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)
November 28, 2018

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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))

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 November 28, 2018, electroCore, Inc. issued a press release announcing FDA clearance for its gammaCore™ (non-invasive vagus nerve stimulator (nVNS)) therapy for adjunctive use for the preventive treatment of cluster headache in adults. A copy of the press release is filed herewith as Exhibit 99.1 and incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description of Exhibit**
99.1	Press release dated November 28, 2018

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.

November 28, 2018

/s/ Glenn S. Vraniak
Glenn S. Vraniak
Chief Financial Officer

Exhibit 99.1

electroCore Recieves FDA Clearance for gammaCore™ (nVNS) for Adjunctive Use for the Preventive Treatment of Cluster Headache in Adults

Basking Ridge, NJ, November 28, 2018 – electroCore, Inc. (Nasdaq: ECOR), a commercial-stage bioelectronic medicine company, today announced that it received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for an expanded label for gammaCore™ [non-invasive vagus nerve stimulator (nVNS)] therapy for adjunctive use for the preventive treatment of cluster headache in adult patients. This milestone marks the first and only product FDA cleared for the prevention of cluster headache. There are currently no FDA-approved pharmacologic treatments for the prevention of cluster headache.

“The FDA clearance of gammaCore for adjunctive use for the preventive treatment of cluster headache has the potential to help the approximately 350,000 Americans impacted by this debilitating condition often referred to as a ‘suicide headache,’” said Frank Amato, Chief Executive Officer at electroCore. “We are pleased that cluster headache patients now have a FDA-cleared option, and one that is both safe and effective, especially given the difficulty in treating cluster headache and the limitations of current treatments.”

This clearance was supported by results from two studies, including from the PREVA (**PREV**ention and **A**cute treatment of chronic cluster headache) pivotal study, a prospective, open-label, controlled randomized clinical trial that demonstrated the safety and effectiveness of gammaCore as an adjunctive therapy for the preventive treatment of cluster headache. The second study reviewed by the FDA was a real world retrospective study examining the daily clinical use of gammaCore preventively and acutely for the treatment of cluster headache.

In the PREVA study, intention-to-treat (ITT) patients who received the standard of care and gammaCore (SoC plus nVNS, n=45; control, n=48) during the randomized phase had a greater reduction from the baseline (−5.9) in the number of cluster attacks per week than those receiving standard of care (−2.1), for a mean therapeutic gain of 3.9 fewer cluster attacks per week (P=0.02). In the site-adjusted model, the mean therapeutic gain was 4.2 fewer attacks per week (P=0.02).

Furthermore, 40 percent of patients who received gammaCore in addition to standard of care experienced a 50 percent or greater reduction in weekly cluster attacks, compared to 8.3 percent of patients who received standard of care alone (P<0.001).

In addition, there was a 57 percent decrease in the frequency of abortive medication use among patients who received gammaCore plus standard of care (P<0.001), while patients who received standard of care alone did not experience a substantial reduction in abortive medication use (P=0.59).

In this study, gammaCore was found to be safe and well tolerated. The incidence of adverse events was similar between patients using gammaCore plus standard of care compared to standard of care alone. The majority of the adverse events were mild and transient. The most common adverse events reported in five percent of patients or more in the gammaCore group were headache (8%), dizziness (6%) and neck pain (6%). None of the serious adverse events were considered device-related.

To prevent cluster headache, adult patients should self-administer two gammaCore treatments daily. Each treatment consists of three consecutive 2-minute stimulations. The first treatment should be applied within one hour of waking up and the second treatment should be applied at least 7-10 hours later.

gammaCore is available by prescription only and patients should speak with their doctor about whether gammaCore is right for them.

About gammaCore™
gammaCore™ (nVNS) is the first non-invasive, hand-held medical therapy applied at the neck as an adjunctive therapy to prevent cluster headache and acutely treats the pain associated with episodic cluster headache and migraine in adult patients 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 cleared in the U.S. as an adjunctive treatment to prevent cluster headache and for the acute treatment of pain associated with episodic cluster headache and migraine headache in adult patients. gammaCore is the only FDA-cleared product for the prevention of cluster headache.

IMPORTANT SAFETY INFORMATION REGARDING GAMMACORE

- The safety and effectiveness of the gammaCore (nVNS) have not been established in the acute treatment of chronic cluster headache.
- gammaCore has not been shown to be effective for the preventive treatment of migraine headache.
- The long-term effects of the chronic use of gammaCore have not been evaluated.
- Safety and efficacy of gammaCore have not been evaluated in the following patients, and therefore is NOT indicated for:
  - 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)

Note: This list is not all inclusive. Please refer to the gammaCore Instructions for Use for all important warnings and precautions before using or prescribing this product.

gammaCore is available by prescription only. U.S. Federal Law restricts this device to sale by or on the order of a licensed healthcare provider.

About Cluster Headache
Cluster headache is a series of relatively short but extremely painful headaches that has been described by patients and physicians as one of the most painful conditions in medicine. The suicide rate among these patients is 20 times the U.S. national average, leading to the condition being referred to as the “suicide headache.” There are approximately 350,000 cluster headache sufferers in the United States, approximately 225,000 of whom seek treatment each year primarily from the same headache specialists who treat migraine.

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, 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 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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