Company Clinical Case Studies

The following series of thermal images (right side of chart) shows the thermal emissoins of a migraine patient prior to treatment and the subsequent reduction in temperature associated with pain relief following a 10-minute treatment.

IAVACEN

Clinical Case Studies

				Before Thermal
Stage	Age	Gender	Result	Emissions
Prodrome	65	F	Prevented	Pain 5
	55	M	Prevented	
	43	F	Prevented	After Reduced
	35	F	Prevented *(details below)	
Migraine	65	F	Immediate relief. Eliminated 2 hrs	Pain 3
	45	F	Relief in 30 min	
	20	F	Immediate relief. Eliminated 3 hrs	
	50	F	Immediate relief	3 Hours Later
	35	M	Immediate relief	
	27	F	Immediate relief. Eating again	
	50	F	Immediate relief	Pain 0
	40	M	90% relief after 7 min warming	

^{* 5&}quot; visual symptoms subsided; 10" headache gone; 15" walking. IR camera showed symptom withdrawal coincided with vasodilatation indicated by face and hand temperature change.

Migraine Clinical Trial

The Company has completed an IRB approved pilot controlled clinical trial using migraine suffers to better define the patient population and treatment regimen in which *TES* is most effective. The 15-person crossover study captured the change in pain levels of migraine patients at intervals following treatment. Two separate migraine episodes were treated for each patient. Randomly a patient received either a 10-minute treatment with *TES* or a treatment with a sham (placebo) device.

The studies took place at the Neurocenter of Southern California, a leading migraine treatment center that often runs such clinical trials.

The objective of the study is publication of the results in a leading migraine journal. Additional trials will be needed to get a FDA specific labeling for 'migraine treatment'. The timing of additional studies will depend on the results of the current study and the marketing focus of the Company.

AVACEN study results of the 15 participants that completed the study were as follows:

- 1 participant was disqualified for using medication prior to the 4 hour monitoring window.
- 2 participants showed no difference at 4 hours when using sham and AVACEN treatment.

Of the 12 participants that reported results:

- 2 participants (16.667%) had positive results at 4 hours when using placebo treatment.
- 10 participants (83.333%) had positive results at 4 hours when compared to sham treatment.
- 67% effective rate (less 16.666% assumed placebo)

Imitrex Clinical 4 hour results (\$1.2 Billion annual sales)

- 31.667% had positive results from placebo (separate group from lmitrex group).
- 72.667% had positive results from Imitrex.
- 41% Imitrex effective rate (less 31.667% assumed placebo)