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, 2018

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: Common Stock, Par Value $0.001 Per Share; Common stock traded on the 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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, 2018 was $205,567,325.

The number of shares of Registrant's Common Stock outstanding as of March 11, 2019 was 29,447,196.

Portions of the Registrant's Definitive Proxy Statement relating to the 2019 Annual Meeting of Shareholders, which will be filed with the Securities Exchange Commission within 120 days after the end of the Registrant's fiscal year ended December 31, 2018, 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 (this "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 12 - "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.

Glossary

A glossary of scientific and technical terms used in this Annual Report on Form 10-K is included in beginning on page 44.

PART I

Item 1. Business.

Business Overview

We are a commercial-stage bioelectronic medicine company with a proprietary non-invasive vagus nerve stimulation, or nVNS, therapy. nVNS is a platform therapy that modulates neurotransmitters and immune function through its pharmacologic effects on both the peripheral and central nervous systems. We are initially focused on neurology and rheumatology, and our therapy, gammaCore, is cleared by the U.S. Food and Drug Administration or FDA, for use by adults for the following three neurology indications: the acute treatment of pain associated with each of migraine and episodic cluster headache ("eCH"); and the prevention of cluster headaches. In neurology, we are pursuing further label expansions to include the prevention of migraine, migraine in adolescents, and post-traumatic headache. We are also engaging in clinical development for potential new labeling claims in rheumatology, with an initial focus on rheumatoid arthritis.

gammaCore is the first FDA-cleared, prescription-only non-invasive VNS therapy. Historically, vagus nerve stimulation or VNS, required a highly 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 prescribed on a monthly basis, and is both rechargeable and reloadable via individualized radio-frequency identification, or RFID, cards. gammaCore Sapphire permits patients to self-administer discrete doses of nVNS on an as-needed basis for acute treatment, or at regular intervals for prevention therapy.

Non-invasive delivery of VNS or nVNS by our gammaCore Sapphire is enabled by a proprietary high-frequency burst waveform that safely and comfortably passes through the skin and stimulates targeted A-fibers in the vagus nerve. Multiple published studies suggest that VNS works through the modulation of neurotransmitters, and has a measurable pharmacologic effect similar to several classes of commonly prescribed medications, including selective serotonin reuptake inhibitors, serotonin norepinephrine reuptake inhibitors, and GABA analogues. Research also indicates that VNS, including gammaCore, moderates the inflammatory response producing a measurable reduction in inflammatory cytokine production.

In January 2018, the FDA cleared our gammaCore therapy for our lead indication: the acute treatment of migraine in adults. Migraine is a debilitating primary headache condition that affects approximately 12% of the adult population. 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. Published reports suggest that the total addressable market for the acute treatment of migraine in the United States in 2019 will be approximately $4 billion. In April 2017, the FDA cleared our gammaCore therapy for the acute treatment of cluster headache, or CH, and in December 2018, the FDA cleared our therapy for the prevention of CH. CH is an extremely painful form of headache affecting approximately 350,000 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. According to a 2016 market research survey, 87% of respondents reported dissatisfaction with the then-available treatment options for managing CH. We estimate the total addressable U.S. market for the acute treatment of these CH patients in 2019 is approximately $400 million.

The first three 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 additional label expansions will be possible through the pathway under Section 510(k) of the Federal Drug and Cosmetic Act, and are pursuing clinical programs to support label expansion filings for migraine prevention, migraine in adolescents, and the treatment of post-traumatic headache.

In July 2017, following our initial FDA clearance in CH, we began a year-long commercial registry, managed by four regional business managers in partnership with 40 of the top headache centers in the United States, to gather real-world experiences with gammaCore among CH patients, gain advocacy among 250 physicians, and to drive an initial 1,000 prescriptions into U.S. commercial payers. By June 2018, when the registry program concluded, an additional 40 centers of excellence had requested inclusion in the program, and we hired an additional 10 territory business managers. These efforts generated more than 5,000 prescriptions into commercial payers from more than 800 neurologists, including more than 3,300 prescriptions in the second quarter of 2018. In July 2018, following the successful completion of our initial public offering, we expanded our direct sales force to 32 representatives, who initiated a proactive outreach to more than 6,400 leading headache physicians. In 2018, approximately 15,000 gammaCore prescriptions were written by more than 1,800 prescribing physicians, over 1,000 of whom were defined as regular gammaCore prescribers based on the frequency of their prescriptions. This included approximately 4,400 prescriptions in the third quarter of 2018, and approximately 5,800 in the fourth quarter of 2018. This increasing prescription volume helped us engage with payers, and to execute agreements with commercial and government payers for coverage of more than 50 million lives in the United States.

As of January 2019, we have agreements or arrangements with commercial payers, one pharmacy benefit manager, or PBM and the Federal Supply Schedule, or FSS, that we estimate provide for reimbursement for gammaCore as either a pharmacy benefit or medical benefit for approximately 53 million lives in the United States. Although there can be no assurance of success, our payer access team is negotiating contracts with several additional insurance plans and PBMs covering an additional approximately 90 million commercial lives, and in clinical review with plans covering an additional approximately 50 million lives.

With respect to the broader platform potential of nVNS, modulation of the peripheral immune system by nVNS provides mechanistic support for the study of gammaCore in the treatment of inflammatory disorders. In partnership with academic centers in both Denmark and the United Kingdom, gammaCore has been studied in both rheumatoid arthritis and Sjögren's syndrome. More particularly, early results from an open label pilot trial in patients with rheumatoid arthritis who had failed traditional interventions have provided support for continued work. Similarly, with respect to Sjögren's syndrome, an open label pilot study was followed by a sham-controlled pilot trial, both of which have provided positive early results. If the ongoing work produces similar results, it is expected that we will initiate a pivotal trial in rheumatoid arthritis in 2019 and in Sjögren's syndrome in 2020.

The table below summarizes our areas of focus for gammaCore:

Table 1: Our Pipeline

Indication	Pre Clinical	Pilot Trials	Pivotal Trials	FDA Clearance	Key Milestones
Acute Treatment of eCH	ACT 1 & ACT 2				FDA Clearance April 2017 Full Commercial Launch July 2018
Acute Treatment of Migraine	PRESTO				FDA Label Expansion in January 2018 Full Commercial Launch July 2018
CH Prevention	PREVA				FDA Label Expansion in December 2018 Full Commercial Launch January 2019
Migraine Prevention	PREMIUM I & II				PREMIUM I data publication anticipated in 2Q 2019 PREMIUM II trial enrollment initiated in 4Q 2018
Migraine in Adolescents	ATOM				Pivotal trial initiating in 2H 2019
Post-Traumatic Headache					Pilot trial initiating in 2H 2019
Rheumatoid Arthritis					Pilot trial initiating in 1H 2019 Pivotal trial planned for 2H 2019
Sjögren's Syndrome					Open label pilot trial publication in 4Q 2018 Randomized, sham-controlled pilot trial completed 2Q 2019 Pivotal trial planned for 2020

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, GABA 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. In the periphery, the release of neurotransmitters associated with vagus nerve stimulation has been shown to have multiple beneficial effects, including the reduction of systemic inflammatory cytokines. VNS is being studied for use in a number of inflammatory conditions, including rheumatoid arthritis, Sjögren's syndrome, and Crohn's disease.

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 clearance of gammaCore, this safe and effective therapy can now be noninvasively self-administered, at a fraction of the initial cost, exponentially expanding its accessibility for the potential treatment of multiple medical conditions.

Preclinical Evidence of gammaCore's Activation of the Vagus Nerve

The development of gammaCore required a number of inventions that enable the comfortable passage of our proprietary therapeutic signal to specifically targeted fibers within the vagus nerve. Confirmation that gammaCore successfully activates the vagus nerve has been published by independent scientists and clinicians who have performed multiple lines of research. These lines of research include:

- electric field modeling to demonstrate that our therapy establishes the necessary charge gradients in the targeted nerve fibers;
- electroencephalography experiments showing that gammaCore produces dose-dependent changes in EEG signals similar to those observed with VNS delivered using surgically implanted devices;
- both functional magnetic resonance imaging and magnetoencephalography that produced clear imaging data of gammaCore activating critical areas in the brainstem, including those associated with the release of the target neurotransmitters; and
- multiple animal and human studies demonstrating modulation of the target neurotransmitters and inflammatory markers.

Our Therapy Delivery Platform

Our gammaCore therapy is the first and only treatment that non-invasively activates the therapeutically relevant fibers in the cervical trunk of the vagus nerve, delivered in discrete two-minute doses, using proprietary signals that are capable of passing through skin while minimizing the activation of skin pain receptors.

Our therapy is prescription-only, and like medications delivered by metered-dose inhalers, patients self-administer discrete doses using a handheld unit. gammaCore Sapphire is a non-disposable, rechargeable and reloadable option for patients, with the therapy being dispensed through a prescription from a specialty pharmacy. After the initial prescription is filled, access to therapy is refilled monthly 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.

The prior iteration of the gammaCore delivery device was not reloadable and rechargeable, and was supplanted by the gammaCore Sapphire during the fourth quarter of 2018. While we do not intend to market the non-reloadable, disposable version of our gammaCore product in markets where the gammaCore Sapphire is launched, in select cases, we may continue to use the prior gammaCore product, such as 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 bioelectronic therapy include:

- ***Innovative bioelectronic medicine approach.*** Our gammaCore therapy uses a proprietary electric signal to safely deliver bioelectronic medicine, 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 (several of which are more fully described herein).
- ***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, and is now a first-line treatment option.

- ***Commercializing our therapy through traditional pharmaceutical channels.*** Our monthly prescription model, made possible by our non-invasive delivery modality, empowers medical professionals to prescribe nVNS on a monthly basis through the same channel they would prescribe any other specialty medication. Our RFID refill card enables us to offer nVNS therapy on a monthly basis, at the price of a branded pharmaceutical, which is typical of a traditional drug reimbursement model managed by pharmacy benefit managers and other commercial payers. Beginning in the first quarter of 2019, we have agreements with commercial payers and the Federal Supply Schedule (Veterans Administration and Department of Defense) that we estimate provide reimbursement of gammaCore for approximately 53 million lives. Although there can be no assurance of success, we continue discussions with additional payers and PBMs regarding up to an additional 90 million lives in the United States with a goal of securing reimbursement for an aggregate of 75 million lives in the United States by the beginning of the third quarter of 2019, and an aggregate of 100 million lives in the United States by the end of 2019.
- ***Highly scalable and low investment manufacturing with digital refills***. Our low manufacturing and assembly costs allow us to scale to meet demand with minimal additional investment. With the launch of the gammaCore Sapphire, which uses RFID cards for refills, our gross margins are expected to increase significantly. When the payers are in place, we have the capability to integrate our onboard Bluetooth technology with the payer systems to leverage a cloud-based refill delivery process, which we believe will enable greater efficiencies, further enhancing our gross margins.
- ***Potential for rapid label expansion in headache and regulatory approval in additional indications.*** The safety profile of gammaCore enabled us to utilize the *de novo* regulatory pathway through which the FDA established a new therapeutic category: External Vagus Nerve Stimulator for Headache (21 CFR 882-5892). Through the 510(k) pathway, we received clearance for our gammaCore therapy for the acute treatment of pain associated with migraine in adults in January 2018, and clearance for the prevention of cluster headaches in December 2018. We believe a similar regulatory pathway may be available to us for additional indications in headache, including the prevention of migraine, the expansion of our label to include adolescents, and the treatment of post-traumatic headaches. We also anticipate seeking regulatory authorization to commercialize our therapy in rheumatological conditions through similar pathways.
- ***Broad intellectual property protection.*** Among our key issued patents, we have coverage on using our high-frequency burst 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 pharmaceutical and medical device industries, including positions at Pfizer, Merck, Novartis, Stryker and Zimmer Biomet. Members of our team have been involved in the launch and marketing of products including Motrin, Celebrex, and the migraine drugs Axert and Maxalt. Our team's pharmaceutical experience in clinical development, sales, marketing and reimbursement, and its medical device experience in research, development and regulatory affairs, allow us to pursue our strategy and growth plans.

Our Strategy

Our goal is to be a leader in bioelectronic medicine by using our proprietary non-invasive VNS platform therapy to deliver better patient outcomes. The key elements of our strategy include:

- ***Drive acceptance of our gammaCore products as a leading headache therapy.*** We are establishing gammaCore as a first-line treatment option for neurologists when treating CH patients, who have few alternative treatment options available to them. We are continuing to leverage this position as we expand into the broader headache market for acute migraine treatment. We are working towards gaining additional FDA-clearances in multiple headache indications including migraine prevention, post traumatic headache, and migraine in adolescents. Receipt of each of these FDA-clearances will provide us with greater access into the headache market.
- ***Drive reimbursement of our therapy***. We have been and are actively engaging with over 50 national and regional commercial insurance payers, as well as the Federal Supply Schedule in the United States, with the goal of securing reimbursement coverage. These efforts in 2018 culminated with the initiation of estimated coverage for approximately 53 million lives in the United States as of January 2019. With continuing payer discussions regarding up to an additional 90 million lives, we are seeking to expand the number of covered lives in the United States to an aggregate of 75 million by the beginning of the third quarter of 2019, and to an aggregate of 100 million by the end of 2019, although there can be no assurance of success.

- ***Build a leading commercial presence.*** We have established a robust commercial capacity, including a specialty distribution channel with a patient-focused support service to quickly onboard patients and manage payer interactions. Following our initial public offering, in the third quarter of 2018 we expanded our direct sales force to 32 people who are targeting the 6,400 leading neurology specialists and headache centers that originate the substantial majority of new prescriptions for severe headache patients in the United States.
- ***Rapidly advance our pipeline***. In 2018, we initiated several studies, including an additional pivotal trial to support potential label expansion in migraine prevention. In partnership with academic colleagues in the United Kingdom and Denmark, we also completed our first pilot trial in rheumatology, including rheumatoid arthritis and Sjögren's syndrome. Over the next 24 months, we anticipate additional sponsored trials will be conducted in both neurology and rheumatology, including in migraine in adolescents (our ATOM trial) and rheumatoid arthritis.

Our Lead Indications in Headache

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 was the FDA release we secured through the *de novo* review for the acute treatment of pain associated with episodic cluster headache in April 2017.

Migraine is the third most common disease in the world, and a debilitating condition characterized by severe throbbing pain or a pulsing sensation, usually on one side of the head, often associated with nausea and sensitivity to light and sound. Migraine impacts more than 38 million people in the United States, disproportionately affecting women of childbearing years, with peak onset during the adolescent ages of 12 to 16. While migraine sufferers have a number of approved and available treatments, contraindications, side effects, and incomplete efficacy of these options continues to drive a high level of dissatisfaction with current therapies.

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, statistical significance was achieved for complete pain relief 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). We are currently building and aggregating the necessary data to support the FDA clearance of our label expansion for the prevention of migraine.

Migraine

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

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 38 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 will be approximately $4.0 billion.

Economic Burden. Over the past several decades, migraine has been associated with persistently greater total annual medical costs. An independent study conducted in 1999 found that migraine sufferers in California had annual total medical expenses two and a half times higher than non-migraine sufferers. A 2011 study conducted by GNS Healthcare and sponsored by us demonstrated consistent results among the nearly 5% of 21 million privately insured patients in the United States who receive diagnosis of migraine annually.

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 treatments prescribed 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.

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 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.

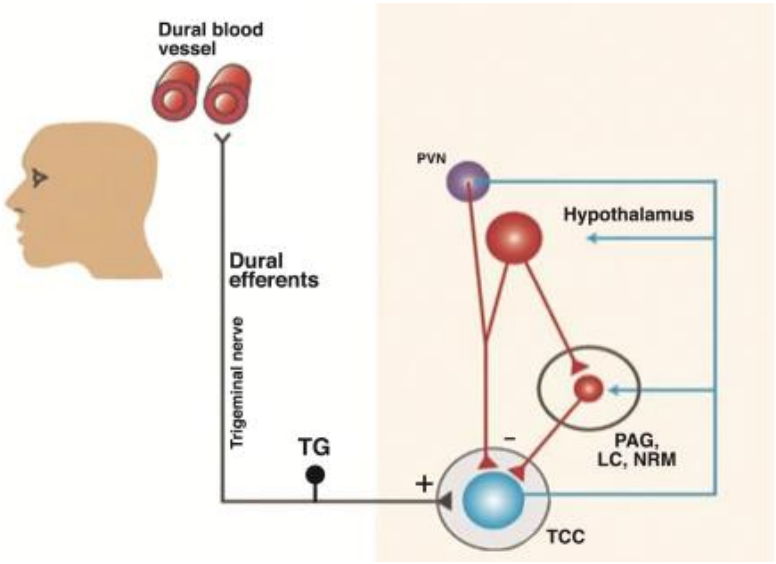
Opioids are often dispensed for migraine attacks in emergency departments; however, in the treatment guidelines referenced by the National Institutes of Health, their use is not recommended for the acute treatment of migraine. Opioid use for migraine is associated with increased disability and health 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. Data from a 2009 study conducted by the American Migraine Prevalence and Prevention Study suggests that about 16% of migraine patients are current opioid users and 16% of those patients are likely dependent.

Although there are more prescription therapies available for migraineurs than CH sufferers, 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.

Preclinical Evidence of nVNS Mechanism of Action in Acute Migraine

Although the cause of migraine is multifactorial, one validated model, shown in Figure 1 below, involves the activation of nerve fibers in the dura. These fibers lie in close proximity to blood vessels passing through the dura, and connect through the trigeminal ganglion to the Trigeminal Cervical Complex, or TCC. The TCC is a region of the brainstem associated with pain processing. Firing of the TCC involves the increased release of the excitatory neurotransmitter glutamate and is associated with migrainous pain. This activation is typically opposed by the release of inhibitory neurotransmitters, including serotonin, norepinephrine, and GABA. Migraine pain may be experienced when excessive firing from the TCC exceeds the inhibitory mechanisms, or if the inhibitory mechanisms are not present.

Figure 1: The neural circuit believed to be associated with migraine



(Figure adapted from S. Akerman and P. Goadsby, with permission)

To show the effects of nVNS, we sponsored a preclinical study at Thomas Jefferson University, published in *Pain* in 2014. In this study, animals were sensitized, rendering them allodynic, or sensitive to touch, and susceptible to increased pain when the known migraine trigger, nitroglycerine, or GTN, was administered. Previous research had shown significant increases in glutamate expression in the TCC, specifically in the trigeminal nucleus caudalis from GTN exposure. The results of our study, provided in Figures 2 and 3 below, showed that administration of nVNS simultaneously with, or 90 minutes after GTN was administered, reduced both the pain behavior and the over-expression of glutamate.

Figure 2: Co-administered nVNS prevents the significant increase in glutamate expression triggered by GTN in sensitized animals.

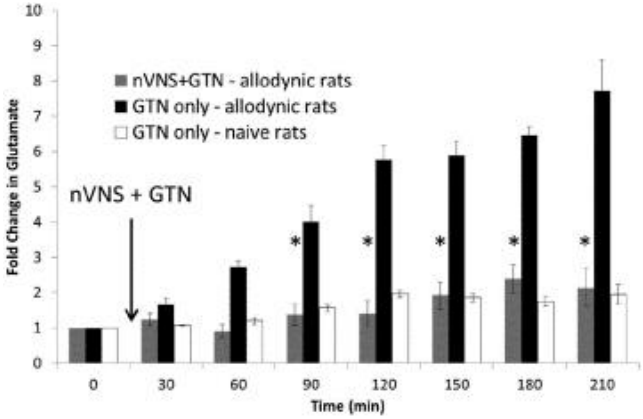
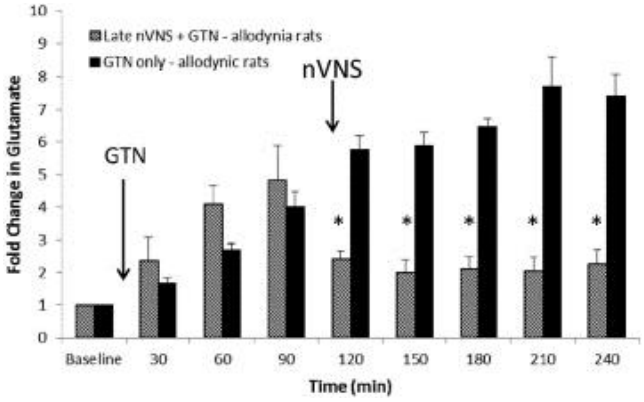


Figure 3: Administration of nVNS, 90 minutes after GTN reduces over-expression of glutamate that occurs in sensitized animals.

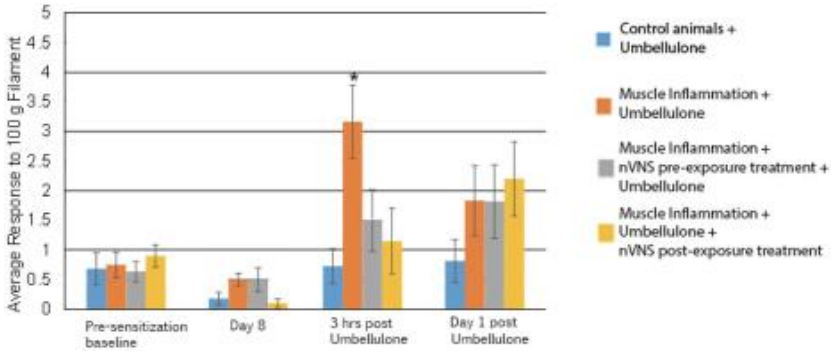


The pulsating character of migraine pain supports the inference of a relationship between activated nerve fibers and blood vessels that are in close proximity with one another. This pulsating feature, typically exacerbated by exercise, led early observers to suspect vasodilation as an underlying cause. As previously mentioned, triptans, which are vasoconstrictors, are the most widely prescribed medications for the acute treatment of migraine. Further, over the past decade, research in headache has included a focus on calcitonin gene-related peptide, or CGRP, which is a peptide released by neurons under a variety of stress and inflammatory conditions. CGRP is the most potent, endogenously produced vasodilator. The administration of exogenous CGRP in sensitized animals and human migraineurs has been shown to trigger pain-related behavior and migraines.

Models of CGRP activity in migraine suggest that neurons releasing CGRP in the TCC result in the activation of pain pathway neurons, leading to acute headache pain. While several stresses can cause the release of CGRP, the inflammatory cytokine tumor necrosis factor alpha, or TNF-a, is known to trigger its synthesis and release from neurons. Heightened expression of TNF-a has been correlated with heightened expression of CGRP as well as its receptors. As previously mentioned, published results of multiple studies show that VNS is capable of suppressing TNF-a in the central nervous system.

To further study the effects of our gammaCore therapy in migraine, and specifically as it relates to CGRP, we sponsored a series of studies in which animals were sensitized by chronic inflammation. These animals experience migraine-like pain upon exposure to a known migraine trigger, umbellulone. The results of this study, as shown in Figure 13 below, demonstrated that nVNS reduces pain responses of sensitized animals relative to that of naïve animals, whether the therapy is delivered before or after the trigger is administered.

Figure 4: Administration of nVNS after umbellulone exposure reduces pain-associated behavior in inflammation-sensitized animals.



In addition to the reduction in pain, nVNS reduced the expression of intracellular biomarkers of inflammation. These biomarkers are associated with an upregulation in TNF-a, and correspondingly, in CGRP synthesis and expression.

Clinical Data in support of gammaCore for Acute Migraine Treatment

We have completed one pilot and one pivotal trial examining the efficacy, safety and tolerability of gammaCore for the acute treatment of migraine headache as summarized in Table 2 below:

Table 2: Overview of Our Acute Migraine Trials for gammaCore

Trial	Phase	Enrolled Patients (n)	Design	Date Published
Acute Treatment	Pilot	30	Open label, single-arm, multiple-attack trial	2014
PRESTO	Pivotal	285	Multi-site, randomized, double-blind, parallel-group, sham-controlled	2017

Our First Open Label Trial in Acute Migraine

We sponsored a multi-center, pilot clinical trial to investigate the use of gammaCore for the acute treatment of migraine headache, published in 2014. The trial was an open-label, single-arm, multiple-attack trial conducted at four headache centers in the United States. Patients were asked to treat up to four acute migraine attacks with gammaCore over a six week period. The trial enrolled 30 patients, 25 of whom were female and 27 of whom treated at least one attack.

Nineteen of the 27 patients treated their first attack at a pain level that was moderate or severe at baseline. Four of these 19 patients (21%) reported being pain free at two hours. Nine of 19 patients (47%) reported pain relief, defined as mild pain or pain free, at the same time point. The eight remaining patients treated their first attack while at mild pain at baseline, five of whom (63%) were pain free at two hours. Overall, these 27 patients treated 80 migraines, 54 of which were treated with a baseline pain level of moderate or severe. Twelve of 54 attacks (22%) were reported as pain free at two hours, and 23 of 54 attacks (43%) reached pain relief. The remaining 26 attacks were treated at mild pain, and pain freedom was achieved for 10 of these attacks (38%). The efficacy results from this trial are similar to other acute treatments for migraine.

This pilot trial demonstrated gammaCore is well tolerated in patients with acute migraine. Adverse events were of mild severity, transient in duration, and included local discomfort during and after gammaCore use, as well as mild skin reactions to the conductive gel. Based on the results of this trial, the authors noted that gammaCore seemed better tolerated than triptan medications and did not appear to have the cardiovascular or cerebrovascular risks associated with them.

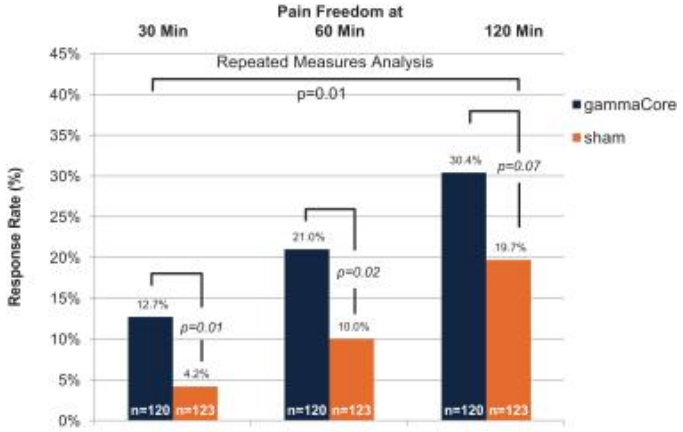
The PRESTO Trial — Our Registration Trial for the Acute Treatment of Migraine

Our PRESTO trial, or PRESTO, was a randomized, double-blind, sham-controlled prospective trial of gammaCore for the acute treatment of migraine. The trial enrolled 285 patients and was conducted at 10 centers in Italy, including academic medical centers and other tertiary headache clinics. Patients treated up to five migraine attacks with gammaCore or sham in a double-blind period, and up to five additional attacks with gammaCore in an open-label period. Two hundred forty eight of the 285 patients who were enrolled into the run-in period were eligible for randomization into the double-blind period (37 patients did not randomize, the majority of whom failed to meet the entry criteria for randomization.) Two hundred forty-three of the 248 enrolled patients treated at least one attack and represent the ITT population (gammaCore, n=120; sham, n=123). Of the ITT population, 239 entered the open label period, and 238 finished the open label period.

The primary endpoint for the trial was response rate, defined as the proportion of patients who achieved pain freedom at 120 minutes after treatment initiation for the first migraine treated. Demographic and baseline characteristics were generally well balanced between the gammaCore and sham cohorts, however, clinically relevant trends were observed with respect to preventative medication use and pain level at baseline. A higher proportion of patients in the gammaCore cohort treated their first attack when its intensity was severe.

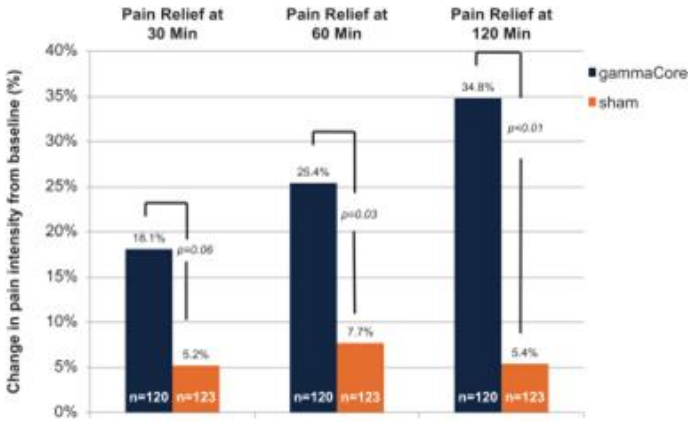
As shown in Figure 1 below, the proportion of patients in the gammaCore cohort who became pain-free after treating the first attack was measurably higher than those who treated with sham at 30 minutes (gammaCore, 12.7%; sham, 4.2%; *p*=0.01) and 60 minutes (gammaCore, 21.0%; sham, 10.0%; *p*=0.02) and at 120 minutes (gammaCore, 30.4%; sham, 19.7%; *p*=0.07; primary endpoint). The loss of statistical significance at 120 minutes was subsequently determined to be the result of autonomic activation by the sham device and a repeated-measures test, recommended by our independent statisticians, was employed to examine the inconsistency between the 120-minute finding and the 30- and 60-minute findings. This statistical test confirmed the statistical significance of gammaCore's superiority over sham for the pain-free outcome through 120 minutes (odds ratio: 2.3; 95% CI: 1.2, 4.4; *p*=0.01).

Figure 5: Primary Endpoint and Repeated Measures Analysis of the PRESTO Trial for Acute Migraine



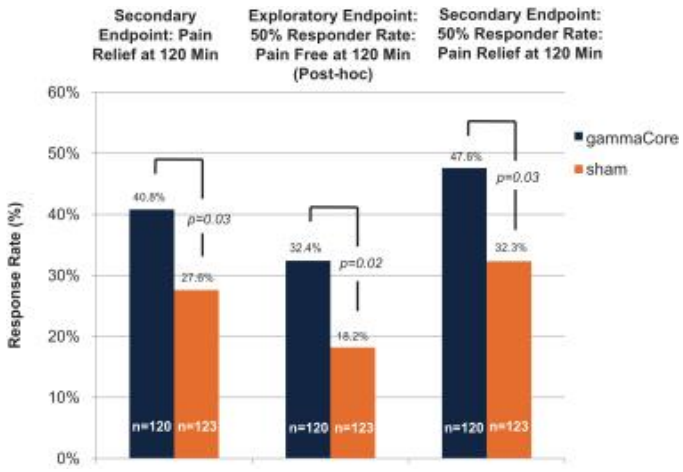
As shown in Figure 6 below, mean percentage pain reduction for the first attack was significantly greater with gammaCore than with sham at 60 minutes (gammaCore, -25.4%; sham, -7.7%; *p*=0.03) and 120 minutes (gammaCore, -34.8%; sham, -5.4%; *p*<0.01).

Figure 6: Percent Pain Relief Results of the PRESTO Trial for Acute Migraine



As shown in Figure 7 below, the proportion of patients who achieved pain relief, defined as mild or no pain, at 120 minutes was significantly higher with gammaCore than with sham for the first treated migraine attack (gammaCore, 40.8%; sham, 27.6%; *p*=0.03). The proportion of patients who responded at 120 minutes for ≥50% of their attacks was significantly higher with gammaCore than with sham for both pain freedom (gammaCore, 32.4%; sham, 18.2%; *p*=0.02) and pain relief (gammaCore, 47.6%; sham, 32.3%; *p*=0.03).

Figure 7: Selected Secondary and Exploratory Results of the PRESTO Trial for Acute Migraine



As has been the case in every trial conducted with gammaCore, no SAEs were attributable to gammaCore in PRESTO.

Migraine Prevention

As previously described, the grant by FDA of our *de novo* submission resulted in a new Class II regulatory category: External Vagus Nerve Stimulator for Headache (21 CFR 882-5892). The establishment of this product category permits us to apply for label expansions through the 510(k) regulatory pathway utilizing our own product as the predicate. With the recent clearance of our label expansion to CH, it is now our intention to seek the expansion of our label for the prevention of migraine. As described below, we have conducted, and continue to conduct clinical studies to support this indication.

Migraine Prophylaxis Market

According to the U.S. Agency for Healthcare Research and Quality, only about 12% of adults with high frequency or chronic migraine take preventive medications. According to the American Migraine Foundation, medication side effects often limit the use of migraine medications.

Currently Used Therapies for Migraine Prevention and Their Limitations. Prior to the approval of CGRP antibodies by the FDA, there were five products approved by the FDA for the prevention of migraine: anti-epileptic drugs, topiramate (Topamax) and valproic acid (Depakote), beta-blockers, propranolol (Inderal) and timolol (Blocadren), and BOTOX. BOTOX is the only product that has been approved by the FDA for the prevention of chronic migraine, and its label is limited to that subgroup. In all cases, these medications were first approved for other uses.

These current treatments are ineffective or inconvenient for some patients, and their use has been limited by issues with tolerability and side effects, including cognitive impairment, nausea, fatigue and sleep disturbance. Anti-epileptic drugs are also associated with poor pregnancy outcomes and fetal abnormalities, which is a concern for women of childbearing years. In clinical trials, these medications require four to six weeks of daily administration before most patients experience measurable clinical benefit. For example, BOTOX requires approximately 31 subcutaneous injections at various sites on the head and neck, repeated every 12 weeks.

There are currently three antibodies to CGRP and its receptor approved by FDA for the prevention of migraine by Teva Pharmaceutical Industries Ltd., and Eli Lilly and Company, and by Amgen Inc., which is in a co-marketing partnership with Novartis International AG, approved by the FDA in May 2018. There are a number of medical devices that have been marketed for the treatment of migraine, including Cefaly and the Spring TMS device.

We believe there is a need for a new therapy that can either prevent migraines or reduce their severity to a level at which supplemental existing abortive therapies can provide relief as needed, with reduced side effects. Such a therapy could provide benefit for both patients on existing therapies and patients who have abandoned therapy.

Mechanisms of Action Evidence Supporting gammaCore Use in Migraine Prevention

Approximately 25% of all migraine patients experience sensory symptoms known as "aura" prior to the pain stage of at least a portion of their migraine attacks. Aura is characterized by disruptions of visual perception and has been associated with synchronized depolarizations known as cortical spreading depressions, or CSDs, which are believed to occur more readily when the brain is in a hyperexcitability state. It is the ability of several anti-epileptic drugs to reduce brain hyperexcitability that led to their use for the prevention of migraine.

Implanted VNS was first developed clinically for the treatment of epilepsy, and early pilot studies in migraine and other severe headache conditions have suggested that VNS could have efficacy in the prevention of headache attacks. To determine the mechanisms of action through which this prophylactic benefit might arise, we sponsored a series of pre-clinical studies at the Massachusetts General Hospital. The results, published in 2016, showed that our gammaCore therapy rapidly reduced brain hyperexcitability, as evidenced by an increase in the thresholds required for triggering CSDs, both through chemical and electrical means. In contrast to the chemical medications mentioned above, however, a two-minute dose of our therapy was able to multiply by approximately 2.5 times the intensity of the electrical trigger required to initiate CSDs within 20 minutes of initial treatment. This resistance to CSDs was also shown to persist for several hours after treatment, both slowing the number of CSDs triggered by a chemical exposure, but also the rate at which the CSDs propagated through the brain. This compares favorably to drug treatments that require weeks to months of daily administration, often with associated side effects, before achieving clinical benefit.

It is not currently conclusively established what leads to hyperexcitation and susceptibility to migraine, however, recently published genetic and epigenetic studies suggest a strong association between migraine and genes tied to severe inflammatory conditions. These findings, coupled with recent breakthroughs in our understanding of how the immune system affects the expression of neurotransmitters, CGRP, and their receptors, may enhance our explanations of how hyperexcitability arises, and how it leads to migraine susceptibility. To further this understanding, we sponsored studies in which prolonged inflammation was used to sensitize animals to respond to migraine triggers.

In this work, twice-daily gammaCore treatments, administered during the prolonged inflammation period, inhibited sensitization. Animals treated with gammaCore during the prolonged period of induced inflammation were indistinguishable with respect to their responsiveness to a migraine trigger from a control animal group that had not been subjected to the prolonged inflammation. In contrast, the active control group (subjected to the prolonged inflammation, but not treated with gammaCore, became sensitized and thus responded with pain behavior when exposed to the migraine trigger. Brainstem tissue from this sensitized group was analyzed and showed evidence of CGRP synthesis. In contrast, both non-sensitized animals and gammaCore-treated animals exhibit normal intracellular biomarkers of CGRP synthesis.

We believe these preclinical studies provide mechanistic support, both as a means for inhibiting a hyperexcitable brain state, as well as through the reduction in the biomarkers associated with pain pathway activation. These pre-clinical results supported the development of gammaCore for the prevention of migraine.

Clinical Data in Support of gammaCore for Migraine Prevention

Our EVENT Trial – Chronic Migraine Headache Prevention with gammaCore

Our EVENT trial was a multi-center, randomized, sham-controlled pilot clinical trial with respect to the use of our gammaCore therapy for the prevention of chronic migraine and was published in 2016. This prospective double-blind pilot trial was conducted at six tertiary care headache centers in the United States. The trial included three consecutive periods: (1) a one-month baseline period during which patients provided data regarding their frequency of headache attacks to serve as a baseline comparator; (2) a two-month, randomized, sham-controlled period during which patients received prophylactic treatment with gammaCore or a sham; and (3) a six-month open-label period during which all patients received gammaCore. The primary objective of the EVENT trial was to assess the feasibility, safety, and tolerability of our gammaCore therapy, and as such, was not powered to reach statistical significance with respect to any efficacy measures. The trial enrolled 59 patients.

At baseline, the mean number of headache days in the gammaCore cohort (n=30) was 20.8 and 22.0 for the sham cohort (n=29). At the conclusion of the randomized period, the gammaCore cohort had experienced an average reduction of 1.4 migraine days while the sham cohort experienced a 0.2 migraine day decrease. The mean change from baseline was not statistically significant between groups. A per protocol cohort was identified in whom the mean migraine day reductions for the gammaCore and sham cohorts were 2.0 and 0.1, respectively.

During the open-label period, the original gammaCore cohort experienced continued reductions in migraine days. In this period, patients who had been assigned to the sham cohort gained access to gammaCore and began to show improvement. The data from this trial demonstrated that continued use of our gammaCore therapy provides increased benefit. A *post hoc* completers analysis demonstrated statistically significant and clinically meaningful reductions from baseline at the conclusion of the trial in both cohorts (initial gammaCore randomization cohort, 8.0 migraine-day reduction; initial sham randomization cohort, 6.0).

The primary purpose of this trial was safety and tolerability. Our gammaCore therapy was well tolerated and mild to moderate adverse events were generally similar in both groups.

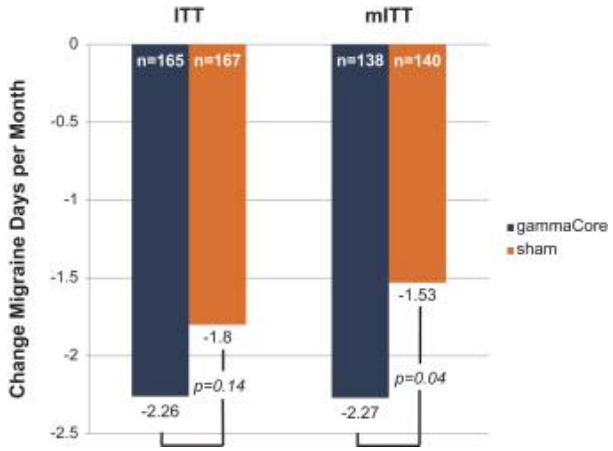
The PREMIUM I Trial – Our Registration Trial for the Prevention of Migraine

Our PREMIUM I trial, or PREMIUM I, was a randomized, double-blind, sham-controlled prospective trial of gammaCore for the prevention of migraine. The trial was conducted at 22 centers in Europe and enrolled 477 patients into a 28-day baseline run-in period, 341 of whom are included in the safety population. Patients were 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 were offered the opportunity to use gammaCore during a 6 month open-label period following a three month blinded randomized period.

The primary endpoint for the trial was 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. Three hundred thirty-two patients (gammaCore, n=165; sham, n=167) were included in the ITT population. Of these patients, 278 (gammaCore, n=138; sham, n=140) complied with the trial requirement to self-administer no fewer than two-thirds of the specified treatments per month during the randomized period. This population represents an mITT.

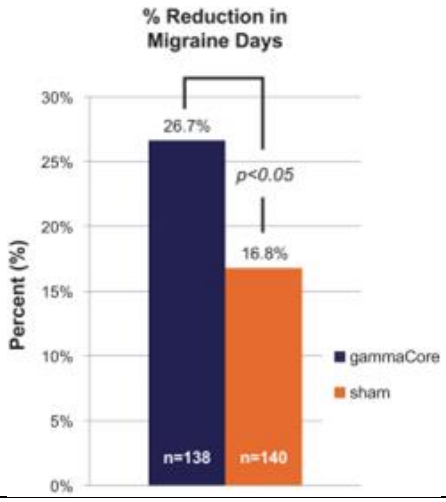
For the ITT and mITT populations, the baseline average number of migraine days per month was similar between the two cohorts (gammaCore, 7.94 and 8.06, respectively; sham, 7.80 and 7.78, respectively). The primary endpoint was not met for the ITT population (gammaCore, -2.26; sham, -1.80; p=0.15; linear regression). However, as shown in Figure 8 below, statistical significance was achieved in reduction of migraine days per month, the primary endpoint metric, for the mITT population (gammaCore, -2.27 migraine days; sham, -1.53 migraine days; p=0.04; linear regression).

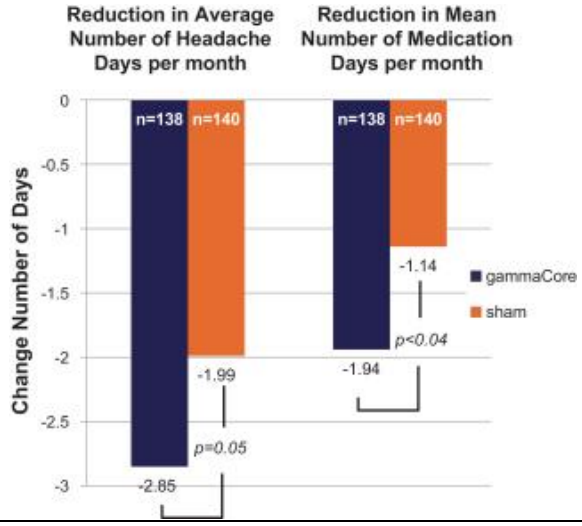
Figure 8: Primary Endpoint Analysis of the ITT and mITT Populations for the PREMIUM Trial



As shown in Figures 9 and 10 below, with respect to key secondary and exploratory endpoints, statistical significance was achieved across several measurements in the mITT population. As shown in Figure 9 below, the average percentage reduction in migraine days per month among the mITT population was greater for the gammaCore cohort compared with sham (gammaCore, 26.7%; sham, 16.8%; p<0.05). As shown in Figure 10 below, the reduction in the average number of headache days per month among the mITT population was greater for the gammaCore cohort compared with sham (gammaCore, -2.85; sham, 1.99; p=0.05). The mean reduction in days on which medication was required was statistically significant greater in the gammaCore cohort as compared with sham among the mITT population (gammaCore, -1.94; sham, -1.14; p<0.04). While not reaching statistical significance, the proportion of patients experiencing at least a 50% reduction in migraine days per month demonstrated a trend toward significance consistent with the previously reported endpoints (gammaCore, 31.6%; sham, 22.1%; p<0.08).

Figures 9 and 10: Additional Secondary and Exploratory Endpoint Analysis for the PREMIUM Trial





Data from the recently completed open-label period of the PREMIUM trial was generally consistent with the earlier results from the randomized period with continued reductions in the number of migraine and headache days per month, as well as an increase in the number of subjects who had 50% reduction in the number of their monthly migraine days compared to when they started the trial. More specifically, during the open-label phase of the study, it should be noted that the patients who were initially assigned to the active therapy continued to show improvement, reaching average reductions of -2.56 migraine days and -2.52 migraine days after 6 and 9 months, respectively, on gammaCore. Similarly, patients who were initially assigned to the sham arm, who were given access to the active therapy reached -1.82 and -2.08 migraine days after 3 and 6 months, respectively, on the active therapy.

In our PREMIUM trial, no SAEs were attributed to gammaCore. The PREMIUM trial demonstrated that our gammaCore therapy for acute migraine treatment has a highly favorable tolerability profile.

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

Our PREMIUM II trial, or PREMIUM II, received its first enrolled patients in the fourth quarter of 2018, and had enrolled 70 patients as of March 15, 2019. Like its predecessor, PREMIUM I, PREMIUM II is a randomized, double-blind, sham-controlled prospective trial of gammaCore for the prevention of migraine. This trial is being conducted at 30 centers in the United States, and is seeking to enroll a total of 400 patients. 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 6-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.

We anticipate that this study will complete enrollment in the first quarter of 2020 with data readout anticipated in the third quarter of 2020.

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 episodic cluster headache, or 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 cluster headache, 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 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 its prevention.

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 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 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.

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 2019 will be approximately $400 million.

Economic Burden. According to a recent 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.

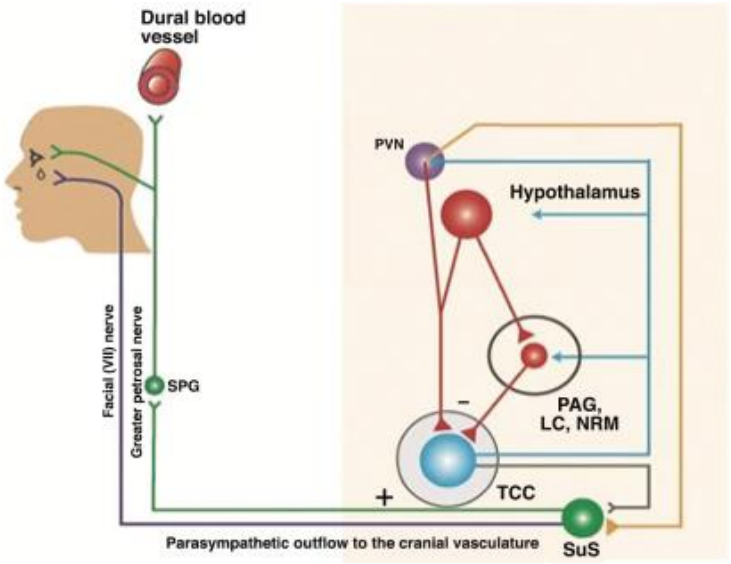
Other Therapies for the Acute Treatment of Cluster Headache. Other than gammaCore, there is only one FDA-approved commercially available therapy for acute treatment for CH, injectable sumatriptan (Imitrex). The side effect profile and cost of Imitrex, however, typically limits patient access to only 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.

Prior to the approval in December 2018 of gammaCore for the prevention of CH, there were no FDA approved pharmaceutical or device treatments for CH prophylaxis. In a 2016 market research survey of CH patients, 87% of the respondents were dissatisfied with the then-available treatment options.

Preclinical Evidence of VNS Mechanisms of Action in Acute Cluster Headache

It is generally believed that the neural circuit involved in CH includes activation and inhibition of the trigeminal cervical complex, or TCC, shown in Figure 11 below. This circuit is similar to the one associated with migraine etiology, which is consistent with the successful use of injected migraine medications for the acute treatment of these attacks. There are important differences, however, between the two circuits. In the case of CH, activation of facial nerves, including those relaying through the sphenopalatine ganglion, or SPG, are believed to be associated with the activation of areas within the TCC. This belief is supported by evidence showing that activation of this pathway can cause CH-like attacks. As was the case with migraine, inhibition of the TCC is provided by inhibitory neurotransmitters, like serotonin, GABA and norepinephrine, which are released by neurons residing in the PAG, the NRM, and the locus coeruleus, or LC.

Figure 11: The neural circuit believed to be associated with CH.



(Figure adapted from S. Akerman and P. Goadsby, with permission)

One possible mechanism by which gammaCore acutely treats CH attacks may be through enhancement of inhibitory signals to the TCC. To test this, we sponsored research in which recording electrodes were inserted into the TCCs of rats to measure the effects of VNS on normal activity, or ongoing spontaneous neuronal firing, and activity under pain-simulated conditions, or dural-evoked pain fiber firing, the latter being caused by irritation of the outermost covering of the brain, or dura. As seen in the published graphs in Figures 12 and 13 below, VNS significantly suppressed activity in the TCC in both cases. These data suggest that the strengthening of the inhibition pathways is a mechanism of action for gammaCore.

Figure 12: VNS applied in two doses, separated by five minutes, was able to suppress ongoing spontaneous firing of the neurons in the TCC, by more than 50%, with a duration of effect greater than two hours.

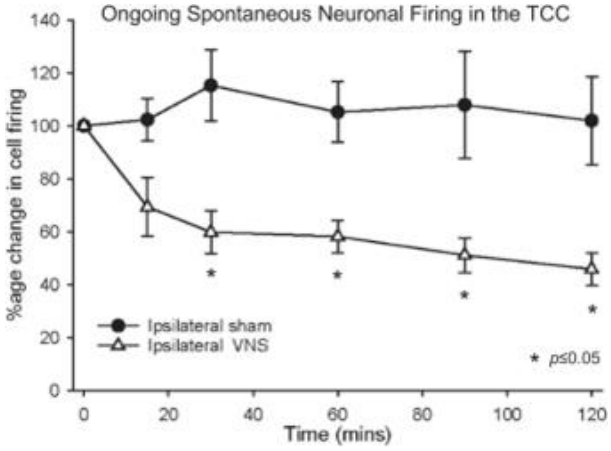
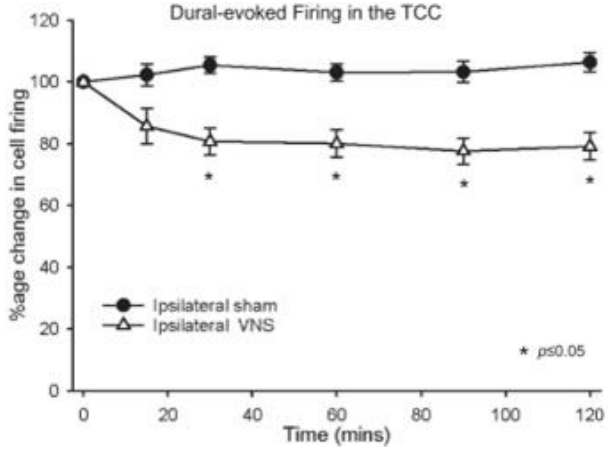


Figure 13: A pair of VNS doses, separated by five minutes was able to suppress firing of the pain fibers in the TCC under pain simulated conditions by approximately 30%, with a stable duration of effect of more than two hours.



Clinical Data of gammaCore as an Acute Treatment for Cluster Headache

We have completed one pilot trial and two parallel pivotal trials examining the efficacy, safety and tolerability of gammaCore for the acute treatment of CH as summarized in Table 2 below:

Table 2: Overview of our CH trials for gammaCore

Trial	Phase	Enrolled Patients (n)	Design	Date Published
Royal Free Hospital Pilot Trial	Pilot	25	Single-site, Open-label	2015
ACT 1	Pivotal	150	Multi-center, randomized, sham-controlled	2016
ACT 2	Pivotal	103	Multi-center, randomized, sham-controlled	2017

Our First Open-Label Trial

We sponsored an open-label trial of gammaCore for the acute treatment and prevention of CH at the Royal Free Hospital, published in *Neurology* in 2015. The trial enrolled 25 patients, 19 of whom provided evaluable data. Of these evaluable patients, 11 had cCH and 8 had eCH. Seven of the cCH patients were considered to be drug-refractory and had failed reasonable attempts with multiple different preventative agents. Five patients with cCH provided long-term data for a full 52 weeks. In this trial, an evaluation of the efficacy of the therapy was based on patient-reported estimates of their CH attack frequency.

Fifteen of the 19 evaluable patients in this trial reported an overall improvement in their condition from baseline, with four stating that their condition had remained the same. No patients reported a worsening of their preexisting condition. Results demonstrated a mean improvement of 48% in CH attack frequency. Five of the eleven cCH patients had a one-year extended follow-up, which showed a mean estimated improvement in attack frequency at 26 weeks of 62% and maintenance at 52 weeks of 58%. In regard to acute efficacy, patients in this trial reported that gammaCore aborted attacks within an average time of 11 minutes of initial treatment. The long-term durability of this response was stable in four of the five patients with cCH who reported on their gammaCore use at both 26 and 52 weeks.

No serious adverse events were reported in this trial during and after treatment. Adverse events of mild severity reported in this trial included local discomfort during and after device use and mild skin reactions to the conductive gel.

Our Registration Trials for Acute Treatment of CH – ACT 1 and ACT 2

Our first FDA clearance, received following the grant of our *de novo* submission, was for the acute treatment of eCH, and is supported by two multi-center, randomized clinical studies, ACT 1 and ACT 2. These trials, in aggregate, enrolled 253 patients, including both eCH and cCH patients. The primary endpoints of these trials were pain reduction and pain freedom within 15 minutes of the onset of the attack, i.e. mild pain or pain-free in ACT 1 and pain-free in ACT 2. Neither trial reached statistical significance with respect to the primary endpoint in the total population, but they did reach statistical significance on the primary endpoint and multiple secondary endpoints in their eCH subpopulation. eCH represents 80-90% of the overall CH population. In ACT 1, our gammaCore therapy demonstrated an ability to reduce pain to mild or pain-free status in eCH patients within 15 minutes of the onset of the attack more than three times as frequently as the sham treatment (gammaCore, 34.2%; sham, 10.6%; $p<0.01$). In ACT 2, which had a more stringent primary endpoint, our gammaCore therapy demonstrated an even stronger therapeutic effect compared to the sham treatment among eCH patients (gammaCore, 47.5%; sham, 6.2%; $p<0.01$).

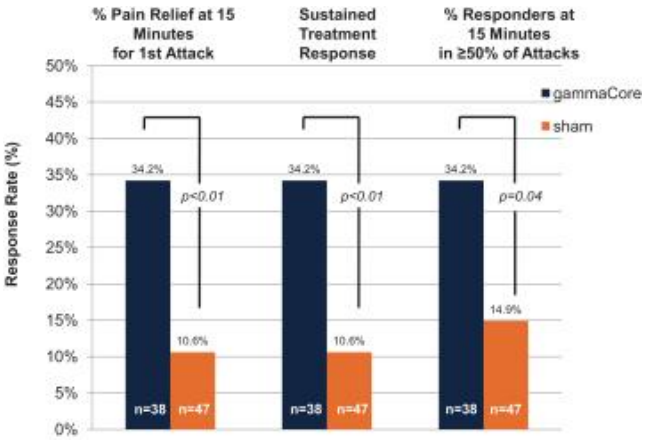
Our ACT 1 and ACT 2 Trials – gammaCore for the Acute Treatment of Episodic Cluster Headache

ACT 1 was a pivotal, randomized, double-blind, sham-controlled prospective trial of gammaCore for the acute treatment of CH. The trial enrolled 150 patients and was conducted at 20 centers in the United States, including academic medical centers and other tertiary headache clinics. Similarly, ACT 2 was a pivotal, randomized, double-blind, sham-controlled prospective trial of gammaCore for the acute treatment of eCH and cCH. It enrolled 103 patients and was conducted in four European countries at academic medical centers and other tertiary headache clinics.

ACT 1 was designed to establish the superiority of our gammaCore therapy in comparison to sham treatment, and in the double-blind phase of the trial 150 patients were enrolled and randomized to receive gammaCore therapy or sham treatment for one month or until five CH attacks were treated. The primary endpoint for the trial was response rate, defined as the proportion of patients who achieved pain relief (pain intensity of 0 or 1 on a 5 point scale) at 15 minutes after treatment initiation for the first CH attack treated. Investigators, patients, and study coordinators were blinded to treatment assignments in the double-blind phase of the trial. The ACT 1 results were published in *Cephalalgia* in 2016.

133 of the 150 patients enrolled in this trial met the criteria for the intent-to-treat, or ITT, population (gammaCore, n=60; sham, n=73). Of the 133 patients in the ITT cohort, most had eCH (85) and the remaining had cCH (48). Response rates for the primary endpoint in the total ITT population, which includes both eCH and cCH patients, were numerically superior for gammaCore as compared with sham treatment (gammaCore, 26.7%; sham, 15.1%; $p=0.1$). More importantly, as shown in Figure 14 below, in a predefined analysis of the eCH subpopulation, a significantly higher response rate was demonstrated with gammaCore than with sham (gammaCore, 34.2%; sham, 10.6%; $p<0.01$). Superior sustained treatment response rates were statistically significant for gammaCore compared with sham among the total population (gammaCore, 26.7%; sham, 12.3%; $p=0.04$), however, this superior response was most pronounced for the eCH subpopulation (gammaCore, 34.2%; sham, 10.6%; $p<0.01$). This observation of strongest clinical benefit in the eCH cohort was also demonstrated with respect to the proportion of patients who were responders at 15 minutes for ≥50% of their treated attacks (gammaCore, 34.2%; sham, 14.9%; $p=0.04$). Results were also significant in the eCH subpopulation for the proportion of those who were pain-free at 15 minutes for ≥50% of treated attacks (gammaCore, 15.8%; sham, 2.1%; $p=0.04$).

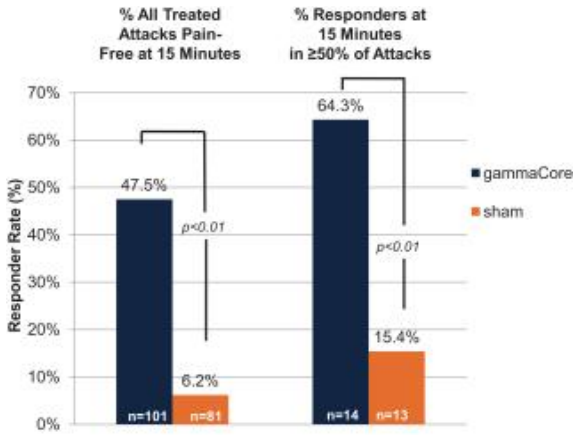
Figure 14: Selected Results for eCH Patients in the ACT 1 Trial



ACT 2 was also designed to assess the superiority of our gammaCore therapy in comparison to sham treatment, with a two-week, randomized, double-blind period during which patients were treated with either our gammaCore or sham therapy. The primary endpoint for the trial was response rate, defined as the proportion of all attacks that achieved pain freedom at 15 minutes after treatment initiation. That is, unlike the ACT 1 trial, in which patients were assessed based upon the only first attack treated, in the ACT 2 trial, all attacks treated during the randomized period were assessed. In total, 495 attacks were treated with active gammaCore therapy and 400 with the sham treatment. The ACT 2 trial results were published in *Cephalalgia* in April 2018.

In the ACT 2 trial, 103 patients were enrolled, 102 patients met the criteria for the safety population, and 92 patients met the criteria for the ITT population (gammaCore, n=48; sham, n=44). Of all 102 patients in the safety population, most had cCH (71%) and the remaining 29% had eCH. Although eCH occurs more frequently than cCH, we enrolled more cCH patients in the ACT 2 trial because a greater proportion of them are in bout at any given time.

Figure 15: Selected Results for predefined eCH subpopulation in the ACT 2 Trial



As shown in Figure 15 above, consistent with the results from the ACT 1 trial, among the eCH subpopulation, a higher proportion of treated attacks achieved pain-free status with gammaCore than with sham (gammaCore, 47.5%; sham, 6.2%; $p<0.01$). The proportion of responders, defined as patients who reached pain-freedom for 50% or more of their treated attacks within 15 minutes of onset of the attack was also statistically significantly greater among the gammaCore cohort than for the sham group (gammaCore 64.3%; sham 15.4%; $p<0.01$).

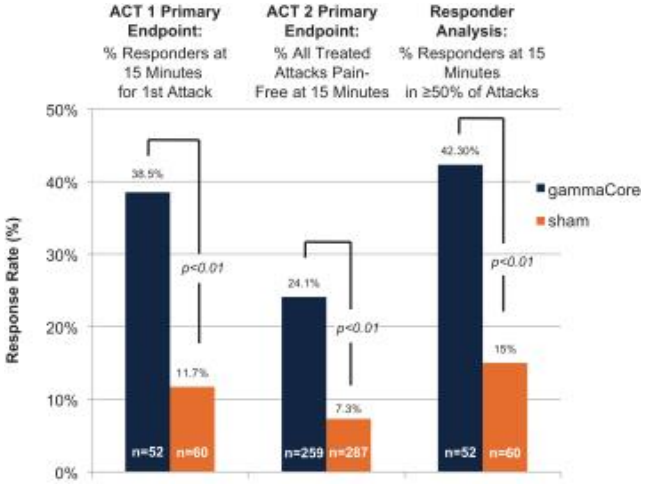
No serious adverse events, or SAEs, were attributable to gammaCore in either ACT 1 or ACT2. In the ACT1 trial, across all patients, 33% (49/150) had one or more adverse events, or AEs, during the double-blind period (gammaCore, 18; sham, 31). AEs occurred in 35 patients during the double-blind phase, at more than double the rate in the sham cohort than the gammaCore subpopulation. Similarly, in the ACT 2 trial, of all patients, 33% (34/102) had one or more AEs during the double-blind phase of the trial. Of the non-serious AEs, 19 patients (gammaCore, 9; sham, 10) experienced one or more treatment-related AEs during the double-blind phase of the trial. The most commonly occurring of these AEs were application site reactions, all of which were mild, transient, and tended to be self-limiting in nature.

Our Pooled Analysis of ACT1 and ACT2 for the Acute Treatment of Episodic Cluster Headache

To further explore the benefits of gammaCore for the acute treatment of eCH, the data from ACT 1 and ACT 2 were pooled to assess the overall response to each trial's primary endpoint, as shown in Figure 16 below. Collectively there were 112 eCH patients and 113 cCH in the pooled data set. Among the 112 patients with eCH, more patients who treated with gammaCore achieved mild or pain-free status at 15 minutes for the first attack treated (the ACT1 primary endpoint) compared with those in the sham cohort (gammaCore, 38.5%; sham, 11.7%; $p<0.01$). Similarly, the proportion of all treated attacks in these eCH subpopulation reaching pain freedom at 15 minutes (the ACT 2 primary endpoint) was greater in the gammaCore cohort compared to the sham cohort (gammaCore, 24.1%; sham, 7.3%; $p<0.01$). Both studies individually met statistical significance on this endpoint (ACT 1: gammaCore, 15%; sham, 6%; $p<0.05$; ACT 2: gammaCore, 48%; sham, 6%; $p<0.05$).

The proportion of these eCH patients who achieved mild or pain-free status at 15 minutes in ≥50% of their treated attacks was higher for gammaCore compared to sham (gammaCore, 42.3%; sham, 15.0%; $p=0.01$). These findings are consistent with the findings of each trial individually (ACT 1: gammaCore, 34.2%; sham, 14.9%; $p=0.04$; ACT 2: gammaCore, 64.3%; sham, 15.4%; $p=0.02$).

Figure 16: Selected Results of the Pooled Analysis of the ACT 1 and ACT 2 Trials for eCH Patients



This analysis demonstrated that gammaCore is effective and well tolerated in aborting attacks in eCH, but did not appear to have similar efficacy in cCH. Important advantages over existing treatment options are that gammaCore is easy-to-use and may be applied for as many attacks as a patient experiences per day, without the frequency-of-use restrictions and contraindications associated with other treatments.

Cluster Headache Prevention

The grant by FDA of our *de novo* submission in 2017 resulted in a new Class II regulatory category: External Vagus Nerve Stimulator for Headache (21 CFR 882-8592). The establishment of this product category permits us to apply for label expansions through the 510(k) regulatory pathway utilizing our own product as the predicate. In December 2018, the FDA cleared our therapy, gammaCore, for the prevention of CH.

Currently Used Therapies for Cluster Headache Prevention and Their Limitations. There are no products, other than gammaCore, that are currently approved by the FDA, or any other regulatory agency in any major market in the world, for the prevention of cluster headache. Medications that have been used, include valproic acid, verapamil, and lithium, all of which carry significant risks, and have limited evidence of efficacy in this regard. We believe there is a need for a therapy that can prevent cluster headaches, with limited side effects. The fact that gammaCore is also cleared for acute treatment in episodic cluster headache, and patients have up to thirty doses of therapy available to them for every day of their prescribed treatment period, it is convenient for patients to use the available doses to prevent attacks through prophylactic treatments, and to acutely treat those attacks that are not eliminated by the preventative use.

Mechanisms of Action Evidence Supporting gammaCore Use in Cluster Headache Prevention

As previously presented in combination with Figure 11, a prevailing theory of cluster headache pathology involves the activation of a neural circuit affecting trigeminal cervical complex, or TCC, a key region of the brainstem associated with pain processing. In this model, activation of facial nerves, including those relaying through the sphenopalatine ganglion, or SPG, activate the TCC. While inhibition of the TCC by upregulation of inhibitory neurotransmitter release may provide acute benefits to abort a cluster attack, the suppression of the causes of facial nerve activation may provide a means for preventing the cluster headaches from arising. Inflammation is an important activator of nerve firing.

For this reason, at the initiation of an episodic cluster headache patient's bout, although there is limited clinical evidence supporting its use, it has been observed that prednisone, which is known to be a potent general anti-inflammatory agent, is often able to reduce the frequency of attacks. Unfortunately, prednisone, and other similar glucocorticoid agents, have significant side effects that become increasingly negative as use of the medication continues beyond the short-term.

Preclinical and clinical evidence has shown that VNS has potent anti-inflammatory effects, through a neurochemically mediated downregulation of immune cell activity known as the cholinergic anti-inflammatory pathway, or CAP. The CAP functions through the release of acetylcholine, binding to a specific receptor expressed on the surface of key cells in the immune system, including macrophages and monocytes in the periphery and microglia in the central nervous system. VNS is known to upregulate the release of acetylcholine, both centrally and peripherally. In accordance with the theory of cluster headache pathophysiology, therefore, it was hypothesized that VNS would serve to reduce inflammatory activation of the facial nerves, and thereby prevent the activation of the neural circuit that causes cluster attacks.

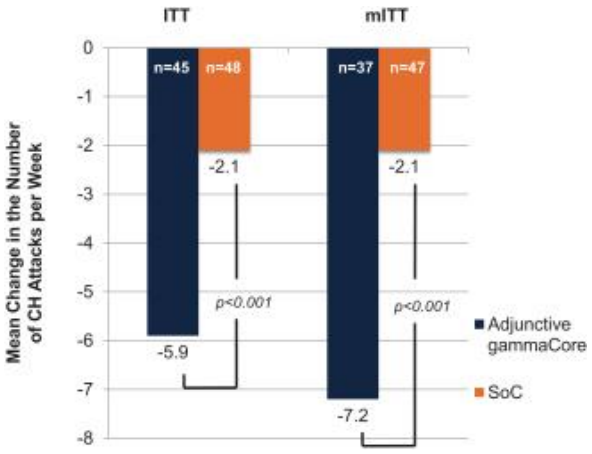
Our Registration Trial for the Prevention of CH – PREVA

Our most recent FDA clearance, received in December 2018, was for the prevention of CH, and is supported by a multi-center, randomized clinical trial, PREVA, as well as accumulated case series data from several clinical sites in the United Kingdom. The PREVA trial enrolled 114 patients with 97 patients randomized and was conducted at 10 sites in Europe, including academic medical centers and other tertiary headache clinics. PREVA was designed to assess the superiority of adjunctive use of our gammaCore therapy with standard of care medications in comparison to standard of care medication alone, and included three periods: (1) a two-week baseline phase during which all patients received only their individualized standard of care, or SoC, (2) a four-week randomized period during which participants were randomly assigned the adjunctive treatment or SoC arms; and (3) a four-week open label period during which all participants received adjunctive gammaCore therapy. The primary endpoint for the trial was defined as the mean change from baseline in the number of weekly attacks in the third and fourth week of the randomized period compared with the average weekly attack rate in the baseline period.

More specifically, in PREVA, 114 patients were enrolled and assessed at baseline, 97 of whom provided baseline data and were considered reliable trial participants. Of these patients, 93 met the criteria for inclusion in the ITT population having provided evaluable data (gammaCore, n=45; SoC, n=48). Of the ITT population, 92 provided data in the open-label period (gammaCore, n=44; SoC, n=48). Demographics and baseline characteristics were similar between these groups and were representative of the overall CH population. Use of SoC medications was also comparable between groups. A modified ITT, or mITT, population, defined to include only patients with measurable data across the respective study periods (gammaCore, 37/45; SoC, 47/48), was also provided in the primary publication of these data in 2016.

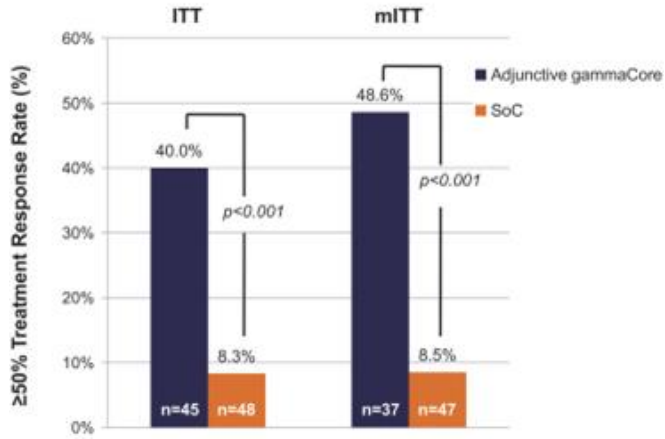
As shown in Figure 17 below, during the randomized period, participants receiving adjunctive gammaCore treatment had a significantly greater reduction from baseline in the number of CH attacks per week compared to those receiving SoC alone (gammaCore, -5.9; SoC, -2.1; $p<0.02$). In the mITT population, the therapeutic benefit was more pronounced in the adjunctive gammaCore cohort (gammaCore, -7.2; SoC, -2.1; $p<0.001$). To determine the efficacy of longer-term prophylactic use of gammaCore, the reduction in the number of CH attacks during the open label period was examined in the 30 patients who continued adjunctive gammaCore use through this period. These patients reported a statistically significant reduction of two CH attacks per week ($p<0.001$) compared with the randomized period, suggesting further benefit with continued adjunctive use of our therapy.

Figure 17: Primary Endpoint Analysis of the ITT and mITT Populations for the PREVA Trial



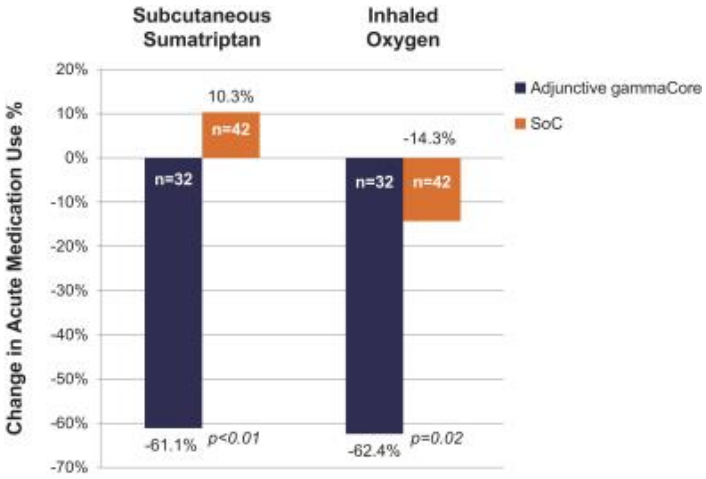
As shown in Figure 18 below, in the ITT population, a significantly higher proportion of the patients receiving adjunctive gammaCore treatment experienced a ≥50% reduction in CH attack frequency during the randomized period compared with the SoC cohort (gammaCore, 40.0%; SoC, 8.3%; $p<0.001$). Similarly, the response rate in the mITT population was also significantly higher for individuals receiving adjunctive gammaCore therapy (gammaCore, 48.6%; SoC, 8.5%; $p<0.001$), suggesting that patients who remained in the trial had greater response.

Figure 18: Responder Rate Analysis for the ITT and mITT Populations in the PREVA Trial



The use of abortive medications to acutely treat CH attacks was reported during all three periods of the trial. Changes in the use of acute medication are generally used as a surrogate for efficacy in preventing the occurrence of CH attacks. Reliable data on the use of abortive medications was only available in the mITT population. The number of times abortive medications were used in this population during the last two weeks of each trial period is shown in Figure 19 below. During the randomized period, the gammaCore cohort reported a statistically significant decrease of 61.1% (p<0.01) in the frequency of use of subcutaneous sumatriptan injections over the baseline period, whereas the SoC cohort reported an 10.3% increase in the use of this injected medication over baseline. Changes in the use of high-flow oxygen showed a similar difference in favor of adjunctive gammaCore use in that the reduction in its use among the gammaCore cohort was 62.4% (p=0.02) compared with only a 14.3% reduction in the SoC cohort. Similar results were seen in the open-label period.

Figure 19: Change in Abortive Medication Use for the mITT Population in the PREVA Trial



In our PREVA trial, no SAEs were attributable to gammaCore. During the two months of treatment, similar proportions of participants in the gammaCore cohort and SoC cohort (gammaCore, 52%; SoC, 49%) reported AEs. Most AEs were mild or moderate (93% (108/116)). Overall, the most common AEs were CH attacks (gammaCore, 1; SoC, 5), along with nasopharyngitis, dizziness, oropharyngeal pain, and neck pain.

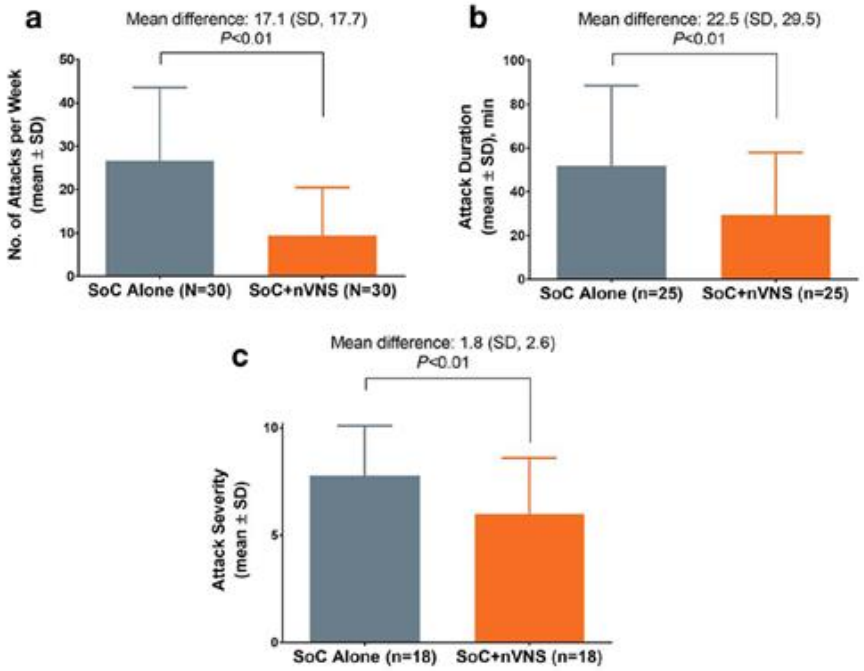
In summary, this trial met its primary endpoint by demonstrating that daily adjunctive prophylactic use of our gammaCore therapy significantly reduced the number of CH attacks per week, which led to substantial reductions in abortive medication use.

Additional Data Supportive of the Prevention of CH – Marin, et al.

In September 2018, Marin, et al., published the findings from 30 patients with chronic (29) and episodic (1) cluster headache from 10 clinical centers through the United Kingdom who had been prescribed gammaCore for an average period of 7.6 (range: 0.9 to 27.5) months. This group was previously taking a variety of medications to prevent and/or acutely treat their cluster headache attacks, and for the purposes of this analysis, these treatments were considered “standard of care”, or SoC, despite none having regulatory approval for the prevention of cluster headache.

Of this group, 16 used gammaCore exclusively for prevention, 13 used the therapy both as an acute treatment as well as preventatively, while only 1 chose to use it exclusively to abort attacks. The mean dosing for prevention was 5.6 (range: 2.0 to 9.0) doses per day, and the average number of doses used acutely was 4.3 (range: 0.4 to 18.0)

As provided in Figure 20a below, among the 29 patients who used the therapy preventatively, the mean attack frequency prior to initiating treatment with gammaCore was 26.6 (range: 3.8 to 77.0) attacks per week, which was considered statistically significant (p<0.01). This dropped to an average of 9.5 (range: 0.0 to 38.5) attacks per week. As shown in Figure 20b below, twenty-five patients reported on the effects of gammaCore on the duration of their attacks, and they reported a decrease from an average of 51.9 (range: 5.0 to 140.0) minutes to 29.4 (range: 2.5-152.5) minutes, which was also statistically significant (p<0.01). As shown in Figure 20c below, the severity of the attacks experienced was also reduced from 7.8 out of 10.0 (range: 3.0 to 10.0) to 6.0 (range 1.0 to 10.0), which was also statistically significant (p<0.01).



Twenty-two of the patients in this analysis reported regular triptan medications in the form of an injection or a nasally administered treatment for their acute management of cluster attacks prior to initiating on the gammaCore therapy. Of the 22, 9 (41%) reported a complete cessation of triptan use, and 12 (55%) reported a reduction in triptan usage. Similarly, 27 of the 30 patients in this analysis reported inhaling high flow oxygen as an abortive treatment prior to initiating on gammaCore therapy. After treatment, 9 (33%) reported complete stoppage of this practice, and 17 (63%) reported a reduction in their use of oxygen. (One patient continued the use of oxygen without change.)

No serious device-related AEs were reported during nVNS therapy, and consistent with these previous studies, AEs were mild and transient and were typically reported early in the evaluation period, when the use of nVNS was relatively novel.

Additional Headache Opportunities

Migraine in Adolescents. Peak migraine penetrance occurs during adolescence and parents may be hesitant to place children on medication. Our clinician advisors have indicated their belief that our gammaCore therapy would be particularly well received in this population given its tolerability profile. We are currently partnered with opinion leaders from academic medical centers and other tertiary headache centers to develop a clinical trial that we expect to initiate in the second half of 2018 to support a label expansion for gammaCore to include patients as young as 12 years of age.

Post-Traumatic Headache. Unlike migraine and CH, which are primary headaches, Post-Traumatic Headaches, or PTH, are classified as secondary headaches because they have a clear causation associated with head trauma. Research has shown that head trauma activates immune cells in the central nervous system. This activation can lead to a disruption in neurotransmitter expression, hyperexcitation, and to the production of CGRP.

VNS, including gammaCore therapy, has been shown to be effective in reducing this immune cell activation. Our clinical and scientific advisors have indicated their belief that our gammaCore therapy has the potential to offer therapeutic benefit for this patient population. We are currently developing a clinical trial that we expect to initiate in the second half of 2018 to support a label expansion for gammaCore to include PTH.

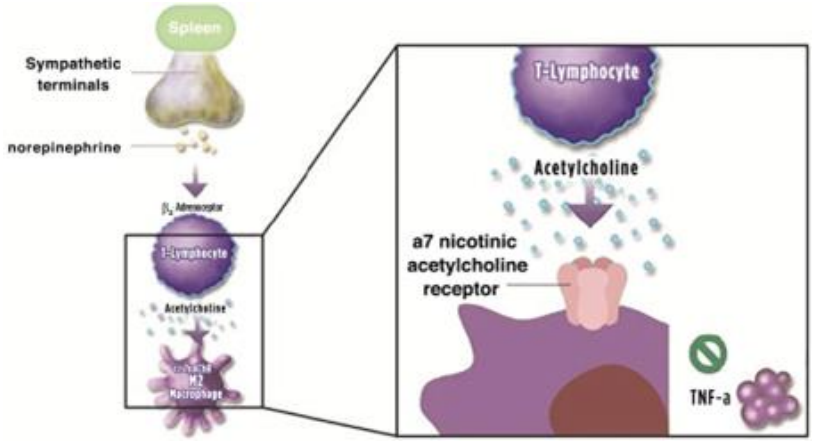
Our Pipeline

Rheumatology

The Anti-inflammatory Mechanisms of VNS

The systemic anti-inflammatory effects of VNS are believed to result from the activation of sympathetic fibers in the splenic nerve, through a connection at the celiac ganglion. These sympathetic fibers release norepinephrine into the spleen in close proximity to a specialized group of immune cells that release acetylcholine, or ACh. This release of ACh activates a receptor, the alpha 7 nicotinic ACh receptor, or a7nAChR, on cytokine-releasing immune cells called macrophages. Activation of these receptors is believed to function by blocking transcription factors that promote inflammatory cytokine expression. Based on the role of ACh in activating this pathway, which is shown in Figure 21 below, it has been termed the cholinergic anti-inflammatory pathway, or CAP.

Figure 21: The Cholinergic Anti-Inflammatory Pathway

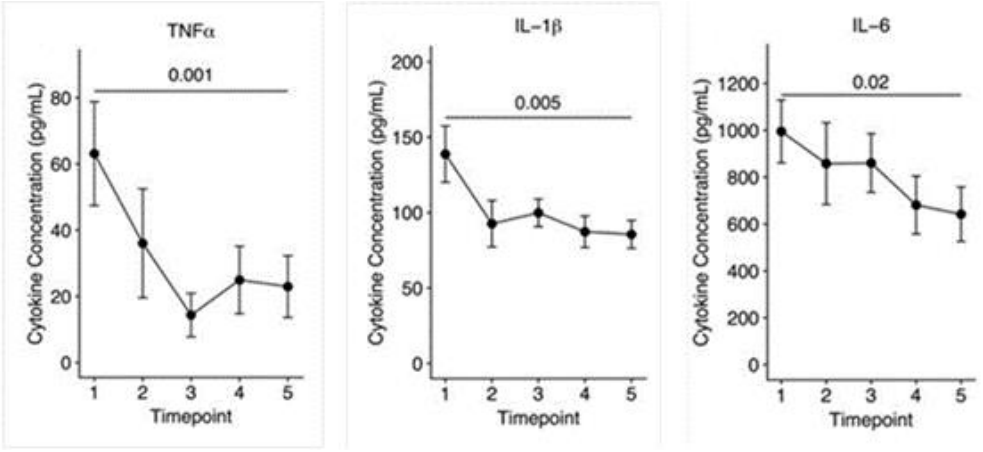


Evidence of gammaCore's Modulation of Peripheral Immune Activity

In order to determine if our non-invasive approach to VNS was able to trigger the CAP, we sponsored several trials to determine the magnitude of the effects of gammaCore on immune activity. The first of these trials was conducted at the University of California San Diego, and its results were published in *Neuromodulation* in 2017. In this trial a total of 20 healthy males and females were randomized to receive either nVNS or sham stimulation. All subjects underwent an initial blood draw at 8:00 AM, followed by stimulation with nVNS or SST at 8:30 AM. Stimulation with either nVNS or sham was repeated at 12:00 PM and 6:00 PM. Additional blood samples were withdrawn 90 minutes and 24 hours after the first stimulation. All samples were tested in accordance with published methods, and levels of cytokines and chemokines were measured, which revealed a significant percent decrease in the levels of the cytokine interleukin-1β (IL-1β), tumor necrosis factor - alpha (TNF-a) levels, and chemokine, interleukin - 8 (IL-8), macrophage inflammatory protein - 1a (MIP-1a), and monocyte chemoattractant protein – 1 (MCP-1) levels was observed in the nVNS group at the 24-hour time point ($p<0.05$).

Subsequent to this trial, researchers at the University of Newcastle studied the effects of gammaCore on circulating cytokine expression among a group of rheumatoid patients with primary Sjögren's Syndrome, or pSS. These results were published in *Neuromodulation* in 2018. In this trial, fifteen female pSS subjects were instructed to treat themselves with the gammaCore twice daily over a 26-day period. At baseline, blood was drawn before and after application of the gammaCore treatment, which was delivered bilaterally, and additional samples were collected after 7, 26, and 28 days, with the final sample being taken two days following the final application of the therapy. In accordance with published methods, levels of TNF-α, IL-1β, IL-6, were all shown to be significantly reduced over the baseline measures at 90 minutes, 7 days, 26 days, and 28 days (See Figure 22 below). In addition, IP-10 and MIP-1α were shown to have decreased by statistically significant amounts by 26 and 28 days (not shown).

Figure 22: Changes in the Cytokine Levels Over One Month Using nVNS Treatment



Rheumatoid Arthritis

Rheumatoid arthritis, or RA, is a chronic autoimmune disorder primarily affecting joints, and in particular the synovial tissue within the joint capsule. The condition is characterized by observable inflammation in the synovial tissue of affected joints, with associated warmth, swelling, pain, and loss of function around the inflammation. Symptoms typically worsen following rest. The most commonly affected areas include smaller joints of the body such as the wrists, hands, and feet, and typically affects the same joints on both sides of the body.

Uncontrolled RA is associated with significant morbidity and increased mortality. The current standard of care involves treating patients early and aggressively to prevent, or significantly retard the progression of joint damage. This is important, as progression of joint damage is directly correlated with debility, disability and loss of function. Approximately 2.4 million patients, predominantly women, suffer from RA in the United States. Current treatments for RA have been shown to possess a disease modifying effect, in addition to being effective at controlling signs and symptoms. Some agents used in the treatment of RA, most notably the biologics have shown effectiveness in the treatment of psoriatic arthritis and ankylosing spondylitis.

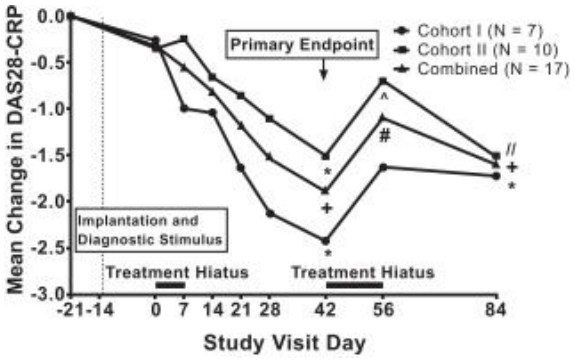
Inflammatory cytokines have long been identified in the pathogenesis of RA. Medications that inhibit immune activity, either broadly, like corticosteroids, or biologic agents, specifically targeting individual cytokines, have been key treatment options for RA patients. Typically, patients with RA initiate treatment with methotrexate, or MTX, which is sufficient to arrest the disease progression and provide relief of the disabling symptoms in approximately 25% of the affected population. Despite being generically available, the average cost of chronic MTX treatment in the United States still averages greater than $200 per month.

Incomplete response to MTX requires additional therapy, typically in the form of a biologic treatment, the most common of which are antibodies or antibody-like proteins that bind to TNF-a. By targeting TNF-a, these treatments alter the normal functioning of the immune system, and as such carry significant risks related to opportunistic infections and several forms of cancers. Approximately 40% of patients with RA are successfully treated with this class of medications, but at an average cost of $30,000 per year. Estimates suggest that of the more than $30 billion of annual global sales of these medications, sales for RA and related conditions of ankylosing spondylitis and psoriatic arthritis exceed $15 billion.

Those patients who are inadequately managed by MTX and/or anti-TNF-a agents, typically advance to other biologic agents that attempt to either block the circulating levels of other target inflammatory cytokines, or agents that block the intracellular pathways that promote the production of inflammatory cytokines. The latter includes the Janus kinase inhibitors, such as Xeljanz, which have an annual cost currently ranging from $40,000 to over $60,000.

Initial clinical evidence for the use of VNS in RA was published in 2016 reporting on an open label pilot trial of implanted VNS among a group of 17 RA patients who had failed standard of care therapy (7 MTX incomplete responders and 10 who had failed at least two biologic agents). As shown in Figure 23 below, the results of this trial demonstrated clinical improvement in disease activity score, or DAS28, over a six-week period of about 2.5 points in MTX incomplete responders and about 1.5 points in biologic failures greater than 1.5 points. Patients had their VNS therapy deactivated for a two-week period following the initial six-week treatment period, during which time DAS28 scores rapidly returned to prior activity levels. This trend reversed and trended towards improvement when VNS therapy was re-initiated.

Figure 23: Mean change in DAS scores reported following implantation of and activation of VNS devices.



In order to rapidly assess whether the cytokine changes demonstrable in healthy normal volunteers and in pSS patients using gammaCore could translate into similar effects as seen in the pilot trial of implanted VNS, our academic partners at Aarhus and Aalborg Universities conducted an open-label pilot trial of gammaCore among 16 RA patients with high disease activity. Participants in the study had their DAS28-CRP, cardiac vagal tone and pro-inflammatory cytokines measured at baseline and after 1 day and 4 days of nVNS. Patients were instructed to treat using two doses of stimulation, delivered bilaterally over the vagus nerve in the neck, three times per day, and were assessed on the 5th day. Patients were excluded if they had received oral, intra-articular or topical corticosteroids within the preceding four weeks.

The results of this trial, which were presented at the EULAR Conference in 2018, showed that among the participants with high rheumatoid arthritis activity, nVNS resulted in a statistically significant reduction in DAS28-CRP (p=0.02), a reduction in C-reactive protein, or CRP (p=0.01), and interferon - γ (IFN- γ) (p=0.02). In addition, the number of swollen joints were significantly reduced (p=0.05) and the reduction in the number of tender joints was trending toward significance (p=0.07). It is important to note that these effects were observed within 4 days of initiating nVNS was well tolerated.

Based on these results, we are currently supporting a multi-centered, open-label, Investigator Initiated Trial, or IIT, among rheumatoid arthritis patients who have failed to achieve satisfactory results with methotrexate and have similarly failed to stop the progression of their disease having tried at least two different biologic agents having different mechanisms of action. We anticipate data from this IIT will guide our decision-making as we move toward sponsoring randomized, sham-controlled registration trials beginning in the latter half of 2019.

To that end, we are preparing for a pre-IDE meeting with the FDA to confer with its reviewers regarding a multi-center, randomized, double blind, sham-controlled trial of gammaCore therapy for the treatment of RA and to confirm that the FDA's review of such an application would proceed through the *de novo* pathway for a signs and symptoms labeling claim. As our potential trials progress, we may, at the appropriate time, conduct premarket activities in rheumatology, such as market analysis, physician and patient segmentation research, and promotional and campaign development.

Sjögren's Syndrome

Based upon the results of the Initial pilot trial conducted at the University of Newcastle among pSS patients, we are interested in paralleling our market penetration strategy in headache. That is, we are interested in further studying the effects of gammaCore in Sjögren's syndrome, a condition with high unmet need and no currently approved disease modifying treatments. We believe that establishing credibility among clinicians, by successfully treating this high unmet need will maximize our ability to penetrate areas like rheumatoid arthritis.

Sjögren's syndrome is a chronic inflammatory condition characterized by damage to, and ultimate loss of, moisture-producing glands. The primary clinical consequence of this damage is dry mouth and dry eyes, which can cause significant tooth loss and ocular injury. Related similar symptoms can include dry skin, a chronic cough, and vaginal dryness. Primary Sjögren's syndrome, defined as being independent of other rheumatologic conditions, affects approximately 600,000 people in the United States, primarily women. Secondary Sjögren's syndrome arises in conjunction with other inflammatory conditions, and increases the number of Sjögren's sufferers to approximately four million people in the United States.

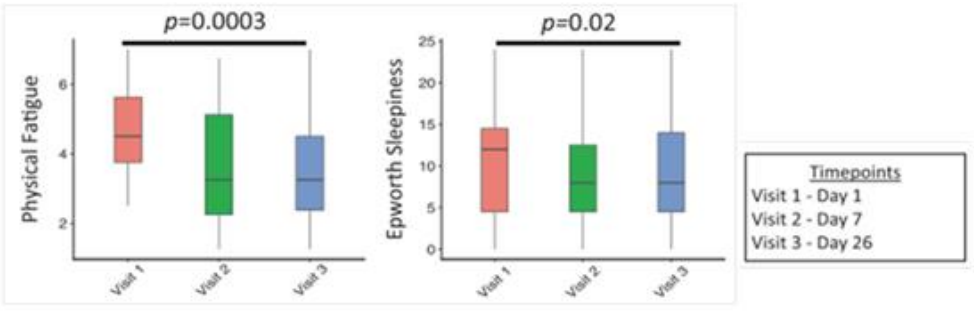
It is believed that the disease begins with increased inflammatory cytokine levels of IL-1β. The elevated level of IL-1βis believed to be the underlying cause of the debilitating fatigue and sleepiness, symptoms that are often the cause of the greatest loss in quality of life among Sjögren's patients. This fatigue is a symptom of what is referred to as cytokine-induced sickness behavior.

Sickness behavior is a coordinated set of behavioral changes associated with extended periods of inflammation, including inability to concentrate, lethargy, malaise, fatigue, sleepiness, hyperalgesia, depression, and anxiety. These symptoms are common across many conditions in rheumatology.

As discussed previously, an initial open label pilot trial of gammaCore for the treatment of pSS was conducted at the University of Newcastle, and partially funded by the U.K. Arthritis Foundation, the results of which were presented at the 2017 American College of Rheumatology annual meeting and subsequently published in *Neuromodulation* in 2018. This trial enrolled 15 patients, all of whom provided evaluable data. At the beginning of this trial, enrolled patients provided baseline self-assessments of multiple key symptoms of their condition and, as previously described, blood samples were taken to establish baseline cytokine and other biomarker expression levels. Patients were instructed to self-administer gammaCore twice daily, each treatment comprising two doses. Patients returned after seven days to provide self-assessments and additional blood samples. Patients continued this treatment protocol through a total of 26 days. On day 28, after a two-day treatment hiatus, patients provided self-assessments of their symptoms and additional blood samples both before, and 90 minutes following a final gammaCore treatment.

In this study, 12 out of 15 participants reported an improvement in their fatigue scores, with 7 showing a ≥30% reduction in fatigue within 28 days. One participant did not report any improvement and two participants observed an initial improvement before returning to their baseline score at the final visit. As shown in Figure 24 below, these clinical results were statistically significant for reductions in physical fatigue and sleepiness, with trends toward significance for mental fatigue and abnormal fatigue. None of the participants reported worsening of their symptoms.

Figure 24: Reductions in key fatigue and sleepiness measurements from baseline through Day 26 in Sjögren's syndrome patients using gammaCore therapy.



The results of this initial trial were sufficient for the academic collaborators at the University of Newcastle to receive a larger continuing grant from the UK Arthritis Foundation, enabling them to conduct a 40-patient randomized, sham-controlled trial of gammaCore for the treatment of pSS. While not yet published, the preliminary results from this trial are consistent with the findings from the initial pilot study, with gammaCore providing statistically significant improvement in the primary efficacy measure, which was fatigue symptoms.

We are currently preparing for a pre-investigational device exemption, or IDE, meeting with the FDA to gain clarity regarding a pivotal trial design that could support an application for a labeling claim for the signs and symptoms of Sjögren's syndrome, and confirm that the FDA's review of such an application would proceed through the *de novo* pathway.

Additional Rheumatology Opportunities

Raynaud's Phenomenon. A common co-morbid symptom experienced by patients with rheumatoid conditions, including scleroderma, is Raynaud's Phenomenon, or simply Raynaud's. Raynaud's is a condition caused by spasms in the smooth muscle lining of the vasculature, which leads to inadequate perfusion to the extremities. Typically triggered by exposure to rapid changes in temperature, such as inserting fingers or hands into cold water, onset of symptoms leads to ischemia of the tissue, pain, loss of sensation or function, and in extreme cases, the ischemia can lead to ulcerations requiring amputation. There is no current therapy for Raynaud's, however, as this condition is associated with an autonomic dysfunction, and because migraine is a frequent co-morbidity among these patients, we were approached by a key academic opinion leader in the field of Raynaud's, and have elected to support his IIT. This trial, which is expected to enroll and randomize 40 patients, is expected to initiate in the first half of 2019.

Chronic Fatigue Syndrome. Similarly, chronic fatigue is a common symptom experienced by many patients with rheumatologic disorders, is highly co-morbid with migraine, and has been associated with dysfunction of the autonomic nervous system. As the name suggests, the primary symptom of the condition, also known as CFS, is debilitating fatigue, of both physical and mental nature. As a result of the publication of the preliminary results from the trial in pSS described above, multiple clinicians have reached out to us asking to conduct IITs among CFS patients who experience migraine. We have initially elected to partner with one clinician to study the effects of gammaCore in this patient population and will assess the opportunity once the trial is completed.

Fibromyalgia. In 2011, a paper was published reporting on the results of an open-label pilot trial of implanted VNS used to treat severe fibromyalgia patients. In the trial, 14 patients were implanted with the VNS stimulators, 12 patients of whom completed the initial 3-month protocol and provided data; and 11 of whom returned for follow-up visits at 5, 8, and 11 months after initiation of stimulation. The researchers reported therapeutic efficacy based on an *a priori* set of stringent composite measures of improved pain, overall wellness, and physical function. Loss of both pain and tenderness criteria for the diagnosis of FM were also reported as *post hoc* analyses based on the unexpectedly positive results observed after 3 months of stimulation. More specifically, at three months, five of the 12 patients had attained the stringent efficacy criteria for success; and of these, two patients no longer met widespread pain or tenderness criteria for the diagnosis of FM; a result not previously observed for any therapy for fibromyalgia. The therapeutic effect seemed to increase over time in that additional participants attained both criteria at 11 months.

Based upon these findings, the fact that nearly 80% of fibromyalgia patients experience migraine and fatigue as frequent symptoms, as well as observations made among a cohort of nearly 1,000 patients who were invited to trial gammaCore for up to 96 weeks in the United Kingdom from 2013 through 2016, we have elected to sponsor a multi-centered, randomized, sham-controlled trial of gammaCore for the treatment of fibromyalgia, which is expected to begin enrollment during the first half of 2019.

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 Basking Ridge, NJ, 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. 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.

As of March 2019, our development and prototype shops were relocated to our new facility in Rockaway, New Jersey. The relocation of manufacturing and related operations, including device assembly, inspection/testing, packaging, storage and shipping is expected to be completed prior to June 2019.

We currently have sufficient capacity, through our primary suppliers and contract manufacturer, to meet anticipated demand for our therapy for the foreseeable future. However, in order to protect against risk of supply chain disruption, we have qualified an approved secondary contract manufacturer, with respect to the handheld stimulator. 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.

Commercialization

In July 2017, following our initial FDA clearance in CH, we began a year-long commercial registry, managed by four regional business managers in partnership with 40 of the top headache centers in the United States, to gather real-world experiences with gammaCore among CH patients, gain advocacy among 250 physicians, and to drive an initial 1,000 prescriptions into U.S. commercial payers. By June 2018, when the registry program concluded, an additional 40 centers of excellence had requested inclusion in the program, and we hired an additional 10 territory business managers. These efforts generated more than 5,000 prescriptions into commercial payers from more than 800 physicians, including approximately 3,300 prescriptions in the second quarter of 2018. In July 2018, upon the successful completion of our initial public offering, we expanded our direct sales force to 32 representatives, who initiated a proactive outreach to more than 6,400 leading headache physicians. In 2018, approximately 15,000 gammaCore prescriptions were written by more than 1,800 prescribing physicians, over 1,000 of whom were defined as regular gammaCore prescribers based on the frequency of their prescriptions. This included approximately 4,400 prescriptions in the third quarter of 2018, and approximately 5,800 in the fourth quarter of 2018. The increasing prescription volume helped us engage with payers, and to execute agreements with commercial and government payers for coverage of more than 50 million lives in the United States. Even without formal reimbursement coverage having been initiated, in 2018 our sales activity generated just under one million dollars in net revenue. In addition, we dispensed approximately $4.7 million in product sales value to patients through our patient voucher and co-pay assistance programs that are not reflected in the net revenue.

Strategy and Implementation

Our commercial strategy has been focused on the following priorities:

- ***Drive advocacy of gammaCore as a leading headache therapy.*** Our advocacy strategy has been to establish gammaCore as a preferred treatment option in CH, and expand from that position into migraine. The core of this strategy is our physician outreach, professional education, peer reviewed publications, and participation in national and global professional society meetings.

  In 2018, implementing our strategy included successful completion of our registry program, in which we developed advocacy for gammaCore among 800 key opinion leaders. We currently have over 2,000 unique prescribers, including in excess of 1,500 targeted clinicians and their staff who are trained on gammaCore use, as well as more than 500 physicians who have written prescriptions without direct sales support. We have contracted with 50 national key opinion leaders, or KOLs, to serve as our gammaCore Faculty to lead a series of programs to educate their colleagues on our clinical data and our specialty pharmacy distribution process. Through the end 2018, these 50 KOLs conducted over 75 educational programs with over 700 attendees. In 2018, we participated at 60 professional society meetings, represented by corporate, medical, clinical and sales executives, including the top societies such as the American Headache Society Meetings, International Headache Congresses, and American Academy of Neurology. At these global and national professional society meetings, we presented more than 30+ posters and/or presentations supporting clinical efficacy and safety of gammaCore across multiple indications and areas of therapeutic need.

- ***Drive reimbursement of our therapy***. Our strategy to secure reimbursement for gammaCore therapy across the majority of CH and migraine patients began 18 months prior to market entry, in early 2016, when we initiated pipeline presentations across the largest two-dozen commercial payers in the United States. Based on the gammaCore monthly prescription model, many payers indicated that we should advocate for reimbursement as a pharmacy benefit, especially among the pharmacy benefit management, or PBM, companies. It is typical for reimbursement from PBMs to come by way of rebate agreements, requiring the company to offer significant discounts, in the form of rebate payments, in return for gaining access to the PBM's population of potential patients. Preferred positioning within the PBM's system, which typically entails the product having the fewest restrictions and the lowest patient co-pay amounts, generally is provided to the companies providing the deepest discounts. It has been our strategy to identify the necessary rebate levels to gain the appropriate access. In addition, we are providing co-pay assistance to minimize the financial burden placed on the patient for filling the prescription. While we have been successful in negotiating several coverage agreements, and are currently in ongoing pharmacy benefit coverage negotiations with other payers, we have encountered some other payers, including the Federal government, who prefer to provide coverage for our therapy as a medical benefit. For these payers, negotiating reimbursement for gammaCore requires a different approach, in which the rebates are smaller or in some cases non-existent, and our support of the patient's co-pay may need to be significantly higher, as medical benefit deductibles are typically much higher than those for pharmacy products.

  In 2018, our strategy focused on engaging, negotiating and securing agreements with the commercial payers and the components of the Federal government programs covering men and women aged 18 to 55, as these payers cover approximately 92% of patients experiencing migraines and cluster headaches. Payers in the United States typically make coverage and reimbursement decisions with respect to new therapies based on three key factors: the strength of the therapy's clinical data; observed patient demand; and the absolute and relative costs of the therapy.

  To implement this strategy, our clinical and research teams published dozens of peer reviewed articles covering scientific and clinical trials of gammaCore. These publications include the first publication of the PRESTO trial in *Neurology* in July 2018. These publications have supported our initial commercialization efforts and have helped to drive the approximately 15,000 prescriptions written in 2018, the vast majority of which led to the patient claims necessary to prompt commercial payers to initiate clinical reviews and enter discussions over reimbursement. To support our arguments for the cost effectiveness of gammaCore among CH and migraine patients, in 2018 we sponsored the publication of a series of supplements in the *American Journal of Managed Care* featuring articles focusing on the efficacy, cost, and impact on quality of life of gammaCore. Collectively, these efforts supported our engagement with national and regional commercial insurance payers in the United States. The goal of these engagements is obtaining reimbursement coverage as either a pharmacy benefit or medical benefit. Our medical and marketing executives have negotiated multiple reimbursement contracts and secured medical policy amendments stating that gammaCore may be medically necessary for headache conditions, as opposed to investigational. In December 2018, we secured a five-year Federal Supply Schedule, or FSS, contract enabling us to sell gammaCore into the Veterans Hospitals and Department of Defense's Military Treatment Facilities.

  As of January 2019, we have agreements or arrangements with commercial payers, one PBM and the FSS that we estimate provide for reimbursement for gammaCore as either a pharmacy benefit or medical benefit for approximately 53 million lives in the United States. Although there can be no assurance of success, our payer access team is negotiating contracts with several additional insurance plans and PBMs covering approximately 90 million commercial lives in the United States, and in clinical review with plans covering an additional approximately 50 million lives in the United States. With continuing payer discussions regarding up to an additional 90 million lives, we are seeking to expand the number of covered lives in the United States to 100 million in 2019.

- ***Build a leading commercial presence.*** To establish a leading commercial presence, we adopted a four-part strategy comprised of: identifying the leading prescribing physicians providing secondary care to complex headache patients; engaging experienced sales specialists with deep knowledge of the target space and the physician community with whom they will be engaged; implementing a distribution platform and specialty hub supporting all aspects of the physician-patient-payer relationship, and creating a marketing engagement program to ensure that patients and physicians are aware of the value proposition of gammaCore.

In 2018, we executed on this strategy by identifying the 9,000 highest-prescribers of headache medications, who represent the top four decile of prescribing specialists in the field. To adequately reach these physicians, we identified 44 territories, the first 32 of which cover 6,400 prescribers. To fill the first 32 territories, we targeted experienced sales professionals with 10 or more years of pharmaceutical sales history, preferably in the headache, pain, and/or neurology field, who had demonstrated superior performance through receipt of national sales awards and recognition in prior positions. Leading these sales professionals are four regional leaders with more than 20 years of experience in sales and sales management roles. Expansion of this sales force to cover the full 44 territories may be implemented based on the extent and nature of insurance coverage provided by payers for gammaCore. We have also partnered with a telehealth company to make gammaCore available to patients nationwide through an online consultation.

To ensure that physicians and patients experience a positive therapy initiation, we partnered with Asembia LLC, or Asembia, a specialty pharmacy hub service, to provide physicians and patients with concierge-like service. This service supports patient initiation and training through direct home-delivery of gammaCore, one-on-one training by a clinical professional, the gammaCore specialist, follow-up with the patient at 21 days to verify efficacy and assist with subsequent refill, and front-to-end support through the insurance claims adjudication process. This concierge service also allows us to establish a unique relationship with physicians via real time information retained in our data warehouse which meets all HIPAA standards. Understanding physician and patient concerns in real time allows our analytics and marketing teams to potentially adjust to our customers' needs quickly.

To ensure that patients and physicians are maximally aware of the value of prescribing gammaCore, in 2018 we expanded our digital presence by upgrading our gammaCore.com website and initiating a search engine optimization, or SEO, program driving web users searching for information on migraine and cluster headache to our website, providing the viewer key features and benefits information about our therapy. In addition, we have provided key support and partnered with major patient advocacy organizations, including American Migraine Disorders, Healthy Woman, Cluster Busters, Miles for Migraine, BASH, and OUCH.

Our Proprietary gammaCore Ecosystem

We continue to seek to build advocacy among leading prescribing physicians, to negotiate to positive coverage decisions with payers to achieve coverage of 100 million lives in the United States by the end of 2019, and to build on our positive base of patients by raising awareness of the benefits of gammaCore as a treatment for severe headache conditions. To accomplish these goals, we continue to integrate the experiences of stakeholders through our proprietary gammaCore ecosystem. A key feature of the highly connected ecosystem we have constructed is our HIPAA-compliant, cloud-based data warehouse. The web portal feature of this network enables unprecedented engagement with patients through which patients can get training and educational material, and diaries that provide patient support. In the future, we may expand these programs to engage with patients through their smart phones, informing them of key information such as the distance they are from their gammaCore and the time to their next dose or refill. We may explore incorporating additional features to allow smartphones to assist patients with identification and/or prediction of their risk factors and triggers. The portal plan is designed to promote patient engagement and the ability for the ecosystem to improve treatment outcomes.

The logistics of gammaCore distribution are significantly more efficient than that of traditional pharmaceutical therapies. Pharmaceutical therapies are typically distributed through a multi-tiered supply chain involving wholesalers, warehoused supply centers, and individual pharmacy branches, all of which separate the patient from the manufacturer. An important limitation of the traditional pharmaceutical distribution model is that manufacturers can only track prescriptions through the purchase of data from a third party, which is typically several months old, making real-time responsiveness impossible. Our system captures real-time information regarding the patient, therapy usage, and refill status. All sales and marketing data are completely current, and available at a maximally granular level, enabling real-time decision-making.

By connecting our proprietary data warehouse directly to the specialty pharmacies that distribute our therapy, gammaCore's distribution eliminates several tiers of the traditional supply chain. Each gammaCore can be refilled electronically through the delivery of unique digital authorization codes, which are maintained in this cloud-based warehouse. We provide these codes to these specialty pharmacies by permitting them access to our database, and to the patient through RFID cards programmed by the pharmacists we have trained. More specifically, following adjudication of the prescription and securing payment or payer authorization, these trained pharmacists are granted access to our cloud-based system and program an RFID card, in real-time, using a tablet computer that we provide. This digital warehouse has the capability to provide refill authorization codes directly from the warehouse to the patient through Bluetooth technology, further increasing the ease and efficiency of prescription refills by eliminating the need for RFID cards.

In October 2016, we entered into a non-exclusive master services agreement for the provision of specialty pharmacy distribution services in the United States with Asembia. Asembia provides us with access to its national network of specialty pharmacies and distribution services pursuant to one or more statements of work, or SOWs, arising under the agreement, including product stocking programs and integrated pharmacy dispensing systems, patient education and support, claims management and reimbursement assistance, professional compliance counseling and a patient hub services program with data capture and reporting capabilities. The agreement has an initial term of three years and is renewable automatically for successive one-year terms unless either party submits a termination notice at least 90 days prior to the end of the then-current term. We may terminate the agreement or all or any part of any SOW at any time upon 90 days' written notice to Asembia. The agreement may also be terminated for cause upon written notice to the other party in the event of a material breach that is uncured for 30 days following written notice of such deficiency. The agreement provides for customary transitional services in those instances where we elect to use another service provider or our own employees to perform the services.

Competition

While we believe that our proprietary gammaCore therapy provides us with competitive advantages, we face potential competition 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 will compete with existing therapies and therapies that may become available in the future.

We believe the key competitive factors affecting the 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 other third-party payers.

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 and marketing 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.

In primary headache, we face 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 inhaled oxygen. Alternative treatments include intranasal triptans and intravenous DHE. Only subcutaneous sumatriptan and intravenous DHE are approved in the United States for the acute treatment of CH. Currently gammaCore is the only FDA-cleared commercially available treatment for the prevention of CH, however, there are medications that are used off-label including verapamil, lithium, and valproate.

Treatments for Migraine

The most frequently prescribed therapy for the acute treatment of migraine are oral or nasal triptans. Additional prescribed products include prescription strength NSAIDs. There are currently three antibodies to CGRP and its receptor approved by FDA for the prevention of migraine by Teva Pharmaceutical Industries Ltd., and Eli Lilly and Company, and by Amgen Inc., which is in a co-marketing partnership with Novartis International AG, approved by the FDA in May 2018. There are a number of medical devices that have been marketed for the treatment of migraine, including the Cefaly and the Spring TMS devices. Small molecule CGRP receptor agonists are currently in Phase 3 development by Allergan plc and Biohaven Pharmaceuticals Inc. for the acute treatment of migraines. Certain classes of anti-epileptic medicine and beta-blocker medications have been approved by the FDA for the prevention of migraine. There is currently only one therapy approved for the prevention of chronic migraine, BOTOX marketed by Allergan plc.

Intellectual Property

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, 2019, we held more than 140 patents and patent applications, including more than 85 issued U.S. patents, more than 20 U.S. patent applications, and more than 45 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. While physically possible to administer electricity through the skin of the neck that will activate the same vagal fibers without these innovations, the intensity of pain receptor activation makes it virtually impossible to do so without causing unacceptably high pain levels.

Additionally, we have pending 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, 2019, our trademark portfolio consisted of seven U.S. trademark registrations, including electroCore®, gammaCore® and gammaCore, three pending U.S. trademark applications, including gammaCore Sapphire and gammaCare, 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 U.S. Food and Drug Administration, or 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 submission 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 we have conducted several additional clinical studies with a view to supporting additional label expansion.

Additionally, we anticipate 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 the CE Mark in Europe for our gammaCore therapy to treat, primary headache, including migraine, cluster headache, and hemicrania continua, as well as medication overuse headache in adults. We received the CE Mark for 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 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 File 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. With respect to Class III devices, the manufacturer must conduct clinical studies to obtain the required clinical data, unless reliance on existing clinical data from equivalent devices can be justified. 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 (Regulation 2017/745) was adopted. The EU Medical Devices Regulation 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 EU Medical Devices Regulation, 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 EU Medical Devices Regulation will however only become applicable three years after publication (in May 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.

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, physician sunshine 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 set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they may not be prosecuted under the federal Anti-Kickback Statute. 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, civil monetary penalties up to $74,792 (and adjusted for inflation) for each violation, plus up to three times the remuneration involved, criminal fines of up to $100,000 and imprisonment of up to 10 years, disgorgement, individual imprisonment, possible exclusion from Medicare, Medicaid and other federal healthcare programs, and the curtailment or restructuring of operations.

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, which prohibits a physician from making a referral for certain designated health services covered by the Medicare 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, civil monetary penalties of up to $24,253 (and adjusted for inflation) 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 a penalty of up to $161,692 (and adjusted for inflation) 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 alleging false and fraudulent claims presented to or paid by the government (or other violations of the statutes) and to share in any amounts paid by the entity to the government in fines or settlement. 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 three times the actual damages sustained by the government, plus mandatory civil penalties of between from $11,181 to $22,363 (and adjusted for inflation) for each false claim, plus treble damages, the potential for exclusion from participation in federal healthcare programs. The majority of states also have statutes or regulations similar to the federal Anti-Kickback and 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.

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) prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payers. Federal criminal law at 18 U.S.C. § 1001, among other sections, prohibits 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.

Health Insurance Portability and Accountability Act of 1996: The federal Health Insurance Portability and Accountability Act, or HIPAA, created several new federal crimes, including healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payers. The false statements statute prohibits 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. Similar to the federal Anti-Kickback Statute, 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, 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 and subcontractors, 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 created four new tiers of civil monetary penalties and gave state attorneys general new 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. Additionally, certain states have adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA and HITECH.

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. Failure to submit required information may result in civil monetary penalties of $11,052 per failure up to an aggregate of $165,786 per year (or up to an aggregate of $1.105 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission, and may result in liability under other federal laws or regulations. Certain states also require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, require pharmaceutical 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 potential referral sources.

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. EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EU Data Protection Directive, as implemented into national laws by the EU member states, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. Failing to comply with these laws could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results. The EU General Data Protection Regulation, or GDPR, became applicable on May 25, 2018 and replaced the EU Data Protection Directive. Unlike the Directive (which needed to be implemented by national laws), the GDPR is directly applicable in each EU Member State, resulting in a more uniform application of data privacy laws across the EU. The GDPR imposes stricter requirements and onerous accountability obligations on companies that process personal data, especially if they process sensitive personal data (such as data concerning health). Fines for non-compliance with the GDPR will be significant – up to € 20 million or 4% of global turnover, whichever is higher. 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 CaCPA. CaCPA has been characterized as the first "GDPR-like" privacy statute to be enacted in the United States because it mirrors a number of the key provisions in the GDPR. Because of this, we may need to engage in additional compliance efforts, including data mapping to identify the personal information we are collecting and the purposes for which such information is collected and enhanced consumer controls with respect to their data. This effort will need to be completed before the currently scheduled effective date of CaCPA on January 2, 2020.

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 the company 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 imposed, among other things, a new federal excise tax on the sale of certain medical devices, which, through a series of legislative amendments, was suspended for 2016 through 2019, and which, absent further legislative action, will be reinstated on medical device sales starting January 1, 2020; 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. We do not yet know the full impact that the Affordable Care Act will have on our business. There have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect additional challenges and amendments in the future. Moreover, the Trump Administration and the U.S. Congress may take further action regarding the Affordable Care Act, including, but not limited to, repeal or replacement. Most recently, the Tax Cuts and Jobs Acts was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance beginning in 2019.

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, included reductions to Medicare payments to providers of 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 2027 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.

Employees

As of March 1, 2019, we employed 91 full-time employees. Substantially all of our employees are located in New Jersey. 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 ("LLC"). electroCore, headquartered in New Jersey, has wholly owned subsidiaries that include: electroCore Bermuda, Ltd., 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.

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 at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549 or 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. Information may be obtained regarding the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Within the Investors section of our website, we provide information concerning corporate governance, including our Corporate Governance Guidelines, Board Committee Charters and Composition, 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.

Glossary

"a7nAChR" refers to a receptor, specifically the alpha 7 nicotinic ACh receptor, that resides on the surface of many cell types, including macrophages and microglia, the dominant immune cell of the brain. Activation of this receptor by neurotransmitters, including acetylcholine, has been shown to cause a change in the inflammation state mediated by these cells, which has led to this immune modulatory pathway being referred to as "the cholinergic anti-inflammatory pathway", or "CAP".

"ACh" means acetylcholine, which is a neurotransmitter released by certain neurons in the brain and by the vagus nerve. ACh is also released by a class of immune cells in response to certain stimuli.

"CAP" means the cholinergic anti-inflammatory pathway, which is an autonomic reflex that inhibits the release of pro-inflammatory proteins called cytokines involving signaling in the vagus nerve, the release of acetylcholine and the activation of alpha 7 nicotinic ACh receptors.

"CGRP" means calcitonin gene–related peptide, which is a protein produced by, and released by neurons. CGRP activates other neurons that are involved in pain perception. CGRP is also known to be a powerful vasodilator, causing dilation of blood vessels.

"CH" means cluster headache, which is a headache disorder in which patients experience attacks of severe head pain, typically centered around the eye on one side, which occur from once every other day to eight times a day for a period that may last for a week, months or years. The attacks typically last 15 minutes to 180 minutes and the pain is typically associated tearing, eyelid dropping, sweating, congestion and/or runny nose.

"cCH" means chronic CH, which is a classification of CH defined by CH attacks occurring for more than one year without remission, or with remission periods lasting less than three months.

"CSD" means cortical spreading depression, which is a slow moving, self-propagated wave of depolarization of neurons and glial cells that spreads across the brain.

"eCH" means episodic CH, which is a classification of CH defined by CH attacks occurring in periods lasting from seven days to one year, separated by pain-free periods lasting at least three months.

"DAS" means disease activity score, which is an assessment used to measure rheumatoid arthritis (RA) disease activity, to determine whether the signs and symptoms have reduced or stopped, and if treatment needs to be adjusted.

"DHE" means dihydroergotamine, which is a medication indicated for medically refractory migraine headaches. Its therapeutic activity has been attributed to activity against certain serotonin receptors, and has potent vasoconstricting effects on intracranial blood vessels.

"EEG" means electroencephalography, which involves the measurement and recording of electrical activity in the brain.

"functional magnetic resonance imaging" is an imaging technique that allows for, among other things, the measurement of brain activity through the detection of changes in blood oxygenation and flow that occur in response to neuronal activity.

"GABA" means gamma-aminobutyric acid, which is one of the primary inhibitory neurotransmitters in the brain.

“IL-1ß“means interleukin-1 beta, which is a pro-inflammatory cytokine involved in immune responses.

“LC” means locus coeruleus, which is a small region of the brainstem that is the sole source of norepinephrine in the brain.

“magnetoencephalography” is an imaging technique utilizing superconducting coils to measure the tiny magnetic fields generated by nerve activity within the brain from outside the skull.

“MTX” means methotrexate, which is an immunosuppressive medication, originally used in oncology, and now used widely as a first line treatment for rheumatoid arthritis (RA) and related inflammatory disorders.

“nVNS” means noninvasive vagus nerve stimulation, which is a therapy employing the modulation of signals carried along certain fibers in the cervical vagus nerve which is achieved by the delivery of electric signals passed through the skin without physically penetrating the body.

“NRM” means the nucleus raphe magnus, which is a structure in the brainstem that is a major component in the endogenous pain inhibitory system and that produces and releases serotonin.

“PAG” means the periaqueductal gray, which is a structure in the brainstem that is a major component in the endogenous pain inhibitory system and that produces and releases the neurotransmitter GABA.

“PTH” means post-traumatic headache, which is a headache condition resembling migraine that results from a traumatic head injury.

“RA” means rheumatoid arthritis, which is a common autoimmune disease characterized by chronic joint inflammation leading to pain, swelling, and ultimately the degeneration of cartilage and bone within the affected joint.

“SN” means the substantia nigra, which is a large midbrain structure that can be divided into two parts, one of which synthesizes and releases a neurotransmitter called dopamine, and the other of which synthesizes and releases the neurotransmitter GABA neurons.

“SPG” means sphenopalatine ganglion, which is a nerve bundle behind the bony structure of the nose that connects to the nerves in and around the eye socket. Activity in the SPG has been associated with CH.

“TCC” means the trigeminal cervical complex, which is a region of the brainstem that serves as a primary center and relay for pain, having inputs known to be associated with the generation and perception of head pain.

“TNF-a” means tumor necrosis factor alpha, which is a pro-inflammatory protein, or cytokine, involved in inflammatory events, and is associated with both the initiation and conclusion of inflammatory processes.

“VNS” means vagus nerve stimulation, which is a therapy involving the triggering of signals within certain fibers of the vagus nerve known to alter biologic function through the promotion of neurotransmitter release.

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 episodic cluster headache, or eCH, the prevention of cluster headache, and the acute treatment of migraine, fund our research and development activities, expand our manufacturing capabilities, 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 $55.8 million and $35.8 million for the year ended December 31, 2018 and 2017, respectively. As of December 31, 2018 and 2017, our accumulated deficit was $38.3 million (subsequent to a reclass of $174.0 million to additional paid in capital as described in Note 12 in the Notes to the Consolidated Financial Statements) and $152.9 million, respectively. 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 for the acute treatment of pain associated with migraine and episodic cluster headache in adults. We intend to continue making significant investments in building our U.S. commercial infrastructure and in recruiting and training our territory business managers. We also intend to continue making significant investments in research and development to expand our gammaCore therapy for the treatment of other indications, including additional headache conditions and conditions in the field of rheumatology.

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 reduce or terminate our operations. As of December 31, 2018, we had cash, cash equivalents and marketable securities of $68.6 million. We believe our current cash resources will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. 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.

Our operations have consumed substantial amounts of cash since inception, and we anticipate this continuing as we utilize our commercial sales force in the United States to increase adoption of gammaCore therapy with physicians and payers, investigate the use of our gammaCore therapy for the treatment of additional new indications, including rheumatoid arthritis and Sjögren's syndrome, and continue to grow our business and transition to operating as a public company. We believe that our growth will depend, in part, on our ability to fund our commercial efforts for our gammaCore therapy for the acute treatment of eCH and the acute treatment of migraine, and to pursue research and development activities for additional indications for our gammaCore therapy. Our existing resources may not allow us to conduct all of the activities that we believe would be beneficial for our future growth. As a result, we may need to seek additional funds in the future. If we 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. For the years ended December 31, 2018 and 2017, our net cash used in operating activities was $47.1 million and $25.3 million, respectively, and as of December 31, 2018 and 2017 we had approximately $68.2 million and $37.2 million in cash and cash equivalents and marketable securities, respectively. We expect that our existing capital resources, will enable us to fund our operating expenses and capital expenditure requirements through at least the next 12 months. 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 competition 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 and obtaining payer coverage
- the scope and timing of our investment in our U.S. commercial infrastructure and sales force;
- the costs of commercialization activities including sales, marketing, manufacturing and distribution;
- the degree and rate of 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 intend to undertake in order to expand our headache indications and enhancements to our gammaCore therapy that we intend to pursue;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- our need to implement additional infrastructure and internal systems;
- our ability to hire additional personnel to support our operations as a public company; and
- the emergence and acceptance of competing therapies or other adverse market developments.

To finance these 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.

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.

If third-party payers do not provide adequate coverage and reimbursement for the use of gammaCore, we will 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 from 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.

Although we estimate that we have procured reimbursement for gammaCore as either a pharmacy benefit or medical benefit for approximately 53 million lives in the United States, and we are negotiating contracts with additional insurance plans and PBMs covering an additional approximately 90 million lives, and we are in clinical review with plans covering an additional approximately 50 million lives, there can be no assurance that we will maintain such existing coverage. Similarly, there can be no assurance that we will add any additional coverage or attain our goal of expanding the number of covered lives in the United States to 100 million by the end of 2019.

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.

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.

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 may not agree to cover gammaCore through pharmacy benefit plans, which will hinder our commercialization strategy and require changes to our existing business that could delay and negatively impact our ability to generate revenue.

Our commercialization strategy in the United States advocates for coverage and reimbursement for gammaCore under payers' pharmacy benefit. This pathway may allow patients to obtain our therapy through payment of a co-payment rather than being personally responsible for the costs of our product until meeting an annual deductible. While some commercial payers may provide coverage under their pharmacy benefit plans, other third-party payers, including government health programs and private insurers, may not be willing or able to cover gammaCore under pharmacy benefit plans, which are often limited to coverage of prescription drug products. For example, Medicare's voluntary pharmacy benefit, Medicare Part D, limits coverage under this benefit to prescription drugs, biologicals, and supplies used in the delivery of insulin, but does not cover medical devices like gammaCore or its supplies. Some commercial payers may determine to only provide coverage for gammaCore through the medical benefit pathway. While this would provide coverage for the therapy under a patient's medical benefit plan, 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 plans may delay or pose more risks to our commercial plan for gammaCore therapy since additional medical device codes may be required and the Company 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.

To obtain coverage and reimbursement from Medicare and any other third-party payer that will not cover gammaCore under a pharmacy benefit, we may be required to seek coverage and reimbursement as a medical device or item of durable medical equipment. If needed to obtain third-party payer coverage and reimbursement under an alternative benefit, 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 could require 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 merits 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. While 510(k) clearance from the U.S. Food and Drug Administration (FDA) was received in November 2018 for an expanded label for gammaCore therapy for adjunctive use for the preventive treatment of cluster headache in adult patients, such clearance does not necessitate adoption by physicians. In order for our gammaCore therapy to gain widespread adoption, we must successfully demonstrate to physicians the merits of our gammaCore therapy for the acute treatment of eCH and the acute treatment of migraine, compared to our competitors' products, including BOTOX marketed by Allergan plc for prevention of chronic migraine, and products recently approved by the FDA for the prevention of migraine by Amgen Inc. (with a co-marketing arrangement with Novartis International AG), Eli Lilly and Company, and Teva Pharmaceutical Industries Ltd., for use in treating patients with cluster and migraine headaches, particularly 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.

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; and
- adverse developments in coverage amounts, benefit pathway, or government and third-party payers' reimbursement policies.

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.

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

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 13485:2003);
- 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, including Sjögren's syndrome and rheumatoid arthritis, 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 U.S. Food and Drug Administration (FDA) was received in November 2018 for an expanded label for gammaCore therapy for adjunctive use for the preventive treatment of cluster headache in adult patients, 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.

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.

For additional information regarding risks related to our intellectual property, see "—Risks Related to Intellectual Property."

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 outside of the acute treatment of eCH and the acute treatment of migraine. 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. While 510(k) clearance from the U.S. Food and Drug Administration (FDA) was received in November 2018 for an expanded label for gammaCore therapy for adjunctive use for the preventive treatment of cluster headache in adult patients, 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 prevention 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 our prevention trial for our gammaCore therapy 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 ("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 our prevention 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 our planned prevention 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 for the expansion of our gammaCore therapy in additional areas of indication, such as Sjögren's syndrome and rheumatoid arthritis, 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.

We could also encounter delays if a clinical trial is suspended or terminated by us, 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 addition, we may encounter delays if the FDA concludes 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 concludes 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 European Economic Area, or EEA, (which is composed of the 28 Member States of the EU plus Norway, Iceland and Liechtenstein), 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.

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

We have been growing the number of physicians willing to write prescriptions for our therapy and the number of prescriptions being written rapidly in recent periods and have a relatively short history of operating as a commercial company. We intend 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.

To achieve our goals, we must successfully increase manufacturing output to meet potential expected customer demand. 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.

In order to continue to market and sell our gammaCore therapy for the acute treatment of eCH, the prevention of cluster headache and the acute treatment of migraine, in the United States, we must continue to build a substantial direct sales force. As we initiate our commercial launch in eCH, cluster headache prevention and migraine and increase our marketing efforts, we will need to retain, grow and develop our direct sales personnel. We have made a significant investment in recruiting and training territory business managers and 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 and acute treatment of migraine headache 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 of 2018 the FDA cleared gammaCore therapy as the first product labeled for the prevention of cluster headache. Furthermore, our gammaCore therapy has not yet been cleared by the FDA for treatment of chronic cluster headache or preventive treatment of migraine. 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., Novartis International AG and Teva Pharmaceutical Industries Ltd., among other established and potential competitors that may be better capitalized and have a history of commercializing products around the world. We estimate the addressable U.S. market for eCH and migraine headache will be approximately $400 million and $4.0 billion in 2019, respectively. 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, we face a particular challenge overcoming the long-standing practices by some physicians 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 less than one year 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 year 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 cluster headache 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, 2016 and 2017, respectively. In 2012, we began selling gammaCore in the EU through distributors. As of February 1, 2018, we sell gammaCore directly in 14 countries in the EU and through distributors and agents located in Munich, Germany and Leeds, UK. 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.

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, prevention of cluster headache and 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 to initially treat eCH, cluster headache prevention and migraine, 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.

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 addition, many of our employees have become or will soon become vested in a substantial amount of stock or number of stock options. Our employees may be more likely to leave us if the shares they own or the shares underlying their vested options have significantly appreciated 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 below 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.

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 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 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, or due to our relative importance as a customer to those suppliers. 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 only one third-party distributor to distribute our products to specialty pharmacies in the United States.

We currently rely upon one specialty pharmaceutical distributor, who collaborates with a large network of specialty pharmacies, to distribute our products in the United States. 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. If our relationship with this distributor terminates, 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 Supply Schedule contractor subjects us to additional compliance and pricing requirements and may be withdrawn, which would make us ineligible to obtain certain federal government contracts and could negatively impact us and our business.

Our status as a contractor on the Federal Supply Schedule, or FSS, requires compliance with applicable federal procurement laws and regulations with respect to procurement, pricing and reporting and also may subject us to contractual remedies and administrative, civil and criminal sanctions. Federal government agencies may choose to award contracts to authorized providers on the FSS to reduce the number of qualified bidders and to expedite the bidding process. The cost of compliance with applicable federal procurement laws and regulations with respect to pricing and reporting, among other increased costs due to our status as an FSS provider could negatively harm us and our business.

Our status as a FSS provider, once obtained, may be withdrawn if we do not comply with the complex procurement laws, pricing requirements, FSS contractual obligations and other federal regulations that would be applicable to us as a consequence of our status as a FSS provider. If we were found not to be in compliance with the foregoing requirements and our status as a FSS provider were to be withdrawn, then we may not be able to obtain new contracts with federal government agencies or renew existing contracts procured under the FSS. If we are unable to obtain new federal government contracts or renew any existing contracts under the FSS, we and our business could be negatively harmed.

We rely on third parties to conduct and support our clinical 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 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 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 collaborations;
- 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 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 them 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 gammaCore 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 inventory obsolesce comparatively.

Risks Related to Intellectual Property

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 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 EU legislative bodies 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 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 File 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. With respect to Class III devices, the manufacturer must conduct clinical studies to obtain the required clinical data, unless reliance on existing clinical data from equivalent devices can be justified. 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, on May 25, 2017 the new Medical Devices Regulation (2017/745 or MDR) entered into force. Following its entry into application on May 26, 2020, the Regulations 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 EU Medical Devices Regulation 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 EU Medical Devices Regulation, 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 EU Medical Devices Regulation will however only become applicable three years after publication (in May 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; 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 Medical Devices Regulation 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 Mark and continue to comply with certain EU Directives and, in the future with the EU Medical Devices Regulation. 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, or BSI), which could impair our ability to market products in the EEA in the future.

If we fail to maintain regulatory approvals and clearances, or are unable to obtain, or experience significant delays in obtaining, FDA clearances or approvals 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 and numerous other federal, state and foreign governmental authorities. The process of obtaining regulatory clearances or approvals 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 premarket approval application, or 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. 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. However, we may need to submit a PMA to expand our labeling claims to include certain indications.

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 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 E.U. 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 premarket approval 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 FDA's Quality System Regulation, or 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, or MDR, 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, cluster headache 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, 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 Competent 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, 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.

Moreover, the policies of the Trump Administration and their impact on the regulation of our products in the United States remain uncertain. Political change 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 Medical Devices Regulation (2017/745 or MDR) was adopted. Following its entry into application on May 26, 2020, the Regulations 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 civil monetary penalties up to $74,792 (as the same may be adjusted for inflation) 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 of up to $100,000 and imprisonment of up to 10 years. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid;
- 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, we may be subject to the federal Stark physician self-referral law, which prohibits a physician from making a referral for certain designated health services covered by the Medicare 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, civil monetary penalties of up to $24,253 (as the same may be adjusted for inflation) 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 a penalty of up to $161,692 (and adjusted for inflation) 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 and criminal false claims laws and civil monetary penalty laws, including civil whistleblower or qui tam actions, that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment of federal funds that are false or fraudulent, 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. These laws 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. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties ranging from $11,181 to $22,363 for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal laws that prohibit 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 by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements. Failure to comply with the HIPAA privacy and security standards can result in civil monetary penalties up to $55,910 per violation, not to exceed $1.68 million per calendar year for non-compliance of an identical provision, and, in certain circumstances, criminal penalties with fines up to $250,000 per violation and/or imprisonment. 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 sunshine requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, which require 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) and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members. Applicable manufacturers are required to submit annual reports to CMS. Failure to submit required information may result in civil monetary penalties of between $1,105 and $11,052 per failure (up to an aggregate of $165,786 per year), and between $11,052 and $110,524 per "knowing" failure (up to an aggregate of $1.105 million per year), for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission, and may result in liability under other federal laws or regulations; 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 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 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 in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA.

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 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. ACA, 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. The ACA included, among other things, a deductible 2.3% excise tax on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions, effective January 1, 2013. Through a series of legislative amendments, the tax was suspended for 2016 through 2019. Absent further legislative action, the device excise tax will be reinstated on medical device sales starting January 1, 2020. If reinstated, this excise tax would result in a significant increase in the tax burden on our industry, and if the efforts we would undertake to offset the excise tax are unsuccessful, the potential increased tax burden could have an adverse effect on our results of operations and cash flows. Other elements of the ACA, including comparative effectiveness research and payment system reforms, including shared savings pilots and other provisions, 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.

We do not yet know the full impact that the ACA will have on our business. The taxes imposed by the ACA and 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. Certain legislative changes to, and regulatory changes under, the ACA have occurred in the 115th Congress and under the Trump Administration. For instance, the Tax Cuts and Jobs Acts was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance beginning in 2019. Additional legislative changes to and regulatory changes under the ACA remain possible. Moreover, all or a portion of the ACA and related subsequent legislation may be modified, repealed or otherwise invalidated through judicial challenge, which could result in lower numbers of insured individuals, reduced coverage for insured individuals and adversely affect our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013, and will remain in effect through 2027 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

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 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 Securities and Exchange Commission, or 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 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;
- 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;
- 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 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 initial public offering, 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 initial public offering 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 initial public offering 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 initial public offering, (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 and, beginning with our second annual report following our initial public offering, which will be for our fiscal year ending December 31, 2019, provide a management 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 are no longer an "emerging growth company," as defined by the JOBS Act. 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. We are in the process of designing and implementing the internal control over financial reporting required to comply with this obligation, which 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 initial public offering at the initial public offering 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 of 1933, as amended (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 15.5 million shares of our outstanding common stock, including shares issuable upon exercise of outstanding options, 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.

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, 2018, 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 approximately 15.8 million shares of our outstanding voting stock and own approximately 61.4% of our outstanding voting stock. 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.

Subject to the disclosure Item 9B, "Other Information" below, 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.

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 the Code, as amended. 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 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.

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. These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. If a court were to find either exclusive-forum provision in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

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 5 years) and an additional approximately 14,000 square feet of warehouse and assembly space in Rockaway, NJ pursuant to a lease that expires in 2024 (subject to our right to extend for an additional 5 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 existing facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such 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.

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 in the Notes to the Consolidated Financial Statements).

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

On June 25, 2018, our common stock began trading on the NASDAQ Global Market under the symbol "ECOR". Prior to that time, there was no public market for our common stock. Shares sold in our initial public offering on June 21, 2018 were priced at $15.00 per share.

On March 15, 2019, the closing price for our common stock as reported on the NASDAQ Global Market was $7.58. The following table sets forth the high and low sales prices per share of our common stock as reported on the NASDAQ Global Market for the period indicated.

Year Ended December 31, 2018	High	Low
Fourth Quarter	$ 14.47	$ 4.16
Third Quarter	$ 17.99	$ 12.85
Second Quarter	$ 20.25	$ 15.22

Stockholders

As of March 11, 2019, there were 307 stockholders of record, which excludes stockholders whose shares are held in nominee or street name by brokers.

Dividend Policy

We have never declared or paid any cash dividends on our common stock. We do not expect to pay dividends on our common stock for the foreseeable future. Instead, we anticipate that all of our earnings, if any, will be used for the operation and growth of our business. Any future determination to pay cash dividends would be subject to the discretion of our board of directors and would depend upon various factors, including our results of operations, financial condition and capital requirements, restrictions that may be imposed by applicable law and our contracts and other factors deemed relevant by our board of directors.

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 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. 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, 2018, we used:

(i) approximately $2.1 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 $0.7 million to fund expansion of our clinical program into additional indications in headache and rheumatology,

(iii) approximately $0.5 million for the build out of our specialty distribution channel for the launch of gammaCore Sapphire, and

(iv) approximately $6.4 million for working capital, including inventory, and other corporate purposes.

Item 6. Selected Financial Data

The selected financial data presented below is derived from our audited financial statements and are not indicative of our future operating results. The following selected financial data should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and the notes thereto included elsewhere in this Annual Report. The selected financial data in this section are not intended to replace our financial statements and the related notes.

	December 31,		
	2018	2017	2016
	(in thousands)		
Consolidated balance sheet data:			
Cash and cash equivalents	$ 7,600.3	$ 13,224.2	$ 416.3
Marketable securities	60,963.1	23,950.6	—
Total assets	73,504.3	39,232.7	622.0
Accounts payable and accrued expenses	7,073.0	3,879.8	3,296.5
Warrant liability	—	2,239.5	480.6
Accumulated deficit	(38,331.2)	(152,928.9)	(100,706.4)
Total stockholders' equity/members' deficit	$ 66,185.7	$ (89,467.6)	$ (61.1)

	Years ended December 31,		
	2018	2017	2016
	(in thousands)		
Consolidated statements of operations data:			
Net sales	$ 993.0	$ 811.5	$ 254.1
Cost of goods sold	578.7	518.5	123.7
Gross profit	414.3	293.0	130.4
Operating expenses			
Research and development	12,466.2	7,830.9	7,971.3
Selling, general and administrative	42,501.6	18,106.7	7,169.3
Total operating expenses	54,967.8	25,937.6	15,140.6
Loss from operations	(54,553.5)	(25,644.6)	(15,010.2)
Other expense, excluding income taxes	1,209.5	10,384.2	771.3
Provision for income taxes	2.4	—	—
Net loss	(55,765.4)	(36,028.8)	(15,781.5)
Less: Net income/(loss) attributable to noncontrolling interest	55.0	(236.4)	(44.1)
Total net loss attributable to Electrocore LLC and electroCore, Inc.	(55,820.4)	(35,792.4)	(15,737.4)
Net loss attributable to Electrocore LLC	$ (21,118.3)	$ (35,792.4)	$ (15,737.4)
Net loss attributable to electroCore, Inc.	$ (34,702.1)	$ —	$ —
Net loss per share basic and diluted (1)	$ (1.19)	$ —	$ —
Weighted average and potential shares outstanding (1)	29,261,943	—	—

(1) Prior to the Corporate Conversion, the Company's ownership structure included several different types of LLC interests including preferred stock, common units and Profits Interests (see Note 12 in the Notes to the Consolidated Financial Statements). The Company analyzed the calculation of earnings per unit for periods prior to the Corporate Conversion and determined that it resulted in values that would not be meaningful to the users of these consolidated financial statements. Therefore, earnings per share information has not been presented for periods prior to the Corporate Conversion on June 21, 2018. Net loss attributable to electroCore, Inc. subsidiaries and affiliate shown above includes the loss attributable to the period of June 21, 2018 to December 31, 2018. In addition, the basic and diluted weighted average shares outstanding calculation for the period from June 21, 2018 to December 31, 2018 is based on the actual days in which the shares were outstanding from June 21, 2018 to December 31, 2018.

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 bioelectronic medicine company with a proprietary non-invasive vagus nerve stimulation, or nVNS, therapy. nVNS is a platform therapy that modulates neurotransmitters and immune function through its pharmacologic effects on both the peripheral and central nervous systems. We are initially focused on neurology and rheumatology, and our therapy, gammaCore, is FDA-cleared for use by adults for the following three neurology indications: the acute treatment of pain associated with each of migraine and episodic cluster headache; and the prevention of cluster headaches. In neurology, we are pursuing further label expansions to include the prevention of migraine, migraine in adolescents, and post-traumatic headache. We are also engaging in clinical development for potential new labeling claims in rheumatology, with an initial focus on rheumatoid arthritis.

Since our inception in 2005, we have devoted substantially all of our resources to the development of vagus nerve stimulation, or VNS, and the commercialization of our gammaCore therapy. 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 cluster headache 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 cluster headache and migraine in adult patients, which was accomplished in the third quarter of 2018. With the clearance of our first label for the prevention of a primary headache condition, i.e., cluster headache, in December 2018, as we move into 2019, we are building upon our existing base of advocacy and patient support. Given our monthly subscription-based business model, which does not require a payer to expend greater resources to provide a patient with both acute and prevention therapy, we believe that our expanded label represents an enhanced value proposition.

Since our IPO in June 2018, we have continued our efforts to drive acceptance of our gammaCore therapy as a first-line treatment for patients suffering from episodic cluster headache and migraine headache. Following the IPO, we expanded our salesforce by adding 14 territory business representatives and two medical science liaisons. This provides us with a full complement of 32 territory business representatives and five medical science liaisons who are expected to cover 6,400 target physicians focused on headache conditions. In 2018, we generated approximately 1,200 prescriptions for our therapy in the first quarter, 3,300 in the second quarter, 4,400 in the third quarter and 5,800 in the fourth quarter for a total of nearly 15,000 prescriptions, written by approximately 1,800 unique prescribers.

We have never been profitable and have incurred net losses in each year since our inception. Our net losses for the years ended December 31, 2018 and 2017 were $55.8 million and $35.8 million, respectively. As of December 31, 2018, our accumulated deficit was $38.3 million, after giving effect to a reclassification of $(174.0) million to additional paid in capital at the time of the conversion. 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. We intend to continue making significant investments in building our U.S. commercial infrastructure and in recruiting and training our sales managers. We also intend to continue making significant investments in research and development to expand our gammaCore therapy for the treatment of other indications, including additional headache conditions and conditions in the field of rheumatology.

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.

As of December 31, 2018, we had cash, cash equivalents and marketable securities of $68.6 million. We believe our current cash resources will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months from the date our Form 10-K was filed. See "—Liquidity and Capital Resources."

Critical Accounting Policies and Estimates

The preparation of our financial statements is in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"). We are required to make estimates and assumptions that affect the reported amounts of assets and liabilities as of the date of the consolidated financial statements, the reported amounts of net sales and expenses during the reporting periods and the related disclosures in the consolidated financial statements. On an ongoing basis, we evaluate these estimates and judgments based on historical experiences and various other factors that are believed to reflect the current circumstances. 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 that the following accounting policies described in Note 2: "Basis of Presentation" in the audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K, are critical because they involve a higher degree of judgment and uncertainty. As a result, these accounting policies could materially affect our financial statements.

Revenue Recognition

We operate in one reportable segment and all of our net sales are derived from sales of our gammaCore product, net of specialty pharmaceutical distribution discounts. Products are sold to a specialty pharmaceutical distributor on a per unit wholesale acquisition cost basis. We recognize revenue upon transferring control of the product to our customer. Transfer of control is deemed to occur when we have transferred physical possession of the product FOB destination, the customer has accepted the product and has legal title and significant risks and rewards of ownership, and we have the right to payment.

Effective January 1, 2018, we adopted ASC Topic 606, *Revenue from Contracts with Customers*. Under this standard, revenue is recognized when an entity transfers control of promised goods to a customer in an amount that reflects the consideration the entity is entitled to receive in exchange for those goods. Indicators that control has transferred include (1) the Company has a present right to payment for the product, (2) the Company has transferred the physical possession of the product, (3) the customer has legal title to the product, (4) the customer has significant risks and rewards of ownership and (5) the customer has accepted the product. The Company determined that, like under ASC 605, revenue is recognized when the delivery of the product is completed.

We adopted ASC 606 using the full retrospective method. The adoption did not result in material impacts to our historical financial statements.

In February 2018, we instituted a voucher program under which 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 copay requirement and the contracted dispensing fee. The amount paid to us 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 recorded as promotional expense within selling, general and administrative expense.

Under ASC 606, 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 to our distributor at no charge ("free voucher units"). 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.

In addition, our co-payment reimbursement program is considered variable consideration and each co-payment reimbursement made was accounted for as a reduction in the transaction price, which impacted our net sales for the year ended December 31, 2018 by $42.5 thousand. At December 31, 2017, the co-payment reimbursement was immaterial.

At the current time, we do not provide an allowance for returns. Products for initial prescriptions and subsequent refills are sold in 31-day increments to our distributor. Once activated, our gammaCore stops delivering therapy after 31 days, at which time the patient discards it and can receive a refill prescription for a gammaCore for the following month. In the case of the gammaCore Sapphire, which commercially launched in the fourth quarter of 2018, patients retain the gammaCore Sapphire and can receive a refill for the next 31 days of therapy via our refill RFID card.

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.

During 2018, prior to effectiveness of any material reimbursement coverage in the United States, we recognized net sales of approximately $1.0 million. During this same year, we dispensed an additional approximately $4.7 million in product sales value to patients through our voucher and co-pay assistance programs which is not included in our net revenue, for an aggregate sales value of product dispensed to patients of approximately $5.8 million. We believe this is an important measure to assess the effectiveness of our promotional activities.

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.

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. 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.

Income Taxes

We use 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. We provide a full valuation allowance on substantially all deferred tax assets. The provision for income taxes in the Statement of Operations represents the current state tax payable for the period. Our federal tax provision is immaterial given we are reporting losses in all our taxable jurisdictions and are recording a full valuation allowance on the net deferred tax asset. We recognize 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.

Stock-Based and Unit-Based Compensation

We record compensation costs related to our stock-based and unit-based awards, based on the fair value of such awards at the grant date. Compensation expense is recognized over the vesting period during which an employee is required to provide services in exchange for the award. All awards are expensed on a straight-line basis over the vesting period, which is up to four years.

The determination of the fair value of each option or profits unit granted involved numerous assumptions by management. Although we calculated the fair value under the Black-Scholes option pricing model, which is a standard option pricing model, this model still required the use of numerous assumptions, including, among others, the expected life (turnover), volatility of the underlying equity security, a risk free interest rate and expected dividends. We have limited operating history and a lack of company-specific historical and implied volatility data, and therefore we estimate stock price volatility based upon an index of the historical volatilities of a group of publicly-traded industry peer companies. We estimate the expected term of our stock options (and prior to our initial public offering, our Common Units issued as Profits Interests) using the “simplified” method, whereby the expected life equals the average of the vesting term and the original contractual term of the option. The use of different values by management in connection with these assumptions in the Black-Scholes option pricing model could produce substantially different results.

Determination of the Fair Value of Common Units

As there had been no public market for our common units until June 21, 2018, the estimated fair value of our common units was supported by third-party valuations with an input of a combination of objective and subjective factors that management believed was relevant. Our third-party valuations resulted in valuations of our Common Units of $0.14 per unit as of March 31, 2017, $0.21 per unit as of June 30, 2017, $0.35 per unit as of September 30, 2017, $0.69 per unit as of December 31, 2017 and $0.77 per unit as of March 31, 2018. These third-party valuations were performed in accordance with the guidance outlined in the AICPA’s Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation.*

Our third-party valuation of common units were prepared using the discounted cash flow, or DCF, method, a form of the income approach, to estimate our equity value. In order to estimate equity value, the DCF method uses the estimated present value of future net cash flows for the expected life of the related assets or business, discounted at a rate of return that considers the relative risk of achieving those cash flows, the time value of money and the current stage of development of the business. The total fair value of equity on a marketable basis was then allocated between each class of equity, including common units, preferred units, Profits Interests, and warrants, applying a hybrid method of allocation. Under the hybrid method, a probability-weighted expected return method and an option pricing model were utilized.

The assumptions underlying these valuations represented management’s best estimates, which involved inherent uncertainties and the application of management judgment. As a result, if factors or expected outcomes changed and we used significantly different assumptions or estimates, our share-based compensation expense could have been materially different.

Profits Interests Granted

The following table summarizes by grant period the number of Profits Interests units granted by us during 2017 and the three months ended March 31, 2018 as well as the estimated fair value of such grants as of the grant date:

Three months ended	Number of units	Fair value per underlying unit at date of grant
March 31, 2017	1,022,500	$ 0.020 - 0.082
June 30, 2017	1,820,000	$ 0.020
September 30, 2017	11,170,335	$ 0.014 - 0.500
December 31, 2017	7,193,754	$ 0.029
March 31, 2018	19,112,218	$ 0.020 - 0.130

Bridge Notes and Warrants

The Bridge Notes, common units and warrants to purchase securities in the Qualified Equity Financing (except that, for issuances prior to September 9, 2016, no Common Units were issued in respect thereof) were issued to investors simultaneously in exchange for cash equal to the principal amount of the Bridge Notes. In addition, the Bridge Notes were issued with an embedded automatic conversion feature in which outstanding Bridge Notes were converted to Series B Preferred Units upon occurrence of the Qualified Equity Financing. Each of these separate financial instruments and embedded features require separate accounting.

The proceeds of the bridge financing transactions were required to be allocated to each of the Bridge Notes, Common Units, and warrants. In addition, the embedded option to convert to Series A Preferred Units and the automatic conversion feature to Series B Preferred Units were determined to be embedded derivatives that require bifurcation from the Bridge Notes and separate accounting.

The warrants were evaluated by management and determined to be liability classified. As such, the warrants were measured at fair value with changes in fair value recognized in net income. After subtracting the fair value of the warrants at issuance, the remaining proceeds were allocated to the Bridge Notes (inclusive of the embedded automatic conversion feature) and common units at their relative fair values. The embedded option to convert to Series A Preferred Units and the automatic conversion feature to Series B Preferred Units was then separated from the Bridge Notes and measured at fair value with changes in fair value recognized in net income. The residual amount of proceeds were then allocated to the Bridge Notes.

As a consequence of the allocation of proceeds of the bridge financing to the financial instruments and embedded derivative described above, the Bridge Notes were issued at a discount. This discount was amortized over the life of the Bridge Notes. The Bridge Notes were converted to Preferred Stock in August 2017. The Preferred Stock was in turn converted to common stock in conjunction with the IPO.

Valuation of Derivative Liability Associated with Bridge Notes

The derivative liability relating to the debt component of the Bridge Notes was measured at fair value and was subsequently remeasured at fair value at each reporting date. Changes in the fair value of the derivative liability were recognized as a component of amortization of debt discount and issuance cost in our consolidated statement of operations. We recognized changes in the fair value of the derivative liability embedded in the Bridge Notes until the conversion into the Qualified Equity Financing, which occurred in connection with the conversion of the Bridge Notes into Series B Preferred Units in August 2017.

The embedded option to convert to Series A Preferred Units was deemed to be de minimus. The derivative liability related to the automatic conversion of the Bridge Notes in the Qualified Equity Financing was recorded at fair value using an alternative discounted cash flow method. The derivative liability related to the Bridge Notes was recorded at fair value determined by using an alternative discounted cash flow method. This method of valuation involved using inputs such as a 50% required rate of return, an 80% probability of a Qualified Equity Financing closing prior to the maturity of the Bridge Notes, and an option's ability to convert at a 10% discount into the expected next Qualified Equity Financing. Changes to the assumptions used in such valuation could have a significant impact on the fair value of the derivative liability.

Valuation of Warrant Liability

As discussed above, the warrants to purchase securities in the Qualified Equity Financing were determined to be liability classified. We determined that such warrants potentially obligated us to repurchase or redeem them in the future Qualified Equity Financing, as the terms of the Qualified Equity Financing was unknown at the time the warrants were issued alongside the Bridge Notes.

On June 21, 2018, we determined that the outstanding warrant liability should be reclassified to equity as the warrants no longer met the criterion to be recognized as a liability. Prior to June 20, 2018, the Company determined the fair value of the liability using the probability weighted expected return method and option pricing models. This valuation method involved using inputs such as the fair value of the Company's Common Units, unit price volatility, the contractual term of the warrants, risk free interest rates and dividend yields. Due to the nature of these inputs, the valuation of the warrant liability was considered a Level 3 measurement.

Valuation of Series B Preferred Units and Warrants

Beginning in August 2017 through December 2017, we issued Series B Preferred Units (which constituted the Qualified Equity Financing noted above), warrants to purchase Series B Preferred Units at $0.70 per unit, warrants to purchase Common Units for $1.25 per unit, and warrants to purchase Common Units for $0.70 per unit. The Series B Preferred Units and warrants were evaluated by management and determined to be equity classified. Both of these instruments require separate accounting and the proceeds of the issuance of the Series B Preferred Units were required to be allocated to each instrument on a relative fair value basis.

In order to allocate proceeds of the issuance of Series B Preferred Units and warrants to purchase Common Units, a valuation of both instruments at fair value was required. We used a hybrid method to value the Series B Preferred Units and warrants to purchase Common Units. Under the hybrid method, a probability-weighted expected return method and an option pricing model were utilized.

The Company issued 35,452,084 warrants for the purchase of Common Units at an exercise price of $1.25 per Unit, which expired unexercised upon the closing of the IPO. 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 Company issued warrants to advisors for the purchase of 2,724,549 common units at an exercise price of $0.70 per Unit. The fair value of these warrants to purchase common units were recorded within additional-paid-in-capital. In connection with the Corporate Conversion, these warrants 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 issued to purchase Series B Preferred Units and warrants to purchase Common Units for $0.70 per unit 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 12) 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.

Research and Development Expenses

We incur significant expenditures on research and development costs, including clinical testing for regulatory purposes and these expenditures have been expensed as incurred. Our research and development expenses primarily consist of pilot and pivotal clinical trials relative to current and future therapeutic indications, product engineering, technical updates, quality assurance and regulatory expenses. Additionally, these expenses are comprised of development and enhancements to our proprietary data warehouse, which maintains patient product serial numbers and interacts in real time, with a device placed at the specialty pharmacy to program RFID refill cards. Research and development expenses also include employee share and unit-based compensation, consulting services, outside services, materials, and supplies relating to clinical trials including products revisions, data statistics and patient recruitment.

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 will 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 as otherwise required by Section 404(b) of the Sarbanes-Oxley Act.

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, 2018 and 2017

The following table summarizes our results of operations for the years ended December 31, 2018 and 2017 with the changes in those items in dollars.

	Years ended December 31,		
	2018	2017	Change
	(in thousands)		
Net sales	$ 993.0	$ 811.5	$ 181.5
Cost of goods sold	578.7	518.6	60.1
Gross profit	414.3	292.9	121.4
Operating expenses			
Research and development	12,466.2	7,830.9	4,635.3
Selling, general and administrative	42,501.6	18,106.7	24,394.9
Total operating expenses	54,967.8	25,937.6	29,030.2
Loss from operations	(54,553.5)	(25,644.7)	(28,908.8)
Other expenses/(income):			
Loss on extinguishment of debt	—	3,868.8	(3,868.8)
Interest expense	—	6,295.9	(6,295.9)
Amortization of debt issuance costs	—	827.3	(827.3)
Change in fair value of warrant liability	1,870.9	(861.8)	2,732.7
Change in fair value of derivative instrument related to convertible bridge notes	—	348.2	(348.2)
Interest and other income, net	(1,006.3)	(99.0)	(907.3)
Other	344.9	4.9	340.0
Total other expenses/(income)	1,209.5	10,384.2	(9,174.7)
Loss before income taxes	(55,763.0)	(36,028.9)	(19,734.1)
Provision for income taxes	2.4	—	2.4
Net loss from operations	(55,765.4)	(36,028.7)	(19,736.7)
Less: Net income/(loss) attributable to noncontrolling interest	55.0	(236.4)	291.4
Total net loss attributable to Electrocore LLC and electroCore, Inc.	$ (55,820.4)	$ (35,792.3)	(20,028.1)

Net Sales

Net sales were $993.0 thousand and $811.5 thousand for the years ended December 31, 2018 and 2017, respectively. The increase of $181.5 thousand is the net of an increase in U.S. sales of $376.6 thousand, an increase in U.K. sales of $26.4 thousands, and offset by a decrease in sales in Germany of $211.7 thousand. The decrease in Germany is a result of the termination of our agreement with a private German pharmaceutical company that purchased product in 2017, a substantial portion of which was units dispensed as free samples. The overall increase in net sales in 2018 over 2017 is attributable to increased prescriptions as a result of our commercial launch of our gammaCore products in the United States.

Costs of Goods Sold

Cost of goods sold was $578.7 thousand and $518.6 thousand for years ended December 31, 2018 and 2017, respectively. The increase of $60.1 thousand was the result of increased sales.

Research and Development

Research and development expenses were $12.5 million and $7.8 million for the years ended December 31, 2018 and 2017, respectively. This increase of $4.7 million is primarily the result of increased personnel costs and stock compensation of $4.7 million and increased monitoring of clinical trials of $0.7 million, offset by a decrease in consulting expense of $1.4 million.

Selling, General and Administrative

Selling, general and administrative expense were $42.5 million and $18.1 million for the years ended December 31, 2018 and 2017, respectively. This $24.4 million increase is primarily a result of increased personnel costs and stock compensation of $11.9 million related to newly hired personnel (principally sales related), increased legal and compliance costs of $2.0 million, increased costs of market preparation, medical education, materials, samples, studies and travel of $1.8 million, increased costs of $3.9 million related to consultants and service providers associated with the commercial launch of gammaCore and gammaCore Sapphire, costs for the voucher programs of $2.4 million, and other expenses of $2.4 million.

Interest Expense

Interest expense was zero and $6.3 million for the years ended December 31, 2018 and 2017, respectively. This decrease is due to the Bridge Notes issued in 2017 being converted to Series B Preferred Units in August 2017.

Loss on Extinguishment of Debt

Upon the conversion of the Bridge Notes into Series B Preferred Units, we incurred a loss on the settlement of $3.9 million in the year ended December 31, 2017. This loss was calculated as the difference between the Series B Preferred Units issued (and the related warrants and Common Units issued in conjunction with the Bridge Financing), and the carrying value of the settled Bridge Notes (which includes the related debt discount and discount for debt issuance costs), accrued interest, and the embedded derivative liability. There was no net loss on settlement for the year ended December 31, 2018 since all Bridge Notes were converted in August 2017.

Amortization of Debt Issuance Costs

Amortization of debt issuance costs, which related to the Bridge Notes issued during 2017 and 2016, was zero and $0.8 million for the years ended December 31, 2018 and 2017, respectively. These debt issuance costs were amortized on a straight-line basis over the term of the Bridge Notes. This decrease was driven by the full amortization of the remaining debt issuance costs as a result of the conversion of the debt to Series B Preferred Units in August 2017.

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 years ended December 31, 2018 and 2017.

Net Loss Attributable to Non-Controlling Interest

Net loss attributable to non-controlling interest increased by $291.4 thousand to net income of $55.0 thousand for the year ended December 31, 2018 from $236.4 thousand for the year ended December 31, 2017. The net income was the result of a write-off of the previous liability from our joint venture in Australia.

Liquidity and Capital Resources

As of December 31, 2018, we had an accumulated deficit of $38.3 million, subsequent to a reclassification of $(174.0) million to additional paid in capital at the time of the corporate conversion (see Note 12 in the Notes Consolidated Financial Statements). We anticipate that we will continue to incur losses for at least the next several years. We believe our cash, cash equivalents and marketable securities are adequate to meet our operating, investing, and financing needs for at least the next 12 months. To the extent additional funds are necessary to meet long-term liquidity needs as we continue to execute our business strategy, we anticipate that they will be obtained through the incurrence of additional indebtedness, additional equity financings or a combination of these potential sources of funds, although we can provide no assurance that these sources of funding will be available on reasonable terms.

Historically, our primary sources of liquidity have been from private equity or debt offerings. In June 2018, we closed our IPO of 5,980,000 shares of common stock at a price of $15.00 per share with net proceeds of $77.5 million, after underwriting discount and other offering expenses. As of December 31, 2018, our cash, cash equivalents and marketable securities was $68.6 million. As of December 31, 2018, we had no outstanding debt.

Until we can generate a sufficient amount of cash from operations, we expect to finance future cash needs through public or private equity or debt offerings. Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly scale back our operations or delay, scale back or discontinue the continuing development of gammaCore. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders and increased fixed payment obligations, and these securities may have rights senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

Cash Flows

The following table sets forth the significant sources and uses of cash for the periods noted below:

	For the Year Ended December 31,	
	2018	2017
	(in millions)	
Net cash (used in) provided by		
Operating activities	$ (47.1)	$ (25.3)
Investing activities	$ (36.8)	$ (24.1)
Financing activities	$ 78.3	$ 62.5

Operating Activities

Net cash used in operating activities was $47.1 million for the year ended December 31, 2018, compared to $25.3 million for the year ended December 31, 2017. This increase in net cash used in operating activities of $21.8 million was associated with net changes in working capital of $1.3 million and an increase in net loss of $19.9 million, which was primarily the result of our increase in expenditures for selling, general and administrative items, including those related to our co-payment and voucher programs as well as additional expenditures for research and development.

Investing Activities

Net cash used in investing activities was $36.8 million for the year ended December 31, 2018 compared to $24.1 million for the year ended December 31, 2017. This increase of $12.7 million is primarily due to increased purchases and sales of investment securities.

Financing Activities

Net cash provided by financing activities was $78.3 million for the year ended December 31, 2018 compared to $62.5 million for the year ended December 31, 2017. This increase of $15.8 million is the result of $78.3 million received in the IPO compared to financing from Series B Preferred Stock and convertible bridge notes of $62.5 million for the year ended December 31, 2017.

Contractual Obligations

In the normal course of business, we enter into obligations and commitments that require future contractual payments. The commitments result primarily from lease for office space and leased equipment. The Company has also entered into commitments for the purchase of component parts of inventory related to its gammaCore Sapphire as well as additional marketing related initiatives.

Our operating lease commitments relate to facility leases for our corporate headquarters in Basking Ridge, New Jersey, a facility leased in Rockaway, New Jersey and office equipment.

	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	Total
Lease Rental Payments	$ 576,743	$ 1,407,509	$ 1,489,738	$ 2,944,382	$ 6,418,372
Purchase Obligations	$ 6,446,524	$ 162,166	$ 162,166	$ —	$ 6,770,856

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. Refer to Note 2 “Basis of Presentation” of the Notes to Consolidated Financial Statements contained in Item 8 of this 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, 2018.

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 either available for sale or held-to-maturity 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, 2018.

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, 2018 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, 2018, were effective for the purposes stated above.

Internal Control Over Financial Reporting

Due to a transition period established by SEC rules applicable to newly public companies, our management is not required to evaluate the effectiveness of our internal control over financial reporting until after the filing of our Annual Report on Form 10-K for the year ended December 31, 2018. As a result, this Annual Report on Form 10-K does not address whether there have been any changes in our internal control over financial reporting.

Notwithstanding the foregoing, 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.

Item 9B. Other Information.

On December 19, 2018, the Delaware Chancery Court issued an opinion in *Sciabacucchi v. Salzberg*, C.A. No. 2017-0931-JTL, invalidating a provision in the certificates of incorporation of three Delaware corporations that each purported to limit to federal court the forum in which a stockholder could bring a claim under the Securities Act of 1933, as amended (the "Securities Act"). The Delaware Chancery Court held that a Delaware corporation can only use its constitutive documents to bind a plaintiff to a particular forum where the claim involves rights or relationships that were established by or under Delaware's corporate law.

Article IX of our Certificate of Incorporation, or Charter contains a similar federal forum selection provision. As such, and in light of the recent *Sciabacucchi* decision, the Company does not currently intend to enforce the foregoing federal forum selection provision unless the *Sciabacucchi* decision is reversed on appeal. If the decision is not appealed or if the Delaware Supreme Court affirms the Delaware Chancery Court's decision, then we will seek approval by our stockholders to amend the Charter at our next regularly-scheduled annual meeting of stockholders to remove the invalid provision.

Claim from Lifehealthercare 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. On March 15, 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 is consulting with legal counsel on this matter and intends to vigorously assert its defenses to the alleged claims but cannot predict the outcome of the matter at this time. However, the financial impact, if any, in connection with the resolution of this matter is not expected to be material.

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 2019 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 2019 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 2019 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 2019 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 2019 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.
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†**	Form of 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*	Office Lease between Anson Logistics Assets LLC and electroCore, Inc.
10.20**	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.
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.

† 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 28, 2019 By: /s/ FRANCIS R. AMATO

Francis R. Amato
Chief Executive Officer and Director
(Principal Executive Officer)

Date: March 28, 2019 By: /s/ GLENN S. VRANIAK

Glenn S. Vraniak
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 28, 2019
/s/ Francis R. Amato **Francis R. Amato**	Director	March 28, 2019
/s/ Michael G. Atieh **Michael G. Atieh**	Director	March 28, 2019
/s/Joseph P. Errico **Joseph P. Errico**	Director	March 28, 2019
/s/Nicholas Colucci **Nicholas Colucci**	Director	March 28, 2019
/s/Thomas J. Errico, M.D. **Thomas J. Errico, M.D.**	Director	March 28, 2019
/s/Trevor J. Moody **Trevor J. Moody**	Director	March 28, 2019
/s/Stephen L. Ondra, M.D. **Stephen L. Ondra, M.D.**	Director	March 28, 2019
/s/James L.L. Tullis **James L.L. Tullis**	Director	March 28, 2019

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, 2018 and 2017, 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, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

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. 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 28, 2019

ELECTROCORE, INC., SUBSIDIARIES AND AFFILIATE

Consolidated Balance Sheets

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 7,600,284	$ 13,224,194
Marketable securities	60,963,087	23,950,566
Accounts receivable	267,599	103,209
Inventories	1,949,402	327,787
Prepaid expenses and other current assets	1,918,164	570,755
Deferred financing costs	—	856,895
Total current assets	72,698,536	39,033,406
Property and equipment – net	380,904	168,646
Other assets	424,896	30,604
Total assets	$ 73,504,336	$ 39,232,656
Liabilities, Convertible Preferred Units and Stockholders' and Members' Equity/(Deficit)		
Current liabilities:		
Accounts payable	$ 2,698,902	$ 840,383
Accrued expenses	4,374,101	3,039,392
Warrant liability	—	2,239,544
Total current liabilities	7,073,003	6,119,319
Noncurrent liabilities:		
Deferred rent	245,632	306,886
Total liabilities	7,318,635	6,426,205
Commitments and contingencies (Note 19)		
Convertible preferred units:		
Series A Preferred Units, 0 Units authorized at December 31, 2018 and 71,050,860 at December 31, 2017; 0 Units issued and outstanding at December 31, 2018 and 70,918,506 at December 31, 2017	—	53,518,463
Series B Preferred Units, 0 Units authorized at December 31, 2018 and 123,000,000 at December 31, 2017; 0 Units issued and outstanding at December 31, 2018 and 105,186,020 at December 31, 2017	—	68,755,544
Series B-1 Preferred Units, 0 Units authorized at December 31, 2018 and December 31, 2017; 0 Units issued and outstanding at December 31, 2018 and December 31, 2017	—	—
Total convertible preferred units	—	122,274,007
Stockholders'/members' equity/(deficit):		
Common Units, 0 Units authorized at December 31, 2018 and 600,000,000 at December 31, 2017; 0 Units issued and outstanding at December 31, 2018 and 218,982,140 at December 31, 2017	—	40,180,619
Preferred Stock, par value $0.001 per share; 10,000,000 shares authorized at December 31, 2018 and 0 shares at December 31, 2017; 0 shares issued and outstanding at December 31, 2018 and December 31, 2017	—	—
Common Stock, par value $0.001 per share; 500,000,000 shares authorized at December 31, 2018 and 0 shares at December 31, 2017; 29,450,035 shares issued and outstanding at December 31, 2018 and 0 at December 31, 2017	29,450	—
Additional paid-in capital	103,791,013	22,596,485
Accumulated deficit	(38,331,215)	(152,928,928)
Accumulated other comprehensive income	60,843	80,213
Total stockholders'/members' equity/(deficit) attributable to electroCore, Inc., subsidiaries and affiliate	65,550,091	(90,071,611)
Noncontrolling interest	635,610	604,055
Total stockholders'/members' equity/(deficit):	66,185,701	(89,467,556)
Total liabilities, convertible preferred units and stockholders' equity/ members' equity	$ 73,504,336	$ 39,232,656

See accompanying notes to the consolidated financial statements.

ELECTROCORE, INC., SUBSIDIARIES AND AFFILIATE

Consolidated Statements of Operations

	Years ended December 31,	
	2018	2017
Net sales	$ 992,953	$ 811,457
Cost of goods sold	578,743	518,532
Gross profit	414,210	292,925
Operating expenses:		
Research and development	12,466,172	7,830,868
Selling, general and administrative	42,501,562	18,106,647
Total operating expenses	54,967,734	25,937,515
Loss from operations	(54,553,524)	(25,644,590)
Other expense/(income)		
Loss on extinguishment of debt	—	3,868,771
Interest expense	—	6,295,854
Amortization of debt issuance costs	—	827,317
Change in fair value of warrant liability	1,870,923	(861,773)
Change in fair value of derivative instrument related to convertible bridge notes	—	348,163
Interest and other income, net	(1,006,332)	(99,027)
Other expense	344,909	4,885
Total other expense/(income)	1,209,500	10,384,190
Loss before income taxes	(55,763,024)	(36,028,780)
Provision for income taxes	2,431	—
Net loss from operations	(55,765,455)	(36,028,780)
Less: Net income/(loss) attributable to noncontrolling interest	55,005	(236,358)
Total net loss attributable to Electrocore LLC and electroCore, Inc. subsidiaries and affiliate	$ (55,820,460)	$ (35,792,422)
Net loss attributable to Electrocore, LLC subsidiaries and affiliate	$ (21,118,337)	$ (35,792,422)
Net loss attributable to electroCore, Inc. subsidiaries and affiliate	$ (34,702,123)	$ —
Net loss per share of common stock - Basic and Diluted (see Note 11)	$ (1.19)	$ —
Weighted average and potential common shares outstanding - Basic and Diluted (see Note 11)	29,261,943	—

See accompanying notes to the consolidated financial statements.

ELECTROCORE, INC., SUBSIDIARIES AND AFFILIATE

Consolidated Statements of Comprehensive Loss

	Years ended December 31,	
	2018	2017
Net loss from operations	$ (55,765,455)	$ (36,028,780)
Other comprehensive (loss) income:		
Foreign currency translation adjustment	3,259	(113,492)
Amount reclassed from accumulated other comprehensive loss	11,024	—
Unrealized losses on marketable securities, net of taxes as applicable	(33,653)	(20,301)
Other comprehensive loss	(19,370)	(133,793)
Comprehensive loss	(55,784,825)	(36,162,573)
Less: Net comprehensive (loss)/income attributable to noncontrolling interest	5,085	(222,405)
Comprehensive loss attributable to Electrocore, LLC and electroCore, Inc. subsidiaries and affiliates	$ (55,789,910)	$ (35,940,168)
Comprehensive loss attributable to Electrocore, LLC subsidiaries and affiliate	$ (21,118,056)	$ (35,940,168)
Comprehensive loss attributable to electroCore, Inc. subsidiaries and affiliate	$ (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 LLC for the year ended December 31, 2017 and electroCore, Inc. for the year ended December 31, 2018									
	Series A Preferred Units		Series B Preferred Units		Common Units		Common Stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income	(Deficit)/Equity attributable to Electrocore LLC and electroCore, Inc. subsidiaries and affiliate	Noncontrolling interest	Total stockholders'/ members' equity/ (deficit)
	Units	Amount	Units	Amount	Units	Amount	Shares	Amount						
Balances as of January 1, 2017	70,918,506	$ 53,518,463	—	$ —	90,711,018	$ 30,912,091	—	$ —	$ 8,126,416	$ (100,706,419)	$ 214,006	$ (61,453,906)	$ 400,421	$ (61,053,485)
Net loss						—	—	—	—	(35,792,423)	—	(35,792,423)	(236,358)	(36,028,781)
Other comprehensive income	—	—	—	—	—	—	—	—	—	—	(133,793)	(133,793)	—	(133,793)
Issuance of Series B Preferred Units, net	—	—	105,186,020	68,755,544	18,340,000	4,074,447	—	—	(2,012,611)	—	—	2,061,836	—	2,061,836
Noncontrolling interest contributions	—	—	—	—	—	—	—	—	—	—	—	—	439,992	439,992
Unit-based compensation	—	—	—	—	—	—	—		462,329	—	—	462,329	—	462,329
Common Units issued in connection with convertible bridge notes, net	—	—	—	—	36,565,948	5,194,081	—	—	(409,735)	—	—	4,784,346	—	4,784,346
Common Units issued in exchange for elimination of preference	—	—	—	—	73,365,174	—	—	—	—	—	—	—	—	—
Common Units issued for initial funding of Series B Preferred Units	—	—	—	—	—	—	—	—	16,430,086	(16,430,086)	—	—	—	—
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

See accompanying notes to the consolidated financial statements.

ELECTROCORE, INC., SUBSIDIARIES AND AFFILIATE

Consolidated Statements of Cash Flows

	Years ended December 31,	
	2018	**2017**
Cash flows from operating activities:		
Net loss from operations	$ (55,765,455)	$ (36,028,780)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of debt discount and debt issuance costs	—	6,079,690
Change in fair value of warrants and embedded derivative	1,870,923	(513,610)
Non-cash interest expense on convertible bridge notes	—	1,045,000
Stock/unit-based compensation	7,599,496	462,329
Depreciation and amortization	66,663	32,306
Net loss on settlement of convertible bridge note	—	3,868,771
Amortization of marketable securities premium/(discount)	(497,267)	—
Cloud computing arrangement implementation costs	(107,754)	—
Other	12,136	436,641
Changes in operating assets and liabilities:		
Accounts receivable	(164,390)	(78,499)
Inventories	(1,621,615)	(279,316)
Prepaid expenses and other current assets	(1,347,410)	(517,286)
Accounts payable and accrued expenses	2,905,578	212,335
Deferred rent	(61,254)	(48,839)
Net cash used in operating activities	(47,110,349)	(25,329,258)
Cash flows from investing activities:		
Purchase of marketable securities	(81,058,590)	(32,427,517)
Proceeds from maturities of marketable securities	44,509,684	8,460,000
Purchases of property and equipment	(278,921)	(152,526)
Net cash used in investing activities	(36,827,827)	(24,120,043)
Cash flows from financing activities:		
Sale of common stock, net of related expenses	78,334,457	—
Proceeds from issuance of Series B Preferred Units	—	46,911,300
Financing costs related to the issuance of Series B Preferred Units	—	(2,819,046)
Proceeds from issuance of convertible bridge notes	—	19,965,091
Deferred financing costs	—	(397,994)
Financing costs related to issuance of convertible bridge notes	—	(1,170,949)
Net cash provided by financing activities	78,334,457	62,488,402
Effect of changes in exchange rates on cash and cash equivalents	(20,191)	(231,243)
Net increase in cash and cash equivalents	(5,623,910)	12,807,858
Cash and cash equivalents – beginning of period	13,224,194	416,336
Cash and cash equivalents – end of period	$ 7,600,284	$ 13,224,194
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	$ —
Deferred financing costs included in accounts payable and accrued expenses	$ —	$ 234,339
Stock dividend distribution in connection with IPO	$ 3,629,092	$ —
Capitalized cloud computing arrangement costs included in accounts payable and accrued expenses	$ 287,650	$ —
Common units issued in exchange for elimination of liquidation preference	$ —	$ 16,430,086
Conversion of convertible bridge notes, including accrued interest, to Series B Preferred Units	$ —	$ 26,718,910
Common units issued in connection with Series B financing	$ —	$ 4,074,447
Series B warrants issued in connection with convertible bridge notes	$ —	$ 2,620,681
Common warrants issued in connection with Series B financing	$ —	$ 362,081
Common units issued in connection with convertible bridge notes	$ —	$ 5,194,081
Deferred financing costs accrued	$ —	$ 458,901
Cash paid during the year for:		
Interest paid	$ —	$ 373
Income taxes paid	$ 45,641	$ —

See accompanying notes to consolidated financial statements.

Note 1. Business

Company Overview

electroCore, Inc. is a bioelectronic medicine company, engaged in the commercialization and development of a range of patient-administered non-invasive Vagus Nerve Stimulation ("nVNS") therapies initially focused on the treatment of multiple conditions in neurology, rheumatology and other fields. electroCore was founded in 2005 and its focus currently is on primary headache (migraine and cluster headache), with trials continuing in other neurological and inflammatory disorders.

electroCore, headquartered in New Jersey, has wholly owned subsidiaries that include: electroCore Bermuda, Ltd., 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 ("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. In December 2017, gammaCore's successor, Sapphire, was FDA released. gammaCore Sapphire is a rechargeable and reloadable version of the product for multi-year use. Effective August 1, 2018, the Company announced gammaCore Sapphire was available in the United States. In general, the Company will only market the previous disposable version of gammaCore in select market segments in the United States where deemed appropriate.

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. This milestone marks the first and only product FDA cleared for the prevention of cluster headache. There are no other FDA-approved pharmacologic treatments for the prevention of cluster headache.

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 12 - 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. The underwriters were Evercore Group L.L.C., Cantor Fitzgerald & Co., JMP Securities. LLC, and BTIG, LLC.

Shares of common stock began trading on the Nasdaq Global Market on June 22, 2018 and began trading on the Nasdaq Global Select Market on June 25, 2018, under the symbol "ECOR". The shares were registered under the Securities Act, on a registration statement on Form S-1, which was declared effective by the Securities and Exchange Commission ("SEC"), on June 21, 2018.

Note 2. Basis of Presentation

(a) 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.

(b) 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.

(c) Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents and all investments with maturities of greater than three months from date of purchase are classified as marketable securities. The Company maintains its U.S. operating cash balances in financial institutions which are insured by the Federal Deposit Insurance Corporation (FDIC) up to $250,000 each. At times, such balances may be in excess of the FDIC insurance limit.

(d) Marketable Securities

Marketable securities, all of which are available-for-sale, consist of corporate debt securities, U.S. bonds, U.S. sponsored agencies and municipal bonds. 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 other income net.

(e) Concentration of Credit Risk

Cash, cash equivalents and investments 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, 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.

(f) 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.

(g) Inventories

Inventory, which consists of the raw materials, work-in-process and finished product of gammaCore, 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.

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.

(h) Property and Equipment

Property and equipment are stated at cost. Depreciation and amortization are 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, and expenditures for major renewals and improvements are capitalized. Upon disposition of property and equipment, the related cost and accumulated depreciation and amortization are removed from the accounts, and any gain or loss is reflected in the accompanying Consolidated Statements of Operations.

Depreciation is computed using the following estimated useful lives:

Machinery and equipment	3–15 years
Furniture and fixtures	5–10 years
Computer equipment	5 years

(i) Other Assets

Implementation costs for our 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 deferred and recognized as other assets.

(j) 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.

(k) Stock-based Compensation

During 2018, the Company issued equity awards to employees, directors and consultants. Types of equity awards that can be granted under the 2018 Equity Incentive Plan include options, restricted stock, restricted stock units, and deferred stock units.

Compensation expense for awards is recognized ratably over the requisite service period of the award, which is up to four years. Compensation expense is based on the actual number of awards that vest. The fair value of stock-based awards is based on the closing price on the date the award was granted. The estimated fair value of the options is computed using the Black-Scholes model on the date of the grant.

(l) Income Taxes

We use 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. We provide a full valuation allowance on substantially all deferred tax assets. The provision for income taxes represents the current state tax payable for the period. Our federal tax provision is immaterial given we are reporting losses in all our taxable jurisdictions and are recording a full valuation allowance on the net deferred tax asset. We recognize 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.

(m) Convertible Preferred Units

The Company classified convertible preferred units (Series A Preferred Units and Series B Preferred Units) as temporary equity in the accompanying consolidated balance sheets due to certain change in control events that could trigger the payment of the Series A Preferred and Series B Preferred liquidation preferences being outside of the Company's control, including sale or transfer of control of the Company, as certain holders of the preferred units could cause the liquidation of the Units in these situations. The Company did not accrete the carrying values of the preferred units to the redemption values since a change in control event did not occur while the Units were outstanding. Subsequent adjustments of the carrying values to the ultimate redemption values are only when it is probable that such a change in control event will occur.

(n) Revenue Recognition

Revenue, net of specialty pharmaceutical distribution discounts, vouchers, rebates, and co-payment assistance is solely generated from the sales of the gammaCore products. Sales are made to a specialty pharmaceutical distributor ("customer") and 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 established wholesale acquisition cost less a contractually agreed upon distributor discount with the customer. Our revenue only reflects sales of gammaCore units exclusive of trade credits, vouchers, rebates, and co-payment assistance.

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

Amounts collected on behalf of third parties, such as value added taxes, are not included in the transaction price, and not included in net revenue, as they are collected from the customer on behalf of the respective taxing authority.

Shipping and handling costs are reported as selling, general and administrative expenses.

(o) Research and Development

Research and development costs are expensed as incurred. Costs incurred for clinical trials for patients and investigators are expensed as services are performed in accordance with the agreements in place with the institutions.

(p) Foreign Currency Translation and Transactions

Operations in non-U.S. entities are recorded in the functional currency of each entity. For financial reporting purposes, the functional currency of an entity is determined by a review of the source of an entity's most predominant cash flows. The results of operations for non-U.S. dollar functional currency entities are translated from functional currencies into U.S. dollars using the average currency rate during each month, which approximates the results that would be obtained using actual currency rates on the dates of individual transactions. Assets and liabilities are translated using currency rates at the end of the period. Adjustments resulting from translating the financial statements of the foreign entities into the U.S. dollar are excluded from the determination of net loss and are recorded as a component of 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.

(q) Net Comprehensive Loss

Net comprehensive loss consists of net loss, foreign exchange translation adjustments and unrealized gains (losses) on securities available for sale and is presented in the Consolidated Statements of Comprehensive Loss.

(r) Segment Information

The Company operates in one reportable segment within the United States, Europe and Australia. Management uses one measurement of profitability and does not segregate its business for internal reporting, making operating decisions, and assessing financial performance.

(s) Recently Adopted Accounting Pronouncements

In May 2014, the FASB issued Accounting Standard Update (ASU) 2014-09, Revenue from Contracts with Customers ("ASC 606"). ASC 606 provided a comprehensive framework under which revenue is recognized when an entity transfers promised goods and services to a customer in an amount that reflects the consideration an entity is entitled to receive in exchange for those goods and services. Furthermore, ASC 606 contained expanded disclosure requirements to enable users of the financial statements to better understand the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers.

The Company adopted ASC 606 effective January 1, 2018, using the full retrospective method. The adoption of ASC 606 did not have a material impact on the consolidated balance sheet, statements of operations, or cash flows for the year ended December 31, 2017. The primary impact of adoption related to the enhancement of the disclosures is provided in Note 4 – Revenue Recognition.

In January 2016, the FASB issued ASU 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities (Subtopic 825-10). The ASU revised the measurement and presentation of investments in certain financial assets and liabilities and enhances disclosures about those investments. The Company adopted this guidance on January 1, 2018, which had no material impact on the balance sheet, statement of operations or statement of cash flows.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments, (Topic 230). This ASU made eight targeted changes to how cash receipts and cash payments are presented and classified in the statement of cash flows. The Company adopted this guidance on January 1, 2018, which had no material impact on the statement of cash flows.

In June 2018, the FASB issued ASU 2018-07, Compensation-Stock Compensation, Topic 718. The amendments in this Update expand the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The amendments specify that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The Company adopted this guidance in the second quarter of 2018, which had no material impact on the balance sheet, statement of operations or statement of cash flows.

In August 2018, the FASB issued ASU 2018-15, Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40), Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract. The amendments in this ASU aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The Company adopted this guidance in the fourth quarter of 2018. The Company capitalized implementation costs of $395.0 thousand (see Note 9).

(t) Recent Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), which requires lessees to recognize most leases on the balance sheet. The provisions of this guidance are effective for annual periods beginning after December 15, 2018, and interim periods within those years, with early adoption permitted. The Company has two leases for office, manufacturing and warehouse space. One lease expires in 2022 and the other in 2024. Each of the leases has a renewal option for an additional five years. The Company leases office equipment. This lease expires in 2022. The Company has elected the practical expedient to not recognize short term leases as assets but to expense its cost monthly. The Company has determined that it will capitalize approximately $4.4 million of right of use assets on January 1, 2019 and also recognize a lease liability of approximately $4.3 million. These assets and liabilities will be recognized over the applicable lease term.

The Company reviewed all other recently issued accounting pronouncements and concluded that they were either not applicable or not expected to have a material impact on the financial statements.

(u) Reclassifications

Reclassifications of certain 2017 balances were necessary to be consistent with the 2018 presentation.

Note 3. Significant Risks and Uncertainties

The Company's cash requirements for 2019 and beyond include expenses related to continuing development and clinical evaluation of its products and therapies, as well as related commercialization of its products. As of December 31, 2018 and 2017, the Company had working capital (current assets less current liabilities) of $65.6 million and $32.9 million, respectively.

On June 21, 2018, the Company closed the IPO of 5,980,000 shares of common stock at a price of $15.00 per share with net proceeds of $77.5 million, net of underwriting discount and other offering expenses. As a public company, additional future liquidity needs will include costs to comply with the requirements of a public company and tax payments to Federal and State governments.

The Company's expected cash requirements for 2019 and beyond are based on the continual development and clinical evaluation of its products and therapies. Based on the Company's available cash resources and cash flow projections, it believes it has sufficient funds to continue operations for at least the next 12 months. Until the Company can generate significant cash from its operations, the Company expects to continue to fund its operations with its available financial resources. To the extent additional funds are necessary to meet long-term liquidity needs as the Company continues to execute its business strategy, the Company anticipates that it will be obtained through the incurrence of indebtedness, equity financings or a combination of these potential sources of funds, although the Company can provide no assurance that these sources of funding will be available on reasonable terms.

The Company has foreign currency exchange risks related to revenue and operating expenses in currencies other than the local currencies in which they operate. The Company is exposed to currency risk from the potential changes in functional currency values of its foreign currency denominated assets, liabilities, and cash flows.

The Company primarily sells to one specialty pharmaceutical distributor in the United States. At December 31, 2018 and 2017, the accounts receivable related to this distributor was $195,730 and $31,740, respectively.

The Company is highly dependent upon the technical and management skills of several of its officers.

The Company's potential growth may cause a significant strain on its management, operational, and financial resources. Its ability to manage its growth effectively will require it to continue to implement and improve its operational and financial systems. The Company's success also depends in large part on a limited number of current key technical, marketing, and sales employees and on the Company's ability to continue to attract and retain additional highly talented personnel.

Note 4. Revenue Recognition

Performance Obligations

Revenue, net of specialty pharmaceutical distribution discounts, vouchers, rebates, and co-payment assistance is solely generated from the sales of the gammaCore products. Sales are made to a specialty pharmaceutical distributor ("customer") and 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 established wholesale acquisition cost less a contractually agreed upon distributor discount with the customer. Our revenue only reflects sales of gammaCore units exclusive of trade credits, vouchers, rebates, and co-payment assistance.

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

Beginning in February 2018, vouchers were used by physicians to provide new patients with a free initial 31-day therapy (i.e., one gammaCore device). Prior to mid-July 2018, the Company sold gammaCore units ("non-voucher units") to the distributor that would ultimately be dispensed under the voucher program in order to provide the one-time 31-day gammaCore therapy to patients at no charge. The revenue associated with the transaction price for the gammaCore units redeemed and estimated to be redeemed in this program were reduced by our reimbursement to the distributor for the patient cost of the gammaCore unit. Accordingly, the transaction price for the voucher units redeemed and estimated to be redeemed were recognized as contra-revenue. The costs 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 gammaCore and gammaCore Sapphire promotional units at no charge ("free voucher units"). 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 without the specialty pharmacy requiring reimbursement on behalf of the patient. In this way, the voucher program is more like a standard sample program where free voucher units 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.

During 2018, the Company dispensed approximately $4.7 million in product sales value to patients, $1.7 million in the last quarter of 2018, through its patient voucher and co-pay assistance programs that are not reflected in the net revenue. During 2017, the reimbursement for co-payment assistance was not considered material.

In accordance with Company policy, no allowance for product returns has been provided. Damaged or defective products are replaced at no charge under the Company's standard warranty. For the year ended December 31, 2018 and 2017, the replacement costs were immaterial.

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 contracts with customers do not give rise to contract assets or liabilities.

Payment for products is due in accordance with the terms agreed upon with customers, generally within 31 days of shipment to the customer. Accordingly, contracts with customers do not include a significant financing component.

Disaggregation of Net Sales

The following table provides additional information pertaining to net sales disaggregated by geographic market for the years ended December31, 2018 and 2017:

	For the Year Ended December 31,	
	2018	2017
Geographic Market		
United States	$ 619,772	$ 243,194
United Kingdom	300,091	273,741
Germany	53,784	265,451
Other	19,306	29,071
Total Net Sales	$ 992,953	$ 811,457

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, 2018 and 2017.

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

As of December 31, 2017

	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Fair Value
Cash and cash equivalents	$ 13,224,280	$ —	$ (86)	$ 13,224,194
Corporate Debt Securities	$ 19,014,590	$ 923	$ (17,827)	$ 18,997,686
Commercial Paper	2,979,367	—	(1,227)	2,978,140
U.S. Government Sponsored Agencies	1,496,824	—	(2,029)	1,494,795
Certificate of Deposits	480,000	—	(55)	479,945
Total marketable securities	$ 23,970,781	$ 923	$ (21,138)	$ 23,950,566
Total cash, cash equivalents and marketable securities	$ 37,195,061	$ 923	$ (21,224)	$ 37,174,760

The Company's corporate debt securities, commercial paper, U.S. government sponsored agency securities, and U.S. treasury bonds all mature within one year.

Note 6. Fair Value Measurements

Certain assets and liabilities are reported on a recurring basis at fair value. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- 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, 2018	**Total**	**(Level 1)**	**(Level 2)**	**(Level 3)**
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	$ —	$ —
December 31, 2017				
Assets				
Cash and cash equivalents	$ 13,224,194	$ 13,224,194	$ —	$ —
Marketable Securities:				
Corporate Debt Securities	18,997,686	18,997,686	—	—
Commercial Paper	2,978,140	2,978,140	—	—
U.S. Government Sponsored Agencies	1,494,795	1,494,795	—	—
Certificate of Deposits	479,945	479,945	—	—
Total	$ 37,174,760	$ 37,174,760	$ —	$ —
Liabilities				
Warrant liabilities	$ 2,239,544	$ —	$ —	$ 2,239,544

Cash and cash equivalents consisted of cash in bank checking and savings accounts, money market funds and U.S. treasury notes and are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices in active markets. Marketable securities are classified as Level 1 and consist of investments in corporate debt securities, commercial paper, and U.S. treasury bonds that are valued using quoted prices in active markets.

During the years ended December 31, 2018 and 2017, the Company has not changed the manner in which it values assets and liabilities that are measured at fair value using Level 3 inputs. 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, 2018 and 2017.

The warrant liability was recorded at fair value until the initial public offering on June 21, 2018 at which time it was determined that the outstanding warrants should be reclassified to equity as these warrants no longer met the criterion to be recognized as a liability. Until June 20, 2018, the Company determined the fair value of the liability using the probability weighted expected return method and option pricing models. This valuation method involved using inputs such as the fair value of the Company's Common Units, unit price volatility, the contractual term of the warrants, risk free interest rates and dividend yields. Due to the nature of these inputs, the valuation of the warrant liability was considered a Level 3 measurement.

As of June 20, 2018 and December 31, 2017, the estimated fair value of the warrant liability was computed using the following assumptions:

	June 20, 2018	December 31, 2017
Stock price volatility	67.8%	65.3%
Risk-free interest rates	2.68%	1.59%
Annual dividend yield	0%	0%
Expected life (years)	3.09	0.65

A roll-forward of the recurring fair value measurements of the liabilities categorized with Level 3 inputs are as follows:

	Warrant liabilities
Opening Balance as of January 1, 2017	$ 480,636
Additions	2,620,681
Settlements	—
Changes in fair value recognized	(861,773)
Balance as of December 31, 2017	2,239,544
Additions	—
Settlements	—
Changes in fair value recognized	1,870,923
Reclassed to equity	(4,110,467)
Balance as of December 31, 2018	$ —

On June 21, 2018, the warrant liability was reclassed to equity as addressed above.

The carrying amount of the Company's receivables and payables approximate their fair values due to their short maturities.

Note 7. Inventory

Inventories are stated at the lower of cost or net realizable value. Cost is determined on a first-in, first-out basis. During the year ended December 31, 2018, the Company determined that raw materials of $147,450 became obsolete due to the development of new product technology. This reserve was recognized in selling, general and administrative expenses. As of December 31, 2018 and 2017, inventories consisted of the following:

	December 31,	
	2018	2017
Raw materials	$ 821,704	$ 116,909
Work in process	951,695	17,115
Finished goods	176,003	193,763
	$ 1,949,402	$ 327,787

Note 8. Property and Equipment – Net

Property and equipment, net, as of December 31, 2018 and 2017 consisted of the following:

	December 31.	
	2018	2017
Machinery and equipment	$ 424,146	$ 452,614
Furniture and fixture	286,268	156,512
Computer equipment	20,783	138,534
Property and equipment - gross	731,197	747,660
Less accumulated depreciation and amortization	(350,293)	(579,014)
Property and equipment - net	$ 380,904	$ 168,646

During the year ended December 31, 2018, there was a write-off of $295,384 for fully depreciated assets in the Company's Bermuda subsidiary and Australian affiliate. Depreciation and amortization expense for the years ended December 31, 2018 and 2017 was $66,663 and $32,306, respectively.

Note 9. Other Assets

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 are deferred and recognized as other assets and will be amortized to expense over the noncancelable term of the arrangement. The Company incurred costs $395,404 thousand in CCA costs in 2018. The implementation of this CCA is expected to be completed by the second quarter of 2019.

Note 10. Accrued Expenses

Accrued expenses as of December 31, 2018 and 2017 consisted of the following:

	December 31,	
	2018	2017
Accrued professional fees	$ 1,273,249	$ 2,231,939
Accrued bonuses	2,152,264	659,333
Other accrued expenses	948,588	148,120
	$ 4,374,101	$ 3,039,392

Note 11. Net Loss Per Share

Basic earnings/(loss) per share is computed by dividing net income/(loss) available to electroCore, Inc. by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings per share is computed by dividing net income 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 earnings per share calculation as they have been determined to be anti-dilutive under the treasury stock method. As described in Note 12, 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 earnings (loss) per share would not be meaningful.

Prior to the Corporate Conversion, the Company's ownership structure included several different types of LLC interests including preferred stock, common units and Profits Interests (see Note 12, Corporate Conversion and Equity). The Company analyzed the calculation of earnings per unit for periods prior to the Corporate Conversion and determined that it resulted in values that would not be meaningful to the users of these consolidated financial statements. Therefore, earnings per share information has not been presented for periods prior to the Corporate Conversion on June 21, 2018. Net loss attributable to electroCore, Inc. subsidiaries and affiliate shown below includes the loss attributable to the period June 21, 2018 to December 31, 2018. In addition, the basic and diluted weighted average shares outstanding calculation for the period June 21, 2018 to December 31, 2018 is based on the actual days in which the shares were outstanding from June 21, 2018 to December 31, 2018.

The following table sets forth the numerators and denominators used to compute basic and diluted earnings per share of the common stock:

	For the period June 21, 2018 to December 31, 2018
Numerator – Basic and Diluted	
Net loss attributable to electroCore, Inc. subsidiaries and affiliate	$ (34,702,123)
Denominator – Basic and Diluted	
Weighted average shares of common stock outstanding	29,261,943
Net loss per common share, Basic and Diluted	$ (1.19)

Note 12. 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, 29,450,034 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 and on June 25, 2018 began trading on the Nasdaq Global Select 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 23,470,034 shares of common stock and options to purchase 2,141,748 shares of common stock as follows:

- holders of common units, or 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), or 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 15 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 15) 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 13. 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 14. Income Taxes

The provision for income taxes for the year ended December 31, 2018 relates only to state minimum taxes. The Company has incurred operating losses since inception in the US and in Germany and has not incurred any other income taxes. Prior to the Corporate Conversion on June 21, 2018, the Company was a limited liability company in the U.S., 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 U.S. 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.

The Tax Cuts and Jobs Act (the Act) was enacted in the U.S. on December 22, 2017. The Act reduced the U.S. federal corporate income tax rate to 21% from 35%, required companies to pay a one-time Transition Tax on earnings of certain foreign subsidiaries that were previously tax deferred, created new taxes on certain foreign-sourced earnings, and made broad and complex changes to the U.S. tax code, including changes to executive compensation and interest deduction limitations, and accelerated depreciation that will allow for full expensing of qualified property.

Additionally, Staff Accounting Bulletin No. 118 ("SAB 118") was issued to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Act. As of December 31, 2018, the Company completed its analysis based on legislative updates relating to the Act and note that the Act does not have an impact to the Company's accounts given that it was not a taxable entity when the Act was enacted, and its history of losses in foreign jurisdictions. The post-conversion corporate entity has accounted for the new U.S. federal corporate rate of 21% upon its conversion. The Company has also elected to account for potential inclusions under the new Global Intangible Low Tax Income (“GILTI”) regime as period costs.

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

Expected benefit for income taxes	21.0%
State tax expected benefit, net of federal benefit	2.6%
Nondeductible expenses	(2.9)%
Loss incurred as pass-through	(7.9)%
Change in valuation allowance for deferred tax assets	(12.8)%
Provision for income taxes	—%

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

Deferred tax assets	
Inventory	$ 66,935
Accrued expenses	735,910
Patent fees	290,098
Loss carryforwards and credits	7,578,570
Deferred rent and other	76,176
Gross deferred tax assets	8,747,689
Valuation allowance	(8,722,389)
Net deferred tax assets, net of valuation allowance	25,300
Deferred tax liabilities	
Fixed assets	(25,300)
Deferred tax liabilities	(25,300)
Total net deferred tax assets/(liabilities)	$ —

As of December 31, 2018, the Company has accumulated non-capital losses totaling $3,656,663 in Germany which can be carried forward indefinitely, and net operating losses of $24,575,093 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.

Under the provisions of the Internal Revenue Code, the net operating loss carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating loss carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50 percent, as defined under Section 382 of the Internal Revenue Code, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. The Company has not had an ownership change as a corporate entity thus has no limitations on its corporate losses. Future ownership changes may affect the use of U.S. net operating losses in future years.

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

	December 31, 2018
Domestic	$ (55,268,310)
Foreign	(494,714)
Total	$ (55,763,024)

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

Federal	$ —
State	2,431
Foreign	—
Total current	2,431
Total deferred	—
Total income tax expense/(benefit)	$ 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, 2018, the Company does not have an accrual relating to uncertain tax positions. It is not anticipated that unrecognized tax benefits would significantly increase or decrease within 12 months of the reporting date.

Note 15. Convertible Bridge Notes

During 2017, the Company issued Bridge Notes aggregating $19,965,692 together with associated 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 discussed in Note 12, the warrants were recorded as liabilities. 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 during 2018. At stated above, 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.

On August 18, 2017 (the initial Series B Preferred Unit closing), all Bridge Notes were converted to Series B Preferred Units (see Note 12 - Corporate Conversion and Equity).

Note 16. 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 Profits Interests to its employees and had forfeitures of 110,354 Profits Interests.

In connection with the Corporate Conversion, holders of 62,765,605 Common Units that were issued as "Profits Interests" that were 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 Profits Interests that were 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 initial exercise price of $15.00 per share.

The number of shares of common stock and the number of options issued for the outstanding Profits Interests was determined based upon the appreciation in value of the Company after the date of grant of the applicable Profits Interests through the completion of the IPO.

The number of shares of common stock issued for each Profits Interest (the "Conversion Shares") was equal to (x) the percentage of the capital account balance associated with such Profits Interest as it related to the total value of the Company at the IPO pre-money valuation (the "PI Capital Account Percentage"), divided by (y) the percentage interest in the Company represented by such Profits Interest on a Unit basis based on the total outstanding Units in the Company immediately prior to the IPO (the "PI Unit Percentage"), multiplied by (z) the total number of Units represented by the applicable Profits Interest. Of the shares of common stock issued for the Profits Interests, 1,157,139 vested immediately and 188,092 are subject to vesting of 25% on January 1, 2019 and the balance over the next succeeding 10 calendar quarters.

The number of options issued in respect of each Profits Interest (the "Conversion Options") 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 Profit Interests, 228,954 will vest 100% on January 1, 2019 and 1,912,797 will vest 25% on January 1, 2019 and the balance will vest 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 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 vest at the time of issuance, the Company recognized $1.2 million immediately. For the common stock awards and the options to purchase common stock that did not vest immediately, the Company will recognize $0.2 million and $1.4 million, respectively, using graded vesting over their respective vesting periods.

The incremental stock compensation expense to be recognized 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 their respective vesting periods.

On June 21, 2018, the Company adopted the 2018 Omnibus Equity Incentive 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 45.0 million shares, and a maximum of 40.0 million shares pursuant to the exercise of stock options. The options issued in conjunction with the corporate conversion were issued under this Plan. Subsequent to the corporate conversion there were 104,373 additional options granted in 2018 and 17,217 option that were cancelled due to forfeitures. At December 31, 2018 there were 3,859,178 shares available to be awarded under the plan.

The following table presents a summary of stock options issued in exchange for Profits Interests and stock options granted during the period June 21, 2018 to December 31, 2018:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Granted June 21, 2018	2,141,748	$ 15.00	
Granted June 22-December 31, 2018	104,373	12.76	
Exercised	—	—	
Cancelled	(17,217)	15.00	
Outstanding, December 31, 2018	2,228,904	$ 14.89	9.5

The vesting period for 228,954 of the options granted upon the IPO was on January 1, 2019; vesting period for 1,912,797 options and 14,158 options granted to employees immediately after the IPO was 25% on January 1, 2019, the remainder will vest in quarterly installment over the next succeeding 14 calendar quarters; the vesting period for 22,850 options issued to independent directors will vest one third on each of the next three succeeding dates of the Annual Stockholder’s meetings, and the vesting period for the remaining options is 25% on the anniversary of the employee’s start date and the remainder over the next succeeding 12 calendar quarters.

The following table presents a summary of restricted stock awards issued in exchange for Profits Interests on June 21, 2018:

	Number of Shares	Weighted Average Grant Date Fair Value
Granted June 21, 2018	1,345,231	$ 15.00
Granted June 22-December 31, 2018	—	—
Exercised	—	—
Cancelled	(2,521)	15.00
Outstanding, December 31, 2018	1,342,710	$ 15.00

The following table presents a summary of restricted and deferred stock units awarded in 2018:

	Number of Shares	Weighted Average Grant Date Fair Value
Granted June 21, 2018	79,998	$ 15.00
Exercised	—	—
Cancelled	—	—
Outstanding, December 31, 2018	79,998	$ 15.00

These awards will vest one third on each of the next three succeeding dates of the Annual Stockholder's meetings. The grant date fair value of these awards was $15.

For the years ended December 31, 2018 and 2017, stock compensation expense reported as a component of selling, general and administrative expense was $4.5 million and $0.4 million, respectively. For the same period, stock compensation expense reported as a component of research and development expense was $2.8 million and $0.05 million, respectively. For the years ended December 31, 2018 and 2017, stock compensation expense reported as a component of cost of goods sold was $0.2 million and $0.1 million, respectively, and $0.1 million was recognized as promotional expense for free units under the Company's free goods program. Total unrecognized compensation cost related to unvested awards as of December 31, 2018 was $5.2 million and is expected to be recognized over the next 3.2 years.

Valuation Information for Stock-Based Compensation

For purposes of determining estimated fair value under FASB ASC 718-10, the Company computed the estimated fair values of stock options using the Black-Scholes model. The fair value of stock options issued during 2018 are provided in the following table:

Period Granted	# Options	Exercise Price ($)	Expected Volatility (%)	Risk-Free Interest Rate (%)	Expected Dividend Yield (%)	Expected Term (Years)
June 2018	20,658	15.00	74.30-74.80	2.794	0.0	6.1
June 2018	22,850	15.00	74.80	2.775	0.0	6.0
August 2018	1,665	15.00	56.41	2.769	0.0	6.1
September 2018	13,600	14.00	62.25 - 64.40	2.769 - 2.912	0.0	6.1
October 2018	24,000	11.65 - 14.28	57.83 - 61.20	2.981 - 3.070	0.0	6.1
November 2018	6,500	10.30	56.29	3.000	0.0	6.6
December 2018	15,100	4.96 - 6.80	63.13 - 72.31	2.866 - 2.715	0.0	6.6

The risk-free interest rate is the average U.S. Treasury rate with a term that most closely resembles the expected life of the award. The expected term of the award was calculated using the simplified method. For volatility, the Company uses comparable public companies as a basis for its expected volatility. The Company does not pay regular dividends on its common stock and does not anticipate paying any dividends in the foreseeable future.

Note 17. 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, 2018 and 2017.

Note 18. Selected Quarterly Financial Data (Unaudited)

The following table presents quarterly unaudited financial data for the periods presented on the consolidated statements of operations (in thousands, except per share amounts):

	2018 Quarter Ended				
	March 31	June 30	September 30	December 31	Total
Net sales	$ 81	$ 393	$ 151	368	$ 993
Total operating expenses	9,131	16,374	13,606	15,857	54,968
Loss from operations	(9,099)	(16,222)	(13,552)	(15,681)	(54,554)
Net loss from operations attributable to Electrocore LLC and electroCore, Inc.	(9,499)	(17,782)	(13,204)	(15,335)	(55,820)
Net loss attributable to Electrocore LLC	(9,499)	(11,619)	—	—	(21,118)
Net loss attributable to electroCore, Inc.	— *	(6,163)	(13,204)	(15,335)	(34,702)
Loss per share attributable to common stockholders basic and diluted of electroCore, Inc.	$ — *	$ (0.21)	$ (0.45)	$ (0.52)	$ (1.19)

* No loss for electroCore, Inc. or per share amount as Company was not public until June 21, 2018

	2017 Quarter Ended				
	March 31	June 30	September 30	December 31	Total
Net sales	$ 117	$ 177	$ 283	234	$ 811
Total operating expenses	4,785	7,569	6,143	7,441	25,938
Loss from operations	(4,741)	(7,431)	(5,988)	(7,485)	(25,645)
Net loss attributable to Electrocore LLC	$ (6,357)	$ (11,568)	$ (12,362)	$ (5,505)	$ (35,792)

Note 19. Commitments and Contingencies

Operating Lease

The Company leases office, warehouse and manufacturing space and office equipment under operating leases through April 2024. The real estate leases have options to renew for five years which the Company is reasonably certain it will exercise. Future minimum lease payments under non-cancelable operating leases (with initial or remaining lease terms in excess of one year) as of December 31, 2018 are as follows:

Year ended December 31,	
2019	$ 576,743
2020	714,616
2021	692,893
2022	737,324
Five years and beyond	3,696,796
	$ 6,418,372

For the years ended December 31, 2018 and 2017, rental expense related to the leases was $496,055 and $493,067.

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 $6.8 million as of December 31, 2018.

Legal Proceedings

From time to time, the Company 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, the Company is not subject to any material legal proceedings.

Note 20. Subsequent Events

Employee Stock Purchase Plan

Effective January 1, 2019, the Company adopted the 2019 Employee Stock Purchase Plan. The Plan is to provide 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 is:

(a) 300,000 shares, plus

(b) an annual increase to be added as of the first day of the Company's fiscal year, beginning in 2020 and occurring each year thereafter through 2029, equal to 1% of the total number of Shares of Common Stock issued and outstanding on a fully-diluted basis as of the end of the Company's immediately preceding fiscal year (or such lesser number of Shares, including no Shares, determined by the Administrator); provided, however, that the aggregate number of additional Shares available for issuance pursuant to this paragraph (b) shall not exceed a total of 4,500,000 Shares.

Settlement Agreement

In January 2019, the Company 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, 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 our common stock at prices ranging from $5.68 per share to $12.60 per share. Substantially all of 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. On March 15, 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 is consulting with legal counsel on this matter and intends to vigorously assert its defenses to the alleged claims but cannot predict the outcome of the matter at this time. However, the financial impact, if any, in connection with the resolution of this matter is not expected to be material.

Exhibit 10.19

LEASE AGREEMENT

ANSON LOGISTICS ASSETS LLC
Landlord

AND

ELECTROCORE, INC.
Tenant

AT

200 Forge Way
Rockaway, New Jersey

LEASE AGREEMENT

THIS LEASE AGREEMENT is made by and between **ANSON LOGISTICS ASSETS LLC,** a Delaware limited liability company ("Landlord") and **ELECTROCORE, INC.,** a Delaware corporation ("Tenant"), and is dated as of the date on which this Lease has been fully executed by Landlord and Tenant.

1. Basic Lease Terms and Definitions.

(a) Premises: Suite 205, consisting of approximately 13,643 rentable square feetas shown on **Exhibit "A".**

(b) **Building:** Approximate rentable square feet: 72,620

Address: 200 Forge Way, Rockaway, New Jersey 07866

(c) **Term:** 62 months (plus any partial month from the Commencement Date until the first day of the next full calendar month during the Term). In the event that Tenant validly exercises the Renewal Option pursuant to Section 30 of this Lease, then all references herein to the "Term" shall be deemed to include the Renewal Term.

(d) **Commencement Date:** The earlier of (i) the date that the Tenant Improvements are Substantially Completed, estimated to be November 1, 2018 (the "Estimated Commencement Date"), or (ii) the date Tenant commences business operations in the Premises.

(e) **Expiration Date:** 11:59 p.m. on the last day of the Term.

(f) **Minimum Annual Rent:** Payable in monthly installments as follows:

Period (in months)	Annual	Monthly
1 - 2 (the "Free Rent Period")	***NIA***	$0.00
3-12	***NIA***	$10,800.71
13-24	$132,848.76	$11,070.73
25-36	$136,170.00	$11,347.50
37-48	$139,574.28	$11,631.19
49-60	$143,063.64	$11,921.97
61 -62	***NIA***	$12,220.02

Notwithstanding anything to the contrary, during the Free Rent Period, Tenant shall be liable for payment of all Annual Operating Expenses as set forth in Sections 5 and 6 hereof and all utilities as set forth in Section 7 hereof. The abatement of Minimum Annual Rent provided for herein is conditioned upon Tenant's full and timely performance of all of its obligations under this Lease. If at any time during the Term an Event of Default by Tenant occurs, the abatement of Minimum Annual Rent provided for herein shall immediately become void, and Tenant shall promptly pay to Landlord, in addition to all other amounts due to Landlord under this Lease, the full amount of all Minimum Annual Rent herein abated.

(g) **Annual Operating Expenses:** $47,341.21, payable in monthly installments of $3,945.10, subject to adjustment as provided in this Lease.

(h) **Tenant's Share:** 18.79% (also see Additional Definitions).

(i) **Use:** Warehouse, light manufacturing, distribution and research and development with appurtenant offices and lawful activities normally incidental thereto, subject to Tenant, at Tenant's sole cost and expense, obtaining any Permits required for Tenant's specific use and occupancy of the Premises and to Tenant determining the suitability of the Premises for Tenant's intended use thereof (excluding any Permits required in connection with the construction of the Tenant Improvements).

(j) **Security Deposit:** $29,491.62.

(k) Addresses For Notices:

Landlord:

c/o Mapletree US Management, LLC
275 7th Avenue, Suite 746, Floor 7
New York, NY 10001

With a copy to:

Exeter Property Group
101 West Elm Street, Suite 600
Conshohocken, PA 19428
Attn: Chief Financial Officer

Tenant:

Before the Commencement Date:

electroCore, Inc.
150 Allen Road, Suite 201
Basking Ridge, NJ 07920
Attention: Vice President, Corporate Comptroller

After the Commencement Date:

electroCore, Inc.
150 Allen Road, Suite 201
Basking Ridge, NJ 07920
Attention: Vice President, Corporate Comptroller

(l) **Additional Definitions:** See Rider for the definitions of other capitalized terms.

(m) Contents: The following are attached to and made a part of this Lease:

Rider - Additional Definitions	Exhibits:	"A" - Plan showing Premises "B" - Building Rules "C" - Tenant Improvements "C-1" - Space Plan "D" - Landlord Lien Subordination Agreement

2. Premises. Landlord leases to Tenant and Tenant leases from Landlord the Premises, together with the right in common with others to use the Common Areas. Tenant accepts the Premises, Building and Common Areas "AS IS", without relying on any representation, covenant or warranty by Landlord other than as expressly set forth in this Lease. Landlord and Tenant stipulate and agree to the rentable square footage set forth in Section 1 above without regard to actual measurement.

(a) Landlord shall cause to be constructed, in compliance with applicable Laws, the improvements, modifications and alterations to the Premises set forth on and in accordance with Exhibits "C" and "C-1" (collectively, the "Tenant Improvements"). In constructing the Tenant Improvements, Landlord shall use Building standard materials and finishes (unless otherwise provided on Exhibits "C" and "C-1") and Landlord reserves the right, subject to Tenant's reasonable approval, to make substitutions of material of equivalent grade and quality if any specified material shall not be readily and reasonably available. Upon the Tenant Improvements being Substantially Completed, Landlord shall notify Tenant, and Tenant or its Agents shall inspect the Tenant Improvements with Landlord within five (5) business days of receipt of such notice from Landlord. Within five (5) business days following such inspection, Tenant shall deliver to Landlord a punchlist of defective or incomplete portions of the Tenant Improvements. Landlord shall cause such punchlist items to be repaired or completed within thirty (30) days of Landlord's receipt of the punchlist. Upon completion of all punchlist items to Tenant's reasonable satisfaction, it shall be presumed that all of the Tenant Improvements shall be free from readily discoverable defects in materials and workmanship, excluding however, all repairs required in connection with routine maintenance and those repairs caused by Tenant.

(b) Notwithstanding the foregoing, in the event that the Tenant Improvements are not Substantially Completed on or before the Estimated Commencement Date, in whole or in part, due to Tenant Delay, then Tenant's obligation to pay Rent hereunder shall not be affected or deferred on account of such delay and, the Commencement Date shall be deemed to be the Estimated Commencement Date and the Term shall be extended for the number of days attributable to Tenant Delay (and Minimum Annual Rent during such extended period shall be the Minimum Annual Rent attributable to the last year of the initial Term of the Lease).

(c) Following the determination of the Commencement Date, the parties shall execute a commencement date memorandum memorializing the Commencement Date, Free Rent Period, Expiration Date, Tenant's acceptance of the Premises and such other items reasonably requested by Landlord.

(d) Notwithstanding the foregoing, upon the Commencement Date, Landlord, at Landlord's sole cost and expense, shall deliver the Premises in compliance with all applicable Laws and shall deliver the roof, walls, floors and all sprinkler, lighting, loading, mechanical, electrical, heating and cooling and plumbing systems servicing the Premises in good working order, provided, however, that Landlord's obligations under this Section 2(d) shall exclude damages or defects to such items caused by Tenant and Tenant's Agents.

3. Use. Tenant shall occupy and use the Premises only for the Use specified in Section 1 above. Tenant shall not permit any conduct or condition which may endanger, unreasonably disturb or otherwise unreasonably interfere with any other Building occupant's normal operations or with the management of the Building. Tenant shall not use or permit the use of any portion of the Property for outdoor storage or installations outside of the Premises. Tenant may use all Common Areas only for their intended purposes. Landlord shall have exclusive control of all Common Areas at all times.

4. Term; Possession. The Term of this Lease shall commence on the Commencement Date and shall end on the Expiration Date, unless sooner terminated in accordance with this Lease. If Landlord is delayed in delivering possession of all or any portion of the Premises to Tenant as of the Commencement Date, Tenant will take possession on the date Landlord delivers possession, which date will then become the Commencement Date (and the Expiration Date will be extended so that the length of the Term remains unaffected by such delay). Landlord shall not be liable for any loss or damage to Tenant resulting from any delay in delivering possession due to the holdover of any existing tenant or other circumstances outside of Landlord's reasonable control.

5. Rent; Taxes. Tenant agrees to pay to Landlord, without demand, deduction or offset, Minimum Annual Rent and Annual Operating Expenses for the Term. Tenant shall pay the Monthly Rent, in advance, on the first day of each calendar month during the Term, at Landlord's address designated in Section 1 above unless Landlord designates otherwise; provided that the Minimum Annual Rent for the first full year (including the Free Rent Period) shall be paid at the signing of this Lease (i.e., $108,007.10). If the Commencement Date is not the first day of the month, the Monthly Rent for that partial month shall be apportioned on a per diem basis and shall be paid on or before the Commencement Date. Tenant shall pay Landlord a service and handling charge equal to 5% of any Rent not paid within 5 days after the date due. In addition, any Rent, including such charge, not paid within 5 days after the due date will bear interest at the Interest Rate from the date due to the date paid. Tenant shall pay before delinquent all taxes levied or assessed upon, measured by, or arising from: (a) the conduct of Tenant's business; (b) Tenant's leasehold estate; or (c) Tenant's property and trade fixtures. Additionally, Tenant shall pay to Landlord all sales, use, transaction privilege, or other excise tax that may at any time be levied or imposed upon, or measured by, any amount payable by Tenant under this Lease.

6. Operating Expenses. The amount of the Annual Operating Expenses set forth in Section 1 above represents Tenant's Share of the estimated Operating Expenses for the calendar year in which the Term commences. Landlord may adjust such amount from time to time if the estimated Annual Operating Expenses increase or decrease; Landlord may also invoice Tenant separately from time to time for Tenant's Share of any extraordinary or unanticipated Operating Expenses. Each year (and as soon as practical after the expiration or termination of this Lease or, at Landlord's option, after a sale of the Property), Landlord shall provide Tenant with a statement of Operating Expenses ("Statement") for the preceding calendar year or part thereof. Landlord shall endeavor to provide Tenant such statement within 150 days of the calendar year end. Within thirty (30) days after delivery of the Statement to Tenant, Landlord or Tenant shall pay to the other the amount of any overpayment or deficiency then due from one to the other or, at Landlord's option, if applicable, Landlord may credit Tenant's account for any overpayment. If Tenant does not give Landlord notice within ninety (90) days after receiving the Statement that Tenant disagrees with such Statement and specifying the items and amounts in dispute, Tenant shall be deemed to have waived the right to contest such Statement. If Tenant disagrees with the Statement and specifies the items and amounts in dispute, Tenant shall, pending the resolution of such dispute, nonetheless pay all of Tenant's Annual Operating Expenses in accordance with such Statement. Upon the resolution of such dispute, the amount due Tenant (if any) shall be credited against future payments of Rent, or, if the Term has expired, Landlord shall promptly (and in any event within thirty (30) days of such resolution) pay to Tenant the amount of any overpayment. Landlord's and Tenant's obligation to pay any overpayment or deficiency due the other pursuant to this Section shall survive the expiration or termination of this Lease. Notwithstanding any other provision of this Lease to the contrary, Landlord may, in its reasonable discretion, determine from time to time the method of computing and allocating Operating Expenses, including the method of allocating Operating Expenses to various types of space within the Building to reflect any disparate levels of services provided to different types of space. If the Building is not fully occupied during any period, Landlord may make a reasonable adjustment based on occupancy in computing the Operating Expenses for such period so that Operating Expenses are computed as though the Building had been fully occupied.

Tenant may audit the Statement under the following conditions: (A) Tenant provides notice of its intent to audit within 90 days after receiving the Statement (which notice shall not be deemed a waiver by Tenant of its rights to contest such Statement); (B) the audit is performed by Tenant or a certified public accountant that has not been retained on a contingency basis or other basis where its compensation relates to the cost savings of Tenant; (C) the audit is completed no later than 30 days after the date Landlord makes all of the necessary books and records available to Tenant or Tenant's auditor; (D) the audit must be conducted during normal business hours, at the location where Landlord maintains its books and records; (E) the contents of the books and records of Landlord shall be kept confidential by Tenant, its auditor and its other professional advisors, other than in the case of any lawsuit concerning such Statement or as required by Laws; and (F) in the event that Tenant or its auditor determines that an overpayment is due Tenant, Tenant or Tenant's auditor shall produce a detailed report addressed to both Landlord and Tenant with its calculated conclusions within 10 days after the completion of the audit. Landlord and Tenant shall work together in good faith to resolve any issues raised in Tenant's audit. Tenant shall be responsible for all costs, expenses and fees incurred in connection with its audit. Upon the resolution of such dispute, any amount due Tenant shall be credited against future payments of Minimum Annual Rent or, if no further Minimum Annual Rent is due, Landlord shall pay such amount to Tenant within 30 days after the date of such resolution. Landlord's obligation to pay any deficiency due Tenant pursuant to this Section shall survive the expiration or termination of this Lease. If the Operating Expenses for the period covered by the applicable Statement have been overstated by more than ten percent (10%), then Landlord shall reimburse Tenant for the reasonable cost and expenses incurred by Tenant in connection with Tenant's audit, not to exceed $2,500.

7. Utilities.

(a) Tenant shall pay for water, sewer, gas, electricity, heat, power, telephone and other communication services and any other utilities supplied to the Premises. Except for any utilities that are not separately metered (for which Landlord shall invoice Tenant for the cost or include the cost in Operating Expenses), Tenant shall obtain utility service in its own name and timely pay all charges directly to the provider. In the event that any meter serving the Premises is not functioning properly or during the period that such meter is being repaired, Tenant shall be responsible for its pro rata share of utility usage based upon Landlord's reasonable estimate. Landlord shall not be responsible or liable for any interruption in such services, nor shall such interruption affect the continuation or validity of this Lease. Notwithstanding anything to the contrary in this Lease, in the event that an interruption in utilities or services that Landlord is required to provide ("Interruption") is directly caused by the sole negligence or willful misconduct of Landlord or its Agents, such that it renders the whole or any material portion of the Premises untenantable for the purposes intended hereunder and Tenant is unable to utilize such untenantable portion then after a period of five (5) consecutive business days after receipt by Landlord of written notice of such untenantability from Tenant, the Monthly Rent shall abate (as to the proportion that the square footage of the Premises actually untenantable by Tenant as a result of an Interruption bears to the total square footage of the Premises) starting on the sixth (6th) business day until the earlier to occur of the date that Tenant re-enters the Premises or the date that such Interruption is remedied. In no event shall Tenant be entitled to abatement if the Interruption is caused in whole or in part by Tenant or Tenant's Agents. Tenant agrees that the rental abatement described in this Section shall be Tenant's sole remedy in the event of an Interruption. Notwithstanding anything to the contrary, Tenant shall waive and release Landlord from and against, all claims of rental abatement as provided above to the extent covered by Tenant's business interruption insurance. Landlord shall have the exclusive right to select, and to change, the companies providing such services to the Building or Premises. Any wiring, cabling or other equipment necessary to connect Tenant's telecommunications equipment shall be Tenant's responsibility, and shall be installed in a manner approved by Landlord. In the event Tenant's consumption of any utility or other service included in Operating Expenses is excessive when compared with other occupants of the Property, Landlord may invoice Tenant separately for, and Tenant shall pay on demand, the cost of Tenant's excessive consumption, as reasonably determined by Landlord.

(b) From time to time, at Landlord's option, Landlord may estimate the monthly cost for all utilities that are not being directly metered and billed to Tenant and bill Tenant the estimated amount therefor. All such estimated amounts shall be paid together with Monthly Rent. Landlord shall deliver to Tenant at least annually (or more frequently at Landlord's election) a statement indicating the actual amount of Tenant's share of such utilities based upon the actual utility invoiced (as may be applicable). If any reconciliation of utilities reveals that any additional payments are due, Tenant shall pay such deficiency to Landlord within fifteen (15) days after invoice therefor. If the reconciliation reveals that Tenant has overpaid utilities for such period, Landlord shall credit such overpayment against Rent hereunder, or if the Term has expired, pay such amount to Tenant. Landlord's and Tenant's obligation to pay any overpayment or deficiency due the other pursuant to this Section shall survive the expiration or termination of this Lease.

8. Insurance; Waivers; Indemnification.

(a) Landlord shall maintain insurance against loss or damage to the Building or the Property with coverage for perils as set forth under the "Causes of Loss-Special Form" or equivalent property insurance policy in an amount equal to the full insurable replacement cost of the Building (excluding coverage of Tenant's personal property and any Alterations by Tenant), and such other insurance, including rent loss coverage, as Landlord may reasonably deem appropriate or as any Mortgagee may require.

(b) Tenant, at its expense, shall keep in effect commercial general liability insurance, including blanket contractual liability insurance, covering Tenant's use of the Property, with such coverages and limits of liability as Landlord may reasonably require, but not less than a $1,000,000 combined single limit with a $3,000,000 general aggregate limit (which general aggregate limit may be satisfied by an umbrella liability policy) for bodily injury or property damage; however, such limits shall not limit Tenant's liability hereunder. The policy shall name Landlord and any other associated or affiliated entity as their interests may appear and at Landlord's request, any Mortgagee(s), as additional insureds, shall be written on an "occurrence" basis and not on a "claims made" basis and shall be endorsed to provide that it is primary to and not contributory to any policies carried by Landlord and to provide that it shall not be cancelable or reduced without at least thirty (30) days prior notice to Landlord. The insurer shall be authorized to issue such insurance, licensed to do business and admitted in the state in which the Property is located and rated at least A VII in the most current edition of *Best's Insuran•ce Reports.* Tenant shall deliver to Landlord on or before the Commencement Date or any earlier date on which Tenant accesses the Premises, and at least twenty (20) days prior to the date of each policy renewal, a certificate of insurance evidencing such coverage.

(c) Landlord and Tenant each waive, and release each other from and against, all claims for recovery against the other for any loss or damage to the property of such party arising out of fire or other casualty coverable by a standard "Causes of Loss-Special Form" property insurance policy with, in the case of Tenant, such endorsements and additional coverages as are considered good business practice in Tenant's business, even if such loss or damage shall be brought about by the fault or negligence of the other party or its Agents; provided, however, such waiver by Landlord shall not be effective with respect to Tenant's liability described in Section 10(d) below. This waiver and release is effective regardless of whether the releasing party actually maintains the insurance described above in this subsection and is not limited to the amount of insurance actually carried, or to the actual proceeds received after a loss. Each party shall have its insurance company that issues its property coverage waive any rights of subrogation, and shall have the insurance company include an endorsement acknowledging this waiver, if necessary. Tenant assumes all risk of damage of Tenant's property within the Property, including any loss or damage caused by water leakage, fire, windstorm, explosion, theft, act of any other tenant, or other cause, except to the extent caused by the negligence or willful misconduct of Landlord or its Agents.

(d) Subject to subsection (c) above, and except to the extent caused by the negligence or willful misconduct of Landlord or its Agents, Tenant will indemnify, defend, and hold harmless Landlord and its Agents from and against any and all claims, actions, damages, liabilities and expenses (including reasonable out-of-pocket fees of attorneys, investigators and experts) which may be asserted against, imposed upon, or incurred by Landlord or its Agents and arising out of or in connection with loss of life, personal injury or damage to property in or about the Premises or arising out of the occupancy or use of the Property by Tenant or its Agents or occasioned wholly or in part by any act or omission of Tenant or its Agents, whether such act or omission occurred prior to, during or after the Term. Tenant's obligations pursuant to this subsection shall survive the expiration or termination of this Lease.

(e) Subject to subsection (c) above, and except to the extent caused by the negligence or willful misconduct of Tenant or its Agents, Landlord will indemnify, defend, and hold harmless Tenant and its Agents from and against any and all claims, actions, damages, liability and expense (including fees of attorneys, investigators and experts) which may be asserted against, imposed upon, or incurred by Tenant or its Agents and arising out of or in connection with loss of life, personal injury or damage to property on or about the Common Areas to the extent caused by any negligent act or omission or willful misconduct of Landlord or its Agents, whether prior to, during or after the Term. Landlord's obligations pursuant to this subsection shall survive the expiration or termination of this Lease.

9. Maintenance and Repairs.

(a) Landlord shall Maintain the: (i) Building footings, foundations, structural steel columns and girders at Landlord's sole expense; (ii) Building roof and exterior walls; (iii) Building Systems; and (iv) Common Areas. Costs incurred by Landlord under the foregoing subsections (ii), (iii) and (iv) will be included in Operating Expenses. If Tenant becomes aware of any condition that is Landlord's responsibility to repair, Tenant shall promptly notify Landlord of the condition.

(b) Except as provided in subsection (a) above, Tenant at its sole expense shall Maintain the Premises, including, but not limited to, all lighting, plumbing fixtures, walls, partitions, dock doors, loading areas, floors, doors, windows, fixtures and equipment in the Premises. All repairs and replacements by Tenant shall utilize materials and equipment which are comparable to those originally used in constructing the Building and Premises. Alterations, repairs and replacements to the Property, including the Premises, made necessary because of Tenant's Alterations or installations, any use or circumstances special or particular to Tenant, or any act or omission of Tenant or its Agents shall be made by Landlord or Tenant as set forth above, but at the sole expense of Tenant to the extent not covered by any applicable insurance proceeds paid to Landlord.

10. Compliance.

(a) Tenant will, at its expense, promptly comply with all Laws now or subsequently pertaining to the Premises or Tenant's use or occupancy and obtain all Permits necessary for Tenant's use, occupancy and/or business conducted at the Premises. Neither Tenant nor its Agents shall use the Premises in any manner that under any Law would require Landlord to make any Alteration to or in the Building or Common Areas (without limiting the foregoing, Tenant shall not use the Premises in any manner that would cause the Premises or the Property to be deemed a "place of public accommodation" under the ADA if such use would require any such Alteration). Tenant shall be responsible for compliance with the ADA, and any other Laws regarding accessibility, with respect to the Premises.

(b) Tenant will comply, and will cause its Agents to comply, with the Building Rules, provided that no modifications or additions shall be inconsistent with or in limitation of the provisions of this Lease or have any material adverse effect on Tenant's rights hereunder.

(c) Tenant agrees not to do anything or fail to do anything which will increase the cost of Landlord's insurance or which will prevent Landlord from procuring policies (including public liability) from companies and in a form satisfactory to Landlord. If any breach of the preceding sentence by Tenant causes the rate of fire or other insurance to be increased, Tenant shall pay the amount of such increase as additional Rent within thirty (30) days after being billed.

(d) Tenant acknowledges and agrees that it has received and reviewed a copy of that certain Phase I Environmental Site Assessment dated September 28, 2015 prepared by URS Corporation (the "Environmental Report"). Landlord has no Actual Knowledge of any Hazardous Materials being present at the Property in violation of Environmental Laws, except to the extent set forth in the Environmental Report. Tenant agrees that (i) no activity will be conducted on the Premises that will use or produce any Hazardous Materials, except for activities which are part of the ordinary course of Tenant's business and are conducted in accordance with all Environmental Laws ("Permitted Activities"); (ii) the Premises will not be used for storage of any Hazardous Materials, except for materials used in the Permitted Activities which are properly stored in a manner and location complying with all Environmental Laws; (iii) no portion of the Premises or Property will be used by Tenant or Tenant's Agents for disposal of Hazardous Materials; (iv) Tenant will deliver to Landlord copies of all Material Safety Data Sheets and other written information prepared by manufacturers, importers or suppliers of any chemical; and (v) Tenant will immediately notify Landlord of any violation by Tenant or Tenant's Agents of any Environmental Laws or the release or suspected release of Hazardous Materials in, under or about the Premises, and Tenant shall immediately deliver to Landlord a copy of any notice, filing or permit sent or received by Tenant with respect to the foregoing. If at any time during or after the Term, any portion of the Property is found to be contaminated by Tenant or Tenant's Agents or subject to conditions prohibited in this Lease caused by Tenant or Tenant's Agents, Tenant will indemnify, defend and hold Landlord harmless from all claims, demands, actions, liabilities, costs, expenses, reasonable out-of-pocket attorneys' fees, damages and obligations of any nature arising from or as a result thereof, and Landlord shall have the right to direct remediation activities, all of which shall be performed at Tenant's cost (which cost shall include the Administrative Fee). Tenant's obligations pursuant to this subsection shall survive the expiration or termination of this Lease. Except to the extent caused by, contributed to or exacerbated by the actions of Tenant or its Agents, Landlord will indemnify, defend and hold Tenant harmless from all losses, damages and expense incurred by Tenant as a result of any Hazardous Materials that are conclusively determined by an independent third party reasonably acceptable to Landlord and Tenant, to have been released or emitted within the Property either (a) prior to Tenant's access, occupancy or possession of the Premises, or (b) by Landlord or Landlord's Agents at any time before, during or after the Lease Term. Landlord's obligations pursuant to this subsection shall survive the expiration or termination of this Lease.

(e) Tenant's shall not operate any business at the Premises which has a North American Industry Classification System ("NAICS") code or other applicable designation that is subject to the Industrial Site Recovery Act, N.J.S.A. 13:1K- 6, et seq., and the regulations promulgated thereunder. Tenant hereby represents that its NAICS number is 334510, as determined by reference to the 2002 NAICS Manual published by the United States Office of Management and Budget or amendments thereto. Tenant's obligations pursuant to this subsection shall survive the expiration or termination of this Lease.

11. **Signs.** Tenant shall not place any signs on the Property without the prior consent of Landlord, other than signs that are located wholly within the interior of the Premises and not visible from the exterior of the Premises, which consent shall not be unreasonably withheld, conditioned or delayed. Tenant shall maintain all signs installed by Tenant in good condition. Tenant shall remove its signs at the termination of this Lease, shall repair any resulting damage, and shall restore the Property to its condition existing prior to the installation of Tenant's signs. Tenant shall have the non-exclusive right, at Tenant's sole cost and expense, to install and maintain signage with Tenant's name and logo on the Building monument sign along with other tenants' names on such Building monument sign, which sign panel shall be subject to Landlord's prior written consent. Upon the expiration or earlier termination of this Lease, Tenant shall remove its sign panel from the Building monument sign and shall repair all damage occasioned thereby.

12. **Alterations.** Except for non-structural Alterations that (i) do not exceed $10,000 in the aggregate for any twelve (12) month period, (ii) are not visible from the exterior of the Premises, (iii) do not affect any Building System or the structural strength of the Building,(iv) do not require penetrations into the floor, roof, ceiling or walls, and (v) do not require work on the roof or within the walls, below the floor or above the ceiling, Tenant shall not make or permit any Alterations in or to the Premises without first obtaining Landlord's consent, which consent shall not be unreasonably withheld, conditioned or delayed. With respect to any Alterations that do not require Landlord's consent, Tenant shall nonetheless provide written notice thereof to Landlord, describing in reasonable detail the nature of the Alteration. With respect to any Alterations made by or on behalf of Tenant (whether or not the Alteration requires Landlord's consent): (1) not less than ten (10) days prior to commencing any Alteration, Tenant shall deliver to Landlord the plans, specifications and necessary permits for the Alteration, if applicable, together with certificates evidencing that Tenant's contractors and subcontractors have adequate insurance coverage naming Landlord and any other associated or affiliated entity as their interests may appear as additional insureds, (2) Tenant shall obtain Landlord's prior written approval of any contractor or subcontractor, (3) the Alteration shall be constructed with new materials, in a good and workmanlike manner, and in compliance with all Laws and, if applicable, the plans and specifications delivered to, and, if required above, approved by Landlord, (4) Tenant shall pay Landlord all reasonable costs and expenses in connection with Landlord's review of Tenant's plans and specifications, and of any supervision or inspection of the construction Landlord reasonably deems necessary, and (5) upon Landlord's request Tenant shall, prior to commencing any Alteration, provide Landlord reasonable security against liens arising out of such construction. Any Alteration by Tenant shall be the property of Tenant until the expiration or termination of this Lease; at that time without payment by Landlord the Alteration shall remain on the Property and become the property of Landlord unless Landlord gives notice to Tenant to remove it, in which event Tenant will remove it, will repair any resulting damage and will restore the Premises to the condition existing prior to Tenant's Alteration. At Tenant's request prior to Tenant making any Alterations, Landlord will notify Tenant whether Tenant is required to remove the Alterations at the expiration or termination of this Lease. Notwithstanding anything to the contrary in this Section 12, Tenant may install and shall be entitled to remove its trade fixtures, furniture and equipment in the Premises, provided that the installation and removal of them will not affect any structural portion of the Property, any Building System or any other equipment or facilities serving the Building or any occupant.

Provided there is no Event of Default at the time of Tenant's request and at the time of the execution of such agreement, Landlord agrees to execute, from time to time after receipt of Tenant's written request therefor, an agreement subordinating Landlord's lien in Tenant's personal property, furniture, fixtures, equipment and other assets (excluding, however, the Tenant Improvements and as otherwise set forth herein), in form reasonably acceptable to Landlord and Tenant and its lender(s), substantially in the form attached hereto as Exhibit "D".

13. **Mechanics' Liens.** Tenant shall pay promptly for any labor, services, materials, supplies or equipment furnished to Tenant in or about the Premises. Tenant shall keep the Premises and the Property free from any liens arising out of any labor, services, materials, supplies or equipment furnished or alleged to have been furnished to Tenant. Tenant shall take all steps permitted by law in order to avoid the imposition of any such lien. Should any such lien or notice of such lien be filed against the Premises or the Property, Tenant shall discharge the same by bonding or otherwise within fifteen (15) days after Tenant has notice that the lien or claim is filed regardless of the validity of such lien or claim.

14. **Landlord's Right of Entry.** Tenant shall permit Landlord and its Agents to enter the Premises at all reasonable times following no less than 24 hours advance notice (except in an emergency or during the existence of an Event of Default, in which case Landlord and its Agents may enter at any time and notice shall not be required) to inspect, Maintain, or make Alterations to the Premises or Property, to exhibit the Premises for the purpose of sale or financing, and, during the last twelve (12) months of the Term, to exhibit the Premises to any prospective tenant. In connection with any such entry, Landlord will make reasonable efforts not to inconvenience Tenant in exercising such rights, but Landlord shall not be liable for any reasonable interference with Tenant's occupancy resulting from Landlord's entry.

15. **Damage by Fire or Other Casualty.** If the Premises or Common Areas shall be damaged or destroyed by fire or other casualty, Tenant shall promptly notify Landlord, and Landlord, subject to the conditions set forth in this Section, shall repair such damage and restore the Premises or Common Areas to substantially the same condition in which they were immediately prior to such damage or destruction, but not including the repair, restoration or replacement of the fixtures, equipment, or Alterations installed by or on behalf of Tenant. Landlord shall notify Tenant, within thirty (30) days after the date of the casualty, if Landlord anticipates that the restoration will take more than one hundred eighty (180) days from the date of the casualty to complete; in such event, either Landlord or Tenant (unless the damage was caused by Tenant or Tenant's Agents) may terminate this Lease effective as of the date of casualty by giving notice to the other within ten (10) days after Landlord's notice. If a casualty occurs during the last twelve (12) months of the Term, Landlord or Tenant may terminate this Lease unless Tenant has the right to extend the Term for at least three (3) more years and does so within thirty (30) days after the date of the casualty. Moreover, Landlord may terminate this Lease if the loss is not covered by the insurance required to be maintained by Landlord under this Lease. Tenant will receive an abatement of Minimum Annual Rent and Annual Operating Expenses to the extent the Premises are rendered untenantable as a result of the casualty, except if caused by Tenant or Tenant's Agents and not covered by Landlord's insurance proceeds.

16. Condemnation. If (a) all of the Premises are Taken, (b) any part of the Premises is Taken and the remainder is insufficient in Landlord's and Tenant's reasonable opinion for the reasonable operation of Tenant's business, or (c) any of the Property is Taken, and, in Landlord's opinion, it would be impractical or the condemnation proceeds are insufficient to restore the remainder, then this Lease shall terminate as of the date the condemning authority takes possession. If this Lease is not terminated, Landlord shall restore the Building to a condition as near as reasonably possible to the condition prior to the Taking, the Minimum Annual Rent shall be abated for the period of time all or a part of the Premises is untenantable in proportion that such rentable square foot area that is untenantable bears to the rentable square footage of the Premises, and this Lease shall be amended appropriately. The compensation awarded for a Taking shall belong to Landlord, except that Tenant shall be entitled to independently pursue a separate award relating to the loss of, or damage to, Tenant's personal property and trade fixtures and Tenant's relocation costs directly associated with the Taking, and the loss of goodwill. Except as set forth in the preceding sentence, Tenant hereby assigns all claims against the condemning authority to Landlord, including, but not limited to, any claim relating to Tenant's leasehold estate.

17. Quiet Enjoyment. Landlord covenants that Tenant, upon performing all of its covenants, agreements and conditions of this Lease, shall have quiet and peaceful possession of the Premises as against anyone claiming by or through Landlord, subject, however, to the terms of this Lease.

18. Assignment and Subletting.

(a) Except as provided in Section 18(b) below, Tenant shall not enter into nor permit any Transfer voluntarily or by operation of law, without the prior consent of Landlord, which consent shall not be unreasonably withheld, conditioned or delayed. Without limitation, Tenant agrees that Landlord's consent shall not be considered unreasonably withheld if (i) the business, business reputation or creditworthiness of the proposed transferee is reasonably unacceptable to Landlord, (ii) Landlord or an affiliate has comparable space available for lease for a comparable term by the proposed transferee, or (iii) there is an Event of Default or any act or omission has occurred which would constitute a default with the giving of notice and/or the passage of time. Consent to one Transfer shall not be deemed to be consent to any subsequent Transfer. In no event shall any Transfer relieve Tenant from any obligation under this Lease. Landlord's acceptance of Rent from any person shall not be deemed to be a waiver by Landlord of any provision of this Lease or to be a consent to any Transfer. Any Transfer not in conformity with this Section 18 shall be void at the option of Landlord.

(b) Landlord's consent shall not be required in the event of any Transfer by Tenant to an Affiliate provided that (i) the Affiliate has a tangible net worth at least equal to that of Tenant as of the date of this Lease, (ii) Tenant provides Landlord notice of the Transfer at least fifteen (15) days prior to the effective date of such Transfer, together with current financial statements of the Affiliate certified by an executive officer of the Affiliate, provided that Landlord executes and delivers to Tenant reasonable non-disclosure agreements as is reasonably requested by Tenant with regard to such information, and (iii) in the case of an assignment or sublease, Tenant delivers to Landlord an assumption agreement or sublease reasonably acceptable to Landlord executed by Tenant and the Affiliate, together with a certificate of insurance evidencing the Affiliate's compliance with the insurance requirements of Tenant under this Lease.

(c) The provisions of subsection (a) above notwithstanding, if Tenant proposes to Transfer all of the Premises (other than to an Affiliate) for the balance of the Term, Landlord may terminate this Lease, either conditioned on execution of a new lease between Landlord and the proposed transferee or without that condition. In the event of any Transfer (other than to an Affiliate), Tenant shall pay to Landlord, immediately upon receipt, fifty percent (50%) of the excess of (i) all compensation received by Tenant for the Transfer less the Transfer Transaction Expenses (defined below), over (ii) the Rent allocable to the Premises transferred. "Transfer Transaction Expenses" shall mean the reasonable out-of-pocket costs and expenses incurred by Tenant in effectuating a Transfer for tenant improvements, allowances, brokerage commissions and other reasonable Transfer related expenses (which expenses shall be allocated evenly over the length of the term of the sublease or the remaining Term, in the event of an assignment).

(d) If Tenant requests Landlord's consent to a Transfer, Tenant shall provide Landlord, at least fifteen (15) days prior to the proposed Transfer, current financial statements of the transferee certified by an executive officer of the transferee, a complete copy of the proposed Transfer documents, and any other information Landlord reasonably requests. Landlord shall endeavor to notify Tenant promptly whether or not it approves such assignment or transfer. Immediately following any approved assignment or sublease, Tenant shall deliver to Landlord an assumption agreement reasonably acceptable to Landlord executed by Tenant and the transferee, together with a certificate of insurance evidencing the transferee's compliance with the insurance requirements of Tenant under this Lease. Tenant agrees to reimburse Landlord for reasonable administrative and reasonable out-of-pocket attorneys' fees in connection with the processing and documentation of any Transfer for which Landlord's consent is requested.

19. Subordination; Mortgagee's Rights.

(a) Tenant accepts this Lease subject and subordinate to any Mortgage now or in the future affecting the Premises, provided that Tenant's right of possession of the Premises shall not be disturbed by the Mortgagee so long as there is no Event of Default under this Lease. This clause shall be self-operative, but within fifteen (15) days after request, Tenant shall execute and deliver any further instruments confirming the subordination of this Lease and any further instruments of attornment that the Mortgagee may reasonably request and which are reasonably acceptable to Tenant. However, any Mortgagee may at any time subordinate its Mortgage to this Lease, without Tenant's consent, by giving notice to Tenant, and this Lease shall then be deemed prior to such Mortgage without regard to their respective dates of execution and delivery; provided that such subordination shall not affect any Mortgagee's rights with respect to condemnation awards, casualty insurance proceeds, intervening liens or any right which shall arise between the recording of such Mortgage and the execution of this Lease.

(b) No Mortgagee shall be (i) liable for any act or omission of a prior landlord, (ii) subject to any rental offsets or defenses against a prior landlord, (iii) bound by any amendment of this Lease made without its written consent, or (iv) bound by payment of Monthly Rent more than one month in advance or liable for any other funds paid by Tenant to Landlord unless such funds actually have been transferred to the Mortgagee by Landlord. Landlord shall use commercially reasonable efforts, at no cost to Landlord, to obtain a subordination, non-disturbance and attornment agreement for Tenant on the standard form of Mortgagee.

(c) The provisions of Sections 15 and 16 above notwithstanding, Landlord's obligation to restore the Premises after a casualty or condemnation shall be subject to the consent and prior rights of any Mortgagee.

20. Tenant's Certificate; Financial Information.

(a) Within fifteen (15) days after Landlord's request from time to time but not more than once during a calendar year (except in the event of a sale or refinancing of the Building), (a) Tenant shall execute, acknowledge and deliver to Landlord, for the benefit of Landlord, Mortgagee, any prospective Mortgagee, and any prospective purchaser of Landlord's interest in the Property, an estoppel certificate in a form reasonably requested by Landlord, modified as necessary to accurately state the facts represented, and (b) Tenant shall furnish to Landlord, Landlord's Mortgagee, any prospective Mortgagee and/or any prospective purchaser any reasonably requested financial information subject to reasonable non-disclosure agreements with any party reviewing such financial information.

(b) Within fifteen (15) days after Tenant's request from time to time but not more than once during a calendar year, Landlord shall execute, acknowledge and deliver to Tenant, an estoppel certificate in a form reasonably requested by Tenant, certifying, among other things, (i) that the Lease is unmodified and in full force and effect (or if there have been modifications, that this Lease as modified is in full force and effect and identifying the modifications); (ii) the date upon which Tenant began paying Rent and the dates to which Rent and other charges have been paid; (iii) that Tenant is not in default under any provision of this Lease, or, if in default, the nature thereof in detail; (iv) that there has been no prepayment of Rent other than provided for in this Lease; and (v) such other matters as may be reasonably requested by Tenant.

21. Surrender.

(a) On the date on which this Lease expires or terminates, Tenant shall return possession of the Premises to Landlord in good condition, except for ordinary wear and tear, and except for casualty damage, Taking or other conditions that Tenant is not required to remedy under this Lease. Prior to the expiration or termination of this Lease, Tenant shall remove from the Property all furniture, trade fixtures, equipment, wiring and cabling (unless Landlord directs Tenant otherwise, except as otherwise provided herein), and all other personal property installed by Tenant or its assignees or subtenants. Tenant shall repair any damage resulting from such removal and shall restore the Property to good order and condition. Any of Tenant's personal property not removed as required shall be deemed abandoned, and Landlord, at Tenant's expense, may remove, store, sell or otherwise dispose of such property in such manner as Landlord may see fit and/or Landlord may retain such property or sale proceeds as its property. If Tenant does not return possession of the Premises to Landlord in the condition required under this Lease, Tenant shall pay Landlord all resulting damages Landlord may suffer.

(b) If Tenant remains in possession of the Premises after the expiration or termination of this Lease, Tenant's occupancy of the Premises shall be that of a tenancy at sufferance. Tenant's occupancy during any holdover period shall otherwise be subject to the provisions of this Lease (unless clearly inapplicable), except that for the first month of any holdover, the Monthly Rent shall be 150% of the Monthly Rent payable for the last full month immediately preceding the holdover, and thereafter, the Monthly Rent shall be double the Monthly Rent payable for the last full month immediately preceding the holdover. No holdover or payment by Tenant after the expiration or termination of this Lease shall operate to extend the Term or prevent Landlord from immediate recovery of possession of the Premises by summary proceedings or otherwise. Any provision in this Lease to the contrary notwithstanding, any holdover by Tenant shall constitute a default on the part of Tenant under this Lease entitling Landlord to exercise, without obligation to provide Tenant any notice or cure period, all of the remedies available to Landlord in the event of a Tenant default, and Tenant shall be liable for all damages, including consequential damages, that Landlord suffers as a result of the holdover.

22. Defaults - Remedies.

(a) It shall be an Event of Default:

(i) If Tenant does not pay in full when due any and all Rent and, except as provided in Section 22(c) below, Tenant fails to cure such default on or before the date that is five (5) days after Landlord gives Tenant notice of default;

(ii) If Tenant enters into or permits any Transfer in violation of Section 18 above;

(iii) If Tenant fails to observe and perform or otherwise breaches any other provision of this Lease, and, except as provided in Section 22(c) below, Tenant fails to cure the default on or before the date that is thirty (30) days after Landlord gives Tenant notice of default; provided, however, if the default cannot reasonably be cured within thirty(30) days following Landlord's giving of notice, Tenant shall be afforded additional reasonable time (not to exceed ninety (90) days following Landlord's notice) to cure the default if Tenant begins to cure the default within thirty (30) days following Landlord's notice and continues diligently in good faith to completely cure the default; or

(iv) If Tenant becomes insolvent or makes a general assignment for the benefit of creditors or offers a settlement to creditors, or if a petition in bankruptcy or for reorganization or for an arrangement with creditors under any federal or state law is filed by or against Tenant, or a bill in equity or other proceeding for the appointment of a receiver for any of Tenant's assets is commenced, or if any of the real or personal property of Tenant shall be levied upon; provided that any proceeding brought by anyone other than Landlord or Tenant under any bankruptcy, insolvency, receivership or similar law shall not constitute an Event of Default until such proceeding has continued unstayed for more than sixty (60) consecutive days.

(b) If an Event of Default occurs, Landlord shall have the following rights and remedies:

(i) Landlord, without any obligation to do so, may elect to cure the default on behalf of Tenant, in which event Tenant shall reimburse Landlord upon demand for any sums paid or costs incurred by Landlord (together with the Administrative Fee) in curing the default, plus interest at the Interest Rate from the respective dates of Landlord's incurring such costs, which sums and costs together with interest at the Interest Rate shall be deemed additional Rent;

(ii) To enter and repossess the Premises, by breaking open locked doors if necessary, and remove all persons and all or any property, by action at law or otherwise, without being liable for prosecution or damages. Landlord may, at Landlord's option, make Alterations and repairs in order to re-let the Premises and re-let all or any part(s) of the Premises for Tenant's account. Tenant agrees to pay to Landlord on demand any deficiency (taking into account all costs incurred by Landlord) that may arise by reason of such re-letting. In the event of re-letting without termination of this Lease, Landlord may at any time thereafter elect to terminate this Lease for such previous breach;

(iii) To accelerate the whole or any part of the Rent for the balance of the Term, and declare the same to be immediately due and payable; and

(iv) To terminate this Lease and the Term without any right on the part of Tenant to save the forfeiture by payment of any sum due or by other performance of any condition, term or covenant broken.

(c) Any provision to the contrary in this Section 22 notwithstanding, (i) Landlord shall not be required to give Tenant the notice and opportunity to cure provided in Section 22(a) above more than twice in any consecutive twelve (12) month period, and thereafter Landlord may declare an Event of Default without affording Tenant any of the notice and cure rights provided under this Lease, and (ii) (ii) Landlord shall not be required to give such notice prior to exercising its rights under Section 22(b) if Tenant fails to comply with the provisions of Sections 13, 27 or in an emergency, and (iii) if Tenant fails to comply with the provisions of Section 20, and Tenant fails to cure the default within five (5) days following Landlord's giving of notice, it shall be an Event of Default and Landlord shall have the rights provided in Section 22(b) above.

(d) No waiver by Landlord of any breach by Tenant shall be a waiver of any subsequent breach, nor shall any forbearance by Landlord to seek a remedy for any breach by Tenant be a waiver by Landlord of any rights and remedies with respect to such or any subsequent breach. Efforts by Landlord to mitigate the damages caused by Tenant's default shall not constitute a waiver of Landlord's right to recover damages hereunder. No right or remedy herein conferred upon or reserved to Landlord is intended to be exclusive of any other right or remedy provided herein or by law, but each shall be cumulative and in addition to every other right or remedy given herein or now or hereafter existing at law or in equity. No payment by Tenant or receipt or acceptance by Landlord of a lesser amount than the total amount due Landlord under this Lease shall be deemed to be other than on account, nor shall any endorsement or statement on any check or payment be deemed an accord and satisfaction, and Landlord may accept such check or payment without prejudice to Landlord's right to recover the balance of Rent due, or Landlord's right to pursue any other available remedy.

(e) If either party commences an action against the other party arising out of or in connection with this Lease, the prevailing party shall be entitled to have and recover from the other party attorneys' fees, costs of suit, investigation expenses and discovery costs, including costs of appeal.

(f) Landlord and Tenant waive the right to a trial by jury in any action or proceeding based upon or related to, the subject matter of this Lease.

(g) Landlord shall use commercially reasonable efforts to relet the Premises following Tenant's vacation of the Premises and Tenant's returning the Premises to the condition required at the time of the expiration of this Lease and to otherwise mitigate Landlord's damages under this Lease; provided, however, that Landlord shall be under no duty to market or relet the Premises prior to leasing other available space in the Building and, in no event shall Landlord be responsible or liable for any failure to relet the Premises or any part thereof, or for any failure to collect any rent due upon areletting.

23. Tenant's Authority. Tenant represents and warrants to Landlord that: (a) Tenant is duly formed, validly existing and in good standing under the laws of the state under which Tenant is organized, and qualified to do business in the state in which the Property is located, (b) the person(s) signing this Lease are duly authorized to execute and deliver this Lease on behalf of Tenant and (c) any financial statements provided by Tenant to Landlord are true, correct and complete and fairly represent the financial condition of Tenant as of the date of such statements.

24. Liability of Landlord. The word **"Landlord"** in this Lease includes the Landlord executing this Lease as well as its successors and assigns, each of which shall have the same rights, remedies, powers, authorities and privileges as it would have had it originally signed this Lease as Landlord. Any such person or entity, whether or not named in this Lease, shall have no liability under this Lease after it ceases to hold title to the Premises except for obligations already accrued (and, as to any unapplied portion of Tenant's Security Deposit, Landlord shall be relieved of all liability upon transfer of such portion to its successor in interest). Tenant shall look solely to Landlord's successor in interest for the performance of the covenants and obligations of the Landlord hereunder which subsequently accrue. Landlord shall not be deemed to be in default under this Lease unless Tenant gives Landlord written notice specifying the default and Landlord fails to cure the default within a reasonable period following Tenant's written notice. In no event shall Landlord be liable to Tenant for any loss of business or profits of Tenant or for consequential, punitive or special damages of any kind. Neither Landlord nor any principal of Landlord nor any owner of the Property, whether disclosed or undisclosed, shall have any personal liability with respect to any of the provisions of this Lease or the

Premises; Tenant shall look solely to the equity of Landlord in the Premises for the satisfaction of any claim by Tenant against Landlord.

25. Miscellaneous.

(a) The captions in this Lease are for convenience only, are not a part of this Lease and do not in any way define, limit, describe or amplify the terms of this Lease.

(b) This Lease represents the entire agreement between the parties hereto and there are no collateral or oral agreements or understandings between Landlord and Tenant with respect to the Premises or the Property. No rights, easements or licenses are acquired in the Property or any land adjacent to the Property by Tenant by implication or otherwise except as expressly set forth in this Lease. This Lease shall not be modified in any manner except by an instrument in writing executed by the parties. The masculine (or neuter) pronoun and the singular number shall include the masculine, feminine and neuter genders and the singular and plural number. The word "including" followed by any specific item(s) is deemed to refer to examples rather than to be words of limitation. The word "person" includes a natural person, a partnership, a corporation, a limited liability company, an association and any other form of business association or entity. Both parties having participated fully and equally in the negotiation and preparation of this Lease, this Lease shall not be more strictly construed, nor any ambiguities in this Lease resolved, against either Landlord or Tenant.

(c) Each covenant, agreement, obligation, term, condition or other provision contained in this Lease shall be deemed and construed as a separate and independent covenant of the party bound by, undertaking or making the same, not dependent on any other provision of this Lease unless otherwise expressly provided. All of the terms and conditions set forth in this Lease shall apply throughout the Term unless otherwise expressly set forth herein.

(d) If any provisions of this Lease shall be declared unenforceable in any respect, such unenforceability shall not affect any other provision of this Lease, and each such provision shall be deemed to be modified, if possible, in such a manner as to render it enforceable and to preserve to the extent possible the intent of the parties as set forth herein. This Lease shall be construed and enforced in accordance with the laws of the state in which the Property is located.

(e) This Lease shall be binding upon and inure to the benefit of Landlord and Tenant and their respective heirs, personal representatives and permitted successors and assigns. All persons liable for the obligations of Tenant under this Lease shall be jointly and severally liable for such obligations.

(f) Tenant shall not record this Lease or any memorandum without Landlord's prior consent.

26. **Notices.** Any notice, consent or other communication under this Lease shall be in writing and addressed to Landlord or Tenant at their respective addresses specified in Section 1 above (or to such other address as either may designate by notice to the other) with a copy to any Mortgagee or other party designated in writing by Landlord. Each notice or other communication shall be deemed given if sent by prepaid overnight delivery service or by certified mail, return receipt requested, postage prepaid or in any other manner, with delivery in any case evidenced by a receipt, and shall be deemed to have been given on the day of actual delivery to the intended recipient or on the business day delivery is refused. The giving of notice by Landlord's attorneys, representatives and agents under this Section shall be deemed to be the acts of Landlord.

27. Security Deposit. At the time of signing this Lease, Tenant shall deposit with Landlord the Security Deposit to be retained by Landlord as cash security for the faithful performance and observance by Tenant of the provisions of this Lease. On or after the first day of the 13th month of the Term, Tenant shall be entitled to a reduction in the amount of the Security Deposit by 50% to $14,745.81, provided that: (i) Tenant, in writing, requests the reduction of Landlord, (ii) Tenant has not been in default beyond any applicable grace or cure period more than once in the prior 12 months or is not currently in default beyond any applicable grace or cure period, (iii) Tenant has timely made all Rent payments due under this Lease, and (iv) Tenant demonstrates to Landlord's satisfaction positive annual earnings before interest, taxes, depreciation and amortization (EBITDA), as determined in accordance with GAAP, for the preceding twelve (12) months. Provided the aforementioned conditions are satisfied, Landlord shall return $14,745.81 to Tenant within thirty (30) days of Tenant's request. Tenant shall not be entitled to further reductions of the Security Deposit prior to the expiration of this Lease. Tenant shall not be entitled to any interest on the Security Deposit. Landlord shall have the right to commingle the Security Deposit with its other funds. Landlord may use the whole or any part of the Security Deposit for the payment of any amount as to which Tenant is in default or to compensate Landlord for any loss or damage it may suffer by reason of Tenant's default under this Lease. If Landlord uses all or any portion of the Security Deposit as herein provided, within 10.days after demand, Tenant shall pay Landlord cash in an amount equal to that portion of the Security Deposit used by Landlord. If Tenant complies fully and faithfully with all of the provisions of this Lease, the Security Deposit shall be returned to Tenant after the Expiration Date and surrender of the Premises to Landlord.

28. Broker.

(a) Tenant represents and warrants to Landlord that Tenant has dealt with no broker, agent or other intermediary in connection with this Lease other than Tenant's Broker, and that insofar as Tenant knows, no other broker, agent or other intermediary represented Tenant in the negotiation of this Lease or introduced Tenant to Landlord or brought the Building to Tenant's attention for the lease of space therein. Tenant agrees to indemnify, defend and hold Landlord and its affiliates, partners, members, employees, agents, their partners, members, shareholders, directors, officers, and trustees, harmless from and against any claims made by any broker, agent or other intermediary other than Tenant's Broker, with respect to a claim for any broker's commission or fee or similar compensation brought by any person in connection with this Lease, provided that Landlord has not in fact retained such broker, agent or other intermediary. Landlord agrees to pay all commissions payable to Tenant's Broker pursuant to a separate, written agreement between Landlord and Tenant's Broker.

(b) Landlord represents and warrants to Tenant that Landlord has dealt with no broker, agent or other intermediary in connection with this Lease other than Landlord's Broker, and that insofar as Landlord knows, no other broker, agent or other intermediary represented Landlord in the negotiation of this Lease. Landlord agrees to indemnify, defend and hold Tenant and its affiliates, partners, members, employees, agents, their partners, members, shareholders, directors, officers, and trustees, harmless from and against any claims made by any broker, agent or other intermediary other than Landlord's Broker, with respect to a claim for any broker's commission or fee or similar compensation brought by any person in connection with this Lease. Landlord agrees to pay all commissions payable to Landlord's Broker pursuant to a separate, written agreement between Landlord and Landlord's Broker.

29. **OFAC.** Tenant represents and warrants that neither it nor any of its officers or directors is, and that, to the actual knowledge of the signatory to this Lease, none of its employees, representatives, or agents is, a person or entity with whom U.S. persons or entities are restricted from doing business under regulations of the Office of Foreign Asset Control ("OFAC") of the Department of the Treasury (including those named on OFAC's Specially Designated and Blocked Persons List) or under any statute, executive order (including the September 24, 2001, Executive Order Blocking Property and Prohibiting Transactions with Persons Who Commit, Threaten to Commit, or Support Terrorism), or other governmental regulation, and that it will not transfer this Lease to, or knowingly contract with or otherwise engage in any dealings or transactions or be otherwise associated with such persons or entities. Tenant represents and warrants that it is currently in compliance with, and shall at all times during the term of this Lease remain in compliance with, the regulations of OFAC and any other governmental requirement relating thereto.

30. **Renewal Option.** Tenant shall have the option to extend the Term of the Lease for all of the then leased Premises for one (1) additional period of five (5) years ("Renewal Option"), under and subject to the following terms and conditions:

(a) The renewal term ("Renewal Term") shall be for a five (5)-year period commencing on the day immediately following the expiration of the initial Term of the Lease and expiring on the day immediately preceding the fifth (5th) anniversary thereof. Tenant must exercise the Renewal Option, if at all, by written notice to Landlord delivered at least three hundred sixty-five (365) days prior to the expiration date of the initial Term of this Lease, time being of the essence.

(b) As a condition to Tenant's exercise of the Renewal Option, at the time Tenant delivers its notice of election to exercise the Renewal Option to Landlord, there shall be no Event of Default, this Lease shall be in full force and effect, and Tenant shall not have assigned this Lease or sublet the Premises.

(c) The Minimum Annual Rent for the first year of the Renewal Term shall be the then current fair market rent for renewals for comparable space in similar buildings within a two (2)-mile radius of the Building, taking into account the size of the Lease, the length of the Renewal Term and the credit of Tenant, but in no event less than the Minimum Annual Rent for the last year of the initial Term and the subsequent years of Minimum Annual Rent during the Renewal Term shall increase consistent with the then fair market annual escalations ("Fair Market Rental"). Landlord shall determine the Fair Market Rental using its good faith judgment and shall provide written notice of such Fair Market Rental within fifteen (15) days after Tenant's exercise notice pursuant to this Section. Tenant shall thereupon have the following options: (i) to accept such proposed Fair Market Rental or (ii) to notify Landlord in writing that Tenant objects to the proposed rental rate. Tenant must provide Landlord with written notification of its election within fifteen (15) days after Tenant's receipt of Landlord's notice, otherwise Tenant shall be deemed to have elected clause (i) above. If Tenant objects to Landlord's proposed Fair Market Rental in accordance with clause (ii) above, Landlord and Tenant will attempt to negotiate a mutually acceptable rental rate within fifteen (15) days following notification by Tenant, and if such negotiations have not been concluded within such fifteen (15) day-period, either party may require an independent determination of the Fair Market Rental for the Renewal Term by giving written notice to the other party no later than five (5) days after the expiration of the fifteen (15)-day period, which notice shall designate a MAI real estate appraiser or real estate broker with at least ten (10) years' experience in the leasing of similar properties in the Northern New Jersey market area ("Qualified Appraiser"). Within ten (10) days after receipt of such notice, the other party to this Lease shall select a Qualified Appraiser and give written notice of such selection to the initiating party. If the two (2) Qualified Appraisers fail to agree upon the Fair Market Rental consistent with this Section 30 within ten (10) days after selection of the second Qualified Appraiser, the two (2) Qualified Appraisers shall select a third (3rd) Qualified Appraiser to determine the Fair Market Rental consistent with this Section 29 within ten (10) day after the appointment of the third (3rd) Qualified Appraiser. The Fair Market Rental applicable to the Renewal Term shall be equal to the arithmetic average of the three (3) determinations; provided, however, that if one (1) Qualified Appraiser's determination deviates by more than five percent (5%) from the median of the three (3) determinations, the Fair Market Rental shall be an amount equal to the average of the other two determinations. The determination of the Fair Market Rental in accordance with the foregoing shall be final, binding and conclusive on Landlord and Tenant. The parties shall each pay the costs and expenses of their appointed Qualified Appraiser and shall split evenly the costs and expenses of the third (3rd) Qualified Appraiser.

(d) Except as set forth in this Section, there shall be no further options to renew the term of the Lease.

[Remainder of page left intentionally blank.]

Landlord and Tenant have executed this Lease on the respective date(s) set forth below.

Landlord:

ANSON LOGISTICS ASSETS LLC,
a Delaware limited liability company

Datesigned: _____

By: _____
Name: Michael Thomas Smith
Title: Director

Date signed: _____

Tenant:

ELECTROCORE, INC., a Delaware corporation

Attest/Witness:

_____
Name:
Title:

By: /s/ Glenn S. Vraniak
Name: Glenn S. Vraniak
Title: Chief Financial Officer

RIDER

ADDITIONAL DEFINITIONS

"Actual Knowledge" means the knowledge of Sander Smith, without investigation or inquiry.

"ADA" means the Americans With Disabilities Act of 1990 (42 U.S.C. § 1201 et seq.), as amended and supplemented from time to time.

"Administrative Fee" means fifteen percent (15%) of the costs incurred by Landlord in curing Tenant's default or performing Tenant's obligations hereunder.

"Affiliate" means (i) any entity controlling, controlled by, or under common control of, Tenant, (ii) any successor to Tenant by merger, consolidation or reorganization, and (iii) any purchaser of all or substantially all of the assets of Tenant as a going concern.

"Agents" of a party mean such party's employees, agents, representatives, contractors, licensees or invitees.

"Alteration" means any addition, alteration or improvement to the Premises or Property, as the case may be.

"Building Rules" means the rules and regulations attached to this Lease as **Exhibit "B"** as they may be amended from time to time, provided that no modifications or additions shall be inconsistent with or in limitation of the provisions of this Lease or have any material adverse effect on Tenant's rights hereunder.

"Building Systems" means any electrical, mechanical, structural, plumbing, heating, ventilating, air conditioning, sprinkler, life safety or security systems serving the Building.

"Common Areas" means all areas and facilities as provided by Landlord from time to time for the use or enjoyment of all tenants in the Building or Property, including, if applicable, driveways, sidewalks, parking, loading and landscaped areas.

"Environmental Laws" means all present or future federal, state or local laws, ordinances, rules or regulations (including the rules and regulations of the federal Environmental Protection Agency and comparable state agency) relating to the protection of human health or the environment.

"Event of Default" means a default described in Section 22(a) of this Lease. "GAAP" means generally accepted accounting principles, consistently applied.

"Hazardous Materials" means pollutants, contaminants, toxic or hazardous wastes or other materials the removal of which is required or the use of which is regulated, restricted, or prohibited by any Environmental Law.

"Interest Rate" means interest at the rate of 1 ½% per month.

"Land" means the lot or plot of land on which the Building is situated or the portion thereof allocated by Landlord to the Building.

"Landlord's Broker" means Exeter Property Group Advisors, L.P.

"Laws" means all laws, ordinances, rules, orders, regulations, guidelines and other requirements of federal, state or local governmental authorities or of any private association or contained in any restrictive covenants or other declarations or agreements, now or subsequently pertaining to the Property or the use and occupation of the Property.

"Maintain" means to provide such maintenance, repair and, to the extent necessary and appropriate, replacement, as may be needed to keep the subject property in good condition and repair.

"Monthly Rent" means the monthly installment of Minimum Annual Rent plus the monthly installment of estimated Annual Operating Expenses payable by Tenant under this Lease.

"Mortgage" means any mortgage, deed of trust or other lien or encumbrance on Landlord's interest in the Property or any portion thereof, including without limitation any ground or master lease if Landlord's interest is or becomes a leasehold estate.

"Mortgagee" means the holder of any Mortgage, including any ground or master lessor if Landlord's interest is or becomes a leasehold estate.

"OFAC" has the meaning set forth in Section 29 of this Lease.

"Operating Expenses" means all costs, fees, charges and expenses incurred or charged by Landlord in connection with the ownership, operation, maintenance and repair of, and services provided to, the Property, including, but not limited to, (i) the charges at standard retail rates for any utilities serving the Common Areas and any utilities provided by Landlord pursuant to Section 7 of this Lease, (ii) the cost of insurance carried by Landlord pursuant to Section 8 of this Lease together with the cost of any deductible paid by Landlord in connection with an insured loss, (iii) Landlord's cost to Maintain the Property, subject to the provisions of Section 9 of this Lease, and all costs and expenses of personnel and vendors or contractors required in connection therewith, inclusive of any property caretakers or administrators; (iv) the cost of trash collection, (v) snow removal, and grounds-keeping and landscaping of the Common Areas; (vi) the costs and charges of any easements and campus associations of which the Property is a part; (vii) to the extent not otherwise payable by Tenant pursuant to Section 5 of this Lease, all levies, taxes (including real estate taxes, sales taxes and gross receipt taxes, but excluding income or franchise, transfer, gift, excise, capital stock, estate, succession and inheritance taxes or any other taxes imposed upon or measured by Landlord's income or profits), assessments, liens, license and permit fees, together with the reasonable cost of contesting any of the foregoing (but excluding any penalties or interest for late payment, unless such penalties and interest arise from Tenant's breach of this Lease), which are applicable to the Term, and which are imposed by any authority or under any Law, or pursuant to any recorded covenants or agreements, upon or with respect to the Property, or any improvements thereto, or directly upon this Lease or the Rent or upon amounts payable by any subtenants or other occupants of the Premises, or against Landlord because of Landlord's estate or interest in the Property, (viii) the annual amortization (over their estimated economic useful life or payback period, whichever is shorter) of the costs (including reasonable financing charges) of capital improvements or replacements, and (ix) a management fee. The foregoing notwithstanding, Operating

Expenses will not include: (1) depreciation on the Building, (2) financing and refinancing costs (except as provided above), interest on debt or amortization payments on any mortgage, or rental under any ground or underlying lease, (3) leasing commissions, advertising expenses, tenant improvements or other costs directly related to the leasing of the Property, (4) income, excess profits or corporate capital stock tax imposed or assessed upon Landlord, unless such tax or any similar tax is levied or assessed in lieu of all or any part of any taxes ineluctable in Operating Expenses above; (5) costs of the initial construction of the Building and repairing, replacing or otherwise correcting defects (but not the costs of repair for normal wear and tear not occasioned by construction defects) in the construction of the Building or in the Building equipment; (6) costs of alterations for the sole benefit of other tenants of the Building; (7) any expenditures for services which are provided to one or more tenants but are not available generally to all office tenants; (8) any expenditures for which Landlord has been reimbursed (other than pursuant to Article 6 or provisions in other leases requiring the tenants thereunder to pay a share of expenses associated with the Building), except as hereinafter provided; (9) payments to affiliates of Landlord (excluding property management fees), but only to the extent that they exceed market rates; (10) to the extent any costs includible in Operating Expenses are incurred with respect to both the Building and other properties, there shall be excluded from Operating Expenses a fair and reasonable percentage thereof which is properly allocable to such other properties; (11) the cost of any judgment, settlement, or arbitration award resulting from any liability of Landlord which is the result of negligence, willful misconduct or fraud (other than a liability for amounts otherwise includible in Operating Expenses hereunder) and all expenses incurred in connection therewith; (12) costs relating to withdrawal liability or unfunded pension liability under the Multi-Employer Pension Plan Act or similar law; (13) costs incurred by Landlord which result from Landlord's breach of a lease; (14) expenditures for repairing and/or replacing any defect in any work performed by Landlord (but not the costs of repair for normal wear and tear not occasioned by such defect); and (15) additional costs incurred to correct violations existing on the Commencement Date of any law, rule, order or regulation affecting the Building beyond those costs incurred in order to maintain the Building in a state of compliance with any such law, rule, order or regulation and any sums paid by Landlord for any fines or penalties as a result of violation of any law, rule, order or regulation. If Landlord elects to prepay real estate taxes during any discount period, Landlord shall be entitled to the benefit of any such prepayment. Landlord shall have the right to directly perform (by itself or through an affiliate) any services provided under this Lease provided that the Landlord's charges included in Operating Expenses for any such services shall not exceed competitive market rates for comparable services.

"Permits" means any permits, certificates of occupancy, consents, environmental permits and approvals, authorization, variances, waivers, licenses, certificates or approvals required by any governmental or quasi-governmental authority.

"Permitted Activities" has the meaning set forth in Section 10(d) of this Lease.

"Property" means the Land, the Building, the Common Areas, and all appurtenances to them.

"Renewal Option" has the meaning set forth in Section 30 of the Lease. "Renewal Term" has the meaning set forth in Section 30 of the Lease.

"Rent" means the Minimum Annual Rent, Annual Operating Expenses and any other amounts payable by Tenant to Landlord under this Lease.

"Statement" has the meaning set forth in Section 6 of this Lease.

"Substantially Completed" means the Tenant Improvements have been completed except for minor or insubstantial details of construction, repair, mechanical adjustment, or finishing touches, which items shall not adversely affect Tenant's occupancy or conduct of its ordinary business activities in the Premises and a permanent or temporary certificate of occupancy has been issued sufficient to allow Tenant to occupy and operate from the Premises. Notwithstanding the foregoing, issuance of such permanent or temporary certificate of occupancy may be conditioned upon Tenant's or Tenant's Agent's installation of its equipment, racking, cabling or furniture or completion of any other work or activity in the Premises for which Tenant is responsible but not conditioned upon Landlord's completion of the Tenant Improvements. In such event, if the governmental authority will not issue such permanent or temporary certificate of occupancy, or schedule an inspection of the Tenant Improvements due to Tenant's or Tenant's Agent's failure to complete such work, installation or activity, then the Tenant Improvements shall be deemed to be Substantially Completed without Landlord having obtained the permanent or temporary certificate of occupancy and correspondingly, the Commencement Date shall be established.

"Taken" or "Taking" means acquisition by a public authority having the power of eminent domain by condemnation or conveyance in lieu of condemnation.

"Tenant Delay" means any material delays that are caused, in whole or in part, by Tenant or Tenant's Agents for any reason, including but not limited to, (i) any interference by Tenant or Tenant's Agents with Landlord's obtaining the Permits or Landlord's construction of the Tenant Improvements, (ii) any delays caused by changes to the Tenant Improvement specifications attached hereto as Exhibits "C" and "C-1", including, without limitation, revising the construction drawings, materials or specifications and obtaining new Permits for the Tenant Improvements, (iii) Tenant's failure to approve construction drawings, permit plans or any matter relating to the Tenant Improvements within three (3) business days following Tenant's receipt of Landlord's request, or (iv) the performance of any work or activity in the Property by Tenant or Tenant's Agents (including, without limitation, the installation of Tenant's equipment, cabling, racking systems or furniture).

"Tenant Improvements" has the meaning set forth in Section 2(a) of this Lease. "Tenant's Broker" means Cornerstone Real Estate Group.

"Tenant's Share" means the percentage obtained by dividing the rentable square feet of the Premises by the rentable square feet of the Building, as set forth in Section 1 of this Lease.

"Transfer" means (i) any assignment, transfer, pledge or other encumbrance of all or a portion of Tenant's interest in this Lease, (ii) any sublease, license or concession of all or a portion of Tenant's interest in the Premises, or (iii) any transfer of a controlling interest in Tenant.

EXHIBIT "A"

PLAN SHOWING PREMISES

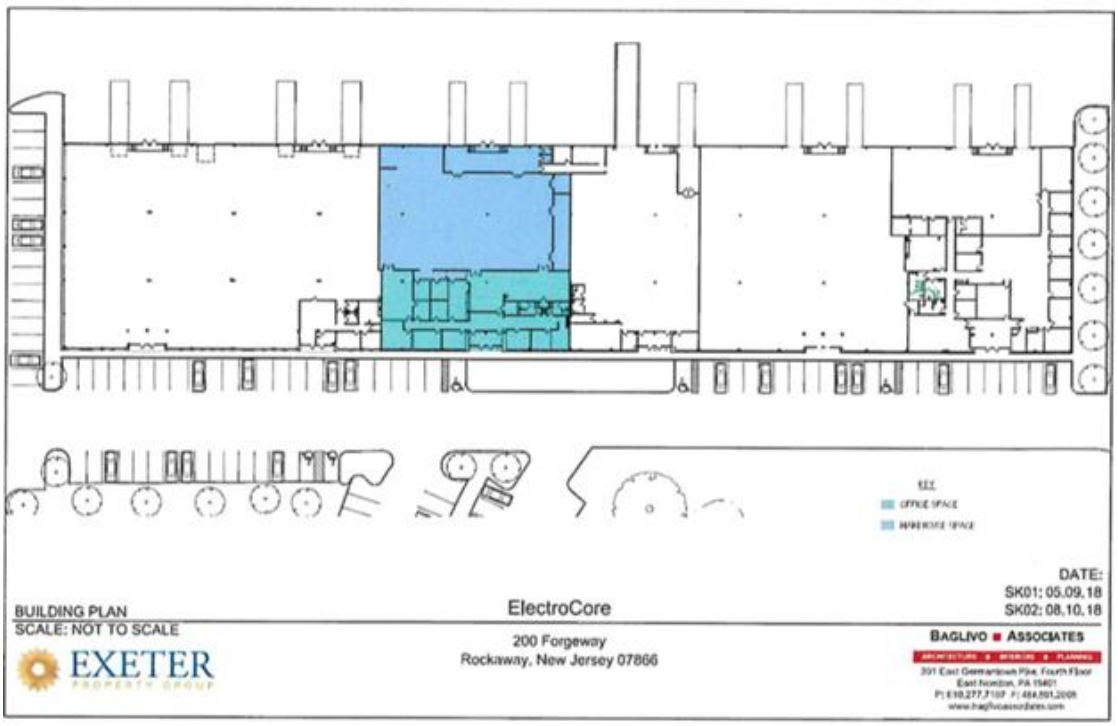


EXHIBIT "B"

BUILDING RULES

1. Any sidewalks, lobbies, passages and stairways shall not be obstructed or used by Tenant for any purpose other than ingress and egress from and to the Premises. Landlord shall in all cases retain the right to control or prevent access by all persons whose presence, in the judgment of Landlord, shall be prejudicial to the safety, peace or character of the Property.

2. The toilet rooms, toilets, urinals, sinks, faucets, plumbing or other service apparatus of any kind shall not be used for any purposes other than those for which they were installed, and no sweepings, rubbish, rags, ashes, chemicals or other refuse or injurious substances shall be placed therein or used in connection therewith or left in any lobbies, passages, elevators or stairways.

3. Tenant shall not impair in any way the fire safety system and shall comply with all safety, fire protection and evacuation procedures and regulations established by Landlord or any governmental agency. No person shall go on the roof without Landlord's prior written consent.

4. Skylights, windows, doors and transoms shall not be covered or obstructed by Tenant, and Tenant shall not install any window covering which would affect the exterior appearance of the Building, except as approved in writing by Landlord. Tenant shall not remove, without Landlord's prior written consent, any shades, blinds or curtains in the Premises.

5. Without Landlord's prior written consent, Tenant shall not hang, install, mount, suspend or attach anything from or to any sprinkler, plumbing, utility or other lines. If Tenant hangs, installs, mounts, suspends or attaches anything from or to any doors, windows, walls, floors or ceilings, Tenant shall spackle and sand all holes and repair any damage caused thereby or by the removal thereof at or prior to the expiration or termination of the Lease. If Tenant elects to seal the floor, Tenant shall seal the entire unfinished floor area within the Premises.

6. Tenant shall not change any locks nor place additional locks upon any doors.

7. Tenant shall not use nor keep in the Building any matter having an offensive odor, nor explosive or highly flammable material, nor shall any animals other than handicap assistance dogs in the company of their masters be brought into or kept in or about the Property.

8. If Tenant desires to introduce electrical, signaling, telegraphic, telephonic, protective alarm or other wires, apparatus or devices, Landlord shall direct where and how the same are to be placed, and except as so directed, no installation boring or cutting shall be permitted. Landlord shall have the right to prevent and to cut off the transmission of excessive or dangerous current of electricity or annoyances into or through the Building or the Premises and to require the changing of wiring connections or layout at Tenant's expense, to the extent that Landlord may deem necessary, and further to require compliance with such reasonable rules as Landlord may establish relating thereto, and in the event of non-compliance with the requirements or rules, Landlord shall have the right immediately to cut wiring or to do what it considers necessary to remove the danger, annoyance or electrical interference with apparatus in any part of the Building. All wires installed by Tenant must be clearly tagged at the distributing boards and junction boxes and elsewhere where required by Landlord, with the number of the office to which said wires lead, and the purpose for which the wires respectively are used, together with the name of the concern, if any, operating same.

9. Tenant shall not place weights anywhere beyond the safe carrying capacity of the Building.

10. The use of rooms as sleeping quarters is strictly prohibited at all times.

11. Tenant shall have the right, at Tenant's sole risk and responsibility, to use only Tenant's Share of the parking spaces at the Property as reasonably determined by Landlord. Tenant shall comply with all parking regulations promulgated by Landlord from time to time for the orderly use of the vehicle parking areas, including without limitation the following: Parking shall be limited to automobiles, passenger or equivalent vans, motorcycles, light four wheel pickup trucks and (in designated areas) bicycles. No vehicles shall be left in the parking lot overnight without Landlord's prior written approval. Parked vehicles shall not be used for vending or any other business or other activity while parked in the parking areas. Vehicles shall be parked only in striped parking spaces, except for loading and unloading, which shall occur solely in zones marked for such purpose, and be so conducted as to not unreasonably interfere with traffic flow within the Property or with loading and unloading areas of other tenants. Tractor trailers shall be parked in areas designated for tractor trailer parking. Employee and tenant vehicles shall not be parked in spaces marked for visitor parking or other specific use. All vehicles entering or parking in the parking areas shall do so at owner's sole risk and Landlord assumes no responsibility for any damage, destruction, vandalism or theft. Tenant shall cooperate with Landlord in any measures implemented by Landlord to control abuse of the parking areas, including without limitation access control programs, tenant and guest vehicle identification programs, and validated parking programs, provided that no such validated parking program shall result in Tenant being charged for spaces to which it has a right to free use under its Lease. Each vehicle owner shall promptly respond to any sounding vehicle alarm or horn, and failure to do so may result in temporary or permanent exclusion of such vehicle from the parking areas. Any vehicle which violates the parking regulations may be cited, towed at the expense of the owner, temporarily or permanently excluded from the parking areas, or subject to other lawful consequence. All vehicles shall follow Landlord's designated points of entrance and exit and turn-arounds and circulation routes for the Property.

12. If Landlord designates the Building as a non-smoking building, Tenant and its

Agents shall not smoke in the Building nor at the Building entrances and exits.

13. If at Tenant's request, Landlord consents to Tenant having a dumpster at the Property, Tenant shall locate the dumpster in the area designated by Landlord and shall keep and maintain the dumpster clean and painted with lids and doors in good working order and, at Landlord's request, locked. Tenant shall screen, at Tenant's sole cost and expense, the dumpster area at Landlord's request.

14. Tenant shall provide Landlord with a written identification of any vendors engaged by Tenant to perform services for Tenant at the Premises (examples: cleaners, security guards/monitors, trash haulers, telecommunications installers/maintenance).

15. Tenant shall comply with any move-in/move-out rules provided by Landlord.

16. Tenant shall cause all of Tenant's Agents to comply with these Building Rules.

17. Landlord reserves the right to rescind, suspend or modify any rules or regulations and to make such other rules and regulations as, in Landlord's reasonable judgment, may from time to time be needed for the safety, care, maintenance, operation and cleanliness of the Property, provided that no modifications or additions shall be inconsistent with or in limitation of the provisions of this Lease or have any material adverse effect on Tenant's rights hereunder. Notice of any action by Landlord referred to in this section, given to Tenant, shall have the same force and effect as if originally made a part of the foregoing Lease. New rules or regulations will not, however, be unreasonably inconsistent with the proper and rightful enjoyment of the Premises by Tenant under the Lease.

18. These Building Rules are not intended to give Tenant any rights or claims in the event that Landlord does not enforce any of them against any other tenants or if Landlord does not have the right to enforce them against any other tenants and such nonenforcement will not constitute a waiver as to Tenant.

EXHIBIT "C"

TENANT IMPROVEMENTS

Landlord, at Landlord's sole cost and expense, shall perform the following improvements using Building standard materials and finishes:

Office
-Patch carpet/install new VCT tile in office space
-Paint walls in office space

Paint and Carpet
-Furnish and install Armstrong Standard VCT
-Furnish and install new vinyl base
-Furnish and install new three (3) new transition strips
-Paint sheetrock soffits/ceilings
-Finish eight (8) doors and frames

Demolition
-Remove drywall partitions to full height
-Remove diamond plate 4' high walls
-Remove ceiling grid and tile
-Remove carpet
-Remove VCT
-Remove flex and diffusers

Carpentry
-Fill in six (6) 8" wall openings
-Furnish and install twenty-four (24) ceiling height partitions
-Construct twenty (20) 4" drop headers in 8" wall.
-Fill in three (3) door openings
-Construct one (1) finished sheetrock opening

Doors and Hardware
-Provide three (3) double metal door units

Acoustical Ceiling Tiles
-Provide new 2x4 ceiling grid and lay in tile

Plumbing
-Furnish and install new sink, required piping, and drain pump

Electrical
-Relocate thirty-two (32) existing lights
-Furnish and install five (5) new light switches
-Furnish and install six (6) new exit signs
-Furnish and install six (6) new emergency lights
-Furnish and install four (4) new duplex outlets
-Furnish and install ten (10) new quad outlets in assembly area
-Furnish and install 220v. line
-Furnish and install power for drain pump
-Furnish and install three (3) dedicated outlets in kitchen area
-Re-switch lighting in engineering lab

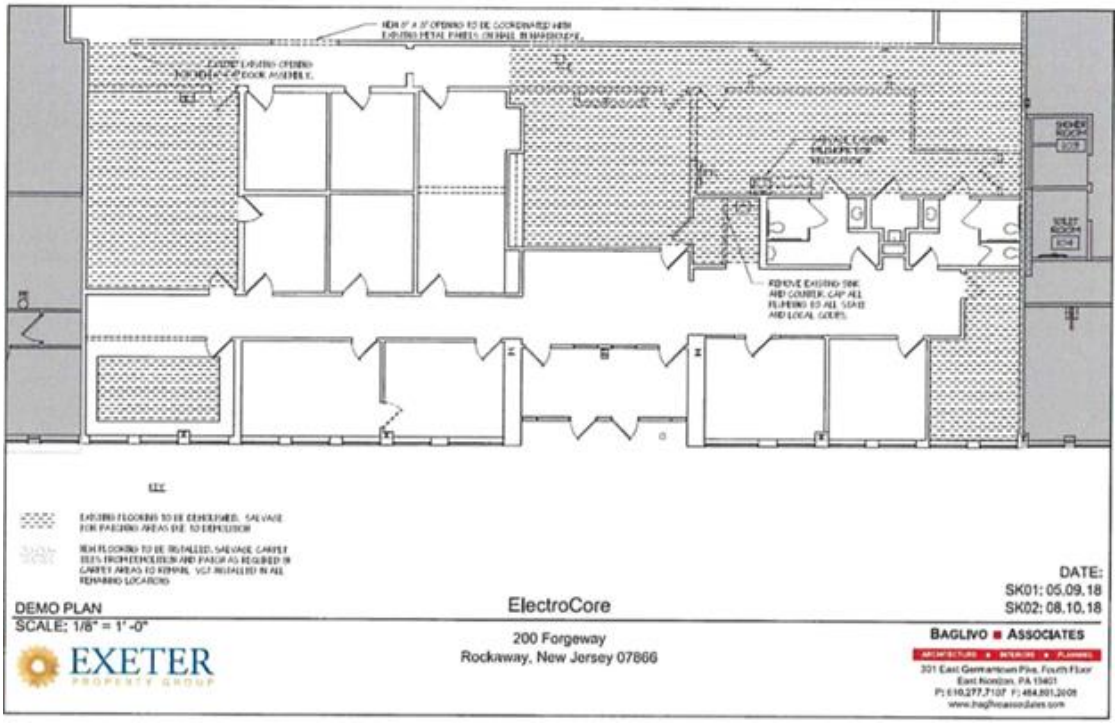
Fire Alarm
-Relocate existing devices
-Furnish and install two (2) new horn/strobe devices

HVAC
-Replace the following portions of the HVAC system:

- (2)RGS090 460v 3 ph 7.5 ton roof top gas unit w/ return smoke det
- (I)RGS180 460v 3 ph 15 ton roof top gas unit w/return smoke det
- (3)Curb adapters

EXHIBIT "C-1"

SPACE PLAN



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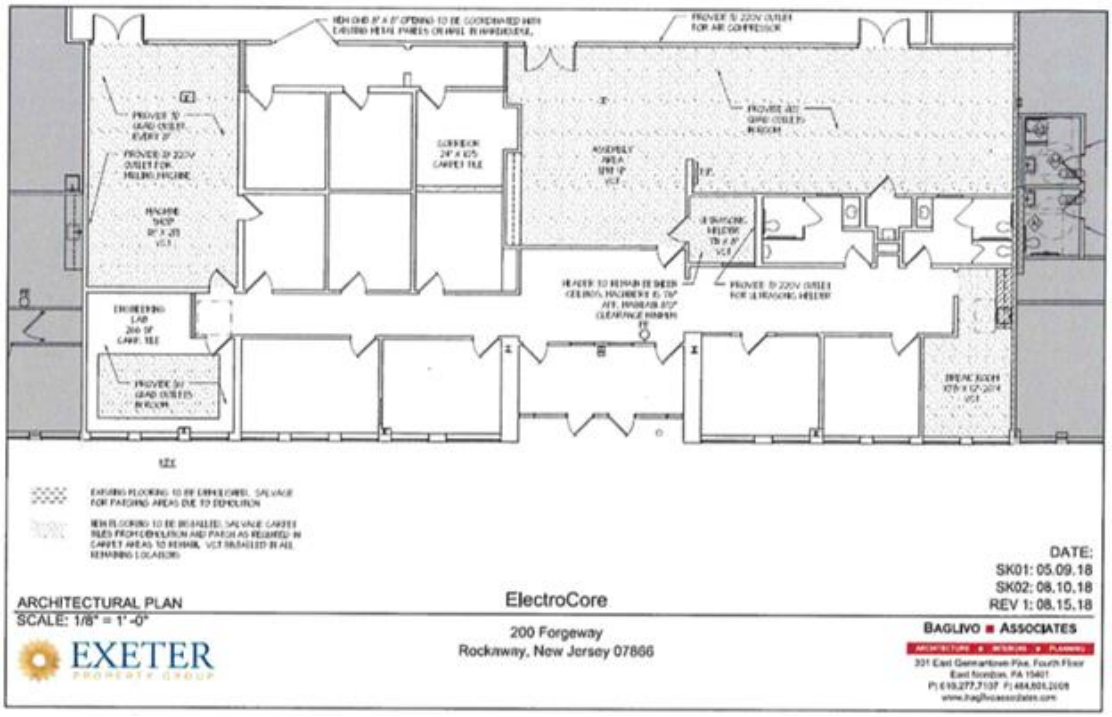

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EXHIBIT "D"

LANDLORD LIEN SUBORDINATION AGREEMENT

THIS AGREEMENT ("Agreement") is made effective as of the_____day of _____ , _____ by **("Landlord"),** in favor of _____**("Lender").**

WHEREAS, Landlord is the owner of _____**("Building"); WHEREAS,** Landlord and _____ **("Tenant")** are parties to that certain _____ dated _____ (collectively, **"Lease")** pursuant to which Tenant leases from Landlord approximately rentable square feet in the Building **("Premises");** and

WHEREAS, Tenant has granted or is granting a continuing lien and security interest to Lender in connection with a loan **("Loan")** from Lender, in Tenant's personal property located at the Premises.

NOW, THEREFORE, for good and valuable consideration and intending to be legally bound hereby, Landlord hereby agrees as follows:

1. Landlord hereby waives, releases and relinquishes to Lender all right, title, interest, claim and lien which Landlord has or may in the future have in, to or against any inventory, equipment, machinery, furniture, trade fixtures, and books and records of Tenant located at the Premises up to the amount of the Loan (collectively, the **"Personal Property").** Notwithstanding the foregoing, under no circumstance shall the Personal Property include any alterations, improvements, fixtures, equipment or Personal Property installed by or paid for by Landlord. The Personal Property shall not be subject to levy, sale on distress or distraint for rent or any claim, lien or demand of any kind by Landlord. Upon the satisfaction of the Loan, Landlord's interest in the Personal Property shall be automatically revived.

2. Subject to the requirements of Section 3 hereof, Landlord hereby authorizes Lender, its attorneys, agents and employees to enter the Premises and to take possession of, remove or dispose of the Personal Property, provided in all cases, Lender shall pay all costs to repair any damages (including any replacements) caused, in whole or in part, by Lender's removal of the Personal Property from the Premises.

3. At such time as Tenant vacates the Premises, voluntarily or involuntarily, the Lease is terminated, or Lender repossesses the Personal Property, Lender may store the Personal Property on the Premises solely for a period of thirty (30) days and otherwise operate the Premises, prepare the Personal Property for sale for such thirty (30) day period, provided that Lender pays to Landlord all rent and other sums due and payable under the Lease (including charges for utilities and operating expenses) and otherwise agrees to and complies with all terms of the Lease during such period, including, but not limited to, the insurance obligations provided in the Lease. Failure to remove any Personal Property within such thirty (30) day period shall be deemed Lender's abandonment of the same. Under no circumstances, however, may Lender conduct a sale, auction or liquidation of such Personal Property on the Premises.

4. This instrument shall be binding upon and inure to the benefit of the parties hereto, their successors and assigns.

[Remainder of page left intentionally blank.]

IN WITNESS WHEREOF, Landlord and Lender have executed this Agreement effective the day and year first above written.

LANDLORD:

ANSON LOGISTICS ASSETS LLC, a Delaware limited liability company

By: _____
Name:
Title:

LENDER:

[NAME OF LENDER]

By: _____
Name:
Title:

Exhibit 21.1

List of Subsidiaries of electroCore, LLC

Subsidiary	Jurisdiction of Incorporation or Organization
electroCore Bermuda, Ltd.	Bermuda
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 statement (No. 333-228863) on Form S-8 of electroCore, Inc. of our report dated March 28, 2019, with respect to the consolidated balance sheets of electroCore, Inc., Subsidiaries and Affiliate as of December 31, 2018 and 2017, 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, 2018, and the related notes (collectively, the consolidated financial statements), which report appears in the December 31, 2018 annual report on Form 10-K of electroCore, Inc.

/s/ KPMG LLP

Short Hills, New Jersey March 28,
2019

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, Francis R. Amato, 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 28, 2019

By: /s/ FRANCIS R. AMATO

Francis R. Amato
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, Glenn S. Vraniak, 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 28, 2019

By: /s/ GLENN S. VRANIAK

Glenn S. Vraniak
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, 2018 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 28, 2019

By: /s/FRANCIS R. AMATO

Francis R. Amato
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, 2018 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 28, 2019

By: /s/ GLENN S. VRANIAK

Glenn S. Vraniak
Chief Financial Officer
(Principal Financial and Accounting Officer)