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SANUWAVE Health (SNWV-OTC)

SNWV: Q3 Results. Financing Update

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	08/10/2011
Current Price (11/16/12)	$0.17
Target Price	**$1.70**

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 Q1 2013.

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	**$1.72**
52-Week Low	**$0.12**
One-Year Return (%)	**-90.86**
Beta	**0.15**
Average Daily Volume (sh)	**3,876**
Shares Outstanding (mil)	**21**
Market Capitalization ($mil)	**$4**
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 (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2012 Estimate	**N/A**
P/E using 2013 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)
2011	252 A	164 A	162 A	225 A	803 A
2012	239 A	210 A	178 A	225 E	852 E
2013					1,107 E
2014					1,411 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-$0.14 A	-$0.17 A	-$0.10 A	-$0.12 A	-$0.52 A
2012	-$0.09 A	-$0.07 A	-$0.07 A	-$0.10 E	-$0.32 E
2013					-$0.15 E
2014					-$0.14 E

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

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WHAT'S NEW…

Q3 RESULTS / FINANCING UPDATE

On November 14, 2012 SANUWAVE announced financial results for the third quarter ending September 30th. Revenue was generally in-line although slightly lower than our estimate. More importantly, given that SNWV is focused on conserving capital as they ready for the start of the supplemental trial, is that operating expenses and cash burn continue to come down and were lower than what we had expected. The other positive news is that SNWV is near closing on additional financing which, along with the cash balance, should get them through to the beginning of 2013 at which point trial enrollment is expected to commence and another, larger cash raise is expected to be consummated.

Q3 revenue came in at $178k compared to our $255k estimate. Operating expenses continue to fall sequentially, coming in at $1.5 million, down , which dipped $457k or 25% from Q1 2012, reflect management's tight control on costs and cash.

Management continues to manage expenses and cash well with operating expenses flat from Q2 at $1.5 million and below our $1.6 million estimate. As a reminder, following the December 2011 FDA major deficiency letter, when it was evident that dermaPACE would not make it to the market in the near-term, management announced that they were implementing cost-cutting initiatives to preserve capital. These initiatives started bearing fruit immediately, with op expenses falling $1.9 million through the first 9 months of 2012 compared to the same period in 2011. Part of these efforts included slashing headcount, which fell from 29 to 18 from Q3 2011 to Q3 2012.

Q3 net income and EPS were ($1.5) million and ($0.07) compared to our ($1.5) million and ($0.06) estimates - the difference in EPS a result of us overestimating the outstanding share count - as a reminder, as we noted in a previous update we used a placeholder assumption that financing would come in the form of equity. We have now removed this assumption as financing will likely come in the form of convertible debt (which we assume is eventually converted to equity in later periods).

Cash
Cash used in operations was $1.04 million in Q3, roughly flat from $1.01 million in Q2, and down from $1.49 million in Q1. SANUWAVE exited Q3 with $361k in cash and equivalents, down from $1.4 million at the end of Q2.

We think management has done a commendable job minimizing cash burn and cutting expenses where possible. Nonetheless the company will need to raise additional capital and indicated in the Q3 earnings release and 10-Q that they expect to sell $1.25MM in convertible debt in the very near-term and hope to close on a bigger capital raise by the end of Q1 2013.

Supplemental Trial Enrollment Slated to Commence Q1 2013
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 Q3 10-Q). 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 Q1 2013 as they needed to secure financing. During Q3 they did finalize selection of clinical sites and continue with the process of getting IRB approvals. Assuming they have the requisite capital and all IRB approvals, they will begin patient enrollment in Q1 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 Q1 2013), we have made some updates to our timelines for launch of dermaPACE - pushing it back by about 4 months from our previous 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 2015 P/S comparables to value SNWV. Smith & Nephew currently trades at approximately 2.5x analyst's 2015 forecasted revenue. Kinetic Concepts was acquired in November 2011 for $6.1 billion, or about 2.8x estimated 2015 revenue. We currently model SNWV to generate revenue of about $13 million in 2015 – based on the two comp 2015 P/S multiples values SNWV at between $1.60/share and $1.75/share. For simplicity, we use the average of the two, which values SNWV at about $1.70/share.

FINANCIAL MODEL

SANUWAVE Health, Inc.

	2011 A	Q1A	Q2A	Q3A	Q4E	2012 E	2013 E	2014 E	2015 E
Total Revenues	$802.6	$238.5	$210.4	$178.3	$225.0	$852.2	$1,107.0	$1,410.9	$12,770.4
YOY Growth	*10.2%*	*-5.2%*	*28.5%*	*10.3%*	*-0.2%*	*6.2%*	*29.9%*	*27.4%*	*805.2%*
Cost of Revenues	$261.9	$71.8	$82.2	$44.0	$67.5	$265.4	$332.1	$425.4	$2,877.3
Gross Income	$540.7	$166.8	$128.2	$134.3	$157.5	$586.8	$774.9	$985.5	$9,893.1
Gross Margin	*67.4%*	*69.9%*	*60.9%*	*75.3%*	*70.0%*	*68.9%*	*70.0%*	*69.9%*	*77.5%*
R&D	$2,731.1	$603.8	$347.6	$440.2	$660.0	$2,051.6	$2,722.0	$3,250.0	$3,450.0
% R&D	*340.3%*	*253.1%*	*165.3%*	*246.9%*	*293.3%*	*240.8%*	*245.9%*	*230.4%*	*27.0%*
SG&A	$6,293.0	$1,237.5	$1,036.7	$977.9	$1,400.0	$4,652.1	$4,644.0	$5,218.0	$9,450.1
% G&A	*784.1%*	*518.8%*	*492.8%*	*548.6%*	*622.2%*	*545.9%*	*419.5%*	*369.8%*	*74.0%*
Depreciation	$19.0	$5.2	$5.1	$5.0	$4.0	$19.3	$20.0	$40.0	$80.0
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	($8,809.2)	($1,756.5)	($1,338.0)	($1,365.4)	($1,983.2)	($6,443.1)	($6,917.9)	($7,829.3)	($3,393.8)
Operating Margin	*-1097.6%*	*-736.3%*	*-636.1%*	*-766.0%*	*-881.4%*	*-756.1%*	*-624.9%*	*-554.9%*	*-26.6%*
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.	$375.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Extinguishment of debt	($1,318.8)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Interest expense, net	($472.1)	($78.9)	($80.4)	($81.9)	($85.0)	($326.2)	($360.0)	($360.0)	($360.0)
Loss of FX	($13.8)	$0.0	($6.2)	$0.0	$0.0	($6.1)	$0.0	$0.0	$0.0
Pre-Tax Income	($10,238.8)	($1,835.3)	($1,424.6)	($1,447.3)	($2,068.2)	($6,775.4)	($7,277.9)	($8,189.3)	($3,753.8)
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%*	*8.0%*
Discontinued Operations	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	($10,238.8)	($1,835.3)	($1,424.6)	($1,447.3)	($2,068.2)	($6,775.4)	($7,277.9)	($8,189.3)	($3,753.8)
YOY Growth	*-31.4%*	*-15.9%*	*-60.1%*	*-30.1%*	*-14.2%*	*-33.8%*	*7.4%*	*12.5%*	*-54.2%*
Net Margin	*-1275.8%*					*-795.1%*	*-657.4%*	*-580.4%*	*-29.4%*
EPS (continuing ops)	($0.52)	($0.09)	($0.07)	($0.07)	($0.10)	($0.32)	($0.15)	($0.14)	($0.06)
Diluted Shares O/S	19,624	20,908	20,908	20,908	21,000	20,931	50,000	60,000	64,000

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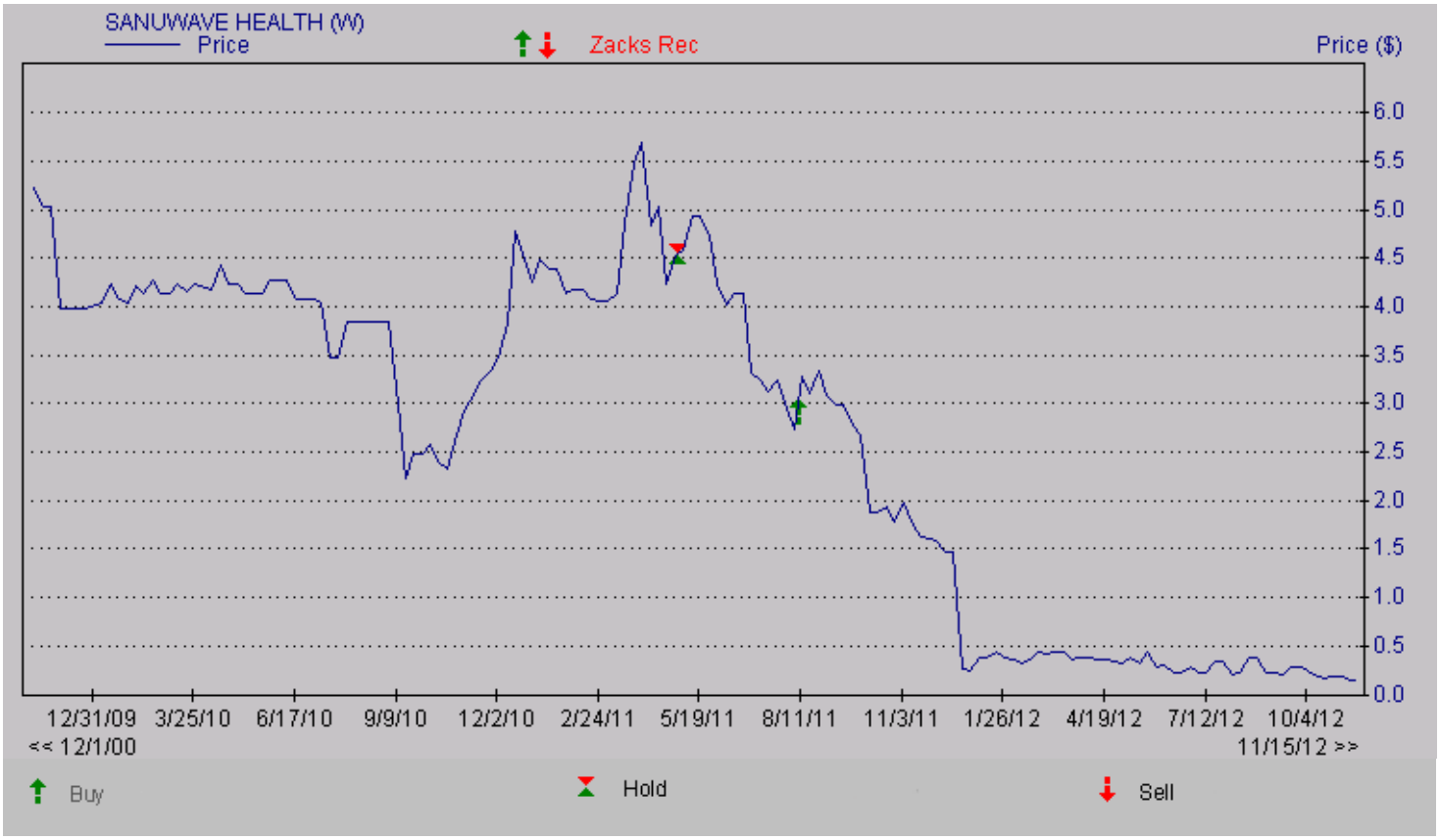

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