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 13, 2021

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)

200 Forge Way, Suite 205
Rockaway, NJ 07866
(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 2.02. Results of Operations and Financial Condition.

On April 13, 2021, electroCore, Inc. (the "Company") issued a press release providing a business update, including preliminary unaudited financial guidance for the first quarter of 2021. A copy of the press release is filed herewith as Exhibit 99.1.

The information in this Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 2.02 and in the press release attached as Exhibit 99.1 to this Current Report shall not be incorporated by reference into any filing with the SEC made by the Company, whether made before or after the date hereof, except as shall be expressly set forth by reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description of Exhibit
99.1	Press release dated April 13, 2021.

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.

April 13, 2021

/s/ Brian Posner

Brian Posner
Chief Financial Officer

Exhibit 99.1

electroCore Provides Business Update and Select First Quarter 2021 Financial Guidance

First quarter 2021 revenue expected to be more than $1.1 million

Net cash used for the first quarter 2021 of approximately $4.1 million

ROCKAWAY, N.J, April 13, 2021 -- electroCore, Inc. (Nasdaq: ECOR), a commercial-stage bioelectronic medicine company, today provided an operating and business update as well as select unaudited preliminary financial guidance for the first quarter of 2021.

“We are pleased to announce a return to strong sequential revenue growth in the first quarter of 2021,” stated Dan Goldberger, Chief Executive Officer of electroCore. In addition to strong performances in the United States and the United Kingdom, our new OUS distributor relationships have begun generating revenue with initial orders totaling approximately $45,000 from Eastern Europe and Australia, and initial revenue from our new Canadian distributor is expected in the second quarter. Additionally, we have recently announced an exclusive distribution agreement with Silvert Medical who will distribute gammaCore™ in the Western European countries of Belgium, Luxembourg, the Netherlands, and France. We look forward to supporting our new OUS distribution relationships and growing the use of gammaCore as a therapeutic option for multiple forms of primary headache by expanding global distribution throughout 2021.”

Operational:

Government Channels: During the first quarter of 2021, we began to see clinician meetings with our staff increase within the Department of Veterans Affairs (“VA”), as the number of COVID-19 cases decreased within the system. There have been a total of 79 VA and Department of Defense (“DoD”) military treatment facilities that have purchased gammaCore products through Q1 2021, as compared to 71 through the fourth quarter of 2020 and 64 through the first quarter of 2020. Also, during the first quarter of 2021, the company shipped approximately 1,768 paid months of therapy pursuant to VA and DoD originating prescriptions, compared to 1,232 during the fourth quarter of 2020 and 1,084 during the first quarter of 2020.

Outside of the U.S.: During the first quarter of 2021, electroCore shipped approximately 1,156 paid months of therapy outside of the United States directly to patients, as compared to 1,123 during the fourth quarter of 2020 and 1,008 during the first quarter of 2020. Note the newly engaged distributors around the world are not included in this metric.

In January 2021, NHS England and NHS Improvement announced that gammaCore would be included in their new long-term reimbursement scheme titled “NHS Improvement MedTech Funding Mandate Policy 2021/22”, which became effective on April 1, 2021. We are working with NHS England to transition providers and commissioners from the NHS Innovation and Technology Program (ITP) to the MedTech Funding Mandate policy.

Similarly, in January 2021 Health Improvement Scotland ("HIS") published a Scottish Health Technology Group ("SHTG") adaptation of our NICE Medical Technology Guidance (MTG46) for NHS Scotland on the use of gammaCore for cluster headache. The SHTG adaptation is now being disseminated across NHS Scotland health boards to inform the use of gammaCore for cluster headache.

In February 2021, gammaCore's listing in the NHS Supply Chain catalogue was extended for an additional two years through June 3, 2023. The NHS Supply Chain helps NHS deliver clinically assured, quality products at the best value to its patients and the inclusion of gammaCore in the catalogue allows hospitals to purchase gammaCore Sapphire™ for their primary headache patients, taking into account their own budgetary restrictions. The listing of gammaCore Sapphire as an e-Direct product marks an important milestone in the Company's provision of its medical technologies to UK patients, in an easy, cost-effective way.

In recent months, we took meaningful steps to expand gammaCore's global availability. In December, we announced an exclusive distribution agreement with Pro Medical Baltic to distribute gammaCore in Eastern Europe, including Lithuania, Latvia, Belarus, Kazakhstan, Ukraine, and most recently, Romania. In January, we entered into a similar agreement with RSK Medical in Canada, and in February, we announced an agreement with Medistar to serve as the exclusive distributor for gammaCore in Australia. Most recently, in March 2021 we announced an exclusive distribution agreement with Silvert Medical to make gammaCore therapy available in certain Western Europe countries such as Belgium, Luxembourg, the Netherlands, and France. We look forward to further expanding our global network with leading medical technology distribution partners to make gammaCore more broadly available outside the USA throughout 2021.

Commercial: The company continues to make measured investments in its Commercial channel.

In January 2021, we announced that CMS published its most recent Level II Healthcare Common Procedure Coding System, commonly known as HCPCS, establishing a unique code "K1020" for "Non-invasive vagus nerve stimulator." All final coding decisions for the second biannual 2020 Coding Cycle for non-drug and non-biological items and services went into effect on April 1, 2021. We view the establishment of a unique HCPCS code for non-invasive vagus nerve stimulation ("nVNS") as an important differentiator, and a potentially significant step forward in obtaining additional coverage of our proprietary nVNS therapy within the medical benefit pathway.

Research and Development: During the first quarter of 2021, we announced that the FDA cleared our 510(k) submission to expand the gammaCore label to include the acute and preventive treatment of migraine in adolescents between 12 and 17 years of age.

In February 2021, we announced that full enrollment had been achieved in the investigator-initiated TR-VENUS study evaluating the utility of nVNS for the acute treatment of stroke. We look forward to reporting data from the TR-VENUS trial later this year.

Also, in February 2021, we announced publication of a study in the journal *Colorectal Disease* that further demonstrates the broad potential of nVNS. The study evaluated the effectiveness of nVNS in preventing post-operative ileus following major elective colorectal surgery. The results detailed in this paper strongly support continued development in this indication and a larger study funded by the National Institute for Health Research in England is ongoing.

Lastly, we recently announced preliminary results from 110 hospitalized patients enrolled in the investigator-initiated SAVIOR-1 trial in Valencia, Spain, which is evaluating nVNS as a potential treatment for COVID-19. nVNS was well tolerated with no major device related adverse events and the results suggest nVNS that could be a viable treatment for patients and possibly help decrease symptoms early in the course of the disease. Full results are expected to be published in a peer reviewed journal later this year.

We will continue to provide updates on the progress of ongoing gammaCore investigator-initiated trials in a variety of conditions as they become available.

Financial Guidance:

electroCore today announced the following preliminary unaudited financial guidance for the first quarter of 2021:

First Quarter 2021 Revenue: electroCore anticipates that first quarter 2021 revenue will be more than $1.1 million, representing greater than 50% growth over first quarter 2020 revenue of $0.7 million and greater than 20% growth over fourth quarter 2020 revenue of $0.9 million.

March 31, 2021 cash: The company ended the first quarter of 2021 with approximately $25.5 million of cash, cash equivalents and marketable securities, compared to $22.6 million as of December 31, 2020. The company raised $6.9 million during the quarter under a stock purchase agreement. That stock purchase agreement was voluntarily terminated by the company before the end of the first quarter. This capital raise was offset by net cash used of approximately $4.1 million to fund operations during the first quarter of 2021.

The company intends to provide a detailed operational and financial update during its first quarter 2021 earnings call in May.

About electroCore, Inc.

electroCore, Inc. is a commercial stage bioelectronic medicine company dedicated to improving patient outcomes through its non-invasive vagus nerve stimulation therapy platform, initially focused on the treatment of multiple conditions in neurology. The company's current indications are the preventive treatment of cluster headache and migraine and the 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 (nVNS) 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, and the acute and preventive treatment of migraine in adolescent (ages 12 and older) and 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.

gammaCore contraindications include but are not limited to:

- Patients with an active implantable medical device, such as a pacemaker, hearing aid implant, or any implanted electronic device
- Patients with a metallic device, such as a stent, bone plate or bone screw, implanted at or near the neck
- Patients who are using another device at the same time (e.g., TENS Unit, muscle stimulator) or any portable electronic device (e.g., mobile phone)

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 (less than 12 years of age)
- Pregnant women
- Patients with clinically significant hypertension, hypotension, bradycardia, or tachycardia

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

The U.S. FDA has cleared the gammaCore Sapphire CV (nVNS) device under an emergency use authorization for acute use at home or in a healthcare setting to treat adult patients with known or suspected COVID-19 who are experiencing an exacerbation of asthma-related dyspnea and reduced airflow, and for whom approved pharmacologic therapies are not tolerated or provide insufficient symptom relief as assessed by their healthcare provider, using noninvasive vagus nerve stimulation (nVNS) on either side of the patient's neck.

gammaCore Sapphire CV has been authorized only for the duration of the statement that circumstances exist that warrant authorization of the emergency use of medical devices under section 564(b)(1) of the Act, 21 U.S.C. § 360bbbb-3(b)(1), until the authorization is terminated or revoked.

More information can be found at:

Letter of authorization: https://www.fda.gov/media/139967/download

Fact sheet for healthcare workers: https://www.fda.gov/media/139968/download

Patient information sheet: https://www.fda.gov/media/139969/download

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

Forward-Looking Statements

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 expectations for revenue and cash used in operations during the first quarter of 2021, its expectations for future performance, as well as electroCore's business prospects and clinical and product development plans for 2021 and beyond, its pipeline or potential markets for its technologies, additional indications for gammaCore, the timing, outcome and impact of regulatory, clinical and commercial developments (including human trials for the study of nVNS in COVID-19-19 patients in Spain, the U.S., or elsewhere, and the business, operating or financial impact of such studies), further international expansion, and statements about anticipated distribution arrangements, government funding arrangements (including those relating to NHS England, HIS and SHTG) 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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