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SANUWAVE Health (SNWV-OTC)

SNWV: 90% Enrollment Complete. $10M Financing Gets SNWV to PMA Submission

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	05/15/2013
Current Price (04/01/14)	$0.68
Target Price	**$1.50**

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 has been brisk and is now 90% complete.
Recent progress also includes new CEO brought on in early 2013 with incentive-laden contract, new financing, expansion of 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	**$0.45**
One-Year Return (%)	**-17.97**
Beta	**1.48**
Average Daily Volume (sh)	**59,662**
Shares Outstanding (mil)	**45**
Market Capitalization ($mil)	**$31**
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 (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2014 Estimate	**N/A**
P/E using 2015 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)
2013	201 A	161 A	148 A	290 A	800 E
2014	152 E	197 E	188 E	218 E	755 E
2015					1,407 E
2016					9,065 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.25 A	-$0.04 A	-$0.14 A	-$0.04 E	-$0.42 E
2014	-$0.05 E	-$0.04 E	-$0.03 E	-$0.02 E	-$0.13 E
2015					-$0.07 E
2016					-$0.02 E

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

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WHAT'S NEW…

Q4 RESULTS

On April 1st SANUWAVE announced financial results for the fourth quarter ending December 31, 2013. Revenue came in better than our estimate, as did gross margin and operating expenses. The much lower operating expenses in particular resulted in operating income about $867k (41%) better than our estimate.

And while Q4 numbers likely benefitted to some degree from timing, the relatively meager expenses in the period (the lowest of any quarter since at least 2007) are at least somewhat indicative of management's success in trimming costs – which we think is particularly impressive given progress with the supplemental clinical trial (which remains mostly within expected timelines), with expanding their international footprint (via recent new distribution agreements and partnership) and with investigating derivative applications for their technology. Aside from all the operational progress, SNWV also recently significantly beefed-up their cash balance – via a $10.1M equity issuance – the cash infusion should get the company at least to PMA submission (assuming trial timelines and results meet expectations) and potentially to FDA approval.

Q4 revenue came in at $290k compared to our $210k estimate. While Q4 revenue was the highest in recent company history, management noted on the call that this benefitted from favorable timing and some stocking orders from their new South Korean distributor – we expect revenue in 2014 to more closely track a $180k - $200k/quarter level.

Gross margin at 72% was also better than our estimate, 70%. For the full-year gross margin was 76%, up from 71% in 2012. GM has benefitted from increased sales of higher margin applicators. Q4 operating expenses of $1.4M fell from $2.0M in Q3 and were well below our $2.2M estimate. Op expenses also likely benefitted to some degree from favorable timing, although we have made some downward revisions to our expenses for 2014. Operating income was ($1.2)M, significantly better than our ($2.1)M estimate.

Net income and EPS were ($1.3) million and ($0.04), compared to our ($2.2) million and ($0.06) estimates.

Relative to operational progress – SNWV has kept the clinical trial mostly on-pace with their (arguably aggressive) timelines that they set out in mid-2013. We view this as testament to management's focus on initial preparations to ensure the study could enroll rapidly with high-quality patients and provide maximum chance that efficacy endpoints could be hit. Given that timelines have only slipped by an estimated 30 days (management noted on the call that adverse winter weather prevented some patients from getting to the trial sites, causing some delay), the initial prep work and trial design, which included bringing on a highly experienced CRO and chief medical officer, using high-enrolling trial sites from the pivotal study, holding pre-study investigator meetings and demanding only highest-quality patients/wounds are enrolled (with patients delivered to the trial sites to maximize treatment compliance) – seems to be paying dividends. This prep work should also maximize the chance that the study hits efficacy endpoints.

Management noted that 90% of the expected 90 patients (45 each arm) have been enrolled through the end of March. While this is slightly off from the 100% enrollment targeted by the end of Q1 - management noted that adverse weather at some trial sites caused some delays in enrollment – SNWV believes full enrollment will be completed in the coming weeks. And while SNWV only can provide limited feedback from the ongoing double-blinded study, anecdotally progress is highly positive. On the Q3 conference call management mentioned that drop-out rates were minimal and on the Q4 call, in response to our inquiry, management indicated that they know of no current issues that would give them concern relative to the trial progress to-date.

Prior to the weather-related delay, hoped-for timelines included that last-patient follow-up would occur in Q2 2014, PMA filing would happen in Q4 2014 and FDA approval would happen sometime in 2015. We think the delay may push back these timelines for approximately 4 – 6 weeks, which we do not view as overly material.

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, including their ongoing success with expanding their international commercialization footprint – which remains a priority for growing revenue in the near-term. SNWV recently signed a licensing and distribution agreement with Wirthlin-Dentons whereby Wirthlin will distribute dermaPACE in the Gulf Cooperation Council region (Saudi Arabia, Kuwait, Iran, United Arab emirates and Qatar) – while on the face, this may not sound like a particularly attractive demographic, management noted that the incidence of diabetes in this region is double that of the U.S. SNWV expects to initiate sales to the GCC region sometime in 2014.

This GCC distribution agreement follows other distribution agreements in S. Korea, Australia and New Zealand. SNWV expects to continue to be active in identifying distributors in other parts of the world for dermaPACe and orthoPACE. They are also actively engaged with their distributors in ways to expand sales in their respective regions.

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 and testing of a scale model for application in cleaning frack water. Management had previously noted that they already have early interest in such an application. 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.

$10M Raise Gets SNWV To PMA Submission

One major hurdle to getting dermaPACE filed for PMA approval was cleared when on 03/18/2014 SNWV announced a $10.1M capital raise through the private placement of common stock with warrants. SNWV issued 6.2M common shares @ $0.50 ($3.1M), 6.18k preferred shares @ $1k ($6.18M) and will convert $815k of convertible debt to common at $0.50/share (1.6M shares).

The aggregate issuance included 200% warrant coverage (25.3M 5yr. w/ $0.50 strike and 15.2M 1yr. w/ $1.50 strike). The preferred are convertible into 2k common shares (i.e. - $0.50 conversion price). In aggregate, the issuance immediately added 7.8M common shares, 37.7M common equivalent in-the-money shares (from warrants and preferred convertibles that are in-the-money at today's trading price) and 15.2M common equivalent out-of-the-money shares (at today's trading price).

We estimate net cash to SNWV from this financing was about $8M. The company exited 2013 with $182k in cash. We estimate cash burn of ~$6.5M - $7.0M in 2014. Assuming SNWV can still hit the anticipated timeline of PMA submission in Q4 of this year, they should not need to tap the capital markets prior to the FDA filing. And the in-the-money warrants, while dilutive if exercised, represent an additional $12.6M in potential incoming cash – which could be more than enough to get them to an FDA filing and potentially to FDA approval. The $1.50 warrants, which expire in March 2015, represent another potential $22.7M if exercised (which will be dependent on SWNV stock price rising above $1.50).

We view the financing as a significant positive as it relieves a potential impediment to hitting clinical trial and regulatory submission timelines.

Cash

Cash used in operations in Q4 was just $549k but excluding changes in working capital, cash used in operations was $879k. Cash used in operations averaged $981k in 2013, ex-changes in working capital this was $1.05M. SNWV exited 2013 with $182k in cash and equivalents (which does not include the ~$8M they put on their balance sheet from the March financing). Management expects monthly cash burn to average about $550k - $650k during the first half of 2014 (during which time enrollment in the trial should be completed) and then decreasing to about $450k - $550k per month in the second half. As noted, we believe that the recent financing, assuming expected timelines are hit, will be sufficient to fund the company to at least PMA filing and, potentially to FDA approval.

OPERATIONAL UPDATE

- **Supplemental Trial:**
  - CRO in place, Dr. Jorgensen overseeing study, trial site training completed

- Enrolling at all 20 clinical study 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 2013. Currently have ~90% or ~81 (up from 45 in November 2013 and ~68 at end of January 2014) patients enrolled which have commenced treatment. Patient screening continues for remaining enrollment
- Management indicated on Q3 call that drop-out rates are minimal and further noted on Q4 call that no serious concerns have arisen. No safety issues have been reported (as expected)
- Our anticipated timelines (~ 4 – 6 week delay from November 2013 update) include; final patient expected to be enrolled in Q2 2014, last patient follow-up in Q2/Q3 2014, submit PMA in Q4 2014/Q1 2015, and FDA approval in late 2015

➢ **Distribution:** SNWV has recently been pursuing additional ex-U.S. distribution for dermaPACE, orthoPACE and Evotron to help build on the current relatively meager revenue contribution. In 2013 SNWV announced entry in the Australian and New Zealand markets. In July 2013 regulators in S. Korea approved orthoPACE for sale and in Q4 2013 SNWV booked revenue related to sales to their S. Korean distributor (KOVE Ltd). In February 2014 SNWV signed a licensing and distribution agreement with Wirthlin-Dentons whereby Wirthlin will distribute dermaPACE in the Gulf Cooperation Council region (Saudi Arabia, Kuwait, Iran, United Arab emirates and Qatar) – an area with incidence of diabetes twice that of the U.S. Sales through Wirthlin are expected to commence later in 2014.

The game-plan going forward is to expand their footprint further in existing geographies including Europe and Asia and to work with current distributors to expand sales in their respective regions. 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 recent earnings calls management 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. Aurora is expected to present case studies at the May 2014 Australian Wound Management Association Conference of successful outcomes with dermaPACE which has been used at several wound care clinics 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 2013 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 2013 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 - 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.

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. 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 (or early 2015) with FDA approval possible in 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 the end of March 2014, ~81 (up from 45 in November 2013) of the minimum 90 patients had been enrolled and started treatment. The study is taking place at up to 20 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 2017 P/S comparables to value SNWV. Smith & Nephew currently trades at approximately 2.5x analyst's 2017 forecasted revenue. We currently model SNWV to generate revenue of about $26 million in 2017 – based on the SNN comp 2017 P/S multiple, this values SNWV at about $1.50/share. We are maintaining our Outperform rating.

FINANCIAL MODEL

SANUWAVE Health, Inc.

	2013 A	Q1E	Q2E	Q3E	Q4E	2014 E	2015 E	2016 E	2017 E
Total Revenues	$800.0	$152.0	$197.0	$188.0	$218.0	$755.0	$1,407.0	$9,065.0	$26,182.5
YOY Growth	*4.0%*	*-24.5%*	*22.7%*	*26.7%*	*-24.8%*	*-5.6%*	*86.4%*	*544.3%*	*188.8%*
Cost of Revenues	$189.8	$43.3	$54.4	$49.8	$61.0	$208.6	$400.0	$2,353.9	$6,033.3
Gross Income	$610.2	$108.7	$142.6	$138.2	$157.0	$546.4	$1,006.9	$6,711.1	$20,149.2
Gross Margin	*76.3%*	*71.5%*	*72.4%*	*73.5%*	*72.0%*	*72.4%*	*71.6%*	*74.0%*	*77.0%*
R&D	$2,296.7	$622.0	$688.0	$694.0	$688.0	$2,692.0	$3,350.0	$2,750.0	$3,018.0
% R&D	*287.1%*	*409.2%*	*349.2%*	*369.1%*	*315.6%*	*356.6%*	*238.1%*	*30.3%*	*11.5%*
SG&A	$3,963.2	$921.0	$955.0	$888.0	$864.0	$3,628.0	$3,825.0	$5,167.0	$13,614.9
% G&A	*495.4%*	*605.9%*	*484.8%*	*472.3%*	*396.3%*	*480.5%*	*74.0%*	*57.0%*	*52.0%*
Depreciation	$19.6	$5.0	$5.0	$5.0	$5.0	$20.0	$40.0	$50.0	$70.0
Amortization	$306.8	$76.7	$76.7	$76.7	$76.7	$306.8	$306.8	$306.8	$55.0
Write down of assets	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($5,976.0)	($1,516.0)	($1,582.1)	($1,525.5)	($1,476.7)	($6,100.4)	($6,514.9)	($1,562.7)	$3,391.3
Operating Margin	*-747.0%*	*-997.4%*	*-803.1%*	*-811.4%*	*-677.4%*	*-808.0%*	*-463.0%*	*-17.2%*	*13.0%*
Total Other Expense	($5,978.3)	($438.0)	($86.0)	($70.0)	($70.0)	($664.0)	($250.0)	($50.0)	($50.0)
Pre-Tax Income	($11,954.2)	($1,954.0)	($1,668.1)	($1,595.5)	($1,546.7)	($6,764.4)	($6,764.9)	($1,612.7)	$3,341.3
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	($11,954.2)	($1,954.0)	($1,668.1)	($1,595.5)	($1,546.7)	($6,764.4)	($6,764.9)	($1,612.7)	$3,341.3
YOY Growth	*86.7%*	*-63.6%*	*103.8%*	*-64.0%*	*16.3%*	*-43.4%*	*0.0%*	*-76.2%*	*-307.2%*
Net Margin	*-1494.2%*					*-895.9%*	*-480.8%*	*-17.8%*	*12.8%*
EPS (continuing ops)	($0.42)	($0.05)	($0.04)	($0.03)	($0.02)	($0.13)	($0.07)	($0.02)	$0.03
Diluted Shares O/S	28,132	39,200	45,400	57,500	68,500	52,650	104,000	106,000	110,000

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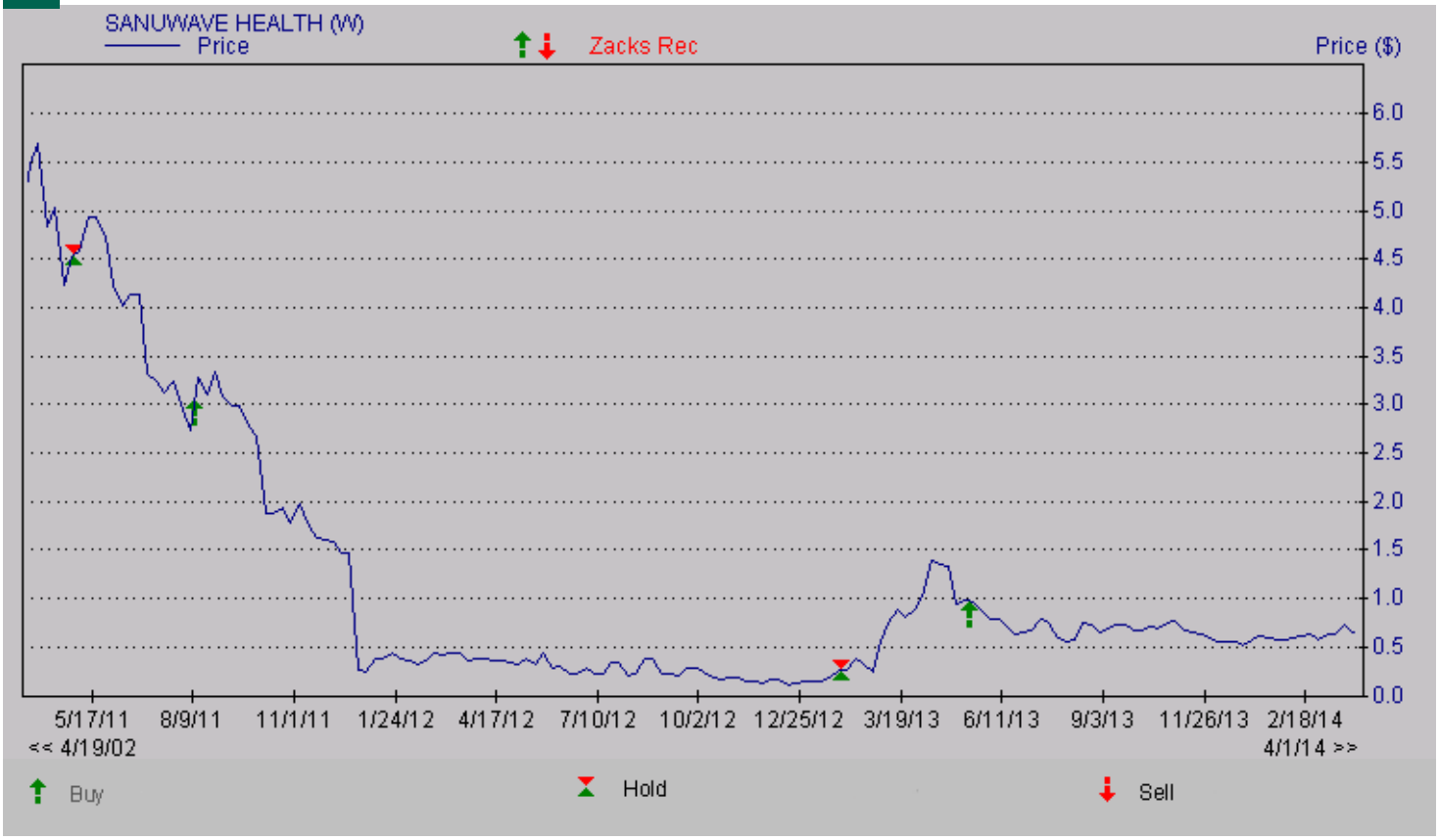
HISTORICAL ZACKS RECOMMENDATIONS



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Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

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