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): February 16, 2021

electroCore, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-38538**	**20-3454976**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(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 February 16, 2021, electroCore, Inc. issued a press release announcing that gammaCore™ non-invasive vagus nerve stimulation was cleared by the U.S. Food and Drug Administration under Section 510(k) of the Federal Food and Drug Act for the treatment of migraine in adolescents between 12 and 17 years of age. 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 February 16, 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.

electroCore, Inc.

February 17, 2021

/s/ Brian Posner

Brian Posner
Chief Financial Officer

electroCore Announces 510(k) Clearance of gammaCore™ Non-Invasive Vagus Nerve Stimulation (nVNS) to Treat Adolescent Migraine

FDA clearance expands gammaCore label to include the acute and preventive treatment of migraine in adolescents 12 to 17 years of age

ROCKAWAY, N.J., February 16, 2021 (GLOBE NEWSWIRE) -- electroCore, Inc. (Nasdaq: ECOR), a commercial-stage bioelectronic medicine company, announced today that on Friday, February 12, 2021, the company received Section 510(k) clearance from the Unites States Food and Drug Administration (FDA) of the company's submission to expand the label of gammaCore nVNS to include the acute and preventive treatment of migraine in adolescents between 12 and 17 years of age. gammaCore is now cleared for most forms of primary headache including the acute and preventive treatment of migraine in adolescents and adults, as well as the acute and preventive treatment of cluster headache in adults.

Dr. Andrew Hershey, Endowed Chair and Director of Neurology at Cincinnati Children's Medical Center and Professor of Pediatrics and Neurology at the University of Cincinnati College of Medicine, commented, "Migraine is a very common disease in adolescents that can affect them at home, school and socially. gammaCore, which can be used acutely to treat migraine attacks, or when used daily can decrease the number of attacks, is an exciting treatment that I look forward to offering to my adolescent patients."

It is estimated that 10% of all school age children and up to 28% of teens between the ages of 15-19 live with migraine[1], while 37% of children find their schoolwork suffers during a headache which can negatively affect a teen's social life.[2]

"gammaCore (nVNS) is the only treatment option, drug or device, that is currently available for the acute and preventive treatment of migraine in adolescents," said Eric Liebler, Senior Vice President of Neurology at electroCore, Inc. "With their interest in technology and desire to avoid prescription drugs, gammaCore represents a unique treatment for adolescents with migraine. We would like to thank the Division of Neuromodulation and Physical Medicine Devices and their colleagues at the FDA for their efforts to review and clear the expanded label for gammaCore. "

The label expansion was based on previously reported randomized controlled trials of gammaCore for the acute and preventive treatment of migraine, and was supported by a small study (n=9) in adolescents where 46.8% of all treated attacks were successfully resolved without the use of any acute rescue medication.[3]

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[1] https://migraineresearchfoundation.org/about-migraine/migraine-in-kids-and-teens/

[2] https://mhni.com/headache-pain-faq/pediatric-headaches/managing-headaches-school#:~:text=Headache%20can%20affect%20how%20well,of%20their%20adolescent%20headache%20patients.

[3] Grazzi L, Egeo G, Liebler E, Padovan AM, Barbanti P. Non-invasive vagus nerve stimulation (nVNS) as symptomatic treatment of migraine in young patients: a preliminary safety study. Neurol Sci. 2017 May;38(Suppl1):197-199. doi: 10.1007/s10072-017-2942-5. PMID: 28527086.

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, and the acute and preventive treatment of migraine in adolescent (ages 12 and older) and 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:
  - Patients diagnosed with narrowing of the arteries (carotid atherosclerosis)
  - Patients who have had surgery to cut the vagus nerve in the neck (cervical vagotomy)
  - 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
  - Have a metallic device such as a stent, bone plate, or bone screw implanted at or near their neck
  - Are using another device at the same time (e.g., TENS Unit, muscle stimulator) or any portable electronic device (e.g., mobile phone)

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 business, operating or financial impact of such studies; the potential of nVNS generally and gammaCore in particular for the acute and preventative treatment of migraine in adolescence 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, and 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. 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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