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SANUWAVE Health (SNWV-OTC)

SNWV: Still Shooting For FDA Filing in Q1 2016

Current Recommendation	**Buy**
Prior Recommendation	Neutral
Date of Last Change	05/15/2013
Current Price (11/16/15)	$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	**$0.04**
One-Year Return (%)	**-29.50**
Beta	**0.31**
Average Daily Volume (sh)	**88,360**
Shares Outstanding (mil)	**63**
Market Capitalization ($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 (%)	**3.0**
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	194 E	788 E
2016					1,262 E
2017					1,889 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					-$0.08 E
2017					-$0.08 E

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

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Q3 Financial Results:

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 below) 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.

Preliminary Analysis Shows Statistical Significance at 20-Weeks: Will complete full analysis, FDA filing ~Q1..

On October 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 and should be viewed as a meaningful de-risking event.

For a summary of the recent road that SNWV has traveled to get to this point see our Backgrounder" below. Relative to the announcement today, these are the relevant points;

- this is preliminary analysis of the combined studies
- there was a statistically significant (95% CI) difference between sham and dermaPACE treated patients favoring dermaPACE on 100% wound closure (primary endpoint) at 20 weeks in both the initial study (n=206) and when data from both studies was combined (n=324), although it was not met when looking at just the supplemental trial data. At 20 weeks the combined data showed that 36.75% (61/166) of patients treated with dermaPACE achieved 100% wound closure versus 24.05% (38/158) of sham patients. The difference was highly statistically significant (p=0.014)

- rates of wound closure in the supplemental trial were “somewhat higher” for both arms as compared to the initial trial and wound closure rates for sham patients were higher than predicted which led to lack of statistical significance at 12 weeks and later in the supplemental trial. The Oct 8th announcement did not provide any more information about this although the full analysis may look at this
- as has been the case throughout both the initial and supplemental studies, there were no serious dermaPACE-treatment related events
- full analysis, including patient demographics and site-to-site performance, which could have potentially influenced the preliminary data (either positively or negatively), is ongoing

Our comments:
While this preliminary analysis showed that statistical significance was not met at 12 or 20 weeks with just the supplemental trial data, more importantly it was met when both the initial and supplemental trial data were combined. It is the combined data, using Bayesian statistical analysis, that has always (since the design of the supplemental trial) been the expectation that FDA will use to make their approval/non-approval decision. However, there remains uncertainty as to whether FDA will consider 20 weeks as an acceptable endpoint with which to base their approvability decision on.

As a reminder, the primary endpoint for both the initial and supplemental trials was 100% wound closure at 12 weeks which was missed in both studies as well as the combined data. After it was known that the combined data would not hit the 12 week endpoint, SNWV met with FDA and the agency indicated that they would consider the totality of the data including potential additional endpoints.

And while the question remains whether 20 weeks will be considered “acceptable” by FDA, there are certain reasons to believe they might. The most obvious one being that if the agency was not going to consider any endpoint other than the initial 12 weeks, they could have and should have made that clear when management met with them in June – at which point SNWV would lick their wounds and likely pack it in. That didn’t happen, so the implication is that a post-12 week endpoint is, at least, under consideration.

The other major unknown is whether the full data analysis will corroborate the preliminary findings. While that typically is the case with device and drug clinical trials, it is possible there are circumstances that could sway the statistical significance or influence the data quality.

“BACKGROUNDER”

SNWV announced an update to their plans for seeking U.S. regulatory approval of dermaPACE for the treatment of diabetic foot ulcers. In a June 30th press release and subsequent conference call with investors management relayed that an outcome of a meeting with FDA was a determination that "the best path to success would be for the Company to retain the original analysis plan." That being to file a regulatory submission using the original 12-week closure endpoint. The supplemental study also included rate of recurrence at 24 weeks as a secondary endpoint.

As a reminder, in early May SNWV announced that based on the analysis of the 130-patients enrolled to-date that the primary efficacy endpoint of 100% wound closure compared to sham at 12-week follow-up had not been met. DMC further surmised that, extrapolating similar results to additional enrollment of a total of 170 patients, that this primary endpoint would still not be hit. Enrollment was suspended as the company considered their options, the choice of which would likely be predicated on the outcome of a requested meeting with FDA.

SNWV's intention, per the Q1 update call (May 6th), was to request that FDA consider a post-12 week endpoint as a co-primary endpoint. The basis for considering a later endpoint mostly had to do with that results of the initial study (n=206), while also missing the primary objective of 100% closure at 12 weeks, showed statistical significance over sham on 100% wound closure at the 20-week mark (follow-up occurred at every week, and the earliest that statistical significance was observed was at week 20). We think another reason for proposing a co-primary endpoint was that there may have been little confidence that FDA would consider approving a PMA with just the 12-week endpoint - particularly given that FDA shot down the original PMA (supported by just the 206-patient original study data) when this primary endpoint was missed.

Based on management’s comments on the June 30th and Q2 call (August 12th) we think FDA probably did not specifically address a question of whether they would consider the possibility of including a post-12 week endpoint

as a co-primary. But instead are interested in seeing the totality of the data including additional endpoints. SNWV did reiterate, however, that they have asked the agency to consider additional analysis of wound closure post-12 weeks and up to and including 24 weeks and noted that the FDA said they were "onboard to analyze secondary objectives." The company also proposed to consider additional statistical analysis including variance and co-variance measures.

And it seems clear, based on management's comments, that dermaPACE's strong safety profile (which has been demonstrated in both the initial pivotal and supplemental studies) is playing in their favor - which would make sense as FDA's chief concern is always weighing therapeutic benefit versus safety risk. Reading (or listening) between the lines we think the implication is that FDA may be conveying an open-minded approach and not necessarily disqualifying the approvability of dermaPACE based solely (or almost entirely) on a missed 12-week 100% closure endpoint. And this seemed to be reflected in management's encouraged tone and positive comments on both the June and August calls which included, "If we had not had such a positive meeting with the FDA and positive interaction with MCRA we would not be making the decisions today that we are to stop the trial and begin the PMA submission process."

And if that is indeed the case, we think there are logical reasons that would support this thinking. For one, FDA's decision criteria is far from static and can evolve with changes in the marketplace and may be influenced by unmet need. And other advanced DFU technologies have been approved with later (longer) closure endpoints. dermaPACE also looks to have several advantages over competing technologies including being the least invasive of all advanced DFU therapies (with a stronger safety profile) and having lower recurrence rates. It also may prove to be significantly less expensive than other advanced therapies - which in the times of the Affordable Care Act and greater emphasis on quality and cost of care could play into FDA's decision-making.

And another reason to remain optimistic, as we noted in our May update, is MCRA's experience in successfully getting medical devices PMA-approved which had missed clinical trial primary endpoints. These include Wright Medical's Augment Bone Graft which had been initially shot down by FDA with a Not Approvable letter.

Later Endpoint Discussion (from our May 2015 update)**:**

Commercial appeal: We consider this a reasonable course forward, although there are some potential drawbacks versus if the 12-week endpoint was viable. Even if a later endpoint is considered as meaningful support for PMA approval by U.S. regulators and assuming dermaPACE eventually gains FDA approval, a 20-week (or whatever length later than 12 weeks it might be) closure timepoint would potentially compromise (at least to some degree) the commercial appeal of the device. Competitive DFU products, such as skin substitutes Dermagraft and Apligraf, gained FDA approval based on 12-week closure trial data. While these skin substitutes suffer from certain drawbacks such as being more invasive and, potentially, having higher rates of recurrence than what might be with dermaPACE (based on a comparison of the initial trial data to respective studies of Dermagraft and Apligraf), faster closure rate is a meaningful advantage. KCI's V.A.C. was approved for the U.S. market when the FDA hurdle was lower and V.A.C.'s pivotal trial used 16 and 20-week endpoints – it also did not require 100% wound closure. But this technology remains the dominant advanced therapy for DFU treatment and, as such, dermaPACE might need to demonstrate obvious advantages to take significant share from it.

On the other side, in November 2015 Derma Sciences halted the clinical trial for its DFU gel compound, aclerastide. While the DMC overseeing the study reported no safety concerns, lack of efficacy (complete wound closure at 12 weeks) doomed the candidate. This may or may not have implications (good or bad) for SNWV and dermaPACE. One question it prompts is if FDA is flexible on a later than 12-week endpoint. To be clear, Derma Sciences gel product and dermaPACE are completely different types of therapies, although both have been developed to target DFU. And, although DSCI voluntarily ceased the study, that does not necessarily mean that FDA would not have considered a later endpoint if they had chosen to go that route.

To be clear, we think dermaPACE can still be very competitive even if approved without meeting a 12 week closure endpoint – as we discussed in our ongoing coverage of SNWV, dermaPACE enjoys certain real advantages over other advanced DFU therapies, including a lower treatment burden, less invasiveness and what appears to be lower recurrence rates – these are potentially meaningful from a competitive standpoint. But, we think there might be at least some compromise from a marketing standpoint given that the 12-week closure objective was not met.

Model update:

Prior to the revelation that the 12-week endpoint would not be viable, we had modeled contribution from U.S. dermaPACE sales to commence in late 2016. However, following the (May 6th) news that the 12-week endpoint would not be met and the significant ambiguity about whether FDA would be open to considering additional data (including other endpoints), we removed all U.S. dermaPACE-related revenue from our model as our confidence in the U.S. approvability of the device fell to the lowest level since we began covering the company in May 2011.

We indicated at that time that our model would again be updated if warranted, which would be based on tangible news flow and future outcomes with interactions with FDA. The most recent feedback from SNWV regarding their meeting with FDA including the agency's willingness to consider additional endpoints and other data now has us more optimistic. And as such, we again updated our model to include some contribution from dermaPACE in the U.S. We have pushed our assumed initial introduction back from 2016 to 2017 due to delays caused by the missed endpoint. We have also applied a significant haircut to our sales estimates - we use a 50% haircut – which we have reduced from 75% following the positive preliminary analysis on Oct 8th. Our haircut represents risk that dermaPACE fails to gain regulatory approval as well as certain operational risks including failure to raise additional, slow adoption of dermaPACE upon launch and insufficient sales/marketing capabilities (whether that be in-house or via 3rd party distribution), among others. Additional positive and tangible headway towards approval as well as mitigation of other operational risks would likely warrant a further reduction in this risk discount. We had modeled year-2 (year-2 had been assumed to be 2017, we now assume it is 2018 or potentially sometime into 2019) U.S. sales of approximately $17.5 million - which equates to $8.75 million with the risk discount. We model 70% (or $6.1M) of this $8.75M in 2018 and the remainder in 2019.

We had not previously and still do not incorporate any potential contribution from non-medical applications. This is also subject to updating and is contingent upon further development progress, solidifying proof-of-concept and additional progress towards eventual commercialization – whether organically or via licensing / partnering. It is also possible SNWV looks to just monetize the related IP – which also holds potential promise for revenue, or at least financing upside. To be clear, we think certain of these non-medical applications may have real and, potentially significant value and we continue to remain encouraged by the recent development and validation progress – but we still feel it is too early to assign an estimated value – whether on a related-revenue or related-monetization basis.

Our modeled revenue also consists of OUS sales of ortho/dermaPACE. We think it is reasonable to assume that management's recent efforts to grow ex-U.S. sales via new distribution agreements and entry into new geographically territories can pay dividends in the form of a steepening of the overseas revenue curve. We have OUS sales growing from about $788k in the current year to approximately $2.9M in 2018.

We have used P/S comp as our valuation methodology – for consistency, we continue to use that. Smith & Nephew currently trades at approximately 3x analyst's 2018 forecasted revenue. We have SNWV generating approximately $9M in revenue in 2018 ($6.1M U.S., $2.9M OUS) - based on the SNN comp 2018 P/S multiple, this values SNWV at about $0.45/share.

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	$194.0	$788.0	$1,262.0	$1,889.0	$9,004.0
YOY Growth	*5.9%*	*45.0%*	*0.8%*	*-36.9%*	*-18.0%*	*-7.0%*	*60.1%*	*49.7%*	*376.7%*
Cost of Revenues	$220.0	$58.8	$75.8	$38.8	$55.9	$229.2	$379.6	$567.0	$4,566.3
Gross Income	$627.4	$151.6	$164.2	$104.9	$138.1	$558.8	$882.4	$1,322.1	$4,437.7
Gross Margin	*74.0%*	*72.1%*	*68.4%*	*73.0%*	*71.2%*	*70.9%*	*69.9%*	*70.0%*	*49.3%*
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%*	*409.3%*	*311.5%*	*225.4%*	*147.1%*	*29.9%*
SG&A	$3,269.1	$566.3	$636.6	$778.6	$665.0	$2,646.5	$2,624.0	$2,984.6	$3,997.8
% G&A	*385.8%*	*269.1%*	*265.3%*	*542.2%*	*342.8%*	*335.8%*	*207.9%*	*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)	($1,398.5)	($4,852.7)	($4,900.4)	($4,535.6)	($2,363.1)
Operating Margin	*-703.8%*	*-535.5%*	*-419.5%*	*-919.6%*	*-720.9%*	*-615.8%*	*-388.3%*	*-240.1%*	*-26.2%*
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)	($1,542.5)	($5,179.0)	($5,960.4)	($5,795.6)	($3,863.1)
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)	($1,542.5)	($5,179.0)	($5,960.4)	($5,795.6)	($3,863.1)
YOY Growth	*-49.9%*	*-54.3%*	*-10.3%*	*-31.7%*	*577.8%*	*-13.6%*	*15.1%*	*-2.8%*	*-33.3%*
Net Margin	*-707.3%*	*-556.8%*	*-634.3%*	*-715.0%*	*-795.1%*	*-657.2%*	*-472.3%*	*-306.8%*	*-42.9%*
EPS (continuing ops)	($0.12)	($0.02)	($0.02)	($0.02)	($0.02)	($0.08)	($0.08)	($0.08)	($0.05)
Diluted Shares O/S	48,213	62,931	63,057	63,057	63,100	63,036	72,000	76,000	80,000

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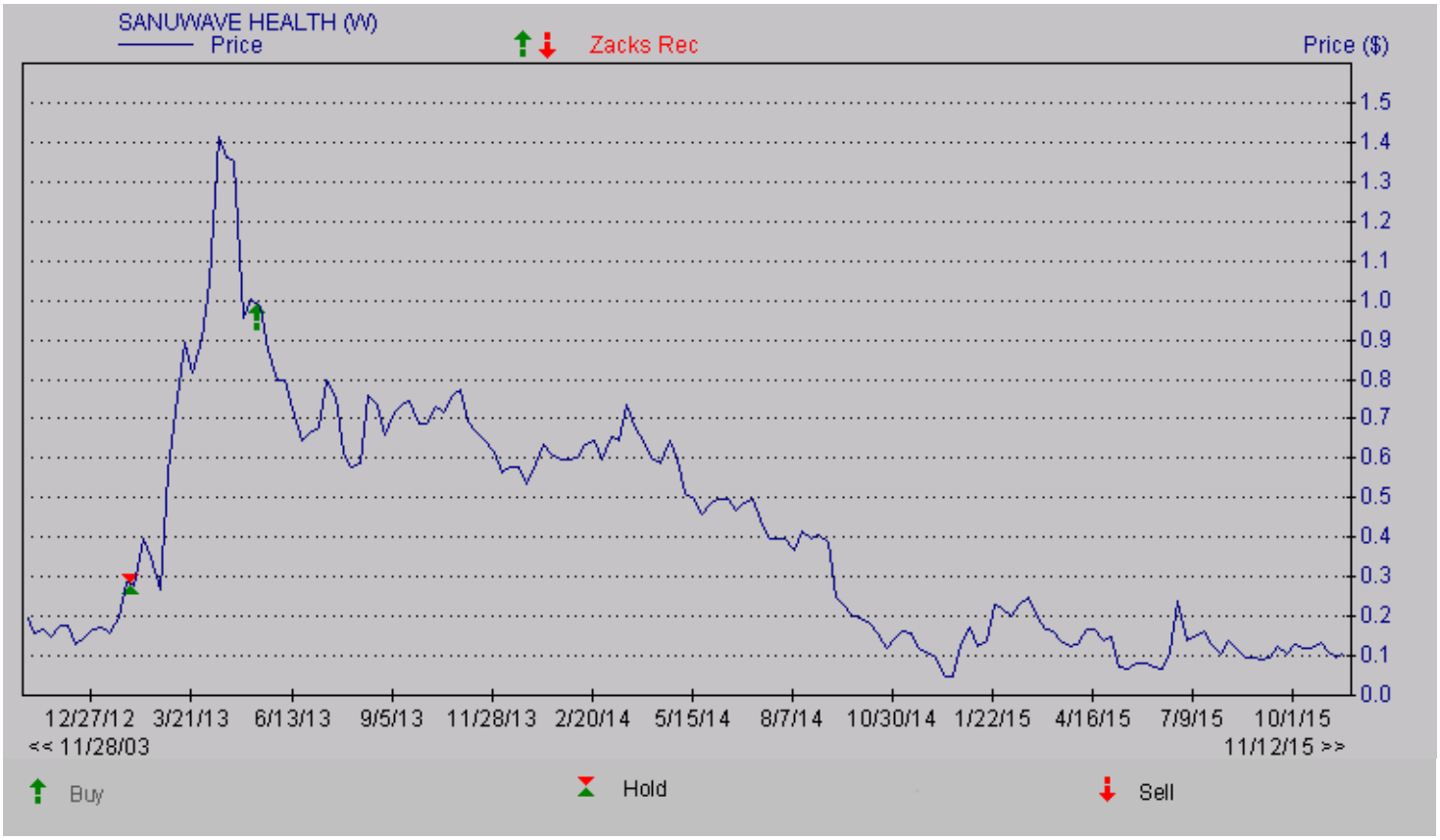

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The current distribution is as follows: Buy/Outperform- 25.4%, Hold/Neutral- 56.2%, Sell/Underperform – 14.6%. Data is as of midnight on the business day immediately prior to this publication.