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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: Trial Timelines Intact, Enrollment 50% Completed

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	05/15/2013
Current Price (11/12/13)	$0.70
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 off to strong start and now one-half complete.
Recent progress also includes new CEO brought on in early 2013 with incentive-laden contract, 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	**$0.09**
One-Year Return (%)	**349.38**
Beta	**1.84**
Average Daily Volume (sh)	**60,676**
Shares Outstanding (mil)	**36**
Market Capitalization ($mil)	**$25**
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 (%)	**-4.6**
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	161 A	148 A	210 E	720 E
2014					1,140 E
2015					2,155 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	-$0.04 A	-$0.14 A	-$0.05 E	-$0.35 E
2014					-$0.15 E
2015					-$0.06 E

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

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WHAT'S NEW…

Q3 RESULTS

On November 12th SANUWAVE announced financial results for the third quarter ending September 30, 2013. Revenue came in lower than our estimate but stronger than modeled gross margin and an in-line level of operating expenses netted out to operating income just about dead-on with our number. SNWV also did some balance sheet cleaning during the quarter, converting the $2.2 million principal and interest of senior notes to equity. Highlights on the operational side include the dermaPACE supplemental trial continuing to track previous announced timelines with 50% of the minimum number of patients now enrolled and completion still expected in Q1 2014.

Q3 revenue came in at $148k compared to our $205k estimate. Gross margin, which jumped to 85% in Q2 (for reference, GM was 71.4% in 2012), remained very healthy in Q3 at 80% and was substantially better than our 70% estimate. GM has benefitted from increased sales of higher margin applicators. Operating expenses of $2.0 million were in-line with our $2.0 million estimate. Operating income was ($1.9) million, compared to our ($1.9) million estimate.

Net income and EPS were ($4.4) million and ($0.14). Excluding $2.0 million in non-cash expense, which is mostly related to the conversion of debt to equity, net income and EPS were ($2.4) million and ($0.08), compared to our ($2.3) million and ($0.08) estimates.

Timelines relative to patient enrollment and estimated completion of the supplemental dermaPACE trial continues to track earlier expectations, which we view as a major positive and a testament to efforts of the clinical trial team, CRO and the initial leg-work done in design of the trial and site selection as well as in ensuring continued high-quality patient enrollment. With 45 patients now enrolled and initiated treatment, the minimum patient enrollment is now at the halfway point. Of significance and for reference to the swiftness of enrollment, as management pointed out on the call, is that this supplemental trial has reached the 45-patients enrolled point at about 4 months after initiation while the initial pivotal phase III study took 9 months to hit the 45-patient mark. Inclusion of high-quality patients, low drop out rates and adherence to the strict trial protocol should also help facilitate FDA review and, assuming eventual regulatory approval, provide a compelling message of utility and efficacy of dermaPACE in the treatment of DFU to the medical community. Management noted on the call that patient drop out has been minimal, which can be key to hitting the Q1 2014 estimated completion date.

The first patient was enrolled in June and through early November, 45 of the minimum 90 patients have been enrolled. All enrolled patients have started treatment. Anticipated trial timelines remain intact including; 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. As we've noted in the past, we believe the trial design, including using treatment boosts to improve on efficacy, the use of Bayesian statistics, and the detailed preparatory work in putting the study together and executing the study (experienced CRO and Chief Medical Officer, investigator meetings, strong relationships with trial sites, detailed selection of patients, etc.) bode well for the chances for hitting the primary endpoint.

Management also provided an update on other aspects of the business during the conference call. Relative to derivative applications of the PACE technology (all of which are likely somewhat back-burner projects as they dedicate most of their focus and resources towards dermaPACE for the U.S. market), work continues on building a scale model for application in cleaning frack water. Management noted that they already have early interest in such an application. As we noted previously, we view this as a potentially attractive market given the recent explosion in hydrocracking for natural gas extraction and concerns over toxicity of frack water. Blood sterilization is another area that the company has investigated and noted that they recently began working with a "major university" to collect data for this potential application.

Relative to commercialization outside of the U.S., SANUWAVE continues to make headway in their quest to expand their international footprint. In September orthoPACE received regulatory approval in South Korea where SANUWAVE has penned an agreement with KOVE Ltd for distribution. Management again noted on the conference call that continued growth OUS is priority and discussions with distributors in various parts of Europe are ongoing.

Cash
Cash used in operations in Q3 was $1.4 million but excluding changes in working capital, cash used in operations was $1.3 million. SNWV exited Q3 with $334k in cash and equivalents. In addition the balance sheet was cleaned

up with the conversion of all of the senior secured notes which were issued in late 2012 and early 2013. Including accrued interest, $2.2MM was converted to common stock. Management continues to expect monthly cash burn to average about $575k - $625k during the course of the trial. They have estimated that direct costs of the trial will be about $3.8MM through 2014 and that they will need about $8.5 million total to get them through FDA approval. They will be looking to opportunistically raise additional capital in the near term and expect the next raise to occur in Q4.

OPERATIONAL UPDATE

- **Supplemental Trial:**
  - CRO in place, Dr. Jorgensen overseeing study, trial site training completed
  - Indentified 20 clinical study sites and have IRB approvals at all sites. 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
  - Enrollment commenced in June. Currently have 45 (up from 30 in mid-August) patients enrolled which have commenced treatment. Patient screening continues for remaining enrollment
  - Management indicated on Q3 call that drop-out rates are minimal
  - 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. In September orthoPACE received regulatory approval in South Korea where SANUWAVE has penned an agreement with KOVE Ltd for distribution. 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. On the Q3 call they noted that discussions are ongoing with distributors in parts of Europe, including Italy, Belgium and the Netherlands. Also noting that their Australian distributor, Aurora Biosciences has been successful in developing account and key opinion leader relationships to help facilitate adoption in that country.

- **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 recently had a meeting with FDA 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 was to find the quickest pathway for approval of orthoPACE. Management noted on the Q3 call that the likely game-plan would be to run small clinical studies to help determine which application, tendinitis or plantar fasciitis, provides the most early potential prior to committing to larger studies. We however, do not expect substantial time or resources to be spent on this while the company is focused on FDA approval of dermaPACE.

- **Derivative Applications**: Management recently announced that they started 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 last few earnings calls 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. On the Q3 call management noted that they have begun working with a "major university" on collecting data for animal blood purification - which will be the initial step prior to moving to human blood.

Management also recently talked about applications for microsurgery and frack water cleaning. Dr. Maria Siemionow, Head of Microsurgical Training at the Cleveland Clinic, made a presentation at the 2013 World Congress of Microsurgery in July of pre-clinical results using PACE technology in reducing tissue injury from surgery by inducing an anti-inflammatory effect. SANUWAVE expects to investigate a potential application for use as an adjunct during microsurgery procedures - management noted that they may have more details on this in the next few months - although this is still a back-burner project. The other potential near-term application that management appears to be excited about is for use in cleaning frack water which is used to extract gas from shale in gas well drilling. Proof of concept has been completed and is now in process of building a small scale model which can be used for demonstration purposes - which could be completed in the next couple of months. Management noted that they already have early interest in such an application. With the recent explosion in hydrocracking for natural gas extraction and concerns over toxicity of frack water, this would be a potentially large market.

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." SNWV management mentioned on the Q3 call that Aurora has been successful in developing account and key opinion leader relationships to help facilitate adoption.

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 Q3 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 this was pushed back due to the need to secure additional financing. With bridge financing in place, enrollment commenced in June 2013 and through early November, 45 (up from 30 in August) of the minimum 90 patients had been enrolled and started treatment. IRB approvals have now been attained at all 20 trial sites. 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 has been that there was substantial success in this regard.

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 2x analyst's 2017 forecasted revenue. We currently model SNWV to generate revenue of about $25 million in 2017 – based on the SNN comp 2017 P/S multiple, this values SNWV at about $1.60/share. We are maintaining our Outperform rating.

FINANCIAL MODEL

SANUWAVE Health, Inc.

	2012 A	Q1A	Q2A	Q3A	Q4E	2013 E	2014 E	2015 E	2016 E
Total Revenues	$769.2	$201.2	$160.6	$148.4	$210.0	$720.3	$1,140.0	$2,155.3	$16,972.7
YOY Growth	*-4.2%*	*-15.6%*	*-23.6%*	*-16.7%*	*47.9%*	*-6.4%*	*58.3%*	*89.1%*	*687.5%*
Cost of Revenues	$220.3	$55.8	$23.8	$29.5	$63.0	$172.1	$342.0	$659.0	$4,141.6
Gross Income	$548.9	$145.4	$136.8	$119.0	$147.0	$548.2	$798.0	$1,496.3	$12,831.1
Gross Margin	*71.4%*	*72.3%*	*85.2%*	*80.1%*	*70.0%*	*76.1%*	*70.0%*	*69.4%*	*75.6%*
R&D	$1,762.2	$344.7	$624.5	$775.7	$865.0	$2,609.9	$3,850.0	$3,350.0	$2,750.0
% R&D	*229.1%*	*171.3%*	*388.8%*	*522.6%*	*411.9%*	*362.4%*	*337.7%*	*155.4%*	*16.2%*
SG&A	$4,522.0	$851.9	$1,157.1	$1,151.7	$1,294.0	$4,454.7	$5,218.0	$1,594.9	$9,674.4
% G&A	*587.9%*	*423.3%*	*720.4%*	*776.0%*	*616.2%*	*618.5%*	*457.7%*	*74.0%*	*57.0%*
Depreciation	$20.4	$5.0	$5.0	$4.9	$5.1	$19.9	$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)	($1,726.5)	($1,890.0)	($2,093.8)	($6,843.2)	($8,616.8)	($3,835.5)	($25.1)
Operating Margin	*-788.2%*	*-563.0%*	*-1074.9%*	*-1273.4%*	*-997.0%*	*-950.1%*	*-755.9%*	*-178.0%*	*-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	($1,073.6)	$0.0	($1,073.6)	$0.0	$0.0	$0.0
Loss on derivative revaluation	$0.0	($3,737.0)	$2,328.0	($964.8)	$0.0	($2,373.8)	$0.0	$0.0	$0.0
Interest expense, net	($331.7)	($508.9)	($1,416.1)	($509.8)	($85.0)	($2,519.9)	($360.0)	($250.0)	($50.0)
Loss of FX	($7.5)	$1.9	($3.7)	$1.4	$0.0	($0.4)	$0.0	$0.0	$0.0
Pre-Tax Income	($6,401.6)	($5,369.3)	($818.3)	($4,436.8)	($2,178.8)	($10,429.5)	($8,976.8)	($4,085.5)	($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)	($818.3)	($4,436.8)	($2,178.8)	($10,429.5)	($8,976.8)	($4,085.5)	($75.1)
YOY Growth	*-37.5%*	*192.6%*	*-42.6%*	*206.6%*	*28.6%*	*62.9%*	*-13.9%*	*-54.5%*	*-98.2%*
Net Margin	*-832.3%*					*-1448.0%*	*-787.4%*	*-189.6%*	*-0.4%*
EPS (continuing ops)	($0.31)	($0.25)	($0.04)	($0.14)	($0.05)	($0.35)	($0.15)	($0.06)	($0.00)
Diluted Shares O/S	20,916	21,278	21,757	31,874	44,000	29,727	60,000	69,000	74,000

Brian Marckx, CFA

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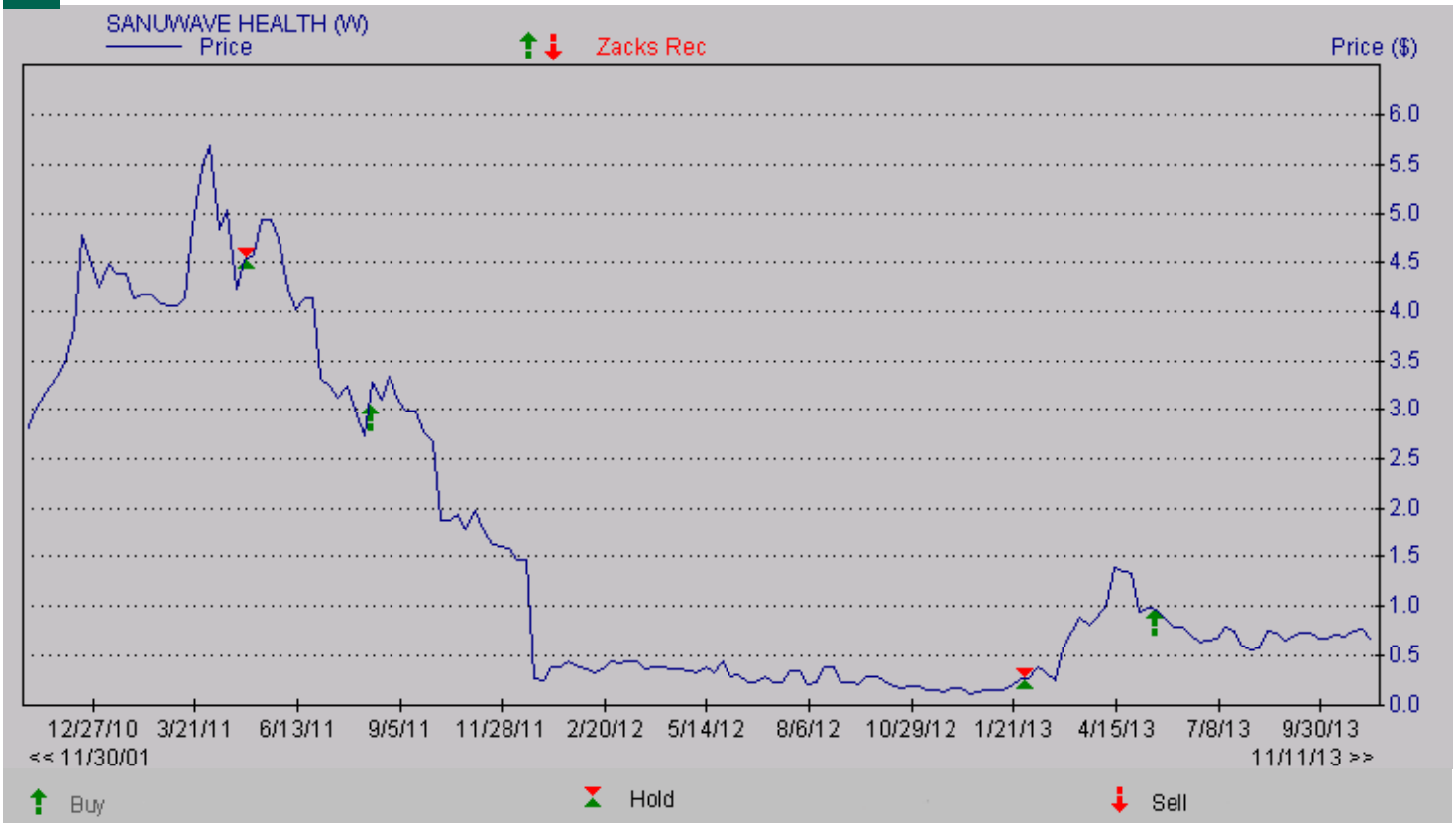
HISTORICAL ZACKS RECOMMENDATIONS



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