August 12, 2015

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: Data Unblinding in Sept, PMA Filing Could Come Shortly Afterward

Current Recommendation	**Buy**
Prior Recommendation	Neutral
Date of Last Change	05/15/2013
Current Price (08/12/15)	$0.13
Target Price	**$0.35**

OUTLOOK

There was a recent 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. Expect data announcement in September – if positive, SNWV will proceed with PMA submission.

SUMMARY DATA

52-Week High	**$0.44**
52-Week Low	**$0.04**
One-Year Return (%)	**-64.47**
Beta	**0.36**
Average Daily Volume (sh)	**125,578**
Shares Outstanding (mil)	**63**
Market Capitalization ($mil)	**$8**
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 (%)	**4.6**
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	240 A	244 E	258 E	952 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 E	-$0.02 E	-$0.09 E
2016					-$0.09 E
2017					-$0.08 E

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

© Copyright 2015, Zacks Investment Research. All Rights Reserved.

Q2 Financial Results, Operational Update: Data Unblind in Sept, Continue to Expect PMA Filing Afterwards..

SNWV reported financial results for the second quarter ending June 30th and provided a business update. The financials came in somewhat better than our estimate, mostly from lower than expected spend on R&D – which came down more than we anticipated from reduced clinical trial-related expenses. Cash burn moderated some as compared to the first quarter of the year. Cash balance stood at about $1.6 million at the end of Q2 and is expected to be enough to fund the company into the fourth quarter. SNWV is looking to raise additional capital and is open to considering other options, including JV's and partnerships.

Relative to the operational update, there was not much more news relative to dermaPACE and the quest to get it to the U.S. market since the company's investor call on June 30th. The next major milestone is still expected to be sometime in September (next month) when SNWV hopes to be able to announce top-line data. We provide discussion about the current status below.

Financials:
Q2 revenue came in at $240k compared to our $231k estimate. OpEx of $1.2 million was down from Q1 ($1.3 million) and below our $1.4 million estimate. This was the beneficiary of low R&D expense which relates to the relative lull in clinical trial and regulatory activities during Q2. We think this will come back up though with data analysis and PMA submission activities. Meanwhile SG&A was up slightly from Q1 and came in right at our number. Net loss and EPS, excluding $429k non-cash loss on derivative revaluation, were approximately $1.1 million and ($0.02), compared to our $1.3 million and ($0.02) estimates.

SNWV successfully extended the maturity of the HealthTronics notes ($5.3 million principal) from August 2015 (original) to January 2017 (amended). As we noted in our June Investor Note, the terms look to be fairly favorable. The notes, which originally were unsecured are now fully secured by all assets of the company and HT receives 3.3 million, 10-year warrants with $0.55 strike - that, in our opinion, is about as painless as could be hoped for. But while this relieves a near-term issue, the company will still need to raise capital or fund themselves in other ways (JV, partnership, etc) to maintain operations.

In July shareholders approved increasing the number of authorized common shares from 155 million to 355 million (although add'l common raise is just one option). SNWV noted on the Q2 call that they are also pursuing discussions with potential partners to potentially help fund the PMA process and to (potentially) distribute dermaPACE if and when approved in the U.S. Potential partners could include other companies in the DFU space which already have established sales and marketing infrastructure. We may hear more about this on the expected Sept data call.

Clinical Trial Update: positive feedback from FDA, forging ahead with PMA…

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.

The next significant timepoint is expected to be sometime in September when SNWV hopes to be able to announce top-line data. Once unblinded and analyzed they will then make a decision about whether or not to go forward with a PMA submission. While there is still significant ambiguity of what FDA will consider “acceptable” in terms of supporting data to approve dermaPACE, management noted on the Q2 call that a minimum hurdle that they are confident will have to be cleared is to show statistical significance. So we think it is reasonable to think that SNWV will go forward with the PMA submission if statistical significance is demonstrated (at, for example 20 weeks or 24 weeks). SNWV will provide an update when the data is unblinded – roughly 4 to 6 weeks from now.

Assuming the data is positive, they anticipate a PMA filing could happen in Q4 of this year or early Q1 of next.

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.

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.

HealthTronics Loan Extended, Provides More Breathing Room (from our June 18th update):

On June 18th SNWV announced that they amended the maturity date of the $5.3 million HealthTronics notes from August 2015 (original) to January 31, 2017 (amended date). Terms look to be fairly favorable. The notes, which originally were unsecured are now fully secured by all assets of the company and HT receives 3.3 million, 10-year warrants with $0.55 strike - that, in our opinion, is about as painless as could be hoped for.

As we noted in our update following Q1 results announcement, we expected that HT would 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. This amendment provides not only additional breathing room for SNWV to advance its pipeline but should also eliminate what might have been a significant hindrance to raising additional capital.

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 75% haircut which we think fairly represents the risk that dermaPACE fails to gain U.S. approval. Additional positive and tangible headway towards approval would likely warrant a reduction in this risk discount. We had modeled year-2 (year-2 had been assumed to be 2017, we now assume it is 2018) U.S. sales of approximately $17.5 million - which equates to $4.4 million with the risk discount.

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 $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. We have SNWV generating approximately $7.3M in revenue in 2018 ($4.3M U.S., $3M OUS) - based on the SNN comp 2018 P/S multiple, this values SNWV at about $0.35/share.

FINANCIAL MODEL

SANUWAVE Health, Inc.

	2014 A	Q1A	Q2A	Q3E	Q4E	2015 E	2016 E	2017 E	2018 E
Total Revenues	$847.4	$210.5	$240.0	$244.0	$258.0	$952.4	$1,262.0	$1,889.0	$2,961.0
YOY Growth	*5.9%*	*45.0%*	*0.8%*	*7.3%*	*9.0%*	*12.4%*	*32.5%*	*49.7%*	*56.7%*
Cost of Revenues	$220.0	$58.8	$75.8	$70.8	$74.3	$279.7	$379.6	$567.0	$888.3
Gross Income	$627.4	$151.6	$164.2	$173.2	$183.7	$672.8	$882.4	$1,322.1	$2,072.7
Gross Margin	*74.0%*	*72.1%*	*68.4%*	*71.0%*	*71.2%*	*70.6%*	*69.9%*	*70.0%*	*70.0%*
R&D	$3,000.8	$634.6	$456.8	$762.0	$794.0	$2,647.4	$2,844.0	$2,778.0	$2,688.0
% R&D	*354.1%*	*301.6%*	*190.3%*	*312.3%*	*307.8%*	*278.0%*	*225.4%*	*147.1%*	*90.8%*
SG&A	$3,269.1	$566.3	$636.6	$681.0	$665.0	$2,548.9	$2,624.0	$2,229.0	$2,285.9
% G&A	*385.8%*	*269.1%*	*265.3%*	*279.1%*	*257.8%*	*267.6%*	*207.9%*	*118.0%*	*77.2%*
Depreciation	$14.3	$0.9	$0.9	$5.0	$5.0	$11.9	$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)	($1,006.8)	($1,351.5)	($1,357.0)	($4,842.1)	($4,942.4)	($3,810.0)	($3,016.2)
Operating Margin	*-703.8%*	*-535.5%*	*-419.5%*	*-553.9%*	*-526.0%*	*-508.4%*	*-391.6%*	*-201.7%*	*-101.9%*
Total Other Expense	($10.6)	($32.2)	($514.8)	($203.0)	($215.0)	($965.0)	($1,060.0)	($1,260.0)	($1,500.0)
Pre-Tax Income	($5,974.1)	($1,159.1)	($1,521.5)	($1,554.5)	($1,572.0)	($5,433.8)	($6,002.4)	($5,070.0)	($4,516.2)
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)	($1,554.5)	($1,572.0)	($5,433.8)	($6,002.4)	($5,070.0)	($4,516.2)
YOY Growth	*-49.9%*	*-54.3%*	*-10.3%*	*3.4%*	*590.8%*	*-9.3%*	*10.5%*	*-15.5%*	*-10.9%*
Net Margin	*-707.3%*					*-570.5%*	*-475.6%*	*-268.4%*	*-152.5%*
EPS (continuing ops)	($0.12)	($0.02)	($0.02)	($0.02)	($0.02)	($0.09)	($0.09)	($0.08)	($0.06)
Diluted Shares O/S	48,213	62,931	63,057	63,210	63,300	63,124	65,000	66,000	70,000

Brian Marckx, CFA

© Copyright 2015, Zacks Investment Research. All Rights Reserved.

HISTORICAL ZACKS RECOMMENDATIONS



© Copyright 2015, Zacks Investment Research. All Rights Reserved.

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, Brian Marckx, CFA, CFA, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESMENT BANKING, REFERRALS, AND FEES FOR SERVICE

Zacks SCR does not provide nor has received compensation for investment banking services on the securities covered in this report. Zacks SCR does not expect to receive compensation for investment banking services on the Small-Cap Universe. Zacks SCR may seek to provide referrals for a fee to investment banks. Zacks & Co., a separate legal entity from ZIR, is, among others, one of these investment banks. Referrals may include securities and issuers noted in this report. Zacks & Co. may have paid referral fees to Zacks SCR related to some of the securities and issuers noted in this report. From time to time, Zacks SCR pays investment banks, including Zacks & Co., a referral fee for research coverage.

Zacks SCR has received compensation for non-investment banking services on the Small-Cap Universe, and expects to receive additional compensation for non-investment banking services on the Small-Cap Universe, paid by issuers of securities covered by Zacks SCR Analysts. Non-investment banking services include investor relations services and software, financial database analysis, advertising services, brokerage services, advisory services, equity research, investment management, non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per client basis and are subject to the number of services contracted. Fees typically range between ten thousand and fifty thousand USD per annum.

POLICY DISCLOSURES

Zacks SCR Analysts are restricted from holding or trading securities placed on the ZIR, SCR, or Zacks & Co. restricted list, which may include issuers in the Small-Cap Universe. ZIR and Zacks SCR do not make a market in any security nor do they act as dealers in securities. Each Zacks SCR Analyst has full discretion on the rating and price target based on his or her own due diligence. Analysts are paid in part based on the overall profitability of Zacks SCR. Such profitability is derived from a variety of sources and includes payments received from issuers of securities covered by Zacks SCR for services described above. No part of analyst compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports are based on data obtained from sources we believe to be reliable, but are not guaranteed as to be accurate nor do we purport to be complete. Because of individual objectives, this report should not be construed as advice designed to meet the particular investment needs of any investor. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

ZACKS RATING & RECOMMENDATION

ZIR uses the following rating system for the 1164 companies whose securities it covers, including securities covered by Zacks SCR:
Buy/Outperform: The analyst expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters.
Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution is as follows: Buy/Outperform- 29.0%, Hold/Neutral- 53.0%, Sell/Underperform – 15.0%. Data is as of midnight on the business day immediately prior to this publication.