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SANUWAVE Health (SNWV-OTC)

SNWV: Revenue Momentum Continues As Does International Expansion. Two New JVs Signed in Q2….

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 $34M revenue in 2021 – which values the company at approximately $0.75/share.

Current Price (08/31/18)	$0.22
Valuation	**$0.75**

OUTLOOK

SNWV is delivering on their strategy to bring in additional JV partnerships – including two JV agreements signed in Q2 alone. These new JVs are expected to expand their reach to 14 more countries in southeast Asia and Latin America. In addition, the upfront fees paid to SNWV, including $500k received in Q2 (with another $500k expected in Q3) from the initial agreement with Johnfk Medical Inc. ("FKS"), provide meaningful and non-dilute operating funds. As a reminder, these upfront fees are brought on the balance sheet and recognized as revenue over a certain amount of time (and contribute to revenue in the remainder of 2018). Encouragingly, management expects revenue to continue to grow through the remainder of 2018 and benefit from international growth. Depending on initial rates of VA-related adoption and utilization as well as (likely more incremental) OVA (i.e. outside VA in U.S.) interest, we could see material growth in U.S. revenue later this year. Nonetheless, we continue to think the U.S. market is likely to be one where incremental gains are made over time, particularly pre-reimbursement.

SUMMARY DATA

52-Week High	**$0.64**
52-Week Low	**$0.10**
One-Year Return (%)	**85.84**
Beta	**-2.80**
Average Daily Volume (sh)	**138,969**
Shares Outstanding (mil)	**155**
Market Capitalization ($mil)	**$34**
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 (%)	**9.0**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**N/A**
P/E using 2019 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)
2017	150 A	111 A	162 A	316 A	739 A
2018	344 A	453 A	683 E	778 E	2,259 E
2019					6,581 E
2020					15,736 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.00 A	-$0.01 A	-$0.01 A	-$0.02 A	-$0.04 A
2018	-$0.04 A	-$0.02 A	-$0.02 E	-$0.01 E	-$0.08 E
2019					-$0.03 E
2020					-$0.02 E

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

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Q2 Results, Operational Update: *International Expansion Continues With 2 New JVs Signed in Q2….*

SANUWAVE reported Q2 2018 financial results and provided a business update. Revenue continues to gain momentum, reflecting initial contribution from the recent U.S. launch and, to a greater degree, SNWV's ever-expanding international footprint. Q2 revenue of $453k, which is the second-highest quarterly revenue in company history, was up more than 300% from the prior year and 32% from Q1 '18. It also marks the fourth consecutive quarter of sequential revenue growth and extends the number of consecutive quarters with revenue of more than $300k to three – a new record.

Initial sales to Premiere Shockwave accounted for approximately one-third of SNWV's total revenue in Q1, although U.S. sales contributed relatively little (~6%) in the most recent period. Instead, international expansion and consummation of additional JV agreements were the major catalysts in Q2. While we continue to believe that domestic activity and related revenue will gain traction, we think the bulk of the opportunity for near-term topline growth is overseas.

SNWV is delivering on their strategy to bring in additional JV partnerships – including two agreements signed in Q2 alone. These new JVs are expected to expand their reach to 14 more countries in southeast Asia and Latin America. In addition, the upfront fees, including $500k received by SNWV in Q2 (with another $500k expected in Q3) from the initial agreement with Johnfk Medical Inc. ("FKS"), provide meaningful and non-dilute operating funds. As a reminder, these upfront fees are brought on the balance sheet and then amortized to revenue (including during the remainder of 2018).

The JV with FKS covers distribution in Taiwan, Singapore, Malaysia, Brunie, Cambodia, Myanmar, Laos, Indonesia, Thailand, Philippines and Vietnam while a JV with Tarbaca Lightning covers Costa Rica, Panama and el Salvador. We expect we will hear more in the near future relative to regulatory and commercialization activities surrounding these JVs as well as MundiMed (for Brazil).

Encouragingly, management expects revenue to continue to grow through the remainder of 2018 and benefit from international shipments to and demand from Romania, SE Asia, Italy, Benelux region and Australia. In early May SNWV announced that AMBIENSYS SRL will handle distribution in Romania (with expected revenue of $400k over 3 years). The Middle East may soon present an opportunity as well – SNWV brought on MenaCare (consultants) to help with their commercialization strategy in that part of the world. ANVISA (Brazil) approval, which previously had been expected to happen by current year-end, is now more likely an early-2019 event. Nonetheless, that represents another potential near-term revenue catalyst.

Canada represents a fairly new opportunity and, with a KOL now 'onboarded', dermaPACE could begin to generate meaningful interest there. In May SNWV announced that Dr. Perry Mayer, principal of The Mayer Institute, joined the company's Clinical Advisory Board. SNWV's PR notes that TMI is "one of Canada's prominent preventative diabetic foot care, advanced wound care and diabetes education clinics". TMI treats 80 to 90 wounds per day. While we do not expect significant revenue from Canada in the immediate term, having a resident-KOL in place is a key piece of SNWV's initial commercialization strategy and one which should afford relatively efficient means of building early awareness of dermaPACE to the Canadian wound therapy community. Case studies as well as, potentially, post-marketing studies are also key components of initial awareness-building efforts.

In terms of the U.S., management indicated that Premier has already been busy at trade shows and visiting military bases. Depending on initial rates of VA-related adoption and utilization as well as (likely more incremental) OVA (i.e. outside VA in U.S.) interest, we could see material growth in U.S. revenue later this year. Nonetheless, we continue to think the U.S. market is likely to be one where incremental gains are made over time, particularly pre-reimbursement. (See our Appendix for background on the U.S. market).

So, with (effectively) no reimbursement, we continue to think 2018 will be more important as an opportunity to build additional awareness and clinical evidence and to educate wound-care KOLs about dermaPACE. We are encouraged by the reasonableness of management's initial U.S. strategy – which, essentially, clearly recognizes challenges posed by lack of reimbursement and addresses those challenges by what appears to be a systematic approach towards both initial commercialization (via already established Premier relationship targeting non-insurance providers) and evidence-based approach to encourage adoption.

SNWV dedicated much of 1H '18 to initial awareness-building – essentially 'introducing' dermaPACE to the U.S. wound community with attendance at numerous industry events. 2H '18, as explained on the Q1 call, is the next step – that is, educating wound experts and KOLs on how and when to use dermaPACE. This timeline sets up

early 2019 for a more dedicated commercialization push – which corresponds to when SNWV expects to have a CPT III ('tracking code') in place (Jan 1, 2019).

Financials
Q2 revenue was $453k, up 308% yoy, up 32% yoy and inline with our $445k estimate. This was the highest Q2 revenue in company history and follows the same record in Q1 – which also means that revenue in 1H'18 was the best 1H in company history. This is also the only consecutive three quarter period in with revenue in each quarter above $300k.

Contribution from distribution fees totaled $170k, or 38% of total revenue, and represented a significant portion of both the yoy and qoq growth. But, international device and applicator sales were also meaningful components of total revenue (42%) and international revenue growth. International device and applicator sales, which increased $120k (+167%) from Q2'17 and $71k (+59%) from Q1'18, is a (rough) gauge of OUS demand.

Meanwhile, U.S. sales were just $25k in Q2'18, compared to $6k in Q2'17 and $123k in Q1'18. While not particularly meaningful and down significantly from Q1 of this year, we had expected as much. In fact, we had modeled only $20k in estimated U.S. revenue for Q2 (as noted, we expect incremental gains in the U.S. over time). The sequential contraction was anticipated as Q1 benefitted from initial device sales for training purposes.

Most of our forecasted 2018 revenue is still OUS. Recognition of upfront fees from the JV agreements will show up as revenue in 2H'18 and into 2019. dermaPACE is still awaiting ANVISA approval in Brazil – assuming that happens, MundiMed related revenue contribution could be material – but likely not until next year. Meanwhile, 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. 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 in Canada. And, finally, as it relates to potential international catalysts – SNWV has delivered on its previously announced strategy of new JV agreements – and more could be forthcoming.

OpEx was $2.4M, compared to $1.4M and $1.3M in the prior year and quarter periods – almost all of the difference relates to non-cash stock compensation (to employees and/or consultants). SG&A has ticked up considerably since Q3 of last year. With some incremental headcount additions planned throughout 2018 – which could include positions in R&D/clinicals, reimbursement/billing, sales and accounting – as well as implementation of the initial U.S. strategy, we think operating expenses will increase through the end of the year. But, we also expect sales growth will offset at least a portion of the incremental cost.

Recently bolstered by additional net borrowings and upfront JV fees, cash balance was $671k at Q2 quarter-end, up from $154k at the close of Q1'18. Cash flow from operating activities was actually an inflow of $250k in Q2 and an outflow of $1.9M through 1H'18. Excluding changes in working capital, cash flow from operating activities was negative $1.2M in Q2 and $2.5M in 1H'18. SWNV continues to guide for cash burn to average $375k - $675k per quarter. Additional cash could come from warrant exercises – as of the close of Q2, warrants representing more than $7M were in-the-money. And, as noted, new JV agreements could be another source of funds.

Model:
We approached modeling U.S. revenue two different ways, one based on market penetration and the other 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);

Market penetration model:

Market size:
  - maximum market (i.e. liberal case): 1M patients per year
  - minimum market (i.e. conservative case): 240k patients per year
  - base market: avg of the two
  - market grows at 1%/year
- Penetration: insignificant in 2018, penetration increases by 1% per year
- Number of treatments: assume an avg of 6 treatments per patient for all cases
- Margin per treatment to SNWV:
  - $100 liberal, $75 base, $50 conservative

		2018	2019	2020	2021	2022	2023
Market size							
	liberal	1,000,000	1,010,000	1,020,100	1,030,301	1,040,604	1,051,010
	base	620,000	626,200	632,462	638,787	645,174	651,626
	conservative	240,000	242,400	244,824	247,272	249,745	252,242
Penetration	liberal	0.3%	1.0%	2.0%	3.0%	4.0%	5.0%
	base	0.3%	1.0%	2.0%	3.0%	4.0%	5.0%
	conservative	0.3%	1.0%	2.0%	3.0%	4.0%	5.0%
Treatments	liberal	20,000	60,600	122,412	185,454	249,745	315,303
	base	12,400	37,572	75,895	114,982	154,842	195,488
	conservative	4,800	14,544	29,379	44,509	59,939	75,673
Margin	liberal	$100	$101	$102	$103	$104	$105
	base	$75	$76	$77	$77	$78	$79
	conservative	$50	$51	$51	$52	$52	$53
Revenue	liberal	$2,000,000	$6,120,600	$12,487,248	$19,107,363	$25,988,561	$33,138,664
	base	$1,120,000	$3,427,536	$6,992,859	$10,700,123	$14,553,594	$18,557,652
	conservative	$240,000	$734,472	$1,498,470	$2,292,884	$3,118,627	$3,976,640

Unit placements model:

Utilization:

- on the low end (i.e. conservative), we assume one treatment per console per day and an average of 6 treatments per patient (equal to ~4 patients per console per month)
- on the high end (i.e. liberal), we assume 1.5 to 2.0 treatments per console per day and an average of 6 treatments per patient (equal to ~8 patients per console per month)
- base case is the average of the two

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

		2018	2019	2020	2021
Consoles	liberal	20	80	160	240
	base	15	60	110	165
	conservative	10	40	60	90
Patients/console/mth	liberal	7	9	18	27
	base	6	8	14	20
	conservative	4	6	9	14
Treatments	liberal	10,555	52,776	211,104	474,984
	base	6,118	35,028	124,992	281,232
	conservative	2,880	17,280	38,880	87,480
Margin	liberal	$100	$101	$102	$103
	base	$50	$76	$77	$77
	conservative	$50	$51	$51	$52
Revenue	liberal	$1,055,520	$5,330,376	$21,534,719	$48,937,649
	base	$599,760	$3,101,508	$11,758,897	$26,722,093
	conservative	$144,000	$872,640	$1,983,074	$4,506,537

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 2021.

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 $738k in 2017 to $1.3M (exc JV fees) in 2018 and to just under $4M in 2021.

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 $34M in revenue in 2021 – which values the company at approximately $0.75/share.

FINANCIAL MODEL

SANUWAVE Health, Inc.

	2016 A	Q1A	Q2A	Q3A	Q4A	2017 A	Q1A	Q2A	Q3E	Q4E	2018 E	2019 E	2020 E	2021 E
Total Revenues	$1,376.1	$149.6	$111.0	$161.6	$316.3	$738.5	$344.3	$453.2	$683.0	$778.0	$2,258.5	$6,580.5	$15,735.9	$30,939.1
YOY Growth	*42.5%*	*-44.5%*	*-45.4%*	*-36.8%*	*-51.2%*	*-46.3%*	*130.2%*	*308.1%*	*322.7%*	*145.9%*	*205.8%*	*191.4%*	*139.1%*	*96.6%*
Cost of Revenues	$565.1	$55.14	$24.7	$61.7	$100.5	$242.0	$165.5	$166.6	$169.1	$179.7	$680.9	$2,111.8	$4,972.54	$9,683.94
Gross Income	$810.9	$94.4	$86.4	$99.9	$215.9	$496.6	$178.8	$286.6	$513.9	$598.3	$1,577.6	$4,468.7	$10,763.4	$21,255.2
Gross Margin	*58.9%*	*63.1%*	*77.8%*	*61.8%*	*68.2%*	*67.2%*	*51.9%*	*63.2%*	*64.0%*	*65.5%*	*69.9%*	*67.9%*	*68.4%*	*68.7%*
R&D	$1,128.6	$260.3	$437.9	$266.8	$327.4	$1,292.5	$349.4	$368.3	$501.0	$449.0	$1,667.8	$2,026.0	$2,415.0	$2,785.0
% R&D	*82.0%*	*174.1%*	*394.4%*	*165.1%*	*103.5%*	*175.0%*	*101.5%*	*81.3%*	*73.4%*	*57.7%*	*73.8%*	*30.8%*	*15.3%*	*9.0%*
SG&A	$2,673.8	$448.6	$951.9	$475.4	$1,128.5	$3,004.4	$945.6	$2,030.8	$1,328.0	$1,644.0	$5,948.4	$9,127.2	$13,863.3	$23,575.6
% G&A	*194.3%*	*299.9%*	*857.2%*	*294.2%*	*356.8%*	*406.8%*	*274.7%*	*448.1%*	*194.4%*	*211.3%*	*101.6%*	*138.7%*	*88.1%*	*76.2%*
Depreciation	$19.9	$6.1	$6.0	$5.5	$6.6	$24.1	$5.0	$6.0	$6.0	$6.8	$23.8	$75.0	$92.0	$108.0
Operating Income	($3,316.5)	($620.6)	($1,309.4)	($647.8)	($1,246.6)	($3,824.5)	($1,121.3)	($2,121.7)	($1,321.1)	($1,501.5)	($6,065.6)	($6,759.5)	($5,607.0)	($5,213.4)
Operating Margin	*-241.0%*	*-415.0%*	*-1179.2%*	*-400.9%*	*-394.1%*	*-517.9%*	*-325.7%*	*-468.2%*	*-193.4%*	*-193.0%*	*-268.6%*	*-102.7%*	*-35.6%*	*-16.9%*
Total Other Expense	($3,121.5)	$127.1	($106.5)	($203.5)	($1,530.6)	($1,713.5)	($4,735.4)	($766.5)	($1,950.0)	($485.0)	($7,936.9)	($1,300.0)	($1,300.0)	($1,300.0)
Pre-Tax Income	($6,438.0)	($493.5)	($1,415.9)	($851.3)	($2,777.2)	($5,538.0)	($5,856.7)	($2,888.3)	($3,271.1)	($1,986.5)	($12,190.4)	($8,059.5)	($6,907.0)	($6,513.4)
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	($6,456.9)	($493.5)	($1,415.9)	($851.3)	($2,777.2)	($5,538.0)	($5,856.7)	($2,888.3)	($3,272.0)	($1,987.3)	($12,192.1)	($7,493.1)	($6,104.9)	($5,345.9)
YOY Growth	*33.9%*	*-71.3%*	*25.5%*	*-25.5%*	*12.6%*	*-14.2%*	*-9.3%*	*485.2%*	*131.1%*	*133.4%*	*120.2%*	*-38.5%*	*-18.5%*	*-12.4%*
Net Margin	*-469.2%*	*-330.0%*	*-1275.1%*	*-526.9%*	*-878.0%*	*-749.9%*	*-1701.2%*	*-637.3%*	*-479.1%*	*-255.4%*	*-539.8%*	*-113.9%*	*-38.8%*	*-17.3%*
EPS (continuing ops)	($0.06)	($0.00)	($0.01)	($0.01)	($0.02)	($0.04)	($0.04)	($0.02)	($0.02)	($0.01)	($0.08)	($0.03)	($0.02)	($0.02)
Diluted Shares O/S	107,620	138,042	138,993	139,100	139,179	138,828	139,754	148,582	165,000	196,000	162,334	250,000	285,000	330,000

Brian Marckx, CFA

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Appendix

U.S. Market Opportunities and Challenges

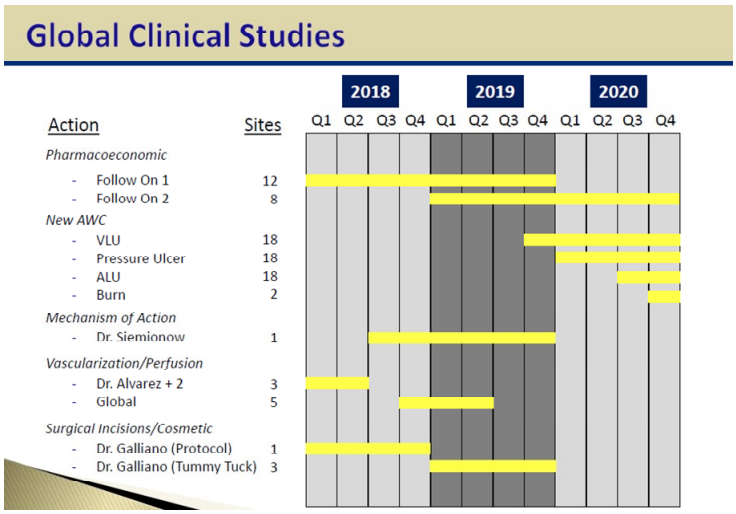
Premier Shockwave:
In February SNWV announced what effectively was the kick-off of their U.S. strategy – including securing non-dilutive equipment financing and a commercialization partnership with Premier Shockwave focused on the VA, Indian Health Service (IHS) and U.S. military treatment facilities. SNWV has had a long relationship with **Premier Shockwave**, which has offered orthopedic pain therapy (for ailments such as tennis elbow and plantar fasciitis) via treatment with SANUWAVE's OssaTron device. Mike Stolarski, principal of Premier, has similarly had a long relationship with SNWV, including serving (from 2005 – 2008) as the company's V.P. of Business Development prior to joining SNWV's board of directors in 2016.

Under this new deal, Premier will purchase the dermaPACE equipment from SNWV and then be responsible for placing the machines. Per-procedure revenue will be split between SNWV and Premier. While detailed terms were not disclosed, we think a small margin on the equipment and somewhere in the range of 5% - 15% of the per-procedure fee would not be unreasonable for SNWV. The agreement calls for Premier to purchase at least 100 units over three years. Entry into the VA channel will first require acceptance on the GSA Schedules. We think this partnership could (over time) prove meaningful from a revenue, cash flow and margin perspective. More significant, however, (at least in the very near-term) is that the partnership facilitates initial entry of dermaPACE into the U.S., provides early awareness and, hopefully, also generates clinical experience – which can be critical in helping to drive further adoption as well as (eventually) for reimbursement-related purposes.

Initial shipments to Premier happened in Q1 and resulted in SNWV's first U.S. dermaPACE-related revenue. SNWV indicated that Premier has already been active attending events and visiting military bases.

U.S. Strategy Hinges on Awareness and Clinical Evidence…
SNWV is implementing a systematic U.S. roll-out strategy which hinges on building both awareness and additional clinical evidence. With no dedicated or widespread reimbursement available, SNWV will need to pick their spots and do so with a focus on efficiency. Building the clinical data databases and generating awareness among wound-care influencers fit that mold – and appear to be high on the company's list of priorities. SNWV expects to initiate several studies in different indications and both in conjunction with, as well as against, other advanced DFU therapies. One of the first is a perfusion study, which will be conducted at Rutgers University and UCLA. We expect to hear more specifics about their plans including study designs (initially these may be mostly case studies, but expect larger, robust RCTs to be in the gameplan as well) – in the meantime, SNWV's February 2018 investor presentation provides a current outline.

Expected Upcoming Clinical and Case Studies

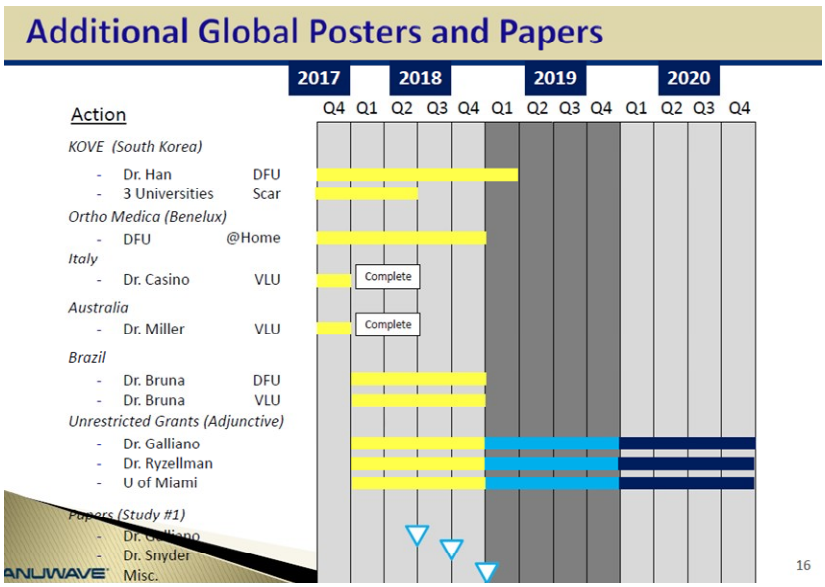


SOURCE: SNWV Feb 2018 Investor Presentation

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Awareness-building includes regular attendance at major wound care conferences – SNWV has already been very active on this front. This initial awareness push is largely focused on introducing dermaPACE to U.S. wound experts. Next steps, will be to educate them on how and when to use it. SNWV will look to have studies published and presented. KOL-engagement is a key strategy for launch of novel devices in the U.S. and expect SNWV to be active on that front as well including recruiting to lead clinical studies.

Expected Presentations and Publications



SOURCE: SNWV Feb 2018 Investor Presentation

In terms of U.S. reimbursement, novel devices often initially go to market in the U.S. sans-dedicated Medicare reimbursement. That'll be the case with dermaPACE. Initially, providers (perhaps, particularly influential KOLs) may have some success billing under a more generic CPT III code (expected availability January 1, 2019) although 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. Kick-off of SNWV's first pharmacoeconomic study ("follow-on 1") is imminent, results of which are expected to help support their case to these regional payers. This is a topic that we will be eager to hear updates on given its outsized influence on whether a provider chooses to use a particular modality or therapy.

Competitive considerations….

Despite lack of available reimbursement, we think competitive differentiation of dermaPACE as compared to other advanced DFU therapies means dermaPACE may find meaningful interest and adoption. These planned follow-on studies will undoubtedly be aimed at demonstrating these competitive points of differentiation of dermaPACE to help drive initial adoption.

There are several types of advanced DFU wound therapies approved for sale in the U.S. The most common are NPWT (such as KCI's VAC) and skin substitutes, such Apligraft and Dermagraft. Growth factors (i.e. topicals), matrices and stem cells are other therapies that have been used in the treatment of DFU. Ultrasound and electrical stimulation have also been employed as has hyperbaric oxygen therapy.

Given that NPWT has been used for decades in the treatment of chronic wounds and much of the clinical evidence surrounding chronic wound therapy lies with it (i.e. NPWT) as well as the skin substitutes, these are the modalities which we view as the most meaningful competition to dermaPACE. All of these are more invasive, require greater skill to employ and are much more expensive than is treatment with dermaPACE. SNWV estimates cost of full treatment regimen with dermaPACE is approximately $3k, as compared to ~$15k for NWPT and ~$10k for skin substitutes.

We also note that while all of three of these other products did achieve 100% wound closure in their respective FDA pivotal trials, the practical efficacy difference as compared to dermaPACE may be much less meaningful. In their initial IDE trial, median closure in dermaPACE treated ulcers achieving > 90% closure was over 99% and anything greater than 70% indicates that the wound is well on its way to being completely healed. In addition, ulcers treated with dermaPACE were almost 60% larger than those in the control group (making achieving significance that much more difficult). Also noteworthy is that trial protocol in VAC's FDA study allowed for full closure of ulcers to be completed with surgery - this was not allowed in the dermaPACE study - had it and it's conceivable that dermaPACE would have shown statistical significance in 100% closure over standard of care. See our Appendix for more detail on our comparison of dermaPACE vs. these other therapies.

Also important is that dermaPACE will not necessarily need to compete directly with these or any other advanced DFU therapies given that wound healing is often a trial and error approach if one modality fails, the clinician will move to the next, and so on. While the initial goal is to heal the wound as fast as possible, the ultimate goal is to at least eventually heal it and avoid amputation. But, the more competitive the product, likely the better chance it has to be closer to the front in the continuum of care. We think this type of application, that is, dermaPACE in conjunction with legacy advanced DFU therapies - especially for wounds that fail to close (with amputation as potentially the only other option), may represent one of the more receptive initial markets for SNWV's device. Importantly, given its non-invasive nature, dermaPACE is the only advanced DFU therapy that can be used in conjunction with another advanced DFU therapy.

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