

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): May 6, 2021

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)

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 May 6, 2021, electroCore, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2021. 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 May 6, 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.

May 6, 2021

electroCore, Inc.

/s/ Brian Posner

Brian Posner

Chief Financial Officer



electroCore Announces First Quarter 2021 Financial Results

Record First quarter 2021 net sales of \$1.2 million, increased 64% over first quarter 2020 and 30% sequentially

Company to host a conference call and webcast today, May 6, 2021 at 4:30 pm ET

May 6, 2021 at 4:05 pm ET

ROCKAWAY, NJ, — electroCore, Inc. (Nasdaq: ECOR), a commercial-stage bioelectronic medicine company, announced first quarter 2021 financial results and provided an operational update.

First Quarter 2021 and Recent Highlights

- Posted revenue of \$1.2 million, representing an increase of 64% over first quarter 2020 and 30% sequentially;
- Net cash used was \$4.1 million during the first quarter 2021 leaving approximately \$25.5 million of cash, cash equivalents, and marketable securities at March 31, 2021;
- Secured unique CMS Level II HCPCS reimbursement code for "Non-invasive vagus nerve stimulator";
- Announced inclusion of gammaCore in the 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 RSK Medical, Medistar, Silvert Medical and East Agency for distribution of gammaCore Sapphire in Canada, Australia, Western Europe, and Qatar, respectively; and
- Obtained 510(k) clearance of gammaCore from the FDA to expand its indication into preventative and acute treatment of adolescent migraine (ages 12-17).

Dan Goldberger, Chief Executive Officer of electroCore, commented: “During the quarter, we demonstrated continued progress in operating metrics across all of our revenue channels, despite the challenges and headwinds of the pandemic. We delivered 64% 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 increased the number of signed ex-U.S. distribution agreements, we continued expanding the FDA cleared gammaCore indications for use to include adolescents suffering from migraine, we announced publications highlighting the power of nVNS as a platform in the Journal of Colorectal Disease for post-operative ileus and Nature Reviews as an emerging treatment for cluster headache, we saw topline results in the SAVIOR-1 investigator initiated trial, and the progression of clinical trials in four additional indications: stroke, post-operative ileus, opioid use disorder, and post traumatic headache, and we realized continued support by NHS England to cover gammaCore therapy through inclusion in the new NHS Improvement MedTech Funding Mandate.”

“I believe we have taken steps to pursue continued growth of gammaCore in our core revenue generating channels while working to establish and capitalize on new opportunities. 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.”

“Notably, we were able to demonstrate continued momentum across our business while also maintaining discipline around expense and cash management. We believe our cash balance of \$25.5 million at March 31, 2021 provides a solid pathway to execute our plan into 2022.”

First Quarter 2021 Financial Results

For the quarter ended March 31, 2021, electroCore reported net sales of \$1.2 million compared to \$928,000 in the fourth quarter of 2020 and \$734,000 during same period of 2020.

Revenue from the Department of Veterans Affairs (“VA”) and Department of Defense (“DOD”) increased 33% sequentially to \$679,000 in the first quarter of 2021 from \$509,000 in the fourth quarter of 2020 and increased 49% as compared to \$454,000 in the first quarter of 2020. Paid months of therapy shipped to the VA and DOD increased 44% sequentially to 1,768 in the first quarter of 2021 from 1,232 in the fourth quarter of 2020 and increased 63% as compared to 1,084 in the first quarter of 2020.

Revenue from outside the United States increased sequentially by 22% to \$380,000 in the first quarter of 2021 from \$311,000 in the fourth quarter of 2020 and increased 38% as compared to \$276,000 in the first quarter of 2020. First quarter 2021 OUS revenue included initial orders from our new distributors in Eastern Europe and Australia. Paid months of therapy shipped directly to patients outside the United States increased 1% sequentially to 1,156 from 1,143 in the fourth quarter of 2020 and 15% from 1,008 in the first quarter of 2020.

Gross profit for the first quarter of 2021 was \$840,000 as compared to \$109,000, for the fourth quarter of 2020 and \$436,000 for the first quarter of 2020. Gross profit for the fourth quarter of 2020 was reduced by an increase in inventory reserves of \$434,000. Gross margin for the first quarter of 2021 was 70%, compared to 59% (excluding the increase in inventory reserves) in the fourth quarter of 2020 and 59% in the first quarter of 2020.

Total operating expenses in the first quarter of 2021 were approximately \$6.2 million, a reduction of approximately \$200,000 from \$6.4 million in the fourth quarter of 2020 and a reduction of \$2.2 million from \$8.4 million in the first quarter of 2020.

Research and development expense in the first quarter of 2021 was \$500,000, as compared to \$1.0 million in the fourth quarter of 2020, a reduction of approximately \$1.0 million from \$1.5 million in the first quarter of 2020.

Selling, general and administrative expense in the first quarter of 2021 was \$5.7 million as compared to \$5.4 million in the fourth quarter of 2020. Selling, general and administrative expense decreased by 13% from \$6.6 million in the first quarter of 2020.

GAAP net loss in the first quarter of 2021 was \$5.4 million compared to fourth quarter 2020 GAAP net loss of \$6.3 million. GAAP net loss decreased by 33% or \$2.6 million as compared to a GAAP net loss of \$8.0 million in the first quarter of 2020.

Adjusted EBITDA net loss in the first quarter of 2021 was \$4.2 million as compared to \$4.3 million during the fourth quarter of 2020 and as compared to a loss of \$6.4 million in the first quarter of 2020.

The company defines adjusted EBITDA net loss as GAAP net loss, excluding depreciation and amortization, stock-compensation expense, 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 March 31, 2021, exclusive of financing activities, was approximately \$4.1 million, as compared to \$3.7 million in the fourth quarter of 2020, and \$8.4 million in the first quarter of 2020.

Cash, cash equivalents and marketable securities at March 31, 2021 totaled approximately \$25.5 million, as compared to approximately \$22.6 million at December 31, 2020. The company raised \$6.9 million during the first quarter of 2021 under a stock purchase agreement that was voluntarily terminated by the company before the end of the first quarter.

Second Quarter 2021 Outlook

For the second quarter of 2021, the Company expects net revenue to exceed \$1.2 million and net cash usage, exclusive of financing activities, to approximate Q1 2021 levels.

Webcast and Conference Call Information

electroCore's management team will host a conference call today, May 6, 2021, beginning at 4:30pm ET.

Investors interested in listening to the conference call, or webcast may do so by dialing 877-269-7756 for domestic callers or 201-689-7817 for international callers, using Conference ID: 13718262, or by connecting to the Web: electroCore 1Q21 Business Update Webcast

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

About gammaCore™

gammaCore™ (nVNS) is the first non-invasive manual medical therapy delivered to the neck as adjunctive therapy to treat migraine and cluster headache using mild electrical stimulation of 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 medications. When placed on the patient's neck over the vagus nerve, gammaCore stimulates afferent nerve fibers, which can lead to a reduction in pain for patients.

gammaCore is cleared by the FDA in the United States for adjunctive use in 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 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 Continuous Hemicrania) and Drug Use Headache in adults. In 2019, NICE published an evidence-based Medical Technology Guidance document recommending the use of gammaCore for cluster headache within the NHS in England.

- The safety and efficacy of gammaCore have not been evaluated in the following patients:
 - o Patients diagnosed with narrowing of the arteries (carotid atherosclerosis).
 - o Patients who have undergone surgery for resection of the vagus nerve in the neck (cervical vagotomy).
 - o Pediatric patients
 - o Pregnant women
 - o Patients with clinically significant hypertension, hypotension, bradycardia or tachycardia
- Patients should not use gammaCore if:
 - o Have an active implantable medical device, such as a pacemaker, hearing aid implant, or any implanted electronic device
 - o Has a metallic device such as a stent, bone plate, or bone screw implanted in or near the neck
 - o You are using another device at the same time (e.g. TENS unit, muscle stimulator) or any portable electronic device (e.g. cell phone).

In the United States, the FDA has not cleared gammaCore for the treatment of pneumonia and/or respiratory disorders, such as COVID-19-associated acute respiratory stress disorder. Refer to the gammaCore Instructions for Use for all important warnings and precautions before using or prescribing this product.

The U.S. FDA has cleared 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 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, available under an emergency access mechanism called EUA.

gammaCore Sapphire CV has not been cleared or approved for acute use in the home or 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 during pandemic Coronavirus Disease 2019 (COVID-19).

gammaCore Sapphire CV has been cleared by the FDA for the above emergency use under an emergency use authorization.

The 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. § 360bbb-3(b)(1), unless 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>

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.

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 business prospects and clinical and product development plans, its expected cash runway, expected revenue and net cash used for the second quarter of 2021, 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.
Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except per share data)

	Three months ended March 31,	
	2021	2020
Net sales	\$ 1,203.8	\$ 733.7
Cost of goods sold	364.0	298.1
Gross profit	839.8	435.6
Operating expenses:		
Research and development	499.0	1,523.1
Selling, general and administrative	5,724.5	6,560.7
Restructuring and other severance related charges	—	365.0
Total operating expenses	6,223.5	8,448.8
Loss from operations	(5,383.7)	(8,013.2)
Other (income)/expense		
Interest and other income	(3.4)	(63.0)
Other expense	3.5	9.1
Total other (income)/expense	0.1	(53.9)
Net loss	\$ (5,383.8)	\$ (7,959.3)
Net loss per share of common stock - Basic and Diluted	\$ (0.11)	\$ (0.27)
Weighted average number of common shares outstanding - Basic and Diluted	47,653,202	29,774,226

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

	March 31, 2021	December 31, 2020
Cash and cash equivalents	\$ 9,064.4	\$ 4,241.9
Marketable securities	\$ 16,388.3	\$ 18,386.2
Total assets	\$ 33,750.2	\$ 31,518.2
Current liabilities	\$ 5,345.0	\$ 5,890.3
Total liabilities	\$ 7,082.8	\$ 7,873.6
Total equity	\$ 26,667.4	\$ 23,644.6

(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 defines adjusted EBITDA net loss as GAAP net loss, excluding depreciation and amortization, stock-compensation expense, 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.

	Three months ended	
	March 31,	
	2021	2020
	(in thousands)	
GAAP net loss	\$ (5,383.8)	\$ (7,959.3)
Depreciation and amortization	95.7	97.4
Stock-based compensation	942.2	744.9
Restructuring and other severance related charges	—	365.0
Legal fees associated with stockholders litigation	151.4	395.6
Total other (income)/expense	0.1	(53.8)
Adjusted EBITDA net loss	\$ (4,194.4)	\$ (6,410.2)

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.