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)
July 13, 2020

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)**

150 Allen Road, Suite 201
Basking Ridge, NJ 07920
(Address of principal executive offices and zip code)

(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 Stock 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 July 13, 2020, electroCore, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration has issued an Emergency Use Authorization ("EUA") for use of gammaCore Sapphire™ non-invasive vagus nerve stimulation (nVNS) at home or in a healthcare setting to acutely treat adult patients with known or suspected COVID-19 who are experiencing exacerbation of asthma-related dyspnea and reduced airflow, and for whom approved drug therapies are not tolerated or provide insufficient symptom relief. A copy of the press release is filed with this Form 8-K as Exhibit 99.1.

There can be no assurance as to what impact, if any, the EUA for gammaCore Sapphire will have on the Company, its business, operations or financial condition.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description of Exhibit
99.1	Press release dated July 13, 2020

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.

July 13, 2020

/s/ Brian Posner

Brian Posner
Chief Financial Officer

electroCore Announces FDA Emergency Use Authorization for use of gammaCore Sapphire™ CV for the Acute Treatment of Asthma Exacerbations in Known or Suspected COVID-19 Patients

Intended use allows gamaCore Sapphire CV use at home or in a healthcare setting

BASKING RIDGE, N.J., July 13, 2020 -- electroCore, Inc. (Nasdaq: ECOR), a commercial-stage bioelectronic medicine company, today announced that the FDA has issued an Emergency Use Authorization (EUA) authorizing the use of gammaCore Sapphire™ CV non-invasive vagus nerve stimulation (nVNS) at home or in a healthcare setting to acutely treat adult patients with known or suspected COVID-19 who are experiencing exacerbation of asthma-related dyspnea and reduced airflow, and for whom approved drug therapies are not tolerated or provide insufficient symptom relief.

“Needless to say, we are very pleased to have received this EUA, and we intend work vigorously to make this novel therapy available to physicians treating known or suspected COVID 19 patients who are experiencing exacerbation of asthma-related breathing difficulty,” said Dan Goldberger, Chief Executive Officer of electroCore.

Peter Staats, MD, Chief Medical Officer, went on to say, “Results from prior pilot studies that evaluated gammaCore for the acute treatment of asthma support our belief that nVNS may provide much needed relief to patients who are experiencing asthma-related breathing difficulty, which can be particularly debilitating in patients with COVID-19.”

JP Errico, electroCore Board member, co-founder and co-inventor of gammaCore, commented, “This FDA decision is an encouraging first step toward developing evidence that may provide a basis for electroCore to pursue expansion of nVNS into reactive airway disease (RAD), which was the first area of research for electroCore.”

The EUA is based on preliminary data from two prospective studies of use of VNS or nVNS to treat asthma:

Study	Design	N	Findings
VNS for the treatment of acute asthma exacerbations	Prospective, multicenter, open-label study	4	90 minutes after acute percutaneous VNS treatment, FEV_1 improved from baseline by a mean of 73%, and mean VAS dyspnea score decreased from 8 (at baseline) to 1
nVNS for the relief of acute bronchoconstriction due to asthma	Prospective, multicenter, open-label study	30	90 minutes after acute nVNS treatment, 93% of patients reported improvement in VAS dyspnea score, and 86% had improvements in FEV_1

Abbreviations: FEV_1, forced expiratory volume in 1 second; nVNS, non-invasive vagus nerve stimulation; VAS, visual analog scale.

Staats.P, Giannakopoulos.G, Blake.J, Liebler.E, Levy.R. April 27, 2020. Use of Non-Invasive Vagus Nerve Stimulation to Treat Respiratory Symptoms Associated with COVID-19: A Theoretical Hypothesis and Early Clinical Experience, Neuromodulation: Technology at the Neural Interface

electroCore will provide additional details on the pricing and distribution of gammaCore CV under this EUA in the coming weeks.

About The EUA
The United States FDA has authorized use of the gammaCore Sapphire CV device for acute use at home or in a healthcare setting to treat adult patients with known or suspected COVID-19 who are experiencing exacerbation of asthma-related dyspnea and reduced airflow, and for whom approved drug therapies are not tolerated or provide insufficient symptom relief as assessed by their healthcare provider, by using non-invasive vagus nerve stimulation (VNS) on either side of the patient's neck, available under an emergency access mechanism called an EUA.

The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of medical devices during the COVID-19 pandemic. This device has not undergone the same type of review as an FDA-approved or cleared device. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, or available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that it is reasonable to believe that the device meets certain criteria for safety, performance, and labeling, and that it may be effective in treating patients with COVID-19.

The EUA for the gammaCore Sapphire CV device is in effect for the duration of the COVID-19 declaration justifying emergency use of these devices, unless terminated or revoked (after which the products may no longer be used). An FDA approved or cleared device should be used instead of the gammaCore Sapphire CV under EUA, when applicable and available. Further information is available at:

Authorization Letter: https://www.fda.gov/media/139967/download

Fact Sheet for Healthcare Providers: https://www.fda.gov/media/139968/download

Fact Sheet for Patients: https://www.fda.gov/media/139969/download

Instructions for gammaCore use https://www.fda.gov/media/139970/download

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 initial targets 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 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), Bronchoconstriction 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)
    - Pediatric patients
    - 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)

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 of the important warnings and precautions specific to gammaCore CV and its use pursuant to the EUA.

Forward-Looking Statement

This press release 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 including potential human trials for the study of nVNS in COVID-19 patients in Spain, the U.S., or elsewhere, the business, operating or financial impact of such studies, 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™, 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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