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Zacks Small-Cap Research

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SANUWAVE Health (SNWV-OTC)

Q3 2019 Update: Commentary Suggests U.S. Roll-Out May Be Stronger Than Previously Anticipated

We value SNWV at 9x forward sales, reflecting high-growth opportunity in the U.S. 2021 sales est of $17.7M values SNWV at ~$160M, or ~$0.60/share. (While fair value est. increased by ~9% on a mrkt cap basis, our target price fell from $0.75 as a result of the increase in outstanding shares).

Current Price (12/16/19)	$0.16
Valuation	**$0.60**

OUTLOOK

Management's comments, including those related to accelerating utilization, progressively improving reimbursement picture, growing clinician (including KOL) interest and initial positive provider feedback, are encouraging and suggests that demand-pull may not only already be present but also meaningfully benefitting these initial U.S. dermaPACE commercialization efforts. The steepening unit placement rates despite carrying just a skeleton crew of a direct sales force may suggest the same. But while anecdotal at this point and much too early for us to have any confidence in the validity of that supposition, an inability to reasonably discredit over the coming quarters would likely significantly bolster our confidence that clinical utility of dermaPACE, as opposed to more capitalistic influences, are driving interest in the product. 'Significant' clinical utility could be a home run for SNWV.

While our 2019 'base case' estimate of 75 systems remains constant, the recent addition of third-party distribution and positive (albeit perhaps largely anecdotal at this point) comments related to reimbursement, initial utilization and clinician feedback may be reflective of a market with greater and/or earlier appetite for adoption of dermaPACE than we had previously anticipated.

SUMMARY DATA

52-Week High	**$0.31**
52-Week Low	**$0.10**
One-Year Return (%)	**-47.69**
Beta	**-1.73**
Average Daily Volume (sh)	**228,860**
Shares Outstanding (mil)	**268**
Market Capitalization ($mil)	**$43**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**1**
Insider Ownership (%)	**38**
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	178 A	317 A	198 A	889 E	1,582 E
2020					6,734 E
2021					17,769 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 A	-$0.01 A	-$0.01 E	-$0.05 E
2020					-$0.03 E
2021					-$0.02 E

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

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Q3 Results, Operational Update: *U.S. Roll-Out May Be Stronger Than Previously Anticipated…*

SANUWAVE (SNWV) reported financial results for their third quarter ending September 30th and provided a business update. As it relates to the financials, while revenue remains uninspiring, it has yet to reflect any substantive contribution from the U.S. dermaPACE business – which represents the majority of the long-term upside potential in SNWV's revenue and equity value. Importantly, it appears that swift and critical progress continues to be made as it relates to putting the various pieces of the domestic dermaPACE roll out puzzle together. Given the number of moving parts, not insignificant regulatory and reimbursement challenges and SNWV's tight budget, we have been pleasantly surprised by the speed and apparent near error-free successes of their early U.S. commercialization strategy.

Management's comments, including those related to accelerating utilization, progressively improving reimbursement picture, growing clinician (including KOL) interest and initial positive provider feedback, are encouraging and suggests that demand-pull may not only already be present but also meaningfully benefitting the initial U.S. dermaPACE commercialization efforts. The steepening unit placement rates despite carrying just a skeleton crew of a direct sales force may suggest the same. But while anecdotal at this point and much too early for us to have any confidence in the validity of that supposition, an inability to reasonably discredit over the coming quarters would likely significantly bolster our confidence that clinical utility of dermaPACE, as opposed to more capitalistic influences, are driving interest in the product. 'Significant' clinical utility could be a home run for SNWV.

As we discuss in our valuation section, below, *we have made some slight yet meaningful updates to our installed base projections. While our 2019 'base case' estimate of 75 systems remains constant, the recent addition of third-party distribution and positive (albeit perhaps largely anecdotal at this point) comments related to reimbursement, initial utilization and clinician feedback may be reflective of a market with greater and/or earlier appetite for adoption of dermaPACE than we had previously anticipated. Our projected 'base case' installed base has moved from 188 in 2020 to 263, from 281 in 2021 to 394 and from 360 to 504 in 2022.*

Financials

Q3 revenue was $198k ($16k U.S., $182k OUS), down 67% yoy, down 38% from Q2'19 and barely one-half of our $396k estimate. Revenue through the first nine months was $693k, $167k, or 24% of which relates to sales in the U.S. YTD revenue is down 50%, from $1.4M through the first nine months of 2018. We note, however, that $435k, or 62% of the yoy YTD decrease relates to lower licensing fees in the current period. Licensing fees mostly relate to upfront (or otherwise lumpy) JV / distribution agreement receipts which are typically amortized to revenue over several quarters (and are not necessarily reflective of historical or projected operational performance).

Q3'U19 **U.S. sales** were just $16k, accounting for 8% of total revenue. $148k, or 89% of total U.S. revenue through the first three quarters of 2019, came from product sales – just better than flat from $141k in U.S. product sales in the comparable prior-year period.

With the installed base and number of clinicians trained on dermaPACE continuing to grow (and largely tracking management's guidance), utilization-related revenue now begun, positive reimbursement-related comments from management and expansion of the sales force and support infrastructure, we should see U.S. revenue begin to significantly accelerate.

Approximately 200 clinicians had been trained on dermaPACE as of early November with another ~100 potentially learning the system by year-end. Clinician training is a necessary prerequisite to utilization and with 200 or more now versed on dermaPACE, we expect to see procedural volume and related billings and collections meaningfully increase. SNWV noted that more than 1,500 treatments had been performed and that they have had at least some success with insurance billing and claims.

As of the end of Q3'19, 58 dermaPACE systems had been placed and (as of SNWV's Q3 earnings call in mid-November) 85 devices were anticipated to be in place by the close of November. SNWV continues to guide for 110 placements by year-end 2019 and for another 300 units to be in the field by the close of 2020. SNWV is now supplementing their direct sales force with third-party domestic distribution including the Ametus Group (with ~50 sales reps dedicated to the wound care space), which was brought on in November to facilitate increasing the device placement rate.

Meanwhile**, international sales** were $182k in Q3 and $526k through the first nine months of 2019 – while down 69% and 57% from the respective prior-year periods, the majority of the decreases relate to lower licensing fees in

the current year. As we noted in a prior recent update, the distribution license agreements had not worked out as planned. MundiMed defaulted on their JV agreement with SNWV (for commercialization in Brazil) which was followed by Johnfk Medical Inc. (covering Taiwan, Singapore, Malaysia, Brunie, Cambodia, Myanmar, Laos, Indonesia, Thailand, Philippines and Vietnam) bowing out and defaulting on their agreement earlier this year.

Per management, these and others like it, were expected to bring in potentially many millions of dollars in license fees and sales-related revenues and reduce the company's reliance on external capital to fund operations. However, given recent history, we think there's enough writing on the wall to suggest these types of agreements were either too early, poorly crafted or otherwise highly susceptible to failure. That prompted us to subsequently remove all assumed contribution from these agreements from our model.

However, in **November of this year SNWV announced a new JV agreement** that is expected to pay them $600k cash, including $500k upfront at closing (management anticipates that to happen this month) and $100k upon ANVISA (Brazilian regulatory) approval of dermaPACE (which is currently anticipated in Q3 2020). If and when the JV generates revenue and related income from commercialization of dermaPACE in Brazil, profits will be shared equally between SNWV and their partner, IDIC Group (located in Sao Paulo, Brazil). Per SNWV's November 7th PR announcing the deal, completion of the Medical Device Single Audit Program (MDSAP), which was announced in late-October, is expected to help facilitate faster ANVISA approval.

As we have detailed in prior reports, given the high prevalence of diabetes, lack of sufficient and cost-effective options for treating DFUs in that country and other characteristics that potentially make that region of the world particularly receptive to dermaPACE adoption and utilization, SNWV's continued pursuit of that market is encouraging. However, given SNWV's historic lack of significant success in monetizing these types of agreements, we are taking a more cautious approach to modeling this IDIC deal. We currently apply a 50% risk discount to projected financial contribution from this JV agreement – which will be adjusted accordingly over time.

And while licensing revenue accounted for the majority of the YTD yoy decrease in international revenue, OUS product sales have also been disappointing. International product sales fell $86k, or 37%, for the quarter and by $266k, or 47%, YTD, as compared to the comparable prior-year periods. While approximately $113k of the decrease in international sales (in Q3 and YTD'19) relates to credits to Johnfk Medical (for equipment returns), there is clearly a lack of significant traction in the OUS business as a whole.

SNWV recently brought in Alira Health to lead its European commercial efforts. And, we reiterate that recent expansion of SNWV's OUS footprint, expanding 'label' from orthopedics-only to, more recently, 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 in early 2020.

We should provide some context, however, as while we have been disappointed by the lack of consistent growth in international sales, we have always viewed the U.S. market as representing the vast majority of the commercial opportunity for dermaPACE. Management has indicated that the OUS business is (or at least has been in the past) profitable (in at least some countries) and that they believe it will grow. But OUS product sales have all but stalled and the international growth that was supposed to materialize years ago, didn't. While we do believe that there are reasonable reasons why OUS could pick up, given the developing U.S. opportunity (particularly following the update by NGS) and the resources (capital, time, leadership, etc) required to take advantage of it, we wonder if another serious strategic review of OUS operations is warranted.

Cash balance was $403k at Q3 quarter-end.
Cash used in operating activities was $1.3M and $4.7M ($2.2M and $5.9M ex-changes in working capital), compared to $673k and $2.3M ($1.0M and $3.5M) in the prior year periods. Management is guiding for monthly cash burn of ~$275k - $350k per month through the end of 2019.

U.S. roll-out underway, comments are encouraging…
SNWV noted that they had 58 (up from 35 in August 2019) units placed in the U.S. at the end of Q3 and are shooting for 110 by the end of the year. Also, as of November ~200 users (up from ~116 in August) had been trained and certified to use dermaPACE and over 1,500 treatments performed on more than 200 (up from 130 in August) patients. They continue to expect to have 300 clinicians trained by year-end.

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 has been on steepening the placement rate, while a more determined focus on driving utilization will happen in 2020 – although the (favorable) NGS coding change, effective July 1, 2019, likely resulted in procedural volume beginning slightly sooner than expected.

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 most payers will use it to monitor usage and for making policy, reimbursement and rate decisions (this is not as applicable to NGS as reimbursement should eventually be relatively seamless). 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 – which presumably helped facilitate the favorable change by NGS. We will continue to be eager to hear updates about the outcome of discussions with payers.

As it relates to NGS, given that reimbursement claims will be 'individually reviewed to determine medical necessity', payment is not guaranteed. But we expect it should provide much more certainty than if the procedure was considered not medically necessary. And while, 'individually reviewed to determine medical necessity' may mean that most or all initial claims are looked through with a fine toothed comb, we think it is reasonable to believe that as each provider builds trust with a history of valid claims that it will speed and ease the billing and review process and reduce risk of claim denials. Assuming that proves to be true, it will directly benefit procedural revenue and, given its validation of the economics of dermaPACE DFU treatment in the U.S., should almost certainly benefit adoption as well.

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, 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 expected to happen in the near-term. 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's initial commercialization territories in the U.S., which they chose due to their potential receptiveness to adoption and use of dermaPACE (under a CPT III code), are Texas, California, North and South Carolina, Pennsylvania and Illinois (these are the initial territories and are in addition to the 10 NGS states). 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.

Ametus was brought on in November 2019 to supplement SNWV's direct sales efforts. Ametus has ~50 reps dedicated to the wound care space with a presence in the U.S. Midwest, Texas and the West coast. Management noted that their U.S. roll-out strategy has Ametus initially focusing on NGS territories – including those in Illinois, Minnesota and Wisconsin – and subsequently moving to the western portion of the country. Meanwhile, SNWV's direct sales team will focus on NGS's northeastern coverage including New York and parts of New England.

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 and utilization model:

Installed base: we have made some slight yet meaningful updates to our installed base projections. While our 2019 'base case' estimate of 75 systems remains constant, the recent addition of third-party distribution and positive (albeit perhaps largely anecdotal at this point) comments related to reimbursement, initial utilization and clinician feedback may be reflective of a market with greater and/or earlier appetite for adoption of dermaPACE than we had previously anticipated. Our projected 'base case' installed base has moved from 188 in 2020 to 263, from 281 in 2021 to 394 and from 360 to 504 in 2022.

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

		2018	2019	2020	2021	2022
Consoles	liberal	20	110	385	578	693
	base	15	75	263	394	504
	conservative	10	40	140	210	315
Patients/console/mth	liberal	1.00	1.00	3.50	7.00	8.75
	base	0.75	0.75	2.63	5.25	7.00
	conservative	0.50	0.50	1.75	3.50	5.25
Treatments	liberal	1,440	7,920	97,020	291,060	436,590
	base	810	4,680	57,330	171,990	277,830
	conservative	360	1,440	17,640	52,920	119,070
Margin	liberal	$100	$101	$102	$103	$104
	base	$50	$76	$77	$77	$78
	conservative	$50	$51	$51	$52	$52
Revenue	liberal	$144,000	$799,920	$9,897,010	$29,987,941	$45,431,730
	base	$81,000	$436,320	$5,398,369	$16,357,059	$25,813,483
	conservative	$18,000	$72,720	$899,728	$2,726,176	$6,195,236

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.

The updates to our installed base projections resulted in estimated U.S. revenue increasing from $4.3M (previously) in 2020 to $5.4M (currently), from $15.9M in 2021 to $16.4M and from $24.6M in 2022 to $25.8M. Meanwhile, we have OUS revenue rangebound between ~$1M and $1.5M each year from 2020 through 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.

Valuation

We value SNWV at 9x forward sales, which we think fairly reflects the potential high-growth opportunity, particularly in the U.S. We note our P/S multiple was increased from 7.5x to reflect the risk reduction and potential for accelerated time to cash-flow break even as a result of the NGS coding update and, most recently from 8.5x to reflect additional progress with the U.S. roll-out (as well as what appears to be incremental favorable market and reimbursement developments). With the updates to our model, we have SNWV generating approximately $17.7M in revenue in 2021 – which values the company at approximately $160M or $0.60/share. (While our estimated fair value increased by almost 9% on a market capitalization basis from our August update, our target price fell from $0.75 as a result of the increase in outstanding shares).

FINANCIAL MODEL

SANUWAVE Health, Inc.

	2017 A	Q1A	Q2A	Q3A	Q4A	2018 A	Q1A	Q2A	Q3A	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	$317.0	$197.6	$888.9	$1,581.5	$6,734.4	$17,769.1	$27,269.5
YOY Growth	*-46.3%*	*130.2%*	*308.1%*	*268.7%*	*44.4%*	*150.5%*	*-48.3%*	*-30.1%*	*-66.8%*	*94.6%*	*-14.5%*	*325.8%*	*163.9%*	*53.5%*
Cost of Revenues	$242.0	$165.5	$166.6	$183.6	$178.0	$693.7	$93.9	$185.9	$122.9	$301.3	$704.0	$2,544.62	$6,002.14	$8,523.07
Gross Income	$496.6	$178.8	$286.6	$412.2	$278.8	$1,156.4	$84.1	$131.1	$74.7	$587.6	$877.5	$4,189.8	$11,766.9	$18,746.5
Gross Margin	*67.2%*	*51.9%*	*63.2%*	*69.2%*	*61.0%*	*62.5%*	*47.3%*	*41.4%*	*37.8%*	*66.1%*	*55.5%*	*62.2%*	*66.2%*	*68.7%*
R&D	$1,292.5	$349.4	$368.3	$661.7	$284.3	$1,663.9	$261.0	$307.3	$299.9	$510.3	$1,378.5	$2,102.7	$2,394.5	$2,901.2
% R&D	*175.0%*	*101.5%*	*81.3%*	*111.1%*	*62.3%*	*89.9%*	*146.7%*	*96.9%*	*151.7%*	*57.4%*	*87.2%*	*31.2%*	*13.5%*	*10.6%*
SG&A	$3,004.4	$945.6	$2,034.0	$2,415.1	$1,255.8	$6,650.5	$1,675.2	$1,833.9	$2,138.1	$2,414.8	$8,062.0	$10,121.8	$15,814.5	$19,770.4
% G&A	*406.8%*	*274.7%*	*448.8%*	*405.4%*	*274.9%*	*359.5%*	*941.3%*	*578.6%*	*1081.8%*	*271.7%*	*509.8%*	*150.3%*	*89.0%*	*72.5%*
Depreciation	$24.1	$5.0	$6.0	$5.7	$5.6	$22.3	$8.4	$9.5	$22.3	$24.0	$64.2	$176.0	$260.0	$340.0
Operating Income	($3,824.5)	($1,121.3)	($2,121.7)	($2,670.4)	($1,267.0)	($7,180.3)	($1,860.4)	($2,019.5)	($2,385.7)	($2,361.6)	($8,627.2)	($8,210.7)	($6,702.0)	($4,265.1)
Operating Margin	*-517.9%*	*-325.7%*	*-468.2%*	*-448.2%*	*-277.4%*	*-388.1%*	*-1045.4%*	*-637.1%*	*-1207.1%*	*-265.7%*	*-545.5%*	*-121.9%*	*-37.7%*	*-15.6%*
Total Other Expense	($1,713.5)	($4,735.4)	($766.5)	$1,845.2	($794.4)	($4,451.1)	($336.9)	($714.9)	($362.4)	($447.6)	($1,848.6)	($2,487.6)	($1,697.2)	($1,541.1)
Pre-Tax Income	($5,538.0)	($5,856.7)	($2,888.3)	($825.1)	($2,061.4)	($11,631.4)	($2,197.3)	($2,734.4)	($2,748.0)	($2,809.2)	($10,475.7)	($10,698.3)	($8,399.3)	($5,806.2)
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)	($2,734.4)	($2,748.0)	($2,809.2)	($10,475.7)	($10,698.3)	($8,399.3)	($5,806.2)
YOY Growth	*-14.2%*	*-9.3%*	*485.2%*	*-41.7%*	*142.1%*	*110.0%*	*-60.3%*	*-53.3%*	*-4.9%*	*240.4%*	*-9.9%*	*2.1%*	*-21.5%*	*-30.9%*
Net Margin	*-749.9%*	*-1701.2%*	*-637.3%*	*-138.5%*	*-451.3%*	*-628.7%*	*-1234.7%*	*-862.7%*	*-1390.4%*	*-316.0%*	*-662.4%*	*-158.9%*	*-47.3%*	*-21.3%*
EPS (continuing ops)	($0.04)	($0.04)	($0.02)	($0.01)	($0.01)	($0.08)	($0.01)	($0.02)	($0.01)	($0.01)	($0.05)	($0.03)	($0.02)	($0.01)
Diluted Shares O/S	138,828	139,754	148,582	151,826	157,989	149,538	157,113	174,731	211,423	244,257	196,881	330,000	400,000	425,000

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APPENDIX

Major Regional CMS Contractor Coverage Update Should Benefit Adoption of dermaPACE
While we have made some downward revisions to our OUS sales, with SNWV's mid-August announcement that Medicare regional contractor, National Government Services, Inc. (NGS), updated coverage guidance for two specific codes that will cover the use of dermaPACE for the treatment of DFU's (applicable to certain conditions), we are more encouraged than ever by the domestic opportunity. Specifically, as it relates to NGSs update, per SNWV's 8/14/19 PR, effective July 1, 2019, CPT codes 0512T and 0513T (Extracorporeal shockwave therapy for integumentary wound healing, high energy) have been reclassified from Group 1 (i.e. 'not medically necessary') to CPT 3 (i.e. 'individually reviewed to determine medical necessity'). NGS's updated coverage guidance is available here (https://go.cms.gov/2L3cAgE).

NGS administers benefits to 7M A/B Medicare members in 10 states; NY, ME, RI, VT, CT, NH, MA, MN, WI, and IL which, in aggregate (per SNWV, which cites the American Diabetes Association), represents 47.5M people including 5.8M with diabetes. SNWV estimates that more than 600k people fit the treatment profile for dermaPACE in these 10 states, representing what they calculate to be a total market opportunity of more than $1B.

We had not anticipated this level of coverage nearly this soon, particularly for such a large covered-lives population. While NGS' update does not guarantee every claim will be paid, it should provide much more certainty than if the procedure was considered not medically necessary. SNWV management indicated on the Q2 call that as long as providers only use dermaPACE for its FDA indicated uses, providers should have success in receiving reimbursement under these codes.

Per CMS.gov, these two codes are not currently listed in the Medicare fee schedule but instead are contractor priced (i.e. NGS, in this case). While we will not know how 'robust' (i.e. average $ payment and proportion of valid claims that are paid) NGS reimbursement will be, management noted that Medicare will pay $314 per procedure and, again, indicated that they expect most claims will be paid (without having doctors having to endure repeated denials and rebillings). As is commonplace, private payers, if they follow NGS' lead (a topic which we will be eager to hear updates about), could be expected to pay a significantly higher rate than Medicare.

NGS Updated Coding: dermaPACE Covered Under 0512T and 0513T

Group 3 Paragraph:

The CPT codes below will be individually reviewed to determine medical necessity.

Effective for services rendered on or after July 1, 2019, 0543T- 0551T and 0553T-0562T were added to Group 3 (CPT codes that will be individually reviewed to determine medical necessity) and will be added to the tabular listing when the database has been updated.

Group 3 Codes:

CODE	DESCRIPTION
0510T	REMOVAL OF SINUS TARSI IMPLANT
0511T	REMOVAL AND REINSERTION OF SINUS TARSI IMPLANT
0512T	EXTRACORPOREAL SHOCK WAVE FOR INTEGUMENTARY WOUND HEALING, HIGH ENERGY, INCLUDING TOPICAL APPLICATION AND DRESSING CARE; INITIAL WOUND
0513T	EXTRACORPOREAL SHOCK WAVE FOR INTEGUMENTARY WOUND HEALING, HIGH ENERGY, INCLUDING TOPICAL APPLICATION AND DRESSING CARE; EACH ADDITIONAL WOUND (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)

Source CMS.gov. Article A56195, *Billing and Coding: Category III CPT Codes*

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