SECURITIES & EXCHANGE COMMISSION EDGAR FILING

SANUWAVE Health, Inc.

Form: 8-K

Date Filed: 2019-08-19

Corporate Issuer CIK: 1417663

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) **August 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 August 15, 2019, SANUWAVE Health, Inc., a Nevada Corporation (the "Company"), announced its financial results for the three and six months ended June 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 August 15, 2019, issued by SANUWAVE Health, Inc., titled “SANUWAVE Health reports second quarter 2019 financial results.”
99.2	Transcript of the August 15, 2019, SANUWAVE Health, Inc. conference call to discuss the three months ended June 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: August 19, 2019

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

SANUWAVE HEALTH REPORTS SECOND QUARTER 2019 FINANCIAL RESULTS

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

Highlights from the second quarter and last few weeks:

- Placed 36 dermaPACE® Systems in the United States, exceeding expectation of 35 devices by end of second quarter. On track to reach 65 by end of third quarter and 110 by year end.
- NGS change in reimbursement status leads to adding 10 new states to the strategic growth plan. Accelerating placement plan by one full year.
- Presented abstracts, symposium, and posters at 5 conferences in second quarter
- Progress on completing two perfusion studies and one international Diabetic Foot Ulcer (DFU) treatment study.
- Two peer review articles published in Q2: "Focused shockwave therapy in diabetic foot ulcers: secondary endpoints of two multicentre randomized controlled trials" by Robert Galiano M.D, Robert Snyder, DPM, Perry Mayer MB, Oscar Alvarez PhD, Lee C. Rogers DPM in the June 2019 issue of the Journal of Wound Care and "Extended Extracorporeal Shockwave Therapy for Chronic Diabetic Foot Ulcers: A Case Series" by Wen-Yi Chou, MD, Ching-Jen Wang, MD, Jai-Hong Cheng, PhD, Jen-Hong Chen, MD, Chien-Chang Chen, MD and Yur-Ren Kuo, MD in the May 2019 issue of Wounds.
- Over 130 patients treated
- 116 clinicians certified to use and treat with dermaPACE System.
- Expecting initial procedural revenue in Q3.

"SANUWAVE's focus during 2019 remains placing devices with qualified clinicians in fifteen target states. We recently added New York, Illinois, Massachusetts, Vermont, Rhode Island, New Hampshire, Maine, Connecticut, Minnesota, and Wisconsin to our targeted markets due to a change in reimbursement policy put forth by National Government Services (NGS). We exceeded our goal for placements in the second quarter and are on pace to achieve our goal for the third quarter. Second quarter revenue was lower due to $150,000 in license fees which occurred in 2018 which were not included in 2019 numbers. License fees tend to be one time in nature and lumpy and the timing is difficult to predict. Revenue growth is expected to accelerate dramatically later in the year as devices move from placement to revenue producing. We are being very deliberate and balanced on this initial roll out, and once we gain reimbursement coverage in specific markets, we will then accelerate growth in those geographies," stated Kevin Richardson, CEO.

SANUWAVE President, Shri Parikh comments, "We are very encouraged by the success we are having with clinicians and patients. Over the past few busy traveling weeks I've had the pleasure to meet with many clinical and economic customers, as well as patients, and the response on the experience with our technology has been terrific. We are excited share many of these testimonials with you on our newly improved website in the near future. Once we achieve reimbursement standards in focused markets, our business model allows for a rapid expansion. The NGS announcement yesterday redirected our immediate attention on the northeast and Midwest markets. The team is focused on placing devices within this NGS market, helping to rapidly begin recognizing revenue. Our top focus remains appropriate customer placements for DFU treatments, which will lead to revenue growth as we exit 2019 and throughout 2020."

Goals for 2019 and update on progress

- 110 dermaPACE system placements and 300 certified users
    - 36 at end of Q2, 65 by Q3, and 110 by year end
    - 116 certified users on track for over 300 by year end
- Finish with at least 10 million covered lives for insurance reimbursement
    - NGS's 7 million lives allows SANUWAVE to achieve this target
- Launch 2-3 domestic clinical studies. On track with 2 perfusion studies 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.

2019 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.

Second Quarter Financial Results

Revenues for the three months ended June 30, 2019 were $316,976, compared to $453,210 for the same period in 2018, a decrease of $136,234, or 30%. Revenue resulted primarily from sales in Europe of our orthoPACE devices and related applicators and sales in the United States of our dermaPACE applicators. The decrease in revenue for 2019 is primarily due to a decrease in sales of new and refurbished applicators in Asia/Pacific and the European Community and lower upfront international distribution fees, as compared to the prior year. This is partially offset by higher device sales in the United States and Asia/Pacific.

Operating expenses for the three months ended June 30, 2019 were $2,150,610, compared to $2,408,314 for the same period in 2018, a decrease of $257,704, or 11%. Research and development expenses decreased by $21,480. The decrease was due to a reclassification of employees and related costs from research and development to general and administrative in 2019. This is partially offset by an increase in contracting for temporary services and increased study expenses related to our new dosage study in Poland. Selling and marketing expenses increased by $248,782. The increase was due to an increase in hiring of trainers and salespeople and increased travel expenses for placement and training related to the commercialization of dermaPACE. General and administrative expenses decreased by $485,283. 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 investor relations costs. This is partially offset by an increase in salary, bonus and benefits related to new hires in 2018.

Net loss for the three months ended June 30, 2019 was $2,734,431, or ($0.02) per basic and diluted share, compared to a net loss of $2,888,259, or ($0.02) per basic and diluted share, for the same period in 2018, a decrease in the net loss of $153,828, or 5%.

Cash and cash equivalents decreased by $210,103 for the six months ended June 30, 2019 and decreased by $59,470 for the six months ended June 30, 2018. For the six months ended June 30, 2019 and 2018, net cash used by operating activities was $3,386,634 and $1,598,202, respectively, primarily consisting of compensation costs, dermaPACE commercialization activities and general corporate operations. The increase of $1,788,432 in the use of cash for operating activities for the six months ended June 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 six months ended June 30, 2019 and 2018, consisted of purchase of property and equipment of $25,839 and $13,612, respectively. Net cash provided by financing activities for the six months ended June 30, 2019 was $3,219,279, which consisted of $1,403,257 from the exercise of warrants, $1,231,000 from the issuance of short term notes payable and $585,022 from an advance from related parties. Net cash provided by financing activities for the six months ended June 30, 2018 was $1,563,313, 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, $85,000 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 Thursday, August 15, 2019, beginning at 9AM Eastern Time to discuss the second quarter financial results, provide a business update and answer questions.

Shareholders and other interested parties can participate in the conference call by dialing 844-369-8770 (U.S.) or 862-298-0840 (international) or via webcast at https://www.investornetwork.com/event/presentation/53271.

A replay of the conference call will be available beginning two hours after its completion through August 22, 2019, by dialing 877-481-4010 (U.S.) or 919-882-2331 and entering PIN #53271 and a replay of the webcast will be available at https://www.investornetwork.com/event/presentation/53271 until November 15, 2019.

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

	June 30, 2019	December 31, 2018
ASSETS	(Unaudited)	
CURRENT ASSETS		
Cash and cash equivalents	$ 154,446	$ 364,549
Accounts receivable, net of allowance for doubtful accounts of $58,293 in 2019 and $33,045 in 2018	175,041	234,774
Due from related parties	-	1,228
Inventory	423,932	357,820
Prepaid expenses and other current assets	251,616	125,111
TOTAL CURRENT ASSETS	1,005,035	1,083,482
PROPERTY AND EQUIPMENT, net	85,782	77,755
RIGHT OF USE ASSETS	398,698	-
OTHER ASSETS	23,561	16,491
TOTAL ASSETS	$ 1,513,076	$ 1,177,728
LIABILITIES		
CURRENT LIABILITIES		
Accounts payable	$ 1,456,727	$ 1,592,643
Accrued expenses	795,458	689,280
Accrued employee compensation	865,900	340,413
Contract liabilities	114,814	131,797
Lease liability - right of use	167,437	-
Advances from related parties	585,022	-
Line of credit, related parties	726,009	883,224
Accrued interest, related parties	1,504,453	1,171,782
Short term notes payable	3,079,767	1,883,163
Convertible promissory notes, net	2,860,478	2,652,377
Notes payable, related parties, net	5,372,743	5,372,743
Warrant liability	-	1,769,669
TOTAL CURRENT LIABILITIES	17,528,808	16,487,091
NON-CURRENT LIABILITIES		
Contract liabilities	67,361	46,736
Lease liability - right of use	272,413	-
TOTAL NON-CURRENT LIABILITIES	339,774	46,736
TOTAL LIABILITIES	17,868,582	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; 188,650,891 and 155,665,138 issued and outstanding in 2019 and 2018, respectively	188,651	155,665
ADDITIONAL PAID-IN CAPITAL	103,774,485	101,153,882
ACCUMULATED DEFICIT	(120,254,865)	(116,602,778)
ACCUMULATED OTHER COMPREHENSIVE LOSS	(63,777)	(62,868)
TOTAL STOCKHOLDERS' DEFICIT	(16,355,506)	(15,356,099)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 1,513,076	$ 1,177,728

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

	Three Months Ended June 30, 2019	Three Months Ended June 30, 2018	Six Months Ended June 30, 2019	Six Months Ended June 30, 2018
REVENUES				
Product	$ 220,667	$ 243,465	$ 285,232	$ 482,033
License fees	66,808	203,757	173,058	287,873
Other revenue	29,501	5,988	36,649	27,576
TOTAL REVENUES	316,976	453,210	494,939	797,482
COST OF REVENUES				
Product	178,458	128,716	243,570	254,309
Other	7,423	37,927	36,164	77,800
TOTAL COST OF REVENUES	185,881	166,643	279,734	332,109
GROSS MARGIN	131,095	286,567	215,205	465,373
OPERATING EXPENSES				
Research and development	307,273	328,753	567,922	678,197
Selling and marketing	407,477	158,695	565,559	210,654
General and administrative	1,426,405	1,911,688	2,943,860	2,805,335
Depreciation	9,455	6,008	17,812	11,024
Loss on sale of property and equipment	-	3,170	-	3,170
TOTAL OPERATING EXPENSES	2,150,610	2,408,314	4,095,153	3,708,380
OPERATING LOSS	(2,019,515)	(2,121,747)	(3,879,948)	(3,243,007)
OTHER INCOME (EXPENSE)				
Gain (loss) on warrant valuation adjustment	195,310	1,161,520	227,669	(1,812,162)
Interest expense	(790,178)	(1,735,509)	(938,439)	(3,291,265)
Interest expense, related party	(112,984)	(194,246)	(332,671)	(383,457)
Gain (loss) on foreign currency exchange	(7,064)	1,723	(8,359)	(15,023)
TOTAL OTHER INCOME (EXPENSE), NET	(714,916)	(766,512)	(1,051,800)	(5,501,907)
NET LOSS	(2,734,431)	(2,888,259)	(4,931,748)	(8,744,914)
OTHER COMPREHENSIVE INCOME (LOSS)				
Foreign currency translation adjustments	1,489	(11,904)	(909)	(10,969)
TOTAL COMPREHENSIVE LOSS	$ (2,732,942)	$ (2,900,163)	$ (4,932,657)	$ (8,755,883)
LOSS PER SHARE:				
Net loss - basic and diluted	$ (0.02)	$ (0.02)	$ (0.03)	$ (0.06)
Weighted average shares outstanding - basic and diluted	174,730,747	148,582,386	165,921,811	144,168,215

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)

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)

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

	Six Months Ended June 30, 2019	Six Months Ended June 30, 2018
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (4,931,748)	$ (8,744,914)
Adjustments to reconcile loss from operations		
to net cash used by operating activities		
Depreciation	17,812	11,024
Change in allowance for doubtful accounts	25,248	(61,344)
Stock-based compensation	31,758	836,796
Warrants issued for consulting services	36,067	737,457
Waived proceeds from warrant exercise	16,000	-
Stock issued for consulting services	-	106,500
Loss (gain) on warrant valuation adjustment	(227,669)	1,812,162
Accrued interest	936,658	168,787
Interest payable, related parties	332,671	156,746
Amortization of debt issuance costs	-	2,683,936
Amortization of debt discount	-	75,484
Loss on sale of fixed assets	-	3,170
Amortization of operating lease	(3,471)	-
Changes in operating assets and liabilities		
Accounts receivable - trade	34,485	69,534
Inventory	(66,112)	15,216
Prepaid expenses	(126,505)	(54,528)
Contract assets	-	(40,000)
Due from related parties	1,228	-
Other assets	(7,070)	(3,872)
Accounts payable	(135,916)	(425,489)
Accrued expenses	106,178	91,459
Accrued employee compensation	525,487	194,194
Operating leases	44,623	-
Contract liabilties	3,642	769,480
NET CASH USED BY OPERATING ACTIVITIES	(3,386,634)	(1,598,202)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(25,839)	(13,612)
NET CASH USED BY INVESTING ACTIVITIES	(25,839)	(13,612)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from short term note	1,215,000	85,000
Proceeds from warrant exercise	1,403,257	38,528
Advances from related parties	585,022	156,000
Proceeds from convertible promissory notes, net	-	1,159,785
Proceeds from line of credit, related party	-	280,500
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	3,203,279	1,563,313
EFFECT OF EXCHANGE RATES ON CASH	(909)	(10,969)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(210,103)	(59,470)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	364,549	730,184
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 154,446	$ 670,714
NON-CASH INVESTING AND FINANCING ACTIVITIES		
Other warrant exercise	$ 724,168	$ -
Conversion of line of credit, related party to equity	$ 180,000	$ -
Reclassification of warrant liability to equity	$ 262,339	$ -
Advances from related and unrelated parties converted to Convertible promissory note	$ -	$ 310,000
Accounts payable converted to convertible promissory notes	$ -	$ 120,000
Beneficial conversion feature on convertible debt	$ -	$ 745,223

Warrants issued with debt	$ -	$ 844,562

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

Operator
Good day ladies and gentlemen, and welcome to the SANUWAVE Second Quarter 2019 Earnings Call. All lines have been placed in a listen-only mode and the floor will be open for questions following the presentation. [Operator instructions]. At this time, it is my pleasure to turn the floor over to 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 now provide an update of our most recent activities, as well as our 2019 second quarter financial results. Our quarterly report on Form 10-Q was filed with the SEC on Wednesday, August 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, August 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 the presentation later. Placements, placements, placements, that's the mantra for 2019 at SANUWAVE. It's all about getting the devices placed, and training and certifying clinicians. To that end, we are ahead of where we expected to be, and with the recent change in reimbursement policy at NGS, we will be accelerating our procedural revenue ramp in the coming quarters ahead of what we had expected.

Placements lead to revenue and so our focus is on placements. I wanted to spend a moment just on that placement mantra because it really is something that resonates throughout the entire organization at SANUWAVE. We know that that's the most important aspect and goal in 2019 for everyone at the company.

Let's review the second quarter. The second quarter marks progress on our roadmap for full commercialization. We have laid out our plan for 2019 which is driven mainly by placing devices. We exceeded our target for Q2 having 36 placed. This puts us on track to achieve 65 by the end of Q3 and 110 by the end of the year. A placement involves training and certifying clinicians to use the device and we are excited today to say we have 116 certified users and are on track to hit 300 by the end of the year. We have stated our goal is to hit 2,000 devices in the next four years and that if we are successful that would generate at least $100 million in revenue.

These initial placements are the first as we head towards that goal for this year and next. We're now beginning to see revenue generated from these devices which I will discuss more, later. Most important in the quarter is that we've treated over 130 patients and we're seeing great results. Shri will discuss what he has seen in the field, but the stories we are getting back are amazing and the results are happening better than expected. We won't be providing patient counts on every call, but we felt it was important for investors to understand that clinicians are getting great results treating these patients so far. And these are, quite frankly, the train wreck patients that they're treating and they're seeing great results.

To achieve all this growth that we're talking about, we've worked with NFS Financial, who will be our leasing partner, and they are in place for our ramp into 2019 and 2020 as we get more aggressive with our placement model.

During the second quarter we had two peer review articles published in distinguished publications. These articles along with the clinical research, we continue to develop or how we stand out and it allowed SANUWAVE to enter clinician's offices.

They loved the fact that we performed a real-life study with real life patients, 336 to be exact. Many wound studies today tend to jury rig their inclusion and exclusion criteria to make sure that their results look good, but in the real-world, diabetic foot ulcer patients, they do smoke, they are overweight, and they aren't that compliant. So, our 336 patient study reflects the real world and this allows us to stand out with our clinical study. This research and peer review articles are the first step in getting in the door. Patient results and outcomes are what will keep us there and improve usage rates.

Also, we're beginning to get a lot of word of mouth referrals coming to us from the clinicians that are using us. Our plan is in place to leverage the research and continue to invest and add indications for broader approvals.

The biggest news is really on the reimbursement front. Yesterday, we announced a coverage change in policy at NGS, National Government Services, that's in 10 states. The policy change will allow dermaPACE to receive an easier, clearer path for reimbursement for Medicare. This does not guarantee a claim will be accepted, but it moves it up to a category where we feel extremely comfortable with how we are approaching reimbursement. The process before would be to submit a claim, potentially be denied then go-through a long laborious appeals process.

The change in NGS allows each individual use to be determined based on necessity. Since we have a strong clinical support that statistically shows we have better way to heal a DFU than standard of care when a clinician submits a claim under this protocol, they are very likely to be approved. It is due to this change that we're adding additional sales and clinical managers in this region.

We expect a growing mix of our procedures to come from this area in Q4 and 2020. That does not mean we won't be in the Carolinas or Texas or Pennsylvania. In fact, we are already seeing claims processed in those areas today. The change in reimbursement allows us to accelerate moving placements to revenue more quickly. Our initial placements would spend 90 days in an evaluation. With the change today, we are eliminating that evaluation phase and moving straight to contracts as we move forward, which means revenue recognition earlier on a go-forward basis. During Q3 we will begin to see the initial revenue from procedures and in Q4 we expect a larger percentage of our revenue will come from procedures.

Our expectation is we will average between $200 and $250 per procedure. These are still being worked out and we'll refine them as we go out throughout the remainder of 2019, but just remember placements lead to procedures, procedures lead to revenue. It's highly recurring with strong incremental margins. This should allow us also to get to a break-even standpoint faster than originally expected. We expect to provide guidance on break even before the end of the year.

The second quarter revenue was below last year due to timing of exclusive license payments. In 2018, exclusive license payments were $150,000 higher than in 2019. As I've mentioned before, these tend to be lumpy. Until we get the procedural revenue stream up and running, the fluctuation of international orders and exclusivity fees will continue to exist. We do expect to have at least one or two exclusivity fees before year end and we have already placed over 20 devices shipping in the third quarter, which will cause lumpiness, but in a positive context. I wish we could smooth them out, but they can't, they have to be recognized under certain accounting pronouncements.

I will spend one minute, discussing our goals for 2019 and our accomplishments for the first six months, then I will turn it over to Shri and Lisa and then we'll conclude with Q&A. Our goals for 2019, to repeat, 110 devices placed, which we are on track for. Over 300 clinicians certified, and as I mentioned earlier, we're on track for that. At least 10 million covered lives those are patients that insurance will pay for the treatment. And with NGS that's $7 million, so we're well on our way there. Our goal is to launch two to three clinical trials, we've started that already. Add three to four new countries, we will exceed that number. Add additional science advisors that's coming in the second half and the key personnel that's an ongoing function, and Shri will address some of the people we're targeting currently. We are well on our way to achieving all these goals which is part of our grand plan which we have discussed in the past. It's to provide a device anywhere and everywhere that a DFU is treated. If we are successful in that plan, we will have over 2,000 devices placed and achieve well over $100 million in revenue in the next four years.

Over time, we will also add other indications for wound treatment and work with other companies on treating wounds in conjunction with other modalities. We've laid it out this in our investor presentation with the milestones we need to achieve on a timeline, so shareholders can measure how we are progressing along the way.

Let me turn it over to Shri Parikh, our President, who will share some insights from the field followed by Lisa, who will review financials. And then I will conclude with some more discussion about 2019. Shri?

Shri Parikh – President

Thank you, Kevin. Good morning everyone and thank you all for joining our Q2 call. I'd like to take this opportunity to share what we've learned from my travels and discussions with customers, clinicians and patients. I'll also take a moment to share where we are in our hiring efforts and explain where and why we're focused in specific markets as we prepare to scale and the quality of the applicants we're seeking and hearing from.

As Kevin shared, the feedback from our dermaPACE treatment and technology remains astounding. Our clinicians and patients continue to see and feel better than expected results. Perhaps the best example of this was during a recent visit to North Carolina and learning of a patient that was treated for DFU for over a year. Everything from skin substitutes to hyperbarics, the negative pressure wound therapy was attempted and ultimately the patient's vascular surgical team recommended amputation.

The patient was in a skilled nursing home facility delaying having to lose her leg and it was here that one of our podiatrists' customers with whom we have recently placed our dermaPACE device began and initiated treatment. She responded very well, experiencing vascularization and healing after seven weeks and healed enough to avert needing an amputation. Given the data, all well published and which we recently shared in our recent newsletter, amputated patients had a 70% mortality rate at five years. This patient was on this path, but thankfully did not have to surrender to this profoundly unfortunate statistic.

This is compelling, if not for the dermaPACE treatment, this patient would have likely had to lose her leg and entered into the pool of unfortunate probability, that being almost a 70% likelihood that she would die within five years following her amputation procedure. Here at SANUWAVE, we continue to believe that our early wave of commercialization is still targeting the hard to heal or train wreck patients as shared in this example.

What remains encouraging is we begin to treat patients earlier in the DFU development process, we expect better and faster outcomes. Our clinical account managers and sales teams are committed to this educating and with our increased engagement support with improved patient selection, treatment guidance and with recent contracting developments, such as with NGS, we are hiring in these markets so we can support the claims opportunities from this favorable Class III or proving medical necessity claim, as well as train and certify more clinicians on patient selection and treatment with dermaPACE in our 15 states of focus.

As patient volumes are increasing and DFU successfully treated, positive reimbursement activity and submitted claims recovery remains our highest focus. Our partnership with the reimbursement group or TRG, we are confident we'll assist with the process for increasing claims submissions, while demonstrated continued clinical outcomes and supporting documentation. So, the goal to accentuate the data and accelerate deserved payment becomes increasingly clear.

In terms of the quality of resumes and candidate pool we're seeing, we're simply humbled. Yes, the job market is strong for the moment, but for us, a relatively small yet opportunistic growing company, we're seeing high quality and high interest from many candidates with years of security at larger companies and candidates with strong clinical and sales performance, from the wound care and other medical device areas and markets. Given our recent focus to NGS markets, we have many candidate interviews scheduled later this week and the coming weeks, as we listed and shared in our newsletter last week. We're looking forward to adding to our team in the coming months and early into Q4. As always, we value referrals particularly from you, who have history of our journey, so we certainly appreciate you sending any quality candidates our way from the markets in which we focused.

Thank you, again. I'll turn it back to you Lisa.

Lisa Sundstrom – Chief Financial Officer

Thank you, Shri. Revenues for the second quarter of 2019 were $317,000 a decrease of $136,000 or 30% from the prior year. Our revenues resulted primarily from sales in Europe over orthoPACE devices and related applicators, and sales in the United States of our dermaPACE applicators. The decrease in revenue for 2019 is primarily due to a decrease in sales of new and refurbished applicators in Asia Pacific and the European Community and lower upfront international distribution fees as Kevin mentioned. This is partially offset by higher device sales in the United States.

Research and development expenses for the second quarter of 2019 were $307,000, a decrease of $21,000 or 7%. The decrease in research and development expenses in 2019 was due to a reclassification of employees and related costs from research and development to general administrative in 2019. This is partially offset by an increase in contracting for temporary services and increased study expenses related to our new dosage study in Poland. Selling and marketing expenses for the second quarter of 2019 was $407,000, an increase of $249,000 or 157%. This increase in selling and marketing expenses was due to increase in hire of trainers and salespeople and increased traveling expenses for placement and training related to the commercialization of dermaPACE as we have discussed.

General and administrative expenses for the second quarter of 2019 were $1.4 million, a decrease of $485,000 or 25%. The decrease in general and administrative expenses was due to a decrease in stock-based compensation expense related to options issued in 2018, lease expense related to pay-off lease agreements for devices in 2018 and lower investor relation costs. This is partially offset by an increase in salary, bonus and benefits related to new hires in 2018.

Net loss for the three months ended June 30, 2019 was $2.7 million or $0.02 per basic and diluted share, compared to a net loss of $2.9 million or $0.02 per basic and diluted share, for the same period in 2018, a decrease in the net loss of $153,000 or 5%. As of June 30th, 2019, we had cash on hand of $154,000, compared with 365,000 at December 31st, 2018. Net cash used by operating activities was $3.4 million for the second quarter of 2019, compared to $1.6 million for the same period in 2018. The increase in the use of cash 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 will be approximately $225,000 to $300,000 per month in 2019 as we launched the commercialization of dermaPACE including hiring of new employees, continue to expand our international market and continue research and development of non-medical uses of the technologies.

Now let me turn the call back to Kevin. Kevin.

Kevin Richardson – Chairman and Chief Executive Officer

Thanks, Lisa. Before we turn to Q&A, I want to conclude with just one final thought, which is the team is really driven by our vision, which is to get out as many dermaPACE devices as possible to save as many limbs as possible to save as many lives as possible. And as we do that, it’s addictive and we're really seeing that within the wound care community as they see the benefits we get from our device, the dermaPACE System. It’s gaining a lot of momentum out in the marketplace. I'll leave it with that just because it's something that you can't see as an investor, but if you're at the trade shows and if you're out talking to people who are suffering from diabetic foot ulcers, the buzz is real and it's happening.

So, with that, let me turn it over to Q&A and we can dive into some questions.

Operator

Thank you. The floor is now open for questions. [Operator instructions]. Okay, and our first question comes from Brian Marckx from Zacks Investment. Please state your question.

Q: Hey Kevin. Congrats on all the progress and on the reimbursement code in particular. Just wondering if you can provide any more details around the reimbursement code, the NGS change, things like, what prompted the change, and specifics in terms of the descriptor of the code uses the word integumentary, I don’t know if that’s how you say it. Just wanted to make sure that the descriptor of the code is consistent with the way that clinicians would use your device for DFUs.

Kevin Richardson – Chairman and Chief Executive Officer

Sure. Thanks Brian. We've been working on the reimbursement plans and strategies for a while with different groups, some of them are consultants that we engage, some are presentations that our team has made in front of the policy panels over the years and it's a process. A lot of that also involves getting peer review articles out, getting the study out and then getting feedback from the field. It's really important that we get clinicians talking about how powerful and strong the device is. So that it'd be, I don't want to say get the buzz, but it begins to get more favorable feeling within those communities, specifically with NGS. It probably relates to some of the consultants that we've had working for us that have a good background within CMS and appreciate our methodical approach to coming to market.

A lot of the wound care space is littered with companies that have kind of willy-nilly and done whatever, and again, done clinical work that's not necessarily the highest standard, it's not double-blinded and then they hop on to a different code. And quite frankly, it's not necessarily the most scrupulous space. And I think it's appreciated. And I mentioned earlier that when we did our study, we made it real world. A lot of the studies today exclude smokers, exclude BMIs over 35, over 30. I mean, they're just very, I don't want to say jury-rigged, and what we've done from the get-go is tried to be as honest as we can about how we're going to treat things in the real world.

So that's a little in the background of how it moved from one level to the next. And then what we're seeing is that our—remember we're cleared for diabetic foot ulcer treatments and so, when we're coding something, we have to code it as a diabetic foot ulcer and then we have to grade it and there is a scale which you grade it. And that's what falls within that category with NGS. And as long as we're following kind of the protocols the right way, it should move very well from a necessity standpoint. And so that's really what we're focused on.

And I hope that answers the question, Brian. I mean, it's really about a lot of behind the scenes work that's been going on for a long time and working with the clinician community and the different medical associations and the consultants.

Q: Yes. That's great. Kevin, I appreciate that. So on the code itself, I assume that there is a payment amount associated with it. If you could just verify, that's the case. And assuming that, that is the case, is it "enough" to encourage adoption by physicians' adoption and utilization from an economic standpoint?

Kevin Richardson – Chairman and Chief Executive Officer

Yes. That's the million dollar question, isn't it? So it's great that we have an FDA cleared device, it's great that it actually works, but if the clinicians aren't going to make any money, they're not going to use it. This is the number one (kind of), number three question we usually get when we go in to talk to the doctors, And right now the Medicare is $314.08, on a Medicare claim, that's what they will receive. The wound clinic will receive $314.08 when they submit their claim.

And remember there'll also be commercial claims that will occur as well with other insurers and they usually have a charge master where it's a multiple something higher than that. We think the blended average when you take 65% of the population is Medicare and 35% are onthe commercial pay side, you get to about a blended rate of about 450 somewhere in that range. And we're in the $200 to $250 range of what we'll be receiving per procedure, which leaves a nice amount for the wound clinic.

I think we're making the economics really nice for them. Remember when we're placing a device, they're not purchasing the device, we're placing it there, they're using it, they have minimum requirements on usage, which I don't see that going to be a problem at all. We're definitely seeing a lot of patient usage increase pretty dramatically once they get used to it. I think we have a pretty good economic model figured out, it's taken us a while. We've kind of, as you know, been working on this for a long time, but now that we got the $314.08 in place that kind of sets it so that we can now collect $200 to $250 per procedure ourselves.

Kevin Richardson – Chairman and Chief Executive Officer

Yes, I mean we're happy with it because, if you look at the constituencies that you need to make happy, we've always talked about the 3Ps, that is the patient, the physician and the payer, right? And the patient is happy because he's getting treated and he's not going to get amputated and it's a quick five minute procedure versus a hyperbaric 90 minute dunk in a hyperbaric tank every day for a month. He likes it because he doesn't have to wear a boot like a vac. So the patient likes it from the ease of use and they're compliant because it's pretty straight forward. The doctor likes it because it doesn't take a lot of his time and he is getting paid a good chunk of change based on this reimbursement model.

And the other important part of why we think we're going to be accepted so quickly is that, we're reducing the overall cost of wound care because we can get the wound closed faster using the dermaPACE System. And so with eight treatments, we're coming in below where the cost to close the same room would be for a vac for negative pressure. For hyperbaric those are $500 to $700 per session and there's usually 20 sessions, so you can kind of do the math. For skin substitutes, those are really expensive and it takes multiple surgeries to get a wound closed. We have found a sweet spot where we're helping the payers save money, we're helping the doctors make money, and especially when you look at a return on time, which is their most valuable asset, and the patients like it. The net-netis - we feel pretty good about how we've positioned ourselves going forward.

Q: Yes, that's great, Kevin. And not to take too much time on this particular subject or on the Q&A in general, but it's an important subject I think and it's a major announcement, so just trying to get a little bit more detail on the specifics. One of the really attractive things about dermaPACE from my viewpoint is that it can be used as an adjunct, it's not invasive, so it can be used with or after other treatments. So in the context of the NGS reimbursement, I assume that, that does not—that they can still use whatever, skin substitute and then they can apply dermaPACE and they can get reimbursed for the skin substitute with whatever code that is, and then apply and get paid for this.

Kevin Richardson – Chairman and Chief Executive Officer

Yes. Maybe not in that order, but yes, it might be using the dermaPACE first before you put on the skin substitute. But yes, this is not going to prevent them from getting the other ancillary revenues that they were getting previously. And what it's led to Brian is that we've been contacted by lots of the skin substitute companies who are under some pressure from a reimbursement standpoint as well, about doing a lot of combination therapy studies. And we're not ready to announce with all the different players that we're going to be talking to over the next few months, but suffice it to say in 2020, there'll be a number of projects that are launched on combinations with some big name companies that are in the skin sub space. I could envision, we have one doctor up in Wisconsin, who wants to do something in hyperbaric with us, there is a group in Texas that wants to do the same thing.

And that's where you get the bigger bang for the buck, Brian, is when we can show that we can work in combination with other therapies and that we're a tool that's additive to the wound clinic, and again, we have to do the right clinical work to support that, and once we do that and can roll that type of a story out, it won't just be our sales force talking about dermaPACE, it will be the skin substitute sales force, the hyperbaric sales force, these other companies that are promoting our product as an adjunctive therapy with them.

So that was a long winded answer of yes, they can keep billing but there is a strategic element to that that's extremely important too, which is working, not competitively but in partnership, with a lot of the companies that are out there.

Q: Okay, great. One last one, I think you said in your prepared remarks that you do not anticipate moving resources from the initial territories that you talked about in the last couple of calls or so, that you will still be there and then you will now target these ten states covered by NGS, is that right?

Kevin Richardson – Chairman and Chief Executive Officer

Yes, I mean, we're a small company, so we're have to be nimble and agile. We're not going to—Shri was with one of our guys in the Carolinas last week on his, I call it the ACC Basketball tour, right? They were at Wake, UNC, Duke and talking to all their medical centers. And we're not going to stop from that, we're not going to stop from the stuff we're doing in Texas or Pennsylvania. But what I think it does is the team is ready to hop on a plane and get up to New York and help do an installation if need be or a placement at Mass General or wherever it needs to be, the team is ready We are very fortunate, we have a great team that's willing to go anywhere and everywhere to get the device out placed and trained and certified.

Until we get the right salespeople and as Shri mentioned there, these are high quality people, we're seeing resumes from the Integras, the KCIs, Smith and Nephew, 3Ms, some of these big names that all see us as kind of the next thing and they all want to be part of it.

So, we're going to hire the right people. We'll implement it the right way, but in the meantime, we're not going to lose focus on the inroads we've made in the Carolinas, Texas and Pennsylvania.

Q: All right, great. Thanks. Thanks, Kevin. And congrats.

Kevin Richardson – Chairman and Chief Executive Officer
Thanks.

Operator
Thank you. Our next question comes from Terry Thompson. Please state your question.

Q: Hi, Kevin.

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

Q: This is maybe a stupid question, but I wondered if the company is looking at using the dermaPACE in treatment of other problems other than the diabetic foot ulcer, I realized that's the concentration right now, but it seems to me as a layman that this is something that might have much, much wider applications in other medical treatments can you give me any background?

Kevin Richardson – Chairman and Chief Executive Officer
Yes, sure. Terry, the focus really is on what we're cleared for, which is diabetic foot ulcers and that's a massive market for us. The math, if I just do kind of the NGS territory for us from a population, and if I just look at the advanced diabetic foot ulcers, it's $1 billion market opportunity just in the NGS territories for us to go after. That's one of the ten MACs that run Medicare in the U.S., so that's one region. So it's a big opportunity and we have to stay focused right now.

Are there other indications? Absolutely, our game plan is to add, I think about it like an indication a year, but we're going to do it with the right clinical support and studies behind that. We're not going just do it willy-nilly. It's really following our discipline that we've always had to make sure there's the clinical evidence and support that can get out in front of the clinicians. And then they can read the peer review articles and say, "oh yes", this really does work.

With regard to other non-wound areas of concentration, we've had talks with different folks about can we get into partnership with them, but we have to make sure that we don't distract ourselves from the goal right now, which is wound care and getting to 2,000 devices placed in the next four years. There are some ancillary benefits in the wound care space that we'll talk about over the next few months, the clinicians are coming back to us and are talking about the benefits they're seeing that are above and beyond just the wound healing. Things like inflammatory response and things like treatment of neuropathy.

These are areas that we have not done the necessary clinical work behind, but we have doctors approaching us, asking us if they can run a quick case study for us or a clinical study for us. And we'll decide on which ones have the highest priority for us as we move forward, but these are also big market opportunities as well. We just have to make sure that we're doing it in a disciplined fashion, Terry.

Q: Well that makes sense. Focus is always important, but I was curious, looking further down the down the road—

Kevin Richardson – Chairman and Chief Executive Officer
I can get very distracted very easily and go chase a lot of butterflies, Terry. There are so many opportunities with the platform, but for us to be successful in the near-term, I think we really have to stay focused on what we have in front of us. And maybe a year from now we'll be talking about other verticals, but right now, it's we have to stay focused on wound care.

Q: That makes perfect sense and hope to get down to Georgia one of these days and meet you face-to-face. Thank you for your call and the information.

Kevin Richardson – Chairman and Chief Executive Officer
Thanks Terry. Appreciate it.

Operator
Thank you. Our next question comes from James Terwilliger, please state your question.

Q: Congratulations on the reimbursements. Couple of quick questions, really three, the first one is, remind me again, what's the process of getting the clinician certified? What's the process of getting a machine placed?

Kevin Richardson – Chairman and Chief Executive Officer
So identifying where to go, we've talked about on a past conference call, but what we've done is we've looked at, where is the right volume, so there are enough diabetic foot ulcer patients and again there's data available. So we crunch a lot of data to figure out where to target. And then once we've chosen a target, we approach them, and we go into talking about the device, giving them some references, showing them the clinical study, showing them the papers and kind of building our support to get it placed.

Once it's placed, we have our clinical account managers and sales reps out, training them. And the training involves hopefully a few people in the office and they'll go over the basics from turning it on to putting on the sterile sleeve, the gels and then it's answering a lot of the questions. And to get certified, they need to show that they can do it by one of our clinical account managers.

Our clinical account manager has to see them perform it the right way and answer a lot of questions with the patient. And so that's how we certify that they are approved to use it. And then we monitor it. We follow up on a monthly basis. We'll soon be tracking, I'm hoping in the next month or so on a daily basis, a lot of the wounds but that's something that we're still rolling out in kind of beta format right now. And then we will be able to really stay on top of every single patient that we're treating on a real-time basis, so that's the certification process.

In the past it would sit there for 30, 60, 90 days and they'd evaluate it. How does it work in the workflow of the office, how does it work with our nurses and then we'd go to contract. What we've realized is that they don't need 30, 60, 90 days and that we can move to contract faster, James. So that's probably one of the bigger changes. A nuance in our press release, in our talk today, is that we're going to be moving faster to contracted, which means that we can then accept procedural revenue. So whenever they use it, we'll collect the fee. And that's something that we've learned, again, from being out in the field, we've learned that we can move that evaluatory phase very quickly.

Q: Okay, great. I'm just trying to get the process and make sure I'm thinking about this correctly. My second question is, you have 36 machines placed. I know this might be a tough one, but how many states are you in, because you have this focus of six states prior to the reimbursement. And then when you say you've done 130 patients, how many machines of the 36 are really up and running? How many machines of the 36 are treating those 130 patients?

Kevin Richardson – Chairman and Chief Executive Officer
Yes, so we have over, I think it's been over 1,300 treatments too, so we're treating a lot of the train wrecks. I would say of the 36 in the second quarter, I think we got our six in the last few weeks. So we probably have about 30 up and running. And each of those are doing anywhere from, one or two patients up to, we have one, Dr. Sanchez down in San Antonio, she has 20 that she's treating currently, and so it depends on the market.

We'll update that number as we get into Q3, but it's dramatically higher as we've gone through the quarter and again, it's that engagement that they're now focusing not just on the train wreck but on the diabetic foot ulcer patients. So a little earlier in the cycle and especially with this reimbursement change, James, I think that's going to really accelerate the usage, whereas before they were kind of playing with a new toy, but they didn't have to pay for it and they weren't going to get paid for it. And now that they know they're getting paid for it, there's a different incentive for them to use it a little more aggressively.

Q: Okay, great. And again, congrats on the reimbursement announcement. Lastly, can you update me on the Indian Health and the VA contracts?

Kevin Richardson – Chairman and Chief Executive Officer
Sure. With Premier, the focus more on Indian Health in rural areas where the Indians are serving, and I'll go through, with the VA, they like to purchase equipment and the per procedure model has been a little difficult for them to get their arms around. With that said, they presented at 90 different VA's and I think we're getting closer to that opening up as they get comfortable with the revenue model that we're proposing in that it's not a capital equipment purchase, it's a per procedure basis.

But in Indian Health the pipeline there is very strong. The Premier guys have done a really good job penetrating that market. I know that they have a bunch of procedures scheduled over the next—not procedures, but installs. They have 5 signed contracts, 12 are in various stages, there will probably be somewhere around 20 systems in Indian Health-like rural markets by the end of the year, and they're seeing revenue generated in those markets.

They presented at a conference recently called the Diabetes in the Indian Country conference, it was in Oklahoma City. And one of our key opinion leaders, Brian Lepo [ph] actually touted the dermaPACE product, unbeknownst to us and unbeknownst to Premier, so it was truly, he talked about how it's the best new product on the market and it drove a lot of traffic. So we're seeing a lot of flow on the Indian Health side and I think VA, it's just a bottleneck where they'll work it through, and we'll see that probably open up back half of this year or early next year.

Q: Okay, great. Thanks for taking my questions. I'll jump back in queue.

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

Operator
Thank you. That appears to be our last question. I'll now turn the floor over back to Kevin for closing remarks.

Kevin Richardson – Chairman and Chief Executive Officer
Great. Thank you very much everyone, shareholders. We appreciate all the support that you've provided us and as we get closer to the revenue ramp that we've long been waiting for, we'll begin to see the first of it in the third quarter with it really becoming apparent in the fourth quarter and as we go into 2020. Thank you very much, and if you have any questions, as always, please feel free to call any of us on the line. Thank you very much. Have a good day.