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SANUWAVE Health (SNWV-OTC)

SNWV: DMC Rec Expected in Q1

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	05/15/2013
Current Price (11/13/14)	$0.15
Target Price	**$1.50**

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 90-patient minimum. In Sept DMC recommended increasing enrollment to 130 patients. Expect next analysis point sometime in Q1 2015.
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. mrkt in late 2015/early 2016.

SUMMARY DATA

52-Week High	**$0.90**
52-Week Low	**$0.35**
One-Year Return (%)	**-76.78**
Beta	**1.66**
Average Daily Volume (sh)	**154,885**
Shares Outstanding (mil)	**51**
Market Capitalization ($mil)	**$8**
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 (%)	**0.4**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2014 Estimate	**N/A**
P/E using 2015 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Growth**
Industry	**Med Products**

ZACKS ESTIMATES

Revenue
(in 000s of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	201 A	161 A	148 A	290 A	800 E
2014	145 A	238 A	228 A	218 E	829 E
2015					1,303 E
2016					6,303 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.25 A	-$0.04 A	-$0.14 A	-$0.04 E	-$0.42 E
2014	-$0.06 A	-$0.04 A	-$0.03 A	-$0.03 E	-$0.16 E
2015					-$0.06 E
2016					-$0.02 E

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

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WHAT'S NEW…

Q3 Results, Operational Update

SANUWAVE reported financial results for the third quarter ending September 30th and provided a business update. Financial results came in moderately better than our estimates with a beat on both revenue and operating expenses, only slightly offset by lower than modeled gross margin. The net result was a fairly big beat on the bottom line with net loss about $400k better than our number and EPS coming in $0.01 higher.

But the big news (announced about 2 months ago), not nearly as positive as the financial results but not something we see as a show-stopper either, is that the supplemental trial will be extended to now include at least another 40 patients. In September SNWV announced that 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. Further discussion on this below.

Q3 revenue came in at $228k compared to our $188k estimate. This is the second straight quarter where revenue beat our estimate - and in both instances actual was about 21% better than our forecast. The revenue beat appears to be coming mostly from S. Korea, where orthoPACE was approved by regulators in July 2013 and which management indicated has been a recent area of growth for the company. We think an additional incremental uptick could come as SNWV gains traction in the Middle East. The company is also finalizing regulatory filing for dermaPACE in S. Korea with sales expected to begin sometime next year which could be another tailwind to revenue growth.

Gross margin was 70.1% compared to our 73.5% estimate. Similar to revenue, GM can be somewhat variable q-to-q and is affected on mix of consoles versus consumables. As such, we would read nothing into the current quarter miss on GM. SNWV did beat big on OpEx, however. Q2 operating expenses were $1.57M ($708k R&D, $861 SG&A), compared to our $2.0M ($1.0M R&D, $970k SG&A) estimate. OpEx, particularly R&D, came down significantly from Q2 ($1.8M inc $1.0M R&D). We think OpEx stays at near these levels through the remainder of the current year and throughout 2015, assuming total enrollment in the supplemental study past 130 patients is not necessary.

Net income and EPS were ($1.5) million and ($0.03), compared to our ($1.9) million and ($0.04) estimates.

Cash
Cash used in operations in Q3 was $1.5 million but excluding changes in working capital, cash used in operations was $1.4 million. Management expects cash burn to average about $550k - $650k per month through the end of 2014 and then, following patient enrollment and follow-up, to fall to about $450k - $550k per month during 2015. SNWV exited Q3 with $4.7 million in cash and equivalents. Despite the trial elongation to now include another 40 patients, we think cash balance could still be sufficient to fund the company to a PMA filing (assuming no additional trial delays).

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 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 currently (as of today's report date) has 126 patients enrolled. The company now believes they can complete enrollment of the additional 40 patients by the end of November. Enrollment will cease at 130 patients. SNWV expects to hear back from the

DMC with their data analysis of the entire 130-patient set by the end of Q1 2015 - which we will be eagerly awaiting. As we noted following DMC's recommendation to enroll to 130 patients, we do not view this as overly significant, particularly given that it has no real bearing on the ultimate approvability of dermaPACE or our long-term outlook for the company or the commercial potential for the device. Instead, we see this as a set-back and short-term delay but still believe in the chances of ultimate FDA approval of dermaPACE.

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 finalize a PMA filing, which could happen in 2015 and potential FDA approval the following year.

> 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 signed a licensing and distribution agreement with Wirthlin-Dentons whereby Wirthlin will distribute dermaPACE in the Gulf Cooperation Council 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 expects to initiate sales to the GCC region sometime in 2014 - this timeline was reiterated on the Q3 call.

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.

> 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 of 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 2017 P/S comparables to value SNWV. Smith & Nephew currently trades at approximately 2.5x analyst's 2017 forecasted revenue. We currently model SNWV to generate revenue of about $23 million in 2017 – based on the SNN comp 2017 P/S multiple, this values SNWV at about $1.20/share. We are maintaining our Outperform rating.

FINANCIAL MODEL

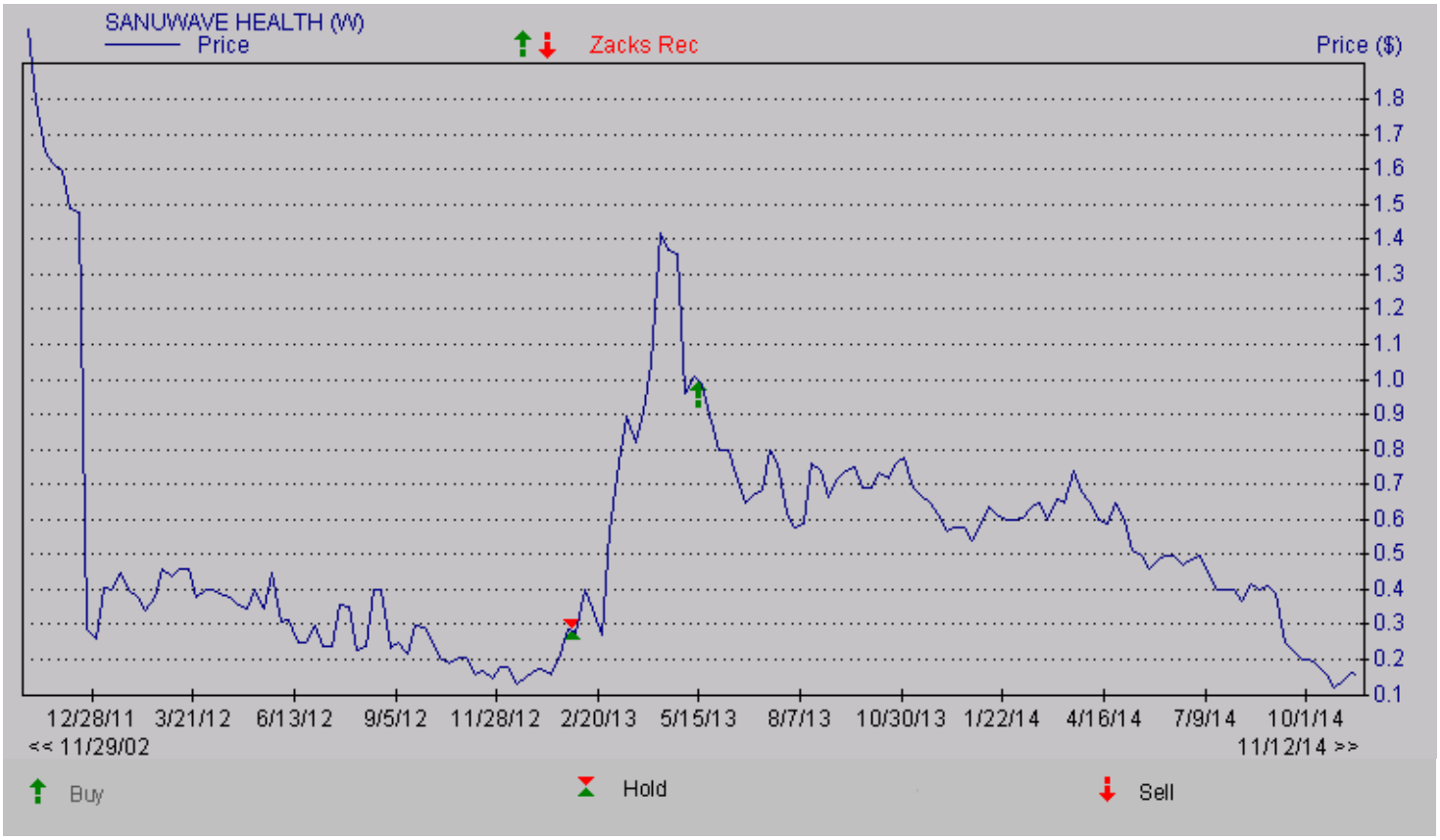
SANUWAVE Health, Inc.

	2013 A	Q1A	Q2A	Q3A	Q4E	2014 E	2015 E	2016 E	2017 E
Total Revenues	$800.0	$145.1	$238.1	$227.5	$218.0	$828.7	$1,303.0	$6,302.6	$22,762.5
YOY Growth	*4.0%*	*-27.9%*	*48.3%*	*53.3%*	*-24.8%*	*3.6%*	*57.2%*	*383.7%*	*261.2%*
Cost of Revenues	$189.8	$18.3	$63.4	$68.1	$61.0	$210.9	$364.8	$1,636.8	$5,257.4
Gross Income	$610.2	$126.8	$174.7	$159.4	$157.0	$617.9	$938.2	$4,665.8	$17,505.1
Gross Margin	*76.3%*	*87.4%*	*73.4%*	*70.1%*	*72.0%*	*74.6%*	*72.0%*	*74.0%*	*76.9%*
R&D	$2,296.7	$764.8	$1,013.7	$708.3	$804.0	$3,290.8	$3,066.0	$2,750.0	$3,018.0
% R&D	*287.1%*	*527.1%*	*425.7%*	*311.4%*	*368.8%*	*397.1%*	*235.3%*	*43.6%*	*13.3%*
SG&A	$3,963.2	$1,300.3	$694.4	$780.1	$821.0	$3,595.8	$3,825.0	$3,592.5	$11,836.5
% G&A	*495.4%*	*896.2%*	*291.6%*	*342.9%*	*376.6%*	*433.9%*	*74.0%*	*57.0%*	*52.0%*
Depreciation	$19.6	$4.7	$4.8	$3.8	$5.0	$18.3	$40.0	$50.0	$70.0
Amortization	$306.8	$76.7	$76.7	$76.7	$76.7	$306.8	$306.8	$306.8	$55.0
Write down of assets	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($5,976.0)	($2,019.8)	($1,614.8)	($1,409.5)	($1,549.7)	($6,593.9)	($6,299.6)	($2,033.4)	$2,525.6
Operating Margin	*-747.0%*	*-1392.0%*	*-678.2%*	*-619.6%*	*-710.9%*	*-795.7%*	*-483.5%*	*-32.3%*	*11.1%*
Total Other Expense	($5,978.3)	($544.2)	($78.9)	($83.4)	($72.0)	($778.4)	($250.0)	($50.0)	($50.0)
Pre-Tax Income	($11,954.2)	($2,564.0)	($1,693.7)	($1,492.9)	($1,621.7)	($7,372.2)	($6,549.6)	($2,083.4)	$2,475.6
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	($11,954.2)	($2,565.4)	($1,697.2)	($1,503.1)	($1,621.7)	($7,372.2)	($6,549.6)	($2,083.4)	$2,475.6
YOY Growth	*86.7%*	*-52.2%*	*107.4%*	*-66.1%*	*22.0%*	*-38.3%*	*-11.2%*	*-68.2%*	*-218.8%*
Net Margin	*-1494.2%*					*-889.6%*	*-502.7%*	*-33.1%*	*10.9%*
EPS (continuing ops)	($0.42)	($0.06)	($0.04)	($0.03)	($0.03)	($0.16)	($0.06)	($0.02)	$0.02
Diluted Shares O/S	28,132	39,647	48,423	50,707	51,222	47,500	104,000	106,000	110,000

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