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SANUWAVE Health (SNWV-OTC)

SNWV: Minimum Enrollment Complete. We Remain Very Positive on Chances for Trial Success

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	05/15/2013
Current Price (05/14/14)	$0.51
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 has completed the 90-patient minimum.

We remain very positive on chances of supplemental trial hitting efficacy endpoint. Recent financing shored up cash balance which should be enough to get to PMA filing and possibly to FDA approval. Other parts of the business also progressing including expansion of ex-U.S. distribution and in exploring 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	**$1.05**
52-Week Low	**$0.45**
One-Year Return (%)	**-50.00**
Beta	**1.49**
Average Daily Volume (sh)	**62,918**
Shares Outstanding (mil)	**40**
Market Capitalization ($mil)	**$24**
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 (%)	**-4.1**
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	**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)
2013	201 A	161 A	148 A	290 A	800 E
2014	145 A	197 E	188 E	218 E	748 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	-$0.06 A	-$0.04 E	-$0.03 E	-$0.02 E	-$0.14 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…

Q1 RESULTS

On May 13th SANUWAVE announced financial results for the first quarter ending March 31, 2014. Relative to our estimates, revenue was inline, gross margin better and operating expenses higher. The net result was net loss and EPS moderately unfavorable to our numbers. But while the bottom-line numbers missed our estimates, more importantly from a current financial perspective is that cash used in operations (ex-changes in working capital) was well within our expectations (as well as management's guidance). And from a more operational, non-financial perspective, the company continues to hit their arguably aggressive timelines related to enrollment of the supplemental clinical trial.

Q1 revenue came in at $145k compared to our $152k estimate. We have made no revision to our revenue estimates and still look for roughly flat to slightly negative revenue growth in 2014.

Gross margin at 87% was well ahead of our 72% number and, while at the highest level in at least several years, we do not necessarily see this as a new trend as GM can jump around quite a bit from q-to-q based on mix of consoles versus consumables. Q1 GM benefitted from a favorable mix of higher than average consumables sales. Q1 operating expenses of $2.1M were well ahead of our $1.5M estimate - the majority of the difference was ~$400k in non-cash cost for consulting services (mostly related to the recent financing) that we had not modeled.

Net income and EPS were ($2.6) million and ($0.06), compared to our ($2.0) million and ($0.05) estimates.

Cash
Cash used in operations in Q1 was $2.1M but excluding changes in working capital, cash used in operations was $1.5M. Management continues to expect cash burn to average about $550k - $650k per month through July and then, following enrollment and patient follow-up related to the clinical trial, fall to about $450k - $550k per month through the end of 2014. SNWV exited Q1 with $7.2M in cash and equivalents which was bolstered by the recent financings which netted ~$9.1M. We continue to believe that the current cash balance, assuming no material delays, will be sufficient to fund the company to at least a PMA filing.

Relative to operational progress, SNWV continues to hit their expected timelines for the clinical trial. As a reminder, on the Q4 call (April 1) management noted that they expected the minimum number (90) of patients to be enrolled in the coming weeks - on April 30th the company announced that the 90th patient had been enrolled. As we've repeated the last several quarters, the company and clinical trial team and trial sites have done an impressive job of keeping the trial timelines on track. Other than a (several week) weather-related delay in Winter, the schedule has been met.

An independent Data Monitoring Committee (DMC) will analyze the data from the 90+ -patient set after the last patient (90th) has completed the 12-week treatment protocol. Management believes they will have feedback from the DMC in Q3 of this year. In the meantime, the clinical trial will continue to enroll patients. The initial feedback is expected to be whether the minimum 90-patient enrollment is sufficient or additional patients need to come into the study. If additional patients need to be included, it would be in an initial tranche of 40 patients - beyond that it could be extended to another 70 patients. As enrollment has paced ~10 patients/month and is still ongoing, it's possible an additional 40 patients (if needed) could be brought into the study by mid-to-late Summer.

Assuming positive feedback from the DMC, the clinical trial will then cease enrollment. We think, assuming positive results and no material delays, that initial efficacy data could be available in Q4 of this year and a regulatory filing made in early 2015 - which is commensurate with our prior timelines. In the event additional patients need to be enrolled, we estimate this may cause a delay of between ~6 months (40 patients) and ~12 months (70 patients).

However, we reiterate that we believe the supplemental trial has a strong chance of success based on the fact that the initial pivotal trial barely missed the primary efficacy endpoint with no safety issues, that the supplemental trial design incorporates treatment "boosts" to get efficacy over that endpoint hurdle and that the supplemental trial was prepared in a way to provide the maximum chance that efficacy endpoints could be hit. These preparations 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). This clearly seems to have paid dividends in terms of rapid enrollment - we think this has an excellent chance to pay dividends in terms of efficacy outcomes as well.

Management also recently provided updates on other aspects of the business, 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 and made additional headway in that regard during Q1.

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 (potentially by 2014 year-end). 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.

OPERATIONAL UPDATE

- **Supplemental Trial:**
  - 20 clinical sites included in the study. Seven of these sites are the highest enrolling sties from the pivotal trial and projected to enroll ~70% of the ~90-patient total enrollment of the supplemental trial
  - Management indicated on Q3 2013 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)
  - Enrollment commenced in June 2013. On April 30, 2014 90th patient was enrolled.
  - Independent Data Monitoring expected to analyze the 90-patient data - feedback from which is expected in Q3. In the meantime will continue to enroll past 90 patients in the event additional patients need to be added to the study. Assuming positive feedback from DMC, patient enrollment will cease
  - Assuming no material delays, we think interim efficacy data could be available in Q4 2014 and regulatory filing submitted in early 2015
  - If all goes to plan, FDA approval could happen 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. Earlier this month Aurora is presented

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 2013 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 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 2014 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 by 2014 year-end. 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. In May 2014 SNWV received a U.S. claims patent for use of its technology in cleaning and sterilizing fluids and food liquids - a prerequisite to the company spending much energy on such an application.

Supplemental Trial *(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 April 2014, 100% 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.

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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 is also being 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	Q1A	Q2E	Q3E	Q4E	2014 E	2015 E	2016 E	2017 E
Total Revenues	$800.0	$145.1	$197.0	$188.0	$218.0	$748.1	$1,407.0	$9,065.0	$26,182.5
YOY Growth	*4.0%*	*-27.9%*	*22.7%*	*26.7%*	*-24.8%*	*-6.5%*	*88.1%*	*544.3%*	*188.8%*
Cost of Revenues	$189.8	$18.3	$54.4	$49.8	$61.0	$183.6	$400.0	$2,353.9	$6,033.3
Gross Income	$610.2	$126.8	$142.6	$138.2	$157.0	$564.5	$1,006.9	$6,711.1	$20,149.2
Gross Margin	*76.3%*	*87.4%*	*72.4%*	*73.5%*	*72.0%*	*75.5%*	*71.6%*	*74.0%*	*77.0%*
R&D	$2,296.7	$764.8	$724.0	$694.0	$688.0	$2,870.8	$3,350.0	$2,750.0	$3,018.0
% R&D	*287.1%*	*527.1%*	*367.5%*	*369.1%*	*315.6%*	*383.8%*	*238.1%*	*30.3%*	*11.5%*
SG&A	$3,963.2	$1,300.3	$955.0	$888.0	$864.0	$4,007.3	$3,825.0	$5,167.0	$13,614.9
% G&A	*495.4%*	*896.2%*	*484.8%*	*472.3%*	*396.3%*	*535.7%*	*74.0%*	*57.0%*	*52.0%*
Depreciation	$19.6	$4.7	$5.0	$5.0	$5.0	$19.7	$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)	($2,019.8)	($1,618.1)	($1,525.5)	($1,476.7)	($6,640.1)	($6,514.9)	($1,562.7)	$3,391.3
Operating Margin	*-747.0%*	*-1392.0%*	*-821.4%*	*-811.4%*	*-677.4%*	*-887.6%*	*-463.0%*	*-17.2%*	*13.0%*
Total Other Expense	($5,978.3)	($544.2)	($86.0)	($78.0)	($72.0)	($780.2)	($250.0)	($50.0)	($50.0)
Pre-Tax Income	($11,954.2)	($2,564.0)	($1,704.1)	($1,603.5)	($1,548.7)	($7,420.3)	($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)	($2,565.4)	($1,704.1)	($1,603.5)	($1,548.7)	($7,420.3)	($6,764.9)	($1,612.7)	$3,341.3
YOY Growth	*86.7%*	*-52.2%*	*108.2%*	*-63.9%*	*16.5%*	*-37.9%*	*-8.8%*	*-76.2%*	*-307.2%*
Net Margin	*-1494.2%*					*-991.9%*	*-480.8%*	*-17.8%*	*12.8%*
EPS (continuing ops)	($0.42)	($0.06)	($0.04)	($0.03)	($0.02)	($0.14)	($0.07)	($0.02)	$0.03
Diluted Shares O/S	28,132	39,647	45,400	57,500	68,500	52,762	104,000	106,000	110,000

Brian Marckx, CFA

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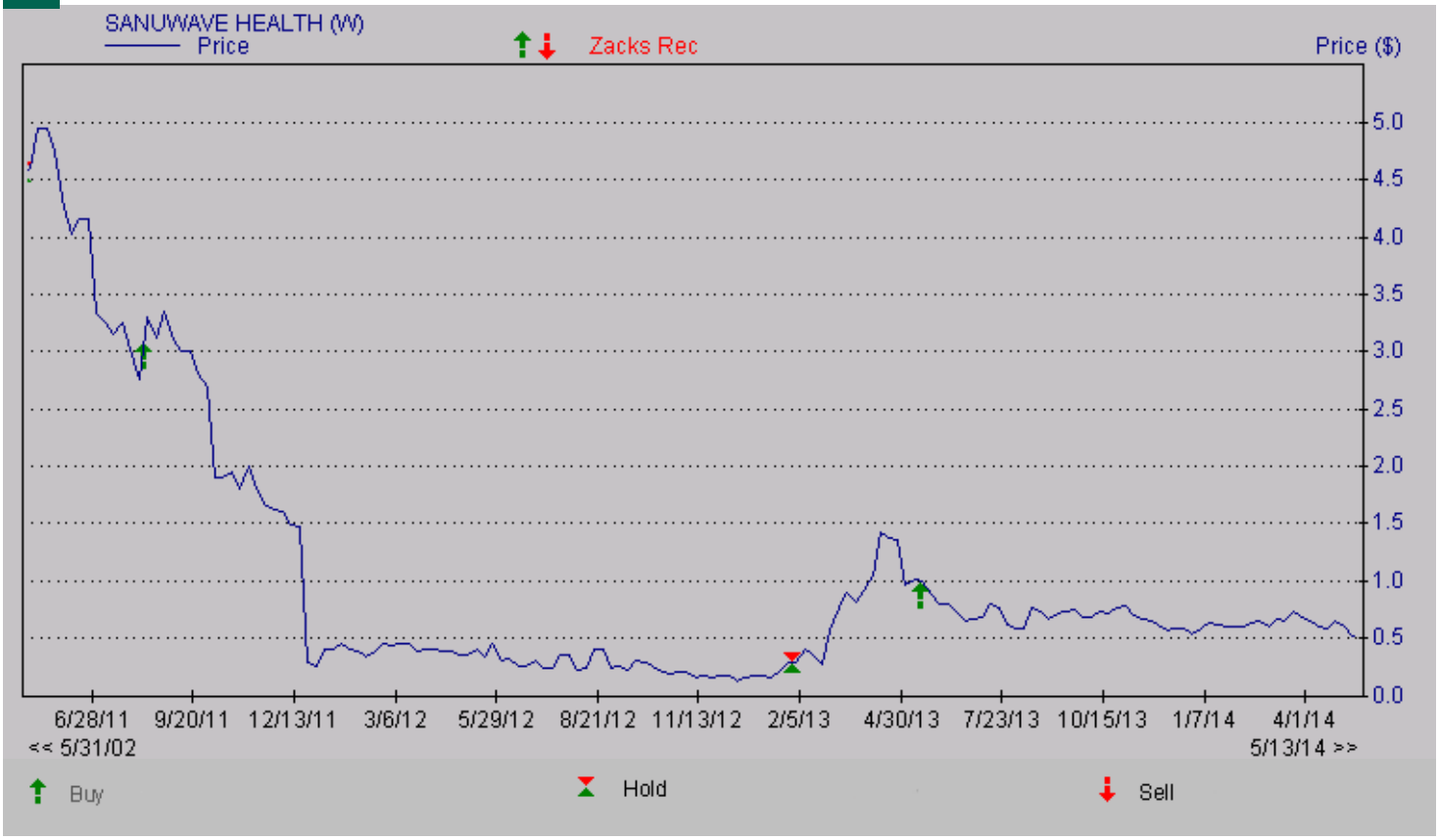
HISTORICAL ZACKS RECOMMENDATIONS



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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.

The current distribution is as follows: Buy/Outperform- 16.8%, Hold/Neutral- 75.9%, Sell/Underperform – 6.4%. Data is as of midnight on the business day immediately prior to this publication.