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Brian Marckx, CFA
bmarckx@zacks.com
Ph (312) 265-9474

Zacks Small-Cap Research

scr.zacks.com

10 S. Riverside Plaza, Ste 1600, Chicago, IL 60606

SANUWAVE Health (SNWV-OTC)

SNWV: DMC Recommendation Causes At Least 4 Month Delay

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	05/15/2013
Current Price (09/10/14)	$0.30
Target Price	**$1.20**

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	**$0.82**
52-Week Low	**$0.30**
One-Year Return (%)	**-46.55**
Beta	**1.50**
Average Daily Volume (sh)	**60,886**
Shares Outstanding (mil)	**51**
Market Capitalization ($mil)	**$15**
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	**N/A**
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	188 E	218 E	789 E
2015					1,303 E
2016					6,302 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	-$0.04 E	-$0.03 E	-$0.15 E
2015					-$0.07 E
2016					-$0.02 E

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

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WHAT'S NEW…

Enrollment Increased From 90 to 130 Patients, Causes At Least 4 Month Delay

This morning (9/10/2014) 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.

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. SNWV noted on the Q2 earnings call that they expected to hear back from the DMC around mid-September relative to their analysis of the data from these 90 patients and their recommendation of whether enrollment could cease at that point due to positive efficacy, should continue to the next enrollment tier (i.e. - the addition of another 40 patients, or 130 patients in total) or cease due to poor effiicacy.

SNWV continued to enroll patients (past the 90th) as they awaited word from the DMC and believes they can complete enrollment of the additional 40 patients by the end of October. The DMC will analyze data from the entire 130-patient set after all patients have completed the 12-week efficacy analysis. So we would not expect to hear back from DMC prior to the end of January 2015 - and potentially a little later.

The DMC's recommendation following analysis of the 130 patient set (which is similar to the DMC's options following the initial 90 patients) will be to either cease 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.

So while this morning's news is a disappointment and will result in at least a four month delay before we have hard efficacy data of dermaPACE versus sham in the treatment of diabetic foot ulcers, it's somewhat of a "kissing your sister" event. Clearly a recommendation from DMC to halt enrollment at 90 patients due to sufficient efficacy would have been preferable but it's much better than if DMC would have recommended halting due to poor results.

And while we have made some delay-related adjustments to our model as well as forecasted cash-consumption, the impact of these updates are almost entirely near-term related. We do not view this morning's news 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.

We may hear more insight from management on the Q3 call - which should be ~mid-November, although we expect the next time point for specifics in terms of trial timeframes and/or data outcomes will likely not be until at least late January.

The delay has slightly impacted our valuation as a result of modifications to our model. We use a 2017 P/S comparable to value SNWV. Smith & Nephew currently trades at approximately 2.6x 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. Our price target has moved from $1.50/share to $1.20/share. We are maintaining our Outperform rating.

FINANCIAL MODEL

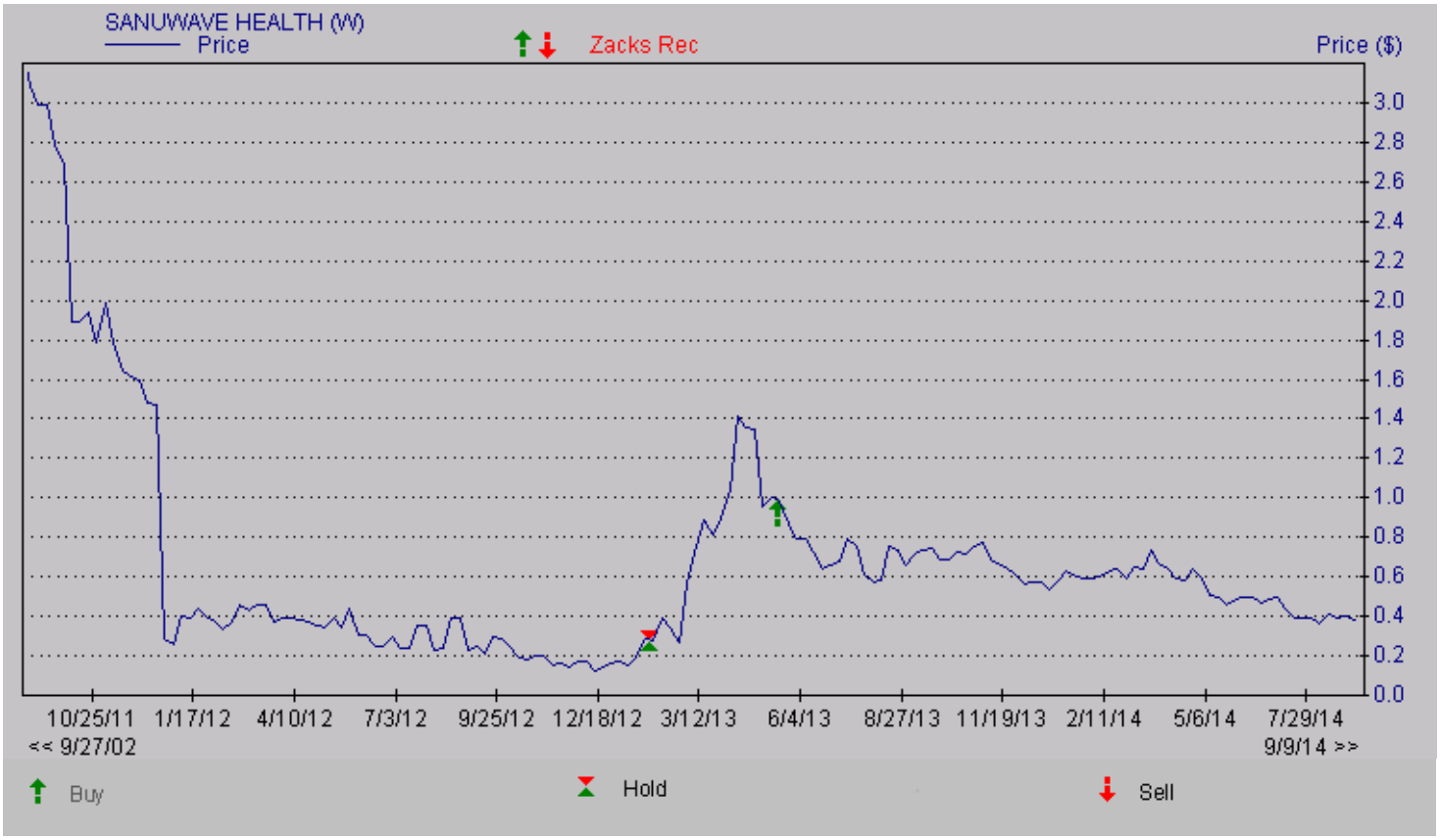
SANUWAVE Health, Inc.

	2013 A	Q1A	Q2A	Q3E	Q4E	2014 E	2015 E	2016 E	2017 E
Total Revenues	$800.0	$145.1	$238.1	$188.0	$218.0	$789.2	$1,303.0	$6,302.6	$22,762.5
YOY Growth	*4.0%*	*-27.9%*	*48.3%*	*26.7%*	*-24.8%*	*-1.4%*	*65.1%*	*383.7%*	*261.2%*
Cost of Revenues	$189.8	$18.3	$63.4	$49.8	$61.0	$192.6	$364.8	$1,636.8	$5,257.4
Gross Income	$610.2	$126.8	$174.7	$138.2	$157.0	$596.6	$938.2	$4,665.8	$17,505.1
Gross Margin	*76.3%*	*87.4%*	*73.4%*	*73.5%*	*72.0%*	*75.6%*	*72.0%*	*74.0%*	*76.9%*
R&D	$2,296.7	$764.8	$1,013.7	$1,010.0	$1,000.0	$3,788.5	$3,350.0	$2,750.0	$3,018.0
% R&D	*287.1%*	*527.1%*	*425.7%*	*537.2%*	*458.7%*	*480.0%*	*257.1%*	*43.6%*	*13.3%*
SG&A	$3,963.2	$1,300.3	$694.4	$888.0	$864.0	$3,746.7	$3,825.0	$3,592.5	$11,836.5
% G&A	*495.4%*	*896.2%*	*291.6%*	*472.3%*	*396.3%*	*474.7%*	*74.0%*	*57.0%*	*52.0%*
Depreciation	$19.6	$4.7	$4.8	$5.0	$5.0	$19.5	$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)	($1,841.5)	($1,788.7)	($7,264.9)	($6,583.6)	($2,033.4)	$2,525.6
Operating Margin	*-747.0%*	*-1392.0%*	*-678.2%*	*-979.5%*	*-820.5%*	*-920.5%*	*-505.3%*	*-32.3%*	*11.1%*
Total Other Expense	($5,978.3)	($544.2)	($78.9)	($78.0)	($72.0)	($773.0)	($250.0)	($50.0)	($50.0)
Pre-Tax Income	($11,954.2)	($2,564.0)	($1,693.7)	($1,919.5)	($1,860.7)	($8,037.9)	($6,833.6)	($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)	($1,919.5)	($1,860.7)	($8,037.9)	($6,833.6)	($2,083.4)	$2,475.6
YOY Growth	*86.7%*	*-52.2%*	*107.4%*	*-56.7%*	*39.9%*	*-32.8%*	*-15.0%*	*-69.5%*	*-218.8%*
Net Margin	*-1494.2%*					*-1018.5%*	*-524.5%*	*-33.1%*	*10.9%*
EPS (continuing ops)	($0.42)	($0.06)	($0.04)	($0.04)	($0.03)	($0.15)	($0.07)	($0.02)	$0.02
Diluted Shares O/S	28,132	39,647	48,423	52,250	68,500	52,205	104,000	106,000	110,000

Brian Marckx, CFA

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