
**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)
September 25, 2019**

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 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 September 25, 2019, electroCore, Inc. issued a press release with an update on its 510(k) submission for gammaCore use in migraine prevention. A copy of the press release is filed herewith as Exhibit 99.1 and incorporated herein by reference.

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

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
99.1	Press release dated September 25, 2019.

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.

September 25, 2019

electroCore, Inc.

/s/ Brian Posner

Brian Posner

Chief Financial Officer



electroCore Provides Update on 510(k) Submission Seeking Expanded Indication for gammaCore™

Additional information requested by FDA; Premium 2 trial progressing as planned

September 25, 2019 at 8:00am ET

BASKING RIDGE, N.J., September 25, 2019 — electroCore, Inc. (Nasdaq: ECOR, or the “Company”), a commercial-stage bioelectronic medicine company, today announced that the U.S. Food and Drug Administration (“FDA”) has requested more information and analysis of the clinical data included in the Company’s premarket notification, or “510(k)” submission, seeking an expanded indication for the use of gammaCore™ (non-invasive vagus nerve stimulator). Although the Company has 180 days to respond to FDA’s request, the Company expects to meet with the FDA in the fourth quarter to discuss the information request. gammaCore™ is currently FDA-cleared for the treatment of pain associated with episodic cluster headache and migraine headache, and adjunctive use for the prevention of cluster headache.

The data submitted in the 510(k) include the results of the Premium 1 study, a randomized, double-blind, sham-controlled trial of gammaCore™ recently published in the journal *Cephalalgia* (<https://journals.sagepub.com/doi/pdf/10.1177/0333102419876920>).

“We look forward to meeting soon with the FDA to discuss our 510(k) submission and are committed to working with the agency to address their questions as quickly as possible,” said Tony Fiorino, Chief Medical Officer of electroCore. “Meanwhile we continue to recruit subjects into the Premium 2 study which we anticipate will further define the clinical utility of gammaCore™ in the migraine space.”

Premium 2 Clinical Trial Update

Premium 2 is a randomized, double-blind, sham-controlled clinical trial of gammaCore™ for the prevention of migraine being conducted at approximately 30 sites in the United States (ClinicalTrials.gov identifier NCT03716505). Premium 2 was designed to support an expanded FDA clearance and the commercialization and reimbursement of gammaCore™. Currently, the enrollment in Premium 2 is nearing 50% of its target of approximately 400 subjects, and recruitment is expected to conclude in the first half of 2020.

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 and rheumatology. The Company’s initial targets are the preventative treatment of cluster headache and acute treatment of migraine and episodic cluster headache.

For more information, visit www.electrocore.com.



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, future cash flow projections, the timing and impact of regulatory, clinical and commercial developments, its pipeline or potential markets for its technologies, 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 successfully 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.

Investors:

Hans Vitzthum
LifeSci Advisors
617-430-7577
hans@lifesciadvisors.com

or

Media Contact:

Sara Zelkovic
LifeSci Public Relations
646-876-4933
sara@lifescipublicrelations.com