

**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 27, 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
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 April 27, 2020, electroCore, Inc. (the “Company”) issued a press release with an update on the Company’s ongoing non-invasive vagus nerve stimulation initiatives related to COVID-19, including the commencement of enrollment of COVID-19 patients in an investigator-initiated, randomized, controlled clinical trial of nVNS therapy in Spain.

The Company also announced that a paper, entitled “*Use of Non-Invasive Vagus Nerve Stimulation to Treat Respiratory Symptoms Associated with COVID-19: A Theoretical Hypothesis and Early Clinical Experience*” has gone through peer review and been accepted for publication by the journal *Neuromodulation: Technology at the Neural Interface*. The paper is available at <https://onlinelibrary.wiley.com/doi/abs/10.1111/ner.13172>.

A copy of the press release is filed with this Form 8-K as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
99.1	Press release dated April 27, 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.

May 1, 2020

electroCore, Inc.

/s/ Brian Posner

Brian Posner
Chief Financial Officer

electroCore Provides Update on COVID-19 Clinical Initiatives

Randomized controlled investigator-initiated trial (IIT) of non-invasive vagus nerve stimulation (nVNS) therapy currently enrolling COVID-19 patients in Spain

*Peer-reviewed paper, “Use of Non-Invasive Vagus Nerve Stimulation to Treat Respiratory Symptoms Associated with COVID-19: A Theoretical Hypothesis and Early Clinical Experience,” accepted for publication in the journal *Neuromodulation: Technology at the Neural Interface**

BASKING RIDGE, N.J., April 27, 2020 — electroCore, Inc. (Nasdaq: ECOR), a commercial-stage bioelectronic medicine company, today provided an update on ongoing nVNS COVID-19 initiatives.

The company announced today that an investigator-initiated, randomized, controlled clinical trial of nVNS therapy has commenced enrolling COVID-19 patients in Spain. The trial, “Prospective, Randomized, Controlled Study to Evaluate the Effect of Non-Invasive Electrical Vagus Nerve Stimulation on Respiratory Symptoms due to CoViD-19 (SAVIOR),” is designed to assess the ability of nVNS to decrease the number of hospitalized COVID-19 patients requiring use of a ventilator. In the treatment group, nVNS will be provided in addition to the current standard of care. nVNS will be used prophylactically, three times a day, as well as acutely when needed by patients, with the goal of improving breathing and decreasing the need for mechanical ventilation. The control group will consist of patients matched to the stimulation group in terms of severity and will be treated with standard of care alone. The trial is being led by Dr. Carlos Tornero, M.D., Head of the Anesthesiology-Resuscitation Department, Hospital Clínico Universitario de Valencia.

Multiple US institutions have expressed interest in conducting additional controlled clinical studies of nVNS’ potential utility in treating COVID-19 patients. A second investigator-initiated randomized, controlled trial protocol (SAVIOR-2) was recently approved by the Institutional Review Board (IRB) at one U.S. institution and should commence soon. Additional U.S. investigator-initiated trials are under consideration.

“COVID 19 is causing a worldwide pandemic, the likes of which we have not seen before. Worldwide data indicate that COVID 19 causes a lethal cytokine storm in a small percentage of people who contract the virus, so strategies directed at blocking cytokine release hold promise,” commented Peter S. Staats, MD, Chief Medical Officer of electroCore. “Pre-clinical work and early pilot studies in respiratory indications such as asthma and bronchoconstriction, the ability of nVNS to block cytokine release, and literature demonstrating that VNS blocks the cytokine storm in animals, all support the hypothesis that nVNS may improve outcomes in patients with COVID-19.”

Dr. Staats continued, “We applaud Dr. Tornero for initiating the first controlled clinical trial of nVNS therapy in COVID-19 patients, and we look forward to results from important research.”

The company also announced today that a paper, entitled, “*Use of Non-Invasive Vagus Nerve Stimulation to Treat Respiratory Symptoms Associated with COVID-19: A Theoretical Hypothesis and Early Clinical Experience*,” has gone through peer review and been accepted for publication by the highly-regarded journal *Neuromodulation: Technology at the Neural Interface*. The paper will be made available via open access when published online in the near future.

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 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.

- o Safety and efficacy of gammaCore have not been evaluated in the following patients: 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 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 <http://www.sec.gov/clincial/>.

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