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): January 11, 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 07920
(Address of principal executive offices and zip code)

150 Allen Road, Suite 201
Basking Ridge, NJ 07920
(Former name or former address, if changed since last report.)

(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 January 11, 2021, electroCore, Inc. (the "Company") issued a press release providing a business update, including preliminary unaudited financial guidance for the fourth quarter of 2020. 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 January 11, 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.

January 11, 2021

/s/ Brian Posner

Brian Posner
Chief Financial Officer

electroCore Provides Business Update and Select Financial Guidance

Full year 2020 revenue expected at the upper end of previously announced guidance range of $3.3M - $3.5M; greater than 40% growth over full year 2019 revenue of $2.4M

Net cash used for the fourth quarter 2020 of $3.7 million, compares favorably to previously announced guidance of $4M

December 31, 2020 cash and cash equivalents of $22.6M

BASKING RIDGE, N.J., January 11, 2021 -- electroCore, Inc. (Nasdaq: ECOR), a commercial-stage bioelectronic medicine company, today provided an operating and business update as well as select unaudited financial guidance for the fourth quarter.

"Notwithstanding the resurgence of COVID-19 case counts which began midway through the fourth quarter and impacted our customers and our ability to access them, we were able to deliver greater than 40% year-over-year revenue growth," stated Dan Goldberger, Chief Executive Officer of electroCore. "In addition, we made progress on many clinical and operational fronts. Our COVID-19 initiatives, including our investigator initiated clinical studies, are ongoing. Additionally, a third investigator-initiated trial commenced, for opioid use disorders. We have signed a distribution agreement outside of the U.S. and UK into Eastern Europe and expect to announce additional international distribution agreements in the coming months. We reported favorable topline data from our PREMIUM II study, further supporting our previously announced label expansion into the important migraine prevention market. Finally, we bolstered our government channels initiatives through the addition of retired Navy Commander Sylvester Steele, a seasoned U.S. Navy and business development executive. We are well financed, and we are eager to turn the page on a new year with numerous opportunities in front of us."

COVID-19: The company previously announced that gammaCore Sapphire^{TM} CV has been made available to known or suspected COVID-19 patients with asthma exacerbations under an FDA Emergency Use Authorization. The therapy is available by prescription through the VA or DoD, from Premier Specialty Pharmacy, and telehealth consults are available at www.getgammacore.com. While the gammaCore Sapphire CV has not generated significant revenue, the company is pleased with the level of interest in from clinicians and patients, which leverages one of the earliest areas of research for the company – reactive airway disease (RAD).

Government Channels: During the fourth quarter of 2020, 71 Department of Veterans Affairs (VA) and Department of Defense (DoD) military treatment facilities purchased gammaCore™ products, as compared to 68 during the third quarter of 2020 and 54 during the fourth quarter of 2019. Also, during the fourth quarter of 2020, the company shipped approximately 1,232 paid months of therapy pursuant to VA and DoD originating prescriptions, compared to 1,571 paid months of therapy during the third quarter of 2020 and 829 during the fourth quarter of 2019. Fourth quarter sales and paid months of therapy to VA and DoD facilities continue to be impacted by the ongoing COVID-19 pandemic, which saw case counts surge in many parts of the country beginning in mid-Q4. The company continues to leverage all telehealth and other virtual capabilities at its disposal and management believes it remains well positioned to resume normalized outreach activities when the pandemic subsides.

To facilitate growth of gammaCore within the VA and DoD, and to develop new revenue opportunities within other government agencies, electroCore announced in October the appointment of business development and retired U.S. Navy veteran Commander Sylvester Steele as VP and General Manager of its Government Channels Business Unit.

Outside of the U.S.: During the fourth quarter of 2020, electroCore shipped approximately 1,123 paid months of therapy outside of the United States, as compared to 1,020 paid months of therapy outside of the United States during the third quarter of 2020 and 961 during the fourth quarter of 2019.

As noted previously, in October 2020, NHS England's Innovation and Technology Payment (ITP) Program, which provided reimbursement for gammaCore in adult cluster headache patients, again extended its coverage for a six-month period through March 2021, with the option to extend for an additional three years. The total contract opportunity, assuming exercise of the three-year option, could be up to approximately £3.6 million. gammaCore has been reimbursed through ITP since April 2019 and the company views its continued reimbursement through this program as an important validation of nVNS technology. electroCore is concurrently working collaboratively with NHS on the launch of a new funding policy titled the 'Medtech Funding Mandate,' details of which the company expects to be published in the coming months.

In December 2020, electroCore announced that it entered into an exclusive agreement with Pro Medical Baltic (PMB) whereby PMB will be the exclusive distributor of gammaCore to patients suffering from primary headache disorders in Eastern Europe, including Lithuania, Latvia, Belarus, Kazakhstan and Ukraine. PMB is a leading distributor of medical technology in the region and has extensive experience in neuromodulation products. The company is pleased with the interest received for international distribution of nVNS technology and expect to announce additional international distribution agreements in the coming months.

Commercial: The company continues to make measured investments in its Commercial channel, most notably through large insurers and pharmacy benefit managers, for the purpose of expanding the population of gammaCore covered lives.

To further support its commercial initiatives, the company continues to work toward establishing a unique HCPCS code that would streamline reimbursement for both government and commercial payers. The Centers for Medicare and Medicaid Services (CMS) held a public hearing on the matter on December 22, 2020 and the company looks forward to the agency's final recommendation in early 2021.

Research and Development: As previously announced, gammaCore Sapphire CV is currently being evaluated in two investigator initiated trials (IITs) in hospitalized COVID-19 patients, one at Hospital Clínico Universitario de Valencia in Valencia, Spain (SAVIOR-1, NCT04368156) and one at Allegheny General Hospital in Pittsburgh, Pennsylvania (SAVIOR-2, NCT04382391). Enrollment in these studies has fluctuated based on the local level of COVID-19 cases, and the recent surge in COVID-19 cases in many parts of the world has resulted in investigators enrolling patients at an accelerated pace. In SAVIOR-1, 37 of 90 patients have now been enrolled and completed the study and in SAVIOR-2, 20 of 60 patients have been enrolled.

In December 2020, the company reported positive topline results from the PREMIUM II study assessing gammaCore for the prevention of migraine. The PREMIUM II study was terminated in early April 2020 due to COVID-19, and topline results were based on the 113 patients in the modified intent to treat population (mITT).

In this population, 44.9% of the subjects using gammaCore nVNS had at least a 50% decrease in the number of migraine days compared to 26.8% for those receiving sham stimulation (secondary endpoint; p=0.048). Of particular clinical relevance were the results in the predefined sub-population of patients diagnosed as having migraine with aura. In this group, patients using nVNS had 5.5 fewer headache days compared to 2.7 fewer headache days in the sham group (p=0.041). Patients using gammaCore also reported a statistically significant decrease in migraine associated disability and improvement in their quality of life across all quality of life (QOL) endpoints in the study. There were no serious adverse effects reported in the study, which is consistent with nVNS' strong safety and tolerability profile.

The company expects to publish full study results in a peer reviewed medical journal in 2021. gammaCore received 510(k) clearance for the preventative treatment of migraine on March 26, 2020.

Also, in December 2020, electroCore announced that gammaCore has been selected for a National Institute on Drug Abuse (NIDA)-sponsored study in opioid use disorders. The study is being run by Dr. Douglas Bremner at Emory University in collaboration with the Georgia Institute of Technology and the City University of New York (NCT04556552). The 40-subject study will assess the ability of nVNS to decrease opioid cravings in subjects with a history of opioid use disorder who are stable on medication, as well as examine the possible mechanisms that might facilitate this clinical effect.

This is in addition to the IIT assessing the utility of gammaCore in mild traumatic brain injury (mTBI) and Post-Traumatic Stress Disorder (PTSD) that electroCore announced during the third quarter. That study is also being conducted by Dr. Bremner and is being supported by the VA's Office of Research and Development and the Atlanta VA Medical Center (NCT04437498).

In addition to the programs discussed above, gammaCore investigator-initiated trials continue to progress in stroke, subarachnoid hemorrhage headache, and certain rheumatologic conditions.

Financial Guidance:

electroCore today announced the following preliminary unaudited financial guidance for the fourth quarter of 2020:

Full-year 2020 Revenue: electroCore anticipates that full-year 2020 revenue will be at the upper end of the previously announced guidance range of $3.3 million to $3.5 million, representing greater than 40% growth over full-year 2019 revenue of $2.4 million.

Q4 2020 net cash used: Net cash used during the fourth quarter of 2020 is expected to be approximately $3.7 million. For the full year 2020, net cash used was approximately $20.2 million, representing a 55% decline as compared to net cash used of $44.5 million for the full year 2019.

December 31, 2020 cash: The company ended the fourth quarter of 2020 with approximately $22.6 million of cash, cash equivalents and marketable securities.

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 current indications are for the preventative treatment of cluster headache 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 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), Bronchoconstriction and Medication Overuse Headache in adults.

- 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
  - Pregnant women
  - Patients with clinically significant hypertension, hypotension, bradycardia, or tachycardia

- Patients should not use gammaCore™ if they:
  - Have an active implantable medical device, such as a pacemaker, hearing aid implant, or any implanted electronic device
  - Have a metallic device such as a stent, bone plate, or bone screw implanted at or near their neck; or
  - 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 U.S., 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 available at www.gammacore.com.

The United States FDA has authorized use of the gammaCore Sapphire CV device for acute use at home or in a healthcare setting to treat adult patients with known or suspected COVID-19 who are experiencing exacerbation of asthma-related dyspnea and reduced airflow, and for whom approved drug therapies are not tolerated or provide insufficient symptom relief as assessed by their healthcare provider, by using non-invasive vagus nerve stimulation (VNS) on either side of the patient's neck, available under an emergency access mechanism called an EUA.

gammaCore Sapphire CV has neither been cleared nor approved for acute use at home or in a healthcare setting to treat adult patients with known or suspected COVID-19 who are experiencing exacerbation of asthma-related dyspnea and reduced airflow, and for whom approved drug therapies are not tolerated or provide insufficient symptom relief as assessed by their healthcare provider, by using non-invasive Vagus nerve Stimulation (nVNS) on either side of the patient's neck during the Coronavirus Disease 2019 (COVID-19) pandemic.

gammaCore Sapphire CV has been authorized for the above emergency use by FDA under an Emergency Use Authorization.

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

Further information is available at:

Authorization Letter: https://www.fda.gov/media/139967/download

Fact Sheet for Healthcare Providers: https://www.fda.gov/media/139968/download

Fact Sheet for Patients: https://www.fda.gov/media/139969/download

Instructions for gammaCore use 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 fourth quarter of 2020, its expectations for full year 2020 and 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, the business, operating or financial impact of such studies, further international expansion 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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