



Commercial-Stage Bioelectronic  
Medicine Company

1<sup>st</sup> FDA-cleared non-invasive vagus  
nerve stimulation platform therapy



# Disclaimer

This presentation may contain forward-looking statements. All forward-looking statements are subject to a number of risks, uncertainties and assumptions, and you should not rely upon forward-looking statements as predictions of future events. All forward-looking statements will be based upon current estimates and expectations about future events and financial and other trends. There is no guarantee that future results, performance or events reflected in the forward-looking statements will be achieved or occur. No person assumes responsibility for the accuracy and completeness of the forward-looking statements, and, except as required by law, no person undertakes any obligation to update any forward-looking statements for any reason after the date of this presentation.

Forward-looking statements include all statements that are not historical facts and, in some cases, can be identified by terms such as "anticipates," "believes," "could," "seeks," "estimates," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would" or similar expressions and the negatives of those terms. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements represent our management's beliefs and assumptions only as of the date of the prospectus, and are only predictions that may be inaccurate. You should read the prospectus, including the Risk Factors set forth therein, and the documents that we have filed as exhibits to the registration statement, of which the prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons why actual results could differ materially from those or our situation may change in the future.

# Investment Highlights

<b>Platform Therapy</b>	Only FDA-cleared non-invasive delivery of bioelectronic medicine primed to unlock the broad potential of this highly targeted and safe therapy
<b>Pharma Distribution</b>	Distributed through standard specialty pharmacy channels
<b>Large Initial Market</b>	Primary headache market opportunity for cluster headache and migraine estimated to be in excess of \$4 billion
<b>Robust Pipeline</b>	Robust product pipeline in neurology and rheumatology, with key pivotal trials initiating in 2018 and 2019
<b>Highly Scalable</b>	Low investment manufacturing that meets all potential market demand
<b>Strong IP Portfolio</b>	Key patent coverage extends through 2033

# Experienced Management Team



**Frank Amato**  
Chief Executive Officer &  
Board Member  
**26 years**



**J.P. Errico, Esq**  
Founder, Chief Science & Strategy  
Officer & Board Member  
**23 years**



**Glenn Vraniak**  
Chief Financial Officer  
**14 years**



**Peter Staats, MD**  
Chief Medical Officer  
**33 years**



**Dan Duhart**  
Chief Commercial Officer  
**33 years**



**Steve Mendez**  
Chief Technical Officer  
**28 years**



**Eric Liebler**  
SVP of Neurology  
**20 years**



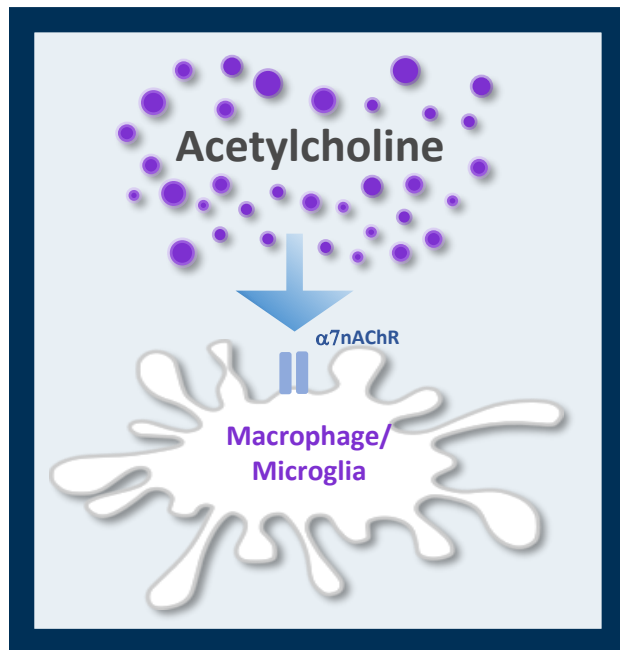
**Bruce Simon, PhD**  
VP of Research  
**16 years**



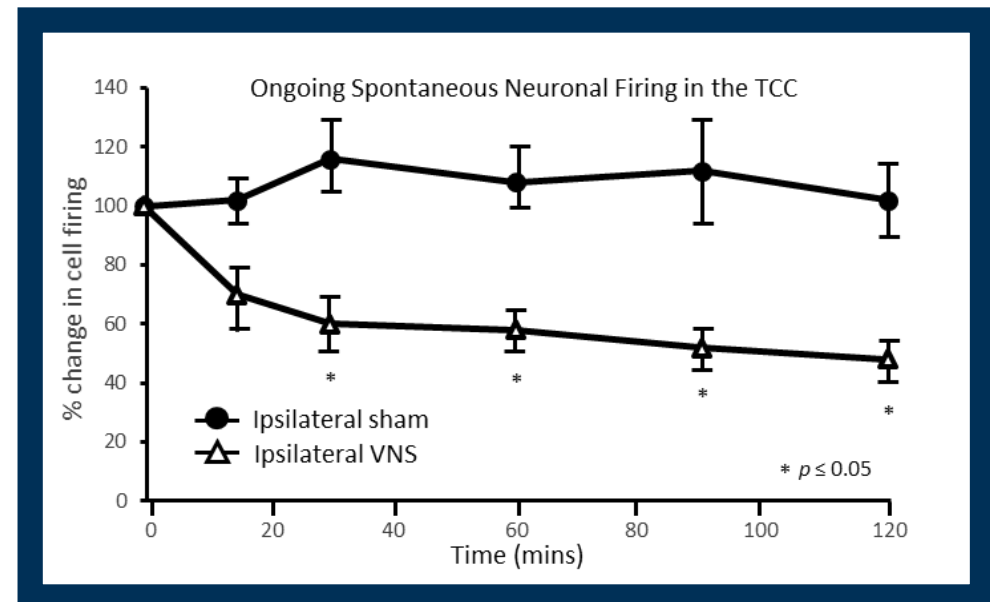
# Mechanisms of Action of VNS

In both the CNS and the periphery, **VNS triggers the release of acetylcholine and norepinephrine.**

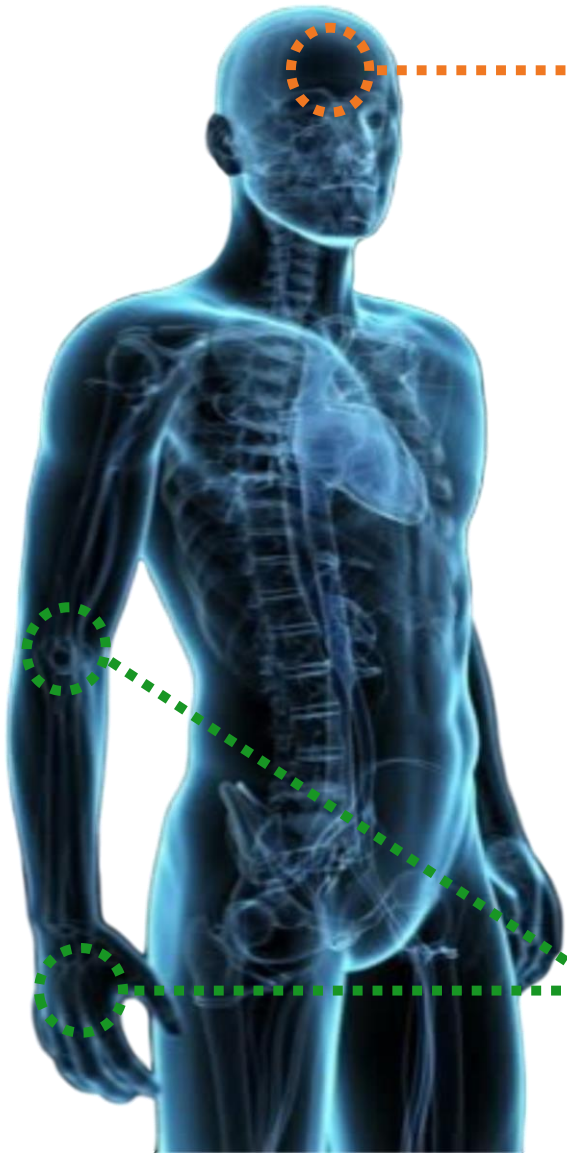
Centrally and peripherally, this release activates the cholinergic anti-inflammatory pathway, or CAP, **suppressing pro-inflammatory activity of macrophages and microglia**



In the CNS, this release and associated changes in immune cell activity, **alter synthesis, transport, and receptor populations for other neurotransmitters, e.g., serotonin and GABA, moderating neuronal hyperexcitability and pain perception**



# Clinical Potential of VNS



Neurological Disorders

In the CNS, gammaCore's VNS effects *are similar to multiple major classes of drugs, including SSRIs, SNRIs, GABA analogues, and acetylcholine esterase inhibitors*

Peripherally, gammaCore affects immune activity, *suppressing the expression of TNF- $\alpha$  and other inflammatory cytokines*, resulting in effects similar to drugs used to suppress severe inflammation

Autoimmune Diseases



Bluetooth-  
enabled

Hand-held,  
simple-to-use,  
highly targeted  
therapy

Rechargeable  
unit refilled by  
RFID cards



# gammaCore Sapphire®

1<sup>st</sup> FDA-cleared non-invasive  
vagus nerve stimulator

- Fast acting, comfortable option for acute treatment and prevention\*, with only local, mild, and transient side effects
- Initial indications in **cluster headache and migraine**
- **Unique RFID card authorization** system for on-site specialty pharmacy encoding
- **Bluetooth-enabled** for patented web-based delivery of the therapy

# Cluster Headache & Migraine

20X

Cluster Headache

Suicide rate vs. the U.S. average



**350,000 affected in the U.S.**

**Estimated addressable market of \$400M<sup>(1)</sup>**

Up to eight 15-180 min attacks per day

Typically in bout 4-24 weeks per year

Only one other available FDA-approved therapy

#3

Migraine

Most prevalent illness



**36 million affected in the U.S.**

**Estimated addressable market of \$3.8B<sup>(1)</sup>**

Migraines last 4-72 hours

Multiple attacks per month

Limited satisfaction with other therapy options

(1) – based on industry sources



# Headache Pipeline

Indication	PreClinical / Pilot Trials	Pivotal Trials	FDA Clearance	Commercial Launch	Key Milestones
Acute Treatment of Episodic Cluster Headaches	ACT 1 & ACT 2				FDA clearance April 2017 Commercial registry initiated 3Q 2017 Full commercial launch expected 3Q 2018
Acute Treatment of Migraine	PRESTO				FDA label expansion January 2018 Full commercial launch expected 3Q 2018
Episodic Cluster Headache Prevention	PREVA				Submit 510(k) with FDA before end of 2018 for the prevention of cluster headache
Migraine Prevention	PREMIUM				Final PREMIUM trial data publication expected 2H 2018 Second pivotal trial initiation expected 2H 2018
Migraine in Adolescents					Pivotal trial initiation expected 2H 2018
Post-Traumatic Headache					Initial preclinical studies in progress Pilot trial initiation expected 2H 2018

# Clinical Trial Overview

Study	Location	Enrollment (Randomized)	ITT Population	Number of Centers	Duration of Study
<b>Migraine</b>					
✓ <b>PRESTO</b> (Acute Migraine)	EU	285 (248)	243	10	3 months
<b>PREMIUM</b> (Migraine Prevention)	EU	477 (341)	332	22	10 months
<b>Cluster Headache</b>					
✓ <b>ACT 1</b> (Acute CH)	US	150 (150)	133	20	4 months
✓ <b>ACT 2</b> (Acute CH)	EU	103 (102)	92	9	2 months
<b>PREVA</b> (CH Prevention)	EU	114 (97)	93	10	2.5 months

✓ FDA-cleared indications

# Therapy-Related Adverse Events

## Acute Treatment Trials (ACT 1, ACT 2, and PRESTO)<sup>(1)</sup>

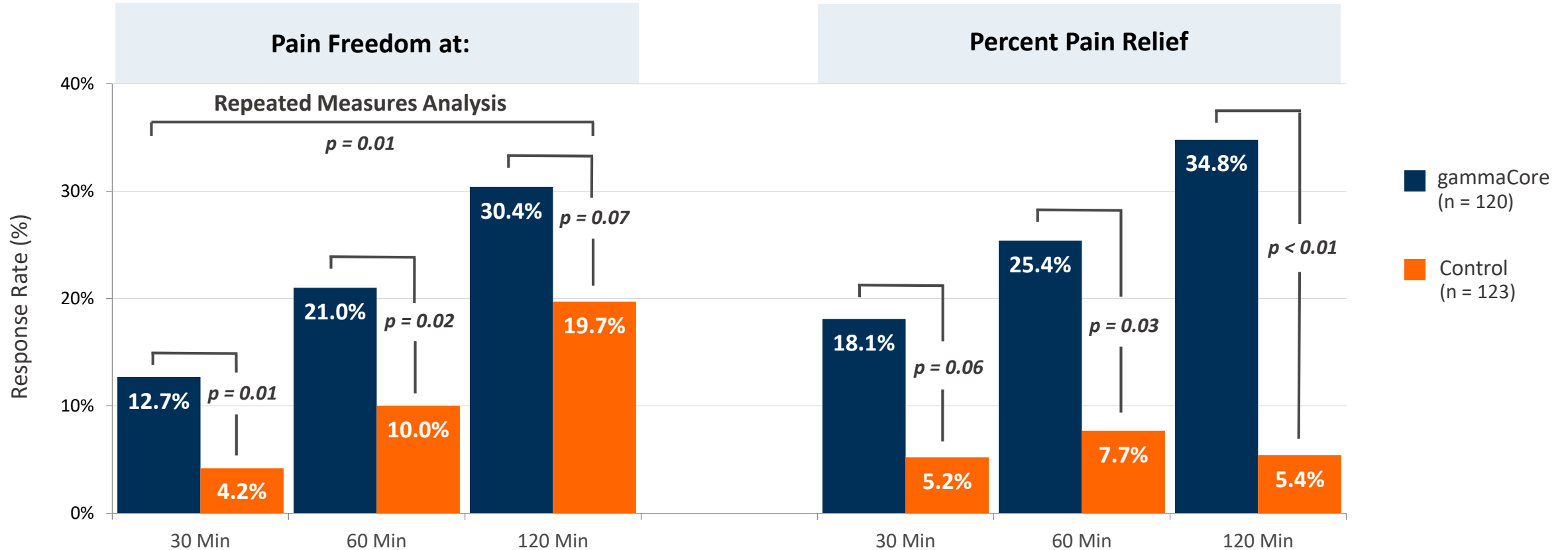
Symptom	gammaCore (n=245)	Control (n=255)
Application site reactions, i.e., skin irritation, tingling (%)	12 (4.9)	26 (20.8)
Muscle twitching	8 (3.3)	1 (0.4)
Neuro (headache, dizziness)	0 (0.0)	9 (3.5)

## Prevention Treatment Trials (PREVA and PREMIUM)

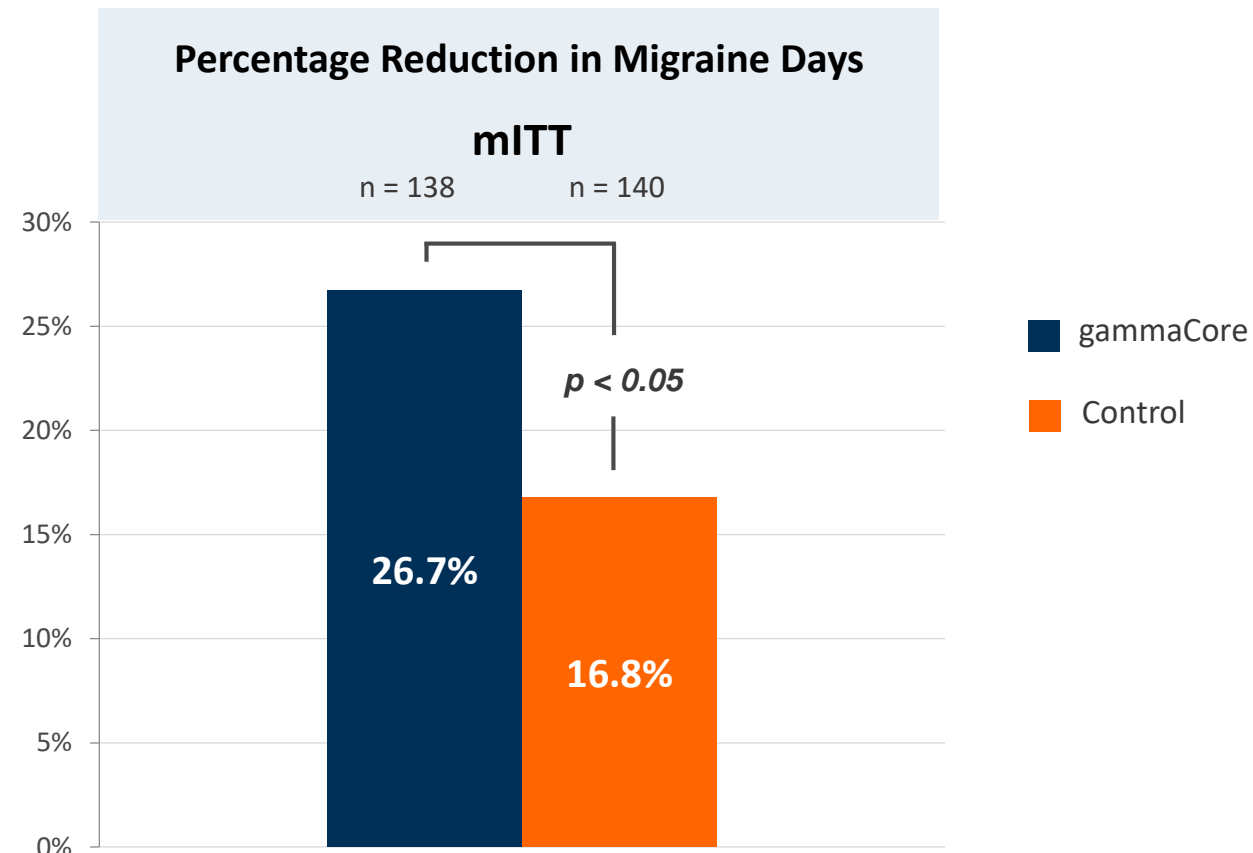
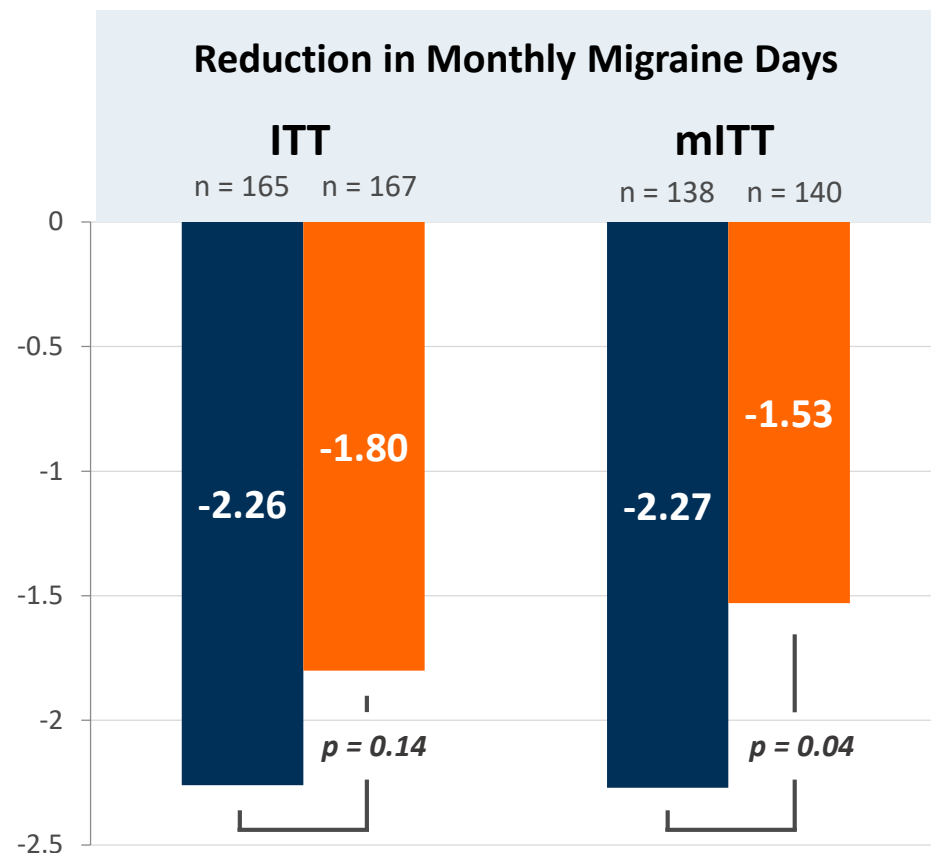
Symptom	gammaCore (n=217)	Control (n=221)
Application site reactions, i.e., skin irritation, tingling (%)	10 (4.6)	12 (5.4)
Neuro (headache, dizziness)	8 (3.7)	4 (1.8)

(1) – includes results from the double-blind periods of ACT 1 and ACT 2 and all periods in PRESTO

# ✓ Acute Migraine: PRESTO Trial



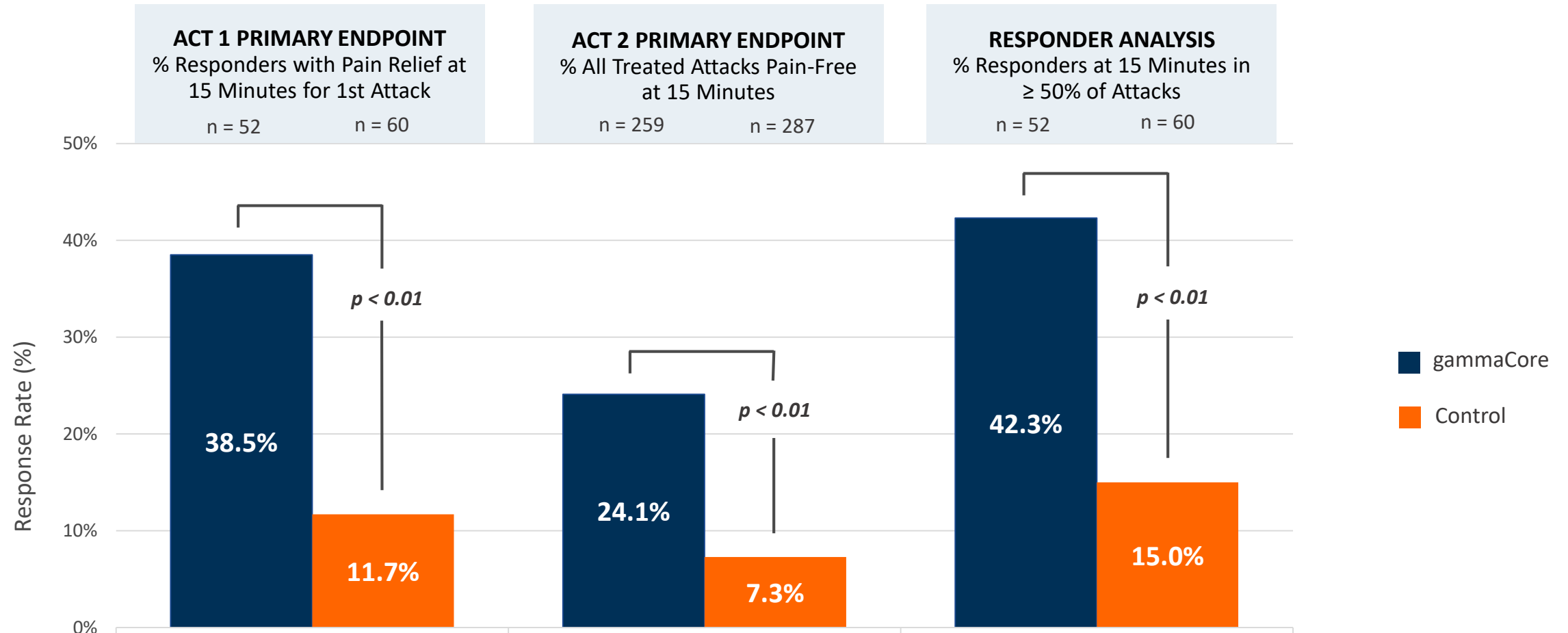
# Migraine Prevention: Interim Results from PREMIUM Trial



mITT – Patient population that complied with the trial requirement to self-administer no fewer than two-thirds of the specified treatments per month during the randomized period

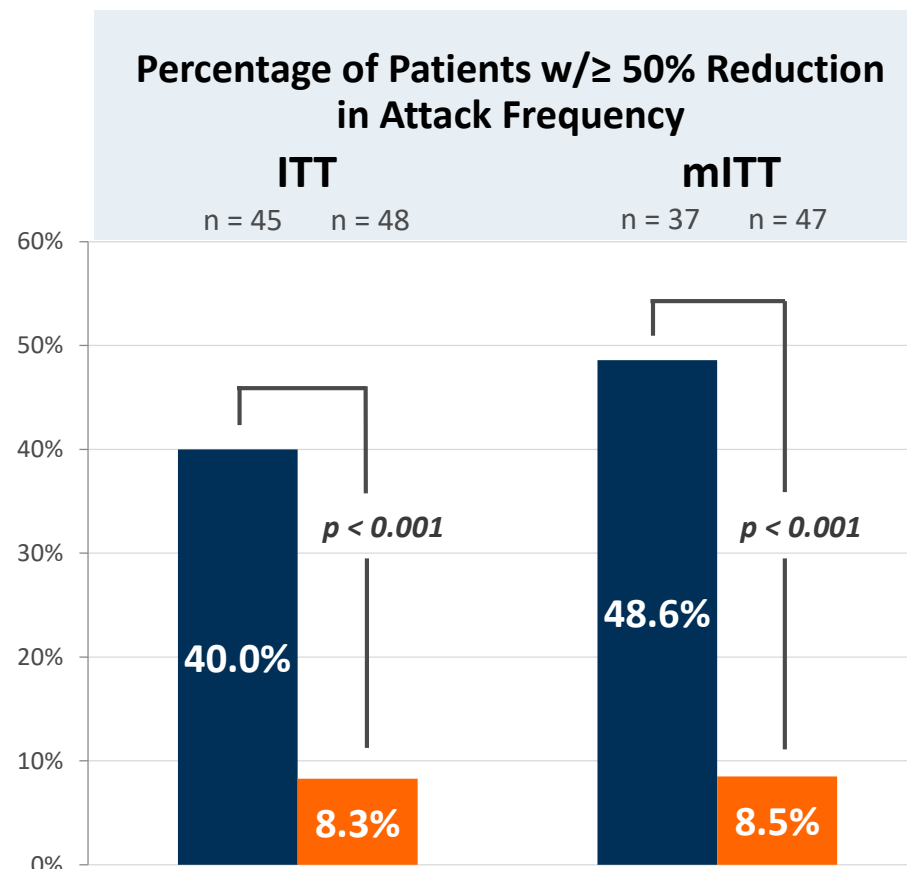
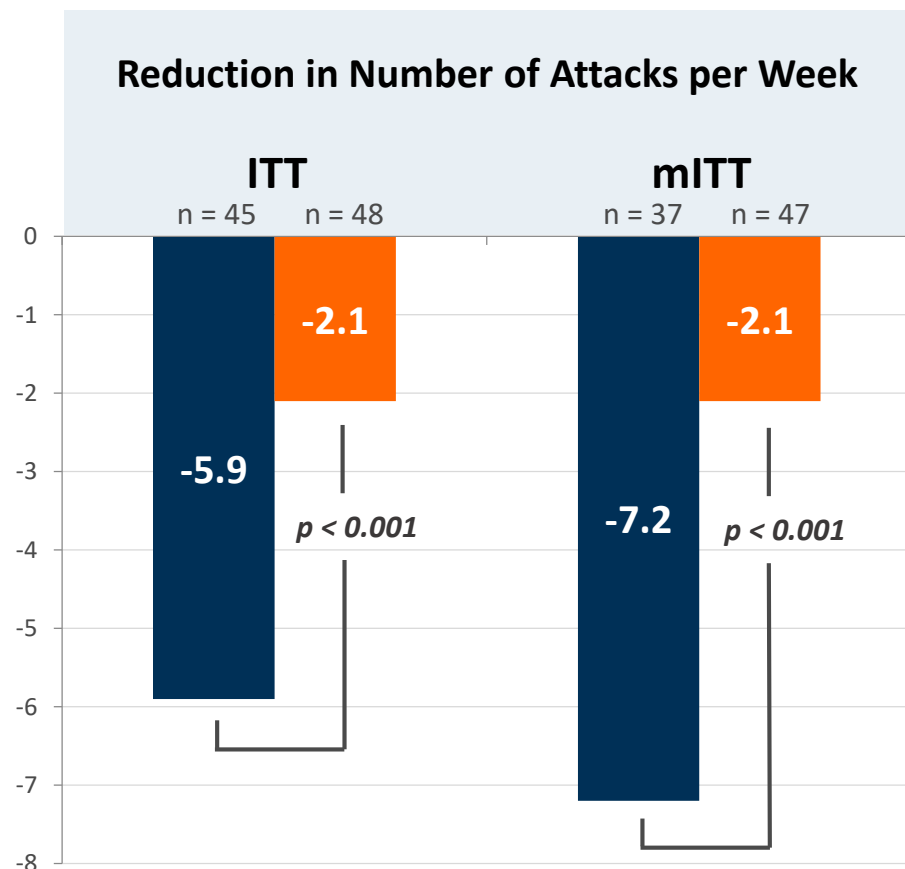
# ✓ Acute Cluster Headache: ACT 1 & ACT 2

Pooled-analysis of Episodic Cluster Headache from ACT 1 & ACT 2 Trials





# Cluster Headache Prevention: PREVA Trial



■ Adjunctive gammaCore  
■ Standard of care

mITT - Patients who provided data in the randomized period sufficient to compare to baseline measurements

# Market Penetration & Development Strategy

## Registry in Cluster Headache



### Build KOL advocacy

Demonstrate efficacy in the hard-to-treat and dissatisfied population



### Gain payor approval as pharmacy benefit

Drive prescriptions into the commercial payors

Drive pharmacy benefit reimbursement

## Expand into Migraine and Beyond



### Leverage success into migraine

Expand commercial footprint to 48 sales reps

Continue physician peer to peer education



### Use expedited FDA pathway to continue label expansion

Expand our labeling claims with new data into other areas of headache

# Create Market Demand

Registry plan – drive ~1,000 patient claims into commercial payors for reimbursement decisions

## Headache Key Opinion Leaders

- Original sales team goal: 40 registry-participating headache centers
- Original planned: build advocacy among 250 to 300 neurologists



**> 80 registry sites**  
**~ 4,500 Rx's**  
**~ 800 prescribing physicians**

## Commercial Payors

- Engage > 50 commercial payors with goal of pharmacy benefit coverage
- Agreements with commercial payors we believe, based on estimates, will provide pharmacy benefit reimbursement for ~ 17M lives and could grow to as many as 45M lives under those agreements



**Establishing pharmacy benefit reimbursement pathway**

## Pharmacy Benefit Managers

- Partnering with Magellan to identify commercial cost data for treating both migraine and cluster headache
- Publish key incidence and cost data
- Developing treatment guidelines for gammaCore with key employers and IDNs



**Published 5 AJMC articles supporting payor diligence**

# Pathway to Reimbursement

Aligned to stakeholder experience



## PHYSICIANS

Write a prescription  
for use at home



## PATIENTS

Acquire gammaCore from  
a specialty pharmacy with  
simple refill process



## PAYORS

Manage utilization  
through pharmacy  
benefit reimbursement

## Strong Commercial Payor Response

### Current Payor Relationship

- National plan coverage up to 45M lives as a pharmacy benefit as discussed above

### Additional Payor Engagement

- Active negotiations with multiple national plans covering ~120M additional lives

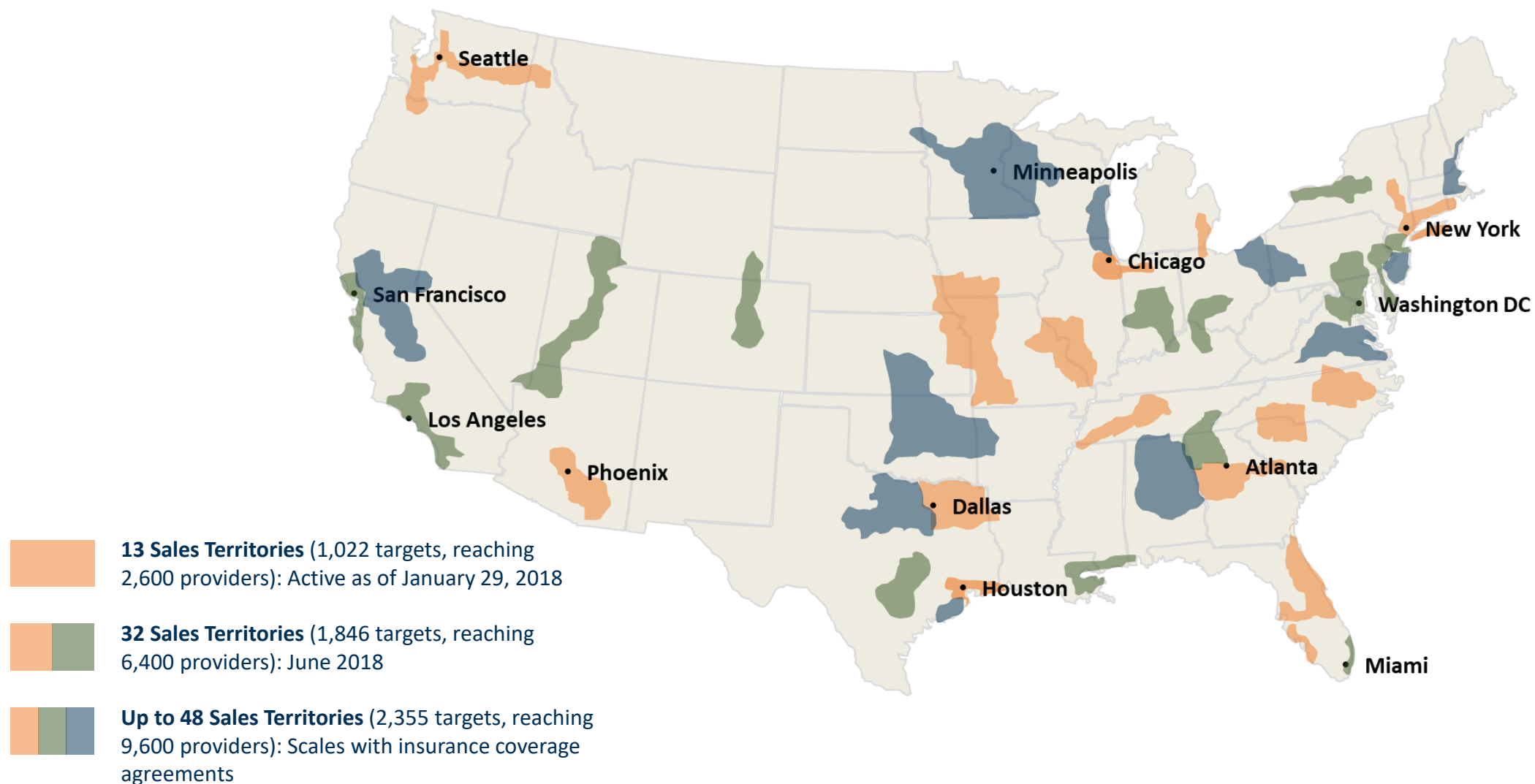
### Reimbursement Path

- Pharmacy benefit based on prescription model with monthly refill

### Suggested Payment

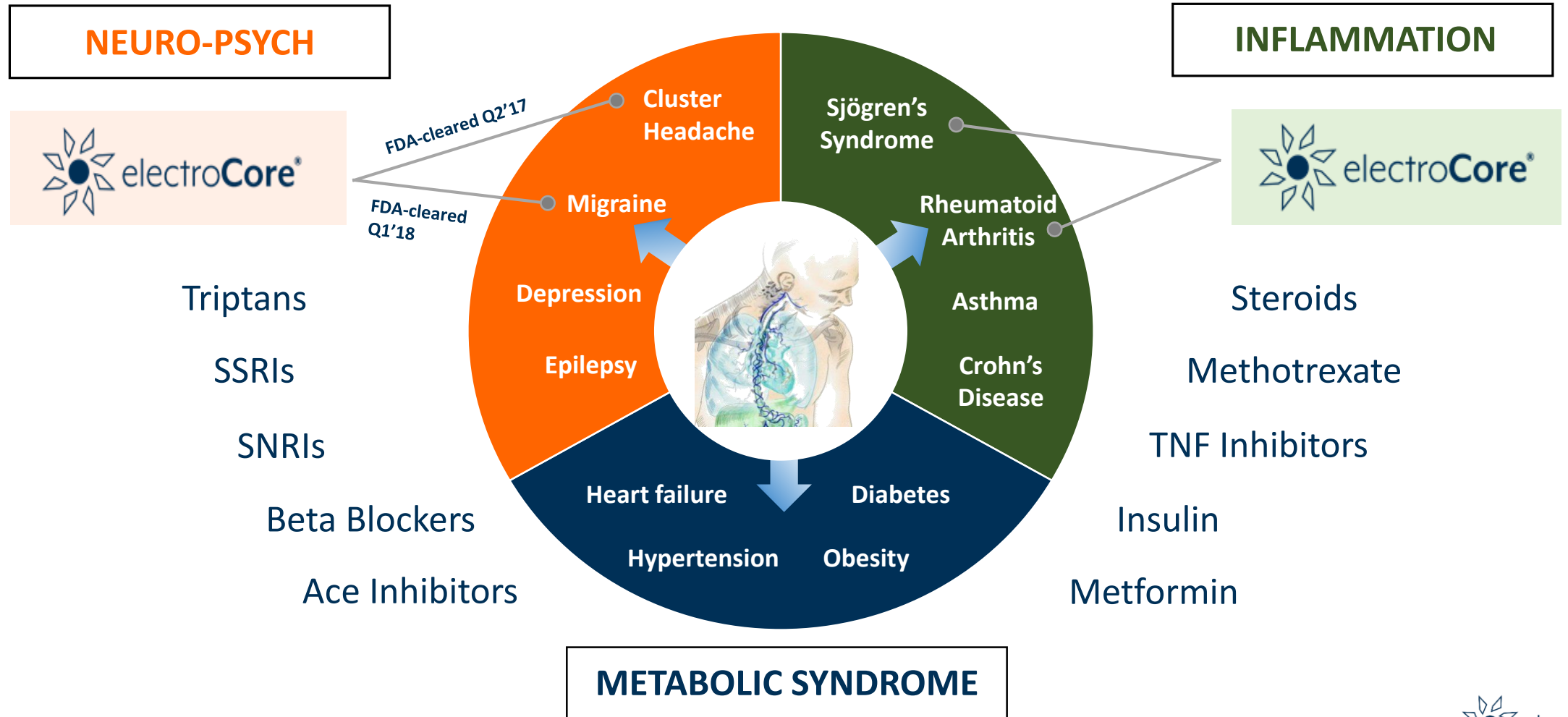
- No major hurdles to current pricing

# Building a Leading Commercial Presence



# Bioelectronic Medicine: Expansive Platform Potential

gammaCore is the **only** non-invasive VNS therapy





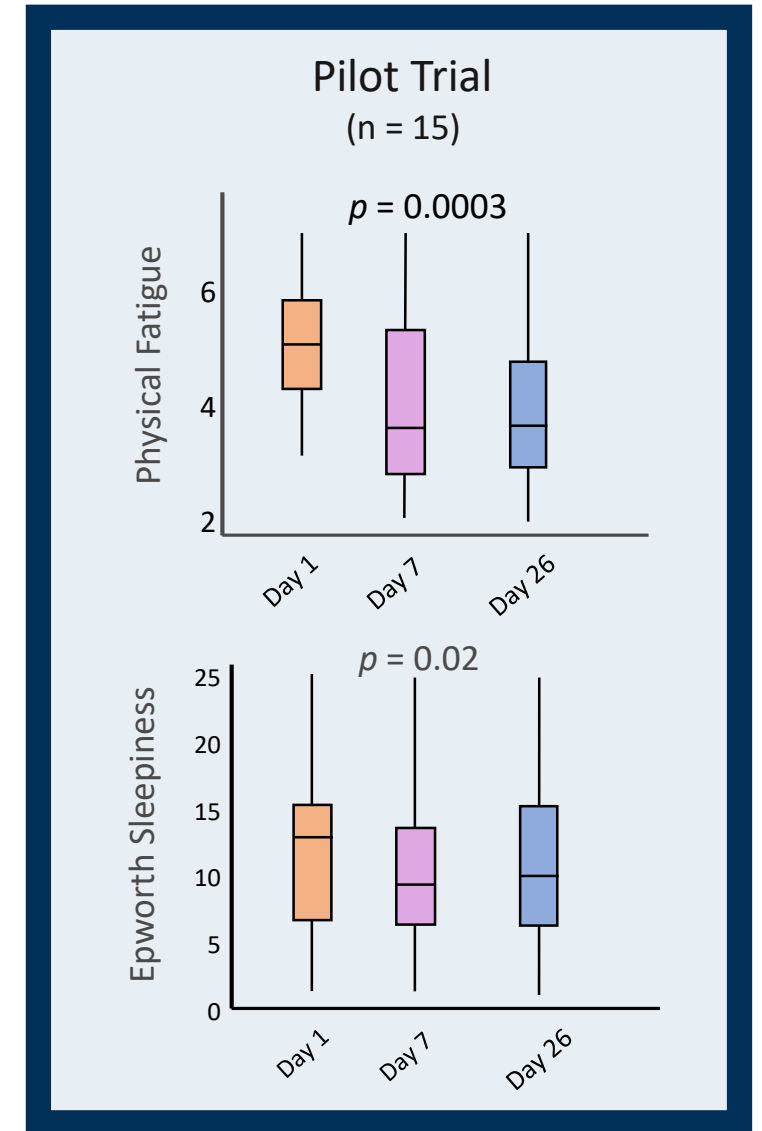
# Sjögren's Syndrome

- An autoimmune disease with inflammation and autonomic dysfunction
- Affects approximately 600,000 Americans (predominantly women)
- Key symptom measures showed significant and sustained improvement with gammaCore

A pilot trial of 15 patients of **gammaCore as a treatment for Sjögren's Syndrome** was funded by the UK Arthritis Foundation

Key cytokines and self-assessments were provided at multiple time points

- A pilot sham-controlled RCT is underway, and a pivotal trial is in development



# Intellectual Property

We are inventors/owners of all patents on which therapy relies

**Our expansive pioneering IP covers all non-invasive, transdermal neuro-stimulation in the neck**

We have key patent coverage extending out through 2033, including:

- High-frequency burst signals capable of passing comfortably through the skin
- Low-pass signal filtration that reduces signal harmonics that cause pain

**>140**

PATENTS AND PATENT  
APPLICATIONS

**>70**

Issued U.S. patents

**>25**

U.S. patent applications

**>40**

International patents  
and applications

# Investment Highlights

<b>Platform Therapy</b>	Only FDA-cleared non-invasive delivery of bioelectronic medicine primed to unlock the broad potential of this highly targeted and safe therapy
<b>Pharma Distribution</b>	Distributed through standard specialty pharmacy channels
<b>Large Initial Market</b>	Primary headache market opportunity for cluster headache and migraine estimated to be in excess of \$4 billion
<b>Robust Pipeline</b>	Robust product pipeline in neurology and rheumatology, with key pivotal trials initiating in 2018 and 2019
<b>Highly Scalable</b>	Low investment manufacturing that meets all potential market demand
<b>Strong IP Portfolio</b>	Key patent coverage extends through 2033

