Rate - Next 5 Years %	N/A
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WHAT'S NEW...

Q4 / Full-Year 2014 Financial Results, Operational Update

SNWV reported financial results for the fourth quarter and year-ending 12/31/2014 and provided a business update. Financial results came in meaningfully better than our numbers, with revenue coming in moderately higher but with most of the beat a result of OpEx well below our estimates. And while GM was a hair narrower than our estimate, the significantly lower operating expenses fueled a ~\$600k beat in operating loss. The OpEx run-rate in 2015 will likely step-up from the level in Q4 for the full current year, but it should be meaningfully lower than what it was in 2014. This assumes that DMC's recommendation – expected sometime in April, is that sufficient efficacy has been seen in the current 130-patient set and SNWV will not be required enroll to 170 patients.

As expected there was no substantive new information on the Q4 call relative to the supplemental trial – the next major event, as noted, will be in April – we think likely mid-to-late April – when DMC recommendation is expected. This recommendation has huge implications for SNWV and the potential of dermaPACE. Our model still incorporates the assumption that DMC recommends halting enrollment at the current 130 patients and SNWV uses this data to support an eventual PMA filing. Potential significant (adverse) adjustments to our model will likely be appropriate if DMC recommends halting the study due to insufficient efficacy or to continue enrollment to 170 patients.

There was a somewhat new development relative to current commercialization – that being the news in December that SNWV signed a memorandum of understanding to create a JV with Dasman Diabetes Institute and Kuwait Life Sciences for commercialization of dermaPACE in the GCC territories. GCC, as the company has noted in the last several conference calls, represents a very attractive market for dermaPACE given the very high incidence of diabetes in that region of the world. The roll-out in GCC will likely be measured, initially involving use in and by Dasman-affiliated facilities and physicians, and then (hopefully) a broader roll-out supported by the clinical experience from Dasman.

Management also noted that the Premier Shockwave relationship – related to further commercialization of OssaTron in the U.S. – should also contribute revenue in the current year – although we do not expect this to be overly substantial over the near-term.

SNWV added to its patent portfolio recently when USPTO, in late February, granted a patent titled, "Medical Treatment System Including an Ancillary Medical Treatment Apparatus with an Associated Data Storage Medium". The patent's main applicability is with dermaPACE's per-procedure treatment/revenue model although, as management explained on the Q4 call, it has potential wide and valuable use in other applications – both medical and non-medical.

Q4 revenue came in at \$237k, about 9% better than our \$218k estimate. For the full year, revenue was \$847k, up 6% from the \$800k generated in 2013 with growth mainly driven by further penetration of orthoPACE in Korea. As noted we expect dermaPACE introduction in GCC areas as well as the Premier Shockwave relationship to contribute to revenue growth in 2015 and, combined with anticipated continued growing sales of orthoPACE in S. Korea to result in double-digit top-line growth through the end of the current year.

Q4 gross margin was 70.4% compared to our 72% estimate. For the full year GM came in at a healthy 74%. Q4 OpEx were \$1.1 million, well below our \$1.7 million estimate. Conclusion of the treatment phase of the supplemental trial benefitted R&D expense in the quarter while lower stock compensation kept SG&A down. For the full year OpEx were \$6.6 million, flat from 2013 with ~\$700k increase in R&D related to the clinical study offset by lower employee and consulting stock-based compensation. We currently model OpEx to come down by about 10% in 2015 (assuming 130 patients is sufficient for efficacy) – with most of the anticipated savings related to R&D.

Q4 operating loss was \$919k versus our \$1.6 million estimate – the difference related to the beat in OpEx. Q4 and full-year EPS was (\$0.00) and (\$0.12).

We currently model 2015 revenue, net income and EPS of \$1.1 million, (\$5.4) million and (\$0.06).

Cash

Cash used in operations in Q4 and the full year 2014 was \$1.1 million and \$6.7 million. Cash used in the year included \$703k drawdown of A/P (A/P ended 2014 at \$232k, down from \$935k at 2013 year-end). Management

expects cash burn to average \$400k - \$500k/month in 2015 – which is down from ~\$560k/month in 2014 - again, most of the expected difference is related to reduced clinical trial activities. SNWV exited 2014 with \$3.6 million in cash and equivalents – which represents ~8 months worth of operating capital. HealthTronics' debt in the amount of \$5.4 million comes due on August 1, 2015. SNWV is actively seeking additional capital. Our model, which is unchanged from prior updates, assumes SNWV raises additional funds (via equity or convertible debt/preferreds) throughout the current year which is reflected in our estimated o/s share count.

Recent Business Update:

> On September 9th SANUWAVE announced the Data Monitoring Committee (DMC) overseeing data analysis of the company's supplemental dermaPACE trial recommended, following analysis of the first 90 patients (i.e. - minimum enrollment), that the trial continue to enroll to the next enrollment tier - that being 130 total patients. Management noted on the Q3 2014 call that feedback from DMC did not include specifics in terms of data analysis or efficacy measures but instead was more generally that the trial needed to continue to enroll to the next 40-patient tranche. Feedback, however, did include safety, which was reported to not have any material issues.

As a reminder, on April 30th the company announced that the 90th patient (minimum number required for enrollment) had been enrolled. The last of the 90 patients completed the final 12-week follow-up assessment sometime around early August. DMC came back on Sept 9th with a recommendation that SNWV increase enrollment to a total of 130 patients.

SNWV continued to enroll patients (past the 90th) as they awaited word from the DMC and in early December the 130th patient was enrolled in the study. SNWV expects to hear back from the DMC with their data analysis of the entire 130-patient set sometime in April – we think it may be mid-to-late April and it is something that we are eagerly awaiting.

DMC's recommendation will be either forego any additional enrollment due to sufficient efficacy of dermaPACE versus sham, to enroll another 40 patients (to a total of 170) or to stop the trial due to insufficient efficacy versus sham. Assuming positive results, SNWV will then aggregate the data (full data analysis, per mgmt's guidance, could be available sometime this summer) and finalize a PMA filing. Timing for a potential PMA filing would likely be towards the end of the current year. And potential FDA approval could come in 2016.

If, on the other hand, DMC's recommendation is to continue to enroll to 170 patients, SNWV will have a decision to make. Management noted on the Q4 call that they will evaluate their options if and when that happens. In lieu of enrolling to 170, another possible option would be to file the PMA with the 130-patient data and request review from an FDA advisory committee. But again, we need to wait until DMC's recommendation.

> Management also recently provided updates on other aspects of the business, including their ongoing success with expanding their international commercialization footprint – which remains a priority for growing revenue in the near-term. SNWV recently announced a memorandum of understanding with Dasman Diabetes Institute and Kuwait Life Sciences Co. to form a JV for introduction of dermaPACE in Gulf Cooperation Council (GCC) region (Saudi Arabia, Kuwait, Iran, United Arab Emirates and Qatar). While on the face, this may not sound like a particularly attractive demographic, management noted that the incidence of diabetes in this region is double that of the U.S. SNWV had expected to initiate sales to the GCC region sometime in 2014 but this has now been pushed back to early 2015. The game plan is for Dasman, a leading diabetes institute in the GCC region, to use dermaPACE at and by its facilities and physicians and then for these physicians to help facilitate marketing as key opinion leaders. We expect the roll-out of dermaPACE in GCC to be measured, at least in the near-term as Dasman builds clinical experience.

This GCC distribution agreement follows other distribution agreements in S. Korea, Australia and New Zealand. SNWV expects to continue to be active in identifying distributors in other parts of the world for dermaPACE and orthoPACE. They are also actively engaged with their distributors in ways to expand sales in their respective regions - particularly in Europe.

Sales of OssaTron to S. Korea, as noted earlier, have been a catalyst to driving recent growth. We expect this will continue to be an area of the world that holds additional opportunity. And in that regard SNWV is in process of finalizing a regulatory filing in that country for dermaPACE.

The company also continues to look at other revenue generating opportunities, particularly ones with little risk and low-cash requirements as they remain focused on conserving financial resources to fund the last leg of the supplemental dermaPACE trial and their push towards U.S. commercialization of their flagship product. The most

recent endeavor in regards to broadening their revenue generating base is a deal signed with Premier Shockwave related to SNWV's legacy OssaTron device. OssaTron uses similar technology as dermaPACE but is much larger, heavier and much more cumbersome to use. OssaTron is FDA cleared (via PMA) for use in the treatment of chronic lateral epicondylitis or tennis elbow and plantar fasciitis or heel pain. Under the agreement with Premier, which is the largest mobile OssaTron service provider, SNWV will lend their OssaTron devices for free (many or all of which were likely generating no revenue for SNWV) and SNWV will be paid a (undisclosed) royalty when the devices are used. And while we do not expect this to be a significant revenue source, we see it as meaningful for a few reasons - it may provide some incremental revenue for devices that had likely been just collecting dust, it comes at virtually no cost or risk to SNWV and, perhaps more importantly, it affords SNWV the opportunity to get their technology and name in front of physicians that will likely be on the short list of potential initial customers for dermaPACE, once approved in the U.S. - this early awareness building comes at no cost to SNWV. Management expects incremental revenue from this Premier relationship to begin in Q1 of this year.

> Relative to derivative applications of the PACE technology (all of which are likely somewhat back-burner projects as they dedicate most of their focus and resources towards dermaPACE for the U.S. market):

- work continues on a water cleaning application - potentially for frack water which is used in hydrocracking for natural gas extraction. In 2013 SNWV was granted a patent for use of shockwaves to destroy pathogens and pollutants in blood, water, food liquids and other fluids. This patent is applicable to both SNWV's interest in using the technology for blood sterilization and frack water cleaning. SNWV has started testing for an application in cleaning water with a small-scale model with "very promising" results so far. The next step is likely to include finding a partner so as to test the small-scale model in the field. Given the recent explosion in hydrocracking for natural gas extraction and concerns over toxicity of frack water, we view this as a potentially attractive market.

- significant headway appears to have been made in the blood sterilization application in which SNWV is working with the University of Georgia. A study was initiated in September which is expected to be followed with a subsequent study, the latter which will include actual infected blood and should provide greater insight into the effectiveness of SNWV's shock wave technology in cleaning blood. Assuming eventual success, SNWV envisions cleaning of blood for blood banks as one possible commercialization opportunity - possibly through some sort of partnership or licensing deal.

- stem cell research has been another area that SNWV has focused on and has been on the company's radar for some time. Several studies have been published from 2009 - 2012 in peer-reviewed journals showing efficacy of SNWV's PACE technology in the proliferation of stem cells and in bone repair in small animals - rats and rabbits. SNWV has just recently begun to further research in this area and is working with Harvard University for similar applications in larger animals, namely goats currently. We view this another high-potential application, given the potential enormous markets.

VALUATION / RECOMMENDATION

We use 2018 P/S comparables to value SNWV. Smith & Nephew currently trades at approximately 2.4x analyst's 2018 forecasted revenue. We currently model SNWV to generate revenue of about \$32 million in 2018 – based on the SNN comp 2018 P/S multiple, this values SNWV at about \$1.00/share. We are maintaining our Outperform rating.

FINANCIAL MODEL

SANUWAVE Health, Inc.

	2014 A	Q1E	Q2E	Q3E	Q4E	2015 E	2016 E	2017 E	2018 E
Total Revenues	\$847.4	\$252.0	\$261.0	\$274.0	\$288.0	\$1,075.0	\$4,573.3	\$18,859.3	\$32,487.0
<i>YOY Growth</i>	5.9%	73.7%	9.6%	20.4%	21.7%	26.9%	325.4%	312.4%	72.3%
Cost of Revenues	\$220.0	\$74.3	\$76.5	\$79.5	\$82.9	\$313.2	\$1,153.9	\$4,674.9	\$7,830.3
Gross Income	\$627.4	\$177.7	\$184.5	\$194.5	\$205.1	\$761.8	\$3,419.4	\$14,184.3	\$24,656.7
<i>Gross Margin</i>	74.0%	70.5%	70.7%	71.0%	71.2%	70.9%	74.8%	75.2%	75.9%
R&D	\$3,000.8	\$697.0	\$651.0	\$622.0	\$624.0	\$2,594.0	\$2,550.0	\$2,614.0	\$2,688.0
<i>% R&D</i>	354.1%	276.6%	249.4%	227.0%	216.7%	241.3%	55.8%	13.9%	8.3%
SG&A	\$3,269.1	\$802.0	\$751.0	\$732.0	\$724.0	\$3,009.0	\$3,558.0	\$11,013.8	\$17,283.1
<i>% G&A</i>	385.8%	318.3%	287.7%	267.2%	251.4%	74.0%	77.8%	58.4%	53.2%
Depreciation	\$14.3	\$5.0	\$5.0	\$5.0	\$5.0	\$20.0	\$50.0	\$70.0	\$75.0
Amortization	\$306.7	\$76.7	\$76.7	\$76.7	\$76.7	\$306.8	\$306.8	\$55.0	\$40.0
Write down of assets	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Operating Income	(\$5,963.5)	(\$1,403.0)	(\$1,299.2)	(\$1,241.2)	(\$1,224.6)	(\$5,168.0)	(\$3,045.4)	\$431.5	\$4,570.6
<i>Operating Margin</i>	-703.8%	-556.8%	-497.8%	-453.0%	-425.2%	-480.7%	-66.6%	2.3%	14.1%
Total Other Expense	(\$10.6)	(\$80.0)	(\$80.0)	(\$65.0)	\$0.0	(\$225.0)	(\$50.0)	(\$50.0)	\$0.0
Pre-Tax Income	(\$5,974.1)	(\$1,483.0)	(\$1,379.2)	(\$1,306.2)	(\$1,224.6)	(\$5,393.0)	(\$3,095.4)	\$381.5	\$4,570.6
Taxes	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<i>Tax Rate</i>	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	(\$5,993.3)	(\$1,483.0)	(\$1,379.2)	(\$1,306.2)	(\$1,224.6)	(\$5,393.0)	(\$3,095.4)	\$381.5	\$4,570.6
<i>YOY Growth</i>	-49.9%	-42.2%	-18.7%	-13.1%	438.2%	-10.0%	-42.6%	-112.3%	1098.0%
<i>Net Margin</i>	-707.3%					-501.7%	-67.7%	2.0%	14.1%
EPS (continuing ops)	(\$0.12)	(\$0.02)	(\$0.02)	(\$0.01)	(\$0.01)	(\$0.06)	(\$0.03)	\$0.00	\$0.04
Diluted Shares O/S	48,213	67,200	85,400	101,320	104,000	89,480	107,000	110,000	115,000

Brian Marcxx, CFA

HISTORICAL ZACKS RECOMMENDATIONS



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The current distribution is as follows: Buy/Outperform- 15.5%, Hold/Neutral- 75.5%, Sell/Underperform – 8.3%. Data is as of midnight on the business day immediately prior to this publication.