May 16, 2013

Brian Marckx, CFA
bmarckx@zacks.com
Ph (312) 265-9474

Zacks Small-Cap Research

scr.zacks.com 111 North Canal Street, Chicago, IL 60606

SANUWAVE Health (SNWV-OTC)

SNWV: Q1 Results, Supplemental Trial Gearing Up

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	05/15/2013
Current Price (05/15/13)	$1.00
Target Price	**$1.60**

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 Q2 2013.
Recent progress also includes new CEO brought on in early 2013 with incentive-laden contract, $2MM+ in new financing, game-plan to expand ex-U.S. distribution, investigating derivative applications of technology for possible out-licensing.

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	**$1.59**
52-Week Low	**$0.09**
One-Year Return (%)	**167.65**
Beta	**0.23**
Average Daily Volume (sh)	**54,071**
Shares Outstanding (mil)	**21**
Market Capitalization ($mil)	**$21**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**24**
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 2013 Estimate	**N/A**
P/E using 2014 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)
2012	239 A	210 A	178 A	142 A	769 A
2013	201 A	174 E	212 E	225 E	812 E
2014					1,177 E
2015					2,170 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	-$0.09 A	-$0.07 A	-$0.07 A	-$0.08 A	-$0.31 E
2013	-$0.25 A	-$0.10 E	-$0.08 E	-$0.06 E	-$0.30 E
2014					-$0.15 E
2015					-$0.06 E

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

© Copyright 2013, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW…

Q1 RESULTS

On May 14th SANUWAVE announced financial results for the first quarter ending March 31, 2013. Results were largely in-line and actually slightly better (ex-non cash items) than our estimates. While revenue was about 22% higher than our estimate, the more meaningful "beat" compared to our numbers was in operating expenses which management continues to closely watch. And the most meaningful part of Q1 had to do with management's significant progress with getting the supplemental trial geared up (along with movement on other areas of the business) - while keeping cash burn and expenses to a minimum.

Q1 revenue came in at $201k compared to our $165k estimate. Operating expenses of $1.3 million were at the lowest level in at least the last five years and below our 1.5 million estimate. Operating income was ($1.1) million, well ahead of our ($1.4) million estimate. Q1 net income and EPS were ($5.4) million and ($0.25). Important to note is that SNWV recorded a $3.7 million (non-cash) expense related to revaluation of embedded derivatives (conversion feature) in the recently issued convertible notes (which relates to the recent significant appreciation of the stock price) as well as $429k of non-cash debt-discount amortization (also related to the conversion feature).

Meanwhile, the company continues to build on their recent operational progress. SNWV had already recently brought on a new CEO, raised bridge financing, and expanded both their commercial geographic footprint as well as the potential applications for their technology. The most recent highlights are the hiring of Dr. Dan Jorgensen as the company's Chief Medical Officer and who will be in charge of overseeing the supplemental dermaPACE trial and a successful investigator meeting which was held just days ago. Dr. Jorgensen comes with broad experience in overseeing clinical trials (management noted on the call he's led ~25 trials) and with FDA submissions and approvals with biotech and pharmaceutical companies, including Pfizer. We view the addition of Dr. Jorgensen as a significant positive, not only for the experience he brings but also as indicative support for the potential of dermaPACE to gain FDA approval and eventually be successful in the clinical marketplace.

Dr. Jorgensen noted on the call that the investigator meeting, held May 10th-11th in Atlanta, drew about 75 representatives from 18 of the expected 20 clinical trial sites and was overwhelmingly positive. Management outlined the importance of completing training of the site participants to ensure effective and maximum enrollment, adherence to study protocols, and to maximize the chances to hit the study endpoints - the message from management on the call was there was substantial success in this regard. Timelines relative to screening patients and enrollment remain on-track with earlier expectations.

Cash
Cash used in operations in Q1 was $1.0 million but excluding changes in working capital, cash used in operations was $620k. SNWV exited Q1 with $671k in cash and equivalents. SNWV notes in the 10-Q that they expect to raise an additional ~$600k through the issuance of promissory notes through June (a portion of which has already been raised). They have also filed an S-1 to raise up to $6 million in equity. The funds will be used for the supplemental trial as well as ongoing operating expenses.

The currently outstanding 18% senior secured convertible promissory notes mature 6 months from the subscription date ($430k in May 2013, $1.6MM in August 2013), are convertible to common stock at anytime at $0.20/share and will automatically convert if SNWV consummates a qualified financing (common stock offering or a stock offering plus technology licensing/royalty agreement) of at least $4 million.

Management noted on the call that 2013 cash burn is anticipated to be ~$575k/mth - $625k/mth during the course of the trial (we ballpark ~$5.0MM - $5.5MM for the full year).

OPERATIONAL UPDATE

- **Supplemental Trial:**
  - CRO in place, Dr. Jorgensen overseeing study, trial site training largely completed
  - Indentified 20 clinical study sites and currently have contracts with 18 of these. Seven of these sites are the highest enrolling sties from the pivotal trial and are expected to enroll ~70% of the ~90-patient total enrollment of the supplemental trial

- Patient screening for the supplemental trial is expected to be imminent. Enrollment could also commence Q2 2013.
- SNWV's anticipated timelines (intact from earlier guidance) include; final patient expected to be enrolled in Q1 2014, last patient follow-up in Q2 2014, submit PMA in Q4 2014, and FDA approval in 2015

- **Distribution:** SNWV is now pursuing additional ex-U.S. distribution for dermaPACE, orthoPACE and Evotron to help build on the current relatively meager revenue contribution. Earlier this year SNWV announced entry in the Australian and New Zealand markets (see below). The game-plan going forward is to expand their footprint further in existing geographies including Europe and Asia. SNWV had previously not pursued much in the way of expanding their ex-U.S. presence - partly due to the focus on the U.S. development of dermaPACE. Reimbursement is also an issue outside the U.S. - so we expect SNWV will be picking its spots - both geographically as well as engaging distributors that have experience with navigating the reimbursement issues inherent in these countries.

- **orthoPACE FDA Pathway:** SNWV is now in the early stage of investigating the FDA regulatory pathway for orthoPACE, which is currently sold only outside of the U.S. Management noted that they could only provide limited details at this juncture but did say that they have a meeting with FDA in the coming weeks to discuss a pathway for approval and hope to be able to potentially build off of the approval for their legacy OssaTron device (used for Plantar Fascitis and heel pain), which is the successor to orthoPACE but unlike the ~800lb OssaTron, orthoPACE is compact and portable. Goal of the meeting is to find the quickest pathway for approval of orthoPACE.

- **Derivative Applications**: Management is now looking at derivative applications for its shockwave technology including non-medical uses such as in energy production (enhanced oil extraction, fracking water cleaning), in food applications (food preservation, meat tenderizing) and in other industrial applications. Management provided some color on this on the Q4 call (and again on the Q1 2013 call) and clearly views this as a real opportunity. The company believes there are real potential out-licensing opportunities for its technology and noted on the call that early/initial discussions have already begun with at least one potential interested party. Indications are that this is still on the very front end with no expectations of near-term financial contribution from this - but we think it's fair to categorize this as having a potential mid-to-long-term opportunity.

  Along the theme of derivative applications, in April SNWV announced receipt of a U.S. patent to sterilize blood using shock waves. Blood sterilization could potentially be one of the low-hanging-fruit opportunities for SNWV outside of the medical space. Shock wave technology has been used for years in lithotripsy devices to break up kidney stones. In fact SNWV acquired Healthtronics' orthopedic business in 2005 which facilitated the development of the company's dermaPACE device. HealthTronics is a leading manufacturer of lithotripsy devices. It was found that when lithotripsy devices were first being used to break up kidney stones that the shock waves also had the effect of killing bacteria. This anti-bacterial effect has also been observed during wound treatment therapy. Shock waves have also shown to have a similar effect on viruses. Given this anti-bacterial/anti-virus efficacy and a significant unmet need for a safe and effective means to clean blood (for example for blood transfusions and blood donations), blood cleaning seems like a natural pursuit for SNWV's endeavor to broaden the potential market for their technology.

LAUNCH IN AUSTRALIA / NEW ZEALAND

Earlier this year SNWV announced that dermaPACE has received regulatory approval in Australia and New Zealand for treating acute and chronic wounds, an annual market opportunity estimated at approximately 500k+ patients. In connection with the launch in those countries, the company penned a distribution agreement with Aurora BioScience, which caters to a number of large customers including public departments of health, the Australian Red Cross Blood Service, and public and private hospitals. Relative to the opportunity for dermaPACE in Australia and New Zealand, Aurora BioScience's Managing Director, Darren Banks noted, "We believe the dermaPACE device can provide improved patient outcomes at reduced costs. We are expecting the first procedures to be undertaken in Australia in late March with many hospitals and clinics extremely excited to evaluate the product."

Supplemental Trial Enrollment Slated to Commence Q2 2013 *(per our 11/16/2012 report, with current updates)*
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 on the Q1 2013 call). 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 Q2 2013 as they needed to secure financing. Bridge financing has since been put in place, with a larger capital raise expected in the next few months to help fund the study. During Q1 2013 they finalized selection of the 20 sites and have contracts with 18 of them. An investigator meeting was held in May 2013 which drew about 75 representatives from 18 of the expected 20 clinical trial sites and was overwhelmingly positive. Management outlined the importance of completing training of the site participants to ensure effective and maximum enrollment, adherence, and to maximize the chances to hit the study endpoints to study protocol - the message from management on the Q1 call was there was substantial success in this regard. Patient screening followed by enrollment should commence imminently.

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.

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 2016 P/S comparables to value SNWV. Smith & Nephew currently trades at approximately 2.2x analyst's 2016 forecasted revenue. We currently model SNWV to generate revenue of about $17 million in 2016 – based on the SNN comp 2016 P/S multiple, this values SNWV at about $1.60/share.

FINANCIAL MODEL

SANUWAVE Health, Inc.

	2012 A	Q1A	Q2E	Q3E	Q4E	2013 E	2014 E	2015 E	2016 E
Total Revenues	$769.2	$201.2	$174.0	$212.0	$225.0	$812.2	$1,177.0	$2,170.3	$16,972.7
YOY Growth	*-4.2%*	*-15.6%*	*-17.3%*	*18.9%*	*58.4%*	*5.6%*	*44.9%*	*84.4%*	*682.1%*
Cost of Revenues	$220.3	$55.8	$52.2	$63.6	$67.5	$239.1	$353.1	$663.5	$4,141.6
Gross Income	$548.9	$145.4	$121.8	$148.4	$157.5	$573.1	$823.9	$1,506.8	$12,831.1
Gross Margin	*71.4%*	*72.3%*	*70.0%*	*70.0%*	*70.0%*	*70.6%*	*70.0%*	*69.4%*	*75.6%*
R&D	$1,762.2	$344.7	$450.0	$725.0	$865.0	$2,384.7	$3,850.0	$3,350.0	$2,750.0
% R&D	*229.1%*	*171.3%*	*258.6%*	*342.0%*	*384.4%*	*293.6%*	*327.1%*	*154.4%*	*16.2%*
SG&A	$4,522.0	$851.9	$1,125.0	$1,222.0	$1,294.0	$4,492.9	$5,218.0	$1,606.0	$9,674.4
% G&A	*587.9%*	*423.3%*	*646.6%*	*576.4%*	*575.1%*	*553.2%*	*443.3%*	*74.0%*	*57.0%*
Depreciation	$20.4	$5.0	$5.1	$5.1	$5.1	$20.3	$40.0	$80.0	$125.0
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	($6,062.5)	($1,132.9)	($1,535.0)	($1,880.4)	($2,083.3)	($6,631.6)	($8,590.9)	($3,836.1)	($25.1)
Operating Margin	*-788.2%*	*-563.0%*	*-882.2%*	*-887.0%*	*-925.9%*	*-816.5%*	*-729.9%*	*-176.8%*	*-0.1%*
Gain (loss) on asset sale	$0.0	$7.5	$0.0	$0.0	$0.0	$7.5	$0.0	$0.0	$0.0
Svcs provided to Pulse Vet.	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Extinguishment of debt	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Loss on derivative revaluation	$0.0	($3,737.0)	$0.0	$0.0	$0.0	($3,737.0)	$0.0	$0.0	$0.0
Interest expense, net	($331.7)	($508.9)	($750.0)	($800.0)	($665.0)	($2,723.9)	($360.0)	($250.0)	($50.0)
Loss of FX	($7.5)	$1.9	$0.0	$0.0	$0.0	$1.9	$0.0	$0.0	$0.0
Pre-Tax Income	($6,401.6)	($5,369.3)	($2,285.0)	($2,680.4)	($2,748.3)	($9,346.0)	($8,950.9)	($4,086.1)	($75.1)
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%*	*0.0%*
Discontinued Operations	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	($6,401.6)	($5,369.3)	($2,285.0)	($2,680.4)	($2,748.3)	($9,346.0)	($8,950.9)	($4,086.1)	($75.1)
YOY Growth	*-37.5%*	*192.6%*	*60.4%*	*85.2%*	*62.2%*	*46.0%*	*-4.2%*	*-54.4%*	*-98.2%*
Net Margin	*-832.3%*					*-1150.7%*	*-760.5%*	*-188.3%*	*-0.4%*
EPS (continuing ops)	($0.31)	($0.25)	($0.10)	($0.08)	($0.06)	($0.30)	($0.15)	($0.06)	($0.00)
Diluted Shares O/S	20,916	21,278	23,500	35,000	44,000	30,945	60,000	69,000	74,000

Brian Marckx, CFA

© Copyright 2013, Zacks Investment Research. All Rights Reserved.

HISTORICAL ZACKS RECOMMENDATIONS



DISCLOSURES

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

ZIR or Zacks SCR Analysts do not hold or trade securities in the issuers which they cover. Each analyst has full discretion on the rating and price target based on their 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 non-investment banking services. 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 blog.

ZIR and Zacks SCR do not make a market in any security nor do they act as dealers in securities. Zacks SCR has never received compensation for investment banking services on the small-cap universe. Zacks SCR does not expect received compensation for investment banking services on the small-cap universe. 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. Non-investment banking services include investor relations services and software, financial database analysis, advertising services, brokerage services, advisory services, investment research, and investment management.

Additional information is available upon request. Zacks SCR reports are based on data obtained from sources we believe to be reliable, but is not guaranteed as to accuracy and does not purport to be complete. Because of individual objectives, the 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. Reports are not to be construed as an offer or the solicitation of an offer to buy or sell the securities herein mentioned. Zacks SCR uses the following rating system for the securities it covers. 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 of Zacks Ratings is as follows on the 1028 companies covered: Buy/Outperform- 15.0%, Hold/Neutral- 78.7%, Sell/Underperform – 5.4%. Data is as of midnight on the business day immediately prior to this publication.

© Copyright 2013, Zacks Investment Research. All Rights Reserved.