

**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)  
April 2, 2020**

**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)

**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
<b>Common Stock, Par Value \$0.001 Per Share</b>	<b>ECOR</b>	<b>NASDAQ Global Select Market</b>

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.

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**Item 8.01. Other Events**

On April 2, 2020, electroCore, Inc. (the “Company”) issued a press release announcing that it has submitted an Emergency Use Authorization (“EUA”) application to the U.S. Food and Drug Administration (“FDA”) to facilitate the study and clinical use of its gammaCore Sapphire non-invasive vagus nerve stimulation therapy for respiratory symptoms associated with COVID-19. A copy of the press release is filed with this Form 8-K as Exhibit 99.1.

Although the Company believes that clinical data from certain pilot studies may suggest a possible benefit for patients with respiratory distress associated with COVID-19, it should be noted that preclinical and clinical data are often susceptible to varying interpretations and analyses, and that such data may not be adequate for the FDA to issue an EUA. It should also be noted that to date no randomized clinical trials have been performed utilizing gammaCore in patients with COVID-19. In addition, there can be no assurance as to the timing of the review of an EUA submission nor whether the EUA ultimately will be granted. There also can be no assurance as what impact, if any, an EUA for gammaCore Sapphire will have on the Company, its business, operations or financial condition.

**Item 9.01. Financial Statements and Exhibits.***(d) Exhibits.*

<b>Exhibit No.</b>	<b>Description of Exhibit</b>
99.1	<a href="#">Press release dated April 2, 2020.</a>

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**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.

April 2, 2020

**electroCore, Inc.**

/s/ Brian Posner

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Brian Posner

Chief Financial Officer

# electroCore Submits Emergency Use Authorization Application to Allow the Study and Use of gammaCore nVNS Therapy to Treat Respiratory Symptoms Associated with COVID-19

**BASKING RIDGE, N.J., April 2, 2020** -- electroCore, Inc. (Nasdaq: ECOR), a commercial-stage bioelectronic medicine company, today announced that the company has submitted an Emergency Use Authorization (EUA) application to the U.S. Food and Drug Administration (FDA) to facilitate the study and clinical use of its gammaCore Sapphire™ non-invasive vagus nerve stimulation therapy, or nVNS, for respiratory symptoms associated with COVID-19.

The EUA includes data from early clinical and non-clinical work that examined the use of the company's VNS, including non-invasive therapy, in several pilot studies that involved patients with a variety of respiratory disorders. These studies suggest a possible benefit for patients with respiratory distress associated with COVID-19. Additionally, gammaCore's strong safety and tolerability profile suggest that it would be safe to study or use in patients with COVID-19.

Peter Staats, MD, MBA, co-founder and Chief Medical Officer of electroCore, commented: "In the face of the current pandemic, we all have a responsibility to explore any treatment that could help patients suffering from COVID-19. Data from multiple pilot studies in patients with respiratory conditions, such as asthma and chronic pulmonary obstructive disorder, along with the possible method of action of nVNS, suggests that gammaCore could provide some needed relief in critically ill patients with COVID-19."

electroCore has received CE Mark in the European Union for gammaCore in certain respiratory indications, including for the treatment or prevention of symptoms of reactive airway disease, which includes asthma, bronchoconstriction, exercise induced bronchospasm, and COPD in adults.

The FDA's Emergency Use Authorization (EUA) authority permits the agency to expedite the clearance and emergency use of previously approved medical products to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, and available alternatives.

Although the Company believes that clinical data from the referenced pilot studies may suggest a possible benefit for patients with respiratory distress associated with COVID-19, it should be noted that preclinical and clinical data are often susceptible to varying interpretations and analyses, and that such data may not be adequate for the FDA to issue an EUA. It should also be noted that to date no randomized clinical trials have been performed utilizing gammaCore in patients with COVID-19.

In addition, there can be no assurance as to the timing of the review of an EUA submission nor whether the EUA ultimately will be granted. There also can be no assurance as what impact, if any, an EUA for gammaCore Sapphire will have on the Company, its business, operations or financial condition.

## **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

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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 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. 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.

- Safety and efficacy of gammaCore have not been evaluated in the following patients:
  - Patients with an active implantable medical device, such as a pacemaker, hearing aid implant, or any implanted electronic device
  - 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 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 acute treatment of chronic cluster headache.

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

### **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 product development plans, its pipeline or potential markets for its technologies, seeking to secure an EUA from the FDA for gammaCore in relation to COVID-19, 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

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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](http://www.sec.gov).

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