

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): January 19, 2021

electroCore, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-38538
(Commission File Number)

20-3454976
(I.R.S. Employer
Identification Number)

200 Forge Way, Suite 205
Rockaway, NJ 07920
(Address of principal executive offices and zip code)

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

(973) 290-0097
(Registrant's telephone number, including area code)

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:

- 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 Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, Par Value \$0.001 Per Share	ECOR	NASDAQ Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 8.01. Other Events.

On January 19, 2021, electroCore, Inc. (the “Company”) issued a press release announcing that the Centers for Medicare and Medicaid Services established a unique Level II HCPCS code K1020 “Non-invasive vagus nerve stimulator,” which covers the Company’s gammaCore Sapphire D. A copy of the press release is filed herewith as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. **Description of Exhibit**

99.1 [Press release dated January 19, 2021.](#)

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.

January 22, 2021

electroCore, Inc.

/s/ Brian Posner

Brian Posner

Chief Financial Officer

electroCore, Inc. Announces the Establishment of a Unique Level II HCPCS Code for “Non-Invasive Vagus Nerve Stimulator”

ROCKAWAY, N.J., Jan. 19, 2021 (GLOBE NEWSWIRE) -- electroCore, Inc. (Nasdaq: ECOR), a commercial-stage bioelectronic medicine company, today announced that Centers for Medicare and Medicaid Services (“CMS”) published its most recent Level II Healthcare Common Procedure Coding System (“HCPCS”) decisions on January 15, 2021, establishing a unique code K1020 “Non-invasive vagus nerve stimulator.” The coding decision covers the Company’s gammaCore Sapphire™ D and is in response to the application submitted by the Company during CMS’ second biannual 2020 Coding Cycle for non-drug and non-biological items and services, which application focused on the clinical and economic advantages of gammaCore therapy. All final coding decisions for the second biannual 2020 Coding Cycle for non-drug and non-biological items and services will go into effect on April 1, 2021.

“The establishment of a unique HCPCS code for non-invasive vagus nerve stimulation is a major step forward in obtaining additional coverage within the medical benefit pathway with the goal of providing patients with easier access to our therapy” said Dan Goldberger, CEO of electroCore, Inc.

“We are pleased with the decision by CMS to recommend a unique HCPCS code for non-invasive vagus nerve stimulation and appreciate the efforts by CMS and our team during the process to achieve this milestone” said Joshua Lev, VP of Business Development, Strategy, and FP&A. “The unique code is further validation of our differentiated technology of non-invasive vagus nerve stimulation and how our therapy can help patients suffering from different forms of primary headache.”

The CMS decision can be viewed at: <https://www.cms.gov/files/document/2020-hcpcs-application-summary-bi-annual-2-2020-durable-medical-equipment-dme-and-accessories.pdf>

About electroCore, Inc.

electroCore, Inc. is a commercial-stage bioelectronic medicine company dedicated to improving patient outcomes through its platform non-invasive vagus nerve stimulation therapy initially focused on the treatment of multiple conditions in neurology. The company's current indications are the preventative treatment of cluster headache and migraine and acute treatment of migraine and episodic cluster headache.

For more information, visit www.electrocore.com.

About gammaCore™

gammaCore™ (nVNS) is the first non-invasive, hand-held medical therapy applied at the neck as an adjunctive therapy to treat migraine and cluster headache through the utilization of a mild electrical stimulation to the vagus nerve that passes through the skin. Designed as a portable, easy-to-use technology, gammaCore can be self-administered by patients, as needed, without the potential side effects associated with commonly prescribed drugs. When placed on a patient's neck over the vagus nerve, gammaCore stimulates the nerve's afferent fibers, which may lead to a reduction of pain in patients.

gammaCore is FDA cleared in the United States for 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 acute treatment of pain associated with migraine headache in adult patients, and the prevention of migraine in adult patients. gammaCore is CE-marked in the European Union for the acute and/or prophylactic treatment of primary headache (Migraine, Cluster Headache, Trigeminal Autonomic Cephalalgias and Hemicrania Continua) and Medication Overuse Headache in adults.

- Safety and efficacy of gammaCore have not been evaluated in the following patients:
 - o Patients diagnosed with narrowing of the arteries (carotid atherosclerosis)
 - o Patients who have had surgery to cut the vagus nerve in the neck (cervical vagotomy)
 - o Pediatric patients
 - o Pregnant women
 - o Patients with clinically significant hypertension, hypotension, bradycardia, or tachycardia
- Patients should not use gammaCore if they:
 - o Have an active implantable medical device, such as a pacemaker, hearing aid implant, or any implanted electronic device
 - o Have a metallic device such as a stent, bone plate, or bone screw implanted at or near their neck
 - o Are using another device at the same time (e.g., TENS Unit, muscle stimulator) or any portable electronic device (e.g., mobile 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.

Forward-Looking Statements

This press release and other written and oral statements made by representatives of electroCore may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, but are not limited to, statements about electroCore's business prospects and clinical and product development plans; its pipeline or potential markets for its technologies; the timing, outcome and impact of regulatory, clinical and commercial developments; the Company's business prospects in Eastern Europe and other new markets and other statements that are not historical in nature, particularly those that utilize terminology such as "anticipates," "will," "expects," "believes," "intends," other words of similar meaning, derivations of such words and the use of future dates. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, the ability to raise the additional funding needed to continue to pursue electroCore's business and product development plans, the inherent uncertainties associated with developing new products or technologies, the ability to commercialize gammaCore™, the potential impact and effects of COVID-19 on the business of electroCore, electroCore's results of operations and financial performance, any measures electroCore has and may take in response to COVID-19 and any expectations electroCore may have with respect thereto, competition in the industry in which electroCore operates and overall market conditions, and risks associated with the uncertainty of ultimate Medicare coverage, pricing and reimbursement for electroCore's gammaCore therapy, if any. Any forward-looking statements are made as of the date of this press release, and electroCore assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law. Investors should consult all of the information set forth herein and should also refer to the risk factor disclosure set forth in the reports and other documents electroCore files with the SEC available at www.sec.gov.

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