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)
March 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 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 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 2.02 Results of Operations and Financial Condition.

On March 11, 2021, electroCore, Inc. issued a press release announcing its financial results for the quarter and year ended December 31, 2020. A copy of the press release is furnished herewith as Exhibit 99.1 and incorporated by reference.

Except for information relating to Adjusted EBITDA net loss from operations and its reconciliation to generally accepted accounting principles (GAAP), the information contained in this Item 2.02 and Item 9.01 in this Current Report on Form 8-K, including the accompanying Exhibit 99.1 hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filings, unless expressly incorporated by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description of Exhibit
99.1	Press release dated March 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.

March 11, 2021

/s/ Brian Posner

Brian Posner
Chief Financial Officer

Exhibit 99.1

electroCore Announces Fourth Quarter and Full Year 2020 Financial Results

Full year 2020 net sales of approximately $3.5 million increased 46% over $2.4 million for full year 2019

Further reduced net cash usage to $3.7 million in the fourth quarter 2020 versus $4.1 million in the third quarter 2020

Ended 2020 with cash and cash equivalents of $22.6 million, excluding $6.9 million raised subsequent to the end of the year

Company to host conference call and webcast today, March 11, 2021 at 4:30pm ET

March 11, 2021 at 4:05 PM ET

Rockaway, N.J., March 11, 2021 — electroCore, Inc. (Nasdaq: ECOR), a commercial-stage bioelectronic medicine company, today announced fourth quarter and full year 2020 financial results and provided an operational update.

Fourth Quarter 2020 and Recent Highlights

- Reported full year 2020 net sales of approximately $3.5 million, representing an increase of 46% over $2.4 million for full year 2019; fourth quarter net sales of approximately $928,000, an increase of 38% over the fourth quarter of 2019;
- Used net cash of approximately $3.7 million, down from $4.1 million in the third quarter of 2020 and $9.4 million in the fourth quarter of 2019;
- Secured unique CMS Level II HCPCS reimbursement code for "Non-invasive vagus nerve stimulator";
- Announced inclusion of gammaCore in new NHS England and NHS Improvement MedTech Funding Mandate Policy 2021/22, and two-year extension of gammaCore listing in the NHS Supply Chain Catalogue;
- Announced Scottish Health Technology Group recommendation for use of gammaCore™ in NHS Scotland cluster headache patients;
- Executed distribution agreements with Pro Medica Baltic, RSK Medical and Medistar for distribution of gammaCore Sapphire in Eastern Europe, Canada and Australia, respectively;
- Obtained 510(k) clearance of gammaCore to expand its indication into preventative and acute treatment of adolescent migraine (ages 12-17);
- Announced completion of enrollment in the investigator-initiated SAVIOR-1 clinical trial evaluating gammaCore Sapphire CV in hospitalized COVID-19 patients exhibiting respiratory symptoms;
- Announced publication of a peer reviewed paper entitled: “Non-Invasive vagus nerve stimulation to reduce ileus after major colorectal surgery: Early development study” in the journal Colorectal Disease on use of nVNS to reduce post-operative ileus after major colorectal surgery;
- Announced selection of gammaCore for NIDA-sponsored study in opioid use disorders;
- Announced full enrollment in study of gammaCore for the acute treatment of stroke supported by the Turkish Neurological Society; and
- Presented positive topline results from the PREMIUM II study evaluating gammaCore for the prevention of migraine subsequent to early trial termination in March 2020 due to COVID-19.

Dan Goldberger, Chief Executive Officer of electroCore, commented: “We had a highly productive fourth quarter across all facets of our business in spite of the challenges and headwinds of the pandemic. We delivered 38% year-over-year revenue growth in the quarter, we achieved a major U.S. reimbursement milestone in the establishment of a unique Level II HCPCS code for ‘Non-invasive vagus nerve stimulator’, we signed three ex–U.S. distribution agreements, we continued expanding the gammaCore indication for use to include adolescents suffering from migraine, we saw the progression of clinical trials in four additional indications: COVID-19, stroke, post-operative ileus and opioid use disorder, and we realized continued support by NHS England to cover gammaCore therapy through inclusion in the new NHS Improvement MedTech Funding Mandate.

“Notably, we were able to achieve all of this while continuing to manage our cash prudently. Our net cash usage for the fourth quarter of $3.7 million was down from $4.1 million in the third quarter of 2020 and down significantly from $9.4 million in the same period last year. Our cash balance at December 31, 2020 provides substantial runway to execute our plan into 2022.

“Looking ahead, while the course of the pandemic remains difficult to predict, I believe we have taken steps to ensure continued growth of gammaCore in our core revenue generating channels while working to establish and capitalize on new opportunities. I believe gammaCore has broad potential utility across a very diverse range of indications, and along with the entire electroCore team, I remain committed to making this therapy available to every individual who can potentially benefit from it.”

Fourth Quarter and Full Year 2020 Financial Results

For the quarter ended December 31, 2020, electroCore reported net sales of approximately $928,000 compared to $675,000 in the same period of 2019, and at the upper end of guidance provided in the company’s January 11, 2021 business update. For the full year 2020, the company reported net sales of approximately $3.5 million, as compared to net sales of approximately $2.4 million for the full year 2019.

Revenue from the Department of Veterans Affairs (“VA”) and Department of Defense (“DOD”) decreased 21% sequentially to $509,000 in the fourth quarter of 2020 from $646,000 in the third quarter of 2020 and increased 35% as compared to $378,000 in the fourth quarter of 2019. Paid months of therapy shipped to the VA and DOD decreased 22% sequentially to 1,232 in the fourth quarter of 2020 from 1,571 in the third quarter of 2020 and increased 49% as compared to 829 in the fourth quarter of 2019.

Revenue from outside the United States increased sequentially to $311,000 in the fourth quarter of 2020 from $278,000 in the third quarter and increased 6% as compared to $294,000 in the fourth quarter of 2019. Paid months of therapy shipped outside the United States increased 12% sequentially to 1,143 in the fourth quarter of 2020 from 1,020 in the third quarter of 2020 and increased 19% as compared to 961 in the fourth quarter of 2019.

Gross profit for the fourth quarter of 2020 was $109,000 inclusive of an increase of $434,000 in inventory reserves, as compared to $284,000 for the fourth quarter of 2019. Gross margin for the fourth quarter excluding the increase to inventory reserves was 59%, compared to 42% in the fourth quarter of 2019. Gross margin for the full year 2020 was 50% as compared to 52% for the full year of 2019. Excluding the increase to inventory reserves, gross margin for full year 2020 was 63%.

Total operating expenses in the fourth quarter of 2020 were approximately $6.4 million, a reduction of approximately $2.5 million from $8.9 million in the fourth quarter of 2019. Total operating expenses for the full year 2020 were $26.5 million as compared to $47.3 million for the full year 2019.

Research and development expense in the fourth quarter of 2020 was $1.0 million, as compared to $1.6 million for the same period in 2019. Research and development expenses for the full year 2020 were $4.2 million as compared to $9.9 million for the full year 2019.

Selling, general and administrative expense in the fourth quarter of 2020 was $5.4 million, as compared to $7.3 million for the same period in 2019. Selling, general and administrative expense for the full year 2020 was $21.8 million as compared to $35.4 million for the full year 2019.

GAAP net loss in the fourth quarter of 2020 was $6.3 million as compared to a GAAP net loss of $8.5 million in the fourth quarter of 2019. GAAP net loss for the full year 2020 was a loss of $23.5 million as compared to a GAAP net loss of $45.1 million for the full year 2019.

Adjusted EBITDA net loss in the fourth quarter of 2020 was a loss of $4.3 million as compared to a loss of $6.7 million in the fourth quarter of 2019. Adjusted EBITDA net loss for the full year 2020 was a loss of $18.4 million as compared to an adjusted EBITDA net loss of $39.0 million for the full year 2019.

The company defines adjusted EBITDA net loss as GAAP net loss, excluding income tax expense/benefit, depreciation and amortization, stock-compensation expense, write-off of right of use operating lease, increase in inventory reserves, restructuring and other severance related charges, legal fees associated with stockholders' litigation and total other income/expense. A reconciliation of GAAP net loss to Non-GAAP adjusted EBITDA net loss has been provided in the financial statement tables included in this press release.

Net cash used in the quarter ended December 31, 2020 was approximately $3.7 million, as compared to $4.1 million in the third quarter of 2020, and $9.4 million in the fourth quarter of 2019. Net cash used for the full year 2020 was $20.2 million as compared to net cash used of $44.5 million for the full year 2019.

Cash and cash equivalents and marketable securities at December 31, 2020 totaled approximately $22.6 million, as compared to approximately $24.1 million at December 31, 2019. Subsequent to the end of the fourth quarter, the company raised approximately $6.9 million through the company's previously announced stock purchase agreement, resulting in a pro forma cash and cash equivalents and marketable securities balance of $29.5 million as of December 31, 2020.

Webcast and Conference Call Information

electroCore's management team will host a conference call today, March 11, 2021, beginning at 4:30 p.m. ET.

Investors interested in listening to the conference call or webcast may do so by dialing 877-407-4018 for domestic callers or 201-689-8471 for international callers, using conference ID: 13715729, or through the following link: http://public.viavid.com/index.php?id=143276

An archived webcast of the event will be available on the "Investors" section of the company's website at: www.electrocore.com.

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 migraine and acute treatment of migraine and episodic cluster headache.

For more information, visit www.electrocore.com.**About gammaCore^{e}^{TM}**

gammaCore^{TM} (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, 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 is contraindicated for patients with:
  - An active implantable medical device, such as a pacemaker, hearing aid implant, or any implanted electronic device
  - A metallic device, such as a stent, bone plate, or bone screw, implanted at or near the neck
  - An open wound, rash, infection, swelling, cut, sore, drug patch, or surgical scar(s) on the neck at the treatment location

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

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.

gammaCore SapphireTM CV has received Emergency Use Authorization (EUA) from the FDA 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 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 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.

Please refer to gammaCore Sapphire CV (nVNS) Instructions for Use for Use for all of the important warnings and precautions before using or prescribing gammaCore Sapphire CV (nVNS).

Forward-Looking Statement

This press release and other written and oral statements made by representatives of electroCore 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 expected cash runway, its pipeline or potential markets for its technologies, the timing, outcome and impact of regulatory, clinical and commercial developments including commercialization of, and potential reimbursement for, gammaCore Sapphire CV, 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™, the potential impact and effects of COVID-19 on the business of electroCore, electroCore's results of operations and financial performance, and any measures electroCore has and may take in response to COVID-19 and any expectations electroCore may have with respect thereto, 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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electroCore, Inc.
Consolidated Statements of Operations
(Unaudited)
(In thousands, except per share data)

	Three months ended December 31,		Year ended December 31,	
	2020	**2019**	**2020**	**2019**
Net sales	$ 928.2	$ 675.0	$ 3,495.8	$ 2,390.3
Cost of goods sold	818.9	391.0	1,737.5	1,157.0
Gross profit	109.3	284.0	1,758.3	1,233.3
Operating expenses:				
Research and development	1,018.7	1,623.0	4,201.3	9,902.2
Selling, general and administrative	5,413.8	7,267.0	21,840.9	35,422.3
Restructuring and other severance related charges	—	—	464.6	1,997.3
Total operating expenses	6,432.5	8,890.0	26,506.8	47,321.8
Loss from operations	(6,323.2)	(8,606.0)	(24,748.5)	(46,088.5)
Other (income)/expense				
Interest and other income	(3.8)	(121.0)	(84.3)	(970.6)
Other expense/(income)	4.4	(4.3)	17.8	12.3
Total other expense/(income)	0.6	(125.3)	(66.5)	(958.3)
Loss before income taxes	(6,323.8)	(8,480.7)	(24,682.0)	(45,130.2)
(Provision)/benefit for income taxes	—	(17.7)	1,170.9	(17.7)
Net loss	(6,323.8)	(8,498.4)	(23,511.1)	(45,147.9)
Net loss per share of common stock - Basic and Diluted	(0.14)	(0.29)	(0.60)	(1.54)
Weighted average number of shares common shares outstanding - Basic and Diluted	45,398,309	29,561,345	38,998,698	29,379,975

electroCore, Inc.
Consolidated Balance Sheet Information
(Unaudited)
(in thousands)

	As of December 31,	
	2020	**2019**
Cash and cash equivalents	$ 4,241.9	$ 13,563.8
Marketable securities	$ 18,386.2	$ 10,495.4
Total assets	$ 31,518.2	$ 35,461.7
Current liabilities	$ 5,890.3	$ 9,144.7
Total liabilities	$ 7,873.6	$ 10,564.6
Total equity	$ 23,644.6	$ 24,897.1

(Unaudited) Use of Non-GAAP Financial Measure

The company is presenting adjusted EBITDA net loss because it believes this measure is a useful indicator of its operating performance. electroCore management uses this non-GAAP measure principally as a measure of the company's core operating performance and believes that this measure is useful to investors because it is frequently used by the financial community, investors, and other interested parties to evaluate companies in the company's industry. The company also believes that this measure is useful to its management and investors as a measure of comparative operating performance from period to period. Additionally, the company believes its use of non-GAAP adjusted EBITDA net loss from operations facilitates management's internal comparisons to historical operating results by factoring out potential differences caused by charges not related to its regular, ongoing business, including, without limitation, non-cash charges and certain large and unpredictable charges such as restructuring expenses.

The company has presented adjusted EBITDA net loss as a non-GAAP financial measure in this press release. The company defines adjusted EBITDA net loss as its reported GAAP net loss excluding income tax expense/benefit, depreciation and amortization, stock-based compensation, write-off of right of use operating lease, increase in inventory reserves, restructuring and other severance related charges, legal fees associated with stockholders litigation and total other income/expense.

	Three months ended December 31,		Year ended December 31,	
	2020	2019	2020	2019
	(in thousands)			
GAAP net loss	**$ (6,323.8)**	**$ (8,498.4)**	**$ (23,511.1)**	**$ (45,147.9)**
Provision/(benefit) for income taxes	—	17.7	$ (1,170.9)	$ 17.7
Depreciation and amortization	110.6	97.3	$ 399.2	$ 249.6
Stock-based compensation	775.7	1,205.4	$ 3,266.3	$ 3,895.8
Write-off of right of use operating lease	557.5	—	557.5	—
Increase in inventory reserves	434.0	—	434.0	—
Restructuring and other severance related charges	—	—	$ 464.6	$ 1,997.3
Legal fees associated with stockholders' litigation	135.5	$ 641.0	$ 1,205.3	$ 963.0
Total other (income)/expense	0.6	$ (125.3)	$ (66.5)	$ (958.3)
Adjusted EBITDA net loss	**$ (4,309.9)**	**$ (6,662.3)**	**$ (18,421.6)**	**$ (38,982.8)**

The company's use of a non-GAAP measure has limitations as an analytical tool, and you should not consider it in isolation or as a substitute for analysis of its results as reported under GAAP. Some of these limitations are: the non-GAAP measure does not reflect interest or tax payments that may represent a reduction in cash available; although depreciation and amortization are non-cash charges, the assets being depreciated and amortized may have to be replaced in the future, and the non-GAAP measure does not reflect cash capital expenditure requirements for such replacements or for new capital expenditure requirements; the non-GAAP measure does not reflect the potentially dilutive impact of equity-based compensation; and the non-GAAP measure does not reflect changes in, or cash requirements for, working capital needs; other companies, including companies in electroCore's industry, may calculate adjusted EBITDA net loss differently, which reduces its usefulness as a comparative measure.

Because of these and other limitations, you should consider the non-GAAP measure together with other GAAP-based financial performance measures, including various cash flow metrics, net loss, and other GAAP results. A reconciliation of GAAP net loss to non-GAAP adjusted EBITDA net loss has been provided in the preceding financial statements table of this press release.