May 8, 2015

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SANUWAVE Health (SNWV-OTC)

SNWV: Looking To Extend Endpoint as 12-Weeks No Good

Current Recommendation	**Buy**
Prior Recommendation	Neutral
Date of Last Change	05/15/2013
Current Price (05/08/15)	$0.07
Target Price	**$0.15**

OUTLOOK

While there were no major surprises to the Q1 financials, there was a disappointment and surprise related to operations – that being that DMC's analysis of the 130-patient supplemental trial data concluded that the primary endpoint (100% wound closure at 12 week follow-up) had not been met. While clearly not good news and "strike two", SNWV remains resilient to get on base with dermaPACE and management has a game plan which they hope will get their flagship device eventually approved by FDA.

We think the game plan makes sense and outline why we think there remains reasons to be optimistic. And while an adverse FDA decision and/or non-viable data would be another major gut-punch, we don't think it would necessarily be a death blow.

SUMMARY DATA

52-Week High	**$0.55**
52-Week Low	**$0.04**
One-Year Return (%)	**-87.90**
Beta	**1.19**
Average Daily Volume (sh)	**227,347**
Shares Outstanding (mil)	**63**
Market Capitalization ($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 (%)	**5.6**
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	231 E	244 E	258 E	944 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 E	-$0.03 E	-$0.03 E	-$0.09 E
2016					-$0.09 E
2017					-$0.08 E

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

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Q1 Financial Results, Operational Update: endpoint not met, may now pursue PMA w/ 20-week data…

SNWV reported financial results for the first quarter ending 3/31/2015 and provided a business update. While there were no major surprises to the financials, there was a disappointment and surprise related to operations – that being that DMC's analysis of the 130-patient supplemental trial data concluded that the primary endpoint (100% wound closure at 12 week follow-up) had not been met. While clearly not good news and "strike two", SNWV remains resilient to get on base with dermaPACE and management has a game plan which they hope will get their flagship device eventually approved by FDA.

Financials:
Q1 revenue came in at $211k compared to our $252k estimate. OpEx was one of the few positives in the quarter, coming in at just $1.2M and below our $1.5M estimate as management continues to look at areas to conserve resources. Net loss and EPS were $1.2M and ($0.02), compared to our $1.5M and ($0.02) estimates.

SNWV exited the quarter with approximately $2.5M in cash and equivalents. Management expects cash burn to average ~$400k - $500k per month going forward which implies the cash balance at 3/31/15 represented ~4 to 5 months worth of operating funds. The company continues to look for additional financing and has been exploring several potential options – including funding from international distribution partners, monetizing non-medical IP (licensing or potential sale) and looking at traditional financing via sale of securities.

In August the $5.4M principal of Healthtronics debt matures – management has indicated, and repeated on the Q1 call, that they have and continue to be in discussions with the lender to either modify or extend the terms of the loan. While the maturity date is looming and the debt sits at the top of the capital structure, we think it's reasonable that HT will be open to relief options given that SNWV is likely worth more alive than dead, particularly with the potential that FDA approval of dermaPACE is still a possibility.

Supplemental Study Misses Endpoint, Mgmt Considering Options:
Concurrent with the earnings release, SANUWAVE 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.

Management is now considering options:

- File PMA w/ 130 patient data: instead of the 12-week follow-up, a later endpoint is under consideration. SNWV has already engaged FDA for feedback on whether the agency will consider a later (i.e. – longer than 12 weeks) endpoint to support a potential PMA filing. The basis for considering a later endpoint mostly has to do with that results of the initial study (n=206), while also missing the 100% closure at 12 weeks primary endpoint, 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).

  The supplemental study includes a secondary endpoint, rate of recurrence at 24 weeks, so DMC has recommended that since patients are being followed for this long and 20 weeks showed statistical significance in the initial study, that consideration be given using an endpoint past the 12-week mark as a new primary 100% closure endpoint. Management expects to hear back from FDA regarding a later endpoint by the end of Q2.

  Management provided some rough potential timelines on the call if this route is followed. The last of the 130 patients is expected to hit the 24-week mark in June, data analysis would follow, then putting together the PMA package. Best-case, per management would be a filing in Q4 of this year and possibly have a decision by FDA in Q2/Q3 2016.

- Continue to enroll to 170: if FDA indicates that a later endpoint is a viable option and the data suggests that while the 130 patient data will not be sufficient but 170 patients might to hit a post-12 week endpoint, then SNWV will go ahead and add the next 40-patient tranche which would bring total enrollment to 170 patients.

  Enrolling to 170 would essentially be a last-ditch effort to get dermaPACE approved in the U.S.. It would require significantly more cash and draw out the process by at least several more months.

Later Endpoint Discussion:

- **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 green-lighted by U.S. regulators and assuming dermaPACE eventually gains FDA approval, a 20-week (or whatever length later than 12 weeks it might be) endpoint 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.

  To be clear, we think dermaPACE can still be very competitive even if approved with a post-12 week 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 by moving the endpoint to later than 12 weeks.

- **FDA:** Will FDA green-light a later endpoint? We don't know and neither does DMC, MCRA or SNWV. But we think there are reasons to be optimistic. While 12 weeks was used for Apligraf and Dermagraft, it's mostly arbitrary. Obviously the shorter time-to-heal the better but, as management noted on the call, if a wound has not improved for months using standard of care and the patient is facing amputation, if it takes dermaPACE 16 or 20 weeks to heal it instead of 12, the difference is mostly meaningless.

  Other points favoring the possibility of moving the endpoint back (or incorporating it as a co-endpoint) is:
  - there were no safety issues in the dermaPACE studies – while skin substitutes have had treatment-related adverse events.
  - SNWV will be presenting the full, un-massaged data set – as management noted, not cherry-picked in away way. So it should be black-and-white whether they hit a later endpoint.
  - retained MCRA to lead the discussion and presentation to FDA. MCRA's a heavy-hitter and recently had success with getting Wright Medical's Augment Bone Graft FDA approved via PMA after it had been initially shot down by the agency with a Not Approvable letter.
  - KCI's V.A.C was approved at 16 and 20 weeks. And more recently the pivotal study for Integra LifeSciences' Dermal Regenerative Template (collagen matrix skin substitute) used a 16 week endpoint

What happens if data isn't viable or FDA shoots down later endpoint?

If either of these things happen, there's significant repercussions. In the near-term, it may negatively affect the ease of finding financing. In the longer-term, it likely significantly lowers the ceiling of potential dermaPACE-related revenue. But, if SNWV can raise additional capital and extend the HT loan (both of which we think are possible), ex-U.S. markets, sales to which have been historically fairly tepid, could still offer substantial opportunity. SNWV has been much more aggressive as of late in tapping OUS markets including S. Korea, the GCC territory, Africa and New Zealand / Australia – in addition to looking to expand in Europe.

And while the non-medical applications are still at an early stage of development, progress continues to be made at a fairly healthy pace. Management again talked on the call about advances in both biofilm and blood purification. These are areas that have real potential to be exploited with the PACE technology – either through licensing or partnerships.

So while adverse opinion from FDA on the endpoint or non-viable post-12 week data would be another painful gut-punch, the PACE technology, we believe, has meaningful value even if dermaPACE does not make it to the U.S. market (although total value will be less and may take more time to extract).

Model update:

Prior to the revelation that 12-week endpoint is likely not viable, we had modeled contribution from U.S. dermaPACE sales to commence in late 2016. Given the ambiguity of whether post-12 weeks will be acceptable and whether the data will support a PMA filing, we have removed all U.S. dermaPACE-related revenue from our

model. This will be re-updated if and when appropriate – including likely re-incorporating U.S. revenue with positive news from FDA and data unblinding.

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 current modeled revenue now 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 revenue curve. We have OUS sales growing from about $950k in the current year to approximately $3M 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. With the changes to our model, we now have SNWV generating approximately $3M in revenue in 2018 (all of which is OUS) - based on the SNN comp 2018 P/S multiple, this values SNWV at about $0.15/share.

While our price target has moved to $0.15/share, we reiterate that positive outcomes from FDA and data unblinding will likely have us re-incorporating U.S. dermaPACE estimates and will likely have the effect of moving our price target up.

FINANCIAL MODEL

SANUWAVE Health, Inc.

	2014 A	Q1A	Q2E	Q3E	Q4E	2015 E	2016 E	2017 E	2018 E
Total Revenues	$847.4	$210.5	$231.0	$244.0	$258.0	$943.5	$1,262.0	$1,889.0	$2,961.0
YOY Growth	*5.9%*	*45.0%*	*-3.0%*	*7.3%*	*9.0%*	*11.3%*	*33.8%*	*49.7%*	*56.7%*
Cost of Revenues	$220.0	$58.8	$67.7	$70.8	$74.3	$271.6	$379.6	$566.7	$888.3
Gross Income	$627.4	$151.6	$163.3	$173.2	$183.7	$671.9	$882.4	$1,322.3	$2,072.7
Gross Margin	*74.0%*	*72.1%*	*70.7%*	*71.0%*	*71.2%*	*71.2%*	*69.9%*	*70.0%*	*70.0%*
R&D	$3,000.8	$634.6	$651.0	$794.0	$814.0	$2,893.6	$2,844.0	$2,778.0	$2,688.0
% R&D	*354.1%*	*301.6%*	*281.8%*	*325.4%*	*315.5%*	*306.7%*	*225.4%*	*147.1%*	*90.8%*
SG&A	$3,269.1	$566.3	$644.0	$681.0	$665.0	$2,556.3	$2,624.0	$2,715.0	$2,777.0
% G&A	*385.8%*	*269.1%*	*278.8%*	*279.1%*	*257.8%*	*271.0%*	*207.9%*	*143.7%*	*93.8%*
Depreciation	$14.3	$0.9	$5.0	$5.0	$5.0	$15.9	$50.0	$70.0	$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)	($1,213.4)	($1,383.5)	($1,377.0)	($5,100.7)	($4,942.4)	($4,295.7)	($3,507.3)
Operating Margin	*-703.8%*	*-535.5%*	*-525.3%*	*-567.0%*	*-533.7%*	*-540.6%*	*-391.6%*	*-227.4%*	*-118.4%*
Total Other Expense	($10.6)	($32.2)	($80.0)	($203.0)	($215.0)	($530.2)	($1,060.0)	($1,260.0)	($1,500.0)
Pre-Tax Income	($5,974.1)	($1,159.1)	($1,293.4)	($1,586.5)	($1,592.0)	($5,687.0)	($6,002.4)	($5,555.7)	($5,007.3)
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)	($1,293.4)	($1,586.5)	($1,592.0)	($5,687.0)	($6,002.4)	($5,555.7)	($5,007.3)
YOY Growth	*-49.9%*	*-54.3%*	*-23.8%*	*5.5%*	*599.6%*	*-5.1%*	*5.5%*	*-7.4%*	*-9.9%*
Net Margin	*-707.3%*					*-602.8%*	*-475.6%*	*-294.1%*	*-169.1%*
EPS (continuing ops)	($0.12)	($0.02)	($0.02)	($0.03)	($0.03)	($0.09)	($0.09)	($0.08)	($0.07)
Diluted Shares O/S	48,213	62,931	63,100	63,210	63,300	63,135	65,000	66,000	70,000

Brian Marckx, CFA

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