December 21, 2015

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SANUWAVE Health (SNWV-OTC)

SNWV: Int'l Sales Picking Up, FDA Meeting Q1 2016

Current Recommendation	**Buy**
Prior Recommendation	Neutral
Date of Last Change	05/15/2013
Current Price (12/21/15)	$0.10
Target Price	**$0.45**

OUTLOOK

On Oct 8th SNWV announced that a preliminary analysis of the combined data from the initial (n=206) and supplemental (n=130) dermaPACE clinical trials showed statistical significance of complete wound closure at 20-weeks. This is a highly positive development as had the data not demonstrated significance at 20-weeks, it likely would have meant that dermaPACE had little to no chance of eventually gaining FDA approval. And while U.S. regulatory approval is still not a given as the full analysis still needs to be completed and some ambiguity remains regarding exactly what decision-making criteria FDA will use, the news significantly improves the chances that dermaPACE makes it to the U.S. market. Mgmt is shooting for FDA filing in Q1 2016.

SUMMARY DATA

52-Week High	**$0.28**
52-Week Low	**$0.04**
One-Year Return (%)	**98.17**
Beta	**0.33**
Average Daily Volume (sh)	**116,753**
Shares Outstanding (mil)	**63**
Market Capitalization ($mil)	**$6**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**23**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**2.0**
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**

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	211 A	240 A	144 A	325 E	919 E
2016					1,522 E
2017					1,997 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 A	-$0.02 A	-$0.02 A	-$0.02 E	-$0.08 E
2016					-$0.05 E
2017					-$0.05 E

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

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Business Update Dec 15:

SNWV released a business update on December 15th which included:

- **Management expects Q4 2015 revenue of $300k - $400k.** Revenue is entirely from overseas. The company has recently entered several new territories and increased their efforts in others. This includes GCC territories, S. Korea and Australia. The Q4 guidance was well ahead of our modeled ~$200k and more than double what SNWV posted in Q3. We have since upwardly adjusted our revenue estimate for Q4. And while we had already anticipated significant OUS revenue growth going into 2016, we have also slightly increased our international sales forecasts for our out-years.

- **Management expects to meet with FDA in Q1.** Shortly following the meeting, which is to "finalize the submission strategy", SNWV expects to submit their PMA application. As a reminder, as of the Q3 conference call (Nov 13th) SNWV's timelines were to have the regulatory package filed in Q1 – so this recent news appears to be in general concurrence.

- **Warrant exchange offer.** SNWV is working to encourage holders of the Series A warrants (23.2M warrants, $0.50 original strike) to exchange their warrants for shares of common stock and, for certain holders, to exchange for shares of the newly created Series B convertible preferred stock. The exchange is being done to help facilitate a capital raise. As of the date of the update, 89% of warrant holders had accepted the offer. The offered exchange ratio was not disclosed in the business update.

We are maintaining our Buy recommendation and $0.45 price target.

Q3 Financial Results: *(per our November 16th Earnings Update):*

SNWV reported financial results for the third quarter ending September 30th. While revenue came in significantly lighter than what we had expected and was down considerably on both a yoy and sequential basis, operating loss was inline with our estimate as a result of expenses coming in lower than what we modeled. Management noted on the call that they expect revenue to pick up again in Q4 and that top-line growth could be as much as 100% in 2016, fueled at least in part from launch in new territories which they expect to happen following gaining requisite regulatory approvals.

Q3 revenue came in at $144k, which is down 37% yoy and 40% sequentially and significantly lower than our $244k estimate. Not much insight into the big drop on the topline but, as noted, this is expected to turn back North. And the slide in revenue is, in a big-picture view, mostly inconsequential at this time as these are all international sales and most of the value of dermaPACE likely lies in the U.S. market.

OpEx of $1.4 million was up from $1.1 million in Q2 but below our $1.5 million estimate – we had anticipated that additional data analysis activities would push up R&D expense a little more than it did which explains most of the difference. We continue to model this to trend higher though in the coming quarters as SNWV prepares their FDA package – which the company expects they will be ready to file in Q1 of next year.

Net loss and EPS, excluding non-cash gain on asset sale and loss on derivative revaluation, were $1.4M and ($0.02) compared to our $1.5M and ($0.02) estimates.

SNWV exited the quarter with $625k in cash and equivalents. Management expects to use between $200k and $250k per month through the end of 2015, exclusive of any FDA submission costs. The company is actively seeking additional funding, which could include potentially tapping the capital markets or a partnership arrangement. Securing additional funding is critical and management sounded optimistic on the call that that would happen.

Management also provided an update to their quest for FDA approval of dermaPACE – most of which was covered in their October update call (see our November 16th update) when they announced preliminary results. The only noteworthy update from this morning's call is that they now do not expect to announce additional information towards the end of this month. While they will continue to analyze the data, the next substantive announcement relative to the data analysis may not come until they submit their regulatory filing. Management hopes to have the package finalized and submitted in Q1 2016.

FINANCIAL MODEL

SANUWAVE Health, Inc.

	2014 A	Q1A	Q2A	Q3A	Q4E	2015 E	2016 E	2017 E	2018 E
Total Revenues	$847.4	$210.5	$240.0	$143.6	$325.0	$919.0	$1,522.0	$1,997.0	$9,092.0
YOY Growth	*5.9%*	*45.0%*	*0.8%*	*-36.9%*	*37.3%*	*8.5%*	*65.6%*	*31.2%*	*355.3%*
Cost of Revenues	$220.0	$58.8	$75.8	$38.8	$93.6	$266.9	$457.6	$567.0	$4,540.2
Gross Income	$627.4	$151.6	$164.2	$104.9	$231.4	$652.1	$1,064.4	$1,430.1	$4,551.8
Gross Margin	*74.0%*	*72.1%*	*68.4%*	*73.0%*	*71.2%*	*71.0%*	*69.9%*	*71.6%*	*50.1%*
R&D	$3,000.8	$634.6	$456.8	$569.1	$794.0	$2,454.5	$2,844.0	$2,778.0	$2,688.0
% R&D	*354.1%*	*301.6%*	*190.3%*	*396.3%*	*244.3%*	*267.1%*	*186.9%*	*139.1%*	*29.6%*
SG&A	$3,269.1	$566.3	$636.6	$778.6	$665.0	$2,646.5	$2,624.0	$3,155.3	$4,036.8
% G&A	*385.8%*	*269.1%*	*265.3%*	*542.2%*	*204.6%*	*288.0%*	*172.4%*	*158.0%*	*44.4%*
Depreciation	$14.3	$0.9	$0.9	$0.9	$0.9	$3.7	$8.0	$40.0	$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)	($1,126.9)	($1,006.8)	($1,320.6)	($1,305.2)	($4,759.4)	($4,718.4)	($4,598.2)	($2,288.0)
Operating Margin	*-703.8%*	*-535.5%*	*-419.5%*	*-919.6%*	*-401.6%*	*-517.9%*	*-310.0%*	*-230.3%*	*-25.2%*
Total Other Expense	($10.6)	($32.2)	($514.8)	$293.7	($144.0)	($397.3)	($1,060.0)	($1,260.0)	($1,500.0)
Pre-Tax Income	($5,974.1)	($1,159.1)	($1,521.5)	($1,026.8)	($1,449.2)	($5,085.7)	($5,778.4)	($5,858.2)	($3,788.0)
Taxes	$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	($5,993.3)	($1,171.8)	($1,522.3)	($1,026.8)	($1,449.2)	($5,085.7)	($5,778.4)	($5,858.2)	($3,788.0)
YOY Growth	*-49.9%*	*-54.3%*	*-10.3%*	*-31.7%*	*536.9%*	*-15.1%*	*13.6%*	*1.4%*	*-35.3%*
Net Margin	*-707.3%*	*-556.8%*	*-634.3%*	*-715.0%*	*-445.9%*	*-553.4%*	*-379.7%*	*-293.4%*	*-41.7%*
EPS (continuing ops)	($0.12)	($0.02)	($0.02)	($0.02)	($0.02)	($0.08)	($0.05)	($0.05)	($0.03)
Diluted Shares O/S	48,213	62,931	63,057	63,057	63,100	63,036	110,000	121,000	125,000

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