

## A Commercial-Stage Bioelectronic Medicine Company

Nasdaq: ECOR

## **Corporate Presentation**

August 2021

## **Forward Looking Statement**

In addition to historical information, this presentation may contain forward-looking statements with respect to our business, capital resources, strategy and growth reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. 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 may 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, 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.

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 they are made and are only predictions that may be inaccurate. You should read the Risk Factors set forth in our reports filed from time to time with the Securities and Exchange Commission, which factors may cause our actual future results to be materially different from what we expect.

Additionally, in an effort to provide additional information management believes is a useful indicator of operating performance for the period ended June 30, 2021, this presentation contains a financial measure not determined by generally accepted accounting principles (GAAP): Adjusted EBITDA net loss. A reconciliation to the most directly comparable GAAP financial measure of Net Loss is available on the presentation slide entitled "Adjusted EBITDA Reconciliation." The rationale for management's use of non-GAAP information is included in Exhibit 99.1 to the Company's Form 8-K furnished with the SEC August 5, 2021, and in slide 18 of this presentation.





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## electroCore At-a-Glance

#### NASDAQ

Headquarters:

Market cap\*:

Recent close:

Cash, cash equivalents & marketable securities (Approx. as of 6/30/21)\*\*:

ECOR

Rockaway, NJ

~\$72.2M (8/06/21)

\$1.04 (8/06/21)

\$23.7 million

\* Includes 20.7 million shares newly issued in the July 2021 public offering \*\*Excludes approximately \$18.8 million of cash raised in the recent public offering which closed subsequent to 6/30/21



gammaCore



## **Experienced Management Team**



**Dan Goldberger** Chief Executive Officer



Brian Posner Chief Financial Officer



Peter Staats Chief Medical Officer



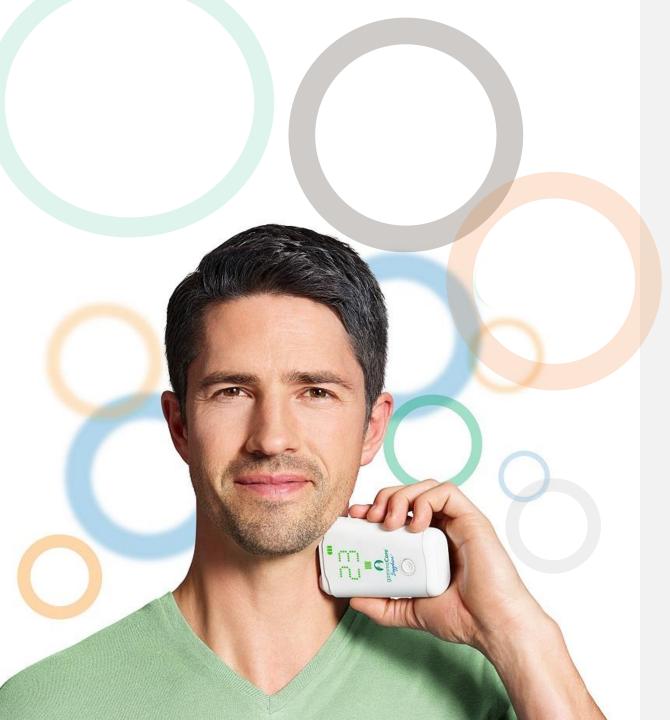






## **Investment Summary**

Platform Therapy	FDA cleared; proprietary, non-invasive vagus nerve stimulator (nVNS) positioned to unlock the broad potential of bioelectronic medicine
Large Initial Market	Cluster headache and migraine estimated to affect more than 39 million <sup>1</sup> adults in the U.S.
Attractive Revenue Model	Recurring revenue business model
Strong IP Portfolio	Patent coverage extends through 2033 <sup>1</sup> American Migraine Foundation
electro <b>Core</b>	5





## gammaCore



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

- Fast acting, highly targeted, comfortable, easy to use hand-held option
- Cleared for the prevention and treatment of cluster headache
- Cleared for the prevention of migraine and treatment of acute migraine in adults and adolescents
- Use alongside existing treatments; no drug-drug interactions or drug-like side effects
- Can use multiple times per day or month
- UK NICE guidance supporting first-year benefit when gammaCore therapy is used in conjunction with standard of care

## **nVNS and the Benefits of gammaCore**

The vagus nerve affects multiple organs and systems



Activates multiple mechanisms of action



Evidence supports possible future treatment for many indications



Self-treating and no off-target effects



Complementary to existing care



## **Unmet Need in Migraine & Cluster Headache**



#### **MIGRAINE**

#### 39 million U.S. adults<sup>1</sup>

Indirect costs associated with migraine in the U.S. has been estimated at \$19.3 billion (inflated to 2019 (US\$))<sup>2</sup>

Triptans represent 80% of prescribed acute therapies 40% of patients are dissatisfied or unresponsive to triptans<sup>3</sup>

More than half of insured migraineurs receive no Rx treatment<sup>3</sup>

gammaCore is FDA-cleared for migraine prevention and treatment of acute migraine

#### 1. American Migraine Foundation

2. CPI for all urban consumers (CPI-U). Bureau of Labor Statistics. Accessed May 17, 2019.

3. IMS Pharmetrics Plus.



#### **CLUSTER HEADACHE**

#### **400,000 U.S.** patients<sup>4</sup>

Up to eight 15-180 min attacks per day

Considered one of the most painful conditions known; a "suicide headache"

gammaCore is FDA-cleared for the prevention of all types of cluster headache and for the acute treatment of episodic cluster headache

nVNS is recommended as a first line treatment for both the acute and preventative treatment of cluster headache and highly relevant treatment option for patients suffering from migraine<sup>5</sup>

Identified as the only emerging treatment for cluster headache that has been shown to be effective in clinical trial for both the acute treatment of episodic cluster headache as well as the preventive treatment of cluster headache<sup>6</sup>

Cephalalgia. 2008 Jun;28(6):614-8. doi: 10.1111/j.1468-2982.2008.01592.x. Epub 2008 Apr 16.
 Cephalalgia. 2020 Jul 27; In-Press. Non-invasive vagus nerve stimulation for primary headache: a clinical update
 Nature Reviews: Neurology 2021 Mar 29; In-Press: Cluster headache pathophysiology - insights from current and emerging treatments. doi: 10.1038/s41582-021-00477-w. Epub ahead of print. PMID: 33782592



## **U.S. Reimbursement Pathway**

Aligned to stakeholder experience



#### **PHYSICIANS** Write a prescription for use at home



#### PATIENTS

Acquire gammaCore from a specialty pharmacy or directly from the company with a simple refill process



#### PAYERS

Manage utilization through pharmacy or medical benefit reimbursement

### **Payer Response**

#### CURRENT PAYER COVERAGE

CVS Caremark, Express Scripts, Highmark Blue Cross Blue Shield, North Dakota Blue Cross Blue Shield, Federal Supply Schedule (VA, DoD, Indian Health Service), EmblemHealth (Sapphire CV), Connecticare (Sapphire CV), HCSC (BCBS Illinois, BCBS Texas, BCBS Oklahoma, BCBS New Mexico, BCBS Montana – Sapphire CV), cash pay

#### PAYER ENGAGEMENT

Active discussions with multiple regional and national plans leveraging unique Level II HCPCS code K1020 "Non-invasive vagus nerve stimulator"

#### **REIMBURSEMENT PATH**

Prescription model with periodic refill; can be reimbursed as pharmacy or medical benefit



## **Commercial Headache Reimbursement**

#### **CVS/Caremark**

gammaCore is reimbursed by CVS/Caremark at a non-exclusionary co-pay of roughly \$50 - \$75/month for those beneficiaries who have a benefit design that does not differentiate between drugs and devices

Approximately five million CVS/Caremark members currently have a benefit design of this type

#### **Express Scripts (ESI)**

gammaCore is reimbursed by ESI on all National Standard Formularies at a preferred copay of roughly \$25 - \$45/month for those beneficiaries who have a benefit design that does not differentiate between drugs and devices

#### **CMS (HCPCS)**

Unique Level II Healthcare Common Procedure Coding System (HCPCS) code K1020 "Noninvasive vagus nerve stimulator" established by the Centers for Medicare and Medicaid Services, effective April 1, 2021



## **Medical Benefit Headache Reimbursement**

#### **Positive coverage Example: Highmark**

Non-implantable vagus nerve stimulation devices (e.g., gammaCore) may be considered medically necessary for the abortive treatment of episodic migraine or episodic cluster headache under **ALL** of the following circumstances:

- The individual has a diagnosis of episodic migraine or episodic cluster headache; and
- The individual has failed or has contraindication or has intolerance to at least two medications from each of the following categories: NSAIDS, Triptans, and Ergotamines; and
- The individual must be re-evaluated in 30 days. In order to obtain renewal of the device, there must be documentation of significant efficacy in the medical record.

In order to maintain coverage for gammaCore, the following efficacy must be documented:

 Reduction of pain from moderate or severe to mild or pain free within 60 minutes, without the use of rescue medicine, for at least 50% of attacks.

Non-implantable stimulation devices are considered experimental/investigational for **ANY** other indications and circumstances except those outlined above and therefore, non-covered because the safety and/or effectiveness of this service cannot be established by the available published peer reviewed literature.



## **Active Channels With Revenue Growth Opportunities**

Driving Department of Defense and Community Care Network sales through the Department of Veterans Affairs and Military Treatment Facilities

Growth in the UK by leveraging: 1) Innovation Technology Program Award for cluster headache (transitioning to broader coverage through the MedTech Funding Mandate), 2) support from the National Institute for Health and Care Excellence (NICE) for the treatment of cluster headache, 3) Scottish Health Technology Group (SHTG) adaptation for NHS Scotland on the use of gammaCore for cluster headache; and 4) similar approvals in Wales and Northern Ireland expected

International expansion through recently executed gammaCore Sapphire distribution agreements covering Eastern Europe, Canada, Australia, Belgium, Luxembourg, the Netherlands, France, Qatar, Taiwan, and China.



## **Expanding Federal Sales Opportunities**

## >20 million

covered lives between the VA (9m<sup>1</sup>), DoD (9.6m<sup>2</sup>), and Indian Health Service (2.2m<sup>3</sup>) across ~1,800<sup>1,2</sup> treatment facilities

electro**Core** 

## ~400,000 patients

saw VA healthcare providers for headache in 2018<sup>4</sup>

## Migraine grew 10-fold

in the VA between 2004-2012<sup>5</sup>

More than 27,000 veterans suffer from cluster headache<sup>6</sup>

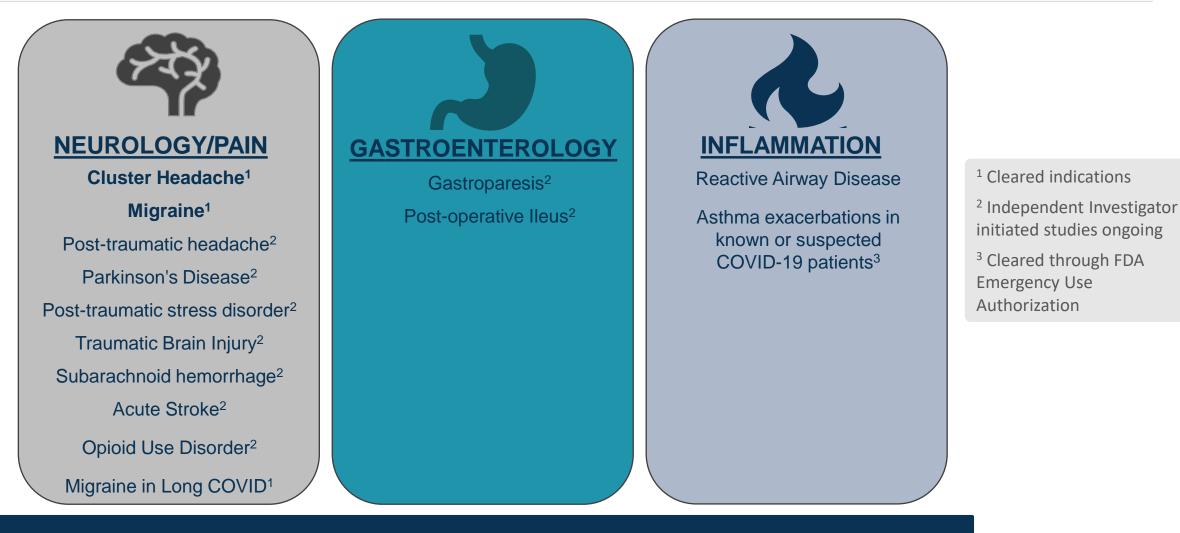






- 1. https://www.va.gov/health/aboutvha.asp
- 2. https://www.tricare.mil/About/Facts
- 3. https://www.ihs.gov/newsroom/factsheets/quicklook/
- . Grinberg et al. Understanding the Prevalence and Geographic Distribution of Headache Disorders within the Veterans Health Administration. Poster presentation, AHS 2019
- 5. Altalib et al. Increase in migraine diagnoses and guideline-concordant treatment in veterans, 2004-2012 Cephalalgia 2017;37:3-10
- 6. Dr. Sico et al. The headache & Migraine Policy Forum: Chronic Headache Disorders & Toxic Exposure, 2021, pg. 5

## **nVNS – A Platform Technology**



#### gammaCore is the only FDA cleared non-invasive VNS therapy in headache



gammaCore (nVNS) currently is FDA-cleared for prevention of migraine and cluster headache, and acute treatment of migraine and episodic cluster headache, as well as the acute and preventive treatment of migraine in adolescents between 12 and 17 years of age

## **Potential Key Near-term Milestones**

<u>2Q 2021</u>	<u>3Q 2021</u>	<u>4Q 2021</u>	<u>1Q 2022</u>	<u>2Q 2022</u>
	VA / [	DoD channel revenue growth pe	riod	
	Uł	K channel revenue growth period	d	
	Reesta	ablish commercial headache rev	enue	
	Ρ	ositive US payer determinations	;	
	Northern Irelan reimbursement a			
	Clinical publications re:	PTSD, PTH, TBI, Gastroparesi	s, Parkinson's, Stroke	
	VENUS top lin	e stroke data		VENUS stroke publication
	Potenti	al distribution partner announce	ments	
	Adequate	e cash to execute current operat	ing plan	
			* 5	



## **Broad Intellectual Property Portfolio**

electroCore owns all intellectual property on which the technology relies

# Expansive pioneering IP coverage of non-invasive, transdermal neuro-stimulation in the neck

We have patent coverage extending out through 2033:

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

## >170

## PATENTS AND PATENT APPLICATONS

~100 issued U.S. patents

>30 U.S. patent applications

>40 International patents and applications



## **Summary Financials**

\$ In thousands	1Q 2020	2Q 2020	3Q 2020	4Q 2020	1Q 2021	2Q 2021
Net sales	734	753	1,081	928	1,204	1,270
R&D	1,523	1,031	629	1,019	499	825
SG&A	6,561	5,273	4,593	5,414	5,725	5,273
Operating loss	(8,013)	(5,923)	(4,489)	(6,323)	(5,384)	(5,203)
GAAP net loss	(7,959)	(4,742)	(4,486)	(6,324)	(5,384)	(2,894)
Adjusted EBITDA net loss	(6,410)	(4,322)	(3,280)	(4,310)	(4,194)	(4,103)
Net cash burn*	\$8,400	\$5,200	\$4,100	\$3,700	\$4,100	\$3,200

Cash, Cash Equivalents & Marketable Securities as of 6/30/21\*\*: \$23.7 million

#### Preliminary Q3 2021 guidance (dated August 5, 2021):

Q3 2021 Revenue: >\$1.5 million

Q3 2021 net cash consumed by operations: ~\$4.5 million



\*\* Excludes approximately \$18.8 million of cash raised in the recent public offering which closed subsequent to 6/30/21 Please see reconciliation of GAAP net loss to adjusted EBITDA net loss on slide 18

\*Excludes capital raising activity

## **Adjusted EBITDA Reconciliation**

	1Q 2020	2Q 2020	3Q 2020	4Q 2020	1Q 2021	2Q 2021
(\$ in thousands)						
GAAP net loss	\$ (7,959)	\$ (4,742)	\$ (4,486)	\$ (6,324)	\$ (5,384)	\$ (2,894)
Benefit from income taxes	\$ -	\$ (1,171)	\$ -	\$ -	\$ -	\$ (885)
Depreciation and amortization	\$ 97	\$ 97	\$ 95	\$ 111	\$ 96	\$ 96
Stock-based compensation	\$ 745	\$ 1,003	\$ 743	\$ 776	\$ 942	\$ 838
Write-off of right of use operating lease	\$ -	\$ -	\$ -	\$ 558	\$ -	\$ -
Increase in inventory reserves	\$ -	\$ -	\$ -	\$ 434	\$ -	\$ -
Restructuring and other severance related charges	\$ 365	\$ 100	\$ -	\$ -	\$ -	\$ -
Legal fees associated with stockholders' litigation	\$ 396	\$ 402	\$ 371	\$ 136	\$ 151	\$ 166
Gain on extinguishment of debt	\$ -	\$ -	\$ -	\$ -	\$ -	\$ (1,422)
Total other income	\$ (54)	\$ (11)	\$ (2)	\$ 1	\$ 1	\$ (1)
Adjusted EBIDTA net loss	\$ (6,410)	\$ (4,322)	\$ (3,280)	\$ (4,310)	\$ (4,194)	\$ (4,103)

The company is presenting adjusted EBITDA net loss because it believes this measure is a useful indicator of its operating performance. electroCore management uses this non-GAAP measure principally as a measure of the company's core operating performance and believes that this measure is useful to investors because it is frequently used by the financial community, investors, and other interested parties to evaluate companies in the company's industry. The company also believes that this measure is useful to its management and investors as a measure of comparative operating performance from period to period. Additionally, the company believes its use of non-GAAP adjusted EBITDA net loss from operations facilitates management's internal comparisons to historical operating results by factoring out potential differences caused by charges not related to its regular, ongoing business, including, without limitation, non-cash charges and certain large and unpredictable charges such as restructuring expenses.

The company defines adjusted EBITDA net loss as GAAP net loss, excluding depreciation and amortization, stock-compensation expense, restructuring and other severance related charges, legal fees associated with stockholders' litigation, total other income/expense, extinguishment of debt, and benefit from income taxes. A reconciliation of GAAP net loss to Non-GAAP adjusted EBITDA net loss has been provided in the financial statement tables included in this press release.



## **Capitalization Table**

Fully diluted as of June 30, 2021

Common shares	69,390,424	Includes 20.7 million shares sold in the July'21 public offering
Warrants*	216,944	Exercise prices ranging from \$5.68 to \$15.30; expirations largely through August 31, 2022
Options	5,070,536	Weighted average exercise price = \$4.47, options generally vest over 4-year period (first options granted June 21, 2018)
Restricted Stock Units	1,222,746	RSUs which vest through February 2025.
Total	75,900,650	



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electro <b>Core</b>	20

## **Indication and Important Safety Information**

gammaCore Sapphire<sup>™</sup> (non-invasive vagus nerve stimulator) is intended to provide non-invasive vagus nerve stimulation (nVNS) on the side of the neck. gammaCore is indicated for:

- The preventive treatment of migraine headache in adolescent and adult patients.
- The acute treatment of pain associated with migraine headache in adolescent and adult patients.
- Adjunctive use for the preventive treatment of cluster headache in adult patients.
- The acute treatment of pain associated with episodic cluster headache in adult patients.

#### The safety and effectiveness of gammaCore (nVNS) have not been established in the acute treatment of chronic cluster headache

#### The long-term effects of the chronic use of gammaCore have not been evaluated

#### Safety and efficacy of gammaCore have not been evaluated in the following patients, and therefore gammaCore is NOT indicated for:

- Patients diagnosed with narrowing of the arteries (carotid atherosclerosis).
- Patients who have undergone surgery for resection of the vagus nerve in the neck (cervical vagotomy).
- Pediatric patients (Younger than 12 years)
- Pregnant women
- Patients with clinically significant hypertension, hypotension, bradycardia or tachycardia

#### Patients should not use gammaCore if they:

- Have an active implantable medical device, such as a pacemaker, hearing aid implant, or any implanted electronic device
- Has a metallic device such as a stent, bone plate, or bone screw implanted in or near the neck
- You are using another device at the same time (e.g., TENS unit, muscle stimulator) or any portable electronic device (e.g., cell phone).

In the US, the FDA has not cleared gammaCore for the treatment of pneumonia and/or respiratory disorders, such as acute respiratory stress disorder associated with COVID-19.

Please refer to the gammaCore Instructions for Use for all of the important warnings and precautions before using or prescribing this product: www.gammacore.com

Please also see the instructions for Use for gammaCore CV for all the important warnings and precautions specific to gammaCore CV and its use pursuant to the Emergency Use Authorization (EUA): <u>https://www.fda.gov/media/139970/download</u>





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## **Global Approvals**

#### **FDA-Cleared Indications for the US**

- The preventive treatment of migraine headache in adolescent (age 12 and older) and adult patients.
- The acute treatment of pain associated with migraine headache in adolescent (age 12 and older) and adult patients.
- Adjunctive use for the preventive treatment of cluster headache in adult patients.
- The acute treatment of pain associated with episodic cluster headache in adult patients.

#### CE Marks for the EU/EFTA/EEA and UK

- Acute and/or prophylactic treatment of primary headache (migraine, cluster headache, and hemicrania continua) and medication overuse headache in adults.
- Treatment or prevention of symptoms of reactive airway disease, including asthma, bronchoconstriction, exercise-induced bronchospasm, and COPD.
- Adjunctive therapy for adults to reduce the symptoms of certain anxiety and depression conditions (including panic disorder, posttraumatic stress disorder, obsessive-compulsive disorder, and major depressive disorder).
- Adjunctive therapy in the prevention of partial onset and generalized seizures associated with epilepsy in adults.
- Adjunctive therapy for adults to reduce the symptoms of gastric motility disorders and irritable bowel syndrome (including nausea, vomiting, bloating/distention, early satiety, and abdominal pain).

#### Health Canada License for Canada

Acute and/or prophylactic treatment of migraine and cluster headache in adults.

#### **ARTG Certificate for Australia**

Acute and/or prophylactic treatment of migraine and cluster headache in adults.

