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Zacks Small-Cap Research

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SANUWAVE Health (SNWV-OTC)

U.S. Roll-Out Strategy Coming Together, Placement Guidance Raised 10% to 110 Units

We value SNWV at 7.5x forward sales, which we think fairly reflects the potential high-growth opportunity, particularly in the U.S. We have SNWV generating approximately $18.2M revenue in 2021 – which values the company at approximately $0.80/share.

Current Price (05/29/19)	$0.17
Valuation	**$0.80**

OUTLOOK

While international sales were very weak in Q1, the good news is that SNWV continues to make what appears to be very substantive progress towards its U.S. commercialization strategy. As the U.S. market has always represented the majority of the growth opportunity, continued progress towards putting additional pieces in place to leverage that opportunity is of obvious importance. Meanwhile, SNWV made the decision to hand off their European strategy to Alira Health – which, given the relatively massive upside that is represented by the U.S. market and constraint on time and resources that will accompany the pursuit of the domestic market, we think this was a wise move.

SNWV has not only already hit their initial system placement goal (of at least 15 units by the end of Q1- a goal that we knew they would meet or exceed by the time of their Q4'18 call in late-March) but has also increased their FY'19 placement guidance – from 100 units (previously) to 110 units (as of their Q1 call on May 21st). They also noted that claims submissions have begun – and should result in initial utilization-based revenue by Q2.

SUMMARY DATA

52-Week High	**$0.45**
52-Week Low	**$0.14**
One-Year Return (%)	**-59.64**
Beta	**-2.01**
Average Daily Volume (sh)	**263,576**
Shares Outstanding (mil)	**177**
Market Capitalization ($mil)	**$29**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**23**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**13.4**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2019 Estimate	**N/A**
P/E using 2020 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)
2018	344 A	453 A	596 A	457 A	1,850 A
2019	178 A	460 E	443 E	772 E	1,853 E
2020					6,450 E
2021					18,197 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-$0.04 A	-$0.02 A	-$0.01 A	-$0.01 A	-$0.08 A
2019	-$0.01 A	-$0.02 E	-$0.01 E	-$0.01 E	-$0.06 E
2020					-$0.04 E
2021					-$0.02 E

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

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Q1 Results, Operational Update: *International Sales Disappoint But U.S. Strategy Coming Together. Utilization-Based Revenue on the Horizon….*

SANUWAVE reported financial results for their first quarter ending March 31st and provided a business update. As it relates to the financials, following two relatively very strong consecutive quarters, revenue fell sharply through the first quarter of the year. Recognition of licensing fees, related to upfront and subsequent payments under recently-penned joint venture and OUS distribution agreements, has helped buoy international sales. While this was again the case in Q1, a very weak product sales number resulted in total revenue coming in at the lowest level since Q3'17.

The good news is that SNWV continues to make what appears to be very substantive progress towards its U.S. commercialization strategy. As the U.S. market has always represented the majority of the growth opportunity, continued progress towards putting additional pieces in place to leverage that opportunity is of obvious importance. Meanwhile, SNWV made the decision to hand off their European strategy to Alira Health – which, given the relatively massive upside that is represented by the U.S. market and constraint on time and resources that will accompany the pursuit of the domestic market, we think this was a wise move.

SNWV has not only already hit their initial system placement goal (of at least 15 units by the end of Q1- a goal that we knew they would meet or exceed by the time of their Q4'18 call in late-March) but has also increased their FY'19 placement guidance by 10% – from 100 units (previously) to 110 units (as of their Q1 call on May 21st). They also noted that claims submissions have begun – and should result in initial utilization-based revenue by Q2.

Financials

Q1 revenue was $178k ($24k U.S., $154k OUS), down 48% yoy, -61% from Q4'18 and well below our $496k ($60k U.S., $356k OUS) estimate.

U.S. sales of $24k included $18M and $6M of product and license revenue, respectively. U.S. sales accounted for 13% of the total and were down from $123k and $75k in the prior-year and three-month periods, respectively. As Q1'18 represented the first quarter of sales to Premiere, we assume that included some inventory stocking initial placements at the VA and Indian Health, which reflects much of the yoy decrease as compared to the most recent quarter. The decrease in U.S. revenue (and miss to our estimate) is largely immaterial at this early stage, however, particularly as utilization-based revenue (the anticipated long-term driver of sales) has yet to make any meaningful contribution. As noted, SNWV expects to begin generating per-use revenue by the current quarter (i.e. Q2'19).

Meanwhile, international sales were $154k and included $47k ($131k in Q1'18) of product sales, $100k ($78k in Q1'18) of license fees and $7k ($13k in Q1'18) in other revenue. International sales, which fell 31% yoy and 60% from Q4'18, accounted for 87% of the total in Q1. The relatively weak showing in OUS product sales, which fell 64% (from $131k) from Q1'18 and 74% (from $178k) from Q4'18, was particularly disappointing given all of the progress that SNWV has made in expanding their international distribution footprint. In fact, excluding license fee revenue, Q1 revenue may have been the weakest – or nearly the weakest, in company history.

Encouragingly management indicated that they expect OUS sales to pick up and cited adverse order timing as largely the reason for the soft start to the year for international revenue. SNWV noted on the call that all of their distribution partners are "expecting dramatic growth in orders" for the full year 2019.

We reiterate what we have mentioned in the past that recent expansion of SNWV's OUS footprint, expanding 'label' from orthopedics-only to now include wound treatment in several territories and new distributor relationships are all potential catalysts that could have a positive impact on international revenue growth going forward. Certainly, FDA clearance, while largely meaningless from an OUS regulatory standpoint, can act as a proxy 'stamp of approval' and prove an important and influential marketing message and help drive adoption. New clinical studies have also recently commenced, positive results of which could also aid in adoption and utilization. Among these are a dose-optimization study in Poland (as well as a U.S.-based perfusion study), which commenced in April 2019 and is expected to complete later this year. And, finally, more JV agreements could be forthcoming and further help drive international sales growth.

OpEx was $1.9M, inline with our $1.9M estimate and up from $1.3M in Q1'18 and from $1.5M in Q4'18. All (and more) of the yoy and sequential increases relates to SG&A (as opposed to R&D) expense – most of which we think relates to activities associated with the U.S. roll out of dermaPACE. This includes recently added personnel – including sales reps and clinical trainers in many of the six states where SNWV will focus their initial domestic commercialization efforts. As it relates to R&D expense, while new clinical/case and pharmacoeconomic-related

studies are either already underway or expected to commence in the near-term, we do not expect these to result in a substantial increase in R&D expenses during the year.

Cash balance was $99k but subsequent to Q1 quarter-end, SNWV raised additional operating capital. Cash used in operating activities was $1.3M ($1.8M ex-changes in working capital) in Q1, compared to $1.9M ($1.2M ex-changes in w/c) in the year-earlier period and $1.4M ($870k ex-changes in w/c) in the three months ending 12/31/18. Management is guiding for monthly cash burn to average between $225k and $300k in Q2 and between $275k and $350k during the second half of the year. Additional cash could come from warrant exercises. And, new JV agreements could be another source of funds.

U.S. roll-out underway…

As noted, management mentioned on the call that they already have 16 units placed in the U.S. via their direct efforts. They are now guiding to have a U.S. installed base of at least 35 units by the end of Q2, 70 by Q3 (recently increased from 65) and 110 by the close of 2019 (increased from 100). SNWV is also aiming to have 300 users (clinicians/technicians) trained and certified on the devices by the end of 2019. As a reminder, SNWV places the devices for free and generates revenue when they are used – which means it is critical that not only are devices placed, but that users are trained. Management noted that their main focus for 2019 is on steepening the placement rate, while a more determined focus on driving utilization will happen in 2020. SNWV has yet to disclose the expected per-procedure rate but has recently indicated that they are working towards establishing that with sufficient claims data.

A CPT III tracking code became effective January 1, 2019. Clinicians will use this to submit for reimbursement (which they may or may not receive) and payers will use it to monitor usage and for making policy, reimbursement and rate decisions. As we have noted in prior updates, novel medical devices, such as dermaPACE often initially go to market in the U.S. sans-dedicated Medicare reimbursement. While we think that providers (perhaps, particularly influential KOLs) may have some success billing under this CPT III, we expect spotty reimbursement, at best, initially or at least until there is more usage data and perhaps, until following conclusion of supportive post-approval clinical utility and pharmacoeconomic studies. Eventual issuance of a CPT I code will likely be the goal, although that could be a years-long process and will undoubtedly require sufficient usage and economic data.

SNWV mentioned that they have brought on consultants to help with their initial reimbursement strategy – which will include picking certain regional payers and engaging with an evidence-based approach. Initial discussions with private insurers and MACs (i.e. regional Medicare) are underway – results of which we will be eager to hear updates about.

SNWV has indicated that they will conduct an initial pharmacoeconomic study and that results will be used to help support their case to these regional payers. Importantly, a manuscript of the two pivotal (initial and supplemental) studies used as primary support for SNWV's application seeking FDA clearance of dermaPACE was published in the peer-reviewed Journal of Wound Care in December 2018. This is a significant event in our opinion, particularly in the context of communicating the benefits and utility of dermaPACE in treating DFUs at the clinician level. Other post-marketing studies, aimed at clinician adoption and utilization, are also planned in the U.S.

In fact a skin perfusion study, being conducted in New Jersey and California, just commenced in April 2019. The study will evaluate the effects of their dermaPACE technology on local skin perfusion (blood flow) and its effect on healing DFU's. Additional studies, aimed at supporting the U.S. roll-out, are also expected to begin during 2019. These are topics that we will be eager to hear updates on given their potential outsized influence on whether a provider chooses to use, or a payor chooses to reimburse for, a particular modality or therapy.

SNWV has already identified their initial commercialization territories in the U.S. Based on certain criteria which management believes makes these areas of the U.S. more receptive to adoption and use of dermaPACE (under a CPT III code), the company's initial territories are Texas, California, North and South Carolina, Pennsylvania and Illinois. The criteria under which these areas were chosen includes population density, presence of doctors with high volume of DFU patients and payors that have shown to be more amenable to reimbursing for novel technologies.

Management indicated on their recent earnings calls that initial feedback from U.S. clinicians has been positive. Among the feedback were comments from doctors of 'great results' with using dermaPACE for chronic wounds, that safety of the device was noteworthy, plans to use dermaPACE for DFUs in conjunction with other therapies and use of dermaPACE when other therapies have failed.

Valuation

We approach modeling U.S. revenue based on unit placements. Our model incorporates three cases; conservative, base and liberal – which are based on assumed margin (to SNWV), market opportunity, unit placements rate and number of treatments per console.

We incorporate the following assumptions (all of which are subject to updating);

Unit placements model:

Utilization:

- o on the low end (i.e. conservative), we assume one patient treated per (business) day per every four consoles (which implies initially, 75% of placed units are idle) and an average of 6 treatments per patient (equal to ~0.5 patients per console per month)
- o on the high end (i.e. liberal), we assume one patient treated per (business) day per very two consoles (which implies initially, 50% of placed units are idle) and an average of 6 treatments per patient (equal to ~1 patient per console per month)
- o base case is the average of the two

- Margin per treatment to SNWV:
  - o $100 liberal, $75 base, $50 conservative

		2019	2020	2021	2022
Consoles	liberal	110	275	413	495
	base	75	188	281	360
	conservative	40	100	150	225
onsole/mth	liberal	1.00	4.00	10.00	12.50
	base	0.75	2.75	6.13	7.94
	conservative	0.50	1.50	2.25	3.38
Treatments	liberal	7,920	79,200	297,000	445,500
	base	4,680	45,000	160,650	250,088
	conservative	1,440	10,800	24,300	54,675
Margin	liberal	$101	$102	$103	$104
	base	$76	$77	$77	$78
	conservative	$51	$51	$52	$52
Revenue	liberal	$799,920	$8,079,192	$30,599,940	$46,358,909
	base	$436,320	$4,315,023	$15,925,878	$24,601,830
	conservative	$72,720	$550,854	$1,251,816	$2,844,751

Based on our belief that the early years of U.S. commercialization will be based on "picking their spots" based on hospitals, regional payers, wound centers and clinics as well as KOLs where reimbursement may be most favorable, we think the unit placement model may be most appropriate as a guide. This is also the reason why we do not extend this model past the year 2022.

We reiterate that our model is subjecting to updating. It will almost certainly change based on when there is more definitive information to make more informed judgments about inputs. And while we assume conservative, base and liberal cases, our inputs for each should not be interpreted to mean that, for example, margin cannot significantly exceed $100 per treatment. Meanwhile, we have OUS revenue growing from $1.6M in 2018 to approximately $3M in 2022.

Valuation

We value SNWV at 7.5x forward sales, which we think fairly reflects the potential high-growth opportunity, particularly in the U.S. With the updates to our model, we have SNWV generating approximately $18.2M in revenue in 2021 – which values the company at approximately $0.80/share.

FINANCIAL MODEL

SANUWAVE Health, Inc.

	2017 A	Q1A	Q2A	Q3A	Q4A	2018 A	Q1A	Q2E	Q3E	Q4E	2019 E	2020 E	2021 E	2022 E
Total Revenues	$738.5	$344.3	$453.2	$595.8	$456.8	$1,850.0	$178.0	$460.1	$443.2	$771.6	$1,852.9	$6,450.0	$18,197.3	$26,857.9
YOY Growth	*-46.3%*	*130.2%*	*308.1%*	*268.7%*	*44.4%*	*150.5%*	*-48.3%*	*1.5%*	*-25.6%*	*68.9%*	*0.2%*	*248.1%*	*182.1%*	*47.6%*
Cost of Revenues	$242.0	$165.5	$166.6	$183.6	$178.0	$693.7	$93.9	$162.9	$152.9	$260.8	$670.4	$2,038.21	$5,622.96	$8,030.51
Gross Income	$496.6	$178.8	$286.6	$412.2	$278.8	$1,156.4	$84.1	$297.2	$290.3	$510.8	$1,182.4	$4,411.8	$12,574.3	$18,827.4
Gross Margin	*67.2%*	*51.9%*	*63.2%*	*69.2%*	*61.0%*	*62.5%*	*47.3%*	*64.6%*	*65.5%*	*66.2%*	*63.8%*	*68.4%*	*69.1%*	*70.1%*
R&D	$1,292.5	$349.4	$368.3	$661.7	$284.3	$1,663.9	$261.0	$388.6	$477.7	$588.2	$1,715.5	$2,284.7	$2,574.6	$3,098.5
% R&D	*175.0%*	*101.5%*	*81.3%*	*111.1%*	*62.3%*	*89.9%*	*146.7%*	*84.5%*	*107.8%*	*76.2%*	*92.6%*	*35.4%*	*14.1%*	*11.5%*
SG&A	$3,004.4	$945.6	$2,034.0	$2,415.1	$1,255.8	$6,650.5	$1,675.2	$1,857.2	$2,055.6	$2,174.5	$7,762.5	$9,365.4	$16,141.0	$19,472.0
% G&A	*406.8%*	*274.7%*	*448.8%*	*405.4%*	*274.9%*	*359.5%*	*941.3%*	*403.7%*	*463.8%*	*281.8%*	*418.9%*	*145.2%*	*88.7%*	*72.5%*
Depreciation	$24.1	$5.0	$6.0	$5.7	$5.6	$22.3	$8.4	$8.6	$8.8	$8.8	$34.6	$48.0	$85.0	$110.0
Operating Income	($3,824.5)	($1,121.3)	($2,121.7)	($2,670.4)	($1,267.0)	($7,180.3)	($1,860.4)	($1,957.2)	($2,251.8)	($2,260.7)	($8,330.1)	($7,286.3)	($6,226.3)	($3,853.1)
Operating Margin	*-517.9%*	*-325.7%*	*-468.2%*	*-448.2%*	*-277.4%*	*-388.1%*	*-1045.4%*	*-425.4%*	*-508.1%*	*-293.0%*	*-449.6%*	*-113.0%*	*-34.2%*	*-14.3%*
Total Other Expense	($1,713.5)	($4,735.4)	($766.5)	$1,845.2	($794.4)	($4,451.1)	($336.9)	($582.6)	($615.8)	($649.5)	($2,183.5)	($2,017.4)	($1,447.8)	($1,100.3)
Pre-Tax Income	($5,538.0)	($5,856.7)	($2,888.3)	($825.1)	($2,061.4)	($11,631.4)	($2,197.3)	($2,539.8)	($2,867.6)	($2,910.2)	($10,513.6)	($9,303.7)	($7,674.1)	($4,953.4)
Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$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%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	($5,538.0)	($5,856.7)	($2,888.3)	($825.1)	($2,061.4)	($11,631.4)	($2,197.3)	($2,539.8)	($2,867.6)	($2,911.1)	($10,514.4)	($9,303.7)	($7,674.1)	($4,953.4)
YOY Growth	*-14.2%*	*-9.3%*	*485.2%*	*-41.7%*	*142.1%*	*110.0%*	*-60.3%*	*-56.6%*	*-0.7%*	*252.8%*	*-9.6%*	*-11.5%*	*-17.5%*	*-35.5%*
Net Margin	*-749.9%*	*-1701.2%*	*-637.3%*	*-138.5%*	*-451.3%*	*-628.7%*	*-1234.7%*	*-552.0%*	*-647.0%*	*-377.3%*	*-567.5%*	*-144.2%*	*-42.2%*	*-18.4%*
EPS (continuing ops)	($0.04)	($0.04)	($0.02)	($0.01)	($0.01)	($0.08)	($0.01)	($0.02)	($0.01)	($0.01)	($0.06)	($0.04)	($0.02)	($0.01)
Diluted Shares O/S	138,828	139,754	148,582	151,826	157,989	149,538	157,113	169,121	195,100	205,200	181,633	265,000	315,000	335,000

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