April 3, 2019

Zacks Small-Cap Research

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

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

SANUWAVE Health (SNWV-OTC)

Strong Finish to 2018. U.S. Roll-Out Underway, Guiding for 100 Placements in 2019

We value SNWV at 6.5x forward sales, which we think fairly reflects the potential high-growth opportunity, particularly in the U.S. We have SNWV generating approximately $20M revenue in 2021 – which values the company at approximately $0.80/share.

Current Price (04/03/19)	$0.20
Valuation	**$0.80**

OUTLOOK

Management mentioned on the call that they already have 16 units placed in the U.S. via their direct efforts. They are guiding to have a U.S. installed base of at least 15 units by the end of Q1 (which they've already exceeded), 35 by Q2, 65 by Q3 and 100 by the close of 2019. SNWV is also aiming to have 300 users (clinicians/technicians) trained and certified on the devices by the end of 2019. 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. 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, albeit not unexpected, 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.

SUMMARY DATA

52-Week High	**$0.64**
52-Week Low	**$0.14**
One-Year Return (%)	**-61.32**
Beta	**-1.67**
Average Daily Volume (sh)	**129,106**
Shares Outstanding (mil)	**160**
Market Capitalization ($mil)	**$32**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**39**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**12.6**
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	496 E	637 E	735 E	876 E	2,743 E
2020					8,060 E
2021					19,911 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 E	-$0.01 E	-$0.01 E	-$0.01 E	-$0.06 E
2020					-$0.03 E
2021					-$0.02 E

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

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Q4 Results, Operational Update: *Strong Finish to 2018. U.S. Roll-Out Underway, Guiding for 100 Placements in 2019….*

SANUWAVE announced Q4 / full-year 2018 financial results and provided a business update. As it relates to the financials, Q4 was a relatively strong quarter with revenue coming in at the third highest in company history, although down about 23% sequentially. The strong showing in both Q3 and Q4'18 meant that revenue in the second half of the year was the best consecutive two-quarter period in SANUWAVE's existence. That also resulted in 2018 being a record year for sales. Continued progress with putting the U.S. commercialization strategy in place means domestic revenue should begin to accelerate later this year. Meanwhile, expansion of the international footprint and increasing sales in existing territories should benefit OUS revenue growth.

Financials

Q4 revenue was $457k, up 44% yoy, down 23% qoq and largely inline with our $470k estimate. The $1.85M in revenue for the full year, which was up 151% from 2017, was 35% higher than the prior best ($1.38M in 2016).

U.S. sales were $75k and $235k in Q4 and FY'18, accounting for 16% and 13% of the total in those respective periods. This compares to $6k (2%) and $25k (3%) in the prior year periods. Domestic sales in 2018 benefitted from initial system placements by Premier (which distributes to the VA and Indian Health and from which SNWV receives revenue on both the system sale and on a per-use basis) while the current year should see initial utilization-based revenue as a result of dermaPACE installations by the company's in-house sales efforts (targeting the private healthcare market). Noteworthy is that management mentioned that they already have 16 systems placed (as of the March 29th Q4'18 earnings call) and expect to have 100 dermaPACE units installed by year-end. Moreover, they expect to begin generating per-use revenue by the current quarter (i.e. Q2'19).

Q4 marked the third consecutive quarter with revenue above $450k, a level that SNWV breached only one time prior to 2018. While both product sales and international license fees were the main contributors to the revenue growth through the first nine months of the year, product sales – both in the U.S. and internationally – represented the main catalysts driving revenue growth in Q4. Product sales accounted for 54% of revenue in Q4 and 51% for the full year, with U.S. product sales contributing 15% and 11% of total revenue in those same periods. International license fees accounted for almost all of the remainder.

While license and upfront fees bolstered revenue in 2018, 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. Clinical studies are also expected to initiate outside of the U.S. – including a dose-optimization study in Poland – which could help drive adoption and use internationally as well as domestically. This particular study is expected to begin in April and finish sometime in the third quarter of this year. And, finally, as it relates to potential international catalysts, more JV agreements could be forthcoming.

OpEx was $1.5M in Q4 and $8.3M in FY'18, compared to $1.5M and $4.3M in the prior-year periods. More than 40% of the full-year increase relates to higher non-cash stock compensation. While R&D expense increased by less than $400k during 2018, G&A jumped by more than $3.6M. Much of this, we think, relates to activities associated with readying for SNWV's direct U.S. launch of dermaPACE. Some additional personnel were added during 2H'18 and, with the roll-out accelerating, SNWV is further adding headcount. This includes sales managers and clinical trainers, which will be brought on to lead the dermaPACE roll-out in the six selected initial territories. And while new clinical/case and pharmacoeconomic-related studies will be initiated, we do not expect these to result in a substantial increase in R&D expenses through 2019.

Cash balance was $365k at 2018 year-end, compared to $72k and $730k at the close of Q3'18 and FY'17, respectively. Cash used in operating activities was $1.4M and $3.6M ($870k and $4.4M, ex-changes in working capital) in the three and twelve months ending 12/31/18, compared to $584k and $1.5M ($370k and $2.8M, ex-changes in working capital) in the respective prior-year periods. Going forward, SNWV is guiding for cash burn to average $675k - $900k per quarter. 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 guiding to have a U.S. installed base of at least 15 units by the end of Q1 (which they've already exceeded), 35 by Q2, 65 by Q3 and 100 by the close of 2019. 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 establish how much the per-procedure rate will be but expects to made headway in that regard once they have a sufficient amount of 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, albeit not unexpected, 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. One U.S.-based study that SNWV has indicated could start imminently is a skin perfusion study. The study will evaluate the effects of their dermaPACE technology on local skin perfusion (blood flow) and its effect on healing DFU's. The study will be conducted at two sites, in NJ and California, and is expected to commence this month. 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 the Q4 call 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.

International update…

International revenue was $1.6M in 2018, an increase of 126% and accounted for 87% of the total. This was split relatively evenly between license fees of $795k (vs $211k in 2017) and product revenue of $740k (vs $457k in 2017).

Among the recognized license fees in 2018 was that related to an agreement with Johnfk Medical Inc (FKS). Under that agreement, in June 2018 Johnfk paid SNWV $500k for initial distribution rights in Taiwan. Another $500k was due by year-end for distribution rights in Singapore, Malaysia, Brunie, Cambodia, Myanmar, Laos, Indonesia, Thailand, Philippines and Vietnam. But, by November a joint venture had been formed and incorporated between FKS and SNWV. The JV, Holistic Wellness Alliance pte Ltd (HWA), is owned 50/50 between the partners and is focused on distribution to Singapore, Malaysia, Brunei, Cambodia, Myanmar, Laos, Indonesia, Thailand, Philippines and Vietnam. Net profits of the JV will initially be used to repay the $500k paid by FKS to SNWV. While this was not the expected outcome of this agreement (at least not as it was initially explained), it does nonetheless provide for distribution in these territories.

The MundiMed JV did not materialize as had been hoped. As per first disclosed in the Q3 10-Q, MundiMed defaulted on the terms of their agreement with SNWV. As we noted in our Q3 update, while we had hoped that ANVISA (Brazil) approval might happen sometime in 2019, with the MundiMed JV now dead, it is unclear if regulatory clearance in that country is likely to happen in the foreseeable future. While management indicated on the Q4 call that they expect Brazil to be back online by the Q1'19 call (i.e. ~mid-May) and to begin generating revenue by current year-end, we have removed any contribution from that territory from our model. Our assumptions our subject to updating.

Management hopes to sign one or more JV-type deals in 2019 – which could further expand their global footprint as well as provide upfront operating capital. In addition, international revenue should benefit from continued growth in product sales driven by both increasing adoption in legacy territories and entry into new regions. High potential areas such as Southeast Asia and Mexico, which were established with distribution in 2018 but had yet to be commercialized, are expected to come online and begin contributing this year. SNWV expects to add two to three new major international territories in 2019 and is guiding for international shipments to double from the prior year's level.

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 $1.1M to just under $4M in 2022.

Valuation

We value SNWV at 6.5x 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 $20M 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	Q1E	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	$495.8	$636.6	$734.6	$876.3	$2,743.3	$8,060.0	$19,910.9	$28,586.8
YOY Growth	*-46.3%*	*130.2%*	*308.1%*	*268.7%*	*44.4%*	*150.5%*	*44.0%*	*40.5%*	*23.3%*	*91.9%*	*48.3%*	*193.8%*	*147.0%*	*43.6%*
Cost of Revenues	$242.0	$165.5	$166.6	$183.6	$178.0	$693.7	$194.4	$225.4	$253.4	$296.2	$969.3	$2,546.97	$6,152.46	$8,547.46
Gross Income	$496.6	$178.8	$286.6	$412.2	$278.8	$1,156.4	$301.4	$411.2	$481.2	$580.1	$1,774.0	$5,513.1	$13,758.4	$20,039.4
Gross Margin	*67.2%*	*51.9%*	*63.2%*	*69.2%*	*61.0%*	*62.5%*	*60.8%*	*64.6%*	*65.5%*	*66.2%*	*64.7%*	*68.4%*	*69.1%*	*70.1%*
R&D	$1,292.5	$349.4	$368.3	$661.7	$284.3	$1,663.9	$358.7	$402.7	$554.6	$621.6	$1,937.6	$2,366.1	$2,684.5	$3,127.6
%R&D	*175.0%*	*101.5%*	*81.3%*	*111.1%*	*62.3%*	*89.9%*	*72.3%*	*63.3%*	*75.5%*	*70.9%*	*70.6%*	*29.4%*	*13.5%*	*10.9%*
SG&A	$3,004.4	$945.6	$2,034.0	$2,415.1	$1,255.8	$6,650.5	$1,545.7	$1,857.2	$2,055.6	$2,174.5	$7,633.0	$9,583.4	$16,844.6	$20,411.0
% G&A	*406.8%*	*274.7%*	*448.8%*	*405.4%*	*274.9%*	*359.5%*	*311.8%*	*291.7%*	*279.8%*	*248.1%*	*278.2%*	*118.9%*	*84.6%*	*71.4%*
Depreciation	$24.1	$5.0	$6.0	$5.7	$5.6	$22.3	$5.6	$5.6	$5.6	$5.6	$22.4	$22.4	$65.0	$65.0
Operating Income	($3,824.5)	($1,121.3)	($2,121.7)	($2,670.4)	($1,267.0)	($7,180.3)	($1,608.6)	($1,854.3)	($2,134.6)	($2,221.6)	($7,819.0)	($6,458.8)	($5,835.7)	($3,564.2)
Operating Margin	*-517.9%*	*-325.7%*	*-468.2%*	*-448.2%*	*-277.4%*	*-388.1%*	*-324.4%*	*-291.3%*	*-290.6%*	*-253.5%*	*-285.0%*	*-80.1%*	*-29.3%*	*-12.5%*
Total Other Expense	($1,713.5)	($4,735.4)	($766.5)	$1,845.2	($794.4)	($4,451.1)	($551.8)	($582.6)	($615.8)	($649.5)	($2,399.7)	($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)	($2,160.4)	($2,436.9)	($2,750.4)	($2,871.1)	($10,218.7)	($8,476.2)	($7,283.5)	($4,664.5)
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)	($2,163.8)	($2,436.9)	($2,750.4)	($2,871.9)	($10,223.0)	($8,476.2)	($7,283.5)	($4,664.5)
YOY Growth	*-14.2%*	*-9.3%*	*485.2%*	*-41.7%*	*142.1%*	*110.0%*	*-60.9%*	*-58.4%*	*-4.8%*	*248.1%*	*-12.1%*	*-17.1%*	*-14.1%*	*-36.0%*
Net Margin	*-749.9%*	*-1701.2%*	*-637.3%*	*-138.5%*	*-451.3%*	*-628.7%*	*-436.4%*	*-382.8%*	*-374.4%*	*-327.7%*	*-372.7%*	*-105.2%*	*-36.6%*	*-16.3%*
EPS (continuing ops)	($0.04)	($0.04)	($0.02)	($0.01)	($0.01)	($0.08)	($0.01)	($0.01)	($0.01)	($0.01)	($0.06)	($0.03)	($0.02)	($0.01)
Diluted Shares O/S	138,828	139,754	148,582	151,826	157,989	149,538	159,852	162,500	195,100	205,200	180,663	265,000	315,000	335,000

Brian Marckx, CFA

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