SECURITIES & EXCHANGE COMMISSION EDGAR FILING

SANUWAVE Health, Inc.

Form: 8-K

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 OR 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) **November 15, 2019**

SANUWAVE HEALTH, INC.

(Exact name of registrant as specified in its charter)

Nevada	**000-52985**	**20-1176000**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

3360 Martin Farm Road, Suite 100, Suwanee, Georgia	**30024**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code **(770) 419-7525**

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

[ ] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

[ ] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

[ ] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

[ ] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock, par value $0.001 per share	SNWV.QB	OTC Bulletin Board

Indicate by check mark whether the registration is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company. ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 15, 2019, SANUWAVE Health, Inc., a Nevada Corporation (the "Company"), announced its financial results for the three and nine months ended September 30, 2019 and provided a business update via conference call. A copy of the related press release is furnished as Exhibit 99.1 to this Form 8-K. A copy of the transcript of such call is furnished as Exhibit 99.2 to this Form 8-K.

The information in this Item 2.02 of this Current Report on Form 8-K and the exhibits attached hereto shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release, dated November 15, 2019, issued by SANUWAVE Health, Inc., titled "SANUWAVE Health reports third quarter 2019 financial results."

99.2	Transcript of the November 15, 2019, SANUWAVE Health, Inc. conference call to discuss the three months ended September 30, 2019 financial results and provide a business update.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SANUWAVE HEALTH, INC.

Date: November 18, 2019

By: /s/ *Lisa E. Sundstrom*
Lisa E. Sundstrom
Controller and Chief Financial Officer

SANUWAVE HEALTH REPORTS THIRD QUARTER 2019 FINANCIAL RESULTS

EXPECTS FOURTH QUARTER REVENUE TO EXCEED ONE MILLION DOLLARS

SUWANEE, GA, November 15, 2019 - SANUWAVE Health, Inc. (OTCQB: SNWV) reported financial results for the three and nine months ended September 30, 2019 with the SEC on Thursday, November 14, 2019. The Company will also host a conference call today, November 15, 2019, at 9:00 a.m. Eastern Time**.**

Highlights from the third quarter and last few weeks:

- Expect Q4 revenue to exceed $1million, due to the Brazil deal, Strong International orders, and domestic procedural revenue commencing.
- Placed 58 dermaPACE® Systems in the United States in total by the end of the third quarter and have achieved 70 placed by the end of October. On track to reach 85 by end of November and 110 by year end. We plan to place at least 300 in 2020.
- Presented abstracts, symposium, and posters at four conferences in third quarter; DFCon, SAWC, AAWC Sacramento and Wounds Canada. Our global partners also participated in three conferences.
- Over 200 patients treated and over 1,500 treatments performed.
- Over 200 clinicians certified to use and treat with dermaPACE System.
- Successful completion of Medical Device Single Audit Program (MDSAP) and Korean Ministry of Food and Drug Safety (MFDS).
- Attendance at Global Diabetic Foot Course (GDFC) in Muscat, Oman with our partners in the region, Taiba Healthcare and MenaCare.
- Signing of a term sheet for a Brazilian joint venture for the dermaPACE System with IDIC Group of São Paulo, Brazil. Fees for partnership are $600,000 with cash payments already occurring.
- Signing of a distribution partnership agreement with Ametus Group for the commercialization of the dermaPACE System.

“SANUWAVE’s focus during 2019 remains placing devices with qualified clinicians in fifteen target states. We have added some significant talent in 2019 with new employees joining us from very well established wound companies and medical backgrounds. The buzz around our device and product is growing through our expanded presence at tradeshows, addition of new hires, published articles, increased social media footprint, but most importantly through word of mouth from professionals to each other about how great and successful the device is in treating DFU’s. Third quarter was one of our busier quarters on record for activity and the team performed extremely well. We also began to refine our processes from learnings in the field. The refinement in implementation and support and sales cycles will help improve our efficiency and customer interactions as we move forward. Through these process improvements we are comfortable that we will achieve our placement goals for 2019. Added to this comfort is the recently announced agreement with Ametus Group to help support and accelerate our growth in 2019, 2020 and beyond. The playbook we are following is the same playbook used by many successful medical device companies. The fourth quarter will begin the revenue trends from all the hard work as we begin recognizing revenue from these placements. We are confident we will exceed one million dollars in revenue in the fourth quarter driven by Brazil, other international partners and dermaPACE procedural revenue. We are still working with our auditing firm to determine how much of the initial procedural revenue will be recognized in Q4, and we will discuss this more on the year end call,” stated Kevin Richardson, CEO.

SANUWAVE President, Shri Parikh added, “The 300 qualified customer leads from the past four wound care conferences and ongoing payments of reimbursement claims activity continue to validate the cost efficiency of SANUWAVE’s dermaPACE technology on the treatment of DFUs and the cost avoidance of amputation. Commercializing this only FDA cleared shockwave technology, with our new and growing sales and clinical professionals experienced in wound care together with clinicians that are deeply committed to driving positive change in today’s healthcare ecosystem is highly rewarding.”

Goals for 2019 and update on progress

- 110 dermaPACE system placements and 300 certified users
    - 58 at end of Q3, 85 by end of November, and 110 by year end
    - 200 certified users on track for over 300 by year end
- Finish with at least 10 million covered lives for insurance reimbursement
- Launch 2-3 domestic clinical studies. On track with 2 perfusion studies and dosage study under way
- Add 3-4 new countries. On track to exceed this goal.
- Add additional advisors to our scientific board. On track for additions in second half
- Add other key senior management positions. Continuous process with success to date.

This year sets the stage for SANUWAVE to shift from a clinical research company to a rapidly growing commercialization company. The process involves placing devices, training clinicians, gaining reimbursement, and supporting the infrastructure with more clinical research, published articles, and case studies. The method will allow SANUWAVE to achieve the goal of delivering a dermaPACE System anywhere and everywhere a DFU is treated. This allows SANUWAVE to accomplish the vision of providing a positive impact on life and the environment, one shock at a time.

We are well on our way of achieving our stated goals for 2019 which will allow for rapid revenue growth in 2020 and beyond. Our stated long term goal is to reach 2,000 placed devices and $100 million in Revenue in three to four years. To accomplish this long term goal, we establish yearly goals and objectives by which investors can measure managements performance. 2019 is on track to meet or exceed our objectives for the year. SANUWAVE will release their goals for 2020 in early 2020, but plan to have at least 300 devices placed during 2020 as part of those goals.

Third Quarter Financial Results

Revenues for the three months ended September 30, 2019 were $197,640, compared to $595,789 for the same period in 2018, a decrease of $398,149, or 67%. Revenue resulted primarily from sales in Europe and Asia/Pacific of our orthoPACE devices and related applicators. The decrease in revenue for 2019 was primarily due to a return of sales of devices and applicators as a result of the termination of distribution deal with Johnfk Medical Inc. (“FKS”), lower sales of refurbished applicators and lower upfront international distribution fees, as compared to the prior year. This is partially offset by device sales in Asia/Pacific. Although procedures occurred in the third quarter, we did not begin to bill and receive payments from vendors until the fourth quarter.

Operating expenses for the three months ended September 30, 2019 were $2,460,372, compared to $3,082,551 for the same period in 2018, a decrease of $622,179, or 20%. Research and development expenses decreased by $322,249. The decrease was due to a reclassification of employees and related costs from research and development to general and administrative in 2019 and lower stock based compensation expense as compared to the prior year. This is partially offset by an increase in contracting for temporary services and increased study expenses related to our dosage study in Poland. Selling and marketing expenses increased by $124,818. The increase was due to an increase in hiring of trainers and salespeople, increased travel expenses for placement and training related to the commercialization of dermaPACE and increased participation in domestic tradeshows. General and administrative expenses decreased by $441,377. The decrease was due to a decrease in stock based compensation expense related to options issued in 2018, lease expense related to pay-off of lease agreement for devices in 2018 and lower outside consultant costs. This is partially offset by an increase in salary, bonus and benefits related to new hires in 2019.

Net loss for the three months ended September 30, 2019 was $2,748,018, or ($0.01) per basic and diluted share, compared to a net loss of $825,142, or ($0.01) per basic and diluted share, for the same period in 2018, an increase in the net loss of $1,922,876, or 233%.

Cash and cash equivalents increased by $38,107 for the nine months ended September 30, 2019 and decreased by $657,873 for the nine months ended September 30, 2018. For the nine months ended September 30, 2019 and 2018, net cash used by operating activities was $4,684,611 and $2,271,566, respectively, primarily consisting of compensation costs, dermaPACE commercialization activities and general corporate operations. The increase of $2,413,045 in the use of cash for operating activities for the nine months ended September 30, 2019, as compared to the same period for 2018, was primarily due to the increased accrued operating and payroll related expenses and increased inventory and prepaid expenses in 2019. Net cash used by investing activities for the nine months ended September 30, 2019 and 2018, consisted of purchase of property and equipment of $28,990 and $32,171, respectively. Net cash provided by financing activities for the nine months ended September 30, 2019 was $4,738,556, which consisted of $1,378,142 from the exercise of warrants, $1,215,000 from the issuance of short term notes payable, $90,000 from increase in related party line of credit and $2,055,414 from advances from related parties. Net cash provided by financing activities for the nine months ended September 30, 2018 was $1,663,063, which consisted of $144,000 net from advances from related parties, $38,528 from exercise of warrants, $1,159,785 from the issuance of convertible promissory notes, $184,750 from issuance of short term notes payable and $136,000 net from increase in line of credit, related party.

Conference Call

The Company will also host a conference call on Friday, November 15, 2019, beginning at 9AM Eastern Time to discuss the third quarter financial results, provide a business update and answer questions.

Shareholders and other interested parties can participate in the conference call by dialing 844-602-0380 (U.S.) or 862-298-0970 (international) or via webcast at https://www.investornetwork.com/event/presentation/56798.

A replay of the conference call will be available beginning two hours after its completion through November 29, 2019, by dialing 877-481-4010 (U.S.) or 919-882-2331 and entering PIN #56798 and a replay of the webcast will be available at https://www.investornetwork.com/event/presentation/56798 until February 15, 2020.

About SANUWAVE Health, Inc.

SANUWAVE Health, Inc. (OTCQB:SNWV) (www.SANUWAVE.com) is a shockwave technology company initially focused on the development and commercialization of patented noninvasive, biological response activating devices for the repair and regeneration of skin, musculoskeletal tissue and vascular structures. SANUWAVE's portfolio of regenerative medicine products and product candidates activate biologic signaling and angiogenic responses, producing new vascularization and microcirculatory improvement, which helps restore the body's normal healing processes and regeneration. SANUWAVE applies its patented PACE® technology in wound healing, orthopedic/spine, plastic/cosmetic and cardiac conditions. Its lead product candidate for the global wound care market, dermaPACE®, is US FDA cleared for the treatment of Diabetic Foot Ulcers. The device is also CE Marked throughout Europe and has device license approval for the treatment of the skin and subcutaneous soft tissue in Canada, South Korea, Australia and New Zealand. SANUWAVE researches, designs, manufactures, markets and services its products worldwide, and believes it has demonstrated that its technology is safe and effective in stimulating healing in chronic conditions of the foot (plantar fasciitis) and the elbow (lateral epicondylitis) through its U.S. Class III PMA approved OssaTron® device, as well as stimulating bone and chronic tendonitis regeneration in the musculoskeletal environment through the utilization of its OssaTron, Evotron® and orthoPACE® devices in Europe, Asia and Asia/Pacific. In addition, there are license/partnership opportunities for SANUWAVE's shockwave technology for non-medical uses, including energy, water, food and industrial markets.

Forward-Looking Statements

This press release may contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, such as statements relating to financial results and plans for future business development activities, and are thus prospective. Forward-looking statements include all statements that are not statements of historical fact regarding intent, belief or current expectations of the Company, its directors or its officers. Investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, many of which are beyond the Company's ability to control. Actual results may differ materially from those projected in the forward-looking statements. Among the key risks, assumptions and factors that may affect operating results, performance and financial condition are risks associated with the regulatory approval and marketing of the Company's product candidates and products, unproven pre-clinical and clinical development activities, regulatory oversight, the Company's ability to manage its capital resource issues, competition, and the other factors discussed in detail in the Company's periodic filings with the Securities and Exchange Commission. The Company undertakes no obligation to update any forward-looking statement.

For additional information about the Company, visit www.sanuwave.com.

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SANUWAVE Health, Inc.

Kevin Richardson II

CEO and Chairman of the Board

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(FINANCIAL TABLES FOLLOW)

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2019	December 31, 2018
ASSETS	(Unaudited)	
CURRENT ASSETS		
Cash and cash equivalents	$ 402,656	$ 364,549
Accounts receivable, net of allowance for doubtful accounts	56,308	234,774
Due from related parties	-	1,228
Inventory	290,936	357,820
Prepaid expenses and other current assets	208,118	125,111
TOTAL CURRENT ASSETS	958,018	1,083,482
PROPERTY AND EQUIPMENT, net	79,300	77,755
RIGHT OF USE ASSETS	576,927	-
OTHER ASSETS	30,058	16,491
TOTAL ASSETS	$ 1,644,303	$ 1,177,728
LIABILITIES		
CURRENT LIABILITIES		
Accounts payable	$ 1,697,051	$ 1,592,643
Accrued expenses	816,866	689,280
Accrued employee compensation	1,181,813	340,413
Contract liabilities	61,429	131,797
Lease liability - right of use	227,981	-
Advances from related parties	1,094,765	-
Line of credit, related parties	338,279	883,224
Accrued interest, related parties	1,679,975	1,171,782
Short term notes payable	1,061,408	1,883,163
Convertible promissory notes, net	1,012,458	2,652,377
Notes payable, related parties, net	5,372,743	5,372,743
Warrant liability	-	1,769,669
TOTAL CURRENT LIABILITIES	14,544,768	16,487,091
NON-CURRENT LIABILITIES		
Contract liabilities	61,179	46,736
Lease liability - right of use	356,530	-
TOTAL NON-CURRENT LIABILITIES	417,709	46,736
TOTAL LIABILITIES	14,962,477	16,533,827
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' DEFICIT		
PREFERRED STOCK, par value $0.001, 5,000,000 shares authorized; no shares issued and outstanding	-	-
PREFERRED STOCK, SERIES A CONVERTIBLE, par value $0.001, 6,175 designated; 6,175 shares issued and 0 shares outstanding in 2019 and 2018	-	-
PREFERRED STOCK, SERIES B CONVERTIBLE, par value $0.001, 293 designated; 293 shares issued and 0 shares outstanding in 2019 and 2018	-	-
COMMON STOCK, par value $0.001, 350,000,000 shares authorized; 245,768,619 and 155,665,138 issued and outstanding in 2019 and 2018, respectively	245,768	155,665
ADDITIONAL PAID-IN CAPITAL	109,488,657	101,153,882
ACCUMULATED DEFICIT	(123,002,883)	(116,602,778)
ACCUMULATED OTHER COMPREHENSIVE LOSS	(49,716)	(62,868)
TOTAL STOCKHOLDERS' DEFICIT	(13,318,174)	(15,356,099)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 1,644,303	$ 1,177,728

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(UNAUDITED)

	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
REVENUES				
Product	$ 158,855	$ 240,759	$ 444,087	$ 703,054
License fees	16,250	335,697	189,307	623,570
Other revenue	22,535	19,333	59,185	66,647
TOTAL REVENUES	197,640	595,789	692,579	1,393,271
COST OF REVENUES				
Product	91,179	151,624	334,749	413,447
Other	31,744	31,970	67,908	102,256
TOTAL COST OF REVENUES	122,923	183,594	402,657	515,703
GROSS MARGIN	74,717	412,195	289,922	877,568
OPERATING EXPENSES				
Research and development	299,903	622,152	867,825	1,339,933
Selling and marketing	335,472	210,654	901,031	268,051
General and administrative	1,802,659	2,244,036	4,746,519	5,163,044
Depreciation	22,338	5,709	40,150	16,733
Loss on sale of property and equipment	-	-	-	3,170
TOTAL OPERATING EXPENSES	2,460,372	3,082,551	6,555,525	6,790,931
OPERATING LOSS	(2,385,655)	(2,670,356)	(6,265,603)	(5,913,363)
OTHER INCOME (EXPENSE)				
Gain (loss) on warrant valuation adjustment	-	2,241,008	227,669	428,846
Interest expense	(182,001)	(195,613)	(1,120,440)	(3,486,878)
Interest expense, related party	(175,522)	(199,991)	(508,193)	(583,448)
Gain (loss) on foreign currency exchange	(4,840)	(190)	(13,199)	(15,213)
TOTAL OTHER INCOME (EXPENSE), NET	(362,363)	1,845,214	(1,414,163)	(3,656,693)
NET LOSS	(2,748,018)	(825,142)	(7,679,766)	(9,570,056)
OTHER COMPREHENSIVE INCOME (LOSS)				
Foreign currency translation adjustments	(14,061)	(6,230)	13,152	(17,199)
TOTAL COMPREHENSIVE LOSS	$ (2,762,079)	$ (831,372)	$ (7,666,614)	$ (9,587,255)
LOSS PER SHARE:				
Net loss - basic and diluted	$ (0.01)	$ (0.01)	$ (0.04)	$ (0.06)
Weighted average shares outstanding - basic and diluted	211,423,362	151,852,757	181,088,995	147,550,321

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
(UNAUDITED)

	Preferred Stock		Common Stock					
	Number of Shares Issued and Outstanding	Par Value	Number of Shares Issued and Outstanding	Par Value	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
Balances as of January 1, 2018	-	$ -	139,300,122	$ 139,300	$ 94,995,040	$ (104,971,384)	$ (43,783)	$ (9,880,827)
Net loss	-	-	-	-	-	(5,856,655)	-	(5,856,655)
Cashless warrant exercises	-	-	1,023,130	1,023	117,815	-	-	118,838
Proceeds from warrant exercise	-	-	175,666	176	13,352	-	-	13,528
Shares issued for services	-	-	551,632	552	78,448	-	-	79,000
Warrants issued with convertible promissory notes	-	-	-	-	808,458	-	-	808,458
Beneficial conversion feature on convertible promissory notes	-	-	-	-	709,827	-	-	709,827
Warrants issued with promissory note	-	-	-	-	36,104	-	-	36,104
Beneficial conversion feature on promissory notes	-	-	-	-	35,396	-	-	35,396
Foreign currency translation adjustment	-	-	-	-	-	-	935	935
Balances as of March 31, 2018	-	$ -	141,050,550	$ 141,051	$ 96,794,440	$ (110,828,039)	$ (42,848)	$ (13,935,396)
Net loss	-	-	-	-	-	(2,888,259)	-	(2,888,259)
Warrant exercises	-	-	227,273	227	24,773	-	-	25,000
Cashless warrant exercises	-	-	4,606,675	4,607	(4,607)	-	-	-
Shares issued for services	-	-	71,532	71	27,429	-	-	27,500
Warrants issued for services	-	-	-	-	737,457	-	-	737,457
Conversion of promissory notes	-	-	5,896,727	5,897	642,743	-	-	648,640
Stock-based compensation	-	-	-	-	836,796	-	-	836,796
Foreign currency translation adjustment	-	-	-	-	-	-	(11,904)	(11,904)
Balances as of June 30, 2018	-	$ -	151,852,757	$ 151,853	$ 99,059,031	$ (113,716,298)	$ (54,752)	$ (14,560,166)
Net loss	-	-	-	-	-	(2,966,150)	-	(2,966,150)
Cashless warrant exercises	-	-	653,859	654	(654)	-	-	-
Conversion of promissory notes	-	-	2,600,511	2,600	283,456	-	-	286,056
Stock-based compensation	-	-	-	-	1,637,700	-	-	1,637,700
Foreign currency translation adjustment	-	-	-	-	-	-	(6,230)	(6,230)
Balances as of September 30, 2018	-	$ -	155,107,127	$ 155,107	$ 100,979,533	$ (116,682,448)	$ (60,982)	$ (15,608,790)

	Preferred Stock		Common Stock					
	Number of Shares Issued and Outstanding	Par Value	Number of Shares Issued and Outstanding	Par Value	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
Balances as of January 1, 2019	-	-	155,665,138	155,665	101,153,882	(116,602,778)	(62,868)	(15,356,099)
Net loss	-	-	-	-	-	(2,197,317)	-	(2,197,317)
Cashless warrant exercises	-	-	704,108	704	(704)	-	-	-
Proceeds from warrant exercise	-	-	620,000	620	52,580	-	-	53,200
Other warrant exercise	-	-	3,333,334	3,334	263,333	-	-	266,667
Reclassification of warrant liability to equity	-	-	-	-	262,339	1,279,661	-	1,542,000
Foreign currency translation adjustment	-	-	-	-	-	-	(2,398)	(2,398)
Balances as of March 31, 2019	-	$ -	160,322,580	$ 160,323	$ 101,731,430	$ (117,520,434)	$ (65,266)	$ (15,693,947)
Net loss	-	-	-	-	-	(2,734,431)	-	(2,734,431)
Cashless warrant exercises	-	-	2,997,375	2,997	13,003	-	-	16,000
Proceeds from warrant exercise	-	-	17,051,769	17,052	1,333,005	-	-	1,350,057
Other warrant exercise	-	-	5,804,167	5,804	451,697	-	-	457,501
Conversion of line of credit, related parties to equity	-	-	2,475,000	2,475	177,525	-	-	180,000
Stock-based compensation	-	-	-	-	31,758	-	-	31,758
Warrants issued for consulting services	-	-	-	-	36,067	-	-	36,067
Foreign currency translation adjustment	-	-	-	-	-	-	1,489	1,489
Balances as of June 30, 2019	-	$ -	188,650,891	$ 188,651	$ 103,774,485	$ (120,254,865)	$ (63,777)	$ (16,355,506)
Net loss	-	-	-	-	-	(2,748,018)	-	(2,748,018)
Cashless warrant exercises	-	-	1,710,674	1,711	18,289	-	-	20,000
Proceeds from warrant exercise	-	-	10,506,593	10,506	961,528	-	-	972,034
Other warrant exercise	-	-	40,355,006	40,355	4,014,500	-	-	4,054,855
Conversion of line of credit, related parties to equity	-	-	4,545,455	4,545	495,455	-	-	500,000
Stock-based compensation	-	-	-	-	224,400	-	-	224,400
Foreign currency translation adjustment	-	-	-	-	-	-	14,061	14,061
Balances as of September 30, 2019	-	$ -	245,768,619	$ 245,768	$ 109,488,657	$ (123,002,883)	$ (49,716)	$ (13,318,174)

SANUWAVE HEALTH, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)

	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (7,679,766)	$ (9,570,056)
Adjustments to reconcile loss from operations		
to net cash used by operating activities		
Depreciation	40,150	16,733
Change in allowance for doubtful accounts	(18,835)	(49,847)
Stock-based compensation	256,158	2,474,496
Warrants issued for consulting services	36,067	737,457
Waived proceeds from warrant exercise	36,000	-
Stock issued for consulting services	-	106,500
Loss (gain) on warrant valuation adjustment	(227,669)	(428,846)
Accrued interest	1,139,904	280,975
Interest payable, related parties	508,193	319,237
Amortization of debt issuance costs	-	2,767,361
Amortization of debt discount	-	112,984
Loss on sale of fixed assets	-	3,170
Amortization of operating lease	(14,634)	-
Changes in operating assets and liabilities		
Accounts receivable - trade	197,301	49,661
Inventory	66,884	(9,441)
Prepaid expenses	(83,007)	(76,871)
Due from related parties	1,228	-
Other assets	(13,567)	(3,901)
Accounts payable	118,908	184,442
Accrued expenses	127,586	72,483
Accrued employee compensation	863,400	362,823
Operating leases	9,513	-
Contract liabilties	(48,425)	379,074
NET CASH USED BY OPERATING ACTIVITIES	(4,684,611)	(2,271,566)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(28,990)	(32,171)
NET CASH USED BY INVESTING ACTIVITIES	(28,990)	(32,171)
CASH FLOWS FROM FINANCING ACTIVITIES		
Advances from related parties	2,055,414	156,000
Proceeds from warrant exercise	1,378,142	38,528
Proceeds from short term note	1,215,000	184,750
Proceeds from line of credit, related party	90,000	280,500
Proceeds from convertible promissory notes, net	-	1,159,785
Proceeds from note payable, product	-	96,708
Payment on line of credit, related party	-	(144,500)
Payments on note payable, product	-	(96,708)
Payments on advances from related parties	-	(12,000)
NET CASH PROVIDED BY FINANCING ACTIVITIES	4,738,556	1,663,063
EFFECT OF EXCHANGE RATES ON CASH	13,152	(17,199)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	38,107	(657,873)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	364,549	730,184
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 402,656	$ 72,311
NON-CASH INVESTING AND FINANCING ACTIVITIES		
Other warrant exercise	$ 924,649	$ -
Conversion of line of credit, related party to equity	$ 680,000	$ -
Conversion of short term notes payable to equity	$ 2,860,769	$ -

Conversion of convertible promissory notes to equity	$ 1,918,254	$ -
Reclassification of warrant liability to equity	$ 1,542,000	$ -
Advances from related and unrelated parties converted to Convertible promissory note	$ -	$ 310,000
Accounts payable and Accrued employee compensation converted to convertible promissory notes	$ -	$ 120,000
Accounts payable and Accrued employee compensation converted to equity	$ 36,500	$ -
Beneficial conversion feature on convertible debt	$ -	$ 745,223
Warrants issued with debt	$ -	$ 844,562

The accompanying notes to condensed consolidated financial statements are an integral part of these statements.

SANUWAVE HEALTH, INC.
CONFERENCE CALL TO DISCUSS THIRD QUARTER 2098
FINANCIAL RESULTS AND PROVIDE A BUSINESS UPDATE
Friday, November 15, 2019
9:00 a.m. Eastern Time

Operator
Good day, ladies and gentlemen, and welcome to the SANUWAVE Third Quarter 2019 Earnings Conference Call. All lines have been placed on a listen-only mode and the floor will be open for your questions and comments following the presentation. [Operator instructions].

At this time, it is my pleasure to turn the floor over to your host for today, Ms. Lisa Sundstrom. Ma'am, the floor is yours.

Lisa Sundstrom – Chief Financial Officer
Thank you and good morning. We appreciate your interest in SANUWAVE and in today's call. SANUWAVE will provide an update of our most recent activities as well as our 2019 third quarter financial results. Our quarterly form on Form 10-Q was filed with the SEC on Thursday, November 14, 2019. If you would like to be added to the Company's distribution list, please call SANUWAVE at 770-419-7525 or go to the Investor Relations section of our website at www.sanuwave.com.

Before we begin, I would like to caution that comments made during this conference call by management will contain forward-looking statements that involve risks and uncertainties regarding the operations and future results of SANUWAVE. We encourage you to review the Company's filings with the Securities and Exchange Commission, including without limitation our Forms 10-K and 10-Q, which identify specific factors that may cause actual events or results to differ materially from those described in the forward-looking statements.

Furthermore, the content of this conference call contains time-sensitive information that is accurate only as of the date of the live broadcast, November 15, 2019. SANUWAVE undertakes no obligation to revise or update any statements to reflect events or circumstances after the date of this conference call.

I would now like to turn the call over to our Chairman of the Board, Kevin Richardson. Kevin.

Kevin Richardson – Chairman and Chief Executive Officer
Thank you, Lisa. On today's call, we also have our President, Shri Parikh, who will be giving part of his presentation later on some leads and commercialization efforts, followed by our CFO, Lisa, discussing the financial results.

My portion of the presentation will cover our efforts to begin commercialization of dermaPACE in the US. Shri will again go into more detail with the discussion of leads, trade shows, trainings, placements and reimbursement. I will discuss the newly announced deal with our partner Ametus and a brief discussion on international deals. I will review our status on the goals for 2019, followed by an update on our clinical and operations. Towards the end of this call, we will also go over forward-looking guidance with regard to placements for Q4, revenue in Q4 and placements for 2020.

Let me start with the commercialization efforts. 2019 marks a year SANUWAVE makes its transition from an R&D company to full commercialization. We are following a playbook which has proven successful for others in the wound care and medical device space. It involves educating the marketplace about the benefits of the device for use in treating diabetic foot ulcers. It involves education, teaching the reimbursement carriers about the cost savings and benefits of using the dermaPACE system.

It involves educating the clinicians and office staff on how to properly bill for a new procedure. It also involves clinical work to support further indications for wound care and expansion. These areas include venous leg ulcers, arterial leg ulcers and pressure ulcers. It involves constant follow-up from our clinical account managers to work with clinicians with any problems that may arise as simple as a technical glitch or billing problem to just learnings that they are getting from their customers.

As a new product in the wound care space, we have a heavy lift to accomplish these goals, but the team we put in place is moving ahead in achieving all these goals at the right pace.

The steps are pretty straightforward. Placements, proper training payments, then drive usage that drives revenue, which drives more clinical and more revenue.

Step one is about placements. It is a team's mantra for 2019 – "placements, placements, placements". You've heard us say this since our first call this year. We are on track to meet or exceed the 110 goal we established earlier this year. We have a few more direct sales on the team in the NGS markets and recently announced a partnership with Ametus to help or expand our coverage reach with their direct sales force in 2019. But more importantly, they will help us expand and exceed our expectations going into 2020.

We have been fortunate in the mix of placements. We are in now over 70 locations. Some are large, well-established, well-known hospital systems and some smaller single office wound care centers as well. We are observing usage trends, which currently are bit all over the map to be quite frank. Some are using the device 30 times a week. Others are using it once or twice a week. We're trying to learn from each of the sites, so we can implement best practices at all of the sites that are using it less than expected to drive usage rates higher.

Step two with placements is leading to revenue, so our focus is on placements and payments. Once a site is trained, then we focus on billings and claims. We work with TRG who helps us on our reimbursement side of the equation. And so far, we're having very good success in certain markets. We'll keep working the claims to get the sites paid because that is what leads to revenue. We have found once a site begins to see revenue flow to them, the usage- surprise, surprise - increases. We did not begin to bill for treatments with our system until October this year as we were still working with our accountants to determine exactly how we should recognize revenue as it's received.

We have begun receiving payments for treatments. By the fourth quarter year-end call, we will have a much better feeling and understanding surrounding the questions about how revenue should be recognized going forward for the procedural treatments.

Step three, after placements and training, billing and revenue is increased. We service the account which means face to face interaction as often as we can with constant updates about the clinical work we're doing, posters we're generating and the results we're gaining from the registry of data we're collecting.

Suffice it to say, we have accomplished a lot and put in place the systems to allow for an aggressive revenue ramp beginning in Q4 of this year and into 2020. As we head into 2020, we have had to make some decisions about staffing up our sales force. Building out our direct sales force to cover the entire country is an extremely expensive proposition and it takes a lot of time.

We found Ametus after exploring many partner alternatives. Ametus is a group of independent wound care consultative sales reps who have many years of experience in this space. With over 50 direct sales people covering the Midwest states, down to Texas, across to California, the entire West Coast, they will be able to cover the entire country as we phase in Ametus in 2020.

We have a three-phase rollout with Ametus. The first phase is in the existing NGS states, Illinois, Minnesota and Wisconsin. This will supplement our already established direct sales forces in New York and New England. Actually, the training session for Ametus began yesterday and continuing today. That's where Shri is calling in from. The agreement will expand to the other states and the regions when the reimbursement calls for that to occur, so expect to have the entire region covered at some point in 2020. They will have milestones to meet, which makes us confident in our ability to achieve and drive growth in 2020 for placements, also.

Also, it's important to let you know that Ametus have experience with other products in the area which allows them to get in the doors of many wound care centers faster than we would have on our own. This, along with adding new direct sales force in the Northeast, will help us achieve our goals this year and next.

On the international front, we signed an agreement with Brazil, replacing the prior agreement and once again gaining an exclusivity fee. We have the next payment triggered when the deal closes in December and then another when we receive an ANVISA approval later in 2020. ANVISA is kind of like their FDA, and it should be made easier given our successful MDSAP audit which occurred earlier this year. Brazil is our gateway to South America and you should expect at least one more deal announced in this region before the end of the year.

The Middle East is new for us, although we've tried efforts in the past unsuccessfully. We are now dealing with direct distributors in the wound care product space and having spent the last week there at a diabetic foot conference, the demand is great. The GCC is the fastest growing region in the world for diabetes and the number of people with diabetes will double in the next 20 years. We generated over 30 leads and expect to ship 48 devices in the region in the fourth quarter, along with announcing some new partner countries.

On the operations and clinical front, the two perfusion studies are going well and should reach conclusion later this year or early next. The Poland study, which is helping refine dosage rates, is also progressing extremely well and should conclude sometime later this year or early next year. It's also led to some other research which we'll talk about on our fourth quarter call.

On the operating front, the team successfully passed the MDSAP audit and the Korean audit. These are a bigger deal than some on this call may realize. It's a major hurdle, especially for smaller companies to compete with the larger companies and accomplish. The team that we have in place spent effectively a week in the audits and passed with flying colors. It's a tribute to their hard work and effort and it makes it easier for us to enter new countries as we move forward.

Before I turn it over to Shri, I will quickly review our goals for 2019, and please remember we provide this guidance as a check to make sure we were on the right path to ultimately achieve $100 million in revenue and 2,000 placements in three to four years. And this is year one of such a commercialization effort. We needed to get to 110 devices by the end of the year and we will meet or exceed that number. We'll need to train 300 certified users. We are at 200 now and we should get to right around 300 in the coming weeks. We are adding reimbursement coverage and we'll have more updates on this before our next conference call. We've been adding sales people and will continue to add more and do so as effectively and efficiently as possible. An example is engaging with Ametus. Before year-end, we'll also add more science and medical advisors to assist us in our growth and our future clinical work. And lastly, we've been adding the number of countries we expected this year and are probably a little ahead of plan in that regard.

The team is focused on these goals: placements, training, usage, claims and revenue. We will break down each step and continuously improve. We remain confident we will achieve the long-term goal for a series of short-term milestones which you can monitor. Ultimately, the one overriding goal of the company is focused on delivering a device anywhere and everywhere a wound is treated.

With that, let me turn it over to Shri Parikh, our President. Shri?

Shri Parikh – President

Thank you, Kevin. Good morning, everyone, and thank you all for joining our Q3 call. Apologies for my voice as I caught a cold here in Milwaukee at our Ametus and new hire training. I'll try to get through it as best as I can without a sneeze or a cough.

While we are feeling much interest globally, we are clearly understanding that the current importance of successfully commercializing is indeed in the US. So, while we balance our global expansion strategy, our focus and resource investments remain primarily directed here at the US market. This morning I will share information pertaining to the following three areas: conference activities and feedback from customers; observations and current placement sites; and a reimbursement update, meetings, and other ongoing activities.

First - conference activities and feedback from customers. Conference, symposium and participant engagement activity has been strong and remains very impressive. Conference activity typically accelerates the latter part of the year. One main reason for this is that there are continuing medical education credits or often referred to as CME credits that are requirements that many clinicians attempt to fulfill before the year-end. We support sponsoring these meetings because of the broad exposure it provides for SANUWAVE and an introduction to our dermaPACE technology.

As we sit today with greater than 70 placements, conference participation and customer engagement is what you would expect; increasing as one of the newest and hottest technologies in wound care. What is not what we would have expected is the outcome of DFU wound treatment when the many patients are treated with dermaPACE. These results have created a greater than 92% overall impressive satisfaction rate and speaks to the high compliance clinicians are experiencing with their patients, and the subsequent results are better, or faster, than what we observed in our studies.

We sent out a press release sharing our plans to attend many trade shows and conferences earlier in Q3. To illustrate just a few of these, SAWC, which is Symposium on Advanced Wound Care which was in Vegas, had roughly 1,400 participants, of which we generated 141 qualified leads. DFCon, the Diabetic Foot Conference, which was held in Los Angeles, had roughly 300 participants of where we generated 64 leads, and AAWC, Association for the Advancement of Wound Care was in Sacramento, and again, a smaller regional participation volume of 75 participants of 17 leads.

We built a comprehensive database to follow up with each of these leads, greater than 200, in just these three examples, to provide requested information and feedback leading to an office clinic placement and ultimately treatment. Familiarity, excitement surrounding our dermaPACE technology is increasing and getting louder. dermaPACE is indeed the hottest new technology in wound care and the activity at these conferences is validating this.

On to number two and observations from our current placement sites. Customers in San Antonio, Texas to others in Statesville and Winston-Salem to Lenoir, North Carolina have heavy DFU population. Markets appreciate that dermaPACE is a technology influential and driving change in today's healthcare ecosystem. From an industry vantage point, prevention has long been a critical puzzle piece to driving down healthcare costs. Our goal, for much of our careers, has been to deliver innovative, cost-effective products and solutions that help to reduce costs and better improve outcomes, quality and functionality of patients treated with these technologies and solutions. dermaPACE is indeed such a technology.

Clinicians in the markets I just mentioned were skeptical at first, as they should be with anything new. Prior to using, clinicians at these clinics understand where it would ideally fit within their practice protocols. What we have learned is that this group and others are moving dermaPACE higher amongst their DFU treatment options and experiencing the faster, better results and wound healing than expected. Neovascularization, profusion and closure, are all of the dynamics regarding the healing cascade supporting this. These practices referenced roughly 20 to 30 DFU patients a week with this dermaPACE technology and are having very positive results.

And finally, on to number three, our reimbursement. As shared in previous calls and updates, we've developed a comprehensive reimbursement strategy targeting three major sectors of payers in our market. These include Medicare, Medicaid and the private commercial payers. Understanding this factor to be the most critical and customer decision-making for overall assessment for dermaPACE usage, we've engaged with the right resources that have not only helped us secure reimbursement codes, which are referenced as the CPT tracking codes, but quantified to a reimbursable amount.

Executing on our strategy also requires proper support of claim submissions and assisting our customers through this oftentimes challenging process, particularly challenging with a relatively new product and treatment modality. We partnered with a claims company TRG, that Kevin referenced earlier, that helps our customers and supports this activity of reimbursement while we continue to schedule and participate in meetings with each of the payer groups I'd referenced. With over 1,400 patient treatments and increasing our claims submissions with each patient, subsequent reimbursement meetings at regional and national payer levels will continue to occur.

We've had successful ones in the past few months and clarity surrounding our value proposition is indeed growing. Our value proposition and goal is to achieve full coverage reimbursement for DFU treatment with dermaPACE. The way to do this is via local coverage determination, Medicare approval at the individual state, region levels, like we have recently shared on our bulletin with the NGS (National Government Services) announcement.

You've read updates on recent coverage wins as the cost benefit of dermaPACE treatment is increasingly understood. Reimbursement success and claims payments will continue to occur. We will continue meetings and orienting the payers in the new cost-efficient approach that dermaPACE offers them compared to more cost expensive alternatives that are in the marketplace.

With that, I'll turn it over to you, Lisa.

Lisa Sundstrom – Chief Financial Officer

Thank you, Shri. Revenues for the third quarter of 2019 were $198,000, a decrease of $398,000, or 67% from the prior year. Revenue resulted primarily from the sales in Europe and Asia-Pacific of our orthoPACE devices and related applicators. The decrease in revenue for 2019 is primarily due to a return of sales of devices and applicators as a result of the termination of our distribution deal with FKS. Also, a part of that is lower sales of refurbished applicators and lower upfront international distribution fees as compared to the prior year. This is partially offset by an increase in device sales in the Asia-Pacific.

Research and development expenses for the third quarter of 2019 were $300,000, a decrease of $322,000, or 52%. The decrease in research and development expenses was due to a reclassification of employees and related costs from research and development to general administrative in 2019 and lower stock-based compensation expenses compared to prior year. This is partially offset by an increase in contracting for temporary services and increased study expenses related to our dosage study in Poland.

Selling and marketing expenses for the third quarter of 2019 were $335,000, an increase of $125,000, or 59%. This increase in selling and marketing expenses was due to an increase in the hire of trainers and sales people and increased travel expenses for placements and training related to the commercialization of dermaPACE and increased participation in domestic trade shows.

General and administrative expenses for the third quarter of 2019 were $1.8 million, a decrease of $441,000, or 20%. The decrease in general and administrative expenses was due to a decrease in stock-based compensation expense related to options issued in 2018, the lease expense related to a pay-off of a lease agreement for devices in 2018, and lower investor relations costs in 2019. This is partially offset by an increase in salary bonus and benefits related to new hires from 2018.

Net loss for the three months ended September 30, 2019 was $2.7 million or a negative $0.01 per basic and diluted share compared to a net loss of $825,000, or negative $0.01 per basic and diluted share for the same period in 2018, an increase in the net loss of $1.9 million or 233%. As of September 30, 2019, we had cash on hand of $403,000 as compared with $365,000 at December 31, 2018. Net cash used by operating activities was $4.7 million for the first nine months of 2019 as compared to $2.3 million for the same period in 2018. The increase in the use for operating activities was primarily due to increase in accrued operating and payroll related expenses and increased inventory and prepaid expenses in 2019.

We continue to protect our burn rate from operations and stretch payables. Our burn rate has increased to $450,000 to $550,000 per month in the third quarter and will continue at this rate for the remainder of 2019 and early into 2020. The increase is mainly due to the commercialization of dermaPACE through new hires and sales and customer account managers, and the new distribution agreement with Ametus Group. This new distribution group will however be much more cost effective than hiring our own sales people. We expect our burn rates to decrease as we move through 2020 as we see payment on dermaPACE procedures and improve our billing and collection process.

With that, I'll turn it back over to Kevin. Kevin.

Kevin Richardson – Chairman and Chief Executive Officer

Thanks, Lisa. I want to conclude with a few thoughts. Our team is really driven by our vision, which is to get as many dermaPACE devices as possible out to save as many limbs and as many lives as possible. As we do that, it's an addictive feeling within the Company, and we're really seeing that within the wound care community as they see the benefits we get from our device, the dermaPACE system, is gaining a lot of momentum out in the marketplace.

You've heard from myself, Shri, and Lisa, and have been given updates on our goals for 2019. We discussed international, clinical work, operating improvements, leads, pipeline conference, reimbursements and Ametus. With all that, it gives me comfort to say Q4 should exceed $1 million in revenue for the first time since we've been a public company. That'll be driven by the Brazil deal, but also the other international revenues with product shipping in the fourth quarter and procedural revenue for the first time being recognized.

We will end with at least 110 placements, the majority of which will be generating revenue for us. During 2020, our current plan is to add at least 300 placements, which will generate revenue. The addition of the direct sales team we have mentioned, and Ametus, give us tremendous confidence in this number. We may end up exceeding it, but it's too early to comment on that currently.

International sales should also be a record in 2020, as we should see increases in all geographies, given some rollouts and reimbursement changes in certain regions. We will also kick off some additional studies in 2020, which will add to the usage momentum in future years. Lastly, we're getting closer to the point where we will be breakeven. Currently, our best estimate is when we get to around 200 devices generating procedural revenue, which should occur sometime in the first half of 2020; we should be at a point that's close to breakeven.

So with that, let me now turn it back over to Q&A and open it up for questions.

Operator
Thank you. [Operator instructions]. We'll go first to Brian Marckx, Zacks Investment Research.

Q: Hi, good morning, Kevin, and everybody else. I jumped on the call a little bit late, so I apologize if you've covered some of this stuff. In terms of usage, Kevin, are you generating revenue for usage at this point?

Kevin Richardson – Chairman and Chief Executive Officer
We've received money; we have been getting claims. People have been getting paid. So, the horse has left the barn; the ship has left its station. I mean it's starting. So that game is beginning. The first payments were received in Q4. Usage is going well. It's a little mixed. It depends. Some sites that are getting paid are using it more; some sites are using it more just because they're seeing the effects of it. And some, we just have to spend a little more time educating on usage and really working the claims process with them. Some are just unfamiliar with it. They don't understand how the process works. So we're doing a lot on the educational front.

But right now, we're seeing some really heavy users and then some lightly users, too. But it's usage in general, is a little stronger than we were anticipating when you average everything. But I don't want to extrapolate averages because it's the law of low numbers right now. On any given week, as we add more clinicians that number can fluctuate a lot right now.

Q: Okay, great. So is it, when they use it, are they able to file under the NGS reimbursement? Or is it, do they get paid some way else? Can you talk about roughly what percentage of the users are successfully getting paid through claims?

Kevin Richardson – Chairman and Chief Executive Officer
Sure. I don't have all of that information, but I can walk you through the process. After a clinician uses the device, they'll submit a claim using the code 0512T or 0513T. They'll submit that if it's an NGS, that means it's a Medicare patient. If it's not NGS like maybe it's in Texas, they might submit it to Humana as an Advantage patient or something like that. And they'll put down a specific rate that they're looking to get reimbursed for. They'll work with our clinical, our reimbursement specialists, to make sure they're doing that the proper way. And then when they get paid, we get paid.

And so far we've had some good experience on the payment side and on the claim side. I would say where we've had the poor experience has been where they filled out the claim forms incorrectly, and we've had to work with TRG to fill out the forms the proper way. Again, it's a new procedure and it's a new claim so there's some hoops that they're having to jump through a little more. We're trying to make that easier for their billing people to submit claims.

Q: Okay. So I'm trying to get a better understanding in terms of the placements and where the placements are going and whether these are clinicians that are actually using it or they're just saying, sure why not, it fits in a corner.

Kevin Richardson – Chairman and Chief Executive Officer
Yes. Yes, sorry. Everywhere that we have a device, they're using it. And then part of the agreement is that they need to submit claims. Our agreement has that there's a 60-day period where they can use it on a trial basis, but they're still supposed to submit claims during that period. And if after 60 days they don't like it, they can basically say, "Hey I don't like it" and give it back. We haven't had that occur yet anywhere From a claim standpoint, it's really us following up and making sure they're submitting it the right way. So we're having good success. We have a lot of treatments that have occurred based on our logs.

And there also is, how much we'll end up collecting and how much they're going to get paid. That's really the million dollar question, Brian. I mean, they're going to submit and try to get paid. But in areas where there is no coverage or there's not a negative, not a positive coverage, it's just kind of a neutral coverage, it's unclear whether and how much they will get paid for using the device. And that's really the million dollar question right now.

Q: Yes. Okay. And just one on your sales force and now that you have the agreement with Ametus, what does that look like going forward? Can you give us an idea of how big the sales force is today, if you can break it out between your direct and Ametus, and then what does that look like, say, through the end of next year?

Kevin Richardson – Chairman and Chief Executive Officer
Sure. I'll go through our direct sales force today is five direct sales people and we have a number of clinical managers supporting them. That will expand, I think, maybe it's one a month or one every two or three months next year, and it's specifically east of the Mississippi. West of the Mississippi it'll be Ametus. They're in three states now, Illinois, Minnesota and Wisconsin, with I believe, it's five or six reps in those regions. The phase two will kick off sometime in Q1 and that will be in the Texas area. And then phase three would be the West Coast, the California area, probably in Q2.

And so we're trying to map it so that it matches to the reimbursement We are making sure that reimbursement's in place. It's just a lot easier to sell because then the claims process is more or less going to happen. It is just an easier placement to make when they don't have to go through the hassle of appeals.

And right now we're having good success in a lot of markets, a better success in some markets than we were expecting. And so that's how we'll roll out next year. They have 50 direct sales people in their force. I'd probably expect us to add probably somewhere between five and 15 next year. That really depends on where and when the markets open up to us, and then we'll make sure that we have the right direct sales in place to support that.

Q: Okay, great. And is your sales force in certain geographies and Ametus is somewhere else?

Kevin Richardson – Chairman and Chief Executive Officer
We don't overlap. Our clinical account managers will be there to support them and us. But we're not going to have one of ours and one of theirs in Illinois. We're not going to compete. There's an exclusivity for those territories, where they can and focus on ramping up. They have certain milestones that need to be met. Our direct sales have certain quotas that need to be met. That's why we're very comfortable with our guidance for next year, placing at least 300 devices.

Q: Okay.

Kevin Richardson – Chairman and Chief Executive Officer
Revenue producing devices. Yes, exactly.

Q: Yes. That's even better. Thank you.

Operator
We'll move next to Private Investor, Terry Thompson.

Q: Good morning, Kevin.

Kevin Richardson – Chairman and Chief Executive Officer
Morning, Terry.

Q: Exciting times. I have a little more basic question. I have a couple of family members that are diabetic. Is there somewhere on a website or with the company, where a person could go and find out where in their area there'd be a clinic or a doctor that has the dermaPACE system?

Kevin Richardson – Chairman and Chief Executive Officer
Not yet, but eventually, we will have that. If you want to call me or Shri or Lisa offline, we'll be glad to help you out. But ultimately, probably in the first quarter next year, we'll have one of those zip code finders, where you'll put in your zip code and it'll tell you where the closest device is. But that'll roll out in the first quarter next year.

Q: Okay. Very good. Thank you very much. Keep up the good work and excited to see what's coming up in the next quarter.

Kevin Richardson – Chairman and Chief Executive Officer
Great. Thanks, Terry.

Operator
[Operator instructions]. We'll go next to Private Investor, James Terwilliger.

Q: Hi, Kevin. Can you hear me?

Kevin Richardson – Chairman and Chief Executive Officer
I can hear you, James. How are you doing?

Q: Good. How are you?

Kevin Richardson – Chairman and Chief Executive Officer
I'm great.

Q: So, it seems like this Q3 here is kind of the calm before the storm so to speak. My question first, and I know you don't want to get into guidance too much, because there's too many moving parts, but when I look at 2020, we have a number of devices placed in the US, they should be generating revenue. We have reimbursement with this price procedure that changed maybe the model in terms of your launch. You recently have a partner in the US for distribution in three states, maybe more announcements to come. You're going direct and other states. So, there's a lot of moving parts here. But how should I think of maybe 2020 revenue from a global perspective?

Kevin Richardson – Chairman and Chief Executive Officer
Sure. Maybe, I'll start with just how our revenue model works in the US, and then we can talk on some of the challenges we'll face with revenue recognition, which I'll get to. Right now, the way it works is that when a device is used to treat a diabetic foot ulcer, we are paid $200. And then we're also getting some money, a small amount of money for a wound kit and that's the way we've priced our model. So, that's a fixed item so to speak, as you're trying to think about modeling this out, James.

The next piece will be placements and then the other is usage. And if they're using it one time a day, that's five times a week, five times $200 is $1,000 a week. So that's the math on how we think about a revenue per placement.

And as I've mentioned, we're running a little higher than that now on average, but it's too early to tell what the true usage number will be. I mean we have some sites at 30 a week in some at one or two a week. So, we have some that are well below and some that are well above. Our job as a company with our clinical account managers will be to drive that usage number higher and that's about education and training and making sure that the claims process is as simple as possible, so they know they're getting paid.

From a revenue recognition standpoint, the difficulty we're going to have is how often we're going to get paid, because we only collect when they get paid. We're not going to charge them for an event that they don't get paid on, otherwise no one would do it. If they knew they're going to lose $200, they're never going to touch our device. So, we only get paid when they get paid, and that's going to come down to making sure we have the claims done the right way and that we're following up with that.

We follow up with a few different methods. One is the applicators; we can find out usage rates so we can track and monitor how often it's been used and bill them based on that. We can also track the number of wound kits used, which gives us an indication of how often they've used the device for treatment. And then finally, as we roll out our tissue analytics partnership, we'll able to collect data and see within a registry exactly what's happening on a daily basis with our device. So, we'll be able to track and bill much more effectively going into 2020.

Currently though, this is the part, James, I wish I had a crystal ball and could say yes, we're going to collect on a 100% of what's treated. And if we did, then yes, you can get to a hypothetical revenue number that's pretty substantial right now, because we are going to be placing devices that are generating revenue. We made that shift midsummer once we got the NGS movement.

So, as we're going through 2020, we're going to begin seeing a lot of revenue. I'm not really sure what will end up from a rev-rec standpoint. If it's on a gross billing basis, the number is actually high, very high. How much we receive is going to be the determination we're trying to figure out with the accountants on what we'll be able to report, whether it's a net revenue number or is there an allowance for non-paid treatments. That's all stuff we're trying to figure out right now. And unfortunately, we don't have enough data to be actuarially accurate going forward so we're in a little bit of limbo. The one thing I know is it's going to be a lot more than it is today. The one thing I know is that we're seeing treatment revenue increase each week. We're seeing the number of treatments getting paid each week increase.

Everything's trending in the right directions. We're moving towards a pretty big number and the model, as you do the math, expands pretty exponentially. And importantly, the most important and what's going to drive this is the word of mouth, where we're helping the patients get better faster and we're going to save insurance companies a lot of money. That is really the two driving factors that are going to help us roll out at an extremely quick rate next year. We have the direct sales force, again, ready to roll out in East. We have the Ametus agreement phased approach for 2020 starting in the NGS states, rolling into the Southwest, then to the West Coast, so that we'll have pretty much the entire country covered by the end of next year.

Q: Okay, fantastic. And then lastly, then I'll jump back in queue, on the Brazil deal, is that recognized in the fourth quarter or is that revenue recognition allocated throughout 2020? How should we think of the Brazilian deal? You talked about, I think, $600,000 in the press release. How does that work from a revenue recognition accounting standpoint?

Kevin Richardson – Chairman and Chief Executive Officer
Yes. The way it works is that there's an exclusivity fee that has two triggers. One is a trigger when the deal closes. That trigger of $500,000 will be recognized in the fourth quarter with cash already coming in and will continue to come in and help us this year. And then there'll be another $100,000 that comes in when we get the ANVISA approval, which is basically their FDA approval, which should occur sometime in the second, third or fourth quarter next year. And then upon that event, we'll recognize it, whenever that occurs.

Q: Okay, great. I'm going to jump back in queue. Thank you very much.

Kevin Richardson – Chairman and Chief Executive Officer
Great. Thanks, James.

Operator
With no other questions holding, I'll turn the conference back to Mr. Richardson for any additional or closing comments.

Kevin Richardson – Chairman and Chief Executive Officer
Great. Well, we'd like to thank everyone for participating in the call. As always, feel free to reach out to us if you have any questions or concerns or would like to stop by and visit our site. We look forward to further updates this year and our fourth quarter call next year. Thank you very much.