UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2019

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE TRANSITION PERIOD FROM TO

Commission File Number 001-38538

electroCore, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**20-3454976**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
150 Allen Road, Suite 201	
Basking Ridge, NJ	**07920**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (973) 290-0097

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**

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
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. ☒

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on the Nasdaq Global Select Stock Market on June 30, 2019 was $45,501,518.

The number of shares of Registrant's Common Stock outstanding as of March 26, 2020 was 29,959,565.

Portions of the Registrant's Definitive Proxy Statement relating to the 2020 Annual Meeting of Stockholders, which will be filed with the Securities Exchange Commission within 120 days after the end of the Registrant's fiscal year ended December 31, 2019, are incorporated by reference into Part III of this Report.

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Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K, or Annual Report, contains forward-looking statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations and financial position, strategy and plans, and our expectations for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “could,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue” or the negative of these terms or other comparable terminology. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described under the heading “Risk Factors” contained in Item 1A of this Annual Report. In light of these risks, uncertainties and assumptions, actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements in this Annual Report and you should not place undue reliance on these forward-looking statements.

Any forward-looking statements in this Annual Report reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

References to electroCore

In this Annual Report, unless otherwise stated or the context otherwise indicates, references to “ECOR,” “electroCore,” “the Company,” “we,” “us,” “our” and similar references refer to electroCore, Inc., a Delaware corporation. References herein to the “Corporate Conversion” or “corporate conversion” refer to all the transactions related to the conversion of Electrocore, LLC into electroCore, Inc., including the conversion of all outstanding membership units of Electrocore, LLC into shares of common stock of electroCore, Inc., effected on June 21, 2018. See Note 14 - “Corporate Conversion and Equity,” of the notes to our consolidated financial statements in this Annual Report.

Trademarks and Tradenames

The electroCore logo, gammaCore and other trademarks of electroCore, Inc. appearing in this Annual Report on Form 10-K are the property of electroCore, Inc. All other trademarks, service marks and trade names in this Annual Report on Form 10-K are the property of their respective owners. We have omitted the ® and ™ designations, as applicable, for the trademarks used in this Annual Report on Form 10-K.

Market Data and Forecasts

Unless otherwise indicated, information in this Annual Report on Form 10-K concerning economic conditions, our industry, and our markets, including our general expectations and competitive position, market opportunity and market size, is based on a variety of sources, including information from independent industry analysts and publications, as well as our own estimates and research.

Our estimates are derived from industry and general publications, studies and surveys conducted by third parties, as well as data from our own internal research. These publications, studies and surveys generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information, and we have not independently verified industry data from such third-party sources. While we believe our internal research is reliable and that our internal estimates are reasonable, such research has not been verified by any independent source and our internal estimates are based on our good faith beliefs as of the respective dates of such estimates. We are responsible for all of the disclosure in this Annual Report on Form 10-K.

Item 1. Business.

Business Overview

We are a commercial stage medical device company with a proprietary non-invasive vagus nerve stimulation, or nVNS, therapy. nVNS is a platform bioelectronic medical therapy that modulates neurotransmitters and immune function through its effects on both the peripheral and central nervous systems. We are initially focused on neurology and our therapy, gammaCore, is cleared by the U.S. Food and Drug Administration, or FDA, for use by adults for the following four neurology indications: the acute treatment of pain associated with each of migraine and episodic cluster headache, or eCH, the preventive treatment of migraine headache and adjunctive use for the preventive treatment of cluster headaches, or CH. We are also considering the potential for several additional indications for our nVNS technology which is being studied in a number of investigator-initiated studies.

Our gammaCore treatment is the first FDA-cleared, prescription-only nVNS therapy. Historically, vagus nerve stimulation, or VNS, required an invasive surgical procedure to permanently implant a costly medical device. These limitations prevented VNS from being used, other than for the most severe patients. Our lead product, gammaCore Sapphire, is a proprietary, simple-to-use handheld delivery system intended for multi-year use. Currently, it is prescribed on a monthly or on a 93-day basis and is both rechargeable and reloadable. gammaCore Sapphire permits patients to self-administer doses of nVNS on an as-needed basis for acute treatment, or at regular intervals for prevention therapy.

Non-invasive delivery of VNS by our gammaCore Sapphire is enabled by a proprietary high-frequency burst waveform that safely and comfortably passes through the skin and stimulates therapeutically relevant fibers in the vagus nerve. Multiple published studies suggest that VNS works through the modulation of neurotransmitters and has a measurable effect similar to several classes of commonly prescribed medications.

The FDA cleared our gammaCore therapy for the acute treatment of pain associated with migraine in adults in January 2018, and for preventive treatment of migraine headache in adult patients on March 26, 2020. Migraine is a debilitating primary headache condition that is estimated to affect approximately 12% of the global adult population and disproportionately affects women of child-bearing years. Migraine is estimated to affect 36 million adults in the United States. Some reports suggest that up to 60% of migraine suffers are dissatisfied with or have contraindications to the current standard of care treatments for migraine, such as “triptan” medications. In April 2017, the FDA cleared gammaCore for the acute treatment of pain associated with eCH, and in December 2018, the FDA cleared gammaCore for adjunctive use for the prevention of CH. CH is an extremely painful form of headache affecting approximately 400,000 people in the United States. Prior to gammaCore, injectable sumatriptan was the only FDA-approved, commercially available acute CH treatment, and there was no FDA-approved therapy for the prevention of CH.

The four FDA clearances of our gammaCore therapy were facilitated by the FDA’s creation of a new regulatory category: External Vagus Nerve Stimulator for Headache (21 CFR 882-5892). Based on this category’s description, we anticipate that some additional label expansions may be possible through the pathway under Section 510(k) of the Federal Drug and Cosmetic Act.

In September 2011, we received a CE Certificate of Conformity for gammaCore for the treatment of primary headache from the British Standards Institution, a European Union notified body. This CE Certificate of Conformity allowed us to affix the CE Mark on gammaCore and to commercialize it in the European Economic Area and other countries that recognize the European CE Mark, including the United Kingdom, which is currently our predominant geographic market outside the United States. In addition to the CE Certificate of Conformity for primary headache, between September 2011 and October 2013 we received CE Certificates of Conformity on gammaCore covering four other specific indications for use, including reactive airway disease and gastric motility disorders. In 2019, the National Institute for Health and Care Excellence, or NICE published a Medical Technology Guidance document recommending the use of gammaCore for CH within England’s National Health Service.

Background of VNS

The vagus nerve is the largest and most extensive cranial nerve, connecting the brainstem to nearly every organ in the chest and abdomen. Modulating the firing rate of the fibers within the vagus nerve can trigger the release of neurotransmitters, both in the central and peripheral nervous systems, affecting how the brain and peripheral organs function. In the central

nervous system, VNS activates areas of the brainstem that release norepinephrine, acetylcholine, serotonin, gamma aminobutvric acid and other important biochemicals. The release of these substances, which have been the targets of numerous pharmaceutical agents, can be used to treat multiple conditions, including epilepsy, depression and headache.

Over the past two decades, the body of scientific evidence in support of VNS in multiple medical conditions has been growing. Prior to gammaCore, however, the cost and requirement for invasive surgery meant that VNS was only appropriate for the most refractory patients. With the FDA clearances of gammaCore, this safe and effective therapy can now be noninvasively self-administered, at a fraction of the cost of a surgical implant, exponentially expanding its accessibility for the potential treatment of multiple medical conditions.

Our Therapy Delivery Platform

Our gammaCore therapy is prescription-only, and patients self-administer discrete doses using a handheld unit. Our flagship gammaCore Sapphire is a portable, reusable, rechargeable and reloadable option for patients, with the prescription being written by a health care provider and dispensed from a specialty pharmacy or through the patient's healthcare system. After the initial prescription is filled, access to therapy is refilled periodically through the input of a unique, prescription-only authorization code. This code is currently delivered in the form of an RFID card, dispensed by mail by our specialty pharmacy distribution partner. In the future, this refill may be dispensed directly through the internet using Bluetooth technology.

Our prior iteration of the gammaCore delivery device was not reloadable or rechargeable and was supplanted by our introduction of the gammaCore Sapphire during the third quarter of 2018.We continue to market the non-reloadable, disposable version of our gammaCore products in certain markets and to deploy it for use in clinical studies where a rechargeable version is not necessary.

Competitive Strengths

We believe the competitive strengths of our company and our novel and proprietary self-administered nVNS therapy include:

Innovative bioelectronic medicine approach. Our gammaCore therapy uses a proprietary electrical signal to safely deliver VNS, which causes targeted pharmacologic-like changes in neurotransmitter expression and in the immune system, without systemic exposure to exogenous chemicals, in a manner that has been shown to have minimal side effects through clinical studies encompassing thousands of patients.

Our non-invasive therapy unlocks the long-held potential of VNS. VNS therapy can, for the first time, be delivered safely and comfortably through the skin using gammaCore. This eliminates the need for costly, invasive surgery that requires the implantation of an expensive medical device. VNS therapy is no longer reserved for the most refractory patients.

Commercial arrangements in the United States and the United Kingdom. In the United States, we expect that a majority of our 2020 sales of gammaCore will be made pursuant to our qualifying contract under the Federal Supply Schedule, or FSS, which was secured by us in December 2018, and open market sales to individual facilities. We have access to workers compensation and personal injury patients through our distribution agreement with Doctor's Medical, LLC announced in August 2019. In the United Kingdom, the NHS, awarded gammaCore a place on the Innovation Technology Payment program for the treatment of refractory cluster headache, a reimbursement pathway that opened in April 2019. Furthermore, in December 2019 NICE published a Medical Technology Guidance document recommending the use of gammaCore for CH within the NHS. Together, we believe that these independent validations offer the potential for us to generate revenue from the treatment of CH.

Broad intellectual property protection. Among our key issued patents, we have coverage on using our high-frequency burst electrical signal for treating certain medical conditions until 2031, the low-pass filtering of that signal to ensure safe and comfortable transmission through the skin until 2031, the non-invasive treatment of headache conditions until 2029, and the remote network-enabled communication for the delivery of neuromodulation therapy for a broad range of medical conditions until 2033.

Highly experienced management team. Our management team includes a diverse group of executives with significant experience in senior positions in the medical device and pharmaceutical industries. Our team's experience in clinical development, regulatory affairs, reimbursement and sales and marketing, allow us to pursue our strategy and growth plans.

Our Strategy

Our goal is to be a leader in non-invasive neuromodulation medicine by using our proprietary nVNS platform therapy to deliver better patient outcomes.

In May 2019, we announced significant adjustments to the deployment of personnel and resources across our organization. We reduced the size of our organization, including our field sales force and clinical operations in order to reduce expenses. We are currently focusing our resources on channels that are currently generating revenue, including the following:

- the Veterans Administration, or VA, and the Department of Defense, or DoD, which includes sales that are being made pursuant to our qualifying contract on the FSS, which was secured by us in December 2018, and open market sales to individual VA facilities. According to a presentation at the 2019 annual Scientific Meeting of the American Headache Society, approximately 400,000 patients saw a VA healthcare provider in 2018, for headache and we believe they can benefit from gammaCore therapy. The VA/DoD has become our primary source of US revenue and, accordingly, we have redeployed substantially all of our sales function to generating sales of our gammaCore and gammaCore Sapphire products from this channel.
- the United Kingdom, where a recent award from the Innovation Technology Payment Program of the NHS and evidence-based recommendations published in December 2019 by NICE offers the potential for us to generate revenue from the treatment of CH in the United Kingdom. In its final evidence-based recommendation issued in December 2019, NICE affirmed that gammaCore, when used with the appropriate standard of care, can save an average of £450 per patient in the first year of treatment through a reduction in acute rescue medications use, and with us offering no cost evaluations for all patients. Additionally, NHS has indicated to us that it is extending the previously announced Innovation Technology Payment Program through April 2021 and that it has identified gammaCore as being eligible for the new MedTech Funding Mandate mechanism, which, if confirmed, could potentially provide a basis for the long-term, sustainable reimbursement of gammaCore in the United Kingdom ; and
- other potential revenue opportunities, such as in workers compensation and personal injury claims through our distribution agreement with Doctor’s Medical, LLC announced in August 2019, as well as other potential distribution arrangements for our products, which may include exploration of international distributors the direct-to-consumer and private pay markets.

As part of our cost savings measures, we have also postponed certain clinical trials in indications that are more exploratory in nature. We enrolled subjects in our Premium II clinical trial to support the potential label expansion for migraine prevention and to support the potential commercialization of gammaCore Sapphire as a migraine prevention therapy following potential FDA clearance, which clearance we received on March 26, 2020. To date, we have randomized approximately 60% of the subjects planned for the study. In February 2020, we paused enrollment of the Premium II trial. We have also reduced our medical affairs activities consistent with our current focus. Given the recent FDA clearance for migraine prevention in adults, and challenges to study protocols, related datasets, and our business arising out of the novel coronavirus pandemic, we may also choose to terminate the Premium II study and take other actions to further reduce operating costs including reductions in our workforce.

Migraine

In January 2018, gammaCore was cleared by the FDA, through a 510(k) review, for commercial sale in the United States as an acute treatment for pain associated with migraine in adults. The predicate for this clearance from the FDA was through the *de novo* review for the acute treatment of pain associated with episodic CH in April 2017.

Our FDA clearance for the acute treatment of migraine in adults is principally supported by our pivotal trial, PRESTO. The primary endpoint of PRESTO was pain-freedom at 120 minutes. While this trial did not reach statistical significance with respect to its primary endpoint at two hours, statistical significance was achieved for pain freedom at 30 minutes (12.7%; p=0.01), and maintained at 60 minutes (21.0%; p=0.02), and under a repeated-measures analysis, through the full 120-minute period (30.4%; p=0.01).

The clearance by FDA on April 14, 2017 of our *de novo* submission resulted in a new Class II regulatory category: External Vagus Nerve Stimulator for Headache (21 CFR 882-5892). We believe the establishment of this product category will permit us to apply for label expansions through the 510(k) regulatory pathway utilizing our own product as the predicate.

In March 2020, gammaCore was cleared by the FDA, through a 510(k) review, for commercial sale in the United States as a preventive treatment of migraine headache in adults.

Our FDA clearance for preventive treatment of migraine in adults is principally supported by our Premium I and Event studies. The Premium I study was a prospective, randomized, double-blind, sham-controlled, multicenter study in patients with episodic migraine conducted at 22 European sites from June 2015-November 2017. It consisted of a 4-week run-in period of no study treatment, which was followed by a 12-week double blind phase of randomly assigned preventive treatment with a sham device and a 24-week open-label phase which all participants received nVNS therapy. Post hoc analysis of the modified intent-to treat population showed significant difference between groups in favor of the study's primary endpoint, mean reduction in the number of migraine days per month (therapeutic gain, 0.74; P=0.043), as well as for headache days per month (therapeutic gain, 0.86; P=0.045) and a reduction in acute medication days per month (therapeutic gain, 0.80; P=0.039).

The Premium II Trial – Our US Trial for the Prevention of Migraine

Our Premium II trial, or Premium II, is a randomized double-blind, sham-controlled prospective trial of gammaCore for the prevention of migraine, like the completed and published Premium I trial. Patients are instructed to treat themselves with two 120-second doses of gammaCore therapy or sham treatment, three times per day. Patients randomized to the sham treatment are being offered the opportunity to use gammaCore during a 3-month open-label period following a 3-month blinded randomized period.

The primary endpoint for the trial is a reduction in the average number of migraine days per month during the third month of the randomized period compared to the average number of migraine days per month in the baseline period between the two cohorts. In order to be admitted into the ITT population, patients must comply with the trial requirement to self-administer no fewer than two-thirds of the specified treatments per month during the randomized period. To date, we have enrolled approximately 60% of our target of 300 patients. In February 2020, we paused patient enrollment for the Premium II trial. This decision was made as a result of our focus on channels that are currently generating revenue and the need to further reduce operating costs. Given the recent FDA clearance of gammaCore Sapphire for the preventive treatment of migraine and challenges to study protocols, related datasets, and our business arising out of the novel coronavirus pandemic, we may also choose to terminate the Premium II study and take other actions to further reduce operating costs including reductions in our workforce.

Market Factors

Prevalence and Market Size. According to the World Health Organization, migraine ranks as the third most common disease in the world and the leading cause of disability among neurological disorders. Migraine will affect approximately 12% of the adult population globally, currently affecting approximately 36 million people in the United States, the majority of whom are women of childbearing years. Population-based studies of insured individuals reveal that, annually, 4.5% of the adult population seeks treatment for primary headache, the vast majority of which is for migraine. In the United States and EU, research has found that the age of first diagnosis of migraine peaks in the early-to-mid teens and the disease continues to persist throughout adulthood for many of these sufferers, demonstrating that it is often a disorder of long duration.

An estimated five million migraine patients in the United States require the care of a headache specialist. Among these specialists, many of whom also treat CH, are the approximately 1,100 physicians who are board-certified in the treatment of headache, many of whom practice in over 120 tertiary care centers in the United States. Although the triptan drug class is the current standard of care for the acute treatment of migraine, according to the U.S. Pharmacist, a leading pharmacy publication, more than 60% of patients have reported dissatisfaction with, or have contraindications to, the current standard of care, such as triptan medications. This dissatisfaction may partly explain the sub-25% penetration rate for available generic triptan medications. Despite these limitations, we estimate that the addressable market for the acute treatment of migraine in the United States in 2019 was approximately $4.0 billion.

Current Acute Migraine Treatments and Their Limitations. Triptan medications, or Triptans, are a family of tryptamine-based drugs first sold in the 1990s, which account for approximately 80% of the acute prescriptions written annually for migraine. Triptans are sold in oral, nasal, and subcutaneous formulations. Through their binding to specific seratonin receptor subgroups, Triptans cause constriction of blood vessels in the outer covering of the brain, or the meninges. This vasoconstrictive activity may also affect blood vessels in other areas of the body, including the heart, which accounts for important risks associated with their use, and labeling limitations on the frequency of their use. Since October 2019, the FDA has approved three new products for the acute treatment of migraine. Lasmiditan is a serotonin receptor agonist and ubrogepant and rimagepant are both calcitonin gene-related peptide receptor antagonists. These products are currently being launched in the United States and their impact on the acute market is uncertain.

Other less commonly prescribed acute migraine treatments include ergotamines and analgesics, including non-steroidal anti-inflammatory drugs, or NSAIDs, acetaminophen and antiemetics. Dihydroergotamine, or DHE, is a grain fungus derivative that, like triptans, is a potent vasoconstrictor. DHE has been used for more than 50 years for the treatment of migraine, but modern physicians rarely prescribe it because of its significant side effects. More specifically, ergotamines and triptans are both vasoconstrictors with labels citing the risk of their use in migraine sufferers with risk factors for cardiovascular disease.

Opioids are often dispensed for migraine attacks in emergency departments; however, in the treatment guidelines referenced by the National Institutes of Health, their use is not recommended for the acute treatment of migraine. Opioid use for migraine is associated with increased disability and health care utilization. The U.S. Centers for Disease Control and Prevention has recognized the growing issue of opioid misuse, abuse and addiction and officially classified prescription opioid abuse as an epidemic.

According to the U.S. Pharmacist, a leading pharmacy publication, upwards of 60% of the migraine patient population has reported dissatisfaction with, or has contraindications to, the current standard of care treatments for migraine. These medications include triptans, ergotamines and anti-epileptic medications. Despite the fact that neurologists recognize the limited efficacy of, and the potential for abuse associated with, opioids, they continue to be prescribed at high rates, particularly in emergency departments for the treatment of migraine. Many other primary headache conditions, and secondary headaches, such as post-traumatic headache, have proven refractory to pharmaceutical interventions, presenting a significant unmet need in the market.

Cluster Headache

As mentioned above, in April 2017, FDA granted our *de novo* submission, clearing our gammaCore for commercial sale in the United States for the acute treatment of pain associated with eCH in adults. In accordance with our strategy to establish gammaCore as the preferred treatment for neurologists across headache, we initially targeted the high unmet need population of CH sufferers to establish relevance with prescribing clinicians and gain reimbursement from payers. In furtherance of this strategy, in December 2018, we were successful in receiving FDA clearance for gammaCore Sapphire as a prevention for CH, the first product in the United States or Europe to receive regulatory approval for this indication.

CH is a condition in which patients experience relatively short but extremely painful headache attacks that have been described by patients and physicians as some of the most painful known to medicine. CH predominantly affects males in their prime earning ages of 20 to 50, and the attacks of pain occur in bouts, known as cluster periods, during which attacks are experienced at a frequency ranging from every other day to as often as eight times per day. Individual attacks typically last from 15 minutes to as long as three hours. Among CH patients, 85% to 90% experience eCH, with their cluster periods, or bouts, lasting from two to 12 weeks, followed by a remission period, often cycling into bout twice per year. Chronic CH, or cCH, patients experience no periods of remission or remission periods of less than three months in a 12-month period. There is only one other FDA-approved commercially available pharmaceutical option for acute CH treatment, and gammaCore is the only FDA-cleared option for the prevention of all forms of CH.

Our first FDA clearance, received following the grant of our *de novo* submission, was for the acute treatment of eCH in adults, and is supported by two pivotal trials: our ACT 1 trial, or ACT 1, and our ACT 2 trial, or ACT 2. The primary endpoints of these trials were pain reduction and pain-freedom within 15 minutes of the onset of the attack, respectively. While neither trial reached statistical significance compared to a sham device with respect to its primary endpoint in the combined eCH and cCH populations, both trials reached statistical significance (ACT 1; 34.2%; ACT 2; 47.5%; $p<0.01$ in each trial) on the primary endpoint in the eCH cohort.

Our FDA clearance for the prevention of CH in adults is principally supported by our pivotal trial, PREVA. The primary endpoint of PREVA was the reduction in number of CH attacks experienced per week during a test period (weeks 3 and 4 after initiating 3x daily treatments with gammaCore), as compared with the number of attacks per week during a baseline comparison period prior to initiation of gammaCore therapy. This trial met its primary endpoint with statistical significance compared to a sham device for the reduction in the number of cluster attacks (-5.9 vs. -2.1; $p<0.001$).

The Limitations of Pharmaceutical Treatment Options in Cluster Headache

There is only one FDA-approved commercially available pharmaceutical treatment for the acute treatment of CH, injectable sumatriptan. Patients have typically been limited to fewer than 10 injections per month, primarily due to cost and potential toxicity. In addition, the technical difficulty of subcutaneously self-injecting a medication during a CH attack may also limit use of this therapy. As a result, some patients typically have enough medication to treat, on average, only a fraction of their monthly CH attacks. Prior to gammaCore, there were no approved treatments for the prevention of CH, driving patients to

use off-label medications, such as lithium, valproic acid and high-dose verapamil, which have unproven efficacy and the potential for significant toxicity, including adverse cardiac events. In a 2016 market research survey of CH patients, 87% of the respondents were dissatisfied with the then-available treatment options.

In late 2019, Galcanezumab, a CGRP monoclonal antibody, was approved for the preventive treatment of eCH.

Cluster Headache Market Factors

Prevalence and market size. The estimated prevalence of CH in the United States ranges from 0.1% to 0.2% of the total population, with consensus around 350,000 as the number of affected patients, of which 225,000 patients seek medical treatment annually. eCH patients average approximately four months per year in bout. We estimate the total addressable market for the acute treatment of eCH in the United States in 2020 will be approximately $400 million.

Economic Burden. According to a February 2020 published study in The American Journal of Managed Care, the overall average medical costs for eCH patients over a three-year period exceeded $22,500, compared with $10,140 among non-headache sufferers. Similarly, the overall average pharmacy costs per eCH patient during this period were $8,200, which was nearly double that of the non-headache sufferers. Participants in surveys of sufferers indicate that CH is associated with a large socioeconomic burden. For example, research found that nearly 20% of patients with CH reported loss of employment and approximately 8% are unemployed or receiving disability services due to the disorder.

Other Therapies for the Acute Treatment of Cluster Headache. Other than gammaCore, there is only one FDA-approved commercially available therapy for acute treatment for CH, injectable sumatriptan (Imitrex). The side effect profile and cost of Imitrex, however, typically limits patient access to only six to 10 doses per month, which usually enables patients to treat only a small fraction of their attacks each month. Even at this limited access level, the monthly cost of Imitrex for CH patients and their insurance providers averages more than $700. Imitrex use is also limited by the requirement for patients to subcutaneously self-inject, which may be particularly difficult to do while experiencing a CH attack.

Manufacturing

We are the FDA-registered manufacturer of our gammaCore Sapphire and related products. We rely upon third-party contract manufacturers and suppliers, located both within and outside the United States, for substantially all of the components of our gammaCore products, including the handheld stimulator assembly, charging case, RFID cards and conductive gel.

At our facility in Rockaway, New Jersey, we inspect inbound component parts to ensure they meet our design and manufacturing specifications. This quality process involves physical inspection and electrical performance testing. After successful completion of this inspection, each gammaCore is configured to deliver our prescribed therapy, and a final test is performed on the unit to ensure it meets our performance specifications. At the time of configuration, each unit is programmed with a unique set of proprietary activation codes that will correspond to codes that are programmed onto RFID cards by our specialty pharmacy and delivered to the patient to activate and refill their therapy. The unit is then packaged, along with appropriate labeling, instructions for use, an initial RFID card, and conductive gel, and shipped into our distribution network, direct-to-consumer or direct-to-end user. Each RFID card that will be programmed by the specialty pharmacy has its own unique pre-programmed authorization code that is required to access our database of activation codes.

The relocation of development and prototype shops, as well as manufacturing and related operations, including device assembly, inspection/testing, packaging, storage, and shipping to our new facility in Rockaway, New Jersey was completed in 2019.

As of December 31, 2019, we had approximately $6.9 million of inventory. In the aggregate, our inventory significantly exceeds current demand for the gammaCore therapy.

However, in order to protect against risk of supply chain disruption, we have qualified an approved secondary contract manufacturer. Additionally, we retain the internal expertise and capabilities to perform all assembly aspects of our commercial product. These measures include purchasing a sufficient advanced supply of key components to reasonably assure that no component shortages will interrupt our ability to manufacture and deliver our products to patients on a timely basis.

The generation of our proprietary therapeutic signal does not require custom electronic components. Therefore, we believe long-term manufacturing, supply and quality agreements with electronic component suppliers are not necessary, as all the

electronic components used in our products are either high-volume, non-custom commodity components, or are readily available from multiple vendors. The majority of these components have multiple sources, and the few with single sources have been purchased with sufficient reserves to permit continued production while simple product design modifications can be made.

Competition

While we believe that our proprietary gammaCore therapy provides us with competitive advantages, there is fierce competition, particularly in the migraine market, from many different sources, including pharmaceutical, biotechnology and other healthcare companies. In addition, academic institutions, governmental agencies and public and private research institutions are actively conducting research in overlapping fields of interest. Our gammaCore therapy competes and will compete with numerous existing therapies and therapies that may become available in the future.

We believe the key competitive factors affecting the potential success of our therapy are its safety, efficacy, convenience, price, the availability of generic drugs and the availability of coverage and reimbursement from government and certain other third-party payers. There can be no assurance, however, given the competitive landscape in the markets in which gammaCore competes, that demand for our products may not be constrained, or face significant pricing pressure, or that the scope of coverage and reimbursement from third-party payers will expand or not be curtailed.

Many of the companies we are competing with now, or with which we may compete in the future, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, sales and marketing and obtaining third-party payer coverage for approved drugs than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

The completion of our competitors' clinical trials with respect to their headache products could negatively impact the perception of us or our gammaCore therapy. The perception by physicians, payers or patients that a competitor's product is superior to our gammaCore therapy or offers comparable benefits at a lower cost or lower incidence of undesirable side effects as compared against our gammaCore therapy, could have a material adverse effect on us.

In primary headache, we face stiff competition from companies that develop and/or sell the following types of treatments:

Treatments for Cluster Headache

The most frequently used acute treatments for CH attacks are subcutaneous sumatriptan and high flow rate inhaled oxygen. Alternative treatments include intranasal triptans and intravenous dihydroergotamine, or DHE. Only subcutaneous sumatriptan and intravenous DHE are approved in the United States for the acute treatment of CH, and one calcitonin gene-related peptide, or CGRP receptor agonist that is produced by Eli Lilly and Company was recently approved by the FDA for the treatment of eCH. Approval and commercialization of additional therapies may be forthcoming. Currently gammaCore is the only FDA-cleared commercially available treatment for the prevention of all forms of CH, however, there are medications that are used by patients off-label, including verapamil, lithium, and valproate.

Treatments for Migraine

The most frequently prescribed therapy for the acute treatment of migraine are oral, nasal or injectable triptans. Additional prescribed products include prescription strength NSAIDs. There are currently several antibodies to CGRP and its receptor approved by FDA for the prevention of migraine including products sold by Teva Pharmaceutical Industries Ltd., Eli Lilly and Company, Amgen Inc., which is in a co-marketing partnership with Novartis International AG and H. Lundbeck A/S. The FDA has recently approved two oral small molecule calcitonin gene-related peptide receptor antagonists for the acute treatment of migraine with or without aura in adults. These products are marketed by Allergan and Biohaven Pharmaceuticals Inc. The FDA also approved Eli Lilly's lasmiditan in the third quarter of 2019 and it was subsequently launched in the first quarter of 2020. There are a number of neuromodulation devices that have been marketed for the acute treatment and/or prevention of migraine, including the Cefaly, Nerivio, and the sTMS mini devices. Certain classes of anti-epileptic medicine and beta-blocker medications have been approved by the FDA for the prevention of migraine. BOTOX marketed by Allergan plc, is specifically approved for the prevention of chronic, but not episodic, migraine.

Given the size of the existing and potential primary headache markets in the United States and abroad, we expect that as we continue to seek to expand our commercial efforts our current and future competitors will take aggressive action to grow, enhance and protect their market positions to our potential detriment.

We actively seek to protect the intellectual property and proprietary technology that we believe is important to our business, which includes seeking and maintaining patents covering our technology and products, proprietary processes and any other inventions that are commercially or strategically important to the development of our business. We also rely upon trademarks to build and maintain the integrity of our brand, and we seek to protect the confidentiality of trade secrets that may be important to the development of our business. For more information, please see "Risk Factors—Risks Related to Intellectual Property."

Patents and Patent Applications

As of February 1, 2020, we held more than 165 patents and patent applications, including more than 100 issued U.S. patents, more than 25 U.S. patent applications, and more than 40 international patents and applications. All of our current issued patents are projected to expire between 2026 and 2033.

More specifically, our current therapy embodies a number of critical proprietary innovations, including a patented high-frequency burst signal that is capable of passing comfortably through the capacitance of the skin. In addition, our therapy utilizes a patented low pass filtration that substantially eliminates high frequency harmonics that would otherwise activate pain receptors in the skin. The combined result is a mild sensation that activates the target fibers in the cervical vagus nerve.

Additionally, we have issued claims covering the methods of treating various headache conditions using our innovative therapy. We also have claims covering our innovative distribution capabilities, including the remote network-enabled communication for delivery of neuromodulation therapy for a broad range of medical conditions.

The term of individual patents depends on the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. We cannot assure you that patents will be issued from any of our pending applications or that, if patents are issued, they will be of sufficient scope or strength to provide meaningful protection for our technology. Notwithstanding the scope of the patent protection available to us, a competitor could develop treatment methods or devices that are not covered by our patents. Furthermore, numerous U.S. and foreign issued patents and patent applications owned by third parties exist in the fields in which we are developing products. Because patent applications can take many years to issue, there may be applications unknown to us, which applications may later result in issued patents that our existing or future products or proprietary technologies may be alleged to infringe.

There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. In the future, we may need to engage in litigation to enforce our issued patents, to protect our trade secrets or know-how, to defend against claims of infringement of the rights of others or to determine the scope and validity of the proprietary rights of others. Litigation could be costly and could divert our attention from other functions and responsibilities. Adverse determinations in litigation could subject us to significant liabilities to third parties, could require us to seek licenses from third parties and could prevent us from manufacturing, selling or using our gammaCore products, any of which could severely harm our business.

Copyrights, Trademarks and Trade Secrets

The software programs associated with gammaCore and our proprietary ecosystem are protected by U.S. copyright law.

As of February 1, 2020, our trademark portfolio consisted of seven U.S. trademark registrations, including electroCore and gammaCore, three pending U.S. trademark applications, including gammaCore Sapphire and gammaCore, and one registered European trademark, electroCore.

We also rely upon trade secrets, know-how and continuing technological innovation, and may pursue licensing opportunities in the future, to develop and maintain our competitive position. We seek to protect our proprietary rights through a variety of methods, including confidentiality agreements and proprietary information agreements with suppliers, employees, consultants and others who may have access to proprietary information, under which they are bound to assign to us inventions made during the term of their employment or term of service.

Government Regulation

United States

Our products and operations are subject to extensive and rigorous regulation by the FDA under the Federal Food, Drug, and Cosmetic Act, or FFDCA, and its implementing regulations, guidance documentation, and standards. Our gammaCore products are regulated by the FDA as medical devices. The FDA regulates the design, development, research, testing, manufacturing, safety, labeling, storage, recordkeeping, promotion, distribution, sale and advertising of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. The FDA also regulates the export of medical devices manufactured in the United States to international markets. Any violations of these laws and regulations could result in a material adverse effect on our business, financial condition and results of operations. In addition, if there is a change in law, regulation or judicial interpretation, we may be required to change our business practices, which could have a material adverse effect on our business, financial condition and results of operations.

Under the FFDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of control needed to ensure safety and effectiveness.

Class I devices are those for which safety and effectiveness can be assured by adherence to FDA's "general controls" for medical devices, which include compliance with the applicable portions of the FDA's Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials. Some Class I devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below.

Class II devices are subject to FDA's general controls, and any other "special controls" deemed necessary by FDA to ensure the safety and effectiveness of the device, such as performance standards, product-specific guidance documents, special labeling requirements, patient registries or post-market surveillance. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification procedure, though certain Class II devices are exempt from this premarket review process. When a 510(k) is required, the manufacturer must submit to the FDA a premarket notification submission demonstrating that the device is "substantially equivalent" to a legally marketed device, which in some cases may require submission of clinical data. Unless a specific exemption applies, 510(k) premarket notification submissions are subject to user fees. If the FDA determines that the device, or its intended use, is not substantially equivalent to a legally marketed device, the FDA will place the device, or the particular use of the device, into Class III, and the device sponsor must then fulfill much more rigorous premarketing requirements.

Class III devices, consisting of devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a predicate device. The safety and effectiveness of Class III devices cannot be assured solely by general or special controls. Submission and FDA approval of a premarket approval, or PMA, application is required before marketing of a Class III device can proceed. As with 510(k) submissions, unless subject to an exemption, PMA submissions are subject to user fees. The PMA process is much more demanding than the 510(k) premarket notification process. A PMA application, which is intended to demonstrate that the device is safe and effective, must be supported by extensive data, typically including data from preclinical studies and human clinical trials.

510(k) Clearance

To obtain 510(k) clearance for a medical device, an applicant must submit to the FDA a premarket notification demonstrating that the proposed device is "substantially equivalent" to a legally marketed device, known as a "predicate device." A legally marketed predicate device may include a device that was legally marketed prior to May 28, 1976 for which a PMA is not required (known as a "pre-amendments device" based on the date of enactment of the Medical Device Amendments of 1976), a device that has been reclassified from Class III to Class II or Class I, or a device that was found substantially equivalent through the 510(k) process. A device is substantially equivalent if, with respect to the predicate device, it has the same intended use and has either (i) the same technological characteristics, or (ii) different technological characteristics, but the information provided in the 510(k) submission demonstrates that the device does not raise new questions of safety and effectiveness and is at least as safe and effective as the predicate device. A showing of substantial equivalence sometimes, but not always, requires clinical data.

Before the FDA will accept a 510(k) submission for substantive review, the FDA will first assess whether the submission satisfies a minimum threshold of acceptability. If the FDA determines that the 510(k) submission is incomplete, the FDA will issue a "Refuse to Accept" letter which generally outlines the information the FDA believes is necessary to permit a substantive review and to reach a determination regarding substantial equivalence. An applicant must submit the requested information before the FDA will proceed with additional review of the submission. Once the 510(k) submission is accepted for review, by regulation, the FDA has 90 days to review and issue a determination. As a practical matter, clearance often takes longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence.

If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the "de novo" process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

After a device receives 510(k) marketing clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) marketing clearance or, depending on the modification, PMA approval. The determination as to whether or not a modification could significantly affect the device's safety or effectiveness is initially left to the manufacturer using available FDA guidance. Many minor modifications today are accomplished by a "letter to file" in which the manufacture documents the rationale for the change and why a new 510(k) is not required. However, the FDA may review such letters to file to evaluate the regulatory status of the modified product at any time and may require the manufacturer to cease marketing and recall the modified device until 510(k) clearance or PMA approval is obtained. The manufacturer may also be subject to significant regulatory fines or penalties.

PMA Approval

A PMA must be submitted to the FDA for any device that is classified in Class III or otherwise cannot be cleared through the 510(k) process (although the FDA has discretion to continue to allow certain pre-amendment Class III devices to use the 510(k) process). PMA applications must be supported by, among other things, valid scientific evidence demonstrating the safety and effectiveness of the device, which typically requires extensive data, including technical, preclinical, clinical and manufacturing data. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities, and controls used for manufacturing, and proposed labeling. Following receipt of a PMA application, once the FDA determines that the application is sufficiently complete to permit a substantive review, the FDA will formally accept the application for review. The FDA, by statute and by regulation, has 180-days to review an "accepted" PMA application, although the review of an application more often occurs over a significantly longer period of time, and can take up to several years. During the review period, the FDA will typically request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the QSR.

If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted. Once granted, PMA approval may be withdrawn by the FDA if compliance with post-approval requirements, conditions of approval or other regulatory standards is not maintained, or problems are identified following initial marketing.

In approving a PMA, the FDA may also require some form of post-market surveillance when necessary to protect the public health or to provide additional safety and effectiveness data for the device. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients.

New PMAs or PMA supplements are required for modifications that affect the safety or effectiveness of a PMA-approved device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling and design. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel.

De Novo Classification

Medical device types that the FDA has not previously classified as Class I, II or III are automatically classified into Class III regardless of the level of risk they pose. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the *de novo* classification procedure. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act of 2012, or the FDASIA, a medical device could only be eligible for *de novo* classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the *de novo* classification pathway by permitting manufacturers to request *de novo* classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. Under FDASIA, the FDA is required to classify the device within 120 days following receipt of the *de novo* submission. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed.

In March 2014 we filed a pre-submission package with the FDA requesting a meeting to discuss the viability of using the *de novo* pathway to gain authorization to commercialize our gammaCore product for an initial indication in CH. In June 2014, FDA met with us and confirmed that the *de novo* pathway would be appropriate for our submission. In October 2014 we filed our initial *de novo* submission with FDA. As is customary for many applications for commercial approval (Class II or Class III), FDA in a letter to us in May 2015 denied our initial application stating that our initial filing did not yet support a *de novo* clearance based on the information in the initial filing. In June 2015 we participated in an in-person meeting with FDA representatives to discuss the issues raised by the FDA in its May 2015 denial letter. In October 2015, based on our June 2015 meeting with FDA, we resubmitted our *de novo* submission with two proposed indications: (i) acute treatment of eCH; and (ii) prophylactic treatment of cCH. In February 2016, we received a letter from FDA indicating that our *de novo* submission, with some further requested re-analysis, included sufficient data to support *de novo* classification and clearance of gammaCore for at least one indication. We performed and submitted to the FDA the requested re-analysis in March 2016 and, following additional correspondence and meetings with FDA, in April 2017, FDA approved our *de novo* classification request and cleared our gammaCore therapy in the United States for the acute treatment of pain associated with eCH in adults.

Based on this approval, of our *de novo* classification request, gammaCore has been down classified to Class II under a new Class II device regulatory category for non-invasive cervical vagus nerve stimulators for the treatment of headache. The establishment of this category created a 510(k) regulatory pathway for the potential expansion of the gammaCore label to include acute treatment and/or prevention of pain associated with migraine and cCH, as well as acute treatment and/or prevention of other primary and secondary headaches. In January 2018, the FDA cleared gammaCore for acute treatment of pain associated with migraine headaches in adult patients, and on March 26, 2020 the FDA cleared our gammaCore therapy for prevention of migraine in adult patients and we have conducted several additional clinical studies with a view to supporting additional label expansion, although we have paused patient enrollment for our Premium II trial. This decision was made as a result of our desire to focus our resources on channels that are currently generating revenue and the need to further reduce operating costs. Given the recent FDA clearance, and challenges to study protocols, related datasets, and our business arising out of the novel coronavirus pandemic, we may also choose to terminate the Premium II study and take other actions to further reduce operating costs including reductions in our workforce.

Additionally, we may consider utilizing the *de novo* classification process to obtain marketing authorization for our product candidates under development outside the headache field.

Clinical Studies

When FDA clearance or approval of a Class I, Class II or Class III device requires human clinical trials, and if the device presents a "significant risk" to human health, the device sponsor is required to file an IDE application with the FDA and obtain IDE approval prior to commencing the human clinical trial. If the device is considered a "non-significant risk," IDE submission to FDA is not required. Instead, only approval from the Institutional Review Board, or IRB, overseeing the investigation at each clinical trial site is required. Human clinical studies are generally required in connection with approval of Class III devices and may be required for Class I and II devices. The FDA or the IRB at each institution at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable health risk. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA clearance or approval to market the product in the United States.

Continuing Regulation

After a device is placed on the market, numerous regulatory requirements apply. These include:

- Product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared or unapproved "off-label" uses;
- clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices;
- approval of product modifications that affect the safety or effectiveness of one of our approved devices;
- medical device reporting regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;
- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations;
- regulations pertaining to voluntary recalls; and
- notices of corrections or removals.

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. Recently, promotional activities for FDA-regulated products of other companies have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims. If the FDA determines that our promotional materials or training constitutes promotion of an unapproved or uncleared use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved or uncleared use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged, and adoption of the products would be impaired.

Furthermore, our products could be subject to voluntary recall if we or the FDA determine, for any reason, that our products pose a risk of injury or are otherwise defective. Moreover, the FDA can order a mandatory recall if there is a reasonable probability that our gammaCore therapy would cause serious adverse health consequences or death.

The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of some of our subcontractors. Failure by us or by our suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or other regulatory authorities, which may result in sanctions including, but not limited to:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions
- customer notifications for repair, replacement, refunds;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or PMA approval of new products or modified products;
- operating restrictions;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

To date, our facility has not been inspected by the FDA.

International

Our international sales are subject to regulatory requirements in the countries in which our products are sold. The regulatory review process varies from country to country and may in some cases require the submission of clinical data.

We received CE Certificate of Conformity in the European Economic Area (which is composed of all the EU member states plus Norway, Iceland and Liechtenstein), or EEA, for our gammaCore therapy to treat, primary headache, including migraine, CH, and hemicrania continua, as well as medication overuse headache in adults. The CE Certificate of Conformity was extended to additional indications, including for the treatment or prevention of symptoms of reactive airway disease, which includes asthma, bronchoconstriction, exercise induced bronchospasm, and COPD in adults.

In the EEA, gammaCore must currently comply with the essential requirements laid down in Annex I to Directive 93/42/EEC on the approximation of the laws of the member states relating to medical devices or the EU Medical Devices Directive. Compliance with these requirements is a prerequisite to be able to affix the CE mark to gammaCore, without which they cannot be marketed or sold in the EEA. To demonstrate compliance with the essential requirements and obtain the right to affix the CE Mark medical devices manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low risk medical devices (Class I with no measuring function and which are not sterile), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the Essential Requirements, a conformity assessment procedure requires the intervention of a notified body, which is an organization designated by a competent authority of an EEA country to conduct conformity assessments. Depending on the relevant conformity assessment procedure, the notified body would audit and examine the technical documentation and the quality system for the manufacture, design and final inspection of the medical devices. The notified body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the essential requirements. This Certificate entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

As a general rule, demonstration of conformity of medical devices and their manufacturers with the Essential Requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use and that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device (e.g., product labeling and instructions for use) are supported by suitable evidence. This assessment must be based on clinical data, which can be obtained from (1) clinical studies conducted on the devices being

assessed, (2) scientific literature from similar devices whose equivalence with the assessed device can be demonstrated or (3) both clinical studies and scientific literature. The gammaCore is a Class IIa medical device in the EU. The conduct of clinical studies in the EEA is governed by detailed regulatory obligations. These may include the requirement of prior authorization by the competent authorities of the country in which the study takes place and the requirement to obtain a positive opinion from a competent ethics committee. This process can be expensive and time-consuming.

Moreover, in May 2017, the EU Medical Devices Regulation 2017/745, or MDR was adopted. The MDR repeals and replaces the EU Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA member states, the regulations would be directly applicable, i.e., without the need for adoption of EEA Member State laws implementing them, in all EEA member states and are intended to eliminate current differences in the regulation of medical devices among EEA member states. The MDR, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation. The MDR will be applicable on May 26, 2020. Once applicable, the new regulations will among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU;
- strengthened rules for the assessment of certain high-risk devices which may have to undergo an additional check by experts before they are placed on the market.

It will be necessary for notified bodies to be accredited by the EU Member States' accreditation bodies to conduct assessment procedures for medical devices in accordance with the Regulation. There are currently a relatively small number of notified bodies that have been accredited to conduct these assessments. This may delay conformity assessment procedures in the future in the EU.

On March 29, 2017 the United Kingdom formally notified the EU of its intention to withdraw from the Union pursuant to Article 50 of the Lisbon Treaty, commonly referred to as Brexit. The United Kingdom and EU have now agreed on the terms of the exit deal, which will include a transitional period following the United Kingdom's exit which occurred on January 31, 2020. The transitional period will continue until December 31, 2020 during which the EU and the United Kingdom will seek to negotiate new arrangements for the period from January 1, 2021. During the transitional period most obligations imposed by EU legislation will remain applicable to and in the United Kingdom. Since a significant proportion of the regulatory framework in the United Kingdom is derived from EU directives and regulations, the "hard" withdrawal of the United Kingdom from the EU (where no deal is agreed for the period after the transitional period ending December 31, 2020) could materially impact the regulatory regime with respect to the CE Certificate of Conformity in the United Kingdom. CE Certificates of Conformity issued by a notified body accredited in the EU may no longer be recognized in the UK. Similarly, notified bodies accredited in the UK will no longer be able to issue CE Certificates of Conformity.

Other Regulations

We are also subject to healthcare fraud and abuse regulation in the jurisdictions in which we will conduct our business. These laws include, without limitation, applicable anti-kickback, false claims, transparency and patient privacy and security laws and regulations.

Anti-Kickback Statute: The federal Anti-Kickback Statute prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. The federal Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. The term "remuneration" includes kickbacks, bribes, or rebates and also has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests, relieving a referral source of a financial or administrative burden and providing anything at less than its fair market value. In

addition, longstanding OIG guidance makes clear that the opportunity for a referring physician to earn a profit, including through an investment in an entity for which he or she generates business, could constitute illegal remuneration under the Anti-Kickback Statute. The Anti-Kickback Statute is violated if even one purpose of the remuneration is to induce such referrals.

There are a number of narrow statutory exceptions and regulatory safe harbors protecting certain defined business arrangements from prosecution under the federal Anti-Kickback Statute. These statutory exceptions and safe harbors protect an entity from prosecution under the federal Anti-Kickback Statute if the entity meets every requirement of a specific exception or safe harbor. The failure of a transaction or arrangement to fit precisely within one or more applicable statutory exceptions or safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy all requirements of an applicable safe harbor may result in increased scrutiny by government enforcement authorities and will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Further, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act which is discussed below. Penalties for violations of the Anti-Kickback Statute include, but are not limited to, significant civil monetary penalties for each violation, criminal fines, disgorgement, individual imprisonment, exclusion from Medicare, Medicaid and other federal healthcare programs, and the possible curtailment or restructuring of operations.

Physician Self-Referral Law: In the event that third-party payers require us to be a DME supplier or we sell our products directly to providers who are DME suppliers that submit claims to such payers, we may be subject to the federal Stark physician self-referral law, or Stark Law, which prohibits a physician from making a referral for certain designated health services covered by the Medicare program or Medicaid program, including DME, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services, and prohibits that entity from billing or presenting a claim for the designated health services furnished pursuant to the prohibited referral, unless an exception applies. Sanctions for violating the Stark Law include denial of payment, significant per claim civil monetary penalties, and exclusion from the federal health care programs. Failure to refund amounts received as a result of a prohibited referral on a timely basis may constitute a false or fraudulent claim and may result in civil penalties and additional penalties under the FCA. The statute also provides for financial penalties for a circumvention scheme. Various states also have corollary laws to the Stark Law, including laws that require physicians to disclose any financial interest they may have with a healthcare provider to their patients when referring patients to that provider. Both the scope and exceptions for such laws vary from state to state.

Federal Civil False Claims Act: The federal civil False Claims Act prohibits, among other things, persons or entities from knowingly presenting or causing to be presented a false or fraudulent claim for, or the knowing use of false statements to obtain, payment of federal funds. In addition, private individuals have the ability to bring actions under the civil False Claims Act in the name of the government and themselves and to share in any monetary recover. Such suits, known as qui tam actions, have increased significantly in the healthcare industry in recent years. Manufacturers can be held liable under these laws if they are deemed to “cause” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Penalties for a federal civil False Claims Act violation include significant per claim or statement mandatory civil penalties, plus treble damages, and the potential for exclusion from participation in federal healthcare programs.

Civil Monetary Penalties. The Civil Monetary Penalty Act of 1981 imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent, or offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary’s decision to order or receive items or services reimbursable by the government from a particular provider or supplier.

Federal Healthcare Fraud Laws. Other federal healthcare fraud-related laws also provide criminal liability for violations. The criminal healthcare fraud statute (18 U.S.C. § 1347) enacted by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) prohibits, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payers. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the HIPAA fraud statute or specific intent to violate it in order to have a committed a violation. Federal criminal false statement laws at 18 U.S.C. §§ 1001 and 1035, among other sections, prohibit, among other things, knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services, or in any matter within the jurisdiction of the federal government.

Health Insurance Portability and Accountability Act of 1996: HIPAA and its implementing regulations established uniform standards for certain covered entities, which are healthcare providers, health plans and healthcare clearinghouses, as well as their business associates, governing the conduct of specified electronic healthcare transactions and protecting the security and privacy of protected health information. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH has four tiers of civil monetary penalties and state attorneys have general authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. The Department of Justice also may impose criminal penalties. Additionally, certain states have adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA and HITECH, and numerous federal and state laws, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, including for example, Section 5 of the Federal Trade Commission Act of 1914, as amended, and the California Consumer Privacy Act (CCPA), govern the collection, use, and disclosure and protection of certain health-related and other personal information.

The Federal Physician Payments Sunshine Act: The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with certain exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to "payments or other transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and to report annually to CMS certain ownership and investment interests held by physicians and their immediate family members. The government may impose significant civil monetary penalties, for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives.

Analogous State Laws: The majority of states also have statutes or regulations similar to the federal Anti-Kickback Statute and federal civil False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Certain states also require device and drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, require device and drug companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other specified recipients.

EU Data Protection Legislation: We are subject to laws and regulations in non-U.S. countries covering data privacy and the protection of health-related and other personal information. The EU, EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. The EU General Data Protection Regulation, or GDPR, became applicable on May 25, 2018 and is directly applicable in each EU member state and is hoped to, result in a more uniform application of data privacy laws across the EU. The GDPR imposes strict requirements and onerous accountability obligations on companies that process personal data, especially if they process sensitive personal data (such as data concerning health), including significant fines for non-compliance with the GDPR. Implementation of the GDPR has influenced other jurisdictions to either amend or propose legislation to amend their existing data privacy and cybersecurity laws to resemble the requirements of GDPR. For example, on June 27, 2018, California adopted the California Consumer Privacy Act of 2018, or CCPA. The CCPA has been characterized as the first "GDPR-like" institutes a comprehensive consumer privacy framework. The CCPA became effective January 1, 2020, but enforcement will not begin until July 1, 2020, and the California Attorney General's Implementation Regulations have yet to be adopted. Like the GDPR, the CCPA imposes strict requirements and obligations on companies that collect, use, and share personal information. Fines and penalties for non-compliance range from $2,500 per violation to $7,500 per intentional violation. Unlike the GDPR, the CCPA gives California residents a private right of action where California resident's nonencrypted and nonredacted personal information is subject to a date breach as a result of a business's failure to implement reasonable security procedures.

The Foreign Corrupt Practices Act: The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring such companies to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for our products. The cost containment measures that payers and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products.

The implementation of the Affordable Care Act in the United States, for example, has changed healthcare financing and delivery by both governmental and private insurers substantially, and affected medical device manufacturers significantly. The Affordable Care Act, among other things, provided incentives to programs that increase the federal government's comparative effectiveness research, and implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. Additionally, the Affordable Care Act has expanded eligibility criteria for Medicaid programs and created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. Certain aspects of the Affordable Care Act have been subject to judicial challenges as well as efforts to repeal or replace them or to alter their interpretation and implementation. For example, the Tax Cuts and Jobs Act was enacted on December 22, 2017, which, among other things, eliminated the shared responsibility payment for individuals who fail to maintain minimal essential coverage under section 5000A of the Internal Revenue Code of 1986, commonly referred to as the individual mandate, as of January 1, 2019. Additional legislative changes to and regulatory changes under the Affordable Care Act remain possible, but the nature and extent of such additional changes are uncertain at this time.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction, which triggered the legislation's automatic reductions. In concert with the subsequent legislation, this has resulted in aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2029 unless additional Congressional action is taken. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

We expect additional state and federal healthcare reform measures to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

Federal Contracting Regulations

Our qualifying contract on the FSS and open market sales to individual VA facilities necessitates compliance with applicable federal procurement laws and regulations, including commercial price disclosures, commercial-to-federal price indexing, and various federal programs. We are subject to contractual remedies as well as potential administrative, civil, and criminal sanctions for non-compliance.

Employees

As of March 1, 2020, we employed 51 full-time employees. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Company History

electroCore, Inc. was founded in 2005 as a limited liability company. electroCore, headquartered in New Jersey, and has two wholly owned subsidiaries: electroCore Germany GmbH and electroCore UK Ltd. In addition, an affiliate, electroCore (Aust) Pty Limited, is subject to electroCore's control on basis other than voting interests and is a variable interest entity, for which electroCore is the primary beneficiary. Our Internet website address is www.electrocore.com. The content reflected on our website is not incorporated by reference herein unless expressly noted.

Available Information

Our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K and proxy statements, and all amendments thereto, are available free of charge on our Internet website. These reports are posted on our website as soon as reasonably practicable after such reports are electronically filed with the SEC. The public may read and copy any materials that we file with the SEC electronically through the SEC website (www.sec.gov). The information contained on the SEC's website is not incorporated by reference into this Form 10-K and should not be considered to be part of this Form 10-K. Within the Investors section of our website, we provide information concerning corporate governance, including our Corporate Governance Guidelines, board committee charters, Code of Conduct and other information. The content reflected on any website reflected in this Form 10-K is not incorporated by reference herein unless expressly noted.

Item 1A. Risk Factors.

RISK FACTORS

You should carefully consider the following risk factors, in addition to the other information in this report on Form 10-K, including the section of this report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes. If any of the events described in the following risk factors and the risks described elsewhere in this report on Form 10-K occurs, our business, operating results and financial condition could be seriously harmed. This report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this report.

Risks Related to our Financial Position, Operating Results and Need for Additional Capital

We have a history of significant losses. If we do not achieve and sustain profitability, our financial condition could suffer. Our failure to become and remain profitable could negatively impact the results of our operations and your investment.

We have experienced significant net losses, and we expect to continue to incur losses for the foreseeable future as we operate our sales and marketing infrastructure, increase market acceptance of our gammaCore therapy for the acute treatment of eCH, the prevention of CH, and the acute and preventive treatment of migraine, and fund our research and development activities, and obtain regulatory clearance or approval for other products or indications in the United States and internationally. We have never been profitable and have incurred net losses in each year since our inception.

We incurred net losses of $45.1 million and $55.8 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, our accumulated deficit was $83.5 million. Our prior losses, combined with expected future losses, have had and will continue to have, for the foreseeable future, an adverse effect on our stockholders' deficit and working capital.

To become and remain profitable, we must successfully commercialize our gammaCore therapy and continue to identify promising new areas of treatment with significant market potential. This will require us to be successful in a range of challenging activities, including obtaining adequate coverage and reimbursement from payers, marketing and selling any current and future product candidates for which we may obtain marketing clearance or approval, developing commercial scale manufacturing processes, completing clinical trials of gammaCore for additional therapeutic indications, obtaining additional marketing clearance or approval from regulatory authorities, manufacturing, and satisfying any post-marketing requirements. We face a variety of challenges and risks that we will need to address and manage as we pursue our strategy, including our ability to achieve adequate payer coverage, develop and retain an effective sales force, achieve market acceptance of gammaCore among physicians, patients and third-party payers, and expand the use of gammaCore to additional therapeutic indications. Because of the numerous risks and uncertainties associated with our commercialization efforts, as well as research and clinical development activities, we are unable to predict the timing or amount of increased expenses, or when, if ever, we will be able to achieve or maintain profitability. We expect to continue to incur substantial net losses and negative cash flows from operations as we commercialize gammaCore. We intend to continue to make targeted investments in building our U.S. commercial infrastructure.

Even if we are able to increase sales of gammaCore, increase adoption of gammaCore therapy among physicians and payers and achieve desired payer coverage levels, we may not achieve profitability and even if we do, we may not be able to sustain or increase profitability in subsequent periods. If we fail to become profitable or are unable to sustain profitability, then we may be unable to continue our operations at planned levels and be forced to further reduce or terminate our operations. As of December 31, 2019, we had cash and cash equivalents of $13.6 million and marketable securities of $10.5 million. Based on our available cash resources and current cash flow projections, we may need to reduce our activities significantly more than our current operating plan and cash flow projections assume in order to fund operations to the end of 2020. There can be no assurance that we will have sufficient cash flow and liquidity to fund our planned activities, which could force us to significantly reduce or curtail our activities and, ultimately, potentially cease operations. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment.

We will be required to obtain additional funds in the future, and these funds may not be available on acceptable terms or at all, which could impair our ability to continue as a going concern.

Our operations have consumed substantial amounts of cash since inception, and we anticipate this continuing into at least 2021 as we continue seeking to grow our business. We believe that our growth will depend, in part, on our ability to fund our

commercial efforts for our gammaCore therapy, and to opportunistically pursue research and development activities for additional indications for our gammaCore therapy. Our existing resources are unlikely to allow us to conduct all of the activities that we believe could be beneficial for our future growth. As a result, we may need to seek additional funds in the future or curtail or forgo some or all of such activities. If we seek to and are unable to raise funds on favorable terms, or at all, we may not be able to support our commercialization efforts or increase our research and development activities and the growth of our business may be negatively impacted. As a result, we may be unable to compete effectively. Although we expect that our existing capital resources, will enable us to fund our operating expenses and capital expenditure requirements into the beginning of 2021, this estimate is based on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. Changes, including those relating to the payer and competitive landscape, our development activities and regulatory matters, may occur beyond our control that would cause us to consume our available capital more quickly. Our future capital requirements will depend on many factors, including:

- the outcome, timing of, and costs involved with negotiating, obtaining, maintaining and enhancing payer coverage;
- the scope and timing of our investment in our U.S. and U.K. commercial infrastructure and sales force;
- the costs of commercialization activities including sales, marketing, manufacturing and distribution;
- the costs incurred in defending against pending securities class-action litigations and other potential litigation, as well as the costs of any potential judgements or settlements;
- the degree and rate of payer, physician, patient and market acceptance of our gammaCore therapy;
- the outcome, timing of, and costs involved in, seeking and obtaining clearances or approvals from the FDA and other regulatory authorities, including the potential for the FDA and other regulatory authorities to require that we perform more studies, clinical trials or tests on our gammaCore therapy than we currently expect;
- the research and development activities we may undertake in order to expand our headache indications and enhancements to our gammaCore therapy;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the need for us and third parties, including payers and service providers, to potentially need to implement new or revised policies, infrastructure and internal systems;
- our ability to hire additional personnel to support our operations, including as a public company; and
- the emergence and acceptance of competing therapies or other adverse market developments.

To finance our activities, we may seek funds through borrowings or through additional rounds of financing, including public equity or debt offerings and collaborative arrangements with corporate partners. We may be unable to raise funds on favorable terms, if at all. Other than the Purchase Agreement with Lincoln Park, we do not currently have any agreements or understandings with respect to any potential financing. Our low stock price, low market capitalization trading volume, and other macro-economic factors may affect our ability to raise funds and the terms on which we will be able to raise funds. Our failure to obtain additional necessary financing could impair our ability to conduct our operations, and any such failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to (i) pursue our business plans and strategies and (ii) maintain our listing on the Nasdaq Stock Market.

In addition, our auditors' report for our 2019 financial statements contains a statement concerning our ability to continue as a "going concern." Our lack of sufficient liquidity could make it more difficult for us to secure additional financing terms acceptable to us, if at all, and may materially and adversely affect the terms of any financing that we may obtain and our stock price generally. Our continuation as a "going concern" is dependent upon, among other things, our ability to increase revenue, reduce operating expenses and obtain additional funding through the sale of equity and or debt securities, debt financing, a strategic transaction or otherwise. However, there are significant risks and uncertainties as to our ability to achieve these goals or obtain required funding on commercially reasonable terms or at all, including as a result of the potential adverse impact on our business from the COVID-19 pandemic. Due to these risks and uncertainties, we may need to reduce our activities significantly more than our current operating plan and cash flow projections assume in order to fund operations to the end of 2020. There can be no assurance that we will have sufficient cash flow and liquidity to fund our planned activities, which could force us to significantly reduce or curtail our activities and, ultimately, potentially cease operations.

The sale of additional equity or convertible debt securities could result in additional dilution to our stockholders. If we borrow additional funds or issue debt securities, lenders or security holders could have rights superior to holders of our common stock and such indebtedness could contain covenants that will restrict our operations. We might have to obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to our technologies, therapeutic candidates, or products that we otherwise would not relinquish. If we do not obtain additional resources, our ability to capitalize on business opportunities will be limited, we may be unable to compete effectively, and the growth of our business will be harmed.

SEC regulations limit the amount of funds we can raise during any 12-month period pursuant to our shelf registration statement on Form S-3.

SEC regulations limit the amount that companies with a public float of less than $75 million may raise during any 12-month period pursuant to a shelf registration statement on Form S3, or the Baby Shelf Rule. We are currently limited by the Baby Shelf Rule and are not able to use the remaining availability under our shelf registration statement to raise more than one-third of our public float. Furthermore, if we are required to file a new registration statement on another form, we may incur additional costs and be subject to delays due to review by the SEC staff.

Our reported financial results may be adversely affected by new accounting pronouncements or changes in existing accounting standards and practices.

Generally accepted accounting principles in the United States, or GAAP, are subject to interpretation by the Financial Accounting Standards Board, or FASB, the American Institute of Certified Public Accountants, or the AICPA, the SEC and various bodies formed to promulgate and interpret appropriate accounting principles.

Such changes to our accounting and GAAP reporting may significantly affect our results of operations to the extent that actual results differ significantly from estimated and previous quarter results or vary materially from quarter to quarter. While the adoption of the new standards will not change the cash flows, we receive from our contracts with customers, the changes to our reporting practices and the potential fluctuations in our reported results could cause a decline and/or fluctuation in the price of our common stock.

Risks Related to Our Business and the Development of Our gammaCore Therapy

If third-party payers do not provide adequate coverage and reimbursement for the use of gammaCore, we may be unable to generate significant revenues.

Our success in marketing and commercializing gammaCore depends and will depend in large part on whether U.S. and international government health administrative authorities, private health insurers and other payer organizations provide adequate coverage and reimbursement for the cost of our products. Many third-party payers do not currently cover VNS for any indications other than epilepsy because they have determined all other VNS modalities to be investigational or experimental. If physicians or insurers do not find our clinical data compelling or wish to wait for additional studies, they may choose not to use or provide coverage and reimbursement for gammaCore. We cannot provide assurance that data we or others may generate in the future will be consistent with that observed in our existing clinical studies, or that our current or future published clinical evidence will be sufficient to obtain adequate coverage and reimbursement for our products.

In the United States, we expect to derive nearly all of our sales from prescriptions of gammaCore written by neurologists and primary care physicians. Access to adequate coverage and reimbursement by third-party payers for treatment of cluster and migraine headaches using our gammaCore therapy is essential to the acceptance of our products by customers and patients, because without such coverage and reimbursement, customers and patients will have to be willing to bear the entire cost of our therapy.

Third-party payers, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for our gammaCore therapy exists among third-party payers. Therefore, coverage and reimbursement for our gammaCore therapy can differ significantly from payer to payer. In addition, payers continually review new technologies for possible coverage and can, without notice, deny coverage for these new products and procedures. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our gammaCore therapy to each payer separately, with no assurance that coverage and adequate reimbursement will be obtained or maintained if obtained.

Reimbursement systems in international markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. In many international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Further, many international markets have government-managed healthcare systems that control reimbursement for new devices and procedures. In most markets, there are private insurance systems as well as government-managed systems. If sufficient and timely coverage and reimbursement is not available for our current or future products, in either the United States or internationally, the demand for our products and our revenues will be adversely affected.

Regulatory requirements from executing upon our commercialization strategy and changes to payers' prescription benefit plans and medical pathway plans could adversely impact our business and financial results.

While we have started discussions with the Centers for Medicare and Medicaid Services, our products are not currently covered by Medicare and Medicaid. Applicable Medicare Part D regulations and federal and state laws will impose additional requirements on us upon execution of our commercialization strategy. Our commercialization strategy, including our planned reimbursement approach with respect to our gammaCore therapy, is likely to subject us to additional audit oversight requirements, and if material contractual or regulatory non-compliance were to be identified, applicable sanctions and/or monetary penalties may be imposed, which could have an adverse effect on our financial position, results of operations or cash flows.

In time, changes in payer prescription benefit plans or medical pathway plans could have the effect of rendering existing pharmacy benefit plans or medical pathway plans less valuable to beneficiaries and reduce the total market for our gammaCore therapy. In addition, some payers could decide to discontinue providing full or partial coverage to their members for our gammaCore therapy, which could have an adverse effect on our financial position, results of operations or cash flows.

The recent outbreak of the novel coronavirus could have a significant negative impact on the Company's business, revenues, financial condition and results of operations.

The novel coronavirus outbreak has severely restricted the level of economic activity around the world. Many governments are taking preventative or protective actions, including restrictions on travel and business operations and advising or requiring individuals to limit or forego their time outside of their homes. Temporary closures of many businesses have been ordered and numerous other businesses have temporarily closed voluntarily. Further, individuals' ability to travel has been curtailed through mandated travel restrictions and may be further limited through additional voluntary or mandated closures of travel-related businesses. These actions have expanded significantly in the past several weeks and are expected to continue to expand in scope, type and impact.

We cannot predict the degree to, or the time period over, which our business will be affected by the coronavirus outbreak. There are numerous associated uncertainties, including the number of individuals who will become infected, whether a vaccine or cure that mitigates the effect of the virus will be synthesized, and, if so, when such vaccine or cure will be ready to be used, the extent of the protective and preventative measures that have been put in place by both governmental entities and other businesses and those that may be put in place in the future, whether the virus's impact will be seasonal and numerous other uncertainties. The aforementioned uncertainties may result in delays or modifications to our plans and initiatives.

This coronavirus outbreak has also impacted, and may continue to impact, our headquarters and warehouses, as well as those of its third party vendors, including through the effects of facility closures, reductions in operating hours, staggered shifts and other social distancing efforts, labor shortages, decreased productivity and unavailability of materials or components. For example, we have closed our New Jersey office and warehouse as a result of state-imposed restrictions. The novel coronavirus outbreak may also impact our ability to sell our products and may increase our costs.

Additionally, our sales and marketing efforts with the VA and DoD are adversely affected by recent implemented protocols for screening and restricting outside visitors and vendors. Officially imposed quarantines and self-quarantines could also interfere with patients' ability to see a health care provider and obtain our gammaCore therapy.

For the reasons set forth above and other reasons that may come to light due to the novel coronavirus outbreak and any associated protective or preventative measures, we ae unable to reasonably estimate the impact to our business, revenues, financial condition and results of operations; however, such impact could be significantly negative.

Our commercialization strategy may expose us to increased billing, cash application and credit risks.

Our commercialization strategy may involve funding for our gammaCore therapy through medical benefit coverage, the majority of which is provided by private insurers, as well as reimbursement by government agencies. Such claims are generally for very high-priced medicines, and collection of payments from insurance companies, patients and other payers generally takes substantially longer than for those claims administered through a pharmacy benefit manager. Because of the high cost of these claims, complex billing requirements and the nature of the medical benefit coverage determination process, these accounts receivable are characterized by higher risk in collecting the full amounts due and applying the associated payments.

Revenues from the sale of our gammaCore therapy depend on the continued availability of reimbursement by government and private insurance plans. The government's Medicare regulations are complex and, as a result, the billing and collection process is time-consuming and typically involves the submission of claims to multiple payers whose payment of claims may be contingent upon the payment of another payer. Because of the coordination with multiple payers and the complexity in determining reimbursable amounts, these accounts receivable have higher risk in collecting the full amounts due and applying the associated payments.

Our gammaCore therapy commercialization strategy may require premium payments from members for the ongoing benefit, as well as amounts due from insurers and government-sponsored or national health insurance programs. As a result of the demographics of the consumers covered under these programs and the complexity of the calculations, as well as the potential magnitude and timing of settlement for amounts due from insurers and government-sponsored or national health insurance programs, these accounts receivable may be subject to billing and realization risk. Additionally, we may be subject to increased credit risk associated with state and local government agencies experiencing increased fiscal challenges. As a result of these aforementioned risks, our commercialization strategy, even if successful, may involve recordation of bad debt expenses potentially impacting our results of operations and liquidity.

Third-party payers have been resistant to cover gammaCore through pharmacy benefit plans, which has hindered our commercialization strategy and required changes to our existing business that could delay and negatively impact our ability to generate revenue.

In the United States our initial strategy to obtain reimbursement for gammaCore under payers' pharmacy benefit has not achieved adequate coverage and reimbursement. To obtain coverage and reimbursement from Medicare and any other third-party payer that will not cover gammaCore under a pharmacy benefit, we are seeking coverage and reimbursement as a medical device or item of durable medical equipment. While this would provide coverage for the therapy under a patient's medical insurance, patients may be unwilling to pay out of pocket for deductibles and co-pays for the therapy. Any determination by commercial payers to provide coverage for gammaCore through the medical benefit pathway and not through pharmacy benefit pathway will further delay or pose more risks to our commercial plan for gammaCore therapy since additional medical device codes required and we may incur additional direct and indirect expenses in assisting patients with their co-pay or other costs emergent from the determination by payers to not cover gammaCore under the pharmacy benefit pathway. Coverage by commercial payers through the medical benefit pathway or other decisions by commercial payers that have the effect of making patients personally responsible for the costs of, or costs associated with, our gammaCore therapy could adversely impact our results of operations and financial condition.

These potential changes may entail numerous risks, including increased operating expenses, requirements to comply with healthcare regulatory laws, the loss of or delay in obtaining revenue, and uncertainty in our ability to successfully implement the modifications. The failure to obtain recognition by third-party payers under the pharmacy benefit model has required us to modify our commercialization strategy, our distribution model, our pricing, and our operations, any of which could have a material adverse effect on the sales of gammaCore and the results of our operations and financial condition.

We must demonstrate to physicians the medical and economic benefits of our gammaCore therapy compared to those of our competitors.

Physicians play a significant role in determining the course of a patient's treatment and, as a result, the type of product that will be used to treat a patient. As a result, our success depends, in large part, on effectively marketing our gammaCore therapy to physicians. We have received several 510(k) clearances from the FDA for gammaCore therapy, however, such clearances do not necessitate adoption by physicians. In order for our gammaCore therapy to gain widespread adoption, we must successfully demonstrate to physicians the medical and economic benefits of our gammaCore therapy compared to competitors' products, including (i) BOTOX marketed by Allergan plc, (ii) CGRP receptor agonists marketed by Amgen Inc. (with a co-marketing arrangement with Novartis International AG), Allergan plc, Eli Lilly and Company, and Teva Pharmaceutical Industries Ltd., Biohaven Pharmaceuticals Inc., (iii) lasmiditan, marketed by Eli Lilly, (iv) Vycpti, an intravenous preventive treatment for migraine marketed by H. Lundbeck A/S, and (v) neuromodulation devices that have been marketed for the acute treatment and/or prevention of migraine, including the Cefaly, Eneura, Nerivio, and the sTMS mini devices. We also may face challenges because noninvasive VNS, or nVNS, is relatively new as compared to existing traditional treatments for cluster and migraine headaches. Acceptance of our gammaCore therapy depends on educating physicians as to the distinctive characteristics, perceived benefits, safety, ease of use and cost-effectiveness of our

gammaCore therapy as compared to our competitors' products and communicating to physicians the proper use of our gammaCore therapy. If we are not successful in convincing physicians of the merits of our gammaCore therapy or educating them on the benefits of our gammaCore therapy, they may not prescribe our gammaCore therapy and we may be unable to increase our sales, sustain our growth or achieve profitability. In addition, we believe support of our products by physicians is essential for market acceptance and adoption. If we do not receive support from physicians or long-term data does not show the benefits of using our gammaCore therapy, physicians may not use it. In such circumstances, our results of operations would be materially adversely affected.

Stimulating therapeutically relevant fibers in the vagus nerve by a proprietary high-frequency burst waveform that passes through the skin cells represents a novel approach to treating pain, and we must overcome significant challenges in order to successfully develop, commercialize and manufacture our product.

We have concentrated our development and commercialization efforts on products based on a platform of stimulating therapeutically relevant fibers in the vagus nerve by a proprietary high-frequency burst waveform that passes through the skin. We believe that our product platform represents a novel approach to treating pain. However, to date, the FDA has cleared only our product for commercialization based on this platform. The processes and requirements imposed by the FDA or other applicable health authorities may cause delays and additional costs in obtaining approvals for marketing authorization for our products. Because our platform is novel, regulatory agencies, as well as insurance and other coverage providers and payers, may lack experience in evaluating product candidates like gammaCore and gammaCore Sapphire. This inexperience may lengthen the regulatory review process, increase our development costs and delay or prevent reimbursement and commercialization of our platform products. Additionally, advancing this novel platform creates significant challenges for us, including:

- training a sufficient number of medical personnel on how to properly administer our product;
- enrolling sufficient numbers of patients in clinical trials;
- manufacturing our products on a large scale and in a cost-effective manner;
- submitting applications for and obtaining regulatory approval, as the FDA and other regulatory authorities have limited experience with commercial development of our product platform for treating pain; and
- establishing sales and marketing capabilities, as well as developing a manufacturing process and distribution network to support the commercialization of any approved products.

We must be able to overcome these challenges in order for us to successfully develop, commercialize and manufacture our product candidates.

Our operating results may vary significantly from quarter to quarter because of seasonality or otherwise.

Our quarterly revenue and results of operations may fluctuate from quarter to quarter due to, among others, the following reasons:

- physician and payer acceptance of our gammaCore therapy;
- the timing of when individual payer coverage becomes available;
- the timing, expense and results of research and development activities, clinical trials and regulatory clearance or approvals;
- fluctuations in our expenses associated with expanding our commercial operations and operating as a public company;
- the introduction of new products, therapies and technologies by competitors;
- the productivity of our territory business managers;
- supplier, manufacturing or quality problems with our products;
- the timing of stocking orders from our distributors;
- changes in our pricing policies or in the pricing policies of our competitors or suppliers;
- adverse developments in coverage amounts, benefit pathway, or government and third-party payers' reimbursement policies; and
- the timing of customer budget cycles.

Our results may also fluctuate on a seasonal basis due to the seasonality of cluster and migraine headache attacks, which could affect the comparability of our results between periods. These seasonal variations are difficult to predict accurately, may vary across different markets, and at times may be entirely unpredictable, which introduces additional risk into our business as we may rely upon forecasts of customer demand to build inventory in advance of anticipated sales. In addition, we believe our limited history commercializing our gammaCore therapy has, in part, made our seasonal patterns more difficult to discern, making it more difficult to predict future seasonal patterns.

Because of these and other factors, it is likely that in some future period our operating results will not meet investor expectations or those of public market analysts.

Any unanticipated change in revenues or operating results is likely to cause our stock price to fluctuate. New information may cause investors and analysts to revalue our business, which could cause a decline in our stock price.

Failure to protect our information technology infrastructure against cyber-based attacks, network security breaches, service interruptions, or data corruption could significantly disrupt our operations and adversely affect our business and operating results.

We rely on information technology and telephone networks and systems, including the internet, to process and transmit sensitive electronic information and to manage or support a variety of business processes and activities, including sales, billing, marketing, procurement and supply chain, manufacturing, and distribution. We also rely on information technology systems to support our proprietary data warehouse, which, among other things, maintains patient product serial numbers and allows for prescription refills at specialty pharmacies through RFID cards. In addition, we use enterprise information technology systems to record, process, and summarize financial information and results of operations for internal reporting purposes and to comply with regulatory, financial reporting, legal, and tax requirements. Our information technology systems, some of which are managed by third-parties, and the information technology systems of third parties may be susceptible to damage, disruptions, or shutdowns due to computer viruses, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures, user errors, or catastrophic events. Despite the precautionary measures we and third parties have taken to prevent breakdowns in information technology and telephone systems, if these systems are breached or suffer severe damage, disruption, or shutdown and we are unable to effectively resolve the issues in a timely manner, our business and operating results may suffer, and we may be subject to related lawsuits.

We may engage in future acquisitions that increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

We may evaluate various strategic transactions, including licensing or acquiring complementary therapies, products, technologies or businesses. Any potential acquisitions may entail numerous risks, including increased operating expenses and cash requirements, assimilation of operations and products, retention of key employees, diversion of our management's attention and uncertainties in our ability to maintain key business relationships of the acquired entities. In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

If serious adverse events or other undesirable side effects are identified during the use of our gammaCore therapy in investigator-sponsored trials, it may adversely affect our development of such product candidates.

Undesirable side effects caused by our gammaCore therapy could cause us or regulatory authorities to interrupt, delay or halt nonclinical studies and clinical trials, or could make it more difficult for us to enroll patients in our clinical trials and could, if injuries occur, result in product liability litigation. If serious adverse events or other undesirable side effects or unexpected characteristics of our gammaCore therapy are observed in investigator-sponsored trials, further clinical development of such product candidate may be delayed or we may not be able to continue development of such product candidate at all, and the occurrence of these events could have a material adverse effect on our business. Undesirable side effects caused by our gammaCore therapy could also result in the delay or denial of regulatory clearance or approval by the FDA or other regulatory authorities or in more restrictive labels than we desire.

Clinical trials are very expensive, time-consuming and difficult to design and implement and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials.

The risk of failure for our gammaCore therapy in additional treatment areas is high. It is difficult if not impossible to predict when or if any of our product candidates will receive regulatory clearance or approval in additional areas of indication. To obtain the requisite regulatory clearance or approvals to market and sell our gammaCore therapy in additional indications, we must demonstrate through extensive preclinical studies and clinical trials that it is safe and effective in humans for use in each additional target indication. Clinical testing is expensive and can take many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the clinical trial process.

In addition, the results of preclinical studies and early clinical trials may not be predictive of the results of later-stage preclinical studies or clinical trials. The results generated to date in preclinical studies or clinical trials for our gammaCore therapy in cluster and migraine headaches do not ensure that later preclinical studies or clinical trials will demonstrate similar results in other therapeutic indications, and it should be noted that we did not achieve the primary endpoints in our pivotal trials for cluster and migraine headaches. There can be no assurance that the FDA and other regulatory authorities will be satisfied by data from our clinical trials for other treatment indications, even where we believe such data to be compelling. Our gammaCore therapy may fail to show the desired safety and efficacy traits in additional areas of indication in future clinical trials despite having progressed through preclinical and earlier stage clinical trials. Many companies in the pharmaceutical and medical device industries have suffered significant setbacks in later-stage clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials, and we cannot be certain that we will not face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing clearance or approval of their products.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen and other clinical trial protocols, and the rate of dropout among clinical trial participants. If we fail to produce positive results in our planned preclinical studies or clinical trials of any of our product candidates, the development timeline and regulatory clearance and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, would be materially adversely affected.

Any clinical trial we conduct in the United States may subject us to additional costs and detriments compared to a foreign clinical trial, which may negatively impact our financial condition and our business.

Conducting any clinical trial within the United States may subject us to additional costs and drawbacks, which may negatively impact our financial condition and our business. The costs of a foreign clinical trial, or FCT, may be significantly lower than costs of an equivalent trial in the United States, as the materials and location costs of an FCT may be lower than a trial within the United States. Electing to run a clinical trial within the United States may impose significant added financial costs compared to a FCT. Among other factors, the faster recruitment of patients overseas and completion of trials in a FCT may represent considerable cost savings that we would forego in conducting clinical trials within the United States. These and other costs from conducting any clinical trial for our gammaCore therapy instead of a FCT may negatively impact our financial condition and our business. In addition, a FCT may offer other non-financial benefits such as a larger potential population of qualified patients to participate in clinical trials compared against the potential enrollee population in the United States, where clinical trials may compete for a limited number of the same potential patients. These and other foregone benefits of a FCT may negatively impact our financial condition and our business.

We depend on enrollment of patients in our clinical trials for our product candidates. If we are unable to enroll patients in our clinical trials, our research and development efforts could be adversely affected.

Identifying and qualifying patients to participate in clinical trials for our gammaCore therapy in additional areas of indications is critical to our success. Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients who remain in the study until its conclusion. If we are unable to enroll a sufficient number of patients in our clinical trials, our timelines for recruiting patients, conducting clinical trials and obtaining regulatory clearance or approval of our gammaCore therapy in additional areas of indication may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of our clinical trials altogether.

We cannot predict how successful we will be at enrolling patients in future clinical trials. Patient enrollment is affected by other factors including:

- the eligibility criteria for the trial in question;
- the perceived risks and benefits of the product candidate in the trial;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating or drugs that may be used off-label for these indications;
- the size of the patient population required for analysis of the trial's primary endpoints;
- competition for patients for competitive product candidates undergoing clinical trials;
- the efforts to facilitate timely enrollment in clinical trials;
- the design of the trial;

- the patient referral practices of physicians;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the ability to monitor patients adequately during and after treatment;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion;
- the ability to obtain and maintain patient consents;
- the number of patients with the indication being studied and the difficult of diagnosing the relevant condition or disease; and
- the proximity and availability of clinical trial sites for prospective patients.

In addition, our clinical trials will compete with other clinical trials that are in the same therapeutic areas as we are targeting, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors.

Delays in the completion of any clinical trial of our gammaCore therapy will increase our costs, slow down our expansion into additional treatment indications and approval process, and delay or potentially jeopardize our ability to commence product sales and generate future revenue. In addition, many of the factors that may lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory clearance or approval of our gammaCore therapy in additional treatment indications.

Clinical trials may be delayed, suspended or terminated for many reasons, which will increase our expenses and delay the time it takes to develop and expand our gammaCore therapy in additional treatment indications.

We may experience delays in our ongoing or future preclinical studies or clinical trials, and we do not know whether future preclinical studies or clinical trials will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. The commencement and completion of clinical trials may be delayed, suspended or terminated as a result of many factors, including:

- the FDA or other regulators disagreeing as to the design, protocol or implementation of our clinical trials;
- the delay or refusal of regulators or institutional review boards, or IRBs, to authorize us to commence a clinical trial at a prospective trial site;
- changes in regulatory requirements, policies and guidelines;
- delays or failure to reach agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in patient enrollment and variability in the number and types of patients available for clinical trials;
- the inability to enroll a sufficient number of patients in trials, particularly in orphan indications, to observe statistically significant treatment effects in the trial;
- having clinical sites deviate from the trial protocol or dropping out of a trial;
- negative or inconclusive results from ongoing preclinical studies or clinical trials, which may require us to conduct additional preclinical studies or clinical trials or to abandon projects that we expect to be promising;
- safety or tolerability concerns that could cause us to suspend or terminate a trial if we find that the participants are being exposed to unacceptable health risks;
- reports from preclinical or clinical testing of other similar therapies that raise safety or efficacy concerns;
- regulators or IRBs requiring that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or safety concerns, among others;
- lower than anticipated retention rates of patients and volunteers in clinical trials;
- our CROs or clinical trial sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a trial;
- delays relating to adding new clinical trial sites;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- delays in establishing the appropriate dosage levels;
- the quality of the product candidate falling below acceptable standards;
- the inability to manufacture sufficient quantities of our gammaCore therapy to commence or complete clinical trials; and
- exceeding budgeted costs due to difficulty in accurately predicting costs associated with clinical trials.

In particular, in connection with the comprehensive redeployment plan and cost reduction implemented in June 2019, we have postponed certain clinical trials in indications that are more exploratory in nature.

We could also encounter delays if a clinical trial is suspended, terminated, or paused by us, as we have done with our Premium II trial, by the IRBs or ethics committees of the institutions at which such trials are being conducted, by the data safety monitoring board for such trial or by the FDA or other regulatory authorities. Such authorities may suspend or

terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements, including the FDA's current Good Clinical Practice, or GCP, regulations, or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In light of the March 2020 FDA clearance, as well as challenges to study protocols, related datasets, and our business arising out of the novel coronavirus pandemic, we may also choose to terminate the Premium II study and take other actions to further reduce operating costs including reductions in our workforce.

In addition, we may encounter delays if the FDA, or other regulators, conclude that our financial relationships with investigators results in a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of the data generated at the applicable clinical trial site or the utility of the clinical trial itself. Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash compensation and/or stock options in connection with such services. If these relationships and any related compensation to or ownership interest by the clinical investigator carrying out the study result in perceived or actual conflicts of interest, or if the FDA or other regulators conclude that the financial relationship may have affected interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA. Any such delay or rejection could prevent us from commercializing any of our products currently in development.

If we experience delays in the commencement or completion of any clinical trial of our product candidates, or if any of our clinical trials are terminated, the commercial prospects of our gammaCore therapy may be harmed, and our ability to generate revenue from sales may be delayed or materially diminished.

We do not know whether any of our future preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence sales and generate associated revenue. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial, suspension or revocation of expanded regulatory clearance or approval of our product candidates. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates.

Even if our products are approved or cleared in the United States and obtained a CE Certificate of Conformity in the EEA, comparable regulatory authorities of additional foreign countries must also approve the manufacturing and marketing of our products in those countries. Approval and clearance procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States or the EEA, including additional preclinical studies or clinical trials. Any of these occurrences may harm our business, financial condition and prospects significantly.

Our reduction in force and cost-control efforts might not assure profitability and may affect morale and make it difficult to retain employees or attract new ones.

In June 2019, we implemented a reduction in force affecting approximately 32 employees (approximately 33% of our workforce), and redeployed resources across our organization. The effort was intended to focus us on currently available and near-term revenue opportunities and on clinical programs specifically designed to expand the gammaCore product labeling. However, our cost reduction efforts do not assure profitability. Additional cost reductions are expected to be implemented in the future, and cost savings may be offset by future hiring or other costs incurred in pursuing strategic objectives. The reduction in force and strategic redeployment could adversely affect morale in our organization and our reputation as an employer, which could lead to the loss of valued employees and could make it more difficult for us to hire new employees in the future, and the reduction of our headcount could adversely affect our operations and make it more difficult for us to pursue new opportunities and initiatives in the future.

If we fail to properly manage our anticipated growth, our business could suffer

We have a relatively short history of operating as a commercial company. We intend to seek to continue to grow and may experience periods of rapid growth and expansion, which could place a significant additional strain on our limited personnel, information technology systems and other resources. In particular, maintaining our direct sales force in the United States requires significant management, financial and other supporting resources. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our commercialization and development goals.

In the future, we may experience difficulties with manufacturing, quality control, component supply, inventory, distribution and shortages of qualified personnel, among other problems. These problems could result in delays in availability of our gammaCore therapy and increases in expenses. Any such delay or increased expense could adversely affect our ability to generate our revenue.

Future growth will also impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. In addition, rapid and significant growth will place a strain on our administrative and operational infrastructure.

In order to manage our operations and growth we will need to continue to improve our operational and management controls, reporting and information technology systems and financial internal control procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our operating results and business could suffer.

If we fail to develop and retain an effective direct sales force in the United States, our business could suffer.

We have significantly reduced our direct salesforce as part of our cost control efforts. In order to continue to market and sell our gammaCore therapy, in the United States, we may in the future need to substantially expand, our direct sales force. There is significant competition for such personnel. Once hired, the training process is lengthy because it requires significant education for new territory business managers to achieve the level of clinical competency with our products expected by physicians. Upon completion of the training, our territory business managers typically require lead time in the field to grow their network of accounts and achieve the productivity levels we expect them to reach in any individual territory. Furthermore, the use of our products often requires or benefits from direct support from us. If we are unable to attract, motivate, develop and retain a sufficient number of qualified sales personnel, and if our territory business managers do not achieve the productivity levels, we expect them to reach, our revenue will not grow at the rate we expect and our financial performance will suffer. Also, to the extent we hire personnel from our competitors, we may have to wait until applicable non-competition provisions have expired before deploying such personnel in restricted territories or incur costs to relocate personnel outside of such territories, and we have been in the past, and may be subject to future allegations that these new hires have been improperly solicited, or that they have divulged to us proprietary or other confidential information of their former employers. Any of these risks may adversely affect our business.

We only recently began commercializing our gammaCore therapy for the acute treatment of eCH, prevention of cluster headache, preventive or acute treatment of migraine in the United States and we may never achieve market acceptance.

We have a limited history of commercializing our product outside the United States, and a very limited history of selling our gammaCore therapy in the United States. Our gammaCore therapy received *de novo* grant and clearance by the FDA for the acute treatment of pain associated with eCH in adults in April 2017. Our gammaCore therapy was later cleared by the FDA in January 2018 for the acute treatment of pain associated with migraine in adults and in December 2018 the FDA cleared gammaCore therapy as the first product labeled for the prevention of CH. In March 2020, the FDA cleared gammaCore therapy for the preventive treatment of migraine. Furthermore, our gammaCore therapy has not yet been cleared by the FDA for treatment of chronic CH. We have limited experience engaging in commercial activities and limited established relationships with physicians, hospitals and payers as well as third-party suppliers on whom we depend for the manufacture of our product components. We may be unable to gain broader market acceptance in the countries in which we have already begun to commercialize our gammaCore therapy, or, if approved by the FDA for additional indications, unable to successfully commercialize it in the United States for a number of reasons, including:

- established competitors with strong relationships with customers, including physicians, hospitals and third-party suppliers;
- limitations in our ability to demonstrate differentiation and advantages of our product compared to competing products and the relative safety, efficacy and ease of use of our product;
- the limited size of our sales force and the learning curve required to gain experience selling our product;
- the inability to obtain sufficient supply of the product components for our gammaCore therapy from our primary and secondary manufacturers and suppliers;
- insufficient financial or other resources to support our commercialization efforts necessary to reach profitability; and
- the introduction and market acceptance of new, more effective or less expensive competing products and technologies.

If our competitors are better able to develop and market CH and migraine treatments that are safer, more effective, less costly, easier to use or otherwise more attractive than our gammaCore therapy, our business will be adversely impacted.

The pharmaceutical and medical device industries are highly competitive and subject to rapid innovation and change. Our success depends, in part, upon our ability to establish a competitive position in the cluster and migraine markets by securing broad market acceptance of our gammaCore therapy. We believe that the primary competitive factors in the cluster and migraine markets are demonstrated clinical effectiveness, product safety, reliability and durability, ease of use, product support and service, minimal side effects and salesforce experience and relationships. We face significant competition in the United States and internationally, which we believe will intensify over time. Many of the companies developing or marketing competing products enjoy several advantages over us, including:

- more experienced and larger sales forces;
- greater name recognition;
- more established sales and marketing programs and distribution networks;
- earlier regulatory clearance or approval;
- long established relationships with physicians and hospitals;
- significant patent portfolios, including issued U.S. and foreign patents and pending patent applications, as well as the resources to enforce patents against us or any of our third-party suppliers and distributors;
- the ability to acquire and integrate our competitors and/or their technology;
- demonstrated ability to develop product enhancements and new product offerings;
- established history of product reliability, safety and durability;
- the ability to offer rebates or bundle multiple product offerings to offer greater discounts or incentives;
- greater financial and human resources for product development, sales, and marketing; and
- greater experience in and resources for conducting research and development, clinical studies, manufacturing, preparing regulatory submissions, obtaining regulatory clearance or approval for products and marketing approved products.

Our competitors may develop and patent processes or products earlier than us, obtain patents that may apply to us at any time, obtain regulatory clearance or approvals for competing products or processes more rapidly than us or develop more effective or less expensive products or technologies that render our technology or products obsolete or less competitive. We also face fierce competition in recruiting and retaining qualified sales, scientific, and management personnel, establishing clinical trial sites and enrolling patients in clinical studies. If our competitors are more successful than us in these matters, our business may be harmed.

Many of our competitors are large, well-established companies with substantially greater resources than us and have a long history of competing in the CH and migraine markets.

Many of our current and potential competitors are publicly traded, or are divisions of publicly traded, major pharmaceutical and medical device companies that have substantially greater financial, technical, sales and marketing resources than we do. We will face steep competition from Allergan plc, Amgen Inc., H. Lundbeck A/S, Novartis International AG, Teva Pharmaceutical Industries Ltd., and Eli Lilly and Company, among other established and potential competitors that may be better capitalized and have a history of commercializing products around the world. Also, several neuromodulation devices are approved for the treatment and/or prevention of migraine, including Cefaly, Eneura, SpringTMS and Nerivo Migra. Given the size of the existing and potential market in the United States, we expect that as we continue our commercial efforts in the United States our current and future competitors will take aggressive action to protect their current market position.

We will face significant competition in establishing our market share in the United States and may encounter unforeseen obstacles and competitive challenges in the United States. In addition, some physicians have a long-standing practice of using the headache products of our larger, more established competitors. Physicians who use our competitors' products for the treatment of cluster and migraine headache may be reluctant to try new products from a source with which they are less familiar. If these physicians do not try and subsequently adopt our product, then our financial performance will be adversely affected.

Further, a number of our competitors are currently conducting, or we anticipate will be conducting, clinical trials to demonstrate the results of their headache products. The results of these trials may be equivalent to, or potentially better than, the results of our clinical trials, which could have a material adverse effect on us. The completion of our competitors' clinical trials with respect to their headache products could negatively impact the perception of us or our gammaCore therapy. In addition, perception by physicians, payers or patients that a competitor's product is superior to our gammaCore therapy or offers comparable benefits at a lower cost or lower incidence of undesirable side effects as compared against our gammaCore therapy, among other perception-driven outcomes in the market following competitors' completion of their clinical trials, could have a material adverse effect on us.

Traditional products used to treat CH and migraine have been available for decades, while our gammaCore therapy has only been commercially available in Europe for several years, and for approximately two years in the United States, and, as a result, we have a limited track record compared to our competitors.

Traditional products used to treat CH and migraine have been commercially available for decades, while we only began commercializing our gammaCore therapy in Europe to treat CH and migraine several years ago, and within the past two years in the United States. Because we have a limited commercial track record compared to our competitors and our gammaCore therapy generally has been utilized by patients for less time than other headache therapies, physicians may be slower to adopt or recommend our gammaCore therapy. Further, while we believe our international commercial experience and our clinical trials support the safety and effectiveness of our gammaCore therapy for the acute treatment of eCH, prevention of CH and migraine headache, future studies or patient experience over a longer period of time may indicate that treatment with gammaCore is less attractive than treatment with competitive products or that our gammaCore therapy causes unexpected or serious complications or other unforeseen negative effects. Such results would likely slow the adoption of our gammaCore therapy and significantly reduce our sales, which would harm our business and adversely affect our results of operations. Furthermore, if patients with traditional or other headache products were to experience unexpected or serious complications or other unforeseen effects, the market for our gammaCore therapy may be adversely affected, even if such effects are not directly attributable to our gammaCore therapy.

We may expend our limited resources to pursue a particular product candidate or disease and fail to capitalize on product candidates or diseases that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus our research programs and product candidates on specific conditions. As a result, we may forego or delay pursuit of opportunities with other product candidates or other diseases or conditions that may later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific conditions may not yield any commercially viable products.

Our international operations subject us to certain operating risks, which could adversely impact our results of operations and financial condition.

Sales of gammaCore outside the United States represented a substantial portion of our net sales in the years ended December 31, 2019 and 2018, respectively. In 2012, we began selling gammaCore in the EU through distributors. We sell gammaCore directly in four countries in the EU and through distributors and agents located in Munich, Germany and Leeds, U.K. The sale and shipment of gammaCore across international borders, as well as the purchase of components from international sources, subjects us to U.S. and foreign governmental trade, import and export, and customs regulations and laws.

Compliance with these regulations and laws is costly and exposes us to penalties for non-compliance. Other laws and regulations that can significantly impact us include various anti-bribery laws, including the U.S. Foreign Corrupt Practices Act, as well as export controls laws. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities and exclusion or debarment from government contracting.

The administration of President Trump has publicly supported potential trade proposals, including import tariffs and other tariffs, including the U.S. administration's recent introduction of tariffs on China and China's retaliatory tariffs on certain products from the United States, as well as modifications to international trade policy and other changes that may affect U.S. trade relations with other countries. We source a significant amount of the components used in gammaCore from Chinese sources so any tariffs or other trade restrictions impacting the import of these components from China could have a material adverse impact on us.

In addition, a pandemic of respiratory illness caused by a new coronavirus named COVID-19, or Coronavirus, which was first detected in Wuhan City, China, has resulted in tens of thousands of infections in China. If the Coronavirus worsens in China or if the Chinese government's efforts to contain the Coronavirus continue to restrict the movement of goods and people in China, our ability to import gammaCore components from China could be adversely affected.

Our international operations expose us and our distributors to risks inherent in operating in foreign jurisdictions. These risks include:

- difficulties in enforcing our intellectual property rights and in defending against third-party threats and intellectual property enforcement actions against us, our distributors or any of our third-party suppliers;
- reduced or varied protection for intellectual property rights in some countries;

- pricing pressure that we may experience internationally;
- a shortage of high-quality salespeople and distributors;
- third-party reimbursement policies that may require some of the patients who receive our products to directly absorb medical costs or that may necessitate the reduction of the selling prices of gammaCore;
- competitive disadvantage to competition with established business and customer relationships;
- foreign currency exchange rate fluctuations;
- the imposition of additional U.S. and foreign governmental controls or regulations;
- economic instability;
- changes in duties and tariffs, license obligations and other non-tariff barriers to trade;
- the imposition of restrictions on the activities of foreign agents, representatives and distributors;
- scrutiny of foreign tax authorities which could result in significant fines, penalties and additional taxes being imposed on us;
- laws and business practices favoring local companies;
- longer payment cycles;
- difficulties in maintaining consistency with our internal guidelines;
- difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- the imposition of costly and lengthy new export licensing requirements;
- the imposition of U.S. or international sanctions against a country, company, person or entity with whom we do business that would restrict or prohibit continued business with the sanctioned country, company, person or entity; and
- the imposition of new trade restrictions.

If we experience any of these risks, our sales in non-U.S. jurisdictions may be harmed and our results of operations would suffer.

Our results may be impacted by changes in foreign currency exchange rates.

We have international operations and, as a result, an increase in the value of the U.S. dollar relative to foreign currencies could require us to reduce our selling price or risk making our products less competitive in international markets, or our costs could increase. Also, if our international sales increase, we may enter into a greater number of transactions denominated in non-U.S. dollars, which could expose us to increased foreign currency risks, including currency fluctuations and exchange rate risks. We do not currently engage in any hedging transactions. If we are unable to address these risks and challenges effectively, our international operations may not be successful, and our business could be harmed.

We may not be able to establish or strengthen our brand.

We believe that establishing and strengthening the electroCore and gammaCore brands is critical to achieving widespread acceptance of our gammaCore therapy to treat eCH, prevent CH, prevent and treat migraine, particularly because of the highly competitive nature of the market for headache therapies. Promoting and positioning our brand will depend largely on the success of our marketing efforts and our ability to provide physicians with a reliable product for successful treatment of cluster and migraine headaches. Given the established nature of our competitors, and our lack of commercialization in the United States, it is likely that our future marketing efforts will require us to incur significant additional expenses. These brand promotion activities may not yield increased sales and, even if they do, any sales increases may not offset the expenses we incur to promote our brand. If we fail to successfully promote and maintain our brand, or if we incur substantial expenses in an unsuccessful attempt to promote and maintain our brand, our gammaCore therapy may not be accepted by physicians, which would adversely affect our business, results of operations and financial condition.

We may face product liability claims that could result in costly litigation and significant liabilities.

Manufacturing and marketing of gammaCore, and clinical testing of our gammaCore therapy may expose us to individual product liability claims, class action lawsuits or actions, and other individual or mass tort claims. Although we have, and intend to maintain, liability insurance, the insurers may deny our claims, coverage limits of our insurance policies may not be adequate and one or more successful claims brought against us may have a material adverse effect on our business and results of operations. These risks are heightened in the event any product recalls take place as a result of any product design defect or defect in product warnings or labeling. Product liability claims could negatively affect our reputation, our continued product sales and our ability to obtain and maintain regulatory clearance or approval for our products.

Our operating results and profitability may be adversely affected by increases in reserves for product returns, doubtful accounts receivable and inventory.

Our net sales and profitability are affected by changes in reserves to account for product returns, doubtful account receivable and inventory. Significant management judgment must be used, and estimates must be made in connection with establishing these reserves, and any increase thereto could adversely affect our reported financial results by reducing our net revenues and/or profitability for the reporting period.

If the financial condition of our customers were able to deteriorate resulting in an impairment of their ability to make payments or if third-party payors were to deny claims, additional provisions for doubtful accounts may be required.

We permit the return of damaged or defective products and accept limited amounts of product returns in certain instances. While such returns are expected to be nominal and within management's expectations and the provisions established, future return rates may increase more than anticipated. We have established a reserve in our financial statements for product returns and we will continue to analyze our returns to determine the adequacy of the reserve. Any significant increase in damaged or defective products or expected returns could have a material adverse effect on our operating results for the period or periods in which such returns materialize.

Additionally, damaged or defective products could (i) adversely affect our reputation and our end customers' willingness to buy products from us, (ii) adversely affect market acceptance or perception of our products, (iii) increase our service costs, (iv) cause us to lose significant end-customers, and (v) subject us to liability for damages and divert our resources from other tasks, any of which could materially and adversely affect our business, results of operations and financial condition.

If we fail to retain our key executives or recruit and hire new employees, our operations and financial results may be adversely affected while we attract other highly qualified personnel.

Our future success depends, in part, on our ability to continue to retain our executive officers and other key employees and recruit and hire new employees. All of our executive officers and other employees are at-will employees, and therefore may terminate employment with us at any time with no advance notice. The replacement of any of our key personnel likely would involve significant time and costs, may significantly delay or prevent the achievement of our business objectives and may harm our business. In particular, our potential revenue in the United Kingdom is dependent on a small number of certain key U.K. personnel.

In addition, many of our employees have unvested equity awards in a substantial amount of stock or stock options that have lost significant value since they were granted. Our employees may be more likely to leave us if the shares they own or the shares underlying unvested options have significantly depreciated in value relative to the original purchase prices of the shares or the exercise prices of the options, or if the exercise prices of the options that they hold are significantly above the market price of our common stock. Further, our employees' ability to exercise those options and sell their stock in a public market may result in a higher than normal turnover rate. In addition, our financial condition may preclude us from giving additional cash compensation to mitigate this risk.

Our future success also depends on our ability to retain executive officers and other key employees and attract new key employees. Many executive officers and employees in the pharmaceutical and medical device industries are subject to strict non-compete or confidentiality agreements with their employers, which may include our main competitors. In addition, some of our existing and future employees are or may be subject to confidentiality agreements with previous employers. Our competitors may allege breaches of and seek to enforce such non-compete agreements or initiate litigation based on such confidentiality agreements. Such litigation, whether or not meritorious, may impede our ability to attract or use executive officers and other key employees who have been employed by our competitors and may result in intellectual property claims against us. It is likely that we will experience similar aggressive lawsuit tactics by our competitors as they seek to protect their market position, particularly as we prepare to expand in new or existing markets.

Our future success depends on our leadership development and succession planning.

Effective succession planning is important to our long-term success. Failure to ensure effective transfer of knowledge and smooth transitions involving key employees and senior executives could hinder our strategic planning and execution. In particular, we appointed a new Chief Executive Officer in October 2019. Our ability to execute our business strategies, ensure a cohesive management team, and attract and retain key executives may be adversely affected by the uncertainty associated with the transition to a new chief executive officer.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or unauthorized activities that violates (1) the laws and regulations of the FDA and other similar regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (2) manufacturing standards, (3) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad, such as the General Data Protection Regulation in the European Union, and (4) laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of product candidates, which could result in regulatory sanctions and serious harm to our reputation.

Although we have adopted a code of business conduct and ethics, it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm and the curtailment or restructuring of our operations.

Risk Related to our Dependence on Third Parties

We rely upon primary and secondary third-party manufacturers for components of our gammaCore product, and multiple suppliers of consumer electronic components, and in certain cases sole-source suppliers for components and materials used in gammaCore, and for critical packaging services, making us vulnerable to supply shortages and problems and price fluctuations, which could harm our business.

A number of the critical components used in gammaCore are supplied to us from either a primary, or secondary manufacturer, and multiple suppliers of high-demand consumer electronic components, and in certain cases sole-source, suppliers. Our manufacturers and suppliers may encounter problems during manufacturing for a variety of reasons, including, for example, failure to follow specific protocols and procedures, failure to comply with applicable legal and regulatory requirements, equipment malfunction and environmental factors, failure to properly conduct their own business affairs, and infringement of third-party intellectual property rights, any of which could delay or impede their ability to meet our requirements. Our ability to supply gammaCore commercially depends, in part, on our ability to obtain a supply of these components that has been manufactured in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing. We have not entered into manufacturing, supply or quality agreements with suppliers of consumer electronic components, some of which supply components critical to our products. Although we believe that long-term agreements with these suppliers are not necessary as all the components in our products are either high-volume, non-custom commodity components or are readily available from multiple vendors, there can be no assurance that our multiple-source or sole-source suppliers will be able to meet our demand for their products and services, either because of the informal nature of our arrangements with those suppliers, or our limited experience with those suppliers, due to our relative importance as a customer to those suppliers, or due to supply chain disruptions that may arise such as those relating to the recent COVID-19, or Coronavirus pandemic or similar events. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers.

Establishing additional or replacement suppliers for the components or processes used in gammaCore, if required, may not be accomplished quickly. If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay. While we seek to maintain adequate inventory of the single-source or sole-source components and materials used in our products, any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders.

If our third-party suppliers fail to deliver the required commercial quantities of materials, or the level of services we require, on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality and on a timely basis, the continued commercialization of gammaCore would be impeded, delayed, limited or prevented, which could harm our business, results of operations, financial condition and prospects.

We rely in part on a small group of third-party distributors to effectively distribute our products outside the United States.

We depend in part on a small group of third-party distributors for the warehousing, programming and shipment of our products in certain territories in Europe. We depend on these distributors' efforts, yet we are unable to control their efforts completely. These distributors typically sell a variety of other non-competing products that may limit the resources they dedicate to our gammaCore therapy. In addition, we are unable to ensure that our distributors comply with all applicable laws regarding the sale of our products. If our distributors fail to effectively distribute gammaCore in full compliance with applicable laws, our operating results and business may suffer. Recruiting and retaining qualified third-party distributors and training them in our technology and product offerings requires significant time and resources. To develop and expand our distribution, we must continue to scale and improve our processes and procedures that support our distributors.

Further, if our relationship with a successful distributor terminates, we may be unable to replace that distributor without disruption to our business. If we fail to maintain positive relationships with our distributors, fail to develop new relationships with other distributors, including in new markets, fail to manage, train or incentivize existing distributors effectively, or fail to strike agreements with attractive terms, or if these distributors are not successful in their businesses, our revenue may decrease and our operating results, reputation and business may be harmed.

We rely upon a third-party distributor to distribute our products to specialty pharmacies in the United States.

For sales of gammaCore through specialty pharmacies in the United States, we currently rely upon one specialty pharmaceutical distributor. We depend on this distributor to distribute our products but are unable to control its performance. This distributor may distribute a variety of other specialty pharmaceutical products that may limit the resources dedicated to the distribution of our products. In addition, we are unable to ensure that this distributor will comply with all applicable laws related to the distribution of our products. If this distributor fails to distribute our products in compliance with applicable laws, our operating results and business may suffer. Recruiting, training and retaining third-party distributors in the distribution of our proprietary product offerings requires significant time and resources. In addition, an affiliate of this distributor provides adjudication of prescriptions and reimbursement claims, pharmaceutical patient hub services, including patient support and training, for patients that are prescribed our gammaCore therapy, and has been electronically integrated with our proprietary data warehouse system and web portal. Our agreement with this distributor is scheduled to expire on May 31, 2020. If our relationship with this distributor terminates, however, we may be unable to replace this distributor without disruption to our business. Any new distributor may not integrate as seamlessly with our data warehouse system and web portal, leading to disruptions in service for patients that are prescribed our therapy, which may cause these patients to seek alternative therapy. Our distributor also may not pay us on time or at all due to disputes, financial issues or bankruptcy events. Any such payment issues may materially affect our operating results until we are able to resolve the issues or find a sufficient replacement for our distributor.

Our status as a federal contractor subjects us to a wide variety of regulatory compliance, pricing, and contract-based requirements. Failure to comply with these requirements could adversely impact our ability to obtain future federal contracts, which could negatively impact us and our business.

We expect that a majority of our 2020 U.S. sales of gammaCore will be made pursuant to our qualifying contract on the FSS and open market sales to individual VA facilities. Our status as a contractor on FSS means that we are obligated to comply with a variety of federal procurement laws, regulations, and contract terms that require commercial price disclosures, commercial-to-federal price indexing, and compliance with various federal programs. Furthermore, as a federal contractor, we are also subject to contractual remedies and potential administrative, civil, and criminal damages and penalties for noncompliance with contract terms, overbilling, or misconduct. The cost of maintaining compliance with these requirements could adversely impact us and our business and complying with these requirements could divert managerial and financial resources. Additionally, failure to comply could result in us being excluded from the opportunity to renew existing federal contracts or to bid on federal future contracts for a period of time lasting up to several years. Any of these contingencies could have a material adverse effect on our business, financial condition and results of operations.

Our potential revenue in the United Kingdom is substantially dependent on government funding arrangements

In the United Kingdom, a recent award from the Innovation Technology Payment Program of the NHS and evidence-based recommendations published in December 2019 by NICE offer the potential for us to generate revenue from the treatment of CH. This is the primary commercial channel from which our United Kingdom revenue is derived. The cost of compliance with applicable U.K. laws and regulations could negatively harm us and our business. Additionally, the government funding arrangements provided by the NHS and NICE could be withdrawn if we do not comply with the terms and conditions of such arrangements, or if the programs are not extended or curtailed. Any of these contingencies could have an adverse effect on our potential U.K. revenue.

We rely on third parties to conduct and support our clinical trials and investigator – initiated trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We do not independently conduct clinical trials for our product candidates. We rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to perform this function. Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. Furthermore, some of the sites for our clinical trials and investigator-initiated trials are outside the United States. The performance of these sites may be adversely affected by various issues, including less advanced medical infrastructure, lack of familiarity with conducting clinical trials in accordance with U.S. standards, insufficient training of personnel, communication difficulties or change in local regulations. We remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the study. Moreover, the FDA requires us to comply with GCP for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of patients in clinical trials are protected. Furthermore, these third parties may also have relationships with other entities, including our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory clearance or approval for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products.

We also may rely on other third parties to store and distribute supplies for our clinical trials. Any performance failure on the part of our existing or future distributors could delay clinical development or regulatory clearance or approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenues.

If we do not successfully enter into future collaborations for the development, regulatory clearance and commercialization of our gammaCore therapy in international markets our business may be harmed.

We may choose to enter into collaboration agreements with third parties with respect to development, regulatory clearance and commercialization of our gammaCore therapy in international markets. We will have limited control over the amount and timing of resources that our collaborators dedicate to the development, regulatory clearance, or commercialization of our gammaCore therapy. Our ability to generate revenues from these arrangements will depend in part on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Despite carefully written collaboration agreements, collaborations involving our gammaCore therapy, are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development, regulatory clearance and commercialization of our product candidates or may elect not to continue or renew development, regulatory clearance, or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering our products that result from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

Any termination or disruption of any future collaboration could result in delayed development of product candidates, increased cost to develop product candidates or termination of development of a product candidate.

If we are not able to establish or maintain collaborations, we may have to alter some of our future development, regulatory clearance and commercialization plans.

Our product development programs, regulatory clearance and the potential commercialization of our gammaCore therapy will require substantial additional capital to fund expenses. For some of our product candidates, we may decide to collaborate with pharmaceutical and medical device companies for the future development, regulatory clearance and potential commercialization of those product candidates. Furthermore, we may find that our programs require the use of proprietary rights held by third parties, and the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights.

We face significant competition in seeking appropriate collaborators, and a number of more established companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Whether we reach a definitive agreement for a collaboration will depend upon, among other things, our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of clearance or approval by the FDA, compliance with the Essential Requirements of the EU Medical Devices Directive and from May 26, 2020, the General Safety and Performance Requirements of the EU Medical Devices Regulation or similar foreign regulations, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under existing license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. Even if we are able to obtain a license to intellectual property of interest, we may not be able to secure exclusive rights, in which case others could use the same rights and compete with us. If we are unable to successfully obtain rights to required third-party

intellectual property rights or maintain the existing intellectual property rights we have, we may have to curtail the development of such product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

We, or third-party manufacturers on whom we rely, may be unable to successfully sustain and to further scale-up manufacturing of our gammaCore therapy or its component parts in sufficient quality and quantity, which would delay or prevent us from developing and commercializing any approved products.

In order to conduct clinical trials of our gammaCore therapy and continue to commercialize approved products, we, or our manufacturers, will need to manufacture products in large quantities. We, or our manufacturers, may be unable to successfully sustain, or increase manufacturing capacity in a timely or cost-effective manner, or at all. In addition, quality issues may arise during further scale-up activities. If we, or any of our manufacturers, are unable to successfully sustain, or further scale-up manufacturing in sufficient quality and quantity, the development, testing, and clinical trials of our gammaCore therapy may be delayed or infeasible, and regulatory clearance, approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. If we are unable to obtain or maintain third-party manufacturing for commercial supply of our product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our gammaCore therapy successfully.

We are required to maintain high levels of inventory with our third-party manufacturers, due to lead times with single-source consumer electronic components vendors, which could consume a significant amount of our resources, reduce our cash flows and lead to inventory impairment charges.

Our gammaCore therapy consists of a substantial number of individual components. In order to market and sell effectively, we often must maintain high levels of inventory of the product and its components.

The manufacturing process requires lengthy lead times during which electronic components of our gammaCore therapy may become obsolete, and we may over- or under-estimate the amount needed of a given component, in which case we may expend extra resources or be constrained in the amount of end product that we can produce. As compared to direct manufacturers, our dependence on third-party manufacturers exposes us to greater lead times increasing our risk of adverse financial impact of inventory obsolescence comparatively. In addition, as of December 31, 2019 we had approximately $6.9 million of inventory. Our inventory significantly exceeds current demand for the gammaCore therapy, which also could result in an increased risk of adverse financial impact from inventory obsolescence.

Risks Related to Intellectual Property

We may in the future become involved in lawsuits to protect or enforce our intellectual property, which could be expensive and time consuming, and ultimately unsuccessful, and could result in the diversion of significant resources, thereby hindering our ability to effectively commercialize our existing or future products. If we are unable to obtain, maintain, protect, and enforce our intellectual property, our business will be negatively affected.

The markets in which we compete and expect to compete are subject to rapid technological change and frequent litigation regarding patent and other intellectual property rights. It is possible that our patents or licenses may not withstand challenges made by others or protect our rights adequately.

Our success depends in large part on our ability to secure effective patent protection for our products and processes in the United States and internationally. We have filed and intend to continue to file patent applications for various aspects of our technology and trademark applications to protect our brand and business, and copyright applications to protect our software. We seek to obtain and maintain patents and other intellectual property rights to restrict the ability of others to market products or services that misappropriate our technology and work product and/or infringe our intellectual property to compete with our products and services.

However, we face the risks that:

- We may fail to secure necessary patents, potentially permitting competitors to market competing products and services and make, use or sell products or offer services that are substantially the same as ours without incurring the sizeable development costs that we have incurred, which would adversely affect our ability to compete.
- Patents may not issue from any of our currently pending or future patent applications.

- Our already-granted patents and any future patents may not survive legal challenges to their scope, validity or enforceability, or provide significant protection for us, and they may be challenged in a post grant review or inter partes review proceeding, re-examined or invalidated, and/or may be found to be unenforceable or not cover competing processes, products or services.
- Even if our patents are determined by the U.S. Patent and Trademark Office, or USPTO, foreign patent office, or a court to be valid and enforceable, they may not be drafted or interpreted sufficiently broadly to prevent others from marketing products and services similar to ours or designing around our patents. For example, third parties may be able to develop therapies, or make systems or devices, that are similar to ours but that are not covered by the claims of our patents. Third parties may assert that we or our licensors were not the first to make the inventions covered by our issued patents or pending patent applications. The claims of our issued patents or patent applications when issued may not cover our commercial technology or the future products and services that we develop. We may not have freedom to operate unimpeded by the patent rights of others. Third parties may have dominating, blocking or other patents relevant to our technology of which we are not aware. In addition, because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after the filing of certain priority documents (or, in some cases, are not published until they issue as patents) and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for our technology or our contemplated technology. Any such patent applications may have priority over our patent applications or issued patents, which could further require us to obtain rights from third parties to issued patents or pending patent applications covering such technologies to allow us to commercialize our technology. If another party has filed a U.S. patent application on inventions similar to ours, depending on when the timing of the filing date falls under certain patent laws, we may have to participate in a priority contest (such as an interference proceeding) declared by the USPTO to determine priority of invention in the United States. There may be prior public disclosures of which we are not aware that could invalidate our patents or a portion of the claims of our patents. Further, we may not develop additional proprietary technologies and, even if we do, they may not be patentable.
- Patent law can be highly uncertain and involve complex legal and factual questions for which important principles remain unresolved. In the United States and in many foreign jurisdictions, policies regarding the breadth of claims allowed in patents can be inconsistent. The U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications, our ability to obtain patents, or the patents and patent applications of our licensors. Future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage, which could adversely affect our financial condition and results of operations.
- Monitoring unauthorized uses of our intellectual property is difficult and costly. From time to time, we seek to analyze our competitors' therapies, products and services, and may in the future seek to enforce our patents or other proprietary rights against potential infringement. However, the steps we have taken to protect our proprietary rights may not be adequate to prevent misappropriation of our intellectual property. We may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. Our competitors may also independently develop similar technology. Any inability to meaningfully protect our intellectual property could result in competitors offering products that incorporate our product features, which could reduce demand for our gammaCore therapy. In addition, we may need to defend our patents from third-party challenges, including interferences, derivation proceedings, re-examination proceedings, post-grant review, inter partes review, third-party submissions, oppositions, nullity actions, or other patent proceedings. We may need to initiate infringement claims or litigation. Adverse proceedings such as litigation can be expensive, time consuming and may divert the efforts of our technical and managerial personnel, which could in turn harm our business, whether or not we receive a determination favorable to us. In addition, in an infringement proceeding, a court may decide that the patent we seek to enforce is invalid or unenforceable or may refuse to enjoin the other party from using the technology at issue on the grounds that the patent in question does not cover the technology in question. An adverse result in any litigation could place one or more of our patents at risk of being invalidated or interpreted narrowly. Some of our competitors may be able to devote significantly more resources to intellectual property litigation, and may have patent portfolios, including significantly broader patent portfolios, to assert against us, if we assert our rights against them. Further, because of the substantial discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be disclosed or otherwise compromised during litigation.
- We may not be able to accurately estimate or control our future operating expenses in relation to obtaining, enforcing and/or defending intellectual property, which could lead to cash shortfalls. Our operating expenses may

fluctuate significantly in the future as a result of the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other patent related costs, including litigation costs and the results of such litigation.

- We may also be forced to enter into cross-license agreements with competitors in order to manufacture, use, sell, offer for sale, import and/or export products or services that are covered by our competitors' intellectual property rights. If we need to use our intellectual property to enter such cross-license agreements, it may compromise the value of our intellectual property due to the fact that our competitors may be able to manufacture, use, sell, offer for sale, import and/or export our patented technology.

We rely on a variety of intellectual property rights, and if we are unable to maintain or protect our intellectual property, our business and results of operations will be harmed.

Our commercial success will depend, in part, on our ability to obtain and maintain intellectual property protection for our products, processes, and related technologies in the United States, Europe and elsewhere, successfully defend our intellectual property rights against third-party challenges and successfully enforce our intellectual property rights to prevent third-party infringement. While we rely primarily upon a combination of patents, copyrights, trademarks and trade secret protection, as well as nondisclosure, confidentiality and other contractual agreements to protect the intellectual property related to our brands, products and other proprietary technologies, protection derived from patents is relatively limited.

The process of obtaining patent protection is expensive and time-consuming, and we may not be able to prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may choose not to seek patent protection for certain innovations or products and may choose not to pursue patent protection in certain jurisdictions, and under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope and, in any event, any patent protection we obtain may be limited. As a result, some of our products are not, and in the future may not be, protected by patents. We generally apply for patents in those countries where we intend to make, have made, use, offer for sale, or sell products and where we assess the risk of infringement to justify the cost of seeking patent protection. However, we do not seek protection in all countries where we sell products and we may not accurately predict all the countries where patent protection would ultimately be desirable. If we fail to timely file a patent application in any such country or major market, we may be precluded from doing so at a later date. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories in which we have patent protection that may not be sufficient to terminate infringing activities.

Furthermore, we cannot guarantee that any patents will be issued from any pending or future owned or licensed patent applications, or that any current or future patents will provide us with any meaningful protection or competitive advantage. Even if issued, existing or future patents may be challenged, including with respect to ownership, narrowed, invalidated, held unenforceable or circumvented, any of which could limit our ability to prevent competitors and other third parties from developing and marketing similar products or limit the length of terms of patent protection we may have for our products and technologies. Other companies may also design around technologies we have patented, licensed or developed. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our products or practicing our own patented technology.

The patent positions of pharmaceutical and medical device companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. The standards that the USPTO and its foreign counterparts use to grant patents are not always applied predictably or uniformly. Changes in either the patent laws, implementing regulations or the interpretation of patent laws may diminish the value of our rights. The legal systems of certain countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions.

Because patent applications in the United States, Europe and many other jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to conceive or reduce to practice the inventions claimed in our issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patents or pending patent applications. We can give no assurance that all of the potentially relevant art relating to our patents and patent applications has been found; overlooked prior art could be used by a third party to challenge the validity, enforceability and scope of our patents or prevent a patent from issuing from a pending patent application. As a result, we may not be able to obtain or maintain protection for certain inventions. Therefore, the validity, enforceability and scope of our patents in the United States, Europe and in other countries cannot be predicted with certainty and, as a result, any patents that we own, or license may not provide sufficient protection against our competitors.

Third parties may challenge any existing patent or future patent we own or license through adversarial proceedings in the issuing offices or in court proceedings, including as a response to any assertion of our patents against them. In any of these proceedings, a court or agency with jurisdiction may find our patents invalid and/or unenforceable, or even if valid and enforceable, insufficient to provide protection against competing products and services sufficient to achieve our business objectives. We may be subject to a third-party pre-issuance submission of prior art to the USPTO, or reexamination by the USPTO if a third party asserts a substantial question of patentability against any claim of a U.S. patent we own or license. The adoption of the Leahy-Smith America Invents Act, or the Leahy-Smith Act, in September 2011 established additional opportunities for third parties to invalidate U.S. patent claims, including inter partes review and post-grant review proceedings. Outside of the United States, patents we own, or license may become subject to patent opposition or similar proceedings, which may result in loss of scope of some claims or the entire patent. In addition, such proceedings are very complex and expensive, and may divert our management's attention from our core business. If any of our patents are challenged, invalidated, circumvented by third parties or otherwise limited or expire prior to the commercialization of our products, and if we do not own or have exclusive rights to other enforceable patents protecting our products or other technologies, competitors and other third parties could market products and use processes that are substantially similar to, or superior to, ours and our business would suffer.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep a competitive advantage. For example:

- others may be able to develop products that are similar to, or better than, ours in a way that is not covered by the claims of our patents;
- we might not have been the first to conceive or reduce to practice the inventions covered by our patents or pending patent applications;
- we might not have been the first to file patent applications for our inventions;
- any patents that we obtain may not provide us with any competitive advantages or may ultimately be found invalid or unenforceable; or
- we may not develop additional proprietary technologies that are patentable.

We may become involved in lawsuits to protect or enforce our patents, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file one or more lawsuit and assert infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable or may refuse to enjoin the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. The standards that courts use to interpret patents are not always applied predictably or uniformly and can change, particularly as new technologies develop. As a result, we cannot predict with certainty how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court. Further, even if we prevail against an infringer in U.S. district court, there is always the risk that the infringer will file an appeal and the district court judgment will be overturned at the appeals court and/or that an adverse decision will be issued by the appeals court relating to the validity or enforceability of our patents. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted in a manner insufficient to achieve our business objectives.

Our commercial success depends significantly on our ability to operate without infringing upon the intellectual property rights of third parties.

The pharmaceutical and medical device industries are subject to rapid technological change and substantial litigation regarding patent and other intellectual property rights. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for or obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products and services. Numerous third-party patents exist in the fields relating to our products and services, and it is difficult for industry participants, including us, to identify all third-party patent rights relevant to our products, services and technologies. Moreover, because some patent applications are maintained as confidential for a certain period of time, we cannot be certain that third parties have not filed patent applications that cover our products, services and technologies.

Patents could be issued to third parties that we may ultimately be found to infringe. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing products using our technology. Our failure to obtain or maintain a license to any technology that we require may materially harm our business, financial condition and results of operations. Furthermore, we would be exposed to a threat of litigation.

From time to time, we may be party to, or threatened with, litigation or other proceedings with third parties, including non-practicing entities, who allege that our products, components of our products, services, and/or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights. The types of situations in which we may become a party to such litigation or proceedings include:

- we or our collaborators may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties or to obtain a judgment that our products or processes do not infringe those third parties' patents;
- we or our collaborators may participate at substantial cost in International Trade Commission proceedings to abate importation of products that would compete unfairly with our products;
- if our competitors file patent applications that claim technology also claimed by us or our licensors, we or our licensors may be required to participate in interference, derivation or opposition proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third party with a dominant patent position;
- if third parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights, we and our collaborators will need to defend against such proceedings;
- if third parties initiate litigation or other proceedings seeking to invalidate patents owned by or licensed to us or to obtain a declaratory judgment that their products, services, or technologies do not infringe our patents or patents licensed to us, we will need to defend against such proceedings;
- we may be subject to ownership disputes relating to intellectual property, including disputes arising from conflicting obligations of consultants or others who are involved in developing our products; and
- if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or products infringe or misappropriate its patent or other intellectual property rights and/or that we breached our obligations under the license agreement, and we and our collaborators would need to defend against such proceedings.

These lawsuits and proceedings, regardless of merit, are time-consuming and expensive to initiate, maintain, defend or settle, and could divert the time and attention of managerial and technical personnel, which could materially adversely affect our business. Any such claim could also force use to do one or more of the following:

- incur substantial monetary liability for infringement or other violations of intellectual property rights, which we may have to pay if a court decides that the product, service, or technology at issue infringes or violates the third party's rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the third party's attorneys' fees;
- pay substantial damages to our customers or end users to discontinue use or replace infringing technology with non-infringing technology;
- stop manufacturing, offering for sale, selling, using, importing, exporting or licensing the product or technology incorporating the allegedly infringing technology or stop incorporating the allegedly infringing technology into such product, service, or technology;
- obtain from the owner of the infringed intellectual property right a license, which may require us to pay substantial upfront fees or royalties to sell or use the relevant technology and which may not be available on commercially reasonable terms, or at all;
- redesign our products, services, and technology so they do not infringe or violate the third party's intellectual property rights, which may not be possible or may require substantial monetary expenditures and time;
- enter into cross-licenses with our competitors, which could weaken our overall intellectual property position;
- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property against others;
- find alternative suppliers for non-infringing products and technologies, which could be costly and create significant delay; or
- relinquish rights associated with one or more of our patent claims, if our claims are held invalid or otherwise unenforceable.

Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays, or prohibit us from manufacturing, marketing or otherwise commercializing our products, services and technology. Any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operation, financial condition or cash flows.

In addition, we may indemnify our customers and distributors against claims relating to the infringement of intellectual property rights of third parties related to our products. Third parties may assert infringement claims against our customers or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or

distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers, suppliers or distributors, or may be required to obtain licenses for the products or services they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products or services.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a material adverse effect on the price of our common stock. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. The occurrence of any of these events may have a material adverse effect on our business, results of operation, financial condition or cash flows.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed.

In addition to patent, copyright, and trademark protection, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our consultants and vendors, or our former or current employees. We also enter into confidentiality and invention and patent assignment agreements with our employees and consultants. Despite these efforts, however, any of these parties may breach the agreements and disclose our trade secrets and other unpatented or unregistered proprietary information, and once disclosed, we are likely to lose trade secret protection. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to enforce trade secret protection.

Further, our competitors may independently develop knowledge, methods and know-how similar, equivalent, or superior to our proprietary technology. Competitors could purchase our products and attempt to reverse engineer and replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology, or develop their own competitive technologies that fall outside of our intellectual property rights. In addition, our key employees, consultants, suppliers or other individuals with access to our proprietary technology and know-how may incorporate that technology and know-how into projects and inventions developed independently or with third parties. As a result, disputes may arise regarding the ownership of the proprietary rights to such technology or know-how, and any such dispute may not be resolved in our favor. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us and our competitive position could be adversely affected. If our intellectual property is not adequately protected so as to protect our market against competitors' products and processes, our competitive position could be adversely affected, as could our business.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products and processes.

As is the case with other pharmaceutical and medical device companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and is therefore costly, time-consuming, and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith Act was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, and switched the United States patent system from a "first-to-invent" system to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had conceived or reduced to practice the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, in particular, the first-to-file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and pending patent applications. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. Furthermore, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our own, which would have a material adverse effect on our business.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We may not be able to protect our rights in these trademarks and trade names, which we need in order to build name recognition with potential partners or customers in our markets of interest. In addition, third parties have used trademarks similar and identical to our trademarks in foreign jurisdictions and have filed or may in the future file for registration of such trademarks. If they succeed in registering or developing common law rights in such trademarks, and if we are not successful in challenging such third-party rights, we may not be able to use these trademarks to market our products in those countries. In any case, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected.

If we cannot show access and copying, then our copyrights may not provide protection for our software and our business may be adversely affected.

Copyrights protect works of authorship such as software, but proving infringement requires a showing of access to the work and copying of the work. Because software is not readily available or accessible, it may be difficult to determine and prove that a third party had access to our software and/or that they copied our software. Because our software may be accessible by obtaining or accessing our product offerings and technology, third parties may be able to download or reproduce our software and reverse engineer our software programs. Software programs can be rewritten in ways that significantly modify it from the original program, which may make it difficult to prove the copying prong of a copyright infringement showing. If we are unable to establish the two prongs of a copyright infringement analysis, then our copyrights may provide limited or no protection for our software. Copyright infringement suits are expensive and any damages we seek may be inadequate to compensate us for the costs of litigation and for damage to our business resulting from the copyright infringement.

We may not be able to adequately protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries may not protect our intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories in which we have patent protection that may not be sufficient to terminate infringing activities.

We do not have patent rights in certain foreign countries in which a market may exist. Moreover, in foreign jurisdictions where we do have patent rights, proceedings to enforce such rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and our patent applications at risk of not issuing. Additionally, such proceedings could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Thus, we may not be able to stop a competitor from marketing and selling in foreign countries products and services that are the same as or similar to our products and services, and our competitive position in the international market would be harmed.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect our ability to develop and market our products.

We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our products in any jurisdiction. For example, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our products could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our products. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our products and services. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products and services.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our products that are held to be infringing. We might, if possible, also be forced to redesign products or services so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time.

Patents have a limited lifespan, and the protection patents afford is limited. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Even if patents covering our products are obtained, once the patent life has expired for patents covering a product, we may be open to competition from competitive products and services. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

Intellectual property rights do not necessarily address all potential threats to our business.

Once granted, patents may remain open to invalidity challenges including opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked or may lose the allowed or granted claims altogether.

In addition, the degree of future protection afforded by our intellectual property rights is uncertain because even granted intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology, but that are not covered by the claims of the patents that we own or control, assuming such patents have issued or do issue;
- we or our licensors or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed;
- we or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- third parties performing manufacturing or testing for us using our products or technologies could use the intellectual property of others without obtaining a proper license;
- parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights over that intellectual property;
- we may not develop or in-license additional proprietary technologies that are patentable;
- we may not be able to obtain and maintain necessary licenses on commercially reasonable terms, or at all; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business and results of operations.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties.

We do and may employ individuals who were previously employed at universities or other pharmaceutical or medical device companies, including our licensors, competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, and we are not currently subject to any claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties, we may in the future be subject to such claims. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees and could result in customers seeking other sources for the technology, or in ceasing from doing business with us.

Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology.

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact conceives or develops intellectual property that we regard as our own. Our assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

We may not be successful in obtaining necessary intellectual property rights to future products through acquisitions and in-licenses.

Although we intend to develop products and technology through our own internal research, we may also seek to acquire or in-license technologies to grow our product offerings and technology portfolio. However, we may be unable to acquire or in-license intellectual property rights relating to, or necessary for, any such products or technology from third parties on commercially reasonable terms or at all. In that event, we may be unable to develop or commercialize such products or

technology. We may also be unable to identify products or technology that we believe are an appropriate strategic fit for our company and protect intellectual property relating to, or necessary for, such products and technology.

The in-licensing and acquisition of third-party intellectual property rights for product candidates is a competitive area, and a number of more established companies are also pursuing strategies to in-license or acquire third-party intellectual property rights for products that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. If we are unable to successfully obtain rights to additional technologies or products, our business, financial condition, results of operations and prospects for growth could suffer.

In addition, we expect that competition for the in-licensing or acquisition of third-party intellectual property rights for products and technologies that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. We may be unable to in-license or acquire the third-party intellectual property rights for products or technology on terms that would allow us to make an appropriate return on our investment.

Our platform utilizes open source software, and any failure to comply with the terms of one or more of these open source licenses could negatively affect our business.

Our platform utilizes software governed by open source licenses. The terms of various open source licenses have not been interpreted by United States courts, and there is a risk that such licenses could be construed in a manner that imposes unanticipated conditions or restrictions on our ability to market our platform. By the terms of certain open source licenses, if we combine certain proprietary software with open source software in a specified manner, we could be required to release the source code of our proprietary software and make it available under open source licenses. In the event that portions of our platform are determined to be subject to an open source license, we could be required to publicly release the affected portions of our source code, or to re-engineer all or a portion of our technologies or otherwise be limited in licensing activities, each of which could reduce or eliminate the value of our technologies. In addition to risks related to license requirements, the use of open source software can lead to greater risks than use of third-party commercial software, as open source licensors generally do not provide warranties or controls on the origin of the software. Many of the risks associated with the use of open source software cannot be eliminated and could negatively affect our business.

Cyber-security incidents, including data security breaches or computer viruses, could harm our business by disrupting our delivery of services, damaging our reputation or exposing us to liability.

We receive, process, store, and transmit, often electronically, data of our customers and others which may be confidential. Unauthorized access to our computer systems or stored data could result in the theft or improper disclosure of confidential information, the deletion or modification of records, or could cause interruptions in our operations. These cyber-security risks increase when we transmit information from one location to another, including transmissions over the Internet or other electronic networks. Despite implemented security measures, our facilities, systems, and procedures, and those of our third-party service providers, may be vulnerable to security breaches, acts of vandalism, software viruses, misplaced or lost data, programming and/or human errors, or other similar events which may disrupt our delivery of services or expose the confidential information of our customers and others. Any security breach involving the misappropriation, loss or other unauthorized disclosure or use of confidential information of our customers or others, whether by us or a third party, could: (i) subject us to civil and criminal penalties; (ii) have a negative impact on our reputation; or (iii) expose us to liability to our customers, third parties or government authorities. Any of these developments could have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to Regulation of our Industry

Our business is subject to extensive governmental regulation that makes it expensive and time consuming for us to bring our gammaCore therapy to market in the United States and to expand the use of our gammaCore therapy to additional therapeutic indications.

Our gammaCore therapy must comply with regulatory requirements imposed by the FDA in the United States and by similar agencies in foreign jurisdictions. These requirements involve lengthy and detailed laboratory and clinical testing procedures, sampling activities, extensive agency review processes, and other costly and time-consuming procedures. It often takes several years to satisfy these requirements, depending on the complexity and novelty of the product. We also are subject to numerous additional licensing and regulatory requirements relating to safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. Some of the most important requirements we must comply with include:

- the Federal Food, Drug, and Cosmetic Act and the FDA's implementing regulations (Title 21 CFR);
- CE mark requirements of the European Union, or EU;

- Medical Device Quality Management System Requirements (ISO 13485:2016);
- Occupational Safety and Health Administration requirements; and
- New Jersey Department of Health Services requirements.

Government regulation may impede our ability to conduct clinical trials and to manufacture and sell our existing therapy and any future products. Government regulation also could delay our marketing of new products for a considerable period of time and impose costly procedures on our activities. The FDA and other regulatory agencies may not clear or approve our gammaCore therapy in additional therapeutic areas that we may pursue, on a timely basis, if at all. Any delay in obtaining, or failure to obtain, such clearances or approvals could negatively impact our marketing of our gammaCore therapy and impede our ability to bring future products to market.

While 510(k) clearance from the FDA has been received to expand the label for gammaCore therapy for several indications our gammaCore therapy will remain subject to strict regulatory controls on manufacturing, marketing and use. We may be forced to modify or recall a product after release in response to regulatory action or unanticipated difficulties encountered in general use. Any such action could have a material effect on the reputation of our gammaCore therapy and on our business and financial position.

Further, regulations may change, and any additional regulation could limit or restrict our ability to use any of our technologies, which could harm our business. We could also be subject to new international, federal, state or local regulations that could affect our research and development programs and harm our business in unforeseen ways. If this happens, we may have to incur significant costs to comply with such laws and regulations, which will harm our results of operations.

Our future success depends on our ability to develop, receive regulatory clearance or approval for, and introduce new products or product enhancements that will be accepted by the market in a timely manner.

It is important to our business that we build a pipeline of product offerings for treatment of our target indications. As such, our success will depend in part on our ability to develop and introduce new products. However, we may not be able to successfully develop and obtain regulatory clearance or approval for product enhancements, or new products, or these products may not be accepted by physicians or the payers who financially support many of the procedures performed with our products.

The success of any new product offering or enhancement to an existing product will depend on a number of factors, including our ability to:

- identify and anticipate physician and patient needs properly;
- develop and introduce new products or product enhancements in a timely manner;
- avoid infringing upon the intellectual property rights of third parties;
- demonstrate, if required, the safety and efficacy of new products with data from preclinical and clinical studies;
- obtain the necessary regulatory clearances or approvals for new products or product enhancements;
- comply fully with FDA and foreign regulations on marketing of new devices or modified products;
- provide adequate training to potential users of our products; and
- receive adequate coverage and reimbursement for procedures performed with our products.

If we do not develop new products or product enhancements in time to meet market demand or if there is insufficient demand for these products or enhancements, or if our competitors introduce new products with functionalities that are superior to ours, our results of operations will suffer.

gammaCore is subject to extensive governmental regulation, and our failure to comply with applicable requirements could cause our business to suffer.

The medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies and authorities, such as the European Commission and the EEA member states, competent authorities and notified bodies. The FDA and other U.S., EEA and foreign governmental agencies and authorities regulate and oversee, among other things, with respect to medical devices:

- design, development and manufacturing;
- testing, labeling, content and language of instructions for use and storage;
- clinical trials;
- product safety;
- risk assessment and management;
- marketing, sales and distribution;
- pre-market regulatory clearance and approval;

- conformity assessment procedures;
- record-keeping procedures;
- advertising and promotion;
- recalls and other field safety corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- post-market studies; and
- product import and export.

The laws and regulations to which we are subject are complex and have tended to become more stringent over time. Legislative or regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales.

Our failure to comply with U.S. federal and state regulations or EEA or other foreign regulations applicable in the countries where we operate could lead to the issuance of warning letters or untitled letters, the imposition of injunctions, suspensions or loss of regulatory clearance or approvals, product recalls, termination of distribution, product seizures or civil penalties. In the most extreme cases, criminal sanctions or closure of our manufacturing facilities are possible. If any of these risks materialize, our business would be adversely affected.

gammaCore is also subject to extensive governmental regulation in foreign jurisdictions, such as Europe, and our failure to comply with applicable requirements could cause our business to suffer.

In the EEA, gammaCore must currently comply with the Essential Requirements laid down in Annex I to Directive 93/42/EEC on the approximation of the laws of the member states relating to medical devices or the EU Medical Devices Directive. Compliance with these requirements is a prerequisite to be able to affix the CE mark to gammaCore, without which they cannot be marketed or sold in the EEA. To demonstrate compliance with the Essential Requirements and obtain the right to affix the CE Mark medical devices manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low risk medical devices (Class I with no measuring function and which are not sterile), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the Essential Requirements, a conformity assessment procedure that requires the intervention of a notified body, which is an organization designated by a competent authority of an EEA country to conduct conformity assessments. Depending on the relevant conformity assessment procedure, the notified body would audit and examine the technical documentation and the quality system for the manufacture, design and final inspection of the medical devices. The notified body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the Essential Requirements. This Certificate entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

As a general rule, demonstration of conformity of medical devices and their manufacturers with the Essential Requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use and that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device, such as product labeling and instructions for use, are supported by suitable evidence. This assessment must be based on clinical data, which can be obtained from (1) clinical studies conducted on the devices being assessed, (2) scientific literature from similar devices whose equivalence with the assessed device can be demonstrated or (3) both clinical studies and scientific literature. gammaCore is a Class IIa medical device in the EU. The conduct of clinical studies in the EEA is governed by detailed regulatory obligations. These may include the requirement of prior authorization by the competent authorities of the country in which the study takes place and the requirement to obtain a positive opinion from a competent ethics committee. This process can be expensive and time-consuming.

Moreover, in May 2017 the new MDR, entered into force. Following its entry into application on May 26, 2020, the regulation will introduce substantial changes to the obligations with which medical device manufacturers must comply in the EU. High risk medical devices will be subject to additional scrutiny during the conformity assessment procedure. Specifically, the MDR repeals and replaces the EU Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA member states, the regulations would be directly applicable, i.e., without the need for adoption of EEA member state laws implementing them, in all EEA member states and are intended to eliminate current differences in the regulation of medical devices among EEA member states. The MDR among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation. Once applicable, the Medical Devices Regulation will among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;

- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthen rules for the assessment of certain high-risk devices which may have to undergo an additional check by experts before they are placed on the market.

Once applicable, the MDR may impose increased compliance obligations for us to access the EU market.

In order to continue to sell gammaCore in Europe, we must maintain our CE Certificate of Conformity for the device and continue to comply with the Medical Devices Directive and, from May 26, 2020, with the MDR. The Medical Devices Regulation imposes a number of new requirements on manufacturers of medical devices. This may impact our activities in the EEA and in the UK, the renewal of our existing CE Certificates of Conformity and conformity assessment related to future bodies. Our failure to continue to comply with applicable foreign regulatory requirements, including those administered by authorities of the EEA countries, could result in enforcement actions against us, including refusal, suspension or withdrawal of our CE Certificates of Conformity by our notified body (the British Standards Institution), which could impair our ability to market products in the EEA in the future.

On March 29, 2017, the United Kingdom formally notified the EU of its intention to withdraw from the Union pursuant to Article 50 of the Lisbon Treaty, commonly referred to as Brexit. The United Kingdom and EU have now agreed on the terms of the exit deal, which will include a transitional period following the United Kingdom's exit which occurred on January 31, 2020. The transitional period will continue until December 31, 2020 during which the EU and the United Kingdom will seek to negotiate new arrangements for the period from January 1, 2021. The United Kingdom's withdrawal from the EU, or Brexit could lead to legal uncertainty and potentially divergent national laws and regulations in the EU and the United Kingdom. Given the lack of comparable precedent, it is unclear what Brexit's financial, regulatory, and legal implications would be and how it would affect us. However, potentially changing regulatory schemes and tariffs engendered by Brexit may add additional complexity, cost and delays in marketing or selling our products in the United Kingdom. Our revenue and profit, supply and demand for our products, and customer retention and acquisition in both the long term and short term could be adversely affected. During the transitional period most obligations imposed by EU legislation will remain applicable to and in the United Kingdom. Since a significant proportion of the regulatory framework in the United Kingdom is derived from EU directives and regulations, the "hard" withdrawal of the United Kingdom from the EU (where no deal is agreed for the period after the transitional period ending December 31, 2020) could materially impact the regulatory regime with respect to the CE Certificates of Conformity in the United Kingdom. CE Certificates of Conformity issued by a notified body accredited in the EU may no longer be recognized in the UK. Similarly, notified bodies accredited in the UK will no longer be able to issue CE Certificates of Conformity. Obtaining new CE Certificates of Conformity or certification for the UK may have a significant impact on our activities.

If we fail to maintain regulatory approvals and clearances, or are unable to obtain, or experience significant delays in obtaining FDA clearances, approvals or CE Certificates of Conformity for our future products or product enhancements, our ability to commercially distribute and market these products could suffer.

Our products are subject to rigorous regulation by the FDA, notified bodies, and numerous other federal, state and foreign governmental authorities. The process of obtaining regulatory clearances, approvals, or CE Certificates of Conformity to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all. In particular, the FDA permits commercial distribution of a new medical device only after the device has received clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or is the subject of an approved PMA unless the device is specifically exempt from those requirements. The FDA will clear marketing of a lower risk medical device through the 510(k) process if the manufacturer demonstrates that the new product is substantially equivalent to a legally marketed "predicate" device. For novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device, the FDA may determine that the "de novo" process is the appropriate route to market. The "de novo" process is more costly, time consuming and uncertain than the traditional 510(k) process. High risk devices deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices, or devices not deemed substantially equivalent to a legally marketed "predicate" device, require the approval of a PMA. The PMA process is more costly, lengthy and uncertain than the 510(k)-clearance process. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use. Our currently commercialized gammaCore products have been cleared through the 510(k) process or the "de novo" process. In the future, we may need to submit a PMA or continue to utilize the "de novo" process to expand our labeling claims to include certain indications, which likely will be more costly, time consuming and uncertain than the traditional 510(k) process.

Our failure to comply with U.S. federal, state and foreign governmental regulations could lead to the issuance of warning letters or untitled letters, the imposition of injunctions, suspensions or loss of regulatory clearance or approvals, product recalls, termination of distribution, product seizures or civil penalties. In the most extreme cases, criminal sanctions or closure of our manufacturing facility are possible.

Foreign governmental authorities and notified bodies that regulate the manufacture and sale of medical devices have become increasingly stringent and, to the extent we market and sell our products internationally, we may be subject to rigorous international regulation in the future. In these circumstances, we would rely significantly on our foreign independent distributors to comply with the varying regulations, and any failures on their part could result in restrictions on the sale of our products in foreign countries.

Modifications to our products may require new regulatory clearances or approvals or may require us to recall or cease marketing our products until clearances or approvals are obtained.

Modifications to or expansion of our indications for use of our gammaCore products may require new regulatory approvals or clearances, including 510(k) clearances or PMA approvals, or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine that a modification does not significantly affect safety or efficacy and does not represent a major change in its intended use, so that no new 510(k) clearance is not necessary. However, the FDA can review a manufacturer's decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval is required. We may make modifications to our products in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing our products as modified, which could require us to redesign our products and harm our operating results. In these circumstances, we may be subject to significant enforcement actions.

If a manufacturer determines that a modification to an FDA-cleared device could significantly affect its safety or efficacy or would constitute a major change in its intended use, then the manufacturer must file for a new 510(k) clearance or possibly a PMA application. Where we determine that modifications to our products require a new 510(k) clearance or PMA application, we may not be able to obtain those additional clearances or approvals for the modifications or additional indications in a timely manner, or at all. For those products sold in the EU, we must notify our notified body, if significant changes are made to the products or if there are substantial changes to our quality assurance systems affecting those products. Obtaining clearances and approvals can be a time-consuming process, and delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

There is no guarantee that the FDA will grant 510(k) clearance or PMA approval of our future products and failure to obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business.

Some of our new products or expanded indications for use will require FDA clearance of a 510(k) or may require FDA approval of a PMA. The FDA may not approve or clear these products for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510(k) clearance or PMA of new products, new intended uses or modifications to existing products. Failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

Even if our products are cleared or approved by regulatory authorities, if we or our manufacturers, or suppliers fail to comply with ongoing FDA or other foreign regulatory authority requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain clearance or approval, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our suppliers are required to comply with the FDA's QSR, and International Standards Organization, or ISO, regulations for the manufacture of our products and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain clearance or approval. Regulatory bodies, such as the FDA, enforce the QSR and other regulations through periodic inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions
- customer notifications for repair, replacement, refunds;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or PMA approval of new products or modified products;
- operating restrictions;
- withdrawing 510(k) clearances on PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

If any of these actions were to occur, it would harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

Even if regulatory clearance or approval of a product is granted, such clearance or approval may be subject to limitations on the intended uses for which the product may be marketed and reduce our potential to successfully commercialize the product and generate revenue from the product. If the FDA determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory clearances or approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

The misuse or off-label use of our gammaCore therapy may harm our image in the marketplace, result in injuries that lead to product liability suits, which could be costly to our business, or result in costly investigations and sanctions from the FDA and other regulatory bodies if we are deemed to have engaged in off-label promotion.

gammaCore has been CE Marked in the EEA and cleared by the FDA for the acute treatment of eCH, CH prevention and the acute treatment of migraine headache in the United States. We may only promote or market our gammaCore therapy for its specifically approved indications as described on the approved label. We train our marketing and sales force against promoting our products for uses outside of the approved indications for use, known as "off-label uses." We cannot, however, prevent a physician from prescribing our product off-label, when in the physician's independent professional medical judgment, he or she deems appropriate. There may be increased risk of injury to patients if patients attempt to use our product off-label, whether prescribed by physicians or not. Furthermore, the use of our product for indications other than those cleared or approved by the applicable regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

Patients may also misuse our product or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our product is misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. In addition, if our products are approved for sale in the United States and the FDA determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, and the curtailment of our operations. Further, our competitors could bring civil actions under relevant unfair competition and advertising laws should they believe our business activities and product promotional activities are improper. Any of these events could significantly harm our business and results of operations and cause our stock price to decline.

Further, the advertising and promotion of our products is subject to EEA member states' national laws implementing Directive 93/42/EEC on the approximation of the laws of the member states relating to medical devices, or the Medical Devices Directive and applying the Medical Devices Regulation, Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other EEA member state legislation governing the advertising and promotion of medical devices. EEA member state legislation may also restrict or impose limitations on our ability to advertise our products directly to the general public. In addition, voluntary EU and national codes of conduct provide guidelines on the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals.

gammaCore may in the future be subject to notifications, recalls, or voluntary market withdrawals that could harm our reputation, business and financial results.

The FDA, EEA authorities and similar foreign governmental authorities have the authority to request or require the recall of commercialized products in the event of regulatory noncompliance or material deficiencies or defects in design or manufacture that could affect patient safety. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. We must notify the FDA of all device recalls and corrections, and certain classifications of recalls and corrections require more extensive reporting within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls and corrections, even if they are not subject to more extensive reporting requirements. We may initiate voluntary market withdrawals or other market actions involving our gammaCore products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls or corrections when they were conducted. Consumer class action claims and/or product liability claims are a greater risk following a product recall or market withdrawal.

We are required to report certain malfunctions, deaths, and serious injuries associated with our products, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA MDR regulations, medical device manufacturers are required to submit information to the FDA when they receive a report or become aware that a device has or may have caused or contributed to a death or serious injury or has or may have a malfunction that would likely cause or contribute to death or serious injury if the malfunction were to recur. All manufacturers placing medical devices on the market in the EEA are legally bound to report incidents involving devices they produce or sell to the regulatory agency, or competent authority, in whose jurisdiction the incident occurred. Under the Directive 93/42/EEC on the approximation of the laws of the member states relating to medical devices or EU Medical Device Directive and from May 26, 2020 the EU Medical Devices Regulation, an incident is defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health.

Malfunction of our products could result in future voluntary corrective actions, such as recalls, including corrections, or customer notifications, or agency action, such as inspection or enforcement actions. If malfunctions do occur, we may be unable to correct the malfunctions adequately or prevent further malfunctions, in which case we may need to cease manufacture and distribution of the affected products, initiate voluntary recalls, and redesign the products. Regulatory authorities may also take actions against us, such as ordering recalls, imposing fines, or seizing the affected products. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

Legislative or regulatory reforms may make it more difficult and costly for us to obtain regulatory clearance of our product candidates and to manufacture, market and distribute our products after clearance is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory clearance, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

Political change as a result of elections could result in significant legislative and regulatory reforms impacting the FDA's regulation of our products. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

In the EU, on May 25, 2017 the new MDR was adopted. Following its entry into application on May 26, 2020, the MDR will introduce substantial changes to the obligations with which medical device manufacturers must comply in the EU. High risk medical devices will be subject to additional scrutiny during the conformity assessment procedure.

We are subject to federal, state and foreign healthcare laws and regulations, and a finding of failure to comply with such laws and regulations could have a material adverse effect on our business.

We are subject to healthcare fraud and abuse regulation and enforcement by federal, state and foreign governments, which could significantly impact our business. In the United States, the laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Violations of the federal Anti-Kickback Statute may result in significant civil monetary penalties for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines and imprisonment, and exclusion from participation in government healthcare programs, including Medicare and Medicaid;
- the Stark Law, in the event that third-party payers require us to be a durable medical equipment, or DME, supplier or we sell our products directly to providers who are DME suppliers that submit claims to such payers. The Stark Law

prohibits a physician from making a referral for certain designated health services covered by the Medicare program or Medicaid program, including DME, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services, and prohibits that entity from billing or presenting a claim for the designated health services furnished pursuant to the prohibited referral, unless an exception applies. Sanctions for violating the Stark Law include denial of payment, significant civil monetary penalties per claim submitted and exclusion from the federal health care programs. Failure to refund amounts received as a result of a prohibited referral on a timely basis may constitute a false or fraudulent claim and may result in civil penalties and additional penalties under the FCA. The statute also provides for significant civil monetary penalties for a circumvention scheme. Various states also have corollary laws to the Stark Law, including laws that require physicians to disclose any financial interest they may have with a healthcare provider to their patients when referring patients to that provider. Both the scope and exceptions for such laws vary from state to state;

- The federal civil False Claims Act, which prohibits, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment of federal funds, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the federal government. The federal civil False Claims Act can apply to manufacturers who provide information on coverage, coding, and reimbursement of their products to persons who bill third-party payers. Private individuals can bring False Claims Act "qui tam" actions, on behalf of the government and such individuals, commonly known as "whistleblowers," may share in amounts paid by the entity to the government in fines or settlement. Penalties for a federal civil False Claims Act violation include three times the actual damages sustained by the government, plus significant mandatory civil penalties for each false claim, and the potential for exclusion from participation in federal healthcare programs. There are also federal criminal false claims and federal civil monetary penalty laws that carry significant monetary and other penalties for submissions of false or fraudulent claims and statements;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal laws that prohibit, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. A person or entity does not need to have actual knowledge of these statutes or specific intent to violate them;
- HIPAA, as amended, and its implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates, relating to the privacy, security and transmission of individually identifiable health information, including mandatory contractual terms as well as privacy and security standards and requirements. Failure to comply with the HIPAA privacy and security standards can result in civil monetary penalties, and, in certain circumstances, criminal penalties with fines. State attorneys general can also bring a civil action to enjoin a HIPAA violation or to obtain statutory damages on behalf of residents of his or her state;
- the federal Physician Payments Sunshine Act, implemented as the Open Payments program, which requires certain applicable manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, or CHIP, to report annually to the U.S. Department of Health and Human Services Centers for Medicare and Medicaid Services, or CMS, information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), teaching hospitals, and, beginning in 2022, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives; teaching hospitals, and ownership and investment interests held by physicians and their immediate family members. The government may impose significant civil monetary penalties for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission; and
- state and foreign law equivalents of each of the above federal laws, such as state anti- kickback and false claims laws that may apply to items or services reimbursed by any third-party payer, including commercial insurers; state laws that require device and drug companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device and drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information, such as the CCPA, many of which differ from each other in significant ways and often are not preempted by HIPAA or other federal privacy and security requirements.

These laws and regulations, among other things, constrain our business, marketing and other promotional activities by limiting the kinds of financial arrangements we may have with physicians or other entities or individuals in a position to purchase, prescribe or recommend our products. We have entered into consulting agreements and other arrangements with physicians, including some who have ownership interests in us and/or prescribe our products to patients. Compensation under some of these arrangements included the equity interests in our company. We could be adversely affected if regulatory

agencies determine our financial relationships with such physicians to be in violation of applicable laws. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

If our operations are challenged or found to be in violation of any of the laws described above or any other governmental regulations that apply to us now or in the future, we may be subject to penalties, including civil and criminal penalties, damages, fines, disgorgement, exclusion from governmental health care programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

Healthcare legislative reform measures may have a material adverse effect on us.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. The Affordable Care Act, which was passed in 2010, substantially changed the way health care is financed by both governmental and private insurers and significantly impacts the U.S. healthcare industry. Elements of the Affordable Care Act, including comparative effectiveness research and payment system reforms, including shared savings pilots, may significantly affect the payment for, and the availability of, healthcare services and result in fundamental changes to federal healthcare reimbursement programs, any of which may materially affect numerous aspects of our business.

Certain provisions of the Affordable Care Act have been subject to judicial challenges as well as efforts to repeal or replace them or to alter their interpretation and implementation. For instance, the Tax Cuts and Jobs Acts was enacted, which, among other things, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additional legislative changes, regulatory changes, and judicial challenges related to the Affordable Care Act remain possible. It is unclear how the Affordable Care Act, as well as efforts to repeal or replace, or invalidate, the Affordable Care Act, or portions thereof, will affect our business, financial condition and results of operations. It is possible that the Affordable Care Act, as currently enacted or as it may be amended or replaced in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our business and our industry generally. Specifically, the expansion in the government's role in the U.S. healthcare industry may result in decreased profits to us, lower reimbursement by payers for our products, and/or reduced medical procedure volumes, all of which may have a material adverse impact on our business, financial condition, results of operations, or cash flows.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things includes aggregate reductions of Medicare payments to providers of, on average, 2% per fiscal year, which went into effect on April 1, 2013, and, due to subsequent legislative amendments to the statute, will remain in effect through 2029 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law which, among other things, further reduced Medicare payments to certain providers, including hospitals.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Risks Related to Our Common Stock

Our failure to meet the continued listing requirements of the Nasdaq Stock Market, or Nasdaq, could result in a delisting of our common stock.

If we fail to satisfy Nasdaq's continued listing requirements, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair stockholders' ability to sell or purchase their common stock when they wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

A share price of less than $1.00 may impact our Nasdaq listing.

If the closing bid price of our stock is less than $1.00 for 30 consecutive trading days, we would receive a deficiency letter from Nasdaq regarding our failure to comply with the minimum bid price requirement for continued listing. Such letter would trigger an automatic 180 calendar day period within which we could regain compliance. Compliance would be regained at any time during this period if the closing bid price of our stock is $1.00 per share or more for a minimum of 10 consecutive trading days.

We may be eligible for an additional 180-day compliance period if we apply to transfer from the Nasdaq Global Select Stock Market to the Nasdaq Capital Market which would require us to (i) have at least $1 million in market value of publicly held shares, (ii) satisfy all requirements for initial listing on the Nasdaq Capital Market (except for the bid price requirement), and (iii) provide written notice to Nasdaq that we intend to regain compliance with the bid price requirement during such second 180-day compliance period, including by effecting a reverse stock split if necessary. However, there can be no guarantee that we will be eligible for the second 180-day compliance period or that if eligible, we will be able to regain compliance during such period.

If we do not regain compliance during any applicable compliance periods, our stock could be delisted from Nasdaq. The failure to maintain our listing on Nasdaq could have an adverse effect on the liquidity and market price of our stock.

We have incurred, currently incur and will incur significantly increased costs and devote substantial management time as a result of operating as a public company.

As a public company, we have incurred and will incur significant legal, accounting and other expenses that we did not incur as a private company. For example, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or Exchange Act, and will be required to comply with the applicable requirements of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules and regulations subsequently implemented by the SEC and Nasdaq, including the establishment and maintenance of effective disclosure and financial controls and certain corporate governance practices. We expect that compliance with these requirements will increase our legal and financial compliance costs and will make some activities more time consuming and costly.

In addition, we expect that our management and other personnel will need to divert attention from operational and other business matters to devote substantial time to our public company requirements. In particular, we incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act, which will increase when we are no longer an emerging growth company, as defined by the Jumpstart Our Business Startups Act, or the JOBS Act. We will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge and may need to establish an internal audit function. We cannot predict or estimate the amount of additional costs we may incur as a result of the foregoing or the timing of such costs. Additional compensation costs and any future equity awards will increase our compensation expense, which would increase our general and administrative expense and could adversely affect our profitability. We also expect that operating as a public company will make it more difficult and expensive for us to obtain director and officer liability insurance on reasonable terms. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers.

Our stock price may be volatile, and you may not be able to resell shares of our common stock at or above the price you paid.

The trading price of our common stock could be highly volatile and could be subject to wide fluctuations in response to various factors, including factors which are beyond our control. These factors include those discussed in the other "Risk Factors" section of this Report on Form 10-K and others such as:

- announcements related to regulatory clearance to market gammaCore for the treatment of various conditions in the United States;
- results from, or any delays in, clinical trial programs relating to our product candidates;
- announcements of new products by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- our operating results and financial position;
- changes or developments in laws or regulations applicable to our products;
- any adverse changes in our relationship with any manufacturers or suppliers;
- the success of our efforts to acquire or develop additional products;
- any intellectual property infringement actions in which we may become involved;
- announcements concerning our competitors or the medical device industry in general;
- achievement of expected product sales and profitability;
- changes or developments in our commercial strategy and tactics;
- manufacture, supply or distribution shortages;
- actual or anticipated fluctuations in our operating results;
- FDA or other U.S. or foreign regulatory actions affecting us or our industry or other healthcare reform measures in the United States;
- changes in financial estimates or recommendations by securities analysts;
- trading volume of our common stock;
- sales of our common stock by us, our executive officers, directors or stockholders;
- general economic and market conditions and overall fluctuations in the U.S. equity markets; and
- the loss of any of our key scientific or management personnel.

In addition, the stock markets in general, and the markets for pharmaceutical and medical device stocks in particular, have experienced volatility. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our management would be diverted from the operation of our business, which could seriously harm our financial position. Any adverse determination in litigation could also subject us to significant liabilities.

We are currently subject to securities class action lawsuits against us, which could result in adverse outcomes.

As described in *Item 3. Legal Proceedings*, we and certain of our present and past directors and officers have been named in putative securities class action lawsuits alleging violations of the Securities Act of 1933, or Securities Act, and the Exchange Act. We are generally required to indemnify our current and former directors and officers who are named as defendants in these types of lawsuits. We also have certain contractual indemnification obligations to the underwriters of our initial public offering, or IPO, regarding the securities class action lawsuits. While a certain amount of insurance coverage may be available for expenses or losses associated with these lawsuits, this coverage may not be sufficient. Although we plan to defend the lawsuits vigorously, there can be no assurances that favorable final outcomes will be obtained. Based on information currently available, we are unable to determine the reasonable probability of loss or a range of potential loss, and accordingly, we have not established an accrual for potential losses, if any, that could result from any unfavorable outcome, and there can be no assurance that these litigation matters, as well as any other lawsuits that might be brought by stockholders, will not result in substantial defense costs and/or judgments or settlements that could have a materially adverse impact on our financial position, results of operations and cash flows.

We have broad discretion to determine how to use our financial resources and may use them in ways that may not enhance our operating results or the price of our common stock.

Our management has broad discretion over the use of our financial resources, including proceeds from our IPO and the stock purchase agreement we entered into with Lincoln Park Capital Fund, LLC, in March 2020, and we could spend such proceeds in ways our stockholders may not agree with or that do not yield a favorable return, if at all. If we do not invest or apply our financial resources, including the proceeds from our IPO and such purchase agreement in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline.

An active, liquid and orderly market for our common stock may not develop, and our stockholders may not be able to resell their shares at a desired market price and could lose all or part of their investment.

Prior to our IPO in June 2018, there was no public market for shares of our common stock. Although our common stock is listed on the Nasdaq Global Select Market, or Nasdaq, we cannot assure you that an active, liquid trading market for our shares will continue to develop or be sustained. A public trading market having the desired characteristics of depth, liquidity and orderliness depends upon the presence in the marketplace and independent decisions of willing buyers and sellers of our common stock, over which we have no control. The lack of an active market may impair our stockholders' ability to sell their shares at the desired time or at a price that our stockholders consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies or in-license new product candidates using our shares as consideration. We cannot offer any assurance that an active trading market for our common stock will develop or how liquid that market may become. As a result, relatively small trades may have a disproportionate impact on the price of our common stock, which may contribute to the price volatility of our common stock and could limit stockholders' ability to sell their shares. In addition, the stock market in general, and the market for smaller biotechnology companies in particular, have experienced extreme price and volume fluctuations that may be unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The above factors could adversely affect the value of our common stock and cause you to lose all or part of your investment.

If securities or industry analysts cease publishing regular research or reports about our business or issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts may publish about us or our business. If any of the analysts who cover us were to cease publishing research or reports about our business or were to issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

We are an "emerging growth company" and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

If we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be adversely affected.

As a public company, we are required to implement and maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting. Beginning with our second annual report following our IPO, for our fiscal year ended December 31, 2019, management provided a report on internal control over financial reporting. The Sarbanes-Oxley Act also requires that our management report on internal control over financial reporting be attested to by our independent registered public accounting firm, to the extent we (i) are no longer an "emerging growth company," as defined by the JOBS Act, and (ii) pursuant to new SEC rules, have annual revenues greater than $100 million in the most recent fiscal year for which audited financial statements are available. We do not expect to have our independent registered public accounting firm attest to our management report on internal control over financial reporting for so long as we are an emerging growth company or have annual revenues under $100 million. If we have to design and implement the internal control over financial reporting required to comply with this obligation, such process will be time consuming, costly and complicated.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. Certain of our former unitholders, including entities affiliated with certain of our directors and former directors, purchased common stock in our IPO at the IPO price per share. Shares which are held by our directors, executive officers and other affiliates may be subject to restrictions under Rule 144 of the Securities Act, among other restrictions that make such shares not freely tradable. If these additional shares of common stock are sold pursuant to the applicable exemptions from such restrictions, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Additionally, the holders of approximately 7.0 million shares of our outstanding common stock, including shares issuable upon exercise of outstanding options and warrants, are entitled to rights with respect to the registration of their shares under the Securities Act, subject to vesting schedules. Sales of registered securities by these stockholders could have a material adverse effect on the trading price of our common stock.

The sale or issuance of our common stock to Lincoln Park may cause dilution and the sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall.

On March 27, 2020, we entered into a Purchase Agreement, or Purchase Agreement, with Lincoln Park Capital Fund, LLC, or Lincoln Park, pursuant to which Lincoln Park committed to purchase up to $25 million of our common stock. Shares of our common stock may be sold pursuant to the Purchase Agreement by us to Lincoln Park at our discretion from time to time over a 36-month period, subject to certain limitations and conditions. The purchase price for shares that we may sell to Lincoln Park under the Purchase Agreement will fluctuate based on the price of our common stock. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall.

We have the right to control the timing and amount of any sales of our shares to Lincoln Park in our sole discretion, subject to certain limits on the amount of shares that can be sold on a given date and other conditions and limitations set forth in the Purchase Agreement, including certain limitations on Variable Rate Transactions (as defined in the Purchase Agreement). Sales of shares of our common stock, if any, to Lincoln Park will depend upon market conditions and other factors to be determined by us. Therefore, Lincoln Park may ultimately purchase all, some or none of the shares of our common stock that may be sold pursuant to the Purchase Agreement and, after it has acquired shares, Lincoln Park may sell all, some or none of those shares. Sales to Lincoln Park by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales, which could have a materially adverse effect on our business and operations.

We may not be able to access sufficient funds under the Purchase Agreement when needed.

Our ability to sell shares to Lincoln Park and obtain funds under the Purchase Agreement is limited by the terms and conditions in the Purchase Agreement, including restrictions on the amounts we may sell to Lincoln Park at any one time, and a limitation on our ability to sell shares to Lincoln Park to the extent that it would cause Lincoln Park to beneficially own more than 4.99% of our outstanding shares of common stock. Additionally, we will only be able to sell or issue to Lincoln Park a number of shares equal to 19.99% of the shares of common stock outstanding on the date of the Purchase Agreement unless we obtain shareholder approval or the issuances and sales of shares of our common stock pursuant to the Purchase Agreement are not deemed to be “below market” as determined under the applicable rules of the Nasdaq. Therefore, we currently do not, and may not in the future, have access to the full amount otherwise available to us under the Purchase Agreement. In addition, any amounts we sell under the Purchase Agreement may not satisfy all of our funding needs, even if we are able and choose to sell and issue all of our common stock otherwise issuable pursuant to the Purchase Agreement.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of December 31, 2019, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates, including Core Ventures II, LLC and Core Ventures IV, LLC, entities controlled by two of our directors, Joseph P. Errico and Thomas J. Errico, M.D., and Merck Global Health Innovation Fund, LLC, beneficially owned, including shares issuable upon the exercise or delivery of options, warrants, restricted stock units and deferred stock units that are currently vested or will vest within 60 days from the date hereof, an approximately 8.6 million shares of our voting stock which represents approximately 28.3% of our outstanding voting stock (treating all such vested options, warrants, restricted stock units and deferred stock units held by such persons as outstanding). These stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or

approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that our stockholders may feel are in their best interest.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our certificate of incorporation and bylaws provisions that could significantly reduce the value of our shares to a potential acquirer or delay or prevent changes in control or changes in our management without the consent of our board of directors. The provisions in our charter documents include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the required approval of at least 66 2/3% of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of at least 66 2/3% of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

In addition, these provisions would apply even if we were to receive an offer that some stockholders may consider beneficial.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our certificate of incorporation and bylaws provide that we will indemnify our directors and officers to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, or the DGCL, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;
- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;

- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;
- we will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification;
- the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and
- we may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

Our business and stock price could be negatively affected as a result of actions of activist stockholders, and such activism could impact the trading value of our securities.

Stockholders may, from time to time, engage in proxy solicitations or advance stockholder proposals, or otherwise attempt to effect changes and assert influence on our board of directors and management. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition. A proxy contest would require us to incur significant legal and advisory fees, proxy solicitation expenses and administrative and associated costs and require significant time and attention by our board of directors and management, diverting their attention from the pursuit of our business strategy. Any perceived uncertainties as to our future direction and control, our ability to execute on our strategy, or changes to the composition of our board of directors or senior management team arising from a proxy contest could lead to the perception of a change in the direction of our business or instability which may result in the loss of potential business opportunities, make it more difficult to pursue our strategic initiatives, or limit our ability to attract and retain qualified personnel and business partners, any of which could adversely affect our business and operating results. If individuals are ultimately elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively implement our business strategy and create additional value for our stockholders. We may choose to initiate, or may become subject to, litigation as a result of the proxy contest or matters arising from the proxy contest, which would serve as a further distraction to our board of directors and management and would require us to incur significant additional costs. In addition, actions such as those described above could cause significant negative or other fluctuations in our stock price based upon temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

We do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on your common stock for the foreseeable future. Since we do not intend to pay dividends, your ability to receive a return on your investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.

Comprehensive U.S. federal income tax reform could adversely affect us.

On December 22, 2017, President Trump signed into law the “Tax Cuts and Jobs Act”, or TCJA, that significantly reforms the Internal Revenue Code of 1986, or as amended, the Code. The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest, allows for the expensing of capital expenditures and puts into effect the migration from a “worldwide” system of taxation to a modified territorial system. We continue to examine the impact this tax reform legislation may have on our business. The impact of this tax reform on us and on holders of our common stock is uncertain and could be adverse. There can be no assurance that the TCJA will not negatively impact our operating results, financial condition, or our future business operations. This Report on Form 10-K does not discuss any such tax legislation or the manner in which it might affect purchasers of our common stock. We urge our stockholders to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock.

New legislation or regulation which could affect our tax burden could be enacted by any governmental authority. We cannot predict the timing or extent of such tax-related developments which could have a negative impact on our financial results. Additionally, we use our best judgment in attempting to quantify and reserve for these tax obligations. However, a challenge by a taxing authority, our ability to utilize tax benefits such as carryforwards or tax credits, or a deviation from other tax-related assumptions may cause actual financial results to deviate from previous estimates.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware, or Chancery Court, and the federal district courts of the United States will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising under the Delaware General Corporation Law, our certificate of incorporation, or our bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine,

in each case provided that the Chancery Court has subject matter jurisdiction. If the Chancery Court does not have subject matter jurisdiction, then such actions may be brought in any state court located in the state of Delaware, or State Courts, or, if and only if the State Courts lack subject matter jurisdiction, in the federal district court for the District of Delaware.

This exclusive forum provision does not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder.

Our certificate of incorporation further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, although stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder. The enforceability of similar choice of forum provisions in some other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any action, a court could find the choice of forum provisions contained in our certificate of incorporation to be inapplicable or unenforceable.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal offices occupy approximately 25,000 square feet of leased office space in Basking Ridge, New Jersey, pursuant to a lease agreement that expires in 2022 (subject to our right to extend for an additional five years) and an additional approximately 14,000 square feet of warehouse and assembly space in Rockaway, New Jersey pursuant to a lease that expires in 2024 (subject to our right to extend for an additional five years). We believe that our current facilities are suitable and adequate to meet our current needs. We may in the future add new facilities or expand or relinquish existing facilities as our needs evolve, and we believe that should the need arise, suitable additional or substitute space will be available as needed to accommodate any expansion of our operations.

Item 3. Legal Proceedings

From time to time, we may become involved in various legal proceedings, including those that may arise in the ordinary course of business. Although the outcomes of these legal proceedings cannot be predicted with certainty, other than as set forth below, we are not subject to any material legal proceedings.

On July 8, 2019 and August 1, 2019, purported stockholders of our company served putative class action lawsuits in the Superior Court of New Jersey for Somerset County, captioned *Paul Kuehl vs. electroCore, Inc., et al.*, Docket No. SOM-L 000876-19 and *Shirley Stone vs. electroCore, Inc., et al.*, Docket No. SOM-L 001007-19, respectively. In addition to our company, the defendants include present and past directors and officers, Evercore Group L.L.C., Cantor Fitzgerald & Co., JMP Securities LLC and BTIG, LLC, the underwriters for our IPO; and two of our stockholders. On August 15, 2019, the Superior Court entered an order consolidating the *Kuehl* and *Stone* actions, which are proceeding under Docket No. SOM-L 000876-19. Each plaintiff was appointed a co-lead plaintiff. The plaintiffs filed a consolidated amended complaint, which sought certification of a class of stockholders who purchased our common stock in our IPO or whose purchases are traceable to that offering. The consolidated amended complaint alleged that the defendants violated Sections 11, 12(a)(2) and 15 of the Securities Act with respect to the registration statement and related prospectus for the IPO. The complaint sought unspecified compensatory damages, interest, costs and attorneys' fees. On October 31, 2019, we filed a motion to dismiss the complaint or in the alternative to stay the action in favor of the pending federal action (discussed below). On February 21, 2020 the

court granted the defendants' motion to dismiss the consolidated amended complaint with prejudice. On March 2, 2020 the court entered an amended order dismissing the consolidated amended complaint with prejudice. On March 27, 2020, the plaintiffs filed a notice of appeal with the N.J. Superior Court – Appellate Division.

On September 26, 2019 and October 31, 2019, purported stockholders of our company served putative class action lawsuits in the United States District Court for the District of New Jersey captioned *Allyn Turnofsky vs. electroCore, Inc., et al.*, Case 3:19-cv-18400, and *Priewe vs. electroCore, Inc., et al.*, Case 1:19-cv-19653, respectively. In addition to our company, the defendants include present and past directors and officers, and Evercore Group L.L.C., Cantor Fitzgerald & Co., JMP Securities LLC and BTIG, LLC, the underwriters for our IPO. The plaintiffs each seek to represent a class of stockholders who (i) purchased our common stock in our IPO or whose purchases are traceable to the IPO, or (ii) who purchased common stock between the IPO and September 25, 2019. The complaints each allege that the defendants violated Sections 11 and 15 of the Securities Act and Sections 10(b) and 20(a) of the Exchange Act, with respect to (i) the registration statement and related prospectus for the IPO, and (ii) certain post-IPO disclosures filed with the SEC. The complaints seek unspecified compensatory damages, interest, costs and attorneys' fees.

In the *Turnofsky* case, several plaintiffs and their counsel are engaged in motion practice to select a lead plaintiff and lead plaintiff's counsel. Briefing is complete on the motions, but the court has not yet ruled. On February 19, 2020, the *Priewe* case was voluntarily dismissed.

We intend to continue to vigorously defend ourselves in these matters. However, in light of, among other things, the preliminary stage of these litigation matters, we are unable to determine the reasonable probability of loss or a range of potential loss. Accordingly, we have not established an accrual for potential losses, if any, that could result from any unfavorable outcome, and there can be no assurance that these litigation matters will not result in substantial defense costs and/or judgments or settlements that could adversely affect our financial condition.

In January 2019, we settled a dispute with one of our former advisors, Madison Global Partners, who had filed a complaint against us in the Supreme Court of the State of New York, County of New York (Index No. 652329/2018) as previously reported. As part of that settlement, we paid Madison Global $325,000 and issued to Madison Global and its representatives warrants to purchase in the aggregate 62,181 shares of our common stock at prices ranging from $5.68 per share to $12.60 per share. Substantially all such amounts were accrued in prior accounting periods. (See Note 20 "Commitments and Contingencies" of the notes to our consolidated financial statements in this Annual Report.

Item 4. Mine Safety Disclosures

None.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock is traded on the Nasdaq Market under the symbol "ECOR".

Stockholders

As of March 11, 2020, there were 455 stockholders of record, which excludes stockholders whose shares are held in nominee or street name by brokers.

Dividend Policy

We do not anticipate paying any cash dividends in the foreseeable future.

Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Issuer Purchases of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Annual Report.

Use of Proceeds from Registered Securities

In June 2018, we completed our IPO and issued 5,980,000 shares of common stock, including the underwriter's exercise of their right to purchase additional shares, at an initial offering price to the public of $15.00. We received net proceeds from the IPO of approximately $77.5 million, after deducting underwriting discounts and commissions and offering costs of approximately $12.2 million.

Through December 31, 2019, we used:

(i) approximately $7.3 million to fund activities related to commercialization of our gammaCore products which included hiring additional territory business managers as well as patient and professional promotional activities across multiple media channels,

(ii) approximately $3.9 million to fund expansion of our clinical program into additional indications in headache and rheumatology,

(iii) approximately $3.7 million for the build out of our specialty distribution channel for the launch of gammaCore Sapphire, and

(iv) approximately $40.7 million for working capital, including inventory, and other corporate purposes.

Item 6. Selected Financial Data

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing elsewhere in this Annual Report. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this Annual Report, including those set forth under Item 1A. "Risk Factors" and under "Forward-Looking Statements" in this Annual Report.

Overview

We are a commercial stage medical device company with a proprietary non-invasive vagus nerve stimulation, or nVNS. nVNS is a platform bioelectronic medical therapy that modulates neurotransmitters and immune function through its effects on both the peripheral and central nervous systems. We are initially focused on neurology, and our therapy, gammaCore, is cleared by the FDA for use by adults for the following four neurology indications: the acute treatment of pain associated with each of migraine and eCH, the preventive treatment of migraine headache and adjunctive use for the preventive treatment of CH. We are considering the potential for several new indications for our nVNS technology, which is being studied in a number of investigator-initiated studies.

Following our initial FDA clearance in early 2017, our commercial strategy was to establish gammaCore as a first-line treatment option for the acute treatment of episodic CH in adult patients, who have few alternative treatment options available to them. This strategy was supported by a product registry conducted from July 2017 through June 2018 to build advocacy among key opinion leaders in leading headache centers in the United States, and to generate patient demand in the form of prescriptions submitted to payers. With an earlier-than-anticipated FDA clearance for our acute treatment of migraine indication, we leveraged this advocacy during the registry period as we expanded into migraine, and prepared for a full commercial launch of gammaCore and gammaCore Sapphire for the acute treatment of pain associated with episodic CH and migraine in adult patients, which was accomplished in the third quarter of 2018. With the clearance of adjunctive use for the prevention of CH, in December 2018, we continued to build upon our existing base of advocacy and patient support. In March 2020, the FDA cleared gammaCore for the preventive treatment of migraine headache in adult patients.

Recent Developments

In May 2019, we announced significant adjustments to the deployment of personnel and resources across our organization. We reduced the size of our organization, including our field sales force and clinical operations in order to reduce expenses. We are currently focusing our resources on channels that are currently generating revenue, including the following:

- the Veterans Administration, or VA, and the Department of Defense, or DoD, which includes sales that are being made pursuant to our qualifying contract under the Federal Supply Schedule, or FSS, which was secured by us in December 2018 and open market sales to individual VA facilities**.** According to a presentation at the annual Scientific Meeting of the American Headache Society, approximately 400,000 patients saw a VA healthcare provider in 2018, for headache and we believe they can benefit from gammaCore therapy. The VA/DoD has become our primary source of US revenue and, accordingly, we have redeployed substantially all of our sales function to generating sales of our gammaCore and gammaCore Sapphire products to this channel.
- the United Kingdom, where a recent award from the Innovation Technology Payment Program of the NHS and evidence-based recommendations published in December 2019 by NICE, offers the potential for us to generate revenue from the treatment of CH. In its final evidence-based recommendation, NICE affirmed that gammaCore, when used with the appropriate standard of care, can save an average of £450 per patient in the first year of treatment through a reduction in acute rescue medications use, and with us offering no cost evaluations for all patients. Additionally, NHS has indicated to us that it is extending the previously announced Innovation Technology Payment Program through April 2021 and that it has identified gammaCore as being eligible for the new MedTech Funding Mandate mechanism, which, if confirmed, could potentially provide a basis for the long-term, sustainable reimbursement of gammaCore in the United Kingdom, and
- other potential revenue opportunities, such as in workers compensation and personal injury claims through our distribution agreement with Doctor's Medical, LLC announced in August 2019, as well as other potential distribution arrangements for our products, which may include exploration of international distributors, the direct-to-consumer and private pay markets.

In order to focus our resources on channels that are currently generating revenue and further reduce operating costs, we have also postponed certain clinical trials in indications that are more exploratory in nature. In February 2020, we paused patient enrollment in our Premium II study for migraine prevention. Given the recent FDA clearance for migraine prevention in adults, and challenges to study protocols, related datasets, and our business arising out of the novel coronavirus pandemic, we may also choose to terminate the Premium II study and take other actions to further reduce operating costs including reductions in our workforce.

We have never been profitable and have incurred net losses in each year since our inception. We incurred net losses of $45.1 million and $55.8 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, our accumulated deficit was $83.5 million. We expect to continue to incur substantial net losses and negative cash flows from operations for at least the next several years as we commercialize gammaCore. Our prior losses, combined with expected future losses, have had and will continue to have, for the foreseeable future, an adverse effect on our stockholders' deficit and working capital.

We face a variety of challenges and risks that we will need to address and manage as we pursue our strategy, including our ability to develop and retain an effective sales force, achieve market acceptance of gammaCore among physicians, patients, and third-party payers, and expand the use of gammaCore to additional therapeutic indications.

Because of the numerous risks and uncertainties associated with our commercialization efforts, as well as research and clinical development activities, we are unable to predict the timing or amount of increased expenses, or when, if ever, we will be able to achieve or maintain profitability. Even if we are able to increase sales of gammaCore, we may not become profitable. If we fail to become profitable or are unable to sustain profitability, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

Our expected cash requirements for 2020 and beyond are based on the commercialization success of our products and our ability to reduce operating expenses. There are significant risks and uncertainties as to our ability to achieve these operating results, including as a result of the adverse impact on our business from the COVID-19 pandemic. Due to these risks and uncertainties, we may need to reduce our activities significantly more than our current operating plan and cash flow projections assume in order to fund operations to the end of 2020. There can be no assurance that we will have sufficient cash flow and liquidity to fund our planned activities, which could force us to significantly reduce or curtail our activities and, ultimately, potentially cease operations. These conditions raise substantial doubt about our ability to continue as a going concern. See "-Liquidity and Capital Resources."

Stock Purchase Agreement with Lincoln Park

On March 27, 2020, we entered into a purchase agreement, or Purchase Agreement, and a registration rights agreement, or Registration Rights Agreement, with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which we have the right to sell to Lincoln Park shares, or Purchase Shares, of our common stock having an aggregate value of up to $25,000,000, subject to certain significant limitations of the amount and timing of any such sales due to terms and conditions set forth in the Purchase Agreement.

Over the 36-month term of the Purchase Agreement, for up to an aggregate amount of $25,000,000 of shares of common stock (subject to certain limitations and conditions), we have the right, but not the obligation, from time to time, in our sole discretion, to direct Lincoln Park to purchase up to 200,000 shares, or the Regular Purchase Share Limit, of the common stock (each such purchase, a Regular Purchase). The Regular Purchase Share Limit will increase to 250,000 shares if the closing price of the common stock on the applicable purchase date is not below $1.00 per share and will further increase to 300,000 shares if the closing price of the common stock on the applicable purchase date is not below $1.50 per share. In any case, Lincoln Park's maximum obligation under any single Regular Purchase will not exceed $1,000,000, unless we and Lincoln Park mutually agree to increase the maximum amount of such Regular Purchase. The purchase price for shares of common stock to be purchased by Lincoln Park under a Regular Purchase will be equal to the lower of (in each case, subject to the adjustments described in the Purchase Agreement): (i) the lowest sale price for the common stock on the applicable purchase date and (ii) the arithmetic average of the three lowest sales prices for the common stock during the 10 consecutive trading days prior to the purchase date.

If we direct Lincoln Park to purchase the maximum number of shares of common stock that we may sell in a Regular Purchase, then in addition to such Regular Purchase, and subject to certain conditions and limitations in the Purchase Agreement, we may direct Lincoln Park to make an "accelerated purchase" of an additional number of shares of common stock which may not exceed the lesser of: (i) 300% of the number of shares purchased pursuant to the corresponding Regular Purchase and (ii) 30% of the total number of shares of the common stock traded during a specified period on the applicable

purchase date as set forth in the Purchase Agreement. The purchase price for such shares will be the lesser of 97% of the volume weighted average price of the common stock over a certain portion of the date of sale as set forth in the Purchase Agreement and (ii) the closing sale price of the common stock on the date of sale. Under certain circumstances and in accordance with the Purchase Agreement, we may direct Lincoln Park to purchase shares in multiple "accelerated purchases" on the same trading day.

In addition to the Regular Purchases and "accelerated purchases" described above, we may deliver to Lincoln Park, after the 30-day anniversary of the commencement date of the Purchase Agreement, a "tranche purchase notice" in accordance with the terms of the Purchase Agreement, whereby we may direct Lincoln Park to purchase up to 1,000,000 Purchase Shares at a purchase price equal to 95% of the lower of: (i) the lowest sale price of the common stock on that purchase date and (ii) the arithmetic average of the three lowest sales prices for the common stock during the 10 consecutive trading days prior to the purchase date. We may only deliver a tranche purchase notice to Lincoln Park if at least 30 business days have passed since the most recent tranche purchase. We may only deliver a total of four tranche purchase notices under the Purchase Agreement, and Lincoln Park shall not be obligated to purchase more than $1,000,000 of common stock in any individual tranche purchase.

The Purchase Agreement also prohibits us from directing Lincoln Park to purchase any shares of common stock if those shares, when aggregated with all other shares of common stock then beneficially owned by Lincoln Park and its affiliates, would result in Lincoln Park and its affiliates having beneficial ownership, at any single point in time, of more than 4.99% of the then total outstanding shares of common stock as calculated pursuant to Section 13(d) of the Exchange Act, and Rule 13d-3 thereunder.

Under applicable rules of Nasdaq, we may not issue or sell to Lincoln Park under the Purchase Agreement more than 19.99% of the shares of the common stock outstanding immediately prior to the execution of the Purchase Agreement (or 5,991,912 shares, based on 29,959,565 shares outstanding immediately prior to the execution of the Purchase Agreement), unless (i) stockholder approval is obtained or (ii) the issuances and sales of common stock pursuant to the Purchase Agreement are not deemed to be "below market" in accordance with the applicable rules of Nasdaq.

The Purchase Agreement does not limit our ability to raise capital from other sources at its sole discretion, except that, subject to certain exceptions, we may not enter into any Variable Rate Transaction unless such Variable Rate Transaction qualifies as an Exempt Issuance (as each such term is defined in the Purchase Agreement) during the 36 months after the commencement date of the Purchase Agreement.

In consideration for entering into the Purchase Agreement, we issued an aggregate of 461,676 of initial shares of our common stock to Lincoln Park as a commitment fee. In addition, we shall issue to Lincoln Park up to an aggregate of 230,838 additional commitment shares of our common stock based on a pro-rata percentage of the first $5,000,000 of Purchase Shares issued to Lincoln Park under the Purchase Agreement. We will not receive any cash proceeds from the issuance of any of these commitment shares.

The net proceeds under the Purchase Agreement to us will depend on the frequency and prices at which shares of common stock are sold to Lincoln Park. Actual sales of shares of common stock to Lincoln Park under the Purchase Agreement and the amount of such net proceeds will depend on a variety of factors, including market conditions, the trading price of the common stock and determinations by us, as to other available and appropriate sources of funding for us. We expect to use the proceeds from the offering of shares of our common stock pursuant to the Purchase Agreement for general corporate purposes and working capital.

Changes to Board of Directors

On March 26, 2020, we announced the appointments of three new independent members to our Board of Directors effective April 2, 2020. The newly appointed board members are John Gandolfo, Thomas Patton and Peter Cuneo. We also announced that current Board members Nick Colucci and Jim Tullis will be stepping down from the Board prior to our annual meeting of stockholders that is expected to be held in June 2020. Chairman Carrie S. Cox is stepping down from the Board on April 1, 2020 and will be succeeded in that role by independent Board member Michael G. Atieh.

Critical Accounting Policies and Estimates

The significant accounting policies and basis of presentation of our consolidated financial statements are described in Note 2 "Summary of Significant Accounting Policies" of the consolidated financial statements included with the annual report on Form 10-K.

The preparation of our financial statements is in accordance with U.S. Generally Accepted Accounting Principles, or GAAP, and we are required to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and other related disclosures. While we believe our estimates, assumptions and judgments are reasonable, they are based on information presently available. Actual results may differ significantly from these estimates due to changes in judgments, assumptions and conditions as a result of unforeseen events or otherwise, which could have a material impact on our financial position and results of operations.

We believe the judgements estimates and assumptions associated with the following critical accounting policies have the greatest potential impact on the consolidated financial statements:

- Revenue recognition
- Inventories
- Income taxes
- Stock-based and unit-based compensation
- Research and development

Revenue Recognition

Our principal source of revenue is product sales. Our contracts with customers generally contain a single performance obligation and we recognize revenue from product sales when we have satisfied our performance obligation by transferring control of the product to our customers. Control of the product generally transfers to the customer upon delivery. Revenue is recognized at the amount to which we expect to be entitled in exchange for the sale of our products. Variability in the transaction price for our products pursuant to our contract with customers primarily arises from discounts and rebates. We offer discounts and rebates to certain distributors and customers under our arrangements. In many cases, these amounts are fixed at the time of sale and the transaction price is reduced accordingly.

U.S. Commercial Revenue Outside of Federal Supply Schedule Channel

We instituted a voucher program, in February 2018, whereby new patients could acquire one-month of gammaCore therapy at no cost from our specialty pharmacy if their insurance provider failed to reimburse for our therapy. Under this program, therapy being dispensed to patients by our specialty pharmacy were commercial goods that had been sold by us to our distributor and in turn re-sold to the specialty pharmacy. We reimbursed the specialty pharmacy an amount equal to the amount the specialty pharmacy would have received had a commercial payer reimbursed for this unit, inclusive of any co-payment requirement and the contracted dispensing fee. The amount we received from the original sale of our therapy to our distributor was recognized as revenue by us at the time of the sale, however, as a result of our reimbursement for a unit to the specialty pharmacy, under our voucher program, the amount we received from the distributor for that unit was classified as contra revenue and therefore not recognized. The difference of the amount reimbursed by us to the specialty pharmacy and received by us for the sale of the unit to the distributor was recognized as promotional expense within selling, general and administrative expense.

The vouchers issued under our voucher program, which was modified in mid-July 2018, represented consideration payable to our specialty pharmacy. The vouchers were accounted for as a reduction in transaction price to be paid by the specialty pharmacy. Accordingly, we excluded from revenue both the number of vouchers actually redeemed in the period, and an estimate of the number of vouchers to be redeemed from product already sold to the distributor but not yet dispensed to a patient. The balance of the reimbursement amount paid by us associated with the vouchers was recorded as a promotional expense within selling, general and administrative expenses. Variable consideration estimates were made using the expected value amount method, which is appropriate when there are limited outcomes of variable consideration. In this case, vouchers are either redeemed, or they are not redeemed.

After mid-July 2018, we modified our voucher program to provide gammaCore and gammaCore Sapphire promotional units, or “free voucher units,” to our distributor at no charge. These free voucher units have a distinct product item number that enables ease of tracking and allows the product to be dispensed to the patient at no cost to the specialty pharmacy. In this way, the voucher program is more like a standard sample program where free voucher units, which provide 31-days of therapy, are issued to the patient, rather than being sold and subject to specialty pharmacy reimbursement and therefore recognized as contra-revenue. The cost to produce the free voucher units given to patients under this modified voucher program are now recognized as promotional expense. Our net sales reflect only gammaCore and gammaCore Sapphire units

sold either for new patients, or existing patients' refills, and none of the gammaCore and gammaCore Sapphire units prescribed and dispensed through our voucher program. Our voucher program was terminated in December 2019.

Managed care rebates represent our estimated obligations to pharmacy benefit managers. Rebate accruals are recognized in the same period the related revenue is recognized. Co-payment assistance represents financial assistance to qualified patients, to assist them with co-payments for gammaCore therapy. The calculation of the accrual is based on an estimate of claims and the cost per claim that we expect to incur associated with inventory that exists in the distribution channel at period end. Effective March 1, 2020, the mount of monthly co-payment assistance has been reduced to a maximum of $100 per prescription.

We expense the cost, as incurred, of product damaged as a result of shipping to our specialty pharmaceutical distributor. This expense, historically, has been immaterial. We expect to receive payment on all of our customer receivables within one year and therefore classify all receivables as current assets. In accordance with our policy, damaged or defective products are replaced at no charge under our standard warranty. A cash refund is allowed in our discretion under specific circumstances for undamaged and non-defective returned product.

Accounts receivable are net of an allowance for doubtful accounts, which are accounts from which payment is not expected to be received although product was provided, and revenue was earned. Receivables are written off when deemed uncollectible. Recoveries of receivables previously written off are recorded when received.

Revenue from the Veterans Administration and the Department of Defense

Revenue from sales of our products are recognized under terms of the Federal Supply Schedule, or FSS, and purchase orders from individual VA sites and a distributor who purchases our products on behalf of the DoD. Revenue from the VA includes sales of therapy for up to 93 days.

Sales to the VA and DoD are at a fixed price and are usually paid at the time of delivery.

A cash refund is allowed under specific circumstances for undamaged and non-defective products. Damaged or defective products are replaced at no charge.

United Kingdom Revenue

In the United Kingdom, a recent award from the Innovation Technology Payment program of the NHS and evidence-based recommendations published in December 2019 by NICE offer the potential for us to generate revenue from the treatment of CH. This is the primary commercial channel from which our United Kingdom revenue is derived.

Sales in the U.K. are primarily in increments of 93-day therapy at a fixed price and are paid within 30 days.

Inventories

We value inventory at the lower of cost or net realizable value. Cost is determined on a first in first out basis. This policy requires us to make estimates regarding the net realizable value of our inventory, including an assessment of excess or obsolete inventory. We evaluate inventory for excess quantities and obsolescence based on an estimate of the future demand for our product within a specified timeframe and record an allowance to reduce the carrying value of inventory as determined necessary. The estimates we use for demand are also used for near-term capacity planning and inventory purchasing and are consistent with our revenue forecasts. We evaluate inventory with respect to our operating cycle and classify inventory as either current or long-term on our balance sheet. If our actual demand is less than our forecast demand, we may be required to take additional excess inventory charges, which would decrease gross margin and adversely impact net operating results in the future.

Emerging Growth Company Status

In April 2012, the JOBS Act was enacted by the federal government. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected to "opt out" of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

In addition, as an emerging growth company, we are not be required to provide an auditor's attestation report on our internal control over financial reporting in future annual reports on Form 10-K.

We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Results of Operations

Comparison of the years ended December 31, 2019 and 2018

The following table summarizes our results of operations for the years ended December 31, 2019 and 2018 with the changes in those items in dollars.

	Years ended December 31,		Change
	2019	2018	
	(in thousands)		
Net sales	$ 2,390.3	$ 993.0	$ 1,397.3
Cost of goods sold	1,157.0	578.7	578.3
Gross profit	1,233.3	414.3	819.0
Operating expenses:			
Research and development	9,902.2	12,466.2	(2,564.0)
Selling, general and administrative	35,422.3	42,501.6	(7,079.3)
Restructuring and other severance related charges	1,997.3	—	1,997.3
Total operating expenses	47,321.8	54,967.8	(7,646.0)
Loss from operations	(46,088.5)	(54,553.5)	8,465.0
Other expenses/(income):			
Change in fair value of warrant liability	—	1,870.9	(1,870.9)
Interest and other income, net	(970.6)	(1,006.3)	35.7
Other	12.3	344.9	(332.6)
Total other (income) loss	(958.3)	1,209.5	(2,167.8)
Loss before income taxes	(45,130.2)	(55,763.0)	10,632.8
Provision for income taxes	17.7	2.4	15.3
Net loss from operations	(45,147.9)	(55,765.4)	10,617.5
Less: Net income/(loss) attributable to noncontrolling interest	—	55.0	(55.0)
Total net loss attributable to Electrocore LLC and electroCore, Inc.	$ (45,147.9)	$ (55,820.4)	$ 10,672.5

Net Sales

Net sales increase of $1.4 million reflects an increase in U.S. sales of $1.0 million, primarily the result of increased VA sales of $0.7 million, and an increase in U.K. sales of $0.4 million.

Costs of Goods Sold

Cost of goods sold increased $0.6 million as the result of increased sales of both devices and refill cards.

Research and Development

Research and development expenses decreased by $2.6 million primarily due to decreased personnel costs of $3.3 million as a result of our June 2019 reduction in force, offset by increased costs of physician studies of $0.7 million.

Selling, General and Administrative

Selling, general and administrative expense decreased by $7.1 million, primarily as a result of decreased personnel costs of $1.0 million, decreased commercial consulting costs of $9.1 million, decreased costs for meetings and tradeshows of $1.2

million and decreased insurance costs of $0.6 million. These costs were offset by increased advertising costs of $1.7 million, increased shipping and distribution costs of $0.9 million, increased sales force automation and payor management costs $0.8 million, increased legal fees of $0.9 million and increased sample and voucher unit costs of $0.5 million.

Restructuring and Other Severance Related Expenses

Restructuring and other severance related costs for the year ended December 31, 2019 consists of severance related expenses. There was no such expense for the year ended December 31, 2018.

Change in Fair Value of Warrant Liability and Derivative Instrument related to Convertible Bridge Notes

The change in fair value of the warrant liability and derivative instrument is based on revaluation of those instruments occurring during the year ended December 31, 2018.

Interest and Other Income, Net

The decrease of $35.7 thousand reflects the decreases of marketable securities balances as a result of their conversion to cash.

Liquidity and Capital Resources

At December 31, 2019 our cash, cash equivalents, and marketable securities was $24.1 million compared to $68.6 million at December 31, 2018.

	December 31,	
	2019	**2018**
	(in millions)	
Net cash (used in) provided by		
Operating activities	$ (45.1)	$ (47.1)
Investing activities	$ 51.0	$ (36.8)
Financing activities	$ 0.2	$ 78.3

Operating Activities

Cash used in operating activities is net loss adjusted for certain non-cash items and change in assets and liabilities.

For 2019 compared to 2018, the $2.0 million decrease in cash used in operating activities was primarily attributable to our decreased net loss with minimal change in working capital. The reduction in loss was primarily due to the reduction in force and cost control efforts in 2019 which resulted in a significant decrease in salaries and wages as well as other costs. Increases in our inventory were offset by similar increases in our accounts payable and accrued expenses.

Investing Activities

Investing cash flows consist primarily of the purchases and maturity of our marketable securities.

For 2019 compared to 2018, cash provided by investing activities increased as a result of the increase in proceeds from maturities of marketable securities with a reduction in the amount of purchases of marketable securities.

Financing Activities

For 2019 compared to 2018, cash provided by financing activities primarily decreased as a result of the issuance of common stock in our 2018 IPO. The 2019 issuance and partial repayment of short-term debt slightly offset this decrease.

Liquidity Outlook

Because we have had recurring losses, negative cash flows from operating activities, limited cash on hand and expect to continue to incur losses for the near future, the report of our independent auditors with respect to our financial statements as of December 31, 2019 and for the year ended December 31, 2019 contains an explanatory paragraph as to the factors that raise substantial doubt about the Company’s ability to continue as a going concern.

Our financial statements have been prepared assuming we will continue as a going concern. We have experienced recurring losses since our inception. We incurred a net loss of $45.1 million and used $45.1 million in cash from operations for the year ended December 31, 2019 and had an accumulated deficit of $83.5 million as of December 31, 2019. At December 31, 2019, we had approximately $13.6 million of cash and cash equivalents and $10.5 million of marketable securities.

Our expected cash requirements for 2020 and beyond are based on the commercialization success of our products and our ability to reduce operating expenses. There are significant risks and uncertainties as to our ability to achieve these operating results, including as a result of the potential adverse impact on our business from the ongoing COVID-19 pandemic, Due to these risks and uncertainties, we may need to reduce our activities significantly more than our current operating plan and cash flow projections assume in order to fund operations to the end of 2020. There can be no assurance that we will have sufficient cash flow and liquidity to fund our planned activities, which could force us to significantly reduce or curtail our activities and, ultimately, potentially cease operations. These conditions raise substantial doubt about our ability to continue as a going concern.

Even if we are not required to curtail our activities sooner, our ability to execute our operating plan beyond 2020 depends on our ability to increase revenue, reduce operating expenses and obtain additional funding through the sale of equity and or debt securities, a strategic transaction or otherwise. However, these alternatives may not be available to us on attractive terms, or at all. There is no assurance that we will generate sufficient cash flow and funding through our operating results or the sale of securities or from a strategic transaction or otherwise, raising substantial doubt about our ability to continue as a going concern within one year of the date these financial statements are issued. The inability to generate sufficient cash flow or raise funds through the sources discussed above could have a material adverse effect on our business, results of operations, and financial condition, and could require us to reduce or curtail activities, or cease operations.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not have any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Impact of Recently Issued Accounting Standards

In the normal course of business, we evaluate all new accounting pronouncements issued by the FASB, SEC, or other authoritative accounting bodies to determine the potential impact they may have on our Consolidated Financial Statements. See Note 2 “Basis of Presentation” of the notes to our consolidated financial statements in this Annual Report for additional information about these recently issued accounting standards and their potential impact on our financial condition or results of operations.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We develop our products in the United States and sell those products into more than four countries. As a result, our financial results could be affected by factors such as changes in foreign currency exchange rates or weak economic conditions in foreign markets. Most of our sales in Europe are denominated in the U.S. dollar and Euro. As our sales in currencies other than the U.S. dollar increase, our exposure to foreign currency fluctuations may increase. In addition, changes in exchange rates also may affect the end-user prices of our products compared to those of our foreign competitors, who may be selling their products based on local currency pricing. These factors may make our products less competitive in some countries.

If the U.S. dollar uniformly increased or decreased in strength by 10% relative to the currencies in which our sales were denominated, our net income would have correspondingly increased or decreased by an immaterial amount for the year ended December 31, 2019.

Our exposure to market interest rate risk is confined to our cash and cash equivalents and marketable securities. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we may maintain a portfolio of cash equivalents and investments in a variety of securities of high credit quality. The securities in our investment portfolio, if any, are not leveraged, are classified as available for sale and are, due to their very short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our cash equivalents, we do not believe that an increase in market rates would have any material negative impact on interest income recognized in our statement of operations. We have no investments denominated in foreign currencies and therefore our investments are not subject to foreign currency exchange risk. We contract with CROs, investigational sites, suppliers and other vendors in Europe and internationally. We are subject to fluctuations in foreign currency rates in connection with these agreements. We do not hedge our foreign currency exchange rate risk.

All of the potential changes noted above are based on sensitivity analyses performed on our financial position as of December 31, 2019.

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report. An index of those financial statements is found in Item 15.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the rules and forms, and that such information is accumulated and communicated to us, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, as ours are designed to do, and we apply our judgment in evaluating whether the benefits of the controls and procedures that we adopt outweigh their costs.

As required by Rule 13a-15(b) of the Exchange Act, an evaluation as of December 31, 2019 was conducted under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act). Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures, as of December 31, 2019, were effective for the purposes stated above.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Rule 13a-15(f) under the Exchange Act. Internal control over financial reporting is a process designed under the supervision and with the participation of our management including our Chief Executive Officer and Chief Financial Officer to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets: (ii) provide reasonable assurance (a) transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting policies (b) our receipts and expenditures are being made only in accordance with authorizations of our management and directors: and (c) regarding the prevention or timely detection of the unauthorized acquisition use or disposition of assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

As of December 31, 2019, our management conducted an evaluation of the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control – Integrated Framework (2013). Based on this evaluation, our management concluded that, as of December 31, 2019 our internal control over financial reporting was effective.

Management remediated the material weakness related to its internal control over financial reporting related to accounting for complex transactions that was disclosed in our prospectus dated June 21, 2018, filed with the SEC, pursuant to Rule 424(b) under the Securities Act.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit us to provide only management's report in this annual report.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the quarter ended December 31, 2019 that has materially affected or is reasonably likely to materially affect our internal control over financial reporting.

Item 9B. Other Information.

On March 26, 2020 we received notification from the FDA that our gammaCore therapy may be commercially marketed for the preventive treatment of migraine headache in adults.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2020 Annual Meeting of Stockholders or an amendment to this Annual Report, which we intend to file with the SEC within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

Item 11. Executive Compensation.

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2020 Annual Meeting of Stockholders or an amendment to this Annual Report, which we intend to file with the SEC within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Item 404 of Regulation S-K. The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2020 Annual Meeting of Stockholders or an amendment to this Annual Report, which we intend to file with the SEC within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2020 Annual Meeting of Stockholders or an amendment to this Annual Report, which we intend to file with the SEC within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

Item 14. Principal Accounting Fees and Services.

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2020 Annual Meeting of Stockholders or an amendment to this Annual Report, which we intend to file with the SEC within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this report:

(1) Financial Statements:

(2) Financial Statement Schedules:

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(3) Exhibits. The exhibits filed as part of this Annual Report on Form 10-K are set forth on the Exhibit Index immediately following Item 16. The Exhibit Index is incorporated herein by reference.

Item 16. Form 10-K Summary

None.

Exhibit Number	Description
3.1***	Certificate of Incorporation of electroCore, Inc.
3.2***	Bylaws of electroCore, Inc.
4.1*****	Registration Rights Agreement, dated March 27, 2020, between electroCore, Inc. and Lincoln Park Capital Fund, LLC
10.1**	Amended and Restated Investors' Rights Agreement, dated as of August 18, 2017, by and among Electrocore, LLC and the investors party thereto
10.2†**	electroCore, Inc. 2018 Omnibus Equity Incentive Plan
10.3†**	Form of Employee Incentive Stock Option Agreement for electroCore, Inc. 2018 Omnibus Equity Incentive Plan
10.4†**	Form of Non-qualified Stock Option Agreement for electroCore, Inc. 2018 Omnibus Equity Incentive Plan
10.5†**	Form of Employee Restricted Stock Award Agreement for electroCore, Inc. 2018 Omnibus Equity Incentive Plan
10.6†**	Form of Non-Employee Director Inaugural Deferred Stock Unit Award Agreement for electroCore, Inc. 2018 Omnibus Equity Incentive Plan
10.7†**	Form of Non-Employee Director Inaugural Non-qualified Stock Option Agreement for electroCore, Inc. 2018 Omnibus Equity Incentive Plan
10.8†**	Form of Non-Employee Director Inaugural Restricted Stock Unit Agreement for electroCore, Inc. 2018 Omnibus Equity Incentive Plan
10.9†**	Form of Non-Employee Director Annual Deferred Stock Unit Award Agreement for electroCore, Inc. 2018 Omnibus Equity Incentive Plan
10.10†**	Form of Non-Employee Director Annual Non-qualified Stock Option Agreement for electroCore, Inc. 2018 Omnibus Equity Incentive Plan
10.11†**	Form of Non-Employee Director Annual Restricted Stock Unit Agreement for electroCore, Inc. 2018 Omnibus Equity Incentive Plan
10.12†**	Form of Indemnification Agreement between the Registrant and each of its executive officers and directors
10.13†**	Form of electroCore, Inc. Management Severance Plan
10.14†**	electroCore, Inc. Non-Employee Director Compensation Policy
10.15†**	Employment Offer Letter, dated as of July 18, 2016, by and between ElectroCore, LLC and Francis R. Amato
10.16†**	Employment Offer Letter, dated as of July 18, 2016, by and between ElectroCore, LLC and Joseph P. Errico
10.17†**	Employment Offer Letter, dated as of May 1, 2017, by and between ElectroCore, LLC and Peter S. Staats
10.18†**	Employment Offer Letter, dated as of July 25, 2016, by and between ElectroCore, LLC and Glenn S. Vraniak
10.19****	Rockaway, NJ Office Lease between Anson Logistics Assets LLC and electroCore, Inc.
10.20**	Basking Ridge, NJ Office Lease between 150 Allen Road, LLC and Electrocore, LLC
10.21**	Form of Common Unit Warrant
10.22**	Form of Series A Warrant
10.23**	Form of Bridge Warrant
10.24**	Master Services Agreement dated October 17, 2016 between ElectroCore, LLC and Asembia LLC
10.25†	Brian Posner Employment Agreement, dated as of January 30, 2019, incorporated by reference to the Company's Current Report on Form 8-K, as filed with the Commission on March 12, 2019.
10.26†	Amendment to Brian Posner Employment Agreement, dated as of August 8, 2019, incorporated by reference to the Company's Quarterly Report on Form 10-Q, as filed with the Commission on August 14, 2019.

10.27†	Employment Offer Letter, dated as of September 26, 2019, between electroCore, Inc. and Daniel Goldberger, incorporated by reference to the Company's Current Report on Form 8-K, as filed with the Commission on October 2, 2019.
10.28*****	Purchase Agreement, dated March 27, 2020, between electroCore, Inc. and Lincoln Park Capital Fund, LLC
21.1*	List of subsidiaries of electroCore, Inc.
23.1*	Consent of KPMG LLP
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

** Incorporated by reference to the Company's Registration Statement on Form S-1, Registration No. 333-228863.

*** Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2018 as filed with the Commission on August 14, 2018.

**** Incorporated by reference to the Company's Annual Report on Form 10-K for the period ended December 31, 2018 as filed with the Commission on March 28, 2019.

***** Incorporated by reference to the Company's Current Report on Form 8-K as filed with Commission on March 27, 2020.

† Indicates management agreement

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

electroCore, Inc.

Date: March 30, 2020 By: /s/ DANIEL S. GOLDBERGER

Daniel S. Goldberger
Chief Executive Officer and Director
(Principal Executive Officer)

Date: March 30, 2020 By: /s/ BRIAN M. POSNER

Brian M. Posner
Chief Financial Officer
(Principal Financial and Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Carrie S. Cox **Carrie S. Cox**	Chairman of the Board	March 30, 2020
/s/ Daniel S. Goldberger **Daniel S. Goldberger**	Director	March 30, 2020
/s/ Michael G. Atieh **Michael G. Atieh**	Director	March 30, 2020
/s/Joseph P. Errico **Joseph P. Errico**	Director	March 30, 2020
/s/Nicholas Colucci **Nicholas Colucci**	Director	March 30, 2020
/s/Thomas J. Errico, M.D. **Thomas J. Errico, M.D.**	Director	March 30, 2020
/s/Trevor J. Moody **Trevor J. Moody**	Director	March 30, 2020
/s/Stephen L. Ondra, M.D. **Stephen L. Ondra, M.D.**	Director	March 30, 2020
/s/James L.L. Tullis **James L.L. Tullis**	Director	March 30, 2020

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
electroCore, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of electroCore, Inc., Subsidiaries and Affiliate (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations, comprehensive loss, changes in stockholders equity and members' deficit, and cash flows for each of the years in the two-year period ended December 31, 2019, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3 to the consolidated financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 3. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2015.

Short Hills, New Jersey
March 30, 2020

ELECTROCORE, INC., SUBSIDIARIES AND AFFILIATE

Consolidated Balance Sheets

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 13,563,791	$ 7,600,284
Marketable securities	10,495,350	60,963,087
Accounts receivable	496,140	267,599
Inventories, net	890,992	1,949,402
Prepaid expenses and other current assets	1,087,111	1,918,164
Total current assets	26,533,384	72,698,536
Inventories, noncurrent	6,020,180	—
Property and equipment, net	345,236	380,904
Operating lease right of use assets	1,430,641	—
Other assets	1,132,238	424,896
Total assets	$ 35,461,679	$ 73,504,336
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,208,979	$ 2,698,902
Accrued expenses	3,337,379	4,374,101
Note payable	111,878	—
Current portion of operating lease liability	486,445	—
Total current liabilities	9,144,681	7,073,003
Deferred rent	—	245,632
Operating lease liabilities	1,419,880	—
Total liabilities	10,564,561	7,318,635
Commitments and contingencies (Note 20)		
Preferred Stock,par value $0.001 per share; 10,000,000 shares authorized at December 31, 2019 and December 31, 2018; 0 shares issued and outstanding at December 31, 2019 and December 31, 2018	—	—
Common Stock, par value $0.001 per share; 500,000,000 shares authorized at December 31, 2019 and December 31, 2018; 29,835,183 shares issued and outstanding at December 31, 2019, and 29,450,035 shares issued and outstanding at December 31, 2018	29,835	29,450
Additional paid-in capital	107,752,066	103,791,013
Accumulated deficit	(83,479,098)	(38,331,215)
Accumulated other comprehensive (loss)/income	(41,295)	60,843
Total stockholders' equity	24,261,508	65,550,091
Noncontrolling interest	635,610	635,610
Total equity	24,897,118	66,185,701
Total liabilities and stockholders' equity	$ 35,461,679	$ 73,504,336

See accompanying notes to the consolidated financial statements

ELECTROCORE, INC., SUBSIDIARIES AND AFFILIATE

Consolidated Statements of Operations

	Year ended December 31,	
	2019	2018
Net sales	$ 2,390,279	$ 992,953
Cost of goods sold	1,156,957	578,743
Gross profit	1,233,322	414,210
Operating expenses:		
Research and development	9,902,254	12,466,172
Selling, general and administrative	35,422,301	42,501,562
Restructuring and other severance related charges	1,997,292	—
Total operating expenses	47,321,847	54,967,734
Loss from operations	(46,088,525)	(54,553,524)
Other (income)/expense		
Change in fair value of warrant liability	—	1,870,923
Interest and other income, net	(970,594)	(1,006,332)
Other expense	12,253	344,909
Total other (income)/expense	(958,341)	1,209,500
Loss before income taxes	(45,130,184)	(55,763,024)
Provision for income taxes	17,699	2,431
Net loss from operations	(45,147,883)	(55,765,455)
Less: Net income attributable to noncontrolling interest	—	55,005
Total net loss attributable to Electrocore LLC and electroCore, Inc., subsidiaries and affiliate	$ (45,147,883)	$ (55,820,460)
Net loss attributable to Electrocore LLC, subsidiaries and affiliate	$ —	$ (21,118,337)
Net loss attributable to electroCore, Inc., subsidiaries and affiliate	$ (45,147,883)	$ (34,702,123)
Net loss per share of common stock - Basic and Diluted (see Note 13)	$ (1.54)	$ (1.19)
Weighted average and potential common shares outstanding - Basic and Diluted (see Note 13)	29,379,975	29,261,943

See accompanying notes to the consolidated financial statements.

ELECTROCORE, INC., SUBSIDIARIES AND AFFILIATE

Consolidated Statements of Comprehensive Loss

	Year ended December 31,	
	2019	2018
Net loss from operations	$ (45,147,883)	$ (55,765,455)
Other comprehensive (loss) income:		
Foreign currency translation adjustment	(145,418)	3,259
Amount reclassed from accumulated other comprehensive loss	—	11,024
Unrealized gain(loss) on marketable securities, net of taxes as applicable	43,280	(33,653)
Other comprehensive loss	(102,138)	(19,370)
Comprehensive loss	(45,250,021)	(55,784,825)
Less: Comprehensive income attributable to noncontrolling interest	—	5,085
Comprehensive loss attributable to Electrocore LLC and electroCore, Inc., subsidiaries and affiliates	$ (45,250,021)	$ (55,789,910)
Comprehensive loss attributable to Electrocore LLC, subsidiaries and affiliate	$ —	$ (21,118,056)
Comprehensive loss attributable to electroCore, Inc., subsidiaries and affiliate	$ (45,250,021)	$ (34,671,854)

See accompanying notes to consolidated financial statements.

ELECTROCORE, INC., SUBSIDIARIES AND AFFILIATE

Consolidated Statements of Changes in Stockholders' Equity and Members' Deficit

	Convertible Preferred Units				electroCore, Inc. for the years ended December 31, 2019 and 2018									
	Series A Preferred Units		Series B Preferred Units		Common Units		Common Stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income(loss)	(Deficit)/Equity attributable to Electrocore LLC and electroCore, Inc., subsidiaries and affiliate	Noncontrolling interest	Total equity/ (deficit)
	Units	Amount	Units	Amount	Units	Amount	Shares	Amount						
Balances as of December 31, 2017	70,918,506	$ 53,518,463	105,186,020	$ 68,755,544	218,982,140	$ 40,180,619	—	$ —	$ 22,596,485	$ (152,928,928)	$ 80,213	$ (90,071,611)	$ 604,055	$ (89,467,556)
Net loss attributable to Electrocore, LLC subsidiaries and affiliates	—	—	—	—	—	—	—	—	—	(21,118,337)	(5,085)	(21,123,422)	60,090	(21,063,332)
Reclass of accumulated deficit to APIC	—	—	—	—	—	—	—	—	(174,047,265)	174,047,265	—	—	—	—
Other comprehensive income	—	—	—	—	—	—	—	—	—	—	(14,285)	(14,285)	(5,085)	(19,370)
Conversion of Series A preferred units to common stock	(70,918,506)	(53,518,463)	—	—	—	—	3,939,917	3,940	53,514,523	—	—	53,518,463	—	53,518,463
Conversion of Series B preferred units to common stock	—	—	(105,186,020)	(68,755,544)	—	—	5,843,668	5,844	68,749,700	—	—	68,755,544	—	68,755,544
Conversion of members common units to common stock	—	—	—	—	(218,982,140)	(40,180,619)	12,099,280	12,099	40,168,520	—	—	—	—	—
Stock dividend issued to Series A preferred holders	—	—	—	—	—	—	241,939	242	3,628,850	(3,629,092)	—	—	—	—
Common stock issued related to initial public offering	—	—	—	—	—	—	5,980,000	5,980	89,692,675	—	—	89,698,655	—	89,698,655
Issuance costs related to initial public offering	—	—	—	—	—	—	—	—	(12,222,438)	—	—	(12,222,438)	—	(12,222,438)
Reclass of warrant liability to equity	—	—	—	—	—	—	—	—	4,110,467	—	—	4,110,467	—	4,110,467
Noncontrolling interest distributions	—	—	—	—	—	—	—	—	—	—	—	—	(23,450)	(23,450)
Stock issued upon conversion of profit interests	—	—	—	—	—	—	1,345,231	1,345	—	—	—	1,345	—	1,345
Stock and Unit-based compensation	—	—	—	—	—	—	—	—	7,599,496	—	—	7,599,496	—	7,599,496
Net loss attributable to electroCore, Inc., subsidiaries and affiliates	—	—	—	—	—	—	—	—	—	(34,702,123)	—	(34,702,123)	—	(34,702,123)
Balances as of December 31, 2018	—	$ —	—	$ —	—	$ —	29,450,035	$ 29,450	$ 103,791,013	$ (38,331,215)	$ 60,843	$ 65,550,091	$ 635,610	$ 66,185,701
Net loss	—	—	—	—	—	—	—	—	—	(45,147,883)	—	(45,147,883)	—	(45,147,883)
Other comprehensive income	—	—	—	—	—	—	—	—	—	—	(102,138)	(102,138)	—	(102,138)
Issuance of warrants in lawsuit settlement	—	—	—	—	—	—	—	—	16,692	—	—	16,692	—	16,692
Issuance of common stock in connection with employee stock plans, net	—	—	—	—	—	—	385,148	385	48,580	—	—	48,965	—	48,965
Stock based compensation	—	—	—	—	—	—	—	—	3,895,781	—	—	3,895,781	—	3,895,781
Balances as of December 31, 2019	—	$ —	—	$ —	—	$ —	29,835,183	$ 29,835	$ 107,752,066	$ (83,479,098)	$ (41,295)	$ 24,261,508	$ 635,610	$ 24,897,118

See accompanying notes to the consolidated financial statements

ELECTROCORE, INC., SUBSIDIARIES AND AFFILIATE

Consolidated Statements of Cash Flows

	Year ended December 31,	
	2019	2018
Cash flows from operating activities:		
Net loss from operations	$ (45,147,883)	$ (55,765,455)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of warrants and embedded derivative	—	1,870,923
Stock based compensation	3,895,781	7,599,496
Depreciation and amortization	249,583	66,663
Amortization of marketable securities discount	(530,104)	(497,267)
Cloud computing arrangement implementation costs	(1,114,568)	(107,754)
Noncash lease expense, net	57,780	—
Noncash portion of litigation settlement	16,692	—
Other	76,279	12,136
Changes in operating assets and liabilities:		
Accounts receivable, net	(228,541)	(164,390)
Inventories	(4,961,770)	(1,621,615)
Prepaid expenses and other assets	859,204	(1,347,410)
Accounts payable	2,797,727	1,858,519
Accrued expense and other current liabilities	(1,036,721)	1,047,059
Deferred rent	—	(61,254)
Net cash used in operating activities	(45,066,541)	(47,110,349)
Cash flows from investing activities:		
Purchase of marketable securities	(37,224,879)	(81,058,590)
Proceeds from maturities of marketable securities	88,266,000	44,509,684
Purchases of property and equipment	(69,675)	(278,921)
Net cash provided by (used in) investing activities	50,971,446	(36,827,827)
Cash flows from financing activities:		
Proceeds from note issued	807,347	—
Repayments of note issued	(695,469)	—
Sale of common stock, net of related expenses	—	78,334,457
Proceeds from shares issued in connection with employee stock purchase plan	48,965	—
Net cash provided by financing activities	160,843	78,334,457
Effect of changes in exchange rates on cash and cash equivalents	(102,241)	(20,191)
Net increase (decrease) in cash and cash equivalents	5,963,507	(5,623,910)
Cash and cash equivalents – beginning of period	7,600,284	13,224,194
Cash and cash equivalents – end of period	$ 13,563,791	$ 7,600,284
Supplemental schedule of noncash financing activity:		
Series A preferred units converted to common stock	$ —	$ 53,518,463
Series B preferred units converted to common stock	$ —	$ 68,755,544
Members' common units converted to common stock	$ —	$ 40,180,619
Reclass of warrant liability to additional paid in capital	$ —	$ 4,110,467
Reclass of deferred financing costs to additional paid in capital	$ —	$ 856,985
Stock dividend distribution in connection with IPO	$ —	$ 3,629,092
Capitalized cloud computing arrangement costs included in accounts payable and accrued expenses	$ —	$ 287,650
Cash paid during the year for:		
Income taxes paid	$ 29,542	$ 45,641
Interest paid	$ 3,457	$ —

See accompanying notes to consolidated financial statements

Note 1. Business

Company Overview

electroCore, Inc. (“electroCore” or the “Company”) is a commercial stage medical device company, engaged in the commercialization and development of a range of patient administered non-invasive Vagus Nerve Stimulation (“nVNS”) therapies. electroCore was founded in 2005 and its focus currently is on primary headache conditions (migraine and cluster headache).

electroCore, headquartered in New Jersey, has wholly owned subsidiaries that include: electroCore Germany GmbH, and electroCore UK Ltd. The Company’s subsidiary, electroCore Bermuda, Ltd. was dissolved in October 2019. In addition, an affiliate, electroCore (Aust) Pty Limited, is subject to electroCore’s control on a basis other than voting interests and is a variable interest entity (“VIE”), for which electroCore is the primary beneficiary.

In January 2018, the U.S. Food and Drug Administration ("FDA") released the use of gammaCore, the Company's first generation disposable non-invasive vagus nerve stimulator therapy for the treatment of pain associated with migraine headache in adult patients. Previously in April 2017, the FDA released the use of gammaCore for the acute treatment of pain associated with episodic cluster headache in adult patients. Effective August 1, 2018, the Company announced gammaCore Sapphire, a rechargeable and reloadable version of the product for multi-year use, was available in the United States. The Company continues to market the non-reloadable disposable version of its gammaCore products in certain markets and to deploy it for use in clinical studies where a rechargeable version is not necessary.

In November 2018, the FDA provided 501(k) clearance for an expanded label for gammaCore nVNS therapy for adjunctive use for the preventive treatment of cluster headache in adult patients.

In March 2020, the FDA provided 501(k) clearance for an expanded label for gammaCore nVNS therapy for the preventive treatment of migraine headache in adult patients.

Corporate Conversion and Initial Public Offering

Effective June 21, 2018, the Company converted into a Delaware corporation pursuant to a statutory conversion and changed its name to electroCore, Inc. Previously, the Company operated as a Delaware limited liability company under the name Electrocore, LLC. As a result of the corporate conversion, the holders of the different series of units of Electrocore, LLC, or Units, became holders of common stock and options to purchase common stock of electroCore, Inc. Warrants to purchase Units were converted to warrants to purchase common stock of electroCore, Inc. The number of shares of common stock, options to purchase common stock, and warrants to purchase common stock that holders of Units and warrants to purchase Units were entitled to receive in the corporate conversion was determined in accordance with a plan of conversion that was based upon the terms of the Third Amended and Restated Limited Liability Company Agreement, dated November 21, 2017 (the “Operating Agreement”), and varied depending on which class and series of Units a holder owned, and the terms of the applicable warrants. See Note 14 - Corporate Conversion and Equity.

In June 2018, the Company completed its initial public offering ("IPO") and issued 5,980,000 shares of common stock, including the underwriter’s exercise of their right to purchase additional shares, at an initial offering price to the public of $15.00. The Company received net proceeds from the IPO of approximately $77.5 million, after deducting underwriting discounts and commissions and offering costs of approximately $12.2 million.

Note 2. Significant Accounting Policies

(a) Basis of Presentation

The accompanying consolidated financial statements were prepared in conformity with U.S. generally accepted accounting principles (“U.S. GAAP”).

(b) Principles of Consolidation

The accompanying consolidated financial statements include the accounts of electroCore and its wholly owned subsidiaries. electroCore (Aust) Pty Limited, a VIE for which electroCore is the primary beneficiary, is also consolidated with the non-controlled equity presented as non-controlling interest. All intercompany balances and transactions have been eliminated in consolidation.

(c) Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant items subject to such estimates and assumptions include the useful lives of fixed assets; allowances for doubtful accounts and sales returns; valuation of inventory, property and equipment, warrants and derivative instruments, stock compensation, and contingencies.

(d) Revenue Recognition

The Company accounts for its revenue transactions under Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC Topic 606"). In accordance with ASC Topic 606, the Company recognizes revenues when its customers obtain control of its product for an amount that reflects the consideration it expects to receive from its customers in exchange for that product. To determine revenue recognition for contracts that are determined to be in scope of ASC Topic 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies the performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. Once the contract is determined to be within the scope of ASC Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when such performance obligation is satisfied.

The transaction price is based on the consideration that the Company expects to receive in exchange for its products and includes the fixed per-unit price of the product and variable consideration in the form of trade credits, vouchers, rebates, and co-payment assistance. The per-unit price is based on the Company's established wholesale acquisition cost less a contractually agreed upon distributor discount with the customer.

Trade credits are discounts that are contingent upon a timely remittance of payment and are estimated based on historical experience. Damaged or defective products are replaced at no charge under the Company's standard warranty. A cash refund is allowed under specific circumstances for undamaged and non-defective returned products.

Shipping fees are not billed to the customer and are reflected as part of selling, general, and administrative expenses.

(e) Cash and Cash Equivalents

Cash and cash equivalents include all highly liquid investments with a maturity of three months or less when purchased.

(f) Marketable Securities

Marketable securities, all of which are available-for-sale, consist of corporate debt securities, U.S. bonds and U.S. sponsored agencies. Marketable securities are carried at fair value, with unrealized gains and losses reported as accumulated other comprehensive income, except for losses from impairments which are determined to be other-than-temporary. Realized gains and losses and declines in value judged to be other-than-temporary are included in the determination of net loss and are included in interest and other income net. Fair values are based on quoted market prices at the reporting date. Interest and dividends on available-for-sale securities are included in Interest and other income.

(g) Concentration of Credit Risk

Cash, cash equivalents and marketable securities are financial instruments that potentially subject the Company to concentration of credit risk. The Company periodically invests its cash in corporate debt securities, U.S. bonds, and U.S. sponsored agencies and municipal bonds with strong credit ratings. The Company has established guidelines relative to diversification and maturities that are designed to help ensure safety and liquidity. These guidelines are periodically reviewed to take advantage of trends in yields and interest rates.

(h) Accounts Receivable

Accounts receivable are recorded at the invoiced amount and do not bear interest. The Company maintains an allowance for doubtful accounts for estimated losses inherent in its accounts receivable portfolio. Management considers an account receivable to be past due when it is not settled under its stated terms. In establishing the required allowance, management considers historical losses adjusted to take into account current market conditions and customers' financial condition, the amount of receivables in dispute, and the current receivables aging and current payment patterns. Account balances are charged off against the allowance after all means of collection have been exhausted and the potential for recovery is considered remote. The Company does not have any off balance sheet credit exposure related to its customers.

The Company controls its exposure to credit risk through credit analysis and approvals, credit limits, and monitoring procedures. Collateral is generally not required for the Company's accounts receivables. Management believes the credit risk is limited.

(i) Inventories

Inventory, which consists of raw materials, work-in-process and finished product, is stated at the lower of cost and net realizable value. Inventory is valued on a first-in first-out basis. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation.

The Company evaluates inventory with respect to its operating cycle and classifies inventory as current or long-term on its balance sheet. Based upon estimated production needs and current inventory levels, the Company determined the amount of inventory necessary for the next twelve months. Any amounts over this projection are reclassified as *Inventories, noncurrent*.

In addition, the Company's product is subject to strict quality control and monitoring which the Company performs throughout the manufacturing process. If certain units of product no longer meet quality specification or become obsolete, the Company records a charge to cost of sales sold to write down such unmarketable inventory to zero.

(j) Property and Equipment

Property and equipment are stated at historical cost. Depreciation is computed by the straight-line method based on the estimated useful lives of the respective assets, as discussed below. Leasehold improvements are amortized over the lesser of the lease terms or the estimated useful lives of the assets. Amounts expended for maintenance and repairs are charged to expense as incurred.

Depreciation and leasehold improvement amortization is computed using the following estimated useful lives:

Machinery and equipment	3–15 years
Leasehold improvements	Lease term
Furniture and fixtures	5–10 years
Computer equipment	5 years

(k) Leases

The Company determines if an arrangement is a lease at inception. For each lease, the lease term is determined at the commencement date and includes renewal options and termination options when it is reasonably certain that the Company will exercise that option. Operating leases with the lease terms greater than one year are included in operating lease right-of-use ("ROU") assets and current and long-term operating lease liabilities in the Company's consolidated balance sheets.

Operating lease ROU assets represent the right to use an underlying asset for the lease term and lease liabilities represent the obligation to make lease payments arising from the lease. Operating lease liabilities are recognized at commencement date based on the present value of lease payments over the lease term using an estimated rate of interest the Company would have to pay to borrow equivalent funds on a collateralized basis at the lease commencement date. The operating lease ROU assets are based on the liability adjusted for any prepaid or deferred rent and lease incentives. The incremental borrowing rate was utilized to discount lease payments over the expected term given that the Company's operating leases do not provide an implicit rate. The Company estimates the incremental borrowing rate to reflect the profile of secured borrowing over the expected term of the leases based on the information available at the later of the date of adoption or the lease commencement date. Rent expense for the operating lease is recognized on a straight-line basis over the lease term.

The new lease accounting guidance permits companies to utilize certain practical expedients in their implementation of the new standard. The Company elected this package of practical expedients and was therefore not required to reassess the following upon adoption: (i) whether an expired or existing contract met the definition of a lease; (ii) the lease classification at January 1, 2019 for existing leases; and (iii) whether leasing costs previously capitalized as initial direct costs would continue to be amortized. This allowed the Company to continue to account for its existing office space leases as operating leases. Upon adoption, the Company did not have an adjustment to the opening balance of retained earnings due to the election of these practical expedients.

(l) Cloud Computing Arrangement

Implementation costs for the Company's cloud computing arrangement ("CCA") are capitalized and amortized using the straight-line method over the life of the arrangement. The Company has capitalized implementation costs incurred in implementing its cloud computing arrangements, which is a hosting arrangement that is a service contract per FASB Accounting Standards Update ("ASU") 2018-15. These costs include payroll costs of employees devoting time to the project and external direct costs for materials and services are capitalized. Software maintenance and training costs are expensed in the period in which they are incurred. The capitalized costs are included as a component of other assets.

(m) Impairment of Long-Lived Assets

Long lived assets, such as property, plant, and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances require a long-lived asset or asset group be tested for possible impairment, the Company first compares undiscounted cash flows expected to be generated by that asset or asset group to its carrying amount. If the carrying amount of the long-lived asset or asset group is not recoverable on an undiscounted cash flow basis, an impairment is recognized to the extent that the carrying amount exceeds its fair value. Fair value is determined through various valuation techniques including discounted cash flow models, quoted market values, and third-party independent appraisals, as considered necessary.

(n) Stock-based Compensation

The Company accounts for stock-based compensation in accordance with the ASC Topic 718, *Compensation – Stock Compensation*. The Company estimates the fair value of stock option awards using the Black-Scholes option pricing model on the date of the grant. Restricted stock unit awards and restricted stock awards without a market condition are valued based on the closing price of the Company's common stock on the date of the grant. Compensation expense reflects actual forfeitures and is primarily recognized on a straight-line basis over the requisite service period of the individual grants, which typically equals the vesting period.

In June 2018, the FASB issued ASU 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share Based Payment Accounting* ("ASU 2018-07"), which expands the scope of ASC Topic 718, *Compensation – Stock Compensation* to include share-based payments issued to non-employees for goods or services.

Consequently, the Company's accounting for share-based payments to non-employees and employees was substantially aligned.

(o) Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Under this method, deferred taxes are recognized based on the differences between financial statement and income tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized. The Company provides a full valuation allowance on substantially all deferred tax assets. The provision for income taxes represents the current state tax payable for the period. The federal tax provision is immaterial given the Company reports losses in all its taxable jurisdictions and is recording a full valuation allowance on the net deferred tax asset. The Company recognizes the effect of an income tax position only if, based on its merits, the position is more likely than not to be sustained on audit by the taxing authorities. Interest and penalties related to uncertain tax positions are recorded as income tax expense.

(p) Research and Development

Research and development costs are expensed as incurred. These costs include, but are not limited to, costs related to clinical trials, and compensation and related overhead for employees and consultants involved in research and development activities.

(q) Foreign Currency Translation and Transactions

The functional currency of the Company's international operations has been determined to be the respective local currency. The Company translates functional currency assets and liabilities to their U.S. dollar equivalents at exchange rates in effect at the balance sheet date and translates functional currency income and expense amounts to their U.S. dollar equivalents at average exchange rates for the period. The U.S. dollar affects that arise from changing translation rates are recorded in other comprehensive loss. Foreign currency transaction gains and losses related to assets and liabilities that are denominated in a currency other than the functional currency are reported in the Consolidated Statements of Operations in the period they occur.

(r) Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision-maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business as one operating segment.

(s) Recently Adopted Accounting Pronouncements

In February 2016, the FASB established Topic 842, Leases by issuing ASU No. 2016-02 which requires lessees to recognize leases on the balance sheet and disclose key information about leasing arrangements. Topic 842 was subsequently amended by ASU No. 2018-01, Land Easement Practical Expedient for Transition to Topic 842; ASU No 2018-10, Codification Improvements to Topic 842, Leases, and ASU No. 2018-11, Targeted Improvements. The new standard establishes a right-of-use (ROU) model that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as finance or operating.

At January 1, 2019, the Company recognized Lease ROU Assets and Lease Liabilities, principally for its office space leases, in which it is the lessee, on the Consolidated Balance Sheets. (See Note 9. Leases)

(t) Recently Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, Financial Instruments – Credit Losses (Topic 326); Measurement of Credit Losses on Financial Instruments, ASU 2016-13 changes the impairment model for most financial assets and certain other instruments. For trade and other receivables, the Company will be required to use a new forward looking "expected loss" model that will replace the current "incurred loss" model and generally will result in the earlier recognition for losses. The Company is required to adjust this new guidance effective January 1, 2020. The Company is reviewing the pronouncement of the new standard and currently does not expect a material effect on its consolidated financial statements.

Note 3. Significant Risks and Uncertainties

The Company is subject to risks common to emerging medical device companies, including uncertainties related to commercialization of products and failing to secure additional funding.

The Company has experienced significant net losses, and it expects to continue to incur losses for the near future as it operates its sales and marketing infrastructure, increases market acceptance of its gammaCore therapy for the acute treatment of episodic cluster headache, or eCH, the prevention of cluster headache, and the preventive and acute treatment of migraine, and fund its research and development activities. The Company has never been profitable and has incurred net losses in each year since its inception.

The Company incurred net losses of $45.1 million and $55.8 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, its accumulated deficit was $83.5 million.

The Company's expected cash requirements for 2020 and beyond are based on the commercialization success of its products and its ability to reduce operating expenses. There are significant risks and uncertainties as to its ability to achieve these operating results, including as a result of the potential adverse impact on its business from the COVID-19 pandemic. Due to these risks and uncertainties, the Company may need to reduce its activities significantly more than in its current operating plan and cash flow projections assume in order to fund its operations to the end of 2020. There can be no assurance that the Company will have sufficient cash flow and liquidity to fund its planned activities, which could force it to significantly reduce or curtail our activities and, ultimately, potentially cease operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

Even if the Company is not required to curtail its activities sooner, its ability to execute its operating plan beyond 2020 depends on its ability to increase revenue, reduce operating expenses and obtain additional funding through the sale of equity and or debt securities, a strategic transaction or otherwise. There is no assurance that the Company will generate sufficient funding through its operating results or sale of securities, raising substantial doubt about the Company's ability to continue as a going concern within one year of the date these financial statements are issued. The accompanying financial statements do not include any adjustment that might result from the outcome of this uncertainty.

Note 4. Revenue Recognition

Geographical Market Net Sales

The following table presents net sales disaggregated by geographic area:

	Year ended December 31,	
	2019	2018
Geographic Market		
United States	$ 1,605,814	$ 619,772
United Kingdom	665,627	300,091
Germany	102,427	53,784
Other	16,411	19,306
Total Net Sales	$ 2,390,279	$ 992,953

Performance Obligations

Revenue, net of distribution discounts, vouchers, rebates, returns, and co-payment assistance is solely generated from the sales of the gammaCore products. Revenue is recognized when delivery of the product is completed. The Company deems control to have transferred upon the completion of delivery because that is the point in which (1) it has a present right to payment for the product, (2) it has transferred the physical possession of the product, (3) the customer has legal title to the product, (4) the customer has risks and rewards of ownership and (5) the customer has accepted the product. After the products have been delivered and control has transferred, the Company has no remaining unsatisfied performance obligations.

Revenue is measured based on the consideration that the Company expects to receive in exchange for gammaCore, which represents the transaction price. The transaction price includes the fixed per-unit price of the product and variable consideration in the form of trade credits, vouchers, rebates, and co-payment assistance. The per-unit price is based on the

Company's established wholesale acquisition cost less a contractually agreed upon distributor discount with the customer. Any reserves based on estimated rebates with private payers was determined to be immaterial.

Trade credits are discounts that are contingent upon a timely remittance of payment and are estimated based on historical experience.

From February 2018 to mid-July 2018, the Company had a voucher program under which vouchers were issued to physicians to provide new patients with free therapy (i.e., one gammaCore device) by delivering non-voucher units for free therapy. The transaction price of the non-voucher units redeemed and estimated to be redeemed was recognized as contra-revenue. The cost to produce these units, in addition to any processing fees, are included as promotional expenses in selling, general, and administrative expense. After mid-July 2018, the Company modified its voucher program to provide its distributor with gammaCore and gammaCore Sapphire promotional units at no charge ("voucher units"). The voucher units have a distinct product item number to be used for the voucher program. The costs to produce these voucher units given to patients under the voucher program are recognized in promotional expense.

In October 2018, the Company launched its *Partners for Coverage* program that allows eligible commercial insurance patients uninterrupted access to gammaCore for up to two months while insurance coverage is being pursued. In February 2019, this program was modified to provide therapy to patients for up to 12 months while insurance coverage is being pursued. In December 2019, the Company terminated this program.

In addition, reimbursement for co-payments made by patients under the co-payment assistance program is considered variable consideration. Beginning in February 2019, eligible patients could receive a reduction of up to $300 from the cost of co-payments for the first month of therapy and a reduction of up to $250 from the cost of each refill for a maximum of 12 months. For the years ended December 31, 2019 and 2018, net sales reflect a reduction for the reduced cost of therapy under the co-payment assistance program. The calculation of the accrual is based on an estimate of claims and the cost per claim that the Company expects to incur associated with inventory that exists in the distribution channel at period end.

Effective March 1, 2020, the amount of monthly co-payment assistance has been reduced to a maximum of $100 per prescription.

Managed care rebates represent our estimated obligations to pharmacy benefit managers. Rebate accruals are recognized in the same period the related revenue is recognized. Gross to net accruals based on estimated rebates were determined to be de minimis.

Contract Balances

The Company generally invoices the customer and recognizes revenue once its performance obligations are satisfied, at which point payment is unconditional. Accordingly, under ASC 606, the Company's contracts with customers did not give rise to contract assets or liabilities during the year ended December 31, 2019 and 2018.

Agreed upon payment terms with customers are within 120 days of shipment. Accordingly, contracts with customers do not include a significant financing component.

The Company earns a significant amount of its revenue in the U.S. from the Veterans Administration and Department of Defense pursuant to its qualifying contract under the Federal Supply Schedule and open market sales to individual VA facilities and in the U.K. under the National Health Service.

Note 5. Cash, Cash Equivalents and Marketable Securities

The following tables summarizes the Company's cash, cash equivalents and marketable securities as of December 31, 2019 and 2018.

As of December 31, 2019

	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Fair Value
Cash and cash equivalents	$ 13,564,252	$ —	$ (461)	$ 13,563,791
U.S. Treasury Bonds	10,494,539	811	—	10,495,350
Total marketable securities	$ 10,494,539	$ 811	$ —	$ 10,495,350
Total cash, cash equivalents and marketable securities	$ 24,058,791	$ 811	$ (461)	$ 24,059,141

As of December 31, 2018

	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Fair Value
Cash and cash equivalents	$ 7,600,284	$ —	$ —	$ 7,600,284
Corporate Debt Securities	$ 18,961,145	$ —	$ (25,888)	$ 18,935,257
Commercial Paper	6,970,867	—	(4,927)	6,965,940
U.S. Treasury Bonds	35,074,005	—	(12,115)	35,061,890
Total marketable securities	$ 61,006,017	$ —	$ (42,930)	$ 60,963,087
Total cash, cash equivalents and marketable securities	$ 68,606,301	$ —	$ (42,930)	$ 68,563,371

The Company's U.S. treasury bonds mature within one year.

Note 6. Fair Value Measurements

Financial assets and liabilities carried at fair value are classified and disclosed in one of the following three levels of the fair value hierarchy:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

A summary of the assets and liabilities carried at fair value in accordance with the hierarchy defined above is as follows:

		Fair Value Hierarchy		
December 31, 2019	**Total**	**(Level 1)**	**(Level 2)**	**(Level 3)**
Assets				
Cash and cash equivalents	$ 13,563,791	$ 13,563,791	$ —	$ —
Marketable Securities:				
U.S. Treasury Bonds	10,495,350	10,495,350	—	—
Total	$ 24,059,141	$ 24,059,141	$ —	$ —
December 31, 2018				
Assets				
Cash and cash equivalents	$ 7,600,284	$ 7,600,284	$ —	$ —
Marketable Securities:				
Corporate Debt Securities	18,935,257	18,935,257	—	—
Commercial Paper	6,965,940	6,965,940	—	—
U.S. Treasury Bonds	35,061,890	35,061,890	—	—
Total	$ 68,563,371	$ 68,563,371	$ —	$ —

The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers within the hierarchy during the years ended December 31, 2019 and 2018. The carrying amount of the Company's receivables and payables approximate their fair value due to their maturity.

Note 7. Inventory

As of December 31, 2019 and 2018, inventories consisted of the following:

	December 31,	
	2019	**2018**
Raw materials	$ 1,065,345	$ 821,704
Work in process	5,314,763	951,695
Finished Goods	531,064	176,003
Total Inventory	6,911,172	1,949,402
Less: noncurrent inventory	6,020,180	—
Total current inventory	$ 890,992	$ 1,949,402

As of December 31, 2019, the Company reserved $287,544 for obsolete inventory. As of December 31, 2018, the Company determined that raw materials of $147,450 became obsolete due to the development of new product technology. The 2019 charge was recorded in cost of goods sold, and the 2018 charge was recorded in selling, general, and administrative expense.

Noncurrent inventory is comprised of approximately $1 million of raw materials and $5 million of work in process.

Note 8. Property and Equipment, Net

Property and equipment, net, as of December 31, 2019 and 2018 consisted of the following:

	December 31.	
	2019	2018
Machinery and equipment	$ 393,154	$ 424,146
Furniture and fixture	310,820	286,268
Computer equipment and software	20,783	20,783
Leasehold improvements	8,880	—
Property and equipment - gross	733,637	731,197
Less: accumulated depreciation	(388,401)	(350,293)
Property and equipment, net	$ 345,236	$ 380,904

During the year ended December 31, 2019, $70,639 of fully depreciated laboratory and production equipment, and office furniture were written off. During the year ended December 31, 2018, $295,384 of fully depreciated assets in the Company's Bermuda subsidiary and Australian affiliate were written off. Depreciation expense for the years ended December 31, 2019 and 2018 was $108,546 and $66,663, respectively.

Note 9. Leases

The Company implemented FASB ASU 2016-02, Leases (Topic 842), which required lessees to recognize most leases on its balance sheet effective January 1, 2019. The Company recognized $3.9 million of right of use assets for leases for office, manufacturing and warehouse space and office equipment. The Company also recognized $4.2 million for lease liabilities. The Company has elected not to recognize right of use assets and lease liabilities for short term leases, i.e., leases with a noncancelable period of 12 months or less.

The Company's leases have remaining lease terms of approximately three to five years, some of which include options to extend the leases for up to an additional five years. For the leases for the office space in Basking Ridge New Jersey and the manufacturing and warehouse space in Rockaway New Jersey, the Company recognized the options to renew the leases as part of the right of use asset and the lease liability as the Company deemed that the renewal options were reasonably certain to be exercised. However, due to the Company's decision to implement a comprehensive redeployment and cost reduction plan implemented in June 2019, the Company determined the renewal option for the office space at the Basking Ridge location is no longer reasonably certain to be exercised. The Company remeasured the Basking Ridge right of use asset and the lease liability beginning June 1, 2019 utilizing the newly expected lease term.

The incremental borrowing rate used to determine the net present value of the leases at inception was 9.75%. This is the incremental borrowing rate that represents the rate of interest that the Company would expect to pay to borrow an amount equal to the lease payments under similar terms. As the Company does not borrow on a collateralized basis, the non-collateralized borrowing rate is used as an input in deriving the incremental borrowing rate. Following the comprehensive redeployment and cost reduction plan announcement and as required in the lease remeasurement process under Topic 842, the incremental borrowing rate was reassessed and increased to 13.75% at the time of remeasurement. The remeasurement updated the net present value of all operating leases from inception using the new discount rate at June 1, 2019.

For the years ended December 31, 2019 and 2018, the Company recognized lease expense of $787,952 and $496,055, respectively. This expense does not include non-lease components associated with the lease agreements as the Company elected not to include such charges as part of the lease expense.

The tables below provide the details of the right of use assets and lease liabilities:

Supplemental Balance Sheet Information for Operating Leases:

	December 31, 2019
Operating leases:	
Operating lease right of use assets	$ 1,430,641
Operating lease liabilities:	
Current portion of operating lease liabilities	486,445
Noncurrent operating lease liabilities	1,419,880
Total operating lease liabilities	$ 1,906,325
Weighted average remaining lease term (in years)	5.9
Weighted average discount rate	13.75%

Supplemental Statement of Cash Flows Information for Operating Leases:

	For the year ended December 31, 2019
Noncash lease expense	315,458
Change in operating lease liabilities	(257,678)

Future minimum lease payments under non-cancellable operating leases as of December 31, 2019:

Financial year	
2020	$ 712,076
2021	690,358
2022	337,254
2023	142,892
2024	146,044
2025 and thereafter	676,260
Total future minimum lease payments	2,704,884
Less: Amounts representing interest	(798,559)
Total	$ 1,906,325

Total lease expense, in accordance with the superseded lease standard was $496,055 for 2018. Future minimum lease payments under non-cancellable operating leases as of December 31, 2018 were as follows:

Financial year	
2019	$ 576,743
2020	714,616
2021	692,893
2022	737,324
2023 and thereafter	3,696,796
Total	$ 6,418,372

Note 10. Cloud Computing Arrangement

In 2018, the Company entered into a contract to obtain a cloud computing arrangement ("CCA"). In accordance with ASU 2018-15, the implementation costs incurred in the CCA were deferred and recognized as other assets and are being amortized to expense over the noncancelable term of the arrangement. The Company capitalized $826,918 in CCA costs for the year ended December 31, 2019 and $395,404 in 2018. The implementation of this CCA was completed on June 30, 2019. Beginning July 1, 2019, the Company went live with the cloud computing Enterprise Resource Planning system and all future related costs are expensed as incurred. In July 2019, the Company began amortizing the related deferred costs over the remaining period of the noncancelable arrangement. Amortization costs for the year ended December 31, 2019 were $141,037.

Note 11. Accrued Expenses

Accrued expenses as of December 31, 2019 and 2018 consisted of the following:

	December 31,	
	2019	2018
Accrued professional fees	$ 1,255,494	$ 1,273,249
Accrued bonuses	804,082	2,152,264
Other accrued expenses	1,277,803	948,588
	$ 3,337,379	$ 4,374,101

Note 12. Note Payable

On July 1, 2019, the Company entered into a Commercial Insurance Premium Finance and Security Agreement ("the Agreement"). The Agreement provides for a single borrowing by the Company of $807,347, with a seven-month term, and an annual interest rate of 2.99%. The proceeds from this transaction were used to partially fund the premiums due under some of the Company's insurance policies. The amounts payable are secured by the Company's rights under such policies. At December 31, 2019, the remaining balance is $111,878 and during the year ended December 31, 2019, the Company recognized $3,457 in interest expense. The balance was fully paid as of January 2020.

Note 13. Net Loss Per Share

Basic net loss per share is computed by dividing net loss available to electroCore, Inc. by the weighted-average number of shares of common stock outstanding during the period. Diluted loss per share is computed by dividing net loss available to electroCore, Inc. by the weighted-average number of shares of common stock outstanding adjusted to give effect to potentially dilutive securities. Restricted stock awards and units, and stock options have not been included in the diluted loss per share calculation as their inclusion would have had an anti-dilutive effect.

As described in Note 14, Corporate Conversion and Equity, on June 21, 2018, electroCore, Inc. completed a Corporate Conversion as well as its initial public offering to, among other things, provide for a single class of common stock of electroCore, Inc., in exchange for the previous convertible preferred units and common units of the Company. This conversion changed the relative ownership of electroCore, Inc. such that retroactive application of the conversion to periods prior to the IPO for the purposes of calculating loss per share would not be meaningful. Net loss attributable to electroCore, Inc. subsidiaries and affiliate for the year ended December 31, 2018 of $1.19 per share includes the loss attributable to the period June 21, 2018 to December 31, 2018 and is based on the number of days in which the shares were outstanding during the period June 21, 2018 to December 31, 2018.

The potential common stock equivalents that have been excluded from the computation of diluted loss per share consist of the following:

	December 31,	
	2019	2018
Outstanding stock options	3,131,266	2,228,904
Nonvested restricted stock and unit awards	1,368,998	265,569
Stock purchase warrants	62,181	—

Note 14. Corporate Conversion and Equity

On June 21, 2018, the Company completed the Corporate Conversion. Pursuant to the certificate of incorporation effected in connection with the Corporate Conversion, the Company's authorized capital stock consists of 500 million shares of common stock, par value $0.001 per share and 10 million shares of preferred stock, par value $0.001 per share. As a result of this conversion and related initial public offering, 29,450,035 shares of common stock and zero shares of preferred stock were issued. On June 22, 2018, the common stock began trading on the Nasdaq Global Market under the symbol "ECOR". Prior to the Corporate Conversion of the Company, the Operating Agreement permitted the issuance of four classes of Units - Series A Preferred Units, Series B Preferred Units, Series B-1 Preferred Units and Common Units. Except as otherwise provided in the Operating Agreement, each member was entitled to one vote for each Unit held and the Units of all classes and series voted together as a single class on all matters (on an as converted to common unit basis).

Upon the Corporate Conversion, all Units were converted into an aggregate of 23,470,035 shares of common stock and options to purchase 2,141,748 shares of common stock as follows:

- holders of Common Units, other than Common Units that were originally issued as "profits interests" (as such term is used for purposes of the Internal Revenue Code) ("Profits Interests") received an aggregate of 12,099,280 shares of common stock;
- holders of Series A Preferred Units received an aggregate of 4,181,856 shares of common stock, which included 241,939 shares of common stock as payment in full of the approximately $3.6 million accrued and unpaid preferred return that was payable in respect of the Series A Preferred Units;
- holders of Series B Preferred Units received an aggregate of 5,843,668 shares of common stock;
- holders of Profits Interests received an aggregate of 1,345,231 shares of common stock; and
- holders of Profits Interests who were employees or consultants at the time of the corporate conversion received options to purchase an aggregate of 2,141,748 shares of common stock, with an exercise price of $15.00 which was equal to the initial public offering price.

Additionally, upon the conversion, the accumulated deficit of Electrocore LLC, subsidiaries and affiliates was reclassed to additional paid in capital in accordance with SEC SAB Topic 4B.

Series A Preferred Units

The Series A Preferred Units were entitled to a preference on distributions, ahead of the Common Units but behind Series B Preferred Units, in the amount of $54,923,430 plus the Series A Preferred Return (as described below), as of June 20, 2018.

The Series A Preferred Units were entitled to a return in an annual non-compounded amount with respect to each outstanding Series A Preferred Unit equal to the product of the Series A Preferred Return Percentage and the Series A Unreturned Capital Value for each Unit, which accrued to the extent not paid. The Series A Preferred Return Percentage was 4% and could be reduced to 2% if certain requirements were met as outlined in the amended and restated Operating Agreement. Upon an IPO, the payment of the Series A Preferred Return was at the sole discretion of the Board of Managers. As of June 20, 2018, the Series A Preferred Return payable, following the 2017 amendments to the Operating Agreement, upon a public offering of the Company's common stock was fixed at $3,629,092. This amount was paid with the issuance of 241,939 shares of common stock upon the IPO.

The Series A Preferred Units were converted into common stock mandatorily immediately prior to the initial public offering as outlined in the amended and restated Operating Agreement, and then subject to a 1:18 stock conversion.

As of December 31, 2018, there were no outstanding warrants to purchase Series A Preferred Units, except for warrants to purchase in the aggregate 221,766 Series A Preferred Units issued in connection with the December 2015 term loan (which was repaid and/or converted into equity in 2016) and as compensation to one of the financial advisors. In connection with the IPO, these outstanding Series A warrants by their terms converted into warrants to purchase in the aggregate 12,321 shares of common stock at an exercise price of $15.30 per share.

Series B Preferred Units

In 2017, the Company entered into a Series B Preferred Unit Purchase Agreement with multiple investors, including Core Ventures II, LLC and Merck Global Health Innovation Fund. Under the terms of the Purchase Agreement, as amended, through December 31, 2017, the Company received cash proceeds of $46,911,300 and converted $26,718,910 of outstanding promissory notes (the "Bridge Notes") and related accrued and unpaid interest for an aggregate amount of $73,630,210 (inclusive of amounts mentioned in Note 17 related to conversion of Bridge Notes and related accrued and unpaid interest) through the sale of Series B Preferred Units at an initial closing and several additional closings.

Each Series B Preferred Unit was converted into one Common Unit mandatorily upon the occurrence of the Corporate Conversion as outlined in the amended and restated Operating Agreement, and then subject to an 1:18 stock conversion pursuant to the terms of the plan of conversion for the Corporate Conversion. In connection with all Series B Preferred Unit closings, the Company issued warrants for the purchase of 35,452,084 Common Units at an exercise price of $1.25 per Unit, which expired unexercised upon the closing of the IPO. The Company also issued warrants to advisors for the purchase of 2,724,549 common units at an exercise price of $0.70 per Unit. The Company also issued 72,000 warrants to purchase common units with an exercise price of $1.25 per Unit, which expired upon the closing of the IPO. The fair value of these warrants to purchase common units were recorded within additional-paid-in-capital. In connection with the Corporate Conversion, the 2,724,549 warrants issued to advisors were converted to warrants to purchase 151,364 shares of common stock at an exercise price of $12.60 per share of common stock.

As of June 21, 2018, the Series B warrants that were issued to purchasers of the Bridge Notes were converted to (i) warrants to purchase 429,948 shares of common stock at an exercise price of $12.60 per share (see Note 17) and (ii) the Series B Preferred warrants that were issued to financial advisors were converted into warrants to purchase 101,119 shares of common stock at an exercise price of $12.60 per share.

Note 15. Variable Interest Entity

As discussed in Note 1, electroCore is the primary beneficiary of electroCore (Aust) Pty Limited. electroCore has contributed certain intellectual property rights, all rights to distribute, market and sell specified products in Australia and New Zealand, and other rights outlined in the shareholders' deed of electroCore (Aust) Pty Limited in return for 50% of the shares of such entity. In addition, electroCore can also appoint two of the four directors and can exercise significant influence. This along with the fact that electroCore is electroCore (Aust) Pty Limited's only supplier causes electroCore, for accounting purposes, to be the primary beneficiary of electroCore (Aust) Pty Limited. The activities related to electroCore (Aust) Pty Limited are not material to the consolidated financial statements.

Note 16. Income Taxes

The provision for income taxes for the years ended December 31, 2019 and 2018 related to foreign taxes and state minimum taxes. The Company has incurred operating losses since inception in the US. Prior to the Corporate Conversion on June 21, 2018, the Company was a limited liability company in the United States, which is treated as a flow-through entity for Federal and state income tax purposes. Accordingly, the Company was not subject to U.S. income taxes until its conversion.

The Company has evaluated the available evidence supporting the realization of its deferred tax assets, including the amount and timing of future taxable income, and has determined that it is more likely than not that its net deferred tax assets will not be realized in the United States and certain foreign jurisdictions. Due to uncertainties surrounding the realization of the deferred tax assets, the Company maintains a full valuation allowance against all of its net deferred tax assets. When the Company determines that it will be able to realize some portion or all of its deferred tax assets, an adjustment to its valuation allowance on its deferred tax assets would have the effect of increasing net income in the period such determination is made.

A reconciliation of the income tax provision computed at statutory rates to the reported income tax provision for the years ended December 31, 2019 and 2018 is as follows:

	Year ended December 31,	
	2019	2018
Statutory rate	21.0%	21.0%
State tax expected (recovery), net of federal benefit	6.7%	2.6%
Nondeductible expenses	(0.13)%	(2.9)%
Loss incurred as pass-through	—%	(7.9)%
Change in valuation allowance for deferred tax assets	(27.6)%	(12.8)%
Provision for income taxes	(0.04)%	—%

The net change in the valuation allowance was an increase of $12.4 million.

The significant components of the Company's deferred income tax assets and liabilities after applying enacted corporate tax rates are as follows:

	Year ended December 31,	
	2019	2018
Deferred tax assets		
Net operating loss carryforwards	$ 18,883,686	$ 7,578,570
Accrued expenses	796,849	735,910
Intangibles	355,288	290,098
Inventory	78,206	66,935
Deferred rent	—	65,574
Charitable contributions	19,028	10,602
R&D credit	394,981	—
Lease liabilities	518,480	—
Stock compensation	750,449	—
Deferred tax assets	21,796,967	8,747,689
Less valuation allowance	(21,171,967)	(8,722,389)
Total deferred tax assets	625,000	25,300
Fixed assets	(15,222)	(25,300)
Prepaid expenses	(220,673)	—
Right of use asset	(389,105)	—
Total deferred tax liabilities	(625,000)	(25,300)
Deferred tax assets, net	$ —	$ —

As of December 31, 2019 and 2018, the Company had accumulated non-capital losses totaling $3.5 and $3.7 million, respectively, in Germany which can be carried forward indefinitely, and net operating losses of $65.7 and $24.6 million respectively, in the U.S. (federal and state), which may be available to carry forward and offset future years' taxable income. U.S. federal losses can be carried forward indefinitely, and state losses expire in various amounts beginning in 2026.

However, the NOL carryforwards may be, or become subject to, an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, as well as similar state tax provisions. This could limit the amount of NOLs that the Company can utilize annually to offset future taxable income or tax liabilities. The amount of the annual limitation, if any, will be determined based on the value of the Company immediately prior to an ownership change. Subsequent ownership changes may further affect the limitation in future years. If and when the Company utilizes the NOL carryforwards in a future period, it will perform an analysis to determine the effect, if any, of these loss limitation rules on the NOL carryforward balances.

Domestic and foreign components of loss before provision for income taxes is as follows:

	December 31, 2019	December 31, 2018
Domestic	$ (43,661,897)	$ (55,268,310)
Foreign	(1,468,287)	(494,714)
Total	$ (45,130,184)	$ (55,763,024)

The income tax provision from continuing operations contains the following components:

	December 31, 2019	December 31, 2018
Federal	$ —	$ —
State	$ 7,712	$ 2,431
Foreign	$ 9,987	$ —
Total current	17,699	2,431
Total deferred	—	—
Total income tax expense/(benefit)	$ 17,699	$ 2,431

Uncertain Tax Positions

The Company has adopted certain provisions of ASC 740, “Income Taxes”, which prescribes a recognition threshold and measurement attribute for the recognition and measurement of tax positions taken or expected to be taken in income tax returns. The provisions also provide guidance on the de-recognition of income tax assets and liabilities, classification of current and deferred income tax assets and liabilities, and accounting for interest and penalties associated with tax positions.

The Company files income tax returns in the U.S. federal jurisdiction, and in various state and foreign jurisdictions. The Company’s tax returns are subject to tax examinations by U.S. federal and state tax authorities, or examinations by foreign tax authorities until the expiration of the respective statutes of limitation. The Company currently has no tax years under examination.

As of December 31, 2019, the Company does not have an accrual relating to uncertain tax positions. Interest and penalties, if any, as they relate to income taxes assessed, are included in the income tax provision. It is not anticipated that unrecognized tax benefits would significantly increase or decrease within 12 months of the reporting date.

Note 17. Warrant Liability

During the period ended June 30, 2017, the Company issued bridge notes together with associated warrants (“Bridge Note Warrants”). Since the Bridge Note Warrants entitled the holders to purchase securities in the qualified equity round at the purchase price payable for the related equity securities, the exercise price of the warrants was undetermined at the time of their issuance. Also, because the terms of redemption of the Series B Preferred Units were unknown at the time of their issuance as well as the deemed liquidation terms, the warrant liability was recorded at fair value and marked to market. The valuation of the warrant liability was determined using Level 3 inputs. In connection with the bridge note closings, at the time of the qualified equity round, the Company issued 7,739,092 Bridge Note Warrants all of which were outstanding as of March 31, 2018. At the time of the Corporate Conversion, these warrants were converted to warrants to purchase 429,948 shares of common stock at an exercise price of $12.60 and were reclassified to equity upon the determination that they no longer met the criteria to be classified as liabilities.

Note 18. Stock Compensation and Unit-Based Compensation

The issuance of common stock and options to purchase common stock to prior holders of Profits Interests in connection with the Corporate Conversion was accounted for as a type-1 modification of the old awards. Under the previous LLC structure, in connection with employment and service provider agreements, the Company granted Units that constitute profits interests for income tax purposes to grantees pursuant to Unit Forfeiture Agreements, subject to certain restrictions defined in each such agreement. The Company maintained a Unit award account for each of the grantees. Generally, the Units vested 25% on the one-year anniversary of the employment start date or agreement date and the balance ratably per quarter thereafter over an additional three-year period. After the restrictions lapsed, the grantees became fully vested in such Units. In 2018, the Company granted 19,447,218 Units to its employees, of which 110,354 were forfeited immediately prior to the Corporate Conversion.

In connection with the Corporate Conversion, 62,765,605 Units (outstanding immediately prior to the IPO) were converted, in the aggregate, into (i) 1,345,231 shares of common stock, and (ii) with respect to Units held by current employees and consultants at the time of the conversion, options to purchase 2,141,748 shares of electroCore, Inc. common stock at an exercise price of $15.00 per share.

The number of shares of common stock and the number of options issued for the outstanding units were determined based upon the appreciation in value of the Company after the date of Unit grant through the completion of the IPO.

The number of shares of common stock issued for each Unit (the "Conversion Shares") was equal to (x) the percentage of the capital account balance associated with such Unit as it related to the total value of the Company at the IPO pre-money valuation, divided by (y) the percentage interest in the Company represented by such Unit based on the total outstanding Units in the Company immediately prior to the IPO, multiplied by (z) the total number of Units represented by the applicable Profits Interest. Of the shares of common stock issued for the Units, 1,157,139 vested immediately, 188,092 vested January 1, 2019, and the balance vesting over the next succeeding 10 calendar quarters. The Company accounts for the 1,345,231 shares of common stock as restricted stock awards as reflected in the table below. As of December 31, 2018, the total number of restricted shares outstanding was 185,571 as 2,521 share awards were forfeited and no further share awards were granted in 2018.

The number of options issued in respect of each Unit was equal to (i) the total number of Units represented by such Profits Interest prior to the corporate conversion minus (ii) the Conversion Shares issued in respect of such Profits Interest. Of the options issued for the Units, 228,954 vested 100% on January 1, 2019, 1,912,797 vested 25% on January 1, 2019, and the balance vesting over the next succeeding 14 calendar quarters. The options have an exercise price of $15.00 per share.

Stock compensation expense for the Profits Interests not recognized prior to the Corporate Conversion was $2.8 million. This expense was allocated to the common stock and options to purchase common stock awards based on their relative fair value on the date of the IPO. For the common stock awards that vested at the time of issuance, the Company recognized $1.2 million immediately. At the time of issuance of stock compensation expense for the common stock awards and the options to purchase common stock that did not vest immediately totaled, $0.2 million and $1.4 million, respectively, and is being amortized over the respective vesting periods.

The incremental stock compensation expensed due to the modification was $7.8 million. This expense was allocated to the common stock and the options to purchase common stock based on their fair value on the date of the awards. For the common stock that vested at the time of issuance, the Company recognized $3.8 million. For the common stock awards and the options to purchase common stock that did not vest immediately, the Company will recognize $0.4 million and $3.6 million, respectively, over the respective vesting periods.

On June 21, 2018, the Company adopted the 2018 Omnibus Equity Incentive Plan (“Plan”). This plan reserved 6.2 million shares with an increase to be added annually beginning in 2019 through 2028 up to 4% of the total number of shares of common stock issued and outstanding on a fully diluted basis as of the end of the immediately preceding fiscal year, providing that the aggregate number of additional shares shall not exceed a total of 45 million shares, and a maximum of 40 million shares pursuant to the exercise of stock options. Effective January 1, 2019, the amount of shares reserved under the Plan was increased to approximately 6.9 million. The Company’s policy is to issue new shares of its common stock upon the exercise of stock options, new grants of restricted stock awards, and settlement of restricted stock units. Stock options issued under the plan have a contractual life of 10 years and are generally forfeited upon separation from the Company. The options issued in conjunction with the Corporate Conversion were issued under this Plan. At December 31, 2019 there were approximately 2,120,000 shares available to be awarded under the Plan.

The following table presents a summary of stock options granted:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, December 31, 2018	2,228,904	$ 14.89	9.5	*
Granted	2,146,699	4.68		
Exercised	—	—		
Cancelled	(1,244,337)	13.34		
Outstanding, December 31, 2019	3,131,266	$ 8.53	8.9	*
Exercisable, December 31, 2019	1,348,994	$ 11.99	8.6	*

* *de minimis*

The intrinsic value is calculated as the difference between the fair market value at December 31, 2019 and the exercise price per share of the stock options. The fair market value per share of common stock as of December 31, 2019 was $1.59. In general, option awards granted to employees and consultants vest over four years.

The following table provides additional information about stock options that are outstanding and exercisable at December 31, 2019:

Exercise Price	Options Outstanding	Weighted Average Remaining Contractual Life (Years)	Options Exercisable
$1.40 - $2.50	1,019,495	9.7	95,635
$2.51 - $7.52	647,629	9.2	324,900
$7.53 - $15.00	1,464,142	8.6	928,459

The following table presents a summary of restricted stock awards granted:

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested, December 31, 2018	185,571	$ 15.00
Granted	204,088	6.88
Vested	(139,473)	14.25
Cancelled	(122,681)	9.27
Nonvested, December 31, 2019	127,505	$ 8.09

In general, restricted stock awards granted to employees and consultants in 2019 vest over 4 years.

The following table presents a summary of restricted and deferred stock units (“Stock Units”) granted:

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested, December 31, 2018	79,998	$ 15.00
Granted	1,566,205	2.47
Vested	(274,939)	4.62
Cancelled	(129,771)	1.90
Nonvested, December 31, 2019	1,241,493	$ 2.86

In general, Stock Units awarded to employees and consultants vest over two years.

Immediately following the Company's annual meeting of stockholders, the Company generally grants each non-employee director an equity award that vests over a 12-month period. Upon a non-employee director's initial appointment or election to the board of directors, the Company grants such non-employee director an equity award subject to vesting as determined by the board of directors.

For the years ended December 31, 2019 and 2018, stock compensation expense reported as a component of selling, general and administrative expense was $2.7 million and $4.6 million, respectively. For the same period, stock compensation expense reported as a component of research and development expense was $1.1 million and $2.8 million, respectively. For the years ended December 31, 2019 and 2018, stock compensation expense reported as a component of cost of goods sold was $0.1 million and $0.2 million respectively. Total unrecognized compensation cost related to equity awards as of December 31, 2019 was $7.9 million and is expected to be recognized over the next 3 years.

Valuation Information for Stock-Based Compensation

The fair value of each stock option award granted was estimated on the date of grant using the Black-Scholes model. Expected volatility was based on historical volatility of the Company's common stock. The risk-free interest rate was based on the average U.S. Treasury rate that most closely resembles the expected life of the related award. The expected term of the award was calculated using the simplified method. No dividend was assumed as the Company does not pay regular dividends on its common stock and does not anticipate paying any dividends in the foreseeable future.

The weighted average assumptions used in the Black-Scholes option pricing model in valuing stock options granted in the periods presented were:

	2019	2018
Fair value at grant date	$ 3.39	$ 2.50
Expected volatility	95.9%	70.9%
Risk-free interest rate	2.1%	2.7%
Expected holding period, in years	5.9	5.9
Dividend yield	—	—

The fair value of restricted stock awards and restricted stock units is the market close price of the Company's common stock on the trading day immediately preceding the date of grant.

Employee Stock Purchase Plan

Effective January 1, 2019, the Company adopted the 2019 Employee Stock Purchase Plan. The plan, which was terminated effective January 1, 2020, provided eligible employee of the Company with an opportunity to purchase common stock of the Company through accumulated payroll deductions. The maximum number of shares reserved for delivery under the plan was 300,000 shares, plus an annual increase not to exceed an aggregate of 4,500,000 shares over the life of the plan.

The weighted average assumptions used in the Black-Scholes valuation of the fair value of the discount for the year ended December 31, 2019 were:

	2019
Fair value at grant date	$ 0.75
Expected volatility	169%
Risk-free interest rate	2.3%
Expected holding period	6 months
Dividend yield	—

Note 19. Employee Benefit Plan

The Company has a defined contribution 401(k) profit sharing plan which covers all employees. Employees are eligible upon date of hire. Employee contributions are voluntary and are based on specific percentages of compensation, which may not

exceed maximum amounts established by Internal Revenue Code. Employer contributions are discretionary. There were no employer contributions for the years ended December 31, 2019 and 2018.

Note 20. Commitments and Contingencies

Stockholders Litigation

On July 8, 2019 and August 1, 2019, purported stockholders of the Company served putative class action lawsuits in the Superior Court of New Jersey for Somerset County, captioned *Paul Kuehl vs. electroCore, Inc., et al.*, Docket No. SOM-L 000876-19 and *Shirley Stone vs. electroCore, Inc., et al.*, Docket No. SOM-L 001007-19, respectively. In addition to the Company, the defendants include present and past directors and officers, Evercore Group L.L.C., Cantor Fitzgerald & Co., JMP Securities LLC and BTIG, LLC, the underwriters for its IPO; and two of the Company's stockholders. On August 15, 2019, the Superior Court entered an order consolidating the *Kuehl* and *Stone* actions, which are proceeding under Docket No. SOM-L 000876-19. Each plaintiff was appointed a co-lead plaintiff. The plaintiffs filed a consolidated amended complaint, which sought certification of a class of stockholders who purchased common stock in the IPO or whose purchases are traceable to that offering. The consolidated amended complaint alleged that the defendants violated Sections 11, 12(a)(2) and 15 of the Securities Act with respect to the registration statement and related prospectus for the IPO. The complaint sought unspecified compensatory damages, interest, costs and attorneys' fees. On October 31, 2019, the Company filed a motion to dismiss the complaint or in the alternative to stay the action in favor of the pending federal action (discussed below). On February 21, 2020 the court granted the defendants' motion to dismiss the consolidated amended complaint with prejudice. On March 2, 2020 the court entered an amended order dismissing the consolidated amended complaint with prejudice. On March 27, 2020, the plaintiffs filed a notice of appeal with the N.J. Superior Court – Appellate Division.

On September 26, 2019 and October 31, 2019, purported stockholders of the Company served putative class action lawsuits in the United States District Court for the District of New Jersey captioned *Allyn Turnofsky vs. electroCore, Inc., et al.*, Case 3:19-cv-18400, and *Priewe vs. electroCore, Inc., et al.*, Case 1:19-cv-19653, respectively. In addition to the Company, the defendants include present and past directors and officers, and Evercore Group L.L.C., Cantor Fitzgerald & Co., JMP Securities LLC and BTIG, LLC, the underwriters for the IPO. The plaintiffs each seek to represent a class of stockholders who (i) purchased the Company's common stock in the IPO or whose purchases are traceable to the IPO, or (ii) who purchased common stock between the IPO and September 25, 2019. The complaints each allege that the defendants violated Sections 11 and 15 of the Securities Act and Sections 10(b) and 20(a) of the Exchange Act, with respect to (i) the registration statement and related prospectus for the IPO, and (ii) certain post-IPO disclosures filed with the SEC. The complaints seek unspecified compensatory damages, interest, costs and attorneys' fees.

In the *Turnofsky* case, several plaintiffs and their counsel are engaged in motion practice to select a lead plaintiff and lead plaintiff's counsel. Briefing is complete on the motions, but the court has not yet ruled. On February 19, 2020, the *Priewe* case was voluntarily dismissed.

The Company intends to continue to vigorously defend itself in these matters. However, in light of, among other things, the preliminary stage of these litigation matters, the Company is unable to determine the reasonable probability of loss or a range of potential loss. Accordingly, the Company has not established an accrual for potential losses, if any, that could result from any unfavorable outcome, and there can be no assurance that these litigation matters will not result in substantial defense costs and/or judgments or settlements that could adversely affect the Company's financial condition.

The Company expenses associated legal fees in the period they are incurred.

Settlement Agreement

In January 2019, the Company settled a dispute with one of its former advisors, Madison Global Partners, who had filed a complaint against us in the Supreme Court of the State of New York, County of New York (Index No. 652329/2018) as previously reported. As part of that settlement, the Company paid Madison Global $325,000 and issued to Madison Global and its representatives warrants to purchase in the aggregate 62,181 shares of Company common stock at prices ranging from $5.68 per share to $12.60 per share. Substantially all such amounts were accrued in prior accounting periods. The warrants issued are shown in the following table:

# Warrants	Exercise Price	Expiration Date
8,576	$ 8.86	April 1, 2021
22,253	$ 5.68	March 30, 2022
17,066	$ 12.60	June 30, 2022
14,286	$ 12.60	August 31, 2022

Claim from Lifehealthcare Pty Ltd.

The Company was party to a joint venture arrangement ("JV Arrangement") in Australia with Lifehealthcare Pty Ltd ("LHP"). In 2017, the parties agreed to terminate the JV Arrangement. In March 2019, the Company received a letter from LHP alleging certain breaches by the Company under the JV Arrangement, primarily arising out of the Company's alleged failure to notify LHP of the Company's IPO. The Company strongly disputes these allegations and notified LHP in writing in April 2019 of its position on this matter and its intent to vigorously defend itself against these claims. The Company has received no further communications from LHP since that time. Although no assurance can be given that LHP will not pursue this matter further, the financial impact, if any, in connection with any potential resolution of this matter is not expected to be material.

Purchase Commitments

The Company enters into contracts in the normal course of business with contract research organizations for its clinical trials, contract manufacturing organizations for the manufacture and supply of its clinical and commercial product needs and other vendors for other research and development and commercial activities, as well as services and products for operating purposes. The Company's agreements generally provide for termination with notice. Such agreements that are cancelable contracts are not included as purchase commitments. The Company has included as purchase obligations its commitments under agreements to the extent they are quantifiable and are not cancelable. The Company has purchase obligations of approximately $1.7 million as of December 31, 2019.

Note 21. Restructuring Charges and Other Severance Related Charges

Restructuring charges

On May 29, 2019, the Company announced significant adjustments to the deployment of personnel and resources across the organization. The effort was intended to focus the Company on currently available and near-term revenue opportunities and on clinical programs specifically designed to expand the gammaCore product labeling. To achieve this goal, the Company reduced the size of its organizational structure, including its field sales force and clinical operations.

The costs associated with this initiative primarily represent severance and other costs associated with employee terminations, the majority of which have been settled in cash, and totaled approximately $1,050,000. In June 2019, as part of this process, the Company formally communicated the termination of employment to 32 employees, and as of September 30, 2019, the Company had terminated all of these employees. As of December 31, 2019, the Company has paid all obligations related to the restructuring charges.

Other Severance Related Charges

Officer Separation Costs

On June 10, 2019, Frank Amato, the Company's former Chief Executive Officer, offered his resignation. The Company entered into a Separation Agreement with Mr. Amato, pursuant to which he remained as Chief Executive Officer and a

member of the board until September 30, 2019 (the "Separation Date"). Pursuant to the Separation Agreement, Mr. Amato was paid $800,000 on October 1, 2019. In addition, all options to purchase Company common stock held by Mr. Amato continued to vest through the Separation Date and remain exercisable until the one-year anniversary of the Separation Date. All restricted stock units held by Mr. Amato continued to vest through the Separation Date.

Since Mr. Amato provided substantial services to the Company, the Company recognized all costs related to the Separation Agreement over the period from June 10, 2019 to September 30, 2019. In connection with the Separation Agreement, the Company recorded a cash charge of $800,000 for the year ended December 31, 2019.

Additional Executive Separation Costs

Effective July 31, 2019, the Company entered into a Separation Agreement with a former officer. Pursuant to the agreement, a severance payment of $147,500 was recognized and is to be paid evenly over the subsequent six months. As of December 31, 2019, the remaining balance of approximately $25,000 has been accrued.

Note 22. Subsequent Events

Stock Purchase Agreement with Lincoln Park

On March 27, 2020, the Company and Lincoln Park Capital Fund, LLC ("Lincoln Park") entered into a purchase agreement pursuant to which the Company has the right to sell to Lincoln Park shares of common stock having an aggregate value of up to $25,000,000, subject to certain significant limitations of the amount and timing of any such sales due to terms and conditions set forth in the purchase agreement.

In consideration for entering into the purchase agreement with Lincoln Park, the Company issued an aggregate of 461,676 shares of common stock to Lincoln Park as a commitment fee. In addition, the Company shall issue to Lincoln Park up to an aggregate of 230,838 additional shares of common stock as a further commitment fee based on a pro-rata percentage of the first $5,000,000 of shares of common stock issued to Lincoln Park under the Purchase Agreement as Purchase Shares (as such term is defined in the purchase agreement with Lincoln Park). The Company will not receive any cash proceeds from the issuance of any of the foregoing commitment shares.

The net proceeds under the purchase agreement to the Company will depend on the frequency and prices at which shares of common stock are sold to Lincoln Park. Actual sales of shares of common stock to Lincoln Park under the purchase agreement and the amount of such net proceeds will depend on a variety of factors, including market conditions, the trading price of the common stock and determinations by the Company as to other available and appropriate sources of funding for the Company. The Company expects to use the proceeds from this agreement for general corporate purposes and working capital.

Changes to Board of Directors

On March 26, 2020, the Company announced the appointments of three new independent members to its Board of Directors effective April 2, 2020. The newly appointed board members are John Gandolfo, Thomas Patton and Peter Cuneo. The Company also announced that current Board members Nick Colucci and Jim Tullis will be stepping down from the Board prior to the Company's annual meeting of stockholders that is expected to be held in June 2020. Chairman Carrie S. Cox is stepping down from the Board on April 1, 2020 and will be succeeded in that role by independent Board member Michael G. Atieh.

Exhibit 21.1

List of Subsidiaries of electroCore, Inc.

Subsidiary	Jurisdiction of Incorporation or Organization
electroCore Germany GmbH	Germany
electroCore UK Ltd.	United Kingdom

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
electroCore, Inc.:

We consent to the incorporation by reference in the registration statements (No. 333-232655) on Form S-3 and (No. 333-225864) on Form S-8 of electroCore Inc. Subsidiaries and Affiliate of our report dated March 30, 2020, with respect to the balance sheets of electroCore Inc. Subsidiaries and Affiliate as of December 31, 2019 and 2018, and related consolidated statements of operations, comprehensive loss, changes in stockholders equity and members' deficit, and cash flows for each of the years in the two-year period ended December 31, 2019, and the related notes (collectively, the "financial statements") which report appears in the December 31, 2019 annual report on Form 10-K of electroCore Inc.

Our report dated March 30, 2020 contains an explanatory paragraph that states that the Company has suffered recurring losses from operations and has a net capital deficiency, which raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of that uncertainty.

/s/ KPMG LLP

Short Hills, New Jersey
March 30, 2020

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Daniel S. Goldberger, certify that:

1. I have reviewed this Annual Report on Form 10-K of electroCore, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the small business issuer as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) (Omitted pursuant to Exchange Act Rule 13a-14(a));

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the small business issuer's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2020

By: /s/ DANIEL S. GOLDBERGER

Daniel S. Goldberger
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Brian M. Posner, certify that:

1. I have reviewed this Annual Report on Form 10-K of electroCore, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the small business issuer as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) (Omitted pursuant to Exchange Act Rule 13a-14(a));

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the small business issuer's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2020

By: /s/ BRIAN M. POSNER

Brian M. Posner
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of electroCore, Inc. (the "Company") on Form 10-K for the period ending December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 30, 2020

By: /s/ DANIEL S. GOLDBERGER

Daniel S. Goldberger
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of electroCore, Inc. (the "Company") on Form 10-K for the period ending December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 30, 2020

By: /s/ BRIAN M. POSNER

Brian M. Posner
Chief Financial Officer
(Principal Financial and Accounting Officer)